ENDO PHARMACEUTICALS HOLDINGS INC
Form 10-K
March 16, 2005

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the fiscal year ended December 31, 2004

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the transition period from to .

Commission file number: 001-15989

ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

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

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

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

Securities registered pursuant to Section 12(b) of the Act: N/A

Securities registered pursuant to Section 12(g) of the Act:

Title of Each Class

	Name of Each Exchange on Which Registered
Common Stock	NASDAQ

Annual Report for the Year Ended December 31, 2004

Indicate by check þ whether the registrant: (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check þ if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter (June 30, 2004): $1,131,747,769 based on the last reported sale price on the NASDAQ on June 30, 2004.

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of March 10, 2005: 131,873,319.

Documents Incorporated by Reference

Portions of the registrant s proxy statement to be filed with the SEC pursuant to Regulation 14A in connection with the registrant s 2005 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the SEC not later than 120 days after the conclusion of the registrant s fiscal year ended December 31, 2004.

ENDO PHARMACEUTICALS HOLDINGS INC.

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FOR THE YEAR ENDED DECEMBER 31, 2004

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Forward Looking Statements

We have made forward-looking statements in this document within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. These statements, including estimates of future net sales, future net income and future earnings per share, contained in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations, are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. Also, statements including words such as believes, expects, anticipates, intends, estimates, or similar expressions are forward-looking statements. We have based these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described in Management s Discussion and Analysis of Financial Condition and Results of Operations , Business and elsewhere in this Report could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained in this Report. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in this Report include, among others:

Our growth and development will depend on our ability to successfully develop, commercialize and market new products, including both our own products and those developed with our collaboration partners. If we do not do so successfully, our growth and development will be impaired.

Timing and results of clinical trials to demonstrate the safety and efficacy of products as well as the FDA s approval of products are uncertain. Before obtaining regulatory approvals for the sale of any of our products, other than generic products, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large-scale trials. A failure to demonstrate safety and efficacy would result in our failure to obtain regulatory approvals.

We face intense competition for the business of our branded and generic products, and in connection with our acquisition of rights to intellectual property assets. Competitive factors include: (i) the development of new products by our competitors that make our products or technologies uncompetitive or obsolete, (ii) competition with our branded products by generic versions that are generally significantly cheaper than the branded version, and, where available, may be required or encouraged in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies for branded versions by law, and (iii) competition to acquire intellectual property assets that we require to continue to develop and broaden our product range.

We are required to make significant cash payments to Endo Pharma LLC pursuant to a tax sharing agreement under which we have been and may be required to pay Endo Pharma LLC the amount of tax benefits usable by us as a result of the exercise of certain stock options into shares of our common stock held by Endo Pharma LLC.

Once approved by FDA, there is no guarantee that the market will accept our future products, and this may have an adverse effect on our profitability and cash flows.

The pharmaceutical industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business. The federal, state and local governmental authorities in the United States, the principal one of which is the FDA, impose substantial requirements on the development, manufacture, labeling, sale, distribution, marketing, advertising, promotion

and introduction of therapeutic pharmaceutical products through lengthy and detailed laboratory and clinical testing and other costly and time-consuming procedures. NDA approvals, if granted, may not include all uses for which we may seek to market a product. The FDA actively enforces regulations prohibiting marketing of products for non-indicated uses. Failure to comply with applicable regulatory requirements in this regard can result in, among other things, suspensions of approvals, seizures or recalls of products, injunctions against a product s manufacture, distribution, sales and marketing, operating restrictions, civil penalties and criminal prosecutions. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals. The effect of government regulation may be to delay marketing of our new products for a considerable period of time, to impose costly procedures upon our activities and to furnish a competitive advantage to larger companies that compete with us. We cannot assure you that the FDA or other regulatory agencies will approve any products developed

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or in-licensed by us on a timely basis, if at all, or, if granted, that approval will not entail limiting the indicated uses for which we may market the product, which could limit the potential market for any of these products.

Most of our net sales come from a small number of products. Net sales of Lidoderm®, Endocet®, Percocet® and generic morphine sulfate accounted for 50%, 19%, 14% and 10% of our net sales for the year ended December 31, 2004, respectively. If we were unable to continue to market any of these products, if any of them lost market share, for example, as the result of the entry of new competitors, or if the prices of any of these products declined significantly, our net sales, profitability and cash flows would be materially adversely affected.

We are dependent on outside manufacturers for the manufacture of our products. Third-party manufacturers currently manufacture all of our products pursuant to contractual arrangements. Accordingly, we have a limited ability to control the manufacturing process or costs related to this process. Increases in the prices we pay our manufacturers, interruptions in our supply of products or lapses in quality could adversely impact our margins, profitability and cash flows. We are reliant on our third-party manufacturers to maintain the facilities at which they manufacture our products in compliance with FDA, DEA, state and local regulations. If they fail to maintain compliance with FDA, DEA or other critical regulations, they could be ordered to cease manufacturing which would have a material adverse impact on our business, profitability and cash flows. In addition to FDA and DEA regulation, violation of standards enforced by the Environmental Protection Agency, or EPA, and the Occupational Safety and Health Administration, or OSHA, and their counterpart agencies at the state level, could slow down or curtail operations of third-party manufacturers. Certain of our manufacturers currently constitute the sole source of one or more of our products. Because of contractual restraints and the lead-time necessary to obtain FDA approval, and possibly DEA registration, of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of products to customers.

We are dependent on third parties to supply all raw materials used in our products and to provide many services for the core aspects of our business. Any interruption or failure by these suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, profitability and cash flows.

Most of our core products contain narcotic ingredients. As a result of reports of misuse or abuse of prescription narcotics, the sale of such drugs may be subject to new regulation, including the development and implementation of risk management programs, which may prove difficult or expensive to comply with, and we and other pharmaceutical companies may face lawsuits.

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

Our ability to protect our proprietary technology, which is vital to our business, is uncertain. Our success, competitive position and amount of potential future income will depend in part on our ability to obtain patent protection relating to the technologies, processes and products we are currently developing and that we may develop in the future.

If the efforts of manufacturers of branded pharmaceuticals to use litigation and legislative and regulatory efforts to limit the use of generics and certain other products are successful, our sales may suffer. Pharmaceutical companies that produce patented brand products are increasingly employing a range of legal and regulatory strategies to delay the introduction of competing generics and certain other products to which we do not have a right of reference to all necessary preclinical and clinical data. Opposing such measures can be costly and time-consuming and result in delays in the introduction of our products.

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

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

The availability of third-party reimbursement for our products is uncertain, and thus we may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third-party reimbursement is not adequately provided. Our ability to commercialize our products depends in part on the extent to which reimbursement for the costs of these products is available from government health administration authorities, private health insurers and others. We cannot assure you that third-party insurance coverage will be adequate for us to maintain price levels sufficient for realization of an appropriate return on our investment. Government, private insurers and other third-party payers are increasingly attempting to contain health care costs by (1) limiting both coverage and the level of reimbursement for new products approved for marketing by the FDA, (2) refusing, in some cases, to provide any coverage for uses of approved products for indications for which the FDA has not granted marketing approval and (3) requiring or encouraging, through more favorable reimbursement levels or otherwise, the substitution of generic alternatives to branded products.

The outcome of any litigation is uncertain, including claims asserting violations of the Federal False Claims Act, Anti-Kickback Statute or other violations in connection with Medicare and/or Medicaid; and

We are dependent on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of our total net sales. We sell our products directly to a limited number of large pharmacy chains and through a limited number of wholesale drug distributors who, in turn, supply our products to pharmacies, hospitals, governmental agencies and physicians. Three distributors and one pharmacy chain individually accounted for 29%, 18%, 18% and 9% respectively, of net sales in 2004, 26%, 26%, 19% and 11% respectively, of net sales in 2003, and 24%, 24%, 23% and 11% respectively, of net sales in 2002. If we were to lose the business of any of these customers, or if any were to experience difficulty in paying us on a timely basis, our net sales, profitability and cash flows could be materially and adversely affected.

We do not undertake any obligation to update our forward-looking statements after the date of this Report for any reason, even if new information becomes available or other events occur in the future. You are advised, however, to consult any further disclosures we make on related subjects in our 10-Q and 8-K reports to the SEC. Also note that we provide the preceding cautionary discussion of risks, uncertainties and possibly inaccurate assumptions relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the preceding to be a complete discussion of all potential risks or uncertainties.

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PART I

Item 1. *Business*

Overview

Endo Pharmaceuticals Holdings Inc. (the Company or we), through its wholly owned subsidiary, Endo Pharmaceuticals Inc. (Endo), is engaged in the sales, marketing, research and development of branded and generic pharmaceutical products primarily in the United States. On November 19, 1999, the Company formed Endo Inc. as a wholly owned subsidiary of the Company to effect the acquisition of Algos Pharmaceutical Corporation (Algos). On December 31, 2001, Endo Inc. was merged with and into Endo. The stock of Endo is the only asset of the Company, and the Company has no other operations or business. 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 in the opioid analgesics segment. Total U.S. sales for this 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 brand names such as Lidoderm®, Percocet®, Percodan®, Frova®, DepoDur™ and Zydone®. Branded products comprised approximately 69% of our net sales in 2004. Our generic portfolio, which accounted for 31% of our net sales in 2004, currently consists of products that cover a variety of indications, most of which are focused in pain management. We concentrate on generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing.

We have established research and development expertise in analgesics and devote significant resources to this effort so that we can maintain and develop our product pipeline. Our late-stage branded products pipeline includes two filed new drug applications, or NDAs, two products in Phase III clinical trials and five products in Phase II clinical trials.

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

Through a dedicated sales force of approximately 370 sales representatives in the United States, including 115 hired in early 2005, we market our branded pharmaceutical products primarily to high-prescribing physicians in pain management, surgery, oncology and primary care. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

Endo was incorporated on November 18, 1997 under the laws of the state of Delaware and has its principal executive offices at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317 (telephone number: (610) 558-9800).

Our Strategy

Our business strategy is to continue to strengthen our position as a market leader in pain management while also pursuing other markets, especially those with complementary therapeutic or physician bases. The elements of our strategy include:

Capitalizing on our established brand names and brand awareness through focused marketing and promotional efforts. Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, continues to increase market penetration due to our ongoing promotional and educational efforts. We consider two of our brands, Percocet® and Percodan®, to be gold standards of pain management. Percocet® has been prescribed by physicians since 1976, while Percodan® has been prescribed since 1950. We believe that we have established credibility with physicians as a result of these products history of demonstrated effectiveness and safety. We plan to continue to capitalize on this brand awareness to market new products and explore new indications for existing products as well as market new formulations and dosages of our existing branded products. During 2004, we launched Frova®, which we believe has differentiating features from other migraine products, including the longest half-life in the triptan class and a very low reported recurrence rate in its clinical program. We believe these distinct characteristics have yet to be fully exploited in the North American market and that we will be able to capitalize on Frova® s clinical benefits and commercial potential by targeting the specialty physician audience and effectively leveraging the relationships and reputation that we have built with the neurology and pain specialist community over the years. During 2004, we began our educational efforts to physicians

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including advocacy development for DepoDur™ the first and only single-dose epidural injection that can provide up to 48 hours of pain control to help ease pain for people undergoing major surgery in the United States. We began commercial shipments of DepoDur™ in December 2004. We believe that our strong corporate and product reputation leads to more rapid adoption of our new products by physicians.

Leveraging our pain management expertise by developing proprietary products and generic products with significant barriers to market entry. To capitalize on our expertise in pain management, we are developing new products to address acute, chronic and neuropathic pain conditions. Specifically, we are developing new patent-protected products that may substantially improve the treatment of pain. We are co-developing an oral extended-release (ER) version of oxymorphone with Penwest Pharmaceuticals Co. and are internally developing an oral immediate-release (IR) version of oxymorphone. The NDAs for these oxymorphone ER tablets and IR tablets were filed with the FDA in December 2002, and we received Approvable Letters for these two products in October 2003. In 2004, we reached agreement with the FDA as to the design of new clinical trials to provide requested additional safety and efficacy data of oxymorphone ER and oxymorphone IR in support of our NDAs for these developmental products. We had submitted the trial protocol to the FDA under the Special Protocol Assessment (SPA) process and the protocol was approved by the FDA in November 2004 for oxymorphone ER. Based on the duration of the trial and the number of patients to be enrolled, we believe that, assuming the data are favorable, we will be in a position to finish the study and submit the complete response to the FDA in early 2006. At that point, the FDA will have six months regulatory review time to act on this complete response to its October 2003 approvable letter. In September 2004, we received final approval from the FDA of the clinical trial protocol relating to our developmental product, oxymorphone IR. We had submitted this trial protocol to the FDA under the Special Protocol Assessment (SPA) process. In addition, in May 2004, we and SkyePharma, Inc., our collaboration partner, announced that the FDA had approved SkyePharma s NDA for DepoDur™ for the treatment of pain following major surgery. Previously referred to as DepoMorphine™, DepoDur™ is a novel single dose sustained-release injectable formulation of morphine. We launched DepoDur™ in December 2004.

We have also developed an extended-release oxycodone, an AB rated generic version of OxyContin®, a product of The Purdue Frederick Company that is indicated for the management of moderate-to-severe pain when continuous, around-the-clock analgesic is needed for an extended period of time. According to IMS National Sales Perspective data, OxyContin® generated U.S. sales of approximately $1.8 billion in 2004. In March 2004, we received final approval from the FDA for bioequivalent versions of the 10mg, 20mg, 40mg and 80mg strengths of OxyContin®. We are the first company to have filed an abbreviated new drug application, or ANDA, with the FDA for the bioequivalents versions of the 10mg, 20mg and 40mg strengths of OxyContin® (which represent approximately 68% of the U.S. branded sales of OxyContin®), thereby entitling us to 180 days of generic product ANDA marketing exclusivity with respect to these strengths of this product. For several reasons, including potential marketing exclusivity, we believe it is a significant advantage to be the first successful filer of an ANDA for a generic drug. We currently are in litigation with Purdue Frederick with respect to this product, and the trial was completed in June 2003. On January 5, 2004, the U.S. District Court for the Southern District of New York issued an Opinion and Order dismissing Purdue s claims that Endo s oxycodone extended-release tablets, 10mg, 20mg, 40mg and 80mg, a bioequivalent version of Purdue Frederick s OxyContin®, infringe Purdue s U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, declaring these patents invalid, and enjoining Purdue from enforcing the patents. Purdue filed an appeal, as well as motions to expedite the appeal and to stay the injunction against enforcement of the patents until the appeal is resolved. Both motions were denied on March 18, 2004. In turn, we have cross-appealed the district court s infringement ruling. Briefing on the appeal and cross-appeal concluded in July 2004. By an earlier order, the judge bifurcated the antitrust counterclaims for a separate and subsequent trial. On November 3, 2004, the oral arguments relating to the appeal of this case were heard by the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., at which hearing both sides presented their arguments before a three-judge panel. We are awaiting the outcome of this appeal. See Item 3. Legal Proceedings.

Acquiring and in-licensing complementary products, compounds and technologies. We look to continue to enrich our product line through selective product acquisitions and in-licensing, or acquiring licenses to products, compounds and technologies from third parties. In February 2004, we entered into an agreement for the exclusive U.S. and Canadian marketing and distribution rights to Noven Pharmaceuticals, Inc. s developmental transdermal fentanyl patch intended to be the generic equivalent of Johnson & Johnson s Duragesic® (fentanyl transdermal system), which had U.S. sales of approximately $1.6 billion in 2004. The agreement also establishes an ongoing collaboration between the two companies for the development of additional prescription transdermal products. In August 2004, we entered into a license agreement with Vernalis Development Limited, (Vernalis), under which Vernalis agreed to exclusively license to us rights to market Frova® (frovatriptan) in North America. Launched in the U.S. in June 2002, Frova® is indicated for the acute treatment of migraine headaches in adults. In August 2004, we entered into an agreement granting us the exclusive rights to develop and market Orexo AB s (a privately held Swedish company) patented sublingual muco-adhesive fentanyl product (Rapinyl) in North America. Rapinyl is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. The benefits of Rapinyl are believed to include both a fast onset of action and patient convenience. In March 2005, we entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and available in the U.S. only in oral form. Also in March 2005, we entered into an agreement that will give us the exclusive license to develop and commercialize DURECT s sufentanil-containing transdermal patch in the U.S. and Canada. The sufentanil patch, which is in early-stage clinical development, employs DURECT s proprietary TRANSDUR drug-adhesive matrix formulation and is intended to provide relief of moderate-to-severe chronic pain for up to seven (7) days.

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Our Competitive Strengths

We believe that we have established a position as a market leader among specialty pharmaceutical companies by capitalizing on our following core strengths:

Established portfolio of branded products. We have assembled a portfolio of branded pharmaceutical products to treat and manage pain. These products include Lidoderm®, a topical patch containing lidocaine, which is the first FDA-approved product to treat the pain associated with post-herpetic neuralgia. The FDA has granted Lidoderm® orphan drug status, which means, generally, that no other lidocaine-containing product can be approved for this indication until March 2006. Additionally, Lidoderm® is protected by certain patents until 2015. Net sales of Lidoderm® increased 73% from $178.3 million in 2003 to $309.2 million in 2004. We consider Percocet®, our oxycodone/acetaminophen combination product and Percodan®, our oxycodone/aspirin combination product, which have been marketed since 1976 and 1950, respectively, to be gold standards of pain management based on their long history of demonstrated product safety and effectiveness. According to IMS Health data, approximately 77% of prescriptions written for oxycodone with acetaminophen are in fact written as Percocet. We believe our close relationships with physicians who are considered to be pain management thought leaders in pain centers, hospitals, and other pain management institutions enable us to improve our market penetration. During 2004, we added Frova® to our portfolio of branded products, which we believe has differentiating features from other migraine products, including the longest half-life in the triptan class and a very low reported recurrence rate in its clinical program. We believe these distinct characteristics have yet to be fully exploited in the North American market and that we will be able to capitalize on Frova® s clinical benefits and commercial potential by targeting the specialty physician audience and effectively leveraging the relationships and reputation that we have built with the neurology and pain specialist community over the years. We believe this interaction with the thought leaders and our track record of developing and launching new products has enabled us to pursue, through in-licensing and acquisitions, novel products for the treatment of pain and complementary therapeutic areas.

Substantial pipeline focused on pain management with a balanced focus on complementary therapeutic areas. As a result of our focused research and development efforts, we filed two NDAs with the FDA in December 2002 for oxymorphone ER tablets and oxymorphone IR tablets. We received approvable letters from the FDA for both the oxymorphone ER and oxymorphone IR in October 2003. In these approvable letters, the FDA requested that we 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. In 2004, we reached agreement with the FDA as to the design of a new clinical trial to provide additional safety and efficacy data of oxymorphone ER in support of our NDA for this developmental product. We had submitted the trial protocol to the FDA under the Special Protocol Assessment (SPA) process and the protocol was approved by the FDA in November 2004. Based on the duration of the trial and the number of patients to be enrolled, we believe that, assuming the data are favorable, we will be in a position to finish the study and submit the complete response to the FDA in early 2006. At that point, the FDA will have six months to act on this complete response to its October 2003 approvable letter. In addition, we currently have two products in Phase III clinical trials and five products in Phase II clinical trials.

Research and development expertise. Our research and development effort is focused on expanding our product portfolio by capitalizing on our core expertise with analgesics. We have assembled an experienced and multi-disciplined research and development team of scientists and technicians with a proven expertise working with analgesics and complex formulations. We believe this expertise allows for timely FDA approval of our products. We have demonstrated our ability to commercialize our research and development efforts during the last seven years through the launch of a number of new products and product line extensions since August 1997.

Targeted national sales and marketing infrastructure. We market our products directly to physicians through an internal sales force of approximately 300 specialty and office-based representatives and approximately 70

hospital-based representatives. Through our sales force, we market our branded pharmaceutical products to just over 50,000 physicians, which include both specialists and primary care physicians. These physicians treat patients with the neuropathic pain of post-herpetic neuralgia and represent approximately 82% of the prescriptions written for Lidoderm® (lidocaine patch 5%).

Selective focus on generic products. Our generic product portfolio includes products focused on pain management. Development of these products involves barriers to entry such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. We believe products with these characteristics will face a lesser degree of competition and therefore provide longer product life cycles and higher profitability than commodity generic products. We have executed our generic product development strategy successfully to date with products such as morphine sulfate extended-release tablets, which we introduced in November 1998 as a bioequivalent version of MS Contin, a product of The Purdue Frederick Company. In addition, we are the first company to have filed

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an ANDA with the FDA for the bioequivalent version of the 10mg, 20mg and 40mg strengths of Purdue Frederick s OxyContin®. For several reasons, including potential marketing exclusivity, we believe it is a significant advantage to be the first successful filer of an ANDA for a generic drug. In 2004, we received final approval from the FDA for all four strengths (10mg, 20mg, 40mg and 80mg) of our generic OxyContin®. We currently are in litigation with Purdue Frederick with respect to this product, and the trial was completed in June 2003. On January 5, 2004, the U.S. District Court for the Southern District of New York issued an Opinion and Order dismissing Purdue s claims that Endo s oxycodone extended-release tablets, 10mg, 20mg, 40mg and 80mg, a bioequivalent version of Purdue Frederick s OxyContin®, infringe Purdue s U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, declaring these patents invalid, and enjoining Purdue from enforcing the patents. Purdue filed an appeal, as well as motions to expedite the appeal and to stay the injunction against enforcement of the patents until the appeal is resolved. Both motions were denied on March 18, 2004. In turn, we have cross-appealed the district court s infringement ruling. Briefing on the appeal and cross-appeal concluded in July 2004. By an earlier order, the judge bifurcated the antitrust counterclaims for a separate and subsequent trial. On November 3, 2004, the oral arguments relating to the appeal of this case were heard by the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., at which hearing both sides presented their arguments before a three-judge panel. We are awaiting the outcome of this appeal. See Item 3. Legal Proceedings.

Experienced and dedicated management team. Our senior management team has a proven track record of building our business through internal growth as well as through acquisitions and licensing. Members of our senior management led the purchase of the company from The DuPont Merck Pharmaceutical Company in August 1997 as well as the licensing of Lidoderm®, CHRONOGESIC™, DepoDur™, Propofol IDD-D™, Frova® and Rapinyl™. Management has received FDA approval on more than fifteen new products and product line extensions since 1997, and as a result of several successful product launches, has grown our net sales from approximately $108.4 million in 1998 to approximately $615.1 million in 2004. In addition, management has vested stock options to acquire approximately 11% of our common stock. Substantially all of these options are exercisable solely for shares currently held by Endo Pharma LLC, a limited liability company holding a significant portion of our common stock, in which affiliates of Kelso & Company and certain members of management have an interest, and the exercise of these options will not dilute the ownership of our other existing common stockholders. See Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies; Compensation Related to Stock Options Endo Pharma LLC Stock Option Plans.

Our Industry

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. In 2004, analgesics were the third most prescribed medication in the United States with over 272 million prescriptions written for this classification. These products are used primarily for the treatment of pain associated with orthopedic fractures and sprains, back injuries, migraines, joint diseases, cancer and various surgical procedures.

Opioid analgesics comprised approximately 75% of the analgesics prescriptions in 2004. This market segment has grown to $6.3 billion in 2004, representing a compounded annual growth rate of 20% since 1999. If branded products were substituted for generic products, we believe the dollar value of this market segment would be substantially larger. The growth in this segment has been primarily attributable to:

- increasing physician recognition of the need and patient demand for effective treatment of pain;
- aging population (according to the U.S. Census Bureau, in 2000 the population aged 65 and older reached 35 million people and is expected to grow to 40 million people by 2010, representing 14% growth over this period);

introduction of new and reformulated branded products; and

increasing incidence of chronic pain conditions, such as cancer, arthritis and low back pain.

Product Overview

The following table summarizes select products in our marketed portfolio as well as selected products in development:

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Product	Active Ingredient(s)	Branding	Status
Lidoderm®	lidocaine 5%	Branded	Marketed
Percocet®	oxycodone and acetaminophen	Branded	Marketed
Percodan®	oxycodone and aspirin	Branded	Marketed
Zydone®	hydrocodone and acetaminophen	Branded	Marketed
Frova® (1)	frovatriptan	Branded	Marketed
DepoDur™ (2)	morphine sulfate	Branded	Marketed
Endocet®	oxycodone and acetaminophen	Generic	Marketed
Morphine Sulfate ER	morphine sulfate	Generic	Marketed
Oxymorphone ER(3)	oxymorphone hydrochloride	Branded	Approvable Letter
Oxymorphone IR	oxymorphone hydrochloride	Branded	Approvable Letter
Propofol IDD-D™ (2)	propofol	Branded	Phase III
Frova® (menstrually related migraine) (1)	frovatriptan	Branded	Phase III
CHRONOGESIC™ (4)	sufentanil	Branded	Phase II
Lidoderm® (chronic low back pain)	lidocaine 5%	Branded	Phase II
LidoPAIN® BP(5)	lidocaine	Branded	Phase II
Rapinyl™ (oral, fast dissolving) (6)	fentanyl	Branded	Phase II
Topical Ketoprofen Patch(9)	ketoprofen	Branded	Phase II
Transdermal Sufentanil Patch(4)	sufentanil	Branded	Early stage
Transdermal Fentanyl Patch(7)	fentanyl	Generic	ANDA filed; under FDA review
Oxycodone ER(8)	oxycodone	Generic	Approved; subject to ongoing litigation

(1) Licensed marketing rights from Vernalis Development Limited.

(2) Licensed marketing rights from SkyePharma, Inc.

(3) Co-developed with Penwest Pharmaceuticals Co.

(4) Licensed marketing rights from DURECT Corporation.

(5) Licensed marketing rights from EpiCept Corporation.

(6) Licensed marketing rights from Orexo AB.

(7) Licensed marketing rights from Noven Pharmaceuticals, Inc.

(8) See Item 3. Legal Proceedings.

(9) Licensed marketing rights from ProEthic Pharmaceuticals, Inc.

Branded Products

Lidoderm®. Lidoderm® was launched in September 1999. A topical patch product containing lidocaine, it is the first FDA-approved product for the relief of the pain associated with post-herpetic neuralgia. There are approximately

200,000 patients per year who suffer from this condition in the United States, the majority of whom are elderly. The FDA has granted Lidoderm® orphan drug status, generally meaning that no other lidocaine-containing patch product can be approved for this indication until March 2006. Certain exceptions apply (for example, a product shown to be clinically superior may be approved); however, we are unaware that any such product has been, or is being, developed. Lidoderm® is also currently protected by patents for, among other things, a method of treating post-herpetic neuralgia and the composition of the lidocaine-containing patch. The last of these patents will expire in 2015. In 2002, 2003 and 2004, Lidoderm® net sales were $83.2 million, $178.3 million and $309.2 million, respectively. Lidoderm® accounted for approximately 50% of our 2004 net sales.

In addition, we are currently exploring potential new indications for Lidoderm® and have initiated a Phase II clinical trial in chronic low back pain.

Percocet®. We consider Percocet® to be a gold standard of pain management. Launched in 1976, Percocet® is approved for the treatment of moderate-to-moderately severe pain. Although Percocet® has faced generic competition for nearly 20 years, in 2004, according to the IMS National Prescription Audit, approximately 17.9 million new prescriptions for this combination of oxycodone hydrochloride and acetaminophen were written for the brand name Percocet, of which, due to generic substitution, only approximately 7% were filled by pharmacists with our brand Percocet®.

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During the fourth quarter of 2001, we launched two new formulations: Percocet® 7.5/325 and Percocet® 10.0/325. These new dosage strengths allow physicians the flexibility of increasing the dose of opioid while still maintaining a low level of acetaminophen. In October 2003, a competitor announced that it was launching its generic versions of Percocet® 7.5/325 and Percocet® 10.0/325. The Percocet® family of products had net sales of $144.6 million, $214.2 million and $86.5 million in the years 2002, 2003 and 2004, respectively. The Percocet® franchise accounted for approximately 14% of our 2004 net sales.

Frova®. We began shipping Frova® upon closing of the license agreement with Vernalis in mid-August 2004 and initiated our promotional efforts in September. We believe that Frova® has differentiating features from other migraine products, including the longest half life in the triptan class and a very low reported recurrence rate in its clinical program. We believe these distinct characteristics have yet to be fully exploited in the North American market and that we will be able to capitalize on Frova® s clinical benefits and commercial potential by targeting the specialty physician audience and effectively leveraging the relationships and reputation that Endo has built with the neurology and pain specialist community over the years. We believe we can create an advocacy base among thought leaders who treat patients with the most intractable migraines. Further, Frova® s potential future application for the prevention of menstrually related migraine makes it one of the company s most promising products. Net sales of Frova® were $11.4 million in 2004.

DepoDur™. DepoDur™, our newest product, became available when we began commercial shipments of the product in December of 2004. DepoDur™ is FDA-approved for the treatment of pain following major surgery. DepoDur™ is the first and only single-dose epidural injection that can provide up to 48 hours of pain control to help ease pain for people undergoing major surgery in the United States.

Percodan®. Launched in 1950 for the treatment of moderate-to-moderately severe pain, we also consider Percodan® to be a gold standard of pain management. According to the IMS National Prescription Audit, in 2004, approximately 283,000 prescriptions for oxycodone hydrochloride and oxycodone terephthalate in combination with aspirin were written for the brand name Percodan. Due to generic substitution, only approximately 17% of these prescriptions were filled by pharmacists with our brand Percodan®.

Zydone®. In February 1999, we launched Zydone® tablets, branded hydrocodone/acetaminophen products for the relief of moderate-to-moderately severe pain. Zydone® is available in three strengths, 5.0mg, 7.5mg and 10.0mg, each in combination with 400mg acetaminophen. There is currently no generic equivalent available for this product.

Other. The balance of our branded portfolio consists of a number of products, none of which accounted for more than 5% of our total net sales in the 2004 fiscal year.

Generic Products

When a branded pharmaceutical product is no longer protected by any relevant patents, normally as a result of a patent s expiration, or by other, non-patent market exclusivity, third parties have an opportunity to introduce generic counterparts to such branded product. Generic pharmaceutical products are therapeutically equivalent to their brand-name counterparts and are generally sold at prices significantly less than the branded product. Accordingly, generic pharmaceuticals may provide a safe, effective and cost-effective alternative to users of branded products.

Our generic portfolio is currently comprised of products that cover a range of indications, most of which are focused in pain management. One of our generic products is morphine sulfate extended-release tablets, which accounted for 10% of our total net sales in 2004. In addition, we have a generic oxycodone hydrochloride and acetaminophen product, Endocet®, which accounted for 19% of our total net sales in 2004. We also offer a generic of Sinemet® (carbidopa/levodopa) for the treatment of the symptoms of idiopathic Parkinson s disease. The balance of

our generic portfolio consists of a few other products, none of which accounted for more than 5% of our total net sales for 2004.

We principally pursue the development and marketing of generic pharmaceuticals that have one or more barriers to entry. The characteristics of the products that we may target for generic development may include:

complex formulation or development characteristics;

regulatory or legal challenges; or

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difficulty in raw material sourcing.

We believe products with these characteristics will face a lesser degree of competition, therefore providing longer product life cycles and/or higher profitability than commodity generic products.

Products in Development

Our pipeline portfolio contains products intended to address acute pain, chronic pain and neuropathic pain conditions as well as products in complementary therapeutic areas. We cannot predict when or if any of these products will be approved by the FDA.

Oxymorphone ER. In December 2002, we filed an NDA for oxymorphone ER with the FDA. We received an approvable letter from the FDA for oxymorphone ER in October 2003. In this approvable letter, the FDA requested that we address certain questions and provide additional clarification and information, including some form of additional clinical trials to further confirm the safety and efficacy of this product. In 2004, we reached agreement with the FDA as to the design of a new clinical trial to provide additional safety and efficacy data of oxymorphone ER in support of our NDA for this developmental product. We had submitted the trial protocol to the FDA under the Special Protocol Assessment (SPA) process and the protocol was approved by the FDA in November 2004. Based on the duration of the trial and the number of patients to be enrolled, we believe that, assuming the data are favorable, we will be in a position to finish the study and submit the complete response to the FDA in early 2006. At that point, the FDA will have six months to act on this complete response to its October 2003 approvable letter. If approved, oxymorphone ER is intended to treat moderate-to-severe pain in patients requiring continuous, around-the-clock opioid therapy for an extended period of time. We co-developed this oral extended-release version of oxymorphone with Penwest Pharmaceuticals. If approved, we expect oxymorphone ER will compete in the approximately $4.2 billion U.S. long-acting strong opioid market.

Oxymorphone IR. In December 2002, we filed an NDA for oxymorphone IR with the FDA. We received an approvable letter from the FDA for oxymorphone IR in October 2003. In this approvable letter, the FDA requested that we address certain questions and provide additional clarification and information, including some form of additional clinical trials to further confirm the safety and efficacy of this product. In 2004, we reached agreement with the FDA as to the design of a new clinical trial to provide additional safety and efficacy data of oxymorphone IR in support of our NDA for this developmental product. We had submitted the trial protocol to the FDA under the Special Protocol Assessment (SPA) process and the protocol was approved by the FDA in September 2004. If approved, oxymorphone IR is intended to treat acute moderate-to-severe pain. In Phase III clinical studies in post-surgical pain, we believe patients taking oxymorphone IR demonstrated statistically significant pain relief.

Propofol IDD-D™. Currently in Phase III clinical trial development, Propofol IDD-D™ is an intravenous, or IV, formulation of propofol as the sole active ingredient using SkyePharma s patented Insoluble Drug Delivery (IDD-D™) technology. Propofol IDD-D™ is intended for the maintenance of anesthesia in adults during surgery and for sedation of adults hospitalized in an intensive-care setting.

Frova® MRM. Currently in Phase III clinical trial development, Frova® is also being studied as a potential prophylactic treatment for Menstrually Related Migraine (MRM). If approved for this indication, we believe that Frova® would be the first triptan to be indicated for the prevention of any type of migraine. We anticipate filing a supplemental New Drug Application (sNDA) for this indication following the completion by our partner Vernalis of the second of two Phase III clinical trials.

CHRONOGESIC™. Currently in Phase II development, CHRONOGESIC™ is intended to treat patients with opioid responsive chronic pain that results from a variety of causes. CHRONOGESIC™ is designed to deliver sufentanil continuously for three months of pain therapy. CHRONOGESIC™ is a self-driven titanium implant that is

placed just under the skin, similar in size to a matchstick, from which drug is released by the natural process of osmosis at a controlled rate. The CHRONOGESIC™ clinical development program is on temporary hold pending DURECT s implementation of some necessary design and manufacturing enhancements to the CHRONOGESIC™ product. DURECT anticipates that the implementation of these design and manufacturing enhancements will continue to delay the restart of clinical trials.

LidoPAIN® BP. Currently in Phase II clinical trial development, LidoPAIN® BP is a patent-protected, adhesive-backed, high-concentration lidocaine-based patch product, intended for the treatment of acute lower back pain. LidoPAIN® BP is being developed by EpiCept.

Rapinyl™. Currently in Phase II clinical trial development, Rapinyl™ is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. The benefits of Rapinyl™ are believed to include rapid absorption of the active

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substance, a fast onset of action and patient convenience, which we believe will improve compliance in cancer patients who experience breakthrough pain. Endo anticipates that it will commence Phase III clinical trials in 2005.

Topical Ketoprofen Patch. Currently in Phase II clinical trials in the U.S., the ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains. Two Phase III placebo-controlled studies in soft-tissue injury and ankle sprains have been completed in Europe by ProEthic s European partner APR Applied Pharma Research AG, with statistically significant results. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form.

Transdermal Sufentanil Patch. The sufentanil patch, which is in early-stage clinical development, employs DURECT s proprietary TRANSDUR™ drug-adhesive matrix formulation and is intended to provide relief of moderate-to-severe chronic pain for up to seven days.

Transdermal Fentanyl Patch. Currently under FDA review, the ANDA for a transdermal fentanyl patch was accepted for filing as of October 1, 2003. This product was developed by Noven Pharmaceuticals, Inc. If approved, this product would be the generic equivalent of Johnson & Johnson s Duragesic® (fentanyl transdermal system) which had U.S. sales of approximately $1.6 billion in 2004. In February 2005, the FDA approved a Supplemental New Drug Application filed by Johnson & Johnson for new labeling for its Duragesic® product. Noven has been advised by the FDA that all pending ANDAs relating to the Duragesic® product, including its ANDA, will be required to be amended prior to approval to reflect recent changes in the Duragesic® label. Noven is currently working with the FDA with respect to a revised label for the fentanyl patch. Once finalized, existing inventory will be repackaged to reflect the revised labeling. We are unable to predict the timing or impact of all ANDAs required labeling changes, nor the timing of approval of any of the ANDAs relating to the Duragesic® product.

Oxycodone ER. We have also developed an extended-release oxycodone, an AB rated generic version of OxyContin®, a product of The Purdue Frederick Company. According to IMS Retail Provider Perspective data, OxyContin® generated U.S. sales of approximately $1.8 billion in 2004. We have received final approval from the FDA for bioequivalent versions of the 10mg, 20mg, 40mg and 80mg strengths of OxyContin®. We currently are in litigation with Purdue Frederick regarding our generic version of OxyContin®. The trial was completed in June 2003. On January 5, 2004, the U.S. District Court for the Southern District of New York issued an Opinion and Order dismissing Purdue s claims that Endo s oxycodone extended-release tablets, 10mg, 20mg, 40mg and 80mg, infringe Purdue s U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, declaring these patents invalid, and enjoining Purdue from enforcing the patents. Purdue filed an appeal, as well as motions to expedite the appeal and to stay the injunction against enforcement of the patents until the appeal is resolved. Both motions were denied on March 18, 2004. In turn, we have cross-appealed the district court s infringement ruling. Briefing on the appeal and cross-appeal concluded in July 2004. By an earlier order, the judge bifurcated the antitrust counterclaims for a separate and subsequent trial. On November 3, 2004, the oral arguments relating to the appeal of this case were heard by the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., at which hearing both sides presented their arguments before a three-judge panel. We are awaiting the outcome of this appeal. See Item 3. Legal Proceedings. We are the first company to have filed an ANDA with the FDA for the bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin®, thereby entitling us to 180 days of generic product ANDA marketing exclusivity with respect to these strengths of this product. Given the recent passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003, with accompanying amendments to the Hatch-Waxman Act, our marketing exclusivity would generally begin to run upon the earlier of our commercial launch of these products or following an appellate court decision affirming the district court s decision. The rules governing market exclusivity, however, are complex and may be affected by factors outside our control. Accordingly, even assuming we otherwise qualify for 180-day marketing exclusivity, we cannot guarantee that we will be able or willing to market our product during the relevant period.

Other. We also have other undisclosed analgesic products addressing the broad spectrum of pain management in various stages of development, and we are currently exploring potential new indications for Lidoderm®.

Competition

The pharmaceutical industry is highly competitive. Our competitors vary depending upon therapeutic and product categories. Competitors include the major brand name and generic manufacturers of pharmaceuticals doing business in the United States, including Abbott Laboratories, Elan Corporation plc, Johnson & Johnson, Ligand Pharmaceuticals Incorporated, Mallinckrodt Inc., Mylan Laboratories Inc., Pfizer, Inc., The Purdue Frederick Company, Roxane Laboratories, Inc. and Watson Pharmaceuticals, Inc.

We compete principally through our targeted product development and acquisition and in-licensing strategies. In addition to product development and acquisition, other competitive factors in the pharmaceutical industry include product quality and price, reputation and access to technical information.

The competitive environment of the branded product business requires us to continually seek out technological innovations and to market our products effectively. However, some of our current branded products not only face competition from other brands, but also from generic versions. Generic versions are generally significantly less expensive than branded versions, and, where available, may be required in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies.

The entrance of generic competition to one of our branded products generally reduces our market share and adversely affects our profitability and cash flows.

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Newly introduced generic products with limited or no other generic competition are typically sold at higher selling prices. As competition from other generic products increases, selling prices of the generic products typically decline. Consequently, the maintenance of profitable operations in generic pharmaceuticals depends, in part, on our ability to select, develop and launch new generic products in a timely and cost efficient manner and to maintain efficient, high quality manufacturing relationships.

We have witnessed a consolidation of our customers as chain drug stores and wholesalers merge or consolidate. In addition, a number of our customers have instituted preferred-source and bundling programs that enhance the access that suppliers who participate in such source programs have to the customers of the wholesaler. Consequently, there is heightened competition among drug companies for the business of this smaller and more selective customer base of chain drug stores and large wholesalers.

Research and Development

We devote significant resources to research and development. At December 31, 2004, our research and development staff consisted of 63 employees, primarily based in Westbury, New York and at our corporate headquarters in Chadds Ford, Pennsylvania. For fiscal years 2002, 2003 and 2004, our expenditures on research and development were $56.8 million, $51.0 million and $50.5 million, respectively. In addition to our internal research and development staff, we have agreements and arrangements with various contract research organizations to conduct and coordinate our pre-clinical and clinical studies. In addition, many of the research and development activities of products that we have licensed the marketing rights to are performed by our partners.

Seasonality

Although our business is affected by the purchasing patterns and concentration of our customers, our business is not materially impacted by seasonality.

Customers

We sell our products directly to a limited number of large pharmacy chains and through a limited number of wholesale drug distributors that, in turn, supply products to pharmacies, hospitals, governmental agencies and physicians. Three distributors and one pharmacy chain individually accounted for 24%, 24%, 23% and 11%, respectively, of our net sales in 2002. Three distributors and one pharmacy chain individually accounted for 26%, 26%, 19% and 11%, respectively, of our net sales in 2003. Three distributors and one pharmacy chain individually accounted for 29%, 18%, 18% and 9%, respectively, of our net sales in 2004.

In recent years, there have been numerous mergers and acquisitions among wholesale distributors as well as rapid 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.

Patents, Trademarks, Licenses and Proprietary Property

As of March 9, 2005, we held approximately: 19 U.S. issued patents, 20 U.S. patent applications pending, 34 foreign issued patents, and 87 foreign patent applications pending with respect to our products. In addition, as of March 9, 2005, we have licenses for approximately: 77 U.S. issued patents, 26 U.S. patent applications pending, 152 foreign issued patents and 101 foreign patent applications pending.

The effect of these issued patents is that they provide us with patent protection for the claims covered by the patents. The coverage claimed in a patent application can be significantly reduced before the patent is issued.

Accordingly, we do not know whether any of the applications we acquire or license will result in the issuance of patents, or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because unissued U.S. patent applications are maintained in secrecy for a period of 18 months and U.S. patent applications filed prior to November 29, 2000 are not disclosed until patents issue, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, or in opposition proceedings in a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued, would be held valid by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology.

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We believe that our patents, the protection of discoveries in connection with our development activities, our proprietary products, technologies, processes and know-how and all of our intellectual property are important to our business. All of our brand products and certain generic products, such as Endocet® and Endodan®, are sold under trademarks. To achieve a competitive position, we rely on trade secrets, non-patented proprietary know-how and continuing technological innovation, where patent protection is not believed to be appropriate or attainable. In addition, as outlined above, we have a number of patent licenses from third parties, some of which may be important to our business. See Licenses and Collaboration Agreements. There can be no assurance that any of our patents, licenses or other intellectual property will afford us any protection from competition.

We rely on confidentiality agreements with our employees, consultants and other parties to protect, among other things, trade secrets and other proprietary technology. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that other third parties will not otherwise gain access to our trade secrets and other intellectual property.

We may find it necessary to initiate litigation to enforce our patent rights, to protect our intellectual property and to determine the scope and validity of the proprietary rights of others. Litigation is costly and time-consuming, and there can be no assurance that our litigation expenses will not be significant in the future or that we will prevail in any such litigation. See Item 3. Legal Proceedings.

Governmental Regulation

The manufacture, development, testing, packaging, labeling, distribution, sales and marketing of our products and our ongoing product development activities are subject to extensive and rigorous regulation at both the federal and state levels. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal and state statutes and regulations govern or influence the testing, manufacture, safety, packaging, labeling, storage, record keeping, approval, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements can result in fines, recall or seizure of products, total or partial suspension of production and/or distribution, refusal of the government to enter into supply contracts or to approve NDA and ANDAs, civil sanctions and criminal prosecution.

FDA approval is typically required before each dosage form or strength of any new drug can be marketed. Applications for FDA approval must contain information relating to efficacy, safety, toxicity, pharmacokinetics, product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling, and quality control. The FDA also has the authority to revoke previously granted drug approvals. Product development and approval within this regulatory framework requires a number of years and involves the expenditure of substantial resources.

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

In particular, the FDA has expressed interest in specific chemical structures that may be present as impurities in a number of opioid narcotic active pharmaceutical ingredients, such as oxycodone, which based on certain structural characteristics, may indicate the potential for having mutagenic effects. If, after testing, such effects are ultimately demonstrated to exist, more stringent controls of the levels of these impurities may be required for FDA approval of products containing these impurities, such as oxymorphone. Also, labeling revisions, formulation or manufacturing

changes and/or product modifications may be necessary for new or existing products containing such impurities. The FDA s more stringent requirements together with any additional testing or remedial measures that may be necessary could result in increased costs for, or delays in, obtaining approval for certain of our products in development. Although we do not believe that the FDA would seek to remove a currently marketed product from the market unless such mutagenic effects are believed to indicate a significant risk to patient health, we cannot make any such assurance.

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. President Bush has recently announced measures intended to speed the process by which generic versions of brand name drugs are introduced to the market. Additionally, the Senate recently approved a bill that would

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limit regulatory delays of generic drug applications and penalize companies that reach 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 operation.

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.

NDA Process

FDA approval is typically required before any new drug can be marketed. An NDA is a filing submitted to the FDA to obtain approval of new chemical entities and other innovations for which thorough applied research is required to demonstrate safety and effectiveness in use. The NDA must contain complete preclinical and clinical safety and efficacy data or a reference to such data. Before the dosing of a new drug in healthy human subjects or patients may begin, stringent government requirements for preclinical data must be satisfied. The preclinical data, typically obtained from studies in animals, as well as from laboratory studies, are submitted in an Investigational New Drug application, or IND, or its equivalent in countries outside the United States where clinical trials are to be conducted. The preclinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initiation of clinical trials.

Clinical trials are typically conducted in three sequential phases, although the phases may overlap.

Phase I, which frequently begins with the initial introduction of the compound into healthy human subjects prior to introduction into patients, involves testing the product for safety, adverse effects, dosage, tolerance, absorption, metabolism, excretion and other elements of clinical pharmacology.

Phase II typically involves studies in a small sample of the intended patient population to assess the efficacy of the compound for a specific indication, to determine dose tolerance and the optimal dose range as well as to gather additional information relating to safety and potential adverse effects.

Phase III trials are undertaken to further evaluate clinical safety and efficacy in an expanded patient population at typically dispersed study sites, in order to determine the overall risk-benefit ratio of the compound and to provide an adequate basis for product labeling.

Each trial is conducted in accordance with certain standards under protocols that detail the objectives of the study, the parameters to be used to monitor safety, and efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. In some cases, the FDA allows a company to rely on data developed in foreign countries or previously published data, which eliminates the need to independently repeat some or all of the studies.

Data from preclinical testing and clinical trials are submitted to the FDA in an NDA for marketing approval and to other health authorities as a marketing authorization application. The process of completing clinical trials for a new drug may take several years and require the expenditures of substantial resources. Preparing an NDA or marketing authorization application involves considerable data collection, verification, analysis and expense, and there can be no assurance that approval from the FDA or any other health authority will be granted on a timely basis, if at all. The approval process is affected by a number of factors, primarily the risks and benefits demonstrated in clinical trials as well as the severity of the disease and the availability of alternative treatments. The FDA or other health authorities may deny an NDA or marketing authorization application if the regulatory criteria are not satisfied, or such authorities may require additional testing or information.

As a condition of approval, the FDA or other regulatory authorities may require further studies, including Phase IV post-marketing studies to provide additional data. Other post-marketing studies could be used to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested. Also, the FDA or other regulatory authorities require post-marketing reporting to monitor the adverse effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the products.

There is a type of NDA, referred to as a Section 505(b) (2) NDA, that may sometimes be submitted when an applicant does not have a right of reference to all preclinical and clinical data necessary to support an NDA. Section 505(b) (2) NDAs are subject to requirements for patent certifications and notification similar to ANDAs (see next section). Approval of these NDAs also may be

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delayed by market exclusivity that covers the reference product.

ANDA Process

FDA approval of an ANDA is required before a generic equivalent of an existing or reference-listed drug can be marketed. The ANDA process is abbreviated in that the FDA waives the requirement of conducting complete preclinical and clinical studies and instead relies on bioequivalence studies. Bioequivalence compares the rate of absorption and levels of concentration of a generic drug in the body with those of the previously approved drug. When the rate and extent of absorption of the test and reference drugs are the same, the two drugs are bioequivalent and regarded as therapeutically interchangeable.

An ANDA also may be submitted for a product authorized by approval of an ANDA suitability petition. Such petitions may be submitted to secure authorization to file an ANDA for a product that differs from a previously approved drug in active ingredient, route of administration, dosage form or strength. For example, the FDA has authorized the substitution of acetaminophen for aspirin in certain combination drug products and switching the drug from a capsule to tablet form. Bioequivalence data may be required, if applicable, as in the case of a tablet in place of a capsule, although the two products would not be rated as interchangeable. Congress enacted pediatric testing legislation in December 2002 that, depending on the FDA s implementation, may limit the ability of pharmaceutical firms to use this option in the future.

The timing of final FDA approval of ANDA applications depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the manufacturer of the listed drug is entitled to one or more statutory exclusivity periods, during which the FDA is prohibited from approving generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date. For example, the FDA may now extend the exclusivity of a product by six months past the patent expiration date if the manufacturer undertakes studies on the effect of their product in children, a so-called pediatric extension.

The Generic Drug Enforcement Act of 1992, or Generic Act, allows the FDA to impose debarment and other penalties on individuals and companies that commit certain illegal acts relating to the drug approval process. In some situations, the Generic Act requires the FDA to not accept or review applications for a period of time from a company or an individual that has committed certain violations. It also provides for temporary denial of approval of applications during the investigation of certain violations that could lead to debarment and also, in more limited circumstances, provides for the suspension of the marketing of approved drugs by the affected company. Lastly, the Act allows for civil penalties and withdrawal of previously approved applications. We believe neither we nor any of our employees have ever been subject to debarment.

Patent and Non-Patent Exclusivity Periods

A sponsor of an NDA is required to identify in its application any patent that claims the drug or a use of the drug subject to the application. Upon NDA approval, the FDA lists these patents in a publication referred to as the Orange Book. Any person that files an ANDA to secure approval of a generic version of this first, or listed drug, or a type of NDA that relies upon the data in the application for which the patents are listed, must make a certification in respect to listed patents. The FDA may not approve such an application for the drug until expiration of the listed patents unless (1) the ANDA applicant certifies that the listed patents are invalid, unenforceable or not infringed by the proposed generic drug and gives notice to the holder or the NDA for the listed drug of the bases upon which the patents are challenged, and (2) the holder of the listed drug does not sue the later applicant for patent infringement within 45 days of receipt of notice. Under the current law, if an infringement suit is filed, the FDA may not approve the later application until the earliest of: 30 months after submission; entry of a court judgment holding the patent invalid,

unenforceable or not infringed; such time as the court may order; or the patent expires.

In addition, the holder of the NDA for the listed drug may be entitled to certain non-patent exclusivity during which the FDA cannot approve an application for a competing generic product or 505(b) (2) NDA product. If the listed drug is a new chemical entity, the FDA may not accept any application for five years; if it is not a new chemical entity, the FDA may not approve a competitive application for three years. Certain other periods of exclusivity may be available if the listed drug is indicated for use in a rare disease or is studied for pediatric indications.

Quality Assurance Requirements

The FDA enforces regulations to assure that the methods used in, and facilities and controls used for, the manufacture, processing, packing and holding of drugs conform with current good manufacturing practices, or cGMP. The cGMP regulations the FDA enforces

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are comprehensive and cover all aspects of operations, from receipt of raw materials to finished product distribution, insofar as they bear upon whether drugs meet all the identity, strength, quality, purity and safety characteristics required of them. To assure compliance requires a continuous commitment of time, money and effort in all operational areas.

The FDA conducts pre-approval inspections of facilities engaged in the development, manufacture, processing, packing, testing and holding of the drugs subject to NDAs and ANDAs. If the FDA concludes that the facilities to be used do not meet cGMP, GLP or GCP requirements, it will not approve the application. Corrective actions to remedy the deficiencies must be performed and verified in a subsequent inspection. In addition, manufacturers of both pharmaceutical products and active pharmaceutical ingredients, or APIs, used to formulate the drug also ordinarily undergo a pre-approval inspection, although the inspection can be waived when the manufacturer has had a passing cGMP inspection in the immediate past. Failure of any facility to pass a pre-approval inspection will result in delayed approval and would have a material adverse effect on our business, results of operations and financial condition.

The FDA also conducts periodic inspections of facilities to assess their cGMP status. If the FDA were to find serious cGMP non-compliance during such an inspection, it could take regulatory actions that could adversely affect our business, results of operations and financial condition. Imported API and other components needed to manufacture our products could be rejected by U.S. Customs. In respect to domestic establishments, the FDA could initiate product seizures or request product recalls and seek to enjoin a product s manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include preventing the company from receiving the necessary licenses to export its products and classifying the company as an unacceptable supplier , thereby disqualifying the company from selling products to federal agencies.

We believe that we and our suppliers and outside manufacturers are currently in compliance with cGMP requirements.

Other FDA Matters

If there are any modifications to an approved drug, including changes in indication, manufacturing process or labeling or a change in a manufacturing facility, an application seeking approval of such changes must be submitted to the FDA or other regulatory authority. Additionally, the FDA regulates post-approval promotional labeling and advertising activities to assure that such activities are being conducted in conformity with statutory and regulatory requirements. Failure to adhere to such requirements can result in regulatory actions that could have a material adverse effect on our business, results of operations and financial condition.

Drug Enforcement Administration

We sell products that are controlled substances as defined in the Controlled Substances Act, which establishes certain security and record keeping requirements administered by the U.S. Drug Enforcement Administration, or DEA. The DEA is concerned with the control of registered handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, with Schedule I and II 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, sufentanil, fentanyl and hydrocodone, are listed by the DEA as Schedule II or III substances under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a

high degree of regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Furthermore, the amount of scheduled substances we can obtain for clinical trials and commercial distribution is limited by the DEA.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture or distribute controlled substances must be registered to perform these activities and have the security, control and accounting mechanisms required by the DEA to prevent loss and diversion. Failure to maintain compliance, particularly as manifested in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could eventuate in criminal proceedings.

We and our third-party API suppliers, dosage form manufacturers, distributors and researchers have necessary registrations, and we believe all registrants operate in conformity with applicable requirements.

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Government Benefit Programs

Medicaid, Medicare and other reimbursement legislation or programs govern provider reimbursement levels, including requiring that all pharmaceutical companies rebate to individual states a percentage of their net sales arising from Medicaid-reimbursed products. The federal and/or state governments may continue to enact measures in the future aimed at reducing the cost of prescription pharmaceuticals paid for with federal and state funds. We cannot predict the nature of such measures or their impact on our profitability and cash flows. These efforts could, however, have material consequences for the pharmaceutical industry as a whole and consequently, also for the Company.

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

Service Agreements

We contract with various third parties to provide certain critical services including manufacturing, warehousing, distribution, customer service, certain financial functions, certain research and development activities and medical affairs.

Third Party Manufacturing/Supply Agreements

We contract with various third party manufacturers and suppliers to provide us with raw materials used in our products and finished goods including, among others, Novartis Consumer Health, Teikoku Seiyaku Pharmaceuticals and until December 2003, Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals). While we generally have not had difficulty obtaining finished goods, raw materials and components from suppliers in the past, we cannot assure you that these necessary finished goods, raw materials and components will continue to be available on commercially acceptable terms in the future. If for any reason we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products, this may have a material adverse effect on our business, financial condition and/or results of operations. In addition, we have incurred significant costs in obtaining the regulatory approvals and taking other steps necessary to begin commercial production at other manufacturers, including Novartis, of all our products formerly manufactured at Bristol-Myers Squibb. A description of the material terms of our material third party manufacturing/supply contracts follows:

Novartis Consumer Health, Inc. On May 3, 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. whereby Novartis has agreed to manufacture certain of our commercial products and products in development. We are required to purchase, on an annual basis, a minimum amount of product from Novartis. The purchase price per product is equal to a predetermined amount per unit, subject to periodic adjustments. As of December 31, 2004, we are required to purchase a minimum of $4.7 million and $4.3 million of product from Novartis in 2005 and 2006, respectively. However, actual amounts purchased could be significantly higher based on the actual mix of products purchased. This agreement has a five-year term, with

automatic five-year renewals thereafter. Either party may terminate this agreement on three-years notice, effective at any time after the initial five-year term. In addition, we may terminate this agreement effective prior to the fifth anniversary of the agreement upon three-years notice and the payment of certain early termination fees. Either party may also terminate this agreement on account of a material breach by the other.

Teikoku Seiyaku Co., Ltd. Under the terms of this agreement, Teikoku, a Japanese manufacturer, manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We also have an option to extend the supply area to other territories within a defined period of time. We are required to purchase, on an annual basis, a minimum amount of product from Teikoku. The purchase price for the product is equal to a predetermined amount per unit of product. As of December 31, 2004, we are required to purchase a minimum of $33.6 million of product from Teikoku in 2005. The term of this agreement is from November 23, 1998 until the shorter of (1) the expiration of the last to expire patent that is licensed to us from Hind Healthcare Inc., the developer of Lidoderm®, or (2) November 20, 2011. This agreement may be terminated for material breach by either party and by us if the Hind Healthcare license agreement is terminated.

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Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals). Bristol-Myers Squibb previously manufactured a number of our brand and generic pharmaceutical products. Bristol-Myers Squibb manufactured certain of the products that we purchased from DuPont Pharmaceuticals as a result of our August 1997 acquisition from DuPont Pharmaceuticals, as well as some of our new products. The products were manufactured at either the Bristol-Myers Squibb facility in Garden City, New York or the Bristol-Myers Squibb facility in Manati, Puerto Rico. Both of these facilities were FDA- and DEA-approved. For these manufacturing services, we paid Bristol-Myers Squibb compensation in the form of (1) a fixed amount to cover Bristol-Myers Squibb s fixed manufacturing costs for both manufacturing facilities and (2) an amount, adjusted on an annual basis, to cover Bristol-Myers Squibb s variable manufacturing costs plus a reasonable profit. The initial term of this agreement was five years, expiring on August 26, 2002. On August 27, 2002, we entered into an amendment to the agreement, which provided that Bristol-Myers Squibb would continue to manufacture our products until August 26, 2003, with an option to extend to December 31, 2003, at which time the agreement expired, and we would be able to transfer up to 100% of our products to another manufacturer at any time.

In addition to manufacturing services, Bristol-Myers Squibb provided other ancillary services to us in connection with the manufacture of our products such as raw material procurement, inventory management and quality control services. Compensation for these services was included in the compensation for manufacturing services. We no longer use any services of Bristol-Myers Squibb.

Mallinckrodt Inc. Under the terms of this agreement, Mallinckrodt manufactures and supplies to us narcotic active drug substances, in bulk form, and raw materials for inclusion in our controlled substance pharmaceutical products. We are required to purchase a fixed percentage of our annual requirements of each narcotic active drug substance from Mallinckrodt. The purchase price for these substances is equal to a fixed amount, adjusted on an annual basis. The initial term of this agreement is July 1, 1998 until June 30, 2013, with an automatic renewal provision for unlimited successive one-year periods. Either party may terminate this agreement for a material breach.

In addition, under a separate agreement, Mallinckrodt exclusively manufactures and supplies to us a narcotic active drug substance that is not covered under the previously discussed Mallinckrodt agreement. We are required to purchase a fixed percentage of our annual requirements of this narcotic active drug substance from Mallinckrodt. The purchase price of the substance is a fixed amount that may be adjusted annually in the event of Mallinckrodt product cost increases. The current term of this agreement is April 1, 1998 until June 30, 2004, as extended pursuant to an amendment, dated as of May 8, 2000, with an automatic renewal provision for unlimited successive one-year periods, unless terminated by either party. The current renewal term expires on June 30, 2005. This agreement may also be terminated for material breach by either party.

Other Service Agreements

In addition to the material long-term manufacturing agreements described above, we have agreements with (1) UPS Supply Chain Solutions, Inc. (f/d/b/a Livingston Healthcare Services, Inc.) for customer service support, warehouse and distribution services and certain financial functions and (2) Kunitz and Associates Inc. for medical affairs services. In addition, until December 31, 2003, we had an agreement with Ventiv Health U.S. Sales Inc. for sales promotion. We also have agreements and arrangements with various contract research organizations for our pre-clinical and clinical studies. Although we have no reason to believe that these agreements will not be honored, failure by any of these third parties to honor their contractual obligations may have a materially adverse effect on our business, financial condition and results of operations.

A description of the material terms of these agreements follows:

UPS Supply Chain Solutions, Inc. (f/d/b/a Livingston Healthcare Services, Inc.) Under the terms of this agreement, we appointed UPS Supply Chain Solutions to provide customer service support, chargeback processing, accounts receivables management and warehouse and distribution services for our products in the United States. During the term of the agreement, the UPS personnel responsible for providing our customer service, chargeback processing and accounts receivable management services may not provide these services to any third party for any third party products that directly compete with our products covered under the agreement. We currently pay UPS (1) a fixed monthly fee for all services and (2) certain out-of-pocket expenses, which, in the aggregate, may, depending on the facts and circumstances at the time, represent material costs to us. For the years ended December 31, 2004, 2003 and 2002, these fees and expenses were approximately $7.5 million, $6.3 million and $5.0 million. The current term of the agreement for all services provided UPS Supply Chain Solutions expires in February 2010. The agreement may be renewed upon mutual agreement of the parties. The agreement may be terminated for material breach and by us, with prior notice: (1) for a sale of our company or a sale of substantially all of our business; (2) for a change in our stock ownership or company control; (3) if we decide

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to have these services provided in-house or by an affiliate; or (4) if UPS fails to provide additional storage space for our products upon request. In the event of termination under certain circumstances, we are required to pay UPS for certain capital investments and wind-down expenses.

Kunitz and Associates Inc. Under the terms of the agreement, we appointed Kunitz as our exclusive provider in the United States of pharmacovigilance, medical communications, product information support, adverse drug experience surveillance and medical literature search support, with respect to all of our products. During the term of this agreement, Kunitz may not provide identical or similar services to or for any third party whose products directly compete with our products in the prescription pain management therapeutic category. For these services, we pay Kunitz a fixed amount, in equal monthly installments. This agreement, as amended, will expire on December 31, 2005. The agreement may be terminated by either party for material breach or by us, with notice, for no reason.

Ventiv Health U.S. Sales Inc. Under the terms of this agreement, a team of Ventiv professional sales representatives, under our management s direction, had exclusively promoted certain of our products to healthcare professionals in the United States. Under the agreement, we had reserved the option to hire all of these sales representatives and managers as our full-time employees at any time. During the fourth quarter of 2003, we hired as full-time employees substantially all of the sales representatives and managers that were then under the contract with Ventiv. On December 31, 2003, our agreement with Ventiv expired in accordance with its terms.

Licenses and Collaboration Agreements

We enter into licenses and collaboration agreements to develop, use, market and promote certain of our products from or with other pharmaceutical companies and universities. A description of the material terms of our significant third party collaboration agreements follows:

Penwest Pharmaceuticals

In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals to exclusively co-develop opioid analgesic products for pain management, using Penwest s patent-protected proprietary technology, for commercial sale worldwide. On April 2, 2002, we amended and restated this agreement to provide, among other things, that this collaboration would cover only that opioid analgesic product currently under development by the parties, namely, oxymorphone ER. We have historically shared on an equal basis the costs of products developed under this agreement and will, in the future, share costs and profits on an equal basis (subject to the recoupment discussed below). On March 18, 2003, we received notice from Penwest that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of oxymorphone ER on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we are now responsible for funding 100% of these remaining costs until oxymorphone ER is approved by the FDA, at which time we will recoup from the royalties due to Penwest the full amount of what Penwest should have contributed had it not exercised such right. On May 7, 2004, we announced that the FDA is requiring us to initiate a new clinical trial to provide additional safety and efficacy data of oxymorphone ER in support of our New Drug Application (NDA) for this developmental product. On July 7, 2004, we announced that we had reached agreement with the FDA as to the design of a new clinical trial to provide additional safety and efficacy data of oxymorphone ER in support of our NDA for this developmental product. On September 20, 2004, we announced that the FDA has asked us to clarify some aspects of the analysis of the study outcome prior to granting final approval of this protocol. This additional request did not affect the already agreed-upon design of the oxymorphone ER clinical trial, and we have now complied with this request. We had submitted the trial protocol to FDA under the Special Protocol Assessment (SPA) process and the protocol was approved by the FDA in November 2004. Under the terms of the SPA, we have initiated a 12-week, multicenter, double-blinded, placebo-controlled trial of oxymorphone ER. We have exclusive U.S. marketing rights with respect to oxymorphone ER, subject to the terms and conditions contained in this

agreement.

Hind Healthcare Inc.

In November 1998, Endo entered into a license agreement (the Hind License Agreement) with Hind Healthcare Inc. (Hind) for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in the United States. Under the terms of the Hind License Agreement, Endo paid Hind approximately $10 million (the Hind License Fee) based upon the achievement of certain milestones and capitalized this amount as an intangible asset representing the fair value of these exclusive rights. In addition, Endo pays Hind nonrefundable royalties based on net sales of the product. Royalties are recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. The royalty rate was 8% of net sales from March 19, 2001 through March 18, 2002 and is 10% of net sales from March 19, 2002 through the shorter of (1) the

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expiration of the last licensed patent or (2) November 20, 2011, including a minimum royalty of at least $500,000 per year. During 2004, 2003 and 2002, we accrued $34.5 million, $19.9 million and $9.1 million for these royalties to Hind, respectively, which were recorded as a reduction to net sales. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

Lavipharm Laboratories, Inc.

In November 1999, Endo entered into a collaboration agreement with Lavipharm Laboratories, Inc. pursuant to which Endo obtained exclusive worldwide rights to Lavipharm s existing drug delivery technology platforms. Under the terms of this collaboration agreement, Endo paid an upfront license fee of $1 million. In September 2001, we amended this agreement to limit its scope to one of Lavipharm s existing drug delivery technologies in combination with two specific active drug substances. In January 2004, we terminated this agreement and made a termination payment to Lavipharm of $3 million plus the potential for up to an additional $5 million in contingent termination payments upon the occurrence of future events. We wrote-off the unamortized portion of the upfront license fee and expensed the termination payment of $3 million during the year ended December 31, 2004.

DURECT Corporation

In November 2002, Endo entered into a license agreement (DURECT CHRONOGESIC™ License Agreement) with DURECT Corporation (DURECT) to develop and commercialize DURECT s CHRONOGESIC™ (sufentanil) Pain Therapy System for the U.S. and Canada. In January 2004 and November 2004, we amended the Agreement with DURECT essentially modifying Endo s funding obligations of the ongoing development costs of CHRONOGESIC™ to take into account the program delay. The clinical development program of CHRONOGESIC™ is on temporary hold pending DURECT s implementation of some necessary design and manufacturing enhancements to CHRONOGESIC™. DURECT has informed us that it anticipates that the implementation of these design and manufacturing enhancements will further delay the restart of the clinical development program. DURECT had initiated the process of clinical manufacturing of CHRONOGESIC™ following a series of promising results of in vitro studies and in vivo animal studies of the most recent CHRONOGESIC™ system design. However, they learned during 2004 from a further animal study that they have not yet solved the pre-mature shutdown problem (a stoppage in the delivery of drug before the intended full duration of delivery). DURECT continues to work to address this issue in order to bring this product to market. Once a specified clinical trial of CHRONOGESIC™ is started or beginning on January 1, 2006 (whichever is earlier), Endo will be obligated to fund 50% of the ongoing development costs of CHRONOGESIC™. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the DURECT CHRONOGESIC™ License Agreement could total up to $52.0 million. Endo and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC™. In addition, the DURECT CHRONOGESIC™ License Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT CHRONOGESIC™ License Agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, the DURECT CHRONOGESIC™ License Agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT $10.0 million. Finally, in connection with this agreement, on November 8, 2002, Endo purchased approximately $5.0 million of newly issued common shares of DURECT.

On March 14, 2005, we announced that we have signed an agreement that will give us the exclusive license to develop and commercialize DURECT s sufentanil-containing transdermal patch in the U.S. and Canada (the DURECT Sufentanil Agreement). The sufentanil patch, which is in early-stage clinical development, employs DURECT s proprietary TRANSDUR drug-adhesive matrix formulation and is intended to provide relief of moderate-to-severe chronic pain for up to seven days. Effective immediately, we will assume all remaining development and regulatory

filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, we will pay DURECT an upfront fee of $10 million, with additional payments of approximately $35 million upon achievement of predetermined regulatory and commercial milestones. We will also pay royalties to DURECT on net sales of the sufentanil transdermal patch. In addition, the DURECT Sufentanil Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT Sufentanil Agreement will continue in effect until terminated. The DURECT Sufentanil Agreement provides each party with specified termination rights, including the right of each party to terminate the DURECT Sufentanil Agreement upon material breach of the DURECT Sufentanil Agreement by the other party and the right of Endo to terminate the DURECT Sufentanil Agreement at any time without cause subject to a specified notice period.

SkyePharma, Inc.

In December 2002, we entered into a Development and Marketing Strategic Alliance Agreement with SkyePharma, Inc. and SkyePharma Canada, Inc. relating to two of SkyePharma s patented development products, DepoDur™, previously referred to as

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DepoMorphine™, and Propofol IDD-D™ (collectively, the Skye Products). Under the terms of the Agreement, Endo received an exclusive license to the U.S. and Canadian marketing and distribution rights for the Skye Products, with options for certain other development products. In return, Endo made a $25 million upfront payment to SkyePharma, which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We are amortizing this intangible asset over its useful life of 17 years. In addition, we may be required to make milestone payments in addition to the $25 million upfront payment of up to $95 million which include total milestones of $10 million for DepoDur™ through FDA approval. During 2003, we paid and expensed a $5 million milestone payment to SkyePharma upon the acceptance by the FDA of the NDA for DepoDur™. In 2004, we paid and expensed a $5 million milestone payment to SkyePharma upon approval of the NDA for DepoDur™. The milestone payments also include $50 million for Propofol IDD-D™, payable when the product successfully achieves certain regulatory milestones, including FDA approval. In 2004, we paid and expensed a $5 million milestone payment to SkyePharma upon the advancement of Propofol IDD-D™ into Phase III. The total further includes a $15 million milestone payable when net sales of DepoDur™ exceed $125 million in a calendar year, and a $20 million milestone payable when net sales of DepoDur™ exceed $175 million in a calendar year. SkyePharma will also receive a share of each product s sales revenue that will increase from 20% initially, to a maximum of 60%, of net sales as the Skye Products combined net sales achieve certain thresholds. This agreement provides for the parties to work together to complete the necessary clinical, regulatory and manufacturing work for North American regulatory approval of the Skye Products. SkyePharma will be primarily responsible for clinical development up to final FDA approval, and for the manufacture of the Skye Products, including all associated costs. Upon approval, we will market each Skye Product in the U.S. and Canada, with SkyePharma as the supplier. We are responsible for funding and conducting any post-marketing studies and for all selling and marketing expenses. Under this agreement, we also obtained options on other SkyePharma development products, including DepoBupivicaine™, a long-acting, sustained release formulation of the local anesthetic bupivacaine. We have the option to obtain commercialization rights for this product when SkyePharma successfully completes its Phase II trials, as well as any further SkyePharma products formulated using the DepoFoam™ technology successfully developed for the prophylaxis or treatment of pain. In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, this agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require us to pay SkyePharma $5.0 million.

Noven Pharmaceuticals, Inc.

In February 2004, we entered into a License Agreement and a Supply Agreement with Noven Pharmaceuticals, Inc. under which Noven exclusively licensed to us the U.S. and Canadian rights to its developmental transdermal fentanyl patch, which is intended to be the generic equivalent of Johnson & Johnson s Duragesic® (fentanyl transdermal system). We made an upfront payment of $8.0 million, $1.5 million of which we expensed as research and development costs and $6.5 million of which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We are amortizing this intangible asset over its useful life of 11 years. Upon our first commercial sale of the fentanyl patch, Noven is entitled to receive an additional payment ranging from $5.0 million to $10.0 million, depending on the timing of launch and the number of generic competitors on the market. Noven will manufacture and supply the product at its cost, and the two companies will share profits. The License Agreement also establishes an ongoing collaboration between the two companies to identify and develop additional new transdermal therapies. As part of this effort, Noven will undertake feasibility studies to determine whether certain compounds identified by the parties can be delivered through Noven s transdermal patch technology. Endo is expected to fund and manage clinical development of those compounds proceeding into clinical trials. In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts for a term of ten years from the first commercial sale of the developmental transdermal fentanyl patch product. With respect to termination

rights, this agreement permits us to terminate our continued participation under a number of circumstances.

EpiCept Corp.

In December 2003, we entered into a license granting us exclusive, worldwide rights to certain patents of EpiCept Corp. as well as exclusive, worldwide commercialization rights to EpiCept s LidoPAIN® BP product. The license agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept s LidoPAIN® BP product. Under this agreement, we made an upfront payment to EpiCept of $7.5 million which we capitalized as an intangible asset representing the fair value of the exclusive right and the patents. We are amortizing this intangible asset over its useful life of 13 years. EpiCept has also retained an option to co-promote the LidoPAIN® BP product. Milestone payments made by Endo under this agreement, including regulatory milestones and sales thresholds, could total up to $82.5 million. In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the

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underlying patents expire.

Vernalis Development Limited

In July 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to exclusively license to us rights to market Frova® (frovatriptan) in North America. Launched in the U.S. in June 2002, Frova® is indicated for the acute treatment of migraine headaches in adults. Under the terms of the license agreement, we paid Vernalis an upfront fee of $30 million and we will make anniversary payments for the first two years at $15 million each year, and a $40 million milestone payment upon U.S. Food and Drug Administration, FDA, approval for the menstrually related migraine indication (MRM). We have capitalized the $30 million up-front payment, the present value of the two $15 million anniversary payments and the difference of $6.2 million between the face amount of the note and its present value at inception as an intangible asset representing the fair value of the exclusive license to market Frova®. We are amortizing this intangible asset over its estimated useful life of 15 years. In addition, Vernalis will receive one-time milestone payments for achieving defined annual net sales targets. These sales milestone payments increase based on increasing net sales targets ranging from a milestone of $10 million on $200 million in net sales to a milestone of $75 million on $1.2 billion in net sales. These sales milestones could total up to $255 million if all of the defined net sales targets are achieved. We will also pay royalties to Vernalis based on the net sales of Frova®. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement is for the shorter of the time (i) that there are valid claims on the Vernalis patents covering Frova® or there is market exclusivity granted by a regulatory authority, whichever is longer, or (ii) until the date on which a generic version of Frova® is first offered, but in no event longer than 20 years. We can terminate the license agreement under certain circumstances, including upon one years written notice.

Orexo AB

In August 2004, we entered into an agreement granting us the exclusive rights to develop and market Orexo AB s (a privately held Swedish company) patented sublingual muco-adhesive fentanyl product (Rapinyl) in North America. Rapinyl is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. Rapinyl is based on Orexo s unique patented technology for sublingual administration. The agreement provided for us to make an up-front license fee payment of $10 million, which we capitalized as an intangible asset representing the fair value of the exclusive right to market the product and are amortizing over its estimated useful life of 20 years, in addition to other license fees and payments based on development and regulatory milestones, which may total up to $22.1 million through FDA approval of Rapinyl s New Drug Application. The agreement also provides for royalties upon commercial sales and may include sales milestones if defined sales thresholds are achieved. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the expiration of any market exclusivity right. We can terminate the license agreement under certain circumstances, including upon six months written notice, and we may be required to pay a termination fee of up to $1.5 million.

ProEthic Pharmaceuticals, Inc.

On March 14, 2005, we announced that we have entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and available in the U.S. only in oral form. Currently in Phase II clinical trials in the U.S., the ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains. Two Phase III placebo-controlled studies in soft-tissue injury and ankle sprains have been

completed in Europe by ProEthic s European partner APR Applied Pharma Research AG, with statistically significant results. Under the terms of the agreement, we will make a $10.0 million upfront payment and payments of approximately $14.0 million for the achievement of certain regulatory milestones. We will also pay royalties on net sales of the ketoprofen patch. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the tenth (10^{th}) anniversary of the date of the first commercial sale of the product. We can terminate the agreement at any time upon no more than ninety (90) days written notice.

Other

We have licensed from universities and other companies rights to certain technologies or intellectual property generally in the field of pain management. We are generally required to make upfront payments as well as other payments upon successful completion of regulatory or sales milestones. In addition, these agreements generally require us to pay royalties on sales of the products arising from

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these agreements. These agreements generally permit Endo to terminate the agreement with no significant continuing obligation.

Environmental Matters

Our operations are subject to substantial and evolving federal, state and local environmental laws and regulations concerning, among other matters, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous substances. We believe that our facilities and the facilities of our third party service providers are in substantial compliance with all provisions of federal, state and local laws concerning the environment and do not believe that future compliance with these provisions will have a material adverse effect on our financial condition or results of operations.

Summary of Recent Transactions

On March 9, 2005, we announced that Peter A. Lankau, the current president and chief operating officer of Endo, has been appointed president and chief executive officer by our Board of Directors, effective May 20, 2005, the day following the Annual Meeting of Endo Stockholders. Carol A. Ammon, Endo s current chief executive officer, will continue to serve Endo as Chairman of the Board of Directors. In addition, Endo s Board of Directors has appointed Lankau to the Endo Board of Directors, effective immediately. This appointment expands the number of directors to 11.

On March 14, 2005, we announced that we have signed an agreement that will give us the exclusive license to develop and commercialize DURECT s sufentanil-containing transdermal patch in the U.S. and Canada (the DURECT Sufentanil Agreement). The sufentanil patch, which is in early-stage clinical development, employs DURECT s proprietary TRANSDUR drug-adhesive matrix formulation and is intended to provide relief of moderate-to-severe chronic pain for up to seven days. Effective immediately, we will assume all remaining development and regulatory filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, we will pay DURECT an upfront fee of $10 million, with additional payments of approximately $35 million upon achievement of predetermined regulatory and commercial milestones. We will also pay royalties to DURECT on net sales of the sufentanil transdermal patch.

Also on March 14, 2005, we announced that we have entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. Currently in Phase II clinical trials in the U.S., the ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains. Two Phase III placebo-controlled studies in soft-tissue injury and ankle sprains have been completed in Europe by ProEthic s European partner APR Applied Pharma Research AG, with statistically significant results. Under the terms of the agreement, we will make a $10.0 million upfront payment and payments of approximately $14.0 million for the achievement of certain regulatory milestones. We will also pay royalties on net sales of the ketoprofen patch.

Description of Credit Facility

In December 2001, we amended and restated our senior secured credit facility with a number of lenders. This amended and restated credit facility provides us with a line of credit of $75.0 million. The line of credit matures on December 21, 2006. Any loans outstanding under the amended and restated credit facility are secured by a first priority security interest in substantially all of our assets. On April 30, 2004, we amended our credit facility to allow us to file a shelf registration statement on Form S-3, which we initially filed on April 30, 2004, providing for the sale

by Endo Pharma LLC and certain other selling stockholders to be named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. On July 13, 2004, we amended our credit facility to allow us to enter in the transaction with Vernalis. As of December 31, 2004, we have not borrowed under the credit facility.

Borrowings under the Amended and Restated Credit Agreement bear interest, which is payable at least quarterly, at a rate equal to the bank s floating alternate base rate plus a premium ranging from .75% to 1.25%, or at a rate equal to LIBOR plus a premium ranging from 1.75% to 2.25%, depending on the type of borrowing and our performance against certain criteria.

Additionally, fees are charged on the average daily unused amount of the Amended and Restated Credit Agreement at a rate ranging from .375% to .50% depending on our performance against certain criteria. This commitment fee is payable quarterly.

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The Amended and Restated Credit Agreement contains limitations and restrictions concerning, among other things, additional indebtedness, acquisition or disposition of assets, dividend payments and transactions with affiliates. In addition, the Amended and Restated Credit Agreement requires us to maintain certain ratios (as defined therein).

Employees

As of December 31, 2004, we had 549 employees, of which 63 are engaged in research and development, 22 in regulatory work, 334 in sales and marketing, 26 in quality assurance and 104 in general and administrative capacities. Our employees are not represented by unions, and we believe that our relations with our employees are good.

Executive Officers of the Registrant

Set forth below is information regarding each of our current executive officers, as of March 10, 2005:

Name	Age	Position and Offices
Carol A. Ammon	53	Chief Executive Officer and Chairman of the Board
Jeffrey R. Black	40	Executive Vice President, Chief Financial Officer and Treasurer
Peter A. Lankau	52	President and Chief Operating Officer
David A.H. Lee, M.D., Ph.D.	55	Executive Vice President, Research & Development and Chief Scientific Officer
Caroline B. Manogue	36	Executive Vice President, Chief Legal Officer and Secretary

CAROL A. AMMON, 53, is Chief Executive Officer and Chairman of the Board of Endo. Effective May 20, 2005, Ms. Ammon will retire from the position of Chief Executive Officer and remain as Chairman of the Board of Endo. In February 2002, Ms. Ammon was appointed Chairman of the Board in addition to her then current roles of President and Chief Executive Officer. Prior to April 2003, Ms. Ammon also served as the President of Endo. Prior to joining Endo in August 1997, Ms. Ammon was the President of DuPont Merck s U.S. Pharmaceuticals Division from 1996 through 1997, and from 1993 through 1995 she was the President of Endo Laboratories, L.L.C. She also serves as a director on the boards of the Christiana Care Health System and the St. Louis School of Pharmacy in St. Louis, Missouri.

JEFFREY R. BLACK, 40, is Executive Vice President, Chief Financial Officer and Treasurer of Endo. Prior to joining Endo in September 1997, Mr. Black became a Partner in June 1997 with Deloitte & Touche LLP in the New York Merger and Acquisition Services Group, after joining that firm in 1986.

PETER A. LANKAU, 52, is President and Chief Operating Officer of Endo and also a member of the Board of Endo, effective March 9, 2005. Effective May 20, 2005, Mr. Lankau will become President and Chief Executive Officer of Endo. Prior to April 2003, Mr. Lankau was Senior Vice President, U.S. Business of Endo. Prior to joining Endo in June 2000, Mr. Lankau was Vice President, Sales and Marketing for Alpharma USPD, Inc. in Baltimore, Maryland. He was Vice President, Sales-U.S. Pharmaceuticals for Aventis Pharmaceuticals Inc. (f/k/a Rhone Poulenc Rorer, Inc.) from 1996 to 1999, based in Collegeville, Pennsylvania. Mr. Lankau was Executive Director, Strategy and Development for Aventis from 1995 to 1996. Prior to 1995, he held various management positions at Aventis including business unit management, and had responsibility for Aventis generics business as well as managed care.

DAVID A.H. LEE, M.D. Ph.D., 55, is Executive Vice President, Research & Development and Chief Scientific Officer of Endo. Prior to joining Endo in December of 1997, Dr. Lee was Executive Vice President, Research and Development for CoCensys, Inc., an emerging pharmaceuticals company based in Irvine, California, from 1992 through 1997. Prior to joining CoCensys, Dr. Lee held various positions at Solvay Pharmaceuticals in the Netherlands, ranging from head of global clinical development programs to his final position as Vice President, Research and Development. Dr. Lee received his M.D. and Ph.D. degrees from the University of London and specialized in internal medicine and gastroenterology, prior to joining the pharmaceutical industry.

CAROLINE B. MANOGUE, 36, is Executive Vice President, Chief Legal Officer and Secretary of Endo. Prior to joining Endo in September 2000, Ms. Manogue was an Associate at the law firm Skadden, Arps, Slate, Meagher & Flom LLP since 1995.

We have employment agreements with each of our executive officers.

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Dividend Policy

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

Available Information

Our Internet address is http://www.endo.com. The contents of our website are not part of this Annual Report on Form 10-K, and our Internet address is included in this document as an inactive textual reference only. We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the Securities and Exchange Commission.

Item 2. *Properties*

We lease all of our properties. Of these, the most significant are our research and development facility located in Westbury, New York and our corporate headquarters in Chadds Ford, Pennsylvania. A description of the material terms of each of the agreements pertaining to these properties follows:

Chadds Ford, Pennsylvania

Painters Crossing One Associates, L.P. Lease Agreement. On May 5, 2000, we entered into a ten-year lease with Painters Crossing One Associates, L.P. pursuant to which Painters Crossing leases to us a building comprised of approximately 47,756 square feet located in Chadds Ford, Pennsylvania. By amendment dated February 26, 2001, this lease commenced on August 1, 2001 and will end on August 31, 2010. However, we, at our discretion, have the right to terminate this lease at the end of the fifth year, by providing two years notice and paying a fixed termination fee to Painters Crossing. During the term of the lease, the annual rent is a fixed amount paid in equal monthly installments that increase after the first five years of the lease.

Painters Crossing Two Associates, L.P. Lease Agreement. On November 13, 2003, we entered into a ten-year lease with Painters Crossing Two Associates, L.P. pursuant to which Painters Crossing will lease to us a building comprised of approximately 64,424 square feet located across the street from our corporate headquarters in Chadds Ford, Pennsylvania. By amendment dated February 16, 2005, this lease commenced on February 1, 2005 and will end on January 31, 2015. We, at our discretion, have the right to terminate this lease at the end of the sixth year, by providing two years notice and paying a fixed termination fee to Painters Crossing. During the term of the lease, the annual rent is a fixed amount paid in equal monthly installments that increase after the first five years of the lease.

Westbury, New York

Dawson Holding Company. Under this agreement, dated January 6, 2003, we lease a 24,190 square foot facility in Westbury, New York. The annual rent due for this facility is $152,397 in the first year of the lease, escalating by 4% each year thereafter. This ten-year lease is not assignable without the consent of the landlord, Dawson Holding. This lease may by terminated (1) by us, at the end of the fifth year with the payment to Dawson Holding of approximately $239,000 plus 75% of any additional rent owed during the fifth lease year, (2) by us, with 30 days notice, if the facility has suffered a fire or other casualty and Dawson Holding has not substantially restored it to its condition

existing immediately prior to the fire or other casualty within one year from the date Dawson Holding received insurance proceeds, (3) by Dawson Holding, for our default under the lease, or (4) by either Dawson Holding or us, within 30 days of any condemnation.

Item 3. ***Legal Proceedings***

Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 00 Civ. 8029 (SHS) (S.D.N.Y.); Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 01 Civ. 2109 (SHS) (S.D.N.Y.); Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 01 Civ. 8177 (SHS) (S.D.N.Y.)

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On October 20, 2000, The Purdue Frederick Company and related companies (Purdue Frederick) filed suit against us and our subsidiary, Endo Pharmaceuticals Inc. (EPI), in the U.S. District Court for the Southern District of New York alleging that EPI s bioequivalent version of Purdue Frederick s OxyContin® (oxycodone hydrochloride extended-release tablets), 40mg strength, infringes three of its patents. This suit arose after EPI provided the plaintiffs with notice that its ANDA submission for a bioequivalent version of Purdue Frederick s OxyContin®, 40mg strength, challenged the listed patents for OxyContin® 40mg tablets. On March 13, 2001, Purdue Frederick filed a second suit against us and EPI in the U.S. District Court for the Southern District of New York alleging that EPI s bioequivalent versions of Purdue Frederick s OxyContin®, 10mg and 20mg strengths, infringe the same three patents. This suit arose from EPI having amended its earlier ANDA on February 9, 2001 to add bioequivalent versions of the 10mg and 20mg strengths of OxyContin®. On August 30, 2001, Purdue Frederick filed a third suit against us and EPI in the U.S. District Court for the Southern District of New York alleging that EPI s bioequivalent version of Purdue Frederick s OxyContin®, 80mg strength, infringes the same three patents. This suit arose from EPI having amended its earlier ANDA on July 30, 2001 to add the bioequivalent version of the 80mg strength of OxyContin®.

For each of the 10mg, 20mg, 40mg and 80mg strengths of this product, EPI made the required Paragraph IV certification against the patents listed in the FDA s Orange Book as covering these strengths of OxyContin®. EPI pleaded counterclaims that the patents asserted by Purdue Frederick are invalid, unenforceable and/or not infringed by EPI s formulation of oxycodone hydrochloride extended-release tablets, 10mg, 20mg, 40mg and 80mg strengths. EPI also counterclaimed for antitrust damages based on allegations that Purdue Frederick obtained the patents through fraud on the United States Patent and Trademark Office and is asserting them while aware of their invalidity and unenforceability.

The trial of the patent claims in all three of the suits against us and EPI concluded on June 23, 2003. On January 5, 2004, the district court issued an opinion and order holding that, while Endo infringes the three Purdue patents, the patents are unenforceable due to inequitable conduct. The district court, therefore, dismissed the patent claims against us and EPI, declared the patents invalid, and enjoined Purdue from further enforcement of the patents. Purdue filed an appeal, as well as motions to expedite the appeal and to stay the injunction against enforcement of the patents until the appeal is resolved. Both motions were denied on March 18, 2004. In turn, we have cross-appealed the district court s infringement ruling. Briefing on the appeal and cross-appeal concluded in July 2004. By an earlier order, the judge bifurcated the antitrust counterclaims for a separate and subsequent trial. On November 3, 2004, the oral arguments relating to the appeal of this case were heard by the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., at which hearing both sides presented their arguments before a three-judge panel. We are awaiting the outcome of this appeal.

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

Litigation similar to that described above may also result from products we currently have in development, as well as those that we may develop in the future. We, however, cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

Linda Serafin, et al. v. Purdue Pharma L.P., et al., No. 103031/04 (Supreme Court of the State of New York, County of New York)

On February 27, 2004, EPI was named, along with three other pharmaceutical companies, a hospital, and a doctor, as a defendant in a lawsuit filed by Linda Serafin and Michael Serafin in the Supreme Court of the State of New York, County of New York. According to the complaint, each of the pharmaceutical companies manufactured or distributed the drugs oxycodone and OxyContin®. The complaint alleges that EPI and another defendant manufactured oxycodone, OxyContin® and/or Percocet®. The complaint alleges that the defendants failed to adequately warn about the dangers involved with these drugs and that as a result of this failure to warn, plaintiffs sustained injury. EPI intends to defend itself vigorously in this case.

Litigation similar to that described above may also be brought by other plaintiffs in other jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

Pricing Litigation

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The City of New York v. Abbott Laboratories, Inc., et al., MDL 1456, Civ. Action No. 1:01-CV-12257 (D. Mass)

On August 4, 2004, EPI was named, along with 65 other pharmaceutical companies, as a defendant in a lawsuit filed by the City of New York in the U.S. District Court for the Southern District of New York, alleging that these pharmaceutical companies violated federal and state law with respect to Medicaid reimbursements, among other things. On October 13, 2004, this case was transferred to the United States District Court for the District of Massachusetts by order of the United States Judicial Panel on Multidistrict Litigation. EPI intends to defend itself vigorously in this case.

County of Rockland v. Abbott Laboratories, Inc., et al., MDL 1456, Civ. Action No. 1:01-CV-12257 (D. Mass); County of Westchester v. Abbott Laboratories, Inc., et al., MDL 1456, Civ. Action No. 1:01-CV-12257 (D. Mass).

On January 26, 2005, the County of Rockland and the County of Westchester filed complaints against EPI and 71 other companies in the Multidistrict Litigation in the United States District Court for the District of Massachusetts, alleging violations almost identical to those alleged by the City of New York and naming virtually the same defendants as those named in the action brought by the City of New York.

County of Onondaga v. Abbott Laboratories, Inc., et al., Civ. Action No. 5:05-CV-00088 (N.D.N.Y.).

On January 26, 2005, the County of Onondaga filed a lawsuit against EPI and 71 other companies in the United States District Court for the Northern District of New York, alleging violations almost identical to those alleged by the City of New York and naming virtually the same defendants as those named in the action brought by the City of New York.

State of Alabama v. Abbott Laboratories, Inc., et al., Civ. Action No. CV-2005-219 (Cir. Ct. Montgomery Cty. Ala.).

On January 26, 2005, the State of Alabama filed a complaint in the Circuit Court of Montgomery County, Alabama against EPI and 78 other pharmaceutical companies alleging violations of Alabama common law for conduct similar to that alleged in the cases named above.

County of Erie v. Abbott Laboratories, Inc., Index No. 2005-2439 (N.Y. Sup.Ct.)

On March 8, 2005, the County of Erie filed a complaint in the New York Supreme Court of Erie County against EPI and 77 other pharmaceutical companies alleging violations of New York law for conduct similar to that alleged in the cases named above.

The Company intends to contest all of these cases vigorously. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against the Company.

Other Legal Proceedings

In addition to the above proceedings, we are involved in, or have been involved in, arbitrations or various other legal proceedings that arise from the normal course of our business. We cannot predict the timing or outcome of these claims and other proceedings. Currently, we are not involved in any arbitration and/or other legal proceeding that we expect to have a material effect on our business, financial condition, results of operations or cash flows.

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

No matters were submitted to a vote of security holders during the fourth quarter of our fiscal year ended December 31, 2004.

PART II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Market Information. Our common stock is traded on the NASDAQ under the symbol ENDP . The following table sets forth the quarterly high and low share price information for the periods indicated. The prices shown represent quotations between dealers, without adjustment for retail markups, markdowns or commissions, and may not represent actual transactions.

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	Endo Common Stock	
	High	Low
Year Ending December 31, 2004		
1st Quarter	$ 25.00	$ 18.78
2nd Quarter	$ 27.15	$ 20.34
3rd Quarter	$ 23.59	$ 15.78
4th Quarter	$ 22.78	$ 17.17
Year Ending December 31, 2003		
1st Quarter	$ 14.10	$ 7.49
2nd Quarter	$ 19.45	$ 12.72
3rd Quarter	$ 22.26	$ 13.99
4th Quarter	$ 24.00	$ 14.50

Holders. As of March 15, 2005, we estimate that there were approximately 131 record holders of our common stock.

Dividends. We have not declared or paid any cash dividends on our capital stock, and do not anticipate paying any cash dividends in the foreseeable future. Our credit facility contains limitations and restrictions on the payment of dividends.

Equity Compensation Plan Information. The following information relates to plans in effect as of December 31, 2004 under which equity securities of Endo may be issued to employees and directors. Although the Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans provide that stock options may be granted thereunder to non-employee consultants, Endo has never granted any such options to any such consultants.

Plan Category	Column A Number of securities to be issued upon exercise of outstanding options, warrants and rights	Column B Weighted-average exercise price of outstanding options, warrants and rights	Column C Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column A)
Equity compensation plans approved by security holders			
Endo Pharma LLC Amended and Restated 1997 Executive Stock Option Plan	22,719,888(a)	$ 2.68	804,584(b)
Endo Pharma LLC Amended and Restated 1997 Employee Stock Option Plan	2,309,404(a)	$ 2.65	804,584(b)
Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan	3,857,878	$ 12.88	38,160
Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan	129,668	$ 19.38	3,870,332

Equity compensation plans not approved by security holders
Not Applicable.

(a) All of the stock options granted under these plans are exercisable solely for shares currently held by Endo Pharma LLC (an affiliate of Kelso & Company in which certain members of management have an interest), and their exercise will not dilute the ownership of our other common stockholders.

(b) These shares are available for future issuance under either the Endo Pharma LLC Amended and Restated 1997 Executive Stock Option Plan or the Endo Pharma LLC Amended and Restated 1997 Employee Stock Option Plan, but not both.

Item 6. ***Selected Financial Data***

The consolidated financial data presented below have been derived from our audited financial statements. The selected historical consolidated financial data presented below should be read in conjunction with Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data. The selected data in this

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section is not intended to replace the consolidated financial statements. The information presented below is not necessarily indicative of the results of our future operations.

	Year Ended December 31,				
	2004	2003	2002	2001	2000
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Net sales	$ 615,100	$ 595,608	$ 398,973	$ 251,979	$ 197,429
Cost of sales	140,989	135,671	98,857	74,891	63,041
Gross profit	474,111	459,937	300,116	177,088	134,388
Selling, general and administrative	180,200	155,827	110,907	79,505	56,537
Research and development	50,546	51,024	56,823	38,994	26,012
Depreciation and amortization	10,630	6,272	3,142	49,234	27,624
Loss on disposal of other intangible	3,800				
Compensation related to stock options (primarily, selling, general and administrative)		144,524	34,659	37,253	15,300
Purchased in-process research and development		(6,966)	20,300		133,200
Manufacturing transfer fee			9,000		
Merger and other related costs					1,583
Separation benefits					22,034
Operating income (loss)	228,935	109,256	65,285	(27,898)	(147,902)
Interest (income) expense, net	(2,161)	258	4,391	13,290	15,119
Income (loss) before income tax (benefit)	231,096	108,998	60,894	(41,188)	(163,021)
Income tax (benefit)	87,787	39,208	30,081	(4,646)	(6,181)
Net income (loss)	$ 143,309	$ 69,790	$ 30,813	$ (36,542)	$ (156,840)
Basic and Diluted Net Income (Loss) Per Share:					
Basic	$ 1.09	$ 0.54	$ 0.30	$ (0.40)	$ (1.97)
Diluted	$ 1.08	$ 0.53	$ 0.30	$ (0.40)	$ (1.97)
Shares Used to Compute Basic Net Income (Loss) Per Share	131,805	128,417	102,064	91,505	79,454

Shares Used to Compute Diluted Net Income (Loss) Per Share	132,718	132,439	102,126	91,505	79,454
Net income (loss) Pro Forma to Exclude Amortization of Goodwill and Workforce-in-Place (1)	$ 143,309	$ 69,790	$ 30,813	$ 3,203	$ (85,032)
Basic and Diluted Net Income (Loss) Per Share Pro Forma to Exclude Amortization of Goodwill and Workforce-in-Place:					
Basic	$ 1.09	$ 0.54	$ 0.30	$ 0.04	$ (1.07)
Diluted	$ 1.08	$ 0.53	$ 0.30	$ 0.04	$ (1.07)
Shares Used to Compute Basic Net Income (Loss) Per Share Pro Forma	131,805	128,417	102,064	91,505	79,454
Shares Used to Compute Diluted Net Income (Loss) Per Share Pro Forma	132,718	132,439	102,126	91,505	79,454

(1) Effective January 1, 2002, we changed our method of accounting for goodwill and other intangible assets and discontinued the amortization of goodwill and workforce-in-place.

	As of and for the Year Ended December 31,				
	2004	**2003**	**2002**	**2001**	**2000**
			(in thousands)		
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 278,034	$ 229,573	$ 56,902	$ 95,357	$ 59,196
Working capital	294,329	287,922	105,058	65,259	72,759
Total assets	947,491	753,880	512,972	470,995	467,840
Total debt				91,259	198,525
Other long-term obligations, including capitalized leases	18,293	589	7,851	207	7,218
Stockholders equity	655,950	567,617	352,692	295,122	198,173
Other Financial Data:					
Net cash provided by operating activities	$ 172,072	$ 218,259	$ 109,638	$ 80,486	$ 35,069
Net cash (used in) provided by investing activities	(109,351)	(45,159)	(22,274)	(6,546)	18,077
Net cash used in financing activities	(14,260)	(429)	(125,819)	(37,779)	(15,978)

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Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

Except for the historical information contained in this Report, this Report, including the following discussion, contains forward-looking statements that involve risks and uncertainties. See Forward-Looking Statements beginning on page 3 of this Report.

Overview

We, through our wholly owned subsidiary, Endo Pharmaceuticals Inc., are engaged in the research, development, sales and marketing of branded and generic prescription pharmaceuticals used primarily for the treatment and management of pain. Branded products comprised approximately 63%, 70% and 69% of net sales for the years ended December 31, 2002, 2003 and 2004. On August 26, 1997, an affiliate of Kelso & Company and the then members of management entered into an asset purchase agreement with the then DuPont Merck Pharmaceutical Company to acquire certain branded and generic pharmaceutical products and exclusive worldwide rights to a number of new chemical entities in the DuPont research and development pipeline from DuPont Merck through the newly-formed Endo Pharmaceuticals Inc. The stock of Endo Pharmaceuticals Inc. is our only asset, and we have no other operations or business.

Recent Developments

On March 23, 2004, the U.S. Food and Drug Administration (FDA) granted final approval of our abbreviated new drug application (ANDA) for oxycodone extended-release tablets, 10mg, 20mg and 40mg, and confirmed its tentative approval of our 80mg dosage strength. We have since received final FDA approval of our 80mg dosage strength. Our oxycodone extended-release tablets are AB-rated bioequivalent versions of the 10mg, 20mg, 40mg and 80mg strengths of OxyContin®, a product of The Purdue Frederick Company that is indicated for the management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. OxyContin® had combined 2004 U.S. branded sales of approximately $1.8 billion. The 10mg, 20mg and 40mg strengths represent approximately 68% of the U.S. branded sales of OxyContin®. As announced on May 17, 2004, we have decided to wait until appellate review of the district court s decision to launch our bioequivalent versions of generic OxyContin®. However, if upon further examination we determine that is in our best interest to launch one or more of our bioequivalent versions of OxyContin® in advance of the appellate court decision and the district court s ruling is overturned on appeal, we may be liable for lost profits and damages to Purdue and costs associated with the launching of our products. Any launch by us of one or more of our bioequivalent versions of OxyContin® could significantly impact our future results. On November 3, 2004, the oral arguments relating to the appeal of this case were heard by the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., at which hearing both sides presented their arguments before a three-judge panel. We are awaiting the outcome of this appeal.

On April 30, 2004, we filed a shelf registration statement on Form S-3, as amended on June 10, June 14, and June 25, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. The shelf registration statement was declared effective by the Securities and Exchange Commission on June 28, 2004. After the closing of the August 9, 2004 offering of 11 million shares and the November 29, 2004 offering of 8 million shares discussed below, up to 11 million shares remain eligible for sale under this shelf registration statement. The shelf registration statement enables one or more offerings of common stock, subject to market conditions. The nature and terms of any offering will be established at the time of the offering and set forth in a prospectus supplement. Any offering will not increase the number of our outstanding shares of common stock, and we will not receive any proceeds from any offering covered by this shelf registration.

On May 19, 2004, we and SkyePharma, Inc., our collaboration partner, announced that the FDA had approved SkyePharma s NDA for DepoDufor the treatment of pain following major surgery. Previously referred to as DepoMorphine, DepoDur is a novel single dose sustained-release injectable formulation of morphine. We believe the approval of DepoDur is an important step in fulfilling our vision of building our franchise in pain management as well as extending our reach into complementary therapeutic areas such as anesthesiology. We launched DepoDur in December 2004, however, due to the inability to reasonably estimate provisions for chargebacks, rebates, sales incentives and allowances, royalties and returns and losses, we did not recognize any net sales in 2004 in accordance with accounting principles generally accepted in the United States. This launch could significantly impact our future results.

On July 7, 2004, we announced that we had reached agreement with the FDA as to the design of a new clinical trial to provide additional safety and efficacy data of oxymorphone ER in support of our NDA for this developmental product. On September 20, 2004, we announced that the FDA has asked us to clarify some aspects of the analysis of the study outcome prior to granting final

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approval of this protocol. This additional request did not affect the already agreed-upon design of the oxymorphone ER clinical trial and we have now complied with this request. We had submitted the trial protocol to the FDA under the Special Protocol Assessment (SPA) process and the protocol was approved by the FDA in November 2004. Under the terms of the SPA, we have initiated a 12-week, multicenter, double-blinded, placebo-controlled trial of oxymorphone ER. As previously disclosed on October 20, 2003, the FDA issued an approvable letter for our oxymorphone ER NDA but had requested that we address certain questions and provide additional clarification and information, including some form of additional clinical trial to further confirm the safety and efficacy of this product. Also as previously announced, the FDA, following a meeting with us in early May, indicated its concern that the outcome of two of the three Phase III efficacy trials submitted in the NDA that met their predefined primary end-points may have been favorably biased by the statistical handling of data from patients who did not complete the trials. The design of this additional clinical trial is intended to address this issue. Based on the duration of the trial and the number of patients to be enrolled, we believe that, assuming the data are favorable, we will be in a position to finish the study and submit the complete response to the FDA in early 2006. At that point, the FDA will have six months to act on this complete response to its October 2003 approvable letter.

On September 20, 2004, we announced that we had received final approval from the FDA of the clinical trial protocol relating to our developmental product, oxymorphone immediate-release tablets (oxymorphone IR). We had submitted the trial protocol to the FDA under the Special Protocol Assessment (SPA) process.

On July 14, 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to exclusively license to us rights to market Frova® (frovatriptan) in North America. Launched in the U.S. in June 2002, Frova® is indicated for the acute treatment of migraine headaches in adults. Net sales of Frova® in the U.S. were $37.5 million in 2003. Under the terms of the license agreement, we paid Vernalis an upfront fee of $30 million and we will make anniversary payments for the first two years at $15 million each year, and a $40 million milestone payment upon U.S. Food and Drug Administration, FDA, approval for the menstrually related migraine indication. In addition, Vernalis will receive one-time milestone payments for achieving defined annual net sales targets. These sales milestone payments increase based on increasing net sales targets ranging from a milestone of $10 million on $200 million in net sales to a milestone of $75 million on $1.2 billion in net sales. These sales milestones could total up to $255 million if all of the defined net sales targets are achieved. We will also pay royalties to Vernalis based on the net sales of Frova®. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement is for the shorter of the time (i) that there are valid claims on the Vernalis patents covering Frova® or there is market exclusivity granted by a regulatory authority, whichever is longer, or (ii) until the date on which a generic version of Frova® is first offered, but in no event longer than 20 years. We can terminate the license agreement under certain circumstances, including upon one years written notice. Under the loan agreement, Endo provided Vernalis with a loan of $50 million at closing. The loan was primarily used to make a payment in full and final settlement of the amounts due to Elan Corporation from Vernalis in connection with Vernalis reacquisition of the North American rights to Frova®. The balance of the loan was available for general corporate purposes. The loan is secured against the revenues receivable by Vernalis under the license agreement. At Endo s election, Endo is able to offset $20 million of the $40 million MRM approval milestone and 50% of all royalties to be paid under the license agreement to Vernalis to repay the loan. To the extent not previously repaid, the loan is due in full after five years. Interest is at the rate of 5% per annum payable semi-annually. However, Vernalis has the option to defer payment of interest and increase the loan outstanding each time an interest payment becomes due. In January 2005, Vernalis elected to defer payment of the first semi-annual interest payment otherwise due January 31, 2005.

On August 18, 2004, we announced that we had entered into an agreement granting us the exclusive rights to develop and market Orexo AB s (a privately held Swedish company) patented sublingual muco-adhesive fentanyl product (Rapinyl) in North America. Rapinyl is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. The benefits of Rapinyl are believed to include both a fast onset of action and

patient convenience. Rapinyl is based on Orexo s unique patented technology for sublingual administration. This novel pharmaceutical preparation is believed to provide rapid absorption of the active substance and a fast onset of action. Currently in Phase II clinical development, this product is intended for the management of breakthrough pain in opioid-tolerant cancer patients. We anticipate that it will commence Phase III clinical trials in 2005. The agreement provides for us to make an up-front license fee payment of $10 million, in addition to other license fees and payments based on development and regulatory milestones, which may total up to $22.1 million through FDA approval of Rapinyl s New Drug Application. The agreement also provides for royalties upon commercial sales and may include sales milestones if defined sales thresholds are achieved.

On March 9, 2005, we announced that Peter A. Lankau, the current president and chief operating officer of Endo, has been appointed president and chief executive officer by our Board of Directors, effective May 20, 2005, the day following the Annual Meeting of Endo Stockholders. Carol A. Ammon, Endo s current chief executive officer, will continue to serve Endo as Chairman of

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the Board of Directors. In addition, Endo s Board of Directors has appointed Lankau to the Endo Board of Directors, effective immediately. This appointment expands the number of directors to 11.

On March 14, 2005, we announced that we have signed an agreement that will give us the exclusive license to develop and commercialize DURECT s sufentanil-containing transdermal patch in the U.S. and Canada (the DURECT Sufentanil Agreement). The sufentanil patch, which is in early-stage clinical development, employs DURECT s proprietary TRANSDUR drug-adhesive matrix formulation and is intended to provide relief of moderate-to-severe chronic pain for up to seven days. Effective immediately, we will assume all remaining development and regulatory filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, we will pay DURECT an upfront fee of $10 million, with additional payments of approximately $35 million upon achievement of predetermined regulatory and commercial milestones. We will also pay royalties to DURECT on net sales of the sufentanil transdermal patch.

Also on March 14, 2005, we announced that we have entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. Currently in Phase II clinical trials in the U.S., the ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains. Two Phase III placebo-controlled studies in soft-tissue injury and ankle sprains have been completed in Europe by ProEthic s European partner APR Applied Pharma Research AG, with statistically significant results. Under the terms of the agreement, we will make a $10.0 million upfront payment and payments of approximately $14.0 million for the achievement of certain regulatory milestones. We will also pay royalties on net sales of the ketoprofen patch.

Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations are primarily due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products, the impact of competitive products and pricing as well as charges incurred for compensation related to stock options and milestone payments.

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Critical Accounting Policies and Estimates

To understand our financial statements, it is important to understand our critical accounting policies and estimates. The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of sales deductions for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses. Significant estimates and assumptions are also required in the appropriateness of capitalization and amortization periods for identifiable intangible assets, inventories and related inventory reserves and the potential impairment of goodwill and other intangible assets. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption made by us, there may also be other estimates or assumptions that are reasonable. Although we believe that our estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made. Actual results may differ significantly from our estimates. Our most critical accounting policies and estimates are described below:

Sales Deductions

When we recognize revenue from the sale of our products, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses. These provisions are estimated based on historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with our wholesale and indirect customers and other competitive factors. If the assumptions we used to calculate these adjustments do not appropriately reflect future activity, our financial position, results of operations and cash flows could be impacted. The provision for chargebacks is one of the most significant and the most complex estimate used in the recognition of our revenue. We establish contract prices for indirect customers who are supplied by our wholesale customers. A chargeback represents the difference between our invoice price to the wholesaler and the indirect customer s contract price. Provisions for estimating chargebacks are calculated primarily using historical chargeback experience, estimated wholesaler inventory levels and estimated future trends. We also establish contracts with wholesalers, chain stores and indirect customers that provide for rebates, sales incentives and other allowances. Some customers receive rebates upon attaining established sales volumes. We estimate rebates, sales incentives and other allowances based upon the terms of the contracts with our customers, historical experience, estimated inventory levels of our customers and estimated future trends. We estimate an accrual for Medicaid rebates as a reduction of revenue at the time product sales are recorded. The Medicaid rebate reserve is estimated based upon the historical payment experience, historical relationship to revenues and estimated future trends. Medicaid pricing programs involve particularly difficult interpretations of statutes and regulatory guidance, which are complex and thus our estimates could differ from actual experience. Royalties represent amounts accrued pursuant to the license agreement with Hind Healthcare Inc. (Hind). Royalties are recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. Royalties are paid to Hind at a rate of 10% of net sales of Lidoderm®. Our return policy allows customers to receive credit for expired products within three months prior to expiration and within one year after expiration. We estimate the provision for product returns based upon the historical experience of returns for each product, historical relationship to revenues, estimated future trends, estimated customer inventory levels and other competitive factors. We continually monitor the factors that influence each type of sales deduction and make adjustments as necessary.

Inventories

Inventories consist of finished goods held for distribution, raw materials and work in process. Our inventories are stated at the lower of cost or market. Cost is determined by the first-in, first-out method. We write down inventories to

net realizable value based on forecasted demand and market conditions, which may differ from actual results. Inventories also include costs associated with certain products prior to regulatory approval and/or resolution of patent infringement litigation based on management s judgment of probable future commercial use and net realizable value.

Goodwill and Other Intangibles

Goodwill and other intangibles represent a significant portion of our assets and stockholders equity. As of December 31, 2004, goodwill and other intangibles comprised approximately 31% of our total assets and 45% of our stockholders equity. Effective January 1, 2002, we adopted the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets,* and no longer amortize goodwill and workforce in place. SFAS No. 142 prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit s fair value to all of its assets and

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liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit s goodwill is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

We have one reportable segment, pharmaceutical products. Goodwill arose as a result of the August 26, 1997 acquisition of certain branded and generic pharmaceutical products, related rights and certain assets of the then DuPont Merck Pharmaceutical Company (n/k/a Bristol-Myers Squibb Pharma Company) and the July 17, 2000 acquisition of Algos. Although goodwill arose in two separate transactions, the components of our operating segment have been integrated and are managed as one reporting unit. Our components extensively share assets and other resources with the other components of our business and have similar economic characteristics. In addition, our components do not maintain discrete financial information. Accordingly, the components of our business have been aggregated into one reporting unit and are evaluated as such for goodwill impairment. Goodwill is evaluated for impairment on an annual basis on January 1st of each year unless events or circumstances indicate that an impairment may have occurred between annual dates. On January 1, 2005, 2004 and 2003, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

Licenses are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives ranging from eleven to twenty years. The determination to capitalize amounts related to licenses is based on management s judgments with respect to stage of development, the nature of the rights acquired, alternative future uses, developmental and regulatory issues and challenges, the net realizable value of such amounts based on projected sales of the underlying products, the commercial status of the underlying products and/or various other competitive factors. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the license and an acceleration of related amortization expense, which could cause our operating income, net income and earnings per share to decrease. The value of these licenses is subject to continuing scientific, medical and marketplace uncertainty. Patents acquired in the Algos merger are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives of seventeen years.

Licenses and patents are assessed for impairment, in accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144), whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset s carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. As a result of the significance of our amortizable intangibles, any recognized impairment loss could have a material adverse impact on our financial position and/or results of operations.

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

	December 31,	December 31,

	2004	2003
Goodwill	$ 181,079	$ 181,079
Amortizable Intangibles:		
Licenses	$ 123,600	$ 43,500
Patents	3,200	3,200
	126,800	46,700
Less accumulated amortization	(9,542)	(4,657)
Other Intangibles, net	$ 117,258	$ 42,043

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

2005	$ 8,159
2006	8,159
2007	8,159
2008	8,159
2009	8,159

Compensation Related to Stock Options Endo Pharma LLC Stock Option Plans

In our 2001 fiscal year we incurred a non-cash charge of $37.3 million, in our 2002 fiscal year we recorded a non-cash charge of $34.7 million and in our 2003 fiscal year we recorded non-cash charges of $144.5 million, in each case for stock-based compensation relating to the vesting of options that were issued under the Endo Pharma LLC 1997 Amended and Restated Executive Stock Option Plan and the Endo Pharma LLC 1997 Amended and Restated Employee Stock Option Plan (together, the Endo Pharma LLC 1997 Stock Option Plans) and the Endo Pharma LLC 2000 Supplemental Employee Stock Option Plan and the Endo Pharma LLC 2000 Supplemental Executive Stock Option Plan (collectively, the Endo Pharma LLC 2000 Supplemental Stock Option Plans). Under the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans, tranches of options vested if we attained certain stock price targets. As each tranche vested, we incurred a non-cash charge representing the difference between the market price of the shares underlying the options and the exercise price of such options. Upon exercise, no additional shares of our common stock will be issued, however, because these stock options are exercisable only into shares of our common stock that are held by Endo Pharma LLC. Accordingly, these stock options do not dilute the public stockholders. In addition, Endo Pharma LLC, and not us, will receive the exercise price payable in connection with these options. Further, the shares of common stock that individuals receive upon exercise of stock options granted pursuant to the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

For a discussion of the tax sharing agreement between the Company and Endo Pharma LLC relating to the Endo Pharma LLC Stock Options, see Liquidity and Capital Resources; Tax Sharing Agreement.

Compensation Related to Stock Options Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans

All the stock options we have granted pursuant to the Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans have exercise prices equal to the market price of our stock on the date granted and, under accounting principles generally accepted in the United States, a measurement date occurs on the date of each grant. Consequently, we have not incurred charges upon the vesting or exercise of these options. In December 2004, the FASB issued SFAS No. 123, *Share-Based Payments (revised 2004),* (SFAS No. 123R). This statement eliminates the option to apply the intrinsic value measurement provisions of APB Board Opinion No. 25, *Accounting for Stock Issued to Employees*, to stock compensation awards issued to employees. Rather, the Statement requires companies to measure the cost of employee services received in exchange for an award of equity instruments based on the grant date fair value of the award. That cost will be recognized over the period during which an employee is required to provide services in exchange for the award the requisite service period (usually the vesting period). SFAS No. 123R will be effective for the Company s fiscal quarter beginning July 1, 2005. The Company is currently evaluating the impact of the adoption of this statement on its financial statements.

Results of Operations

Net Sales

Our net sales consist of revenues from sales of our pharmaceutical products, less estimates for certain chargebacks, rebates, sales incentives and allowances, royalties and returns and losses. We recognize revenue when products are shipped and title and risk of loss has passed to the customer, which is typically upon delivery to the customer. Our shipping terms are generally free on board customer s destination.

The following table presents our net sales by product category for the years ended December 31, 2004, 2003 and 2002.

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	Year Ended December 31,		
	2004	2003	2002
		(in thousands)	
Lidoderm®	$ 309,230	$ 178,299	$ 83,218
Percocet®	86,510	214,187	144,623
Frova®	11,449		
Other brands	15,481	21,870	22,046
Total brands	422,670	414,356	249,887
Total generics	192,430	181,252	149,086
Total net sales	$ 615,100	$ 595,608	$ 398,973

The following table presents our net sales as a percentage of total net sales for select products for the years ended December 31, 2002, 2003 and 2004.

	Year Ended December 31,		
	2004	2003	2002
Lidoderm®	50%	30%	21%
Percocet®	14	36	36
Frova®	2		
Other brands	3	4	6
Total brands	69	70	63
Total generics	31	30	37
Total	100%	100%	100%

Year Ended December 31, 2004 Compared to the Year Ended December 31, 2003

Net Sales. Net sales for the year ended December 31, 2004 increased by 3% to $615.1 million from $595.6 million in the comparable 2003 period. This increase in net sales was primarily due to the increase in the net sales of Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, net sales of Frova®, and an increase in the net sales certain generic products offset by the reduction in the net sales of Percocet®. Net sales of Lidoderm® increased to $309.2 million from $178.3 million in the comparable 2003 period. In September 1999, we launched Lidoderm®, which continues to gain market share due to our ongoing promotional and educational efforts. Net sales of Frova® were $11.4 million for the year ended December 31, 2004. We began shipping Frova® upon the closing of the license agreement in mid-August 2004 and initiated our promotional efforts in September 2004. Net sales of our generic products increased to $192.4 million from $181.3 million in the comparable 2003 period primarily due to the increase in the net sales of Endocet® as a result of our launch in the fourth quarter of 2003 of two new strengths of Endocet® offset by a decrease in the net sales of our morphine sulfate extended-release tablets as a result of generic competition introduced in the fourth quarter of 2003. During the second half of 2004, we have begun to experience both pricing pressure as well as a reduction in our share for both Endocet® and our morphine sulfate extended-release tablets due to generic competition. We expect that competitors will continue to have an impact on our market share and price of both of these generic products, which will adversely affect the net sales and profitability of our generic products. Percocet® net sales decreased to $86.5 million 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. Due to the expected increases in the net sales of Lidoderm®, Frova® and DepoDur partially offset by generic competition with our Percocet®, Endocet® and morphine sulfate extended-release tablets, we expect net sales in 2005 to be approximately $650 to $660 million.

Gross Profit. Gross profit for the year ended December 31, 2004 increased by 3% to $474.1 million from $459.9 million in the comparable 2003 period. Gross profit margins remained at 77% for the years ended December 31, 2004 and 2003. The gross profit margin for 2003 includes a charge of $24.6 million to fully reserve for the inventory of extended-release oxycodone tablets that were manufactured during that year. Pricing pressures on our generic products, combined with the introduction in April 2004 of more costly single-pouch child-resistant packaging for Lidoderm® were the primary factors affecting the gross profit margin for the year ended December 31, 2004. We expect gross profit margins to decline slightly in 2005 due to competition with Percocet®, Endocet® and our extended-release morphine sulfate product. In addition, we expect to experience lower gross profit margins in 2005 on Lidoderm® due to the introduction in the second quarter of 2004 of the higher cost single-pouch child-resistant packaging.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the year ended December 31, 2004 increased by 16% to $180.2 million from $155.8 million in the comparable 2003 period. This increase was due to an increase in sales, education and promotional efforts in 2004 over the comparable 2003 period to support our products as well as support for our growing business including our products Lidoderm®, Frova® and DepoDur, and in preparation of new product launches. We expect selling, general and administrative expenses to increase in 2005 primarily due to the hiring in early 2005 of approximately 70

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sales representatives to bring the total number of sales representatives supporting both Lidoderm® and Frova® to approximately 300 and the additional hiring of approximately 45 sales representatives in early 2005 to bring the total number of hospital sales representatives to support the launch of DepoDur to approximately 70.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2004 remained essentially unchanged at $50.5 million compared to $51.0 million in the comparable 2003 period. Excluding milestone payments to partners, we anticipate increasing our research and development spending in 2005 as compared to 2004. During 2005, we will focus our development efforts on various projects primarily focused in the area of pain management, including completing the studies for oxymorphone extended-release tablets and immediate-release tablets and the initiation of the Phase III clinical studies of Rapinyl.

Depreciation and Amortization. Depreciation and amortization for the year ended December 31, 2004 increased to $10.6 million from $6.3 million in the comparable 2003 period primarily due to an increase in amortization expense as a result of new license rights acquired during 2004 and an increase in depreciation expense as a result of an increase in capital expenditures. We expect depreciation and amortization to continue to increase as we increase our capital expenditures for new office and lab space and automobiles for our newly hired sales representatives, and as we continue to license in products and technologies.

Compensation Related to Stock Options. Compensation related to stock options for the year ended December 31, 2004 decreased to $0 from $144.5 million in the comparable 2003 period. Effective January 1, 2003, the Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective resulting in the issuance of approximately 10.7 million stock options to certain employees and members of management. Because approximately 9.2 million of these stock options were immediately vested upon their issuance, we recorded a non-cash compensation charge of approximately $48.5 million in the first quarter of 2003 representing the difference between the market price of the common stock of $7.70 and the exercise price of these stock options of $2.42. In addition, we recorded a non-cash compensation charge of $96.0 million in October 2003 as a result of the vesting of the 4.8 million Class C4 stock options representing the difference between the market price of the common stock of $22.59 and the exercise price of these options of $2.63. No additional shares of our common stock will be issued, however, because these stock options are exercisable only into shares of our common stock that are held by Endo Pharma LLC. Accordingly, the exercise of these stock options does not dilute the ownership of our other public stockholders.

Purchased In-Process Research and Development. Purchased in-process research and development during the year ended December 31, 2003 reflects a gain of $7.0 million related to the extinguishment of a contingent liability as a result of our decision to discontinue our development program for the oral rinse (0.1% triclosan) for the treatment of oral mucositis that we had obtained in the acquisition of BML Pharmaceuticals in July 2002.

Interest (Income) Expense, Net. Interest (income) expense, net for the year ended December 31, 2004 was $2.2 million in interest income compared to $0.3 million in interest expense in the comparable 2003 period. This change is substantially due to the increased interest income earned as a result of higher average cash balances during 2004 and interest income earned on our note receivable from Vernalis.

Income Tax. Income tax for the year ended December 31, 2004 increased to $87.8 million from $39.2 million in the comparable 2003 period. This increase is due to the increase in income before income tax for the year ended December 31, 2004 as well as an increase in the effective tax rate from 36.0% in 2003 to 38.0% in 2004. The effective tax rate in 2003 was favorably impacted by the recognition of a gain of $7.0 million in 2003 related to the reversal of a contingent liability related to the BML acquisition which had no tax impact.

Year Ended December 31, 2003 Compared to the Year Ended December 31, 2002

Net Sales. Net sales for the year ended December 31, 2003 increased by 49% to $595.6 million from $399.0 million in the comparable 2002 period. This increase in net sales was primarily due to the increase in the net sales of Lidoderm®, Percocet®, and certain generic products. Net sales of Lidoderm® increased to $178.3 million from $83.2 million in the comparable 2002 period. Percocet® net sales increased to $214.2 million from $144.6 million in the comparable 2002 period due to the increase in net sales of Percocet® 7.5/325 and Percocet® 10.0/325. On October 20, 2003, Watson Pharmaceuticals announced that it was launching its generic versions of Percocet® 7.5/325 and Percocet® 10.0/325. Net sales of our generic products increased 22% to $181.3 million from $149.1 million in the comparable 2002 period primarily due to the growth of Endocet® and our generic morphine sulfate extended-release tablets. In October 2003, we launched two new strengths of our generic product Endocet®. During the third quarter of 2003, the FDA approved all five strengths of Mallinckrodt Inc. s generic extended-release morphine sulfate.

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Gross Profit. Gross profit for the year ended December 31, 2003 increased by 53% to $459.9 million from $300.1 million in the comparable 2002 period. Gross profit margins increased to 77% from 75% due to a more favorable mix of higher margin brand and generic products resulting from the products discussed above. Included in cost of sales is a charge of $24.6 million in 2003 and $8.0 million in 2002 to fully reserve for the inventory of extended-release oxycodone tablets that were manufactured during those years.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the year ended December 31, 2003 increased by 40% to $155.8 million from $110.9 million in the comparable 2002 period. This increase was due to a $31.2 million increase in sales and promotional efforts in 2003 over the comparable 2002 period to support Lidoderm® and Percocet® and in preparation of new product launches. In addition, we experienced an increase in costs in the general and administrative functions in order to support our new product marketing and new product development.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2003 decreased by 10% to $51.0 million from $56.8 million in the comparable 2002 period. This decrease reflects the overall stage of development of our development portfolio. During 2002, we were performing clinical trials on our extended-release and immediate-release oxymorphone products and MorphiDex®. During 2003, our development efforts were focused on a Phase III clinical trial on an oral mucositis product as well as other earlier stage projects focused in the area of pain management and other complementary therapeutic areas. We decided in 2003 to cease our development efforts related to the oral mucositis product. This decrease is partially offset by a $5.0 million milestone charge we incurred pursuant to our Development and Marketing Strategic Alliance Agreement with SkyePharma Inc. Under the terms of this agreement, a $5.0 million milestone becomes due upon acceptance for substantive review by the FDA of DepoMorphine . DepoMorphine was accepted for substantive review by the FDA during the third quarter of 2003.

Depreciation and Amortization. Depreciation and amortization for the year ended December 31, 2003 increased to $6.3 million from $3.1 million in the comparable 2002 period primarily due to an increase in depreciation of $1.7 million related to an increase in capital expenditures and an increase in amortization of $1.5 million primarily due to an increase in license fees arising from the SkyePharma license entered into on December 31, 2002.

Compensation Related to Stock Options. Compensation related to stock options for the year ended December 31, 2003 increased to $144.5 million from $34.7 million in the comparable 2002 period. Effective January 1, 2003, the Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective resulting in the issuance of approximately 10.7 million stock options to certain employees and members of management. Because approximately 9.2 million of these stock options were immediately vested upon their issuance, we recorded a non-cash compensation charge of approximately $48.5 million in the first quarter of 2003 representing the difference between the market price of the common stock of $7.70 and the exercise price of these stock options of $2.42. In addition we recorded a non-cash compensation charge of $96.0 million in October 2003 as a result of the vesting of the 4.8 million Class C4 stock options representing the difference between the market price of the common stock of $22.59 and the exercise price of these options of $2.63. No additional shares of our common stock will be issued, however, because these stock options are exercisable only into shares of our common stock that are held by Endo Pharma LLC. Accordingly, the exercise of these stock options will not dilute the ownership of our other public stockholders.

In the year ended December 31, 2002, we recorded a non-cash compensation charge of $34.7 million as a result of the vesting of the 6.9 million Class C3 stock options representing the difference between the market price of the common stock of $7.70 and the exercise price of these options of $2.69. These options are exercisable into shares of common stock that are presently held by Endo Pharma LLC. As a result, the exercise of these options will not result in the issuance of additional shares of common stock and will not dilute the other public stockholders of Endo.

Purchased In-Process Research and Development. Purchased in-process research and development during the year ended December 31, 2003 reflects a gain of $7.0 million related to the extinguishment of a contingent liability as a result of our decision to discontinue our development program for the oral rinse (0.1% triclosan) for the treatment of oral mucositis that we had obtained in the acquisition of BML Pharmaceuticals in July 2002. Purchased in-process research and development for the year ended December 31, 2002 of $20.3 million resulted from the estimated fair value of our oral rinse (0.1% triclosan) for oral mucositis development product that we acquired in the acquisition of BML Pharmaceuticals.

Manufacturing Transfer Fee. Manufacturing transfer fee during the year ended December 31, 2002 was the consideration paid to Bristol-Myers Squibb Pharma Company which allowed Endo to transfer up to 100% of any Endo product out of any Bristol-Myers Squibb facility at any time, and for the assistance of Bristol-Myers Squibb Pharma Company in the transfer.

Interest Expense, Net. Interest expense, net for the year ended December 31, 2003 decreased to $0.3 million from $4.4 million in

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the comparable 2002 period. This decrease is substantially due to the repayment on August 26, 2002 of the promissory notes issued to Bristol-Myers Squibb in connection with our 1997 acquisition from Bristol-Myers Squibb Pharma Company (f/k/a The DuPont Merck Pharmaceutical Company).

Income Tax. Income tax for the year ended December 31, 2003 increased to $39.2 million from $30.1 million in the comparable 2002 period. This increase is due to the increase in income before income tax for the year ended December 31, 2003 offset by a decrease in the effective tax rate from 49.4% in 2002 to 36.0% in 2003. The effective tax rate in 2002 was negatively impacted by the write-off of in-process research and development costs of $20.3 million related to the acquisition of BML Pharmaceuticals in 2002, which was not deductible for tax purposes. The effective income tax rate for 2003 was favorably impacted by the recognition of a gain of $7.0 million in 2003 related to the reversal of a contingent liability related to the BML acquisition which had no tax impact.

Liquidity and Capital Resources

Our principal source of liquidity is cash generated from operations. Under our credit facility, we may borrow up to $75.0 million on a revolving basis for certain purposes as described below. Our principal liquidity requirements are for working capital for operations, acquisitions, licenses and capital expenditures.

Net Cash Provided by Operating Activities. Net cash provided by operating activities decreased to $172.1 million for the year ended December 31, 2004 from $218.3 million for the year ended December 31, 2003. This decrease primarily reflects an increase in accounts receivable and an increase in our inventory levels. The increase in accounts receivable is substantially attributable to the timing of purchases by our customers during the fourth quarter of 2004 versus the fourth quarter of 2003. The increase in our inventory levels is primarily due to an increase in our inventory of Lidoderm®. Historically, we have carried low inventory levels of Lidoderm® due to our manufacturing not being able to keep up with demand. This year, additional capacity has been added and our manufacturing of Lidoderm® has not only been able to keep up with demand, but we have been able to build a safety stock of Lidoderm® inventory. We are at this time, however, carrying more Lidoderm® inventory than we would like to. Although we do not believe that there is a risk of obsolescence with this inventory, we and our manufacturer will be working together in the first half of 2005 to bring the Lidoderm® inventory to more appropriate levels. In addition, during 2004, we made the decision to manufacture an additional $4.8 million of our generic oxycodone extended-release tablets. We did not reserve for this inventory and, although there can be no assurance, we remain confident that the decision of the U.S. District Court for the Southern District of New York declaring Purdue s OxyContin® patents unenforceable will be affirmed by the U.S. Court of Appeals for the Federal Circuit.

Net Cash Used in Investing Activities. Net cash used in investing activities increased by $64.2 million to $109.4 million for the year ended December 31, 2004 from $45.2 million for the year ended December 31, 2003. During the year ended December 31, 2004, the Company loaned $50 million to a third party, paid $46.5 million in license fees, paid a termination penalty of $3.0 million to Lavipharm and had capital expenditures of $9.6 million primarily related to our new research and development facility in Westbury, NY and leasehold improvements to a second corporate office building in Chadds Ford, PA. During the year ended December 31, 2003, the Company paid $32.5 million in license fees and had $12.2 million in capital expenditures primarily related to our new research and development facility in Westbury, NY and leasehold improvements to a second corporate office building in Chadds Ford, PA.

Net Cash Used in Financing Activities. Net cash used in financing activities increased to $14.3 million for the year ended December 31, 2004 from $0.4 million for the year ended December 31, 2003 primarily due to $13.5 million in payments to Endo Pharma LLC pursuant to the tax sharing agreement and an increase in capital lease obligations repayments made during the year ended December 31, 2004 compared to 2003 partially offset by an increase in the proceeds received from the exercise of stock options during the year ended December 31, 2004

compared to 2003. See Tax Sharing Agreement below.

Credit Facility. In December 2001, we amended and restated our senior secured credit facility with a number of lenders. This amended and restated credit facility provides us with a line of credit of $75.0 million. The line of credit matures on December 21, 2006. Any loans outstanding under the amended and restated credit facility are secured by a first priority security interest in substantially all of our assets. The credit facility contains representations and warranties, covenants, including a covenant requiring us to maintain minimum EBITDA of $50 million over the prior four-quarter period, events of default and other provisions customarily found in similar agreements. Our ability to borrow under the credit facility is dependent, among other things, on our compliance with those provisions. On April 30, 2004, we amended our credit facility to allow us to file a shelf registration statement on Form S-3, which we initially filed on April 30, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders to be named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. On July 13, 2004, we amended our credit facility to allow us to enter in the transaction with Vernalis. As

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of December 31, 2004, we have not borrowed any amounts under our credit facility.

Tax Sharing Agreement. On July 14, 2000, Endo Pharma LLC was formed in connection with the Algos merger to ensure that the stock options granted pursuant to the Endo Pharma LLC Stock Option Plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Endo Pharma LLC is a limited liability company that currently holds a significant portion of our common stock, in which affiliates of Kelso & Company and certain members of management have an interest. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC will be delivered. Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we are required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, which occurred on August 9, 2004 as described further below, the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of December 31, 2004, approximately 10.4 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC. Upon exercise of any of these Endo Pharma LLC stock options, we generally will be permitted to deduct as a compensation charge, for federal income tax purposes, an amount equal to the difference between the market price of our common stock and the exercise price paid upon exercise of these options (as of December 31, 2004, approximately $147 million), which is estimated to result in a tax benefit amount of approximately $56 million. Under the tax sharing agreement, we are required to pay this $56 million to Endo Pharma LLC to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto.

Using a weighted average exercise price of $2.60 per share and an assumed effective tax rate of 38.3%, if all 36.3 million stock options under the Endo Pharma LLC Stock Option Plans were vested and exercised (including the 10.4 million stock options already exercised as discussed above):

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

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

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

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

On April 30, 2004, the tax sharing agreement was amended to provide for a specific schedule upon which payments currently contemplated by the tax sharing agreement would be made once a liquidity event has occurred. The amendment provides that upon the occurrence of a liquidity event (which occurred on August 9, 2004), we are required pay to Endo Pharma LLC, within 30 business days, the amount of the tax benefits usable by us in each of the previous taxable years for which we have filed a federal income tax return. In addition, the amended tax sharing agreement provides that with respect to all taxable years following the occurrence of a liquidity event, the amount of the tax benefits usable by us in each such year will be paid to Endo Pharma LLC in two installments: (i) 50% of the estimated amount shall be paid within 15 business days of our receipt from our independent registered public accounting firm of an opinion on our final audited financial statements, and (ii) the remaining amount shall be paid within 30 business days of the filing of our federal income tax return. Finally, the amendment also clarified two matters related to determining the occurrence of

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

A secondary sale of 11 million shares by Endo Pharma LLC closed on August 9, 2004. This offering, when combined with the 16.6 million shares sold in July 2003, constituted a liquidity event and thus triggered a payment obligation. Endo Pharma LLC has informed us that, subject to a variety of factors, including market conditions and stock price levels, it may initiate additional secondary offerings of our common stock in the future.

In 2004, we paid $13.5 million to Endo Pharma LLC to satisfy the tax sharing obligations attributable to 2001, 2002 and 2003. Since 3.8 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised into common stock and sold in the offering on August 9, 2004, at a price of $17.46, with a weighted average exercise price of $2.44, an assumed tax rate of 38.3% and assuming the attributable compensation charge deductions are usable to reduce our taxes in 2004, we are obligated to pay Endo Pharma LLC a tax benefit of approximately $22 million. In addition, since 2.8 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised into common stock and sold in the offering on November 29, 2004, at a price of $20.02, with a weighted average exercise price of $2.44, an assumed tax rate of 38.3% and assuming the attributable compensation charge deductions are usable to reduce our taxes in 2004, we are obligated to pay Endo Pharma LLC a tax benefit of approximately $19 million. Fifty percent of the tax benefit amount attributable to these two 2004 offerings and any other Endo Pharma LLC stock option exercises in 2004 will be due within 15 business days of the date we received the opinion on our audited 2004 financial statements from our independent registered public accounting firm and the remaining fifty percent of the tax benefit amount attributable to 2004 is due within 30 business days of the date on which we file our 2004 tax return with the Internal Revenue Service (which we estimate will occur in September 2005). As of December 31, 2004, approximately $43 million is payable to Endo Pharma LLC related to estimated tax sharing payments that we are obligated to pay which are attributable to 2004. All payments made and accrued pursuant to the tax sharing agreement have been reflected as a reduction of stockholders equity in the accompanying financial statements. The estimated tax benefit amount payment to Endo Pharma LLC attributable to Endo Pharma LLC stock options exercised may increase if certain holders of Endo Pharma LLC stock options exercise additional stock options in the future.

On April 30, 2004, we filed a shelf registration statement on Form S-3, as amended on June 10, June 14 and June 25, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. The shelf registration statement was declared effective by the Securities and Exchange Commission on June 28, 2004. After the closing of the August 9 and November 29, 2004 offerings, which totaled 19 million shares, up to 11 million shares remain eligible for sale by Endo Pharma LLC under this shelf registration statement. The shelf registration statement enables one or more offerings of common stock, subject to market conditions. The nature and terms of any offering will be established at the time of the offering and set forth in a prospectus supplement. Any offering would most likely trigger an additional tax sharing payment due to Endo Pharma LLC, would not increase the number of our outstanding shares of common stock and we would not receive any proceeds from any offering covered by this shelf registration.

Fluctuations. Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations are primarily due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products and the impact of competitive products and pricing. Further, a substantial portion of our net sales are through wholesale drug distributors who in turn supply our products to pharmacies, hospitals and physicians. Accordingly, we are potentially subject to a concentration of credit risk with respect to our trade receivables.

Growth Opportunities. We continue to evaluate growth opportunities including strategic investments, licensing arrangements and acquisitions of product rights or technologies, which could require significant capital resources.

Non-U.S. Operations. We currently have no operations outside of the United States. As a result, fluctuations in foreign currency exchange rates do not have a material effect on our financial statements.

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

Expected Cash Requirements for Contractual Obligations. The following table presents our expected cash requirements for contractual obligations outstanding as of December 31, 2004 (in thousands):

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	Payment Due by Period						
Contractual Obligations	**Total**	**2005**	**2006**	**2007**	**2008**	**2009**	**Thereafter**
Operating Lease Obligations	$ 24,878	$ 2,773	$ 2,874	$ 2,727	$ 2,733	$ 2,740	$ 11,031
Capital Lease Obligations	3,339	1,872	1,178	269	13	7	
Minimum Purchase Commitments to Teikoku	33,600	33,600					
Minimum Purchase Commitments to Novartis	8,972	4,681	4,291				
Estimated Tax Sharing Payments Due to Endo Pharma LLC	42,939	42,939					
License Payments Due to Vernalis	30,000	15,000	15,000				
Total	$ 143,728	$ 100,865	$ 23,343	$ 2,996	$ 2,746	$ 2,747	$ 11,031

Novartis Consumer Health, Inc. On May 3, 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. whereby Novartis has agreed to manufacture certain of our commercial products and products in development. We are required to purchase, on an annual basis, a minimum amount of product from Novartis. The purchase price per product is equal to a predetermined amount per unit, subject to periodic adjustments. As of December 31, 2004, we are required to purchase a minimum of $4.7 million and $4.3 million of product from Novartis in 2005 and 2006, respectively. However, actual amounts purchased could be significantly higher based on the actual mix of products purchased. This agreement has a five-year term, with automatic five-year renewals thereafter. Either party may terminate this agreement on three-years notice, effective at any time after the initial five-year term. In addition, we may terminate this agreement effective prior to the fifth anniversary of the agreement upon three-years notice and the payment of certain early termination fees. Either party may also terminate this agreement on account of a material breach by the other.

Teikoku Seiyaku Co., Ltd. Under the terms of this agreement, Teikoku, a Japanese manufacturer, manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We also have an option to extend the supply area to other territories within a defined period of time. We are required to purchase, on an annual basis, a minimum amount of product from Teikoku. The purchase price for the product is equal to a predetermined amount per unit of product. As of December 31, 2004, we are required to purchase a minimum of $33.6 million of product from Teikoku in 2005. The term of this agreement is from November 23, 1998 until the shorter of (1) the expiration of the last to expire patent that is licensed to us from Hind Healthcare Inc. or (2) November 20, 2011. This agreement may be terminated for material breach by either party and by us if the Hind Healthcare license agreement is terminated.

Life Sciences Opportunities Fund (Institutional) II, L.P. On December 12, 2003, we entered into a subscription agreement to invest up to $10 million into Life Sciences Opportunities Fund (Institutional) II, L.P., a Delaware limited partnership formed to carry out investments in life science companies. As part of this investment, we are able to capitalize on the knowledge of LOF Partners, LLC, the general partner, and its access to, life sciences entities with promising pharmaceutical assets, technologies and management talent and on the general partner s wide range of industry contacts and resources. As of December 31, 2004, we have invested $1 million in this partnership.

In addition, we agreed to certain contingent payments in certain of our license and other agreements. Payments under these agreements generally become due and payable only upon the achievement of certain developmental, regulatory and/or commercial milestones. Specifically:

Penwest Pharmaceuticals. Under the terms of the amended and restated strategic alliance agreement with Penwest Pharmaceuticals Co. (Penwest), Penwest is entitled to receive royalties equal to a percentage beginning at 50%, which could decline to 40% based upon the achievement of certain criteria, of the net realization (as defined in the agreement) of oxymorphone ER. On March 18, 2003, we received notice from Penwest that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of this product on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly,

we are now be responsible for funding 100% of these remaining costs until oxymorphone ER is approved by the FDA, at which time we will recoup from the royalties due to Penwest the full amount of what Penwest should have contributed had it not exercised such right.

DURECT Corporation. Once a specified clinical trial of CHRONOGESIC is started or beginning on January 1, 2006 (whichever is earlier), unless the agreement is earlier terminated, Endo will be obligated to fund 50% of the ongoing development costs of CHRONOGESIC. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the License Agreement could total up to $52.0 million. Endo and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC. In addition, the DURECT agreement also

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contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. With respect to termination rights, this agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT $10.0 million.

On March 14, 2005, we announced that we have signed an agreement that will give us the exclusive license to develop and commercialize DURECT s sufentanil-containing transdermal patch in the U.S. and Canada (the DURECT Sufentanil Agreement). The sufentanil patch, which is in early-stage clinical development, employs DURECT s proprietary TRANSDUR drug-adhesive matrix formulation and is intended to provide relief of moderate-to-severe chronic pain for up to seven days. Effective immediately, we will assume all remaining development and regulatory filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, we will pay DURECT an upfront fee of $10 million, with additional payments of approximately $35 million upon achievement of predetermined regulatory and commercial milestones. We will also pay royalties to DURECT on net sales of the sufentanil transdermal patch. In addition, the DURECT Sufentanil Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT Sufentanil Agreement will continue in effect until terminated. The DURECT Sufentanil Agreement provides each party with specified termination rights, including the right of each party to terminate the DURECT Sufentanil Agreement upon material breach of the DURECT Sufentanil Agreement by the other party and the right of Endo to terminate the DURECT Sufentanil Agreement at any time without cause subject to a specified notice period.

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

Milestone Event		Milestone Payment
The first time net sales of DepoDur in a calendar year exceed $125,000	$	15,000
The first time net sales of DepoDur in a calendar year exceed $175,000		20,000
Total contingent sales milestones for DepoDur	$	35,000
FDA acceptance of the NDA for Propofol IDD-D in the United States		5,000
FDA final approval of the NDA for Propofol IDD-D in the United States		40,000
Total contingent regulatory milestones for Propofol IDD-D	$	45,000

In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, this agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require us to pay SkyePharma $5.0 million.

Noven Pharmaceuticals, Inc. Under the terms of the license agreement with Noven, upon our first commercial sale of the fentanyl patch, Noven is entitled to receive an additional payment ranging from $5.0 million to $10.0 million, depending on the timing of launch and the number of generic competitors on the market. The profit on the product

will be shared. This license agreement also establishes an ongoing collaboration between the two companies to identify and develop additional new transdermal therapies. As part of this effort, Noven will undertake feasibility studies to determine whether certain compounds identified by the parties can be delivered through Noven s transdermal patch technology. Endo is expected to fund and manage clinical development of those compounds proceeding into clinical trials. Additionally, we are bearing a portion of the risk of loss related to inventory costs associated with the fentanyl patch that have been incurred by us and by Noven. If final regulatory approval of the product is denied or delayed, our risk of loss is approximately $3.4 million. No amounts have been expensed as of December 31, 2004 related to our risk of loss based upon our judgment of probable future commercial use.

EpiCept Corp. The license agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept s LidoPAIN® BP product. EpiCept has also retained an option to co-promote the LidoPAIN® BP product. Under this agreement, Endo also received an exclusive, worldwide license to certain patents of EpiCept Corp. Milestone payments made by Endo under this agreement, including regulatory milestones and sales thresholds, could total up to $82.5 million.

Vernalis Development Limited Under the terms of the license agreement, we will make anniversary payments for the first two years of $15 million in 2005 and 2006, and a $40 million milestone payment upon U.S. Food and Drug Administration, FDA, approval for the menstrually related migraine indication. In addition, Vernalis will receive one-time milestone payments for achieving defined annual net sales targets. These sales milestone payments increase based on increasing net sales targets ranging from a milestone of $10 million on $200 million in net sales to a milestone of $75 million on $1.2 billion in net sales. These sales milestones

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could total up to $255 million if all of the defined net sales targets are achieved. We will also pay royalties to Vernalis based on the net sales of Frova®.

Orexo AB The agreement provides for us to make additional license fees and payments based on development and regulatory milestones, which may total up to $22.1 million through FDA approval of Rapinyl s New Drug Application. The agreement also provides for royalties upon commercial sales and may include sales milestones, up to $39.2 million, if defined sales thresholds are achieved. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the expiration of any market exclusivity right. We can terminate the license agreement under certain circumstances, including upon six months written notice, and we may be required to pay a termination fee of up to $1.5 million.

ProEthic Pharmaceuticals, Inc. On March 14, 2005, we entered into an agreement with ProEthic Pharmaceuticals