

ENDO PHARMACEUTICALS HOLDINGS INC  
Form 10-K  
March 01, 2007  
Table of Contents

---

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, DC 20549**

**FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**  
For the fiscal year ended December 31, 2006

or

**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**  
(State or other jurisdiction of  
incorporation or organization)

**13-4022871**  
(I.R.S. Employer  
Identification Number)

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

**19317**  
(Zip Code)

(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:

# Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Title of Each Class Common Stock of \$0.01 par value	Name of Each Exchange on Which Registered NASDAQ
<b>Annual Report for the Year Ended December 31, 2006</b>	

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES  NO

Indicate by check 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  No

Indicate by check 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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES  NO

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, 2006): \$4,294,385,560 based on the last reported sale price on the NASDAQ on June 30, 2006.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of February 22, 2007: 133,607,185.

## 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 2007 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, 2006.

---

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**INDEX TO FORM 10-K**

**FOR THE YEAR ENDED DECEMBER 31, 2006**

<u>Forward Looking Statements</u>	1
<b>PART I</b>	3
<u>Item 1 Business</u>	
<u>Item 1A Risk Factors</u>	3
	38
<u>Item 1B Unresolved Staff Comments</u>	60
<u>Item 2 Properties</u>	60
<u>Item 3 Legal Proceedings</u>	62
<u>Item 4 Submission of Matters to a Vote of Security Holders</u>	62
<b>PART II</b>	62
<u>Item 5 Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	62
<u>Item 6 Selected Financial Data</u>	63
<u>Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	64
<u>Item 7A Quantitative and Qualitative Disclosures about Market Risk</u>	88
<u>Item 8 Financial Statements and Supplementary Data</u>	89
<u>Item 9 Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	89
<u>Item 9A Controls and Procedures</u>	89
<u>Item 9B Other Information</u>	89
<b>PART III</b>	90
<u>Item 10 Directors, Executive Officers and Corporate Governance</u>	90
<u>Item 11 Executive Compensation</u>	91
<u>Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	92
<u>Item 13 Certain Relationships and Related Transactions, and Director Independence</u>	92
<u>Item 14 Principal Accountant Fees and Services</u>	92
<b>PART IV</b>	93
<u>Item 15 Exhibits, Financial Statement Schedules</u>	93
<u>Signatures</u>	94
<u>Certifications</u>	
<u>Exhibit Index</u>	

**Table of Contents**

**FORWARD LOOKING STATEMENTS**

This document contains information that includes or is based on forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements, including estimates of future net sales, future expenses, 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, plan, will, may or similar expressions are forward-looking statements. We believe that 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 Item 1A Risk Factors in this document, supplement, and as otherwise enumerated herein, 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 document. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in this document include those factors described in this document under Item 1A titled Risk Factors, including, among others:

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

timing and results of pre-clinical or clinical trials on new products;

our ability to obtain regulatory approval of any of our pipeline products;

competition for the business of our branded and generic products, and in connection with our acquisition of rights to intellectual property assets;

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

market acceptance of our future products;

government regulation of the pharmaceutical industry;

our dependence on a small number of products;

our dependence on outside manufacturers for the manufacture of our products;

our dependence on third parties to supply raw materials and to provide services for certain core aspects of our business;

new regulatory action or lawsuits relating to our use of narcotics in most of our core products;

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

our exposure to product liability claims and product recalls and the possibility that we may not be able to adequately insure ourselves;

**Table of Contents**

our ability to protect our proprietary technology;

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

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

regulatory or other limits on the availability of controlled substances that constitute the active ingredients of some of our products and products in development;

the availability of third-party reimbursement for our products;

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

our dependence on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of our total net sales;

significant litigation expenses to defend or assert patent infringement claims;

any interruption or failure by our suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us;

a determination by a regulatory agency that we are engaging in inappropriate sales or marketing activities, including promoting the off-label use of our products;

existing suppliers become unavailable or lose their regulatory status as an approved source, causing an inability to obtain required components, raw materials or products on a timely basis or at commercially reasonable prices; and

the loss of branded product exclusivity periods and related intellectual property.

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 Securities and Exchange Commission (or 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.

**Table of Contents**

**PART I**

**Item 1. *Business*  
Overview**

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 Wolters Kluwer Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$19.7 billion in 2006. This represents an approximately 8% compounded annual growth rate since 2002. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2006, analgesics were the fourth most prescribed medication in the United States with over 260 million prescriptions written for this classification. Opioid analgesics is a segment that comprised approximately 80% of the analgesics prescriptions for 2006. Total U.S. sales for the opioid analgesic segment were \$7.3 billion in 2006, representing a compounded annual growth rate of 8% since 2002.

We have a portfolio of branded products that includes established brand names such as Lidoderm<sup>®</sup>, Percocet<sup>®</sup>, Frova<sup>®</sup> and Percodan<sup>®</sup>, as well as three newly launched products in 2006 Opana<sup>®</sup> ER, Opana<sup>®</sup> and Synera<sup>™</sup>. Branded products comprised approximately 80% of our net sales in 2006, with 62% of our net sales coming from Lidoderm<sup>®</sup>. Our non-branded generic portfolio, which accounted for 20% of net sales in 2006, currently consists of products primarily focused in pain management, with our generic oxycodone extended-release tablets accounting for 6% of our net sales in 2006. We focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing.

We have established research and development expertise in analgesics and devote significant resources to this effort so that we can maintain and develop our product pipeline. Our late-stage branded product pipeline includes one filed supplemental New Drug Application (sNDA), two products in Phase III clinical trials and three products in Phase II clinical trials.

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

Through a dedicated sales force of approximately 590 sales representatives in the United States, we market our branded pharmaceutical products to high-prescribing physicians in pain management, neurology, surgery, anesthesiology, oncology and primary care. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

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

Our wholly-owned subsidiary, Endo Pharmaceuticals Inc. (EPI), commenced operations in 1997 by acquiring certain pharmaceutical products, related rights and assets of The DuPont Merck Pharmaceutical Company, which subsequently became

## **Table of Contents**

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

We were incorporated in Delaware as a holding company on November 18, 1997 and have our 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 in complementary therapeutic areas such as neurology and supportive care oncology. To supplement our internal efforts in support of our business strategies, we continually evaluate business development opportunities that we believe will strengthen our product portfolio. We regularly evaluate opportunities, particularly in the areas of strategic product acquisitions and/or corporate mergers and acquisitions. We also evaluate partnership arrangements that may involve new technology platforms on which to expand our high-barrier to market entry generic strategy, and products or companies for new proprietary therapeutic categories. As we continue to grow, we expect that our business development activities, including product and company acquisitions will continue to play an important part in our strategy. The elements of our strategy include:

***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 have co-developed an oral extended-release (ER) version of oxymorphone with Penwest Pharmaceuticals Co. and internally developed an oral immediate-release (IR) version of oxymorphone. On December 22, 2005, we filed complete responses to the U.S. Food and Drug Administration's FDA approvable letters on the Company's New Drug Applications (NDAs) for each of its investigational products containing oxymorphone. As previously disclosed on October 20, 2003, the FDA issued approvable letters for oxymorphone ER and IR tablets but had requested that we address certain questions and provide more clarification and information, including data from additional clinical trials to further confirm the safety and efficacy of these products. In order to meet the FDA's request for more clinical information for oxymorphone ER, we conducted two separate multi-center, randomized, double-blind, placebo-controlled, 12-week, parallel group trials evaluating this product in two distinct groups of patients with chronic low back pain: opioid-naive and opioid-experienced. These trials demonstrated statistically ( $p < 0.0001$ ) and clinically significant efficacy in these patient populations. The trial involving opioid-naive patients was conducted under the FDA's Special Protocol Assessment (SPA) process. We also reported that the complete response to the oxymorphone IR approvable letter included previously disclosed positive results for a placebo-controlled, multi-center Phase III trial for oxymorphone IR in the treatment of acute post-operative pain. Endo also conducted this study under the FDA's SPA process. The data from the two new oxymorphone ER Phase III studies and from the one oxymorphone IR Phase III study supplemented the previously submitted Phase III trials for both products that the Company believed the FDA already had accepted as demonstrating efficacy in the intended patient populations. On June 22, 2006, the NDAs for each of these products were approved by the FDA, and during the second half of 2006, we launched oxymorphone ER and IR under the brand names Opana® and Opana ER®. Opana® ER competes in the market for long-acting, strong opioids.



---

**Table of Contents**

On June 7, 2005, we announced that the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., had affirmed the Opinion and Order issued in Endo's favor by the U.S. District Court for the Southern District of New York on January 5, 2004, which found Purdue had committed inequitable conduct in the U.S. Patent and Trademark Office. This affirmation by the Federal Circuit Court dismissed the 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, and permanently enjoined Purdue from enforcing these patents. The U.S. Food and Drug Administration had previously granted final approval of Endo's Abbreviated New Drug Application (ANDA) for all four strengths of the product in 2004. Endo's oxycodone extended-release tablets are AB-rated bioequivalent versions of OxyContin®, indicated for the management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. On February 1, 2006, we announced that the Federal Circuit Court of Appeals had vacated its unanimous June 7, 2005 affirmation of the Opinion and Order in our favor and affirmed the District Court's finding that, if Purdue's patents are enforceable, Endo's oxycodone extended-release tablets infringe these patents. Further, the Federal Circuit issued a new opinion on February 1, 2006 remanding the case to the same District Court for its further consideration as to whether the Purdue patents are unenforceable. On August 28, 2006, we announced that we reached an agreement with The Purdue Frederick Company, The P.F. Laboratories, Inc., and Euro-Celtique, S.A. to settle this long-running litigation. Pursuant to this settlement, Endo continued selling to its customers its oxycodone extended-release products until December 31, 2006. Endo, as well as its manufacturers, distributors, purchasers, and patients, were released from all liability for infringement of Purdue's patents in connection with Endo's prior and future sales of these products. Though the settlement agreement was submitted to the U.S. Federal Trade Commission and the Antitrust Division of the Department of Justice as required by statute, the release will survive unless overturned by a court order. On October 6, 2006, the district court entered a Consent Judgment the effect of which is to conclude the litigation in accordance with the terms of the settlement agreement. See Item 3. Legal Proceedings .

***Acquiring and in-licensing complementary products, compounds and technologies.*** We look to continue to enhance our product line through selective product acquisitions and in-licensing, or acquiring licenses to products, compounds and technologies from third parties. 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. During the third quarter of 2006, the FDA accepted for substantive review the sNDA relating to Frova® for the short-term (six days per menstrual cycle) prevention of menstrual migraine (MM) and confirmed May 19, 2007 as the review completion date for this application. Subject to FDA approval, we intend to launch Frova® during the second half of 2007 for the anticipated expanded indication for prevention of menstrual migraine.

In August 2004, we entered into an agreement granting us the exclusive rights to develop and market Orexo AB's (a 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 2005, Rapinyl advanced into Phase III clinical trials. The projected NDA (New Drug Application) filing date for Rapinyl has been changed from the second half of 2007 to the first half of 2008 due to slower than expected enrollment of patients in its two ongoing Phase III trials.

## **Table of Contents**

This reflects the inherent challenges in recruiting cancer patients for placebo-controlled trials, as well as competition in 2006 with other pharmaceutical companies seeking to enroll patients in trials for the same indication. With the completion of many of these competing trials, the Company expects the pace of patient recruitment to accelerate in 2007.

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 currently 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, is intended to provide relief of moderate-to-severe chronic pain for up to seven (7) days. In January 2006, we licensed in Synera, an FDA-approved topical local anesthetic patch for which we acquired the exclusive North American marketing rights. We launched Synera during the second half of 2006.

During the fourth quarter of 2006, the Company purchased RxKinetic, Inc., a privately held company headquartered in Boulder, Colorado, that develops new formulations of approved products for oral mucositis and other supportive care oncology conditions. RxKinetic's lead product, now named EN 3285, is a topical oral rinse with the active ingredient formulated in its proprietary ProGelz® drug delivery platform. EN 3285 is in clinical Phase II for the prevention of oral mucositis (OM), painful mouth sores that often occur in cancer patients undergoing radiation and chemotherapeutic treatment. We believe a product such as EN 3285, if approved, would be a natural extension of our cancer-related portfolio consisting of the recently launched Opana® ER and Opana® tablets, and Rapinyl, our quick-dissolving fentanyl tablet in development for breakthrough cancer pain, currently in Phase III trials. See the disclosures under Note 3. Acquisitions, included in the consolidated financial statements in Part IV, Item 15 of this Report for further information.

***Capitalizing on our established brand names and brand awareness through focused marketing and promotional efforts.*** We believe that our strong corporate and product reputation combined with focused marketing and promotional efforts leads to more rapid adoption of our new products by physicians and institutions.

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. Continued growth will be supported by the product's proven clinical effectiveness combined with incremental promotional support generated by the expansion of Endo's sales force in 2006.

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.

## **Table of Contents**

During 2004, we launched Frova® for the treatment of migraine headaches in adults. We believe 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 we have built with the neurology and pain specialist community over the years.

During 2006, we launched Synera™, the first self-contained topical patch for prevention of pain associated with superficial venous access and superficial dermatological procedures in patients three years of age and older. The Synera™ patch addresses an important issue in the area of topical pain management, particularly in the pediatric population. The Synera™ patch is marketed in the institutional setting and while we are redeploying our existing 70-person hospital sales force to a Specialty II sales force, we will continue to promote Synera primarily in key pediatric institutions to drive awareness and increase usage of this topical local anesthetic patch.

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.

During the second half of 2006, we launched Opana® and Opana ER® and during the fourth quarter of 2006, we implemented a full range of promotional activities to generate broader physician awareness and continued steady adoption of these products. Endo is committed to providing healthcare professionals and patients with safe and effective opioid analgesic medications and support programs that will facilitate the appropriate and responsible use of opioid analgesics. Through extensive experience with opioid analgesics and communicating with the FDA and industry experts, Endo has developed a comprehensive risk minimization action plan for Opana® ER and Opana®. Evolving from this risk minimization action plan is a new initiative to further help reduce the inherent risk of misuse, abuse and diversion of opioid analgesics: The Partnership for Responsible Opioid Management through Information, Support, and Education (PROMISE). The PROMISE initiative contains essential information and guidance to healthcare professionals so that they can prescribe opioids to patients responsibly and appropriately. PROMISE includes educational support and practical patient management tools. For patients, the program raises the level of knowledge of those suffering from moderate-to-severe pain and empowers them to manage their condition with the help of their healthcare professional.

### **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® was launched in September 1999. A topical patch product containing lidocaine, it was 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 FDA had granted Lidoderm® orphan drug status, generally meaning that no other lidocaine-containing topical patch product can be approved for this indication until the

---

**Table of Contents**

orphan drug status expiration date, which occurred on March 19, 2006. On October 17, 2006, Endo became aware that, in response to an independent inquiry, the FDA's Office of Generic Drugs (OGD) had proposed that a study of blood levels of lidocaine should be used as the key measure in proving bioequivalence of a generic version of Lidoderm®. On December 19, 2006 the Company submitted a Citizen Petition with the FDA requesting that the FDA apply existing bioequivalence regulations to any ANDA seeking regulatory approval of a generic drug product that references Endo's Lidoderm®. The petition emphasizes that this proposed new standard deviates from applicable regulations and OGD's past practices, both of which contemplate demonstration of bioequivalence for a topically acting product like Lidoderm® through a comparative clinical efficacy study. We believe blood levels of the active ingredient, lidocaine, cannot be used as the key measure in proving bioequivalence. To appropriately assess the efficacy and safety of any generic version of Lidoderm®, Endo believes that it is critical that the FDA require any ANDA satisfy the regulations by following these additional criteria to those that FDA has proposed by (1) conducting comparative clinical studies demonstrating identical safety and efficacy between the generic version and Lidoderm®, and (2) for an applicant relying on Lidoderm® as its Reference Listed Drug, to show that its product produces the same local analgesic effect as Lidoderm® without producing a complete sensory block, in order to assure that the generic product has the same labeling, efficacy and safety profile as Lidoderm®. To our knowledge, there is no competitive product that has been, or is being developed. Lidoderm® is also currently protected by Orange Book-listed 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 2006, 2005 and 2004, Lidoderm® net sales were \$566.8 million, \$419.4 million and \$309.2 million, respectively. Lidoderm® accounted for approximately 62% of our 2006 net sales. In addition, we are currently exploring the safety and efficacy of Lidoderm® in other indications and have initiated both Phase II and Phase IV clinical trials. On January 17, 2007, we received a subpoena from the U.S. Department of Health and Human Services, Office of Inspector General, requesting documents from 1999 to the present regarding the Company's sales and promotional practices relating to Lidoderm®. We are cooperating with this request. The subpoena requests documents generally related to the Company's knowledge of the use of Lidoderm® for non-indicated uses by physicians. See Item 3. Legal Proceedings for further details.

Percocet®, our oxycodone/acetaminophen combination product, and Percodan®, our oxycodone/aspirin combination product, which have been marketed since 1976 and 1950, respectively, are our gold standards of pain management based on their long history of demonstrated product safety and effectiveness. Net sales of Percocet® were \$102.7 million for the year ended December 31, 2006 compared with \$110.7 million in the same period in 2005. 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 maintain our market penetration.

Frova®, for the treatment of migraine headaches in adults, was added to our portfolio of branded products during 2004. We believe 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 we have built with the neurology and pain specialist community over the years. Net sales of Frova® were \$40.6 million for the year ended December 31, 2006 compared with \$38.1 million in 2005.

## Table of Contents

Opana<sup>®</sup> ER and Opana<sup>®</sup> were launched during the second half of 2006. A new oral extended-release opioid analgesic treatment option for patients, Opana<sup>®</sup> ER is indicated for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. This is the first time oxymorphone is available in an oral, extended-release formulation and is available in 5mg, 10mg, 20mg and 40mg tablets. Opana<sup>®</sup> (the immediate-release version) is indicated for the relief of moderate-to-severe acute pain where the use of an opioid is appropriate and is available in 5mg and 10mg tablets. Both Opana<sup>®</sup> ER and Opana<sup>®</sup> are available by prescription only. Net sales for 2006 of Opana<sup>®</sup> ER and Opana<sup>®</sup>, representing end-user demand, were recorded as \$6.8 million. Although commercial shipments totaling \$20.6 million of Opana<sup>®</sup> ER and Opana<sup>®</sup> to customers began during the third quarter of 2006, the Company determined that it was not appropriate to recognize revenue for these shipments at that time under accounting principles generally accepted in the United States. The approximately \$13.8 million balance of deferred revenue may be recorded as net sales in future periods. Both of these products were approved by the FDA on June 22, 2006 and became commercially available on July 21, 2006, with active promotion of Endo's 590-person sales force beginning in the third quarter 2006.

***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 have a robust development pipeline and are well-positioned to capitalize on our core expertise with analgesics.

In July 2006, we submitted to the FDA a sNDA for Frova<sup>®</sup> 2.5 mg tablets for the short-term (six days per menstrual cycle) prevention of menstrual migraine (MM). This sNDA for Frova<sup>®</sup> is supported by data from four studies, including two Phase III studies examining the efficacy and safety of once- and twice-daily dose regimens of Frova<sup>®</sup> in the short-term prevention of MM, a pharmacokinetics and tolerability study of once and twice-daily dosing of Frova<sup>®</sup>, and a 12-month open-label safety study evaluating a six-day dosing regimen of Frova<sup>®</sup> in 525 women. During the third quarter of 2006, the FDA accepted for substantive review the sNDA relating to Frova<sup>®</sup> for the short-term (six days per menstrual cycle) prevention of menstrual migraine (MM) and confirmed May 19, 2007 as the review completion date for this application. Subject to FDA approval, we intend to launch Frova<sup>®</sup> during the second-half of 2007 for the anticipated expanded indication for prevention of menstrual migraine.

In August 2004, we entered into an agreement granting us the exclusive rights to develop and market Orexo AB's (a Swedish company) patented sublingual muco-adhesive fentanyl product (Rapinyl<sup>®</sup>) in North America. Rapinyl<sup>®</sup> is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. The benefits of Rapinyl<sup>®</sup> are believed to include both a fast onset of action and patient convenience. In 2005, Rapinyl<sup>®</sup> advanced into Phase III clinical trials and currently has two ongoing Phase III trials. The NDA (New Drug Application) filing date for Rapinyl<sup>®</sup> is expected to be submitted to the FDA in the first half of 2008.

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 currently available in the U.S. only in oral form. Currently in Phase III 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.

## **Table of Contents**

In addition, we currently have three products in Phase II clinical trials and one product in Phase I 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 nine 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 590 specialty and office-based representatives. Through our sales force, we market our branded pharmaceutical products to just over 70,000 physicians, which include both specialists and primary care physicians.

**Selective focus on generic products.** Our generic product portfolio includes products focused on pain management. Development of these products involves significant 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 and oxycodone extended-release tablets, which we introduced in June 2005 as a bioequivalent version of Purdue's OxyContin. See Item 3. Legal Proceedings .

## **Table of Contents**

***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 licensing and acquisitions, including the recent acquisition of RxKinetix, Inc. Members of our senior management were responsible for the licensing of Lidoderm<sup>®</sup>, CHRONOGESIC<sup>®</sup>, Frova<sup>®</sup>, Rapinyl<sup>®</sup> and Synera<sup>®</sup>, as well as two other products, a topical ketoprofen patch being studied for soft tissue injuries, and a 7-day transdermal sufentanil patch being studied for moderate to severe chronic pain. Management has received FDA approval on more than seventeen new products and product line extensions since 1997, and as a result of several successful product launches, has grown our net sales from \$108.4 million in 1998 to \$909.7 million in 2006.

## **Our Industry**

According to Wolters Kluwer Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$19.7 billion in 2006. This represents an approximately 8% compounded annual growth rate since 2002. Our primary area of focus within this market is analgesics. In 2006, analgesics were the fourth most prescribed medication in the United States with over 260 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 80% of the U.S. analgesics prescriptions in 2006. This market segment has grown to \$7.3 billion in 2006, representing a compounded annual growth rate of 8% since 2002. 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.

**Table of Contents****Product Overview**

The following table summarizes select products in our marketed portfolio as well as selected products in development as of December 31, 2006:

<b>Product</b>	<b>Active ingredient(s)</b>	<b>Branding</b>	<b>Status</b>
Lidoderm®	lidocaine 5%	Branded	Marketed
Percocet®	oxycodone and acetaminophen	Branded	Marketed
Percodan®	oxycodone and aspirin	Branded	Marketed
Frova®(1)	frovatriptan	Branded	Marketed
DepoDur®(2)	morphine sulfate	Branded	Marketed
Synera™ (3)	lidocaine and tetracaine	Branded	Marketed
Opana® ER(4)	oxymorphone hydrochloride	Branded	Marketed
Opana®	oxymorphone hydrochloride	Branded	Marketed
Endocet®	oxycodone and acetaminophen	Generic	Marketed
Morphine Sulfate ER	morphine sulfate	Generic	Marketed
Oxycodone ER(5)	oxycodone hydrochloride	Generic	Marketed
Frova® (menstrual migraine)(1)	frovatriptan	Branded	PDUFA date May 19, 2007
Rapinyl (6)	fentanyl	Branded	Phase III
Topical Ketoprofen Patch(7)	ketoprofen	Branded	Phase III
Lidoderm® (new indications)	lidocaine 5%	Branded	Phase II
LidoPAIN® BP(8)	lidocaine	Branded	Phase II
EN 3285 oral rinse	N-acetylcysteine	Branded	Phase II
Transdermal Sufentanil Patch(9)	sufentanil	Branded	Phase I
CHRONOGESIC (10)	sufentanil	Branded	Early Stage

(1) Licensed marketing rights from Vernalis Development Limited.

(2) Licensed marketing rights from SkyePharma, Inc. The licensing agreement has been terminated by Endo with an effective date of March 31, 2007.

(3) Licensed marketing rights from ZARS Pharma.

(4) Marketed pursuant to an alliance agreement with Penwest Pharmaceuticals Co.

(5) Pursuant to a settlement agreement with The Purdue Frederick Company and related companies, Endo ceased all commercial activity on December 31, 2006. See Item 3. Legal Proceedings for further details.

(6) Licensed marketing and development rights from Orexo AB.



(7) Licensed marketing and development rights from ProEthic Pharmaceuticals, Inc.

(8) Licensed marketing rights from EpiCept Corporation.

(9) Licensed marketing and development rights from DURECT Corporation.

(10) Licensed marketing rights from DURECT Corporation.

---

## **Table of Contents**

### ***Branded Products***

**Lidoderm**<sup>®</sup>. Lidoderm<sup>®</sup> was launched in September 1999. A topical patch product containing lidocaine, it was 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 FDA had granted Lidoderm<sup>®</sup> orphan drug status, generally meaning that no other lidocaine-containing topical patch product can be approved for this indication until the orphan drug status expiration date, which occurred on March 19, 2006. On October 17, 2006, Endo became aware that, in response to an independent inquiry, the FDA's Office of Generic Drugs (OGD) had proposed that a study of blood levels of lidocaine should be used as the key measure in proving bioequivalence of a generic version of Lidoderm<sup>®</sup>. On December 19, 2006 the Company submitted a Citizen Petition with the U.S. Food and Drug Administration requesting that the FDA apply existing bioequivalence regulations to any ANDA seeking regulatory approval of a generic drug product that references Endo's Lidoderm<sup>®</sup>. The petition emphasizes that this proposed new standard deviates from applicable regulations and OGD's past practices, both of which contemplate demonstration of bioequivalence for a topically acting product like Lidoderm<sup>®</sup> through a comparative clinical efficacy study. We believe blood levels of the active ingredient, lidocaine, cannot be used as the key measure in proving bioequivalence. To appropriately assess the efficacy and safety of any generic version of Lidoderm<sup>®</sup>, Endo believes that it is critical that the FDA require any ANDA satisfy the regulations by following these additional criteria to those that FDA has proposed by (1) conducting comparative clinical studies demonstrating identical safety and efficacy between the generic version and Lidoderm<sup>®</sup>, and (2) for an applicant relying on Lidoderm<sup>®</sup> as its Reference Listed Drug, to show that its product produces the same local analgesic effect as Lidoderm<sup>®</sup> without producing a complete sensory block, in order to assure that the generic product has the same labeling, efficacy and safety profile as Lidoderm<sup>®</sup>. To our knowledge, there is no competitive product to Lidoderm<sup>®</sup> that has been, or is being developed. Lidoderm<sup>®</sup> is also currently protected by Orange Book-listed 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 is set to expire in 2015. In 2006, 2005 and 2004, Lidoderm<sup>®</sup> net sales were \$566.8 million, \$419.4 million and \$309.2 million, respectively. Lidoderm<sup>®</sup> accounted for approximately 62% of our 2006 net sales.

In addition, we are currently exploring the safety and efficacy of Lidoderm<sup>®</sup> in other indications and have initiated both Phase II and Phase IV clinical trials.

On January 17, 2007, we received a subpoena from the U.S. Department of Health and Human Services, Office of Inspector General, requesting documents from 1999 to the present regarding the Company's sales and promotional practices relating to Lidoderm<sup>®</sup>. We are cooperating with this request. The subpoena requests documents generally related to the Company's knowledge of the use of Lidoderm<sup>®</sup> for non-indicated uses by physicians. See Item 3. Legal Proceedings for further details.

**Percocet**<sup>®</sup>. We consider Percocet<sup>®</sup> to be a gold standard of pain management. Launched in 1976, Percocet<sup>®</sup> is approved for the treatment of moderate-to-moderately severe pain. The Percocet<sup>®</sup> family of products had net sales of \$102.7 million, \$110.7 million and \$86.5 million in the years 2006, 2005 and 2004, respectively. The Percocet<sup>®</sup> franchise accounted for approximately 11% of our 2006 net sales.

**Frova**<sup>®</sup>. We began shipping Frova<sup>®</sup> upon closing of the license agreement with Vernalis in mid-August 2004 and initiated our promotional efforts in September 2004. We believe that Frova<sup>®</sup> 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<sup>®</sup>'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. During the third quarter of 2006, the

---

**Table of Contents**

FDA accepted for substantive review the sNDA relating to Frova<sup>®</sup> for the short-term (six days per menstrual cycle) prevention of menstrual migraine (MM) and confirmed May 19, 2007 as the review completion date (known as the PDUFA date) for this application. Subject to FDA approval, we intend to launch Frova<sup>®</sup> during the second-half of 2007 for the anticipated expanded indication for prevention of menstrual migraine. Net sales of Frova<sup>®</sup> were \$40.6 million in 2006, \$38.1 million in 2005 and \$11.4 million for the period August 2004, when we began to market the product, to December 2004.

**DepoDur<sup>®</sup>.** DepoDur<sup>®</sup> became available when we began commercial shipments of the product in December of 2004. No revenue was recognized on this product in 2004. Net sales of DepoDur<sup>®</sup> were \$3.0 million and \$3.9 million for the years ended December 31, 2006 and 2005, respectively. The company began promoting DepoDur<sup>®</sup> in early 2005 with its then 70-representative hospital sales force. In January 2007, following an assessment of the status of DepoDur<sup>®</sup>, we announced that we notified SkyePharma PLC of our intent to terminate our development and commercialization agreement for this product and, in February 2007, entered into a termination agreement with SkyePharma whereby the Development and Marketing Strategic Alliance Agreement will terminate in its entirety on March 31, 2007. In order to provide for the continued commercial support of the DepoDur<sup>®</sup> product and the transition of such product to SkyePharma on March 31, 2007, Endo will continue to provide a number of services and undertake certain activities. Specifically, Endo will use commercially reasonable efforts to maintain and continue all U.S. commercial activities in support of DepoDur<sup>®</sup> through March 31, 2007, and at SkyePharma's option, on a month-to-month basis after March 31, 2007 but not beyond June 30, 2007; and support and/or undertake the transition of certain Endo functions and activities (including third party activities) to SkyePharma that are useful and necessary for SkyePharma to assume commercial and related responsibilities for DepoDur<sup>®</sup> in the U.S. During the year ended December 31, 2006, as a result of the continued lack of commercial success of DepoDur<sup>®</sup> and, we recorded an impairment charge of \$14.8 million related to the remaining unamortized portion of our SkyePharma intangible asset.

**Opana<sup>®</sup> and Opana<sup>®</sup> ER.** Opana<sup>®</sup> ER and Opana<sup>®</sup> were launched during the second half of 2006. A new oral extended-release opioid analgesic treatment option for patients, Opana<sup>®</sup> ER is indicated for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. This is the first time oxymorphone is available in an oral, extended-release formulation and is available in 5mg, 10mg, 20mg and 40mg tablets. Opana<sup>®</sup> (the immediate-release version) is indicated for the relief of moderate-to-severe acute pain where the use of an opioid is appropriate and is available in 5mg and 10mg tablets. Both Opana<sup>®</sup> ER and Opana<sup>®</sup> are available by prescription only. Net sales for 2006 of Opana<sup>®</sup> ER and Opana<sup>®</sup>, representing end-user demand, were recorded as \$6.8 million. Although commercial shipments totaling \$20.6 million of Opana<sup>®</sup> ER and Opana<sup>®</sup> to customers began during the third quarter of 2006, the Company determined that it was not appropriate to recognize revenue for these shipments at that time under accounting principles generally accepted in the United States. The approximately \$13.8 million balance of deferred revenue may be recorded as net sales in future periods. Both of these products were approved by the FDA on June 22, 2006 and became commercially available on July 21, 2006, with active promotion of Endo's 590-person sales force beginning in the third quarter of 2006.

**Percodan<sup>®</sup>.** Launched in 1950 for the treatment of moderate-to-moderately severe pain, we also consider Percodan<sup>®</sup> to be a gold standard of pain management.

**Synera.** Synera is a topical local anesthetic patch for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the FDA on June 23, 2005, Synera became commercially available in the second half of 2006. The safety and efficacy of Synera have been demonstrated in a series of clinical trials that included more than 660 pediatric (aged three to 17 years) and adult patients undergoing superficial dermatological procedures. Synera is also being studied for use with additional procedures, such as pediatric immunization.

---

**Table of Contents**

**Other.** The balance of our branded portfolio consists of a number of products, none of which accounted for more than 1% of our total net sales in the 2006 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.

On June 7, 2005, the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. affirmed the district court's decision that, while Endo's oxycodone extended-release tablets infringe the Purdue OxyContin® patents, the patents are unenforceable. On June 21, 2005, Purdue filed a petition with the Federal Circuit seeking rehearing of the appeal. On February 1, 2006, the Federal Circuit granted Purdue's motion for rehearing, vacated the June 7, 2005 decision of the district court, and remanded the case to the district court for further proceedings. The Federal Circuit's decision on rehearing directed the district court to give further consideration to its previous finding of unenforceability due to inequitable conduct. The Federal Circuit also affirmed the district court's finding that Endo's oxycodone extended-release tablets infringe the Purdue patents. Following the remand, we entered into settlement discussions with Purdue. On August 28, 2006, we executed a settlement agreement with Purdue pursuant to which we continued selling our oxycodone extended-release products until December 31, 2006. We and our subsidiary, Endo Pharmaceuticals Inc. (EPI), as well as our manufacturers, distributors, purchasers, and patients, were released from all liability for infringement of Purdue's patents in connection with EPI's prior and future sales of these products. See Item 3. Legal Proceedings for further information.

One of our generic products is morphine sulfate extended-release tablets, which accounted for 4% of our total net sales in 2006. In addition, we sell a generic oxycodone hydrochloride and acetaminophen product, Endocet®, which accounted for 9% of our total net sales in 2006. 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 2006.

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

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.

## **Table of Contents**

### ***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, such as oral mucositis, the painful ulcers often associated with certain forms of cancer treatment. We cannot predict when or if any of these products will be approved by the FDA. We believe our pipeline portfolio provides a platform for sustainable growth.

***Frova® MM.*** On July 19, 2006, Endo submitted to the FDA a sNDA for Frova® (frovatriptan succinate) 2.5 mg tablets for the short-term (six days per menstrual cycle) prevention of menstrual migraine (MM). If the sNDA is approved by the FDA, Frova® will be the only triptan indicated in the U.S. for the prevention of MM. Currently, Frova® is FDA-approved for the acute treatment of migraine attacks with or without aura in adults where a clear diagnosis of migraine has been established. Approximately 21 million American women suffer from migraines. Of these female migraineurs, approximately 60 percent, or 12 million women, are estimated to suffer from menstrual migraines, a condition which can have a serious and debilitating impact. Compared to non-menstrual migraines, menstrual migraines can be more severe and are reported to be longer in duration, often lasting up to three days. The sNDA for Frova® is supported by data from four studies, including two Phase III studies examining the efficacy and safety of once-and twice-daily dose regimens of Frova® in the short-term prevention of MM, that both met their primary efficacy end-points, a pharmacokinetics and tolerability study of once- and twice-daily dosing of Frova®, and a 12-month open-label safety study evaluating a six-day dosing regimen of Frova® in 525 women. During the third quarter of 2006, the FDA accepted for substantive review the sNDA relating to Frova® for the short-term (six days per menstrual cycle) prevention of menstrual migraine (MM) and confirmed May 19, 2007 as the review completion date for this application. Subject to FDA approval, we intend to launch Frova® during the second half of 2007 for the currently anticipated expanded indication for prevention of menstrual migraine

***Transdermal Sufentanil Patch.*** The sufentanil patch, is intended to provide relief of moderate-to-severe chronic pain for up to seven days. Phase I clinical studies are currently being conducted and it is currently anticipated that Phase II patient studies will begin in the U.S. during the first half of 2007.

## **Table of Contents**

**EN 3285 Oral Rinse.** During the fourth quarter of 2006, the Company purchased RxKinetix, Inc., a privately held company headquartered in Boulder, Colorado, that develops new formulations of approved products for oral mucositis and other supportive care oncology conditions. RxKinetix's lead product, now named EN 3285, is a topical oral rinse with the active ingredient formulated in its proprietary ProGel<sup>®</sup> drug delivery platform. EN 3285 is in clinical Phase II trials for the prevention of oral mucositis (OM), painful mouth sores that often occur in cancer patients undergoing radiation and chemotherapeutic treatment. The anticipated benefits of EN 3285 are ease of use for patients and no systemic side-effects.

**Topical Ketoprofen Patch.** Currently in Phase III clinical trials in the U.S., the topical 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. 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. The anticipated benefits of the topical ketoprofen patch include bypassing of the bloodstream to minimize gastrointestinal and cardiovascular side effects of ketoprofen, local targeted pain control and convenience of once-daily dosing. We anticipate being in a position to file the NDA for the topical ketoprofen patch with the FDA in the first half of 2008.

**Rapinyl<sup>®</sup>** . Currently in Phase III clinical trial development, Rapinyl<sup>®</sup> is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. The benefits of Rapinyl<sup>®</sup> are believed to include rapid absorption of the active substance, a fast onset of action and patient convenience, which we believe will improve compliance in cancer patients who experience breakthrough pain. We anticipate being in a position to file the NDA for Rapinyl<sup>®</sup> with the FDA in the first half of 2008.

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

**CHRONOGESIC<sup>®</sup>** . Currently in early-clinical development, CHRONOGESIC<sup>®</sup> is intended to treat patients with opioid responsive chronic pain that results from a variety of causes. CHRONOGESIC<sup>®</sup> is an implantable drug-dispensing osmotic pump designed to deliver sufentanil continuously for a period of up to three months of pain therapy. The CHRONOGESIC<sup>®</sup> clinical development program is on temporary hold pending DURECT's implementation of some necessary design and manufacturing enhancements to the CHRONOGESIC<sup>®</sup> product. DURECT anticipates that the implementation of these design and manufacturing enhancements will continue to delay the restart of clinical trials.

**Other.** We also have other undisclosed products in our therapeutic areas of interest in early development.

## **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, Alpharma Inc., Johnson & Johnson, King Pharmaceuticals, Inc., Mallinckrodt Inc., Pfizer, Inc., The Purdue Frederick Company, Cephalon, Inc., and Watson Pharmaceuticals, Inc.

## **Table of Contents**

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 continually to 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.

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 pharmaceutical companies who are awarded availability to 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, 2006, our research and development and regulatory affairs staff consisted of 90 employees, primarily based in Westbury, New York and at our corporate headquarters in Chadds Ford, Pennsylvania. For fiscal years 2006, 2005 and 2004, our expenditures on research and development, including milestone payments were \$82.8 million, \$88.3 million and \$51.5 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 to which we have licensed the marketing rights 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.

**Table of Contents****Major Customers**

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 products to pharmacies, hospitals, governmental agencies and physicians. Net sales to customers who accounted for 10% or more of our net sales during the years ended December 31, 2006, 2005 and 2004 were as follows:

	2006	2005	2004
Company A	29%	31%	29%
Company B	28%	27%	18%
Company C	15%	13%	18%

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. Some wholesale distributors are demanding that pharmaceutical manufacturers, including us, enter into what are referred to as distribution service agreements pursuant to which the wholesale distributors provide the pharmaceutical manufacturers with specific services, including the provision of periodic retail demand information and current inventory levels and other information. To date, we have entered into three such agreements.

**Patents, Trademarks, Licenses and Proprietary Property**

As of February 23, 2007, we held approximately: 26 U.S. issued patents, 46 U.S. patent applications pending, 92 foreign issued patents, and 114 foreign patent applications pending with respect to our products. In addition, as of February 23, 2007, we have licenses for approximately: 48 U.S. issued patents, 22 U.S. patent applications pending, 141 foreign issued patents and 56 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 such patents are issued, 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.

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,



## **Table of Contents**

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 or 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.

## **Table of Contents**

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. Congress also passed measures intended to speed the process by which generic versions of brand name drugs are introduced to the market. Among other things, these measures are intended to limit regulatory delays of generic drug applications and penalize companies that reach agreements with makers of brand name drugs to delay the introduction of generic versions. These changes could result in increased generic competition for our branded and generic products and could have a material adverse effect on our business, financial condition and results of operations.

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.

## **Table of Contents**

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.

On January 30, 2007, the FDA announced a drug safety initiative to implement a number of proposals made by the Institute of Medicine in a September 2006 report. As part of this initiative, the FDA has launched a pilot program under which the safety of certain newly approved drugs will be monitored for 18 months after launch. As part of this program, the FDA will also begin publishing a newsletter that will contain non-confidential, non-proprietary information regarding post-marketing review of new drug products. The FDA also intends to assess the need for greater input from the Office of Surveillance and Epidemiology in reviewing NDAs for approval and in making post-marketing decisions regarding drug products, and to evaluate the effectiveness of existing risk minimization action plans and risk management tools through annual evaluations. Finally, the FDA is proposing to develop guidance for the industry on how to test, detect and prevent safety problems during drug development, including tests that would identify preclinical biomarkers of toxicity. Because these initiatives have just been announced and remain to be implemented, it is unclear what impact, if any, they may have on our ability to obtain approval of new drugs or on our sales of existing products.

In addition to these initiatives, the Prescription Drug User Fee Act (PDUFA) will expire on September 30, 2007. FDA and members of Congress are developing proposals to reauthorize PDUFA. In connection with that reauthorization legislation, the FDA has announced that it will be requesting that the fees cover funding for a number of safety initiatives included in the January 30, 2007

## **Table of Contents**

report, as well as additional initiatives to expedite new drug development and collect fees from companies that engage in direct-to-consumer television advertising. The initiatives FDA is proposing, if adopted, could impact our ability to market existing and new products.

Section 505(b)(2) of the Federal Food Drug and Cosmetic Act provides a procedure for an applicant to seek approval of a drug for which safety and/or efficacy has been established through preclinical and clinical data that the applicant does not have proprietary rights to use. Under that section, despite not having a right of reference, an applicant can cite to studies containing such clinical data to prove safety or efficacy, along with any additional clinical data necessary to support the application. Section 505(b)(2) NDAs are subject to patent certification and notification requirements that are similar to those that are required for ANDAs (see next section). Approval of Section 505(b)(2) NDAs, like ANDAs, also may be delayed by market exclusivity that covers the reference product. However, despite the similarities, Section 505(b)(2) applications are not permitted when an applicant could submit and obtain approval of an ANDA.

### ***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 generally involves a comparison of 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 systemically acting test and reference drugs are the same, the two drugs are bioequivalent and regarded as therapeutically interchangeable. There are other or additional measures FDA relies upon to determine bioequivalence in locally acting products, including comparative clinical efficacy trials.

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 2003 which may continue to affect pharmaceutical firms' ANDA products.

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.

## **Table of Contents**

### ***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 a Section 505(b)(2) NDA, the type of NDA that relies upon the data in the application for which the patents are listed, or an ANDA to secure approval of a generic version of this first, or listed drug, 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 generic applicant certifies that the listed patents are invalid, unenforceable or not infringed by the proposed generic drug and gives notice to the holder of 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.

One of the key motivators for challenging patents is the 180-day market exclusivity period vis a vis other generic applicants granted to the developer of a generic version of a product that is the first to have its application accepted for filing by the FDA and whose filing includes a certification that the applicable patent(s) are invalid, unenforceable and/or not infringed (a Paragraph IV certification ) and that prevails in litigation with the manufacturer of the branded product over the applicable patent(s). Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the 2003 Medicare Act, with accompanying amendments to the Hatch Waxman Act, this marketing exclusivity would begin to run upon the earlier of the commercial launch of the generic product or upon an appellate court decision in the generic company's favor.

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, in certain circumstances, the FDA may not approve 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 ensure 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 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.

## **Table of Contents**

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, good laboratory practices or GLP or good clinical practices 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 applicant must notify FDA, and in many cases, approval for 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.

## **Table of Contents**

The DEA limits the availability of the active ingredients used in many of our current products and products in development, and we must annually apply to the DEA for procurement quota in order to obtain these substances. As a result, our procurement quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials, product launches or could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial position and results of operations.

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.

### ***Government Benefit Programs***

Statutory and regulatory requirements for Medicaid, Medicare and other government health care 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 containing or reducing payment levels for prescription pharmaceuticals paid for in whole or in part with government 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 Medicare Modernization Act of 2003. The Medicare Modernization Act created a new prescription drug coverage program for people with Medicare through a new system of private market insurance providers; the program began in January 2006. This new benefit 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 such 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 annual out-of-pocket beneficiary deductible established by the Medicare Modernization Act. Further, beginning in 2006, Medicare prescription drug program beneficiaries are not permitted to purchase private insurance policies, known as Medigap policies, to cover the cost of off-formulary medications. If our products are excluded from these new formularies, demand for our products may decrease, and we may be forced to lower prices for our products, which may adversely affect our business and our results of operations.

## **Table of Contents**

### **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 and Other Service Agreements***

We contract with various third party manufacturers and suppliers to provide us with our raw materials used in our products and finished goods. Our most significant agreements are with Novartis Consumer Health, Teikoku Seiyaku Pharmaceuticals and Mallinckrodt. 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 results of operations.

##### *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. This agreement had a five-year term, with automatic five-year renewals thereafter. In August 2005, we extended this agreement until 2011. As of December 31, 2006, we are required to purchase a minimum of \$17 million of product per year through December 31, 2009. Either party may terminate this agreement on three-years' notice, effective at any time after the initial five-year term. 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. 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.



**Table of Contents**

*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.

*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 this 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, 2006, 2005 and 2004, these fees and expenses were approximately \$8.2 million, \$9.7 million and \$7.5 million, respectively. 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 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.

*PPD Development, LP*

Under the terms of this agreement, PPD Development, LP has agreed to provide us with clinical development services, business development support and medical information services. We currently pay PPD (1) on a project-by-project basis 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 year ended December 31, 2006 and 2005, these fees and expenses were approximately \$29.7 million and \$5.8 million, respectively. The current term of this agreement expires in May 2008, but this agreement automatically renews for successive one year terms unless either party gives written notice not to renew at least three months before the end of the then current term. The agreement may be terminated by either party: (1) upon 90 days written notice without cause; (2) for a material breach upon 30 days prior written notice (provided that the breaching party is given written notice and the opportunity to cure such breach within 30 days); and (3) immediately in connection with bankruptcy. A termination of this agreement does not automatically terminate any ongoing clinical studies PPD may be conducting on our behalf at the time of termination. The agreement calls for certain transition services in the event of termination.

## **Table of Contents**

### *General*

In addition to the manufacturing and supply agreements described above, we have an agreement with PPD and KAI Research, Inc. to assist with our adverse event reporting as well as agreements with other manufacturers and suppliers. 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.

### **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 strategic alliance agreement between the parties (the 2002 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, now known as Opana® ER. We had historically shared, on an equal basis, the costs of products developed under this agreement. 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 were responsible for funding 100% of these remaining costs until June 22, 2006, the date on which oxymorphone ER received FDA approval. In January 2007, the Company and Penwest entered into an amendment (the 2007 Amendment) to the 2002 Agreement. Under the terms of the 2007 Amendment, Endo and Penwest agreed to restructure the 2002 Agreement to provide that royalties payable to Penwest for U.S. sales of Opana® ER will be calculated based on net sales of the product rather than on operating profit, and to change certain other provisions of the 2002 Agreement. The 2007 Amendment also resolves the parties' ongoing disagreement with regard to sharing of marketing expenses during the period prior to when Opana® ER reaches profitability. The key financial terms of the 2007 Amendment are summarized as follows:

With respect to U.S. sales of Opana® ER, the Company's royalty payments to Penwest will be calculated starting at 22% of annual net sales of the product, and, based on agreed-upon levels of annual net sales achieved, the royalty rate can increase to a maximum of 30%.

No royalty payments will be due to Penwest for the first \$41 million of royalties that would otherwise have been payable beginning from the time of the product launch in July 2006.

Penwest is entitled to receive milestone payments of up to \$90 million based upon the achievement of certain agreed-upon annual sales thresholds.

As noted above, in 2003, Penwest opted out of funding of the development costs for Opana® ER. Under the 2002 Agreement between the parties, the Company was entitled to recoup Penwest's share of these development costs through a temporary adjustment in royalties. Under the 2007 Amendment, the parties have agreed that Penwest's share of these unfunded

---

**Table of Contents**

development costs will be fixed at \$28 million and will be recouped by the Company through a temporary 50% reduction in royalties payable to Penwest. This temporary reduction in royalties will not apply until the threshold for the royalty holiday referred to above has been met.

*Hind Healthcare Inc.*

In November 1998, Endo entered into a license agreement (referred to as the Hind License Agreement) with Hind Healthcare Inc., or 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 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 Lidoderm®. 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 is 10% of net sales through the shorter of (1) the expiration of the last licensed patent or (2) November 20, 2011, including a minimum royalty of at least \$500,000 per year. During 2006, 2005 and 2004, we recorded \$62.8 million, \$46.4 million and \$34.5 million for these royalties to Hind, respectively, which were recorded as a reduction to net sales. At December 31, 2006 and 2005, \$19.2 million and \$14.5 million, respectively, is recorded as royalty payable and included in accounts payable in the accompanying balance sheet. 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. The payment of these additional contingent termination amounts is not likely due the fact that the FDA informed our former partner, Noven Pharmaceuticals, that it would not approve Noven's Abbreviated New Drug Application for its developmental transdermal fentanyl patch, as discussed below. We wrote-off the unamortized portion of the Lavipharm upfront license fee and expensed the termination payment of \$3 million during the year ended December 31, 2004.

*DURECT Corporation*

In January 2006, DURECT and Endo entered into Amendment No. 3 to the DURECT CHRONOGESIC License Agreement. Under Amendment No. 3, Endo has the right to terminate the Agreement in the event that (i) DURECT has not delivered to Endo, on or before March 31, 2007, a written notice that a human pharmacokinetic trial had been completed with the CHRONOGESIC™ product candidate, together with a full study report of the results of the trial or (ii) Endo, determines, in its sole discretion, to terminate the Agreement during the sixty-day period after DURECT's delivery of such notice, *provided that*, in each case Endo delivers to DURECT its written notice of termination prior to April 30, 2007. Under Amendment No. 3, Endo shall not be responsible for any development costs for the CHRONOGESIC™ product candidate prior to May 1, 2007. Commencing on May 1, 2007, unless the Agreement is earlier terminated by Endo, Endo will fund 50% of the ongoing development costs for the CHRONOGESIC™ product

## Table of Contents

candidate in accordance with the terms of the Agreement. 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 up to \$10.0 million.

In addition, in March 2005, we signed an agreement that gives us the exclusive license to develop and commercialize DURECT's sufentanil-containing transdermal patch in the U.S. and Canada (the DURECT Sufentanil Agreement). The sufentanil patch, which is in early-stage clinical development, is intended to provide relief of moderate-to-severe chronic pain for up to seven days. We have assumed all remaining development and regulatory filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, in April 2005, we paid DURECT a \$10 million upfront fee, which was expensed as research and development, and are subject to potential additional payment requirements of up to 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<sup>®</sup> 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 the distribution and marketing rights for DepoDur<sup>®</sup>, with no value being assigned to Propofol IDD-D or any other SkyePharma products. We were amortizing this intangible asset over its estimated useful life of 17 years. During the year ended December 31, 2005, we recorded a receivable from SkyePharma of \$5 million based upon the achievement of certain criteria as specified in the agreement. This receivable was recorded as a reduction to our recorded intangible asset and the remaining intangible asset began to be amortized over its remaining useful life of 15 years. We collected this receivable in January 2006. During the year ended December 31, 2004, we paid and expensed to research and development a \$5 million milestone payment to SkyePharma upon approval of the NDA for DepoDur<sup>®</sup>. During the year ended December 31, 2004, we paid and expensed to research and development a \$5 million milestone payment to SkyePharma upon the advancement of Propofol IDD-D to the end of Phase II clinical development. Under this agreement, we also obtained options on other SkyePharma development products, including DepoBupivacaine, a long-acting, sustained release formulation of the local anesthetic bupivacaine. We had the option

---

**Table of Contents**

to obtain commercialization rights for this product when SkyePharma successfully completed its Phase II trials; however, in February 2006 we relinquished our rights to DepoBupivacaine . During the first quarter of 2006, SkyePharma and the Company decided to discontinue their development and commercialization of the Propofol IDD-D product candidate due to development challenges encountered in attempting to achieve the targeted product profile. In January 2007, following an assessment of the status of DepoDur<sup>®</sup>, we announced that we notified SkyePharma PLC of our intent to terminate our development and commercialization agreement for this product and, in February 2007, entered into a termination agreement with SkyePharma whereby the Development and Marketing Strategic Alliance Agreement will terminate in its entirety on March 31, 2007. In order to provide for the continued commercial support of the DepoDur<sup>®</sup> product and the transition of such product to SkyePharma on March 31, 2007, Endo will continue to provide a number of services and undertake certain activities. Specifically, Endo will use commercially reasonable efforts to maintain and continue all U.S. commercial activities in support of DepoDur<sup>®</sup> through March 31, 2007, and at SkyePharma's option, on a month-to-month basis after March 31, 2007 but not beyond June 30, 2007; and support and/or undertake the transition of certain Endo functions and activities (including third party activities) to SkyePharma that are useful and necessary for SkyePharma to assume commercial and related responsibilities for DepoDur<sup>®</sup> in the U.S. During the year ended December 31, 2006, as a result of the continued lack of commercial success of DepoDur<sup>®</sup> and, we recorded an impairment charge of \$14.8 million related to the remaining unamortized portion of our SkyePharma intangible asset.

*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 was intended to be the generic equivalent of Johnson & Johnson's Duragesic<sup>®</sup> (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 the distribution and marketing rights. We were amortizing this intangible asset over its useful life of 11 years. On September 27, 2005, the FDA informed Noven that it would not approve Noven's ANDA for its developmental transdermal fentanyl patch based on the FDA's assessment of potential safety concerns related to the higher drug content in the Noven product versus the reference-listed product, Duragesic<sup>®</sup>. As a result, we incurred a charge of approximately \$4 million related to the write-off of our portion of the transdermal fentanyl patch inventory and an impairment charge of approximately \$5.5 million, which represented the unamortized portion of the upfront license fee that we paid Noven in February 2004, during the year ended December 31, 2005. On March 2, 2006, we amended our license agreement with Noven, effective as of December 31, 2005, to terminate the provisions of the agreement applicable to the generic fentanyl patch product. As part of such amendment, Endo received a right of first negotiation for certain future generic fentanyl patch products that Noven may develop.

*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<sup>®</sup> BP product. The license agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept's LidoPAIN<sup>®</sup> 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

**Table of Contents**

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<sup>®</sup> 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 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 license exclusively to us rights to market Frova<sup>®</sup> (frovatriptan) in North America. Launched in the U.S. in June 2002, Frova<sup>®</sup> 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 were required to make anniversary payments for the first two years at \$15 million in 2005 and 2006 (both \$15 million anniversary payments have been made), and a \$40 million milestone payment upon FDA approval for the menstrual migraine indication (MM). 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<sup>®</sup>. See the disclosures under Note 8. Note Receivable, included in the consolidated financial statements in Part IV, Item 15 of this Report for further information. 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<sup>®</sup> beginning on January 1, 2007. 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<sup>®</sup> 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<sup>®</sup> is first offered, but in no event longer than 20 years. We can terminate the license agreement under certain circumstances, including upon one year's written notice.

On July 1, 2005, we entered into a co-promotion agreement, as amended on December 22, 2005, with Vernalis. The co-promotion agreement, as amended, is related to the above described license agreement, under which Vernalis agreed to exclusively license to us rights to market the product Frova<sup>®</sup> (frovatriptan) in North America. Pursuant to the license agreement, Vernalis had retained rights to co-promote Frova<sup>®</sup> in the United States. Vernalis has exercised its co-promotion option, and the co-promotion agreement, as amended, sets forth the certain specific terms and conditions governing such co-promotion and amends, restates and supersedes certain sections of the license agreement. Under the terms of both the license and co-promotion agreements, both as amended, beginning in January 2006 and ending on December 31, 2010, we are required to reimburse Vernalis for certain defined costs of their sales personnel.

*Orexo AB*

In August 2004, we entered into an agreement granting us the exclusive rights to develop and market Orexo AB's (a Swedish company) patented sublingual muco-adhesive fentanyl product (Rapinyl<sup>®</sup>) in North America. Rapinyl<sup>®</sup> is a sub-lingual, fast-

## Table of Contents

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 products utilizing Orexo's unique patented technology for sublingual administration 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 (\$5.2 million and \$7.3 million of which were recorded during the years ended December 31, 2006 and 2005, respectively and included in research and development expense). The agreement also provides for royalties based 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 \$750,000.

### *ProEthic Pharmaceuticals, Inc.*

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 currently available in the U.S. only in oral form. 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. Under the terms of the agreement, in March 2005, we paid a \$10 million upfront fee that was expensed as research and development during the year ended December 31, 2005. We made a \$5 million milestone payment upon the achievement of a regulatory milestone that was expensed as research and development during the year ended December 31, 2006. We could be required to make additional payments of approximately \$8 million upon the achievement of certain regulatory and other milestones. We will also pay royalties on net sales of the ketoprofen patch. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the tenth (10th) 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.

### *ZARS Pharma*

On January 6, 2006, we entered into an agreement with ZARS Pharma for the North American rights to Synera<sup>TM</sup> (lidocaine 70 mg and tetracaine 70 mg) topical patch. Synera<sup>TM</sup> is for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the FDA on June 23, 2005, Synera<sup>TM</sup> became commercially available in the second half of 2006.

Under the terms of the agreement, we paid ZARS an upfront fee of \$11 million in January 2006 and an additional \$8 million upon the first commercial shipment of the product in the second half of 2006. Both amounts were capitalized as an intangible asset representing the fair value of the marketing rights to Synera acquired from ZARS. We may be required to make additional payments of up to approximately \$19 million upon achievement of certain commercial milestones. We will also pay ZARS royalties on net sales of Synera<sup>TM</sup>. Following an impairment review of Synera<sup>TM</sup>, we determined that the carrying amount of the recorded intangible asset was not fully recoverable. As a result, we recorded a \$16.5 million impairment charge to write the unamortized portion of this intangible asset down to its fair value, determined using a discounted cash flow model.

## **Table of Contents**

### *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 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**

In January 2007, the Company and Penwest entered into an amendment (the 2007 Amendment) to the 2002 amended and restated strategic alliance agreement between the parties (the 2002 Agreement). Under the terms of the 2007 Amendment, Endo and Penwest agreed to restructure the 2002 Agreement to provide that royalties payable to Penwest for U.S. sales of Opana® ER will be calculated based on net sales of the product rather than on operating profit, and to change certain other provisions of the 2002 Agreement. The 2007 Amendment also resolves the parties' ongoing disagreement with regard to sharing of marketing expenses during the period prior to when Opana® ER reaches profitability. The key financial terms of the 2007 Amendment are summarized as follows:

With respect to U.S. sales of Opana® ER, the Company's royalty payments to Penwest will be calculated starting at 22% of annual net sales of the product, and, based on agreed-upon levels of annual net sales achieved, the royalty rate can increase to a maximum of 30%.

No royalty payments will be due to Penwest for the first \$41 million of royalties that would otherwise have been payable beginning from the time of the product launch in July 2006.

Penwest is entitled to receive milestone payments of up to \$90 million based upon the achievement of certain agreed-upon annual sales thresholds.

As noted above, in 2003, Penwest opted out of funding of the development costs for Opana® ER. Under the 2002 Agreement between the parties, the Company was entitled to recoup Penwest's share of these development costs through a temporary adjustment in royalties. Under the 2007 Amendment, the parties have agreed that Penwest's share of these unfunded development costs will be fixed at \$28 million and will be recouped by the Company through a temporary 50% reduction in royalties payable to Penwest. This temporary reduction in royalties will not apply until the threshold for the royalty holiday referred to above has been met.



**Table of Contents**

In January 2007, following an assessment of the status of DepoDur<sup>®</sup>, we announced that we notified SkyePharma PLC of our intent to terminate our development and commercialization agreement for this product and, in February 2007, entered into a termination agreement with SkyePharma whereby the Development and Marketing Strategic Alliance Agreement will terminate in its entirety on March 31, 2007. In order to provide for the continued commercial support of the DepoDur<sup>®</sup> product and the transition of such product to SkyePharma on March 31, 2007, Endo will continue to provide a number of services and undertake certain activities. Specifically, Endo will use commercially reasonable efforts to maintain and continue all U.S. commercial activities in support of DepoDur<sup>®</sup> through March 31, 2007, and at SkyePharma's option, on a month-to-month basis after March 31, 2007 but not beyond June 30, 2007; and support and/or undertake the transition of certain Endo functions and activities (including third party activities) to SkyePharma that are useful and necessary for SkyePharma to assume commercial and related responsibilities for DepoDur<sup>®</sup> in the U.S. During the year ended December 31, 2006, as a result of the continued lack of commercial success of DepoDur<sup>®</sup> and, we recorded an impairment charge of \$14.8 million related to the remaining unamortized portion of our SkyePharma intangible asset.

**Description of Credit Facility**

Our amended and restated senior secured credit facility expired on December 21, 2006. We did not borrow any amounts under the facility during 2006. The Company has not renegotiated a credit facility at this time.

**Employees**

As of December 31, 2006, we had 1,024 employees, of which 90 are engaged in research and development and regulatory work, 747 in sales and marketing, 29 in quality assurance and 158 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 1, 2007:

<b>Name</b>	<b>Age</b>	<b>Position and Offices</b>
Peter A. Lankau	54	President and Chief Executive Officer
Charles A. Rowland, Jr.	48	Executive Vice President, Chief Financial Officer and Treasurer
David A.H. Lee, M.D., Ph.D.	57	Chief Scientific Officer
Caroline B. Manogue	38	Executive Vice President, Chief Legal Officer and Secretary
Joyce N. LaViscount	44	Chief Accounting Officer

PETER A. LANKAU, 54, is President and Chief Executive Officer of Endo and currently a Director of Endo. Prior to May 2005, Mr. Lankau was President and Chief Operating 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 Alphasigma 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.

## **Table of Contents**

CHARLES A. ROWLAND, JR, 48, is Executive Vice President, Chief Financial Officer and Treasurer of Endo. Prior to joining Endo in December 2006, Mr. Rowland was Senior Vice President and CFO of Biovail Pharmaceuticals, Inc., in Bridgewater, New Jersey. He was Chief Operating and Financial Officer for Breakaway Technologies, a management consulting company, from 2001 to 2004. His pharmaceutical industry career includes positions of increasing scope and responsibility at Pharmacia Corp., where he had global responsibility for Finance and Information Technology for the Pharmaceutical Business and financial responsibility for the Global Supply organization as Vice President, Finance Global Supply and VP Finance & IT-Global Pharma Ops; Novartis Pharmaceuticals Corp., where he was Vice President, Planning and Decision Support, and Bristol-Myers Squibb, where he served as Director of Finance.

DAVID A.H. LEE, M.D. Ph.D., 57, is Chief Scientific Officer of Endo. Prior to December 2006, Dr. Lee was 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, 38, is Executive Vice President, Chief Legal Officer and Secretary of Endo. Prior to April 2004, Ms. Manogue was Senior Vice President, General Counsel 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.

JOYCE N. LAVISCOUNT, 44, is Chief Accounting Officer of Endo. Prior to August 2006, Ms. LaViscount was Vice President of Financial Planning and Analysis of Endo. Prior to joining Endo, Ms. LaViscount held positions of increasing scope and responsibility at Pfizer, Inc (formerly Pharmacia Corporation) in Peapack, New Jersey in both the pharmaceutical and consumer healthcare groups. Prior to joining Pharmacia, Ms. LaViscount held various positions at Bristol-Myers Squibb Company in Princeton, New Jersey, ranging from Senior Accountant to Senior Manager, Financial Analysis. Ms LaViscount began her career in public accounting with Ernst & Young.

We have employment agreements with each of our executive officers.

## **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.

You may also read and copy any materials we file with the SEC at the SEC's Public Reference Room that is located at 100 F Street, N.E., Room 1580, NW, Washington, DC 20549. Information about the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330 or 1-202-551-8090. You can also access our filings through the SEC's internet site: [www.sec.gov](http://www.sec.gov) (*intended to be an inactive textual reference only*).

## **Table of Contents**

### **Item 1A. Risk Factors**

You should carefully consider all of the information set forth in this Form 10-K, including the following risk factors, before deciding to invest in any of the Company's securities. The risks below are not the only ones the Company faces. Additional risks not currently known to the Company or that the Company currently deems immaterial may also impair its business operations. The Company's business, financial condition, results of operations or prospects could be materially adversely affected by any of these risks.

#### **Risks Related to Our Business**

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

The pharmaceutical industry is intensely competitive, and we face competition across the full range of our activities. If we fail to compete successfully in any of these areas, our business, results of operations and financial condition could be adversely affected. Our competitors include many of the major brand name and generic manufacturers of pharmaceuticals, especially those doing business in the United States. In the market for branded pharmaceutical products, our competitors, including Abbott Laboratories, Alparma Inc., Johnson & Johnson, King Pharmaceuticals Inc., Cephalon, Inc., Pfizer, Inc. and The Purdue Frederick Company, vary depending on product category, dosage strength and drug-delivery systems. In addition to product safety, development and efficacy, other competitive factors in the branded pharmaceutical market include product quality and price, reputation, service and access to scientific and technical information. It is possible that developments by our competitors will make our products or technologies uncompetitive or obsolete. Because we are smaller than many of our national competitors in the branded pharmaceutical products sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector.

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

Our branded products face competition from generic versions. Generic versions are generally significantly cheaper than the branded version, and, where available, may be required or encouraged in preference to the branded version under third party reimbursement programs, or substituted by pharmacies for branded versions by law. The entrance of generic competition to our branded products generally reduces our market share and adversely affects our profitability and cash flows. Generic competition with our branded products, including Percocet®, has had and will continue to have a material adverse effect on the net sales and profitability of our branded products.

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

## **Table of Contents**

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

Under the Federal Food, Drug and Cosmetics Act, or the Act, FDA can approve an abbreviated new drug application, or ANDA, for a generic version of a branded drug and what is referred to as a 505(b)(2) application for a branded variation of an existing branded drug without undertaking the clinical testing necessary to obtain approval to market a new drug. We refer to this process as the ANDA process. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product based on pharmacokinetic studies, in addition to any data necessary to establish that any difference in strength, dosage form, inactive ingredients, or delivery mechanism does not result in different safety or efficacy profiles, as compared to the reference drug.

The Act requires an applicant for a drug that relies, at least in part, on the patent of one of our branded drugs to notify us of their application and potential infringement of our patent rights. Upon receipt of this notice we would have 45 days to bring a patent infringement suit in federal district court against the company seeking approval of a product covered by one of our patents. The discovery, trial and appeals process in such suits can take several years. If such a suit is commenced, the Act provides a 30-month stay on the FDA's approval of the competitor's application. Such litigation is often time-consuming and quite costly and may result in generic competition if such patent(s) are not upheld or if the generic competitor is found not to infringe such patent(s). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs and Section 505(b)(2) applications.

We learned, in October 2006, that the Division of Bioequivalence, Office of Generic Drugs, Center for Drug Evaluation and Research, or OGD, has responded to an inquiry requesting bioequivalence recommendations regarding our patent-protected product, Lidoderm® (lidocaine topical patch 5%), pursuant to which a party could seek ANDA approval of a generic version of that product. We also learned that OGD has recommended a bioequivalence study characterizing the pharmacokinetic profile of lidocaine as well as a skin irritation/sensitization study of any lidocaine-containing patch formulation. This recommendation deviates from our understanding of the applicable regulations and of OGD's past practices, which, for a topically acting product such as Lidoderm®, would require demonstration of bioequivalence through a comparative clinical equivalency study rather than through a pharmacokinetic study.

On December 19, 2006, the Company submitted a Citizen Petition with the FDA requesting that the FDA apply existing bioequivalence regulations to any ANDA seeking regulatory approval of a generic drug product that references Endo's Lidoderm®. This Citizen Petition emphasizes that FDA's recommendation deviates from applicable regulations and OGD's past practices, both of which contemplate demonstration of bioequivalence for a topically acting product like Lidoderm® through a comparative clinical efficacy study. We believe blood levels of the active ingredient, lidocaine, cannot properly be used as the key measure in proving bioequivalence. To appropriately assess the efficacy and safety of any generic version of Lidoderm®, we believe that it is critical that the FDA require any ANDA applicant relying on Lidoderm® as its Reference Listed Drug satisfy the regulations by conducting comparative clinical studies demonstrating (1) bioequivalence between the generic version and Lidoderm®, and (2) that the generic version produces the same local analgesic effect as Lidoderm® without producing a complete sensory block, in order to assure that the generic product has the same labeling, efficacy and safety profile as Lidoderm®.

## **Table of Contents**

The filing of any ANDA or 505(b)(2) application in respect to any of our branded drugs, particularly Lidoderm<sup>®</sup>, could have an adverse impact on our stock price. Moreover, if the patents covering our branded drugs, including Lidoderm<sup>®</sup>, were not upheld in litigation or if the generic competitor is found not to infringe these patents, the resulting generic competition would have a material adverse effect on our net sales, gross profit, operating income, net income and cash flows.

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

Our generic products compete with branded products and with generic versions made by or for other manufacturers, such as Mallinckrodt Inc. and Watson Pharmaceuticals, Inc. When additional versions of one of our generic products enter the market, we generally lose market share and our selling prices and margins on the product decline. Because we are smaller than many of our full-line competitors in the generic pharmaceutical products sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector.

On June 7, 2005, we launched the 10mg, 20mg, 40mg and 80mg strengths of our bioequivalent versions of OxyContin<sup>®</sup>. We had 180 days of marketing exclusivity under the Hatch Waxman Act with respect to the 10mg, 20mg and 40mg strengths of this product, since we were the first applicant to file an ANDA containing a Paragraph IV certification for these oxycodone extended-release strengths. However, Purdue marketed an authorized generic through Impax Laboratories, Inc. and Watson Pharmaceuticals, Inc. during this time of our Hatch Waxman Act exclusivity. After the expiration of our marketing exclusivity period on December 5, 2005, several competitors launched bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin<sup>®</sup>.

Although we were successful in our patent challenge against Purdue for our generic OxyContin<sup>®</sup> product, both at trial and on appeal, the Court of Appeals for the Federal Circuit, or the Federal Circuit, vacated its unanimous affirmance of the Opinion and Order in our favor and affirmed the District Court's finding that, if Purdue's patents are enforceable, Endo's oxycodone extended-release tablets infringe these patents. Further, the Federal Circuit issued a new opinion on February 1, 2006 remanding the case to the same District Court for its further consideration as to whether the Purdue patents are unenforceable. During the third quarter of 2006, under the terms of an agreement with The Purdue Frederick Company, The P.F. Laboratories, Inc., and Euro-Celtique, S.A., we settled this litigation. Pursuant to the settlement, we agreed to cease all sales of our oxycodone extended-release products effective December 31, 2006. We, as well as our subsidiary, Endo Pharmaceuticals Inc., our manufacturers, distributors, purchasers, and patients, were released from all liability for infringement of Purdue's patents in connection with our sales of these products prior to December 31, 2006.

**Table of Contents**

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

The following table displays our net sales by product category and as a percentage of total net sales for the years ended December 31, 2006, 2005 and 2004 (dollars in thousands):

	Years Ended December 31					
	2006		2005		2004	
	\$	%	\$	%	\$	%
Lidoderm®	566,785	62	419,418	51	309,230	50
Percocet®	102,707	11	110,700	13	86,510	14
Frova®	40,564	5	38,096	5	11,449	2
Opana® ER and Opana®	6,845	1				
DepoDur®	2,993		3,931	1		
Other brands	11,034	1	11,098	1	15,481	3
<b>Total brands</b>	<b>730,928</b>	<b>80</b>	<b>583,243</b>	<b>71</b>	<b>422,670</b>	<b>69</b>
Generic oxycodone extended-release tablets	57,075	6	113,969	14		
Other generics	121,656	14	122,952	15	192,430	31
<b>Total generics</b>	<b>178,731</b>	<b>20</b>	<b>236,921</b>	<b>29</b>	<b>192,430</b>	<b>31</b>
<b>Total net sales</b>	<b>909,659</b>	<b>100</b>	<b>820,164</b>	<b>100</b>	<b>615,100</b>	<b>100</b>

The FDA granted Lidoderm® orphan drug status for the treatment of the pain associated with post herpetic neuralgia, which meant, generally, that no other lidocaine-containing product could have been approved for this indication prior to March 19, 2006. While the orphan drug exclusivity period for Lidoderm® has expired, that product is covered by patents through 2015, and any party seeking approval for a generic version of Lidoderm® in spite of our patent rights would be obligated to notify us of the filing of an application with the FDA. We have not received notice from any competitor of the filing of a Section 505(b)(2) or ANDA application seeking FDA approval of a generic version of Lidoderm®.

On June 7, 2005, we launched our extended-release oxycodone product, our bioequivalent, or generic, version of OxyContin®. After the expiration of our marketing exclusivity period in December 2005, several competitors launched bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin®. Pursuant to our settlement agreement with Purdue, we ceased all sales of our generic extended-release oxycodone products as of December 31, 2006.

In addition to our discontinuance of sales of our generic OxyContin®, if we are unable to continue to market any of these other products, if any of them were to lose market share, for example, as the result of the entry of new competitors, particularly from generic versions of branded drugs, or if the prices of any of these products were to decline significantly, our net sales, profitability and cash flows would be materially adversely affected.

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

Brand-name pharmaceutical companies have taken aggressive steps to thwart competition from generic equivalents of their brand-name products. In particular, brand-name companies sell directly to the generics market or license their products for sale to the generics market through licensing arrangements or strategic alliances with generic pharmaceutical companies (so-called authorized generics). No significant regulatory approvals are required for a brand-name manufacturer to sell directly or through a third party to the generic market. Brand-name manufacturers do not face any other significant barriers to entry into such market. The introductions of these so-called authorized generics have had and may continue to have an adverse effect by reducing our market share and adversely affecting our profitability and cash flows.

## Table of Contents

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

*We may incur significant liability if it is determined that we are promoting the off-label use of drugs.*

Companies may not promote drugs for off-label uses that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the Federal Food, Drug and Cosmetics Act and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (OIG) and FDA both actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the OIG and the FDA allow companies to engage in truthful, non-misleading, and non-promotional speech concerning their products. Although we believe that all of our communications regarding all of our products are in compliance with the relevant legal requirements, the OIG or the FDA may disagree, and we may be subject to significant liability, including civil and administrative remedies, as well as criminal sanctions. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.

On January 17, 2007, we received a subpoena issued by the OIG. The subpoena requests documents relating to Lidoderm® (lidocaine patch 5%), primarily with regard to Lidoderm® sales, marketing, and promotion, and the Company's knowledge of physicians' use of Lidoderm® for non-indicated uses. We are cooperating with the government to provide the requested documents. Although we believe that we promote all of our products responsibly and appropriately within their currently FDA-approved indications, we cannot assure you that the OIG will agree. If the OIG disagrees and initiates action against us, we could face substantial penalties, which could have an adverse effect on our business, financial condition and results of operations.

## **Table of Contents**

***We may incur liability if our continuing medical or health education programs and/or product promotions are determined, or are perceived, to be inconsistent with regulatory guidelines.***

The FDA provides guidelines with respect to appropriate promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, the FDA or the OIG, may disagree, and we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management's attention could be diverted and our reputation could be damaged.

***We are subject to various regulations pertaining to the marketing of our products.***

We are subject to various federal and state laws pertaining to health-care fraud and abuse, including anti-kickback laws and false-claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, or pay any remuneration in exchange for the referral of business, including the purchase or prescription of a particular drug. The U.S. federal government has published regulations that identify safe harbors, or exemptions, for certain payment arrangements that do not violate federal anti-kickback statutes. We seek to comply with these anti-kickback statutes and the safe harbors, and are unaware of any violations of those laws. However, due to the breadth of the statutory provisions and the absence of uniform guidance in the form of regulations or court decisions, it is possible that some of our practices may be challenged under anti-kickback or similar laws. Violations of such restrictions may be punishable by civil and/or criminal sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from U.S. federal health-care programs (including Medicaid and Medicare). Any such violations could have a material adverse effect on our business, financial condition and results of operations.

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

On July 14, 2000, Endo Pharma LLC was formed in connection with our merger with Algos Pharmaceutical Corporation (Algos) 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 held approximately 15% of our common stock at December 31, 2005, but less than 1% of our common stock as of December 31, 2006, in which affiliates of Kelso & Company and certain current and former 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 have been and will be delivered. Because Endo Pharma LLC, and not us, has been and 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 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, 2006, approximately 36 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, 2006, approximately \$773 million), which is estimated to result in a tax benefit amount of approximately \$298 million. Under the tax sharing agreement, we are required to pay this \$298 million, \$252 million of which has already been paid as of December 31, 2006, 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. Additionally, as part of the tax sharing agreement, Endo Pharma LLC will reimburse us for the after-tax employer payroll taxes paid by us as a result of the exercise of the 36 million options discussed above. We have paid approximately



---

**Table of Contents**

\$11 million in employer payroll taxes, of which Endo Pharma LLC will reimburse us for approximately \$7 million which represents the after-tax employer payroll tax paid by us for the periods from 2001 through December 31, 2006. As of December 31, 2006, our net liability due to Endo Pharma LLC is approximately \$38.7 million. 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.

During the year ended December 31, 2006, approximately 3.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised. Since the attributable compensation charge deductions are usable to reduce our taxes in 2006, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$38.7 million, which is our net liability due to Endo Pharma LLC referred to above. Fifty percent of the estimated tax benefit amount attributable to these exercises and any additional tax benefits attributable to the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2006 will be due within 15 business days of the date we receive an opinion on our final audited 2006 financial statements from our independent registered public accounting firm, and the remaining tax benefit amount attributable to 2006 is due within 30 business days of the date on which we file our 2006 tax return with the Internal Revenue Service.

As of December 31, 2006, there were approximately 0.1 million stock options, which expire in August 2007, remaining to be exercised under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of \$2.42 per share and an assumed tax rate of 38.25%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were vested and exercised, and assuming the price of our common stock was \$27.58 per share, the closing price on December 29, 2006, we would generally be able to deduct, for income tax purposes, compensation of approximately \$2 million, which could result in a tax benefit amount of approximately \$1 million payable to Endo Pharma LLC in 2008. This would represent the final tax sharing payment due to Endo Pharma LLC.

As of December 31, 2006, there were no options remaining to be granted under the Endo Pharma LLC stock option plans.

***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 Minimization Action Plans ( Risk MAP ), which may prove difficult or expensive to comply with, and we and other pharmaceutical companies may face lawsuits.***

Most of our core products contain narcotic ingredients. Misuse or abuse of such drugs can lead to physical or other harm. Specifically, in the past two years, reportedly widespread misuse or abuse of OxyContin<sup>®</sup>, a Purdue product containing the narcotic oxycodone, resulted in the strengthening of warnings on its labeling. In addition, we believe that Purdue, the manufacturer of OxyContin<sup>®</sup>, faces or did face numerous lawsuits, including class action lawsuits, related to OxyContin<sup>®</sup> misuse or abuse. On June 7, 2005, we began commercial sale of our oxycodone extended-release tablets, 10mg, 20mg, 40mg and 80mg strengths, each bioequivalent versions of OxyContin<sup>®</sup>. Pursuant to the settlement agreement with Purdue, all sales of our oxycodone extended-release tablets have ceased as of December 31, 2006. However, we may be subject to litigation similar to the OxyContin<sup>®</sup> suits related to our generic version of OxyContin<sup>®</sup> or any other narcotic containing product we market.

The FDA or the DEA may impose new regulations concerning the manufacture and sale of prescription narcotics. Such regulations may include new labeling requirements, the development and implementation of Risk MAPs, restrictions on prescription and sale of these products and mandatory reformulation of our products in order to make abuse more difficult. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their

## **Table of Contents**

regulations with respect to prescription narcotics in an attempt to curb abuse. In either case, any such new regulations may be difficult and expensive for us to comply with, may delay our introduction of new products, may adversely affect our net sales and may have a material adverse effect on our business, results of operations and financial condition.

*The pharmaceutical industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business.*

The federal, state and local governmental authorities in the United States, the principal one of which applies to our products is the FDA, impose substantial requirements on the development, manufacture, labeling, sale, distribution, marketing, advertising, promotion and introduction of therapeutic pharmaceutical products through lengthy and detailed laboratory and clinical testing and other costly and time-consuming procedures. The submission of an NDA or ANDA to the FDA alone does not guarantee that the FDA will grant approval to market the product. Satisfaction of FDA requirements typically takes a number of years, varies substantially based upon the type, complexity and novelty of the pharmaceutical product and is subject to uncertainty. The NDA approval process for a new product varies in time, generally requiring a minimum of 10 months, but could also take several years from the date of application. The timing for the ANDA approval process for generic products is difficult to estimate and can vary significantly.

NDA approvals, if granted, may not include all uses for which a company may seek to market a product. The FDA actively enforces regulations prohibiting marketing of products for unapproved uses. Failure to comply with applicable regulatory requirements in this regard can result in, among other things, suspensions of approvals, seizures or recalls of products, injunctions against a product's manufacture, distribution, sales and marketing, operating restrictions, civil penalties and criminal prosecutions. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals. The effect of government regulation may be to delay marketing of our new products for a considerable period of time, to impose costly procedures upon our activities and to furnish a competitive advantage to larger companies that compete against us.

We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, 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.

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

In particular, the FDA has expressed interest in specific chemical structures that may be present as impurities in a number of opioid narcotic active pharmaceutical ingredients, such as oxycodone, which based on certain structural characteristics and laboratory tests may indicate the potential for having mutagenic effects. More stringent controls of the levels of these impurities have been required and may continue to be required for FDA approval of products containing these impurities. Also, labeling revisions, formulation or manufacturing changes and/or product modifications may be necessary for new or existing products containing

**Table of Contents**

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

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

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

The stringent DEA regulations on our use of controlled substances include restrictions on their use in research, manufacture, distribution and storage. A breach of these regulations could result in imposition of civil penalties, refusal to renew or action to revoke necessary registrations, or other restrictions on operations involving controlled substances. See also The DEA limits the availability of the active ingredients used in many of our current products and products in development and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials.

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. In addition, Congress passed measures intended to speed the process by which generic versions of brand name drugs are introduced to the market. Among other things, these measures are intended to limit regulatory delays of generic drug applications and penalize companies that reach certain types of agreements with makers of brand name drugs to delay the introduction of generic versions. These changes could result in increased generic competition for our branded and generic products and could have a material adverse effect on our business, financial condition and results of operations. See If generic manufacturers use litigation and regulatory measures to obtain approval for generic versions of

## **Table of Contents**

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

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

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

The rate of patient enrollment sometimes delays completion of clinical studies. There is substantial competition to enroll patients in clinical trials for pain management products, and such competition has delayed clinical development of our products in the past. Delays in planned patient enrollment can result in increased development costs and delays in regulatory approval. In addition, we rely on collaboration partners that may control or make changes in trial protocol and design enhancements that may also delay clinical trials. We cannot assure you that we will not experience delays or undesired results in these or any other of our clinical trials.

We presently have one product under sNDA review, two products in Phase III of clinical trials and three products in Phase II of clinical trials. We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, on a timely basis, if at all, or, if granted, that such approval will not subject the marketing of our products to certain limits on indicated use. Any limitation on use imposed by the FDA or delay in or failure to obtain FDA approvals of products developed by us would adversely affect the marketing of these products and our ability to generate product revenue, as well as adversely affect the price of our common stock.

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

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

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

**Table of Contents**

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

fail to accomplish our strategic objectives;

not be successfully combined with our operations;

not perform as expected; and

expose us to cross border risks.

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

On October 12, 2006, we acquired privately-held RxKinetix, Inc., based in Boulder, Colorado. RxKinetix specializes in developing new therapeutics focused on improving the quality of life for patients being treated for cancer. There are a number of risks associated with this acquisition, which include, but are not limited to, the following:

The necessity of coordinating and consolidating geographically separated organizations, systems and facilities;

The successful integration of our management and personnel and retaining key employees;

The ability to further advance the products in development into an FDA-approved, commercially viable products; and

Charges associated with this transaction, including the write-off of purchased in-process research and development costs that have been paid, the write-off of potential future contingent consideration as purchased in-process research and development, and additional amortization of potential future contingent consideration that may result in the capitalization of intangible assets upon FDA approval, have had and may continue to have a negative impact our net income

If management is unable to successfully integrate the operations and manage these risks, the anticipated benefits of this acquisition may not be realized.

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

In January 2007, following an assessment of the status of DepoDur<sup>®</sup>, we announced that we notified SkyePharma PLC of our intent to terminate our development and commercialization agreement for this product and, in February 2007, entered into a termination agreement with SkyePharma whereby the Development and Marketing Strategic Alliance Agreement will terminate in its entirety on March 31, 2007. In order to provide for the continued commercial support of the DepoDur<sup>®</sup> product and the transition

## **Table of Contents**

of such product to SkyePharma on March 31, 2007, Endo will continue to provide a number of services and undertake certain activities. Specifically, Endo will use commercially reasonable efforts to maintain and continue all U.S. commercial activities in support of DepoDur<sup>®</sup> through March 31, 2007, and at SkyePharma's option, on a month-to-month basis after March 31, 2007 but not beyond June 30, 2007; and support and/or undertake the transition of certain Endo functions and activities (including third party activities) to SkyePharma that are useful and necessary for SkyePharma to assume commercial and related responsibilities for DepoDur<sup>®</sup> in the U.S. During the year ended December 31, 2006, as a result of the continued lack of commercial success of DepoDur<sup>®</sup> and, we recorded an impairment charge of \$14.8 million related to the remaining unamortized portion of our SkyePharma intangible asset.

In addition, following an impairment review of Synera<sup>™</sup>, we determined that the carrying amount of the recorded intangible asset was not recoverable. As a result, we recorded a \$16.5 million impairment charge to write the unamortized portion of this intangible asset down to its anticipated fair value.

***Our growth and development will depend on developing, commercializing and marketing new products, including both our own products and those developed with our collaboration partners. If we do not do so successfully, our growth and development will be impaired.***

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

We conduct research and development primarily to enable us to manufacture and market FDA-approved pharmaceuticals in accordance with FDA regulations. Much of our development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. Typically, research expenses related to the development of innovative compounds and the filing of NDAs for these products are significantly greater than those expenses associated with ANDAs for generic products. As we continue to develop new products, our research expenses will likely increase. Because of the inherent risk associated with research and development efforts in our industry, particularly with respect to new drugs, our research and development expenditures may not result in the successful introduction of FDA approved new pharmaceutical products. Also, after we submit an NDA or ANDA, the FDA may request that we conduct additional studies and as a result, we may be unable to reasonably predict the total research and development costs to develop a particular product.

## **Table of Contents**

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

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

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

## **Table of Contents**

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

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

***If the efforts of manufacturers of branded pharmaceuticals to use litigation and legislative and regulatory means to limit the use of generics and certain other products are successful, our sales may suffer.***

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

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

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

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

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



## **Table of Contents**

*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 care programs, private health insurers and others. We cannot assure you that third party insurance coverage will be adequate for us to maintain price levels sufficient for realization of an appropriate return on our investment. Government, private insurers and other third party payers are increasingly attempting to contain health care costs by (1) limiting both coverage and the level of reimbursement (including adjusting co-pays) for products approved for marketing by the FDA, (2) refusing, in some cases, to provide any coverage for uses of approved products for indications for which the FDA has not granted marketing approval and (3) requiring or encouraging, through more favorable reimbursement levels or otherwise, the substitution of generic alternatives to branded products.

On December 8, 2003, President Bush signed into law the Medicare Modernization Act of 2003. The Medicare Modernization Act created a new prescription drug coverage program for people with Medicare through a new system of private market insurance providers; the program began in January 2006. This new benefit 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 such 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 annual out-of-pocket beneficiary deductible established by the Medicare Modernization Act. Further, beginning in 2006, Medicare prescription drug program beneficiaries are not permitted to purchase private insurance policies, known as Medigap policies, to cover the cost of off-formulary medications. If our products are excluded from these new formularies, demand for our products might decrease and we may be forced to lower prices for our products, which may adversely affect our business and our results of operations.

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

the trend toward managed health care in the United States;

the growth of organizations such as HMOs and managed care organizations;

legislative proposals to reform health care and government insurance programs; and

price controls and non-reimbursement of new and highly priced medicines for which the economic therapeutic rationales are not established.

## **Table of Contents**

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

We are subject to various federal and state laws pertaining to health care fraud and abuse, including prohibitions on the offer of payment or acceptance of kickbacks or other remuneration in return for the purchase of our products. Sanctions for violating these laws include criminal penalties and civil sanctions and possible exclusion from the Medicare, Medicaid, and other government health care programs. There can be no assurance that our practices will not be challenged under these laws in the future or that such a challenge would not have a material adverse effect on our business or results of operations.

We also are subject to federal and state laws prohibiting the presentation (or the causing to be presented) of claims for payment (by Medicare, Medicaid, or other third-party payers) that are determined to be false, fraudulent, or for an item or service that was not provided as claimed. These false claims statutes include the Federal Civil and Criminal False Claims Acts, which allow any person to bring suit in the name of the government alleging false or fraudulent claims presented to or paid by the government (or other violations of the statutes) and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in the health care industry in recent years. These actions against health care companies may result in payment of fines or exclusion from the Medicare, Medicaid, and/or other government health care programs as the result of an investigation arising out of the action.

We and other pharmaceutical companies are defendants in a number of lawsuits filed by local and state government entities, alleging generally that we and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. Endo intends to defend these lawsuits vigorously. Depending on developments in the litigation however, as with all litigation, there is a possibility that the Company will suffer adverse decisions or verdicts of substantial amounts, or that the Company will enter into monetary settlements in one or more of these actions.

Government regulations regarding reporting and payment obligations are complex and we are continually evaluating the methods we use to calculate and report the amounts owed with respect to Medicaid and other government pricing programs. Our calculations are subject to review and challenge by various government agencies and authorities and it is possible that any such review could result either in material changes to the method used for calculating the amounts owed to the pertinent government agency (or agencies), or to the amounts themselves. In addition, because our processes for these calculations and our judgments supporting these calculations involve, and will continue to involve, subjective decisions, these calculations are subject to the risk of errors. As noted above, any governmental agency that commences an investigation of us could impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of the applicable laws impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments and even in the absence of such ambiguity a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. Any such penalties or sanctions could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

**Table of Contents**

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

Even if we obtain regulatory approvals, uncertainty exists as to whether the market will accept our products. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, the price of our products relative to alternative products, the availability of third party reimbursement and the extent of marketing efforts by third party distributors or agents that we retain. We cannot assure you that our products will receive market acceptance in a commercially viable period of time, if at all. We cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially adversely affected, and the market value of our common stock could decline. In addition, many of our products contain narcotic ingredients that carry stringent record keeping obligations, strict storage requirements and other limitations on these products availability, which could limit the commercial usage of these products.

We sell our products to a limited number of wholesale drug distributors and large pharmacy chains. In turn, these wholesale drug distributors and large pharmacy chains supply products to pharmacies, hospitals, governmental agencies and physicians. Net sales to customers who accounted for 10% or more of our net sales during the years ended December 31, 2006, 2005 and 2004 were as follows:

	2006	2005	2004
Company A	29%	31%	29%
Company B	28%	27%	18%
Company C	15%	13%	18%

If we were to lose the business of any of these customers, or if any were to experience difficulty in paying us on a timely basis, our net sales, profitability and cash flows could be materially and adversely affected.

*We are dependent on outside manufacturers for the manufacture of our products; therefore, we will have limited control of the manufacturing process and related costs. Certain of our manufacturers currently constitute the sole source of one or more of our products.*

Third party manufacturers currently manufacture all of our products pursuant to contractual arrangements. 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.

Because all of our products are manufactured by third parties, 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

## Table of Contents

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, results of operations and financial condition. 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.

We have entered into minimum purchase requirement contracts with some of our third party manufacturers. In May 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc., pursuant to which Novartis has agreed to manufacture certain of our commercial products in addition to products in development. As of December 31, 2005, we are required to purchase a minimum of \$17 million per year through December 31, 2009 from Novartis. We also have a long-term contract with Teikoku Seiyaku Co., Ltd. under which Teikoku manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. In addition, we may consider entering into additional manufacturing arrangements with third party manufacturers. In each case, we will incur significant costs in obtaining the regulatory approvals and taking the other steps necessary to begin commercial production by these manufacturers. If the market for the products manufactured by these third parties substantially contracts or disappears, we will continue to be financially obligated under these contracts, an obligation which could have a material adverse effect on our business.

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

We rely on third parties to supply all raw materials used in our products. In addition, we rely on third party suppliers, distributors and collaboration partners to provide services for certain core aspects of our business, including manufacturing, warehousing, distribution, customer service support, medical affairs services, clinical studies, sales and other technical and financial services. All third party suppliers and contractors are subject to FDA, and very often DEA, requirements. Our business and financial viability are dependent on the regulatory compliance of these third parties, and on the strength, validity and terms of our various contracts with these third party manufacturers, distributors and collaboration partners. Any interruption or failure by these suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, financial condition and results of operations.

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

We are dependent upon third parties to provide us with various estimates as a basis for our financial reporting. While we undertake certain procedures to review the reasonability of this information, we cannot obtain absolute assurance over the accounting methods and controls over the information provided to us by third parties. As a result we are at risk of them providing us with erroneous data which could have a material adverse impact on our business.

## **Table of Contents**

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

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our current products and products in development, including oxycodone, oxymorphone, morphine, fentanyl, sufentanil and hydrocodone, are listed by the DEA as Schedule II or III substances under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Furthermore, the DEA limits the availability of the active ingredients used in many of our current products and products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials. We must annually apply to the DEA for procurement quota in order to obtain these substances. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials, product launches or could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial position and results of operations.

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

The network through which we sell our products has undergone significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drug store chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. We expect that consolidation of drug wholesalers and retailers will place competitive pressures on drug manufacturers, including us. If we lose any of these customer accounts, or if our relationship with them were to deteriorate, our business could also be materially and adversely affected. Orders for our products may increase or decrease depending on the inventory levels held by our major customers. Significant increases and decreases in orders from our major customers could cause our operating results to vary significantly from quarter to quarter.

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

## **Table of Contents**

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

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

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

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors will remain highly dependent, in large part, upon our ability to attract and retain qualified scientific, technical and commercial personnel. The loss of key scientific, technical and commercial personnel or the failure to recruit additional key scientific, technical and commercial personnel could have a material adverse effect on our business. While we have consulting agreements with certain key individuals and institutions and have employment agreements with our key executives, we cannot assure you that we will succeed in retaining personnel or their services under existing agreements. There is intense competition for qualified personnel in the areas of our activities, and we cannot assure you that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business.

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

Goodwill and other intangibles represent a significant portion of our assets and stockholders' equity. As of December 31, 2006, goodwill and other intangibles comprised approximately 19% of our total assets and 25% of our stockholders' equity. Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets, prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit's fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount. Our other intangible assets, consisting of licenses and patents, are assessed for impairment, in accordance with Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the

---

**Table of Contents**

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, 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. During the fourth quarter of 2006, we recorded impairment charges of \$31.3 million related to certain intangible assets for Synera™ and DepoDur®. See the disclosures under Note 4. License and Collaboration Agreements, included the consolidated financial statements in Part IV, Item 15 of this Report for further information.

Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. As a result of the significance of goodwill and other intangible assets, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill or other intangible assets occur.

***We are a holding company with no operations.***

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

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

Our quarterly operating results are difficult to predict and may fluctuate significantly from period to period. Accordingly, one cannot predict our quarterly financial results based on our full-year financial guidance. We cannot predict with certainty the timing or level of sales of our products in the future. If our quarterly sales or operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Our operating results may fluctuate due to various factors including those set forth above. As a result of these factors, we believe that period-to-period comparisons of our operating results are not a good indication of our future performance. For example, our 2007 guidance is based upon our assumptions that our sales of Lidoderm®, Opana® and Opana® ER and Frova® will grow over the course of the year, but there can be no assurance.

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

The market prices for securities of healthcare companies in general have been highly volatile and may continue to be highly volatile in the future. Within the last 12 months through December 31, 2006, our stock has traded between \$21.06 and \$34.75 per share. The following factors, in addition to other risk factors described in this section, may cause the market price of our common stock to change:

FDA approval or disapproval of any of the drug applications we have submitted;

the success or failure of our clinical trials;

competitors announcing technological innovations or new commercial products;

introduction of generic substitutes for our products, including the filing of ANDAs with respect to generic versions of our branded products, including Lidoderm®;

**Table of Contents**

developments concerning our or others' proprietary rights, including patents;

competitors' publicity regarding actual or potential products under development;

regulatory developments in the United States and foreign countries, or announcements relating to these matters;

period-to-period fluctuations in our financial results;

new legislation in the United States relating to the sale or pricing of pharmaceuticals;

litigation; and

economic and other external factors, including disasters and other crises.

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

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

Of the 3,910,768 shares that may be issued upon the exercise of options outstanding as of December 31, 2006, 1,436,072 are vested, currently exercisable and eligible for sale.

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

We have not paid any cash dividends since our inception. 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. Further, should the company enter into a new credit facility with a third party lender, it is possible that the lender would limit or restrict the payment of dividends. We anticipate that, for the foreseeable future, we will retain our earnings in order to finance strategic investments in our business. As a result, investors in our stock may not be able to benefit from owning our stock unless the shares that these investors acquire appreciate in value.

***We are exposed to risks if we are unable to comply with changes to laws affecting public companies, including the Sarbanes-Oxley Act of 2002, and also to increased costs associated with complying with such laws.***

Recently enacted and any future changes to the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 in the U.S., will cause us to incur increased costs as we evaluate the implications of new rules and respond to new requirements. Delays or a failure to comply with the new laws, rules and regulations could result in enforcement actions, the assessment of other penalties and civil suits. The new laws and regulations make it more expensive for us under indemnities provided by the Company to our officers and directors and may make it more difficult for us to obtain certain types of



## **Table of Contents**

insurance, including liability insurance for directors and officers; as such, we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, or as executive officers. We may be required to hire additional personnel and utilize additional outside legal, accounting and advisory services all of which could cause our general and administrative costs to increase beyond what we currently have planned.

*Our operations could be disrupted if our information systems fail or if we are unsuccessful in implementing necessary upgrades.*

Our business depends on the efficient and uninterrupted operation of our computer and communications systems and networks, hardware and software systems and our other information technology. If our systems were to fail or we are unable to successfully expand the capacity of these systems, or we are unable to integrate new technologies into our existing systems, our operations and financial results could suffer.

*The publication of negative results of studies or clinical trials may adversely impact our sales revenue.*

From time to time, studies or clinical trials on various aspects of pharmaceutical products are conducted by academics or others, including government agencies. The results of these studies or trials, when published, may have a dramatic effect on the market for the pharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete could adversely affect our sales, the prescription trends for our products and the reputation of our products. In the event of the publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete, our business, financial condition and results of operations could be materially adversely affected.

*Patent litigation which is often time-consuming and expensive could have a material adverse effect on our business, results of operations and financial condition.*

The expense of patent litigation, whether or not we are successful, could have an adverse effect on our business, results of operations and financial condition. Regardless of FDA approval, should we commence a lawsuit against a third party for patent infringement or should there be a lawsuit commenced against us with respect to any alleged patent infringement by us, in either case, whether because of the filing of an ANDA or otherwise, the uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict. The cost of such litigation as well as the ultimate outcome of such litigation, if commenced, could have a material adverse effect on our business, results of operations and financial condition.

### **Item 1B Unresolved Staff Comments**

Not applicable.

### **Item 2. Properties**

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

## **Table of Contents**

### **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 an office 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 July 31, 2011. 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 leases to us an office 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.

*Painters Crossing Three Associates, L.P. Lease Agreement.* On January 19, 2007, we entered into a ten-year lease with Painters Crossing Three Associates, L.P. pursuant to which Painters Crossing will lease to us an office building, currently under construction, to be comprised of approximately 48,600 square feet. This lease will commence on April 1, 2008 and will end on March 31, 2018. 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.

*Brandywine III Associates, L.P. Lease Agreement.* On December 1, 2006, we entered into a two-year lease with Brandywine III Associates, L.P. pursuant to which Brandywine III Associates leases to us certain space comprised of approximately 15,087 square feet located in close proximity to our corporate headquarters in Chadds Ford, Pennsylvania. This lease commenced on December 1, 2006 and will end on November 30, 2008. Subsequent to the initial two-year lease period, the lease will automatically renew for periods of one-year unless or until terminated by either party on 180 days written notice. During the initial lease term, the annual rent is a fixed amount paid in equal monthly installments. During any renewal period the annual rent may increase based on prevailing market rates for comparable space, as determined by Brandywine III Associates L.P.

### **Westbury, New York**

*Dawson Holding Company Lease Agreement.* Under this agreement, dated January 6, 2003, we lease approximately 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 be 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

**Table of Contents**

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**

The disclosures under Note 10. Commitments and Contingencies-Legal Proceedings, included in the consolidated financial statements in Part IV, Item 15 of this Report are incorporated in this Part I, Item 3 by reference.

**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, 2006.

**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.

	Endo Common Stock	
	High	Low
Year Ending December 31, 2006		
1st Quarter	\$ 33.96	\$ 21.06
2nd Quarter	\$ 33.03	\$ 27.76
3rd Quarter	\$ 34.60	\$ 28.88
4th Quarter	\$ 34.75	\$ 26.68
Year Ending December 31, 2005		
1st Quarter	\$ 23.18	\$ 19.52
2nd Quarter	\$ 26.48	\$ 19.02
3rd Quarter	\$ 30.52	\$ 25.11
4th Quarter	\$ 31.93	\$ 24.36

*Holders.* As of February 16, 2007, we estimate that there were approximately 79 record holders of our common stock.

*Dividends.* We have never declared or paid any cash dividends on our capital stock. Prior to its expiration on December 21, 2006, our credit facility contained limitations and restrictions on the payment of dividends. Since these restrictions have lapsed, 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 strategic investments in our business.

**Table of Contents****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 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. Certain prior year amounts have been reclassified to conform to the current year presentation.

	2006	Year Ended December 31,			2002
		2005	2004	2003	
	(in thousands, except per share data)				
<b>Consolidated Statement of Operations Data:</b>					
Net sales	\$ 909,659	\$ 820,164	\$ 615,100	\$ 595,608	\$ 398,973
Cost of sales	201,421	186,350	140,989	135,671	98,857
Gross profit	708,238	633,814	474,111	459,937	300,116
Selling, general and administrative	340,094	211,246	179,270	298,753	144,808
Research and development	82,808	88,307	51,476	52,622	57,581
Depreciation and amortization	17,498	15,497	10,630	6,272	3,142
Loss on disposal of other intangible			3,800		
Impairment of other intangible assets	31,263	5,515			
Purchased in-process research and development	26,046			(6,966)	20,300
Manufacturing transfer fee					9,000
Operating income	210,529	313,249	228,935	109,256	65,285
Interest (income) expense, net	(23,205)	(10,995)	(2,161)	258	4,391
Income before income tax	233,734	324,244	231,096	108,998	60,894
Income tax	95,895	121,949	87,787	39,208	30,081
Net income	\$ 137,839	\$ 202,295	\$ 143,309	\$ 69,790	\$ 30,813
<b>Basic and Diluted Net Income Per Share:</b>					
Basic	\$ 1.03	\$ 1.53	\$ 1.09	\$ 0.54	\$ 0.30
Diluted	\$ 1.03	\$ 1.52	\$ 1.08	\$ 0.53	\$ 0.30
Shares Used to Compute Basic Net Income Per Share	133,178	132,242	131,805	128,417	102,064
Shares Used to Compute Diluted Net Income Per Share	133,911	133,289	132,718	132,439	102,126
Cash dividends declared per share					

	2006	As of and for the Year Ended December 31,			2002
		2005	2004	2003	
	(in thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 628,085	\$ 500,956	\$ 278,034	\$ 229,573	\$ 56,902
Working capital	697,915	483,872	294,329	287,922	105,058
Total assets	1,396,689	1,371,678	947,491	753,880	512,972
Other long-term obligations, including capitalized leases	17,602	18,795	18,293	589	7,851
Stockholders' equity	1,040,988	843,370	655,950	567,617	352,692
<b>Other Financial Data:</b>					
Net cash provided by operating activities	\$ 345,334	\$ 284,644	\$ 170,545	\$ 217,444	\$ 110,029
Net cash used in investing activities	(66,449)	(26,684)	(107,824)	(44,344)	(22,665)
Net cash used in financing activities	(151,756)	(35,038)	(14,260)	(429)	(125,819)

## **Table of Contents**

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ( MD&A ) should be read in conjunction with our audited consolidated financial statements and related notes thereto. 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 1 of this Report.

#### **Overview**

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 Wolters Kluwer Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$19.7 billion in 2006. This represents an approximately 8% compounded annual growth rate since 2002. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2006, analgesics were the fourth most prescribed medication in the United States with over 260 million prescriptions written for this classification. Opioid analgesics is a segment that comprised approximately 80% of the analgesic prescriptions for 2006. Total U.S. sales for the opioid analgesic segment were \$7.3 billion in 2006, representing a compounded annual growth rate of 8% since 2002.

We have a portfolio of branded products that includes established brand names such as Lidoderm<sup>®</sup>, Percocet<sup>®</sup>, Frova<sup>®</sup> and Percodan<sup>®</sup>, as well as three newly launched branded products in 2006 Opana<sup>®</sup> ER, Opana<sup>®</sup> and Synera<sup>™</sup>. Branded products comprised approximately 80% of our net sales in 2006, with 62% of our net sales coming from Lidoderm<sup>®</sup>. Our non-branded generic portfolio, which accounted for 20% of net sales in 2006, currently consists of products primarily focused in pain management, with our generic oxycodone extended-release tablets accounting for 6% of our net sales in 2006. We focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing.

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

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

Through a dedicated sales force of approximately 590 sales representatives in the United States, we market our branded pharmaceutical products to high-prescribing physicians in pain management, neurology, surgery, anesthesiology, oncology and primary care. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

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

## **Table of Contents**

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

### *Recent Developments*

In January 2007, the Company and Penwest entered into an amendment (the 2007 Amendment) to the 2002 amended and restated strategic alliance agreement between the parties (the 2002 Agreement). Under the terms of the 2007 Amendment, Endo and Penwest agreed to restructure the 2002 Agreement to provide that royalties payable to Penwest for U.S. sales of Opana® ER will be calculated based on net sales of the product rather than on operating profit, and to change certain other provisions of the 2002 Agreement. The 2007 Amendment also resolves the parties' ongoing disagreement with regard to sharing of marketing expenses during the period prior to when Opana® ER reaches profitability. The key financial terms of the 2007 Amendment are summarized as follows:

With respect to U.S. sales of Opana® ER, the Company's royalty payments to Penwest will be calculated starting at 22% of annual net sales of the product, and, based on agreed-upon levels of annual net sales achieved, the royalty rate can increase to a maximum of 30%.

No royalty payments will be due to Penwest for the first \$41 million of royalties that would otherwise have been payable beginning from the time of the product launch in July 2006.

Penwest is entitled to receive milestone payments of up to \$90 million based upon the achievement of certain agreed-upon annual sales thresholds.

As noted above, in 2003, Penwest opted out of funding of the development costs for Opana® ER. Under the 2002 Agreement between the parties, the Company was entitled to recoup Penwest's share of these development costs through a temporary adjustment in royalties. Under the 2007 Amendment, the parties have agreed that Penwest's share of these unfunded development costs will be fixed at \$28 million and will be recouped by the Company through a temporary 50% reduction in royalties payable to Penwest. This temporary reduction in royalties will not apply until the threshold for the royalty holiday referred to above has been met.

In January 2007, following an assessment of the status of DepoDur®, we announced that we notified SkyePharma PLC of our intent to terminate our development and commercialization agreement for this product and, in February 2007, entered into a termination agreement with SkyePharma whereby the Development and Marketing Strategic Alliance Agreement will terminate in its entirety on March 31, 2007. In order to provide for the continued commercial support of the DepoDur® product and the transition of such product to SkyePharma on March 31, 2007, Endo will continue to provide a number of services and undertake certain activities. Specifically, Endo will use commercially reasonable efforts to maintain and continue all U.S. commercial activities in support of DepoDur® through March 31, 2007, and at SkyePharma's option, on a month-to-month basis after March 31, 2007 but not beyond

## Table of Contents

June 30, 2007; and support and/or undertake the transition of certain Endo functions and activities (including third party activities) to SkyePharma that are useful and necessary for SkyePharma to assume commercial and related responsibilities for DepoDur® in the U.S. During the year ended December 31, 2006, as a result of the continued lack of commercial success of DepoDur® and, we recorded an impairment charge of \$14.8 million related to the remaining unamortized portion of our SkyePharma intangible asset.

In January 2007, we received a subpoena issued by the OIG. The subpoena requests documents relating to Lidoderm® (lidocaine patch 5%), primarily with regard to Lidoderm® sales, marketing, and promotion, and the Company's knowledge of physicians' use of Lidoderm® for non-indicated uses. We are cooperating with the government to provide the requested documents.

In December 2006, we announced the appointment of Charles A. Rowland, Jr. as Executive Vice President, Chief Financial Officer and Treasurer. Mr. Rowland has more than 20 years of pharmaceutical industry experience, including senior-level positions at Pharmacia Corp., Novartis and Bristol-Myers Squibb and most recently as Senior Vice President and Chief Financial Officer of Biovail Pharmaceuticals, Inc., a specialty pharmaceutical company. In his new role, Mr. Rowland will be responsible for all aspects of Endo's financial and accounting operations, as well as corporate communications.

In December 2006, we submitted a Citizen Petition with the U.S. Food and Drug Administration requesting that the FDA apply existing bioequivalence regulations to any ANDA seeking regulatory approval of a generic drug product that references Endo's Lidoderm®. On October 17, 2006, Endo became aware that, in response to an independent inquiry, the FDA's Office of Generic Drugs (OGD) had proposed that a study of blood levels of lidocaine should be used as the key measure in proving bioequivalence of a generic version of Lidoderm®. This petition emphasizes that this proposed new standard deviates from applicable regulations and OGD's past practices, both of which contemplate demonstration of bioequivalence for a topically acting product like Lidoderm® through a comparative clinical efficacy study. Lidoderm®, as a topical patch and not a systemic patch, acts at the site of application. As such, blood levels of the active ingredient, lidocaine, cannot be used as the key measure in proving bioequivalence. To appropriately assess the efficacy and safety of any generic version of Lidoderm®, Endo believes that it is critical that the FDA require any ANDA satisfy the regulations by following these additional criteria to those that FDA has proposed:

An applicant attempting to demonstrate bioequivalence of its generic product to Lidoderm® must conduct comparative clinical studies demonstrating identical safety and efficacy between the generic version and Lidoderm® and

An applicant relying on Lidoderm® as its Reference Listed Drug must show that its product produces the same local analgesic effect as Lidoderm® without producing a complete sensory block, in order to assure that the generic product has the same labeling, efficacy and safety profile as Lidoderm®.

In October 2006, the Company acquired all of the outstanding stock of RxKinetix, Inc., a privately held company headquartered in Boulder, Colorado, that develops new formulations of FDA-approved compounds for oral mucositis and other supportive care oncology conditions. The purchase price included an up-front payment of \$20 million, with the potential for up to an additional \$95 million in contingent earn-out payments based on clinical development and regulatory milestones.

## Table of Contents

On June 7, 2005, the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. affirmed the district court's decision that, while Endo's oxycodone extended-release tablets (a bioequivalent version of Purdue's OxyContin®) infringe the Purdue patents, the patents are unenforceable. On June 21, 2005, Purdue filed a petition with the Federal Circuit seeking rehearing of the appeal. On February 1, 2006, the Federal Circuit granted Purdue's motion for rehearing, vacated the June 7, 2005 decision of the district court, and remanded the case to the district court for further proceedings. The Federal Circuit's decision on rehearing directed the district court to give further consideration to its previous finding of unenforceability due to inequitable conduct. The Federal Circuit also affirmed the district court's finding that EPI's oxycodone extended-release tablets infringe the Purdue patents. Following the remand, we entered into settlement discussions with Purdue. On August 28, 2006, we executed a settlement agreement with Purdue pursuant to which we continued selling our oxycodone extended-release products until December 31, 2006. We and EPI, as well as our manufacturers, distributors, purchasers, and patients, were released from all liability for infringement of Purdue's patents in connection with EPI's prior and future sales of these products. On October 6, 2006, the district court entered a Consent Judgment, the effect of which is to conclude the litigation in accordance with the terms of the settlement agreement. See Item 3. Legal Proceedings for further information.

Our former Executive Vice President, Chief Financial Officer and Treasurer Jeffrey R. Black retired in August 2006. In August 2006, we appointed Joyce LaViscount, Vice President of Financial Analysis and Planning, as our Chief Accounting Officer pursuant to regulatory requirements.

On July 19, 2006, we and Vernalis plc announced that we had submitted to the FDA a sNDA for Frova® (frovatriptan succinate) 2.5 mg tablets for the short-term (six days per menstrual cycle) prevention of menstrual migraine (MM). This sNDA for Frova® is supported by data from four studies, including two Phase III studies examining the efficacy and safety of once- and twice-daily dose regimens of Frova® in the short-term prevention of MM, that both met their primary efficacy end-points a pharmacokinetics and tolerability study of once- and twice-daily dosing of Frova®, and a 12-month open-label safety study evaluating a six-day dosing regimen of Frova® in 525 women. If the sNDA is approved by the FDA, Frova® will be the only triptan indicated in the U.S. for the prevention of MM. The FDA has confirmed May 19, 2007 as the review completion date. Currently, Frova® is FDA-approved for the acute treatment of migraine attacks with or without aura in adults where a clear diagnosis of migraine has been established.

On March 15, 2006, Brian T. Clingen and Michael W. Mitchell resigned from our board of directors in order to devote more time to their respective current activities. In addition, Michael B. Goldberg and David I. Wahrhaftig, both managing directors of Kelso, also resigned from our board of directors effective on the same date; these resignations are consistent with Kelso's practice of not having its partners serve on the boards of directors of public companies unless Kelso's level of beneficial stock ownership in the Company is significant and warrants such participation. Following such resignations, our board of directors had seven board members, including John J. Delucca who was appointed on January 6, 2006 (see below) to replace Endo board member Frank J. Loverro, a managing director of Kelso, who resigned as a board member on that date. On April 20, 2006, we announced the appointment of Michel de Rosen to our Board of Directors. An independent, outside director, Mr. de Rosen is also a member of the Nominating & Governance Committee of the Board of Directors. Mr. de Rosen has served as the chairman of the board of directors of ViroPharma Incorporated since September 2002, president and chief executive officer since August 2000, and as a director since May 2000. From 1993 to 1999, Mr. de Rosen held several key positions in Rhone-Poulenc Pharma and Rhone-Poulenc Rorer (now Sanofi-Aventis), including chairman and chief executive officer from May 1995 until December 1999. Mr. de Rosen began his career at the French Ministry of Finance and subsequently served in several leading government positions. Mr. de Rosen also served in various executive roles in industry prior to 1993.



## **Table of Contents**

Mr. de Rosen also is a director of ABB Ltd. On August 9, 2006, we announced the appointment of George F. Horner III to our board of directors. Mr. Horner, the former chief executive officer and director of Vicuron Pharmaceuticals Inc. and current President and Chief Executive Officer of Prestwick Pharmaceuticals, Inc., replaced Joseph T. O'Donnell, Jr., who resigned. Mr. O'Donnell, who had served on the Endo board since 2000, had to relinquish his directorship due to a change in employment that precluded him from serving on other corporate boards. Mr. Horner has also been appointed as a member of the Compensation and Audit Committees of the Board of Directors. We continue to have an active process to identify potential candidates qualified to serve as members of our board of directors and may propose such persons for election or appointment in the future.

On January 6, 2006, we announced the appointment of John J. Delucca to our Board of Directors. An independent, outside director, Mr. Delucca also has been appointed as a member of the Compensation Committee and the Chairman of the Audit Committee of the Board of Directors. He replaced Frank J. Loverro, a managing director of Kelso & Company, who had been a member of the Board since July 2000 and who resigned on January 6, 2006. Mr. Delucca, 62, was executive vice president and chief financial officer of the REL Consultancy Group until his retirement in 2004. Prior to that, he served as chief financial officer and executive vice president, finance & administration, of Coty, Inc., from 1999 to 2002. From 1993 to 1999, he was senior vice president and treasurer of RJR Nabisco, Inc. During his career, he also served in executive positions for Hasco Associates, Inc., The Lexington Group, the Trump Group, International Controls Corp., and Textron, Inc. Mr. Delucca is currently a non-executive director and chairs the audit committees of ITC Deltacom, Enzo Biochem, Inc. and The Elliot Company. He also serves as a non-executive director and deputy chairman of the audit committee of British Energy PLC.

In January 2006, the Company completed a public offering of 15,000,000 shares of its common stock by certain of its stockholders. All of these shares were already issued and outstanding, except for approximately 40,000 shares representing shares underlying outstanding stock options. Endo Pharma LLC sold the majority of the shares sold. Certain current and former members of management have an ownership interest in Endo Pharma LLC. Shares were also sold by certain current and former members of management and certain current and former members of the Board of Directors of the Company. In March 2006, the Company completed a public offering of 10,510,108 shares of its common stock by certain of its stockholders. All of these shares were already issued and outstanding, except for approximately 26,250 shares representing shares underlying outstanding stock options. Endo Pharma LLC sold the majority of the shares sold. Shares were also sold by certain current and former members of management and certain current and former members of the Board of Directors of the Company. Following completion of these offerings and other option exercises during 2006, Endo Pharma LLC holds less than 1% of Endo's outstanding common stock.

## **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 revenue recognition and sales deductions for estimated chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, 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, the potential impairment of goodwill and other intangible

## **Table of Contents**

assets, income taxes, contingencies and stock-based compensation. 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:

### ***Revenue Recognition***

Our net sales consist of revenues from sales of our pharmaceutical products, less estimates for chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and losses. We recognize revenue for product sales when title and risk of loss has passed to the customer, which is typically upon delivery to the customer, when estimated provisions for chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and losses are reasonably determinable, and when collectibility is reasonably assured. Revenue from the launch of a new or significantly unique product, for which we are unable to develop the requisite historical data on which to base estimates of returns, due to the uniqueness of the therapeutic area or delivery technology as compared to other products in our portfolio and in the industry, may be deferred until such time that an estimate can be determined and all of the conditions above are met and when the product has achieved market acceptance, which is typically based on dispensed prescription data and other information obtained during the period following launch.

Decisions made by wholesaler customers and large retail chain customers regarding the levels of inventory they hold (and thus the amount of product they purchase from us) can materially affect the level of our sales in any particular period and thus may not correlate to the number of prescriptions written for our products based on external third-party data. We believe that speculative buying of product, particularly in anticipation of possible price increases, has been the historic practice of many pharmaceutical wholesalers. Over the past two years, our wholesaler customers, as well as others in the industry, began modifying their business models from arrangements where they derive profits from the management of various discounts and rebates, to arrangements where they charge a fee for their services. In connection with this new wholesaler business model we have entered into distribution service agreements (or DSAs) with three of our wholesaler customers. These agreements, which pertain to branded products only, obligate the wholesalers to provide us with specific services, including the provision of periodic retail demand information and current inventory levels for our branded products held at their warehouse locations; additionally, under these DSAs, the wholesalers have agreed to manage the variability of their purchases and inventory levels within specified limits based on product demand.

As of December 31, 2006, we received information from our two largest U.S. wholesaler customers about the levels of inventory they held for our branded products. Based on this information, which we have not independently verified, we believe that total branded inventory held at these wholesalers is within normal levels. In addition, we also evaluate market conditions for products primarily through the analysis of wholesaler and other third party sell-through and market research data, as well as internally-generated information. We believe sales recorded for the year ended December 31, 2006 were generally representative of underlying demand for the products.

**Table of Contents****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, certain royalties, DSA fees, returns and losses. These provisions, as described in greater detail below, 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 materially impacted.

The following table presents the activity and ending balances for our product sales provisions for the last three years (in thousands):

	>Returns	Rebates	Chargebacks	Other Sales Deductions	Total
Balance at January 1, 2004	\$ 22,698	\$ 44,784	\$ 28,304	\$ 1,786	\$ 97,572
Current year provision	25,582	107,475	211,904	22,371	367,332
Prior year provision	(1,388)	(4,229)			(5,617)
Payments or credits	(25,243)	(97,257)	(199,918)	(19,707)	(342,125)
<b>Balance at December 31, 2004</b>	<b>\$ 21,649</b>	<b>\$ 50,773</b>	<b>\$ 40,290</b>	<b>\$ 4,450</b>	<b>\$ 117,162</b>
Current year provision	23,391	191,220	325,392	52,858	592,861
Prior year provision	(4,004)	(7,759)			(11,763)
Payments or credits	(19,821)	(138,669)	(314,874)	(41,970)	(515,334)
<b>Balance at December 31, 2005</b>	<b>\$ 21,215</b>	<b>\$ 95,565</b>	<b>\$ 50,808</b>	<b>\$ 15,338</b>	<b>\$ 182,926</b>
Current year provision	22,780	171,185	416,852	33,254	644,071
Prior year provision	1,193	(4,709)	(1,614)		(5,130)
Payments or credits	(25,078)	(189,228)	(432,118)	(42,720)	(689,144)
<b>Balance at December 31, 2006</b>	<b>\$ 20,110</b>	<b>\$ 72,813</b>	<b>\$ 33,928</b>	<b>\$ 5,872</b>	<b>\$ 132,723</b>

**Returns**

Our provision for returns consists of our estimates of future product returns, pricing adjustments and delivery errors. Consistent with industry practice, we maintain a return policy that allows our customers to return product within a specified period of time both prior and subsequent to the product's expiration date. Our return policy allows customers to receive credit for expired products within six months prior to expiration and within one year after expiration. The primary factors we consider in estimating our potential product returns include:

the shelf life or expiration date of each product;

historical levels of expired product returns;

external data with respect to inventory levels in the wholesale distribution channel;

external data with respect to prescription demand for our products; and



## Table of Contents

estimated returns liability to be processed by year of sale based on analysis of lot information related to actual historical returns. In determining our estimates for returns, we are required to make certain assumptions regarding the timing of the introduction of new products and the potential of these products to capture market share. In addition, we make certain assumptions with respect to the extent and pattern of decline associated with generic competition. To make these assessments we utilize market data for similar products as analogs for our estimations. We use our best judgment to formulate these assumptions based on past experience and information available to us at the time. We continually reassess and make the appropriate changes to our estimates and assumptions as new information becomes available to us.

Our estimate for returns may be impacted by a number of factors, but the principal factor relates to the level of inventory in the distribution channel. When we are aware of an increase in the level of inventory of our products in the distribution channel, we consider the reasons for the increase to determine if the increase may be temporary or other-than-temporary. Increases in inventory levels assessed as temporary will not result in an adjustment to our provision for returns. Other-than-temporary increases in inventory levels, however, may be indication that future product returns could be higher than originally anticipated and, accordingly, we may need to adjust our estimate for returns. Some of the factors that may be an indication that an increase in inventory levels will be temporary include:

recently implemented or announced price increases for our products; and

new product launches or expanded indications for our existing products.

Conversely, factors that may be an indication that an increase in inventory levels will be other-than-temporary include:

declining sales trends based on prescription demand;

recent regulatory approvals to extend the shelf life of our products, which could result in a period of higher returns related to older product with the shorter shelf life;

introduction of new product or generic competition;

increasing price competition from generic competitors; and

recent changes to the National Drug Codes ( NDCs ) of our products, which could result in a period of higher returns related to product with the old NDC, as our customers generally permit only one NDC per product for identification and tracking within their inventory systems.

### *Rebates*

We establish contracts with wholesalers, chain stores and indirect customers that provide for rebates, sales incentives, DSA fees, 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. Our rebate programs can generally be categorized into the following four types:

direct rebates;

**Table of Contents**

indirect rebates;

managed care rebates; and

Medicaid and Medicare Part D rebates.

Direct rebates are generally rebates paid to direct purchasing customers based on a percentage applied to a direct customer's purchases from us, including DSA fees paid to wholesalers under our DSA agreements, as described above. Indirect rebates are rebates paid to indirect customers which have purchased our products from a wholesaler under a contract with us.

We are subject to rebates on sales made under governmental and managed-care pricing programs. In estimating our provisions for these types of rebates, we consider relevant statutes with respect to governmental pricing programs and contractual sales terms with managed-care providers and group purchasing organizations. We estimate an accrual for managed-care, Medicaid and Medicare Part D rebates as a reduction of revenue at the time product sales are recorded. These rebate reserves are estimated based upon the historical utilization levels, historical payment experience, historical relationship to revenues and estimated future trends. Changes in the level of utilization of our products through private or public benefit plans and group purchasing organizations will affect the amount of rebates that we owe.

We participate in state government-managed Medicaid programs, as well as certain other qualifying federal and state government programs whereby discounts and rebates are provided to participating government entities. Medicaid rebates are amounts owed based upon contractual agreements or legal requirements with public sector (Medicaid) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. Medicaid reserves are based on expected payments, which are driven by patient usage, contract performance, as well as field inventory that will be subject to a Medicaid rebate. Medicaid rebates are typically billed up to 180 days after the product is shipped, but can be as much as 270 days after the quarter in which the product is dispensed to the Medicaid participant. As a result, our Medicaid rebate provision includes an estimate of outstanding claims for end-customer sales that occurred but for which the related claim has not been billed, and an estimate for future claims that will be made when inventory in the distribution channel is sold through to plan participants. Our calculation also requires other estimates, such as estimates of sales mix, to determine which sales are subject to rebates and the amount of such rebates. Periodically, we adjust the Medicaid rebate provision based on actual claims paid. Due to the delay in billing, adjustments to actual may incorporate revisions of this provision for several periods. Medicaid pricing programs involve particularly difficult interpretations of statutes and regulatory guidance, which are complex and thus our estimates could differ from actual experience.

We continually update these factors based on new contractual or statutory requirements, and significant changes in sales trends that may impact the percentage of our products subject to rebates.

*Chargebacks*

The provision for chargebacks is one of the most significant and the most complex estimate used in the recognition of our revenue. We market and sell products directly to wholesalers, distributors, warehousing pharmacy chains, and other direct purchasing

## Table of Contents

groups. We also market products indirectly to independent pharmacies, non-warehousing chains, managed care organizations, and group purchasing organizations, collectively referred to as indirect customers. We enter into agreements with some indirect customers to establish contract pricing for certain products. These indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices. Alternatively, we may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, we provide credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price. Such credit is called a chargeback. The primary factors we consider in developing and evaluating our provision for chargebacks include:

the average historical chargeback credits;

estimated future sales trends; and

an estimate of the inventory held by our wholesalers, based on internal analysis of a wholesaler's historical purchases and contract sales.

### *Other sales deductions*

We offer our customers 2% prompt pay cash discounts. Provisions for prompt pay discounts are estimated and recorded at the time of sale. We estimate provisions for cash discounts based on contractual sales terms with customers, an analysis of unpaid invoices and historical payment experience. Estimated cash discounts have historically been predictable and less subjective, due to the limited number of assumptions involved, the consistency of historical experience and the fact that we generally settle these amounts within thirty to sixty days.

Shelf-stock adjustments are credits issued to our customers to reflect decreases in the selling prices of our products. These credits are customary in the industry and are intended to reduce a customer's inventory cost to better reflect current market prices. The determination to grant a shelf-stock credit to a customer following a price decrease is at our discretion rather than contractually required. The primary factors we consider when deciding whether to record a reserve for a shelf-stock adjustment include:

the estimated number of competing products being launched as well as the expected launch date, which we determine based on market intelligence;

the estimated decline in the market price of our product, which we determine based on historical experience and input from customers; and,

the estimated levels of inventory held by our customers at the time of the anticipated decrease in market price, which we determine based upon historical experience and customer input.

### *Royalties*

Royalties represent amounts accrued pursuant to the license agreement with Hind Healthcare Inc. (Hind). Royalties, payable to Hind, 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®.

## **Table of Contents**

### ***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.

### ***Goodwill and Other Intangibles***

Goodwill and other intangibles represent a significant portion of our assets and stockholders' equity. As of December 31, 2006, goodwill and other intangibles comprised approximately 19% of our total assets and 25% of our stockholders' equity. SFAS No. 142, *Goodwill and Other Intangible Assets*, prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit's fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount. 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. 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, 2007 and 2006, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

The cost of licenses are either expensed immediately or, if capitalized, are stated at cost, less accumulated amortization and are amortized using the straight-line method over their estimated useful lives ranging from ten to twenty years, with a weighted average useful life of approximately 16 years. 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



**Table of Contents**

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, generally 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. During the year ended December 31, 2006, due to the delay in the anticipated commercial success of DepoDur<sup>®</sup> and Synera<sup>®</sup>, we evaluated our SkyePharma and ZARS intangible assets for impairment and determined that an impairment did exist for each intangible asset. We recorded impairment losses of approximately \$31.3 million during the year ended December 31, 2006 with respect to these intangible assets.

Our goodwill and other intangible assets consist of the following at December 31, 2006 and December 31, 2005, respectively (in thousands):

	December 31, 2006	December 31, 2005
Goodwill	\$ 181,079	\$ 181,079
Amortizable Intangibles:		
Licenses	\$ 94,621	\$ 112,100
Patents	3,200	3,200
	97,821	115,300
Less accumulated amortization	(19,775)	(16,235)
Other Intangibles, net	\$ 78,046	\$ 99,065

Changes in the gross carrying amount of licenses for the two years ended December 31, 2006 were as follows (in thousands):

	Licenses
<i>Balance at January 1, 2005</i>	\$ 123,600
Noven impairment	(6,500)
SkyePharma payment	(5,000)
<i>Balance at December 31, 2005</i>	\$ 112,100
Synera acquisition	19,000
DepoDur <sup>®</sup> impairment	(20,000)
Synera <sup>™</sup> impairment	(16,479)
<i>Balance at December 31, 2006</i>	\$ 94,621

As of December 31, 2006, estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2006 is as follows (in thousands):

2007	\$ 6,209
2008	6,209
2009	6,209

2010	6,209
2011	6,209

---

**Table of Contents*****Income Taxes***

Provisions for income taxes are calculated on reported pre-tax income based on current tax laws, statutory tax rates and available tax incentives and planning opportunities in various jurisdictions in which we operate. Such provisions differ from the amounts currently receivable or payable because certain items of income and expense are recognized in different time periods for financial reporting purposes than for income tax purposes. Significant judgment is required in determining income tax provisions and evaluating tax positions. We establish reserves for income tax when, despite the belief that our tax positions are fully supportable, there remain certain positions that may be challenged and possibly disallowed by various authorities. The tax provision and related accruals include the impact of such reasonably estimable losses as deemed appropriate. The factors used to assess the likelihood of realization are the Company's forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. Failure to achieve forecasted taxable income in applicable tax jurisdictions could effect the ultimate realization of deferred tax assets and could result in an increase in the Company's effective tax rate on future earnings.

***Contingencies***

The Company is subject to various patent, product liability, government investigations and other legal proceedings in the ordinary course of business. Legal fees and other expenses related to litigation are expensed as incurred and included in selling, general and administrative expenses. Contingent accruals are recorded when the Company determines that a loss related to a litigation matter is both probable and reasonably estimable. Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our assessments involve significant judgments regarding future events.

***Stock-Based Compensation***

Prior to January 1, 2006, the Company accounted for its stock-based compensation plans under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations ( APB 25 ), as permitted by FASB Statement No. 123, *Accounting for Stock-Based Compensation*. No stock-based employee compensation cost was recognized in the Statement of Operations for the years ended December 31, 2005 and 2004. Effective January 1, 2006, the Company adopted the fair value recognition provisions of FASB Statement No. 123(R), *Share-Based Payment*, using the modified-prospective-transition method. Under that transition method, compensation cost recognized during the year ended December 31, 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of Statement No. 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of Statement No. 123(R). Results for prior periods have not been restated.

As a result of adopting Statement No. 123(R) on January 1, 2006, the Company's income before income tax and net income for the year ended December 31, 2006, are \$12.4 million (\$10.9 million in selling, general and administrative expenses and \$1.5 million in research and development expenses) and \$7.6 million lower, respectively, than if it had continued to account for share-based compensation under APB 25. Basic and diluted net income per share for the year ended December 31, 2006 are both \$0.06 lower than if the Company had not adopted Statement No. 123(R). This impact of adopting Statement No. 123(R) does not include approximately \$20 million in stock compensation charges related to the 809,893 options granted during the year ended December 31, 2006 under the Endo Pharma LLC plans as the stock-based compensation charge for this particular grant would have been identical under APB 25 and Statement No. 123(R). See the disclosures under Note 16. Related Party Transactions, included the consolidated financial statements in Part IV, Item 15 of this Report for further information.

**Table of Contents**

For all of the Company's stock-based compensation plans, the fair value of each grant was estimated at the date of grant using the Black-Scholes option-pricing model. Black-Scholes utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield (which is assumed to be zero, as the Company has not paid cash dividends to date and does not currently expect to pay cash dividends) and the expected term of the option. Expected volatilities utilized in the model are based mainly on the historical volatility of the Company's stock price and other factors. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The expected term of the option was calculated using the simplified method. Changes in the inputs and assumptions can materially affect the measure of the estimated fair value of our employee stock options. Also, the accounting estimate of stock-based compensation expense is reasonably likely to change from period to period as further stock options are granted and adjustments are made for stock option forfeitures and cancellations. Option-pricing models were developed for use in estimating the value of traded options that have no vesting or hedging restrictions and are fully transferable. Because the Company's employee stock options have certain characteristics that are significantly different from traded options, and because changes in the subjective assumptions can materially affect the estimated value, in management's opinion, the existing valuation models may not provide an accurate measure of the fair value of the Company's employee stock options. Although the fair value of employee stock options has been determined in accordance with SFAS 123(R), using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

As of December 31, 2006, the total remaining unrecognized compensation cost related to non-vested stock options amounted to \$29.2 million. The weighted average remaining requisite service period of the non-vested stock options was 2.6 years. This unrecognized compensation cost does not include the impact of any future stock-based compensation awards.

**Results of Operations for the Three Years Ended December 31, 2006**

Our quarterly and annual 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 compensation paid by Endo Pharma LLC, impairment of intangible assets, purchased in-process research and development charges and certain upfront, milestone and certain other payments made or accrued pursuant to licensing agreements.

**Net Sales**

The following table displays our net sales by product category and as a percentage of total net sales for the years ended December 31, 2006, 2005 and 2004 (dollars in thousands):

	Years Ended December 31					
	2006		2005		2004	
	\$	%	\$	%	\$	%
Lidoderm®	566,785	62	419,418	51	309,230	50
Percocet®	102,707	11	110,700	13	86,510	14
Frova®	40,564	5	38,096	5	11,449	2
Opana® ER and Opana®	6,845	1				
DepoDur®	2,993		3,931	1		
Other brands	11,034	1	11,098	1	15,481	3
<b>Total brands</b>	<b>730,928</b>	<b>80</b>	<b>583,243</b>	<b>71</b>	<b>422,670</b>	<b>69</b>
Generic oxycodone extended-release tablets	57,075	6	113,969	14		
Other generics	121,656	14	122,952	15	192,430	31
<b>Total generics</b>	<b>178,731</b>	<b>20</b>	<b>236,921</b>	<b>29</b>	<b>192,430</b>	<b>31</b>
<b>Total net sales</b>	<b>909,659</b>	<b>100</b>	<b>820,164</b>	<b>100</b>	<b>615,100</b>	<b>100</b>

**Table of Contents**

***Year Ended December 31, 2006 Compared to the Year Ended December 31, 2005***

**Net Sales.** Net sales for the year ended December 31, 2006 increased to \$909.7 million from \$820.2 million in the comparable 2005 period. This increase in net sales was primarily due to increased sales of Lidoderm<sup>®</sup>, as well as initial sales of Opana<sup>®</sup> and Opana<sup>®</sup> ER, which were launched in the second half of 2006. These increases were partially offset by the reduction in sales of our generic oxycodone extended-release tablets as well as reduced sales for Percocet<sup>®</sup>. Net sales of Lidoderm<sup>®</sup> increased to \$566.8 million from \$419.4 million in the comparable 2005 period due to the continued prescription growth of the product. We believe the continued growth of Lidoderm<sup>®</sup> is driven by the product's proven clinical effectiveness combined with incremental promotional support generated by the expansion of our sales force in 2006. In addition, we have benefited from a shift in enrollees, based on estimated patient enrollment, from Medicaid to Medicare under Medicare Part D, which resulted in a net decrease in the relevant rebate accruals. Sales of our generic oxycodone extended-release tablets decreased to \$57.1 million from \$114.0 million in the comparable 2005 period. After the expiration of our marketing exclusivity period on December 5, 2005, several competitors launched bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin<sup>®</sup>. The entrance of these competitors reduced our market share for bioequivalent versions of OxyContin<sup>®</sup>. In addition, in August 2006, we announced that we had reached an agreement with Purdue to settle long-running litigation claiming that our oxycodone extended-release tablets, 10mg, 20mg, 40mg, and 80mg, a bioequivalent versions of Purdue's OxyContin<sup>®</sup>, infringe Purdue's patents. Pursuant to the settlement, we discontinued selling our oxycodone extended-release products effective December 31, 2006. Net sales of our other generic products decreased to \$121.7 million from \$123.0 million in the comparable 2005 period. Continued generic competition has decreased both our market share as well as the price of these other generic products. Generic competition with our products may have a material impact on our results of operations and cash flows in the future. Due primarily to the expected increases in the net sales of Lidoderm<sup>®</sup> and Opana<sup>®</sup> ER and Opana<sup>®</sup> partially offset by the discontinuation of sales of our generic oxycodone extended-release tablets, we expect net sales in 2007 to be approximately \$1.025 billion and \$1.050 billion. There can be no assurance of Endo achieving these results.

**Gross Profit.** Gross profit for the year ended December 31, 2006 increased to \$708.2 million from \$633.8 million in the comparable 2005 period. Gross profit margins increased to 78% from 77%. This increase is primarily attributable to a shift in enrollees, based on estimated patient enrollment, from Medicaid to Medicare under Medicare Part D, as noted above. We expect the full-year 2007 gross profit margin to be essentially unchanged from 2006.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the year ended December 31, 2006 increased to \$340.1 million from \$211.2 million in the comparable 2005 period. The year-over-year increase is due to stock and cash compensation expense and the related employer payroll taxes of approximately \$41.3 million, which was funded entirely by Endo Pharma LLC and are related to the one-time stock and cash bonuses Endo Pharma LLC awarded to certain of our current and former executives

**Table of Contents**

(see the disclosures under Note 16. Related Party Transactions, included the consolidated financial statements in Part IV, Item 15 of this Report for further information), as well as the recording of stock-based compensation expense of approximately \$10.9 million as a result of the adoption of SFAS 123(R) on January 1, 2006. In addition, we escalated our sales and promotional efforts in 2006 over the comparable 2005 period due to our continued investment in our commercial business and our infrastructure to support our products and pipeline, including the addition of approximately 220 sales representatives and the pre-launch and launch expenses for Opana® ER and Opana®. During 2007, selling, general and administrative expenses is expected to rise, excluding the Endo Pharma LLC items noted above, due to increased promotional support behind Endo's key on-market products, including the full-year impact of the expansion of the sales force that occurred in the second half of 2006, combined with continuing investments in infrastructure to support Endo's long-term growth objectives.

**Research and Development Expenses.** Research and development expenses for the year ended December 31, 2006 decreased to \$82.8 million from \$88.3 million in the comparable 2005 period. This decrease is primarily attributable to the year-over-year difference in up-front license fees and milestone payments expensed during 2006 compared to 2005. During the year ended December 31, 2005, we expensed \$20 million related to the up-front license fees for the topical ketoprofen patch and the transdermal sufentanil patch as well as \$7.3 million in milestone payments related to Rapinyl. In comparison, during the year ended December 31, 2006, we expensed milestone payments of \$10.2 million related to the transdermal sufentanil patch and Rapinyl™. In addition, we incurred increased expenditures in 2006 related to the continuing clinical development of Rapinyl™, our topical ketoprofen patch and our transdermal sufentanil patch. In 2007, we expect to direct the majority of our incremental research and development spending on the ongoing clinical trials for Rapinyl™, the topical ketoprofen patch, the transdermal sufentanil patch and EN 3285, our oral rinse for the treatment of oral mucositis obtained through our acquisition of RxKinetix in October 2006. Additionally, we expect to increase our investment in post-marketing clinical studies in support of our on-market products.

**Depreciation and Amortization.** Depreciation and amortization for the year ended December 31, 2006 increased to \$17.5 million from \$15.5 million in the comparable 2005 period primarily due to an increase in amortization expense as a result of Synera™ license rights acquired in 2006 and an increase in depreciation expense as a result of an increase in capital expenditures. We expect depreciation to continue to increase as we increase our capital expenditures on our infrastructure and for new office and lab space and amortization expense may increase in the future as we continue to license in products and technologies.

**Impairment of Other Intangible Assets.** During the year ended December 31, 2006, due to the delay in the anticipated commercial success of DepoDur® and Synera, we evaluated our SkyePharma and ZARS intangible assets for impairment and determined that an impairment did exist for each intangible asset. We recorded impairment losses of approximately \$31.3 million during the year ended December 31, 2006 with respect to these intangible assets. For the year ended December 31, 2005, the impairment of other intangible assets is due to the FDA's decision not to approve Noven's ANDA for its developmental transdermal fentanyl patch and represents the unamortized portion of the upfront license fee that we paid Noven in February 2004.

**Purchased In-Process Research and Development.** Purchased in-process research and development for the year ended December 31, 2006 of \$26.0 million resulted from the estimated fair value of tangible and intangible assets to be used in research and development activities that we acquired from RxKinetix in October 2006. The amount of purchased in-process research and development recorded may increase or decrease in future periods subject to the amount of contingent consideration that may be paid upon the achievement of certain developmental and regulatory milestones.

## **Table of Contents**

**Interest Income, Net.** Interest income, net for the year ended December 31, 2006 was \$23.2 million compared to \$11.0 million in the comparable 2005 period. This increase is primarily due to increased interest income earned as a result of higher average cash balances during 2006.

**Income Tax.** Income tax for the year ended December 31, 2006 decreased to \$95.9 million from \$121.9 million in the comparable 2005 period. This decrease is due to the decrease in income before income tax for the year ended December 31, 2006 partially offset by an increase in our effective tax rate from 37.6% in 2005 to 41.0% in 2006. The higher effective tax rate for 2006 is a result of the non-deductible charge for purchased in-process research and development and certain non-deductible executive compensation charges funded by Endo Pharma LLC.

### ***Year Ended December 31, 2005 Compared to the Year Ended December 31, 2004***

**Net Sales.** Net sales for the year ended December 31, 2005 increased to \$820.2 million from \$615.1 million in the comparable 2004 period. This increase in net sales was primarily due to the increase in the net sales of Lidoderm<sup>®</sup>, Percocet<sup>®</sup>, our generic oxycodone extended-release product, sales of which were not present in the comparable 2004 period, and Frova<sup>®</sup>. These increases were offset by the reduction in the sales of certain of our generic products. Net sales of Lidoderm<sup>®</sup> increased to \$419.4 million from \$309.2 million in the comparable 2004 period due to the continued prescription growth of the product. Percocet<sup>®</sup> net sales increased to \$110.7 million from \$86.5 million in the comparable 2004 period. Net sales of Frova<sup>®</sup> increased to \$38.1 million from \$11.4 million in the comparable 2004 period. We began shipping Frova<sup>®</sup> 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 \$236.9 million from \$192.4 million in the comparable 2004 period primarily due to the net sales of \$114.0 million from our generic oxycodone extended-release product, which we launched in June 2005, offset by the reduction in the net sales of our morphine sulfate extended-release tablets and Endocet<sup>®</sup>, both of which experienced additional generic competition which had decreased both our market share as well as the price of these generic products.

**Gross Profit.** Gross profit for the year ended December 31, 2005 increased to \$633.8 million from \$474.1 million in the comparable 2004 period. Gross profit margins remained at 77% for the years ended December 31, 2005 and 2004.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the year ended December 31, 2005 increased to \$211.2 million from \$179.3 million in the comparable 2004 period. The year-over-year increase is due to our continued investment in our commercial business and our infrastructure to support our products and pipeline, including the addition of approximately 115 sales representatives in early 2005 to promote our products Lidoderm<sup>®</sup>, Frova<sup>®</sup> and DepoDur<sup>®</sup>.

**Research and Development Expenses.** Research and development expenses for the year ended December 31, 2005 increased to \$88.3 million from \$51.5 million in the comparable 2004 period. This increase is primarily related to \$20 million expensed during the year ended December 31, 2005 related to the upfront payments to license the topical ketoprofen patch and the transdermal sufentanil patch, \$7.3 million in milestone payments, incurred during the year ended December 31, 2005, to Orexo related to Rapinyl<sup>™</sup>, our increased developmental efforts with respect to oxymorphone extended-release tablets and immediate-release tablets and the

**Table of Contents**

advancement of other recently acquired products partially offset by \$10 million in milestone payments, incurred during the year ended December 31, 2004, to SkyePharma related to the FDA approval of DepoDur® and the advancement of Propofol IDD-D™ to the end of Phase II clinical development.

**Depreciation and Amortization.** Depreciation and amortization for the year ended December 31, 2005 increased to \$15.5 million from \$10.6 million in the comparable 2004 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.

**Loss on Disposal of Other Intangible.** For the year ended December 31, 2004, the loss on disposal of other intangible is due to the termination of our collaboration agreement with Lavipharm and the resulting write-off of the unamortized portion of the upfront license fee of \$0.8 million. The loss also includes a \$3 million termination payment made by us to Lavipharm.

**Impairment of Other Intangible Assets.** For the year ended December 31, 2005, the impairment of other intangible assets is due to the FDA's decision not to approve Noven's ANDA for its developmental transdermal fentanyl patch and represents the unamortized portion of the upfront license fee that we paid Noven in February 2004.

**Interest Income, Net.** Interest income, net for the year ended December 31, 2005 was \$11.0 million compared to \$2.2 million in the comparable 2004 period. This increase is substantially due to a full year of interest income earned on our note receivable from Vernalis in 2005 compared to a partial period of interest income earned on the note receivable from Vernalis in 2004, as the funds were loaned to Vernalis in August 2004, as well as increased interest income earned as a result higher average cash balances during 2005.

**Income Tax.** Income tax for the year ended December 31, 2005 increased to \$121.9 million from \$87.8 million in the comparable 2004 period. This increase is due to the increase in income before income tax for the year ended December 31, 2005 partially offset by a decrease in the effective tax rate from 38.0% in 2004 to 37.6% in 2005.

**Liquidity and Capital Resources**

Our principal source of liquidity is cash generated from operations. Our principal liquidity requirements are for working capital for operations, acquisitions, licenses, milestone payments and capital expenditures.

The following table summarizes our statement of cash flows and working capital (dollars in thousands):

	2006	2005	2004
Net cash flow provided by (used in):			
Operating activities	\$ 345,334	\$ 284,644	\$ 170,545
Investing activities	(66,449)	(26,684)	(107,824)
Financing activities	(151,756)	(35,038)	(14,260)
Net increase in cash and cash equivalents	127,129	222,922	48,461
Cash and cash equivalents, beginning of period	500,956	278,034	229,573
Cash and cash equivalents, end of period	\$ 628,085	\$ 500,956	\$ 278,034
Working capital	\$ 697,915	\$ 483,872	\$ 294,329
Current ratio	3.1:1	1.9:1	2.1:1
Days sales outstanding	55	50	48



**Table of Contents**

During 2006, we increased cash and cash equivalents by \$127.1 million to a balance of \$628.1 million. These funds, in addition to our cash generated from future operations are expected to be sufficient to meet our normal operating, investing and financing requirements in the foreseeable future, including the funding of our pipeline research and development projects in the event that our collaboration partners are unable or unwilling to fund their portion of any particular project. We may use a portion of our cash and cash equivalents for possible acquisitions and licensing opportunities.

**Net Cash Provided by Operating Activities.** Net cash provided by operating activities increased to \$345.3 million for the year ended December 31, 2006 from \$284.6 million for the year ended December 31, 2005. Significant components of the \$345.3 million of operating cash flows for the year ended December 31, 2006 included net income of \$137.8 million, purchased in-process research and development of \$26.0 million, compensation related to stock options of \$32.3 million, impairment charges of \$31.3 million, selling, general and administrative expenses funded by Endo Pharma LLC of \$21.4 million and a \$78.7 million decrease in net income taxes receivable, primarily due to the receipt of income tax refunds. See Working Capital below for more details.

**Net Cash Used in Investing Activities.** Net cash used in investing activities increased to \$66.4 million for the year ended December 31, 2006 from \$26.7 million for the year ended December 31, 2005. During the year ended December 31, 2006, the Company paid \$13.2 million for capital expenditures, and \$32.9 million for the acquisition of product rights to Synera and Frova<sup>®</sup> and \$20.5 million for all of the outstanding stock of RxKinetix.

**Net Cash Used in Financing Activities.** Net cash used in financing activities increased to \$151.8 million for the year ended December 31, 2006 from \$35.0 million for the year ended December 31, 2005. The increase is primarily due to a \$195.8 million payment to Endo Pharma LLC pursuant to the tax sharing agreement in 2006 compared to a \$42.8 million payment to Endo Pharma LLC pursuant to the tax sharing agreement in 2005 partially offset by \$38.0 million cash inflow related to the tax benefits of stock options exercised.

**Working Capital.** Working capital increased to \$697.9 million as of December 31, 2006 from \$483.9 million as of December 31, 2005. The primary drivers were the increase in cash and cash equivalents as well as a reduction in the amounts due to Endo Pharma LLC as a result of payments to Endo Pharma LLC during 2006 which reduced the balance due to Endo Pharma LLC to \$38.7 million at December 31, 2006 from \$200.5 million at December 31, 2005. Accounts receivable at December 31, 2006 decreased to \$279.2 million from \$290.8 million at December 31, 2005. Day sales in accounts receivable has increased to 55 days as of December 31, 2006 from 50 days as of December 31, 2005. This increase is primarily attributable to the timing of purchases by a major wholesaler customer during the fourth quarter of 2006 as compared to the fourth quarter of 2005. Since the annual calculation of days sales in accounts receivable assumes even sales throughout the year, and our quarterly results have fluctuated primarily due to timing of new product launches, purchasing patterns of our customers, market acceptance of our products and pricing, we believe that an annual calculation may not be meaningful. Therefore, we utilize a different methodology to analyze and assess the turnover and collectibility of our trade accounts receivable balances. Our methodology incorporates the timing of the sales on a more current basis and thus provides, we believe, a more meaningful depiction of the days sales in accounts receivable. Our methodology assumes that the earliest accounts receivable are always paid first which of course is not always the case across customers. Our sales are reported

**Table of Contents**

net of deductions for items such as chargebacks, returns and rebates and our trade accounts receivable are reported on a gross basis prior to these sales deductions with a corresponding liability on the balance sheet for these sales deductions. Our gross sales for the two months ended December 31, 2006 were \$303.8 million compared with gross sales of \$345.7 million for the two months ended December 31, 2005. This decrease in gross sales in these time periods resulted in a relative dollar decrease in our trade accounts receivable balance as of December 31, 2006 when compared to December 31, 2005. These are the inputs that we use in our calculation of days sales in accounts receivable.

**Acquisitions.** On October 12, 2006, the Company acquired all of the outstanding common stock of privately held RxKinetix, Inc. RxKinetix specializes in developing new therapeutics focused on improving the quality of life for patients being treated for cancer. RxKinetix's most advanced product, now named EN 3285, is currently in clinical Phase II for the prevention of oral mucositis, a painful, debilitating and often dose-limiting side effect that afflicts many patients being treated for cancer with radiation and/or chemotherapy. RxKinetix is a development stage company and therefore is being accounted for as an asset acquisition. The results of operations for RxKinetix have been included in our consolidated financial statements beginning on the acquisition date.

The purchase price of RxKinetix, as of the acquisition date, was \$20.5 million which was funded from our existing cash on hand. Additional contingent cash purchase consideration of up to \$95 million may become due upon the achievement of certain clinical and regulatory milestones. The Company has allocated the purchase price to the RxKinetix assets acquired and liabilities assumed at their estimated fair values, based on a number of factors, including the use of an independent appraisal. Estimated fair values were determined through the use of a discounted cash flow analysis using market participant assumptions. Of the purchase price, approximately \$26.0 million has been allocated to tangible and intangible assets to be used in research and development activities and those assets have been written-off to purchased in-process research and development, as of the acquisition date. The excess of fair value of the net assets acquired compared to the amount paid as of the acquisition date has been reflected as estimated amount due seller in accordance with SFAS No. 141, *Business Combinations*. Any contingent consideration paid in the future will be first applied to reduce the amount recorded as estimated amount due seller, and thereafter to the net assets acquired based on their relative fair values. Our preliminary purchase allocation is subject to revision; subsequent revisions, if any, are not expected to be material.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed the date of acquisition (in thousands):

Cash consideration	\$ 20,000
Direct acquisition costs	482
<b>Total purchase price</b>	<b>\$ 20,482</b>
Allocation of purchase price:	
Cash	\$ 9
Property and equipment	127
Purchased in-process research and development	26,046
Other assets	461
Deferred tax assets	10,699
Other liabilities	(1,330)
Estimated amount due seller	(15,530)
<b>Total purchase price</b>	<b>\$ 20,482</b>

**Table of Contents**

**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 provided us with a line of credit of \$75.0 million. We did not borrow any amounts under the facility during 2006, and the line of credit expired on December 21, 2006. The Company has not renegotiated a credit facility at this time.

**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 held approximately 15% of our common stock at December 31, 2005, but less than 1% of our common stock as of December 31, 2006, in which affiliates of Kelso & Company and certain current and former 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 have been and will be delivered. Because Endo Pharma LLC, and not us, has been and 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 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, 2006, approximately 36 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, 2006, approximately \$773 million), which is estimated to result in a tax benefit amount of approximately \$298 million. Under the tax sharing agreement, we are required to pay this \$298 million, \$252 million of which has already been paid as of December 31, 2006, 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. Additionally, as part of the tax sharing agreement, Endo Pharma LLC will reimburse us for the after-tax employer payroll taxes paid by us as a result of the exercise of the 36 million options discussed above. We have paid approximately \$11 million in employer payroll taxes, of which Endo Pharma LLC will reimburse us for approximately \$7 million which represents the after-tax employer payroll tax paid by us for the periods from 2001 through December 31, 2006. As of December 31, 2006, our net liability due to Endo Pharma LLC is approximately \$38.7 million. 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.

During the year ended December 31, 2006, approximately 3.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised. Since the attributable compensation charge deductions are usable to reduce our taxes in 2006, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$38.7 million, which is our net liability due to Endo Pharma LLC referred to above. Fifty percent of the estimated tax benefit amount attributable to these exercises and any additional tax benefits attributable to the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2006 will be due within 15 business days of the date we receive an opinion on our final audited 2006 financial statements from our independent registered public accounting firm, and the remaining tax benefit amount attributable to 2006 is due within 30 business days of the date on which we file our 2006 tax return with the Internal Revenue Service.

---

**Table of Contents**

As of December 31, 2006, there were approximately 0.1 million stock options, which expire in August 2007, remaining to be exercised under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of \$2.42 per share and an assumed tax rate of 38.25%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were vested and exercised, and assuming the price of our common stock was \$27.58 per share, the closing price on December 29, 2006, we would generally be able to deduct, for income tax purposes, compensation of approximately \$2 million, which could result in a tax benefit amount of approximately \$1 million payable to Endo Pharma LLC in 2008. This would represent the final tax sharing payment due to Endo Pharma LLC.

As of December 31, 2006, there were no options remaining to be granted under the Endo Pharma LLC stock option plans.

***Executive Compensation.*** In March 2006, Endo Pharma LLC advised our Board of Directors that it intended to pay a one-time cash bonus to each of Mr. Peter Lankau, our President and Chief Executive Officer, Ms. Caroline Manogue, our Executive Vice President, Chief Legal Officer and Secretary, and Mr. Jeffrey Black, our former Executive Vice President, Chief Financial Officer and Treasurer in the amount of \$3 million, \$6 million and \$10 million, respectively, in recognition of their significant contributions to our success. These bonus payments have been recorded in selling, general and administrative expenses during the year ended December 31, 2006. These payments were made by the Company in April 2006 and repaid to us by Endo Pharma LLC in the third quarter of 2006 with interest. In addition, only a portion of these bonus payments will be deductible for federal and state income tax purposes. We are not required to pay nor will we pay to Endo Pharma LLC the amount of any of the tax benefits related to these bonus payments pursuant to the tax sharing agreement between us and Endo Pharma LLC. These bonuses will be funded entirely by Endo Pharma LLC, with no contribution by us and they have been treated as a capital contribution by Endo Pharma LLC.

Endo Pharma LLC also informed us that, in connection with its eventual winding-up, it would make a special allocation to Ms. Carol Ammon, our Chairman of the Board and former Chief Executive Officer, of approximately \$22 million, with all or a portion of Ms. Ammon's payment being satisfied by granting to her the remaining unallocated Endo Pharma LLC stock options of approximately 0.8 million shares under the Endo Pharma LLC stock option plans. This amount has been recorded in selling, general and administrative expenses during the year ended December 31, 2006 and as a capital contribution by Endo Pharma LLC. This grant of options to Ms. Ammon was made during the fourth quarter of 2006. The 0.8 million options were granted by Endo Pharma LLC to Ms. Ammon in the fourth quarter of 2006 at an exercise price of \$2.42 per share. Therefore, approximately \$20 million of the \$22 million recorded in the first quarter of 2006, described above, was reclassified as a stock compensation expense representing the fair value of the option on the date of grant. These options were immediately vested and exercised by Ms. Ammon and the resulting compensation charge deduction of approximately \$19 million and the resulting tax sharing obligation to Endo Pharma LLC is included in our tax sharing liability discussed above. Endo Pharma LLC intends to pay the remaining \$2 million to Ms. Ammon in 2007.

***Settlement of Contingent Obligation.*** During the year ended December 31, 2005, the Company reached an agreement with an individual to compensate him a total of \$2 million for past services rendered to the Company. This agreement was finalized in May 2005, and the \$2 million has been recorded in selling, general and administrative expenses during the year ended December 31, 2005. Endo Pharma LLC made these payments totaling \$2 million on behalf of the Company, and they have been treated as a capital contribution by Endo Pharma LLC.

***Fluctuations.*** Our quarterly and annual 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

**Table of Contents**

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.

**Off-Balance Sheet Arrangements.** We have no off-balance sheet arrangements as defined in Item 303(a) (4) of Regulation S-K.

**Expected Cash Requirements for Contractual Obligations.** The following table presents our expected cash requirements for contractual obligations outstanding as of December 31, 2006 (in thousands):

Contractual Obligations	Total	2007	Payment Due by Period				Thereafter
			2008	2009	2010	2011	
Operating Lease Obligations	\$ 17,090	\$ 2,875	\$ 2,901	\$ 2,603	\$ 2,392	\$ 1,969	\$ 4,350
Capital Lease Obligations	1,991	1,479	489	23			
Minimum Purchase Commitments to Novartis	51,000	17,000	17,000	17,000			
Estimated Tax Sharing Payments Due to Endo Pharma LLC	38,693	38,693					
Limited Partnership Commitment(1)	7,300	7,300					
Total	\$ 116,074	\$ 67,347	\$ 20,390	\$ 19,626	\$ 2,392	\$ 1,969	\$ 4,350

- (1) 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 of December 31, 2006, we have invested \$2.7 million in this partnership.

In addition, we have agreed to certain contingent payments in certain of our acquisition, license, collaboration and other agreements. Payments under these agreements generally become due and payable only upon the achievement of certain developmental, regulatory, commercial and/or other milestones. Due to the fact that it is uncertain if and when these milestones will be achieved, such contingencies have not been recorded in our consolidated balance sheet, except for the \$15.5 million estimated amount due seller related to our acquisition of RxKinetix, and are not reflected in the table above. In addition, under certain arrangements, we may have to make royalty payments based on a percentage of future sales of the products in the event regulatory approval for marketing is obtained. From a business perspective, we view these payments favorably as they signify that the products are moving successfully through the development phase toward commercialization.

---

## **Table of Contents**

### **Recent Accounting Pronouncements**

In November 2004, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards ( SFAS ) No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*. The purpose of this statement is to clarify the accounting of abnormal amounts of idle facility expense, freight, handling costs and waste material. ARB No. 43 stated that under some circumstances these costs may be so abnormal that they are required to be treated as current period costs. SFAS No. 151 requires that these costs be treated, as current period costs regardless if they meet the criteria of so abnormal. In addition, the statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this Statement were effective for inventory costs incurred beginning on January 1, 2006. The adoption of SFAS No. 151 did not have a material impact on the Company s results of operations or financial position.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29*. SFAS No. 153 was effective for nonmonetary asset exchanges occurring after January 1, 2006. The adoption of SFAS No. 153 did not have a material impact on the Company s results of operations or financial position.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections*, a replacement of APB Opinion No. 20 and Statement No. 3. SFAS 154 changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle as well as to changes required by an accounting pronouncement that does not include specific transition provisions. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 did not have a material impact on the Company s results of operations or financial position.

In July 2006, the FASB issued FASB Interpretation No. 48 ( FIN 48 ), *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes*. FIN 48 creates a single model to address uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. In addition, FIN 48 clearly scopes out income taxes from SFAS No. 5, *Accounting for Contingencies*. FIN 48 is effective for fiscal years beginning after December 15, 2006. We do not expect the adoption of FIN 48 to have a material impact on our financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, which addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under accounting principles generally accepted in the United States. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of the adoption of this Statement on its financial statements.

In September 2006, the SEC staff issued Staff Accounting Bulletin No. 108 ( SAB 108 ), *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*. SAB 108 was issued in order to eliminate the diversity of practice surrounding how public companies quantify financial statement misstatements. In SAB 108, the SEC staff established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the Company s financial statements and the related financial statement disclosures. This model is commonly referred to as a dual approach because it requires quantification of errors under both the iron curtain and the roll-over methods. SAB 108 permits existing public companies to initially apply its provisions either by (i) restating prior financial statements as if the dual approach had always been used or (ii) recording the cumulative effect of initially applying the dual approach as adjustments to the carrying values of assets and liabilities as of January 1, 2006 with an offsetting adjustment recorded to the opening balance of retained

## **Table of Contents**

earnings. Use of the cumulative effect transition method requires detailed disclosure of the nature and amount of each individual error being corrected through the cumulative adjustment and how and when it arose. The adoption of SAB 108 did not have a material impact on the Company's financial statements.

In February 2007, the FASB issued SFAS No. 159 ( SFAS 159 ) *The Fair Value Option for Financial Assets and Financial Liabilities*, providing companies with an option to report selected financial assets and liabilities at fair value. This Standard's objective is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. SFAS 159 helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. SFAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. This Standard requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the Company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the Company has chosen to use fair value on the face of the balance sheet. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of the adoption of this Statement on its financial statements

### **Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

#### *Foreign Currency Risk*

While all of our net sales are within the United States and denominated in U.S. dollars, we purchase Lidoderm®, in U.S. dollars, from Teikoku Seiyaku Co., Ltd., a Japanese manufacturer. As part of the purchase agreement with Teikoku, there is a price adjustment feature that prevents the cash payment in U.S. dollars from falling outside of a certain pre-defined range in Japanese yen even if the spot rate is outside of that range. A 10% change in foreign currency exchange rates would not have a material impact on our financial condition, results of operations or cash flows.

#### *Interest Rate Risk*

The primary objective of our investment of cash surpluses is the protection of principal and, accordingly, we invest in taxable and tax-free money market funds with relatively short maturities. Therefore, our investment of cash surpluses is not subject to significant interest rate risk.

As of December 31, 2006 and December 31, 2005, we have no other assets or liabilities that have significant interest rate sensitivity.

#### *Investment Risk*

At December 31, 2006, we had publicly traded equity securities comprised of DURECT Corporation common stock at fair value totaling \$6.8 million in Other assets. The fair value of this investment is subject to significant fluctuations due to the volatility of the stock market, changes in general economic conditions and changes in the financial condition of DURECT. Based on the fair value of the publicly traded equity securities we held at December 31, 2006, an assumed 25%, 40% and 50% adverse change in the market prices of this security would result in a corresponding decline in total fair value of approximately \$1.7 million, \$2.7 million and \$3.4 million, respectively.

**Table of Contents**

*Inflation*

We do not believe that inflation has had a significant impact on our revenues or operations.

**Item 8. *Financial Statements and Supplementary Data***

The information required by this item is contained in the financial statements set forth in Item 15(a) under the caption Consolidated Financial Statements as part of this Annual Report on Form 10-K.

**Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

**Item 9A. *Controls and Procedures***  
***Disclosure Controls and Procedures***

Our management, including our Chief Executive Officer, Chief Financial Officer and Chief Accounting Officer, has conducted an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer, Chief Financial Officer and Chief Accounting Officer have concluded that our disclosure controls and procedures were effective for timely gathering, analyzing and disclosing the information we are required to disclose in our reports filed with the SEC under the Securities Exchange Act of 1934, as amended.

***Internal Control Over Financial Reporting***

In addition, we evaluated our internal control over financial reporting, and there have been no changes in our internal control over financial reporting that occurred during the fourth quarter of 2006 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Notwithstanding the foregoing, we hired Charles A. Rowland, Jr. as our Chief Financial Officer in December 2006. Inherent with any change in management is a change in understanding of the control environment and the internal controls.

Management's report on our internal control over financial reporting is included on page F-2. The report of our independent registered public accounting firm related to management's assessment of the effectiveness of internal control over financial reporting is included on page F-4.

**Item 9B. *Other Information***

On January 19, 2007, the Registrant's wholly-owned subsidiary Endo Pharmaceuticals Inc. entered into a 10-year lease with Painters Crossing Three Associates, L.P. (the Landlord) pursuant to which the Landlord will lease to us certain property comprised of approximately 48,600 square feet of office space, to be constructed by the Landlord (the Lease Agreement). The property is located on the campus of our corporate headquarters in the Painters Crossing Office Complex in Chadds Ford, Pennsylvania. The commencement date for our lease of this building will be on or after April 1, 2008, when the Landlord delivers the property with a



## **Table of Contents**

substantially completed building. This lease will expire on the last day of the 120<sup>th</sup> full month following the commencement date. This ten-year lease is not assignable without the written consent of the Landlord. During the first five years of the lease term, annual base rent is \$1,246,590 per year, payable in monthly installments. During the last five years of the lease term, annual base rent is \$1,455,570 per year, payable in monthly installments. In addition, the lease requires annual operating expense payments of \$201,690, payable in monthly installments and subject to escalation should the Landlord's actual operating expense exceed \$201,690 in any given lease year. We, along with the Landlord, have the right to terminate this lease at the end of the lease term by giving written notice at least 365 days prior thereto. In the absence of such notice, the lease will continue for a further period of one year and so on from year to year upon the same terms and conditions in force immediately prior to the expiration of the original lease term, except for base rent, which may be adjusted to reflect current market rates. During any such extension period, we may terminate the lease by giving the Landlord 180 days written notice prior to the expiration of the current term. For further information see the Lease Agreement between Painters Crossing Three Associates, L.P. and Endo Pharmaceuticals Inc. dated January 19, 2007 filed hereto as Exhibit 10.40 in Part IV, Item 15 of this Report.

## **PART III**

### **Item 10. *Directors, Executive Officers and Corporate Governance*** **Directors**

The information concerning our directors required under this Item is incorporated herein by reference from our proxy statement, which will be filed with the Securities and Exchange Commission, relating to our 2007 Annual Meeting of Stockholders (our 2007 Proxy Statement).

### **Executive Officers**

For information concerning Endo's executive officers, see Item 1. Business Executive Officers of the Registrant and our 2007 Proxy Statement.

### **Code of Ethics**

The information concerning our Code of Conduct is incorporated herein by reference from our 2007 Proxy Statement.

### **Audit Committee**

The information concerning our Audit Committee is incorporated herein by reference from our 2007 Proxy Statement.

### **Audit Committee Financial Experts**

The information concerning our Audit Committee Financial Experts is incorporated herein by reference from our 2007 Proxy Statement.

**Table of Contents**

**Item 11. *Executive Compensation***

The information required under this Item is incorporated herein by reference from our 2007 Proxy Statement.

**Table of Contents****Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

*Equity Compensation Plan Information.* The following information relates to plans in effect as of December 31, 2006 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)
<b>Equity compensation plans approved by security holders</b>			
Endo Pharma LLC Amended and Restated 1997 Employee Stock Option Plan	75,259(a)	\$ 2.42	
Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan	1,983,227	\$ 15.30	181,005
Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan	1,927,541	\$ 27.26	2,059,320
<b>Equity compensation plans not approved by security holders</b>			
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 current and former members of management have an interest), and their exercise will not dilute the ownership of our other common stockholders.

The other information required under this Item is incorporated herein by reference from our 2007 Proxy Statement.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required under this Item is incorporated herein by reference from our 2007 Proxy Statement.

**Item 14. Principal Accountant Fees and Services**

Information about the fees for 2006 and 2005 for professional services rendered by our independent registered public accounting firm is incorporated herein by reference from our 2007 Proxy Statement. Our Audit Committee's policy on pre-approval of audit and permissible non-audit services of our independent registered public accounting firm is incorporated by reference from our 2007 Proxy Statement.

**Table of Contents****PART IV****Item 15. Exhibits, Financial Statement Schedules**  
*Documents filed as part of this Annual Report on Form 10-K*

1. Consolidated Financial Statements: See accompanying Index to Consolidated Financial Statements.

2. Consolidated Financial Statement Schedule:

**SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS****(dollars in thousands)**

	<b>Balance at</b>			<b>Balance</b>
	<b>Beginning of</b>	<b>Additions,</b>		<b>at end</b>
	<b>Period</b>	<b>Costs</b>	<b>Deductions,</b>	<b>of period</b>
		<b>and</b>	<b>Write-offs</b>	
		<b>Expenses</b>		
<b>Allowance For Doubtful Accounts:</b>				
Year Ended December 31, 2004	\$ 1,106	\$ 341	\$	\$ 1,447
Year Ended December 31, 2005	\$ 1,447	\$ 28	\$	\$ 1,475
Year Ended December 31, 2006	\$ 1,475	\$	\$	\$ 1,475

All other financial statement schedules have been omitted because they are not applicable or the required information is included in the Consolidated Financial Statements or notes thereto.

3. Exhibits: The information called for by this item is incorporated by reference to the Exhibit Index of this Report.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ENDO PHARMACEUTICALS HOLDINGS INC.

(Registrant)

/s/ Charles A. Rowland, Jr.  
Name: Charles A. Rowland, Jr.  
Title: *Executive Vice President,*

*Chief Financial Officer and Treasurer*  
Date: March 1, 2007

Pursuant to the requirements of the Securities Exchange of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Peter A. Lankau Peter A. Lankau	President, Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2007
/s/ Charles A. Rowland, Jr. Charles A. Rowland, Jr.	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer)	March 1, 2007
/s/ Joyce N. LaViscount Joyce N. LaViscount	Chief Accounting Officer (Principal Accounting Officer)	March 1, 2007
* Carol A. Ammon	Chairman and Director	March 1, 2007
* Michel de Rosen	Director	March 1, 2007
* Michael Hyatt	Director	March 1, 2007
* Roger H. Kimmel	Director	March 1, 2007

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

*	Director	March 1, 2007
John J. Delucca		
*	Director	March 1, 2007
Clive A. Meanwell, M.D., Ph.D.		
*	Director	March 1, 2007
George F. Horner, III		
*By: /s/ Caroline B. Manogue	Attorney-in-fact, pursuant to a Power of Attorney filed with this Report as Exhibit 24	March 1, 2007
Caroline B. Manogue		

**Table of Contents**

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Management's Report on Internal Control Over Financial Reporting</u>	F-2
<u>Reports of Independent Registered Public Accounting Firm</u>	F-3, F-4
<u>Consolidated Balance Sheets as of December 31, 2006 and 2005</u>	F-5
<u>Consolidated Statements of Operations for the Years Ended December 31, 2006, 2005 and 2004</u>	F-6
<u>Consolidated Statements of Stockholders' Equity and Comprehensive Income for the Years Ended December 31, 2006, 2005 and 2004</u>	F-7
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2006, 2005 and 2004</u>	F-8
<u>Notes to Consolidated Financial Statements for the Years Ended December 31, 2006, 2005 and 2004</u>	F-9

**Table of Contents**

**MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

The management of Endo Pharmaceuticals Holdings Inc. is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Endo Pharmaceuticals Holdings Inc.'s internal control system was designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation and fair presentation of published financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Endo Pharmaceuticals Holdings Inc.'s management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2006. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*. Based on our assessment we believe that, as of December 31, 2006, the Company's internal control over financial reporting is effective based on those criteria.

Endo Pharmaceuticals Holdings Inc.'s independent registered public accounting firm has issued an attestation report on our assessment of the Company's internal control over financial reporting. This report appears on page F-4.

/s/ Peter A. Lankau  
Peter A. Lankau

President, Chief Executive Officer and Director  
(Principal Executive Officer)

/s/ Charles A. Rowland, Jr.  
Charles A. Rowland, Jr.

Executive Vice President, Chief Financial Officer and  
Treasurer (Principal Financial Officer)

/s/ Joyce N. LaViscount  
Joyce N. LaViscount

Chief Accounting Officer (Principal Accounting Officer)

March 1, 2007



**Table of Contents**

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Endo Pharmaceuticals Holdings Inc.

Chadds Ford, Pennsylvania

We have audited the accompanying consolidated balance sheets of Endo Pharmaceuticals Holdings Inc. and subsidiaries (the Company) as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity and comprehensive income, and cash flows for each of the three years in the period ended December 31, 2006. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Endo Pharmaceuticals Holdings Inc. and subsidiaries as of December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

As discussed in Note 2 to the consolidated financial statements, the Company adopted Statement of Financial Accounting Standards No. 123R, Share-Based Payment, on January 1, 2006.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2006, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 1, 2007 expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Philadelphia, Pennsylvania

March 1, 2007

**Table of Contents**

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Endo Pharmaceuticals Holdings Inc.

Chadds Ford, Pennsylvania

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that Endo Pharmaceuticals Holdings Inc. and subsidiaries (the Company) maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended December 31, 2006 of the Company and our report dated March 1, 2007 expressed an unqualified opinion on those financial statements and financial statement schedule and included an explanatory paragraph relating to the adoption of Statement of Financial Accounting Standards No. 123R in 2006.

/s/ DELOITTE & TOUCHE LLP

Philadelphia, Pennsylvania

March 1, 2007

F-4

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****CONSOLIDATED BALANCE SHEETS****DECEMBER 31, 2006 AND 2005****(In thousands, except share data)**

	2006	2005
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 628,085	\$ 500,956
Accounts receivable, net of allowance of \$1,475 at December 31, 2006 and 2005	279,159	290,826
Income taxes receivable		66,461
Inventories	62,129	50,983
Prepaid expenses and other current assets	11,663	14,445
Deferred income taxes	54,978	69,714
<b>Total current assets</b>	<b>1,036,014</b>	<b>993,385</b>
PROPERTY AND EQUIPMENT, Net	36,565	38,001
GOODWILL	181,079	181,079
OTHER INTANGIBLES, Net	78,046	99,065
NOTE RECEIVABLE, including accrued interest of \$6,185 and \$3,472 at December 31, 2006 and 2005, respectively	52,872	48,925
DEFERRED INCOME TAXES	1,745	
OTHER ASSETS	10,368	11,223
<b>TOTAL ASSETS</b>	<b>\$ 1,396,689</b>	<b>\$ 1,371,678</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 122,647	\$ 94,787
Accrued expenses	164,528	214,276
Due to Endo Pharma LLC	38,693	200,450
Income taxes payable	12,231	
<b>Total current liabilities</b>	<b>338,099</b>	<b>509,513</b>
DEFERRED INCOME TAXES		14,637
ESTIMATED AMOUNT DUE SELLER	15,530	
OTHER LIABILITIES	2,072	4,158
COMMITMENTS AND CONTINGENCIES (NOTE 12)		
<b>STOCKHOLDERS EQUITY:</b>		
Preferred Stock, \$0.01 par value; 40,000,000 shares authorized; none issued		
Common Stock, \$0.01 par value; 175,000,000 shares authorized; 133,600,959 and 132,800,873 shares issued and outstanding at December 31, 2006 and 2005, respectively	1,336	1,328
Additional paid-in capital	679,704	619,336
Retained earnings	358,831	220,992
Accumulated other comprehensive income	1,117	1,714
<b>Total stockholders equity</b>	<b>1,040,988</b>	<b>843,370</b>

TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	\$ 1,396,689	\$ 1,371,678
---	--------------	--------------

See notes to consolidated financial statements.

F-5

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**YEARS ENDED DECEMBER 31, 2006, 2005 AND 2004**

(In thousands, except per share data)

	2006	2005	2004
NET SALES	\$ 909,659	\$ 820,164	\$ 615,100
COST OF SALES <sup>(a)</sup>	201,421	186,350	140,989
<b>GROSS PROFIT</b>	<b>708,238</b>	<b>633,814</b>	<b>474,111</b>
COSTS AND EXPENSES:			
Selling, general and administrative	340,094	211,246	179,270
Research and development	82,808	88,307	51,476
Depreciation and amortization	17,498	15,497	10,630
Loss on disposal of other intangible, including license termination fee of \$3,000			3,800
Impairment of other intangible assets	31,263	5,515	
Purchased in-process research and development	26,046		
<b>OPERATING INCOME</b>	<b>210,529</b>	<b>313,249</b>	<b>228,935</b>
INTEREST INCOME, Net of interest expense of \$1,276, \$1,744 and \$1,255, respectively	(23,205)	(10,995)	(2,161)
<b>INCOME BEFORE INCOME TAX</b>	<b>233,734</b>	<b>324,244</b>	<b>231,096</b>
INCOME TAX	95,895	121,949	87,787
<b>NET INCOME</b>	<b>\$ 137,839</b>	<b>\$ 202,295</b>	<b>\$ 143,309</b>
NET INCOME PER SHARE:			
Basic	\$ 1.03	\$ 1.53	\$ 1.09
Diluted	\$ 1.03	\$ 1.52	\$ 1.08
WEIGHTED AVERAGE SHARES			
Basic	133,178	132,242	131,805
Diluted	133,911	133,289	132,718

(a) Exclusive of amortization of intangible assets.

See notes to consolidated financial statements.

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE INCOME****YEARS ENDED DECEMBER 31, 2006, 2005 AND 2004****(In thousands, except share data)**

	Number Of Shares	Common Stock at Par Value	Additional Paid-in Capital	Retained Earnings (Deficit)	Accumulated	Total Stockholders Equity	Comprehensive Income
					Other Comprehensive Income (Loss)		
BALANCE, JANUARY 1, 2004	131,769,766	\$ 1,318	\$ 691,631	\$ (124,612)	\$ (720)	\$ 567,617	\$
Tax sharing distributions made to Endo Pharma LLC			(13,549)			(13,549)	
Estimated tax sharing distributions due to Endo Pharma LLC			(42,939)			(42,939)	
Exercise of options	86,248	1	772			773	
Unrealized gain on securities, net of tax					739	739	739
Net income				143,309		143,309	143,309
Comprehensive income							\$ 144,048
BALANCE, DECEMBER 31, 2004	131,856,014	\$ 1,319	\$ 635,915	\$ 18,697	\$ 19	\$ 655,950	
Estimated tax sharing distributions due to Endo Pharma LLC			(194,662)			(194,662)	
Selling, general and administrative expenses funded by Endo Pharma LLC			2,000			2,000	
Exercise of options	944,859	9	10,180			10,189	
Tax benefits of stock options exercised			165,903			165,903	
Unrealized gain on securities, net of tax					1,695	1,695	1,695
Net income				202,295		202,295	202,295
Comprehensive income							\$ 203,990
BALANCE, DECEMBER 31, 2005	132,800,873	\$ 1,328	\$ 619,336	\$ 220,992	\$ 1,714	\$ 843,370	
Estimated tax sharing distributions due to Endo Pharma LLC			(39,702)			(39,702)	

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Selling, general and administrative expenses funded by Endo Pharma LLC			21,423				21,423	
Compensation related to stock options			32,279				32,279	
Exercise of options	800,086	8	8,435				8,443	
Tax benefits of stock options exercised			37,933				37,933	
Unrealized loss on securities, net of tax						(597)	(597)	(597)
Net income					137,839		137,839	137,839
Comprehensive income								\$ 137,242
BALANCE, DECEMBER 31, 2006	133,600,959	\$ 1,336	\$ 679,704	\$ 358,831	\$ 1,117	\$ 1,040,988		

See notes to consolidated financial statements.

F-7



**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**YEARS ENDED DECEMBER 31, 2006, 2005 AND 2004**

(In thousands)

	2006	2005	2004
<b>OPERATING ACTIVITIES:</b>			
Net income	\$ 137,839	\$ 202,295	\$ 143,309
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	17,498	15,497	10,630
Purchased in-process research and development	26,046		
Accretion of interest on note receivable	(1,240)	(1,240)	(413)
Deferred income taxes	9,352	(30,894)	6,829
Tax benefits of stock options exercised		206,228	43,345
Amortization of deferred financing costs	351	383	390
Stock-based compensation	32,279		
Loss on disposal of other intangible			3,800
Impairment of other intangible assets	31,263	5,515	
Loss on disposal of property and equipment	942	290	248
Selling, general and administrative expenses to be funded by Endo Pharma LLC	21,423	2,000	
Changes in assets and liabilities which provided (used) cash:			
Accounts receivable	11,667	(146,787)	(37,755)
Inventories	(11,146)	20,432	(20,965)
Note receivable	(2,707)	(2,638)	(834)
Prepaid and other assets	2,781	(2,084)	(5,200)
Accounts payable	30,771	9,968	16,661
Accrued expenses	(34,853)	68,352	22,958
Due to Endo Pharma LLC	(5,624)	5,624	
Income taxes receivable/payable	78,692	(68,297)	(12,458)
Net cash provided by operating activities	345,334	284,644	170,545
<b>INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	(13,219)	(10,491)	(8,118)
Proceeds from sale of property and equipment	143	7	294
Payment of license termination fee			(3,000)
Loan made to Vernalis			(50,000)
License fees	(32,900)	(14,500)	(46,500)
Acquisition, net of cash acquired	(20,473)		
Other investments		(1,700)	(500)
Net cash used in investing activities	(66,449)	(26,684)	(107,824)
<b>FINANCING ACTIVITIES:</b>			
Capital lease obligations repayments	(2,367)	(2,452)	(1,484)
Tax sharing payments to Endo Pharma LLC	(195,835)	(42,775)	(13,549)
Tax benefits of stock options exercised	38,003		
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options	8,443	10,189	773
Net cash used in financing activities	(151,756)	(35,038)	(14,260)

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

NET INCREASE IN CASH AND CASH EQUIVALENTS	127,129	222,922	48,461
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	500,956	278,034	229,573
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 628,085	\$ 500,956	\$ 278,034
SUPPLEMENTAL INFORMATION:			
Interest paid	\$ 1,659	\$ 878	\$ 415
Income taxes paid	\$ 39,978	\$ 17,002	\$ 48,901
SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Purchase of property and equipment financed by capital leases	\$ 172	\$ 5,546	\$ 5,071
Change in accrual for purchases of property and equipment	\$ 3,764	\$ (1,560)	\$ (1,527)

See notes to consolidated financial statements.

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****YEARS ENDED DECEMBER 31, 2006, 2005 AND 2004****1. Description of Business**

Endo Pharmaceuticals Holdings Inc. (the Company or we) is a specialty pharmaceutical company with market leadership in pain management. The Company, through its wholly-owned subsidiary, Endo Pharmaceuticals Inc. (Endo or EPI), is engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used to treat and manage pain, primarily in the United States. The Company was incorporated on November 18, 1997 under the laws of the state of Delaware. The stock of Endo is the only asset of the Company, and the Company has no other operations or business.

**2. Summary of Significant Accounting Policies**

*Principles of Consolidation* The consolidated financial statements include the accounts of Endo Pharmaceuticals Holdings Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated.

*Use of Estimates* The preparation of our financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and use 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. Actual results could differ from those estimates. The most significant estimates made and assumptions used are in the determination of sales deductions for estimated chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and losses; inventory reserves; deferred taxes; contingencies; the valuation of stock-based compensation; the capitalization of and the selection of amortization periods for intangible assets with finite lives; and the assessment of the recoverability of goodwill and other intangible assets.

*Customer, Product and Supplier Concentration* 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 products to pharmacies, hospitals, governmental agencies and physicians. Net sales to customers who accounted for 10% or more of our net sales during the years ended December 31, 2006, 2005 and 2004 were as follows:

	2006	2005	2004
Company A	29%	31%	29%
Company B	28%	27%	18%
Company C	15%	13%	18%

The Company derives a majority of its net sales from a limited number of products. Net sales that accounted for 10% or more of our total net sales during the years ended December 31, 2006, 2005 and 2004 were as follows:

	Years Ended December 31		
	2006	2005	2004
Lidoderm®	62%	51%	50%
Percocet®	11%	13%	14%
Endocet®	9%	8%	19%
Generic oxycodone extended-release tablets	6%	14%	%
Generic morphine sulfate	4%	5%	10%

## **Table of Contents**

We have agreements with Novartis Consumer Health, Inc. and Teikoku Seiyaku Co., Ltd. for the manufacture and supply of a substantial portion of our existing pharmaceutical products (see Note 12).

*Revenue Recognition* Our net sales consist of revenues from sales of our pharmaceutical products, less estimates for chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and losses. We recognize revenue for product sales when title and risk of loss has passed to the customer, which is typically upon delivery to the customer, when estimated provisions for chargebacks, rebates, sales incentives and allowances, certain royalties, distribution service fees, returns and losses are reasonably determinable, and when collectibility is reasonably assured. Revenue from the launch of a new or significantly unique product, for which we are unable to develop the requisite historical data on which to base estimates of returns, due to the uniqueness of the therapeutic area or delivery technology as compared to other products in our portfolio and in the industry, may be deferred until such time that an estimate can be determined and all of the conditions above are met and when the product has achieved market acceptance, which is typically based on dispensed prescription data and other information obtained during the period following launch.

*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, certain royalties, distribution service fees, 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.

*Research and Development* Expenditures for research and development are expensed as incurred. Property and equipment that are acquired or constructed for research and development activities and that have alternate future uses are capitalized and depreciated over their estimated useful lives on a straight-line basis. Upfront and milestone payments made to third parties in connection with agreements with third parties are generally expensed as incurred up to the point of regulatory approval, absent any alternative future uses. Payments made to third parties subsequent to regulatory approval are generally capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

*Purchased In-Process Research and Development* Purchased in-process research and development represents the estimated fair value assigned to research and development projects acquired in a purchase business combination or asset acquisition that have not been completed at the date of acquisition and which have no alternative future use. Accordingly, these costs are charged to expense as of the acquisition date.

*Cash and Cash Equivalents* The Company considers all highly liquid investments with an original maturity date of three months or less to be cash equivalents.

*Concentrations of Credit Risk* Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash equivalents, accounts receivable and our note receivable. We invest our excess cash in high-quality, liquid money market instruments maintained by financial institutions. We have not experienced any significant losses on our cash

## **Table of Contents**

equivalents. We perform ongoing credit evaluations of our customers and generally do not require collateral. We have no history of significant losses from uncollectible accounts. Approximately 81% and 80% of our trade accounts receivable balance represent amounts due from three customers at December 31, 2006 and 2005, respectively. Our note receivable is secured by certain assets of the counterparty and future royalty and milestone payments due from the counterparty (See Note 8).

*Fair Value of Financial Instruments* The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses are a reasonable estimate of their fair values because of the current maturities of these instruments. The carrying amount of our note receivable approximates its fair value as the effective rate for this note is comparable to market rates at December 31, 2006. Marketable securities, which are included in other assets, are comprised of our investment in shares of common stock of DURECT Corporation, are recorded at their fair value of approximately \$6.8 million at December 31, 2006.

*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.

*Property and Equipment* Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed over the estimated useful lives of the related assets, ranging from two to ten years, on a straight-line basis. Leasehold improvements and capital lease assets are amortized on a straight-line basis over the shorter of their estimated useful lives or the terms of their respective leases and this amortization is included in depreciation expense.

*License Rights* Licenses are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives ranging from ten to twenty years, with a weighted average useful life of approximately 16 years. 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 net income per share to decrease.

*Patents* Patents are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives of seventeen years.

*Impairment of Long-Lived Assets* Long-lived assets, which includes property and equipment, license rights 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 generated by that asset. In the event the carrying value of the asset exceeds the undiscounted future cash flows generated by that asset and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs. As a result of the significance of our long-lived assets, any recognized impairment loss could have a material adverse impact on our financial position and/or results of operations.

## **Table of Contents**

*Goodwill* Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, ( SFAS No. 142 ), goodwill is not amortized; rather, it is subject to a periodic assessment for impairment by applying a fair-value-based test. Goodwill is assessed on an annual basis on January 1st of each year for impairment or more frequently if impairment indicators arise. SFAS No. 142 prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit's fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount. On January 1, 2007 and 2006, our goodwill was evaluated for impairment and, based on the fair value of our one reporting unit, no impairment was identified. 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.

*Advertising Costs* Advertising costs are expensed as incurred and included in selling, general and administrative expenses and amounted to \$41.0 million, \$23.2 million and \$30.2 million for the years ended December 31, 2006, 2005 and 2004, respectively.

*Income Taxes* The Company accounts for income taxes and the related accounts under the liability method. Deferred tax liabilities and assets are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted rates expected to be in effect during the year in which the basis differences reverse.

*Contingencies* The Company is subject to litigation in the ordinary course of business. Legal fees and other expenses related to litigation are expensed as incurred and included in selling, general and administrative expenses. Accruals are recorded when the Company determines that a loss related to a litigation matter is both probable and reasonably estimable.

*Stock-Based Compensation* Prior to January 1, 2006, the Company accounted for its stock-based compensation plans under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations ( APB 25 ), as permitted by FASB Statement No. 123, *Accounting for Stock-Based Compensation*. No stock-based employee compensation cost was recognized in the Statement of Operations for the years ended December 31, 2005 and 2004. Effective January 1, 2006, the Company adopted the fair value recognition provisions of FASB Statement No. 123(R), *Share-Based Payment*, using the modified-prospective-transition method. Under that transition method, compensation cost recognized during the year ended December 31, 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of Statement No. 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of Statement No. 123(R), recognized on a straight-line basis. Results for prior periods have not been restated.

**Table of Contents**

As a result of adopting Statement No. 123(R) on January 1, 2006, the Company's income before income taxes and net income for the year ended December 31, 2006, are \$12.4 million (\$10.9 million in selling, general and administrative expenses and \$1.5 million in research and development expenses) and \$7.6 million lower, respectively, than if it had continued to account for share-based compensation under APB 25. Basic and diluted net income per share for the year ended December 31, 2006 are both \$0.06 lower, than if the Company had not adopted Statement No. 123(R). This impact of adopting Statement No. 123(R) does not include approximately \$20 million in stock compensation charges related to the 809,893 options granted during the year ended December 31, 2006 under the Endo Pharma LLC plans as the stock-based compensation charge for this particular grant would have been identical under APB 25 and Statement No. 123(R). (See Note 16 for additional disclosure regarding this particular option grant).

Prior to the adoption of Statement No. 123(R), the Company presented all tax benefits of deductions resulting from the exercise of stock options as operating cash flows in the Statement of Cash Flows. Statement No. 123(R) requires the cash flows resulting from the tax benefits resulting from tax deductions in excess of the compensation cost recognized for those options (excess tax benefits) to be classified as financing cash flows. The \$38.0 million excess tax benefit classified as a financing cash inflow would have been classified as an operating cash inflow if the Company had not adopted Statement No. 123(R).

The following table illustrates the effect on net income and net income per share if the Company had applied the fair value recognition provisions of Statement No. 123 to options granted under the Company's stock-based compensation plans for the years ended December 31, 2005 and 2004 (in thousands, except per share data). For purposes of this pro forma disclosure, the value of the options was estimated using a Black-Scholes option-pricing model and amortized to expense over the options' vesting periods.

	2005	2004
Net income, as reported	\$ 202,295	\$ 143,309
Deduct: Total stock-based employee compensation expense determined under fair value based methods for all awards	(7,203)	(5,901)
Add: Tax effect of stock-based employee compensation expense under fair value based methods	2,766	2,244
Pro forma net income	\$ 197,858	\$ 139,652
Basic earnings per share, as reported	\$ 1.53	\$ 1.09
Basic earnings per share, pro forma	\$ 1.50	\$ 1.06
Diluted earnings per share, as reported	\$ 1.52	\$ 1.08
Diluted earnings per share, pro forma	\$ 1.48	\$ 1.05
Weighted average shares outstanding		
Basic	132,242	131,805
Diluted	133,289	132,718

*Segment Information* We report segment information in accordance with SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*. We have one reportable segment, pharmaceutical products.

*Comprehensive Income* Comprehensive income includes all changes in equity during a period except those that resulted from investments by or distributions to a company's stockholders. Other comprehensive income refers to revenues, expenses, gains and losses that are included in comprehensive income, but excluded from net income as these amounts are recorded directly as an

---

**Table of Contents**

adjustment to stockholders' equity. Our other comprehensive income or loss is comprised of unrealized holding gains and losses, net of income taxes, on the 1.5 million shares of publicly traded common stock of DURECT that we own.

*Recent Accounting Pronouncements*

In November 2004, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards ( SFAS ) No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*. The purpose of this statement is to clarify the accounting of abnormal amounts of idle facility expense, freight, handling costs and waste material. ARB No. 43 stated that under some circumstances these costs may be so abnormal that they are required to be treated as current period costs. SFAS No. 151 requires that these costs be treated, as current period costs regardless if they meet the criteria of so abnormal. In addition, the statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this Statement were effective for inventory costs incurred beginning on January 1, 2006. The adoption of SFAS No. 151 did not have a material impact on the Company's results of operations or financial position.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29*. SFAS No. 153 was effective for nonmonetary asset exchanges occurring after January 1, 2006. The adoption of SFAS No. 153 did not have a material impact on the Company's results of operations or financial position.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections*, a replacement of APB Opinion No. 20 and Statement No. 3. SFAS 154 changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle as well as to changes required by an accounting pronouncement that does not include specific transition provisions. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 did not have a material impact on the Company's results of operations or financial position.

In July 2006, the FASB issued FASB Interpretation No. 48 ( FIN 48 ), *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes*. FIN 48 creates a single model to address uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. In addition, FIN 48 clearly scopes out income taxes from SFAS No. 5, *Accounting for Contingencies*. FIN 48 is effective for fiscal years beginning after December 15, 2006. We do not expect the adoption of FIN 48 to have a material impact on our financial statements.

In September 2006, the FASB issued SFAS No.157, *Fair Value Measurements*, which addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under accounting principles generally accepted in the United States. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of the adoption of this Statement on its financial statements.

In September 2006, the SEC staff issued Staff Accounting Bulletin No. 108 ( SAB 108 ), *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*. SAB 108 was issued in order to eliminate the diversity of practice surrounding how public companies quantify financial statement misstatements. In SAB 108, the SEC staff



---

**Table of Contents**

established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the Company's financial statements and the related financial statement disclosures. This model is commonly referred to as a "dual approach" because it requires quantification of errors under both the "iron curtain" and the "roll-over" methods. SAB 108 permits existing public companies to initially apply its provisions either by (i) restating prior financial statements as if the "dual approach" had always been used or (ii) recording the cumulative effect of initially applying the "dual approach" as adjustments to the carrying values of assets and liabilities as of January 1, 2006 with an offsetting adjustment recorded to the opening balance of retained earnings. Use of the "cumulative effect" transition method requires detailed disclosure of the nature and amount of each individual error being corrected through the cumulative adjustment and how and when it arose. The adoption of SAB 108 did not have an impact on the Company's financial statements.

In February 2007, the FASB issued SFAS No. 159 ( "SFAS 159" ) *The Fair Value Option for Financial Assets and Financial Liabilities*, providing companies with an option to report selected financial assets and liabilities at fair value. This Standard's objective is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Generally accepted accounting principles have required different measurement attributes for different assets and liabilities that can create artificial volatility in earnings. SFAS 159 helps to mitigate this type of accounting-induced volatility by enabling companies to report related assets and liabilities at fair value, which would likely reduce the need for companies to comply with detailed rules for hedge accounting. SFAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. This Standard requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the Company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the Company has chosen to use fair value on the face of the balance sheet. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of the adoption of this Statement on its financial statements

**3. Acquisitions***RxKinetix, Inc.*

On October 12, 2006, the Company acquired all of the outstanding common stock of privately held RxKinetix, Inc. RxKinetix specializes in developing new therapeutics focused on improving the quality of life for patients being treated for cancer. RxKinetix's most advanced product, now named EN 3285, is currently in clinical Phase II for the prevention of oral mucositis, a painful, debilitating and often dose-limiting side effect that afflicts many patients being treated for cancer with radiation and/or chemotherapy. RxKinetix is a development stage company and therefore is being accounted for as an asset acquisition. The results of operations for RxKinetix have been included in our consolidated financial statements beginning on the acquisition date.

The purchase price of RxKinetix, as of the acquisition date, was \$20.5 million which was funded from our existing cash on hand. Additional contingent cash purchase consideration of up to \$95 million may become due upon the achievement of certain clinical and regulatory milestones. The Company has allocated the purchase price to the RxKinetix assets acquired and liabilities assumed at their estimated fair values, based on a number of factors, including the use of an independent appraisal. Estimated fair values were determined through the use of a discounted cash flow analysis using market participant assumptions. Of the purchase price,

**Table of Contents**

approximately \$26.0 million has been allocated to tangible and intangible assets to be used in research and development activities and those assets have been written-off to purchased in-process research and development, as of the acquisition date. The excess of fair value of the net assets acquired compared to the amount paid as of the acquisition date has been reflected as estimated amount due seller in accordance with SFAS No. 141, *Business Combinations*. Any contingent consideration paid in the future will be first applied to reduce the amount recorded as estimated amount due seller, and thereafter to the net assets acquired based on their relative fair values. Our preliminary purchase allocation is subject to revision; subsequent revisions, if any, are not expected to be material.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed the date of acquisition (in thousands):

Cash consideration	\$ 20,000
Direct acquisition costs	482
<b>Total purchase price</b>	<b>\$ 20,482</b>
Allocation of purchase price:	
Cash	\$ 9
Property and equipment	127
Purchased in-process research and development	26,046
Other assets	461
Deferred tax assets	10,699
Other liabilities	(1,330)
Estimated amount due seller	(15,530)
<b>Total purchase price</b>	<b>\$ 20,482</b>

---

**Table of Contents**

**4. License and Collaboration Agreements**

*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 strategic alliance agreement between the parties (the 2002 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, now known as Opana® ER. We had historically shared, on an equal basis, the costs of products developed under this agreement. 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 were responsible for funding 100% of these remaining costs until June 22, 2006, the date on which oxymorphone ER received FDA approval. In January 2007, the Company and Penwest entered into an amendment (the 2007 Amendment) to the 2002 Agreement. Under the terms of the 2007 Amendment, Endo and Penwest agreed to restructure the 2002 Agreement to provide that royalties payable to Penwest for U.S. sales of Opana® ER will be calculated based on net sales of the product rather than on operating profit, and to change certain other provisions of the 2002 Agreement. The 2007 Amendment also resolves the parties' ongoing disagreement with regard to sharing of marketing expenses during the period prior to when Opana® ER reaches profitability. The key financial terms of the 2007 Amendment are summarized as follows:

With respect to U.S. sales of Opana® ER, the Company's royalty payments to Penwest will be calculated starting at 22% of annual net sales of the product, and, based on agreed-upon levels of annual net sales achieved, the royalty rate can increase to a maximum of 30%.

No royalty payments will be due to Penwest for the first \$41 million of royalties that would otherwise have been payable beginning from the time of the product launch in July 2006.

Penwest is entitled to receive milestone payments of up to \$90 million based upon the achievement of certain agreed-upon annual sales thresholds.

As noted above, in 2003, Penwest opted out of funding of the development costs for Opana® ER. Under the 2002 Agreement between the parties, the Company was entitled to recoup Penwest's share of these development costs through a temporary adjustment in royalties. Under the 2007 Amendment, the parties have agreed that Penwest's share of these unfunded development costs will be fixed at \$28 million and will be recouped by the Company through a temporary 50% reduction in royalties payable to Penwest. This temporary reduction in royalties will not apply until the threshold for the royalty holiday referred to above has been met.

*Hind Healthcare Inc.*

In November 1998, Endo entered into a license agreement (referred to as the Hind License Agreement) with Hind Healthcare Inc., or 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 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

---

**Table of Contents**

royalties based on net sales of Lidoderm®. 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 is 10% of net sales through the shorter of (1) the expiration of the last licensed patent or (2) November 20, 2011, including a minimum royalty of at least \$500,000 per year. During 2006, 2005 and 2004, we recorded \$62.8 million, \$46.4 million and \$34.5 million for these royalties to Hind, respectively, which were recorded as a reduction to net sales. At December 31, 2006 and 2005, \$19.2 million and \$14.5 million, respectively, is recorded as royalty payable and included in accounts payable in the accompanying balance sheet. 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. The payment of these additional contingent termination amounts is not likely due the fact that the FDA informed our former partner, Noven Pharmaceuticals, that it would not approve Noven's Abbreviated New Drug Application for its developmental transdermal fentanyl patch, as discussed below. We wrote-off the unamortized portion of the Lavipharm upfront license fee and expensed the termination payment of \$3 million during the year ended December 31, 2004.

*DURECT Corporation*

In January 2006, DURECT and Endo entered into Amendment No. 3 to the DURECT CHRONOGESIC License Agreement. Under Amendment No. 3, Endo has the right to terminate the Agreement in the event that (i) DURECT has not delivered to Endo, on or before March 31, 2007, a written notice that a human pharmacokinetic trial had been completed with the CHRONOGESIC™ product candidate, together with a full study report of the results of the trial or (ii) Endo, determines, in its sole discretion, to terminate the Agreement during the sixty-day period after DURECT's delivery of such notice, *provided that*, in each case Endo delivers to DURECT its written notice of termination prior to April 30, 2007. Under Amendment No. 3, Endo shall not be responsible for any development costs for the CHRONOGESIC™ product candidate prior to May 1, 2007. Commencing on May 1, 2007, unless the Agreement is earlier terminated by Endo, Endo will fund 50% of the ongoing development costs for the CHRONOGESIC™ product candidate in accordance with the terms of the Agreement. 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 up to \$10.0 million.

---

**Table of Contents**

In addition, in March 2005, we signed an agreement that gives us the exclusive license to develop and commercialize DURECT's sufentanil-containing transdermal patch in the U.S. and Canada (the "DURECT Sufentanil Agreement"). The sufentanil patch, which is in early-stage clinical development, is intended to provide relief of moderate-to-severe chronic pain for up to seven days. We have assumed all remaining development and regulatory filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, in April 2005, we paid DURECT a \$10 million upfront fee, which was expensed as research and development, and are subject to potential additional payment requirements of up to 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<sup>®</sup> 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 the distribution and marketing rights for DepoDur<sup>®</sup>, with no value being assigned to Propofol IDD-D or any other SkyePharma products. We were amortizing this intangible asset over its estimated useful life of 17 years. During the year ended December 31, 2005, we recorded a receivable from SkyePharma of \$5 million based upon the achievement of certain criteria as specified in the agreement. This receivable was recorded as a reduction to our recorded intangible asset and the remaining intangible asset began to be amortized over its remaining useful life of 15 years. We collected this receivable in January 2006. During the year ended December 31, 2004, we paid and expensed to research and development a \$5 million milestone payment to SkyePharma upon approval of the NDA for DepoDur<sup>®</sup>. During the year ended December 31, 2004, we paid and expensed to research and development a \$5 million milestone payment to SkyePharma upon the advancement of Propofol IDD-D to the end of Phase II clinical development. Under this agreement, we also obtained options on other SkyePharma development products, including DepoBupivacaine, a long-acting, sustained release formulation of the local anesthetic bupivacaine. We had the option to obtain commercialization rights for this product when SkyePharma successfully completed its Phase II trials; however, in February 2006 we relinquished our rights to DepoBupivacaine. During the first quarter of 2006, SkyePharma and the Company decided to discontinue their development and commercialization of the Propofol IDD-D product candidate due to development challenges encountered in attempting to achieve the targeted product profile. In January 2007, following an assessment of the status of DepoDur<sup>®</sup>, we announced that we notified SkyePharma PLC of our intent to terminate our development and commercialization agreement for this product and, in February 2007, entered into a termination agreement with SkyePharma whereby the Development and Marketing Strategic Alliance Agreement will terminate in its entirety on March 31, 2007. In order to provide for the continued commercial support of the DepoDur<sup>®</sup> product and the transition of such product to SkyePharma on March 31, 2007, Endo will continue to provide a number

## Table of Contents

of services and undertake certain activities. Specifically, Endo will use commercially reasonable efforts to maintain and continue all U.S. commercial activities in support of DepoDur<sup>®</sup> through March 31, 2007, and at SkyePharma's option, on a month-to-month basis after March 31, 2007 but not beyond June 30, 2007; and support and/or undertake the transition of certain Endo functions and activities (including third party activities) to SkyePharma that are useful and necessary for SkyePharma to assume commercial and related responsibilities for DepoDur<sup>®</sup> in the U.S. During the year ended December 31, 2006, as a result of the continued lack of commercial success of DepoDur<sup>®</sup> and, we recorded an impairment charge of \$14.8 million related to the remaining unamortized portion of our SkyePharma intangible asset.

### *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 was intended to be the generic equivalent of Johnson & Johnson's Duragesic<sup>®</sup> (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 the distribution and marketing rights. We were amortizing this intangible asset over its useful life of 11 years. On September 27, 2005, the FDA informed Noven that it would not approve Noven's ANDA for its developmental transdermal fentanyl patch based on the FDA's assessment of potential safety concerns related to the higher drug content in the Noven product versus the reference-listed product, Duragesic<sup>®</sup>. As a result, we incurred a charge of approximately \$4 million related to the write-off of our portion of the transdermal fentanyl patch inventory and an impairment charge of approximately \$5.5 million, which represented the unamortized portion of the upfront license fee that we paid Noven in February 2004, during the year ended December 31, 2005. On March 2, 2006, we amended our license agreement with Noven, effective as of December 31, 2005, to terminate the provisions of the agreement applicable to the generic fentanyl patch product. As part of such amendment, Endo received a right of first negotiation for certain future generic fentanyl patch products that Noven may develop.

### *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<sup>®</sup> BP product. The license agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept's LidoPAIN<sup>®</sup> 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<sup>®</sup> 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 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 license exclusively to us rights to market Frova<sup>®</sup> (frovatriptan) in North America. Launched in the U.S. in

---

**Table of Contents**

June 2002, Frova<sup>®</sup> 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 were required to make anniversary payments for the first two years at \$15 million in 2005 and 2006 (both \$15 million anniversary payments have been made), and a \$40 million milestone payment upon FDA approval for the menstrual migraine indication (MM). 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 (See Note 8) as an intangible asset representing the fair value of the exclusive license to market Frova<sup>®</sup>. 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<sup>®</sup> beginning on January 1, 2007. 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<sup>®</sup> 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<sup>®</sup> 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.

On July 1, 2005, we entered into a co-promotion agreement, as amended on December 22, 2005, with Vernalis. The co-promotion agreement, as amended, is related to the above described license agreement under which Vernalis agreed to exclusively license to us rights to market the product Frova<sup>®</sup> (frovatriptan) in North America. Pursuant to the license agreement, Vernalis had retained rights to co-promote Frova<sup>®</sup> in the United States. Vernalis has exercised its co-promotion option, and the co-promotion agreement, as amended, sets forth the certain specific terms and conditions governing such co-promotion and amends, restates and supersedes certain sections of the license agreement. Under the terms of both the license and co-promotion agreements, both as amended, beginning in January 2006 and ending on December 31, 2010, we are required to reimburse Vernalis for certain defined costs of their sales personnel.

*Orexo AB*

In August 2004, we entered into an agreement granting us the exclusive rights to develop and market Orexo AB's (a Swedish company) patented sublingual muco-adhesive fentanyl product (Rapinyl<sup>®</sup>) in North America. Rapinyl<sup>®</sup> is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. Rapinyl<sup>®</sup> 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 products utilizing Orexo's unique patented technology for sublingual administration 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 (\$5.2 million and \$7.3 million of which were recorded during the years ended December 31, 2006 and 2005, respectively and included in research and development expense). The agreement also provides for royalties based 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 \$750,000.

## **Table of Contents**

### *ProEthic Pharmaceuticals, Inc.*

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 currently available in the U.S. only in oral form. 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. Under the terms of the agreement, in March 2005, we paid a \$10 million upfront fee that was expensed as research and development during the year ended December 31, 2005. We made a \$5 million milestone payment upon the achievement of a regulatory milestone that was expensed as research and development during the year ended December 31, 2006. We could be required to make additional payments of approximately \$8 million upon the achievement of certain regulatory and other milestones. We will also pay royalties on net sales of the ketoprofen patch. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the tenth (10th) 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 days' written notice.

### *ZARS Pharma*

On January 6, 2006, we entered into an agreement with ZARS Pharma for the North American rights to Synera<sup>TM</sup> (lidocaine 70 mg and tetracaine 70 mg) topical patch. Synera<sup>TM</sup> is for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the FDA on June 23, 2005, Synera<sup>TM</sup> became commercially available in the second half of 2006.

Under the terms of the agreement, we paid ZARS an upfront fee of \$11 million in January 2006 and an additional \$8 million upon the first commercial shipment of the product in the second half of 2006. Both amounts were capitalized as an intangible asset representing the fair value of the marketing rights to Synera acquired from ZARS. We may be required to make additional payments of up to approximately \$19 million upon achievement of certain commercial milestones. We will also pay ZARS royalties on net sales of Synera<sup>TM</sup>. Following an impairment review of Synera<sup>TM</sup>, we determined that the carrying amount of the recorded intangible asset was not fully recoverable. As a result, we recorded a \$16.5 million impairment charge to write the unamortized portion of this intangible asset down to its fair value, determined using a discounted cash flow model.

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



**Table of Contents****5. Inventories**

Inventories are comprised of the following at December 31, 2006 and 2005, respectively (in thousands):

	2006	2005
Raw materials	\$ 7,619	\$ 13,094
Work-in-process	9,718	7,868
Finished goods	44,792	30,021
Total	\$ 62,129	\$ 50,983

**6. Property and Equipment**

Property and equipment is comprised of the following at December 31, 2006 and 2005, respectively (in thousands):

	2006	2005
Machinery and equipment	\$ 14,390	\$ 6,278
Leasehold improvements	13,772	13,500
Computer equipment and software	13,483	12,726
Assets under capital leases	7,149	10,506
Furniture and fixtures	5,692	5,527
Assets under construction	6,108	9,196
	60,594	57,733
Less accumulated depreciation	(24,029)	(19,732)
Total	\$ 36,565	\$ 38,001

Depreciation expense was \$8.7 million, \$7.8 million and \$5.5 million for the years ended December 31, 2006, 2005 and 2004, respectively.

**7. Goodwill and Other Intangibles**

Goodwill and other intangibles represent a significant portion of our assets and stockholders' equity. As of December 31, 2006, goodwill and other intangibles comprised approximately 19% of our total assets and 25% of our stockholders' equity. Goodwill and other intangible assets consist of the following at December 31, 2006 and 2005, respectively (in thousands):

	December 31, 2006	December 31, 2005
Goodwill	\$ 181,079	\$ 181,079
Amortizable Intangibles:		
Licenses	\$ 94,621	\$ 112,100
Patents	3,200	3,200
	97,821	115,300
Less accumulated amortization	(19,775)	(16,235)

Other Intangibles, net	\$ 78,046	\$ 99,065
------------------------	-----------	-----------

F-23

**Table of Contents**

Changes in the gross carrying amount of licenses for the two years ended December 31, 2006, are as follows:

<i>(in thousands)</i>	<b>Gross carrying amount</b>
<i>Balance at January 1, 2005</i>	\$ 123,600
Noven impairment	(6,500)
SkyePharma payment	(5,000)
 <i>Balance at December 31, 2005</i>	 \$ 112,100
Synera™ license	19,000
DepoDur® impairment	(20,000)
Synera™ impairment	(16,479)
 <i>Balance at December 31, 2006</i>	 \$ 94,621

Amortization expense was \$8.8 million, \$7.7 million and \$5.1 million for the years ended December 31, 2006, 2005 and 2004, respectively. As of December 31, 2006, estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2006 is as follows (in thousands):

2007	\$ 6,209
2008	6,209
2009	6,209
2010	6,209
2011	6,209

**8. Note Receivable**

In July 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to exclusively license to us the rights to market Frova® (frovatriptan) in North America. Under the loan agreement, we provided Vernalis with a loan of \$50 million in August 2004. The loan was primarily used to make a payment in full and final settlement of the amounts due to Elan Corporation from Vernalis in connection with Vernalis' reacquisition of the North American rights to Frova®. The loan is secured against the revenues receivable by Vernalis under the license agreement. At our election, we are able to offset \$20 million of the \$40 million menstrual migraine indication 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. Vernalis has elected to defer the payment of the first five semi-annual interest amounts otherwise due January 31 and July 31 totaling approximately \$6.2 million as of December 31, 2006.

We estimated that an approximate fair market rate of interest for this type of secured loan was 8% per annum and therefore recorded the note receivable at its present value at inception of \$43.8 million. The note receivable is being accreted up to its face amount at maturity using the effective interest method and thus the effective interest rate over the five-year term will be 8% per annum. The difference of \$6.2 million between the face amount of the note and its present value at inception has been treated as additional consideration paid to acquire the license rights and has been included in other intangibles, net. Interest income recognized on this note receivable was \$3.9 million, \$3.9 million and \$1.2 million for the years ended December 31, 2006, 2005 and 2004, respectively.

**Table of Contents****9. Accrued Expenses**

Accrued expenses are comprised of the following at December 31, 2006 and 2005, respectively (in thousands):

	2006	2005
Chargebacks	\$ 33,928	\$ 50,808
Returns	20,110	21,215
Rebates	72,813	95,565
Other sales deductions	5,872	15,338
License fees		14,633
Deferred revenue	14,393	
Other	17,412	16,717
Total	\$ 164,528	\$ 214,276

**10. 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 provided us with a line of credit of \$75.0 million. We did not borrow any amounts under the facility during 2006, and the line of credit expired on December 21, 2006. We have not renegotiated a credit facility at this time.

**11. Income Taxes**

Income tax consists of the following for 2006, 2005, and 2004 (in thousands):

	2006	2005	2004
Current:			
Federal	\$ 46,814	\$ (53,318)	\$ 32,189
State	1,766	29	5,404
	48,580	(53,289)	37,593
Deferred:*			
Federal	5,186	12,251	43,912
State	4,158	(3,012)	6,300
	9,344	9,239	50,212
Excess tax benefits of stock options exercised	37,933	165,903	
Valuation allowance	38	96	(18)
Total income tax	\$ 95,895	\$ 121,949	\$ 87,787

\* Certain 2005 amounts have been reclassified to confirm to the current year presentation.

A reconciliation of income tax at the federal statutory income tax rate to the total income tax provision for 2006, 2005, and 2004 is as follows (in thousands):

2006	2005	2004
------	------	------

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-K

Federal income tax at the statutory rate	\$ 81,806	\$ 113,485	\$ 80,884
State income tax net of federal benefit	7,295	12,157	7,511
Research and development credit	(950)	(1,686)	(588)
Effect of permanent items:			
Purchased in-process research and development	9,116		
Tax exempt interest income	(5,621)	(1,937)	(345)
Non-deductible executive compensation	2,600		
Other	1,649	(70)	325
<b>Total income tax</b>	<b>\$ 95,895</b>	<b>\$ 121,949</b>	<b>\$ 87,787</b>

F-25

**Table of Contents**

The tax effects of temporary differences that comprise the current and non-current deferred income tax amounts shown on the balance sheets at December 31 are as follows (in thousands):

	2006	2005
Deferred tax assets:		
Accrued expenses	\$ 54,562	\$ 70,146
Compensation related to stock options	4,468	
Purchased in-process research and development	6,549	7,722
Net operating loss carryforward	12,073	4,870
Capital loss carryforward	11,219	5,574
Other intangible assets	15,494	5,429
Other	1,893	698
<b>Total gross deferred income tax assets</b>	<b>106,258</b>	<b>94,439</b>
Deferred tax liabilities:		
Depreciation and amortization	(35,686)	(31,700)
Other	(1,633)	(2,088)
<b>Total gross deferred income tax liabilities</b>	<b>(37,319)</b>	<b>(33,788)</b>
Valuation allowance	(12,216)	(5,574)
<b>Net deferred income tax asset</b>	<b>\$ 56,723</b>	<b>\$ 55,077</b>

As a result of the significant tax deductions generated in 2005 from the exercise of stock options, we incurred a net operating loss in 2005 for tax purposes which permitted us to obtain a tax refund of a portion of prior years' payments during 2006. As a result, we recorded an income tax receivable at December 31, 2005.

The estimated fair value of the RxKinetix purchased in-process research development of \$26.0 million was not a tax deductible item and, therefore, increased our effective income tax rate in 2006. The Company recorded a valuation allowance in 2006 due to the uncertainty of its ability to utilize the capital losses and state net operating losses acquired from RxKinetix. In addition, the Company recorded a valuation allowance on state net operating losses generated subsequent to the acquisition date. At December 31, 2006, the Company had \$29.4 million in capital loss carryforwards, for tax purposes, which expire in 2009. Also, at December 31, 2006, the Company had \$74.7 million in federal and state net operating loss carryforwards which expire at various intervals between 2010 and 2026.

**12. Commitments and Contingencies**

**Manufacturing, Supply and Other Service Agreements** We contract with various third party manufacturers and suppliers to provide us with our raw materials used in our products and finished goods. Our most significant agreements are with Novartis Consumer Health, Inc., Teikoku Seiyaku Co., Ltd., and Mallinckrodt Inc. 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 results of operations.

*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. This agreement had a five-year term, with automatic five-year renewals thereafter. In August 2005, we extended this agreement until 2011. As of December 31, 2006, we are required to purchase a minimum of approximately \$17 million per year through December 31, 2009. Amounts purchased pursuant to this agreement were \$40.8 million, \$39.9 million and \$27.7 million for the years ended December 31, 2006, 2005 and 2004, respectively. Either party may terminate this agreement on three-years' notice, effective at any time after the

initial five-year term. Either party may also terminate this agreement on account of a material breach by the other.

## **Table of Contents**

### *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. 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. Amounts purchased pursuant to this agreement were \$142.2 million, \$89.8 million and \$94.2 million for the years ended December 31, 2006, 2005 and 2004, respectively.

### *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. Amounts purchased pursuant to this agreements were \$15.3 million, \$24.6 million and \$18.9 million for the years ended December 31, 2006, 2005 and 2004, respectively.

### *General*

In addition to the manufacturing and supply 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 that expires in 2010, (2) Kunitz and Associates Inc. for assistance with adverse event reporting and (3) PPD Development, LP for clinical development services, business development support and medical information services. 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.

## **License Agreements, Milestones and Royalties**

### *Hind Healthcare Inc.*

Under the terms of the Hind License Agreement, 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 is 10% of net sales through the shorter of (1) the expiration of the last licensed patent or (2) November 20, 2011, including a minimum royalty of at least \$500,000 per year. During the years ended December 31, 2006, 2005 and 2004, we recorded \$62.8 million, \$46.4 million and \$34.5 million, respectively, for these royalties to Hind. At December 31, 2006 and 2005, \$19.2 million and \$14.5 million, respectively, is recorded as royalty payable and included in accounts payable in the accompanying balance sheet.



---

**Table of Contents**

*Penwest Pharmaceuticals*

In January 2007, the Company and Penwest entered into an amendment (the 2007 Amendment) to the 2002 amended and restated strategic alliance agreement between the parties (the 2002 Agreement). Under the terms of the 2007 Amendment, Endo and Penwest agreed to restructure the 2002 Agreement to provide that royalties payable to Penwest for U.S. sales of Opana® ER will be calculated based on net sales of the product rather than on operating profit, and to change certain other provisions of the 2002 Agreement. The 2007 Amendment also resolves the parties' ongoing disagreement with regard to sharing of marketing expenses during the period prior to when Opana® ER reaches profitability. The key financial terms of the 2007 Amendment are summarized as follows:

With respect to U.S. sales of Opana® ER, Endo's royalty payments to Penwest will be calculated starting at 22% of annual net sales of the product, and, based on agreed-upon levels of annual net sales achieved, the royalty rate can increase to a maximum of 30%.

No royalty payments will be due to Penwest for the first \$41 million of royalties that would otherwise have been payable beginning from the time of the product launch in July 2006.

Penwest is entitled to receive milestone payments of up to \$90 million based upon the achievement of certain agreed-upon annual sales thresholds.

In 2003, Penwest opted out of funding development costs for Opana® ER. Under the 2007 Amendment, the parties have agreed that Penwest's share of these unfunded development costs will be fixed at \$28 million and will be recouped by Endo through a temporary 50% reduction in royalties payable to Penwest. This temporary reduction in royalties will not apply until the threshold for the royalty holiday referred to above has been met.

*DURECT Corporation*

In January 2006, DURECT and Endo entered into Amendment No. 3 to the DURECT CHRONOGESIC License Agreement. Commencing on May 1, 2007, unless the Agreement is earlier terminated by Endo, Endo will fund 50% of the ongoing development costs for the CHRONOGESIC product candidate in accordance with the terms of the Agreement. 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. 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 up to \$10.0 million.

In addition, in March 2005, we signed an agreement that gives us the exclusive license to develop and commercialize DURECT's sufentanil-containing transdermal patch in the U.S. and Canada (the DURECT Sufentanil Agreement). Under the terms of the DURECT Sufentanil Agreement, in April 2005, we paid DURECT a \$10 million upfront fee, which was expensed as research and development, and are subject to potential additional payment requirements of up to 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. 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.

## **Table of Contents**

### *EpiCept Corp.*

Our license agreement with EpiCept provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept's LidoPAIN<sup>®</sup> BP product. EpiCept has also retained an option to co-promote the LidoPAIN<sup>®</sup> 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 with Vernalis, we could be required to make a \$40 million milestone payment upon FDA approval for the menstrual migraine indication (MM). In addition, Vernalis could 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<sup>®</sup> beginning on January 1, 2007. We can terminate the license agreement under certain circumstances, including upon one year's written notice.

On July 1, 2005, we entered into a co-promotion agreement, as amended on December 22, 2005, with Vernalis. Under the terms of both the license and co-promotion agreements, both as amended, beginning in January 2006 and ending on December 31, 2010 we are required to reimburse Vernalis for certain defined costs of their sales personnel.

### *Orexo AB*

Our agreement with Orexo provides for us to make additional license fees and payments based on development and regulatory milestones, which may total up to \$22.1 million (\$5.2 million and \$7.3 million of which were recorded during the years ended December 31, 2006 and 2005, respectively, and included in research and development expense). 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. 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 \$750,000.

### *ProEthic Pharmaceuticals, Inc.*

Under the terms of the agreement, in March 2005, we paid a \$10 million upfront fee that was expensed as research and development during the year ended December 31, 2005. During 2006, we made an additional \$5 million milestone payment that has been expensed as research and development. We could be required to make additional payments of approximately \$8 million upon the achievement of certain regulatory and other milestones. We will also pay royalties on net sales of the ketoprofen patch. We can terminate the agreement at any time upon no more than ninety days' written notice.

## **Table of Contents**

### *Zars Pharma*

Under the terms of the agreement, we may be required to make additional payments of up to approximately \$19 million upon achievement of certain commercial milestones. We will also pay ZARS royalties on net sales of Synera™.

### *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, 2006, we have invested \$2.7 million in this partnership and are accounting for this investment utilizing the equity method.

## **Employment Agreements**

We have entered into employment agreements with certain members of management.

## **Research Contracts**

In addition to our agreement with PPD Development, LP, we routinely contract with universities, medical centers, contract research organizations and other institutions for the conduct of research and clinical studies on our behalf. These agreements are generally for the duration of the contracted study and contain provisions that allow us to terminate prior to completion.

## **Collaboration Agreements**

We have also entered into certain collaboration agreements with third parties for the development of pain management and other products. Potential milestone payments pursuant to these contracts could total up to approximately \$6 million. These agreements require us to share in the development costs of such products and grant marketing rights to us for such products. If our third party partners are unable or unwilling to fund their portion of the collaboration project with us, this may adversely affect our results of operations and cash flows in the foreseeable future.

## **Legal Proceedings**

While we cannot predict the outcome of the following legal proceedings, we believe that the claims against us are without merit, and we intend to vigorously defend our position. An adverse outcome in any of these proceedings could have a material adverse effect on our current and future financial position and results of operations. No amounts have been accrued with respect to any of these unsettled legal proceedings at December 31, 2006.

### *Department of Health and Human Services Subpoena.*

In January 2007, the Company received a subpoena issued by the United States Department of Health and Human Services, Office of Inspector General (OIG). The subpoena requests documents relating to Lidoderm® (lidocaine patch 5%), primarily with regard to Lidoderm®'s sales, marketing and promotion, and our knowledge of physicians' use of Lidoderm® for non-indicated uses. We are cooperating with the government to provide the requested documents.

**Table of Contents**

*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.)*

On October 20, 2000, The Purdue Frederick Company and related companies (Purdue) 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'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's OxyContin®, 40mg strength, challenged the listed patents for OxyContin® 40mg tablets. On March 13, 2001 and August 30, 2001, Purdue filed two more suits for infringement of the same patents against us and EPI in the Southern District of New York, in response to EPI's ANDA amendments adding bioequivalent versions of the 10, 20 and 80 mg strengths of OxyContin®. In each of the three cases, EPI pleaded counterclaims that the patents asserted by Purdue are invalid, unenforceable and/or not infringed by EPI's formulation of oxycodone hydrochloride extended-release tablets, and that Purdue violated antitrust laws by enforcing fraudulently procured patents.

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 dismissed the patent claims against us and EPI, declared the patents invalid, and enjoined Purdue from further enforcement of the patents. On June 7, 2005, the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. affirmed the district court's decision that, while Endo's oxycodone extended-release tablets infringe the Purdue patents, the patents are unenforceable. On June 21, 2005, Purdue filed a petition with the Federal Circuit seeking rehearing of the appeal.

On February 1, 2006, the Federal Circuit granted Purdue's motion for rehearing, vacated the June 7, 2005 decision of the district court, and remanded the case to the district court for further proceedings. The Federal Circuit's decision on rehearing directed the district court to give further consideration to its previous finding of unenforceability due to inequitable conduct. The Federal Circuit also affirmed the district court's finding that EPI's oxycodone extended-release tablets infringe the Purdue patents.

Following the remand, we entered into settlement discussions with Purdue. On August 28, 2006, we executed a settlement agreement with Purdue pursuant to which we agreed to cease selling our oxycodone extended-release products on December 31, 2006. We and EPI, as well as our manufacturers, distributors, purchasers, and patients, are released from all liability for infringement of Purdue's patents in connection with EPI's prior and future sales of these products. Though the settlement agreement has been submitted to the U.S. Federal Trade Commission and the Antitrust Division of the Department of Justice as required by statute, the release will survive unless overturned by a court order. On October 6, 2006, the district court entered a Consent Judgment, the effect of which is to conclude the litigation in accordance with the terms of the settlement agreement.

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.

---

## **Table of Contents**

### *Pricing Litigation*

A number of cases, brought by local and state government entities, are pending that allege generally that EPI and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. These cases generally seek damages, treble damages, disgorgement of profits, restitution and attorneys' fees.

The federal court cases have been or are in the process of being consolidated in the United States District Court for the District of Massachusetts under the Multidistrict Litigation Rules as In re: Pharmaceutical Industry Average Wholesale Price Litigation, MDL 1456. The following previously reported cases are pending in MDL 1456 and have been consolidated into one consolidated complaint: *City of New York v. Abbott Laboratories, Inc., et al.*; *County of Albany v. Abbott Laboratories, Inc., et al.*; *County of Allegany v. Abbott Laboratories, Inc., et al.*; *County of Broome v. Abbott Laboratories, Inc., et al.*; *County of Cattaraugus v. Abbott Laboratories, Inc., et al.*; *County of Cayuga v. Abbott Laboratories, Inc., et al.*; *County of Chautauqua v. Abbott Laboratories, Inc., et al.*; *County of Chemung v. Abbott Laboratories, Inc., et al.*; *County of Chenango v. Abbott Laboratories, Inc., et al.*; *County of Columbia v. Abbott Laboratories, Inc., et al.*; *County of Cortland v. Abbott Laboratories, Inc., et al.*; *County of Dutchess v. Abbott Laboratories, Inc., et al.*; *County of Essex v. Abbott Laboratories, Inc., et al.*; *County of Fulton v. Abbott Laboratories, Inc., et al.*; *County of Genesee v. Abbott Laboratories, Inc., et al.*; *County of Greene v. Abbott Laboratories, Inc., et al.*; *County of Herkimer v. Abbott Laboratories, Inc., et al.*; *County of Jefferson v. Abbott Laboratories, Inc., et al.*; *County of Lewis v. Abbott Laboratories, Inc., et al.*; *County of Madison v. Abbott Laboratories, Inc., et al.*; *County of Monroe v. Abbott Laboratories, Inc., et al.*; *County of Niagara v. Abbott Laboratories, Inc., et al.*; *County of Oneida v. Abbott Laboratories, Inc., et al.*; *County of Onondaga v. Abbott Laboratories, Inc., et al.*; *County of Ontario v. Abbott Laboratories, Inc., et al.*; *County of Orleans v. Abbott Laboratories, Inc., et al.*; *County of Putnam v. Abbott Laboratories, Inc., et al.*; *County of Rensselaer v. Abbott Laboratories, Inc., et al.*; *County of Rockland v. Abbott Laboratories, Inc., et al.*; *County of St. Lawrence v. Abbott Laboratories, Inc., et al.*; *County of Saratoga v. Abbott Laboratories, Inc., et al.*; *County of Schuyler v. Abbott Laboratories, Inc., et al.*; *County of Seneca v. Abbott Laboratories, Inc., et al.*; *County of Steuben v. Abbott Laboratories, Inc., et al.*; *County of Suffolk v. Abbott Laboratories, Inc., et al.*; *County of Tompkins v. Abbott Laboratories, Inc., et al.*; *County of Ulster v. Abbott Laboratories, Inc., et al.*; *County of Warren v. Abbott Laboratories, Inc., et al.*; *County of Washington v. Abbott Laboratories, Inc., et al.*; *County of Wayne v. Abbott Laboratories, Inc., et al.*; *County of Westchester v. Abbott Laboratories, Inc., et al.*; *County of Wyoming v. Abbott Laboratories, Inc., et al.*; and *County of Yates v. Abbott Laboratories, Inc., et al.*

Three previously reported cases, *County of Erie v. Abbott Laboratories, Inc., et al.*, originally filed in the Supreme Court of the State of New York, Erie County, *County of Oswego v. Abbott Laboratories, Inc., et al.*, originally filed in the Supreme Court of the State of New York, Oswego County, and *County of Schenectady v. Abbott Laboratories, Inc., et al.*, originally filed in the Supreme Court of the State of New York, Schenectady County, which name EPI and numerous other pharmaceutical companies, were removed to federal court. On February 7, 2007, the United States Judicial Panel on Multidistrict Litigation issued its final order transferring these cases to MDL 1456.

There is a previously reported case pending in the Circuit Court of Montgomery County, Alabama against EPI and numerous other pharmaceutical companies, *State of Alabama v. Abbott Laboratories, Inc., et al.*

**Table of Contents**

There is a previously reported case against EPI and numerous other pharmaceutical companies: *State of Mississippi v. Abbott Laboratories, Inc., et al.*, originally filed in the Chancery Court of Hinds County, Mississippi, and now removed to and pending in the United States District Court for the Southern District of Mississippi. Prior to removal, the State of Mississippi offered to enter an agreed order of dismissal with respect to Endo, and Endo filed a notice of acceptance of that offer in Hinds County Chancery Court. Endo is now listed as a terminated party for purposes of the litigation in the United States District Court for the Southern District of Mississippi.

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 and results of operations.

**Leases**

We lease office and laboratory facilities under certain noncancelable operating leases that expire through January 2015. These leases are renewable at our option. Our capital leases primarily consist of leased automobiles. A summary of minimum future rental payments required under capital and operating leases as of December 31, 2006 is as follows (in thousands):

	<b>Capital</b>	<b>Operating</b>
	<b>Leases</b>	<b>Leases</b>
2007	\$ 1,479	\$ 2,875
2008	489	2,901
2009	23	2,603
2010		2,392
2011		1,969
Thereafter		4,350
<b>Total minimum lease payments</b>	<b>\$ 1,991</b>	<b>\$ 17,090</b>
Less: Amount representing interest	282	
<b>Total present value of minimum payments</b>	<b>\$ 1,709</b>	
Less: Current portion of such obligations	1,274	
<b>Long-term capital lease obligations</b>	<b>\$ 435</b>	

Rent expense incurred under operating leases was \$3.1 million, \$3.1 million and \$2.5 million for the years ended December 31, 2006, 2005 and 2004, respectively.

**13. Savings and Investment Plan**

On September 1, 1997, we established a defined contribution Savings and Investment Plan covering all employees. Employee contributions are made on a pre-tax basis under section 401(k) of the Internal Revenue Code (the Code). We match up to six percent of the participants contributions subject to limitations under section 401(k) of the Code. Participants are fully vested with respect to their own contributions. Participants are fully vested with respect to our contributions after three years of continuous service. Contributions by us amounted to \$3.7 million, \$3.1 million and \$2.2 million for the years ended December 31, 2006, 2005 and 2004, respectively.



## **Table of Contents**

### **14. Stockholders Equity**

#### **Common Stock**

Payment of dividends was restricted under terms of the Amended and Restated Credit Agreement, which expired on December 21, 2006.

#### **Preferred Stock**

The Board of Directors may, without further action by the stockholders, issue a series of Preferred Stock and fix the rights and preferences of those shares, including the dividend rights, dividend rates, conversion rights, exchange rights, voting rights, terms of redemption, redemption price or prices, liquidation preferences, the number of shares constituting any series and the designation of such series. As of December 31, 2006, no shares of Preferred Stock have been issued.

#### **Endo Pharma LLC 1997 Executive and Employee Stock Option Plans and Endo Pharma LLC 2000 Supplemental Executive and Employee Stock Option Plans**

On November 25, 1997, the Company established the 1997 Employee Stock Option Plan and the 1997 Executive Stock Option Plan (collectively, the 1997 Stock Option Plans ). On July 17, 2000, the 1997 Stock Option Plans were amended and restated. The Endo Pharma LLC 1997 Stock Option Plans are these amended and restated 1997 Stock Options Plans and reserved an aggregate of 25,615,339 shares of common stock of the Company held by Endo Pharma LLC for issuance. Stock options granted under the Endo Pharma LLC 1997 Stock Option Plans expire on August 26, 2007. Upon exercise of these stock options, only currently outstanding shares of common stock of the Company held by Endo Pharma LLC are issued. Exercise of these stock options has not and will not result in the issuance of additional shares in the Company and does not dilute the ownership interests of our public stockholders.

Pursuant to the Algos merger and related recapitalization of the Company on July 17, 2000, the Endo Pharma LLC 2000 Supplemental Stock Option Plans were established. The Endo Pharma LLC 2000 Supplemental Stock Option Plans reserved an aggregate of 10,672,314 shares of common stock of the Company held by Endo Pharma LLC for issuance. Stock options granted under the Endo Pharma LLC 2000 Supplemental Stock Option Plans expire on August 26, 2007. The Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective on January 1, 2003, resulting in the issuance of 10,672,314 stock options to certain employees and members of management. No additional shares of Company common stock have been or will be issued as a result of the exercise of these stock options, because these stock options are exercisable only into shares of Company common stock that are held by Endo Pharma LLC. Accordingly, exercise of these stock options has not and will not result in the issuance of additional shares in the Company and does not dilute the ownership interests of our public stockholders.



**Table of Contents**

A summary of the activity under the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans for the three-year period ended December 31, 2006 is as follows:

	Number of	Weighted	Weighted	Aggregate
	Shares	Average	Average	Intrinsic
		Exercise Price	Remaining	Value
			Contractual Term	
Outstanding, January 1, 2004	31,885,026	\$ 2.63		
Exercised	(6,854,980)	\$ 2.46		
Forfeited	(754)	\$ 2.42		
Outstanding, December 31, 2004	25,029,292	\$ 2.68		
Exercised	(22,219,680)	\$ 2.71		
Forfeited	(347)	\$ 2.42		
Outstanding, December 31, 2005	2,809,265	\$ 2.42		
Granted	809,893	\$ 2.42		
Exercised	(3,543,717)	\$ 2.42		
Forfeited	(182)	\$ 2.42		
Outstanding, vested and exercisable, December 31, 2006	75,259	\$ 2.42	0.65	\$ 1,893,516

The total intrinsic value of options exercised during the years ended December 31, 2006, 2005 and 2004 were \$104.4 million, \$523.3 million and \$110.5 million, respectively. The weighted-average grant date fair value of the stock options granted during the year ended December 31, 2006 was \$24.58, which was equal to the intrinsic value of the options on the date of grant as the options granted were immediately vested and exercised.

As of December 31, 2006, there was no remaining unrecognized compensation cost related to non-vested stock options granted pursuant to the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans. Additionally, no options were available for grant under the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans at December 31, 2006.

**Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans**

In August 2000, we established the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan. The 2000 Stock Incentive Plan reserves an aggregate of 4,000,000 shares of common stock of the Company for issuance to employees, officers, directors and consultants. The 2000 Stock Incentive Plan provides for the issuance of stock options, restricted stock, stock bonus awards, stock appreciation rights or performance awards. In May 2004, our stockholders approved the Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan. The maximum number of shares of Company stock reserved for issuance under the 2004 Stock Incentive Plan is 4,000,000 shares. The 2004 Plan provides for the grant of stock options, stock appreciation rights, shares of restricted stock, performance shares, performance units or other share-based awards that may be granted to executive officers and other employees of the Company, including officers and directors who are employees, to non-employee directors and to consultants to the Company. As of December 31, 2006, only stock options have been awarded under both plans. Stock options granted under the 2000 and 2004 Stock Incentive Plans generally vest over four years and expire ten years from the date of grant. Unlike the stock options granted under the Endo Pharma LLC Stock Option Plans, the exercise of the stock options granted pursuant to the Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans will dilute the ownership interests of our public stockholders.

**Table of Contents**

A summary of the activity under 2000 and 2004 Stock Incentive Plans for the three-year period ended December 31, 2006 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2004	3,330,179	\$ 11.86		
Granted	981,806	\$ 17.61		
Exercised	(86,248)	\$ 8.96		
Forfeited	(238,191)	\$ 15.94		
Outstanding, December 31, 2004	3,987,546	\$ 13.09		
Granted	392,807	\$ 22.13		
Exercised	(944,859)	\$ 10.78		
Forfeited	(136,064)	\$ 14.40		
Outstanding, December 31, 2005	3,299,430	\$ 14.78		
Granted	1,733,530	\$ 28.90		
Exercised	(800,086)	\$ 10.55		
Forfeited	(316,012)	\$ 23.47		
Expired	(6,094)	\$ 18.52		
Outstanding, December 31, 2006	3,910,768	\$ 21.19	7.59	\$ 27,163,169
Vested and expected to vest, December 31, 2006	3,680,348	\$ 20.92	7.52	\$ 26,493,617
Exercisable, December 31, 2006	1,436,072	\$ 14.50	6.04	\$ 18,820,815

The total intrinsic value of options exercised during the years ended December 31, 2006, 2005 and 2004 were \$16.2 million, \$15.9 million and \$1.1 million, respectively.

For all of the Company's stock-based compensation plans, the fair value of each grant was estimated at the date of grant using the Black-Scholes option-pricing model. Black-Scholes utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield (which is assumed to be zero, as the Company has not paid cash dividends to date and does not currently expect to pay cash dividends) and the expected term of the option. Expected volatilities utilized in the model are based mainly on the historical volatility of the Company's stock price over a period commensurate with the expected life of the share option as well as other factors. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The expected term of the option was calculated using the simplified method during 2006. The weighted-average grant date fair value of the stock options granted during the years ended December 31, 2006, 2005 and 2004 were \$15.67, \$11.66 and \$9.83 per option, respectively, determined using the following assumptions:

	2006	2005	2004
Average expected term (years)	6.25	5.0	5.0
Risk-free interest rate	4.6%	3.8%	3.2%
Dividend yield	0.00	0.00	0.00
Expected volatility	50%	58%	63%

As of December 31, 2006, the total remaining unrecognized compensation cost related to non-vested stock options amounted to \$29.2 million. The weighted average remaining requisite service period of the non-vested stock options was 2.6 years. This unrecognized compensation cost does not include the impact of any future stock-based compensation awards. Approximately 6.2 million shares were reserved for future issuance upon exercise of options granted or to be granted under the 2000 and 2004 Stock Incentive Plans.



**Table of Contents**

The following table summarizes information about stock options outstanding under our 2000 and 2004 Stock Incentive Plans at December 31, 2006:

**2000 and 2004 Stock Incentive Plans Options Outstanding**

Number	Weighted Average		Number Exercisable	Exercisable Weighted Average		Range of Exercise Prices
	Remaining Contractual Life	Weighted Average Exercise Price		Exercise Price	Exercise Price	
Outstanding						
470,049	5.1	\$ 9.10	466,931	\$ 9.09	\$ 6.47 - \$9.70	
36,246	5.6	\$ 10.76	32,496	\$ 10.73	\$ 9.71 - \$11.05	
1,121,122	6.8	\$ 15.69	627,428	\$ 15.54	\$ 11.06 - \$16.47	
625,160	7.2	\$ 20.36	288,008	\$ 20.37	\$ 16.48 - \$23.75	
1,658,191	9.0	\$ 28.89	21,209	\$ 28.78	\$ 23.76 - \$34.58	

**15. Earnings Per Share**

The following is a reconciliation of the numerator and denominator of basic and diluted earnings per share for the years ended December 31, 2006, 2005 and 2004 (in thousands, except per share data):

	2006	2005	2004
<b>Numerator:</b>			
Net income available to common stockholders	\$ 137,839	\$ 202,295	\$ 143,309
<b>Denominator:</b>			
For basic per share data weighted average shares	133,178	132,242	131,805
Effect of dilutive stock options	733	1,047	913
For diluted per share data weighted average shares	133,911	133,289	132,718
Basic earnings per share	\$ 1.03	\$ 1.53	\$ 1.09
Diluted earnings per share	\$ 1.03	\$ 1.52	\$ 1.08

Anti-dilutive securities were 1,367,103, 15,698, and 70,629 for 2006, 2005 and 2004, respectively and have not been included above.

**16. Related Party Transactions**

**Tax Sharing Agreement.** On July 14, 2000, Endo Pharma LLC was formed in connection with our merger with Algos Pharmaceutical Corporation (Algos) 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 held approximately 15% of our common stock at December 31, 2005, but less than 1% of our common stock as of December 31, 2006, in which affiliates of Kelso & Company and certain current and former 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 have been and will be delivered. Because Endo Pharma LLC, and not us, has been and 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 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, 2006, approximately 36 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, 2006, approximately \$773 million), which is estimated to result in a tax benefit amount of approximately \$298 million. Under the tax sharing agreement, we are required to pay this \$298 million, \$252 million of which has already been paid as of

December 31, 2006, to Endo Pharma LLC to the

F-37

**Table of Contents**

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. Additionally, as part of the tax sharing agreement, Endo Pharma LLC will reimburse us for the after-tax employer payroll taxes paid by us as a result of the exercise of the 36 million options discussed above. We have paid approximately \$11 million in employer payroll taxes, of which Endo Pharma LLC will reimburse us for approximately \$7 million which represents the after-tax employer payroll tax paid by us for the periods from 2001 through December 31, 2006. As of December 31, 2006, our net liability due to Endo Pharma LLC is approximately \$38.7 million. 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.

During the year ended December 31, 2006, approximately 3.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised. Since the attributable compensation charge deductions are usable to reduce our taxes in 2006, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$38.7 million, which is our net liability due to Endo Pharma LLC referred to above. Fifty percent of the estimated tax benefit amount attributable to these exercises and any additional tax benefits attributable to the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2006 will be due within 15 business days of the date we receive an opinion on our final audited 2006 financial statements from our independent registered public accounting firm, and the remaining tax benefit amount attributable to 2006 is due within 30 business days of the date on which we file our 2006 tax return with the Internal Revenue Service.

As of December 31, 2006, there were approximately 0.1 million stock options, which expire in August 2007, remaining to be exercised under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of \$2.42 per share and an assumed tax rate of 38.25%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were vested and exercised, and assuming the price of our common stock was \$27.58 per share, the closing price on December 29, 2006, we would generally be able to deduct, for income tax purposes, compensation of approximately \$2 million, which could result in a tax benefit amount of approximately \$1 million payable to Endo Pharma LLC in 2008. This would represent the final tax sharing payment due to Endo Pharma LLC.

As of December 31, 2006, there were no options remaining to be granted under the Endo Pharma LLC stock option plans.

***Executive Compensation.*** In March 2006, Endo Pharma LLC advised our Board of Directors that it intended to pay a one-time cash bonus to each of Mr. Peter Lankau, our President and Chief Executive Officer, Ms. Caroline Manogue, our Executive Vice President, Chief Legal Officer and Secretary, and Mr. Jeffrey Black, our former Executive Vice President, Chief Financial Officer and Treasurer in the amount of \$3 million, \$6 million and \$10 million, respectively, in recognition of their significant contributions to our success. These bonus payments have been recorded in selling, general and administrative expenses during the year ended December 31, 2006. These payments were made by the Company in April 2006 and repaid to us by Endo Pharma LLC in the third quarter of 2006 with interest. In addition, only a portion of these bonus payments will be deductible for federal and state income tax purposes. We are not required to pay nor will we pay to Endo Pharma LLC the amount of any of the tax benefits related to these bonus payments pursuant to the tax sharing agreement between us and Endo Pharma LLC. These bonuses will be funded entirely by Endo Pharma LLC, with no contribution by us and they have been treated as a capital contribution by Endo Pharma LLC.

**Table of Contents**

Endo Pharma LLC also informed us that, in connection with its eventual winding-up, it would make a special allocation to Ms. Carol Ammon, our Chairman of the Board and former Chief Executive Officer, of approximately \$22 million, with all or a portion of Ms. Ammon's payment being satisfied by granting to her the remaining unallocated Endo Pharma LLC stock options of approximately 0.8 million shares under the Endo Pharma LLC stock option plans. This amount has been recorded in selling, general and administrative expenses during the year ended December 31, 2006 and as a capital contribution by Endo Pharma LLC. This grant of options to Ms. Ammon was made during the fourth quarter of 2006. The 0.8 million options were granted by Endo Pharma LLC to Ms. Ammon in the fourth quarter of 2006, as described above, at an exercise price of \$2.42 per share. Therefore, approximately \$20 million of the \$22 million recorded in the first quarter of 2006 was reclassified as a stock compensation expense representing the fair value of the option on the date of grant. These options were immediately vested and exercised by Ms. Ammon and the resulting compensation charge deduction of approximately \$19 million and the resulting tax sharing obligation to Endo Pharma LLC is included in our tax sharing liability discussed above. Endo Pharma LLC intends to pay the remaining \$2 million to Ms. Ammon in 2007.

**Settlement of Contingent Obligation.** During the year ended December 31, 2005, the Company reached an agreement with an individual to compensate him a total of \$2 million for past services rendered to the Company. This agreement was finalized in May 2005, and the \$2 million has been recorded in selling, general and administrative expenses during the year ended December 31, 2005. Endo Pharma LLC made these payments totaling \$2 million on behalf of the Company, and they have been treated as a capital contribution by Endo Pharma LLC.

**17. Subsequent Events**

In February 2007, approximately 0.8 million stock options were granted to employees that will vest over four years and expire ten years from the date of grant. The exercise price of the options granted was equal to the closing price on the date of grant. The grant date fair value of the awards granted was approximately \$12.5 million.

**18. Quarterly Financial Data (Unaudited)**

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share data)			
<b>2006(1)</b>				
Net sales	\$ 205,043	\$ 228,020	\$ 217,125	\$ 259,471
Gross profit	\$ 156,306	\$ 177,612	\$ 172,719	\$ 201,601
Operating income	\$ 27,023	\$ 89,230	\$ 65,777	\$ 28,499
Net income	\$ 20,538	\$ 57,636	\$ 44,891	\$ 14,774
Net income per share (basic)	\$ 0.15	\$ 0.43	\$ 0.34	\$ 0.11
Net income per share (diluted)	\$ 0.15	\$ 0.43	\$ 0.33	\$ 0.11
Weighted average shares (basic)	132,877	133,051	133,270	133,505
Weighted average shares (diluted)	133,790	133,936	134,147	134,136

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share data)			
<b>2005(2)</b>				
Net sales	\$ 137,754	\$ 196,380	\$ 245,241	\$ 240,789
Gross profit	\$ 108,169	\$ 154,122	\$ 183,842	\$ 187,681
Operating income	\$ 20,231	\$ 77,119	\$ 104,726	\$ 111,173
Net income	\$ 13,815	\$ 49,046	\$ 66,553	\$ 72,881
Net income per share (basic)	\$ 0.10	\$ 0.37	\$ 0.50	\$ 0.55
Net income per share (diluted)	\$ 0.10	\$ 0.37	\$ 0.50	\$ 0.54
Weighted average shares (basic)	131,871	131,973	132,376	132,736
Weighted average shares (diluted)	132,829	132,929	133,532	133,744

**Table of Contents**

Quarterly and year to date computations of per share amounts are made independently; therefore, the sum of the per share amounts for the quarters may not equal per share amounts for the year.

- (1) Operating income for the year ended December 31, 2006 was impacted by milestone payments to partners of \$10.4 million and compensation expense of \$42.4 million to be funded by Endo Pharma LLC in the first quarter. Operating income for the year ended December 31, 2006 was also impacted by fourth quarter charges to record the impairment of both the Synera™ and DepoDur® intangible assets, which amounted to \$31.3 million, as well as a \$26.0 million charge to expense purchased in-process research and development associated with the acquisition of RxKinetix, and the reversal of a contingent liability of \$6.5 million.
  
- (2) Operating income for the year ended December 31, 2005 was impacted by up-front and milestone payments to partners of \$20 million in the first quarter, \$6.5 million in the third quarter and \$0.8 million in the fourth quarter. Operating income for the year ended December 31, 2005 was also impacted by the write-off of the transdermal fentanyl patch inventory and unamortized portion of the license fee of \$10.5 million in the third quarter and the recovery of \$0.7 million of this write-off in the fourth quarter.

F-40



**Table of Contents**

**Exhibit Index**

<b>Exhibit No.</b>	<b>Title</b>
3.1	Amended and Restated Certificate of Incorporation of Endo Pharmaceuticals Holdings Inc. ( Endo ) (incorporated herein by reference to Exhibit 3.1 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
3.2	Amended and Restated By-laws of Endo (incorporated herein by reference to Exhibit 3.2 of the Form 10-Q for the Quarter ended March 31, 2003 filed with the Commission on May 14, 2003)
4.1	Amended and Restated Executive Stockholders Agreement, dated as of July 7, 2003, by and among Endo, Endo Pharma LLC ( Endo LLC ), Kelso Investment Associates V, L.P. ( KIA V ), Kelso Equity Partners V, L.P. ( KEP V ) and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended June 30, 2003 filed with the Commission on August 14, 2003)
4.1.2	Amendment to Amended and Restated Executive Stockholders Agreement, dated as of June 28, 2004, by and among Endo, Endo LLC, KIA V, KEP V and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended September 30, 2004 filed with the Commission on November 5, 2004) the Commission on July 1, 2003)
4.1.3	Amendment 2 to the Amended and Restated Stockholders Agreement, dated September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Amending Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.2	Amended and Restated Employee Stockholders Agreement, dated as of June 5, 2003, by and among Endo, Endo LLC, KIA V, KEP V and the Employee Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.2 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
4.2.2	Amendment to Amended and Restated Employee Stockholders Agreement, dated as of June 28, 2004, by and among Endo, Endo LLC, KIA V, KEPV and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended September 30, 2004 filed with the Commission on November 5, 2004)
4.2.3	Amendment 2 to the Amended and Restated Employee Stockholders Agreement, dated September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Amending Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.2.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.3	Employee Stockholders Consent and Release, effective September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Employee Stockholders (as defined therein) signatory thereto (incorporated herein by reference to Exhibit 4.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.4	Registration Rights Agreement, dated as of July 17, 2000, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 4.4 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.5	Amendment to Registration Rights Agreement, dated as of June 30, 2003, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 10.1 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
10.1	Shelf Registration Agreement, dated September 21, 2005, by and between Endo, Endo LLC and certain Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
10.2	Shelf Registration Agreement, dated April 30, 2004, between Endo Pharmaceuticals Holdings Inc. and Endo Pharma LLC (incorporated herein by reference to Exhibit 10.2 of Amendment No. 1 to the Form S-3 Registration Statement (Registration No. 333-115032) filed with the Commission on June 10, 2004)

**Table of Contents**

10.3	Amendment to Shelf Registration Agreement, dated June 10, 2004 between Endo Pharmaceuticals Holdings Inc. and Endo Pharma LLC (incorporated herein by reference to Exhibit 10.3 of Amendment No. 1 to the Form S-3 Registration Statement (Registration No. 333-115032) filed with the Commission on June 10, 2004)
10.4	[Intentionally Omitted.]
10.5	[Intentionally Omitted.]
10.6	Amended and Restated Tax Sharing Agreement, dated as of April 30, 2004 by and among Endo, Endo Inc. and Endo LLC (incorporated herein by reference to Exhibit 10.6 of the Form 10-Q for the Quarter ended March 31, 2004 filed with the Commission on May 10, 2004)
10.7	[Intentionally Omitted]
10.8	[Intentionally Omitted]
10.9	[Intentionally Omitted]
10.10	Sole and Exclusive License Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals Inc. ( Endo Pharmaceuticals ) and Hind Health Care, Inc. (incorporated herein by reference to Exhibit 10.10 of the Registration Statement filed with the Commission on June 9, 2000)
10.11	[Intentionally Omitted.]
10.12	[Intentionally Omitted.]
10.13	[Intentionally Omitted.]
10.14	Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd (incorporated herein by reference to Exhibit 10.14 of the Registration Statement filed with the Commission on June 9, 2000)
10.15	Supply Agreement, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt Inc. ( Mallinckrodt ) (incorporated herein by reference to Exhibit 10.15 of the Registration Statement filed with the Commission on June 9, 2000)
10.16	Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16 of the Registration Statement filed with the Commission on June 9, 2000)
10.16.1	First Amendment, effective July 1, 2000, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16.1 of the Current Report on Form 8-K dated April 14, 2006)
10.16.2	Second Amendment, dated April 10, 2006, to the Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16.2 of the Current Report on Form 8-K dated April 14, 2006)
10.17	[Intentionally Omitted.]
10.18	Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, by and between Endo Pharmaceuticals and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 10.18 of the Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2002 filed with the Commission on May 14, 2002)
10.18.1	Amendment, dated January 7, 2007, to the Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, by and between Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Company (incorporated herein by reference to Exhibit 10.18.1 of the Current report on From 8-K dated January 11, 2007)
10.19	Agreement, dated as of February 1, 2000, by and between Endo Pharmaceuticals and UPS Supply Chain Solutions, Inc. (f/d/b/a Livingston Healthcare Services Inc.) (incorporated herein by reference to Exhibit 10.19 of the Registration Statement filed with the Commission on June 9, 2000)
10.20	Medical Affairs Support Services Agreement, dated as of June 1, 1999, by and between Endo Pharmaceuticals and Kunitz and Associates, Inc. (incorporated herein by reference to Exhibit 10.20 of the Registration Statement filed with the Commission on June 9, 2000)
10.21	Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.21 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)

**Table of Contents**

10.22	Endo LLC Amended and Restated 1997 Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.22 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.23	Endo LLC Amended and Restated 1997 Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.23 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.24	Endo LLC 2000 Amended and Restated Supplemental Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.24 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.25	Endo LLC 2000 Amended and Restated Supplemental Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.25 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.26	Amended and Restated Employment Agreement, dated as of December 31, 2006, by and between the Company and Charles A. Rowland, Jr. (incorporated herein by reference to Exhibit 10.26 of the Current Report on Form 8-K dated January 5, 2007)
10.27	Amended and Restated Employment Agreement, dated as of December 31, 2006, by and between the Company and Joyce N. LaViscount (incorporated herein by reference to Exhibit 10.27 of the Current Report on Form 8-K dated January 5, 2007)
10.29	Amended and Restated Employment Agreement, dated as of December 31, 2006, by and between the Company and David A. H. Lee (incorporated herein by reference to Exhibit 10.29 of the Current Report on Form 8-K dated January 5, 2007)
10.30	[Intentionally Omitted.]
10.31	[Intentionally Omitted.]
10.32	[Intentionally Omitted.]
10.33	[Intentionally Omitted.]
10.34	Lease Agreement, dated as of May 5, 2000, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34 of the Registration Statement filed with the Commission on June 9, 2000)
10.34.1	Amendment to Lease Agreement, dated as of November 6, 2006, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34.1 of the Form 10-Q for the quarter ended September 30, 2006 filed with the Commission on November 9, 2006)
10.35	Amended and Restated Employment Agreement, dated as of December 31, 2006, by and between the Company and Caroline B. Manogue (incorporated herein by reference to Exhibit 10.35 of the Current Report on Form 8-K dated January 5, 2007)
10.36	Amended and Restated Employment Agreement, dated as of December 31, 2006, by and between the Company and Peter A. Lankau (incorporated herein by reference to Exhibit 10.36 of the Current Report on Form 8-K dated January 5, 2007)
10.37	Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.37 of the Form 10-Q for the Quarter ended June 30, 2004 filed with the Commission on August 9, 2004)

**Table of Contents**

10.38	[Intentionally Omitted.]
10.39	Master Development and Toll Manufacturing Agreement, dated as of May 3, 2001, by and between Novartis Consumer Health, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.39 of the Form 10-Q for the Quarter Ended June 30, 2001 filed with the Commission on August 14, 2001)
10.39.1	First Amendment, effective February 1, 2003, to the Master Development and Toll Manufacturing Agreement between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.1 of the Form 10-Q for the Quarter Ended June 30, 2005 filed with the Commission on August 8, 2005)
10.39.2	Second Amendment, effective as of December 1, 2004, to the Master Development and Toll Manufacturing Agreement between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.2 of the Form 10-Q for the Quarter Ended June 30, 2005 filed with the Commission on August 8, 2005)
10.40	Lease Agreement between Painters Crossing Three Associates, L.P. and Endo Pharmaceuticals Inc. dated January 19, 2007
10.41	Policy of Endo Pharmaceuticals Holdings Inc. Relating to Insider Trading in Company Securities and Confidentiality of Information (incorporated herein by reference to Exhibit 10.41 of the Form 10-Q for the Quarter ended March 31, 2005 filed with the Commission on May 10, 2005)
10.42	Development, Commercialization and Supply License Agreement, dated as of November 8, 2002, by and between DURECT Corporation and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.42 of the Current Report on Form 8-K dated November 14, 2002)
10.42.2	Amendment to Development, Commercialization and Supply License Agreement, dated January 28, 2004, between DURECT Corporation and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.42.2 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
10.42.3	Amendment No. 2 to the Development, Commercialization and Supply License Agreement, dated November 22, 2004, between DURECT Corporation and Endo Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.42.3 of the Current Report on Form 8-K dated November 29, 2004)
10.42.4	Amendment No. 3 to the Development, Commercialization and Supply License Agreement, dated January 20, 2006, between DURECT Corporation and Endo Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.42.4 of the Current Report on Form 8-K dated January 25, 2006)
10.43	Development and Marketing Strategic Alliance Agreement, dated as of December 31, 2002, by and among Endo Pharmaceuticals, SkyePharma, Inc. and SkyePharma Canada, Inc. (incorporated herein by reference to Exhibit 10.43 of the Current Report on Form 8-K dated January 8, 2003)
10.43.1	Agreement to Terminate the Development and Marketing Strategic Alliance Agreement between Endo Pharmaceuticals Inc., SkyePharma, Inc., and Jagotec AG, assignee of SkyePharma Canada, Inc., effective February 12, 2007 (incorporated herein by reference to Exhibit 10.43.1 of the Current Report on Form 8-K dated January 16, 2007)
10.43.2	Amendment to Development and Marketing Strategic Alliance Agreement, dated March 2, 2004, between Endo Pharmaceuticals, SkyePharma, Inc. and SkyePharma Canada, Inc. (incorporated herein by reference to Exhibit 10.43.2 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
10.44	Lease Agreement, dated as of January 6, 2003, by and between Endo Pharmaceuticals and Dawson Holding Company (incorporated by reference to Exhibit 10.44 of the Annual Report on Form 10-K for the Year Ended December 31, 2002 filed with the Commission on March 27, 2003)
10.45	Lease Agreement, dated as of November 13, 2003, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
10.45.1	Amendment to Lease Agreement, dated as of February 16, 2005, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45.1 of the Current Report on Form 8-K dated February 18, 2005)
10.45.2	Amendment to Lease Agreement, dated as of November 6, 2006, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.34.1 of the Form 10-Q for the quarter ended September 30, 2006 filed with the Commission on November 9, 2006)

**Table of Contents**

10.46	License Agreement, dated as of February 25, 2004, by and between Endo Pharmaceuticals and Noven Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.46 of Amendment No. 2 to the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on June 25, 2004)
10.46.1	Termination Agreement, dated as of February 24, 2006, by and between Noven Pharmaceuticals, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.46.1 of the Annual Report on Form 10-K for the Year Ended December 31, 2005 filed with the Commission on March 8, 2006)
10.47	Supply Agreement, dated as of February 25, 2004, by and between Endo Pharmaceuticals and Noven Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.47 of Amendment No. 2 to the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on June 25, 2004)
10.48	License and Co-Promotion Rights Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.48 of the Current Report on Form 8-K dated July 19, 2004)
10.48.1	Co-Promotion Agreement, dated as of July 1, 2005, by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.1 of the Current Report on Form 8-K dated July 8, 2005)
10.48.2	Second Amendment, dated as of December 12, 2005, to the License Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.2 of the Current Report on Form 8-K dated December 29, 2005)
10.48.3	First Amendment, dated as of December 12, 2005, to the Co-Promotion Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.3 of the Current Report on Form 8-K dated December 29, 2005)
10.49	Loan Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.49 of the Current Report on Form 8-K dated July 19, 2004)
21	Subsidiaries of the Registrant
23	Consent of Independent Registered Public Accounting Firm
24	Power of Attorney
31.1	Certification of the Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.3	Certification of the Chief Accounting Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certificate of the Chief Executive Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certificate of the Chief Financial Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.3	Certificate of the Chief Accounting Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002