

ENDO PHARMACEUTICALS HOLDINGS INC

Form 10-K

March 27, 2003

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**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

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**FORM 10-K**

**FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO**

**SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

(Mark One)

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

For the fiscal year ended December 31, 2002

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: 39040

**ENDO PHARMACEUTICALS HOLDINGS INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

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

100 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:

| Title of Each Class Registered   | Name of Each Exchange on Which |
|--|--------------------------------|
| Common Stock   | Nasdaq                         |
| Class A Transferable Warrants to Purchase<br>Common Stock at \$.01 per Share in Certain<br>Circumstances | Nasdaq                         |

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

Annual Report for the Year Ended December 31, 2002

Indicate by check  whether the registrant: (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been

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subject to such filing requirements for the past 90 days. Yes  No

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2002): \$211,332,000 based on the last reported sale price on the Nasdaq on June 30, 2002.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of March 21, 2003: 131,714,007.

### Documents Incorporated by Reference

Portions of the registrant's Information Statement relating to its 2003 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, and the Company's Registration Statement on Form S-3 dated October 17, 2001, are incorporated by reference into this Report.

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**ENDO PHARMACEUTICALS HOLDINGS INC.**

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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-looking statements. We have based these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described in Management's Discussion and Analysis of Financial Condition and Results of Operations, Business and elsewhere in this Report could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained in this Report. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in this Report include, among others:

our 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.



**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 \$15 billion for the 12 months ended December 31, 2002. Our primary area of focus is analgesics, which according to IMS Health data was the fourth most prescribed class of medication in the United States in 2002.

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).

We have a portfolio of branded products that includes established brand names such as Percocet®, Lidoderm®, Percodan® and Zydone®. Branded products comprised approximately 76%, 67% and 63% of net sales for fiscal years 2000, 2001 and 2002, respectively. Through a national dedicated sales force of approximately 230 sales representatives (70 internal sales representatives and 160 contract sales representatives), we market our branded pharmaceutical products to doctors, retail pharmacies and other healthcare professionals throughout the United States.

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. We enhance our financial flexibility by outsourcing many of our functions, including manufacturing. Currently, our primary suppliers of contract manufacturing services are Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals), Novartis Consumer Health, Inc. and Teikoku Seiyaku Pharmaceuticals.

**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 through focused marketing and promotion efforts.* Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, continues to gain market share 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 selected generics.* To capitalize on our expertise in pain management, we are developing new products to address acute, chronic and neuropathic pain conditions. 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 and developed an oral immediate-release (IR) version of oxymorphone. The New Drug Applications (NDA) for oxymorphone ER and IR were filed with the U.S. Food and Drug Administration (FDA) in December 2002 and were accepted for substantive review in February 2003. We are also developing a patented prescription oral rinse (0.1% triclosan) for the management of oral mucositis, painful mouth sores that often occur in patients undergoing cancer treatment. Currently, no product is approved for either the prevention or treatment of oral mucositis; accordingly, the FDA has agreed

to grant fast-track review to this product. We expect to be in a position to file an NDA for this product by late 2003 or early 2004. In addition, we are developing with our partner SkyePharma, Inc. the patented-protected development products, DepoMorphine™ and Propofol IDD-D™. DepoMorphine™, a sustained-release injectable formulation, and Propofol IDD-D™, administered intravenously, are our first post-surgical, critical-care drugs. If the clinical trials progress as we expect, we anticipate the DepoMorphine™ NDA to be filed with the FDA by mid 2003. Further, we are developing with our partner DURECT Corporation a patented-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 version of oxycodone, an AB-rated generic version of OxyContin, a product of The Purdue Frederick Company. According to IMS Retail Provider Perspective data, OxyContin generated U.S. sales of approximately \$1.6 billion in 2002, up from approximately \$1.5 billion in 2001. 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 (ANDA) with the FDA for the bioequivalents of the 10mg, 20mg and 40mg strengths of OxyContin, thereby entitling us to 180 days of marketing exclusivity with respect to these strengths of this product. 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. During 2002, we added four patent-protected products to our research and development pipeline. Specifically, in July 2002, we acquired BML Pharmaceuticals, which provided us with a great opportunity to gain access to the palliative care side of oncology, which we see as a natural extension of our pain management franchise. In November 2002, we entered into an agreement to collaborate on the development and commercialization of CHRONOGESIC™ for the U.S. and Canada. 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.

*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. Lead by the performance of Percocet® 7.5/325 and Percocet® 10.0/325, net sales of the Percocet® family of products increased 43% from \$101.0 million in 2001 to \$144.6 million in 2002.

## **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 core portfolio of branded pharmaceutical products to treat and manage pain. These products include Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia. Net sales of Lidoderm®, which has orphan drug status through March 2006 and is patent protected through 2015, increased 103% from \$40.9 million in 2001 to \$83.2 million in 2002. These products also include Percocet® and Percodan®, which have been marketed since 1976 and 1950, respectively, and which we consider to be gold standards of pain management based on their long history of demonstrated product safety and effectiveness. According to IMS Health data, approximately 84% 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 allowed 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 and a balanced focus on complementary therapeutic areas.* As a result of our focused research and development effort, we filed two NDAs with the FDA in December 2002 that were accepted for substantive review in February 2003, we have two products in Phase III clinical trials and two products in Phase II clinical trials. If the FDA's review of oxymorphone ER and oxymorphone IR progresses as we anticipate, we expect to receive an action letter from the FDA by the end of 2003. If the clinical trials progress as we expect, we anticipate the DepoMorphine™ NDA to be filed with the FDA by mid 2003. In addition, if the clinical trials progress as we expect, we anticipate filing an NDA with the FDA for our oral rinse product (0.1% triclosan) for oral mucositis by late 2003 or early 2004.

*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 five years through the launch of a number of new products and product extensions all of which, in the aggregate, contributed approximately 56% of our net sales in 2002. In December 2002, we filed two NDAs with the FDA—one for each of oxymorphone ER and oxymorphone IR.

*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 this strategy successfully with products such as morphine sulfate extended-release tablets, which we introduced in November 1998 as a bioequivalent of MS Contin, a Purdue Frederick product. In addition, 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 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 of our generic OxyContin. See Governmental Regulation.

*Targeted national sales and marketing infrastructure.* We market our products directly to physicians through an internal sales force of 70 specialty/institutional representatives and a dedicated contract sales force of approximately 160 community-based field representatives. The sales force focuses on high-prescribing physicians in pain management, surgery, oncology and primary care. The contract sales force is provided exclusively to us pursuant to an agreement with Ventiv Health U.S. Sales Inc (Ventiv). In 2002, we exercised our option to convert the 70 specialty/institutional sales representatives and their managers to Endo employees effective July 1, 2002. We have a flexible arrangement with Ventiv, whereby we have the option to hire all of the 160 community-based field representatives and their managers as our full time employees at any time. We maintain an internal sales management infrastructure to direct and focus these sales force efforts.

*Experienced and dedicated management team.* With an average of approximately 20 years of experience in the pharmaceutical industry, our management team has a proven track record of building our business through internal growth as well as 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™ and the acquisition of BML Pharmaceuticals. Management has received FDA approval on more than fifteen new products and product extensions since 1997 and as a result of several successful product launches has grown Endo's net sales from approximately \$108.4 million in 1998 to approximately \$399.0 million in 2002. In addition, management

has vested stock options to acquire up to 19% of our common stock and has the potential to receive as much as an additional 3% of our common stock through options that will vest if the price of our common stock reaches a specified defined target. All of these options 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. See 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 \$15.0 billion for the 12 months ended December 31, 2002. This represents an approximately 23% compounded annual growth rate since 1998. Our primary area of focus within this market is analgesics. In 2002, analgesics were the fourth most prescribed medication in the United States with over 249 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 74% of the analgesics prescriptions in 2002. This market segment has grown to \$4.6 billion for the 12 months ended December 31, 2002, representing a compound 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 fueled by the:

increasing physician recognition of the need and patient demand for effective treatment of pain;

aging population (according to the U.S. Census Bureau, in 1990 the population aged 65 and older reached 31 million people and is expected to grow to 40 million people by 2010, representing 29% growth over this period);

introduction of new and reformulated branded products; and

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

## Product Overview

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

| Product   | Active ingredient             | 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  | NDA  |
| Oxymorphone IR                                    | oxymorphone hydrochloride     | Branded  | NDA  |
| DepoMorphine™(2)                                  | morphine sulfate              | Branded  | Phase III  |
| Oral Rinse (0.1% triclosan)<br>for Oral Mucositis | triclosan .1%                 | Branded  | Phase III  |
| CHRONOGESIC™(3)                                   | sufentanil                    | Branded  | Phase II   |
| Propofol IDD-D™(2)                                | propofol                      | Branded  | Phase II   |
| Oxycodone ER(4)                                   | oxycodone                     | Generic  | Tentatively<br>approved;<br>subject to<br>litigation |

- (1) Co-developed with Penwest Pharmaceuticals Co.
- (2) Licensed marketing rights from SkyePharma, Inc.
- (3) Licensed marketing rights from DURECT Corporation
- (4) See Item 3. Legal Proceedings.

*Branded Products*

*Lidoderm®*. Lidoderm® was launched in September 1999. A patented, topical patch product containing lidocaine, it is the first FDA-approved product for the relief of the pain from 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 status, meaning that no other lidocaine-containing patch product can be approved for this indication until March 2006. Lidoderm is also patented protected until 2015. In 2000, 2001 and 2002, Lidoderm® net sales were \$22.5 million, \$40.9 million and \$83.2 million, respectively. Lidoderm® accounted for approximately 21% of our 2002 net sales.

*Percocet®*. We consider Percocet® to be a gold standard of pain management. Launched in 1976, Percocet® is approved for the treatment of moderate-to-severe pain. Although Percocet® has faced generic competition for nearly 20 years, in 2002, according to the IMS National Prescription Audit, approximately 13.9 million new prescriptions for this combination of oxycodone hydrochloride and acetaminophen were written for the brand name Percocet, of which, due to generic substitution, only approximately 14% were filled by pharmacists with our brand Percocet®.

During the fourth quarter of 1999, we introduced three new strengths of Percocet®: Percocet® 2.5/325, Percocet® 7.5/500 and Percocet® 10.0/650, complementing the existing Percocet® 5.0/325. Prior to the launch of these products, physician prescribing practices had indicated that over 80% of prescriptions were written for amounts other than the label amount. As an example, the current prescription information for the original Percocet®, Percocet® 5.0/325, calls for one tablet every six hours. Approximately 30% of prescriptions written directed patients to take two tablets every four hours, translating into a dosage of 10mg every four hours. By offering new prescription strengths, we have enabled physicians to prescribe one tablet of the proper dose for their patients, facilitating greater ease of administration and compliance. On January 3, 2001, the Food and Drug Administration approved another manufacturer's ANDA for a generic equivalent to Percocet® 7.5/500 and Percocet® 10.0/650. This generic equivalent became available in April 2001. During the fourth quarter of 2001, we launched two new formulations: Percocet® 7.5/325 and Percocet® 10.0/325. These new dosage forms allow physicians the flexibility of increasing the dose of opioid while still maintaining a low level of acetaminophen. There is currently no generic equivalent available for these new dosage forms. The Percocet® family of products was responsible for net sales of \$92.4 million, \$101.0 million and \$144.6 million in the years 2000, 2001 and 2002, respectively. The Percocet® franchise accounted for approximately 36% of our 2002 net sales.

*Percodan®*. Launched in 1950 for the treatment of moderate-to-severe pain, we also consider Percodan® to be a gold standard of pain management. In 2002, according to the IMS National Prescription Audit, approximately 365,000 prescriptions for oxycodone hydrochloride and oxycodone terephthalate in combination with aspirin were written for the brand name Percodan. Due to generic substitution, only approximately 18% 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-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 2002 fiscal year.

## Generic Products

When a branded pharmaceutical product is no longer protected by the relevant patents, normally as a result of a patent's expiration, 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 22% of our total net sales in 2002. Launched in November 1998, morphine sulphate extended-release tablets are a bioequivalent 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. In addition, we have a generic oxycodone hydrochloride and acetaminophen product, Endocet®, which accounted for 9% of our total net sales in 2002. 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 consisted of a few other products, none of which accounted for more than 5% of our total net sales for 2002.

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, and, therefore provide 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. 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. If approved, oxymorphone ER is intended for 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, low back pain, cancer pain, and post-surgical pain, patients taking oxymorphone ER demonstrated statistically significant pain relief. We co-developed this oral extended-release version of oxymorphone with Penwest Pharmaceuticals and currently expect to receive a first action letter from the FDA by the end of 2003. Once approved, we expect oxymorphone ER will compete in the \$3 billion 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. If approved, oxymorphone IR is intended for acute moderate-to-severe pain. In Phase III clinical studies in post-surgical pain, patients taking oxymorphone IR demonstrated statistically significant pain relief. We currently expect to receive a first action letter from the FDA by the end of 2003.

*DepoMorphine™.* Currently in Phase III clinical trial development, DepoMorphine™ is a sustained-release injectable formulation of morphine sulfate, the sole active ingredient, encapsulated with SkyPharma's patented DepoFoam™ controlled-release delivery technology. DepoMorphine™, administered epidurally, is intended for the management of post-operative pain. The first pivotal Phase III clinical study has shown that DepoMorphine™ administered in patients undergoing hip surgery has a safety profile typical for an epidural opioid agent and that patients experienced dose-related post-operative pain relief for 48 hours. The efficacy results were statistically significant. If the additional clinical trial results are positive, we expect an NDA to be submitted to the FDA in mid-2003.

*CHRONOGESIC*<sup>TM</sup>. Currently in Phase II clinical trial 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 capsule 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 agreement between DURECT and the FDA regarding additional monitoring and data collection. These protocol changes requested by the FDA were not in relation to any observed safety issue or adverse event. In addition, DURECT is implementing some necessary design and manufacturing enhancements to the CHRONOGESIC product. DURECT anticipates that the changes to the existing clinical protocol, and the implementation of these design and manufacturing enhancements, will delay the restart of clinical trials until the second half of 2003.

*Propofol IDD-D*<sup>TM</sup>. Currently in Phase II clinical trial development, Propofol IDD-D<sup>TM</sup> is an IV formulation of propofol as the sole active ingredient using SkyePharma's patented Insoluble Drug Delivery (IDD-~~D~~<sup>M</sup>) technology to improve solubility. Propofol IDD-D<sup>TM</sup> is intended for the maintenance of anesthesia in adults during surgery and for sedation of adults hospitalized in an intensive-care setting.

*Oxycodone ER*. We have also developed an extended-release version of oxycodone, an AB-rated generic version of OxyContin, a product of The Purdue Frederick Company. According to IMS Retail Provider Perspective data, OxyContin generated U.S. sales of approximately \$1.6 billion in 2002, up from approximately \$1.5 billion in 2001. 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 ANDA with the FDA for the bioequivalents of the 10mg, 20mg and 40mg strengths of OxyContin, thereby entitling us to 180 days of marketing exclusivity with respect to these strengths of this product. See Item 3. Legal Proceedings.

*Other*. We also have other products in various stages of development and 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., Pfizer, Inc., The Purdue Frederick Company, Roxane Laboratories, Inc. and Watson Pharmaceuticals, Inc.

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

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

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 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, 2002, our research and development staff consisted of 58 employees, primarily based in Garden City, New York and at our corporate headquarters in Chadds Ford, Pennsylvania. For fiscal years 2000, 2001 and 2002, our expenditures on research and development were \$26.0 million, \$39.0 million and \$56.8 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. Historically, the fourth fiscal quarter has had relatively higher net sales than each of the first three fiscal quarters.

### **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 26%, 16%, 12% and 10%, respectively, of our net sales in 2000. 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.

Recently, 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, 2003, we held 22 U.S. issued patents and 19 foreign issued patents, approximately 7 U.S. patent applications pending and approximately 72 foreign patent applications pending with respect to our products. In addition, as of March 10, 2003, we have licenses for 37 U.S. issued patents, 7 U.S. patent application pending, 63 foreign issued patents and 6 foreign patent applications pending.

The effect of these issued patents is that they provide us 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 filed prior to November 29, 2000 and patent applications filed within the last 18 months are maintained in secrecy 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, or that others will not independently develop equivalent proprietary information or 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, 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 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 required before each dosage form 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.

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.

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 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 pre-clinical and clinical safety and efficacy data or a right of reference to such data sponsored by the applicant. Before dosing 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.

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

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

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

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

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

As a condition of approval, the FDA or other regulatory authorities may require further studies, including Phase IV post-marketing studies to provide additional data on safety. The 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.

#### *ANDA Process*

FDA approval of an ANDA is required before a generic equivalent of an existing, or listed drug can be marketed. We usually receive approval for such products by submitting an ANDA to the FDA. 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.



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 date of patent expiry 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 allows the FDA to impose debarment and other penalties on individuals and companies that commit certain illegal acts relating to the generic drug approval process. In some situations, the Generic Act requires the FDA to not accept or review ANDAs 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 Generic Act allows for civil penalties and withdrawal of previously approved applications. Neither we nor, we believe, 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 an 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 later applicant certifies that the listed patents are invalid, unenforceable or not infringed by the proposed generic drug and gives notice to the holder of the NDA for the listed drug of the bases upon which the patents are challenged, and (2) the holder of the listed drug does not sue the later applicant for patent infringement within 45 days of receipt of notice. Under the current law, if an infringement suit is filed, the FDA may not approve the later application for 30 months or such time as the court may order.

In addition, the holder of the NDA for the listed drug is entitled to certain non-patent exclusivity before which the FDA cannot approve an application for a competing generic product. If the listed drug is a new chemical entity, the FDA may not approve any application for five years; if it is not a new chemical entity, the FDA may not approve a competitive application before expiration of 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 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 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 require 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 Agency*

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

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

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

*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, sales representatives, 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 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. 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 and expect to continue to incur 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 currently manufactured at Bristol-Myers Squibb (f/k/a DuPont Pharmaceuticals). A description of the material terms of our material third party manufacturing/supply contracts follows:

*Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals).* Bristol-Myers Squibb (f/k/a DuPont Pharmaceuticals) currently manufactures a number of our brand and generic pharmaceutical products. Bristol-Myers Squibb manufactures 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 are 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 are FDA- and DEA-approved. For these manufacturing services, we currently pay 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, (2) an amount, adjusted on an annual basis, to cover Bristol-Myers Squibb's variable manufacturing costs plus a reasonable profit.

In addition to manufacturing services, Bristol-Myers Squibb currently provides 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 is included in the compensation for manufacturing services. The initial term of this agreement was five years, expiring on August 26, 2002, with an option to renew for a period of time not to exceed five years (through August 2007) with pricing terms to be negotiated. 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 (at which time the agreement will expire) and that we would be able to transfer up to 100% of our products to another manufacturer at any time. If, prior to August 26, 2003, Bristol-Myers Squibb determines to sell or otherwise transfer either the Garden City plant facility or the Manati plant facility and we determine that the acquirer of such facility would not be an acceptable manufacturer of our products, Bristol-Myers Squibb will implement, at its cost, appropriate arrangements for the manufacture and supply of the products elsewhere.

*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.

*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.

*Mallinckrodt Inc.* Under the terms of this agreement, Mallinckrodt will manufacture and supply to us narcotic active drug substances, in bulk form, and upon the expiration of Mallinckrodt's existing supply agreement with Bristol-Myers Squibb, 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 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, (2) Kunitz and Associates Inc. for medical affairs and (3) 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/k/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 which 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, 2002, these fees and expenses were approximately \$5.0 million. The current term of the agreement for all services provided thereunder 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 all of our business; by us, with prior notice, for a change in our stock ownership or company control; (2) if we decide to have these services provided in-house or by an affiliate or (3) 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 will expire on July 31, 2003, unless we exercise our option to renew the agreement for an additional one-year period (in which case it will expire on July 31, 2004). 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, exclusively promotes certain of our products to healthcare professionals in the United States. The term of this agreement is until December 31, 2003, but will automatically renew for one-year periods thereafter. The agreement may be terminated (1) by either party for material breach, (2) by us (with 90 days' notice) for no reason or (3) by Ventiv (with 180 days' notice) for no reason. Under the agreement, we reserve the option to hire all of these sales representatives and managers as our full-time employees at any time.

#### **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.

*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™. CHRONOGESIC™'s clinical development program is on temporary hold pending agreement between DURECT and FDA regarding additional monitoring and data collection. These protocol changes requested by the FDA were not in relation to any specific safety issue or adverse event. In addition, DURECT is currently implementing some necessary design and manufacturing enhancements to CHRONOGESIC™. The changes to the existing clinical protocol, and the implementation of these design and manufacturing enhancements, will delay the restart of the development program until the second half of 2003. Under the terms of this agreement, we will have no obligation to fund any of the development costs of CHRONOGESIC™ until the clinical trials are restarted (which are currently anticipated to begin in the second half of 2003). In the event that the clinical trials have not restarted by December 31, 2003, then during the six-month period from January 1, 2004 until the earlier of (a) the recommencement of the clinical trials and (b) June 30, 2004, we will be responsible for 25% of the development costs of CHRONOGESIC™ actually incurred each month, up to an aggregate of \$3.0 million of development costs for such period. Once the clinical trials of CHRONOGESIC™ have restarted or beginning on June 30, 2004 (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 Endo the exclusive promotional rights to CHRONOGESIC™ in the U.S. and Canada. Endo will be responsible for marketing, sales and distribution, including providing specialty sales representatives dedicated to supplying technical and training support. DURECT will be responsible for the manufacture of CHRONOGESIC™. Endo 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 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, 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, Endo will receive 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. In addition, SkyePharma may receive further milestone payments totaling \$95 million which include total milestones of \$10 million for DepoMorphine™ through FDA approval. 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 comprises a \$15 million milestone payable when net sales of DepoMorphine™ reach \$125 million in a calendar year, and a \$20 million milestone payable when net sales of DepoMorphine™ reach \$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, Endo 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 DepoBupivacaine™, a long-acting, sustained release formulation of the local anesthetic bupivacaine. We have the option to obtain commercialization rights for this product when SkyePharma successfully completes its Phase II trials, as well as any further SkyePharma products formulated using the DepoFoam™ technology successfully developed for the prophylaxis or treatment of pain.

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

*Virginia Commonwealth University.* We have licensed from Virginia Commonwealth University certain patents and pending patent applications in the field of pain management. These include patents covering Morphidex® and other combinations of the NMDA-receptor antagonist, dextromethorphan, with opioids. Under this license, we are required to pay royalties equal to 4% of sales of products resulting from the licensed patents. In addition, we will pay Virginia Commonwealth University 50% of royalty payments received from any sublicensees until such payments total \$500,000 for a given year, 33% until the payments total an additional \$500,000 for such year and 25% thereafter. This license lasts until the underlying patents expire.

*Penwest Pharmaceuticals.* In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals to exclusively co-develop opioid analgesic products for pain management, using Penwest's patent-protected proprietary technology, for commercial sale worldwide. On April 2, 2002, we amended and restated this agreement to provide, among other things, that this collaboration would cover only that opioid analgesic product currently under development by the parties, namely, oxymorphone ER. We have historically shared on an equal basis the costs of products developed under this agreement and will, in the future, share costs and profits on an equal basis (subject to the recoupment discussed below). On March 18, 2003, we received notice from Penwest that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of this product on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we will 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. 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 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 license pursuant to this license agreement and (2) November 20, 2011, we will pay Hind non-refundable royalties, including a minimum annual royalty of at least \$500,000 per year, on net sales of the product. 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 2002, we accrued \$9.1 million for this royalty. 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 March 15, 2002, we extended the Hind Healthcare Inc. license to cover Lidoderm® in Canada and Mexico. This extension provides us the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in Canada and Mexico.

On April 5, 2002, we amended and restated our collaboration agreement with Penwest Pharmaceuticals to provide, among other things, that this collaboration would cover only that opioid analgesic product currently under development by the parties, namely, 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 will 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. See License and Collaboration Agreements; Penwest Pharmaceuticals.

On July 26, 2002, our wholly owned subsidiary, Endo Pharmaceuticals Inc., acquired BML Pharmaceuticals, Inc. ( BML ), a privately held company including BML's lead pipeline product, an oral rinse (0.1%

triclosan) for oral mucositis. BML operates as a wholly owned subsidiary of Endo Pharmaceuticals Inc. See Management's Discussion and Analysis of Financial Condition and Results of Operations Overview.

On August 26, 2002, we reached an agreement with Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals) which provides that Bristol-Myers Squibb will continue to manufacture our products until August 26, 2003 (at which time the manufacturing agreement will expire) and that we will be able to transfer up to 100% of our products to another manufacturer at any time. See Service Agreement; Third Party Manufacturing/Supply Agreements.

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<sup>™</sup>. In general, under this agreement, DURECT licensed to Endo the exclusive promotional rights to CHRONOGESIC<sup>™</sup> in the U.S. and Canada. Endo will be responsible for marketing, sales and distribution, including providing specialty sales representatives dedicated to supplying technical and training support. DURECT will be responsible for the manufacture of CHRONOGESIC<sup>™</sup>. Endo and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC<sup>™</sup>. See Licenses and Collaboration Agreements; DURECT Corporation.

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, DepoMorphin<sup>™</sup> and Propofol IDD-D<sup>™</sup> (collectively, the Skye Products). Under the terms of this agreement, Endo has received the exclusive license to the U.S. and Canadian marketing and distribution rights for the Skye Products, with options for certain other development products. See Licenses and Collaboration Agreements; SkyePharma, Inc.

On January 6, 2003, we entered into an agreement with Dawson Holding Company to lease a 24,190 square foot facility in Hicksville, 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. This lease is for a term of 10 years.

#### **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, 2002, 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. The 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, 2002, we have not borrowed under the revolving loans.

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, 2002, we had 277 employees, of which 58 are engaged in research and development, 18 in regulatory work, 108 in sales and marketing, 20 in quality assurance and 73 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 current executive officer of Endo, as of March 27, 2003:

| Name                        | Age | Position and Offices   |
|-----------------------------|-----|--|
| Carol A. Ammon              | 51  | President, Chief Executive Officer, Chairman and Director    |
| Mariann T. MacDonald        | 55  | Executive Vice President, Operations                         |
| Jeffrey R. Black            | 38  | Senior Vice President, Chief Financial Officer and Treasurer |
| Peter A. Lankau             | 50  | Senior Vice President, U.S. Business                         |
| David A.H. Lee, M.D., Ph.D. | 53  | Senior Vice President, Research & Development                |
| Caroline B. Manogue         | 34  | Senior Vice President, General Counsel & Secretary           |

CAROL A. AMMON, 51, is President, Chief Executive Officer, Chairman and Director 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.

MARIANN T. MACDONALD, 55, is Executive Vice President, Operations of Endo. Prior to joining Endo, Ms. MacDonald was Vice President of Business Information, Training, Administration & Technology for the U.S. Pharmaceuticals Division of DuPont Merck from 1996 to 1997. In 1996, Ms. MacDonald was the Vice President of Operations for the U.S. Pharmaceuticals Division of DuPont Merck. Prior to that, she was the Vice President of Operations for Endo Laboratories, L.L.C. from 1995 to 1996. From 1991 to 1995, Ms. MacDonald held various management positions in DuPont Merck.

JEFFREY R. BLACK, 38, 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, 50, is Senior Vice President, U.S. Business of Endo. Prior to joining Endo in June 2000, Mr. Lankau was Vice President, Sales and Marketing for Alpharma USPD, Inc. in Baltimore, Maryland. He was Vice President, Sales - U.S. Pharmaceuticals for Aventis (f/k/a Rhone Poulenc Rorer, Inc.) from 1996 to 1999, based in Collegeville, Pennsylvania. Prior to 1996, 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., 53, is Senior 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 V.P. 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, 34, 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 Hicksville, New York, which will become our new research and development facility in late 2003 or early 2004. A description of the material terms of each of the agreements pertaining to these properties follows:

### Chadds Ford, Pennsylvania

*Route 202-Concord Partners (formerly Northstar) Lease Agreement.* Under this agreement, we had leased office space in Chadds Ford, Pennsylvania that had been used for our headquarters and administrative functions until August 2001. The lease commenced on October 1, 1997, for an initial term of five years. The annual base rent was adjusted annually by a fixed percentage. We amended this lease on December 16, 1997, January 6, 1999, November 23, 1999 and November 8, 2000, in order for us to acquire additional office space in the same building for an additional fee. Since we moved to our new headquarters in August 2001, we allowed this lease to lapse on October 1, 2002, in accordance with its terms.

*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.

### Garden City, New York

*Bristol-Myers Squibb Company (f/k/a DuPont Pharmaceuticals) Lease Agreement.* Under this agreement, we 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 may 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 either on December 31, 2003 or June 30, 2004, at our option, at which time we will move into our new research and development facility in Hicksville, New York. See Hicksville, New York.

## Hicksville, New York

*Dawson Holding Company.* Under this agreement, dated January 6, 2003, we lease a 24,190 square foot facility in Hicksville, 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 be terminated (1) by us, at the end of the fifth year with the payment to Dawson Holding of approximately \$239,000 plus 75% of any additional rent owed during the fifth lease year, (2) by us, with 30 days notice, if the facility has suffered a fire or other casualty and 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 has 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 has 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. However, we cannot make any assurances as to the outcome of this patent challenge. Purdue Frederick was granted a preliminary injunction (*Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 98 F. Supp. 2d 362 (SDNY 2000)), which decision was affirmed on appeal (*Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359 (Fed. Cir. 2001)), against a different manufacturer based on the same patents that are being asserted against us and EPI, and in the same court in which Purdue Frederick sued. We believe the defenses rejected in the preliminary injunction decision and in the appellate decision do not substantially impact the principal defenses raised by us and EPI.

The district court has tentatively scheduled the trial of the patent claims in all three of the suits against EPI for June 2003. By an earlier order, the judge bifurcated the antitrust counterclaims for a separate and subsequent trial.

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

*SmithKline Beecham Corporation, et al. v. Endo Pharmaceuticals Inc., Index No. 01 Civ. 5770 (E.D. Pa.)*

On November 15, 2001, SmithKline Beecham Corporation (and related companies) filed suit against EPI in the U.S. District Court for the Eastern District of Pennsylvania alleging that EPI's bioequivalent version of SmithKline's Paxil®, 40 mg strength, infringes five of its patents. The FDA accepted EPI's ANDA submission for a bioequivalent version of SmithKline's Paxil®, 40 mg strength, earlier in 2001. In this ANDA, EPI made the required Paragraph IV certification against all of the SmithKline patents listed in the FDA's Orange Book as covering Paxil®. Paxil® is indicated for the treatment of major depressive disorder, obsessive compulsive disorder, panic disorder, social anxiety disorder, generalized anxiety disorder and posttraumatic stress disorder. For strategic reasons, on May 9, 2002, we submitted to the FDA a request to withdraw this ANDA. As a result, Endo has sought to have the pending action dismissed. On August 2, 2002, the parties filed with the court a Stipulation and Consent Order dismissing this action, with each party bearing its own legal costs. On September 3, 2002, the court entered a Final Stipulation and Consent Order dismissing this action.

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 has been transferred to the United States District Court for the Western District of Washington by order of the United States Judicial Panel on Multidistrict Litigation, where fact and expert discovery is underway. EPI intends to defend itself vigorously in each of these cases.

### *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, 2002.

## 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<br>Common Stock |         |
|-------------------------------|----------------------|---------|
|                               | High                 | Low     |
| 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 |
| Year Ending December 31, 2001 |                      |         |
| 1st Quarter                   | \$ 7.13              | \$ 5.13 |
| 2nd Quarter                   | \$ 11.65             | \$ 6.00 |
| 3rd Quarter                   | \$ 12.15             | \$ 7.24 |
| 4th Quarter                   | \$ 12.00             | \$ 7.32 |

*Holdings.* As of March 21, 2003, we estimate that there were approximately 111 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, 2002 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.

| Plan Category   | Column A<br>Number of securities<br>to be issued<br>upon exercise of<br>outstanding options,<br>warrants and rights | Column B<br>Weighted-average<br>exercise price<br>of outstanding<br>options,<br>warrants and rights | Column C<br>Number of securities remaining<br>available for future issuance<br>under equity compensation<br>plans (excluding securities<br>reflected in Column A) |
|---|---|---|---|
| <b>Equity compensation plans approved by security holders</b>         |   |   |   |
| Endo Pharma LLC Amended and Restated 1997 Executive Stock Option Plan | 21,304,503(a)   | \$ 2.71   | 716,370(b)  |
| Endo Pharma LLC Amended and Restated 1997 Employee Stock Option Plan  | 2,462,252(a)  | \$ 2.71   | 716,370(b)  |
| Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan          | 1,985,223   | \$ 8.82   | 2,014,277   |
| <b>Equity compensation plans not approved by security holders</b>     |   |   |   |
| Not Applicable.   |   |   |   |



- (a) All of the stock options granted under these plans are exercisable solely for shares currently held by Endo Pharma LLC (an affiliate of Kelso & Company in which certain 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.

On January 1, 2003, both the Endo Pharma LLC 2000 Supplemental Executive Stock Option Plan and the Endo Pharma LLC 2000 Supplemental Employee Stock Option Plan became effective, resulting in the issuance of approximately 9.6 million and 1.1 million stock options, respectively. The weighted average exercise price of these stock options is \$2.42. Like the 1997 Plans, 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.

**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, |            |              |             |            |
|---|-------------------------|------------|--------------|-------------|------------|
|   | 1998                    | 1999       | 2000         | 2001        | 2002       |
| (in thousands, except per share data)             |                         |            |              |             |            |
| <b>Consolidated Statement of Operations Data:</b> |                         |            |              |             |            |
| Net sales   | \$ 108,370              | \$ 138,546 | \$ 197,429   | \$ 251,979  | \$ 398,973 |
| Cost of sales                                     | 54,731                  | 58,263     | 63,041       | 74,891      | 98,857     |
| Gross profit                                      | 53,639                  | 80,283     | 134,388      | 177,088     | 300,116    |
| Selling, general and administrative               | 25,540                  | 42,921     | 56,537       | 79,505      | 110,907    |
| Research and development                          | 5,893                   | 9,373      | 26,012       | 38,994      | 56,823     |
| Depreciation and amortization                     | 7,373                   | 8,309      | 27,624       | 49,234      | 3,142      |
| Compensation related to stock options             |                         |            | 15,300       | 37,253      | 34,659     |
| Purchased in-process research and development     |                         |            | 133,200      |             | 20,300     |
| Manufacturing transfer fee                        |                         |            |              |             | 9,000      |
| Merger and other related costs                    |                         |            | 1,583        |             |            |
| Separation benefits                               |                         |            | 22,034       |             |            |
| Operating income (loss)                           | 14,833                  | 19,680     | (147,902)    | (27,898)    | 65,285     |
| Interest expense, net                             | 14,451                  | 14,347     | 15,119       | 13,290      | 4,391      |
| Income (loss) before income tax (benefit)         | 382                     | 5,333      | (163,021)    | (41,188)    | 60,894     |
| Income tax (benefit)                              | 181                     | 2,073      | (6,181)      | (4,646)     | 30,081     |
| Net income (loss)                                 | \$ 201                  | \$ 3,260   | \$ (156,840) | \$ (36,542) | \$ 30,813  |

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| Year Ended December 31,                                    |         |        |           |          |         |
|--|---------|--------|-----------|----------|---------|
|  | 1998    | 1999   | 2000      | 2001     | 2002    |
| (in thousands, except per share data)                      |         |        |           |          |         |
| <b>Basic and Diluted Net Income (Loss) Per Share:</b>      |         |        |           |          |         |
| Basic  | \$ 0.00 | \$ .05 | \$ (1.97) | \$ (.40) | \$ .30  |
| Diluted  | \$ 0.00 | \$ .05 | \$ (1.97) | \$ (.40) | \$ .30  |
| Shares Used to Compute Basic Net Income (Loss) Per Share   | 71,307  | 71,332 | 79,454    | 91,505   | 102,064 |
| Shares Used to Compute Diluted Net Income (Loss) Per Share | 71,307  | 71,332 | 79,454    | 91,505   | 102,126 |

| Year Ended December 31,                             |           |           |           |           |            |
|---|-----------|-----------|-----------|-----------|------------|
|   | 1998      | 1999      | 2000      | 2001      | 2002       |
| (in thousands)                                      |           |           |           |           |            |
| <b>Consolidated Balance Sheet Data:</b>             |           |           |           |           |            |
| Cash and cash equivalents                           | \$ 17,367 | \$ 22,028 | \$ 59,196 | \$ 95,357 | \$ 56,902  |
| Working capital                                     | 37,676    | 49,541    | 72,759    | 65,259    | 105,058    |
| Total assets  | 287,618   | 329,436   | 467,840   | 470,995   | 512,972    |
| Total debt  | 170,544   | 191,203   | 198,525   | 91,259    | 7,851      |
| Other long-term obligations                         | 6,352     | 6,745     | 7,218     | 207       | 7,851      |
| Stockholders' equity                                | 75,358    | 78,587    | 198,173   | 295,122   | 352,692    |
| <b>Other Financial Data:</b>                        |           |           |           |           |            |
| Net cash provided by operating activities           | \$ 20,932 | \$ 13,766 | \$ 35,069 | \$ 80,486 | \$ 109,638 |
| Net cash provided by (used in) investing activities | (3,537)   | (9,074)   | 18,077    | (6,546)   | (22,274)   |
| Net cash provided by (used in) financing activities | (14,549)  | (31)      | (15,978)  | (37,779)  | (125,819)  |
| Consolidated EBITDA(1)                              | 40,726    | 47,232    | 67,687    | 79,523    | 158,142    |

- (1) In evaluating consolidated EBITDA and the trends it depicts, you should consider the following significant factors:

Consolidated EBITDA is not a defined term under generally accepted accounting principles;

Consolidated EBITDA should not be considered as an alternative to operating income or net income as a measure of our operating results or our cash flows as a measure of liquidity;

Consolidated EBITDA may not be comparable to similarly titled measures reported at other companies;

Consolidated EBITDA is presented because management understands consolidated EBITDA is customarily used by investors as a criterion in evaluating companies; and

Consolidated EBITDA is a significant measurement to the lenders under our credit facility and its trends depict our ability to repay our indebtedness and fund our ongoing operations.

Our credit facility defines consolidated EBITDA as consolidated net income for the applicable period plus, without duplication and to the extent deducted from revenues in determining consolidated net income for that period, the sum of (a) the aggregate amount of consolidated cash interest expense for the period, (b) the aggregate amount of letter of credit fees paid during the period, (c) the aggregate amount of income tax expense for the period, (d) all amounts attributable to depreciation and amortization for the period, (e) all extraordinary and



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non-recurring charges during the period (provided that the amount of charges added to consolidated net income pursuant to this clause (e) that are incurred in connection with any transfer of manufacturing operations shall not exceed \$10 million during any fiscal year of Endo or \$20 million in the aggregate) and (f) all other non-cash charges during the period; and minus, without

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duplication and to the extent added to revenues in determining consolidated net income for such period, the sum of (i) all extraordinary gains during the period and (ii) all other non-cash gains during such period, all as determined on a consolidated basis with respect to us and our subsidiaries in accordance with generally accepted accounting principles. The reconciliation of operating income (loss) (as determined by generally accepted accounting principles) to consolidated EBITDA (as defined in our credit facility) is as follows:

|   | Year Ended December 31, |           |              |             |            |
|---|-------------------------|-----------|--------------|-------------|------------|
|   | 1998                    | 1999      | 2000         | 2001        | 2002       |
|   | (in thousands)          |           |              |             |            |
| Operating income (loss)                             | \$ 14,833               | \$ 19,680 | \$ (147,902) | \$ (27,898) | \$ 65,285  |
| Plus: depreciation and amortization                 | 7,373                   | 8,309     | 27,624       | 49,234      | 3,142      |
| Plus: non-cash manufacturing charges                | 14,228                  | 19,135    | 18,683       | 20,934      | 22,213     |
| Plus: compensation related to stock options         |                         |           | 15,300       | 37,253      | 34,659     |
| Plus: purchased in-process research and development |                         |           | 133,200      |             | 20,300     |
| Plus: manufacturing transfer fee                    |                         |           |              |             | 9,000      |
| Plus: manufacturing transfer costs                  |                         |           |              |             | 3,543      |
| Plus: purchase accounting charges                   | 4,292                   | 108       |              |             |            |
| Plus: non-cash separation benefits                  |                         |           | 20,782       |             |            |
| Consolidated EBITDA                                 | \$ 40,726               | \$ 47,232 | \$ 67,687    | \$ 79,523   | \$ 158,142 |

Items excluded from consolidated EBITDA are significant components in understanding and assessing our financial performance. Specifically:

Non-cash manufacturing charges reflect the present value of non-interest bearing promissory notes that were issued annually to DuPont Pharmaceuticals Company (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. These amounts have been excluded from consolidated EBITDA.

Compensation related to stock options is the non-cash charge resulting from the vesting of stock options pursuant to the Endo Pharma LLC stock option plans. Stock options granted pursuant to the Endo Pharma LLC stock option plans vest if our common stock reaches certain defined thresholds. These options are exercisable for shares currently held by Endo Pharma LLC, and their exercise will not dilute the ownership of other holders of our common stock. See Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies; Compensation Related to Stock Options.

Purchased in-process research and development represents the estimated fair value of products in development of companies we acquired. See Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations.

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 Item 1. Business Service Agreements; Third Party Manufacturing/ Supply Agreements; Bristol-Myers Squibb Pharma Company (f/k/a/ DuPont Pharmaceuticals).

Manufacturing transfer costs represent the costs incurred to transfer certain Endo products from Bristol-Myers to alternative manufacturers. Endo anticipates incurring these manufacturing transfer costs during 2002 and 2003.

Purchase accounting charges are related to the allocation of purchase price to the finished goods inventory that we acquired at the date of the acquisition of our business on August 26, 1997. These charges are non-cash and deemed to be non-recurring.

Non-cash separation benefits is the non-cash charge resulting from the acceleration of vesting of stock options held by two former executives pursuant to two separation and release agreements entered into by us in 2000.

**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 76%, 67% and 63% of net sales for the years ended December 31, 2000, 2001 and 2002. 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. On November 19, 1999, we formed Endo Inc. as a wholly owned subsidiary to effect the acquisition of Algos Pharmaceutical Corporation. On December 31, 2001, Endo Inc. was merged with and into Endo Pharmaceuticals Inc. The stock of Endo Pharmaceuticals Inc. is our only asset and we have no other operations or business.

On July 17, 2000, we completed our merger with Algos and effected a recapitalization of the Company. In the merger, we issued to the former Algos stockholders, in the aggregate, 17.8 million shares of our common stock and 17.8 million warrants to purchase in the aggregate up to 20.6 million additional shares of our common stock in certain circumstances as more fully described under footnote 14 to the consolidated financial statements located at the back of this Report. As we have previously disclosed, these warrants, known as the Class A Transferable Warrants (Nasdaq: ENDPW) and the Class B Non-Transferable Warrants, will expire on March 31, 2003 and have no economic value. Accordingly, we will de-list the Class A Transferable Warrants upon their expiration.

In the Algos merger, we also issued to our pre-merger stockholders, in the aggregate, 71.3 million warrants to purchase in the aggregate up to 29.7 million additional shares of common stock in certain other circumstances as more fully described under footnote 14 to the consolidated financial statements located at the back of this Report. On January 8, 2003 we announced that the outstanding warrants that were issued to our pre-merger stockholders have become exercisable. Each of these outstanding 71.3 million warrants is exercisable into 0.416667 shares of our common stock. These warrants are exercisable at an exercise price of \$0.01 per share into a maximum of 29.7 million shares of Common Stock on account of MorphiDex® not having been approved by the FDA for any pain indication prior to December 31, 2002.

The Algos merger has been accounted for using the purchase method of accounting. The assets acquired and liabilities assumed of Algos have been recorded at their fair values based on an independent appraisal.

The assets acquired and liabilities assumed, results of operations and cash flows of Algos have been included in our financial statements and Management's Discussion and Analysis of Financial Condition and Results of Operations prospectively for reporting periods beginning July 17, 2000.

The Algos merger included various on-going projects to research and develop innovative new products for pain management. As a result, the allocation of the fair value of the assets acquired and liabilities assumed includes an allocation to purchased in-process research and development, or IPRD, of \$133.2 million, which was immediately 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 products (significant net cash inflows from Morphidex® were projected in 2003); 3) discount these cash flows based on a risk-adjusted discount rates ranging from 25% to 33% (weighted average discount rate of 27%); and 4) apply the estimated percentage of completion to the discounted cash flow for each individual project ranging from 4% to 81%. The discount rate was determined after considering various uncertainties at the time of the merger, primarily the stage of project completion.

On July 26, 2002, our wholly owned subsidiary, Endo Pharmaceuticals Inc., acquired BML Pharmaceuticals, Inc. ( BML ), a privately held company, for an up-front payment of \$14 million. In addition, upon FDA approval of BML's lead pipeline product, an oral rinse (0.1% triclosan) for oral mucositis, Endo Pharmaceuticals Inc. will pay 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 will operate as a wholly owned subsidiary of Endo Pharmaceuticals Inc. 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 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 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. 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.

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. If this project is not successfully developed, our results of operations and financial position in a future period could be negatively impacted.

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 and expect to continue to incur 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 relating to the shifting of existing production to Novartis. During 2002, we incurred approximately \$3.5 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 Report. 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 provisions for chargebacks is the most significant and complex estimate used in the recognition of our revenue. In brief, 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 continually monitor our assumptions with respect to sales deductions and modify them if 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 seventeen 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.

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### *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, 2002, goodwill and other intangibles comprised approximately 42% of our total assets and 62% 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 (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, 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):

|                               | <b>December 31,<br/>2002</b> | <b>December 31,<br/>2001</b> |
|-------------------------------|------------------------------|------------------------------|
| Goodwill                      | \$ 181,079                   | \$ 182,318                   |
| Amortizable Intangibles:      |                              |                              |
| Licenses                      | \$ 36,000                    | \$ 11,000                    |
| Patents                       | 3,200                        | 3,200                        |
|                               | 39,200                       | 14,200                       |
| Less accumulated amortization | (2,445)                      | (1,705)                      |
| Other Intangibles, net        | \$ 36,755                    | \$ 12,495                    |

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:

|  | <b>Year Ended December 31,</b>                       |             |              |
|--|--|-------------|--------------|
|  | <b>2002</b>  | <b>2001</b> | <b>2000</b>  |
|  | (in thousands, except per share data)<br>(Unaudited) |             |              |
| Reported net income (loss)                   | \$ 30,813  | \$ (36,542) | \$ (156,840) |
| Add back: Goodwill amortization              | 40,431   | 22,494      | 2,711        |
| Add back: Amortization of workforce-in-place | 5,948  | (6,634)     | 46,603       |
| Less: Pro forma income (tax) benefit         | (6,634)  | 46,603      |              |

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|                            |                 |                 |                    |
|----------------------------|-----------------|-----------------|--------------------|
| Adjusted net income (loss) | <u>\$30,813</u> | <u>\$ 3,203</u> | <u>\$ (85,032)</u> |
|----------------------------|-----------------|-----------------|--------------------|

|  | Year Ended December 31, |          |           |
|--|-------------------------|----------|-----------|
|  | 2002                    | 2001     | 2000      |
| (in thousands, except per share data)<br>(Unaudited) |                         |          |           |
| <b>Basic earnings (loss) per share:</b>              |                         |          |           |
| Reported net income (loss)                           | \$.30                   | \$ (.40) | \$ (1.97) |
| Add back: Goodwill amortization                      |                         | .44      | .28       |
| Add back: Amortization of workforce-in-place         |                         | .07      | .03       |
| Less: Pro forma income (tax) benefit                 |                         | (.07)    | .59       |
|  | —                       | —        | —         |
| Adjusted net income (loss)                           | \$.30                   | \$ .04   | \$ (1.07) |
|  | —                       | —        | —         |
| <b>Diluted earnings (loss) per share:</b>            |                         |          |           |
| Reported net (loss) income                           | \$.30                   | \$ (.40) | \$ (1.97) |
| Add back: Goodwill amortization                      |                         | .44      | .28       |
| Add back: Amortization of workforce-in-place         |                         | .07      | .03       |
| Less: Pro forma income (tax) benefit                 |                         | (.07)    | .59       |
|  | —                       | —        | —         |
| Adjusted net income (loss)                           | \$.30                   | \$ .04   | \$ (1.07) |
|  | —                       | —        | —         |

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2002 is as follows (in thousands):

|      |         |
|------|---------|
| 2003 | \$2,212 |
| 2004 | 2,212   |
| 2005 | 2,212   |
| 2006 | 2,212   |
| 2007 | 2,212   |

#### *Compensation Related to Stock Options Endo Pharma LLC Stock Option Plans*

In our 2000 fiscal year we incurred a non-cash charge of \$15.3 million, in our 2001 fiscal year we recorded a non-cash charge of \$37.3 million and in our 2002 fiscal year we recorded a non-cash charge of \$34.7 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). Under the Endo Pharma LLC 1997 Stock Option Plans, tranches of options vest when we attain certain stock price targets. As each tranche vests, we incur a non-cash charge representing the difference between the market price of the shares underlying the options and the exercise price of such options. We may in the future incur one additional charge in relation to the Endo Pharma LLC options as a result of the attainment of a certain common stock price target. If attained, this charge will be substantial. However, 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. Further, the shares of common stock that individuals receive upon exercise of stock options granted pursuant to the Endo Pharma LLC 1997 Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

In connection with the Algos merger and our related recapitalization on July 17, 2000, 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) were established. The Endo Pharma LLC 2000 Supplemental Stock Option Plans reserve an aggregate of 10.7 million shares of our common stock that is held by Endo Pharma LLC for issuance. The Endo Pharma LLC 2000 Supplemental Stock Option Plans were not effective until January 1, 2003. The



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Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective on January 1, 2003, 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 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. 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.

Finally, the remaining unvested class of performance-based stock options (Class C4) under the Endo Pharma LLC Stock Option Plans will vest upon (i) our common stock exceeding an average closing price threshold of \$17.29 for ninety consecutive trading days, (ii) the closing price of our common stock on the last trading day of such ninety consecutive trading day period being greater than or equal to \$14.70 and (iii) the holder being a director, officer or employee of the Company or any of our subsidiaries on such date. The vesting of the approximately 5.0 million outstanding Class C4 stock options will result in an additional compensation charge to the Company. If this vesting occurs, this charge will be substantial. As stated above, these options are exercisable solely into shares of Company 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 ownership of our other public stockholders. Further, the shares of common stock that individuals receive upon exercise of stock options granted pursuant to the Endo Pharma LLC 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 generally accepted accounting principles, 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*

The following table presents our unaudited net sales by product category for the years ended December 31, 2000, 2001 and 2002.

|                 | Year Ended December 31,   |            |            |
|-----------------|---------------------------|------------|------------|
|                 | 2000                      | 2001       | 2002       |
|                 | (in thousands, unaudited) |            |            |
| Percocet®       | \$ 92,366                 | \$ 100,967 | \$ 144,623 |
| Lidoderm®       | 22,539                    | 40,878     | 83,218     |
| Other brands    | 35,375                    | 25,824     | 22,046     |
|                 | 150,280                   | 167,669    | 249,887    |
| Total brands    | 150,280                   | 167,669    | 249,887    |
| Total generics  | 47,149                    | 84,310     | 149,086    |
|                 | 197,429                   | 251,979    | 398,973    |
| Total net sales | \$ 197,429                | \$ 251,979 | \$ 398,973 |

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The following table presents our unaudited net sales as a percentage of total net sales for select products for the years ended December 31, 2000, 2001 and 2002.

|                | Year Ended December 31, |      |      |
|----------------|-------------------------|------|------|
|                | 2000                    | 2001 | 2002 |
|                | (unaudited)             |      |      |
| Percocet®      | 47%                     | 40%  | 36%  |
| Lidoderm®      | 11                      | 16   | 21   |
| Other brands   | 18                      | 11   | 6    |
|                | 76                      | 67   | 63   |
| Total brands   | 76                      | 67   | 63   |
| Total generics | 24                      | 33   | 37   |
|                | 100%                    | 100% | 100% |
| Total          | 100%                    | 100% | 100% |

### *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 which do not currently have generic equivalents. Prescriptions for these new strengths of Percocet® have continued to grow based on our sales and promotional efforts. 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. These products continue to gain market share. 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 existing fixed cost nature of our manufacturing relationship with Bristol-Myers Squibb Pharma Company (formerly DuPont Pharmaceuticals), currently our most significant contract manufacturing relationship. 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 Item 3. Legal Proceedings. If we achieve our forecast for revenue and product mix, we expect the increase in gross profits and gross profit margins to continue.

*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. During 2003, we anticipate increasing our investment in sales, promotional efforts and support of our business over 2002 levels. This anticipated increase is primarily attributable to increased spending on Lidoderm® and Percocet® as well as preparing for the anticipated

launches in 2004 of extended-release and immediate-release oxymorphone, DepoMorphine™ and our oral mucositis product.

*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 2003, we anticipate decreasing our research and development spending compared to 2002 to reflect the overall stage of development of our development portfolio. 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®. During 2003, we will focus our development efforts on our oral rinse (0.1% triclosan) for oral mucositis product which is currently in Phase III clinical trials as well as other projects focused in the area of pain management. In addition, we anticipate the restart by our partner DURECT Corporation of the clinical trials of CHRONOGESIC™ in the second half of 2003. If the clinical trials are restarted during 2003, we will fund 50% of the ongoing development costs.

*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. We expect depreciation and amortization expense to increase in 2003 as a result of the marketing rights acquired from SkyePharma in December 2002.

*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 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 company common stock, 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. The remaining unvested class of performance-based stock options (Class C4) under the Endo Pharma LLC Stock Option Plans vest upon (i) our common stock exceeding an average closing price threshold of \$17.29 for ninety consecutive trading days, (ii) the closing price of our common stock on the last trading day of such ninety consecutive trading day period being greater than or equal to \$14.70 and (iii) the holder being a director, officer or employee of the Company or any of our subsidiaries on such date. The vesting of the approximately 5.0 million outstanding Class C4 stock options will result in an additional compensation charge to the Company. If this vesting occurs, this charge will be substantial. As stated above, these options are exercisable solely into shares of Company 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 ownership of our other public stockholders. Further, the shares of common stock that individuals receive upon exercise of stock

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options granted pursuant to the Endo Pharma LLC 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.

*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 acquired 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 Item 1. 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 (k/ n/ 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.

### *Year Ended December 31, 2001 Compared to Year Ended December 31, 2000*

*Net Sales.* Net sales for the year ended December 31, 2001 increased by 28% to \$252.0 million from \$197.4 million in the comparable 2000 period. This increase in net sales was primarily due to the increase in net sales of Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, and certain generic products. 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 82% to \$40.9 million from \$22.5 million in the comparable 2000 period. Percocet® net sales increased 9% to \$101.0 million from \$92.4 million in the comparable 2000 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 which do not currently have generic equivalents. Generic products increased 79% to \$84.3 million from \$47.1 million in the comparable 2000 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

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launched the 200mg strength of our generic morphine sulfate extended release tablets. These products continue to gain market share. 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, 2001 increased by 32% to \$177.1 million from \$134.4 million in the comparable 2000 period. Gross profit margins increased to 70% from 68% in the comparable 2000 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 existing fixed cost nature of our manufacturing relationship with Bristol-Myers Squibb Pharma Company (formerly DuPont Pharmaceuticals), currently our most significant contract manufacturing relationship. If we achieve our forecast for revenue and product mix, we expect the increase in gross profits and gross profit margins to continue.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses for the year ended December 31, 2001 increased by 41% to \$79.5 million from \$56.5 million in the comparable 2000 period. This increase was due to a \$11.0 million increase in sales and promotional efforts in 2001 over the comparable 2000 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, 2001 increased by 50% to \$39.0 million from \$26.0 million in the comparable 2000 period. This increase was due to our increased spending on new products under development that are focused in pain management including the products under development that had been part of the former Algos pipeline. The results of operations of Algos have been included in our financial statements prospectively for reporting periods beginning July 17, 2000.

*Depreciation and Amortization.* Depreciation and amortization for the year ended December 31, 2001 increased to \$49.2 million from \$27.6 million in the comparable 2000 period. This increase was substantially due to the increase in amortization of goodwill and other intangibles resulting from the intangible assets acquired as a result of the Algos merger. The results of operations of Algos have been included in our financial statements prospectively for reporting periods beginning July 17, 2000.

*Compensation Related to Stock Options.* For the year ended December 31, 2001, compensation related to stock options increased to \$37.3 million from \$15.3 million in the comparable 2000 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 1997 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 representing the difference between the market price of the shares of common stock underlying the options and the exercise price of such options. We may in the future incur an additional compensation charge on account of the Endo Pharma LLC Stock Option Plans as a result of the attainment of this common stock price target. These charges may be substantial. These options are exercisable solely into shares of Company 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 Company common stock and will not dilute the ownership of our other public stockholders. Further, the shares of common stock that individuals receive upon exercise of stock options granted pursuant to the Endo Pharma LLC 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.

*Purchased In-Process Research and Development.* Purchased in-process research and development for the year ended December 31, 2000 of \$133.2 million resulted from the estimated fair value of the products under development that we acquired in the merger with Algos.

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*Merger and Other Related Costs.* Merger and other related costs for the year ended December 31, 2000 of \$1.6 million resulted from fees incurred as a result of our merger with Algos that were not considered direct costs of the acquisition.

*Separation Benefits.* Separation benefits of \$22.0 million for the year ended December 31, 2000 resulted from a \$20.8 million charge related to the acceleration of vesting of stock options held by two former executives and a \$1.2 million charge from compensation and other benefits pursuant to two separation and release agreements we entered into. The stock compensation charge reflects the estimated difference in the fair value and the exercise price of such stock options on the effective date of the separation and release agreements.

*Interest Expense, Net.* Interest expense, net for the year ended December 31, 2001 decreased by 12% to \$13.3 million from \$15.1 million in the comparable 2000 period. The decrease was substantially due to a decrease in interest expense of \$2.0 million due to a decrease in long-term debt outstanding and a decrease in interest expense of \$1.6 million due to a decrease in interest rates. These decreases are partially offset by a \$2.3 million charge for the extinguishment of our term loans on October 29, 2001.

*Income Tax (Benefit).* We recorded an income tax benefit for the year ended December 31, 2001 of \$4.6 million compared to an income tax benefit for the year ended December 31, 2000 of \$6.2 million. 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.

### Liquidity and Capital Resources

Our principal source of liquidity is cash generated from operations. We also have the ability to borrow up to \$75.0 million on a revolving basis for certain purposes as described above under Item 1. Business Description of Credit Facility. 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 \$29.1 million to \$109.6 million for the year ended December 31, 2002 from \$80.5 million for the year ended December 31, 2001. This increase was due to the cash provided by the increase in net sales and gross profit for the year ended December 31, 2002 compared to the year ended December 31, 2001 offset by an increase in selling, general and administrative expenses and research and development expenses for the year ended December 31, 2002 as compared to the year ended December 31, 2001.

*Net Cash Used in Investing Activities.* Net cash used in investing activities was \$22.3 million for the year ended December 31, 2002 compared to \$6.5 million for the year ended December 31, 2001. The increase is substantially due to 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 decreased in 2002 to \$3.1 million from \$6.5 million. This decrease in capital expenditures was due to the purchase in 2001 of leasehold improvements and other furniture and fixtures related to our new principal executive offices, the lease of which commenced in the third quarter of 2001 and the implementation of an electronic document management system during 2001.

*Net Cash Utilized in Financing Activities.* Net cash utilized in financing activities increased by \$88.0 million to \$125.8 million for the year ended December 31, 2002 from \$37.8 million for the year ended December 31, 2001. During the 2002, 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. During the year ended December 31, 2001, we repaid in full the term loans under our old senior secured credit facility. Additionally, in October of

2001, we completed a public offering of 12.9 million primary shares of common stock that provided net proceeds of \$96.2 million.

*Credit Facility.* In December 2001, we amended and restated our senior secured credit facility with a number of lenders, including affiliates of certain of the underwriters of our October 2001 public offering. 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, events of default and other provisions customarily found in similar agreements. See Item 1. Business Description of Credit Facility.

*Tax Sharing Agreement.* On July 14, 2000, Endo Pharma LLC was formed 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 the Company's merger with Algos (see note 14 to the accompanying consolidated financial statements). Upon the exercise of these stock options, only currently outstanding shares of Company common stock held by Endo Pharma LLC will be issued. Because Endo Pharma LLC, and not the Company, will provide the shares issued upon the exercise of these options, the Company has entered into a tax sharing agreement with Endo Pharma LLC under which the Company will pay to Endo Pharma LLC the amount of the tax benefits it receives as a result of the exercise of these stock options into shares of common stock held by Endo Pharma LLC for the years in which these tax benefits arise. As of December 31, 2002, approximately 1.1 million of these stock options have been exercised by former employees into shares of Company common stock held by Endo Pharma LLC. These stock option exercises may permit the Company to deduct, for income tax purposes, compensation equal to the difference between the market price of the Company common stock and the exercise price paid upon exercise of these options (approximately \$8 million), which may result in a tax benefit amount of approximately \$3 million. Under the tax sharing agreement, we are required to pay this \$3 million to Endo Pharma LLC. If all 36.3 million of the stock options under the Endo Pharma LLC Stock Options Plans were vested and exercised when the market price of our common stock was \$10.00 per share, then, using a weighted average exercise price of \$2.61 per share, the Company may be permitted to deduct, for income tax purposes, compensation of approximately \$268 million, which may result in a tax benefit amount of approximately \$100 million. If all 36.3 million of the stock options under the Endo Pharma LLC Stock Options Plans were exercised and vested when the market price of our common stock was \$15.00 per share, then, using a weighted average exercise price of \$2.61 per share, the Company may be permitted to deduct for income tax purposes compensation of approximately \$450 million, which may result in a tax benefit amount of approximately \$168 million. Under the terms of the tax sharing agreement discussed above, the Company must pay any such tax benefit amounts to Endo Pharma LLC; however, these payments need only be made to Endo Pharma LLC upon the occurrence of a liquidity event, which is generally defined as (a) a sale of greater than 20% on a fully diluted basis of the common equity of the Company (either through a primary offering by the Company or a secondary sale by Endo Pharma LLC or a combination of both), (b) a change in control of the Company or (c) a sale of all or substantially all of the assets of the Company. In accordance with the tax sharing agreement, no payments have been made or accrued to date.

*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. 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.

*Ex-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.

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*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, 2002 (in thousands):

| Contractual Obligations     | Payment Due by Period |          |          |          |          |          |            |
|-----------------------------|-----------------------|----------|----------|----------|----------|----------|------------|
|                             | Total                 | 2003     | 2004     | 2005     | 2006     | 2007     | Thereafter |
| Operating Lease Obligations | \$ 10,196             | \$ 1,388 | \$ 1,203 | \$ 1,199 | \$ 1,240 | \$ 1,127 | \$ 4,039   |
| Capital Lease Obligations   | 1,518                 | 584      | 522      | 398      | 14       | —        | —          |
| Total                       | \$ 11,714             | \$ 1,972 | \$ 1,725 | \$ 1,597 | \$ 1,254 | \$ 1,127 | \$ 4,039   |

*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.

In addition, we agreed to certain contingent payments in certain of our acquisitions and licenses entered into during 2002. Specifically:

### *BML Pharmaceuticals*

Upon FDA approval of our development oral rinse product (0.1% triclosan) for oral mucositis, we will pay the former shareholders of BML a \$32 million payment in addition to an earn-out based on a percentage of net sales of this and certain other products that we acquired when we purchased BML on July 26, 2002.

### *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. Once the clinical trials of CHRONOGESIC™ have restarted or beginning on June 30, 2004 (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 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 Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT \$10.0 million. Endo 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 Endo. Milestone payments made by Endo may total up to \$95.0 million which includes total milestones of \$10.0 million for DepoMorphine™ through FDA approval. 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 will 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 \$56.9 million at December 31, 2002. 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.

#### **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 is 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 Critical Accounting Policies; Goodwill and Other Intangibles.

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 rescinds SFAS No. 4 and SFAS No. 64, which relate to the extinguishment of debt, rescinds No. 44 relating to the accounting for intangible assets of motor carriers, and 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. We believe that the adoption of SFAS No. 145 will not have 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. We believe that the adoption of SFAS No. 146 will 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 are 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, 2002, 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.

To the extent that our financial instruments expose us to interest rate risk, they are presented in the table below. The table presents principal cash flows and related interest rates by year of maturity for our term loans, notes payable and interest rate cap as of December 31, 2001. You should read Notes 8 and 9 to our consolidated financial statements for the year ended December 31, 2002, together with the table below. As of December 31, 2002, we have no assets or liabilities that have significant interest rate sensitivity

At December 31, 2002, we had publicly traded equity securities comprised of DURECT Corporation common stock at fair value totaling \$3.1 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, 2002, an assumed 25%, 40% and 50% adverse change in the market prices of this security would result in a corresponding decline in total fair value of approximately \$.8 million, \$1.2 million and \$1.6 million, respectively.

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

## Schedule of Interest Rate Sensitive Assets and Liabilities at December 31, 2001

(dollars in thousands)

|   | Year of Maturity  |      |      |      |            | Total due<br>at Maturity | Fair Value<br>At 12/31/01 |
|---|-------------------|------|------|------|------------|--------------------------|---------------------------|
|   | 2002              | 2003 | 2004 | 2005 | Thereafter |                          |                           |
| <b>Interest rate sensitive liabilities:</b> |                   |      |      |      |            |                          |                           |
| <b>Fixed-rate borrowings</b>                |                   |      |      |      |            |                          |                           |
| Acquisition Note Payable                    | \$ 3,889          |      |      |      |            | \$ 3,889                 | \$ 3,645                  |
| Average interest rate                       | 9.75%             |      |      |      |            | 9.75%                    |                           |
| Other Notes Payable                         | 92,000            |      |      |      |            | 92,000                   | 87,614                    |
| Average interest rate                       | 7.35%             |      |      |      |            | 7.35%                    |                           |
|   | <u>          </u> |      |      |      |            | <u>          </u>        | <u>          </u>         |
| Total interest rate sensitive Liabilities   | \$95,889          |      |      |      |            | \$95,889                 | \$91,259                  |
|   | <u>          </u> |      |      |      |            | <u>          </u>        | <u>          </u>         |
| Weighted average interest rate              | 7.45%             |      |      |      |            | 7.45%                    |                           |
|   | <u>          </u> |      |      |      |            | <u>          </u>        |                           |
| <b>Interest rate instruments:</b>           |                   |      |      |      |            |                          |                           |
| Interest rate cap                           | \$ 0              |      |      |      |            |                          | \$ 0                      |
|   | <u>          </u> |      |      |      |            |                          | <u>          </u>         |
| Cap rate                                    | 8.00%             |      |      |      |            |                          |                           |
|   | <u>          </u> |      |      |      |            |                          |                           |

**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 Form 10-K Annual Report.

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

Not applicable.

**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 2002 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 2002 Information Statement.

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

The information required under this Item is incorporated herein by reference from our 2002 Information Statement.

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

The information required under this Item is incorporated herein by reference from our 2002 Information Statement.

**Item 14. Controls and Procedures****Evaluation of Disclosure Controls and Procedures**

Within 90 days prior to the filing of this Report, an evaluation was carried out by our Chief Executive Officer and Chief Financial Officer, with the assistance of other members of management, of the effectiveness of our disclosure controls and procedures (as defined in Rule 15d-14(c) under the Securities Exchange Act of 1934). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the date of such evaluation, the disclosure controls and procedures were effective in ensuring that all material information relating to the Company required to be included in the Company's reports filed or submitted under the Exchange Act was gathered, analyzed and reported or otherwise made known to them in a timely fashion. There have been no significant changes in our internal controls, or in other factors that could significantly affect these controls, subsequent to the date the evaluation was completed, including any corrective actions with regard to significant deficiencies and material weaknesses.

**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<br>Beginning of<br>Period | Additions | Deductions(1) | Other | Balance<br>at end<br>of period |
|---|--------------------------------------|-----------|---------------|-------|--------------------------------|
| <b>Allowance For Doubtful Accounts:</b> |                                      |           |               |       |                                |
| Year Ended December 31, 2000.           | \$444                                | \$ 1,128  | \$(1,057)     | —     | \$515                          |
| Year Ended December 31, 2001.           | \$515                                | \$ 300    | \$ (102)      | —     | \$713                          |
| Year Ended December 31, 2002.           | \$713                                | \$ 779    | \$ (657)      | —     | \$835                          |

(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.

We filed the following Current Reports on Form 8-K in the quarter ended December 31, 2002:

| Dates             | Items       |
|-------------------|-------------|
| October 24, 2002  | 7 and 9     |
| October 28, 2002  | 5, 7 and 9  |
| November 13, 2002 | 5, 7, and 9 |

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|                   |         |
|-------------------|---------|
| November 14, 2002 | 7 and 9 |
| December 20, 2002 | 5 and 7 |
| December 30, 2002 | 7 and 9 |

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

**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 27, 2003

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             | Chairman, Chief Executive Officer, President and Director (Principal Executive Officer)               | March 27, 2003 |
| Carol A. Ammon                 |   |                |
| /s/ JEFFREY R. BLACK           | Senior Vice President, Chief Financial Officer & Treasurer (Principal Financial & Accounting Officer) | March 27, 2003 |
| Jeffrey R. Black               |   |                |
| *                              | Director  | March 27, 2003 |
| Brian T. Clingen               |   |                |
| *                              | Director  | March 27, 2003 |
| Michael B. Goldberg            |   |                |
| *                              | Director  | March 27, 2003 |
| Michael Hyatt                  |   |                |
| *                              | Director  | March 27, 2003 |
| Roger H. Kimmel                |   |                |
| *                              | Director  | March 27, 2003 |
| Frank J. Loverro               |   |                |
| *                              | Director  | March 27, 2003 |
| Clive A. Meanwell, M.D., Ph.D. |   |                |
| *                              | Director  |                |

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Michael W. Mitchell

March 27,  
2003



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| Signature  | Title  | Date              |
|--|--|-------------------|
| *<br>_____<br>Joseph T. O. Donnell, Jr.                          | Director   | March 27,<br>2003 |
| *<br>_____<br>David I. Wahrhaftig                                | Director   | March 27,<br>2003 |
| *By:     /s/ CAROLINE B. MANOGUE<br>_____<br>Caroline B. Manogue | Attorney-in-fact, pursuant<br>to a Power of Attorney filed with<br>this Report as Exhibit 24 | March 27,<br>2003 |

**CERTIFICATIONS**

I, Carol A. Ammon, certify that:

1. I have reviewed this annual report on Form 10-K of Endo Pharmaceuticals Holdings Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date); and
  - c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ CAROL A. AMMON

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Carol A. Ammon  
*Chairman, Chief Executive Officer & President*

Date: March 27, 2003

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I, Jeffrey R. Black, certify that:

1. I have reviewed this annual report on Form 10-K of Endo Pharmaceuticals Holdings Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date); and
  - c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ JEFFREY R. BLACK

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Jeffrey R. Black  
*Senior Vice President, Chief Financial Officer & Treasurer*

Date: March 27, 2003

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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, 2002 and 2001, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2002. 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, 2002 and 2001, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2002 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  
February 13, 2003  
(March 18, 2003 as to Note 12)

## ENDO PHARMACEUTICALS HOLDINGS INC.

## CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2002 AND 2001

(In thousands, except share data)

|  | 2002              | 2001              |
|--|-------------------|-------------------|
| <b>ASSETS</b>  |                   |                   |
| <b>CURRENT ASSETS:</b>   |                   |                   |
| Cash and cash equivalents  | \$ 56,902         | \$ 95,357         |
| Accounts receivable, net of allowance of \$835 and \$713 at December 31, 2002 and 2001, respectively   | 119,496           | 85,329            |
| Inventories  | 35,516            | 27,766            |
| Prepaid expenses   | 4,354             | 5,527             |
| Deferred income taxes  | 41,219            | 26,946            |
|  | <hr/>             | <hr/>             |
| Total current assets   | 257,487           | 240,925           |
|  | <hr/>             | <hr/>             |
| PROPERTY AND EQUIPMENT, Net  | 11,810            | 9,883             |
| GOODWILL   | 181,079           | 182,318           |
| OTHER INTANGIBLES, Net   | 36,755            | 12,495            |
| DEFERRED INCOME TAXES  | 21,184            | 23,420            |
| RESTRICTED CASH  |                   | 150               |
| OTHER ASSETS   | 4,657             | 1,804             |
|  | <hr/>             | <hr/>             |
| <b>TOTAL ASSETS</b>  | <b>\$ 512,972</b> | <b>\$ 470,995</b> |
|  | <hr/>             | <hr/>             |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>   |                   |                   |
| <b>CURRENT LIABILITIES:</b>  |                   |                   |
| Accounts payable   | \$ 75,443         | \$ 30,705         |
| Accrued expenses   | 68,627            | 50,176            |
| Income taxes payable   | 8,359             | 3,526             |
| Current portion of long-term debt  |                   | 91,259            |
|  | <hr/>             | <hr/>             |
| Total current liabilities  | 152,429           | 175,666           |
|  | <hr/>             | <hr/>             |
| OTHER LIABILITIES  | 7,851             | 207               |
| <b>COMMITMENTS AND CONTINGENCIES</b>   |                   |                   |
| <b>STOCKHOLDERS EQUITY:</b>  |                   |                   |
| Preferred Stock, \$.01 par value; 40,000,000 shares authorized; none issued  |                   |                   |
| Common Stock, \$.01 par value; 175,000,000 shares authorized; 102,064,450 and 102,063,950 shares issued and outstanding in 2002 and 2001, respectively | 1,021             | 1,021             |
| Additional paid-in capital   | 547,249           | 519,316           |
| Accumulated deficit  | (194,402)         | (225,215)         |
| Accumulated other comprehensive loss   | (1,176)           |                   |
|  | <hr/>             | <hr/>             |
| Total Stockholders Equity  | 352,692           | 295,122           |
|  | <hr/>             | <hr/>             |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS EQUITY</b>   | <b>\$ 512,972</b> | <b>\$ 470,995</b> |
|  | <hr/>             | <hr/>             |

See notes to consolidated financial statements.

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## ENDO PHARMACEUTICALS HOLDINGS INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2002, 2001 AND 2000

(In thousands, except per share data)

|   | 2002       | 2001        | 2000         |
|---|------------|-------------|--------------|
| NET SALES   | \$ 398,973 | \$ 251,979  | \$ 197,429   |
| COST OF SALES   | 98,857     | 74,891      | 63,041       |
| GROSS PROFIT  | 300,116    | 177,088     | 134,388      |
| COSTS AND EXPENSES:   |            |             |              |
| Selling, general and administrative   | 110,907    | 79,505      | 56,537       |
| Research and development  | 56,823     | 38,994      | 26,012       |
| Depreciation and amortization   | 3,142      | 49,234      | 27,624       |
| Compensation related to stock options (primary selling, general and administrative)               | 34,659     | 37,253      | 15,300       |
| Purchased in-process research and development   | 20,300     |             | 133,200      |
| Manufacturing transfer fee  | 9,000      |             |              |
| Merger and other related costs  |            |             | 1,583        |
| Separation benefits   |            |             | 22,034       |
| OPERATING INCOME (LOSS)   | 65,285     | (27,898)    | (147,902)    |
| INTEREST EXPENSE, Net of interest income of \$1,155, \$2,830 and \$2,700, respectively            | 4,391      | 13,290      | 15,119       |
| INCOME (LOSS) BEFORE INCOME TAX (BENEFIT)   | 60,894     | (41,188)    | (163,021)    |
| INCOME TAX (BENEFIT)  | 30,081     | (4,646)     | (6,181)      |
| NET INCOME (LOSS)   | \$ 30,813  | \$ (36,542) | \$ (156,840) |
| NET INCOME (LOSS) PER SHARE:  |            |             |              |
| Basic   | \$ .30     | \$ (.40)    | \$ (1.97)    |
| Diluted   | \$ .30     | \$ (.40)    | \$ (1.97)    |
| NET INCOME (LOSS) Pro Forma to Exclude Amortization of Goodwill and Workforce-in-Place:           | \$ 30,813  | \$ 3,203    | \$ (85,032)  |
| NET INCOME (LOSS) PER SHARE Pro Forma to Exclude Amortization of Goodwill and Workforce-in-Place: |            |             |              |
| Basic   | \$ .30     | \$ .04      | \$ (1.07)    |
| Diluted   | \$ .30     | \$ .04      | \$ (1.07)    |
| WEIGHTED AVERAGE SHARES   |            |             |              |
| Basic   | 102,064    | 91,505      | 79,454       |
| Diluted   | 102,126    | 91,505      | 79,454       |

See notes to consolidated financial statements.



## ENDO PHARMACEUTICALS HOLDINGS INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

YEARS ENDED DECEMBER 31, 2002, 2001 AND 2000

(In thousands, except share data)

|  | Number<br>Of Shares | Common<br>Stock at<br>Par<br>Value | Additional<br>Paid-in<br>Capital | Accumulated<br>Deficit | Accumulated<br>Other<br>Comprehensive<br>Loss | Total<br>Stockholders<br>Equity | Comprehensive<br>Income (Loss) |
|--|---------------------|------------------------------------|----------------------------------|------------------------|---|---------------------------------|--------------------------------|
| BALANCE, DECEMBER 31,<br>1999                                | 71,323,644          | \$ 713                             | \$ 109,707                       | \$ (31,833)            |   | \$ 78,587                       |                                |
| Exercise of stock options                                    |                     |                                    | 7                                |                        |   | 7                               |                                |
| Compensation related to stock<br>options separation benefits |                     |                                    | 20,782                           |                        |   | 20,782                          |                                |
| Issuance of Common Stock                                     | 17,810,526          | 178                                | 240,159                          |                        |   | 240,337                         |                                |
| Compensation related to stock<br>options                     |                     |                                    | 15,300                           |                        |   | 15,300                          |                                |
| Net loss   |                     |                                    |                                  | (156,840)              |   | (156,840)                       | (156,840)                      |
| Comprehensive income   |                     |                                    |                                  |                        |   |                                 | \$ (156,840)                   |
| BALANCE, DECEMBER 31,<br>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<br>options                     |                     |                                    | 37,253                           |                        |   | 37,253                          |                                |
| Net loss   |                     |                                    |                                  | (36,542)               |   | (36,542)                        | (36,542)                       |
| Comprehensive income   |                     |                                    |                                  |                        |   |                                 | \$ 36,542                      |
| BALANCE, DECEMBER 31,<br>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<br>securities, net of tax       |                     |                                    |                                  |                        | \$(1,176)                                     | (1,176)                         | \$ (1,176)                     |
| Compensation related to stock<br>options                     |                     |                                    | 34,659                           |                        |   | 34,659                          |                                |
| Net income   |                     |                                    |                                  | 30,813                 |   | 30,813                          | 30,813                         |
| Comprehensive income   |                     |                                    |                                  |                        |   |                                 | \$ 29,637                      |
| BALANCE, DECEMBER 31,<br>2002                                | 102,064,450         | \$ 1,021                           | \$ 547,249                       | \$ (194,402)           | \$(1,176)                                     | \$ 352,692                      |                                |

See notes to consolidated financial statements.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2002, 2001 AND 2000

(In thousands)

|  | 2002             | 2001             | 2000             |
|--|------------------|------------------|------------------|
| <b>OPERATING ACTIVITIES:</b>   |                  |                  |                  |
| Net income (loss)  | \$ 30,813        | \$ (36,542)      | \$(156,840)      |
| Adjustments to reconcile net income (loss) to net cash provided by operating activities: |                  |                  |                  |
| Depreciation and amortization  | 3,142            | 49,234           | 27,624           |
| Purchased in-process research and development  | 20,300           |                  | 133,200          |
| Accretion of promissory notes  | 4,627            | 5,449            | 3,579            |
| Deferred income taxes  | (8,730)          | (4,701)          | (8,732)          |
| Amortization of deferred financing costs   | 390              | 3,603            | 1,234            |
| Non-cash portion of separation benefits  |                  |                  | 20,782           |
| Compensation related to stock options  | 34,659           | 37,253           | 15,300           |
| Changes in assets and liabilities which provided (used) cash:                            |                  |                  |                  |
| Accounts receivable  | (34,167)         | (7,017)          | (15,960)         |
| Inventories  | (7,750)          | 1,980            | (8,477)          |
| Other assets   | (24,668)         | (3,546)          | (238)            |
| Accounts payable   | 44,738           | 14,850           | (6,792)          |
| Accrued expenses   | 41,451           | 25,957           | 27,367           |
| Income taxes payable   | 4,833            | 977              | 2,549            |
| Other liabilities  |                  | (7,011)          | 473              |
| Net cash provided by operating activities  | <u>109,638</u>   | <u>80,486</u>    | <u>35,069</u>    |
| <b>INVESTING ACTIVITIES:</b>   |                  |                  |                  |
| Purchase of property and equipment   | (3,084)          | (6,546)          | (1,534)          |
| Purchase of DURECT common stock  | (5,000)          |                  |                  |
| Acquisition of BML Pharmaceuticals   | (14,190)         |                  |                  |
| Net cash acquired in the Algos merger  |                  |                  | 19,611           |
| Net cash provided by (used in) investing activities                                      | <u>(22,274)</u>  | <u>(6,546)</u>   | <u>18,077</u>    |
| <b>FINANCING ACTIVITIES:</b>   |                  |                  |                  |
| Issuance of Common Stock   |                  | 96,238           |                  |
| Capital Lease Obligations Repayments   | (204)            |                  |                  |
| Exercise of Endo Pharmaceuticals Holdings Inc. stock options                             | 4                |                  | 7                |
| Repurchase of Class A Transferable and Class B Non-Transferable Warrants                 | (6,730)          |                  |                  |
| Repayments of long-term debt   | (118,889)        | (134,017)        | (15,985)         |
| Net cash used in financing activities  | <u>(125,819)</u> | <u>(37,779)</u>  | <u>(15,978)</u>  |
| NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS                                     | (38,455)         | 36,161           | 37,168           |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD   | <u>95,357</u>    | <u>59,196</u>    | <u>22,028</u>    |
| CASH AND CASH EQUIVALENTS, END OF PERIOD   | <u>\$ 56,902</u> | <u>\$ 95,357</u> | <u>\$ 59,196</u> |

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SUPPLEMENTAL INFORMATION:

|                   |                   |                   |                   |
|-------------------|-------------------|-------------------|-------------------|
| Interest paid     | \$ 384            | \$ 7,065          | \$ 13,205         |
|                   | <u>          </u> | <u>          </u> | <u>          </u> |
| Income taxes paid | \$ 33,978         | \$ 3,031          | \$ 75             |
|                   | <u>          </u> | <u>          </u> | <u>          </u> |

SCHEDULE OF NON-CASH INVESTING AND FINANCING  
ACTIVITIES:

|  |                   |                   |                   |
|--|-------------------|-------------------|-------------------|
| Promissory notes issued under Manufacturing and Supply Agreement   | \$ 23,000         | \$ 21,301         | \$ 19,727         |
|  | <u>          </u> | <u>          </u> | <u>          </u> |
| Purchase of property and equipment financed by capital leases      | \$ 1,312          |                   |                   |
|  | <u>          </u> |                   |                   |
| Fair value of net assets acquired in the Algos merger, net of cash |                   |                   | \$ 228,941        |
|  |                   |                   | <u>          </u> |

See notes to consolidated financial statements.

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**YEARS ENDED DECEMBER 31, 2002, 2001 AND 2000**

**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 17).

**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 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. Three distributors and one pharmacy chain individually accounted for 26%, 16%, 12% and 10%, respectively, of our net sales in 2000. 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 an agreement with Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals) 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* Revenues are recognized when products are shipped. Revenues are recorded net of reserves for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses. 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).

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*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*.)

*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 \$14.3 million, \$9.8 million and \$8.1 million for the years ended December 31, 2002, 2001 and 2000, respectively.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

*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 Pronouncements Bulletin ( 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 and with respect to the Class C4 stock options granted under the Endo Pharma LLC Stock Option Plans, 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 60% in 2002, 2001 and 2000; risk-free interest rate of 4.0%, 5.0% and 6.0% for 2002, 2001 and 2000, 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 2002, 2001 and 2000 would have been as follows (in thousands):

|   | Years Ended December 31, |             |              |
|---|--------------------------|-------------|--------------|
|   | 2002                     | 2001        | 2000         |
| Net income (loss)                             | \$ 30,813                | \$ (36,542) | \$ (156,840) |
| APB 25 Compensation Expense                   | 34,659                   | 37,253      | 15,300       |
| Tax effect of APB 25 compensation expense     | (13,274)                 | (14,268)    |              |
| SFAS 123 compensation expense                 | (5,495)                  | (2,998)     | (96,380)     |
| Tax effect of SFAS 123 compensation expense   | 2,104                    | 1,148       |              |
| Net income (loss) pro forma                   | \$ 48,807                | \$ (15,407) | \$ (237,920) |
| Basic earnings (loss) per share as reported   | \$ .30                   | \$ (.40)    | \$ (1.97)    |
| Basic earnings (loss) per share pro forma     | \$ .48                   | \$ (.17)    | \$ (2.99)    |
| Diluted earnings (loss) per share as reported | \$ .30                   | \$ (.40)    | \$ (1.97)    |
| Diluted earnings (loss) per share pro forma   | \$ .48                   | \$ (.17)    | \$ (2.99)    |
| Weighted average shares outstanding           |                          |             |              |
| Basic   | 102,064                  | 91,505      | 79,454       |
| Diluted                                       | 102,126                  | 91,505      | 79,454       |

*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

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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. 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 and warrant holders. 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 is 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 rescinds SFAS No. 4 and SFAS No. 64, which relate to the extinguishment of debt, rescinds No. 44 relating to the accounting for intangible assets of motor carriers, and 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. We believe that the adoption of SFAS No. 145 will not have 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. We believe that the adoption of SFAS No. 146 will not have a material impact on our results of operations or financial position.

In November 2002, the FASB issued FASB Interpretation No. 45, *Guarantors' 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 are effective for our fiscal year ended December 31, 2002 and the initial

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

recognition and measurement provisions are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. At December 31, 2002, 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.

**3. Acquisitions**

*Algos*

On November 29, 1999, the Company and Algos Pharmaceutical Corporation ( Algos ) announced that they had entered into a definitive merger agreement providing for the merger of Algos into Endo Inc., a newly formed, wholly owned subsidiary of the Company. The Algos merger, which was completed on July 17, 2000, has been accounted for by the Company using the purchase method of accounting. The assets acquired and liabilities assumed of Algos were recorded at their fair values at the date of acquisition based on an independent appraisal. The assets acquired and liabilities assumed, results of operations and cash flows of Algos have been included in our financial statements prospectively for reporting periods beginning July 17, 2000.

In the Algos merger, we issued to the former Algos stockholders, in the aggregate, 17,810,526 shares of our common stock and 17,810,526 warrants to purchase in the aggregate up to 20,575,507 additional shares of our common stock in certain circumstances as more fully described under footnote 14 to these consolidated financial statements. In the Algos merger, we also issued to our pre-merger stockholders, in the aggregate, 71,328,424 warrants to purchase in the aggregate up to 29,720,177 additional shares of common stock in certain other circumstances as more fully described under footnote 14 to these consolidated financial statements.

The total purchase price of \$248.6 million (including approximately \$7.0 million in transaction fees) was determined using an average closing price of the Algos common stock for a reasonable period of time before and after the April 17, 2000 measurement date of \$13.54 and the 17,832,106 common shares and common share equivalents outstanding at the date of the Algos merger (including 21,580 outstanding Series A Warrants). The allocation of the fair value of the assets acquired and liabilities assumed includes an allocation to workforce in place of \$11.9 million which had been amortized over its estimated useful life of two years, patents of \$3.2 million which is being amortized over their estimated useful lives of 17 years and goodwill of \$104.8 million which was amortized over its estimated useful life of three years. In addition, we recorded estimated liabilities for exit costs of \$3.1 million related to non-cancelable lease payments and \$1.1 million for employee relocation costs. During 2001, we were released from our obligation under this lease for no consideration and paid \$163,000 for relocation costs. As no further liability exists, we reversed the remaining reserve of approximately \$4.0 million as a reduction to goodwill. Also, as a result of the Algos merger, it had been determined that the utilization of our federal deferred tax assets was uncertain. Accordingly, a valuation allowance had been recorded to fully reserve our federal deferred tax assets. During 2001, we determined that it became more likely than not that we will utilize our deferred tax benefits. Accordingly, we reversed our valuation reserves of \$40.8 million established in connection with the acquisition of Algos with a corresponding reduction of goodwill.



## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Algos merger included various on-going projects to research and develop innovative new products for pain management. 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 \$133.2 million which was immediately expensed in the consolidated statement of operations on the acquisition date. The methodology used by us on the acquisition date in determining the value of IPRD was to: 1) identify the various on-going projects that the Company 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 products (significant net cash inflows from MorphiDex® were projected in 2003); 3) discount these cash flows based on a risk-adjusted discount rates ranging from 25% to 33% (weighted average discount rate of 27%); and 4) apply the estimated percentage of completion to the discounted cash flow for each individual project ranging from 4% to 81%. The discount rate was determined after considering various uncertainties at the time of the Algos merger, primarily the stage of project completion.

The following unaudited pro forma summary presents the net sales, net loss and net loss per share as if the Algos merger occurred January 1, 2000. This unaudited pro forma summary has been prepared for comparative purposes only and is not necessarily indicative of the operating results that we would have achieved had the Algos merger been completed on that date, or of the operating results that we may achieve in the future.

|  | 2000                                     |
|--|--|
|  | (in thousands, except<br>per share data) |
| Net sales                              | \$ 197,429                               |
| Net loss                               | \$ (164,387)                             |
| Net loss per share (basic and diluted) | \$ (1.84)                                |

*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, upon FDA approval of BML's lead pipeline product, an oral rinse (0.1% triclosan) for oral mucositis, Endo will pay 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 will operate as a wholly owned subsidiary of Endo Pharmaceuticals Inc. 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 ( 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

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. If this project is not successfully developed, our results of operations and financial position in a future period could be negatively impacted.

The following unaudited pro forma summary presents the net sales, net income (loss) and net income (loss) per share as if the BML acquisition occurred January 1 of each year. This unaudited pro forma summary has been prepared for comparative purposes only and is not necessarily indicative of the operating results that we would have achieved had the BML acquisition been completed as those dates, or of the operating results that we may achieve in the future.

|   | 2002                                  | 2001        |
|---|---------------------------------------|-------------|
|   | (in thousands, except per share data) |             |
| Net sales                                       | \$398,973                             | \$251,979   |
| Net income (loss)                               | \$ 30,184                             | \$ (57,166) |
| Net income (loss) per share (basic and diluted) | \$ .30                                | \$ (.62)    |

#### 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, 2002. In addition, beginning on March 19, 2001, Endo pays Hind nonrefundable royalties based on net sales of the product. 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 2002 and 2001, we accrued \$9.1 million and \$3.3 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.

##### *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

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(sufentanil) Pain Therapy System for the U.S. and Canada. Once the clinical trials of CHRONOGESIC have restarted or beginning on June 30, 2004 (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, Endo entered into a development and commercialization agreement with SkyePharma, Inc. and SkyePharma Canada, Inc. 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<sup>TM</sup> and Propofol IDD-D<sup>TM</sup>, with options for certain other development products. In return, SkyePharma received a \$25 million upfront payment from Endo. Milestone payments made by Endo may total up to \$95.0 million which includes total milestones of \$10.0 million for DepoMorphine<sup>TM</sup> through FDA approval. The milestone payments also include \$50.0 million for Propofol IDD-D<sup>TM</sup>, 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<sup>TM</sup> reach \$125.0 million in a calendar year and a \$20.0 million milestone payable when net sales of DepoMorphine<sup>TM</sup> reach \$175.0 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 products' combined 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.

*Other*

We have licensed from a university certain patents and pending patent applications in the field of pain management. We are required to pay royalties equal to 4% of sales of licensed products. In addition, we will pay the university 50% of royalty payments received from any sublicensees until such payments total \$500,000 for a given year, 33% until the payments total an additional \$500,000 for such year and 25% thereafter.

**5. Inventories**

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

|                 | <u>2002</u>       | <u>2001</u>       |
|-----------------|-------------------|-------------------|
| Raw Materials   | \$ 9,150          | \$ 395            |
| Work-in-Process | 2,265             | 1,440             |
| Finished Goods  | 24,101            | 25,931            |
|                 | <u>          </u> | <u>          </u> |
| Total           | \$35,516          | \$27,766          |
|                 | <u>          </u> | <u>          </u> |

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 6. Property and Equipment

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

|                                 | 2002      | 2001     |
|---------------------------------|-----------|----------|
| Machinery and equipment         | \$ 6,610  | \$ 5,274 |
| Computer equipment and software | 8,617     | 6,194    |
| Furniture and fixtures          | 4,116     | 3,900    |
|                                 | 19,343    | 15,368   |
| Less accumulated depreciation   | (7,533)   | (5,485)  |
| Total                           | \$ 11,810 | \$ 9,883 |

## 7. Goodwill and Other Intangibles

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

|                               | December 31,<br>2002 | December 31,<br>2001 |
|-------------------------------|----------------------|----------------------|
| Goodwill                      | \$ 181,079           | \$ 182,318           |
| Amortizable Intangibles:      |                      |                      |
| Licenses                      | \$ 36,000            | \$ 11,000            |
| Patents                       | 3,200                | 3,200                |
|                               | 39,200               | 14,200               |
| Less accumulated amortization | (2,445)              | (1,705)              |
| Other Intangibles, net        | \$ 36,755            | \$ 12,495            |

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, 2002, goodwill and other intangibles comprised approximately 42% of our total assets and 62% 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 (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

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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, 2003, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

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## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, |            |             |
|--|-------------------------|------------|-------------|
|  | 2002                    | 2001       | 2000        |
| (in thousands, except per share data)        |                         |            |             |
| Reported net income (loss)                   | \$30,813                | \$(36,542) | \$(156,840) |
| Add back: Goodwill amortization              |                         | 40,431     | 22,494      |
| Add back: Amortization of workforce-in-place |                         | 5,948      | 2,711       |
| Less: Pro forma income (tax) benefit         |                         | (6,634)    | 46,603      |
| Adjusted net income (loss)                   | \$30,813                | \$ 3,203   | \$ (85,032) |
| <b>Basic earnings (loss) per share:</b>      |                         |            |             |
| Reported net income (loss)                   | \$ .30                  | \$ (.40)   | \$ (1.97)   |
| Add back: Goodwill amortization              |                         | .44        | .28         |
| Add back: Amortization of workforce-in-place |                         | .07        | .03         |
| Less: Pro forma income (tax) benefit         |                         | (.07)      | .59         |
| Adjusted net income (loss)                   | \$ .30                  | \$ .04     | \$ (1.07)   |
| <b>Diluted earnings (loss) per share:</b>    |                         |            |             |
| Reported net (loss) income                   | \$ .30                  | \$ (.40)   | \$ (1.97)   |
| Add back: Goodwill amortization              |                         | .44        | .28         |
| Add back: Amortization of workforce-in-place |                         | .07        | .03         |
| Less: Pro forma income (tax) benefit         |                         | (.07)      | .59         |
| Adjusted net income (loss)                   | \$ .30                  | \$ .04     | \$ (1.07)   |

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2002 is as follows (in thousands):

|      |         |
|------|---------|
| 2003 | \$2,212 |
| 2004 | 2,212   |
| 2005 | 2,212   |
| 2006 | 2,212   |
| 2007 | 2,212   |

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**8. Long-Term Debt**

Long-term debt consists of the following at December 31 (in thousands):

|                      | <u>2002</u> | <u>2001</u> |
|----------------------|-------------|-------------|
| Tranche A Term Loan  |             |             |
| Tranche B Term Loan  |             |             |
| Notes payable        |             | \$ 91,259   |
|                      | —           | —           |
|                      |             | 91,259      |
| Less current portion |             | (91,259)    |
|                      | —           | —           |
|                      | \$ 0        | \$ 0        |
|                      | —           | —           |

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 Restated Credit Agreement*). As of 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, 2002, 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





## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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 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 2002, 2001 and 2000 (in thousands):

|                            | <u>2002</u>     | <u>2001</u>      | <u>2000</u>      |
|----------------------------|-----------------|------------------|------------------|
| Current:                   |                 |                  |                  |
| Federal                    | \$32,940        | \$ 1,859         | \$ 1,578         |
| State                      | 5,871           | 2,149            | 972              |
|                            | <u>38,811</u>   | <u>4,008</u>     | <u>2,550</u>     |
| Deferred:                  |                 |                  |                  |
| Federal                    | (7,910)         | (5,312)          | (6,743)          |
| State                      | (820)           | (3,342)          | (1,988)          |
|                            | <u>(8,730)</u>  | <u>(8,654)</u>   | <u>(8,731)</u>   |
| Total income tax (benefit) | <u>\$30,081</u> | <u>\$(4,646)</u> | <u>\$(6,181)</u> |



## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A reconciliation of income tax (benefit) at the federal statutory income tax rate to the total income tax provision (benefit) for 2002, 2001 and 2000 is as follows (in thousands):

|  | 2002            | 2001              | 2000              |
|--|-----------------|-------------------|-------------------|
| Federal income tax (benefit) at the statutory rate | \$21,313        | \$(14,004)        | \$(55,428)        |
| State income tax (benefit) net of federal benefit  | 1,975           | (787)             | (192)             |
| Research and development credit utilized           | (1,000)         | (1,620)           | (607)             |
| Other  |                 |                   | (210)             |
| Effect of permanent items:                         |                 |                   |                   |
| Purchased in-process research and development      | 7,765           |                   | 45,288            |
| Goodwill   |                 | 11,517            | 5,419             |
| Other  | 28              | 248               | (451)             |
| Total income tax (benefit)                         | <u>\$30,081</u> | <u>\$ (4,646)</u> | <u>\$ (6,181)</u> |

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):

|   | 2002             | 2001             |
|---|------------------|------------------|
| Deferred tax assets:                          |                  |                  |
| Accrued expenses                              | \$ 60,000        | \$ 38,451        |
| Purchased in-process research and development | 11,241           | 12,106           |
| Net operating loss carryforward               | 7,030            | 11,987           |
| Other   | 2,644            | 2,294            |
| Total gross deferred income tax assets        | <u>80,915</u>    | <u>64,838</u>    |
| Deferred tax liabilities:                     |                  |                  |
| Depreciation and amortization                 | (18,482)         | (14,092)         |
| Other   | (30)             | (380)            |
| Total gross deferred income tax liabilities   | <u>(18,512)</u>  | <u>(14,472)</u>  |
| Net deferred income tax asset                 | <u>\$ 62,403</u> | <u>\$ 50,366</u> |

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 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 is not a tax deductible item and, therefore, increases our effective income tax rate in 2002. At December 31, 2002, the Company has \$19.8 million in net operating loss carryforwards for tax purposes which expire through 2021.



**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**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. The *Manufacture and Supply Agreement* currently covers substantially all of our 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 has 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 December 31, 2003, with an option to extend until June 30, 2004.

Any interruption or failure by Bristol-Myers Squibb to meet its obligations under the aforementioned agreements could have a material adverse effect on our business, financial condition and results of operations.

*Novartis Consumer Health, Inc.*

On May 3, 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. whereby Novartis has agreed to manufacture certain of our commercial products and products in development. We are required to purchase, on an annual basis, a minimum amount of product from Novartis. The purchase price per product is equal to a predetermined amount per unit, subject to periodic adjustments. This agreement 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.

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*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, (2) Kunitz and Associates Inc. for medical affairs and (3) Ventiv Health U.S. Sales Inc. for sales. We also have agreements and arrangements with various contract research organizations for our toxicology and clinical studies. These agreements expire from 2003 through 2005, 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 will 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.

*BML Pharmaceuticals*

Upon FDA approval of our oral rinse product (0.1% triclosan) for oral mucositis, we will pay the former shareholders of BML a \$32 million payment and an earn-out based on a percentage of net sales of this and certain other products that were in BML's pipeline at the time of the acquisition.

*DURECT Corporation*

Once the clinical trials of CHRONOGESIC<sup>TM</sup> have restarted or beginning on June 30, 2004 (whichever is earlier), Endo will be obligated to fund 50% of the ongoing development costs of CHRONOGESIC<sup>TM</sup>. 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<sup>TM</sup>. In addition, the 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 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.

*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 product's combined sales achieve certain thresholds, future milestone payments may

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

be due SkyePharma under the terms of the development and commercialization agreement as follows (in thousands):

| Milestone Event   | Milestone Payment |
|---|-------------------|
| FDA acceptance of the NDA for DepoMorphine™ in the United States  | \$ 5,000          |
| FDA final approval of the NDA for DepoMorphine™ in the United States  | 5,000             |
| Total contingent regulatory milestones for DepoMorphine™  | \$10,000          |
| 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          |
| FDA approval and acceptance of the protocol of the first of the Phase III clinical trials for Propofol IDD-D™ | \$ 5,000          |
| FDA acceptance of the NDA for Propofol IDD-D™ in the United States  | 5,000             |
| FDA final approval of the NDA for Propofol IDD-D™ in the United States  | 40,000            |
| Total contingent regulatory milestones for Propofol IDD-D™  | \$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.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**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 August 2011. These leases are renewable at our option. A summary of minimum future rental payments required under capital and operating leases as of December 31, 2002 is as follows (in thousands):

|   | <b>Capital<br/>Leases</b> | <b>Operating<br/>Leases</b> |
|---|---------------------------|-----------------------------|
|   | <u>          </u>         | <u>          </u>           |
| 2003                                      | \$ 584                    | \$ 1,388                    |
| 2004                                      | 522                       | 1,203                       |
| 2005                                      | 398                       | 1,199                       |
| 2006                                      | 14                        | 1,240                       |
|   | <u>          </u>         |                             |
| 2007                                      |                           | 1,127                       |
| Thereafter                                |                           | 4,039                       |
|   |                           | <u>          </u>           |
| Total minimum lease payments              | \$ 1,518                  | \$ 10,196                   |
|   | <u>          </u>         | <u>          </u>           |
| Less: Amount representing interest        | 109                       |                             |
|   | <u>          </u>         |                             |
| Total present value of minimum payments   | \$ 1,409                  |                             |
|   | <u>          </u>         |                             |
| Less: Current portion of such obligations | 525                       |                             |
|   | <u>          </u>         |                             |
| Long-term capital lease obligations       | \$ 884                    |                             |
|   | <u>          </u>         |                             |

Rent expense incurred under operating leases was \$1,434,000, \$1,406,000 and \$747,000 for the years ended December 31, 2002, 2001 and 2000, respectively. On January 6, 2003, we entered into a lease for a 24,000 square foot facility in Hicksville, 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.

**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

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**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 \$954,000, \$597,000 and \$429,000 for the years ended December 31, 2002, 2001 and 2000, respectively.

**14. Stockholders Equity**

**Recapitalization**

In connection with the Algos merger, the Company effected a recapitalization of its common stock, Class A common stock and preferred stock (the Recapitalization). The Recapitalization was effected on July 17, 2000 through a stock dividend of approximately 64.59 shares of common stock for each share of common stock and Class A common stock outstanding immediately prior to the Algos merger. Immediately prior to the Algos merger, the Company amended and restated its certificate of incorporation to effect the Recapitalization and to eliminate its Class A common stock. The effect of the Recapitalization has been retroactively reflected in the accompanying financial statements.

**Adjustment Event**

Cash Gross Profit for fiscal year ended December 31, 2000 was equal to \$153.1 million. Cash Gross Profit is defined in the merger agreement with Algos as the difference between net sales (as reflected on the audited statement of operations of Endo attributable to Endo products determined in accordance with generally accepted accounting principles consistently applied for the fiscal year ended December 31, 2000) of \$197.4 million and Cash Cost of Sales of \$44.3 million for the fiscal year ended December 31, 2000. Cash Cost of Sales is defined in the merger agreement with Algos as Cost of Sales (determined in accordance with GAAP and consistent with past practices as reflected on the audited statement of operations of Endo for the fiscal year ended December 31, 2000 attributable to the Endo products) of \$63.0 million less all non-recurring charges and non-cash charges included in Cost of Sales (including, but not limited to, depreciation, amortization and other non-cash manufacturing charges). Non-cash charges included in Cost of Sales for the fiscal year ended December 31, 2000 are comprised of \$18.7 million of non-cash manufacturing charges which reflect the charges to Cost of Sales for the fiscal year ended December 31, 2000 related to the present value of non-interest bearing promissory notes issued to Bristol-Myers Squibb Pharma Company (f/k/a Dupont Pharmaceuticals) over the initial five-year term of the manufacturing and supply agreement.

As a result of the Cash Gross Profit target having been achieved, Endo Pharma LLC, the holding company of substantially all of the shares of the pre-Merger Endo stockholders, was not required to return a portion of its shares of Company common stock to the Company's treasury so that the percentage ownership of the stockholders remained unchanged. In addition, all references to such an Adjustment Event occurring in the Class A Transferable Warrants and the Class B Non-Transferable Warrants issued to the former Algos stockholders in the Merger are no longer applicable.

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**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, 2002, 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 are 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. As of December 31, 2002, there were outstanding 9.2 million of these warrants. These warrants become exercisable on the fifth business day following the date on which we receive approval from the FDA with respect to MorphiDex® for the treatment of one or more pain indications. These warrants will remain exercisable for a period of six months after the exercisability date, at which time they will expire. However, if the FDA does not approve MorphiDex® by March 31, 2003, each of these warrants expires without any payment therefor.

Because MorphiDex® will not be approved prior to March 31, 2003, the Class A Transferable Warrants (Nasdaq: ENDPW) and Class B Non-Transferable Warrants will expire on such date and have no economic value. Accordingly, the Company will de-list the Class A Transferable Warrants (Nasdaq: ENDPW) upon their expiration.

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 are exercisable at an exercise price of \$.01 per share into a specified number of shares of Company common stock if the FDA does not approve MorphiDex® for any pain indication prior to December 31, 2002. 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 is exercisable into 0.416667 shares of common stock of Endo Pharmaceuticals Holdings Inc. These warrants are exercisable at an exercise price of \$0.01 per share into a maximum of 29.7 million shares of Company common stock. The warrants are exercisable until July 8, 2003.

**Endo Pharma LLC 1997 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). Pursuant to the Recapitalization of the Company 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

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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 effect of the Recapitalization has been reflected in the accompanying financial statements. 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.

A summary of the activity under the Endo Pharma LLC 1997 Stock Option Plans from December 31, 1999 through December 31, 2002 is as follows:

|                                | Number of<br>Shares | Weighted<br>Average<br>Exercise<br>Price |
|--------------------------------|---------------------|--|
| Outstanding, December 31, 1999 | 18,651,975          | \$2.50                                   |
| Granted                        | 9,625,633           | \$3.00                                   |
| Exercised                      | (10,892)            | \$2.42                                   |
| Forfeited                      | (2,998,055)         | \$2.44                                   |
| 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                                   |
| Forfeited                      | (27,070)            | \$3.00                                   |
| Outstanding, December 31, 2002 | 23,766,755          | \$2.71                                   |

The following table summarizes information about stock options outstanding under the Endo Pharma LLC Stock Option Plans at December 31, 2002:

## Options Outstanding

| Number<br>Outstanding<br>at 12/31/02 | Weighted Average<br>Remaining<br>Contractual Life | Exercise<br>Price |
|--------------------------------------|---|-------------------|
| 12,870,026                           | 10 years  | \$2.42            |
| 9,498,407                            | 10 years  | \$3.00            |
| 1,398,322                            | 10 years  | \$3.42            |

Of the outstanding Endo Pharma LLC stock options as of December 31, 2002, 1,517,303 shares have vested and are exercisable ratably over service periods of five years and 1,692,815 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 20,556,637 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

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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

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## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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<br>Closing Price<br>Threshold |
|--------------|--|
| C1A and C1B  | \$ 4.28                                    |
| C2           | \$ 6.62                                    |
| C3           | \$ 10.58                                   |
| C4           | \$ 17.29                                   |

As these share price targets are 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. If these charges are recorded by the Company in connection with the above options, they will be significant. They will, however, not result in the issuance of additional shares of Company common stock.

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.

The remaining unvested class of performance-based stock options (Class C4) under the Endo Pharma LLC stock option plans will vest upon (i) our common stock exceeding an average closing price threshold of \$17.29 for ninety consecutive trading days, (ii) the closing price of our common stock on the last trading day of such ninety consecutive trading day period being greater than or equal to \$14.70 and (iii) the holder being a director, officer or employee of the Company or any of our subsidiaries on such date. The vesting of the approximately 5.0 million outstanding Class C4 stock options will result in an additional compensation charge to the Company. If this vesting occurs, this charge will be substantial. As stated above, these options are exercisable solely into shares of Company 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 ownership of our other public stockholders.

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, 2002 and 2001 were 2,527,778 and 2,431,150, respectively. The shares of Company common stock that

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

employees receive upon exercise of stock options pursuant to the Endo Pharma LLC 1997 Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

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

Pursuant to the Algos merger and 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. Further, the shares of common stock that individuals receive upon exercise of stock options pursuant to 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, 2002, only stock options have been awarded. Stock options granted under the 2000 Stock Incentive Plan expire ten years from the date of grant.

A summary of the activity under our 2000 Stock Incentive Plan from December 31, 1999 through December 31, 2002 is as follows:

|                                 | Number of<br>Shares | Weighted<br>Average<br>Exercise<br>Price |
|---------------------------------|---------------------|--|
| Outstanding, December 31, 1999. | 0                   |  |
| Granted                         | 391,250             | \$ 7.20                                  |
| Forfeited                       | 0                   |  |
|                                 | <hr/>               |  |
| Outstanding, December 31, 2000. | 391,250             | \$ 7.20                                  |
| Granted                         | 605,712             | \$ 8.85                                  |
| Forfeited                       | (59,351)            | \$ 7.45                                  |
|                                 | <hr/>               |  |

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

|                                 | Number of<br>Shares         | Weighted<br>Average<br>Exercise<br>Price |
|---------------------------------|-----------------------------|--|
|                                 | <u>                    </u> | <u>                    </u>              |
| Outstanding, December 31, 2001. | 937,611                     | \$ 8.25                                  |
| Granted                         | 1,069,455                   | \$ 9.93                                  |
| Exercised                       | (500)                       | \$ 7.25                                  |
| Forfeited                       | (21,343)                    | \$ 9.38                                  |
|                                 | <u>                    </u> |  |
| Outstanding, December 31, 2002. | 1,985,223                   | \$ 8.82                                  |
|                                 | <u>                    </u> |  |

The following table summarizes information about stock options outstanding under our 2000 Stock Incentive Plan at December 31, 2002:

## 2000 Stock Incentive Plan Options Outstanding

| Number<br>Outstanding<br>at 12/31/02 | Weighted<br>Average<br>Remaining<br>Contractual<br>Life | Range of Exercise<br>Prices |          |
|--------------------------------------|---|-----------------------------|----------|
| <u>                    </u>          | <u>                    </u>                             | <u>                    </u> |          |
| 454,047                              | 8.0   | \$ 6.47                     | \$ 7.50  |
| 41,882                               | 8.7   | \$ 7.51                     | \$ 8.50  |
| 1,405,957                            | 9.3   | \$ 8.51                     | \$ 9.50  |
| 53,012                               | 8.9   | \$ 9.51                     | \$ 10.50 |
| 30,325                               | 9.3   | \$ 10.51                    | \$ 11.00 |

## 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):

|  | 2002                        | 2001                        | 2000                        |
|--|-----------------------------|-----------------------------|-----------------------------|
|  | <u>                    </u> | <u>                    </u> | <u>                    </u> |
| Numerator:   |                             |                             |                             |
| Net income (loss) available to common stockholders | \$ 30,813                   | \$ (36,542)                 | \$ (156,840)                |
|  | <u>                    </u> | <u>                    </u> | <u>                    </u> |
| Denominator:                                       |                             |                             |                             |
| For basic per share data - weighted average shares | 102,064                     | 91,505                      | 79,454                      |
| Effect of dilutive stock options                   | 62                          |                             |                             |
| For diluted per share data                         | 102,126                     | 91,505                      | 79,454                      |
| Basic earnings (loss) per share                    | \$ .30                      | \$ (.40)                    | \$ (1.97)                   |
|  | <u>                    </u> | <u>                    </u> | <u>                    </u> |
| Diluted earnings (loss) per share                  | \$ .30                      | \$ (.40)                    | \$ (1.97)                   |





The dilutive effect of stock options outstanding excludes the effect of warrants exercisable only upon satisfaction of certain defined events as these events have not occurred. On January 8, 2003, we announced that the outstanding Pre-Merger Warrants that were issued to the holders of Company common stock prior to the Algos merger have become exercisable. Each of these outstanding 71.3 million warrants is exercisable into 0.416667 shares of our common stock. These warrants are exercisable at an exercise price of \$0.01 per share into a maximum of 29.7 million shares of common stock on account of MorphiDex® not having been approved by the FDA for any pain indication prior to December 31, 2002. The exercise of these warrants is expected to increase the total number of outstanding shares to approximately 131.8 million.

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. Stock options exercisable pursuant to the



**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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. Separation Benefits**

During the year ended December 31, 2000, the Company entered into separation and release agreements with two executives. Severance and other termination benefits provided by the agreements amounting to \$1,252,000 were recorded. The separation and release agreements provided that certain options granted to the two executives under existing stock option plans became fully vested on the effective dates of the agreements. The agreements also provided that other stock options previously granted to the executives would terminate. The agreements further provided terms and conditions for the exercise of the vested options. Cost related to stock options resulting from the agreements resulted in a charge of \$20,782,000 during the year ended December 31, 2000.

**17. Related Party Transactions**

Prior to July 17, 2000, Kelso & Company provided financial advisory services to us for an annual fee of \$347,000 plus the reimbursement of expenses. Payment for these services and reimbursement of expenses totaled \$366,000 for the year ended December 31, 2000. In connection with the Algos merger, which was completed on July 17, 2000, we terminated this agreement by making a one-time payment to Kelso of \$1.5 million, which is included in Merger and other related costs.

On July 14, 2000, Endo Pharma LLC was formed to ensure that the stock options granted pursuant to the 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans (collectively the Endo Pharma LLC Stock Options 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 the exercise of these stock options, only currently outstanding shares of common stock of the Company held by Endo Pharma LLC will be issued. Because Endo Pharma LLC, and not the Company, will provide the shares issued upon the exercise of these options, the Company has entered into a tax sharing agreement with Endo Pharma LLC under which the Company will pay to Endo Pharma LLC the amount of the tax benefits it receives as a result of the exercise of these stock options into shares of common stock held by Endo Pharma LLC for the years in which these tax benefits arise. As of December 31, 2002, approximately 1.1 million of these stock options have been exercised by former employees into shares of Company common stock held by Endo Pharma LLC. These stock option exercises may permit the Company to deduct, for income tax purposes, compensation equal to the difference between the market price of the Company common stock and the exercise price paid upon exercise of these options (approximately \$8 million), which may result in a tax benefit amount of approximately \$3 million. Under the tax sharing agreement, we are required to pay this \$3 million to Endo Pharma LLC. If all 36.3 million of the stock options under the Endo Pharma LLC Stock Options Plans were vested and exercised when the market price of our common stock was \$10.00 per share, then, using a weighted average exercise price of \$2.61 per share, the Company may be permitted to deduct, for income tax purposes, compensation of approximately \$268 million, which may result in a tax benefit amount of approximately \$100 million. If all 36.3 million of the stock options under the Endo Pharma LLC Stock Options Plans were exercised and vested when the market price of our common stock was \$15.00 per share, then, using a weighted average exercise price of \$2.61 per share, the Company may be permitted to deduct, for income tax purposes, compensation of approximately \$450 million, which may result in a tax benefit amount of approximately \$168 million. Under the terms of the tax sharing agreement discussed above, the Company must pay any such tax benefit amounts to Endo Pharma LLC; however, these payments need only be made to Endo Pharma LLC upon the occurrence of a liquidity event, which is generally defined as (a) a sale of greater than 20% on a fully diluted basis of the common equity of the Company (either through a primary offering by the Company or a secondary sale by Endo Pharma LLC or a combination of both), (b) a change in control of the Company

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

or (c) a sale of all or substantially all of the assets of the Company. In accordance with the tax sharing agreement, no payments have been made or accrued to date.

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

The effect of the Recapitalization has been retroactively reflected in the following quarterly financial data (see Note 14):

|                                       | Quarter Ended                         |            |               |              |
|---------------------------------------|---------------------------------------|------------|---------------|--------------|
|                                       | March 31,                             | June 30,   | September 30, | December 31, |
|                                       | (in thousands, except per share data) |            |               |              |
| <b>2002(1)</b>                        |                                       |            |               |              |
| 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      |

|                                       | Quarter Ended                         |           |               |              |
|---------------------------------------|---------------------------------------|-----------|---------------|--------------|
|                                       | March 31,                             | June 30,  | September 30, | December 31, |
|                                       | (in thousands, except per share data) |           |               |              |
| <b>2001(2)</b>                        |                                       |           |               |              |
| Net sales                             | \$ 39,382                             | \$ 67,857 | \$ 66,268     | \$ 78,472    |
| Gross profit                          | \$ 26,733                             | \$ 46,825 | \$ 45,646     | \$ 57,884    |
| Operating (loss) income               | \$ (10,730)                           | \$ 6,659  | \$ (31,475)   | \$ 7,648     |
| Net (loss) income                     | \$ (14,238)                           | \$ 2,731  | \$ (32,993)   | \$ 7,959     |
| Net (loss) income per share (basic)   | \$ (.16)                              | \$ .03    | \$ (.37)      | \$ .09       |
| Net (loss) income per share (diluted) | \$ (.16)                              | \$ .03    | \$ (.37)      | \$ .09       |
| Weighted average shares (basic)       | 89,139                                | 89,139    | 89,139        | 98,526       |
| Weighted average shares (diluted)     | 89,139                                | 89,213    | 89,139        | 98,649       |

- (1) 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 \$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 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.
- (2) Operating (loss) income and net (loss) income for the year ended December 31, 2001 include charges of \$37.3 million in the quarter ended September 30, 2001 for compensation related to stock options. The number of weighted average shares outstanding increased in the quarter ended December 31, 2001 due to the shares issued in our secondary offering.



## Exhibit Index

| Exhibit No. | Title  |
|-------------|--|
| 2.1         | Amended and Restated Agreement and Plan of Merger, dated as of March 3, 2000 (the Merger Agreement ), by and among Endo Pharmaceuticals Holdings Inc. ( Endo ), Endo Inc. and Algos Pharmaceutical Corporation ( Algos ) (incorporated herein by reference to Exhibit 2.1 of the Registration Statement on Form S-4 of the Registrant (Registration No. 333-39040) (the Registration Statement ), filed with the Securities and Exchange Commission (the Commission ) on June 9, 2000) |
| 2.2         | Amendment, dated as of April 17, 2000, to the Merger Agreement, by and between Endo, Endo Inc. and Algos (incorporated herein by reference to Exhibit 2.2 of the Registration Statement filed with the Commission on June 9, 2000)   |
| 2.3         | Asset Purchase Agreement, dated as of August 27, 1997, by and between Endo Pharmaceuticals Inc. ( Endo Pharmaceuticals ) and The DuPont Merck Pharmaceutical Company ( DuPont Merck Pharmaceutical ) (incorporated herein by reference to Exhibit 2.3 of the Registration Statement filed with the Commission on June 9, 2000)   |
| 3.1         | Amended and Restated Certificate of Incorporation of 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 June 30, 2000 filed with the Commission on August 15, 2000)   |
| 4.1         | Amended and Restated Executive Stockholders Agreement, dated as of July 14, 2000, 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, 2000 filed with the Commission on August 15, 2000)   |
| 4.2         | Amended and Restated Employee Stockholders Agreement, dated as of July 14, 2000, by and among Endo, Endo LLC, KIA V, KEP V and the Employee Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.2 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)  |
| 4.3         | Form of Stock Certificate of Endo Common Stock (incorporated herein by reference to Exhibit 4.3 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)   |
| 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)   |
| 10.1        | Endo Warrant Agreement, dated as of July 17, 2000, by and between Endo and United States Trust Company of New York (incorporated herein by reference to Exhibit 10.1 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)  |
| 10.2        | Algos Warrant Agreement, dated as of July 17, 2000, by and between Endo and United States Trust Company of New York (incorporated herein by reference to Exhibit 10.2 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)   |
| 10.3        | [Intentionally Omitted.]   |
| 10.4        | Letter Agreement, dated as of November 26, 1999, by and among Algos, Endo, KIA V and KEP V (incorporated herein by reference to Exhibit 10.4 of the Registration Statement filed with the Commission on June 9, 2000)  |

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| Exhibit<br>No. | Title   |
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| 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 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 Inc. ( EPI ) 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)  |

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| Exhibit<br>No. | Title   |
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| 10.20          | Medical Affairs Support Services Agreement, dated as of June 1, 1999, by and between Endo Pharmaceuticals and Kunitz and Associates, Inc. (incorporated herein by reference to Exhibit 10.20 of the Registration Statement filed with the Commission on June 9, 2000) |
| * 10.21        | Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.21 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)                         |
| * 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 of 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 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)                    |

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| Exhibit<br>No. | Title  |
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| * 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          | License Agreement, dated as of August 16, 1993, by and between Endo Pharmaceuticals (as successor in interest to Algos Pharmaceutical Corporation) and The Medical College of Virginia (incorporated herein by reference to Exhibit 10.4.1 of the registration statement on Form S-1 of Algos Pharmaceutical Corporation declared effective on September 25, 1996) |
| 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) Development,  |
| 10.42          | Commercialization and Supply License Agreement, dated as of November 8, 2002, by and between DURECT Corporation and Endo Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.42 of the Current Report on Form 8-K dated November 14, 2002)  |
| 10.43          | Development and Marketing Strategic Alliance Agreement, dated as of December 31, 2002, by and among Endo Pharmaceuticals Inc., SkyePharma, Inc. and SkyePharma Canada, Inc. (incorporated herein by reference to Exhibit 10.43 of the Current Report dated January 8, 2003)  |
| 10.44          | Lease Agreement, dated as of January 6, 2003, by and between Endo Pharmaceuticals and Dawson Holding Company   |
| 21             | Subsidiaries of the Registrant   |
| 23             | Independent Auditors Consent   |
| 24             | Power of Attorney  |
| 99.1           | Certificate of the Chairman and Chief Executive Officer of Endo pursuant to Section 906 of the Sarbanes-Oxley Act of 2002  |
| 99.2           | Certificate of the Chief Financial Officer of Endo pursuant to Section 906 of the Sarbanes-Oxley Act of 2002   |

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