ENDO PHARMACEUTICALS HOLDINGS INC
Form S-3ASR
January 19, 2006

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As filed with the Securities and Exchange Commission on January 19, 2006

Registration Statement No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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

100 Endo Boulevard
Chadds Ford, Pennsylvania 19317
(610) 558-9800

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Caroline B. Manogue, Esq.
Executive Vice President, Chief Legal Officer and Secretary
100 Endo Boulevard
Chadds Ford, Pennsylvania 19317
(610) 558-9800

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

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Approximate date of commencement of proposed sale to the public: From time to time 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, please check the following box: o

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, please check the following box: ý

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: o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) 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: o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box: ý

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box: o

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered	Proposed maximum offering price per unit	Proposed maximum aggregate offering price	Amount of registration fee
Common Stock, par value $0.01 per share	(1)	(1)	(1)	(1)

(1) An indeterminate aggregate initial offering price or number of shares of common stock is being registered as may from time to time be offered at indeterminate prices. In accordance with Rules 456(b) and 457(r), the Registrant is deferring payment of all of the registration fee and will pay the registration fee subsequently on a "pay-as-you-go" basis.

PROSPECTUS

Endo Pharmaceuticals Holdings Inc.

Common Stock

Certain selling stockholders from time to time may offer to sell shares of our common stock. We will not receive any proceeds from the sale of shares of our common stock offered by the selling stockholders.

The selling stockholders may offer and sell our common stock to or through one or more underwriters, dealers and agents, or directly to purchasers, on a continuous or delayed basis.

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

Our common stock is quoted on the Nasdaq National Market under the symbol "ENDP." On January 18, 2006, the last sale price of the shares as reported on the Nasdaq National Market was $29.12 per share.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 6 of this prospectus.

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 January 19, 2006.

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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, or the SEC, using a "shelf" registration or continuous offering process. Under this shelf process, certain selling stockholders may from time to time sell the shares of common stock described in this prospectus in one or more offerings.

This prospectus provides you with a general description of the common stock that we and certain selling stockholders may offer. Each time we or a selling stockholder sells common stock, we will provide you with a prospectus supplement containing specific information about the selling stockholders, if any, the terms of the offering and the means of distribution. A prospectus supplement may include other special considerations applicable to such offering of common stock. 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 the prospectus supplement. You should read carefully this prospectus and any prospectus supplement together with the additional information described under the headings "Where You Can Find More Information" and "Incorporation of Certain Documents by Reference."

FORWARD LOOKING STATEMENTS

This prospectus, any supplement hereto and documents incorporated by reference herein or therein 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 of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements, including estimates of future net sales, future net income and future earnings per share, contained in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," 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" in this document, as updated by any prospectus supplement, and as otherwise enumerated herein or therein 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 and any prospectus supplement. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in this prospectus and any accompanying prospectus supplement include those factors described in this prospectus under the section titled "Risk Factors," including, among others:

our ability to successfully develop, commercialize and market new products;

timing and 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;

significant cash payments we may be required to make to Endo Pharma LLC pursuant to a tax sharing agreement;

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;

the successful efforts of manufacturers of branded pharmaceuticals to use litigation and legislative and regulatory efforts to limit the use of generics and certain other products;

our ability to successfully implement our acquisition and in-licensing strategy;

regulatory or other limits on 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;

the outcome of any pending or future litigation or claims by the government; 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.

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 $18.9 billion in 2004. This represents an approximately 16% compounded annual growth rate since 1999. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2004, analgesics were the third most prescribed medication in the United States with over 272 million prescriptions written for this classification. Opioid analgesics is a segment that comprised approximately 75% of the analgesics prescriptions for 2004. Total U.S. sales for the opioid analgesic segment were $6.3 billion in 2004, representing a compounded annual growth rate of 20% since 1999.

We have a portfolio of branded products that includes established brand names such as Lidoderm®, Percocet®, Frova®, Percodan®, Zydone® and DepoDur®. Branded products comprised approximately 69% of our net sales in 2004. Our non-branded generic portfolio, which accounted for 31% of net sales in 2004, currently consists of products primarily focused in pain management. We focus on selective 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 product pipeline includes two filed New Drug Applications, or NDAs, two products in Phase III clinical trials and four products in Phase II clinical trials.

We enhance our financial flexibility by outsourcing certain of our functions, including manufacturing. Currently, our primary suppliers of contract manufacturing services are Novartis Consumer Health, Inc. and Teikoku Seiyaku Co., Ltd.

Through a dedicated sales force of approximately 370 sales representatives in the United States, we market our branded pharmaceutical products to high-prescribing physicians in pain management, neurology, surgery, anesthesiology, oncology and primary care. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

On a continuous basis, we evaluate and, where appropriate, pursue acquisition opportunities on terms we consider favorable. In particular, we look to continue to enrich our product line by acquiring or licensing rights to additional products and compounds and therefore regularly evaluate selective acquisition and license opportunities. Such acquisitions or licenses may be carried out through the purchase of assets, joint ventures and licenses or by acquiring other companies. Currently, however, we have no binding commitment related to any acquisitions.

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 and was thereafter purchased by the Bristol Myers Squibb Pharma Company in 2001. Endo Pharmaceuticals Inc. was formed by some members of the then-existing management of DuPont Merck and an affiliate of Kelso & Company who were also parties to the purchase agreement, under which we acquired these initial assets. We were incorporated in Delaware as a holding company on November 18, 1997.

Our executive offices are located at 100 Endo Boulevard, 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 or any accompanying prospectus supplement.

RISK FACTORS

You should carefully consider the following risk factors in addition to the other information in this prospectus and any accompanying prospectus supplement 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 many of the major brand name and generic manufacturers of pharmaceuticals, especially those doing business in the United States. In the market for branded pharmaceutical products, our competitors, including Abbott Laboratories, Johnson & Johnson, Ligand Pharmaceuticals Incorporated, Pfizer, Inc. and The Purdue Frederick Company, 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. For example, according to the IMS National Prescription Audit, generic versions of Percocet® were used to fill approximately 93% of the approximately 17.9 million new prescriptions for this drug in 2004 compared to 83% of the approximately 16.0 million new prescriptions for this drug in 2003. Percocet® 7.5/325 and Percocet® 10/325, which prior to the introduction of generic competition then represented approximately 75% of our dispensed Percocet® prescriptions, currently face generic competition. Percocet® net sales decreased to $86.5 million for the year ended December 31, 2004 from $214.2 million in the comparable 2003 period due to the introduction of generic versions of Percocet® 7.5/325 and 10/325 during the fourth quarter of 2003. Generic competition with our branded products, including Percocet®, has had and will continue to have a material adverse effect on the net sales and profitability of our branded products.

Additionally, 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 or prevent us from capitalizing on such acquisitions or licensing opportunities. If we fail to compete successfully, our growth may be limited.

If generic manufacturers use litigation and regulatory means to obtain approval for generic versions of our branded drugs, our sales may suffer.

The Hatch Waxman Act permits the FDA to approve ANDAs for generic versions of branded drugs. The ANDA process permits competitor companies to obtain marketing approval for a drug with the same active ingredient for the same uses but does not require the conduct and submission of clinical studies demonstrating safety and efficacy for that product. In place of such clinical studies, an ANDA applicant essentially needs only to submit data demonstrating that its product is bioequivalent to the branded product.

The Hatch Waxman Act requires an applicant for a drug that relies, at least in part, on data from the branded drug regarding the safety and efficacy of the same active ingredient, to notify us of their application and potential infringement of our patent rights. Upon receipt of this notice we would have 45 days to bring a patent infringement suit in federal district court against the company seeking to violate our patent rights. The discovery, trial and appeals process in such suits can take several years. If such a suit is commenced, the Hatch Waxman Act provides a 30-month stay on the approval of the competitor's application. If the litigation is resolved in favor of the generic applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA's review of the application may be completed. Such litigation is often time-consuming and quite costly and may result in generic competition if such patent(s) are not upheld or if the generic competitor does not infringe such patent(s). The filing of any ANDA in respect of any of our branded drugs, particularly Lidoderm®, could have an adverse impact on our stock price and, if the patents covering our branded drugs, including Lidoderm®, were not upheld in litigation or if the generic competitor is found to not infringe these patents, the resulting generic competition would have a material adverse effect on our net sales, gross profit, operating income, net income and cash flows.

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

Our generic products compete with branded products and with generic versions made by or for other manufacturers, such as Impax Laboratories, Inc., Ivax Corporation, Mallinckrodt Inc., Mylan Laboratories Inc., Roxane Laboratories, Inc., Sandoz (a Novartis company), 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 selling prices and margins on the product decline. Because we are smaller than many of our full-line 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.

On June 7, 2005, we launched the 10mg, 20mg, 40mg and 80mg strengths of our bioequivalent versions of OxyContin®. We had 180 days of marketing exclusivity under the Hatch Waxman Act with respect to the 10mg, 20mg and 40mg strengths of this product, since we were the first applicant to file an ANDA containing a Paragraph IV certification for these oxycodone extended release strengths. After the expiration of our marketing exclusivity period on December 5, 2005, several competitors launched bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin®. Other competitors may launch additional generic versions of all four strengths of OxyContin®. The entrance of other competitors has and will continue to reduce our market share for bioequivalent versions of OxyContin® and adversely affect the profitability of these products.

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

For the year ended December 31, 2004, 50% of our net sales came from sales of Lidoderm®, and 19% came from sales of Endocet®, 14% came from sales of our Percocet® franchise and 10% came from sales of morphine sulfate extended release tablets. For the nine months ended September 30, 2005, 50% of our net sales came from sales of Lidoderm®, 9% came from sales of Endocet®, 14% came from sales of our Percocet® franchise and 5% came from sales of morphine sulfate extended release tablets. The FDA has granted Lidoderm® orphan drug status for the treatment of the pain

associated with post herpetic neuralgia, which means, generally, that no other lidocaine containing product can be approved for this indication prior to March 19, 2006. In addition, on June 7, 2005, we launched our generic extended release oxycodone product, our bioequivalent, or generic, version of OxyContin®, which accounted for 14% of our product sales for the nine months ended September 30, 2005. After the expiration of our marketing exclusivity period in December 2005, several competitors launched bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin®. In addition, we could be forced to stop selling our generic OxyContin® product if the Federal Circuit Court of Appeals reverses its decision in our favor or is reversed by the Supreme Court and one or more of the Purdue patents is found valid and enforceable and there is a final court decision adverse to us. See " We face intense competition from other manufacturers of generic versions of our generic products." and " We were successful in our patent challenge against Purdue for our generic OxyContin® product, both at trial and on appeal. Purdue has petitioned the Court of Appeals for a rehearing, 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." If we were unable to continue to market any of these products, if any of them were to lose market share, for example, as the result of the entry of new competitors, particularly from generic versions of branded drugs, or if the prices of any of these products were to decline significantly, our net sales, profitability and cash flows would be materially adversely affected. The introduction of other bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin® has had and will continue to have an adverse effect by reducing our market share and adversely affecting our profitability and cash flows that we would have otherwise achieved if we supplied the exclusive generic equivalent to the 10mg, 20mg and 40mg strengths of OxyContin® and to MS Contin®.

We face intense competition from brand-name companies that sell or license their own generic versions of our generic products or seek to delay the introduction of generic products.

Brand-name pharmaceutical companies have taken aggressive steps to thwart competition from generic equivalents of their brand-name products. In particular, brand-name companies sell directly to the generics market or license their products for sale to the generics market through licensing arrangements or strategic alliances with generic pharmaceutical companies (so-called "authorized generics"). No significant regulatory approvals are required for a brand-name manufacturer to sell directly or through a third party to the generic market. Brand-name manufacturers do not face any other significant barriers to entry into such market. On June 8, 2005, Ivax Corporation, a generic pharmaceutical company, announced that it would distribute the so-called "authorized generic" version of OxyContin® pursuant to a distribution arrangement with Purdue. On July 29, 2005, Ivax Corporation announced that it would also distribute the so-called "authorized generic" version of MS Contin®, the branded version of our morphine sulfate extended release tablets, pursuant to a distribution arrangement with Purdue. The introductions of these so-called "authorized generics" have had and may continue to have an adverse effect by reducing our market share and adversely affecting our profitability and cash flows that we otherwise would have achieved in 2005 and subsequent periods if we supplied the exclusive generic equivalent to the 10mg, 20mg and 40mg strengths of OxyContin® and to MS Contin®.

In addition, brand-name companies continually seek new ways to delay generic introduction and decrease the impact of generic competition, such as filing new patents on drugs whose original patent protection is about to expire; filing an increasing number of patents that are more complex and costly to challenge; filing suits for patent infringement that automatically delay approval by the FDA; developing patented controlled release or other next generation products, which often reduces the demand for the generic version of the existing product for which we may be seeking approval; changing product claims and product labeling; developing and marketing as over-the-counter products those branded products that are about to face generic competition; or filing citizens' petitions with the FDA seeking restraints on our products or seeking to prevent them from coming to market. These strategies may increase the costs and risks associated with our efforts to introduce generic products and may delay or prevent such introduction altogether.

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

Endo Pharma LLC is a limited liability company that currently holds a significant portion of our common stock, in which affiliates of Kelso & Company and certain members of management have an interest. 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. 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 received by holders of such options upon exercise.

Upon exercise of any of these Endo Pharma LLC stock options, we generally will be permitted 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 September 30, 2005, we had recognized compensation deductions of approximately $152 million, which is estimated to result in a tax benefit amount of approximately $59 million). Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of the stock options granted pursuant to the Endo Pharma LLC stock option plans, we entered into a tax sharing agreement with Endo Pharma LLC under which we are required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, the amount of the tax benefit usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of September 30, 2005, approximately 10.7 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC. Under the tax sharing agreement, we are required to pay approximately $59 million to Endo Pharma LLC to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto.

We had no obligation to make any payments under the tax sharing agreement to Endo Pharma LLC prior to the occurrence of a liquidity event. The tax sharing agreement defines a liquidity event 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. 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. The amendment established a formula for calculating when a sale of 20% of the common equity of Endo had occurred and specified that secondary sales of Endo common stock include sales pursuant to a shelf registration statement. The amendment also provides that upon the occurrence of a liquidity event, we are obligated to 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 be paid within 15 business days of our receipt from our independent registered public accounting firm of an opinion on our final audited financial statements, and (ii) the remaining amount shall be paid within 30 business days of the filing of our federal income tax return.

A liquidity event occurred on August 9, 2004, when Endo Pharma LLC completed the secondary sale of 11 million shares of common stock. The closing of this offering, when combined with the sale by Endo Pharma LLC of the sale of 16.6 million shares on July 8, 2003, constituted a liquidity event under the tax sharing agreement and triggered a payment obligation with respect to tax benefits usable by us

in previous years. In 2004, we paid $13.5 million to Endo Pharma LLC to satisfy the tax sharing obligations attributable to 2001, 2002 and 2003.

Since 6.6 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised into common stock and sold in the offerings on August 9, 2004 and November 29, 2004, at prices of $17.46 and $20.02, respectively, with a weighted average exercise price of $2.44, and an assumed tax rate of 38.7%, we were obligated to pay Endo Pharma LLC a tax benefit of approximately $41 million. Fifty percent of the tax benefit amount attributable to these two 2004 offerings and other Endo Pharma LLC stock option exercises in 2004, aggregating $21.4 million, was due and was paid within 15 business days of the date we received an opinion on our audited 2004 financial statements from our independent registered public accounting firm and the remaining fifty percent of the tax benefit amount attributable to 2004 was due within 30 business days of the date on which we filed our 2004 tax return with the Internal Revenue Service (which occurred in September 2005) and approximately $21.4 million was paid in October 2005 to satisfy the tax sharing obligations attributable to 2004.

On October 12, 2005, as part of the sale of 33.35 million shares of our common stock, approximately 19.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised at a market price of $26.04, with a weighted average exercise price of $2.72, and an assumed tax rate of 38.4%. Assuming the attributable compensation charge deductions are usable to reduce our taxes in 2005, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately $175 million, which has been accrued in the fourth quarter of 2005. Fifty percent of the estimated tax benefit amount attributable to the October 12, 2005 offering and any additional tax benefits attributable to the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2005 will be due within 15 business days of the date we receive an opinion on our final audited 2005 financial statements from our independent registered public accounting firm (which we estimate will occur within 60 to 75 days of our fiscal year-end of December 31, 2005) and the remaining tax benefit amount attributable to 2005 is due within 30 business days of the date on which we file our 2005 tax return with the Internal Revenue Service.

Additionally, we estimated that up to 3 million additional stock options granted under the Endo Pharma LLC stock option plans would have been exercised prior to January 1, 2006 and therefore, assuming exercise at a market price of $26.04, with a weighted average exercise price of $2.52, an assumed tax rate of 38.4% and assuming the attributable compensation charge deductions are usable to reduce our taxes in 2005, we will obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately $27 million in 2006. As a result of the significant tax deductions expected to have been generated in 2005 from the exercise of the 22.5 million stock options discussed above, we expected to incur a net operating loss in 2005 for tax purposes which will permit us to obtain a tax refund of prior years' payments during 2006. All payments that have been, or will be, made or accrued pursuant to the tax sharing agreement have been, or will be, reflected as a reduction of stockholders' equity in our consolidated financial statements. Following the exercise of the 19.5 million Class C stock options discussed above and the 3 million additional stock options that are estimated to have been exercised prior to January 1, 2006, there will be approximately 3 million stock options remaining to be exercised under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of $2.52 per share and an assumed tax rate of 38.4%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were vested and exercised, and assuming the price of our common stock was $26.04 per share, we would generally be able to deduct, for income tax purposes, compensation of approximately $71 million, which could result in a tax benefit amount of approximately $27 million payable to Endo Pharma LLC. We estimate the tax sharing liability as of December 31, 2005 payable to Endo Pharma LLC to be approximately $201 million.

We were successful in our patent challenge against Purdue for our generic OxyContin® product, both at trial and on appeal. Purdue has petitioned the Court of Appeals for a rehearing, 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 and related parties filed suit against us and our subsidiary, Endo Pharmaceuticals Inc., or EPI, 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 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 Purdue's patent infringement suit 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. On June 7, 2005, the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. affirmed the Opinion and Order of the District Court issued in Endo's favor on January 5, 2004. This affirmance by the Federal Circuit Court dismissed the claims that Endo's oxycodone extended release tablets infringe Purdue patents, and permanently enjoined Purdue from enforcing these patents.

On June 21, 2005, Purdue filed a petition with the Federal Circuit Court of Appeals seeking rehearing of the case by the panel that issued the June 7, 2005 decision, or alternatively by the entire court. On July 18, 2005, the Federal Circuit Court of Appeals requested that Endo submit a response brief as part of its review process of Purdue's petition for rehearing and rehearing en banc. Endo submitted this response on August 1, 2005. We can make no prediction as to how or when the appellate court will rule on the petition for rehearing, which ruling may be made at any time. Because we commenced commercial sale of our bioequivalent versions of OxyContin®, we could face substantial damages for patent infringement if the Federal Circuit reverses itself or is reversed by the Supreme Court and one or more of the Purdue patents is found valid and enforceable and there is a final court decision adverse to us.

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. Specifically, in the past two years, reportedly widespread misuse or abuse of OxyContin®, a Purdue product containing the narcotic oxycodone, resulted in the strengthening of warnings on its labeling. In addition, Purdue, the manufacturer of OxyContin®, faces numerous lawsuits, including class action lawsuits, related to OxyContin® misuse or abuse. On June 7, 2005, we began commercial sale of our oxycodone extended release tablets, 10mg, 20mg, 40mg and 80mg strengths, each bioequivalent versions of OxyContin®. 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 delay our introduction of new products, may adversely affect our net sales and may have a material adverse effect on our business, profitability and cash flows. See " The DEA limits the availability of the active ingredients

used in our current products and products in development and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials."

On July 13, 2005, the FDA asked Purdue to withdraw its product Palladone (hydromorphone hydrochloride extended release capsules) from the market after acquiring new information that serious and potentially fatal adverse reactions can occur when the product is taken together with alcohol. The data were gathered from a Purdue sponsored study testing the potential effects of alcohol use and showed that when Palladone is taken with alcohol the extended release mechanism is harmed, which can lead to dose-dumping. Dose-dumping is a term that describes the rapid release of the active ingredient from an extended release product into the blood stream, resulting in serious, even fatal, adverse events in some patients. Although we do not currently market any product comprised of a formulation similar to Purdue's Palladone, we cannot predict what, if any, new regulations may result from the FDA's actions with regard to Palladone and what effect such regulations would have on our business.

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 applies to our products 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 or ANDA 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, requiring a minimum of 10 months, but could also take several years from the date of application. The timing for the ANDA approval process for generic products is difficult to estimate and can vary significantly.

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 unapproved 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 against us.

We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, including oxymorphone extended release (ER) or oxymorphone immediate release (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 October 20, 2003, we announced that the FDA had issued approvable letters for both oxymorphone ER and oxymorphone IR. In the letters, the FDA requested that Endo address certain questions and provide additional clarification and information, including some form of clinical trials to further confirm the safety and efficacy of these products. We have undertaken additional clinical trials of both oxymorphone ER and oxymorphone IR to provide the FDA with additional safety and efficacy data. On August 22, 2005, we reported the results from one of these Phase III clinical trails. In this multi center, randomized, double blind, parallel group trial, the safety and efficacy of oxymorphone ER were compared with placebo in 205 opioid naïve patients with moderate-to-serve chronic low back pain. This study demonstrated a statistically significant ($p<0.0001$) difference in pain

scores between oxymorphone ER and placebo during a 12-week treatment period. On October 3, 2005, we reported the results from the second of these two Phase III clinical trials. In this multi-center, randomized, double-blind parallel group trial, the safety and efficacy of oxymorphone ER were again compared with placebo but this time in 142 opioid-experienced patients with moderate-to-severe chronic low back pain. This study demonstrated a statistically significant ($p<0.0001$) difference in pain scores from placebo during a 12-week treatment period. On October 3, 2005, we also announced positive results for a placebo-controlled, multi-center Phase III trial for oxymorphone IR in the treatment of acute post-operative pain. On the primary outcome variable (time to discontinuations for all causes over a 48-hour period), oxymorphone IR 20 mg and 10 mg, given every four to six hours, were both superior to placebo ($p<0.002$ and ($p<0.006$, respectively). In addition, in order to anticipate questions from the FDA with respect to the potential "dose-dumping" effect of opioids given the FDA's experience with Palladone (see "Most of our core products contain narcotic ingredients. As a result of reports of misuse or abuse of prescription narcotics, the sale of such drugs may be subject to new regulation, including the development and implementation of risk management programs, which may prove difficult or expensive to comply with, and we and other pharmaceutical companies may face lawsuits."), we have completed recently both in vitro and human testing of the effect of alcohol on any product oxymorphone ER. In the in vitro testing of alcohol and oxymorphone ER we did not find any effect on the time release mechanism of the product. With respect to the human testing of alcohol and oxymorphone ER, we do not believe that there was evidence of dose-dumping or signs of degradation of the controlled-release mechanism. We did note in this human testing a transient effect on blood levels which we believe reflects a short-lived increase in the absorption rate of oxymorphone already released from the tablet.

However, there is no certainty that the FDA will accept any of the above studies or what, if any, additional information the FDA will require for final approval of oxymorphone ER and oxymorphone IR. The FDA has not provided clear guidance as to whether or what type of in vitro and/or human testing of new extended-release opioid formulations may be required to determine whether dose-dumping occurs when a product is taken together with alcohol, nor has the FDA indicated what action they might take based on any results arising from this testing. 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. If such testing is conducted, we cannot predict what actions, if any, the FDA may take based on the results of such testing. Any delay in obtaining, or failure to obtain, FDA approval of oxymorphone ER or IR would delay our ability to bring these products to market and would adversely affect our ability to generate revenue from these products. If the FDA approves oxymorphone ER and IR, we cannot assure that it may not take other actions, such as requiring certain labeling or restricting the marketing of one or both of these products, either of which may also adversely affect our ability to generate revenue from these products.

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

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

The FDA and the 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.

We cannot determine what effect changes in regulations or legal interpretations, when and if promulgated, may have on our business in the future. Changes could, among other things, require expanded or different labeling, the recall or discontinuance of certain products, additional record keeping and expanded documentation of the properties of certain products and scientific substantiation. Such changes, or new legislation, could have a material adverse effect on our business, financial condition and results of operations. In December 2003, Congress enacted new requirements for testing drug products in children, which may increase the time and cost necessary for new drug development. Congress recently passed measures intended to speed the process by which generic versions of brand name drugs are introduced to the market. Among other things, these measures are intended to limit regulatory delays of generic drug applications and penalize companies that reach certain types of agreements with makers of brand name drugs to delay the introduction of generic versions. These changes could result in increased generic competition for our branded and generic products and could have a material adverse effect on our business, financial condition and results of operations. See also " The DEA limits the availability of the active ingredients used in our current products and products in development and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials."

The evolving and complex nature of regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that from time to time, we will be adversely affected by regulatory actions despite ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

Timing and results of clinical trials to demonstrate the safety and efficacy of products as well as the FDA's approval of products are uncertain.

Before obtaining regulatory approvals for the sale of any of our products, other than generic products, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. Even promising results from preclinical and early clinical studies do not

always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy would result in our failure to obtain regulatory approvals.

The rate of patient enrollment sometimes delays completion of clinical studies. There is substantial competition to enroll patients in clinical trials for pain management products, and such competition has delayed clinical development of our products in the past. Delays in planned patient enrollment can result in increased development costs and delays in regulatory approval. 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.

We presently have two products under NDA review, two products in Phase III of clinical trials and four 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. Any limitation on use imposed by the FDA or delay in or failure to obtain FDA 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 particular, on October 20, 2003, we announced that the FDA had issued approvable letters for both oxymorphone ER and oxymorphone IR. In the letters, the FDA requested that Endo address certain questions and provide additional clarification and information, including some form of additional clinical trials to further confirm the safety and efficacy of these products. We have undertaken additional clinical trials of both oxymorphone ER and oxymorphone IR to provide the FDA with additional safety and efficacy data. On August 22, 2005, we reported the results from one of these Phase III clinical trials. In this multi center, randomized, double blind, parallel group trial, the safety and efficacy of oxymorphone ER were compared with placebo in 205 opioid naïve patients with moderate-to-severe chronic low back pain. This study demonstrated statistically significant ($p<0.0001$) difference in pain scores between oxymorphone ER and placebo during a 12-week treatment period. On October 3, 2005, we reported the results from the second of these two Phase III clinical trials. In this multi-center, randomized, double-blind, parallel group trial, the safety and efficacy of oxymorphone ER were again compared with placebo but this time in 142 opioid-experienced patients with moderate-to-severe chronic low back pain. This study demonstrated a statistically significant ($p<0.0001$) difference in pain scores from placebo during a 12-week treatment period. On October 3, 2005, we also announced positive results for a placebo-controlled, multi-center Phase III trial for oxymorphone IR in the treatment of acute post-operative pain. On the primary outcome variable (time to discontinuations for all causes over a 48-hour period), oxymorphone IR 20 mg and 10 mg, given every four to six hours, were both superior to placebo ($p<0.002$ and $p<0.006$, respectively). We submitted what we believe to be complete responses to the approvable letters to the FDA on December 22, 2005. The FDA has 60 days from December 22, 2005 to decide whether our submissions represent complete responses and to accept them for substantive review. If accepted for substantive review, we expect "action letters" from the FDA approximately six months following these December 22, 2005 submissions. There is no certainty that the FDA will accept these submissions for substantive review or these results or what, if any, additional information 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.

Before obtaining regulatory approvals for certain generic products, we must conduct limited clinical or other 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.

The success of our acquisition and licensing strategy is subject to uncertainty and any completed acquisitions or licenses may reduce our earnings, be difficult to integrate, not perform as expected or require us to obtain additional financing.

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

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

fail to accomplish our strategic objectives;

not be successfully combined with our operations;

not perform as expected; and

expose us to cross border risks.

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

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

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.

We conduct research and development primarily to enable us to manufacture and market FDA-approved pharmaceuticals in accordance with FDA regulations. Much of our development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. Typically, research expenses related to the development of innovative compounds and the filing of NDAs for these products are significantly greater than those expenses associated with ANDAs for generic products. As we continue to develop new products, our research

expenses will likely increase. Because of the inherent risk associated with research and development efforts in our industry, particularly with respect to new drugs, our research and development expenditures may not result in the successful introduction of FDA approved new pharmaceutical products. Also, after we submit an NDA or ANDA, the FDA may request that we conduct additional studies and as a result, we may be unable to reasonably predict the total research and development costs to develop a particular product.

Our ability to protect our proprietary technology, which is vital to our business, is uncertain.

Our success, competitive position and amount of future income will depend in part on our ability to obtain patent protection relating to the technologies, processes and products we are currently developing and that we may develop in the future. Our policy is to seek patent protection and enforce the intellectual property rights we own and license. We cannot assure you that patent applications we submit and have submitted will result in patents being issued. If an advance is made that qualifies as a joint invention, the joint inventor or his or her employer may have rights in the invention. We cannot assure you that a third party will not infringe upon, design around or develop uses not covered by any patent issued or licensed to us or that these patents will otherwise be commercially viable. In this regard, the patent position of pharmaceutical compounds and compositions is particularly uncertain. Even issued patents may later be modified or revoked by the U.S. Patent and Trademark Office, or PTO, or in legal proceedings. Moreover, we believe that obtaining foreign patents may be more difficult than obtaining domestic patents because of differences in patent laws and, accordingly, our patent position may be stronger in the United States than abroad. Foreign patents may be more difficult to protect and/or the remedies available may be less extensive than in the United States. Various countries limit the subject matter that can be patented and limit the ability of a patent owner to enforce patents in the medical field. This may limit our ability to obtain or utilize those patents internationally. Patent applications in the United States are maintained in secrecy until at least 18 months after the filing of the application with the PTO and, since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries, we cannot be certain that we were the first creator of the inventions covered by pending patent applications or the first to file patent applications on those inventions. Several drug companies and research and academic institutions have developed technologies, filed patent applications or received patents for technologies that may be related to our business. Others may file patent applications and may receive patents that may conflict with patents or patent applications we have obtained or licensed for our use, either by claiming the same methods or compounds or by claiming methods or compounds that could dominate those owned by or licensed to us. We cannot assure you that any of our pending patent applications will be allowed, or, if allowed, whether the scope of the claims allowed will be sufficient to protect our products. 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 means to limit the use of generics and certain other products are successful, our sales may suffer.

Pharmaceutical companies that produce patented brand products are increasingly employing a range of legal and regulatory strategies to delay the introduction of competing generics and certain other products to which we do not have a right of reference to all necessary preclinical and clinical data. Opposing such measures can be costly and time-consuming and result in delays in the introduction of our products.

The products for which we are developing generic versions may be claimed by their manufacturer to be protected by one or more patents. If we file an 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 our favor or expiration of the patent(s).

One of the key motivators for challenging patents is the 180-day market exclusivity period vis a vis other ANDA applicants granted to the developer of a generic version of a product that is the first to have its ANDA accepted for filing by the FDA and whose filing includes a certification that the applicable patent(s) are invalid, unenforceable and/or not infringed (a "Paragraph IV certification") and that prevails in litigation with the manufacturer of the branded product over the applicable patent(s). 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 upon an appellate court decision in our favor. However, we cannot assure you that we will be prepared, authorized or willing (depending on the circumstances) to commercialize the applicable product prior to an appellate decision in our favor.

We recently received favorable decisions from the U.S. District Court for the Southern District of New York and the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. in our patent litigation with respect to our extended release oxycodone product. This litigation was instituted by Purdue, 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. On June 7, 2005, the Court of Appeals affirmed the Opinion and Order of the District Court in our favor. On the same day, we launched the 10mg, 20mg, 40mg and 80mg strengths of our bioequivalent versions of OxyContin®.

On June 21, 2005, Purdue filed a petition with the Federal Circuit Court of Appeals seeking rehearing of the case by the panel that issued the June 7, 2005 decision, or alternatively by the entire court. On July 18, 2005, the Federal Circuit Court of Appeals requested that Endo submit a response brief as part of its review process of Purdue's petition for rehearing and rehearing en banc. Endo submitted this response on August 1, 2005. We can make no prediction as to how or when the appellate court will rule on the petition for rehearing, which ruling may be made at any time. Because we commenced commercial sale of our bioequivalent versions of OxyContin®, we could face substantial liability for patent infringement if the Federal Circuit Court of Appeals reverses itself or is reversed by the Supreme Court and one or more of the Purdue patents is found valid and enforceable and there is a final court decision adverse to us.

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

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

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

The availability of third party reimbursement for our products is uncertain, and thus we may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third party reimbursement is not adequately provided.

Our ability to commercialize our products depends, in part, on the extent to which reimbursement for the costs of these products is available from government health administration authorities, private health insurers and others. We cannot assure you that third party insurance coverage will be adequate for us to maintain price levels sufficient for realization of an appropriate return on our investment. Government, private insurers and other third party payers are increasingly attempting to contain health care costs by (1) limiting both coverage and the level of reimbursement (including co-pays) for 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 some or all of a Medicare beneficiary's medications are not listed on the applicable formulary, such Medicare beneficiary may not receive reimbursement for some or 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 demand for our products may decrease and

we may be forced to lower prices for our products, which may adversely affect our business and our results of operations.

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.

Our reporting and payment obligations under the Medicaid rebate program and other governmental pricing programs are complex and may involve subjective decisions. Any failure to comply with those obligations could subject us to penalties and sanctions.

We and other pharmaceutical companies are defendants in a number of lawsuits filed by local and state government entities, alleging generally that we and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. Endo intends to defend these lawsuits vigorously. Depending on developments in the litigation however, as with all litigation, there is a possibility that the company will suffer adverse decisions or verdicts, or that the company will enter into monetary settlements in one or more of these actions. The regulations regarding reporting and payment obligations are complex and we are continually evaluating the methods we use to calculate and report the amounts owed with respect to Medicaid and other government pricing programs. Our calculations are subject to review and challenge by various government agencies and authorities and it is possible that any such review could result either in material changes to the method used for calculating the amounts owed to the pertinent government agency (or agencies), or to the amounts themselves. In addition, because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions, these calculations are subject to the risk of errors. Any governmental agency that commences an investigation of us could impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of the applicable laws impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments and even in the absence of such ambiguity a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. Any such penalties or sanctions could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Once approved, there is no guarantee that the market will accept our future products, and regulatory requirements could limit the commercial usage of our products.

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. We cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new

products as a result of those efforts, our business, financial position and results of operations may be materially adversely affected, and the market value of our common stock could decline. 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.

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 31%, 27%, 13% and 5% respectively, of net sales for the nine months ended September 30, 2005, 29%, 18%, 18% and 9% respectively, of net sales in 2004, 26%, 26%, 19% and 11% respectively, of net sales in 2003, and 24%, 24%, 23% and 11%, respectively of net sales in 2002. If we were to lose the business of any of these customers, or if any were to experience difficulty in paying us on a timely basis, our net sales, profitability and cash flows could be materially and adversely affected.

We 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.

We have entered into minimum purchase requirement contracts with some of our third party manufacturers. 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. We are required to purchase a minimum amount of product from Novartis through 2011. We also have a long-term contract with Teikoku Seiyaku Co., Ltd. under which Teikoku manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We are required to purchase a minimum of $18 million of Lidoderm® at cost of goods from Teikoku in 2006. 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. 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 certain 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 certain core aspects of our business, including manufacturing, warehousing, distribution, customer service support, medical affairs services, clinical studies, sales and other technical and financial services. All third party suppliers and contractors are subject to FDA, and very often DEA, requirements. Our business and financial viability are dependent on the regulatory compliance of these third parties, and on the strength, validity and terms of our various contracts with these third party manufacturers, distributors and collaboration partners. Any interruption or failure by these suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, financial condition, profitability and cash flows.

In addition, we have entered into minimum purchase requirement contracts with some of our third party suppliers. If the market for the products that utilize these raw materials substantially contracts or disappears, we will continue to be financially obligated under these contracts and meeting such obligations 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 procurement 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, sufentanil 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 DEA limits the availability of the active ingredients used in many of our current products and products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials. We must annually apply to the DEA for procurement quota in order to obtain these substances. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials, product launches or, in a case such as oxycodone where the DEA is considering whether the legislation applies, could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial position and results of operations.

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 place competitive pressures on drug manufacturers, including us. If we lose any of these customer accounts, or if our relationship with them were to deteriorate, our business could also be materially and adversely affected. Orders for our products may increase or decrease depending on the inventory levels held by our major customers. Significant increases and decreases in orders from our major customers could cause our operating results to vary significantly from quarter to quarter.

Retail availability of our products is greatly affected by the inventory levels our customers hold. We monitor wholesaler inventory of our products using a combination of methods, including tracking prescriptions filled at the pharmacy level to determine inventory amounts the wholesalers have sold to their customers. Beginning in 2005, pursuant to our agreement with one of our significant wholesale customers, we receive inventory level reports. For other wholesalers where we do not receive inventory level reports, however, our estimates of wholesaler inventories may differ significantly from actual inventory levels. Significant differences between actual and estimated inventory levels may result in excessive inventory production, inadequate supplies of products in distribution channels, insufficient or excess product available at the retail level, and unexpected increases or decreases in orders from our major customers. Forward buying by wholesalers, for example, may result in significant and unexpected changes in customer orders from quarter to quarter. These changes may cause our revenues to fluctuate significantly from quarter to quarter, and in some cases may cause our operating results for a particular quarter to be below our expectations or projections. If our financial results are below expectations for a particular period, the market price of our securities may drop significantly.

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.

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.

Goodwill and other intangibles represent a significant portion of our assets and stockholders' equity. As of September 30, 2005, goodwill and other intangibles comprised approximately 23% of our total assets and 35% of our stockholders' equity. Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets, prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit's fair value to all of its assets and

liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount. Our other intangible assets, consisting of licenses and patents, are assessed for impairment, in accordance with Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. As a result of the significance of 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.