ENDO PHARMACEUTICALS HOLDINGS INC
Form 10-K
March 15, 2004

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SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

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

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the fiscal year ended December 31, 2003

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

100 Painters Drive
Chadds Ford, Pennsylvania 19317
(Address of Principal Executive Offices)

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

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

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

Title of Each Class	**Name of Each Exchange on Which Registered**

Common Stock	Nasdaq

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Annual Report for the Year Ended December 31, 2003

Indicate by check [X] 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 [X] No [ ]

Indicate by check [X] 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. [X]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes [X] 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, 2003): $517,146,904 based on the last reported sale price on the Nasdaq on June 30, 2003.

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of March 8, 2004: 131,788,333.

Documents Incorporated by Reference

Portions of the registrant s Information Statement relating to its 2004 Annual Meeting are incorporated by reference in Part III of this Report. In addition, the Company s Registration Statement on Form S-4 filed with the Securities and Exchange Commission on June 9, 2000, as amended, the Company s Registration Statement on Form S-3 dated October 17, 2001 and the Company s Registration Statement on Form S-3 dated July 1, 2003, are incorporated by reference into this Report.

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Forward Looking Statements

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

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

results of clinical trials on new products;

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

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

market acceptance of our future products;

government regulation of the pharmaceutical industry;

our dependence on a small number of products;

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

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

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

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

our ability to protect our proprietary technology;

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

the availability of controlled substances that constitute the active ingredients of some of our products and products in development;

the availability of third-party reimbursement for our products; and

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

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

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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 IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled $16.6 billion in 2003. This represents an approximately 20% compounded annual growth rate since 1998. Our primary area of focus within this market is in the opioid analgesics segment. Total U.S. sales for this segment were $5.6 billion in 2003, representing a compounded annual growth rate of 25% since 1998.

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

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

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

Through a dedicated sales force of approximately 230 sales representatives in the United States, we market our branded pharmaceutical products to high-prescribing physicians in pain management, surgery, oncology and primary care. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

Endo was incorporated on November 18, 1997 under the laws of the state of Delaware and has its principal executive offices at 100 Painters Drive, 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 pursuing other markets, especially those with complementary therapeutic or physician bases. The elements of our strategy include:

Capitalizing on our established brand names and brand awareness through focused marketing and promotional efforts. Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, continues to increase market penetration due to our ongoing promotional and educational efforts. We consider two of our brands, Percocet® and Percodan®, to be gold standards of pain management. Percocet® has been prescribed by physicians since 1976, while Percodan® has been prescribed since 1950. We believe that we have established credibility with physicians as a result of these products history of demonstrated effectiveness and safety. We plan to continue to capitalize on this brand awareness to market new products and explore new indications for existing products as well as market new formulations and dosages of our existing branded products. We believe that our strong

corporate and product reputation leads to more rapid adoption of our new products by physicians.

Leveraging our pain management expertise by developing proprietary products and generic products with significant barriers to market entry. To capitalize on our expertise in pain management, we are developing new products to address acute, chronic and neuropathic pain conditions. Specifically, we are developing new patent-protected products that may substantially improve the treatment of pain. Recently, we co-developed an oral extended-release (ER) version of oxymorphone with Penwest Pharmaceuticals Co. and developed an oral immediate-release (IR) version of oxymorphone. The NDAs for these oxymorphone ER tablets and IR tablets were filed with the FDA in December 2002, and we received Approvable Letters for these two products in October 2003. In

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addition, we are developing with our partner, SkyePharma, Inc., two of SkyePharma s patent-protected development products, DepoMorphine™ and Propofol IDD-D™. DepoMorphine™, a sustained-release injectable formulation of morphine sulfate, and Propofol IDD-D™, an anesthetic agent administered intravenously, are our first post-surgical, critical-care drugs. Our partner filed an NDA for DepoMorphine™ in July of 2003, and we expect to receive a first action letter by mid-2004. Further, our development partner DURECT Corporation is developing DURECT s patent-protected product, CHRONOGESIC™ (sufentanil) Pain Therapy System, to treat patients with chronic pain resulting from a variety of malignant and non-malignant causes. If approved, this product would represent the first systemic medication that provides patients with uninterrupted pain treatment for three months from a single application.

We have also developed an extended-release oxycodone, a generic version of OxyContin, a product of The Purdue Frederick Company. According to IMS Retail Provider Perspective data, OxyContin generated U.S. sales of approximately $1.9 billion in 2003. We have received tentative approval from the FDA for bioequivalent versions of the 10mg, 20mg, 40mg and 80mg strengths of OxyContin. We believe we are the first company to have filed an abbreviated new drug application, or ANDA, with the FDA for the bioequivalents versions of the 10mg, 20mg and 40mg strengths of OxyContin, thereby potentially entitling us to 180 days of generic product marketing exclusivity with respect to these strengths of this product. For several reasons, including potential marketing exclusivity, we believe it is a significant advantage to be the first successful filer of an ANDA for a generic drug. In July 2002, we received a tentative approval from the FDA for all four strengths (10mg, 20mg, 40mg and 80mg) of our generic OxyContin. We currently are in litigation with Purdue Frederick with respect to this product, and the trial was completed in June 2003. On January 5, 2004, the U.S. District Court for the Southern District of New York issued an Opinion and Order dismissing Purdue s claims that Endo s oxycodone extended-release tablets, 10mg, 20mg, 40mg and 80mg, a bioequivalent version of Purdue Frederick s OxyContin, infringe Purdue s U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, declaring these patents invalid, and enjoining Purdue from enforcing the patents. See Item 3. Legal Proceedings.

Acquiring and in-licensing complementary products, compounds and technologies. We look to continue to enrich our product line through selective product acquisitions and in-licensing, or acquiring licenses to products, compounds and technologies from third parties. In November 2002, we entered into an agreement whereby we received the exclusive promotional rights to the development product CHRONOGESIC™ in the U.S. and Canada. Under this agreement, we will be responsible for marketing, sales and distribution. In December 2002, we entered into a development and commercialization agreement and received an exclusive license to the U.S. and Canadian marketing and distribution rights for DepoMorphine™ and Propofol IDD-D™. If approved, these medications would expand our presence in the hospital-based setting, consistent with our strategy of growing our franchise in pain management and complementary therapies. In February 2004, we entered into an agreement for the exclusive U.S. and Canadian marketing and distribution rights to Noven Pharmaceuticals, Inc. s developmental transdermal fentanyl patch intended to be the generic equivalent of Johnson & Johnson s Duragesic (fentanyl transdermal system), which had U.S. sales of approximately $1.3 billion in 2003. The agreement also establishes an ongoing collaboration between the two companies for the development of additional prescription transdermal products.

Developing and marketing product line extensions of our existing brands. We plan to continue to develop and market extensions of existing products through new formulations, dosages and delivery platforms. During the fourth quarter of 1999, we complemented the existing Percocet® 5.0/325 with three new formulations: Percocet® 2.5/325, Percocet® 7.5/500 and Percocet® 10.0/650. Additionally, during the fourth quarter of 2001, we launched two new formulations: Percocet® 7.5/325 and Percocet® 10.0/325, providing physicians with ever greater flexibility when treating their patients who are in pain. Led by the performance of Percocet® 7.5/325 and Percocet® 10.0/325, net sales of the Percocet® family of products increased 48% from $144.6 million in 2002 to $214.2 million in 2003.

Our Competitive Strengths

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

Established portfolio of branded products. We have assembled a portfolio of branded pharmaceutical products to treat and manage pain. These products include Lidoderm®, a topical patch containing lidocaine, which is the first FDA-approved product to treat the pain relating to post-herpetic neuralgia. The FDA has granted Lidoderm® orphan drug status, which means, generally, that no other lidocaine-containing product can be approved for this indication until March 2006. Additionally, Lidoderm® is protected by certain patents until 2015. Net sales of Lidoderm® increased 114% from $83.2 million in 2002 to $178.3 million in 2003. We consider Percocet®, our oxycodone/acetaminophen combination product and Percodan®, our oxycodone/aspirin combination product, which have been marketed since 1976 and 1950, respectively, to be gold standards of pain management based on their long history of

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demonstrated product safety and effectiveness. According to IMS Health data, approximately 83% of prescriptions written for oxycodone with acetaminophen are in fact written as Percocet. We believe our close relationships with physicians who are considered to be pain management thought leaders in pain centers, hospitals, and other pain management institutions enable us to improve our market penetration. We believe this interaction with the thought leaders and our track record of developing and launching new products has enabled us to pursue, through in-licensing and acquisitions, novel products for the treatment of pain and complementary therapeutic areas.

Substantial pipeline focused on pain management with a balanced focus on complementary therapeutic areas. As a result of our focused research and development efforts, we filed two NDAs with the FDA in December 2002 for oxymorphone ER tablets and oxymorphone IR tablets, which the FDA accepted for substantive review in February 2003. We received approvable letters from the FDA for both the oxymorphone ER and oxymorphone IR in October 2003. In these approvable letters, the FDA requested that we address certain questions and provide additional clarification and information, including some form of additional clinical trials to further confirm the safety and efficacy of these products. We expect to meet with the FDA to discuss the approvable letters on both our oxymorphone ER and oxymorphone IR prior to the end of the first quarter of 2004 and subsequent to that meeting anticipate having further clarity as to the path required to obtain final approvals. Additionally, our development partner, SkyePharma, Inc., filed an NDA with the FDA in July 2003 for DepoMorphine™, which the FDA accepted for substantive review in September 2003. We expect to receive a first action letter from the FDA with respect to this product in mid-2004. In addition, we have four products in Phase II clinical trials.

Research and development expertise. Our research and development effort is focused on expanding our product portfolio by capitalizing on our core expertise with analgesics. We have assembled an experienced and multi-disciplined research and development team of scientists and technicians with a proven expertise working with analgesics and complex formulations. We believe this expertise allows for timely FDA approval of our products. We have demonstrated our ability to commercialize our research and development efforts during the last six years through the launch of a number of new products and product line extensions since August 1997, which, in the aggregate, contributed approximately 56% of our net sales in 2003.

Targeted national sales and marketing infrastructure. We market our products directly to physicians through an internal sales force of 70 full-time specialty/institutional representatives and 160 full-time community-based field representatives. Through our sales force, we market our branded pharmaceutical products to just over 35,000 physicians, which include both specialists and primary care physicians. These physicians treat patients with the neuropathic pain of post-herpatic neuralgia and represent approximately 70% of prescriptions for Lidoderm® (lidocaine patch 5%).

Selective focus on generic products. Our generic product portfolio includes products focused on pain management. Development of these products involves barriers to entry such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. We believe products with these characteristics will face a lesser degree of competition and therefore provide longer product life cycles and higher profitability than commodity generic products. We have executed our generic product development strategy successfully to date with products such as morphine sulfate extended-release tablets, which we introduced in November 1998 as a bioequivalent version of MS Contin, a product of The Purdue Frederick Company. In addition, we believe we are the first company to have filed an ANDA with the FDA for the bioequivalent version of the 10mg, 20mg and 40mg strengths of Purdue Frederick s OxyContin. For several reasons, including potential marketing exclusivity, we believe it is a significant advantage to be the first successful filer of an ANDA for a generic drug. In July 2002, we received a tentative approval from the FDA for all four strengths (10mg, 20mg, 40mg and 80mg) of our generic OxyContin. We currently are in litigation with Purdue Frederick with respect to this product, and the trial was completed in June 2003. On January 5, 2004, the U.S. District Court for the Southern District of New York issued an Opinion and Order dismissing Purdue s claims that Endo s oxycodone extended-release tablets, 10mg, 20mg, 40mg and 80mg, a bioequivalent version of Purdue Frederick s

OxyContin, infringe Purdue s U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, declaring these patents invalid, and enjoining Purdue from enforcing the patents. See Item 3. Legal Proceedings.

Experienced and dedicated management team. With an average of approximately 20 years of experience in the pharmaceutical industry, our senior management team has a proven track record of building our business through internal growth as well as through acquisitions and licensing. Members of our senior management led the purchase of the company from The DuPont Merck Pharmaceutical Company in August 1997 as well as the licensing of Lidoderm®, CHRONOGESIC™, DepoMorphine™ and Propofol IDD-D™. Management has received FDA approval on more than fifteen new products and product line extensions since 1997, and as a result of several successful product launches, has grown our net sales from approximately $108.4 million in 1998 to approximately $595.6 million in 2003. In addition, management has vested stock options to acquire approximately 14% of our common stock. Substantially all of these options are exercisable solely for shares currently held by Endo Pharma LLC, a limited liability company holding the majority of our common stock, in which affiliates of Kelso & Company and certain other members of

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management have an interest, and their exercise will not dilute the ownership of our other existing common stockholders. See Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies; Compensation Related to Stock Options Endo Pharma LLC Stock Option Plans.

Our Industry

According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled $16.6 billion in 2003. This represents an approximately 20% compounded annual growth rate since 1998. Our primary area of focus within this market is analgesics. In 2003, analgesics were the fourth most prescribed medication in the United States with over 259 million prescriptions written for this classification. These products are used primarily for the treatment of pain associated with orthopedic fractures and sprains, back injuries, migraines, joint diseases, cancer and various surgical procedures.

Opioid analgesics comprised approximately 75% of the analgesics prescriptions in 2003. This market segment has grown to $5.6 billion in 2003, representing a compounded annual growth rate of 25% since 1998. If branded products were substituted for generic products, we believe the dollar value of this market segment would be substantially larger. The growth in this segment has been primarily attributable to:

- increasing physician recognition of the need and patient demand for effective treatment of pain;
- aging population (according to the U.S. Census Bureau, in 2000 the population aged 65 and older reached 35 million people and is expected to grow to 40 million people by 2010, representing 14% growth over this period);
- introduction of new and reformulated branded products; and
- increasing incidence of chronic pain conditions, such as cancer, arthritis and low back pain.

Product Overview

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

Product	Active Ingredient(s)	Branding	Status
Lidoderm®	lidocaine 5%	Branded	Marketed
Percocet®	oxycodone and acetaminophen	Branded	Marketed
Percodan®	oxycodone and aspirin	Branded	Marketed
Zydone®	hydrocodone and acetaminophen	Branded	Marketed
Morphine Sulfate ER	morphine sulfate	Generic	Marketed
Oxymorphone ER(1)	oxymorphone hydrochloride	Branded	Approvable Letter
Oxymorphone IR	oxymorphone hydrochloride	Branded	Approvable Letter
DepoMorphine™(2)	morphine sulfate	Branded	NDA filed; under FDA review
CHRONOGESIC™(3)	sufentanil	Branded	Phase II
Propofol IDD-D™(2)	propofol	Branded	Phase II
Lidoderm® (chronic low back pain)	lidocaine 5%	Branded	Phase II
LidoPain® BP(4)	lidocaine	Branded	Phase II

Transdermal Fentanyl Patch(5)	fentanyl	Generic	ANDA filed; under FDA review
Oxycodone ER(6)	oxycodone	Generic	Tentatively approved; subject to ongoing litigation

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(1) Co-developed with Penwest Pharmaceuticals Co.

(2) Licensed marketing rights from SkyePharma, Inc.

(3) Licensed marketing rights from DURECT Corporation.

(4) Licensed marketing rights from EpiCept Corporation.

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

(6) See Item 3. Legal Proceedings.

Branded Products

Lidoderm®. Lidoderm® was launched in September 1999. A topical patch product containing lidocaine, it is the first FDA-approved product for the relief of the pain relating to post-herpetic neuralgia. There are approximately 200,000 patients per year who suffer from this condition in the United States, the majority of whom are elderly. The FDA has granted Lidoderm® orphan drug status, generally meaning that no other lidocaine-containing patch product can be approved for this indication until March 2006. Certain exceptions apply (for example, a product shown to be clinically superior may be approved); however, we are unaware that any such product has been, or is being, developed. Lidoderm® is also currently protected by patents for, among other things, a method of treating post-herpetic neuralgia and the composition of the lidocaine-containing patch. The last of these patents will expire in 2015. In 2001, 2002 and 2003, Lidoderm® net sales were $40.9 million, $83.2 million and $178.3 million, respectively. Lidoderm® accounted for approximately 30% of our 2003 net sales.

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

Percocet®. We consider Percocet® to be a gold standard of pain management. Launched in 1976, Percocet® is approved for the treatment of moderate-to-moderately severe pain. Although Percocet® has faced generic competition for nearly 20 years, in 2003, according to the IMS National Prescription Audit, approximately 16.0 million new prescriptions for this combination of oxycodone hydrochloride and acetaminophen were written for the brand name Percocet, of which, due to generic substitution, only approximately 17% were filled by pharmacists with our brand Percocet®.

During the fourth quarter of 2001, we launched two new formulations: Percocet® 7.5/325 and Percocet® 10.0/325. These new dosage strengths allow physicians the flexibility of increasing the dose of opioid while still maintaining a low level of acetaminophen. In October 2003, a competitor announced that it was launching its generic versions of Percocet® 7.5/325 and Percocet® 10.0/325. Percocet® 7.5/325 and 10.0/325 comprised approximately 74% of the net sales of Percocet® in 2003. The Percocet® family of products had net sales of $101.0 million, $144.6 million and $214.2 million in the years 2001, 2002 and 2003, respectively. The Percocet® franchise accounted for approximately 36% of our 2003 net sales.

Percodan®. Launched in 1950 for the treatment of moderate-to-moderately severe pain, we also consider Percodan® to be a gold standard of pain management. According to the IMS National Prescription Audit, in 2003, approximately 331,000 prescriptions for oxycodone hydrochloride and oxycodone terephthalate in combination with aspirin were written for the brand name Percodan. Due to generic substitution, only approximately 21% of these prescriptions were filled by pharmacists with our brand Percodan®.

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

Other. The balance of our branded portfolio consists of a number of products, none of which accounted for more than 5% of our total net sales in the 2003 fiscal year.

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Generic Products

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

Our generic portfolio is currently comprised of products that cover a range of indications, most of which are focused in pain management. Our primary generic product is morphine sulfate extended-release tablets, which accounted for 16% of our total net sales in 2003. Launched in November 1998, morphine sulfate extended-release tablets are a bioequivalent version of Purdue Frederick s MS Contin. In November 1998, we launched the 15mg, 30mg and 60mg strengths, in May 2001, we launched the 100mg strength and in September 2001, we launched the 200mg strength, thereby completing the product line. During the third quarter of 2003, the FDA approved all five strengths of another company s version of generic morphine sulfate extended-release tablets.

In addition, we have a generic oxycodone hydrochloride and acetaminophen product, Endocet®, which accounted for 11% of our total net sales in 2003. We also offer a generic of Sinemet® (carbidopa/levodopa) for the treatment of the symptoms of idiopathic Parkinson s disease. The balance of our generic portfolio consists of a few other products, none of which accounted for more than 5% of our total net sales for 2003.

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.

Products in Development

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

Oxymorphone ER. In December 2002, we filed an NDA for oxymorphone ER with the FDA, and in February 2003, this NDA was accepted for substantive review. We received an approvable letter from the FDA for oxymorphone ER in October 2003. In this approvable letter, the FDA requested that we address certain questions and provide additional clarification and information, including some form of additional clinical trials to further confirm the safety and efficacy of this product. We expect to meet with the FDA to discuss the approvable letter on our oxymorphone ER prior to the end of the first quarter of 2004 and subsequent to that meeting anticipate having further clarity as to the path required to obtain final approval. If approved, oxymorphone ER is intended to treat moderate-to-severe pain in patients requiring continuous, around-the-clock opioid therapy for an extended period of time. In Phase III clinical studies in each of osteoarthritis pain, chronic low back pain and cancer pain, we believe patients taking oxymorphone ER demonstrated statistically significant pain relief. We co-developed this oral extended-release version of oxymorphone with Penwest Pharmaceuticals. If approved, we expect oxymorphone ER

will compete in the approximately $3.6 billion U.S. strong opioid market.

Oxymorphone IR. In December 2002, we filed an NDA for oxymorphone IR with the FDA and in February 2003, this NDA was accepted for substantive review. We received an approvable letter from the FDA for oxymorphone IR in October 2003. In this approvable letter, the FDA requested that we address certain questions and provide additional clarification and information, including some form of additional clinical trials to further confirm the safety and efficacy of this product. We expect to meet with the FDA to discuss the approvable letter on our oxymorphone IR prior to the end of the first quarter of 2004 and subsequent to that meeting anticipate having further clarity as to the path required to obtain final approval. If approved, oxymorphone IR is intended to treat acute moderate-to-severe pain. In Phase III clinical studies in post-surgical pain, we believe patients taking oxymorphone IR demonstrated statistically significant pain relief.

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DepoMorphine™. DepoMorphine™ is a sustained-release injectable formulation of morphine sulfate, the sole active ingredient, encapsulated with SkyePharma s patented DepoFoam™ controlled-release delivery technology. DepoMorphine™, administered epidurally, is intended for the management of post-operative pain. Our development partner, SkyePharma, Inc., filed an NDA with the FDA in July 2003 for DepoMorphine™, which the FDA accepted for substantive review in September 2003. We expect to receive a first action letter from the FDA on DepoMorphine™ in mid-2004. We believe that the pivotal Phase III clinical studies have shown that DepoMorphine™ administered in patients undergoing various surgeries has a safety profile typical for an epidural opioid agent and that patients experienced dose-related post-operative pain relief for 48 hours. We believe that the efficacy results were statistically significant.

CHRONOGESIC™. Currently in Phase II development, CHRONOGESIC™ is intended to target patients with opioid responsive chronic pain that results from a variety of causes. CHRONOGESIC™ is designed to deliver sufentanil continuously for three months of pain therapy. CHRONOGESIC™ is a miniature, self-driven titanium pump that is placed just under the skin, similar in size to a matchstick, from which drug is dispensed by the natural process of osmosis at a highly controlled rate. The CHRONOGESIC™ clinical development program is on temporary hold pending DURECT s implementation of some necessary design and manufacturing enhancements to the CHRONOGESIC™ product. DURECT anticipates that the implementation of these design and manufacturing enhancements will delay the restart of clinical trials.

Propofol IDD-D™. Currently in Phase II clinical trial development, Propofol IDD-D™ is an intravenous, or IV, formulation of propofol as the sole active ingredient using SkyePharma s patented Insoluble Drug Delivery (IDD-D™) technology to improve solubility. Propofol IDD-D™ is intended for the maintenance of anesthesia in adults during surgery and for sedation of adults hospitalized in an intensive-care setting. We expect Propofol IDD-D™ to advance to Phase III clinical trials during the first half of 2004.

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

Transdermal Fentanyl Patch. Currently under FDA review, the ANDA for a transdermal fentanyl patch was accepted for filing as of October 1, 2003. This product was developed by Noven Pharmaceuticals, Inc. If approved, this product would be the generic equivalent of Johnson & Johnson s Duragesic (fentanyl transdermal system) which had U.S. sales of approximately $1.3 billion in 2003.

Oxycodone ER. We have also developed an extended-release oxycodone, a generic version of OxyContin, a product of The Purdue Frederick Company. According to IMS Retail Provider Perspective data, OxyContin generated U.S. sales of approximately $1.9 billion in 2003, up from approximately $1.6 billion in 2002. We have received tentative approval from the FDA for bioequivalent versions of the 10mg, 20mg, 40mg and 80mg strengths of OxyContin. We currently are in litigation with Purdue Frederick regarding our generic version of OxyContin. The trial was completed in June 2003. On January 5, 2004, the U.S. District Court for the Southern District of New York issued an Opinion and Order dismissing Purdue s claims that Endo s oxycodone extended-release tablets, 10mg, 20mg, 40mg and 80mg, infringe Purdue s U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, declaring these patents invalid, and enjoining Purdue from enforcing the patents. See Item 3. Legal Proceedings. We believe we are the first company to have filed an ANDA with the FDA for the bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin, thereby potentially entitling us to 180 days of generic product marketing exclusivity with respect to these strengths of this product. Given the recent passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003, with accompanying amendments to the Hatch-Waxman Act, our marketing exclusivity would generally begin to run upon the earlier of our commercial launch of these products or 75 days following an appellate court decision affirming the district court s decision. The rules governing market exclusivity, however, are

complex and may be affected by factors outside our control. Accordingly, even assuming we otherwise qualify for 180-day marketing exclusivity, we cannot guarantee that we will be able or willing to market our product during the relevant period.

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

Competition

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

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

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

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

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

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

Research and Development

We devote significant resources to research and development. At December 31, 2003, our research and development staff consisted of 59 employees, primarily based in Garden City, New York and at our corporate headquarters in Chadds Ford, Pennsylvania. On January 6, 2003, we entered into an agreement with Dawson Holding Company to lease a facility in Westbury, New York, which will become our new research and development facility in early 2004. For fiscal years 2001, 2002 and 2003, our expenditures on research and development were $39.0 million, $56.8 million and $51.0 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 toxicology and clinical studies. In addition, many of the research and development activities of products that we have licensed the marketing rights to are performed by our partners.

Seasonality

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

Customers

We sell our products directly to a limited number of large pharmacy chains and through a limited number of wholesale drug distributors that, in turn, supply products to pharmacies, hospitals, governmental agencies and physicians. Three distributors and one pharmacy chain individually accounted for 28%, 24%, 19% and 10%, respectively, of our net sales in 2001. Three distributors and one pharmacy chain individually accounted for 24%, 24%, 23% and 11%, respectively, of our net sales in 2002. Three distributors and one pharmacy chain individually

accounted for 26%, 26%, 19% and 11%, respectively, of our net sales in 2003.

In recent years, there have been numerous mergers and acquisitions among wholesale distributors as well as rapid growth of large retail drug store chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased.

Patents, Trademarks, Licenses and Proprietary Property

As of March 10, 2004, we held approximately: 22 U.S. issued patents, 15 U.S. patent applications pending, 30 foreign issued patents, and 63 foreign patent applications pending with respect to our products. In addition, as of March 10, 2004, we have licenses

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for approximately: 52 U.S. issued patents, 15 U.S. patent applications pending, 81 foreign issued patents and 82 foreign patent applications pending.

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

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

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

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

Governmental Regulation

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

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

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

In particular, the FDA has expressed interest in specific chemical structures that may be present as impurities in a number of opioid narcotic active pharmaceutical ingredients, such as oxycodone, which based on certain structural characteristics may indicate

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

We cannot determine what effect changes in regulations or legal interpretations, when and if promulgated, may have on our business in the future. Changes could, among other things, require expanded or different labeling, the recall or discontinuance of certain products, additional record keeping and expanded documentation of the properties of certain products and scientific substantiation. Such changes, or new legislation, could have a material adverse effect on our business, financial condition and results of operations. In December 2003, Congress enacted new requirements for testing drug products in children, which may increase the time and cost necessary for new drug development. President Bush has recently announced measures intended to speed the process by which generic versions of brand name drugs are introduced to the market. Additionally, the Senate recently approved a bill that would limit regulatory delays of generic drug applications and penalize companies that reach agreements with makers of brand name drugs to delay the introduction of generic versions. These changes could result in increased generic competition for our branded and generic products and could have a material adverse effect on our business, financial condition and results of operation.

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

NDA Process

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

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

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

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

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

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

Data from preclinical testing and clinical trials are submitted to the FDA in an NDA for marketing approval and to other health authorities as a marketing authorization application. The process of completing clinical trials for a new drug may take several years and require the expenditures of substantial resources. Preparing an NDA or marketing authorization application involves considerable

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

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

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

ANDA Process

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

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

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

The Generic Drug Enforcement Act of 1992, or Generic Act, allows the FDA to impose debarment and other penalties on individuals and companies that commit certain illegal acts relating to the drug approval process. In some situations, the Generic Act requires the FDA to not accept or review applications for a period of time from a company or an individual that has committed certain violations. It also provides for temporary denial of approval of applications during the investigation of certain violations that could lead to debarment and also, in more limited circumstances,

provides for the suspension of the marketing of approved drugs by the affected company. Lastly, the Act allows for civil penalties and withdrawal of previously approved applications. We believe neither we nor any of our employees have ever been subject to debarment.

Patent and Non-Patent Exclusivity Periods

A sponsor of an NDA is required to identify in its application any patent that claims the drug or a use of the drug subject to the application. Upon NDA approval, the FDA lists these patents in a publication referred to as the Orange Book. Any person that files an ANDA to secure approval of a generic version of this first, or listed drug, or a type of NDA that relies upon the data in the application for which the patents are listed, must make a certification in respect to listed patents. The FDA may not approve such an application for the drug until expiration of the listed patents unless (1) the ANDA applicant certifies that the listed patents are invalid, unenforceable or not infringed by the proposed generic drug and gives notice to the holder or the NDA for the listed drug of the bases

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upon which the patents are challenged, and (2) the holder of the listed drug does not sue the later applicant for patent infringement within 45 days of receipt of notice. Under the current law, if an infringement suit is filed, the FDA may not approve the later application until the earliest of: 30 months after submission; entry of a court judgment holding the patent invalid, unenforceable or not infringed; such time as the court may order; or the patent expires.

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

Quality Assurance Requirements

The FDA enforces regulations to assure that the methods used in, and facilities and controls used for, the manufacture, processing, packing and holding of drugs conform with current good manufacturing practices, or cGMP. The cGMP regulations the FDA enforces are comprehensive and cover all aspects of operations, from receipt of raw materials to finished product distribution, insofar as they bear upon whether drugs meet all the identity, strength, quality, purity and safety characteristics required of them. To assure compliance requires a continuous commitment of time, money and effort in all operational areas.

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

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

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

Other FDA Matters

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

effect on our business, results of operations and financial condition.

Drug Enforcement Administration

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

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, with Schedule I and II substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our current products and products in development, including oxycodone, oxymorphone, morphine, sufentanil, fentanyl and hydrocodone, are

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listed by the DEA as Schedule II or III substances under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Furthermore, the amount of scheduled substances we can obtain for clinical trials and commercial distribution is limited by the DEA.

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

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

Government Benefit Programs

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

Service Agreements

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

Third Party Manufacturing/Supply Agreements

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

Novartis Consumer Health, Inc. On May 3, 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. whereby Novartis has agreed to manufacture certain of our commercial products and products in development. We are required to purchase, on an annual basis, a minimum

amount of product from Novartis. The purchase price per product is equal to a predetermined amount per unit, subject to periodic adjustments. This agreement has a five-year term, with automatic five-year renewals thereafter. Either party may terminate this agreement on three-years notice, effective at any time after the initial five-year term. In addition, we may terminate this agreement effective prior to the fifth anniversary of the agreement upon three-years notice and the payment of certain early termination fees. Either party may also terminate this agreement on account of a material breach by the other.

Teikoku Seiyaku Co., Ltd. Under the terms of this agreement, Teikoku, a Japanese manufacturer, manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We also have an option to extend the supply area to other territories within a defined period of time. We are required to purchase, on an annual basis, a minimum amount of product from Teikoku. The purchase price for the product is equal to a predetermined amount per unit of product. The term of this agreement is from November 23, 1998 until the shorter of (1) the expiration of the last to expire patent that is licensed to us from Hind Healthcare Inc., the

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developer of Lidoderm®, or (2) November 20, 2011. This agreement may be terminated for material breach by either party and by us if the Hind Healthcare license agreement is terminated.

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

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

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

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

Other Service Agreements

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

A description of the material terms of these agreements follows:

UPS Supply Chain Management, Inc. (f/d/b/a Livingston Healthcare Services, Inc.) Under the terms of this agreement, we appointed UPS Supply Chain Management to provide customer service support, chargeback processing, accounts receivables management and warehouse and distribution services for our products in the United States. During the term of the agreement, the UPS personnel responsible for providing our customer service, chargeback processing and accounts receivable management services may not provide these services to any third party for any third party products that directly compete with our products covered under the agreement. We currently pay UPS (1) a fixed monthly fee for all services and (2) certain out-of-pocket expenses, which, in the aggregate, may, depending on the facts and circumstances at the time, represent material costs to us. For the year ended December 31, 2003, these fees and expenses were approximately $6.3 million. The current term of the agreement for all services provided UPS Supply Chain Management expires on February 28, 2005. 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

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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.

Kunitz and Associates Inc. Under the terms of the agreement, we appointed Kunitz as our exclusive provider in the United States of pharmacovigilance, medical communications, product information support, adverse drug experience surveillance and medical literature search support, with respect to all of our products. During the term of this agreement, Kunitz may not provide identical or similar services to or for any third party whose products directly compete with our products in the prescription pain management therapeutic category. For these services, we pay Kunitz a fixed amount, in equal monthly installments. This agreement, as amended, will expire on December 31, 2004, unless we exercise our option to renew the agreement for an additional one-year period (in which case it will expire on December 31, 2005). The agreement may be terminated by either party for material breach or by us, with notice, for no reason.

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

Licenses and Collaboration Agreements

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

Noven Pharmaceuticals, Inc. On February 25, 2004, we entered into a License Agreement and a Supply Agreement with Noven Pharmaceuticals, Inc., under which Noven exclusively licensed to us the U.S. and Canadian rights to its developmental transdermal fentanyl patch, which is intended to be the generic equivalent of Johnson & Johnson s Duragesic (fentanyl transdermal system). Under this agreement, we made an upfront payment to Noven of $8.0 million, $6.5 million of which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We are amortizing this intangible asset over its useful life of 11 years. Upon our first commercial sale of the fentanyl patch, Noven is entitled to receive an additional payment ranging from $5.0 million to $10.0 million, depending on the timing of launch and the number of generic competitors on the market. Noven will manufacture and supply the product at its cost, and the two companies will share profits on undisclosed terms. The License Agreement also establishes an ongoing collaboration between the two companies to identify and develop additional new transdermal therapies. As part of this effort, Noven will undertake feasibility studies to determine whether certain compounds identified by the parties can be delivered through Noven s transdermal patch technology. We are expected to fund and manage clinical development of those compounds proceeding into clinical trials.

In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts for a term of ten years from the first commercial sale of the developmental transdermal fentanyl patch product. With respect to termination rights, this agreement permits us to terminate our continued participation under a number of circumstances.

EpiCept Corp. On December 19, 2003, we entered into a license granting us exclusive, worldwide rights to certain patents of EpiCept Corp. as well as exclusive, worldwide commercialization rights to EpiCept s LidoPAIN® BP product. The license agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept s LidoPAIN® BP product. EpiCept has also retained an option to co-promote the LidoPAIN® BP product. Under this agreement, we made an upfront payment to EpiCept of $7.5 million which we capitalized as an intangible asset representing the fair value of the exclusive right and the patents. We are amortizing this intangible asset over its useful life of 13 years. Future payments made by us 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.

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DURECT Corporation. On November 8, 2002, we entered into a Development, Commercialization and Supply License Agreement with DURECT Corporation, which relates to DURECT s development product, CHRONOGESIC™. On January 28, 2004, we amended the Agreement with Durect, essentially modifying Endo s funding obligations of the ongoing development costs of CHRONOGESIC™ to take into account the program delay. The clinical development program of CHRONOGESIC™ is on temporary hold pending DURECT s implementation of some necessary design and manufacturing enhancements to CHRONOGESIC™. DURECT has informed us that it anticipates that the implementation of these design and manufacturing enhancements will delay the restart of the clinical development program. Under the terms of this agreement, as amended, for the period commencing January 1, 2004 until the earlier of January 1, 2005 or the commencement of a specified clinical trial, we will fund 25% of the ongoing development costs for the CHRONOGESIC™ product in the U.S. and Canada excluding system redesign costs and pharmacokinetic trials necessitated by any system redesign up to an aggregate amount of $250,000 for the period. Once a specified clinical trial of CHRONOGESIC™ is started or beginning on January 1, 2005 (whichever is earlier), unless the agreement is earlier terminated, we will be obligated to fund 50% of the ongoing development costs of CHRONOGESIC™. We will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under this agreement could total up to $52.0 million.

In addition, under this agreement, DURECT licensed to us the exclusive promotional rights to CHRONOGESIC™ in the U.S. and Canada. We will be responsible for marketing, sales and distribution, including providing technical support representatives dedicated to supplying technical and training support. DURECT will be responsible for the manufacture of CHRONOGESIC™. We and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC™.

Further, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, this agreement permits us to terminate our continued participation under a number of circumstances, one of which could require us to pay DURECT $10.0 million.

Finally, in connection with this agreement, on November 8, 2002, we purchased approximately $5.0 million of newly issued common shares of DURECT, representing approximately 3% of DURECT s then outstanding shares.

SkyePharma, Inc. On December 31, 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, DepoMorphine™ and Propofol IDD-D™ (collectively, the Skye Products). Under the terms of the Agreement, we 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, SkyePharma received a $25 million upfront payment from us, which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We are amortizing this intangible asset over its useful life of 17 years. In addition, SkyePharma may receive milestone payments in addition to the $25 million upfront payment of up to $95 million, which include total milestones of $10 million for DepoMorphine™ through FDA approval. During 2003, we paid $5 million to SkyePharma upon the acceptance by the FDA of the NDA for DepoMorphine™. The milestone payments also include $50 million for Propofol IDD-D™, payable when the product successfully achieves certain regulatory milestones, including FDA approval. The total further includes a $15 million milestone payable when net sales of DepoMorphine™ exceed $125 million in a calendar year, and a $20 million milestone payable when net sales of DepoMorphine™ exceed $175 million in a calendar year. SkyePharma will also receive a share of each product s sales revenue that will increase from 20% initially, to a maximum of 60%, of net sales as the Skye Products combined net sales achieve certain thresholds.

This agreement provides for the parties to work together to complete the necessary clinical, regulatory and manufacturing work for North American regulatory approval of the Skye Products. SkyePharma will be primarily responsible for clinical development up to final FDA approval, and for the manufacture of the Skye Products, including all associated costs. Upon approval, we will market each Skye Product in the U.S. and Canada, with SkyePharma as the supplier. We will be responsible for funding and conducting any post-marketing studies and for all selling and marketing expenses. Under this agreement, we also obtained options on other SkyePharma development products, including DepoBupivicaine™, a long-acting, sustained release formulation of the local anesthetic bupivacaine. We have the option to obtain commercialization rights for this product when SkyePharma successfully completes its Phase II trials, as well as any further SkyePharma products formulated using the DepoFoam™ technology successfully developed for the prophylaxis or treatment of pain.

In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents on the product expire. With

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respect to termination rights, this agreement permits us to terminate our continued participation under a number of circumstances, one of which could require us to pay SkyePharma $5.0 million.

Penwest Pharmaceuticals Co. In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals to exclusively co-develop opioid analgesic products for pain management, using Penwest s patent-protected proprietary technology, for commercial sale worldwide. On April 2, 2002, we amended and restated this agreement to provide, among other things, that this collaboration would cover only that opioid analgesic product currently under development by the parties, namely, oxymorphone ER. We have historically shared on an equal basis the costs of products developed under this agreement and will, in the future, share costs and profits on an equal basis (subject to the recoupment discussed below). On March 18, 2003, we received notice from Penwest that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of oxymorphone ER on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we are now responsible for funding 100% of these remaining costs until oxymorphone ER is approved by the FDA, at which time we will recoup from the royalties due to Penwest the full amount of what Penwest should have contributed had it not exercised such right. At this point in time, we cannot predict the cost of this agreement. We have exclusive U.S. marketing rights with respect to oxymorphone ER, subject to the terms and conditions contained in this agreement. See Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources.

Hind Healthcare Inc. In November 1998, we entered into a license agreement with Hind Healthcare Inc. for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in the United States. We paid Hind up-front fees and milestone payments on the occurrence of certain events. From now until the shorter of (1) the life of the last-to-expire patent licensed pursuant to this license agreement and (2) November 20, 2011, we will pay Hind non-refundable royalties of 10% of net sales of the product, including a minimum annual royalty of at least $500,000 per year. Because these royalty payments are based on the net sales of the product, the maximum cost of these royalty payments is uncertain at this time. During 2003, we accrued $19.9 million for this royalty, which is recorded as a reduction of net sales due to the unique nature of the license agreement and the characteristics of the involvement by Hind in Lidoderm®. Either party may terminate this agreement for material breach, and we may terminate it immediately upon termination of our supply agreement with Teikoku. In September 1999, we launched Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

Environmental Matters

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

Summary of Recent Transactions

On February 25, 2004, we entered into a License Agreement and a Supply Agreement under which Noven Pharmaceuticals, Inc. exclusively licensed to us the U.S. and Canadian rights to its developmental transdermal fentanyl patch, which is intended to be the generic equivalent of Johnson & Johnson s Duragesic (fentanyl transdermal system). Under this agreement, we made an upfront payment of $8.0 million to Noven, $6.5 million of which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We are amortizing this intangible asset over its useful life of 11 years. Upon our first commercial

sale of the fentanyl patch, Noven is entitled to receive an additional payment ranging from $5.0 million to $10.0 million, depending on the timing of launch and the number of generic competitors on the market. Noven will manufacture and supply the product at its cost, and the two companies will share profits on undisclosed terms. The License Agreement also establishes an ongoing collaboration between the two companies to identify and develop additional new transdermal therapies. As part of this effort, Noven will undertake feasibility studies to determine whether certain compounds identified by the parties can be delivered through Noven s transdermal patch technology. We are expected to fund and manage clinical development of those compounds proceeding into clinical trials.

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Description of Credit Facility

On August 26, 1997, we entered into a credit agreement with a number of lenders and The Chase Manhattan Bank (n/k/a JPMorgan Chase Bank), as administrative agent. On October 29, 2001, we repaid in full the $101.1 million of term loans that were outstanding thereunder, and on December 21, 2001, we amended and restated this credit agreement. As of December 31, 2003, no amounts were outstanding under the credit agreement.

Under the credit agreement, we have the ability to borrow on a revolving basis up to $75.0 million. The revolving loans have a final maturity of December 21, 2006.

These loans bear interest at an agreed-upon spread over the applicable base rate (as defined in the credit agreement) or over the London Interbank Offered Rate. The loans outstanding under the credit agreement are secured by a first priority security interest in substantially all of our assets. These loans are subject to mandatory repayment in limited circumstances. Voluntary prepayments of these loans and voluntary reductions of the credit facility are permitted, in whole or in part, at our option in minimum principal amounts, without premium or penalty, subject to reimbursement of the lenders costs under specified circumstances.

The credit agreement contains representations and warranties, covenants, events of default and other provisions customarily found in similar agreements. See Note 8 to the accompanying consolidated financial statements.

Employees

As of December 31, 2003, we had 492 employees, of which 59 are engaged in research and development, 21 in regulatory work, 301 in sales and marketing, 24 in quality assurance and 87 in general and administrative capacities. Our employees are not represented by unions, and we believe that our relations with our employees are good.

Executive Officers of the Registrant

Set forth below is information regarding each of our current executive officers, as of March 10, 2004:

Name	Age	Position and Offices
Carol A. Ammon	52	Chief Executive Officer and Chairman of the Board
Jeffrey R. Black	39	Senior Vice President, Chief Financial Officer and Treasurer
Peter A. Lankau	51	President and Chief Operating Officer
David A.H. Lee, M.D., Ph.D.	54	Executive Vice President, Research & Development

Caroline B. Manogue	35	Senior Vice President, General Counsel & Secretary

CAROL A. AMMON, 52, is Chief Executive Officer and Chairman of the Board of Endo. In February 2002, Ms. Ammon was appointed Chairman of the Board in addition to her then current roles of President and Chief Executive Officer. Prior to April 2003, Ms. Ammon also served as the President of Endo. Prior to joining Endo, Ms. Ammon was the President of DuPont Merck s U.S. Pharmaceuticals Division from 1996 through 1997, and from 1993 through 1995 she was the President of Endo Laboratories, L.L.C. She also serves as a director on the boards of the Christiana Care Health System and the St. Louis School of Pharmacy in St. Louis, Missouri.

JEFFREY R. BLACK, 39, is Senior Vice President, Chief Financial Officer and Treasurer of Endo. Prior to joining Endo, Mr. Black became a Partner in June 1997 with Deloitte & Touche LLP in the New York Merger and Acquisition Services Group, after joining that firm in 1986.

PETER A. LANKAU, 51, is President and Chief Operating Officer of Endo. Prior to April 2003, Mr. Lankau was Senior Vice President,

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U.S. Business of Endo. Prior to joining Endo in June 2000, Mr. Lankau was Vice President, Sales and Marketing for Alpharma USPD, Inc. in Baltimore, Maryland. He was Vice President, Sales-U.S. Pharmaceuticals for Aventis Pharmaceuticals Inc. (f/k/a Rhone Poulenc Rorer, Inc.) from 1996 to 1999, based in Collegeville, Pennsylvania. Mr. Lankau was Executive Director, Strategy and Development for Aventis from 1995 to 1996. Prior to 1995, he held various management positions at Aventis including business unit management, and had responsibility for Aventis generics business as well as managed care.

DAVID A.H. LEE, M.D. Ph.D., 54, is Executive Vice President, Research & Development and Regulatory Affairs 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, 35, is 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.

We have employment agreements with each of our executive officers.

Dividend Policy

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

Available Information

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

Item 2. *Properties*

We lease all of our properties. Of these, the most significant are our research and development facility located in Garden City, New York and our corporate headquarters in Chadds Ford, Pennsylvania. In addition, on January 6, 2003, we entered into an agreement with Dawson Holding Company to lease a facility in Westbury, New York, which will become our new research and development facility in early 2004. A description of the material terms of each of the agreements pertaining to these properties follows:

Chadds Ford, Pennsylvania

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

Painters Crossing Two Associates, L.P. Lease Agreement. On November 13, 2003, we entered into a ten-year lease with Painters Crossing Two Associates, L.P. pursuant to which Painters Crossing will lease to us a building comprised of approximately 64,424 square feet located across the street from our corporate headquarters in Chadds Ford, Pennsylvania. This lease will commence once construction of the building is complete, currently anticipated to be late 2004 or early 2005. 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

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lease.

Garden City, New York

Bristol-Myers Squibb Company (f/k/a DuPont Pharmaceuticals) Lease Agreement. Under this agreement, we currently lease a laboratory and office building from Bristol-Myers Squibb, which is located at Bristol-Myers Squibb s Garden City, New York manufacturing facility. We use these facilities for the research and development of our pharmaceutical products. The lease is not assignable by us without the consent of Bristol-Myers Squibb. The lease may be terminated (1) by us, if substantial premise alteration changes are required in order to comply with government regulations, (2) by Bristol-Myers Squibb, for tenant damage and destruction to the premises and (3) as a result of arbitration between the parties. Pursuant to an amendment dated August 26, 2002, the term of the lease expires on June 30, 2004, prior to which time we will move into our new research and development facility in Westbury, New York. See Westbury, New York.

Westbury, New York

Dawson Holding Company. Under this agreement, dated January 6, 2003, we lease a 24,190 square foot facility in Westbury, New York. Once our current lease of the Bristol-Myers Squibb facility in Garden City, New York expires, we will use this space for the research and development of our pharmaceutical products. Until such time, we are renovating this space to accommodate our needs. The annual rent due for this facility is $152,397 in the first year of the lease, escalating by 4% each year thereafter. This ten-year lease is not assignable without the consent of the landlord, Dawson Holding. This lease may by terminated (1) by us, at the end of the fifth year with the payment to Dawson Holding of approximately $239,000 plus 75% of any additional rent owed during the fifth lease year, (2) by us, with 30 days notice, if the facility has suffered a fire or other casualty and Dawson Holding has not substantially restored it to its condition existing immediately prior to the fire or other casualty within one year from the date Dawson Holding received insurance proceeds, (3) by Dawson Holding, for our default under the lease, or (4) by either Dawson Holding or us, within 30 days of any condemnation.

Item 3. ***Legal Proceedings***

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

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

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

The trial of the patent claims in all three of the suits against us and EPI concluded on June 23, 2003. On January 5, 2004, the district court issued an opinion holding that, while Endo infringes the three Purdue patents, the patents are unenforceable due to inequitable conduct. The district court, therefore, dismissed the patent claims against us and EPI, declared the patents invalid, and enjoined Purdue from further enforcement of the patents. Purdue has begun the appeal process, and has asked the appeals court to

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expedite the appeal and to stay the injunction against enforcement of the patents until the appeal is resolved. Purdue originally requested such a stay from the district court, which the district court denied on February 13, 2004. In turn, we have begun the process of cross-appealing the district court s infringement ruling. By an earlier order, the judge bifurcated the antitrust counterclaims for a separate and subsequent trial.

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.

Rowe, et al. v. Bayer Corp., et al., No. 02-1833 (E.D. La.); In Re: PPA Products Liability Litigation, MDL No. 1407 (W.D. Wash.); Landry, et al. v. Bayer Corp., et al., No. 02-1835, (E.D. La.); In Re: PPA Products Liability Litigation, MDL No. 1407 (W.D. Wash.); Everidge, et al. v. Bayer Corp., et al., No. 02-1834 (E.D. La.); In Re: PPA Products Liability Litigation, MDL No. 1407 (W.D. Wash.); Ackel, et al. v. Bayer Corp., et al., No. 02-1831 (E.D. La.); In Re: PPA Products Liability Litigation, MDL No. 1407 (W.D. Wash.); Ashton, et al. v. Bayer Corp., et al., No. 02-598 (M.D. La.); In Re: PPA Products Liability Litigation, MDL No. 1407 (W.D. Wash.); McCullough, et al. v. American Home Products Corp., et al., No. CV02-1295-S (W.D. La.); In Re: PPA Products Liability Litigation, MDL No. 1407 (W.D. Wash.)

On June 17, 2002, EPI was named, along with ten other pharmaceutical companies, as a defendant in four lawsuits filed by groups of 28, 34, 37, and 43 individual plaintiffs, respectively, in the United States District Court for the Eastern District of Louisiana. On June 18, 2002, EPI was named, along with ten other pharmaceutical companies, as a defendant in a lawsuit filed by Ellen McCullough and Brenda Businelle in the United States District Court for the Western District of Louisiana. On June 21, 2002, EPI was named, along with ten other pharmaceutical companies, as a defendant in a lawsuit filed by Joyce Ashton and Bernadine Johnson in the United States District Court for the Middle District of Louisiana. According to each of these six complaints, each of the defendant pharmaceutical companies allegedly manufactured and sold products containing phenylpropanolamine (PPA). Each complaint alleges that the defendants failed to adequately warn plaintiff of the hazards of the use of the subject products containing PPA and that as a result of this failure to warn, plaintiffs suffered injury. Each of these six cases was transferred to the United States District Court for the Western District of Washington by order of the United States Judicial Panel on Multidistrict Litigation. Each plaintiff in the above-referenced cases was directed by the presiding judge to file, not later than June 29, 2003, a separate, single-plaintiff action identifying particular defendant manufacturers whose products allegedly harmed each plaintiff. EPI neither has been named, nor served with process in any single-plaintiff case filed by any of the foregoing plaintiffs pursuant to the Court s prior order. On October 14, 2003, the Court granted EPI s motions to dismiss with prejudice the claims of 113 individual plaintiffs from the *Rowe*, *Landry*, *Everidge*, *Ackel* and *Ashton* cases on the grounds that those plaintiffs had failed to specifically allege use of an EPI product containing PPA. On October 24, 2003, the Court granted a co-defendant s motion to dismiss with prejudice, as to all defendants including EPI, the claims of 69 individual plaintiffs in the *Rowe*, *Landry*, *Everidge*, *Ackel*, *Ashton* and *McCullough* cases on the grounds that those plaintiffs failed to comply with Court-ordered discovery. One or more of the foregoing orders of dismissal with prejudice applies to every plaintiff in the *Rowe*, *Landry*, *Everidge*, *Ackel*, *Ashton* and *McCullough* cases. Moreover, on August 25, 2003, after providing plaintiffs with the opportunity to file separate single-plaintiff actions, the Court dismissed the *Rowe*, *Landry*, *Everidge*, *Ackel*, *Ashton* and *McCullough* multiplaintiff cases with prejudice. Consequently, EPI is not currently a party defendant in any multidistrict litigation proceedings concerning alleged harm from PPA. However, subsequent to the entry of the orders of dismissal, certain plaintiffs moved the District Court for reconsideration of and for relief from the foregoing August 25, 2003 and October 24, 2003 orders, and the Court has not yet ruled on those motions.

John Fontenot et al. v. Able Laboratories, Inc. et al., No. 98-845 (34th Judicial District Court for the Parish of St. Bernard, State of Louisiana)

On May 7, 2003, EPI was named, along with thirteen other pharmaceutical companies and four pharmacies, as a defendant in a lawsuit filed by John Fontenot, Helen Fontenot Serpas and Andre Paul Fontenot in the 34th Judicial District Court for the Parish of St. Bernard, State of Louisiana. Defendants removed the matter to the U.S. District Court, Eastern District of Louisiana, and a motion to remand, filed by plaintiffs, was set for hearing in September; however, on plaintiffs motion, the hearing was re-set for November 19, 2003. Federal court is the preferred jurisdiction so defendants will vigorously oppose the remand. Discovery has not yet begun as several defendants have not made appearances. According to the complaint, each of the pharmaceutical companies manufactured or distributed the drugs oxycodone, hydrocodone and/or OxyContin. The complaint alleges that the defendants failed to adequately warn physicians and their patients of the dangers involved with these drugs and that as a result of this failure to warn, plaintiffs suffered injury. EPI intended to defend itself vigorously in this case. On or about November 7, 2003, plaintiffs filed a motion to dismiss the case, and the Court signed an order, dismissing the case with prejudice, on November 26, 2003. The order was entered on December 2, 2003. Accordingly, this litigation against EPI has terminated.

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General

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

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

No matters were submitted to a vote of security holders during the fourth quarter of our fiscal year ended December 31, 2003.

PART II

Item 5. ***Market for Registrant s Common Equity and Related Stockholder Matters***

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, 2003		
1st Quarter	$14.10	$ 7.49
2nd Quarter	$19.45	$12.72
3rd Quarter	$22.26	$13.99
4th Quarter	$24.00	$14.50
Year Ending December 31, 2002		
1st Quarter	$13.31	$ 8.80
2nd Quarter	$13.05	$ 4.98
3rd Quarter	$ 9.56	$ 5.81
4th Quarter	$ 9.50	$ 5.90

Holders. As of March 11, 2004, we estimate that there were approximately 128 record holders of our common stock.

Dividends. We have not declared or paid any cash dividends on our capital stock, and do not anticipate paying any cash dividends in the foreseeable future.

Equity Compensation Plan Information. The following information relates to plans in effect as of December 31, 2003 under which equity securities of Endo may be issued to employees and directors. Although the Endo

Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan provides that stock options may be granted thereunder to non-employee consultants, Endo has never granted any such options to any such consultants.

	Column A	Column B	Column C
Plan Category	**Number of securities to be issued upon exercise of outstanding options, warrants and rights**	**Weighted-average exercise price of outstanding options, warrants and rights**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column A)**
Equity compensation plans approved by security holders			
Endo Pharma LLC Amended and Restated 1997 Executive Stock Option Plan	28,882,644(a)	$ 2.63	803,830(b)
Endo Pharma LLC Amended and Restated 1997 Employee Stock Option Plan	3,002,382(a)	$ 2.63	803,830(b)

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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)
Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan	3,330,179	$ 11.86	669,821
Equity compensation plans not approved by security holders			
Not Applicable.			

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

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

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

The consolidated financial data presented below have been derived from our audited financial statements. The selected historical consolidated financial data presented below should be read in conjunction with Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data. The selected data in this section is not intended to replace the consolidated financial statements. The information presented below is not necessarily indicative of the results of our future operations.

	Year Ended December 31,				
	1999	2000	2001	2002	2003
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Net sales	$138,546	$ 197,429	$251,979	$398,973	$595,608
Cost of sales	58,263	63,041	74,891	98,857	135,671

Gross profit	80,283	134,388	177,088	300,116	459,937
Selling, general and administrative	42,921	56,537	79,505	110,907	155,827
Research and development	9,373	26,012	38,994	56,823	51,024
Depreciation and amortization	8,309	27,624	49,234	3,142	6,272
Compensation related to stock options		15,300	37,253	34,659	144,524
Purchased in-process research and development		133,200		20,300	(6,966)
Manufacturing transfer fee				9,000	
Merger and other related costs		1,583			
Separation benefits		22,034			
Operating income (loss)	19,680	(147,902)	(27,898)	65,285	109,256
Interest expense, net	14,347	15,119	13,290	4,391	258
Income (loss) before income tax (benefit)	5,333	(163,021)	(41,188)	60,894	108,998
Income tax (benefit)	2,073	(6,181)	(4,646)	30,081	39,208
Net income (loss)	$ 3,260	$(156,840)	$ (36,542)	$ 30,813	$ 69,790
Basic and Diluted Net Income (Loss) Per Share:					
Basic	$ .05	$ (1.97)	$ (.40)	$ .30	$ .54
Diluted	$ .05	$ (1.97)	$ (.40)	$ .30	$ .53
Shares Used to Compute Basic Net Income (Loss) Per Share	71,332	79,454	91,505	102,064	128,417
Shares Used to Compute Diluted Net Income (Loss) Per Share	71,332	79,454	91,505	102,126	132,439

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	As of and for the Year Ended December 31,				
	1999	2000	2001	2002	2003
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 22,028	$ 59,196	$ 95,357	$ 56,902	$229,573
Working capital	49,541	72,759	65,259	105,058	287,922
Total assets	329,436	467,840	470,995	512,972	753,880
Total debt	191,203	198,525	91,259		
Other long-term obligations	6,745	7,218	207	7,851	589
Stockholders equity	78,587	198,173	295,122	352,692	567,617
Other Financial Data:					
Net cash provided by operating activities	$ 13,766	$ 35,069	$ 80,486	$ 109,638	$218,259
Net cash provided by (used in) investing activities	(9,074)	18,077	(6,546)	(22,274)	(45,159)
Net cash provided by (used in) financing activities	(31)	(15,978)	(37,779)	(125,819)	(429)

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

Except for the historical information contained in this Report, this Report, including the following discussion, contains forward-looking statements that involve risks and uncertainties.

Overview

We, through our wholly owned subsidiary, Endo Pharmaceuticals Inc., are engaged in the research, development, sales and marketing of branded and generic prescription pharmaceuticals used primarily for the treatment and management of pain. Branded products comprised approximately 67%, 63% and 70% of net sales for the years ended December 31, 2001, 2002 and 2003. On August 26, 1997, an affiliate of Kelso & Company and the then members of management entered into an asset purchase agreement with the then DuPont Merck Pharmaceutical Company to acquire certain branded and generic pharmaceutical products and exclusive worldwide rights to a number of new chemical entities in the DuPont research and development pipeline from DuPont Merck through the newly-formed Endo Pharmaceuticals Inc. The stock of Endo Pharmaceuticals Inc. is our only asset, and we have no other operations or business.

On July 26, 2002, our wholly owned subsidiary, Endo Pharmaceuticals Inc., acquired BML Pharmaceuticals, Inc., or BML, a privately held company, for an up-front payment of $14 million. In addition, if the FDA approved BML s lead pipeline product, an oral rinse (0.1% triclosan) for oral mucositis, Endo Pharmaceuticals Inc. would have paid the former shareholders of BML a $32 million payment and an earn-out based on a percentage of net sales of certain products in BML s pipeline. We have accounted for the acquisition using the purchase method of accounting. In accordance with the purchase method of accounting, the purchase price was allocated to BML s assets and liabilities based on their respective fair values on the date of the acquisition.

The BML acquisition included an on-going project to research and develop an oral rinse product (0.1% triclosan) for oral mucositis. As a result, the allocation of the fair value of the assets acquired and liabilities assumed included an allocation to purchased in-process research and development, or IPRD, of $20.3 million which was expensed in the

consolidated statement of operations on the acquisition date. The methodology we used on the acquisition date in determining the value of IPRD was to: 1) identify the various on-going projects that we had determined to prioritize and continue; 2) project net future cash flows of the identified projects based on then current demand and pricing assumptions, less the anticipated expenses to complete the development program, drug application, and launch of the product (significant net cash inflows from the oral rinse product (0.1% triclosan) for oral mucositis were projected in 2004); and 3) discount these cash flows based on a risk-adjusted discount rate of 20%. The discount rate was determined after considering various uncertainties at the time of the acquisition, including the relative risk of the investment and the time value of money. We allocated fair value to one project of BML Pharmaceuticals, the oral rinse (0.1% triclosan) for oral mucositis. The assets acquired and liabilities assumed, results of operations and cash flows of BML have been included in our financial statements and Management s Discussion and Analysis of Financial Conditions and Results of Operations prospectively for reporting periods beginning July 26, 2002.

On October 24, 2003, we announced that our pivotal Phase III clinical trial of the oral rinse (0.1% triclosan) product for oral mucositis did not meet its primary endpoint of preventing oral mucositis. During the fourth quarter of 2003, we made the decision to discontinue our development program for this oral rinse product. As a result we extinguished the contingent liability related to the program resulting in a gain of $7.0 million in 2003.

In May 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 have incurred significant costs associated with the preparation of Novartis manufacturing operations under this agreement. These costs primarily relate to the preparation of test batches of drug product for FDA approval and our own quality assessment and administrative costs

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relating to the shifting of existing production to Novartis. During 2003, we incurred approximately $5.8 million of these costs which are reflected in research and development expense.

Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations are primarily due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products and the impact of competitive products and pricing.

Critical Accounting Policies

To understand our financial statements, it is important to understand our accounting policies. The preparation of our financial statements in conformity with accounting principles generally accepted in the United States (generally accepted accounting principles) requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of sales deductions for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses. Significant estimates and assumptions are also required in the appropriateness of amortization periods for identifiable intangible assets and the potential impairment of goodwill and other intangible assets. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption made by us, there may also be other estimates or assumptions that are reasonable. We believe, however, that given current facts and circumstances, it is unlikely that applying any such other reasonable judgment would cause a material adverse effect on our consolidated results of operations, financial position or cash flows for the periods represented in this section. Our most critical accounting policies are described below:

Sales Deductions

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

Amortizable Intangibles: Licenses

Licenses are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives ranging from thirteen to twenty 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. Licenses are assessed periodically for impairment in accordance with Statement of Financial Accounting Standards No. 144,

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Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of (SFAS No. 144). The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset s carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs.

Goodwill and Other Intangibles

Effective January 1, 2002, we adopted the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets,* and will no longer amortize goodwill and workforce in place. Goodwill and other intangibles represents a significant portion of our assets and stockholders equity. As of December 31, 2003, goodwill and other intangibles comprised approximately 30% of our total assets and 39% of our stockholders equity. We assess the potential impairment of goodwill by comparing the fair value of goodwill to its carrying value for our one reporting unit. An impairment loss would be recognized when the estimated fair value is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

We have one reportable segment, pharmaceutical products. Goodwill arose as a result of the August 26, 1997 acquisition of certain branded and generic pharmaceutical products, related rights and certain assets of the then DuPont Merck Pharmaceutical Company (n/k/a Bristol-Myers Squibb Pharma Company) and the July 17, 2000 acquisition of Algos. Although goodwill arose in two separate transactions, the components of our operating segment have been integrated and are managed as one reporting unit. Our components extensively share assets and other resources with the other components of our business and have similar economic characteristics. In addition, our components do not maintain discrete financial information. Accordingly, the components of our business have been aggregated into one reporting unit and are evaluated as such for goodwill impairment. Goodwill is evaluated for impairment on an annual basis on January 1st of each year unless events or circumstances indicate that an impairment may have occurred between annual dates. Goodwill has been evaluated for impairment upon the adoption of SFAS No. 142 on January 1, 2002 and, based on the fair value of our reporting unit, no impairment was identified. On January 1, 2004 and 2003, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

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

	December 31, 2003	December 31, 2002
Goodwill	$181,079	$181,079
Amortizable Intangibles:		
Licenses	$ 43,500	$ 36,000
Patents	3,200	3,200
	46,700	39,200
Less accumulated amortization	(4,657)	(2,445)

Other Intangibles, net	$ 42,043	$ 36,755

Effective January 1, 2002, we reclassified the carrying amount of workforce-in-place as goodwill. The cost of license fees is capitalized and is being amortized using the straight-line method over the licenses estimated useful lives of twelve to twenty years. The cost of acquired patents is capitalized and is being amortized using the straight-line method over their estimated useful lives of seventeen years.

The pro forma effect of the adoption of SFAS No. 141 and SFAS No. 142 is as follows:

	Year Ended December 31,		
	2003	**2002**	**2001**
	(in thousands, except per share data)		
Reported net income (loss)	$69,790	$30,813	$(36,542)
Add back: Goodwill amortization			40,431
Add back: Amortization of workforce-in-place			5,948
Less: Pro forma income (tax) benefit			(6,634)
Adjusted net income (loss)	$69,790	$30,813	$ 3,203

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	Year Ended December 31,		
	2003	2002	2001
	(in thousands, except per share data)		
Basic earnings (loss) per share:			
Reported net income (loss)	$0.54	$0.30	$(0.40)
Add back: Goodwill amortization			0.44
Add back: Amortization of workforce-in-place			0.07
Less: Pro forma income (tax) benefit			(0.07)
Adjusted net income (loss)	$0.54	$0.30	$ 0.04
Diluted earnings (loss) per share:			
Reported net (loss) income	$0.53	$0.30	$(0.40)
Add back: Goodwill amortization			0.44
Add back: Amortization of workforce-in-place			0.07
Less: Pro forma income (tax) benefit			(0.07)
Adjusted net income (loss)	$0.53	$0.30	$ 0.04

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2003 is as follows (in thousands):

2004	$ 2,788
2005	2,788
2006	2,788
2007	2,788
2008	2,788

Compensation Related to Stock Options Endo Pharma LLC Stock Option Plans

In our 2001 fiscal year we incurred a non-cash charge of $37.3 million, in our 2002 fiscal year we recorded a non-cash charge of $34.7 million and in our 2003 fiscal year we recorded a non-cash charge of $144.5 million, in each case for stock-based compensation relating to the vesting of options that were issued under the Endo Pharma LLC 1997 Amended and Restated Executive Stock Option Plan and the Endo Pharma LLC 1997 Amended and Restated Employee Stock Option Plan (together, the Endo Pharma LLC 1997 Stock Option Plans) and the Endo Pharma LLC 2000 Supplemental Employee Stock Option Plan and the Endo Pharma LLC 2000 Supplemental Executive Stock Option Plan (collectively, the Endo Pharma LLC 2000 Supplemental Stock Option Plans). Under the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans, tranches of options vested if we attained certain stock price targets. As each tranche vested, we incurred a non-cash charge representing the difference between the market price of the shares underlying the options and the exercise price of such options. Upon exercise, no additional shares of our common stock will be issued, however, because these stock options are

exercisable only into shares of our common stock that are held by Endo Pharma LLC. Accordingly, these stock options do not dilute the public shareholders. In addition, Endo Pharma LLC, and not us, will receive the exercise price payable in connection with these options. Further, the shares of common stock that individuals receive upon exercise of stock options granted pursuant to the Endo Pharma LLC 2000 Supplemental Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

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

Compensation Related to Stock Options Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan

All the stock options we have granted pursuant to the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan have exercise prices equal to the market price of our stock on the date granted and, under accounting principles generally accepted in the United States of America, a measurement date occurs on the date of each grant. Consequently, we do not expect to incur a charge upon the vesting or exercise of those options.

Results of Operations

Net Sales

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

The following table presents our unaudited net sales by product category for the years ended December 31, 2001, 2002 and 2003.

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	Year Ended December 31,		
	2001	2002	2003
	(in thousands, unaudited)		
Percocet®	$100,967	$144,623	$214,187
Lidoderm®	40,878	83,218	178,299
Other brands	25,824	22,046	21,870
Total brands	167,669	249,887	414,356
Total generics	84,310	149,086	181,252
Total net sales	$251,979	$398,973	$595,608

The following table presents our unaudited net sales as a percentage of total net sales for select products for the years ended December 31, 2001, 2002 and 2003.

	Year Ended December 31,		
	2001	2002	2003
	(unaudited)		
Percocet®	40%	36%	36%
Lidoderm®	16	21	30
Other brands	11	6	4
Total brands	67	63	70
Total generics	33	37	30
Total	100%	100%	100%

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

Net Sales. Net sales for the year ended December 31, 2003 increased by 49% to $595.6 million from $399.0 million in the comparable 2002 period. This increase in net sales was primarily due to the increase in the net sales of Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, Percocet®, and certain generic products. Net sales of Lidoderm® increased to $178.3 million from $83.2 million in the comparable 2002 period. In September 1999, we launched Lidoderm®, which continues to gain market share due to our ongoing promotional and educational efforts. Percocet® net sales increased to $214.2 million from $144.6 million in the comparable 2002 period due to the increase in net sales of Percocet® 7.5/325 and Percocet®

10.0/325. On October 20, 2003, Watson Pharmaceuticals announced that it was launching its generic versions of Percocet® 7.5/325 and Percocet® 10.0/325. Net sales of our generic products increased 22% to $181.3 million from $149.1 million in the comparable 2002 period primarily due to the growth of Endocet® and our generic morphine sulfate extended-release tablets. In October 2003, we launched two new strengths of our generic product Endocet®. During the third quarter of 2003, the FDA approved all five strengths of Mallinckrodt Inc. s generic extended-release morphine sulfate. Generic competition with our products may have a material impact on our results of operations and cash flows in the future. Due to the generic competition with our Percocet® and morphine sulfate extended-release tablets, partially offset by an expected increase in net sales of Lidoderm®, we expect net sales in 2004 to be approximately $570 to $580 million.

Gross Profit. Gross profit for the year ended December 31, 2003 increased by 53% to $459.9 million from $300.1 million in the comparable 2002 period. Gross profit margins increased to 77% from 75% due to a more favorable mix of higher margin brand and generic products resulting from the products discussed above. Included in cost of sales is a charge of $24.6 million in 2003 and $8.0 million in 2002 to fully reserve for the inventory of extended-release oxycodone tablets that were manufactured during those years. We expect gross profit margins to decline in 2004 due to competition with Percocet® and our extended-release morphine sulfate product. In addition, we expect to experience lower gross profit margins in 2004 on Lidoderm® due to the introduction in 2004 of a higher cost child-resistant single-patch package.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the year ended December 31, 2003 increased by 40% to $155.8 million from $110.9 million in the comparable 2002 period. This increase was due to a $31.2 million increase in sales and promotional efforts in 2003 over the comparable 2002 period to support Lidoderm® and Percocet® and in preparation of new product launches. In addition, we experienced an increase in costs in the general and administrative functions in order to support our new product marketing and new product development. We expect selling, general and administrative expenses to increase in 2004 primarily attributable to increased spending on Lidoderm® and certain of our pipeline products in anticipation of future launches as well as an increase in spending in certain support functions.

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Research and Development Expenses. Research and development expenses for the year ended December 31, 2003 decreased by 10% to $51.0 million from $56.8 million in the comparable 2002 period. This decrease reflects the overall stage of development of our development portfolio. During 2002, we were performing clinical trials on our extended-release and immediate-release oxymorphone products and MorphiDex®. During 2003, our development efforts were focused on a Phase III clinical trial on an oral mucositis product as well as other earlier stage projects focused in the area of pain management and other complementary therapeutic areas. We decided in 2003 to cease our development efforts related to the oral mucositis product. This decrease is partially offset by a $5.0 million milestone charge we incurred pursuant to our Development and Marketing Strategic Alliance Agreement with SkyePharma Inc. Under the terms of this agreement, a $5.0 million milestone becomes due upon acceptance for substantive review by the FDA of DepoMorphine . DepoMorphine was accepted for substantive review by the FDA during the third quarter of 2003. We anticipate decreasing our research and development spending in 2004 as compared to 2003.

Depreciation and Amortization. Depreciation and amortization for the year ended December 31, 2003 increased to $6.3 million from $3.1 million in the comparable 2002 period primarily due to an increase in depreciation of $1.7 million related to an increase in capital expenditures and an increase in amortization of $1.5 million primarily due to an increase in license fees arising from the SkyePharma license entered into on December 31, 2002. We expect depreciation and amortization to continue to increase as we increase our capital expenditures for new office space, new lab space and automobiles for our newly hired sales representatives and continue to license in products and technologies.

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

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

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

Manufacturing Transfer Fee. Manufacturing transfer fee during the year ended December 31, 2002 was the consideration paid to Bristol-Myers Squibb Pharma Company which allowed Endo to transfer up to 100% of any

Endo product out of any Bristol-Myers Squibb facility at any time, and for the assistance of Bristol-Myers Squibb Pharma Company in the transfer.

Interest Expense, Net. Interest expense, net for the year ended December 31, 2003 decreased to $.3 million from $4.4 million in the comparable 2002 period. This decrease is substantially due to the repayment on August 26, 2002 of the promissory notes issued to Bristol-Myers Squibb in connection with our 1997 acquisition from Bristol-Myers Squibb Pharma Company (f/k/a The Dupont Merck Pharmaceutical Company).

Income Tax. Income tax for the year ended December 31, 2003 increased to $39.2 million from $30.1 million in the comparable 2002 period. This increase is due to the increase in income before income tax for the year ended December 31, 2003.

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Year Ended December 31, 2002 Compared to Year Ended December 31, 2001

Net Sales. Net sales for the year ended December 31, 2002 increased by 58% to $399.0 million from $252.0 million in the comparable 2001 period. This increase in net sales was primarily due to the increase in net sales of Percocet®, Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia and certain generic products. Percocet® net sales increased 43% to $144.6 million from $101.0 million in the comparable 2001 period. In April 2001, generic equivalents of Percocet® 7.5/500 and Percocet® 10.0/650 were introduced. In November 2001, we launched Percocet® 7.5/325 and Percocet® 10.0/325. In September 1999, we launched Lidoderm®, which continues to gain market share due to our ongoing promotional and educational efforts. Net sales of Lidoderm® increased 103% to $83.2 million from $40.9 million in the comparable 2001 period. Generic products increased 77% to $149.1 million from $84.3 million in the comparable 2001 period primarily due to the growth of our generic morphine sulfate extended release tablets and Endocet®. In November 1998, we launched the 15mg, 30mg and 60mg strengths, in May 2001, we launched the 100mg strength and in September 2001, we launched the 200mg strength of our generic morphine sulfate extended release tablets. In April 2001, we launched two new strengths of our generic product Endocet®. Generic competition with our products may have a material impact on our results of operations and cash flows in the future.

Gross Profit. Gross profit for the year ended December 31, 2002 increased by 69% to $300.1 million from $177.1 million in the comparable 2001 period. Gross profit margins increased to 75% from 70% in the comparable 2001 period due to a more favorable mix of higher margin brand and generic products resulting from the product launches discussed above, and the discontinuation of some lower margin non-core products. In addition, the increase in gross profit margins was also due to the fixed cost nature of our manufacturing relationship with Bristol-Myers Squibb Pharma Company (formerly DuPont Pharmaceuticals). Further, during the fourth quarter of 2002, we substantially completed the manufacture of the estimated launch quantities of our extended-release oxycodone tablets. Due to the uncertainty surrounding the ultimate timing of this product s final approval and launch, however, an $8.0 million reserve was recorded in the 2002 fourth quarter to fully reserve for this inventory. See Business Legal Proceedings.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the year ended December 31, 2002 increased by 39% to $110.9 million from $79.5 million in the comparable 2001 period. This increase was due to a $15.0 million increase in sales and promotional efforts in 2002 over the comparable 2001 period to support Lidoderm® and Percocet®. In addition, we experienced an increase in personnel-related costs in the general and administrative functions in order to support our new product marketing and new product development.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2002 increased by 46% to $56.8 million from $39.0 million in the comparable 2001 period. This increase was due to our increased spending on new products under development that are focused in pain management and complementary areas. During 2002, we completed the clinical trials of and subsequently filed the New Drug Applications relating to the extended-release and immediate-release oxymorphone products and additionally substantially concluded three Phase III clinical trials of MorphiDex®.

Depreciation and Amortization. Depreciation and amortization for the year ended December 31, 2002 decreased to $3.1 million from $49.2 million in the comparable 2001 period. Effective January 1, 2002, we have adopted the provisions of SFAS No. 142, Goodwill and Other Intangible Assets, and will no longer amortize goodwill unless evidence of an impairment exists. If SFAS No. 142 had been adopted as of January 1, 2001, depreciation and amortization for the year ended December 31, 2001 would have been $2.9 million.

Compensation Related to Stock Options. For the year ended December 31, 2002, compensation related to stock options decreased to $34.7 million from $37.3 million in the comparable 2001 period. Compensation related to stock

options reflects the charge arising from the vesting of performance-based stock options granted pursuant to the Endo Pharma LLC Stock Option Plans. Under these plans, tranches of options vest when we attain certain common stock price targets. As each tranche vests, we incur a non-cash charge

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representing the difference between the market price of the shares of common stock underlying these options and the exercise price of such options. The decrease in compensation related to stock options is due to the decrease in the market price of our common stock as of the measurement date to $7.70 in 2002 from $10.80 in 2001. This is offset in part due to an increase in the number of Endo Pharma LLC stock options that vested in 2002 as compared to 2001. During 2002, 6.9 million of these stock options vested, and during 2001, 4.6 million stock options vested. The weighted average exercise price of these stock options that vested in 2002 and 2001 was $2.69. On January 1, 2003, the Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective resulting in the issuance of approximately 10.7 million stock options to certain employees and members of management. Because approximately 9.2 million of these stock options were immediately vested upon their issuance, we recorded a non-cash compensation charge of approximately $48.5 million during the first quarter of 2003 for the difference between the market price of our common stock as of the measurement date of $7.70 and the weighted average exercise price of these stock options of $2.42. The exercise of these stock options will not result in the issuance of any additional shares of our common stock, however, because these stock options are exercisable only into shares of our common stock that are held by Endo Pharma LLC. Accordingly, these stock options do not dilute the public shareholders. For a discussion of the tax sharing agreement between us and Endo Pharma LLC relating to the Endo Pharma LLC Stock Options, see Liquidity and Capital Resources; Tax Sharing Agreement.

Purchased In-Process Research and Development. Purchased in-process research and development for the year ended December 31, 2002 of $20.3 million resulted from the estimated fair value of our oral rinse (0.1% triclosan) for oral mucositis development product that we obtained in the acquisition of BML Pharmaceuticals.

Manufacturing Transfer Fee. Manufacturing transfer fee is the one-time payment made to Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals) in the third quarter of 2002 in connection with the aforementioned amendment to the manufacturing and supply agreement, which permitted Endo to transfer up to 100% of any Endo product out of any Bristol-Myers facility at any time and compensated Bristol-Myers for its assistance to Endo in the transfer. See Business Service Agreements; Third Party Manufacturing/Supply Agreements; Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals).

Interest Expense, Net. Interest expense, net for the year ended December 31, 2002 decreased by 67% to $4.4 million from $13.3 million in the comparable 2001 period. This decrease is substantially due to our repayment on October 29, 2001 of the term loans outstanding under our credit facility and our repayment on August 26, 2002 of the promissory notes that were issued annually to DuPont Pharmaceuticals (n/k/a Bristol-Myers Squibb Pharma Company) over the initial five-year term (August 1997-August 2002) of the manufacturing and supply agreement with DuPont Pharmaceuticals. Interest expense for the year ended December 31, 2002 substantially represents the accretion of the promissory notes issued to Bristol-Myers Squibb, which we repaid on August 26, 2002, which bore no interest and therefore had been discounted in the accompanying financial statements.

Income Tax (Benefit). Income tax for the year December 31, 2002 increased to $30.1 million from an income tax benefit of $4.6 million in the comparable 2001 period substantially due to the increase in income before income tax. During 2001, we recorded a valuation allowance on our existing deferred tax assets due to the uncertainty of the utilization of such amounts in the foreseeable future. During the fourth quarter of 2001, we evaluated our anticipated future taxable income based upon the repayment of our outstanding term loans, new product approvals and other existing and estimated future product performance and determined that it is more likely than not that we will utilize our deferred tax benefits. Accordingly, we reversed our valuation reserves that had been recorded against those deferred tax assets. The reversal of the reserves established in connection with the acquisition of Algos was recorded as a reduction of goodwill. The reversal of the reserves recorded subsequent to the Algos acquisition was recorded as an increase to income tax benefit. The estimated fair value of the purchased in-process research development of $20.3 million is not a tax deductible item and, therefore, increases our effective income tax rate in 2002.

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Liquidity and Capital Resources

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

Net Cash Provided by Operating Activities. Net cash provided by operating activities increased by $108.7 million to $218.3 million for the year ended December 31, 2003 from $109.6 million for the year ended December 31, 2002. This increase was due to the cash provided by the increase in net sales and gross profit for the year ended December 31, 2003 compared to the year ended December 31, 2002, offset by an increase in selling, general and administrative expenses for the year ended December 31, 2003 as compared to the year ended December 31, 2002.

Net Cash Used in Investing Activities. Net cash utilized in investing activities increased by $22.9 million to $45.2 million for the year ended December 31, 2003 from $22.3 million for the year ended December 31, 2002. During the year ended December 31, 2003, the Company paid a $25.0 million license fee to SkyePharma, Inc. for the marketing rights to DepoMorphine and Propofol IDD-D and paid a $7.5 million license fee to EpiCept for the rights to LidoPain® BP and certain intellectual property rights. Net cash used in investing activities for the year ended December 31, 2002 included the $14.2 million used to acquire BML Pharmaceuticals in 2002 and the $5.0 million used to purchase of DURECT Corporation common stock. Capital expenditures increased in 2003 to $12.2 million from $3.1 million in 2002. This increase in capital expenditures was due primarily to the purchase in 2003 of leasehold improvements for our new research and development facility on Long Island, NY and leasehold improvements to a second corporate office building in Chadds Ford, PA.

Net Cash Utilized in Financing Activities. Net cash utilized in financing activities decreased by $125.4 million to $.4 million for the year ended December 31, 2003 from $125.8 million for the year ended December 31, 2003. During the 2002 fiscal year, we repaid all of the promissory notes issued to Bristol-Myers Squibb which totaled $118.9 million, and we utilized $6.7 million of cash, including fees, to repurchase 8.6 million Class A Transferable Warrants and Class B Non-Transferable Warrants.

Credit Facility. In December 2001, we amended and restated our senior secured credit facility with a number of lenders. This amended and restated credit facility provides us with a line of credit of $75.0 million. The line of credit matures on December 21, 2006. Any loans outstanding under the amended and restated credit facility are secured by a first priority security interest in substantially all of our assets. The credit facility contains representations and warranties, covenants, including a covenant requiring us to maintain minimum EBITDA of $50 million over the prior four-quarter period, events of default and other provisions customarily found in similar agreements. Our ability to borrow under the credit facility is dependent, among other things, on our compliance with those provisions. As of December 31, 2003, we have not borrowed any amounts under our credit facility.

Tax Sharing Agreement. On July 14, 2000, Endo Pharma LLC was formed in connection with the Algos merger to ensure that the stock options granted pursuant to the Endo Pharma LLC Stock Option Plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC will be delivered. Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we will be required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of December 31, 2003, approximately 3.6 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, 2003, approximately $35 million), which is estimated to result in a tax benefit amount of approximately $13 million. Under the tax sharing agreement, we are required to pay this $13 million to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto. If payments are made pursuant to the tax sharing agreement, they will be reflected as a reduction of stockholders equity in the accompanying financial statements.

Using a weighted average exercise price of $2.60 per share and an assumed effective tax rate of 38.3%, if all 36.3 million stock options under the Endo Pharma LLC Stock Option Plans were vested and exercised (including the 3.6 million stock options already exercised as discussed above):

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

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

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

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

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

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

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

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

Expected Cash Requirements for Contractual Obligations. The following table presents our expected cash requirements for contractual obligations outstanding as of December 31, 2003 (in thousands):

		Payment Due by Period					
Contractual Obligations	**Total**	**2004**	**2005**	**2006**	**2007**	**2008**	**Thereafter**
Operating Lease Obligations	27,690	2,648	2,920	2,952	2,805	2,812	13,553

Capital Lease Obligations	1,256	651	532	73			
Total	28,946	3,299	3,452	3,025	2,805	2,812	13,553

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

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

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

In addition, we agreed to certain contingent payments in certain of our acquisitions and licenses agreements. Specifically:

DURECT Corporation. We entered into a license agreement with DURECT Corporation to exclusively develop and commercialize DURECT s CHRONOGESIC (sufentanil) Pain Therapy System for the U.S. and Canada. This agreement was amended in January 2004. Once a specified clinical trial of CHRONOGESIC is started or beginning on January 1, 2005 (whichever is earlier), we will be obligated to fund 50% of the ongoing development costs of CHRONOGESIC . We will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by us under this agreement could total up to $52.0 million. In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. With respect to termination rights, this agreement permits us to terminate our continued participation under a number of circumstances, one of which could require us to pay DURECT $10.0 million. We and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC .

SkyePharma, Inc. We entered into a development and commercialization agreement under which we received an exclusive license to the U.S. and Canadian marketing and distribution rights for two of SkyePharma s patented development products, DepoMorphine and Propofol IDD-D , with options for certain other development products. In return, SkyePharma received a $25 million upfront payment from us. Milestone payments made by us may total up to $95.0 million which includes total milestones of $10.0 million for DepoMorphine through FDA approval. During 2003, we paid $5 million to SkyePharma upon the acceptance by the FDA of the NDA for DepoMorphine . The milestone payments also include $50.0 million for Propofol IDD-D , payable when the product successfully achieves certain regulatory milestones, including FDA approval. The total further comprises a $15.0 million milestone payable when net sales of DepoMorphine reach $125.0 million in a calendar year and a $20.0 million milestone payable when net sales of DepoMorphine reach $175.0 million in a calendar year. SkyePharma will also be paid a share of each product s sales revenue that will increase from 20% initially, to a maximum of 60% net sales as the products combined sales achieve certain thresholds.

Penwest Pharmaceuticals. On March 18, 2003, we received notice from Penwest Pharmaceuticals (a collaboration partner of Endo with which Endo has an alliance agreement and with which Endo is developing its pipeline project, oxymorphone ER) that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of this product on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we are now be responsible for funding 100% of these remaining costs until such time as the FDA approves oxymorphone ER, at which time we will recoup from the royalties due to

Penwest the full amount of what Penwest should have contributed had it not exercised such right. We believe that our cash and cash equivalents and cash flow from operating activities will be more than sufficient to meet our normal operating, investing and financing activities in the foreseeable future, including the funding of 100% of the costs to bring our pipeline products, including oxymorphone ER, to market.

Cash and Cash Equivalents. Our cash and cash equivalents totaled $229.6 million at December 31, 2003. We believe that our (a) cash and cash equivalents, (b) cash flow from operations and (c) our credit facility (which has an available unused line of credit of $75 million) will be sufficient to meet our normal operating, investing and financing requirements in the foreseeable future, including the funding of our pipeline 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.

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Recent Accounting Pronouncements

In January 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. We adopted the provisions of SFAS No. 144 on January 1, 2002, which had no material impact on our results of operations or financial position.

In June 2001, the FASB, issued SFAS No. 141, *Business Combinations,* and SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 141 was effective for all business combinations completed after June 30, 2001. SFAS No. 142 was effective for fiscal years beginning after December 15, 2001. SFAS No. 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS No. 142 establishes revised reporting requirements for goodwill and other intangible assets. See Note 7 to the Consolidated Financial Statements.

In April 2002, the FASB issued SFAS No. 145, *Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections*. SFAS No. 145 (1) rescinds SFAS No. 4 and SFAS No. 64, which relate to the extinguishment of debt, (2) rescinds SFAS No. 44 relating to the accounting for intangible assets of motor carriers, and (3) amends SFAS No. 13 relating to the accounting for leases. SFAS No. 145 also amends certain other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. Certain amounts were reclassified in accordance with SFAS No. 145 in the accompanying financial statements. The adoption of SFAS No. 145 did not have a material impact on our results of operations or financial position.

In July 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*. SFAS No. 146 requires recognition of a liability for a cost associated with an exit or disposal activity when the liability is incurred, as opposed to when the entity commits to an exit plan under previous guidance. This statement is effective for exit or disposal activities initiated after December 31, 2002. The adoption of SFAS No. 146 did not have a material impact on our results of operations or financial position.

In November 2002, the FASB issued FASB Interpretation No. 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45). FIN 45 requires that upon issuance of certain guarantees, a guarantor must recognize a liability for the fair value of an obligation assumed under the guarantee. FIN 45 also requires significant new disclosures, in both interim and annual financial statements, by a guarantor, about obligations associated with guarantees issued. FIN 45 disclosure requirements were effective for our fiscal year ended December 31, 2002 and the initial recognition and measurement provisions are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. At December 31, 2003, we had no guarantees outstanding.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. SFAS No. 148 amends SFAS No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. We have not adopted the fair value based method of accounting for employee stock-based compensation.

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

On December 21, 2001, we entered into a new credit facility that provides for a line of credit of $75.0 million. Borrowings under the new credit facility are variable rate borrowings. There are no amounts outstanding under the new credit facility. We do not utilize financial instruments for trading purposes and hold no derivative financial instruments that could expose us to significant market risk. We monitor interest rates and enter into interest rate agreements as considered appropriate.

As of December 31, 2003 and December 31, 2002, we have no assets or liabilities that have significant interest rate sensitivity

At December 31, 2003, we had publicly traded equity securities comprised of DURECT Corporation common stock at fair value totaling $3.8 million in Other assets. The fair values of this investment are subject to significant fluctuations due to volatility of the stock market and changes in general economic conditions. Based on the fair value of the publicly traded equity securities we held at December 31, 2003, an assumed 25%, 40% and 50% adverse change in the market prices of this security would result in a

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corresponding decline in total fair value of approximately $1.0 million, $1.5 million and $1.9 million, respectively.

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***

Our management, including our Chief Executive Officer and Chief Financial Officer, have 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 and Chief Financial Officer have concluded that our disclosure controls and procedures are 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.

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 quarter covered by this report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART III

Item 10. ***Directors and Executive Officers of the Registrant***

Directors

The information concerning our directors required under this Item is incorporated by reference from our definitive information statement, which will be filed with the Securities and Exchange Commission pursuant to Regulation 14C, relating to our Annual Meeting of Stockholders (our 2003 Information Statement).

Executive Officers

For information concerning Endo s executive officers, see Item 1. Business Executive Officers of the Registrant.

Item 11. ***Executive Compensation***

The information required under this Item is incorporated herein by reference from our 2003 Information Statement.

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

The information required under this Item is incorporated herein by reference from our 2003 Information Statement.

Item 13. ***Certain Relationships and Related Transactions***

The information required under this Item is incorporated herein by reference from our 2003 Information Statement.

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

Information about the fees for 2003 and 2002 for professional services rendered by our independent auditors is incorporated herein by reference from our 2003 Information Statement. Our Audit Committee s policy on pre-approval of audit and permissible non-audit services of our independent auditors is incorporated by reference from our 2003 Information Statement.

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PART IV

Item 15. ***Exhibits, Financial Statement Schedules and Reports on Form 8-K***

(a) *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)

	Balance at Beginning of Period	Additions	Deductions(1)	Other	Balance at end of period
Allowance For Doubtful Accounts:					
Year Ended December 31, 2001	$ 515	$ 300	$ (102)		$ 713
Year Ended December 31, 2002	$ 713	$ 779	$ (657)		$ 835
Year Ended December 31, 2003	$ 835	$ 339	$ (68)		$1,106

(1) Accounts written-off.

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

(b) Reports on Form 8-K.

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We filed the following Current Reports on Form 8-K in the quarter ended December 31, 2003:

Dates	Items
October 23, 2003	7 and 12
November 12, 2003	7 and 9

No financial statements were filed in connection with any such Form 8-K.

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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/ JEFFREY R. BLACK

Name: Jeffrey R. Black
Title: *Senior Vice President and Chief Financial Officer*

Date: March 15, 2004

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/ CAROL A. AMMON Carol A. Ammon	Chairman, Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2004
/S/ JEFFREY R. BLACK Jeffrey R. Black	Senior Vice President, Chief Financial Officer & Treasurer (Principal Financial & Accounting Officer)	March 15, 2004
* Brian T. Clingen	Director	March 15, 2004
* Michael B. Goldberg	Director	March 15, 2004
* Michael Hyatt	Director	

			March 15, 2004
	Roger H. Kimmel		
	*	Director	March 15, 2004
	Frank J. Loverro		
	*	Director	March 15, 2004
	Clive A. Meanwell, M.D., Ph.D.		
	*	Director	March 15, 2004
	Michael W. Mitchell		
	*	Director	March 15, 2004
	Joseph T. O Donnell, Jr.		
	*	Director	March 15, 2004
	David I. Wahrhaftig		
*By:	/S/ CAROLINE B. MANOGUE	Attorney-in-fact, pursuant to a Power of Attorney filed with this Report as Exhibit 24	March 15, 2004
	Caroline B. Manogue		

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INDEPENDENT AUDITORS REPORT

The Board of Directors and Stockholders
Endo Pharmaceuticals Holdings Inc.

We have audited the accompanying consolidated balance sheets of Endo Pharmaceuticals Holdings Inc. and subsidiaries as of December 31, 2003 and 2002, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2003. Our audits also included the financial statement schedule listed in Item 15 of the Company s Annual Report on Form 10-K. These financial statements and the financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and the financial statement schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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, 2003 and 2002, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003 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 Notes 2 and 7 to the consolidated financial statements, the Company changed its method of accounting for goodwill and other intangible assets upon adoption of Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets*, effective January 1, 2002.

/s/ DELOITTE & TOUCHE LLP

Deloitte & Touche LLP
Philadelphia, Pennsylvania
March 15 , 2004

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ENDO PHARMACEUTICALS HOLDINGS INC.

CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2003 AND 2002
(In thousands, except share data)

	2003	2002
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 229,573	$ 56,902
Accounts receivable, net of allowance of $1,106 and $835 at December 31, 2003 and 2002, respectively	101,284	119,496
Inventories	50,450	35,516
Prepaid expenses	7,145	4,354
Deferred income taxes	85,144	41,219
Total current assets	473,596	257,487
PROPERTY AND EQUIPMENT, Net	20,246	11,810
GOODWILL	181,079	181,079
OTHER INTANGIBLES, Net	42,043	36,755
DEFERRED INCOME TAXES	31,045	21,184
OTHER ASSETS	5,871	4,657
TOTAL ASSETS	$ 753,880	$ 512,972
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 65,071	$ 75,443
Accrued expenses	108,567	68,627
Income taxes payable	12,036	8,359
Total current liabilities	185,674	152,429
OTHER LIABILITIES	589	7,851
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY:		
Preferred Stock, $.01 par value; 40,000,000 shares authorized; none issued		
Common Stock, $.01 par value; 175,000,000 shares authorized; 131,769,766 and 102,064,450 shares issued and	1,318	1,021

outstanding in 2003 and 2002, respectively		
Additional paid-in capital	691,631	547,249
Accumulated deficit	(124,612)	(194,402)
Accumulated other comprehensive loss	(720)	(1,176)
Total Stockholders Equity	567,617	352,692
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 753,880	$ 512,972

See notes to consolidated financial statements.

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ENDO PHARMACEUTICALS HOLDINGS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2003, 2002 AND 2001
(In thousands, except per share data)

	2003	2002	2001
NET SALES	$595,608	$398,973	$251,979
COST OF SALES	135,671	98,857	74,891
GROSS PROFIT	459,937	300,116	177,088
COSTS AND EXPENSES:			
Selling, general and administrative	155,827	110,907	79,505
Research and development	51,024	56,823	38,994
Depreciation and amortization	6,272	3,142	49,234
Compensation related to stock options (primary selling, general and administrative)	144,524	34,659	37,253
Purchased in-process research and development	(6,966)	20,300	
Manufacturing transfer fee		9,000	
OPERATING INCOME (LOSS)	109,256	65,285	(27,898)
INTEREST EXPENSE, Net of interest income of $660, $1,155 and $2,830, respectively	258	4,391	13,290
INCOME (LOSS) BEFORE INCOME TAX (BENEFIT)	108,998	60,894	(41,188)
INCOME TAX (BENEFIT)	39,208	30,081	(4,646)
NET INCOME (LOSS)	$ 69,790	$ 30,813	$ (36,542)
NET INCOME (LOSS) PER SHARE:			
Basic	$ .54	$ .30	$ (.40)
Diluted	$ .53	$ .30	$ (.40)
NET INCOME (LOSS) Pro Forma to Exclude Amortization of Goodwill and Workforce-in-Place:	$ 69,790	$ 30,813	$ 3,203

NET INCOME (LOSS) PER SHARE Pro Forma to Exclude Amortization of Goodwill and Workforce-in-Place:			
Basic	$ .54	$ .30	$ .04
Diluted	$ .53	$ .30	$ .04
WEIGHTED AVERAGE SHARES			
Basic	128,417	102,064	91,505
Diluted	132,439	102,126	91,505

See notes to consolidated financial statements.

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ENDO PHARMACEUTICALS HOLDINGS INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
YEARS ENDED DECEMBER 31, 2003, 2002 AND 2001
(In thousands, except share data)

	Number Of Shares	Common Stock at Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders Equity	Comprehensive Income (Loss)
BALANCE, DECEMBER 31, 2000	89,138,950	891	385,955	(188,673)		198,173	
Issuance of Common Stock	12,925,000	130	96,108			96,238	
Compensation related to stock options			37,253			37,253	
Net loss				(36,542)		(36,542)	(36,542)
Comprehensive income (loss)							$ (36,542)
BALANCE, DECEMBER 31, 2001	102,063,950	1,021	519,316	(225,215)		295,122	
Repurchase of Warrants			(6,730)			(6,730)	
Exercise of options	500		4			4	
Unrealized gains (losses) on securities, net of tax					$ (1,176)	(1,176)	$ (1,176)
Compensation related to stock options			34,659			34,659	
Net income				30,813		30,813	30,813
Comprehensive income							$ 29,637
BALANCE, DECEMBER 31, 2002	102,064,450	$1,021	$547,249	$(194,402)	$ (1,176)	$352,692	

Issuance of Common Stock from exercise of warrants	29,687,602	297	(296)			1	
Compensation related to stock options			144,524			144,524	
Exercise of options	17,714		154			154	
Unrealized gains (losses) on securities, net of tax					456	456	456
Net income				69,790		69,790	69,790
Comprehensive income							$ 70,246
BALANCE, DECEMBER 31, 2003	131,769,766	$1,318	$691,631	$(124,612)	$ (720)	$567,617	

See notes to consolidated financial statements.

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ENDO PHARMACEUTICALS HOLDINGS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2003, 2002 AND 2001
(In thousands)

	2003	2002	2001
OPERATING ACTIVITIES:			
Net income (loss)	$ 69,790	$ 30,813	$ (36,542)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	6,272	3,142	49,234
Purchased in-process research and development	(6,966)	20,300	
Accretion of promissory notes		4,627	5,449
Deferred income taxes	(53,774)	(8,730)	(4,701)
Amortization of deferred financing costs	398	390	3,603
Compensation related to stock options	144,524	34,659	37,253
Changes in assets and liabilities which provided (used) cash:			
Accounts receivable	18,212	(34,167)	(7,017)
Inventories	(14,934)	(7,750)	1,980
Other assets	(3,133)	(24,668)	(3,546)
Accounts payable	14,628	44,738	14,850
Accrued expenses	39,565	41,451	25,957
Income taxes payable	3,677	4,833	977
Other liabilities			(7,011)
Net cash provided by operating activities	218,259	109,638	80,486
INVESTING ACTIVITIES:			
Purchase of property and equipment	(12,159)	(3,084)	(6,546)
Purchase of DURECT common stock		(5,000)	
License fees	(32,500)		
Acquisition of BML Pharmaceuticals		(14,190)	
Other investments	(500)		
Net cash (used in) investing activities	(45,159)	(22,274)	(6,546)
FINANCING ACTIVITIES:			
Issuance of Common Stock			96,238
Capital Lease Obligations Repayments	(584)	(204)	
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options and Warrants	155	4	

Repurchase of Class A Transferable and Class B Non-Transferable Warrants		(6,730)	
Repayments of long-term debt		(118,889)	(134,017)
Net cash used in financing activities	(429)	(125,819)	(37,779)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	172,671	(38,455)	36,161
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	56,902	95,357	59,196
CASH AND CASH EQUIVALENTS, END OF PERIOD	$229,573	$ 56,902	$ 95,357
SUPPLEMENTAL INFORMATION:			
Interest paid	$ 378	$ 384	$ 7,065
Income taxes paid	$ 84,751	$ 33,978	$ 3,031
SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Promissory notes issued under Manufacturing and Supply Agreement		$ 23,000	$ 21,301
Purchase of property and equipment financed by capital leases	$ 391	$ 1,312	

See notes to consolidated financial statements.

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ENDO PHARMACEUTICALS HOLDINGS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2003, 2002 AND 2001

1. Organization and Acquisitions

Endo Pharmaceuticals Holdings Inc. (the Company or we), through its wholly owned subsidiary, Endo Pharmaceuticals Inc. (Endo), is engaged in the sales, marketing, research and development of branded and generic pharmaceutical products primarily in the United States.

On November 19, 1999, the Company formed Endo Inc. as a wholly owned subsidiary of the Company to effect the acquisition of Algos Pharmaceutical Corporation (Algos). On December 31, 2001, Endo Inc. was merged with and into Endo. The stock of Endo is the only asset of the Company, and the Company has no other operations or business.

On July 14, 2000, Endo Pharma LLC was formed to ensure that the stock options granted pursuant to the 1997 Employee Stock Option Plan, the 1997 Executive Stock Option Plan (collectively, as amended and restated, the Endo Pharma LLC 1997 Stock Option Plans), the Endo Pharma LLC 2000 Supplemental Employee Stock Option Plan and the Endo Pharma LLC 2000 Supplemental Executive Stock Option Plan (collectively, the Endo Pharma LLC 2000 Supplemental Stock Option Plans and, together with the Endo Pharma LLC 1997 Stock Option Plans, the Endo Pharma LLC Stock Option Plans) diluted only the Endo common stock held by persons and entities that held such shares prior to the Company s merger with Algos (see Note 14). Upon exercise of these stock options, only currently outstanding shares of common stock of the Company held by Endo Pharma LLC will be issued (see Note 16).

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 significant intercompany balances and transactions have been eliminated.

Nature of Operations and Customer and Supplier Concentration The Company, through its wholly owned subsidiary, Endo, is engaged in the marketing and sale of pharmaceuticals. 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. We are potentially subject to a concentration of credit risk with respect to our trade receivables. Three distributors and one pharmacy chain individually accounted for 26%, 26%, 19% and 11%, respectively, of our net sales in 2003. Three distributors and one pharmacy chain individually accounted for 24%, 24%, 23% and 11%, respectively, of our net sales in 2002. Three distributors and one pharmacy chain individually accounted for 28%, 24%, 19% and 10%, respectively, of our net sales in 2001. We perform ongoing credit evaluations of our customers and maintain sufficient allowances for estimated uncollectible accounts. Generally, we do not require collateral from our customers.

We have agreements with Novartis Consumer Health, Inc. and Teikoku Seiyaku Co., Ltd. for the manufacture and supply of substantially all of our existing pharmaceutical products (see Note 11). In the event of any interruption in the manufacture and supply of these products due to regulatory or other causes, there can be no assurance that we could make alternative arrangements on a timely basis, if at all. Such interruption could have a material adverse effect on our business, financial condition and results of operations.

Revenue Recognition Our net sales consist of revenues from sales of our pharmaceutical products, less estimates for certain chargebacks, sales allowances, the cost of returns and losses. We recognize revenue when products are shipped and title and risk of loss has passed to the customer, which is typically upon delivery to the customer. Our

shipping terms are free on board customer s destination. We estimate the accrual for sales deductions 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. Our revenue recognition policies are in accordance with Staff Accounting Bulletin No. 101 (SAB 101) and Staff Accounting Bulletin No. 104 (SAB 104).

Sales Deductions When we recognize revenue from the sale of our products, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses. These provisions are estimated based on historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with our wholesale and indirect customers and other competitive factors. If the assumptions we used to calculate these adjustments do not appropriately reflect future activity, our financial position, results of operations and cash flows could be impacted. The provision

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for chargebacks is the most significant and complex estimate used in the recognition of our revenue. We establish contract prices for indirect customers who are supplied by our wholesale customers. A chargeback represents the difference between our invoice price to the wholesaler and the indirect customer s contract price. Provisions for estimating chargebacks are calculated primarily using historical chargeback experience, estimated wholesaler inventory levels and estimated future trends. We establish contracts with wholesalers, chain stores and indirect customers that provide for rebates, sales incentives and other allowances. Some customers receive rebates upon attaining established sales volumes. We estimate rebates, sales incentives and other allowances based upon the terms of the contracts with our customers, historical experience, estimated inventory levels of our customers and estimated future trends. We estimate an accrual for Medicaid rebates as a reduction of revenue at the time product sales are recorded. The Medicaid rebate reserve is estimated based upon the historical payment experience, historical relationship to revenues and estimated future trends. Royalties represent amounts accrued pursuant to the license agreement with Hind Healthcare Inc. (Hind). Royalties are recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. Royalties are paid to Hind at a rate of 10% of net sales of Lidoderm®. Our return policy allows customers to receive credit for expired products within three months prior to expiration and within one year after expiration. We estimate the provision for product returns based upon the historical experience of returns for each product, historical relationship to revenues, estimated future trends, estimated customer inventory levels and other competitive factors. We continually monitor the factors that influence each type of sales deduction and make adjustments as necessary.

Research and Development Expenditures for research and development are expensed as incurred.

Cash and Cash Equivalents We consider all highly liquid investments with an original maturity date of three months or less to be cash equivalents.

Derivative Financial Instruments Prior to 2002, we used an interest rate cap agreement (Cap), to manage our exposure to fluctuations in interest rates. This Cap was matched with debt and periodic cash payments and was accrued on a net basis as an adjustment to interest expense. Effective January 1, 2001, the carrying value of this derivative financial instrument was marked to market for each reporting period with changes in the fair value reflected as an adjustment to earnings for the period presented. The interest rate cap was extinguished in 2002.

Inventories Inventories are stated at the lower of cost or market. Cost is determined by the first-in, first-out method.

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 on a straight-line basis. Machinery and equipment are depreciated over three to ten years, computer equipment over thirty months to five years, and furniture and fixtures over three to seven years. Computer software and related third-party design, development and implementation fees that benefit future periods are capitalized and amortized using the straight-line method over a useful life of three to five years.

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 thirteen to twenty 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. Licenses are assessed periodically for impairment in accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of* (SFAS

No. 144). The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset s carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs.

Patents Patents acquired in the Algos merger are stated at cost, less accumulated amortization, and are amortized using the a straight-line method over their estimated useful lives of seventeen years. We evaluate our patents for impairment by comparing the future undiscounted cash flows of the underlying assets to their respective carrying amounts. Patents are assessed periodically for impairment whenever events or changes in circumstances indicate that an asset s carrying amount may not be recoverable. (See *Recent Accounting Pronouncements*.)

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Goodwill Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. Goodwill is assessed on an annual basis on January 1st of each year for impairment unless events or circumstances indicate that an impairment may have occurred between annual dates. We assess the potential impairment of goodwill by comparing the fair value of goodwill to its carrying value for our one reporting unit. An impairment loss would be recognized when the estimated fair value is less than its carrying amount. Prior to January 1, 2002, goodwill was amortized over its estimated useful life ranging from three to thirty years. (See *Recent Accounting Pronouncements* and Note 7.)

Long-Lived Assets We assess long-lived assets for impairment whenever events or changes in circumstances indicate that an asset s carrying amount may not be recoverable.

Marketing Costs Marketing costs, including advertising costs, are expensed as incurred. Such costs were $25.5 million, $14.3 million and $9.8 million for the years ended December 31, 2003, 2002 and 2001, respectively.

Deferred Financing Costs Costs incurred in connection with establishment of financing are deferred and amortized as a component of interest expense over the term of the related debt using the straight-line method.

Income Taxes We account for income taxes in accordance with Statement of Financial Accounting Standards (SFAS) No. 109, *Accounting for Income Taxes*.

Stock-based compensation We have adopted the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, while following Accounting Principles Board Opinion (APB) No. 25, *Accounting for Stock Issued to Employees*, and related interpretations in accounting for all of our stock option plans. Under APB No. 25, no compensation expense is recognized when the exercise price of stock options equals at least the market price of the underlying stock at the date of grant or when a measurement date has not yet been reached. Accordingly, with respect to the stock options granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan, no compensation expense has been recognized. If we were to have adopted the accounting provisions of SFAS No. 123, we would have been required to record compensation expense based on the fair value of all of these stock options on the date of grant.

Pro-forma information regarding net income is required to be presented as if we had accounted for our stock options under the provisions of SFAS No. 123. We estimated the fair value of our stock options, as of the respective date of grant, using the Black-Scholes option-pricing model. The following assumptions were used for such estimates: no dividend yield; expected volatility of 70% in 2003 and 60% in 2002 and 2001; risk-free interest rate of 3.2%, 4.0% and 5.0% for 2003, 2002 and 2001, respectively; and a weighted average expected life of the options of 5 years. Had the accounting provisions of SFAS No. 123 been adopted, net income (loss) for 2003, 2002 and 2001 would have been as follows (in thousands):

	Years Ended December 31		
	2003	**2002**	**2001**
Net income (loss)	$ 69,790	$ 30,813	$(36,542)
APB 25 Compensation Expense	144,524	34,659	37,253
Tax effect of APB 25 compensation expense	(55,536)	(13,274)	(14,268)
SFAS 123 compensation expense	(80,116)	(5,495)	(2,998)
Tax effect of SFAS 123 compensation expense	30,786	2,104	1,148

Net income (loss) pro forma	$109,448	$ 48,807	$(15,407)
Basic earnings (loss) per share as reported	$ .54	$ .30	$ (.40)
Basic earnings (loss) per share pro forma	$ .85	$ .48	$ (.17)
Diluted earnings (loss) per share as reported	$ .53	$ .30	$ (.40)
Diluted earnings (loss) per share pro forma	$ .83	$ .48	$ (.17)
Weighted average shares outstanding			
Basic	128,417	102,064	91,505
Diluted	132,439	102,126	91,505

Use of Estimates The preparation of our financial statements in conformity with accounting principles generally accepted in the United States of America (generally accepted accounting principles) requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of sales deductions for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses.

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Significant estimates and assumptions are also required in the appropriateness of amortization periods for identifiable intangible assets and the potential impairment of goodwill and other intangible assets. Actual results could differ from those estimates.

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 (loss) refers to revenues, expenses, gains and losses that under generally accepted accounting principles are included in comprehensive income, but excluded from net income as these amounts are recorded directly as an adjustment to stockholders equity. Our other comprehensive income (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 January 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. We adopted the provisions of SFAS No. 144 on January 1, 2002, which had no material impact on our results of operations or financial position.

In June 2001, the FASB, issued SFAS No. 141, *Business Combinations,* and SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 141 was effective for all business combinations completed after June 30, 2001. SFAS No. 142 was effective for fiscal years beginning after December 15, 2001. SFAS No. 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS No. 142 establishes revised reporting requirements for goodwill and other intangible assets.

In April 2002, the FASB issued SFAS No. 145, *Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections*. SFAS No. 145 (1) rescinds SFAS No. 4 and SFAS No. 64, which relate to the extinguishment of debt, (2) rescinds SFAS No. 44 relating to the accounting for intangible assets of motor carriers, and (3) amends SFAS No. 13 relating to the accounting for leases. SFAS No. 145 also amends certain other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. Certain amounts were reclassified in accordance with SFAS No. 145 in the accompanying financial statements. The adoption of SFAS No. 145 did not have a material impact on our results of operations or financial position.

In July 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*. SFAS No. 146 requires recognition of a liability for a cost associated with an exit or disposal activity when the liability is incurred, as opposed to when the entity commits to an exit plan under previous guidance. This statement is effective for exit or disposal activities initiated after December 31, 2002. The adoption of SFAS No. 146 did not have a material impact on our results of operations or financial position.

In November 2002, the FASB issued FASB Interpretation No. 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45). FIN 45 requires that upon issuance of certain guarantees, a guarantor must recognize a liability for the fair value of an obligation assumed under the guarantee. FIN 45 also requires significant new disclosures, in both interim and annual financial statements, by a guarantor, about obligations associated with guarantees issued. FIN 45 disclosure requirements were effective for our fiscal year ended December 31, 2002 and the initial recognition and measurement provisions are applicable on a

prospective basis to guarantees issued or modified after December 31, 2002. At December 31, 2003, we had no guarantees outstanding.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. SFAS No. 148 amends SFAS No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. We have not adopted the fair value based method of accounting for employee stock-based compensation.

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3. Acquisitions

BML Pharmaceuticals

On July 26, 2002, our wholly owned subsidiary, Endo, acquired BML Pharmaceuticals, Inc. (BML), a privately held company, for an up-front payment of $14 million. In addition, had BML s lead pipeline product, an oral rinse (0.1% triclosan) for oral mucositis, received FDA approval, Endo would have paid the former shareholders of BML a $32 million payment and an earn-out based on a percentage of net sales of certain products in BML s pipeline. BML operates as a wholly owned subsidiary of Endo Pharmaceuticals Inc. We accounted for the acquisition using the purchase method of accounting. In accordance with the purchase method of accounting, the purchase price was allocated to BML s assets and liabilities based on their respective fair values on the date of the acquisition.

The BML acquisition included an on-going project to research and develop an oral rinse product (0.1% triclosan) for oral mucositis. As a result, the allocation of the fair value of the assets acquired and liabilities assumed included an allocation to purchased in-process research and development (IPRD) of $20.3 million which was expensed in the consolidated statement of operations on the acquisition date. The methodology we used on the acquisition date in determining the value of IPRD was to: 1) identify the various on-going projects that we have determined to prioritize and continue; 2) project net future cash flows of the identified projects based on then current demand and pricing assumptions, less the anticipated expenses to complete the development program, drug application, and launch of the products (significant net cash inflows from the oral rinse product (0.1% triclosan) for oral mucositis were projected in 2004); and 3) discount these cash flows based on a risk-adjusted discount rate of 20%. The discount rate was determined after considering various uncertainties at the time of the acquisition, including the relative risk of the investment and the time value of money. The assets acquired and liabilities assumed, results of operations and cash flows of BML have been included in our financial statements prospectively for reporting periods beginning July 26, 2002.

We allocated fair value to one project of BML Pharmaceuticals, an oral rinse (0.1% triclosan) for oral mucositis. The development program for a new pharmaceutical substance involves several different phases prior to drug application. Further, drug applications must be approved by the FDA prior to marketing a new drug. Despite our commitment to completion of this research and development project, many factors may arise that could cause the project to be withdrawn or delayed, including the inability to prove the safety and efficacy of the drug during the development process. Upon withdrawal of an application, it is unlikely that the development activities will have alternative use.

On October 24, 2003, we announced that our pivotal Phase III clinical trial of the oral rinse product did not meet its primary endpoint of preventing oral mucositis. During the fourth quarter of 2003, we made the decision to discontinue our development program for the oral rinse product for the treatment of oral mucositis. As a result, we extinguished the contingent liability related to the program resulting in a gain of $7.0 million in 2003.

4. License and Collaboration Agreements

Hind Healthcare

In November 1998, Endo entered into a license agreement (the Hind License Agreement) with Hind Healthcare Inc. (Hind) for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in the United States. Under the terms of the Hind License Agreement, Endo paid Hind approximately $10 million (the Hind License Fee) based upon the achievement of certain milestones. Costs related to the Hind License Agreement are included in Other Intangible Assets at December 31, 2003. In addition, beginning on March 19, 2001, Endo pays Hind nonrefundable royalties based on net sales of the product. Royalties are recorded as a reduction to net sales due to the nature of the

license agreement and the characteristics of the license involvement by Hind in Lidoderm®. The royalty rate was 8% of net sales from March 19, 2001 through March 18, 2002 and is 10% of net sales from March 19, 2002 through the shorter of (1) the expiration of the last licensed patent or (2) November 20, 2011. During 2003 and 2002, we accrued $19.9 million and $9.1 million for these royalties to Hind, respectively, which were recorded as a reduction to net sales. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

Lavipharm

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

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terminated this agreement and made a termination payment to Lavipharm of $3 million plus the potential for up to an additional $5 million upon the occurrence of future events. We wrote-off the unamortized portion of the upfront license fee and expensed the termination payment of $3 million in the first quarter of 2004.

DURECT Corporation

In November 2002, Endo entered into a license agreement (DURECT License Agreement) with DURECT Corporation (DURECT) to develop and commercialize DURECT s CHRONOGESIC™ (sufentanil) Pain Therapy System for the U.S. and Canada. In January 2004, we amended the Agreement with Durect essentially modifying Endo s funding obligations of the ongoing development costs of CHRONOGESIC to take into account the program delay. Once a specified clinical trial of CHRONOGESIC™ is started or beginning on January 1, 2005 (whichever is earlier), Endo will be obligated to fund 50% of the ongoing development costs of CHRONOGESIC™. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the DURECT 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 License Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. With respect to termination rights, the DURECT License Agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT $10.0 million. Finally, in connection with this agreement, on November 8, 2002, Endo purchased approximately $5.0 million of newly issued common shares of DURECT, representing approximately 3% of DURECT s currently outstanding shares.

SkyePharma

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, DepoMorphine™ and Propofol IDD-D™ (collectively, the Skye Products). Under the terms of the Agreement, Endo received an exclusive license to the U.S. and Canadian marketing and distribution rights for the Skye Products, with options for certain other development products. In return, SkyePharma received a $25 million upfront payment from Endo, which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We are amortizing this intangible asset over its useful life of 17 years. In addition, SkyePharma may receive milestone payments in addition to the $25 million upfront payment of up to $95 million which include total milestones of $10 million for DepoMorphine™ through FDA approval. During 2003, we paid $5 million to SkyePharma upon the acceptance by the FDA of the NDA for DepoMorphine™. The milestone payments also include $50 million for Propofol IDD-D™, payable when the product successfully achieves certain regulatory milestones, including FDA approval. The total further includes a $15 million milestone payable when net sales of DepoMorphine™ exceed $125 million in a calendar year, and a $20 million milestone payable when net sales of DepoMorphine™ exceed $175 million in a calendar year. SkyePharma will also receive a share of each product s sales revenue that will increase from 20% initially, to a maximum of 60%, of net sales as the Skye Products combined net sales achieve certain thresholds. In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, this agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require us to pay SkyePharma $5.0 million.

Noven Pharmaceuticals, Inc.

In February 2004, we entered into a License Agreement and a Supply Agreement under which Noven exclusively licensed the U.S. and Canadian rights to its developmental transdermal fentanyl patch to Endo. We made an upfront

payment of $8.0 million, $6.5 million of which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We are amortizing this intangible asset over its useful life of 11 years. Upon our first commercial sale of the fentanyl patch, Noven is entitled to receive an additional payment ranging from $5.0 million to $10.0 million, depending on the timing of launch and the number of generic competitors on the market. Noven will manufacture and supply the product at its cost, and the two companies will share profits. The License Agreement also establishes an ongoing collaboration between the two companies to identify and develop additional new transdermal therapies. As part of this effort, Noven will undertake feasibility studies to determine whether certain compounds identified by the parties can be delivered through Noven s transdermal patch technology. Endo is expected to fund and manage clinical development of those compounds proceeding into clinical trials.

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EpiCept Corp.

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

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.

5. Inventories

Inventories are comprised of the following at December 31 (in thousands):

	2003	2002
Raw Materials	$12,615	$ 9,150
Work-in-Process	18,195	2,265
Finished Goods	19,640	24,101
Total	$50,450	$35,516

6. Property and Equipment

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

	2003	2002
Machinery and equipment	$ 7,709	$ 6,610
Computer equipment and software	10,727	8,617
Furniture and fixtures	12,917	4,116
	31,353	19,343

Less accumulated depreciation	(11,107)	(7,533)
Total	$ 20,246	$11,810

7. Goodwill and Other Intangibles

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

	December 31, 2003	December 31, 2002
Goodwill	$181,079	$181,079
Amortizable Intangibles:		
Licenses	$ 43,500	$ 36,000
Patents	3,200	3,200
	46,700	39,200
Less accumulated amortization	(4,657)	(2,445)
Other Intangibles, net	$ 42,043	$ 36,755

Effective January 1, 2002, we adopted the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, and will no longer amortize goodwill and workforce in place. Goodwill and other intangibles represents a significant portion of our assets and stockholders equity. As of December 31, 2003, goodwill and other intangibles comprised approximately 30% of our total assets and 39% of our stockholders equity. We assess the potential impairment of goodwill by comparing the fair value of goodwill to its carrying value for our one reporting unit. An impairment loss would be recognized when the estimated fair value is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be

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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 (k/n/a Bristol-Myers Squibb Pharma Company) and the July 17, 2000 acquisition of Algos. Although goodwill arose in two separate transactions, the components of our operating segment have been integrated and are managed as one reporting unit. Our components extensively share assets and other resources with the other components of our business and have similar economic characteristics. In addition, our components do not maintain discrete financial information. Accordingly, the components of our business have been aggregated into one reporting unit and are evaluated as such for goodwill impairment. Goodwill is evaluated for impairment on an annual basis on January 1st of each year unless events or circumstances indicate that an impairment may have occurred between annual dates. Goodwill has been evaluated for impairment upon the adoption of SFAS No. 142 on January 1, 2002 and, based on the fair value of our reporting unit, no impairment has been identified. On January 1, 2004 and 2003, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

Effective January 1, 2002, we reclassified the carrying amount of workforce-in-place as goodwill. The cost of license fees is capitalized and is being amortized using the straight-line method over the licenses estimated useful lives of seventeen to twenty years. The cost of acquired patents is capitalized and is being amortized using the straight-line method over their estimated useful lives of seventeen years.

The pro forma effect of the adoption of SFAS No. 141 and SFAS No. 142 is as follows:

	Year Ended December 31,		
	2003	**2002**	**2001**
	(in thousands, except per share data)		
Reported net income (loss)	$69,790	$30,813	$(36,542)
Add back: Goodwill amortization			40,431
Add back: Amortization of workforce-in-place			5,948
Less: Pro forma income (tax) benefit			(6,634)
Adjusted net income (loss)	$69,790	$30,813	$ 3,203
Basic earnings (loss) per share:			
Reported net income (loss)	$ 0.54	$ .30	$ (.40)
Add back: Goodwill amortization			.44
Add back: Amortization of workforce-in-place			.07
Less: Pro forma income (tax) benefit			(.07)
Adjusted net income (loss)	$ 0.54	$ .30	$ .04

Diluted earnings (loss) per share:			
Reported net (loss) income	$ 0.53	$ .30	$ (.40)
Add back: Goodwill amortization			.44
Add back: Amortization of workforce-in-place			.07
Less: Pro forma income (tax) benefit			(.07)
Adjusted net income (loss)	$ 0.53	$ .30	$ .04

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2003 is as follows (in thousands):

2004	2,788
2005	2,788
2006	2,788
2007	2,788
2008	2,788

8. Long-Term Debt

On August 26, 1997, Endo entered into a revolving credit and term loan agreement (the Original Credit Agreement) with a group of banks to provide funds for the 1997 acquisition of the Company from the then DuPont Merck Pharmaceutical Company (the 1997 Acquisition), working capital and general corporate purposes. On October 29, 2001, we repaid in full the $101.1 million of term loans that were outstanding thereunder. On December 21, 2001, we amended and restated this credit agreement (the Amended and

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Restated Credit Agreement). As of December 31, 2003 and December 31, 2002, no amounts were outstanding under the Amended and Restated Credit Agreement.

Amended and Restated Credit Agreement

Under the Amended and Restated Credit Agreement, we have the ability to borrow on a revolving basis up to $75.0 million. The revolving loans have a final maturity of December 21, 2006. The Original Credit Agreement also provided for a delayed draw term loan with an aggregate principal amount of $25.0 million that was to be utilized, if at all, by August 26, 2002 solely for the purpose of paying off the outstanding promissory notes that were then payable to Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals). The delayed draw term loan expired unused on August 26, 2002. As of December 31, 2003, we have not borrowed under the revolving loans.

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

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

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

Promissory Notes Payable to Bristol-Myers Squibb

We financed a portion of the purchase price of the 1997 acquisition of the business through the issuance of a promissory note to Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals). The note had a face value of $3.9 million and was payable on August 26, 2002. This promissory note bore no interest and therefore was discounted in the accompanying financial statements using a rate of 9.75%, which approximated our borrowing rate for similar instruments at the time of borrowing. This promissory note was repaid on August 26, 2002.

On August 26, 2002, 2001, 2000, 1999 and 1998, Endo issued promissory notes to Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals) in consideration for manufacturing and supply services provided under the Manufacturing and Supply Agreement (see Note 11). These notes each had a face value of $23 million and were payable on August 26, 2002. The promissory notes bore no interest and therefore had been discounted in the accompanying financial statements using 0%, 7.7%, 7.7%, 7.0% and 7.0%, respectively, which approximates our borrowing rate for similar instruments at the time of each borrowing. These promissory notes were repaid on August 26, 2002.

Interest Rate Cap

Effective August 27, 2000, Endo entered into an interest rate cap agreement with a notional amount of $70.0 million for the purpose of minimizing its exposure to fluctuations in interest rates. We do not enter into such transactions for trading or speculative purposes. The cost of this interest rate cap of $350,000 was being amortized as a component of interest expense over the term of the agreement, which was scheduled to expire August 27, 2003. The agreement set a maximum LIBOR rate Endo would pay on the related notional amount of 8.0%. Effective January 1, 2001, the carrying value of this derivative financial instrument was marked to market for each reporting period with

changes in the fair value reflected as an adjustment to earnings for the period presented. The carrying value of this derivative financial instrument was zero at December 31, 2001. The interest rate cap was extinguished in 2002.

9. Fair Value of Financial Instruments

The following methods and assumptions were used to estimate the fair value of each class of financial instrument:

Cash and Cash Equivalents, Accounts Receivable, Accounts Payable and Accrued Expenses The carrying amounts of these items are a reasonable estimate of their fair values because of the current maturities of these instruments.

Marketable Securities Marketable securities are comprised of our investment in shares of common stock of DURECT

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Corporation. We account for this investment at fair value as available-for-sale securities. Unrealized gains and losses related to these marketable securities are reported in accumulated other comprehensive income in the stockholders equity section of the consolidated balance sheets.

10. Income Taxes

Income tax (benefit) consists of the following for 2003, 2002, and 2001 (in thousands):

	2003	2002	2001
Current:			
Federal	$ 80,119	$32,940	$ 1,859
State	12,863	5,871	2,149
	92,982	38,811	4,008
Deferred:			
Federal	(50,828)	(7,910)	(5,312)
State	(8,442)	(820)	(3,342)
	(59,270)	(8,730)	(8,654)
Valuation Allowance	5,496		
Total income tax (benefit)	$ 39,208	$30,081	$(4,646)

A reconciliation of income tax (benefit) at the federal statutory income tax rate to the total income tax provision (benefit) for 2003, 2002, and 2001 is as follows (in thousands):

	2003	2002	2001
Federal income tax (benefit) at the statutory rate	$38,150	$21,313	$(14,004)
State income tax (benefit) net of federal benefit	3,261	1,975	(787)
Research and development credit utilized	(1,400)	(1,000)	(1,620)
Effect of permanent items:			
Purchased in-process research and development		7,765	
Goodwill	(2,438)		11,517
Other	1,635	28	248
Total income tax (benefit)	$39,208	$30,081	$ (4,646)

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):

	2003	2002
Deferred tax assets:		
Accrued expenses	$ 42,563	$ 21,843
Compensation related to stock options	84,058	38,157
Purchased in-process research and development	10,068	11,241
Net operating loss carryforward	494	7,030
Other	2,849	2,644
Total gross deferred income tax assets	140,032	80,915
Deferred tax liabilities:		
Depreciation and amortization	(23,843)	(18,482)
Capital loss carryforward	5,496	
Other		(30)
Total gross deferred income tax liabilities	(18,347)	(18,512)
Valuation allowance	(5,496)	
Net deferred income tax asset	$116,189	$ 62,403

At December 31, 2000, we had evaluated the available evidence about future taxable income and other possible sources of realization of deferred tax assets and believed that a valuation allowance in the amount of $40.8 million was required at December 31, 2000. During the fourth quarter of 2001, we evaluated our anticipated future taxable income based upon the repayment of our outstanding term loans, new product approvals and other existing and estimated future product performance and determined that it was more likely than not that we will utilize our deferred tax benefits. Accordingly, we reversed our valuation reserves that had been recorded against those deferred tax assets. The reversal of the reserves established in connection with the acquisition of Algos were

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recorded as a reduction of goodwill. The reversal of the reserves recorded subsequent to the Algos acquisition were recorded as an increase to income tax benefit. The estimated fair value of the purchased in-process research development of $20.3 million was not a tax deductible item and, therefore, increased our effective income tax rate in 2002. The Company recorded a valuation allowance in 2003 due to the uncertainty of its ability to utilize the capital losses that arose with the write off of the BML acquisition. At December 31, 2003, the Company had $1.4 million and $5.5 million in net operating loss carryforwards and capital loss carryforwards, respectively, for tax purposes, which expire through 2020.

11. 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 including, among others, Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals), Novartis Consumer Health and Teikoku Seiyaku Pharmaceuticals. 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.

Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals)

On August 26, 1997, we entered into an agreement with Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals) to manufacture and supply products (the Manufacture and Supply Agreement) and provide research and development facilities (the R&D Lease).

The Manufacture and Supply Agreement had an original term of five years through August 26, 2002, with options to renew for up to five additional years in the aggregate. When in effect, the Manufacture and Supply Agreement covered substantially all of our then existing and new pharmaceutical products. On August 27, 2002, we amended our manufacturing and supply agreement with the Bristol-Myers Squibb Pharma Company. In consideration for Bristol-Myers allowing Endo to transfer up to 100% of any Endo product out of any Bristol-Myers facility at any time, and for its assistance in the transfer, Endo made a one-time payment to Bristol-Myers of $9.0 million on August 27, 2002. This transfer fee was expensed during 2002. The amended agreement had a term of one year, ending on August 26, 2003.

The R&D Lease had a term of five years, with options to renew for up to five additional years in the aggregate provided that the Manufacture and Supply Agreement had been renewed. The R&D Lease has been renewed through June 30, 2004.

Any interruption or failure by Bristol-Myers Squibb to meet its obligations under the aforementioned agreements would have had 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 has a five-year term, with automatic five-year renewals thereafter. Either party may terminate this agreement on three-years notice, effective at any time after the initial five-year term. In addition, we may terminate this agreement effective prior to the fifth anniversary of the agreement upon three-years notice and the payment of certain early termination fees. Either party may also terminate this agreement on account of a material breach by the other.

Teikoku Seiyaku Co., Ltd.

Under the terms of this agreement, Teikoku, a Japanese manufacturer, manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We also have an option to extend the supply area to other territories within a defined period of time. We are required to purchase, on an annual basis, a minimum amount of product from Teikoku. The purchase price for the product is equal to a predetermined amount per unit of product. 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.

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General

In addition to the material long-term manufacturing agreements described above, we have agreements with (1) UPS Supply Chain Management, Inc. (f/d/b/a Livingston Healthcare Services, Inc.) for customer service support, warehouse and distribution services and certain financial functions and (2) Kunitz and Associates Inc. for medical affairs. In addition, until December 31, 2003, we had an agreement with Ventiv Health U.S. Sales Inc. for sales promotion. We also have agreements and arrangements with various contract research organizations for our toxicology and clinical studies. These agreements continue through 2004, and contain options to renew. 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.

12. Commitments and Contingencies

License Agreements and Milestones

Penwest Pharmaceuticals

Under the terms of the amended and restated strategic alliance agreement with Penwest Pharmaceuticals Co. (Penwest), Penwest is entitled to receive a percentage beginning at 50% of the net realization (as defined in the agreement) of oxymorphone ER. On March 18, 2003, we received notice from Penwest that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of this product on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we are now be responsible for funding 100% of these remaining costs until oxymorphone ER is approved by the FDA, at which time we will recoup from the royalties due to Penwest the full amount of what Penwest should have contributed had it not exercised such right.

DURECT Corporation

Once a specified clinical trial of CHRONOGESIC™ is started or beginning on January 1, 2005 (whichever is earlier), unless the agreement is earlier terminated, Endo will be obligated to fund 50% of the ongoing development costs of CHRONOGESIC™. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the License Agreement could total up to $52.0 million. Endo and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC™. In addition, the DURECT agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. With respect to termination rights, this agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT $10.0 million.

SkyePharma, Inc.

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

Milestone Event	Milestone Payment

FDA final approval of the NDA for DepoMorphine™ in the United States	$ 5,000
The first time net sales of DepoMorphine™ in a calendar year exceed $125,000,000	$ 15,000
The first time net sales of DepoMorphine™ in a calendar year exceed $175,000,000	20,000
Total contingent sales milestones for DepoMorphine™	$ 35,000
With respect to Propofol IDD-D, upon the earlier of (a) the Joint Executive Committee s approval of the FDA protocol submission package, which shall follow Endo s receipt of both the FDA end-of-Phase II (EOPII) meeting minutes and the timeline for the Phase III clinical plan, or (b) 30 days following Endo s receipt of the FDA EOPII meeting minutes and the timeline for the Phase III clinical plan	$ 5,000

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FDA acceptance of the NDA for Propofol IDD-D™ in the United States	5,000
FDA final approval of the NDA for Propofol IDD-D™ in the United States	40,000
Total contingent regulatory milestones for Propofol IDD-D™	$50,000

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

Noven Pharmaceuticals, Inc.

Under the terms of the license agreement with Noven, upon our first commercial sale of the fentanyl patch, Noven is entitled to receive an additional payment ranging from $5.0 million to $10.0 million, depending on the timing of launch and the number of generic competitors on the market. The profit on the product will be shared. This license agreement also establishes an ongoing collaboration between the two companies to identify and develop additional new transdermal therapies. As part of this effort, Noven will undertake feasibility studies to determine whether certain compounds identified by the parties can be delivered through Noven s transdermal patch technology. Endo is expected to fund and manage clinical development of those compounds proceeding into clinical trials.

EpiCept Corp.

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

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.

Employment Agreements

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

Leases

We lease office and laboratory facilities under certain noncancelable operating leases that expire through June 2013. These leases are renewable at our option. A summary of minimum future rental payments required under capital and operating leases as of December 31, 2003 is as follows (in thousands):

	Capital Leases	Operating Leases
2004	651	2,648
2005	532	2,920
2006	73	2,952
2007		2,805
2008		2,812
Thereafter		13,553
Total minimum lease payments	$1,256	$27,690
Less: Amount representing interest	64	
Total present value of minimum payments	$1,192	
Less: Current portion of such Obligations	604	
Long-term capital lease obligations	$ 588	

Rent expense incurred under operating leases was $2,019,000, $1,434,000, and $1,406,000 for the years ended December 31, 2003, 2002 and 2001, respectively. On January 6, 2003, we entered into a lease for a 24,000 square foot facility in Westbury, New York. Once our current lease of the Bristol-Myers Squibb facility in Garden City, New York expires, we will use this space for the

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research and development of our pharmaceutical products. Until such time, we are renovating the Westbury, New York space to accommodate our needs. On November 13, 2003, we entered into a lease for a 64,424 square feet facility located across from our corporate headquarters in Chadds Ford, Pennsylvania.

Research Contracts

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 entered into certain collaboration agreements with third parties for the development of pain management products. 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.

Contingencies

We are, and may in the future be, subject to various claims or legal proceedings arising out of the normal course of business with respect to commercial matters, including product liabilities, patent infringement matters, governmental regulation and other actions. We cannot predict the timing or outcome of these claims or proceedings. Currently, the Company is not involved in any claim and/or legal proceeding with respect to which the amount of ultimate liability will, in the opinion of management, materially affect our financial position, results of operations or liquidity.

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. Our contributions are generally fully vested after five years of continuous service. Effective January 1, 2002, participants are fully vested with respect to our contributions after three years of continuous service. Contributions by us amounted to $1,376,000, $954,000, and $597,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

14. Stockholders Equity

Common Stock

Payment of dividends is restricted under terms of the Amended and Restated Credit Agreement.

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, 2003, no shares of Preferred Stock have been issued.

Class A Transferable Warrants and Class B Non-Transferable Warrants

The Class A Transferable Warrants and Class B Non-Transferable Warrants were exercisable at an exercise price of $.01 per share into a specified number of shares of Company common stock depending on the timing of the FDA s approval of MorphiDex® for one or more pain indications. Because MorphiDex® was not be approved prior to March 31, 2003, the Class A Transferable Warrants (Nasdaq: ENDPW) and Class B Non-Transferable Warrants expired on such date and have no economic value. The Company de-listed the Class A Transferable Warrants (Nasdaq: ENDPW) upon their expiration.

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On December 5, 2001, we commenced a tender offer to purchase up to 13.5 million of our outstanding Class A Transferable Warrants and any and all of our outstanding Class B Non-Transferable Warrants. This tender offer expired at midnight on January 25, 2002. We accepted an aggregate of 8.6 million Class A Transferable Warrants and Class B Non-Transferable Warrants for payment at a purchase price of $0.75 per warrant. We used cash on hand to finance the purchase of the tendered warrants. Following the purchase by us, there were outstanding 9.2 million of these warrants.

Pre-Merger Endo Warrants

The warrants issued to the holders of Company common stock prior to the Algos merger received warrants (known as the Pre-Merger Endo Warrants), which were exercisable at an exercise price of $.01 per share into a specified number of shares of Company common stock. As of December 31, 2002, there were outstanding 71.3 million of these warrants. As the FDA did not approve MorphiDex® before December 31, 2002, these warrants became exercisable. Each of these outstanding 71.3 million warrants were exercisable into 0.416667 shares of common stock of Endo Pharmaceuticals Holdings Inc. All of these warrants were exercised into 29,687,602 shares of common stock at an exercise price of $0.01 per share. The warrants were exercisable until July 8, 2003.

Endo Pharma LLC 1997 Executive and Employee Stock Option Plans and Endo Parma 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 reserve 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 will be issued. Exercise of these stock options will not result in the issuance of additional shares in the Company.

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 reserve an aggregate of 10,672,314 shares of common stock of the Company held by Endo Pharma LLC for issuance. The Endo Pharma LLC 2000 Supplemental Stock Option Plans were only effective on January 1, 2003 in the event that we had not received the approval from the U.S. Food and Drug Administration for MorphiDex® for the treatment of pain by December 31, 2002. Stock options granted under the Endo Pharma LLC 2000 Supplemental Stock Option Plans expire no later than December 31, 2012 unless an initial public offering of the Company common stock held by Endo Pharma LLC occurs, in which case the stock options granted will 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 million stock options to certain employees and members of management. Because approximately 9,188,186 million of these stock options were immediately vested upon their issuance, the Company recorded a non-cash compensation charge of approximately $48.5 million in the first quarter of 2003 for the difference between the market price of the common stock of $7.70 and the weighted average exercise price of these stock options of $2.42. No additional shares of Company common stock will be issued, however, because these stock options are exercisable only into shares of Company common stock that are held by Endo Pharma LLC. Accordingly, these stock options do not dilute the public shareholders.

A summary of the activity under the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans from December 31, 2000 through December 31, 2003 is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2000	25,268,661	$2.70
Exercised	(735,901)	$2.42
Forfeited	(353,734)	$2.57
Outstanding, December 31, 2001	24,179,026	$2.71
Exercised	(385,201)	$2.47

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Forfeited	(27,070)	$3.00
Outstanding, December 31, 2002	23,766,755	$2.71
Granted	10,672,314	$2.42
Exercised	(2,466,803)	$2.46
Forfeited	(87,240)	$2.80
Outstanding, December 31, 2003	31,885,026	$2.63

The following table summarizes information about stock options outstanding under the Endo Pharma LLC Stock Option Plans at December 31, 2003:

Options Outstanding

Number Outstanding at 12/31/03	Weighted Average Remaining Contractual Life	Exercise Price
21,185,993	44 months	$2.42
9,396,330	44 months	$3.00
1,302,703	44 months	$3.42

Of the outstanding Endo Pharma LLC stock options as of December 31, 2003, 1,381,790 shares have vested and are exercisable ratably over service periods of five years and 1,557,754 shares have vested and are exercisable at the end of nine years from the date of grant. The vesting and exercisability of options may be accelerated at the discretion of the Board of Directors or upon the occurrence of certain defined events. The remaining 28,945,482 Endo Pharma LLC stock options vest in four discrete tranches contingent upon (i) the common stock of the Company exceeding a defined average closing price threshold for ninety consecutive trading days, (ii) the closing price of the common stock of the Company on the last trading day of such ninety consecutive trading day period being greater than or equal to 85% of the defined closing price and (iii) the holder being a director, officer or employee of the Company or any of its subsidiaries on such date. The defined average closing price thresholds are as follows:

Option Class	Common Stock Closing Price Threshold

C1A and C1B	$ 4.28
C2	$ 6.62
C3	$10.58
C4	$17.29

As these share price targets have been achieved, resulting in the vesting of each tranche of options, the Company has recorded non-cash compensation charges related to the vesting of certain of the options. Under performance-based options, the measurement of expense is calculated and recorded as a non-cash charge at the time performance is achieved as the difference between the market price of the stock and the exercise price of the options. As these charges have been recorded by the Company in connection with the above options, they have been significant. The exercise of these options will not, however, result in the issuance of additional shares of Company common stock.

During the year ended December 31, 2003, 4,810,936 Class C4 stock options vested upon achievement of the aforementioned conditions. We recorded a $96.0 million compensation charge related to the vesting of these performance-based stock options. The amount represents the estimated difference in the market price and the exercise price of the vested stock options.

During the year ended December 31, 2002, 6,924,363 Class C3 stock options vested upon achievement of the aforementioned conditions. We recorded a $34.7 million compensation charge related to the vesting of these performance-based stock options. The amount represents the estimated difference in the market price and the exercise price of the vested stock options.

During the year ended December 31, 2001, 4,594,535 Class C2 stock options vested upon achievement of the aforementioned conditions. We recorded a $37.3 million compensation charge related to the vesting of these performance-based stock options. The amount represents the estimated difference in the market price and the exercise price of the vested stock options.

During the year ended December 31, 2000, 5,880,713 Class C1A and C1B stock options vested upon achievement of the aforementioned conditions. We recorded a $15.3 million compensation charge related to the vesting of these performance-based stock options. The amount represents the estimated difference in the market price and the exercise price of the vested stock options.

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The Class C1A, C1B, C2, C3 and C4 stock options are generally exercisable, if vested, upon the earlier of (i) the occurrence of a sale, disposition or transfer of Company common stock, after which neither Endo Pharma LLC nor Kelso & Company hold any shares of Company common stock or (ii) January 1, 2006.

Stock options exercisable pursuant to the Endo Pharma LLC 1997 Stock Option Plans as of December 31, 2003 and 2002 were 1,781,348 and 2,527,778, respectively. The shares of Company common stock that individuals receive upon exercise of stock options pursuant to the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan

On August 11, 2000, we established the 2000 Stock Incentive Plan (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. As of December 31, 2003, only stock options have been awarded. Stock options granted under the 2000 Stock Incentive Plan expire ten years from the date of grant. As of December 31, 2003, stock options outstanding under the 2000 Stock Incentive Plan were exercisable into 776,719 shares.

A summary of the activity under our 2000 Stock Incentive Plan from December 31, 2000 through December 31, 2003 is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2000	391,250	$ 7.20
Granted	605,712	$ 8.85
Forfeited	(59,351)	$ 7.45
Outstanding, December 31, 2001	937,611	$ 8.25
Granted	1,069,455	$ 9.93
Exercised	(500)	$ 7.25
Forfeited	(21,343)	$ 9.38
Outstanding, December 31, 2002	1,985,223	$ 8.82

Granted	1,441,290	$15.90
Exercised	(17,714)	$ 8.74
Forfeited	(78,621)	$ 9.95
Outstanding, December 31, 2003	3,330,179	$11.86

The following table summarizes information about stock options outstanding under our 2000 Stock Incentive Plan at December 31, 2003:

2000 Stock Incentive Plan Options Outstanding

Number Outstanding at 12/31/03	Weighted Average Remaining Contractual Life	Range of Exercise Prices
1,814,269	8.2	$ 6.47-$9.50
125,810	8.6	$ 9.51-$12.50
1,030,625	9.7	$12.51-$15.50
204,873	8.7	$15.51-$18.50
154,602	9.6	$18.51-$20.80

15. Earnings Per Share

The following is a reconciliation of the numerator and denominator of basic and diluted earnings (loss) per share (in thousands, except per share data):

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	2003	2002	2001
Numerator:			
Net income (loss) available to common stockholders	$ 69,790	$ 30,813	$(36,542)
Denominator:			
For basic per share data weighted average shares	128,417	102,064	91,505
Effect of dilutive stock options	4,022	62	
For diluted per share data	132,439	102,126	91,505
Basic earnings (loss) per share	$ .54	$ .30	$ (.40)
Diluted earnings (loss) per share	$ .53	$ .30	$ (.40)

For loss periods, weighted average common shares are used for calculating both basic and diluted loss per share as the use of other dilutive securities would be anti-dilutive. Anti-dilutive securities were 359,475, 483,055 and 937,611 for 2003, 2002 and 2001, respectively. Stock options exercisable pursuant to the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans do not result in the issuance of additional shares of the Company and are only exercisable, after the achievement of various conditions, into common stock of the Company held by Endo Pharma LLC.

16. Related Party Transactions

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. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC will be delivered. Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we will be required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of December 31, 2003, approximately 3.6 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, 2003, approximately $35 million), which is estimated to result in a tax benefit amount of approximately $13 million. Under the tax sharing agreement, we are required to pay this $13 million to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto. If payments are made pursuant to the tax sharing agreement, they will be reflected as a reduction of

stockholders equity in the accompanying financial statements.

Using a weighted average exercise price of $2.60 per share and an assumed effective tax rate of 38.3%, if all 36.3 million stock options under the Endo Pharma LLC Stock Option Plans were vested and exercised (including the 3.6 million stock options already exercised as discussed above):

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

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

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

Under the terms of the tax sharing agreement, we must pay all such tax benefit amounts to Endo Pharma LLC to the extent these tax benefits are usable by us, as described above. However, these payments need only be made to Endo Pharma LLC upon the occurrence of a liquidity event, which is generally defined as a transaction or series of transactions resulting in (a) a sale of greater than 20% on a fully diluted basis of our common equity (either through (i) a primary offering by us, (ii) a secondary sale by Endo Pharma LLC or other holders of common stock pursuant to a registration rights agreement or (iii) a combination of both such primary and secondary offerings), (b) a change in control of Endo or (c) a sale of all or substantially all of our assets. In accordance with the tax sharing agreement, no payments have been made or accrued to date. On July 8, 2003, a secondary sale by Endo Pharma LLC was

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closed which represented a sale of, on a fully diluted basis, approximately 12% of our common equity which did not, by itself, trigger a payment under the tax sharing agreement, and was not a liquidity event. That offering may, however, be combined with future offerings to result in a series of transactions that will trigger a payment obligation pursuant to the tax sharing agreement. Endo Pharma LLC has informed us that, subject to a variety of factors, including market conditions and stock price levels, it may initiate additional secondary offerings of our common stock in the future.

17. Quarterly Financial Data (Unaudited)

	Quarter Ended			
	March 31,	**June 30,**	**September 30,**	**December 31,**
	(in thousands, except per share data)			
2003(1)				
Net sales	$152,274	$152,027	$149,355	$141,952
Gross profit	$124,697	$125,769	$122,305	$ 87,166
Operating income (loss)	$ 26,651	$ 73,165	$ 64,312	$ (54,872)
Net income (loss)	$ 16,359	$ 45,168	$ 39,924	$ (31,661)
Net income (loss) per share (basic)	$ .14	$ .34	$ .30	$ (.24)
Net income (loss) per share (diluted)	$ .12	$ .34	$ .30	$ (.24)
Weighted average shares (basic)	118,217	131,734	131,761	131,769
Weighted average shares (diluted)	131,987	132,667	132,636	132,934

	Quarter Ended			
	March 31,	**June 30,**	**September 30,**	**December 31,**
	(in thousands, except per share data)			
2002(2)				
Net sales	$ 67,026	$107,902	$110,554	$113,491
Gross profit	$ 48,135	$ 80,097	$ 86,162	$ 85,722
Operating income (loss)	$ 10,371	$ 36,702	$ (21,375)	$ 39,587
Net income (loss)	$ 5,376	$ 22,001	$ (18,308)	$ 21,744
Net income (loss) per share (basic)	$ .05	$ .22	$ (.18)	$ .21
Net income (loss) per share (diluted)	$ .05	$ .22	$ (.18)	$ .21
Weighted average shares (basic)	102,064	102,064	102,064	102,064
Weighted average shares (diluted)	102,281	102,271	102,064	102,104

(1) Operating income (loss) and net income (loss) for the year ended December 31, 2003 and the quarter ended March 31, 2003 included charges of $48.5 million for compensation related to stock options. Operating income (loss) and net income (loss) for the year ended December 31, 2003 and the quarter ended December 31, 2003 included charges of $96.0 million for compensation related to stock options and charges of $24.6 million for an

inventory reserve for extended-release oxycodone tablets and a $7.0 million gain for purchased in-process research and development.

(2) Operating income (loss) and net income (loss) for the year ended December 31, 2002 and the quarter ended September 30, 2002 included charges of $40.4 million for compensation related to stock options, $13.3 million for purchased in-process research and development and $9.0 million for a manufacturing transfer fee. Operating income (loss) and net income (loss) for the year ended December 31, 2002 and the quarter ended December 31, 2002 included charges of $8.0 million for an inventory reserve for extended-release oxycodone tablets, an adjustment to the non-cash compensation charge taken in the third quarter of $5.7 million

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making the compensation charge for the year ended December 31, 2002 $34.7 million and a $7.0 million additional charge for purchased in-process research and development making the purchased in-process research and development charge $20.3 million for the year ended December 31, 2002.

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Exhibit Index

Exhibit No.	Title
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)
4.2	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)
4.3	[Intentionally Omitted.]
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	[Intentionally Omitted.]
10.2	[Intentionally Omitted.]
10.3	[Intentionally Omitted.]
10.4	[Intentionally Omitted.]
10.5	Tax Sharing Agreement, dated as of July 17, 2000, by and among Endo, Endo Inc. and Endo LLC (incorporated herein by reference to Exhibit 10.5 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
10.6	[Intentionally Omitted.]
10.7	Amended and Restated Credit Agreement, dated as of December 21, 2001, by and between Endo, Endo Pharmaceuticals, the Lenders Party Thereto and JPMorgan Chase Bank (incorporated by reference to Exhibit 10.7 of the Annual Report on Form 10-K for the Year Ended December 31, 2001 filed with the Commission on March 29, 2002)
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

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	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	Analgesic License Agreement, dated as of October 27, 1997, by and among Endo Pharmaceuticals, Endo Laboratories, LLC and DuPont Merck Pharmaceutical (incorporated herein by reference to Exhibit 10.11 of the Registration Statement filed with the Commission on June 9, 2000)
10.12	Anti-Epileptic License Agreement, dated as of October 27, 1997, by and among Endo Pharmaceuticals, Endo Laboratories, LLC and DuPont Merck Pharmaceutical (incorporated herein by reference to Exhibit 10.12 of the Registration Statement filed with the Commission on June 9, 2000)
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)
10.17	Manufacture and Supply Agreement, dated as of August 26, 1997, by and among Endo Pharmaceuticals, DuPont Merck Pharmaceutical and DuPont Merck Pharma (n/k/a Bristol-Myers Squibb Pharma Company) (incorporated herein by reference to Exhibit 10.17 of the Registration Statement filed with the Commission on June 9, 2000)
10.17.2	Amendment Agreement effective August 27, 2002 by and between Endo Pharmaceuticals and Bristol-Myers Squibb Pharma Company as successor-in-interest to DuPont Pharmaceuticals Company formerly known as The DuPont Merck Pharmaceutical Company (incorporated herein by reference to Exhibit 10.17.2 of the Current Report on Form 8-K dated August 27, 2002)
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)
10.19	Agreement, dated as of February 1, 2000, by and between Endo Pharmaceuticals and UPS Supply Chain Management, 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

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	Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
*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	Employment Agreement, dated as of July 17, 2000, by and between Endo and John W. Lyle (incorporated herein by reference to Exhibit 10.26 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 14, 2000)
*10.27	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and Carol A. Ammon (incorporated herein by reference to Exhibit 10.27 of the Current Report on Form 8-K dated August 31, 2001)
*10.28	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and Jeffrey R. Black (incorporated herein by reference to Exhibit 10.28 of the Current Report on Form 8-K dated August 31, 2001)
*10.29	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and David Allen Harvey Lee, MD, Ph.D. (incorporated herein by reference to Exhibit 10.29 of the Current Report on Form 8-K dated August 31, 2001)
*10.30	Amended and Restated Employment Agreement, dated as September 1, 2001, by and between Endo Pharmaceuticals and Mariann T. MacDonald (incorporated herein by reference to Exhibit 10.30 of the Current Report on Form 8-K dated August 31, 2001)
10.31	Separation and Release Agreement, dated as of March 22, 2000, by and between Endo Pharmaceuticals, Endo and Osagie O. Imasogie (incorporated herein by reference to Exhibit 10.31 of the Registration Statement filed with the Commission on June 9, 2000)
10.32	Separation and Release Agreement, dated as of April 20, 2000, by and between Endo Pharmaceuticals, Endo and Louis J. Vollmer (incorporated herein by reference to Exhibit 10.32 of the Registration Statement filed with the Commission on June 9, 2000)
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

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	the Registration Statement filed with the Commission on June 9, 2000)
*10.35	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo and Caroline B. Manogue (formerly Berry) (incorporated herein by reference to Exhibit 10.35 of the Current Report on Form 8-K dated August 31, 2001)
*10.36	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo and Peter A. Lankau (incorporated herein by reference to Exhibit 10.36 of the Current Report on Form 8-K dated August 31, 2001)
10.37	[Intentionally Omitted.]
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)
10.40	[Intentionally Omitted.]
10.41	Service Agreement, dated as of February 1, 2001, by and between Endo Pharmaceuticals and Ventiv Health U.S. Sales Inc. (incorporated herein by reference to Exhibit 10.41 of the Current Report on Form 8-K dated August 31, 2001)
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
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)
10.43.2	Amendment to Development and Marketing Strategic Alliance Agreement, dated March 2, 2004, between Endo Pharmaceuticals, SkyePharma, Inc. and SkyePharma Canada, Inc.
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.
10.46	License Agreement, dated as of February 25, 2004, by and between Endo Pharmaceuticals and Noven Pharmaceuticals, Inc.
10.47	Supply Agreement, dated as of February 25, 2004, by and between Endo Pharmaceuticals and Noven Pharmaceuticals, Inc.
21	Subsidiaries of the Registrant
23	Independent Auditors Consent
24	Power of Attorney
31.1	Certification of the Chairman and 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
32.1	Certificate of the Chairman and Chief Executive Officer of Endo

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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

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* A management contract or compensatory plan or arrangement required to be filed as an Exhibit pursuant to Item 15(c) of Form 10-K.

Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.