

ENDO PHARMACEUTICALS HOLDINGS INC
Form S-3/A
June 11, 2004

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As filed with the Securities and Exchange Commission on June 10, 2004

Registration Statement No. 333-115032

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1
TO

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Endo Pharmaceuticals Holdings Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

13-4022871
(I.R.S. Employer Identification No.)

**100 Painters Drive
Chadds Ford, Pennsylvania 19317
(610) 558-9800**
(Address, Including Zip Code, and Telephone Number, Including Area Code,
of Registrant's Principal Executive Offices)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, check the following box.

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If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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Subject to Completion. Dated June 10, 2004

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 June 9, 2004 was \$21.21 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 2004.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

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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 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 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 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. The introduction of these third-

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party generic versions of our product 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 March 31, 2004, approximately 3.7 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 March 31, 2004, approximately \$36 million, which is estimated to result in a tax benefit amount of approximately \$14 million). Under the tax sharing agreement, we are required to pay this \$14 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 auditors 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 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

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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 all 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 market price of \$ (the last reported stock price of our common stock on the NASDAQ National Market on , 2004) 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 \$ million, 50% of this amount within 15 business days of the date we receive an opinion on our final audited 2004 financial statements from our independent auditors (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 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 all 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 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 market price of our common stock was per share, we generally would be able to deduct, for income tax purposes, compensation of approximately \$ million, which could result in a tax benefit amount of approximately \$ 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. 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 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.

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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 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. 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. Failure to comply with applicable regulatory requirements in this regard can result in, among other things, suspensions of approvals, seizures or recalls of products, injunctions against a product's manufacture, distribution, sales and marketing, operating restrictions, civil penalties and criminal prosecutions. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals. The effect of government regulation may be to delay marketing of our new products for a considerable period of time, to impose costly procedures upon our activities and to furnish a competitive advantage to larger companies that compete with us.

We cannot assure you that the FDA or other regulatory agencies will approve any products developed 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 meetings we had with the FDA in the first half of 2004. 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.

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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 may indicate the potential for having mutagenic effects. If, after testing, such effects are ultimately demonstrated to exist, more stringent controls of the levels of these impurities may 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 penalties, refusal to renew or action to revoke necessary registrations, or other restrictions on operations involving controlled substances.

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

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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.

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

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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. 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 these steps will be successful or that, if unsuccessful, our patent protection will be adequate.

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.

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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, this marketing exclusivity would begin to run upon the earlier of our commercial launch of the generic product or within 75 days of 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.

We recently 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 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

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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.

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.

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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 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.

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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.

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.

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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 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. We assess the potential impairment of goodwill by comparing the fair value of goodwill to its carrying value for our one reporting unit. An impairment loss would be recognized when the estimated fair value is less than its carrying amount. 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.

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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.

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.

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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 and \$13.99 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 June 8, 2004, approximately 83.6 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 3,421,297 shares that may be issued upon the exercise of options outstanding as of June 8, 2004, 818,048 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.

[Back to Contents](#)**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 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.

	High	Low
Year Ended December 31, 2004		
1st Quarter	\$ 25.00	\$ 18.78
2nd Quarter (through June 9, 2004)	\$ 27.15	\$ 20.34
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 June 8, 2004, there were 131,794,344 shares of common stock outstanding. As of June 8, 2004, we had approximately 132 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 MorphoDex® for any pain indication prior to December 31, 2002.

Exercisability and Expiration. As the FDA did not approve MorphoDex® 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. All of these warrants were exercised. The warrants were exercisable until July 8, 2003, at which time they would have expired.

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.

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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 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.

[Back to Contents](#)**SELLING STOCKHOLDERS**

The following table provides information regarding the beneficial ownership of our common stock by the selling stockholders, as of May 31, 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 May 31, 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.

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
Directors and Executive Officers:			
Carol A. Ammon(b)(d)	11,057,131(c)	3,693,488	7,363,643
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
Jeffrey R. Black(b)(d)	3,607,918(o)	1,209,751	2,398,167
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)			
Other Selling Stockholders:			
Endo Pharma LLC(d)(f)	82,219,380	29,674,000(q)	52,545,380
Kelso Investment Associates V, L.P.(d)(f)(r)	38,321,689	14,670,018	23,651,671
Kelso Equity Partners V, L.P.(d)(f)(r)	3,224,525	1,234,388	1,990,137
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)			

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Michael B. Lazar(f)(g)			
Greenwich Street Capital Partners, L.P.(d)(s)	4,910,225	1,879,695	3,030,530
Greenwich Street Capital Offshore Fund, Ltd.(d)(s)	304,764	116,667	188,097
Citigroup GSP Employees Fund, L.P.(d)(s)	1,193,313	456,815	736,498
The Travelers Insurance Company(d)(s)	253,312	96,971	156,341
The Travelers Life and Annuity Company(d)(s)	124,765	47,761	77,004
Mariann T. MacDonald(b)(d)	9,301,159(t)	3,110,546	6,190,613
Other selling stockholders representing less than 1% owners of our common stock(u)	5,383,706	1,561,001(v)	3,822,705

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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.
- (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.
- (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 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 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 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 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 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 83,350 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 828,519 shares underlying options that he holds in 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.
- (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

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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 that she holds in 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 represents the aggregate number of shares beneficially owned by all selling stockholders with the exception of Roger H. Kimmel, Michael Hyatt, and are therefore not to be accounted for in addition to the shares individually listed herein.
- (r) 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.
- (s) 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 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

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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.

- (t) 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.
- (u) 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.
- (v) 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 report on Form 8-K filed on January 5, 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.

[Back to Contents](#)**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution**

The following table sets forth the estimated expenses to be incurred in connection with the issuance and distribution of the securities being registered, other than underwriting discounts, commissions and transfer taxes, to be paid by the Registrant.

Securities and Exchange Commission Registration Fee	\$ 97,629
National Association of Securities Dealers, Inc. filing fee	*
Printing and Engraving Fees and Expenses	*
Accounting Fees and Expenses	*
Legal Fees and Expenses	*
Miscellaneous	*
	<hr/>
Total	\$ *
	<hr/>

Item 15. Indemnification of Directors and Officers

As authorized by section 145 of the Delaware General Corporation Law, each director and officer of a corporation may be indemnified by the corporation against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement, actually and reasonably incurred regarding the defense or settlement of threatened, pending or completed legal proceedings. Each director or officer will have the right of indemnification if he or she:

- ☐ is involved in the legal proceeding because he or she is or was a director or officer of the corporation;
- ☐ acted in good faith and in a manner that he or she reasonably believed was in the best interests of the corporation; and
- ☐ in a criminal action or proceeding, had no reasonable cause to believe that his or her conduct was unlawful.

However, if the legal proceeding is by or in the right of the corporation, the director or officer may not be indemnified for claims, issues or matters as to which the director or officer is adjudged to be liable for negligence or misconduct in the performance of his or her duty to the corporation unless a court determines otherwise.

Article SIXTH of our amended and restated certificate of incorporation contains provisions that authorize the indemnification of directors and officers. Under article SIXTH, we will indemnify our directors and officers to the fullest extent authorized or permitted by law against expenses, judgments, fines and amounts paid in settlement. In addition, this right of indemnification continues to persons who have ceased to be our directors or officers and to his or her heirs, executors and personal and legal representatives. However, unless the legal proceeding was authorized or consented to by our board of directors, we are not obligated to indemnify a director or officer, or his or her heirs, executors or personal or legal representatives, regarding the proceeding initiated by the same director or officer, or his or her heirs, executors or personal or legal representatives. Finally, article SIXTH provides that a repeal or modification of article SIXTH by the stockholders must not adversely affect the rights to indemnification of directors and officers regarding any acts or omissions that occurred before the repeal or modification.

Set forth below are material provisions of article EIGHTH of our amended and restated by-laws that authorize the indemnification of directors and officers:

- ☐ Section 2 of article EIGHTH states that if the director or officer is adjudged to be liable to us by a court of law there would be no right of indemnification unless the court determines upon application that, despite the adjudication of liability but in view of all the circumstances of the case, the director or officer is fairly and reasonably entitled to indemnity.

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- ☐ Under section 3 of article EIGHTH, authorization as to whether a director or officer should be indemnified is made (a) by a majority vote of the directors who are not parties to the action, suit or proceeding, even though less than a quorum, (b) by independent legal counsel in a written opinion if there are no directors who are not parties to the action, suit or proceeding, or (c) by the stockholders. However, if a director or officer has been successful on the merits or defense of the action, suit or proceeding, then that person will be indemnified without authorization.
- ☐ According to section 5 of article EIGHTH, directors or officers may apply to the Court of Chancery in the State of Delaware for indemnification.
- ☐ Section 6 of article EIGHTH provides that the directors and officers have the right to be reimbursed for the expenses incurred in defending or participating in a legal proceeding in advance of the proceeding's final disposition.
- ☐ Pursuant to section 8 of article EIGHTH, we may purchase and maintain insurance on behalf of persons who are or were directors or officers whether or not we would have the power or the obligation to indemnify those persons.

Item 16. Exhibits

The following is a list of all exhibits filed as a part of this registration statement on Form S-3.

Exhibit Number	Description of Exhibits
5.1	Opinion of Skadden, Arps, Slate, Meagher & Flom LLP.*
10.1	Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan.
10.2	Shelf Registration Agreement, dated April 30, 2004, between Endo Pharmaceuticals Holdings Inc. and Endo Pharma LLC.
10.3	Amendment to Shelf Registration Agreement, dated June 10, 2004 between Endo Pharmaceuticals Holdings Inc. and Endo Pharma LLC.
23.1	Consent of Deloitte & Touche LLP, independent registered public accounting firm.
23.2	Consent of Skadden, Arps, Slate, Meagher & Flom LLP (included in Exhibit 5.1).*
24.1	Power of Attorney.*

* Previously filed.

Item 17. Undertakings

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement: (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933; (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities

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offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form or prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; *provided, however*, that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the registration statement is on Form S-3, Form S-8 or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

The undersigned registrant hereby undertakes to deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

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

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Chadds Ford, State of Pennsylvania, on June 10, 2004.

Endo Pharmaceuticals Holdings Inc.

By: /s/ Jeffrey R. Black
 Name: Jeffrey R. Black
 Title: Executive Vice President,
 Chief Financial Officer and
 Treasurer (Principal Financial &
 Accounting Officer)

Each person whose signature appears below hereby constitutes and appoints Carol A. Ammon, James J. Connors II, Jeffrey R. Black and Caroline B. Manogue, and each of them, his true and lawful attorneys-in-fact and agents with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all (1) amendments (including post-effective amendments) and additions to this Registration Statement and (2) Registration Statements, and any and all amendments thereto (including post-effective amendments), relating to the offering contemplated pursuant to Rule 462(b) under the Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, and hereby grants to such attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or his substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
*	Chairman and Chief Executive Officer	June 10, 2004
Carol A. Ammon	(Principal Executive Officer)	
/s/ Jeffrey R. Black	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial & Accounting Officer)	June 10, 2004
Jeffrey R. Black		
*	Director	June 10, 2004
Brian T. Clingen		
*	Director	June 10, 2004
Michael B. Goldberg		
*	Director	June 10, 2004

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Michael Hyatt

*

Director

June 10, 2004

Roger H. Kimmel

*

Director

June 10, 2004

Frank J. Loverro

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<u>Signature</u>	<u>Title</u>	<u>Date</u>
*	Director	June 10, 2004
Clive A. Meanwell		
*	Director	June 10, 2004
Michael W. Mitchell		
*	Director	June 10, 2004
Joseph T. O'Donnell, Jr.		
*	Director	June 10, 2004
David I. Wahrhaftig		
/s/ Jeffrey R. Black	Attorney-in-fact	June 10, 2004
Jeffrey R. Black		

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EXHIBIT INDEX

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24.1	Powers of Attorney.*

* Previously filed.
