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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, 2003**

**or**

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

**For the transition period from            to            .**

**Commission file number: 001-15989**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**(Exact name of registrant as specified in its charter)**

**Delaware**  
(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: N/A**

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

**Title of Each Class**

**Name of Each Exchange on Which  
Registered**

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Common Stock

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Nasdaq

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**Annual Report for the Year Ended December 31, 2003**

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

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

Indicate by check mark whether the registrant is 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, 2003): \$517,146,904 based on the last reported sale price on the Nasdaq on June 30, 2003.

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

**Documents Incorporated by Reference**

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

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ENDO PHARMACEUTICALS HOLDINGS INC.

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FOR THE YEAR ENDED DECEMBER 31, 2003

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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.

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### PART I

#### Item 1. *Business*

##### Overview

We are a specialty pharmaceutical company with market leadership in pain management. We are engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat and manage pain. According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$16.6 billion in 2003. This represents an approximately 20% compounded annual growth rate since 1998. Our primary area of focus within this market is in the opioid analgesics segment. Total U.S. sales for this segment were \$5.6 billion in 2003, representing a compounded annual growth rate of 25% since 1998.

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

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

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

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

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

##### Our Strategy

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

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

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

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

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

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

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

## **Our Competitive Strengths**

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

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

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

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

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

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

***Selective focus on generic products.*** Our generic product portfolio includes products focused on pain management. Development of these products involves barriers to entry such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. We believe products with these characteristics will face a lesser degree of competition and therefore provide longer product life cycles and higher profitability than commodity generic products. We have executed our generic product development strategy successfully to date with products such as morphine sulfate extended-release tablets, which we introduced in November 1998 as a bioequivalent version of MS Contin, a product of The Purdue Frederick Company. In addition, we believe we are the first company to have filed an ANDA with the FDA for the bioequivalent version of the 10mg, 20mg and 40mg strengths of Purdue Frederick’s OxyContin. For several reasons, including potential marketing exclusivity, we believe it is a significant advantage to be the first successful filer of an ANDA for a generic drug. In July 2002, we received a tentative approval from the FDA for all four strengths (10mg, 20mg, 40mg and 80mg) of our generic OxyContin. We currently are in litigation with Purdue Frederick with respect to this product, and the trial was completed in June 2003. On January 5, 2004, the U.S. District Court for the Southern District of New York issued an Opinion and Order dismissing Purdue’s claims that Endo’s oxycodone extended-release tablets, 10mg, 20mg, 40mg and 80mg, a bioequivalent version of Purdue Frederick’s OxyContin, infringe Purdue’s U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, declaring these patents invalid, and enjoining Purdue from enforcing the patents. See “Item 3. Legal Proceedings.”

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



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

## Our Industry

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

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

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

## Product Overview

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

Product	Active Ingredient(s)	Branding	Status
Lidoderm®	lidocaine 5%	Branded	Marketed
Percocet®	oxycodone and acetaminophen	Branded	Marketed
Percodan®	oxycodone and aspirin	Branded	Marketed
Zydone®	hydrocodone and acetaminophen	Branded	Marketed
Morphine Sulfate ER	morphine sulfate	Generic	Marketed
Oxymorphone ER(1)	oxymorphone hydrochloride	Branded	Approvable Letter
Oxymorphone IR	oxymorphone hydrochloride	Branded	Approvable Letter
DepoMorphine™(2)	morphine sulfate	Branded	NDA filed; under FDA review
CHRONOGESIC™(3)	sufentanil	Branded	Phase II
Propofol IDD-D™(2)	propofol	Branded	Phase II
Lidoderm® (chronic low back pain)	lidocaine 5%	Branded	Phase II
LidoPain® BP(4)	lidocaine	Branded	Phase II
Transdermal Fentanyl Patch(5)	fentanyl	Generic	ANDA filed; under FDA review
Oxycodone ER(6)	oxycodone	Generic	Tentatively approved; subject to ongoing litigation



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

## ***Branded Products***

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

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

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

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

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

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

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

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### ***Generic Products***

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

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

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

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

- complex formulation or development characteristics;
- regulatory or legal challenges; or
- difficulty in raw material sourcing.

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

### ***Products in Development***

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

***Oxymorphone ER.*** In December 2002, we filed an NDA for oxymorphone ER with the FDA, and in February 2003, this NDA was accepted for substantive review. We received an approvable letter from the FDA for oxymorphone ER in October 2003. In this approvable letter, the FDA requested that we address certain questions and provide additional clarification and information, including some form of additional clinical trials to further confirm the safety and efficacy of this product. We expect to meet with the FDA to discuss the approvable letter on our oxymorphone ER prior to the end of the first quarter of 2004 and subsequent to that meeting anticipate having further clarity as to the path required to obtain final approval. If approved, oxymorphone ER is intended to treat moderate-to-severe pain in patients requiring continuous, around-the-clock opioid therapy for an extended period of time. In Phase III clinical studies in each of osteoarthritis pain, chronic low back pain and cancer pain, we believe patients taking oxymorphone ER demonstrated statistically significant pain relief. We co-developed this oral extended-release version of oxymorphone with Penwest Pharmaceuticals. If approved, we expect oxymorphone ER will compete in the approximately \$3.6 billion U.S. strong opioid market.

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

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

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

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

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

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

**Oxycodone ER.** We have also developed an extended-release oxycodone, a generic version of OxyContin, a product of The Purdue Frederick Company. According to IMS Retail Provider Perspective data, OxyContin generated U.S. sales of approximately \$1.9 billion in 2003, up from approximately \$1.6 billion in 2002. We have received tentative approval from the FDA for bioequivalent versions of the 10mg, 20mg, 40mg and 80mg strengths of OxyContin. We currently are in litigation with Purdue Frederick regarding our generic version of OxyContin. The trial was completed in June 2003. On January 5, 2004, the U.S. District Court for the Southern District of New York issued an Opinion and Order dismissing Purdue's claims that Endo's oxycodone extended-release tablets, 10mg, 20mg, 40mg and 80mg, infringe Purdue's U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, declaring these patents invalid, and enjoining Purdue from enforcing the patents. See "Item 3. Legal Proceedings." We believe we are the first company to have filed an ANDA with the FDA for the bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin, thereby potentially entitling us to 180 days of generic product marketing exclusivity with respect to these strengths of this product. Given the recent passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003, with accompanying amendments to the Hatch-Waxman Act, our marketing exclusivity would generally begin to run upon the earlier of our commercial launch of these products or 75 days following an appellate court decision affirming the district court's decision. The rules governing market exclusivity, however, are complex and may be affected by factors outside our control. Accordingly, even assuming we otherwise qualify for 180-day marketing exclusivity, we cannot guarantee that we will be able or willing to market our product during the relevant period.

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

## **Competition**

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

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

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

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

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

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

## **Research and Development**

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

## **Seasonality**

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

## **Customers**

We sell our products directly to a limited number of large pharmacy chains and through a limited number of wholesale drug distributors that, in turn, supply products to pharmacies, hospitals, governmental agencies and physicians. Three distributors and one pharmacy chain individually accounted for 28%, 24%, 19% and 10%, respectively, of our net sales in 2001. Three distributors and one pharmacy chain individually accounted for 24%, 24%, 23% and 11%, respectively, of our net sales in 2002. Three distributors and one pharmacy chain individually accounted for 26%, 26%, 19% and 11%, respectively, of our net sales in 2003.

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

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

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

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

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

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

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

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

## **Governmental Regulation**

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

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

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

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



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

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

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

### *NDA Process*

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

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

- Phase I, which frequently begins with the initial introduction of the compound into healthy human subjects prior to introduction into patients, involves testing the product for safety, adverse effects, dosage, tolerance, absorption, metabolism, excretion and other elements of clinical pharmacology.
- Phase II typically involves studies in a small sample of the intended patient population to assess the efficacy of the compound for a specific indication, to determine dose tolerance and the optimal dose range as well as to gather additional information relating to safety and potential adverse effects.
- Phase III trials are undertaken to further evaluate clinical safety and efficacy in an expanded patient population at typically dispersed study sites, in order to determine the overall risk-benefit ratio of the compound and to provide an adequate basis for product labeling.

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

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

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

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

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

### ***ANDA Process***

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

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

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

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

### ***Patent and Non-Patent Exclusivity Periods***

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





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

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

### ***Quality Assurance Requirements***

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

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

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

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

### ***Other FDA Matters***

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

### ***Drug Enforcement Administration***

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

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



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

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

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

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

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

### **Service Agreements**

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

### ***Third Party Manufacturing/Supply Agreements***

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

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

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

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

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

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

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

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

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

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

A description of the material terms of these agreements follows:

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

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all of our business; (2) for a change in our stock ownership or company control; (3) if we decide to have these services provided in-house or by an affiliate; or (4) if UPS fails to provide additional storage space for our products upon request. In the event of termination under certain circumstances, we are required to pay UPS for certain capital investments and wind-down expenses.

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

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

## **Licenses and Collaboration Agreements**

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

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

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

**EpiCept Corp.** On December 19, 2003, we entered into a license granting us exclusive, worldwide rights to certain patents of EpiCept Corp. as well as exclusive, worldwide commercialization rights to EpiCept's LidoPAIN<sup>®</sup> BP product. The license agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept's LidoPAIN<sup>®</sup> BP product. EpiCept has also retained an option to co-promote the LidoPAIN<sup>®</sup> BP product. Under this agreement, we made an upfront payment to EpiCept of \$7.5 million which we capitalized as an intangible asset representing the fair value of the exclusive right and the patents. We are amortizing this intangible asset over its useful life of 13 years. Future payments made by us under this agreement, including regulatory milestones and sales thresholds, could total up to \$82.5 million.

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

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

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

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

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

**SkyePharma, Inc.** On December 31, 2002, we entered into a Development and Marketing Strategic Alliance Agreement with SkyePharma, Inc. and SkyePharma Canada, Inc. relating to two of SkyePharma's patented development products, DepoMorphine™ and Propofol IDD-D™ (collectively, the "Skye Products"). Under the terms of the Agreement, we received an exclusive license to the U.S. and Canadian marketing and distribution rights for the Skye Products, with options for certain other development products. In return, SkyePharma received a \$25 million upfront payment from us, which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We are amortizing this intangible asset over its useful life of 17 years. In addition, SkyePharma may receive milestone payments in addition to the \$25 million upfront payment of up to \$95 million, which include total milestones of \$10 million for DepoMorphine™ through FDA approval. During 2003, we paid \$5 million to SkyePharma upon the acceptance by the FDA of the NDA for DepoMorphine™. The milestone payments also include \$50 million for Propofol IDD-D™, payable when the product successfully achieves certain regulatory milestones, including FDA approval. The total further includes a \$15 million milestone payable when net sales of DepoMorphine™ exceed \$125 million in a calendar year, and a \$20 million milestone payable when net sales of DepoMorphine™ exceed \$175 million in a calendar year. SkyePharma will also receive a share of each product's sales revenue that will increase from 20% initially, to a maximum of 60%, of net sales as the Skye Products' combined net sales achieve certain thresholds.

This agreement provides for the parties to work together to complete the necessary clinical, regulatory and manufacturing work for North American regulatory approval of the Skye Products. SkyePharma will be primarily responsible for clinical development up to final FDA approval, and for the manufacture of the Skye Products, including all associated costs. Upon approval, we will market each Skye Product in the U.S. and Canada, with SkyePharma as the supplier. We will be responsible for funding and conducting any post-marketing studies and for all selling and marketing expenses. Under this agreement, we also obtained options on other SkyePharma development products, including 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



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

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

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

## **Environmental Matters**

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

## **Summary of Recent Transactions**

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

On January 28, 2004, we amended our agreement with Durect, essentially modifying Endo's funding obligations of the ongoing development costs of CHRONOGESIC™ to take into account the program delay.

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On December 19, 2003, we entered into a license granting us exclusive, worldwide rights to certain patents of EpiCept Corp. as well as exclusive, worldwide commercialization rights to EpiCept's LidoPAIN® BP product. The license agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept's LidoPAIN® BP product. EpiCept has also retained an option to co-promote the LidoPAIN® BP product. Under this agreement, we made an upfront payment to EpiCept of \$7.5 million which we capitalized as an intangible asset representing the fair value of the exclusive right and the patents. We are amortizing this intangible asset over its useful life of 13 years. Future milestone payments made by us under this agreement, including regulatory milestones and sales thresholds, could total up to \$82.5 million.

### **Description of Credit Facility**

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

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

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

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

### **Employees**

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

### **Executive Officers of the Registrant**

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

<u>Name</u>	<u>Age</u>	<u>Position and Offices</u>
Carol A. Ammon	52	Chief Executive Officer and Chairman of the Board
Jeffrey R. Black	39	Senior Vice President, Chief Financial Officer and Treasurer
Peter A. Lankau	51	President and Chief Operating Officer
David A.H. Lee, M.D., Ph.D.	54	Executive Vice President, Research & Development
Caroline B. Manogue	35	Senior Vice President, General Counsel & Secretary

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

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

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



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

DAVID A.H. LEE, M.D. Ph.D., 54, is Executive Vice President, Research & Development and Regulatory Affairs of Endo. Prior to joining Endo in December of 1997, Dr. Lee was Executive Vice President, Research and Development for CoCensys, Inc., an emerging pharmaceuticals company based in Irvine, California, from 1992 through 1997. Prior to joining CoCensys, Dr. Lee held various positions at Solvay Pharmaceuticals in the Netherlands, ranging from head of global clinical development programs to his final position as Vice President, Research and Development. Dr. Lee received his M.D. and Ph.D. degrees from the University of London and specialized in internal medicine and gastroenterology, prior to joining the pharmaceutical industry.

CAROLINE B. MANOGUE, 35, is Senior Vice President, General Counsel and Secretary of Endo. Prior to joining Endo in September 2000, Ms. Manogue was an Associate at the law firm Skadden, Arps, Slate, Meagher & Flom LLP since 1995.

We have employment agreements with each of our executive officers.

### **Dividend Policy**

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

### **Available Information**

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

### **Item 2. Properties**

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

#### **Chadds Ford, Pennsylvania**

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

*Painters' Crossing Two Associates, L.P. Lease Agreement.* On November 13, 2003, we entered into a ten-year lease with Painters' Crossing Two Associates, L.P. pursuant to which Painters' Crossing will lease to us a building comprised of approximately 64,424 square feet located across the street from our corporate headquarters in Chadds Ford, Pennsylvania. This lease will commence once construction of the building is complete, currently anticipated to be late 2004 or early 2005. We, at our discretion, have the right to terminate this lease at the end of the sixth year, by providing two years' notice and paying a fixed termination fee to Painters' Crossing. During the term of the lease, the annual rent is a fixed amount paid in equal monthly installments that increase after the first five years of the



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lease.

### **Garden City, New York**

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

### **Westbury, New York**

*Dawson Holding Company.* Under this agreement, dated January 6, 2003, we lease a 24,190 square foot facility in Westbury, New York. Once our current lease of the Bristol-Myers Squibb facility in Garden City, New York expires, we will use this space for the research and development of our pharmaceutical products. Until such time, we are renovating this space to accommodate our needs. The annual rent due for this facility is \$152,397 in the first year of the lease, escalating by 4% each year thereafter. This ten-year lease is not assignable without the consent of the landlord, Dawson Holding. This lease may 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 pleaded counterclaims that the patents asserted by Purdue Frederick are invalid, unenforceable and/or not infringed by EPI's formulation of oxycodone hydrochloride extended-release tablets, 10mg, 20mg, 40mg and 80mg strengths. EPI also counterclaimed for antitrust damages based on allegations that Purdue Frederick obtained the patents through fraud on the United States Patent and Trademark Office and is asserting them while aware of their invalidity and unenforceability.

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

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

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

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

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

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

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



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### *General*

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

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

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

## **PART II**

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

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

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

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

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

*Equity Compensation Plan Information.* The following information relates to plans in effect as of December 31, 2003 under which equity securities of Endo may be issued to employees and directors. Although the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan provides that stock options may be granted thereunder to non-employee consultants, Endo has never granted any such options to any such consultants.

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



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Plan Category	Column A	Column B	Column C
	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column A)
Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan	3,330,179	\$11.86	669,821
<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.

### Item 6. Selected Financial Data

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

	Year Ended December 31,				
	1999	2000	2001	2002	2003
	(in thousands, except per share data)				
<b>Consolidated Statement of Operations</b>					
Data:					
Net sales	\$138,546	\$ 197,429	\$251,979	\$398,973	\$595,608
Cost of sales	58,263	63,041	74,891	98,857	135,671
Gross profit	80,283	134,388	177,088	300,116	459,937
Selling, general and administrative	42,921	56,537	79,505	110,907	155,827
Research and development	9,373	26,012	38,994	56,823	51,024
Depreciation and amortization	8,309	27,624	49,234	3,142	6,272
Compensation related to stock options	—	15,300	37,253	34,659	144,524
Purchased in-process research and development	—	133,200	—	20,300	(6,966)
Manufacturing transfer fee	—	—	—	9,000	—
Merger and other related costs	—	1,583	—	—	—
Separation benefits	—	22,034	—	—	—
Operating income (loss)	19,680	(147,902)	(27,898)	65,285	109,256
Interest expense, net	14,347	15,119	13,290	4,391	258
Income (loss) before income tax (benefit)	5,333	(163,021)	(41,188)	60,894	108,998
Income tax (benefit)	2,073	(6,181)	(4,646)	30,081	39,208
Net income (loss)	\$ 3,260	\$(156,840)	\$(36,542)	\$ 30,813	\$ 69,790

Basic and Diluted Net Income (Loss) Per Share:					
Basic	\$ .05	\$ (1.97)	\$ (.40)	\$ .30	\$ .54
Diluted	\$ .05	\$ (1.97)	\$ (.40)	\$ .30	\$ .53
Shares Used to Compute Basic Net Income (Loss) Per Share	71,332	79,454	91,505	102,064	128,417
Shares Used to Compute Diluted Net Income (Loss) Per Share	71,332	79,454	91,505	102,126	132,439

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As of and for the Year Ended December 31,

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

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

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

#### Overview

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

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

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

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

In May 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc., whereby Novartis has agreed to manufacture certain of our commercial products and products in development. We have incurred significant costs associated with the preparation of Novartis' manufacturing operations under this agreement. These costs primarily relate to the preparation of test batches of drug product for FDA approval and our own quality assessment and administrative costs

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

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

### **Critical Accounting Policies**

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

#### ***Sales Deductions***

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

#### ***Amortizable Intangibles: Licenses***

Licenses are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives ranging from thirteen to twenty years. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the license and an acceleration of related amortization expense, which could cause our operating income, net income and earnings per share to decrease. Licenses are assessed periodically for impairment in accordance with Statement of Financial Accounting Standards No. 144,



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

### Goodwill and Other Intangibles

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

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

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

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

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

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

	Year Ended December 31,		
	2003	2002	2001
	(in thousands, except per share data)		
Reported net income (loss)	\$69,790	\$30,813	\$(36,542)
Add back: Goodwill amortization	—	—	40,431
Add back: Amortization of workforce-in-place	—	—	5,948

Less: Pro forma income (tax) benefit	—	—	(6,634)
Adjusted net income (loss)	\$69,790	\$30,813	\$ 3,203

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

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

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

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

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

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

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

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

## **Results of Operations**

### *Net Sales*

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

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

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

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

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

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

**Net Sales.** Net sales for the year ended December 31, 2003 increased by 49% to \$595.6 million from \$399.0 million in the comparable 2002 period. This increase in net sales was primarily due to the increase in the net sales of Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, Percocet®, and certain generic products. Net sales of Lidoderm® increased to \$178.3 million from \$83.2 million in the comparable 2002 period. In September 1999, we launched Lidoderm®, which continues to gain market share due to our ongoing promotional and educational efforts. Percocet® net sales increased to \$214.2 million from \$144.6 million in the comparable 2002 period due to the increase in net sales of Percocet® 7.5/325 and Percocet® 10.0/325. On October 20, 2003, Watson Pharmaceuticals announced that it was launching its generic versions of Percocet® 7.5/325 and Percocet® 10.0/325. Net sales of our generic products increased 22% to \$181.3 million from \$149.1 million in the comparable 2002 period primarily due to the growth of Endocet® and our generic morphine sulfate extended-release tablets. In October 2003, we launched two new strengths of our generic product Endocet®. During the third quarter of 2003, the FDA approved all five strengths of Mallinckrodt Inc.'s generic extended-release morphine sulfate. Generic competition with our products may have a material impact on our results of operations and cash flows in the future. Due to the generic competition with our Percocet® and morphine sulfate extended-release tablets, partially offset by an expected increase in net sales of Lidoderm®, we expect net sales in 2004 to be approximately \$570 to \$580 million.

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

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the year ended December 31, 2003

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

**Compensation Related to Stock Options.** For the year ended December 31, 2002, compensation related to stock options decreased to \$34.7 million from \$37.3 million in the comparable 2001 period. Compensation related to stock options reflects the charge arising from the vesting of performance-based stock options granted pursuant to the Endo Pharma LLC Stock Option Plans. Under these plans, tranches of options vest when we attain certain common stock price targets. As each tranche vests, we incur a non-cash charge

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

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

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

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

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

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### **Liquidity and Capital Resources**

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

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

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

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

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

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

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

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- upon exercise, assuming the market price of our common stock is then \$20.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$632 million, which could result in a tax benefit amount of approximately \$242 million payable to Endo Pharma LLC.
- upon exercise, assuming the market price of our common stock is then \$25.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$813 million, which could result in a tax benefit amount of approximately \$311 million payable to Endo Pharma LLC.
- upon exercise, assuming the market price of our common stock is then \$30.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$994 million, which could result in a tax benefit amount of approximately \$381 million payable to Endo Pharma LLC.

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

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

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

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

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

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

Contractual Obligations	Payment Due by Period						
	Total	2004	2005	2006	2007	2008	Thereafter
Operating Lease Obligations	27,690	2,648	2,920	2,952	2,805	2,812	13,553
Capital Lease Obligations	1,256	651	532	73			
Total	28,946	3,299	3,452	3,025	2,805	2,812	13,553

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



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

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

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

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

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

*Penwest Pharmaceuticals.* On March 18, 2003, we received notice from Penwest Pharmaceuticals (a collaboration partner of Endo with which Endo has an alliance agreement and with which Endo is developing its pipeline project, oxymorphone ER) that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of this product on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we are now be responsible for funding 100% of these remaining costs until such time as the FDA approves oxymorphone ER, at which time we will recoup from the royalties due to Penwest the full amount of what Penwest should have contributed had it not exercised such right. We believe that our cash and cash equivalents and cash flow from operating activities will be more than sufficient to meet our normal operating, investing and financing activities in the foreseeable future, including the funding of 100% of the costs to bring our pipeline products, including oxymorphone ER, to market.

*Cash and Cash Equivalents.* Our cash and cash equivalents totaled \$229.6 million at December 31, 2003. We believe that our (a) cash and cash equivalents, (b) cash flow from operations and (c) our credit facility (which has an available unused line of credit of \$75 million) will be sufficient to meet our normal operating, investing and financing requirements in the foreseeable future, including the funding of our pipeline projects in the event that our collaboration partners are unable or unwilling to fund their portion of any particular project. We may use a portion of our cash and cash equivalents for possible acquisitions and licensing opportunities.



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### **Recent Accounting Pronouncements**

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

Not applicable.

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

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

In addition, we evaluated our internal control over financial reporting, and there have been no changes in our internal control over financial reporting that occurred during the quarter covered by this report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART III**

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

#### **Directors**

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

#### **Executive Officers**

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

### **Item 11. *Executive Compensation***

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

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

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

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

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

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

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

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**PART IV**

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

(a) Documents filed as part of this Annual Report on Form 10-K

1. Consolidated Financial Statements: See accompanying Index to Consolidated Financial Statements.
2. Consolidated Financial Statement Schedule:

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

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

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(1) Accounts written-off.

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

(b) Reports on Form 8-K.

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

<u>Dates</u>	<u>Items</u>
October 23, 2003	7 and 12
November 12, 2003	7 and 9

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

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**SIGNATURES**

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

ENDO PHARMACEUTICALS HOLDINGS INC.  
(Registrant)

/S/ JEFFREY R. BLACK

\_\_\_\_\_  
Name: Jeffrey R. Black

Title: *Senior Vice President and Chief Financial Officer*

Date: March 15, 2004

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/S/ CAROL A. AMMON</u> Carol A. Ammon	Chairman, Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2004
<u>/S/ JEFFREY R. BLACK</u> Jeffrey R. Black	Senior Vice President, Chief Financial Officer & Treasurer (Principal Financial & Accounting Officer)	March 15, 2004
* _____ Brian T. Clingen	Director	March 15, 2004
* _____ Michael B. Goldberg	Director	March 15, 2004
* _____ Michael Hyatt	Director	March 15, 2004
* _____ Roger H. Kimmel	Director	March 15, 2004
* _____ Frank J. Loverro	Director	March 15, 2004

Clive A. Meanwell, M.D., Ph.D.

\* Director March 15, 2004

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Michael W. Mitchell

\* Director March 15, 2004

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Joseph T. O'Donnell, Jr.

\* Director March 15, 2004

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David I. Wahrhaftig

\*By: /S/ CAROLINE B. MANOGUE Attorney-in-fact, pursuant to a Power of March 15, 2004  
Caroline B. Manogue Attorney filed with this Report as Exhibit 24

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**INDEPENDENT AUDITORS' REPORT**

The Board of Directors and Stockholders  
Endo Pharmaceuticals Holdings Inc.

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

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Endo Pharmaceuticals Holdings Inc. and subsidiaries as of December 31, 2003 and 2002, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

As discussed in Notes 2 and 7 to the consolidated financial statements, the Company changed its method of accounting for goodwill and other intangible assets upon adoption of Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets*, effective January 1, 2002.

/s/ DELOITTE & TOUCHE LLP

Deloitte & Touche LLP  
Philadelphia, Pennsylvania  
March 15, 2004

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**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

	<u>2003</u>	<u>2002</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 229,573	\$ 56,902
Accounts receivable, net of allowance of \$1,106 and \$835 at December 31, 2003 and 2002, respectively	101,284	119,496
Inventories	50,450	35,516
Prepaid expenses	7,145	4,354
Deferred income taxes	85,144	41,219
	<u>473,596</u>	<u>257,487</u>
Total current assets	473,596	257,487
PROPERTY AND EQUIPMENT, Net	20,246	11,810
GOODWILL	181,079	181,079
OTHER INTANGIBLES, Net	42,043	36,755
DEFERRED INCOME TAXES	31,045	21,184
OTHER ASSETS	5,871	4,657
	<u>753,880</u>	<u>512,972</u>
TOTAL ASSETS	\$ 753,880	\$ 512,972
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 65,071	\$ 75,443
Accrued expenses	108,567	68,627
Income taxes payable	12,036	8,359
	<u>185,674</u>	<u>152,429</u>
Total current liabilities	185,674	152,429
OTHER LIABILITIES	589	7,851
COMMITMENTS AND CONTINGENCIES		
<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; 131,769,766 and 102,064,450 shares issued and outstanding in 2003 and 2002, respectively	1,318	1,021
Additional paid-in capital	691,631	547,249
Accumulated deficit	(124,612)	(194,402)
Accumulated other comprehensive loss	(720)	(1,176)
	<u>567,617</u>	<u>352,692</u>
Total Stockholders' Equity	567,617	352,692
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 753,880	\$ 512,972

See notes to consolidated financial statements.

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**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

	<u>2003</u>	<u>2002</u>	<u>2001</u>
NET SALES	\$595,608	\$398,973	\$251,979
COST OF SALES	135,671	98,857	74,891
<b>GROSS PROFIT</b>	<u>459,937</u>	<u>300,116</u>	<u>177,088</u>
<b>COSTS AND EXPENSES:</b>			
Selling, general and administrative	155,827	110,907	79,505
Research and development	51,024	56,823	38,994
Depreciation and amortization	6,272	3,142	49,234
Compensation related to stock options (primary selling, general and administrative)	144,524	34,659	37,253
Purchased in-process research and development	(6,966)	20,300	
Manufacturing transfer fee		9,000	
<b>OPERATING INCOME (LOSS)</b>	<u>109,256</u>	<u>65,285</u>	<u>(27,898)</u>
INTEREST EXPENSE, Net of interest income of \$660, \$1,155 and \$2,830, respectively	258	4,391	13,290
<b>INCOME (LOSS) BEFORE INCOME TAX (BENEFIT)</b>	<u>108,998</u>	<u>60,894</u>	<u>(41,188)</u>
INCOME TAX (BENEFIT)	39,208	30,081	(4,646)
<b>NET INCOME (LOSS)</b>	<u>\$ 69,790</u>	<u>\$ 30,813</u>	<u>\$ (36,542)</u>
<b>NET INCOME (LOSS) PER SHARE:</b>			
Basic	\$ .54	\$ .30	\$ (.40)
Diluted	\$ .53	\$ .30	\$ (.40)
<b>NET INCOME (LOSS) Pro Forma to Exclude Amortization of Goodwill and Workforce-in-Place:</b>			
Workforce-in-Place:	<u>\$ 69,790</u>	<u>\$ 30,813</u>	<u>\$ 3,203</u>
<b>NET INCOME (LOSS) PER SHARE Pro Forma to Exclude Amortization of Goodwill and Workforce-in-Place:</b>			
Basic	\$ .54	\$ .30	\$ .04
Diluted	\$ .53	\$ .30	\$ .04
<b>WEIGHTED AVERAGE SHARES</b>			
Basic	128,417	102,064	91,505
Diluted	132,439	102,126	91,505

See notes to consolidated financial statements.

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**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

	Number Of Shares	Common Stock at Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity	Comprehensive Income (Loss)
BALANCE, DECEMBER 31, 2000	89,138,950	891	385,955	(188,673)		198,173	
Issuance of Common Stock	12,925,000	130	96,108			96,238	
Compensation related to stock options			37,253			37,253	
Net loss				(36,542)		(36,542)	(36,542)
Comprehensive income (loss)							\$(36,542)
BALANCE, DECEMBER 31, 2001	102,063,950	1,021	519,316	(225,215)		295,122	
Repurchase of Warrants			(6,730)			(6,730)	
Exercise of options	500		4			4	
Unrealized gains (losses) on securities, net of tax					\$(1,176)	(1,176)	\$ (1,176)
Compensation related to stock options			34,659			34,659	
Net income				30,813		30,813	30,813
Comprehensive income							\$ 29,637
BALANCE, DECEMBER 31, 2002	102,064,450	\$1,021	\$547,249	\$(194,402)	\$(1,176)	\$352,692	
Issuance of Common Stock from exercise of warrants	29,687,602	297	(296)			1	
Compensation related to stock options			144,524			144,524	
Exercise of options	17,714		154			154	
Unrealized gains (losses) on securities, net of tax					456	456	456
Net income				69,790		69,790	69,790
Comprehensive income							\$ 70,246
BALANCE, DECEMBER 31, 2003	131,769,766	\$1,318	\$691,631	\$(124,612)	\$ (720)	\$567,617	

See notes to consolidated financial statements.

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**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

	<u>2003</u>	<u>2002</u>	<u>2001</u>
<b>OPERATING ACTIVITIES:</b>			
Net income (loss)	\$ 69,790	\$ 30,813	\$ (36,542)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	6,272	3,142	49,234
Purchased in-process research and development	(6,966)	20,300	
Accretion of promissory notes		4,627	5,449
Deferred income taxes	(53,774)	(8,730)	(4,701)
Amortization of deferred financing costs	398	390	3,603
Compensation related to stock options	144,524	34,659	37,253
Changes in assets and liabilities which provided (used) cash:			
Accounts receivable	18,212	(34,167)	(7,017)
Inventories	(14,934)	(7,750)	1,980
Other assets	(3,133)	(24,668)	(3,546)
Accounts payable	14,628	44,738	14,850
Accrued expenses	39,565	41,451	25,957
Income taxes payable	3,677	4,833	977
Other liabilities			(7,011)
	<u>218,259</u>	<u>109,638</u>	<u>80,486</u>
<b>INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	(12,159)	(3,084)	(6,546)
Purchase of DURECT common stock		(5,000)	
License fees	(32,500)		
Acquisition of BML Pharmaceuticals		(14,190)	
Other investments	(500)		
	<u>(45,159)</u>	<u>(22,274)</u>	<u>(6,546)</u>
<b>FINANCING ACTIVITIES:</b>			
Issuance of Common Stock			96,238
Capital Lease Obligations Repayments	(584)	(204)	
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options and Warrants	155	4	
Repurchase of Class A Transferable and Class B Non- Transferable Warrants		(6,730)	
Repayments of long-term debt		(118,889)	(134,017)
	<u>(429)</u>	<u>(125,819)</u>	<u>(37,779)</u>
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>172,671</b>	<b>(38,455)</b>	<b>36,161</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>56,902</b>	<b>95,357</b>	<b>59,196</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 229,573</b>	<b>\$ 56,902</b>	<b>\$ 95,357</b>
<b>SUPPLEMENTAL INFORMATION:</b>			
Interest paid	\$ 378	\$ 384	\$ 7,065
Income taxes paid	\$ 84,751	\$ 33,978	\$ 3,031

SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

Promissory notes issued under Manufacturing and Supply Agreement	—	\$ 23,000	\$ 21,301
Purchase of property and equipment financed by capital leases	\$ 391	\$ 1,312	—

See notes to consolidated financial statements.

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### ENDO PHARMACEUTICALS HOLDINGS INC.

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

##### 1. Organization and Acquisitions

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

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

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

##### 2. Summary of Significant Accounting Policies

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

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

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

*Revenue Recognition* — Our net sales consist of revenues from sales of our pharmaceutical products, less estimates for certain chargebacks, sales allowances, the cost of returns and losses. We recognize revenue when products are shipped and title and risk of loss has passed to the customer, which is typically upon delivery to the customer. Our shipping terms are free on board customer’s destination. We estimate the accrual for sales deductions based on historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with our wholesale and indirect customers and other competitive factors. Our revenue recognition policies are in accordance with Staff Accounting Bulletin No. 101 (“SAB 101”) and Staff Accounting Bulletin No. 104 (“SAB 104”).

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

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

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

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

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

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

*Property and Equipment* — Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed over the estimated useful lives of the related assets on a straight-line basis. Machinery and equipment are depreciated over three to ten years, computer equipment over thirty months to five years, and furniture and fixtures over three to seven years. Computer software and related third-party design, development and implementation fees that benefit future periods are capitalized and amortized using the straight-line method over a useful life of three to five years.

*License Rights* — Licenses are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives ranging from thirteen to twenty years. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the license and an acceleration of related amortization expense, which could cause our operating income, net income and earnings per share to decrease. Licenses are assessed periodically for impairment in accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of* (SFAS No. 144). The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs.

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



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

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

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

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

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

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

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

	Years Ended December 31		
	2003	2002	2001
Net income (loss)	\$ 69,790	\$ 30,813	\$(36,542)
APB 25 Compensation Expense	144,524	34,659	37,253
Tax effect of APB 25 compensation expense	(55,536)	(13,274)	(14,268)
SFAS 123 compensation expense	(80,116)	(5,495)	(2,998)
Tax effect of SFAS 123 compensation expense	30,786	2,104	1,148
Net income (loss) pro forma	\$109,448	\$ 48,807	\$(15,407)
Basic earnings (loss) per share as reported	\$ .54	\$ .30	\$ (.40)
Basic earnings (loss) per share pro forma	\$ .85	\$ .48	\$ (.17)
Diluted earnings (loss) per share as reported	\$ .53	\$ .30	\$ (.40)
Diluted earnings (loss) per share pro forma	\$ .83	\$ .48	\$ (.17)
Weighted average shares outstanding			
Basic	128,417	102,064	91,505
Diluted	132,439	102,126	91,505

**Use of Estimates** — The preparation of our financial statements in conformity with accounting principles generally accepted in the United States of America (generally accepted accounting principles) requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of

revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of sales deductions for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses.

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

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

*Comprehensive Income* — Comprehensive income includes all changes in equity during a period except those that resulted from investments by or distributions to a company's stockholders. Other comprehensive income (loss) refers to revenues, expenses, gains and losses that under generally accepted accounting principles are included in comprehensive income, but excluded from net income as these amounts are recorded directly as an adjustment to stockholders' equity. Our other comprehensive income (loss) is comprised of unrealized holding gains and losses, net of income taxes, on the 1.5 million shares of publicly traded common stock of DURECT that we own.

### *Recent Accounting Pronouncements*

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

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

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

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

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

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

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### **3. Acquisitions**

#### *BML Pharmaceuticals*

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

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

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

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

### **4. License and Collaboration Agreements**

#### *Hind Healthcare*

In November 1998, Endo entered into a license agreement (the “Hind License Agreement”) with Hind Healthcare Inc. (“Hind”) for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in the United States. Under the terms of the Hind License Agreement, Endo paid Hind approximately \$10 million (the “Hind License Fee”) based upon the achievement of certain milestones. Costs related to the Hind License Agreement are included in Other Intangible Assets at December 31, 2003. In addition, beginning on March 19, 2001, Endo pays Hind nonrefundable royalties based on net sales of the product. Royalties are recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. The royalty rate was 8% of net sales from March 19, 2001 through March 18, 2002 and is 10% of net sales from March 19, 2002 through the shorter of (1) the expiration of the last licensed patent or (2) November 20, 2011. During 2003 and 2002, we accrued \$19.9 million and \$9.1 million for these royalties to Hind, respectively, which were recorded as a reduction to net sales. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

#### *Lavipharm*

In November 1999, Endo entered into a collaboration agreement with Lavipharm Laboratories, Inc. pursuant to which Endo obtained exclusive worldwide rights to Lavipharm’s existing drug delivery technology platforms. Under the terms of this collaboration agreement, Endo paid an upfront license fee of \$1 million. In September 2001, we amended this agreement to limit its scope to one of Lavipharm’s existing drug delivery technologies in combination with two specific active drug substances. In January 2004, we

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

### *DURECT Corporation*

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

### *SkyePharma*

In December 2002, we entered into a Development and Marketing Strategic Alliance Agreement with SkyePharma, Inc. and SkyePharma Canada, Inc. relating to two of SkyePharma’s patented development products, DepoMorphine<sup>TM</sup> and Propofol IDD-D<sup>TM</sup> (collectively, the “Skye Products”). Under the terms of the Agreement, Endo received an exclusive license to the U.S. and Canadian marketing and distribution rights for the Skye Products, with options for certain other development products. In return, SkyePharma received a \$25 million upfront payment from Endo, which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We are amortizing this intangible asset over its useful life of 17 years. In addition, SkyePharma may receive milestone payments in addition to the \$25 million upfront payment of up to \$95 million which include total milestones of \$10 million for DepoMorphine<sup>TM</sup> through FDA approval. During 2003, we paid \$5 million to SkyePharma upon the acceptance by the FDA of the NDA for DepoMorphine<sup>TM</sup>. The milestone payments also include \$50 million for Propofol IDD-D<sup>TM</sup>, payable when the product successfully achieves certain regulatory milestones, including FDA approval. The total further includes a \$15 million milestone payable when net sales of DepoMorphine<sup>TM</sup> exceed \$125 million in a calendar year, and a \$20 million milestone payable when net sales of DepoMorphine<sup>TM</sup> exceed \$175 million in a calendar year. SkyePharma will also receive a share of each product’s sales revenue that will increase from 20% initially, to a maximum of 60%, of net sales as the Skye Products’ combined net sales achieve certain thresholds. In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, this agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require us to pay SkyePharma \$5.0 million.

### *Noven Pharmaceuticals, Inc.*

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

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### *EpiCept Corp.*

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

### *Other*

We have licensed from universities and other companies rights to certain technologies or intellectual property generally in the field of pain management. We are generally required to make upfront payments as well as other payments upon successful completion of regulatory or sales milestones. In addition, these agreements generally require us to pay royalties on sales of the products arising from these agreements. These agreements generally permit Endo to terminate the agreement with no significant continuing obligation.

## **5. Inventories**

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

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

## **6. Property and Equipment**

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

	<u>2003</u>	<u>2002</u>
Machinery and equipment	\$ 7,709	\$ 6,610
Computer equipment and software	10,727	8,617
Furniture and fixtures	12,917	4,116
	<u>31,353</u>	<u>19,343</u>
Less accumulated depreciation	(11,107)	(7,533)
Total	<u>\$ 20,246</u>	<u>\$11,810</u>

## **7. Goodwill and Other Intangibles**

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

	<u>December 31, 2003</u>	<u>December 31, 2002</u>
Goodwill	\$181,079	\$181,079
Amortizable Intangibles:		
Licenses	\$ 43,500	\$ 36,000

Patents	3,200	3,200
	<u>46,700</u>	<u>39,200</u>
Less accumulated amortization	(4,657)	(2,445)
	<u>\$ 42,043</u>	<u>\$ 36,755</u>

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

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negatively impacted should an impairment of goodwill occur.

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

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

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

	Year Ended December 31,		
	2003	2002	2001
	(in thousands, except per share data)		
Reported net income (loss)	\$69,790	\$30,813	\$(36,542)
Add back: Goodwill amortization	—	—	40,431
Add back: Amortization of workforce-in-place	—	—	5,948
Less: Pro forma income (tax) benefit	—	—	(6,634)
Adjusted net income (loss)	\$69,790	\$30,813	\$ 3,203
<b>Basic earnings (loss) per share:</b>			
Reported net income (loss)	\$ 0.54	\$ .30	\$ (.40)
Add back: Goodwill amortization	—	—	.44
Add back: Amortization of workforce-in-place	—	—	.07
Less: Pro forma income (tax) benefit	—	—	(.07)
Adjusted net income (loss)	\$ 0.54	\$ .30	\$ .04
<b>Diluted earnings (loss) per share:</b>			
Reported net (loss) income	\$ 0.53	\$ .30	\$ (.40)
Add back: Goodwill amortization	—	—	.44
Add back: Amortization of workforce-in-place	—	—	.07
Less: Pro forma income (tax) benefit	—	—	(.07)
Adjusted net income (loss)	\$ 0.53	\$ .30	\$ .04

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

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



## **8. Long-Term Debt**

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

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

### **Amended and Restated Credit Agreement**

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

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

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

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

### **Promissory Notes Payable to Bristol-Myers Squibb**

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

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

### **Interest Rate Cap**

Effective August 27, 2000, Endo entered into an interest rate cap agreement with a notional amount of \$70.0 million for the purpose of minimizing its exposure to fluctuations in interest rates. We do not enter into such transactions for trading or speculative purposes. The cost of this interest rate cap of \$350,000 was being amortized as a component of interest expense over the term of the agreement, which was scheduled to expire August 27, 2003. The agreement set a maximum LIBOR rate Endo would pay on the related notional amount of 8.0%. Effective January 1, 2001, the carrying value of this derivative financial instrument was marked to market for each reporting period with changes in the fair value reflected as an adjustment to earnings for the period presented. The carrying value of this derivative financial instrument was zero at December 31, 2001. The interest rate cap was extinguished in 2002.

## **9. Fair Value of Financial Instruments**

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

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

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



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

### 10. Income Taxes

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

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

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

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

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

Total gross deferred income tax liabilities	<u>(18,347)</u>	<u>(18,512)</u>
Valuation allowance	<u>(5,496)</u>	
Net deferred income tax asset	<u>\$116,189</u>	<u>\$ 62,403</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

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

### **11. Service Agreements**

We contract with various third party manufacturers and suppliers to provide us with our raw materials used in our products and finished goods including, among others, Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals), Novartis Consumer Health and Teikoku Seiyaku Pharmaceuticals. If for any reason we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products, this may have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

#### *Novartis Consumer Health, Inc.*

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

#### *Teikoku Seiyaku Co., Ltd.*

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

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### *General*

In addition to the material long-term manufacturing agreements described above, we have agreements with (1) UPS Supply Chain Management, Inc. (f/d/b/a Livingston Healthcare Services, Inc.) for customer service support, warehouse and distribution services and certain financial functions and (2) Kunitz and Associates Inc. for medical affairs. In addition, until December 31, 2003, we had an agreement with Ventiv Health U.S. Sales Inc. for sales promotion. We also have agreements and arrangements with various contract research organizations for our toxicology and clinical studies. These agreements continue through 2004, and contain options to renew. Although we have no reason to believe that these agreements will not be honored, failure by any of these third parties to honor their contractual obligations may have a materially adverse effect on our business, financial condition and results of operations.

## **12. Commitments and Contingencies**

### **License Agreements and Milestones**

#### *Penwest Pharmaceuticals*

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

#### *DURECT Corporation*

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

#### *SkyePharma, Inc.*

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

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

clinical plan, or (b) 30 days following Endo's receipt of the FDA  
EOPII meeting minutes and the timeline for the Phase III clinical  
plan

\$ 5,000



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

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

### *Noven Pharmaceuticals, Inc.*

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

### *EpiCept Corp.*

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

### *Life Sciences Opportunities Fund (Institutional) II, L.P.*

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

## Employment Agreements

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

## Leases

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

	Capital Leases	Operating Leases
2004	651	2,648
2005	532	2,920
2006	73	2,952
2007		2,805
2008		2,812
Thereafter		13,553

Total minimum lease payments	\$1,256	\$27,690
	<u>        </u>	<u>        </u>
Less: Amount representing interest	64	
	<u>        </u>	
Total present value of minimum payments	\$1,192	
	<u>        </u>	
Less: Current portion of such Obligations	604	
	<u>        </u>	
Long-term capital lease obligations	\$ 588	
	<u>        </u>	

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

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

### **Research Contracts**

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

### **Collaboration Agreements**

We have entered into certain collaboration agreements with third parties for the development of pain management products. These agreements require us to share in the development costs of such products and grant marketing rights to us for such products. If our third party partners are unable or unwilling to fund their portion of the collaboration project with us, this may adversely affect our results of operations and cash flows in the foreseeable future.

### **Contingencies**

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

### **13. Savings and Investment Plan**

On September 1, 1997, we established a defined contribution Savings and Investment Plan covering all employees. Employee contributions are made on a pre-tax basis under section 401(k) of the Internal Revenue Code (the "Code"). We match up to six percent of the participants' contributions subject to limitations under section 401(k) of the Code. Participants are fully vested with respect to their own contributions. Our contributions are generally fully vested after five years of continuous service. Effective January 1, 2002, participants are fully vested with respect to our contributions after three years of continuous service. Contributions by us amounted to \$1,376,000, \$954,000, and \$597,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

### **14. Stockholders' Equity**

#### **Common Stock**

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

#### **Preferred Stock**

The Board of Directors may, without further action by the stockholders, issue a series of Preferred Stock and fix the rights and preferences of those shares, including the dividend rights, dividend rates, conversion rights, exchange rights, voting rights, terms of redemption, redemption price or prices, liquidation preferences, the number of shares constituting any series and the designation of such series. As of December 31, 2003, no shares of Preferred Stock have been issued.

#### **Class A Transferable Warrants and Class B Non-Transferable Warrants**

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



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

### **Pre-Merger Endo Warrants**

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

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

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

Pursuant to the Algos merger and related recapitalization of the Company on July 17, 2000, the Endo Pharma LLC 2000 Supplemental Stock Option Plans were established. The Endo Pharma LLC 2000 Supplemental Stock Option Plans reserve an aggregate of 10,672,314 shares of common stock of the Company held by Endo Pharma LLC for issuance. The Endo Pharma LLC 2000 Supplemental Stock Option Plans were only effective on January 1, 2003 in the event that we had not received the approval from the U.S. Food and Drug Administration for MorphiDex® for the treatment of pain by December 31, 2002. Stock options granted under the Endo Pharma LLC 2000 Supplemental Stock Option Plans expire no later than December 31, 2012 unless an initial public offering of the Company common stock held by Endo Pharma LLC occurs, in which case the stock options granted will expire on August 26, 2007.

The Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective on January 1, 2003, resulting in the issuance of 10,672,314 million stock options to certain employees and members of management. Because approximately 9,188,186 million of these stock options were immediately vested upon their issuance, the Company recorded a non-cash compensation charge of approximately \$48.5 million in the first quarter of 2003 for the difference between the market price of the common stock of \$7.70 and the weighted average exercise price of these stock options of \$2.42. No additional shares of Company common stock will be issued, however, because these stock options are exercisable only into shares of Company common stock that are held by Endo Pharma LLC. Accordingly, these stock options do not dilute the public shareholders.

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

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



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

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

### Options Outstanding

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

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

Option Class	Common Stock Closing Price Threshold
C1A and C1B	\$ 4.28
C2	\$ 6.62
C3	\$10.58
C4	\$17.29

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

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

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

estimated difference in the market price and the exercise price of the vested stock options.

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

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



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

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

### Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan

On August 11, 2000, we established the 2000 Stock Incentive Plan (“2000 Stock Incentive Plan”). The 2000 Stock Incentive Plan reserves an aggregate of 4,000,000 shares of common stock of the Company for issuance to employees, officers, directors and consultants. The 2000 Stock Incentive Plan provides for the issuance of stock options, restricted stock, stock bonus awards, stock appreciation rights or performance awards. As of December 31, 2003, only stock options have been awarded. Stock options granted under the 2000 Stock Incentive Plan expire ten years from the date of grant. As of December 31, 2003, stock options outstanding under the 2000 Stock Incentive Plan were exercisable into 776,719 shares.

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

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2000	391,250	\$ 7.20
Granted	605,712	\$ 8.85
Forfeited	(59,351)	\$ 7.45
Outstanding, December 31, 2001	937,611	\$ 8.25
Granted	1,069,455	\$ 9.93
Exercised	(500)	\$ 7.25
Forfeited	(21,343)	\$ 9.38
Outstanding, December 31, 2002	1,985,223	\$ 8.82
Granted	1,441,290	\$15.90
Exercised	(17,714)	\$ 8.74
Forfeited	(78,621)	\$ 9.95
Outstanding, December 31, 2003	3,330,179	\$11.86

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

### 2000 Stock Incentive Plan Options Outstanding

Number Outstanding at 12/31/03	Weighted Average Remaining Contractual Life	Range of Exercise Prices
1,814,269	8.2	\$ 6.47-\$9.50
125,810	8.6	\$ 9.51-\$12.50
1,030,625	9.7	\$12.51-\$15.50

204,873	8.7	\$15.51-\$18.50
154,602	9.6	\$18.51-\$20.80

## 15. Earnings Per Share

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

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

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

## 16. Related Party Transactions

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

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

- upon exercise, assuming the market price of our common stock is then \$20.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$632 million, which could result in a tax benefit amount of approximately \$242 million payable to Endo Pharma LLC.
- upon exercise, assuming the market price of our common stock is then \$25.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$813 million, which could result in a tax benefit amount of approximately \$311 million payable to Endo Pharma LLC.
- upon exercise, assuming the market price of our common stock is then \$30.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$994 million, which could result in a tax benefit amount of approximately \$381 million payable to Endo Pharma LLC.

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

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

### 17. Quarterly Financial Data (Unaudited)

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

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share data)			
<b>2002(2)</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

- (1) Operating income (loss) and net income (loss) for the year ended December 31, 2003 and the quarter ended March 31, 2003 included charges of \$48.5 million for compensation related to stock options. Operating income (loss) and net income (loss) for the year ended December 31, 2003 and the quarter ended December 31, 2003 included charges of \$96.0 million for compensation related to stock options and charges of \$24.6 million for an inventory reserve for extended-release oxycodone tablets and a \$7.0 million gain for purchased in-process research and development.
- (2) Operating income (loss) and net income (loss) for the year ended December 31, 2002 and the quarter ended September 30, 2002 included charges of \$40.4 million for compensation related to stock options, \$13.3 million for purchased in-process research and development and \$9.0 million for a manufacturing transfer fee. Operating income (loss) and net income (loss) for the year ended December 31, 2002 and the quarter ended December 31, 2002 included charges of \$8.0 million for an inventory reserve for extended-release oxycodone tablets, an adjustment to the non-cash compensation charge taken in the third quarter of \$5.7 million

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

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### Exhibit Index

Exhibit No.	Title
3.1	Amended and Restated Certificate of Incorporation of Endo Pharmaceuticals Holdings Inc. (“Endo”) (incorporated herein by reference to Exhibit 3.1 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
3.2	Amended and Restated By-laws of Endo (incorporated herein by reference to Exhibit 3.2 of the Form 10-Q for the Quarter ended March 31, 2003 filed with the Commission on May 14, 2003)
4.1	Amended and Restated Executive Stockholders Agreement, dated as of July 7, 2003, by and among Endo, Endo Pharma LLC (“Endo LLC”), Kelso Investment Associates V, L.P. (“KIA V”), Kelso Equity Partners V, L.P. (“KEP V”) and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended June 30, 2003 filed with the Commission on August 14, 2003)
4.2	Amended and Restated Employee Stockholders Agreement, dated as of June 5, 2003, by and among Endo, Endo LLC, KIA V, KEP V and the Employee Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.2 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
4.3	[Intentionally Omitted.]
4.4	Registration Rights Agreement, dated as of July 17, 2000, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 4.4 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.5	Amendment to Registration Rights Agreement, dated as of June 30, 2003, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 10.1 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
10.1	[Intentionally Omitted.]
10.2	[Intentionally Omitted.]
10.3	[Intentionally Omitted.]
10.4	[Intentionally Omitted.]
10.5	Tax Sharing Agreement, dated as of July 17, 2000, by and among Endo, Endo Inc. and Endo LLC (incorporated herein by reference to Exhibit 10.5 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
10.6	[Intentionally Omitted.]
10.7	Amended and Restated Credit Agreement, dated as of December 21, 2001, by and between Endo, Endo Pharmaceuticals, the Lenders Party Thereto and JPMorgan Chase Bank (incorporated by reference to Exhibit 10.7 of the Annual Report on Form 10-K for the Year Ended December 31, 2001 filed with the Commission on March 29, 2002)
10.8	[Intentionally Omitted.]
10.9	[Intentionally Omitted.]
10.10	Sole and Exclusive License Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals Inc. (“Endo

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- Pharmaceuticals”) and Hind Health Care, Inc. (incorporated herein by reference to Exhibit 10.10 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.11 Analgesic License Agreement, dated as of October 27, 1997, by and among Endo Pharmaceuticals, Endo Laboratories, LLC and DuPont Merck Pharmaceutical (incorporated herein by reference to Exhibit 10.11 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.12 Anti-Epileptic License Agreement, dated as of October 27, 1997, by and among Endo Pharmaceuticals, Endo Laboratories, LLC and DuPont Merck Pharmaceutical (incorporated herein by reference to Exhibit 10.12 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.13 [Intentionally Omitted.]
- 10.14 Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd (incorporated herein by reference to Exhibit 10.14 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.15 Supply Agreement, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt Inc. (“Mallinckrodt”) (incorporated herein by reference to Exhibit 10.15 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.16 Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.17 Manufacture and Supply Agreement, dated as of August 26, 1997, by and among Endo Pharmaceuticals, DuPont Merck Pharmaceutical and DuPont Merck Pharma (n/k/a Bristol-Myers Squibb Pharma Company) (incorporated herein by reference to Exhibit 10.17 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.17.2 Amendment Agreement effective August 27, 2002 by and between Endo Pharmaceuticals and Bristol-Myers Squibb Pharma Company as successor-in-interest to DuPont Pharmaceuticals Company formerly known as The DuPont Merck Pharmaceutical Company (incorporated herein by reference to Exhibit 10.17.2 of the Current Report on Form 8-K dated August 27, 2002)
- 10.18 Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, by and between Endo Pharmaceuticals and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 10.18 of the Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2002 filed with the Commission on May 14, 2002)
- 10.19 Agreement, dated as of February 1, 2000, by and between Endo Pharmaceuticals and UPS Supply Chain Management, Inc. (f/d/b/a Livingston Healthcare Services Inc.) (incorporated herein by reference to Exhibit 10.19 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.20 Medical Affairs Support Services Agreement, dated as of June 1, 1999, by and between Endo Pharmaceuticals and Kunitz and Associates, Inc. (incorporated herein by reference to Exhibit 10.20 of the Registration Statement filed with the Commission on June 9, 2000)
- \*10.21 Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.21 of the



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- Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
- \*10.22 Endo LLC Amended and Restated 1997 Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.22 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
- \*10.23 Endo LLC Amended and Restated 1997 Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.23 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
- \*10.24 Endo LLC 2000 Amended and Restated Supplemental Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.24 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
- \*10.25 Endo LLC 2000 Amended and Restated Supplemental Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.25 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
- \*10.26 Employment Agreement, dated as of July 17, 2000, by and between Endo and John W. Lyle (incorporated herein by reference to Exhibit 10.26 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 14, 2000)
- \*10.27 Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and Carol A. Ammon (incorporated herein by reference to Exhibit 10.27 of the Current Report on Form 8-K dated August 31, 2001)
- \*10.28 Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and Jeffrey R. Black (incorporated herein by reference to Exhibit 10.28 of the Current Report on Form 8-K dated August 31, 2001)
- \*10.29 Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and David Allen Harvey Lee, MD, Ph.D. (incorporated herein by reference to Exhibit 10.29 of the Current Report on Form 8-K dated August 31, 2001)
- \*10.30 Amended and Restated Employment Agreement, dated as September 1, 2001, by and between Endo Pharmaceuticals and Mariann T. MacDonald (incorporated herein by reference to Exhibit 10.30 of the Current Report on Form 8-K dated August 31, 2001)
- 10.31 Separation and Release Agreement, dated as of March 22, 2000, by and between Endo Pharmaceuticals, Endo and Osagie O. Imasogie (incorporated herein by reference to Exhibit 10.31 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.32 Separation and Release Agreement, dated as of April 20, 2000, by and between Endo Pharmaceuticals, Endo and Louis J. Vollmer (incorporated herein by reference to Exhibit 10.32 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.33 [Intentionally Omitted.]
- 10.34 Lease Agreement, dated as of May 5, 2000, by and between Endo Pharmaceuticals and Painters' Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34 of

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- the Registration Statement filed with the Commission on June 9, 2000)
- \*10.35 Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo and Caroline B. Manogue (formerly Berry) (incorporated herein by reference to Exhibit 10.35 of the Current Report on Form 8-K dated August 31, 2001)
  - \*10.36 Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo and Peter A. Lankau (incorporated herein by reference to Exhibit 10.36 of the Current Report on Form 8-K dated August 31, 2001)
  - 10.37 [Intentionally Omitted.]
  - 10.38 [Intentionally Omitted.]
  - 10.39 Master Development and Toll Manufacturing Agreement, dated as of May 3, 2001, by and between Novartis Consumer Health, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.39 of the Form 10-Q for the Quarter Ended June 30, 2001 filed with the Commission on August 14, 2001)
  - 10.40 [Intentionally Omitted.]
  - 10.41 Service Agreement, dated as of February 1, 2001, by and between Endo Pharmaceuticals and Ventiv Health U.S. Sales Inc. (incorporated herein by reference to Exhibit 10.41 of the Current Report on Form 8-K dated August 31, 2001)
  - 10.42 Development, Commercialization and Supply License Agreement, dated as of November 8, 2002, by and between DURECT Corporation and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.42 of the Current Report on Form 8-K dated November 14, 2002)
  - 10.42.2 Amendment to Development, Commercialization and Supply License Agreement, dated January 28, 2004, between DURECT Corporation and Endo Pharmaceuticals
  - 10.43 Development and Marketing Strategic Alliance Agreement, dated as of December 31, 2002, by and among Endo Pharmaceuticals, SkyePharma, Inc. and SkyePharma Canada, Inc. (incorporated herein by reference to Exhibit 10.43 of the Current Report on Form 8-K dated January 8, 2003)
  - 10.43.2 Amendment to Development and Marketing Strategic Alliance Agreement, dated March 2, 2004, between Endo Pharmaceuticals, SkyePharma, Inc. and SkyePharma Canada, Inc.
  - 10.44 Lease Agreement, dated as of January 6, 2003, by and between Endo Pharmaceuticals and Dawson Holding Company (incorporated by reference to Exhibit 10.44 of the Annual Report on Form 10-K for the Year Ended December 31, 2002 filed with the Commission on March 27, 2003)
  - 10.45 Lease Agreement, dated as of November 13, 2003, by and between Endo Pharmaceuticals and Painters' Crossing Two Associates, L.P.
  - 10.46 License Agreement, dated as of February 25, 2004, by and between Endo Pharmaceuticals and Noven Pharmaceuticals, Inc.†
  - 10.47 Supply Agreement, dated as of February 25, 2004, by and between Endo Pharmaceuticals and Noven Pharmaceuticals, Inc.†
    - 21 Subsidiaries of the Registrant
    - 23 Independent Auditors' Consent
    - 24 Power of Attorney
  - 31.1 Certification of the Chairman and Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
  - 31.2 Certification of the Chief Financial Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
  - 32.1 Certificate of the Chairman and Chief Executive Officer of Endo

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- pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certificate of the Chief Financial Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

- 
- \* A management contract or compensatory plan or arrangement required to be filed as an Exhibit pursuant to Item 15(c) of Form 10-K.
- † Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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<DESCRIPTION> AMENDMENT TO AGREEMENT DATED 1/28/04  
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January 28, 2004

BY FACSIMILE AND EXPRESS MAIL  
CONFIDENTIAL  
Peter A. Lankau  
President  
Endo Pharmaceuticals Inc.  
100 Painters Drive  
Chadds Ford, PA 19317

Re: Amendment to Development, Commercialization and Supply License Agreement

Dear Peter:

Reference is made to the Development, Commercialization and Supply License Agreement between Endo Pharmaceuticals Inc. ("Endo") and DURECT Corporation ("DURECT") effective November 8, 2002 ("Agreement"). Effective on the date written above, Endo and DURECT hereby agree as follows:

1. Amendment to Section 4.6(a). Section 4.6(a) of the Agreement shall be amended to change "June 30, 2004" to "January 1, 2005".
2. Restatement of Section 4.6(c). Section 4.6(c) of the Agreement shall be deleted in its entirety, and in lieu thereof, the following shall be inserted:

"(c) Notwithstanding anything to the contrary in Sections 4.6(a) and (b) and except as set forth in this Section 4.6(c), Endo shall have no obligations under Sections 4.6(a) and (b) to make any payments to DURECT for any Development Costs incurred up to and including the date on which the first patient is dosed with the Product in the first clinical trial of at least that number of patients necessary to satisfy the FDA which occurs after the Effective Date (such date, the "Trial Commencement Date" and such trial, the "First Trial"). Notwithstanding the foregoing: (i) in the event the Trial Commencement Date has not occurred by December 31, 2003, then during the period commencing on January 1, 2004 until the earlier of the Trial Commencement Date or January 1, 2005, Endo shall be responsible for 25% of the Development Costs incurred in each such calendar month, up to an aggregate payment by Endo to DURECT of \$250,000 of Development Costs for such period; and (ii) in the event the

Trial Commencement Date has not occurred on or before January 1, 2005, then Endo shall be responsible for such portion of the Development Costs incurred after January 1, 2005 in accordance with Section 4.6(a). Furthermore, until the Trial Commencement Date, DURECT hereby agrees to initiate any human trial only if such trial and the initiation thereof is consistent with a reasonable pharmaceutical company's overall global strategic development plan for a product similarly situated to the Product. Finally, in no event shall Endo be liable for any costs associated with any human pharmacokinetic (PK) study undertaken by DURECT prior to the earlier of the Trial Commencement Date or January 1, 2005."

3. Restatement of Section 13.3(d). Section 13.3(d) of the Agreement shall be deleted in its entirety, and in lieu thereof, the following shall be inserted:

"(d) [INTENTIONALLY OMITTED.]"

4. Restatement of Section 13.3(e). Section 13.3(e) of the Agreement shall be deleted in its entirety, and in lieu thereof, the following shall be inserted:

"(e) In the event that the Trial Commencement Date shall not have occurred on or before January 1, 2005, Endo shall have the right to terminate this Agreement effective upon 10 days' written notice with no further rights or obligations hereunder (other than those rights or obligations which are expressly indicated herein to survive termination or expiration of this Agreement); provided that such written notice is delivered to DURECT no later than January 31, 2005."

5. New Section 4.10. A new Section 4.10 shall be added to the Agreement as follows:

"4.10 Retention of Key Personnel. DURECT shall use its reasonable efforts to retain key personnel involved with the development of the Product. Such key personnel shall be those individuals identified as such by the JEC. In the event that a member of the key personnel leaves the employ of DURECT (either on his/her own volition or otherwise), DURECT shall, within three (3) business days of such departure, inform

Endo of (1) such fact and (2) DURECT's plan as to how it intends to address the departure of such key personnel to ensure the smooth continuance of the Development Program."

Except as set forth above, all other terms of the Agreement shall remain the same. Please sign below to indicate Endo's agreement to the foregoing.

Very truly yours,

/s/ JAMES E. BROWN

James E. Brown  
President and CEO

AGREED TO BY ENDO:

By: /s/ PETER A. LANKAU

-----  
Peter A. Lankau  
President

Date: January 28, 2004

</TEXT>  
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[ENDO LOGO]  
100 Painters Dr.  
Chadds Ford, PA 19317  
610-558-9800  
www.endo.com

Exhibit 10.43.2

March 2, 2004

BY FACSIMILE & OVERNIGHT MAIL  
Michael Ashton  
SkyePharma, Inc.  
105 Piccadilly  
London W1J 7NJ  
England

Dear Michael:

Reference is hereby made to that certain Development and Marketing Strategic Alliance Agreement, dated as of December 31, 2002 (as amended, the "Agreement"), among Endo Pharmaceuticals Inc. ("Endo"), SkyePharma, Inc. and SkyePharma Canada Inc. (collectively, "Skye"). Defined terms used but not defined herein shall have the meanings set forth in the Agreement.

The purpose of this letter is to amend and restate the fifth milestone on the chart set forth in Section 4.2 of the Agreement which milestone relates to the FDA's written approval and acceptance of the protocol of the first of the Phase III clinical trials for Propofol IDD-D in the United States (the "Propofol Protocol Milestone"). Now for good and valuable consideration, the sufficiency and receipt of which is hereby acknowledged, the Parties agree that the Propofol Protocol Milestone is amended and restated as follows:

<TABLE>

<S>  
With respect to Propofol IDD-D, upon the earlier of (a) the JEC's approval of the FDA protocol submission package, which shall follow Endo's receipt of both the FDA end-of-Phase II (EOPII) meeting minutes and the timeline for the Phase III clinical plan, or (b) 30 days following Endo's receipt of the FDA EOPII meeting minutes and the timeline for the Phase III clinical plan.

<C> Two (2) days following occurrence of Milestone Event  
<C> \$5,000,000

</TABLE>

<PAGE> 2

Michael Ashton  
SkyePharma, Inc.  
March 2, 2004  
Page Two

Other than as set forth in this letter agreement, all other terms and conditions of the Agreement remain the same and in full force and effect.

If Skye is in agreement with the above, please have a duly authorized, appropriate officer countersign this letter below.

Very truly yours,  
/S/ CAROL A. AMMON  
Carol A. Ammon

ACCEPTED AND AGREED THIS 2nd DAY OF MARCH 2004:

SKYEPHARMA, INC.

By /s/ MICHAEL ASHTON

-----  
Name: Michael Ashton  
Title: CEO

SKYEPHARMA CANADA INC.

By /s/ MICHAEL ASHTON

-----  
Name: Michael Ashton  
Title: Director

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LEASE REFERENCE DATA

LANDLORD: PAINTERS' CROSSING TWO ASSOCIATES, L.P.

TENANT: ENDO PHARMACEUTICALS INC.

LOCATION: LOT # 3, PAINTERS' CROSSING TWO BUILDING, PAINTERS' CROSSING OFFICE CAMPUS, DELAWARE COUNTY, PA

ANNUAL BASE RENT: OFFICE SPACE (58,233 SQ. FT.):

YEARS 1 - 5: \$1,310,242.50 PER YEAR (\$109,186.87 PER MONTH, \$22.50 PER SQUARE FOOT) NET OF ELECTRICITY.

YEARS 6 - 10: \$1,505,323.05 PER YEAR (\$125,443.59 PER MONTH, \$25.85 PER SQUARE FOOT) NET OF ELECTRICITY

BASEMENT SPACE (6,191 SQ. FT.):

YEARS 1 - 5: \$121,343.60 PER YEAR (\$10,111.97 PER MONTH, \$19.60 PER SQUARE FOOT) NET OF ELECTRICITY.

YEARS 6 - 10: \$137,749.75 PER YEAR (\$11,479.15 PER MONTH, \$22.25 PER SQUARE FOOT) NET OF ELECTRICITY

OPERATING EXPENSE ALLOWANCE: \$402,650.00 PER YEAR (\$6.25 PER SQUARE FOOT)

SCHEDULED COMMENCEMENT DATE: OCTOBER 1, 2004

OCCUPATION: COMMENCEMENT DATE  
RENT: COMMENCEMENT DATE

DEMISED TERM: TEN (10) YEARS BEGINNING ON THE COMMENCEMENT DATE FOR THE DEMISED TERM.

SECURITY DEPOSIT: \$238,597.68 (REPRESENTING TWO (2) MONTHS RENT)

TENANT'S PRO RATA SHARE: 100% (64,424 SQUARE FEET DIVIDED BY 64,424 SQUARE FEET)

This Reference Data Section is intended to be a short summary of certain of the business terms for quick reference. It is not intended to be a part of the Lease. If there is any inconsistency between the Reference Data and the Lease Agreement, the Lease Agreement shall control.

LEASE AGREEMENT

Endo Pharmaceuticals Inc.  
Confidential

THIS AGREEMENT, made the 13th day of November, two thousand and three (2003), by and between PAINTERS' CROSSING TWO ASSOCIATES, L.P., (hereinafter called "Landlord"), of the one part, and ENDO PHARMACEUTICALS INC., (hereinafter called "Tenant"), a Corporation, (incorporated in Delaware), of the other part.

1. DEMISED PREMISES.

Landlord does hereby demise and let unto Tenant Lot # 3, containing approximately five plus/minus (5+/-) acres, 200 Painters' Drive, in the Painters' Crossing Office Campus including a building to be constructed thereon to be known as Painter's Crossing Two Building ("Building") consisting of approximately 64,424 square feet as shown on Exhibit "A" attached hereto and made a part hereof (hereinafter called Demised Premises) in the Township of Chadds Ford, the County of Delaware, in the Commonwealth of Pennsylvania, to be used and occupied as office space and for no other purpose.

2. TERM.

a. Term. The Lease shall be for a term of ten (10) years (hereinafter called "Demised Term") beginning on the "Commencement Date", as hereinafter defined, and ending on the last day of the 120th full month following the Commencement Date ("Expiration Date"), at the rent as hereinafter set forth.

b. Commencement Date. The Commencement Date shall be the date Landlord delivers possession of the Demised Premises to Tenant but no sooner than October 1, 2004.

If the Commencement Date would be on a Saturday, Sunday or a holiday, the Commencement Date shall be the first business day following such Saturday, Sunday or holiday. Within thirty (30) days after the Commencement Date, the parties shall confirm in writing the Commencement Date and the Expiration Date.

c. Substantial Completion. "Substantially Complete" shall mean (but be no sooner than October 1, 2004): (I) the completion of improvements to the Demised Premises in accordance with the Plans ("Improvements") (a) so that Tenant can use the Demised Premises for its intended purposes, and (b) the incomplete items shall be minor (for example, touch up plastering and painting of walls and ceilings, missing, chipped or broken fixtures, carpet repair or cleaning, mechanical adjustments to HVAC system and other similar Punchlist items); (ii) the Landlord has obtained a

permanent certificate of occupancy; (iii) the Common Area Facilities are fully usable by tenant and (iv) the Demised Premises is in broom clean condition.

d. Inspection and Punchlist. After notice from Landlord of Substantial Completion, the parties shall inspect the Demised Premises and prepare a Punchlist of any items not completed in accordance with the Plans. Landlord will cause the contractor to complete the items on the Punchlist within thirty (30) days after the Commencement Date, provided that workmen and the necessary materials are available, but in no event shall such completion take longer than sixty (60) days; except for items which are incomplete because of special order requested by Tenant, and Landlord shall complete such special order items within thirty (30) days of receipt. This section does not apply to change order items. If such Punchlist items are not completed within sixty (60) days, Tenant may complete such items and bill Landlord for the cost. Landlord will be required to reimburse Tenant within thirty (30) days of receipt of such bill.

e. Notice. Landlord shall give Tenant ten (10) days notice of the estimated Substantial Completion date if it will be different from October 1, 2004 ("Commencement Date"), and Landlord shall be entitled to a corresponding extension of time to complete such Improvements. If the estimated Substantial Completion date changes at any time after Landlord has previously given notice, then Landlord shall give an additional ten (10) days advance written notice of the new estimated Substantial Completion date with the corresponding extension of time. In the case of an emergency causing delays in the last ten (10) days prior to the Commencement Date, Landlord shall give such notice as is reasonably possible.

### 3. SECURITY DEPOSIT.

The Tenant has deposited with the Landlord, at the signing of this Lease, the sum of Two Hundred Thirty Eight Thousand Five Hundred Ninety Seven and 68/100 Dollars (\$238,597.68) as security for the full and faithful performance by the Tenant of all the terms of this Lease required to be performed by the Tenant. The Landlord may not commingle the Security Deposit with its other funds or monies. Landlord shall establish an interest-bearing account on behalf of Tenant and shall deposit Tenant's security deposit in such account. The security deposit, plus interest, shall be returned to the Tenant after the expiration of this Lease, provided the Tenant has fully and faithfully carried out all of its terms. In the event of a bona fide sale of the Demised Premises, the Landlord shall have the right to transfer such security deposit to the purchaser to be held under the terms of this Lease, and the Landlord shall be released from all liability for the return of such security deposit to the Tenant.

4. ANNUAL BASE RENT.

During the first five (5) years of the Lease Term, the Annual Base Rent shall be One Million Four Hundred Thirty One Thousand Five Hundred Eighty Six and 10/100 Dollars (\$1,431,586.10) lawful money of the United States of America, payable in monthly installments in advance during the said term of this Lease, or any renewal hereof, in sums of One Hundred Nineteen Thousand Two Hundred Ninety Eight and 8/100 Dollars (\$119,298.84) on the first day of each month, rent to begin on the Commencement Date. Rent due and payable without demand, or offset at the office of Landlord (Attention: Accounting Department).

During the last five (5) years of the Lease Term, the Annual Base Rent shall be One Million Six Hundred Forty Three Thousand Seventy Two and 80/100 Dollars (\$1,643,072.80) lawful money of the United States of America, payable in monthly installments in advance during the said term of this Lease, or any renewal hereof, in sums of One Hundred Thirty Six Thousand Nine Hundred Twenty Two and 74/100 (\$136,922.74) on the first day of each month, rent to begin on the first day after five (5) years following the Commencement Date.

5. ESCALATION.

If Landlord's Operating Expense for any Operating Year shall be greater than the Operating Expense Allowance up to Six and 25/100 Dollars (\$6.25) per square foot Tenant shall pay to Landlord as additional rent the Operating Expense Adjustment, being the difference between the Operating Expense and the Operating Expense Allowance. If Tenant occupies the Demised Premises or portion thereof for less than a full Operating Year, the Operating Expense Adjustment will be calculated in proportion to the amount of time in such Operating Year that Tenant occupied the Demised Premises.

Such Operating Expense Adjustment shall be paid in the following manner: within one hundred twenty (120) days following the last day of the first and each succeeding Operating Year ("Expense Adjustment Date"), Landlord shall furnish Tenant an Operating Expense Statement as defined below. Within thirty (30) days following the receipt of such Operating Expense Statement, Tenant shall pay to Landlord as additional rent the Operating Expense Adjustment, if any, for such previous Operating Year. Commencing with the first month of the second Operating Year and each year thereafter, Tenant shall be obligated to pay to Landlord, on account of the Operating Expense Adjustment for such Operating Year, monthly installments in advance equal to one twelfth (1/12th) of Landlord's estimate of the Operating Expense Adjustment for such Operating Year ("Estimated Operating Expense Adjustment"). Landlord shall provide Tenant with

the Estimated Operating Expense Adjustment for the current year at the same time as Landlord provides Tenant with the Operating Expense Statement for the prior year. In the event that Tenant has not received the Estimated Operating Expense Adjustment statement prior to the commencement of the third month of the Operating Year, Tenant shall continue to pay the previous year's Operating Expense Adjustment. However, Tenant shall be obligated to pay Landlord's invoice for the monthly installment of Estimated Operating Expense Adjustment for the third month of the Operating Year (and the fourth month, if the Estimated Operating Expense Adjustment is not delivered by Landlord to Tenant before the beginning of the fourth month) within fifteen (15) days after delivery of the invoice for the Estimated Operating Expense Adjustment payments throughout the Operating Year and shall pay the eleventh and twelfth installments of the Operating Expense Adjustment during the first and second months of the succeeding Operating Year. On the next succeeding Expense Adjustment Date, Tenant shall pay to Landlord (or Landlord shall credit to Tenant) any deficiency (or excess) between the installments paid on account of the preceding year's Estimated Operating Expense Adjustment and the actual Operating Expense Adjustment for such Operating Year.

As used in this Paragraph 5 and Section 1 (Reference Data) where applicable, the following words and terms shall be defined as hereinafter set forth:

a. Operating Year. Shall mean each calendar year, or such other period of twelve (12) months as hereafter may be adopted by Landlord as its fiscal year, occurring during the Demised Term.

b. Operating Expense Allowance. Shall mean Four Hundred Two Thousand Six Hundred Fifty and 00/100 Dollars (\$402,650.00) per year, Six and 25/100 Dollars (\$6.25) per square foot. An estimate of the first year's operating costs is attached hereto as Exhibit "B".

c. Operating Expense Statement. Shall mean a statement in writing signed by Landlord, setting forth in reasonable detail (1) the Operating Expense for the preceding Operating Year, (2) the Operating Expense Allowance and (3) the Tenant's Operating Expense Adjustment for such Operating Year, if any, or portion thereof. The Operating Expense Statement shall constitute a final determination as between Landlord and Tenant of the Operating Expense and the Operating Expense Adjustment for any Operating Year.

d. Operating Expense. Shall mean the following expenses incurred by Landlord in connection with the operation, repair and maintenance of the building and land of which the Demised Premises is a part:



1. Wages, salaries, fees and other compensation and payments and payroll taxes and contributions to any social security, unemployment insurance, welfare, pension or similar fund and payments for other fringe benefits required by law or by union agreement (or, if the employees or any of them are nonunion, then payments for benefits comparable to those generally required by union agreement in first-class office buildings in the Philadelphia suburban area, which are unionized) made to or on behalf of all employees of Landlord performing services rendered in connection with the operation, maintenance, management and administration of the building and the land of which the Demised Premises is a part, including, without limitation, payments made directly to or through independent contractors for performance of such services.

2. Cleaning and maintenance costs for the building and the land of which the Demised Premises is a part, including the windows, sidewalks and parking lots, all snow and rubbish removal and lawn and grounds landscape care (including separate contracts therefor) and the costs of all labor, supplies, equipment and materials incidental thereto.

3. Real estate taxes and other taxes or charges levied in lieu of such taxes, general and special public assessments, charges imposed by any governmental authority pursuant to anti-pollution or environmental legislation, taxes on the rentals of the building of which the Demised Premises is a part, or the use, occupancy or renting of space therein.

4. Premiums and fees for fire and extended coverage insurance, insurance against loss of rentals for space in the building of which the Demised Premises is a part and public liability insurance, all in amounts and coverages (with additional policies against additional risks) as may be required by Landlord or the holder of any mortgage on the building of which the Demised Premises is a part.

5. Water and sewer service charges and other utility charges not separately metered to tenants in the building of which the Demised Premises is a part.

6. Building maintenance and repair costs, repairs and replacements of building supplies and equipment, snow and trash removal and paving (including parking lots), lawn and general grounds upkeep, maintenance and repair, and the costs of all labor, material and supplies incidental thereto.

7. Management fees in the amount of two percent (2%) payable to the managing agent for the building, if any, and if there shall be no managing agent or if the

managing agent is a company affiliated with Landlord, the management fees that would customarily be charged for the management of the building by an independent, first-class managing agent in the Philadelphia suburban area.

8. The cost of operating and maintaining any security system installed to protect the building of which the Demised Premises is a part and the tenants thereof.

9. Any regular or special assessments levied against the Building pursuant to any Declaration of Protective Covenants and Easements now or hereafter affecting the land on which the Building is located and any and all expenditures of Landlord in connection with the operation, repair or maintenance of the land or the building of which the Demised Premises is a part which are proper expenses in accordance with generally accepted accounting principles consistently applied with respect to the operation, repair and maintenance of the first-class office buildings in the Philadelphia suburban area.

Operating Expense shall be "net" and, for that purpose, shall be reduced by the amounts of 1) any reimbursement or credit received or receivable by Landlord with respect to an item of cost that is included in Operating Expense (other than reimbursements to Landlord by tenants of the building pursuant to Operating Expense escalation provisions) and 2) any cash, trade, or quantity discounts received by Landlord in connection with the purchase of any goods, utilities, or services in connection with the operation of the Demised Premises.

To the extent that any item of Operating Expense is incurred in common with another building or lot in the same office park of Landlord, such items of expense shall be apportioned equitably among the properties in such office park.

If Landlord shall eliminate the payment of any wages or other labor costs or otherwise reduce the Operating Expense as a result of the installation of new devices or equipment, or by any other means, then in computing the Operating Expense the corresponding items shall be deducted from the Operating Expense Allowance for the Operating Year.

e. Operating Expense Exclusions. Notwithstanding the foregoing, "Operating Expense" shall not include expenditures for any of the following:

1. The cost of any capital addition made to the building of which the Demised Premises is a part.

2. Replacements, repairs or other work occasioned by fire, windstorm or other insured casualty or hazard, to the extent that Landlord shall receive proceeds of such insurance.

3. Leasing commissions, advertising expenses and other costs incurred in leasing or procuring new tenants.

4. Repairs or rebuilding necessitated by condemnation.

5. Depreciation and amortization of the building of which the Demised Premises is a part.

6. The salaries and benefits of executive officers of Landlord, if any.

7. Electricity and other utilities costs separately metered to Tenant in the Demised Premises.

6. ADDITIONAL RENT.

a. Tenant agrees to pay as rent in addition to the Annual Base Rent herein reserved any and all sums which may become due by reason of Tenant's breach of Lease or the failure of Tenant to comply with all of the covenants of this Lease and any and all damages, costs and expenses, including attorney's fees, which the Landlord may suffer or incur by reason of any default of the Tenant or failure on Tenant's part to comply with the covenants of this Lease.

b. Tenant further agrees to pay to Landlord as additional rent all sums due for repairs made to the Demised Premises, replacing of glass windows, doors, partitions, electric wiring and electric lamps, etc., the keeping of waste and drain pipes open and repairs and replacements to wash basins and plumbing, heating and air-conditioning apparatus, which are necessitated by or caused by misuse or abuse by Tenant, its agents, employees, contractees, visitors and licensees. The same shall be paid by Tenant to Landlord within fifteen (15) days after presentation by Landlord to Tenant of bills therefor.

c. Landlord will provide one initial lamping upon occupancy of the space by Tenant; relamping will be provided and installed by Landlord and charged to the Building as a maintenance item which shall be paid by Tenant as additional rent.

7. TIME AND PLACE OF PAYMENT.

Unless provided otherwise herein, all Annual Base Rent shall be payable in advance without prior notice or demand and without any set off whatsoever at the office of Landlord (or at such other place as Landlord may from time to time designate by notice in writing) and at the times provided for the payment of the Annual Base Rent as set forth above in Paragraph 4. All payments of rent by Tenant may be applied to Base Rent, additional rent, interest or penalties, if any, as Landlord deems appropriate. With respect to additional rent, if any owed by Tenant, Tenant shall pay such additional rent within fifteen (15) days of receipt of a bill from Landlord for such rent.

8. IMPROVEMENT OF DEMISED PREMISES.

a. Landlord's Work. Landlord shall complete and prepare the Demised Premises for Tenant's initial occupancy in a good and workmanlike manner in accordance with Building Plans (Exhibit "C") to be attached hereto when completed utilizing a general contractor selected by Landlord. Exhibit "C" shall be initialed for acceptance by both Landlord and Tenant when completed.

b. Materials Used. Landlord shall use materials as outlined on a Schedule of Construction Specifications and Finishes (Exhibit "C1"), to be attached hereto when completed and which shall be initialed for acceptance by both Landlord and Tenant. Landlord reserves the right, however: (1) to make substitutions of material of equivalent grade and quality when and if any specified material shall not be readily and reasonably available, and (2) to make changes necessitated by conditions met in the course of construction, provided that Tenant's approval of any change shall first be obtained (which approval shall not be unreasonably withheld) so long as there shall be general conformity with Tenant's Improvement Plans and Tenant's intended use of the Demised Premises and which approval must be given or denied (with reasons stated in the case of denial) within forty-eight (48) hours after request or approval shall be conclusively deemed to have been given.

c. Tenant Fit-up Allowance. Tenant is hereby granted an allowance up to a maximum of Thirty Five and 00/100 Dollars (\$35.00) per square foot to be used for Tenant "fit-up" expense for the office space and Twelve and 00/100 Dollars (\$12.00) per square foot to be used for Tenant "fit-up" expense for the basement storage space based on plans and specifications to be approved by Landlord prior to the commencement of any work, all of which shall be performed by

Landlord. All plans and specifications prepared by Landlord's contractors or subcontractors at the direction of Landlord, including, but not limited to, design fees, preliminary fees, engineering plans and construction documents, shall be charged against this allowance. To the extent that the aforementioned expense exceeds the allowance, such excess expense shall be the sole responsibility of the Tenant. Tenant shall pay Landlord for such excess Tenant Fit-Up expense within fifteen (15) days after presentation of invoice for such costs by Landlord.

d. Landlord and Tenant assign the obligations to comply with the provisions of the Americans With Disabilities Act and the regulations issued pursuant thereto (collectively the "ADA") as follows:

(1) Tenant agrees to be responsible for compliance of the Demised Premises with the provisions of the ADA, including the removal of the barriers, ensuring access to areas of primary function, providing auxiliary aids and services to persons with disabilities which are needed for effective communication or for effective use, and compliance with other non-discriminatory requirements of the provisions of the ADA. In the event that Tenant desires to improve, alter or amend the Demised Premises so as to comply with the provisions of the ADA, Tenant shall so advise Landlord in seeking Landlord's approval and consent to make such improvements, alterations or amendments to the Demised Premises.

Tenant agrees to indemnify and hold the Landlord harmless from and against from any all liabilities, costs, expenses, fines and penalties, including reasonable attorneys' fees, that may be asserted against Landlord, including injury or death to persons and damages to property, and the cost of compliance with the provisions of the ADA, arising out of Tenant's failure to comply with its obligations under this paragraph.

(2) Landlord shall be responsible for the compliance of the parking lot, entrance to the building and of the common areas to the provisions of the ADA.

9. POSSESSION.

If the Landlord shall be unable to give possession of the Demised Premises within thirty (30) days after the Commencement Date, because a certificate of occupancy has not been procured, or for any other reason whatsoever, the payment of rent by Tenant shall not commence until possession of the Demised Premises is given to or the Demised Premises is available for occupancy by the Tenant. The failure to give possession on the Commencement Date shall not affect the validity of this Lease or the obligations of the Tenant hereunder, except as stated in this

paragraph, or extend the Demised Term of this Lease, provided, however, in the event Landlord is unable to give possession on or before December 31, 2004 then Tenant shall have the option of declaring the Lease terminated by giving Landlord written notification thereof by registered mail on or before January 15, 2005.

10. ALTERATIONS AND IMPROVEMENTS.

a. Tenant will not make any alterations, improvements or additions to or about the Demised Premises, or affix or attach any articles to or make any holes in or about the Demised Premises or the building of which the Demised Premises is a part without first having submitted plans for same to Landlord for its prior approval. If said plan receives Landlord's approval, Landlord alone will make or do the same on behalf of Tenant and for Tenant's benefit, solely at the cost, expense and risk of Tenant unless otherwise provided in writing; provided, however, that Tenant may make such minor alterations, improvements or additions to the Demised Premises such as hanging pictures or installing door hooks. All alterations, improvements, additions or fixtures, whether installed, made or placed before or after the execution of this Lease, shall remain upon the Demised Premises at the expiration or earlier termination of this Lease and become the property of Landlord unless Landlord shall, at the time Landlord approves such alterations give written notice to Tenant to remove the same at the expiration of the Lease term, in which event Tenant shall remove the same at the expiration of the Lease term and restore the Demised Premises to the same good order and condition in which it now is; provided, however, trade fixtures may be removed if there is no existing default under this Lease.

b. Tenant will not lay any linoleum, oil cloth, rubber or other air-tight covering upon the floors of the Demised Premises, nor fasten articles to or drill holes or drive nails or screws into the walls or partitions of the Demised Premises; nor will Tenant paint, paper or otherwise cover or in any way mark, deface or break said walls or partitions; nor make any attachment to the electric lighting wires of the Demised Premises or building of which the Demised Premises is a part for storing electricity, running electric fans or motors or other purposes; nor will Tenant use any method of heating other than that provided by Landlord provided that Tenant may make such alterations, additions, improvements, and/or repairs to the extent that such alterations, additions, improvements, and/or repairs do not exceed \$500.00 in cost. If Tenant desires to have telephone, telegraph or other similar wires and instruments installed on the Demised Premises, he shall notify Landlord, and Landlord will direct where and how the same are to be installed. Landlord reserves at all times the right to require Tenant to install and use in the Demised Premises such electrical protective devices and to change wires

and their placing and arrangement, as Landlord may deem necessary, and further, to require compliance on the part of all using or seeking access to such wires with such rules as Landlord may establish relating thereto; and further reserves, in the event of non-compliance with such requirements and rules, the right to cut and prevent the use of any wires to which such non-compliance relates.

c. No contract entered into or that may be subsequently entered into by Landlord with Tenant, relative to any alterations, additions, improvements or repairs, nor the failure of Landlord to make such alterations, additions, improvements or repairs as required by any such contract, nor the making by Landlord or his agents or contractors of such alterations, additions, improvements or repairs shall in any way affect the payment of the rent or said other charges at the time specified in this Lease.

d. Items of a decorative nature, such as small pictures, are not intended to be prohibited by this paragraph.

#### 11. SIGNS.

Tenant will not erect or place any sign, advertising matter, lettering, stand, booth, show case, or other matter of any kind in or upon the door, steps, vestibules, outside walls, outside windows or pavements of the building of which the Demised Premises is a part. Tenant will not place any sign, advertising matter, lettering, or other matter of any kind upon the doors giving access into the Demised Premises or upon the interior walls of the building of which the Demised Premises is a part without the prior written approval of Landlord. Notwithstanding the foregoing, after consultation with Landlord, Tenant may erect or place a sign containing its company logo on the exterior of the building providing it is in accordance with the Township ordinances and Tenant has obtained a permit therefor, if a permit is required. In addition, with the approval of Landlord, which approval shall not be unreasonably withheld, Tenant may erect a freestanding sign on the exterior of the Premises in accordance with the ordinance of the Township.

#### 12. MACHINERY, WEIGHTS, LOCKS, INSURANCE RISKS.

a. Tenant will not use or operate in the Demised Premises any machinery that is in Landlord's opinion harmful to the Demised Premises or building of which the Demised Premises is a part, or disturbing to tenants occupying other parts thereof. Normal office business machines are not intended to be prohibited by this clause.

b. Tenant will not place any weights in any portion of the Demised Premises which are in Landlord's opinion beyond the safe carrying capacity of the Demised Premises.

c. Tenant will not place any additional locks upon any doors of the Demised Premises or permit any duplicate keys to the locks therein to be made unless access and copies are given to Landlord.

d. Tenant shall not do or suffer to be done any act, matter or thing, or employ any person as a result of which the fire insurance or any other insurance now in force or hereafter to be placed on the Demised Premises, or any part thereof, or the building of which the Demised Premises are a part, shall become void or suspended, or whereby the same shall be rated as a more hazardous risk than at the date of execution of this Lease, or carry or have any benzine or explosive matter of any kind in and about the Demised Premises unless approved in advance in writing by Landlord.

13. REMOVAL OF GOODS.

a. Tenant will not remove or attempt to remove Tenant's goods or property from the Demised Premises otherwise than in the ordinary and usual course of business, without having first paid and satisfied Landlord for all rent which may be due or become due during the entire term of this Lease.

14. COVENANTS OF TENANT.

Tenant covenants and agrees that it will without demand:

a. Payment. Pay the rent and all other charges herein reserved as rent on the days and times and at the place that the same are made payable, without fail, and if Landlord shall at any time or times accept said rent or rent charges after the same shall have become due and payable, such acceptance shall not excuse delay upon subsequent occasions, or constitute or be construed as a waiver of any of Landlord's rights. Tenant agrees that any charge or payment herein reserved, included or agreed to be treated or collected as rent and/or any other charges or taxes, expenses, or costs herein agreed to be paid by the Tenant may be proceeded for and recovered by the Landlord in the same manner as rent due and in arrears.

b. Care of Demised Premises. Keep the Demised Premises in the same good order in which they now are, reasonable wear and tear and damage by accidental fire or other



casualty alone excepted. Upon completion of Tenant's inspection of the Demised Premises, Tenant shall acknowledge, in writing, that the Demised Premises are in good order, condition and repair and require no alterations, additions or improvements to be made by Landlord except as may be expressly specified in writing by the parties hereto. In the event of the failure of Tenant promptly to perform hereunder, Landlord may go upon the Demised Premises and perform such covenants, the cost hereof, at the sole option of Landlord, to be charged to Tenant as additional and delinquent rent.

c. Compliance of Laws. Comply with any requirements of any state or federal statute or local ordinance or regulation applicable to Tenant's use of the Demised Premises, and save Landlord harmless from penalties, fines, costs or damages resulting from Tenant's failure so to do.

d. Fire Protection. Use every reasonable precaution against fire.

e. Surrender of Demised Premises. Peacefully deliver up and surrender possession of the Demised Premises to Landlord upon the expiration or earlier termination of this Lease or any renewal thereof in broom clean condition and the same good order and condition in which Tenant is obligated to keep the same during the continuance of this Lease. Tenant will upon the expiration or earlier termination of this Lease or any renewal thereof remove all of his property from the Demised Premises so that Landlord may again have and repossess the same not later than noon on the day on which this Lease or the renewal thereof shall terminate or expire and will immediately thereafter deliver to Landlord at its office all keys for the Demised Premises.

f. Notice of Damage. Give to Landlord prompt written notice of any accident, fire, or damage occurring on or to the Demised Premises.

g. Janitorial Access. Permit the janitors and cleaners of Landlord to have access to and to clean the Demised Premises in accordance with the attached Exhibit "D". Tenant waives any right it may have to a claim against Landlord for any damage done to the furniture or other property or effects of Tenant by the janitors or cleaners or other employees of Landlord or by any other person, or for any loss of property of any kind whatever from the Demised Premises, however occurring.

h. Agency for Leasing. Not cause or allow any agent to represent Tenant in any subletting or reletting of the Demised Premises other than an agent approved by the Landlord, if,

with the permission in writing of Landlord, Tenant shall vacate or decide at any time during the Demised Term to vacate the herein Demised Premises prior to the expiration of this Lease, or any renewal hereof, and that should Tenant do so, or attempt to do so, the Landlord may remove any signs that may be placed on or about the Demised Premises by such other agent without any liability to Landlord or to said agent, the Tenant assuming all responsibility for such action.

15. RULES AND REGULATIONS.

The Rules and Regulations attached hereto as Exhibit "E" in regard to the said Demised Premises and/or building of which the Demised Premises is a part and the tenants occupying offices therein, and such amendments, additions and modifications thereof as may from time to time be made by Landlord) shall be deemed a part of this Agreement with the same effect as though written herein. Tenant covenants that said Rules and Regulations shall be faithfully observed by Tenant, Tenant's employees, and all persons visiting the Demised Premises, or claiming under Tenant, the right being hereby expressly reserved by Landlord to add to, alter or rescind, from time to time, such rules and regulations, which changes in rules and regulations shall take effect only after ten (10) business days notice thereof in writing by the Landlord to Tenant.

16. ASSIGNMENT AND SUBLET.

a. Tenant, under penalty of instant forfeiture, shall not assign, mortgage or pledge this Lease, nor underlet or sublease the Demised Premises or any part thereof without the written consent of Landlord first had and obtained; nor after such written consent has been given shall any assignee or sublessee assign, mortgage or pledge this Lease or such sublease or underlet or sublease said Demised Premises or any part thereof without an additional written consent by Landlord; and in neither case without such consent shall any such assignment, mortgage, pledge, underletting or sublease be valid. Notwithstanding the foregoing, Tenant may assign this Lease or sublet the Demised Premises to a parent or subsidiary corporation without first obtaining the consent of Landlord.

b. An assignment within the meaning of this Lease is understood and intended to comprehend not only the voluntary action of Tenant, but also the direct or indirect transfer of fifty percent (50%) or more of the voting stock of a corporate tenant, unless Tenant is publicly traded, or fifty percent (50%) or more of the interest in partnership profits of a partnership Tenant (except by reason of death) of a shareholder or partner, any levy or sale on execution or other

legal process and every assignment for the benefit of creditors, adjudication or sale in bankruptcy or insolvency or under any other compulsory procedure or order of court.

c. No assignment or sublease, if consented to in the manner aforesaid, shall in any way relieve or release Tenant from liability upon any of the covenants under the terms of this Lease, and notwithstanding any such assignment or sublease the, responsibility and liability of Tenant hereunder shall continue in full force and effect until the expiration of the term hereby created and any renewals thereof. No assignment or sublease shall be valid unless the assignee or subtenant shall assent to and agree in writing to be bound by all of the covenants and conditions herein contained and unless such assignment or sublease is to a party that will be an actual user of the Demised Premises.

17. LANDLORD'S RIGHTS.

Tenant covenants and agrees that Landlord shall have the right to do the following things and matters in and about the Demised Premises:

a. Access to the Demised Premises. At all reasonable times and upon written notice three (3) business days in advance to Tenant (except in the case of an emergency, in which event no notice is required), by himself or his duly authorized agents to go upon the Demised Premises without disruption, if reasonably possible, (1) to inspect the same and every part thereof; (2) for the purpose, at his option, of making repairs, alterations, additions, or improvements thereof; (3) for the purpose of making electrical wiring changes in electric service outlets in floor, ceiling and/or walls; (4) for the purpose of making adjustments of any nature to the air-conditioning system; (5) for the purpose of fighting fire within the Demised Premises or elsewhere in the building of which the Demised Premises is a part, or for the control or correction of conditions resulting from flood, either from a broken pipe or from outside sources; (6) for the purpose of performing any covenants herein contained which Tenant has failed to perform within ten (10) days of Landlord's written request to do so; (7) for the purpose of remedying any matter due to breach of covenant of Tenant.

b. Showing the Demised Premises. At any time after notice properly given by either party to the other of an intention to terminate this Lease, and upon forty-eight (48) hours notice to Tenant, to conduct persons who may be interested in leasing the Demised Premises in and about the same, provided that such showing shall be conducted after Tenant's business hours.

c. Control of Building. To control and have dominion over the halls, passages, entrances, elevators, toilets, stairways, balconies and roof of the building of which the Demised Premises is a part, the same being not for the use of the general public; and Landlord shall in all cases have the right to control and prevent access thereto of all persons whose presence in the judgment of Landlord or his agents, shall be prejudicial to the safety, character, reputation and interests of the building of which the Demised Premises is a part and its tenants.

d. Prevention of Access. To prevent access to the building of which the Demised Premises is a part in the event of invasion, mob, riot, public excitement or other commotion by closing doors or otherwise for the safety of tenants and for the protection of property in the building.

18. RESPONSIBILITY OF LANDLORD.

a. HVAC. Landlord and Tenant shall establish a cycle for HVAC usage prior to occupancy of the Building by the Tenant. HVAC use, other than the established cycle by Landlord and Tenant, shall be subject to the use of the Building Energy Management System which specifications are included in Exhibit "C" of this Lease.

b. Landlord Insurance. Landlord shall maintain and pay for fire and extended coverage insurance on the building of which the Demised Premises is a part in such amounts as Landlord and/or Landlord's mortgagees shall require. Payments for losses thereunder shall be made solely to Landlord or the mortgagees of Landlord as their interests shall appear.

c. Repairs and Maintenance. Landlord shall make, at its cost, all structural repairs to the building, all repairs which may be needed to the mechanical, HVAC, electrical and plumbing systems in and servicing the Demised Premises (excluding repairs to any non-building standard fixtures or other improvements installed or made by or at the request of Tenant requiring maintenance or repairs of a type or nature not customarily provided by Landlord to office tenants of the building and excluding any necessary replacements of non-building standard fixtures or improvements), and all repairs to exterior windows and glass. In the event that any repair is required by reason of the negligence or abuse of Tenant or its agents, employees, invitees or of any other person using the Demised Premises with Tenant's consent, express or implied, Landlord may make such repair and invoice the cost thereof to Tenant, which invoice will become due within fifteen (15) days after presentation or when the next installment of rent is due, whichever is the later.

19. INDEMNITY AND INSURANCE.

a. Indemnity. Tenant agrees to indemnify and to relieve and hereby indemnifies and relieves Landlord from all liability and expense by reason of any loss, damage or injury to Tenant or any other person or to any property of Tenant or of any other person which may arise from any cause whatsoever on the Demised Premises or on the pavement, curb, roof, sidewalks, elevators, hallways parking lots, passages or other portions of the building of which the Demised Premises is a part, except to the extent due to the negligence of Landlord, its agents, servants or employees, Tenant further agrees to indemnify and to relieve and hereby indemnifies and relieves Landlord from all liability and expense by reason of any loss, damage or injury to Tenant or to any employee or business invitee of Tenant or to any property of Tenant or any employee or business invitee of Tenant which may occur on the pavement, curb, roof, sidewalks, elevators, hallways, parking lots, passages or other portions (other than the Demised Premises) of the building of which the Demised Premises are a part, except to the extent due to the negligence of the Landlord, his servants, agents or employees.

b. Commercial General Liability Insurance. Tenant shall at all times during the period in which it has any occupancy rights in the Demised Premises, maintain in full force and effect commercial general liability insurance, naming Landlord and its managing agent, if any, as additional insured covering injury to persons and damage to property occurring in or about the Demised Premises, in such amounts as may reasonably be required by Landlord from time to time, but not less than \$1,000,000 combined single limit, with a deductible not to exceed Five Thousand Dollars (\$5,000.00). Tenant shall deliver to Landlord duplicate originals or certificates of such insurance at or prior to the date Tenant shall make any entry into the Demised Premises, together with evidence of paid up premiums, and shall deliver to Landlord renewals thereof at least fifteen (15) days prior to expiration. All such policies of insurance shall be with an insurance company licensed to do business in Pennsylvania, and shall provide that they shall not be cancelled or amended without at least twenty (20) days prior notice to Landlord.

c. Personal Property Insurance. Tenant shall maintain, at its expense, insurance on all of its personal property, including removable trade fixtures, located in the Demised Premises.

d. Certificates of Insurance. Tenant shall, at Landlord's request from time to time, provide Landlord with current certificates of insurance evidencing Tenant's compliance with this Paragraph.

e. Waiver of Subrogation. Tenant and Landlord shall obtain the agreement of their insurers to waive all rights of subrogation against each other with respect to coverages in this Paragraph.

20. FIRE OR OTHER CASUALTY.

Within thirty (30) days from the date of casualty, Landlord shall notify Tenant whether it intends to restore or repair the Demised Premises within the time period set forth herein.

a. Total or Substantial Destruction. In the event that the Demised Premises is totally destroyed or so damaged by fire or other casualty not occurring through fault or negligence of the Tenant or those employed by or acting for him, that, in Landlord's judgment, the same cannot be repaired or restored within one hundred eighty (180) days, this Lease shall absolutely cease, and the rent shall abate as of the date of casualty for the balance of the term.

b. Partial Destruction. If the damage caused as above be only partial and such that the Demised Premises, in Landlord's judgment, can be restored within one hundred eighty (180) days, the Landlord may, at its option, restore the same (excluding fixtures and improvements owned by Tenant) with reasonable promptness, reserving the right to enter upon the Demised Premises for that purpose. The Landlord also reserves the right to enter upon the Demised Premises whenever necessary to repair damage caused by fire or other casualty to the building of which the Demised Premises is a part, even though the effect of such entry be to render the Demised Premises or a part thereof untenable. In either event the rent shall be apportioned and suspended during the time the Landlord is in possession, taking into account the portion of the Demised Premises rendered untenable and the duration of the Landlord's possession.. Tenant agrees to pay the full amount claimed by Landlord. Tenant shall, however, have the right to proceed by law to recover the excess payment, if any, or by arbitration pursuant to the rules of the American Arbitration Association. The parties agree that the loser in the arbitration shall pay the costs of arbitration.

c. Waiver of Damages During Repair. Landlord shall not be liable for any damages, compensation or claim by reason of inconvenience, annoyance, injury or loss resulting from the termination of this Lease by reason of the destruction of the Demised Premises, from the making of repairs, alterations, additions or improvements to any portion of the Demised Premises, the building or the facilities thereof, from any of the services or facilities supplied by Landlord, or from the leaking of rain, snow, water, steam or gas into, in or about the Demised Premises or the building of which the Demised Premises is a part.

d. Mortgage Acceleration. In the event that Landlord does not notify Tenant that, in the Landlord's judgement, the damage cannot be repaired within one hundred and eighty (180) days, or in the event that Landlord fails to notify Tenant if Landlord exercises its election to repair the damage within (120) days, then Tenant shall have the right to give notice to Landlord after the expiration of thirty (30) days from the date of damage, that unless Landlord advises Tenant within ten (10) days after receipt of such notice that Landlord intends to complete the repair of the damage to the Demised Premises within one hundred and eighty (180) days from the date of the damage, it shall be deemed conclusive that Landlord has elected not to complete said repairs, and the Tenant may elect to terminate the Lease, commencing the eleventh day after such notice, at any time prior to the receipt of notice from Landlord of its election to repair the damage to the Demised Premises. Notwithstanding the fact that Landlord may have given notice of election to repair the Demised Premises within said thirty (30) day period, if the mortgagee chooses to accelerate the mortgage due to damage by fire or other casualty to the Demised Premises or the building of which the Demised Premises is a part, Landlord shall have the right to rescind and/or cancel said election to repair and shall have the right to elect not to repair the damaged to the Demised Premises or the building of which the Demised Premises is a part, provided said notification of election not to repair is given to Tenant within thirty (30) days after date of the receipt of said notice of acceleration.

e. In the event that Landlord has given notice that it intends to restore or repair the Demised Premises within one hundred and eighty (180) days and Landlord has caused substantial work to be performed with respect to said restoration or repairs but has not completed the same within one hundred and sixty-five (165) days, Landlord shall be entitled to extend the time to two hundred and ten (210) days from the date of the casualty by giving Tenant written notice at least one hundred and sixty-five (165) days from the date of the casualty that it requires the extra thirty (30) days to complete the said restoration or repairs.

21. DEFAULT AND REMEDIES.

a. Events of Default. If the Tenant:

1. Does not pay within five (5) days after due without any set off or deduction any and all installments of rent and/or any other charge or payment herein reserved, included, or agreed to be treated or collected as rent and/or any other charge, expense, or cost herein agreed to be paid by the Tenant; or

2. violates or fails to perform or otherwise breaches any covenant or agreement herein contained, other than for the payment of money as specified in subparagraph (a)(1) hereof, or as otherwise specified in subparagraphs (3) through (8) hereof and fails to cure the same within thirty (30) days after written notice thereof by Landlord (or such longer period as is reasonably required to correct any such default, provided Tenant promptly commences and diligently continues to effectuate a cure); or

3. vacates the Demised Premises or removes or attempts to remove or manifests an intention to remove any goods or property therefrom otherwise than in the ordinary and usual course of business without having first paid and satisfied the Landlord in full for all rent and other charges then due or that may thereafter become due until the expiration of the then current term, above mentioned; or

4. files a petition under Title II, United States Code, Bankruptcy, as now or hereafter amended or supplemented, whether under Chapter 7, 11 or 13 of the aforesaid Bankruptcy Code, or has filed against Tenant such a petition and the same is not dismissed within sixty (60) days;

5. commences or has commenced against it any action or proceeding under state or federal law for the dissolution or liquidation of the Tenant in connection with bankruptcy or other insolvency, or for the appointment of a receiver or trustee of all or substantially all of the property of the Tenant, and if filed against Tenant, the action proceeding is not dismissed within sixty (60) days;

6. has possession of property of the Tenant taken by any governmental officer or agency so as to exclude Tenant from control thereof, or by any trustee, guardian or other appointee pursuant to statutory authority for the dissolution, rehabilitation, reorganization, or liquidation of the Tenant; or

7. makes an assignment for the benefit of creditors;  
or

8. has its property levied upon by any Sheriff, Marshall or constable, and said levy is not dismissed within ten (10) days;

Then and in any of said events, there shall be deemed to be an Event of Default of this Lease.



b. Remedies. Upon an Event of Default as aforesaid, Landlord, in addition to all other rights and remedies available to it by law or equity or by any other provisions hereof, may at any time thereafter:

1. Acceleration. Declare to be immediately due and payable, on account of the rent and other charges herein reserved for the balance of the term of this Lease, a sum equal to the Accelerated Rent Component (as hereinafter defined), and Tenant shall remain liable to Landlord as hereinafter provided, and/or;

2. Accelerated Rent Component. For purposes hereof, the Accelerated Rent Component shall mean the aggregate of:

(i) all rent, additional rent and other charges, payments, costs and expenses due from Tenant to Landlord and in arrears at the time of the election of Landlord to recover the Accelerated Rent Component;

(ii) the rent reserved for the then entire unexpired balance of the term of this Lease, plus all additional rent and other charges, payments, costs and expenses herein agreed to be paid by Tenant up to the end of said term which shall be capable of precise determination at the time of Landlord's election to recover the Accelerated Rent Component, discounted to present value at four percent (4%) below the then existing prime rate of Citibank of New York (Bank). No estimate of any component of additional rent to accrue pursuant to the provisions of Paragraph 6 of this Lease shall be less than the amount which would be due if each such component continued at the highest monthly rate or amount in effect during the twelve (12) months immediately preceding the default.

3. Termination. Terminate this Lease on at least seven (7) days' notice to Tenant and, on the date specified in said notice, this Lease and the term hereby demised and all rights of Tenant hereunder shall expire and terminate and Tenant shall thereupon quit and surrender possession of the Demised Premises to Landlord in the condition elsewhere herein required and Tenant shall remain liable to Landlord for any obligation or provision which shall survive the termination of this Lease. If Landlord had previously elected to accelerate rent under subparagraph (b)(1) hereof, but has not received complete payment of the Accelerated Rent Component, Landlord may terminate the lease for any current month for which the applicable Accelerated Rent Component has not been paid.

4. Re-entry. Landlord, may, without further notice, enter upon and respossess the Demised Premises, by summary proceedings, ejectment or otherwise, and may dispossess Tenant and enjoy the Demised Premises and the rents and profits therefrom. Landlord may, in its own name, as agent for Tenant, if this Lease has not been terminated, or in its own behalf, if this Lease has been terminated, relet the Demised Premises or any part thereof for such term or terms (which may be greater or less than the period which would otherwise have constituted the balance of the term of this Lease) and on such conditions and provisions (which may include concessions or free rent) as Landlord in its sole discretion may determine. Landlord, may, in connection with any such reletting, cause the Demised Premises to be redecorated, altered, divided, consolidated with other space or otherwise changed or prepared for reletting. No reletting shall be deemed a surrender and acceptance of the Demised Premises by Landlord.

5. Damages. As a cumulative and alternative remedy of Landlord in the event of termination of this Lease by Landlord following any default by Tenant, Landlord, at its option, shall be entitled to recover damages for such default from the date of the termination in an amount equal to the Accelerated Rent Component for the balance of the term, determined without regard to the early termination, less the fair rental value of the Demised Premises for the remainder of the original term of the Lease, discounted to present value at four percent (4%) below the then existing Prime Rate of Bank, and such damages shall be payable by Tenant upon demand.

c. Continuing Liability. Tenant shall, with respect to all periods of time up to and including the expiration of the term or other termination of this Lease, remain liable to Landlord for the rent, additional rent and all other charges payable under this Lease. Tenant shall be entitled to a credit for any portion of the Accelerated Rent Component paid by Tenant to Landlord. In the event that the property has been relet or sublet by Tenant or Landlord for the benefit of Tenant, and the rent therefor shall be paid directly to Landlord by said new tenant or sublet tenant, Tenant shall be entitled to a credit against the rent and all other charges paid or payable under this Lease for the net proceeds received by Landlord after deduction of all costs payable by Landlord incidental to such reletting or subletting. If it shall be determined at the expiration of the term of this Lease that a credit is due Tenant because the net proceeds of reletting, as aforesaid, plus the amounts paid to Landlord by Tenant by Accelerated Rent Component or otherwise, exceed the aggregate of rent and other charges accrued in favor of Landlord to the end of said term, Landlord shall refund such excess to Tenant, without interest, promptly after such determination, after written request by Tenant.

d. No Duty to Relet. In no event shall Landlord be responsible or liable for any failure to relet the Demised Premises or any part thereof, or for any failure to collect any rent due upon a reletting.

e. Bankruptcy. Nothing contained in this Lease shall limit or prejudice the right of Landlord to prove for and obtain as damages incident to a termination of this Lease, in any bankruptcy, reorganization or other court proceedings, the maximum amount allowed by any statute or rule of law in effect when such damages are to be proved.

f. Waiver of Defects. Tenant (further) waives the right to any notices to quit as may be specified in the Landlord and Tenant Act of Pennsylvania, Act of April 6, 1951, as amended in 1995, and agrees that seven (7) days notice shall be sufficient in any case where a longer period may be statutorily specified..

g. Further Remedies of Landlord. In the event of any default as above set forth in this paragraph, the Landlord, or anyone acting on Landlord's behalf, at Landlord's option:

1. May have and exercise any and all other rights and/or remedies, granted or allowed landlords by existing or future Statute, Act of Assembly, or other law of this state in cases where a landlord seeks to enforce rights arising under a lease agreement against a tenant who has defaulted or otherwise breached the terms of such lease agreement; and

2. May have and exercise any and all other rights and remedies contained in this Lease, including the rights and remedies provided by paragraphs 22 and 23 hereof.

23. ENFORCEMENT.

It is hereby covenanted and agreed, any law, usage or custom to the contrary notwithstanding, that Landlord shall have the right at all times to enforce the covenants and provisions of this Lease in strict accordance with its terms notwithstanding any conduct on the part of the Landlord in refraining from so doing at any time or times; and, further, that the failure of Landlord at any time or times to enforce its rights under said covenants and provisions strictly in accordance with the same shall not be construed as having created a waiver or custom in any way or manner contrary to the specific terms, provisions and covenants of this Lease or as having in any way or manner modified the same.

24. RIGHT OF ASSIGNEE OF LANDLORD.

The right to enforce all the provisions of this Lease herein provided for may at the option of any assignee of this Lease, be exercised by any assignee of the Landlord's right, title and interest in this Lease in his, her or their own name, any statute, rule of court, custom, or practice to the contrary notwithstanding.

25. REMEDIES CUMULATIVE.

All of the remedies hereinbefore given to Landlord and all rights and remedies given to it by law and equity shall be cumulative and concurrent. No determination of this Lease or the taking or recovering of the Demised Premises shall deprive Landlord of any of its remedies or actions against Tenant for rent or sums due at the time or which, under the terms hereof, would in the future become due as if there has been no termination; nor shall the bringing of any action for rent or breach of covenant, or the resort to any other remedy herein provided for the recovery of rent be construed as a waiver of the right to obtain possession of the Demised Premises.

26. MECHANIC'S LIEN.

a. Tenant will not permit any mechanic's lien or liens to be placed upon the Demised Premises or the building of which the Demised Premises is a part. Nothing in this Lease shall be deemed or construed in any way as constituting the consent or request of Landlord, express or implied, to any person for the performance of any labor or the furnishing of any materials to all or part of the Demised Premises, nor as giving Tenant any right, power, or authority to contract for or permit the rendering of any services or the furnishing thereof that would or might give rise to any mechanic's or other liens against the Demised Premises or building of which the Demised Premises is a part.

b. If any such lien is claimed against the Demised Premises or building of which the Demised Premises is a part, then, in addition to any other right or remedy of Landlord, Landlord may, but shall not be obligated to, discharge the same by payment to the claimant or by posting a bond in Court of Common Pleas in accordance with the rules of court, as Landowner may elect in its sole discretion. Any amount paid by Landlord for such purposes shall be invoiced to Tenant and paid by Tenant to Landlord as additional rent at the time the next installment of rent is due.

27. CONDEMNATION.

If at any time during the Demised Term the Demised Premises, or any portion thereof, be lawfully condemned or conveyed in lieu of condemnation, the Landlord shall be entitled to, and shall receive the award or payment therefor, and the Tenant shall assign, and does hereby assign and transfer to the Landlord such award or payment as may be made therefor. Tenant, however, shall be entitled to make a separate claim for those damages made payable specifically and solely to a business Tenant under the terms of the Eminent Domain Code of Pennsylvania, Act of June 22, 1964, P.L. 84, as now or hereafter amended, provided however any award to Tenant shall not in way diminish the Landlord's award. This Lease shall, as to the part so taken terminate as of the date title shall vest in the condemnor, and rent shall abate in proportion to the square feet of the Demised Premises taken or condemned. If more than thirty (30%) percent of the Demised Premises is so taken, Landlord or Tenant may give notice of its desire to terminate the Lease. The notice shall be given within thirty (30) days after the condemnation has occurred and the Lease shall terminate thirty (30) days after the date of notice given by Landlord or Tenant to the other.

28. ESTOPPEL CERTIFICATE.

At any time, and from time to time, upon the written request of Landlord or any mortgagee, Tenant within twenty (20) days of the date of such written request agrees to execute and deliver to Landlord and/or such mortgagee, without charge and in form satisfactory to Landlord and/or such mortgagee, a written statement (1) ratifying this Lease; (2) confirming the commencement and expiration date of the term of this Lease and the minimum annual rental rate payable during the lease term; (3) certifying that Tenant is in occupancy of the Demised Premises, and that the Lease is in full force and effect and has not been modified, assigned, supplemented or amended except by such writings as shall be stated; (4) certifying that all conditions and agreements under this Lease to be satisfied or performed by Landlord have been satisfied and performed except as shall be stated; (5) certifying that there is no default by Landlord or Tenant under the Lease and there are no defenses or offsets against the enforcement of this Lease by Landlord or stating the defaults and/or defenses claimed by Tenant; (6) reciting the amount of advance rent, if any, paid by Tenant and the date to which such rent has been paid and, if requested by Landlord and/or Mortgagee, agreeing that Tenant shall not pay rent to Landlord more than thirty (30) days in advance; (7) reciting the amount of security deposited with Landlord, if any; (8) certifying that Tenant has no option or right of first refusal to purchase the Demised Premises or option to extend the term of the Lease (unless specifically set forth to the contrary in the Lease); (9) if requested by Landlord and/or Mortgagee, agreeing that the Lease will not be modified without the prior written consent of the Mortgagee; (10) certifying

that Tenant has not and will not generate, store, handle or otherwise deal with any amount of any hazardous substances or hazardous waste (as defined in federal, state and local law) in or about the Demised Premises, in excess of those levels or quantities specified for regulatory purposes; (11) agreeing, if requested by Mortgagee, that Tenant will give such Mortgagee such notice of any default by Landlord and reasonable opportunity to cure such default, not in excess of thirty (30) days, unless the default cannot be cured within said time, before exercising Tenant's remedies under the Lease; and (12) any other information which Landlord or the mortgagee shall require.

Failure to Execute. The failure of Tenant to execute, acknowledge and deliver to Landlord and/or any mortgagee a statement in accordance with the provisions of this paragraph within the said twenty (20) day period shall constitute acknowledgement by Tenant which may be relied upon by any person holding or intending to acquire any interest whatsoever in the Demised Premises that this Lease has not been assigned, amended, changed, or modified, is in full force and effect and that the minimum annual and additional rent have been duly and fully paid not beyond the respective due dates immediately preceding the date of the request for such statement and shall constitute as to any persons entitled to rely on such statements a waiver of any defaults by Landlord or defenses or offsets against the enforcement of this Lease by Landlord which may exist prior to the date of the written request. Landlord at its option, may treat such failure as a deliberate event of default.;

29. SUBORDINATION AND ATTORNMENT.

Tenant agrees:

a. That, except as hereinafter provided, this Lease is, and all of Tenant's rights hereunder are and shall always be, subject and subordinate to any first mortgage, leases of Landlord's property (in sale-leaseback) pursuant to which Landlord has or shall retain the right of possession of the Demised Premises or security instruments (collectively called "Mortgage") that now exist, or may hereafter be placed upon the Demised Premises or any part thereof and to all advances made or to be made thereunder and to the interest thereon and all renewals, replacements, modifications, consolidations, or extensions thereof; and

b. That if the holder of any such Mortgage ("Mortgagee") or if the purchaser at any foreclosure sale or at any sale under a power of sale contained in any Mortgage shall at its sole option so request, Tenant will attorn to, and recognize such mortgagee or purchaser, as the

case may be, as Landlord under this Lease for the balance then remaining of the term of this Lease, subject to all terms of this Lease; and

c. That the aforesaid provisions shall be self-operative and no further instrument or document shall be necessary unless required by any such mortgagee or purchaser. Notwithstanding anything to the contrary set forth above, mortgagee may at any time subordinate its mortgage to this Lease, without Tenant's consent, by notice in writing to Tenant, and thereupon this Lease shall be deemed prior to such mortgage without regard to their respective dates of execution, delivery and/or recording and in that event such mortgagee shall have the same rights with respect to this Lease as though this Lease had been executed and a memorandum thereof recorded prior to the execution, delivery and recording of the mortgage and as though this Lease had been assigned to such mortgagee. Should Landlord or any mortgagee or purchaser desire confirmation of either such subordination or such attornment, as the case may be, Tenant, upon written request, and from time to time, will execute and deliver without change and in form satisfactory to Landlord and the mortgagee or the purchaser all instruments and/or documents that may be requested to acknowledge such subordination and/or agreement to attorn, in recordable form.

30. QUIET ENJOYMENT.

Tenant, on paying the rent reserved, and performing all the covenants and conditions hereof, shall at all times during the Demised Term, peaceably and quietly have, hold and enjoy the Demised Premises; provided, however, that no eviction of the Tenant by reason of the foreclosure of any mortgage now or hereafter on the Demised Premises shall be construed as a breach of this covenant, nor shall any action by reason thereof be brought against the Landlord; and provided further, that no eviction of the Tenant for any reason whatever, after the Landlord shall have conveyed the fee of the Demised Premises, shall be construed as a breach of this covenant by the present Landlord, and no action therefore shall be brought against the present Landlord.

31. NOTICES.

All notices required to be given shall be by certified mail, return receipt requested, or by a recognized overnight delivery service.

TO LANDLORD: Painters' Crossing Two Associates, L.P.  
112 Chesley Drive, Suite 200

Endo Pharmaceuticals Inc.  
Confidential

Media, PA 19063-1762

ATTN: Accounting Department

TO TENANT:

Endo Pharmaceuticals Inc.  
Painters' Crossing One Building  
Painters' Crossing Office Campus  
Chadds Ford, PA 19317

ATTN: General Counsel

Such addresses may be changed from time to time by either party by serving notices as provided. Notice shall be deemed given two (2) days after postmarked in the case of the U. S. Mail or upon delivery or refusal of delivery in the case of a recognized overnight delivery service.

32. LEASE CONTAINS ALL AGREEMENTS.

It is expressly understood and agreed by and between the parties hereto that this Lease sets forth all the promises, agreements and conditions or understandings between Landlord or his Agent and Tenant relative to the Demised Premises, and that there are no promises, agreements, conditions or understandings, either oral or written, between them other than are herein set forth. It is further understood and agreed that, except as herein otherwise provided, no subsequent alteration, amendment, change or addition to this Lease shall be binding upon Landlord or Tenant unless reduced to writing and signed by them.

33. HEIRS AND ASSIGNEES.

All rights and liabilities herein given to, or imposed upon, the respective parties hereto shall extend to and bind the several and respective heirs, executors, administrators, successors and assigns of said parties; and if there shall be more than one Tenant, they shall all be bound jointly and severally by the terms, covenants and agreements herein, and the word "Tenant" shall be deemed and taken to mean each and every person or party mentioned as a Tenant herein, be the same one or more; and if there shall be more than one Tenant, any notice required or permitted by the terms of this Lease may be given by or to any one thereof, and shall have the same force and effect as if given by or to all thereof. The words "his" and "him" wherever stated herein, shall be deemed to refer to the "Landlord" or "Tenant" whether such Landlord or Tenant be singular or plural and irrespective of gender. No rights, however, shall inure to the benefit of

Endo Pharmaceuticals Inc.  
Confidential

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any assignee of Tenant unless the assignment to such assignee has been approved by Landlord in writing as aforesaid.

34. LATE PAYMENT.

In the event that any payment of Annual Base Rent or additional rent or any other charge required to be paid by Tenant under the provisions of this Lease, shall not be paid within five (5) days of the due date, Tenant shall pay to Landlord a late charge of five percent (5%) of such past due payment; and such late charge shall be deemed "rent" for all purposes under this Lease.

35. HEADINGS NO PART OF LEASE.

Any headings preceding the text of the several paragraphs and subparagraphs hereof are inserted solely for convenience of reference and shall not constitute a part of this Lease nor shall they affect its meaning, construction or effect.

36. SEVERABILITY.

If a provision of this Lease Agreement is held invalid, it is hereby agreed that all valid provisions that are severable from the invalid provision remain in effect. If a provision in this Lease Agreement is held invalid in one or more of its applications, the provision remains in effect in all valid applications.

37. LIABILITY OF LANDLORD.

The liability of Landlord hereunder and all of its partners, if any, whether general or limited, shall be limited to Landlord's estate or other title or interest in the building of which the Demised Premises is a part. It is further covenanted and agreed by the parties hereto that in no case and under no circumstances shall the Landlord be liable for any consequential damage.

38. RECORDING OF LEASE.

Tenant shall not record this Lease. If Tenant violates this covenant, Tenant hereby irrevocably authorizes, empowers and designates Landlord as its lawful attorney for the purpose of having said Lease marked satisfied of record.

39. TERMINATION OF LEASE.

It is hereby mutually agreed that either party hereto may terminate this Lease at the end of the Demised Term by giving to the other party written notice thereof at least three hundred sixty-five (365) days prior thereto, but in default of such notice, this Lease shall continue upon the same terms and conditions in force immediately prior to the expiration of the Demised Term hereof as are herein contained except for Basic Rent which shall be adjusted to reflect the then current market rates for space comparable to the Demised Premises as determined by Landlord based upon other of Landlord's rental properties, for a further period of one (1) year and so on from year to year unless or until termination by either party hereto, giving the other one hundred eighty (180) days written notice for removal previous to expiration of the then current term; PROVIDED, however, that should this Lease be continued for a further period under the terms herein-above mentioned, any allowances given Tenant on the Basic Rent during the original term shall not extend beyond such original term. In the event that Tenant shall give notice, as stipulated in this Lease, of termination of this Lease at the end of the Demised Term, or any renewal or extension thereof, and shall fail or refuse so to vacate the same on or before the date of termination of the Lease, then it is expressly agreed that Landlord shall have the right at any time thereafter to give seven (7) days written notice to quit; whereupon the Tenant expressly agrees to vacate said premises at the expiration of the seven (7) day period:

(a) Should Tenant wrongfully continue to occupy the Demised Premises after expiration of the term of this Lease or any renewal or renewals thereof, or after a forfeiture incurred, such tenancy shall (without limitation on any of Landlord's rights or remedies therefor) be one at sufferance from month to month at a minimum monthly rent equal to one and one-half times the Base Rent plus additional rent payable for the last month of the term of this Lease prior to the holdover.

All powers granted to Landlord by this lease may be exercised and all obligations imposed upon Tenant by this Lease shall be performed by Tenant as well during any extension of the Demised Term of this Lease as during the Demised Term itself.

#### 40. LANDLORD'S ENVIRONMENTAL CLAUSE.

(a) Tenant shall not (either with or without negligence) cause or permit the escape, disposal or release of any biologically or chemically active or other hazardous substances or materials. Tenant shall not allow the storage or use of such substances or materials in any manner not sanctioned by law or by the highest standards prevailing in the industry for the storage and use of such substances except to use in the ordinary course of Tenant's business, and then only after written notice is given to Landlord of the identity of such

substances or materials. Without limitation, hazardous substances and materials shall include those described in the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, 42 U.S.C. Section 9601 et seq., any applicable state or local laws and the regulations adopted under these acts. If any lender or governmental agency shall ever require testing to ascertain whether or not there has been any release of hazardous materials, then the reasonable costs thereof shall be reimbursed by Tenant to Landlord upon demand as additional charges if such requirement applies to the Premises. In addition, Tenant shall execute affidavits, representations and the like from time to time at Landlord's request concerning Tenant's best knowledge and belief regarding the presence of hazardous substances or materials on the Premises. In all events, Tenant shall indemnify Landlord in the manner elsewhere provided in this lease from any release of hazardous materials on the Premises occurring while Tenant is in possession, or elsewhere if caused by Tenant or persons acting under Tenant. The within covenants shall survive the expiration or earlier termination of the lease term.

(b) Tenant shall conduct all of its operations at the Premises in compliance with all federal, state and local statutes (including, but not limited to the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. Section 9601 et. seq, as amended by the Superfund Amendments and Reauthorization Act of 1986, Pub. L. No. 99-499, 100 Stat. 1613 (October 17, 1986) ("CERCLA"); the Resources Conservation and Recovery Act, 42 U.S.C. Section 6901 et. seq. ("RCRA"); the Pennsylvania Solid Waste Management Act, 35 Pa.C.S. Section 6018.101 et. seq.; the Pennsylvania Clean Streams Law, 35 Pa.C.S. Section 691.1 et. seq.; and the Pennsylvania Hazardous Sites Cleanup Act, Act 108 of 1988, 35 Pa.C.S. Section 6020.101 et. seq. ("Pennsylvania Superfund"), the Clean Air Act, 42 U.S.C. Section 7401 et. seq., as amended by the Clean Air Act Amendments of 1990, the Clean Water Act, 33 U.S.C. Section 1251 et. seq., and all applicable federal, state and local statutes related to the environment now or hereafter enacted and any additions and amendments thereto and regulations enacted thereunder, ordinances, regulations, orders and requirements of common law, regarding, but not limited to, (i) discharges to the air, soil, surface or groundwater; and (ii) handling, utilizing, storage, treatment or disposal of any hazardous substances or toxic substances as defined therein ("Environmental Statutes"). Tenant shall obtain all permits, licenses or approvals and shall make all notifications and registrations required by Environmental Statutes and shall submit to Landlord, upon request, for inspecting and copying all documents, permits, licenses, approvals, manifests and records required to be submitted and/or maintained by the provisions of the Environmental Statutes. Tenant shall also provide promptly to Landlord copies of any correspondence, notice of violation, summons, order, complaint or other document received by Tenant pertaining to compliance with Environmental Statutes.

(c) Tenant shall not install at the Premises any temporary or permanent tanks for the storage of any liquid or gas above or below ground except as in compliance with the other provisions of this section and after obtaining written permission to do so from Landlord.

(d) If, because of the manner in which Tenant operates its business, the Landlord, Landlord's mortgage lender or a governmental agency shall require testing by an environmental testing entity of its choice, to ascertain whether there has been a release of Hazardous Materials by Tenant, its agents, servants, employees or business invitees, in or around the Demised Premises, the reasonable costs of such testing shall be reimbursed by Tenant to Landlord as additional rent. Tenant shall execute affidavits or representations, at Landlord's request, stating that, to the best of Tenant's knowledge and belief, since the time that Tenant took possession of the Demised Premises, there have been no and there presently are no Hazardous Materials present in the Demised Premises.

(e) Tenant hereby agrees to indemnify Landlord and to hold Landlord harmless of, from and against any and all expense, loss, cost, fines, penalties, loss of value or liability suffered by Landlord by reason of Tenant's breach of any of the provisions of this section.

(f) The provisions of this section shall survive the termination of Tenant's tenancy or of this Lease.

41. JURISDICTION AND LAW.

Tenant hereby subjects itself to the jurisdiction of the Court of Common Pleas of Delaware County, Pennsylvania. The laws of the Commonwealth of Pennsylvania shall be applicable to this lease and any interpretations thereof.

42. TIME IS OF THE ESSENCE.

Time is of the essence in performing the covenants contained herein.

IN WITNESS WHEREOF, the Landlord and Tenant have duly executed this Lease as of the day and year first above written.

SEALED AND DELIVERED IN THE PRESENCE OF:

LANDLORD:

PAINTERS' CROSSING TWO ASSOCIATES, L.P.  
By: P.C. Two, Inc. (General Partner)

ATTEST: /s/ JOHN B. CONDON  
-----  
John B. Condon, Assistant Secretary

BY: /s/ PATRICK G. TOMLINSON  
-----  
Patrick G. Tomlinson, Vice President

TENANT:

ENDO PHARMACEUTICALS INC.

ATTEST: /s/ CAROLINE B. MANOGUE  
-----  
(Secretary)

BY: /s/ MARIANN MACDONALD  
-----  
Mariann MacDonald  
Executive Vice President, Operations

Endo Pharmaceuticals Inc.  
Confidential

</TEXT>  
</DOCUMENT>

<DOCUMENT>  
<TYPE> EX-10.46  
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<TEXT>

LICENSE AGREEMENT  
DATED AS OF FEBRUARY 25, 2004  
BY AND BETWEEN  
NOVEN PHARMACEUTICALS, INC.  
AND  
ENDO PHARMACEUTICALS INC.

THE CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO A CONFIDENTIAL TREATMENT REQUEST IN ACCORDANCE WITH RULE 24B-2 OF THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED. REDACTED PORTIONS OF THIS EXHIBIT ARE MARKED BY AN \*\*\*.

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LIST OF EXHIBITS

Exhibit A	Noven Patents
Exhibit B	Supply Agreement
Exhibit C	Additional Products
Exhibit D	Evaluation Plan

LICENSE AGREEMENT

This LICENSE AGREEMENT (the "Agreement") is entered into as of this 25TH day of February, 2004 (the "Effective Date"), by and between NOVEN PHARMACEUTICALS, INC., a Delaware corporation ("Noven"), and ENDO PHARMACEUTICALS INC., a Delaware corporation ("Endo").

WITNESSETH:

WHEREAS, Noven has developed and sought regulatory approval relating to, and is the owner of record of, an abbreviated new drug application (the "Product ANDA" as further defined below) relating to a generic fentanyl transdermal patch (the "Licensed Product" as further defined below);

WHEREAS, Noven holds rights to certain intellectual property relating to the Licensed Product including without limitation certain patents, patent applications, and know-how;

WHEREAS, pursuant to the terms of this Agreement Noven wishes to provide a license to Endo to commercialize the Licensed Product under its Product ANDA and its intellectual property rights;

WHEREAS, pursuant to the terms of this Agreement, Endo is willing and able to accept such a license and to fully commercialize the Licensed Products;

WHEREAS, Noven and Endo additionally desire to jointly identify and develop additional compounds for transdermal delivery and for eventual full scale commercialization (the "Additional Products" as further defined below); and,

WHEREAS, Noven and Endo are entering into a supply agreement contemporaneously with the execution of this Agreement under which Noven will supply Licensed Product to Endo (the "Supply Agreement").

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, hereby agree as follows:

ARTICLE I. DEFINITIONS

Section 1.01. Definitions. As used herein, the following capitalized terms have the following meanings:

"Additional Products" means potential products comprising those compounds identified in Exhibit C.

"Affiliate" means with respect to a Person, any legally distinct corporation, firm, individual or other form or business organization which is, directly or indirectly, controlled by, controlling, or under common control with the subject Person hereto. An entity shall be regarded

as being in control of another entity if such first entity has the direct or indirect power to order or cause the direction of the management and policies of the other entity, whether through ownership of at least fifty percent (50%) of the outstanding voting securities or participating profit interest of such entity, through other dominant equity ownership or by contract, statute, regulation or otherwise.

"ANDA" means an abbreviated new drug application filed with the FDA pursuant to 21 U.S.C. 355(j).

"Applicable Law" means, with respect to any Person, any domestic or foreign, federal, state or local statute, treaty, law, ordinance, rule, regulation, administrative interpretation, order, writ, injunction, judicial decision, decree or other requirement of any Governmental Authority applicable to such Person or any of such Person's respective properties, assets, officers, directors, employees, consultants or agents (in connection with such officers', directors', employees', consultants' or agents' activities on behalf of such Person).

"Business Day" means a day other than a Saturday, Sunday or other day on which commercial banks in New York, New York, USA are authorized or required by law to close.

"Code of Federal Regulations," or "C.F.R" means the codification of the general and permanent rules published in the Federal Register. Title 21 of the C.F.R. contains the regulations promulgated by the FDA pursuant to the FDC Act.

"Competing Product" means any transdermal fentanyl drug product approved by a Regulatory Authority that is rated as therapeutically equivalent to Duragesic(R) \*\*\*.

"Confidential Information" means all secret, confidential or proprietary data, know-how and related information, including, without limitation, all confidential Regulatory Applications, Regulatory and Clinical Materials and related filings, applications and data, the content of any unpublished patent applications, operating methods and procedures, marketing, manufacturing, distribution and sales methods and systems, sales figures, pricing policies and price lists and other business information and shall include all confidential information disclosed or accessed by the parties pursuant to the provisions of this Agreement.

"Cost of Goods Sold" means the respective amount paid to Noven by Endo pursuant to the Supply Agreement for Licensed Product sold hereunder.

"Damages" means all liabilities, demands, obligations, assessments, judgments, levies, losses, fines, penalties, damages (including compensatory damages), costs and expenses, including reasonable attorneys', accountants', investigators', and experts' fees and expenses, reasonably sustained or incurred in connection with the defense or investigation of any Proceedings (including any Proceedings to establish insurance coverage).

"FDA" means the United States Food and Drug Administration and any successor agency thereto.

"FDC Act" means the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301 et seq., as amended, and the regulations promulgated there under, as amended from time to time.

"GAAP" means generally accepted accounting principles in effect in the United States from time to time.

"Governmental Authority" means any foreign, domestic, federal, territorial, state or local governmental authority, quasi-governmental authority, instrumentality, court, government or self-regulatory organization (including any national or international securities exchange and "The NASDAQ Stock Market), commission, tribunal or organization or any regulatory, administrative or other agency, or any political or other subdivision, department or branch of any of the foregoing.

\*\*\*

"IND" means an Investigational New Drug Application, as defined in 21 C.F.R. 312.3.

"Intellectual Property Rights" means any and all existing and future proprietary rights, including but not limited to property rights, know-how rights, trade secret rights, copyrights, design rights, any existing or future United States patents and patent applications and all continuations, continuations-in-part, divisions, reissues, reexaminations, extensions or other government actions which extend the subject matter of the foregoing, and any corresponding foreign patent applications, and any corresponding patents, patents of addition, or other equivalent foreign patent rights issuing, granted or registered and all other intellectual property rights (including without limitation the right, if any, to sue or bring other actions for past, present and future infringement of such Intellectual Property Rights). With respect to Noven, the foregoing shall include the Noven Patents.

"Launch" means the sale of product to a major retail chain or a major distributor (as those terms are commonly understood in the industry) after Regulatory Approval.

"Licensed Product" means the fentanyl transdermal patch product submitted for Regulatory Approval in the Product ANDA.

"Net Sales" means the quantity of Licensed Product multiplied by the gross price per unit of Licensed Product, each as invoiced by Endo or its Approved Subdistributors to third parties (other than an Approved Subdistributor), less the total value of cash discounts and/or rebates and charge backs offered \*\*\* for the purchase of such product, and/or required payments under governmental agency programs, including Medicare and Medicaid, as well as any credits or allowances actually granted on account of price adjustments or rejection or return of such product previously sold. \*\*\*

"Noven Patents" means those patents and patent applications listed in Exhibit A together with any and all improvement patents, reissues, confirmations, renewals, extensions, counterparts, divisions, continuations, continuations-in-part or patents-of-addition issued to or assigned to Noven, but only to the extent that they specifically read on the Licensed Product or a Competing Product, as applicable.

"Person" means an individual, a corporation, a general partnership, a limited partnership, a limited liability company, a limited liability partnership, an association, a trust or any other entity or organization, including a Governmental Authority.

"Proceedings" means governmental, judicial, administrative or adversarial proceedings (public or private), litigation, suits, arbitration, disputes, claims, causes of action or investigations involving third party claims.

"Product ANDA" means ANDA no. 76-804, filed by Noven pertaining to a fentanyl transdermal patch product.

"Regulatory and Clinical Materials" means all documents, supporting materials and other materials relating to the Regulatory Application, any Regulatory Approval or other matter required to be submitted to any Regulatory Authority in relation to the Product, including any IND, NDA, ANDA, and documents, supporting materials and other materials relating to any drug master file, investigators' brochures, clinical studies (including any Phase IV clinical studies), safety data, adverse event reports, questionnaires, consultant reports, correspondence (including correspondence with any Regulatory Authority), batch reports, protocols, specifications, quality assurance, quality control, customer queries and any responses thereto, and any compilation or evaluations thereof, and question and answer scripts.

"Regulatory Application" means the applications submitted by Noven to the FDA seeking approval for the development, manufacture, testing, storage, transport, marketing, advertisement, promotion, sale, use, distribution or other disposal of the Product in all or any portion of the Territory, including the Product ANDA.

"Regulatory Approval" means final approval by the applicable Regulatory Authority to market the Product.

"Regulatory Authority" means a Governmental Authority that has the authority over the manufacture, use, storage, import, export, clinical testing transport, marketing, sale or distribution of the Licensed Product in all or any portion of the Territory, including the FDA.

"Securities Laws" means the United States Securities Act of 1933, as amended, the United States Securities Exchange Act of 1934, as amended, and any other similar law or regulation of a Governmental Authority, or any successor to any such laws or regulations, together with any rules, regulations or listing standards, or agreements of any national or international securities exchange or The NASDAQ Stock Market.

"Territory" means the United States of America and Canada.

Section 1.02. Other Definitions. Each of the following terms is defined in the section of this Agreement referenced opposite such term.

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ARTICLE II. LICENSE GRANTS

Section 2.01. License Grant: Subject to the terms and conditions of this Agreement, Noven hereby grants to Endo an exclusive license under the Product ANDA and its Intellectual Property Rights solely to use and sell or otherwise dispose of the Licensed Product solely in the Territory. For purposes of this Agreement, the phrase use and sell, or otherwise dispose of the "Licensed Product" includes only the right to market, advertise, promote, distribute, offer to sell and sell the Licensed Product throughout the Territory pursuant to the associated obligations of Endo under this Agreement. The term "exclusive" as used in this Article means the specific rights conferred on Endo are to the exclusion of all other Persons and entities, including but not limited to Noven.

Section 2.02. Limitations on License Granted Under Section 2.01. No right or license other than those specifically granted to Endo herein are granted, and all rights not specifically granted to Endo herein are hereby explicitly retained by Noven including, without limitation, the right to make Licensed Product and to supply Licensed Product to Endo. Except as specifically set forth in Section 2.04 and Article V of this Agreement below, the license to Endo hereunder shall not include the right of Endo to sublicense any of the rights granted to Endo.

Section 2.03. Quality Control. Endo shall only market, promote, sell, distribute, use or otherwise dispose of the Licensed Product, and any materials used in connection with the

Licensed Product, including any labeling, packaging and advertising, in accordance with all Applicable Laws.

Section 2.04. Sublicense. Subject to Section 5.01 and to the written consent of Noven, which consent may be withheld in Noven's sole discretion, Endo shall have the right (a) to appoint any Person as a subdistributor in the Territory (and/or such other territory as the parties may agree upon from time to time) as provided herein (each such approved subdistributor, an "Approved Subdistributor") and (b) to delegate to such Approved Subdistributor the whole or any part of its obligations; provided that (i) Endo shall remain primarily liable for the Approved Subdistributor's compliance with this Agreement, (ii) prior to or concurrently with its appointment, each Approved Subdistributor shall enter into an agreement with Endo (each, an "Approved Subdistributor Agreement") that is consistent with this Agreement, and that shall not thereafter be amended or modified in any manner inconsistent with the terms hereof, (iii) each Approved Subdistributor Agreement shall name Noven as a third party beneficiary, and (iv) no Approved Subdistributor Agreement shall permit such Approved Subdistributor to appoint or assign such agreement, or delegate any obligations, to any other subdistributor. Endo shall be solely responsible for the fees of, and any other payments to, each Approved Subdistributor. Upon Noven's request, Endo shall make available to Noven a redacted copy of each Approved Subdistributor Agreement evidencing such agreements conformance with the requirements of this Section 2.04. The foregoing notwithstanding, nothing herein shall prevent or prohibit Endo from using subcontractors to perform certain of its internal business functions, such as utilizing a contract sale force, ad agency, contract distribution services and contract safety services: provided, however, that (i) Endo shall retain strategic control over the marketing and sale of Licensed product, (ii) Endo shall remain fully liable and responsible to Noven for all actions and/or inactions of its subcontractors under this Agreement as though such actions and/or inactions were made by Endo itself; and, (iii) Endo shall be solely responsible for the fees of, and any other payments to, each subcontractor.

Section 2.05. Non-compete. Except as provided in Section 2.06, during the term of this Agreement, the Parties shall not make, use, sell, market or distribute any Competing Product \*\*\* in the Territory, or grant to any Third Party a right to make, use, sell, market or distribute a Competing Product in the Territory.

Section 2.06. \*\*\*

#### ARTICLE III. REGISTRATION AND REGULATORY APPROVAL

Noven will be responsible for obtaining, and will use commercially reasonable efforts to obtain, Regulatory Approval of the Product ANDA in the United States. Noven agrees to keep Endo fully informed of its progress in seeking Regulatory Approval, including providing Endo with copies of any and all correspondence between Noven and the FDA relating to the Product ANDA. Within thirty (30) days of the first commercial sale of the Licensed Product, Noven will transfer the Product ANDA to Endo. Thereafter, during the term of this Agreement, Endo will be responsible for maintaining Regulatory Approval in the U.S. Noven shall provide Endo with all data and support reasonably necessary for Endo's maintenance of such Regulatory Approval.

Within thirty (30) days of the expiration or termination of this Agreement, Endo shall transfer all of its right, title and interest in and to the Product ANDA back to Noven for no additional consideration.

ARTICLE IV. COMMERCIALIZATION OF THE LICENSED PRODUCT

Section 4.01. Commercialization Generally. Endo shall use commercially reasonable efforts to Launch the Licensed Product promptly after Regulatory Approval of the Product ANDA and, at its own expense, to actively and diligently promote, market and sell the Licensed Product in the Territory during the term of this Agreement. Such efforts shall be no less than those efforts Endo would undertake for its own generic products with similar market potential.

Section 4.02. Commercial Launch.

(a) Subject to subsections (b), (c) and (d) of this Section 4.02, Endo shall Launch the Licensed Product within the territory within thirty (30) days of Regulatory Approval of the Licensed Product.

(b) Endo's obligation to Launch shall be suspended until such time as it has received all launch supplies of Licensed Product properly ordered from Noven pursuant to the Supply Agreement; provided that any delays or non-delivery of Licensed Product under the Supply Agreement are not a result of a breach of the Supply Agreement by Endo.

(c) Endo's obligation to Launch and to sell Licensed Product shall be suspended \*\*\*

(d) Endo's obligation to Launch and sell Licensed Product shall be suspended for such time as it is prevented from selling Licensed Product by a court order in the relevant territory that Licensed Product infringes a valid claim of a patent of a Third Party or Endo is prohibited from marketing the Licensed Product by any judgment, order, injunction, decree or award of any court, administrative agency, or arbitrator or government body.

(e) Except as otherwise set forth in this Article IV and Section 14.14, if Endo fails to commence to market any Licensed Product in accordance with the requirements of this Article IV, and such failure continues for a period of fifteen (15) business days after written notice from Noven to Endo, then this Agreement shall immediately terminate upon notice to Endo by Noven. Thereafter, Noven shall be free to use and sell Licensed Product in the territory as it may see fit. If Noven determines to terminate this Agreement with respect to the Licensed Product, Endo shall promptly take such actions as Noven may reasonably request, in order to transfer to Noven or its designee, for no additional consideration, all of Endo's right, title, and interest in and to any Regulatory Approvals relating to the Licensed Product in such country, and all information relating to any Regulatory Approvals not previously supplied to Noven.

Section 4.03 Marketing Plan. No later than ninety (90) days before the first commercial sale of Licensed Product, Endo shall provide Noven with a written marketing plan setting forth a detailed description of Endo's strategies and business plan with respect to the marketing, distribution, and sale of the Licensed Product in the Territory (the "Marketing Plan"). Thereafter, Endo Agrees to keep Noven apprised of its strategies and business plan with respect to the marketing, distribution, and sale of the Licensed Product in the Territory, and to provide to



Noven such other marketing related information as Noven shall reasonably request. Endo shall also provide Noven with an updated copy of the Marketing Plan prior to the beginning of each subsequent calendar year during the term of this Agreement. At Noven's request, designated employees of each of the parties shall confer not more than once every calendar quarter either in person at a location to be mutually agreed upon, or by teleconference, to discuss the Marketing Plan, competitive market conditions, strategic changes in the marketplace and Endo's respective actions and planned responses thereto.

Section 4.04 Limitations on Endo's Marketing of the Licensed Product. Endo shall be permitted to market and sell the Product as it would normally market and sell products of comparable market potential in the ordinary course of Endo's business. \*\*\*

ARTICLE V. CANADA AND OTHER TERRITORIES

Section 5.01. Canada. Noven hereby authorizes Endo to appoint an Authorized Subdistributor (as defined in Article II above) to distribute Licensed Product in Canada. The terms of this Agreement and the Supply Agreement shall govern the parties' activities in Canada with respect to Licensed Product, except that in the case of a conflict between this Article V and the rest of the terms of this Agreement and/or the Supply Agreement the terms of this Article V shall govern.

Section 5.02. Supply. Noven shall exclusively supply Licensed Product to Endo, and Endo shall exclusively purchase from Noven Licensed Product, for sale and use in Canada per the terms of the Supply Agreement.

Section 5.03. Regulatory Matters. Endo, together with the Approved Subdistributor, shall be responsible for filing, obtaining and maintaining all necessary Regulatory Approvals in Canada in order to use and sell the Licensed Product in Canada. Endo, together with the Approved Subdistributor, shall use commercially reasonable efforts to obtain such Canadian Regulatory Approval within a reasonable period of time and to thereafter promote, market and sell Licensed Product in Canada. Noven will provide all such information, as reasonably requested by Endo, that Noven may have in its possession in order to support such Canadian regulatory filings.

Section 5.04. Financial Terms. There shall be no profit split regarding sales of licensed Product in Canada.

Section 5.05. Liability. As further addressed in Section 12.01(e), Endo shall be responsible for third party claims for damages associated with selling and using Licensed Product in Canada which are not due to a breach of Noven's warranties in this Agreement or the Supply Agreement.

Section 5.06. Termination. In the event that Endo determines at any time that it will not pursue, or continue to pursue, marketing and selling of Licensed Product in Canada, it will promptly notify Noven and return all rights related to Licensed Product in Canada to Noven for no additional consideration. Endo's rights in Canada pursuant to this Article 5 are contingent upon (i) Endo evaluating the opportunity in Canada and notifying Noven in writing within one year of the Effective Date that it intends to proceed with seeking Regulatory Approval to market

Licensed Product in Canada and to market Licensed Product in Canada upon receiving such Regulatory Approval (the "Canadian Election"), and (ii) that Endo makes a commercial sale of License Product in Canada within two years of the Canadian Election, provided, however, that so long as Endo is using, and continues to use, commercially reasonable efforts to develop, register or launch the Licensed Product in Canada, this contingency shall be extended for up to two additional years. Endo's foregoing obligations of commercially reasonable efforts shall be subject to notice by Noven and cure by Endo per Section 13.02(a). The foregoing notwithstanding, If Endo has not made a commercial sale of Licensed Product in Canada within \*\*\* of its Canadian Election, Endo's rights in Canada under this Agreement and the Supply Agreement shall immediately cease, all rights related to Licensed Product in Canada shall be returned to Noven for no additional consideration, and Noven shall thereafter be free to pursue the Canadian market in any fashion that it sees fit

ARTICLE VI. FEES AND PAYMENTS

Section 6.01. Upfront Payment. Endo shall pay to Noven Eight Million Dollars (\$8,000,000) within three (3) business days of the execution of this Agreement.

Section 6.02. Milestone Payments.

(a) Launch Milestone Payment. Within ten (10) business days of Endo's first commercial sale of Licensed Product, Endo shall pay to Noven Ten Million Dollars (\$10,000,000), if fewer than \*\*\*other generic formulations of Duragesic(R) have been approved or launched, \*\*\*.

(b) Reduced Launch Milestone Payment. Within ten (10) business days of Endo's first commercial sale of Licensed Product, Endo shall pay to Noven Seven Million Five Hundred Thousand Dollars (\$7,500,000) (the "Reduced Launch Milestone Payment"), if \*\*\* or more other generic formulations of Duragesic(R) have been approved or launched, including \*\*\*.

(c) In the event that Endo makes the Reduced Launch Milestone Payment and IMS data proves that fewer than \*\*\* competitors had commenced commercial shipments during the thirty (30) day period immediately following Regulatory Approval of the Licensed Product, and Endo received the launch supplies of Licensed Product properly ordered from Noven pursuant to the Supply Agreement, then Endo shall pay Noven an additional launch milestone payment of \$2.5 million within fifteen (15) business days of Endo's receipt of such data. In no event shall Endo be responsible for more than Ten Million Dollars (\$10,000,000) in total, aggregate launch milestone payments. For the purpose of this paragraph, a competitor to Endo shall not be deemed to have made a "commercial shipment" if they made only a single, token shipment for the purpose of triggering patent litigation.

(d) Delayed Launch Milestone Reduction. In the event that (i) the final ANDA approval for the Licensed Product or (ii) the delivery to and acceptance by Endo of the Licensed Product ordered for the first month of commercial launch by Endo in accordance with the Supply Agreement (provided that shipment by Endo to its customers shall constitute acceptance and, in the absence of any quality issues reasonably identified by Endo, such acceptance shall not occur later than ten business days after Endo's receipt of the Licensed Product and all required

supporting documentation, including the certificate of analysis) occurs thirty (30) days or more after the first shipment of a Competing Product by \*\*\*, then the Launch Milestone or Reduced Launch Milestone otherwise due and payable shall be reduced in accordance with the following schedule:

<TABLE>		
<CAPTION>		
Amount of delay	Reduction in launch milestone	
-----	-----	
<S>	<C>	
30-59 days		\$1,000,000
60-89 days		\$1,500,000
90-119 days		\$2,000,000
120 or more days		\$2,500,000

Section 6.03 \*\*\*. Endo shall pay to Noven \*\*\* in the United States up to and including \*\*\* in any calendar year; and \*\*\* in the United States over \*\*\* in any calendar year. \*\*\* shall be determined on a calendar quarter by calendar quarter basis throughout the term of this Agreement. Endo shall pay to Noven its share of \*\*\* within thirty (30) days of the end of each applicable calendar quarter in which sales of Licensed Product have been made by Endo. Each \*\*\* payment shall be preceded by a statement which includes a detailed calculation of each of the applicable Net Sales, Cost of Goods Sold, \*\*\* and the share of \*\*\* due and payable. Such statement shall be provided to Noven within fifteen (15) days of the end of each calendar quarter following sales of Licensed Product under this Agreement and shall \*\*\*.

Section 6.04 Payments. All payments by Endo to Noven shall be made in United States Dollars by wire transfer to such account as Noven may notify to Endo from time to time.

ARTICLE VII. SUPPLY OF THE LICENSED PRODUCT

Noven shall be the exclusive supplier of Licensed Product to Endo, and shall supply Licensed Product to Endo at Noven's fully loaded manufacturing cost. The supply of Licensed Product to Endo by Noven shall be governed by the Supply Agreement, which shall address, among other things, the supply price, forecasts, purchase orders and minimum orders, and a Quality Agreement, which shall delineate the regulatory responsibilities of the Parties.

ARTICLE VIII. DEVELOPMENT OF ADDITIONAL PRODUCTS

Section 8.01 Noven's Commitment Regarding Additional Products. Following receipt of the Up-Front Payment of Eight Million Dollars (\$8,000,000) pursuant to Section 6.01 above, Noven hereby commits to allocate One Million Five Hundred Thousand Dollars (\$1,500,000) to the evaluation of, and the conduct of feasibility studies for, \*\*\*compounds identified by Endo, and mutually agreed by the parties, as candidates for transdermal delivery. Noven will not unreasonably reject a candidate proposed by Endo. The first such compound is identified in Exhibit C. Endo will nominate the additional \*\*\*candidates by July 1, 2004, and the additional agreed nominees will be added to Exhibit C by amendment upon mutual agreement of the parties. Once a compound has been added to Exhibit C, Endo and Noven shall work exclusively with each other to develop that compound for transdermal delivery. Noven will conduct the

evaluation and feasibility studies pursuant to the Evaluation Plan which will be mutually agreed to between the Parties and set forth in Exhibit D and Noven will use reasonable efforts to provide the deliverables described therein to Endo by December 31, 2004. Endo will establish criteria for determining whether the Additional Products thereafter progress into pilot clinical development. The parties may mutually agree to substitute candidates for development at any time, but there shall be no obligation to substitute a new candidate in place of a candidate that has failed the feasibility studies.

Section 8.02 Additional Commitments Regarding Additional Products. As Noven performs its technical feasibility work, the product candidates will be evaluated by the parties against Endo's clinical development criteria. Endo will determine whether an Additional Product will move into pilot studies within \*\*\* of receiving from Noven its feasibility evaluation. Once Endo has determined that an Additional Product will move into pilot studies, Endo will conduct pilot studies on the successful candidates \*\*\*. Within \*\*\* days of the completion of human pharmacokinetic studies on each Additional Product that has been nominated for pilot studies, Endo will determine whether such Additional Product will move into full clinical development. If Endo determines that an Additional Product is to move into final clinical work then the parties will negotiate a Commercialization Agreement pursuant to Section 8.03 below. Endo will move each nominated Additional Product for which a Commercialization Agreement is entered into between the Parties into full clinical development. If Endo at any time makes a final decision not to advance an Additional Product into pilot studies or nominate it for full clinical development, Noven shall be thereafter free to develop, license and/or commercialize such compound for its own benefit. Noven agrees to work with Endo in good faith to provide additional information to aid Endo in making its determination of whether to move each Additional Product into pilot studies and thereafter into full clinical development. Endo agrees to work with Noven in good faith in determining whether to move each Additional Product into pilot studies and thereafter into full clinical development.

Section 8.03. Commercialization Agreement. Once a product is nominated for full clinical development, the parties will have \*\*\* days to establish business terms for commercialization and to establish a clinical plan and budget for that candidate. Endo will fund and conduct the clinical development. If the parties cannot agree to terms in the \*\*\* period, then \*\*\*.

ARTICLE IX. INTELLECTUAL PROPERTY MATTERS

Section 9.01. Infringement by Third Parties.

(a) If, at any time on or after the Effective Date, either party shall become aware of any infringement or threatened infringement of the Noven Patents or any unfair competition, inappropriate or unauthorized use, disparagement or other tortious act by any third party in relation to the Licensed Product, then the party having such knowledge shall give prompt notice thereof to the other party.

(b) Subject to Section 9.02, Endo shall have the right \*\*\* using counsel reasonably acceptable to Noven, to take such action as it deems appropriate to enforce the Noven Patents in the Territory against any Competing Product that may be infringing the Noven Patents, including

initiating an appropriate Proceeding or threatening to initiate an appropriate Proceeding to prevent or eliminate the infringement of such Noven Patents with regard to any Competing Product, or the unfair competition, inappropriate or unauthorized use, disparagement or other tortious act by any third party in relation to the Licensed Product in the Territory. Subject to Section 9.01(c) below, Noven agrees to cooperate with Endo, \*\*\*, if and to the extent reasonably requested by Endo, including joining as a party to such Proceeding, if necessary to maintain standing.

(c) \*\*\*

(d) Endo shall not enter into any settlement, agreement, consent judgment or other voluntary final disposition of a Proceeding or threatened Proceeding under this Section 9.01, in whole or in part, without the prior written consent of Noven, which shall not be unreasonably withheld.

(e) All amounts awarded as damages, profits or otherwise in connection with any action specified in Section 9.01(b) taken by Endo shall be \*\*\*.

(f) If Endo elects not to take any action of the nature specified in Section 9.01(b) within sixty (60) days of becoming aware or receiving notice under Section 9.01 (a) of any infringement, threatened infringement, unfair competition, disparagement or other tortious act identified in Section 9.01(a), Endo shall give Noven notice of such decision, and Noven thereafter shall have the right to take any action of the nature specified in Section 9.01(g). In such event, all amounts awarded as damages, profits or otherwise in connection with any action taken by Noven shall be \*\*\*.

(g) Except for the rights specifically granted to Endo pursuant to Section 9.01(b) above, Noven shall have the sole and exclusive right to protect and enforce its Intellectual Property Rights in any Proceeding. All associated fees, costs and expenses shall be borne by Noven and all amounts awarded as damages, profits or otherwise in connection with any action specified in this Section 9.01(g) taken by Noven shall be the sole property of Noven.

Section 9.02. Third Party Claims regarding the Noven Patents.

(a) If, at any time on or after the Effective Date, any party shall become aware of any Proceeding or threat of any Proceeding by a third party alleging that any of the Noven Patents (or any claims asserted in the Noven Patents) are invalid or unenforceable, or otherwise seeking to limit the scope, construction or interpretation of any of the Noven Patents (or any claims asserted in the Noven Patents), such party shall promptly notify the other party of the same.

(b) \*\*\*

(c) \*\*\*.

Section 9.03. Rights of Election Regarding Potential Infringement . \*\*\*

Section 9.04. Infringement of Third Party Intellectual Property Rights.

(a) If, at any time on or after the Effective Date, any party shall become aware of any Proceeding or threat of any Proceeding by a third party alleging that the Licensed Product infringes the Intellectual Property Rights of any third party or otherwise seeking to prevent, or seek damages in relation to, the marketing of Licensed Product, such party shall promptly notify the other parties of the same.

(b) \*\*\*

(c) In the event of any Proceeding or threatened Proceeding contemplated by Section 9.03(b), the Controlling Party shall assume control of the defense of such Proceeding or threatened Proceeding, using counsel of its own choosing, that is reasonably acceptable to the other Party. The non-controlling party agrees to cooperate with the Controlling Party, at its own cost and expense, if and to the extent reasonably requested by the Controlling Party.

(d) The Controlling Party shall consult with the other party with respect to whether and how any such Proceeding should be defended, maintained, settled, or appealed throughout the pendency of such Proceeding. The Controlling Party shall keep the other party apprised throughout, and until final disposition of, any such Proceeding and give due consideration to the other party's views in connection with such Proceeding.

(e) The Controlling Party shall not enter into any settlement, agreement, consent judgment or other voluntary final disposition of a Proceeding or threatened Proceeding under this Section 9.04, in whole or in part, without the prior written consent of the other party, which shall not be unreasonably withheld.

(f) \*\*\*

Section 9.05. Certain Litigation. \*\*\*

ARTICLE X. CONFIDENTIALITY

Section 10.01. Confidentiality.

(a) Pursuant to the terms of this Agreement, each party (in such capacity, the "Disclosing Party"), has disclosed and will disclose to the other parties and/or their Affiliates or representatives (in such capacity, the "Receiving Party"), certain Confidential Information of the Disclosing Party. The Receiving Party shall make no use of such Confidential Information except in the exercise of its rights and the performance of its obligations set forth in this Agreement. The Receiving Party shall use the same efforts to keep secret, and prevent the disclosure to third parties of, the Confidential Information of the Disclosing Party as it would use with respect to its own Confidential Information. Confidential Information disclosed by the Disclosing Party shall remain the sole and absolute property of the Disclosing Party, subject to the rights granted herein. The above restrictions on the use and disclosure of Confidential Information shall not apply to any information which (i) is already known to the Receiving Party at the time of disclosure by the Disclosing Party, as demonstrated by competent proof, (ii) is or becomes generally available to the public other than through any act or omission of the Receiving Party in breach of this Agreement, (iii) is acquired by the Receiving Party free of an obligation of confidentiality from a third party who is free to provide the information as such, or

(iv) is developed independently by the Receiving Party without use, direct or indirect, of information that is required to be held confidential hereunder.

(b) Notwithstanding the provisions of Section 10.01(a):

(i) Endo shall be permitted to disclose to its distributors, wholesalers and other direct customers such Confidential Information relating to the Product as Endo shall reasonably determine to be necessary or useful in order to effectively market and distribute the Licensed Product;

(ii) Noven shall be permitted to disclose such Confidential Information relating to the Licensed Product as Noven shall reasonably determine to be necessary or useful in order to effectively perform its obligations under this Agreement and the Supply Agreement;

(iii) Noven shall be permitted to disclose such Confidential Information relating to the Licensed Product as it shall reasonably determine to be necessary or useful in order to pursue or obtain any Regulatory Approvals in respect of any other transdermal drug delivery products;

(iv) each of Noven and Endo shall be permitted to disclose to a Regulatory Authority such Confidential Information relating to the Licensed Product as it shall reasonably determine (but only after consulting with the other parties to the extent practicable) to be necessary to comply with the provisions of Applicable Law; and

(v) nothing in this Section 10.01 shall be interpreted to limit the ability of either Noven or Endo to disclose its own Confidential Information.

(c) Each of Noven and Endo acknowledge and agree that the terms and conditions of this Agreement shall be considered Confidential Information of each party and shall be treated accordingly.

(e) Each party specifically recognizes that any breach by it of this Section 10.01 may cause irreparable injury to the other parties and that actual damages may be difficult to ascertain, and in any event, may be inadequate. Accordingly (and without limiting the availability of legal or equitable, including injunctive, remedies under any other provisions of this Agreement), each party agrees that in the event of any such breach, notwithstanding the provisions of Section 12.02 hereof, the other parties shall be entitled to seek, by way of private litigation in the first instance, injunctive relief and such other legal and equitable remedies as may be available.

#### ARTICLE XI. REPRESENTATIONS AND WARRANTIES

Section 11.01. Representations and Warranties. Each party hereby represents and warrants to the other that as of the Effective Date:

(a) Organization. It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation. As of the Closing Date, it will be

duly qualified to do business in each jurisdiction where the character of its business (after giving effect to this Agreement) make such qualifications necessary to carry on its business.

(b) Power, Authority and Enforceability. It has full corporate power and authority to enter into and perform this Agreement and to consummate the transactions contemplated herein. This Agreement has been or shall be duly executed and delivered by duly authorized signatories. This Agreement constitutes a valid and binding obligation, enforceable against in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws now or hereafter in effect relating to or affecting creditors' rights generally.

(c) No Violation. Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby, will (i) conflict with or result in a breach of any of the terms, conditions or provisions of its certificate of incorporation or other governing or charter document, or of any statute or administrative regulation, or, to the best of its knowledge, of any order, writ, injunction, judgment or decree of any court or governmental authority or of any arbitration award or any agreement binding upon it or its assets, or (ii) to the best of its knowledge, contravene or conflict with, or constitute a violation of, any provisions of any Applicable Law binding upon it.

(d) No Default. It is not a party to any unexpired, undischarged or unsatisfied written or oral contract, agreement, indenture, mortgage, debenture, note or other instrument under the terms of which performance by it according to the terms of this Agreement will be a default, or whereby timely performance by it according to the terms of this Agreement may be prohibited, prevented or delayed.

Section 11.02 Noven hereby represents and warrants to Endo that:

(a) Noven is the owner of, or has sufficient rights to, all of the Noven Intellectual Property Rights in existence on the Effective Date for the Manufacture, marketing and sale of the Products and to grant to Endo the rights granted under this Agreement (including the right to market and promote the Products). To the knowledge of Noven, as of the Effective Date, all of the Noven Intellectual Property Rights are valid, in full force and effect and have been maintained to date, and, are not the subject of any interference or opposition proceedings in the Territory.

(b) As of the Effective Date, to the knowledge and belief of the executive officers and Intellectual Property Counsel of Noven, \*\*\*.

(c) To the actual knowledge of the executives of Noven as of the Effective Date, Noven is not aware of any asserted or unasserted claims, interferences, oppositions or demands of any Third Party against the Noven Intellectual Property Rights or the Licensed Product in existence as of the Effective Date in the Territory.



ARTICLE XII. INDEMNIFICATION AND LIMITATION OF LIABILITY

Section 12.01. Indemnification. In order to allocate between themselves the responsibility for claims arising out of this Agreement, and except as otherwise specifically provided for herein, from and after the Effective Date, the parties shall indemnify each other as provided in this Section 12.01.

(a) Indemnification Obligations of Endo. From and after the Effective Date, Endo shall defend, indemnify and hold Noven, its Affiliates, and each of their respective officers, directors, agents, employees and shareholders (collectively, "Noven Indemnitees"), harmless from and against any and all Damages which Noven Indemnitees may incur or suffer, or with which any of them may be faced arising out of:

(i) the breach by Endo of this Agreement including any breach of its representations, warranties, covenants or obligations under this Agreement;

(ii) the enforcement by Noven Indemnitees of their rights under this Section 12.01(a);

(iii) Endo's violation of any Applicable Law; and

(iv) Endo's negligence or willful misconduct;

provided, however, that, in each such case, Endo shall not be liable hereunder to the extent such Damages arise from the willful misconduct or negligence of, or a violation of any Applicable Law by or from the breach of the provisions of this Agreement or the Supply Agreement by Noven, its Affiliates, agents, employees or contractors or to the extent such liability is allocated in Sections 12.01 (c), (d) or (e) below.

(b) Indemnification Obligations of Noven. From and after the Effective Date, Noven shall defend, indemnify and hold Endo, its Affiliates, and each of their respective officers, directors, agents, employees, shareholders or members (collectively, "Endo Indemnitees") harmless from and against any and all Damages which Endo Indemnitees may incur, or suffer, or with which any of them maybe faced arising out of:

(i) the breach by Noven of this Agreement including any breach of its representations, warranties, covenants or obligations under this Agreement;

(ii) the enforcement by Endo Indemnitees of their rights under this Section 12.01(b);

(iii) Noven's violation of any Applicable Law; and,

(iv) Noven's negligence or willful misconduct;

provided, however, that, in each such case, Noven shall not be liable hereunder to the extent such Damages arise from willful misconduct or negligence of, or a violation of any Applicable Law or from the breach of the provisions of this Agreement or the Supply Agreement by Endo, its

Affiliates, agents, employees or contractors or to the extent such liability is allocated in Sections 12.01 (c), (d) or (e) below.

(c) Product Liability. Except with regard to Section 12.01(e) below, all other provisions of this Agreement notwithstanding, this Section 12.01(c) shall govern the allocation of liability with respect to torts of bodily injury related to the use of the Licensed Product.

(i) From and after the Effective Date, Noven shall defend, indemnify and hold the Endo Indemnitees harmless from and against any and all Damages which the Endo Indemnitees may incur, or suffer, or with which any of them may be faced arising out of \*\*\*.

(ii) From and after the Effective Date, Endo shall defend, indemnify and hold the Noven Indemnitees harmless from and against any and all Damages which the Noven Indemnitees may incur, or suffer, or with which any of them may be faced arising out of \*\*\*.

(iii) To the extent that either the Endo Indemnitees or the Noven Indemnitees incur, suffer, or are faced with Damages arising out of any tort claims of bodily injury relating to or arising out of any use of Licensed Product attributed to any reason other than those set forth in the preceding subsections (i) and (ii), \*\*\*.

(d) Intellectual Property. \*\*\*

(e) Canada. Anything else in this agreement to the contrary notwithstanding, from and after the Effective Date, Endo shall defend, indemnify and hold the Noven Indemnitees harmless from and against any and all Damages which the Noven Indemnitees may incur, or suffer or with which any of them maybe faced arising out of the any and all activities associated with the Licensed Product in Canada; provided, however, that in each such case, Endo shall not be liable hereunder to the extent such Damages are due to any defect in Noven's design of the Licensed Product or any violation of Noven's representations or warranties in this Agreement or the Supply Agreement.

(f) Procedure. If any Proceeding arises as to which a right of indemnification provided in this Article XII applies, the Person seeking indemnification (the "Indemnified Party"), shall within twenty (20) days notify the party obligated under this Article XII to indemnify the Indemnified Party (the "Indemnifying Party"), thereof in writing, except to the extent that such failure to notify within 20 days does not prejudice the Indemnifying Party's ability to defend or contest any such Proceeding, and allow the Indemnifying Party and its insurers to assume direction and control of the defense against such Proceeding, at its sole expense, including the settlement thereof at the sole option of the Indemnifying Party or its insurers; provided, however, that the Indemnifying Party may not enter into any compromise or settlement without the prior written consent of the Indemnified Party unless such compromise or settlement includes as an unconditional term thereof the giving by each plaintiff or claimant to the Indemnified Party of a release from all liability in respect of such claim and only if such compromise or settlement does not include any admission of legal wrongdoing on the part of the Indemnified Party. The Indemnified Party shall fully cooperate with the Indemnifying Party and its insurer in the disposition of any such matter and the Indemnified Party will have the right and option to participate in (but not control) the defense of any Proceeding as to which this Article

VI applies, with separate counsel at its election and cost. If the Indemnifying Party fails or declines to assume the defense of any such Proceeding within thirty (30) days after notice thereof, the Indemnified Party may assume the defense thereof for the account and at the risk of the Indemnifying Party. The Indemnifying Party shall pay promptly to the Indemnified Party any Damages to which the indemnity under this Article XII applies, as incurred.

Section 12.02. LIMITATION OF LIABILITY.

(a) NO PARTY SHALL BE ENTITLED TO RECOVER ANY PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS FROM LOST SALES TO THIRD PARTIES) WHATSOEVER UNDER THIS AGREEMENT, EXCEPT TO THE EXTENT ANY SUCH PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARE PAYABLE TO A THIRD PARTY AND SUBJECT TO INDEMNIFICATION UNDER THIS ARTICLE 12.

(b) Notwithstanding anything to the contrary contained herein, although a party may be entitled to make a claim for indemnification pursuant to more than one section of this Article 12, a party shall not be entitled to recover indemnification for the same claim under more than one section of this Article 12.

ARTICLE XIII. TERM AND TERMINATION

Section 13.01. Term. This Agreement and the license granted hereunder shall take effect as of the Effective Date and continue in full force and effect in each country throughout the Territory for a period of ten (10) years from the first commercial sale of the Licensed Product . Upon expiration of this Agreement, the Parties may mutually agree to extend this Agreement on terms to be negotiated in good faith taking into account the expiration of the applicable patents by giving written notice to the other party of its intention to do so prior to the end of any such term.

Section 13.02. Certain Termination Events.

(a) If either Endo or Noven should fail to discharge fully and promptly any of its material obligations under this Agreement and/or the Supply Agreement attached as Exhibit B, including, without limitation, obligations to make payments, and should such party failing to discharge any of its material obligations fail to cure such failure within thirty (30) days in the case of failure to make payments or with in sixty (60) days for other failures after notice in writing thereof by the other party, which period to cure may be extended for up to sixty (60) days, upon written request, if such additional time is reasonably necessary to effect such cure and provided that such party is using diligent effort to pursue such cure, this Agreement can thereupon be terminated at the aggrieved party's option upon notice to that effect; provided, however, that such termination shall not come into effect unless and until the time period for the chief executive officers of the parties to negotiate a resolution of the dispute, pursuant to Section 14.02 has expired without the dispute having been resolved.

(b) Either party may terminate this Agreement with immediate effect in the event that any proceeding under a Bankruptcy Act or any insolvency, receivership or dissolution

proceeding is filed against the other party and such proceeding is not dismissed within sixty (60) days after the filing thereof.

(c) Either party may terminate this Agreement with immediate effect with respect to any Licensed Product that is permanently and completely withdrawn from all markets in the Territory for serious adverse health or safety reasons.

(d) \*\*\*

(e) Either party may terminate this Agreement with immediate effect upon notice to the other party, if the other party or their Affiliates, makes, markets, sells, or distributes any transdermal product in the Territory that is a Competing Product.

(f) Following launch of the Licensed Product either party may terminate this Agreement upon ninety (90) days prior written notice to the other party if the Gross Margin to be split by the parties pursuant to Section 6.03 is less than \*\*\*of the corresponding Net Sales in any two (2) consecutive calendar quarters. In the event of such a termination, if the non-terminating party desires to continue commercializing the Licensed Product, the terminating party shall transfer to the non-terminating party sufficient rights under this Agreement to enable the non-terminating party to continue to use and sell Licensed Product under the Product ANDA and the Intellectual Property Rights. The terminating party shall have no further obligations under this Agreement but shall be entitled to a royalty of \*\*\* of net sales of Licensed Product by the non-terminating party in the event that the non-terminating party continues to commercialize the Licensed Product.

(g) \*\*\*

(h) Endo may terminate this Agreement with immediate effect upon notice to Noven before the Commercial Launch of Licensed Product in the event that that the delay referred to in Section 6.02(d) exceeds 120 days.

Section 13.03. Effect of Termination.

(a) Upon termination of this Agreement for any reason, Endo shall promptly take such actions as Noven may reasonably request, in order to transfer to Noven or its designee, free of charge, all of Endo's right, title and interest in and to any Regulatory Approvals relating to the Licensed Products, and all information relating to any Regulatory Approvals not previously supplied to Noven.

(b) Upon termination, this Agreement shall forthwith become void and of no further force or effect, except for the following provisions, which shall remain in full force and effect: (a) Article 10 (Confidentiality), (b) this Section 13.03, (c) Section 14.10 (Governing Law), (d) Section 14.15 (Public Announcements and Publications), (e) Section 14.12 (Entire Agreement) and (f) Section 14.13 (Expenses). In addition, in the event of a termination of this Agreement by Noven related to the Licensed Product, Endo may, at its option, continue with the development of any other products in development, and this Agreement shall remain in force and effect to the extent applicable to such development products. The rights and remedies provided in this Article VII shall be cumulative and not exclusive of any rights or remedies provided by Applicable Law.

Any termination of this Agreement shall not affect any right or claim hereunder that arises prior to such termination, which claims and rights shall survive any such termination.

(c) Nature of Licenses. All rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of 11 U.S.C. Section 365(n) of the Bankruptcy Laws, licenses of rights to "intellectual property" as defined under 11 U.S.C. Section 101(35A) of the Bankruptcy Laws. The Parties agree that Endo, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights, including any right to enforce any exclusivity provision of this Agreement, remedies, and elections under Bankruptcy Laws. To the fullest extent permitted by law, the Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Noven under the Bankruptcy Laws, Endo shall be entitled to all applicable rights under 11 U.S.C. Section 365(n) of the Bankruptcy Laws, including copies and access to, as appropriate, any such intellectual property and all embodiments of such intellectual property upon written request therefor by Endo, and such, if not already in its possession, shall be promptly delivered to Endo.

ARTICLE XIV. MISCELLANEOUS

Section 14.01. Notices. All notices, claims, certificates, requests, demands and other communications hereunder shall be in writing and shall be delivered personally or sent by confirmed facsimile transmission, air courier, or registered or certified mail, return receipt requested, addressed as follows:

if to Noven:

Noven Pharmaceuticals, Inc.  
11960 S. W. 144th Street Miami, Florida 33186  
Attention: CEO & General Counsel  
Telecopy: 305-964-3340

with copies (which shall not constitute notice) to:

Frommer Lawrence & Haug LLP  
745 Fifth Avenue  
New York, New York 10151  
Attention: Edgar H. Haug, Esq.  
Telecopy: 212-588-0500

if to Endo:

Endo Pharmaceuticals Inc.

100 Painters Dr.  
Chadds Ford, PA 19317  
Attention: General Counsel  
Facsimile No.: (610) 558-9684

or to such other address as the party to whom notice is to be given may have furnished to the other party in writing in accordance herewith. Any such communication shall be deemed to have been delivered (a) when delivered, if delivered personally, (b) when sent (with written confirmation received), if sent by facsimile transmission on a Business Day, (c) on the first Business Day after dispatch (with written confirmation received), if sent by facsimile transmission on a day other than a Business Day, (d) on the second Business Day after dispatch, if sent by air courier, and (e) on the fifth Business Day after mailing, if sent by mail.

Section 14.02. Disputes. In the event of any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, or the rights or obligations of the parties hereunder, the parties shall try to settle their differences amicably between themselves. Any party may initiate such informal dispute resolution by sending written notice of the dispute to the other parties, and within ten (10) days after such notice, the Chief Executive Officers of the parties shall meet for attempted resolution by good faith negotiations. If they are unable to resolve such disputed matter within thirty (30) days of initiating such negotiations, the parties agree first to try in good faith to settle the dispute by mediation in New York, New York under the Commercial Mediation Rules of the American Arbitration Association. If following any such mediation the parties still have not been able to resolve any such dispute, the parties agree to submit the dispute to final and binding arbitration before a single arbitrator in New York, New York under the Commercial Arbitration Rules of the American Arbitration Association. The parties agree that a judgment may be entered on the arbitrator's award in any court of competent jurisdiction. The arbitrator in reviewing any claim under this Agreement shall have the exclusive authority to determine any issues as to the arbitration of any such claim or related disputes under this Agreement. In reaching a decision, the arbitrator shall interpret, apply and be bound by this Agreement and by Applicable Law. The arbitrator shall have no authority to add to, detract from or modify this Agreement or any Applicable Law in any respect. The arbitrator may not grant any remedy or relief that a court of competent jurisdiction could not grant, nor any relief or remedy greater than that sought by the parties, nor any punitive, incidental or consequential damages, except to the extent any such punitive, incidental or consequential damages are payable to a third party. Any up-front costs of the arbitrator shall be borne equally by the parties; provided, however, that the non-prevailing party in any such arbitration shall pay, and to the extent applicable reimburse the prevailing party for, the costs and expenses of the arbitrator, including costs and expenses payable to the American Arbitration Association and to the arbitrator; and provided further, that in the event each party prevails as to certain claims in connection with any such arbitration, the fees of the arbitrator shall be paid and/or reimbursed in accordance with the decision of the arbitrator. Each party shall bear its own costs incurred in connection with attorneys' fees and related expenses. Notwithstanding the foregoing provisions of this Section 8.02, nothing in this Agreement shall limit or in any way restrict the ability of any party to seek injunctive or other equitable relief in a court or other judicial body.

Section 14.03. Independent Contractors. In making and performing this Agreement, the parties are acting and shall act as independent contractors. Nothing in this Agreement shall be

deemed to create all agency, joint venture or partnership relationship between the parties hereto. No party shall have the authority to obligate another party in any respect, and no party shall hold itself out as having any such authority. All personnel of Noven shall be solely employees of Noven and shall not represent themselves as employees of Endo. All personnel of Endo shall be solely employees of Endo and shall not represent themselves as employees of Noven.

Section 14.04. Assignment. Subject to Section 2.06 the parties may not assign or otherwise transfer this Agreement, in whole or in part, without the prior written consent of the other, and any such attempt to do so shall be null and void, except that each Party may assign its rights and transfer its duties hereunder without obtaining such written consent in the event of such Party's merger, consolidation or sale of all or substantially all of its assets.

Section 14.05. Binding Effect; Benefit. This Agreement shall inure to the benefit of and be binding upon the parties hereto, and their successors and permitted assigns. Nothing in this Agreement, express or implied, is intended to confer on any Person other than the parties hereto, and their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement.

Section 14.06. Amendments. This Agreement shall not be modified, amended or supplemented except pursuant to an instrument in writing executed and delivered on behalf of each of the parties hereto.

Section 14.07. No Waiver. The failure in any one or more instances of a party to insist upon performance of any of the terms, covenants or conditions of this Agreement, to exercise any right or privilege conferred in this Agreement, or the waiver by said party of any breach of any of the terms, covenants or conditions of this Agreement, shall not be construed as a subsequent waiver of any such terms, covenants, conditions, rights or privileges, but the same shall continue and remain in full force and effect as if no such forbearance or waiver had occurred. No waiver shall be effective unless it is in writing and signed by an authorized representative of the waiving party.

Section 14.08. Counterparts. This Agreement shall become binding when any one or more counterparts hereof, individually or taken together, shall bear the signatures of each of the parties hereto. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original as against the party whose signature appears thereon, but all of which taken together shall constitute but one and the same instrument. Each party may execute this Agreement on a facsimile of the Agreement. In addition, facsimile signatures of authorized signatories of any party shall be valid and binding and delivery of a facsimile signature by any party shall constitute due execution and delivery of this Agreement.

Section 14.09. Interpretation. The article and section headings contained in this Agreement are for convenience of reference only and shall not affect the meaning or interpretation of this Agreement. As used in this Agreement, any reference to the masculine, feminine or neuter gender shall include all genders, the plural shall include the singular, and singular shall include the plural. Unless the context otherwise requires, the term "party" when used herein means a party hereto. References herein to a party or other Person include their respective successors and assigns. The words "include," "includes" and "including" when used

herein shall be deemed to be followed by the phrase "without limitation" unless such phrase otherwise appears. Unless the context otherwise requires, references herein to Articles, Sections, Exhibits and Schedules shall be deemed references to Articles and Sections of, and Exhibits and Schedules to, this Agreement. Unless the context otherwise requires, the words "hereof," "hereby" and "herein" and words of similar meaning when used in this Agreement refer to this Agreement in its entirety and not to any particular Article, Section or provision hereof. With regard to each and every term and condition of this Agreement, the parties understand and agree that the same have or has been mutually negotiated, prepared and drafted, and that if at any time the parties desire or are required to interpret or construe any such term or condition or any agreement or instrument subject thereto, no consideration shall be given to the issue of which party actually prepared, drafted or requested any term or condition of this Agreement.

Section 14.10. Governing Law. This Agreement and any claims, disputes or causes of action relating to or arising out of this Agreement shall be construed in accordance with and governed by the substantive laws of the State of New York, without giving effect to the conflict of laws principles thereof.

Section 14.11. Unenforceability. If any provisions of this Agreement are determined to be invalid or unenforceable in any jurisdiction, such provisions shall be ineffective to the extent of such invalidity or unenforceability in such jurisdiction, without rendering invalid or unenforceable the remaining provisions hereof or affecting the validity or enforceability of any of such provisions of this Agreement in any other jurisdiction. The parties will use their best efforts to substitute the invalid or unenforceable provision with a valid and enforceable one which conforms, as nearly as possible, with the original intent of the parties.

Section 14.12. Entire Agreement. This Agreement, together with the Supply Agreement and the Quality Agreement, embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements, commitments, arrangements, negotiations or understandings, whether oral or written, between the parties hereto and their respective Affiliates with respect thereto. There are no agreements, covenants or undertakings with respect to the subject matter of this Agreement other than those expressly set forth or referred to herein and no representations or warranties of any kind or nature whatsoever, express or implied, are made or shall be deemed to be made herein by the parties hereto, except those expressly made in this Agreement, the Supply Agreement and the Quality Agreement.

Section 14.13. Expenses. Except as expressly set forth herein, each party hereto shall bear all fees and expenses incurred by such party in connection with, relating to or arising out of the execution, delivery and performance of this Agreement and the consummation of the Contemplated Transactions, including attorneys', accountants' and other professional fees and expenses.

Section 14.14. Force Majeure. If the performance of this Agreement or any obligation hereunder (except the payment of money) by any party is prevented by reason of any cause beyond the reasonable control of the affected party, including fire, flood, riot, war, explosions, acts of God (including hurricanes and tropical storms), acts of a public enemy, labor disturbances or acts, regulations or laws of any government adopted after the date of this Agreement or



subject to a new interpretation after the date of this Agreement that render impossible or illegal the performance by a Party of its obligations under this Agreement, the party so affected, upon notice to the other parties, shall be excused from such performance; provided that the party so affected shall use diligent effort to avoid or remove such cause or causes of non-performance and shall continue to perform hereunder with the utmost dispatch whenever such cause or causes are removed.

Section 14.15 Public Announcements and Publications. Except as required by law, governmental regulation or by the requirements of any securities exchange on which the securities of a Party hereto are listed, no Party to this Agreement shall make, or cause to be made, any press release or public announcement in respect of this Agreement, including its existence, or the transactions contemplated hereby or otherwise communicate with any news media without the prior written consent of the other Party, which consent shall not be unreasonably withheld, and the parties shall cooperate to the extent practicable as to the timing and contents of any such press release or public announcement. Notwithstanding the foregoing, the Parties hereby agree to jointly prepare a press release announcing the existence of this Agreement, such press release to be approved by each Party prior to any distribution to any media outlet. Notwithstanding the foregoing, the Parties specifically understand and agree that neither Party shall make any public announcement or disclose to any Third Party the identity of any API being investigated and developed hereunder other than fentanyl without mutual written agreement between the parties. In the event that a Party is required to file or disclose the terms of this Agreement pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC"), such Party may file or disclose such Confidential Information to the extent it determines in its sole discretion that it is so required subject to requesting appropriate confidential treatment from the SEC.

IN WITNESS WHEREOF, the parties hereto have entered into this Agreement effective as of the Effective Date.

NOVEN PHARMACEUTICALS, INC.

ENDO PHARMACEUTICALS INC.

By:\_\_\_\_\_

By:\_\_\_\_\_

Name:

Name:

Title:

Title:

Date:

Date:

SCHEDULE 2.06

\*\*\*

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EXHIBIT A  
NOVEN PATENTS

\* \* \*

EXHIBIT B  
SUPPLY AGREEMENT

\*\*\*

EXHIBIT C  
ADDITIONAL PRODUCTS

\*\*\*

EXHIBIT D  
EVALUATION PLAN

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SUPPLY AGREEMENT

DATED AS OF FEBRUARY 25, 2004

BY AND BETWEEN

NOVEN PHARMACEUTICALS, INC.

AND

ENDO PHARMACEUTICALS INC.

THE CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO A CONFIDENTIAL TREATMENT REQUEST IN ACCORDANCE WITH RULE 24B-2 OF THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED. REDACTED PORTIONS OF THIS EXHIBIT ARE MARKED BY AN \*\*\*.



Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (the "Agreement"), is hereby entered into as of February 25, 2004 (the "Effective Date"), by and between Noven Pharmaceuticals, Inc., a Delaware corporation ("Noven"), and Endo Pharmaceuticals Inc., a Delaware corporation ("Endo").

WITNESSETH

WHEREAS, Noven and Endo are contemporaneously herewith entering into a License Agreement (the "License Agreement") related to a fentanyl transdermal patch product (the "Product" as further defined herein) developed by Noven;

WHEREAS, Noven desires to manufacture and supply Endo with its requirements of Product; and,

WHEREAS, Endo desires to purchase its requirements of the Product from Noven pursuant to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements of the parties contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereby agree as follows:

ARTICLE I DEFINITIONS

Section 1.01. Definitions. As used herein, the following capitalized terms have the following meanings:

"ANDA" means an abbreviated new drug application filed with the FDA pursuant to 21 U.S.C. 355(j)

"Affiliate" means with respect to a Person, any legally distinct corporation, firm, individual or other form or business organization which is, directly or indirectly, controlled by, controlling, or under common control with, the subject Person hereto. An entity shall be regarded as being in control of another entity if such first entity has the direct or indirect power to order or cause the direction of the management and policies of the other entity, whether through ownership of at least fifty percent (50%) of the outstanding voting securities or participating profit interest of such entity, through other dominant equity ownership or by contract, statute, regulation or otherwise.

"API" means the active pharmaceutical ingredient fentanyl base.

"Applicable Law" means, with respect to any Person, any domestic or foreign, federal, state or local statute, treaty, law, ordinance, rule, regulation, administrative interpretation, order, writ, injunction, judicial decision, decree or other requirement of any Governmental Authority applicable to such Person or any of such Person's respective properties, assets, officers, directors,

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employees, consultants or agents (in connection with such officers', directors', employees', consultants' or agents' activities on behalf of such Person).

"Business Day" means a day other than a Saturday, Sunday or other day on which commercial banks in New York, New York, USA are authorized or required by law to close.

"Code of Federal Regulations" or "C.F.R." means the codification of the general and permanent rules published in the Federal Register. Title 21 of the C.F.R. contains the regulations promulgated by the FDA pursuant to the FDC Act.

"Confidential Information" means all secret, confidential or proprietary data, know-how and related information, including all regulatory applications and other regulatory filings, regulatory and clinical materials, Materials, the content of any unpublished patent applications, operating methods and procedures, marketing, manufacturing, distribution and sales methods and systems, sales figures, pricing policies and price lists and other business information and shall include all information disclosed or accessed by a party from the other in connection with this Agreement.

"Damages" means all liabilities, demands, obligations, assessments, judgments, levies, losses, fines, penalties, damages (including compensatory damages), costs and expenses, including reasonable attorneys', accountants', investigators', and experts' fees and expenses, reasonably sustained or incurred in connection with the defense or investigation of any Proceedings (including any Proceedings to establish insurance coverage).

"FDA" means the United States Food and Drug Administration and any successor agency thereto.

"FDC Act" means the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301 et seq., as amended, and the regulations promulgated there under, as amended from time to time.

"GAAP" means generally accepted accounting principles in effect in the United States from time to time.

"GMP" means the current Good Manufacturing Practices as that term is presently or hereafter defined by the FDA or other applicable Regulatory Authority.

"Governmental Authority" means any foreign, domestic, federal, territorial, state or local governmental authority, quasi-governmental authority, instrumentality, court, government or self-regulatory organization (including any securities exchange such as The NASDAQ Stock Market), commission, tribunal or organization or any regulatory, administrative or other agency, or any political or other subdivision, department or branch of any of the foregoing.

"Label" shall mean any package (primary or secondary container) labeling designed for use with the Product, including the package insert; and any variation of such term, such as "Labeled" or "Labeling", shall mean the act of doing the foregoing.

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"Materials" means all ingredients, items or substances (including those that may not appear in the Product) used or required for use by Noven to manufacture the Product, including the API, all other active drug ingredients, excipients, packaging components, printed materials and manufacturing materials associated with the Product.

"Manufacturing Facility" means Noven's facility located at 11960 S.W. 144th Street, Miami, Florida 33186 or such other FDA-approved facility as Noven may notify to Endo from time to time.

"Person" means an individual, a corporation, a general partnership, a limited partnership, a limited liability company, a limited liability partnership, an association, a trust or any other entity or organization, including a Governmental Authority.

"Proceedings" means governmental, judicial, administrative or adversarial proceedings (public or private), litigation, suits, arbitration, disputes, claims, causes of action or investigations.

"Product" or "Products" means the products listed in Exhibit C which are the fully packaged, labeled and released fentanyl transdermal patch product that is the subject of the Product ANDA.

"Quality Agreement" means the Quality Agreement attached hereto as Exhibit B.

"Regulatory Authority" means a Governmental Authority that has the authority over the manufacture, use, storage, import, export, clinical testing, transport, marketing, sale or distribution of the Product in all or any portion of the Territory, including the FDA.

"Securities Laws" means the United States Securities Act of 1933, as amended, the United States Securities Exchange Act of 1934, as amended, and any other similar law or regulation of a Governmental Authority, or any successor to any such laws or regulations, together with any rules, regulations or listing standards or agreements of any national or international securities exchange or The NASDAQ Stock Market.

"Specifications" means, collectively, the manufacturing, packaging and testing procedures and standards for Product, including all applicable control procedures and analytical test methods, each as described in the Product ANDA as amended, supplemented or otherwise modified from time to time in accordance with Applicable Law.

"Territory" shall have the meaning set forth in the License Agreement as may be amended from time to time.

"Validation Batches" means the batches which Noven elects to utilize to satisfy the FDA requirements regarding validation of its commercial manufacturing process. \*\*\*.

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Section 1.02. Other Definitions. Each of the following terms is defined in the section of this Agreement referenced opposite such term.

Term.....	Section
----	-----
<S> Agreement .....	<C> Preamble
Collar.....	4.03
Endo.....	Preamble
Effective Date .....	Preamble
Force Majeure Event .....	11.13
Launch Quantities .....	3.09
License Agreement .....	Recitals
Noven.....	Preamble
Rejection Notice .....	3.07 (a)
Tech Transfer Services.....	10.02 (e)
Term .....	10.01

ARTICLE II COMMITMENT TO SUPPLY AND PURCHASE

Section 2.01. Supply. Subject to the terms and conditions of this Agreement and the license rights granted to Endo in the License Agreement, from and after the Effective Date: (1) Noven shall use commercially reasonable efforts to supply Endo with its requirements of Product as ordered by Endo pursuant to the terms of this Agreement; (2) Noven shall not supply Product to any third Party for use or sale within the Territory without the prior written consent of Endo; (3) Endo shall purchase Product exclusively from Noven; and, (4) Endo shall only use and sell Product within the Territory.

Section 2.02. API. In the event that either party is able to secure a lower price for the API from a source that meets Noven's quality requirements, subject to Noven's contractual commitments with its suppliers, Noven will work with Endo in good faith to utilize such API in place of its own source of API. Once agreed to by both parties to qualify a lower price API, Endo and Noven shall equally share all out of pocket expenses in qualifying and otherwise securing such new API source. To the extent that Noven is able to use such lower priced API, the lower cost will be reflected in Noven's manufacturing costs for the Product. \*\*\* In the period prior to commercial launch of the Product, to the extent that Endo supplies Noven with the API, Endo will invoice Noven for the portion of the cost of such API for which Noven is assuming risk pursuant to Section 3.09 below. All such invoices shall be due and payable within thirty days of receipt and shall bear interest at the rate of 1% per month or the maximum allowable by law on any overdue amounts. Noven shall include such API costs in its manufacturing costs and Endo shall deduct the API costs not invoiced to Noven from the next \*\*\* payment otherwise owed Noven under the License Agreement. After the commercial launch of the Product, Endo shall deduct the cost of the API it supplies Noven from the next \*\*\* payment otherwise owed Noven under the License Agreement.

Section 2.03. Compliance with Applicable Law. Endo hereby covenants and agrees that Endo and its Affiliates shall store, handle, transport, market, promote, sell, distribute, use and otherwise dispose of any Product supplied by Noven, and any materials used in connection with such

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Product, including any labeling, packaging and advertising, in accordance with all Applicable Laws.

#### ARTICLE III FORECASTS, ORDERS, DELIVERY AND ACCEPTANCE

Section 3.01. Forecasts. Within 30 days of the Effective Date, Endo shall provide to Noven a good faith, but non-binding, forecast of its requirements for Product for the following twenty-four (24) months. Beginning approximately 9 months before the anticipated commercial launch date of the Product by Endo and within ten Business Days after the first day of each calendar month thereafter during the Term, Endo will provide Noven with a non-binding (except as otherwise provided in Section 3.03), rolling 12-month forecast of its requirements of Product to be delivered by Noven. Endo shall use reasonable commercial efforts to ensure that its forecasts are as accurate as possible.

Section 3.02. Validation Batches and Initial Order. Noven and Endo hereby acknowledge and agree that, in order to address the initial requirements for the commercial launch of the Product, the lead times associated with manufacturing Product and the general preparation for such commercial launch, Noven and Endo will consult with each other in good faith regarding the anticipated commercial launch date. In connection with such discussions Endo will provide a binding initial purchase order to Noven approximately \*\*\* ; the delivery date for such purchase orders shall be between one and thirty days prior to the anticipated commercial launch date of the Product. The initial purchase orders shall be for quantities of the Product sufficient for launch and for the first month of sales of the Product; such amount of product shall be no less than \*\*\* and no greater than \*\*\* of Endo's most recent forecasted requirements for the first month of sales of the Product; provided, however, that upon request by Endo, Noven shall attempt in good faith to supply a quantity of the Product in excess of \*\*\* of the amount.

Section 3.03. Future Orders. For anticipated sales of Product by Endo in the second month following commercial launch of the Product and thereafter during the Term Endo shall submit purchase orders to Noven for such Product on a monthly basis. Each purchase order shall be submitted at least ninety (90) days prior to the expected respective sales month. Each purchase order shall specify an amount of Product that is at least \*\*\* and no greater than \*\*\* of Endo's most recent previous forecast for the applicable month; provided, however, that upon request by Endo, Noven shall attempt in good faith to supply a quantity of the Product in excess of \*\*\* of the amount previously forecasted by Endo for any such month. Each purchase order shall be binding, and shall specify a delivery date that is no sooner than ninety days after submission of the purchase order to Noven. In the event that the terms and conditions of any purchase order are inconsistent with or conflict with the terms and conditions of this Agreement, the terms and conditions of this Agreement shall govern.

Section 3.04. Order Size. All purchase orders for Product placed by Endo shall be for amounts of product equal to a full manufacturing batch or multiples thereof with the amount ordered based on the estimated actual yields. An estimate of the number of units per batch is attached hereto as Exhibit A. The actual number of units delivered pursuant to any purchase order for Product shall be equal to the number of units produced in each batch thereof, subject to

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reduction of the number of units produced in any batch by the number of units not suitable for release or otherwise retained pursuant to the provisions of the Quality Agreement. In the event that Noven shall deliver less than \*\*\* of the units ordered by Endo pursuant to any purchase order (which number shall be determined with reference to the number of units estimated to be yielded by each batch ordered by Endo as reflected on Exhibit A), Noven shall notify Endo in writing of the amount of such shortfall upon discovery of the shortfall of the Product. Endo shall, within 30 days of receipt of such delivery, either (a) accept such delivery in full satisfaction of the purchase order (as to quantity only and not in waiver of Endo's opportunity to reject under pursuant to Section 3.07), or (b) issue a replacement purchase order for an additional batch of the Product, and Noven shall use reasonable commercial efforts to deliver such Product within 60 days of the date of such replacement purchase order; provided, that in either case Endo shall accept and pay to Noven the price for the units of Product delivered. Endo's failure to issue a replacement purchase order within such 30-day period shall be deemed as an acceptance of such delivery pursuant to subsection (a) above. Any replacement Purchase order submitted by Endo to Noven pursuant to this Section 3.04 shall be subject to the same terms and conditions of this Agreement as purchase orders submitted pursuant to section 3.03.

Section 3.05. Delivery. Product shall be delivered to Endo by Noven Ex Works (Incoterms 2000) Noven's Manufacturing Facility. All Products shall be properly prepared for safe and lawful shipment by Noven, shall be shipped to Endo's distribution center in Memphis, Tennessee or other location designated by Endo, via the common carrier selected by Endo, and shall be accompanied by appropriate transportation and other agreed upon documentation including, without limitation, DEA form 222. Noven shall ensure that the common carrier vehicles onto which the Product is loaded are environmentally controlled vehicles. Noven shall make all arrangements for shipping via the common carrier at Endo's expense. No product of any other party shall be shipped with the Products. Shipping cost actually prepaid by Noven will be billed to Endo monthly by Noven on separate invoices.

Section 3.06. Active Ingredient Quota. On April 1 of each calendar year, Endo shall deliver to Noven a forecast of its requirements of the Product for the following calendar year, for the purpose of assisting Noven in projecting its demand for the Active Ingredient for such calendar year for submission to and approval by the DEA.

Section 3.07. Acceptance and Rejection of the Product.

(a) Endo shall, (i) in the case of defects which are discovered during incoming inspection by Endo, within 30 days after Endo receives delivery of shipment of the Product, or (ii) in the case of latent defect, within 30 days from the date that Endo discovered such defect, notify Noven, in writing, of any rejection of any such Product ("Rejection Notice"), on the basis of (A) any non-compliance with the Specifications or (B) failure of any such shipment to conform with any product warranty set forth in this Agreement. Failure to provide Rejection Notice to Noven within the applicable 30-day period shall constitute acceptance by Endo of the shipment. Any such possible Rejection Notice shall state in reasonable detail (sufficient to enable Noven to identify the nature of the problem for tests or studies to be conducted by or on its behalf or to dispute the same) the reason why Endo believes the Product may not be acceptable to Endo. Endo shall, within five business days of its receipt of a request by Noven for

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samples of rejected Product, provide samples of the Product being rejected, if appropriate, and copies of written reports relating to tests, studies or investigations performed to date by or on behalf of Endo on the Product being rejected.

(b) Endo's test results or basis for rejection shall be conclusive unless Noven notifies Endo, within 30 days of receipt by Noven of the Rejection Notice, that it disagrees with such test results or basis for rejection. If Endo and Noven fail to agree within 10 days after Noven's notice to Endo as to whether any Product identified in the Rejection Notice (i) deviates from the Specifications to any extent, or (ii) breaches a representation or warranty in this Agreement to an extent that the Product is not saleable, representative samples of the batch of the Product in question shall be submitted to a mutually acceptable independent laboratory or consultant (if not a laboratory analysis issue) for analysis or review. If such laboratory needs to be qualified, then Endo and Noven will equally share the cost and expense of the qualification. The results of such evaluation shall be binding upon the parties. If Noven and Endo determine by agreement or if such evaluation certifies that the Product was properly rejected by Endo, Endo may reject the Product in the manner contemplated by Section 3.07(c). The party that is determined to have been incorrect in its determination of whether the Product should be rejected shall pay the costs of any such evaluation. Should the fees associated with the work conducted by the independent laboratory or consultant be due up front, Endo and Noven shall each pay 50% of such upfront fees; provided, that if it is determined by the independent laboratory or consultant that either party shall have been incorrect in its determination, such party shall reimburse the other party for such 50% of fees.

(c) In the event an order or partial order is rejected by Endo pursuant to the provisions of this Section 3.07, Endo shall return to Noven (or, at the election of Noven, destroy and provide evidence of such destruction to Noven) any units of such rejected Product. Noven shall, at Endo's election, either (i) credit the original invoice in respect of the rejected Product and re-invoice Endo for the units that were not rejected and credit Endo any reasonable expenses incurred by it related to the shipping of the rejected Product to Endo and the return or destruction of the rejected Product against other amounts then due Noven hereunder or (ii) at Noven's cost and expense, replace such rejected Product with conforming Product as soon as practicable. Noven shall have no obligation to Endo with regard to any defective Product if it is determined that any such defect is attributable to the failure by any Person to properly store, transport or care for such Product after such Product leaves Noven's possession.

(d) Notwithstanding any other provision of this Agreement to the contrary (except Section 3.09 below), in the event that Endo receives Product in violation of the Product dating warranty set forth at Section 5.01(d), Endo will attempt to mitigate the damages caused by such breach by using commercially reasonable efforts to sell such Product with twelve (12) or more months of dating, provided, however, that Noven shall remain responsible for its breach of Section 5.01(d) in the event that Endo is unsuccessful in its efforts to sell such Products or its results result in the Product being sold at a reduced price.

Section 3.08. Notices Regarding Supply. If at anytime during the Term of this Agreement Noven determines that its ability to supply Endo's requirements of Product may be hindered, Noven shall promptly notify Endo.

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Section 3.09 Endo Responsibility for \*\*\*. In the event that any portion of the Validation Batches or orders for the first three months of commercial supply (the "Launch Quantities") become unsaleable due to delay in receiving final FDA Regulatory Approval for the Product, FDA required changes in the Product labeling (including the printed patch backing) or a Force Majeure event (including in each case where the unsaleability is due to a resulting diminished remaining shelf-life), the parties shall share the risk as follows: \*\*\*.

#### ARTICLE IV PRICE AND PAYMENT

Section 4.01. Invoice. Following shipment of each order of the Product to Endo, Noven shall promptly invoice Endo for such shipment. Each invoice shall specify the amount of product shipped, the per unit invoice Price of the Product as further described in Section 4.02 below, and the total invoice amount. Subject to Section 3.07(c), Endo shall pay Noven for each shipment of Product the total invoiced amount within thirty (30) days after the date of receipt of a correct invoice, the Product and all supporting documentation (such as the certificate of analysis) required to perform an incoming quality assurance inspection; provided that with respect to any shipments for which Endo has identified a quality assurance issue during such thirty (30) day period, payment therefore shall be ten (10) business days from the date of resolution of such quality assurance issue. Both parties agree to provide their full cooperation with any quality assurance investigation and to use commercially reasonable efforts to achieve the prompt resolution of any such investigation. All payments required to be made hereunder shall be paid in United States dollars and made by corporate check drawn on a United States bank or a United States branch of a foreign bank, or by wire transfer of immediately available funds to the financial institution, account number and account party's name designated in writing by Noven to Endo from time to time. Should Endo dispute any portion of an invoice, it shall not be required to pay any portion of such invoice until such time as the dispute is resolved and Endo receives a fully corrected invoice; provided that, in such an event, Noven shall have the option of issuing a new, correct invoice for the portion of the original invoice not in dispute, and Endo shall pay such new invoice within 10 business days of the receipt of the corrected invoice (provided that Endo shall have no obligation to pay earlier than when the payment following the original invoice would have been due). Interest shall accrue on any overdue and undisputed amount due and payable to Noven at the lesser rate of 1% per month or the maximum rate permitted by law

Section 4.02. Invoice Price. Noven shall charge Endo for shipped Product manufactured for commercial sale in the United States on a per unit basis at Noven's actual fully loaded manufacturing cost. Noven shall charge Endo for shipped Product manufactured for commercial sale in Canada on a per unit basis at Noven's actual fully loaded manufacturing cost plus \*\*\*. Noven's fully loaded manufacturing cost shall be calculated in accordance with Section 4.03 below. A non-binding estimate of the price for the first year of commercial supply of the U.S. Product, together with a detailed allocation of the calculation of each component of Noven's fully loaded manufacturing costs, is set forth on Schedule 4.02. Noven shall provide Endo with a similar estimate within 30 days of the beginning of each subsequent contract year. The transfer price for the Product charged to Endo in each Invoice will be based on good faith estimates by Noven of the actual fully loaded manufacturing cost of Product. Semi-annually Noven shall



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reconcile the amount invoiced to Endo and paid by Endo with Noven's actual fully loaded manufacturing cost. Noven shall provide a copy of each reconciliation to Endo. To the extent that Noven has overcharged Endo, Noven shall credit to Endo all amounts overcharged. To the extent that Noven has undercharged Endo, Noven shall invoice Endo for the undercharged amount in accordance with the terms of this Agreement. In the event of a dispute between Endo and Noven as to the proper calculation of the Product Price, such dispute shall be referred to an independent accounting firm mutually agreeable to the parties per Section 6.01 below, whose opinion shall be final and binding.

Section 4.03. Limit on Overhead Allocation. For purposes of determining Noven's fully loaded manufacturing cost of Product supplied to Endo hereunder, Noven shall include Noven's actual cost of materials and labor and an allocation of Noven's total manufacturing overhead. This allocation shall be determined using the same methodology Noven uses in determining its cost of goods for the other products it manufactures, all in accordance with GAAP consistently applied, but subject to the further limitations described in this Section 4.03. \*\*\*.

#### ARTICLE V MANUFACTURING STANDARDS AND QUALITY ASSURANCE

Section 5.01. Product Warranties. Noven hereby covenants and agrees that:

- (a) Noven will manufacture and deliver to Endo the Product in accordance with, and the Product will conform with, the Specifications and the Quality Agreement; all Product supplied by Noven to Endo shall be manufactured, packaged, tested, stored and handled in accordance with the then current version of the ANDA and shall not be adulterated or misbranded.
- (b) Noven will comply with all Applicable Laws and current good manufacturing practices relating to the Product.
- (c) All Product supplied by Noven hereunder shall be transferred to Endo free and clear of all liens, title claims, encumbrances and security interests.
- (d) Except for Product manufactured before final approval of the Product in fulfillment of Endo orders for Launch Quantities, all Product supplied by Noven shall have a minimum of \*\*\* of the shelf life set forth in the applicable Product registration still available at the time of delivery to Endo.

Section 5.02. The Specifications. Endo or Noven shall not change the Specifications at any time without the prior written consent of the other party; provided, however, that either party may change the Specifications upon reasonable advance notice to the other party if such change is required by an applicable Regulatory Authority.

Section 5.03. Quality Agreement. Contemporaneously with the execution of this Agreement, the parties are entering into a Quality Agreement which is attached hereto as Exhibit B.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

Section 5.03. Disclaimer. NOVEN HEREBY DISCLAIMS ALL WARRANTIES NOT EXPRESSLY PROVIDED IN THIS AGREEMENT, INCLUDING ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE AND WARRANTIES OF MERCHANTABILITY.

#### ARTICLE VI AUDITS AND INSPECTION RIGHT'S

Section 6.01. Records and Audits. Noven shall keep complete and accurate records concerning its manufacturing costs and any other costs and expenses relevant to the amounts payable to Noven hereunder. Such records shall be kept in accordance with GAAP applied on a consistent basis. Noven shall, at Endo's request and expense, make those records available during normal business hours upon ten (10) business days prior written notice for examination by independent certified public accountants or auditors designated by Endo and reasonably acceptable to Noven; provided, that Endo shall only have access to such records once in each calendar year. In the event an underpayment or overpayment is discovered, the applicable party shall make payment to the other of the respective amount within 15 days of notification of the determination. In the event that an overpayment by Endo of greater than 5% is discovered, the cost of such audit shall be borne by Noven. Notwithstanding any provision in this Agreement to the contrary, the terms of the Quality Agreement will govern all quality assurance inspections.

#### ARTICLE VII ADDITIONAL COVENANTS AND AGREEMENTS OF THE PARTIES

Section 7.01. Confidentiality. The parties hereby agree that the terms and conditions of this Agreement and each party's activities hereunder shall be subject to the confidentiality obligations (and all applicable exceptions thereto) set forth in the License Agreement.

Section 7.02. Packaging and Labeling. All Products supplied hereunder shall be in finished dosage form, packaged and Labeled for commercial sale in accordance with the terms and conditions of this Agreement, the Specifications and applicable Laws. Subject to the provisions of this Section 2.03, Endo shall control the content and type of all Labeling for the Products. Endo shall supply to Noven, in a timely fashion, all artwork required to Label the Products with such trademarks, logos or designs as Endo shall select and in accordance with Applicable Laws. Noven shall have the responsibility for: (i) securing any approvals required by the FDA or other applicable Regulatory Authorities for the initial Label; (ii) securing any approvals required by the FDA or other applicable Regulatory Authorities for any changes or supplements to the Labeling requested by Endo following regulatory approval of the Product ANDA, provided that Noven is the holder of the Product ANDA at such time; and (iii) any Noven information on the Label which shall be approved in advance by Noven. In the event that Endo wishes to modify or change the Label, Endo shall provide reasonable advance notice of such desired change to Noven and forward such modifications or changes to Noven for Noven's review and approval (which shall not be unreasonably withheld).

Section 7.03. Product Recall. Product recalls shall be conducted in accordance with the terms of the Quality Agreement. Each of Noven and Endo shall make a permanent, complete

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and accurate record of all costs incurred by its connection with any Product recall, a copy of which shall be delivered to the other party upon its request as soon after the completion of such recall or seizure as practically may be done. If the cause of, or reason for, said recall is attributable to any reason beyond the reasonable control of the parties, the total cost of the recall to the parties shall be shared equally among the parties. If the cause of, or reason for, said recall or seizure arises is both not attributable to reasons beyond the reasonable control of the parties and is attributable to the negligence or breach of this Agreement by a party hereto, such party shall reimburse the other for all reasonable costs incurred by it in effecting such recall or seizure. If Noven and Endo cannot agree which party is at fault or whether the recall was reasonably beyond the control of the parties, then an independent technical expert, acceptable to both, will be designated to make the determination. The so designated technical expert shall not be an employee, consultant, officer, director or shareholder of or otherwise associated with any party or an Affiliate of any party. The technical expert's determination shall be, in the absence of fraud or manifest error, binding and conclusive upon the parties.

Section 7.04 Product Shelf Life. Noven shall use commercially reasonable efforts to obtain \*\*\* expiration dating, and will to continue to use such efforts even if the Product is initially approved by the FDA with less than \*\*\* expiration dating.

#### ARTICLE VIII REPRESENTATIONS AND WARRANTIES

Section 8.01. Representations and Warranties. Each party hereby represents and warrants to the other that as of the Effective Date:

(a) Organization. It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation. As of the Closing Date, it will be duly qualified to do business in each jurisdiction where the character of its business (after giving effect to the Contemplated Transactions) make such qualifications necessary to carry on its business.

(b) Power, Authority and Enforceability. It has full corporate power and authority to enter into and perform this Agreement and to consummate the transactions contemplated herein. This Agreement has been or shall be duly executed and delivered by duly authorized signatories. This Agreement constitutes a valid and binding obligation, enforceable against it in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws now or hereafter in effect relating to or affecting creditors' rights generally.

(c) No Violation. Neither the execution and delivery of this Agreement nor the consummation by it of the transactions contemplated hereby, will (i) conflict with or result in a breach of any of the terms, conditions or provisions of its certificate of incorporation or other governing or charter document, or of any statute or administrative regulation, or, to the best of its knowledge, of any order, writ, injunction, judgment or decree of any court or Governmental Authority or of any arbitration award or any agreement binding upon it or its assets, or (ii) to the

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best of its knowledge, contravene or conflict with, or constitute a violation of, any provisions of any Applicable Law binding upon it.

(d) No Default. It is not a party to any unexpired, undischarged or unsatisfied written or oral contract, agreement, indenture, mortgage, debenture, note or other instrument under the terms of which performance by it according to the terms of this Agreement will be a default, or whereby timely performance by it according to the terms of this Agreement may be prohibited or delayed.

#### ARTICLE IX INDEMNIFICATION AND LIMITATION OF LIABILITY

Section 9.01 Indemnification. Indemnification for activities related to this Agreement shall be provided pursuant to the License Agreement between the parties entered into on the same date.

Section 9.02. Limitation of Liability. NO PARTY SHALL BE ENTITLED TO RECOVER ANY PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS FROM LOST SALES TO THIRD PARTIES) WHATSOEVER UNDER THIS AGREEMENT EXCEPT TO THE EXTENT ANY SUCH PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES SHALL BE PAYABLE TO A THIRD PARTY.

Section 9.03 \*\*\*.

#### ARTICLE X TERM AND TERMINATION

Section 10.01. Term. This Agreement shall continue in full force and effect until the earlier of (a) the termination of the License Agreement, or (b) termination of this Agreement in accordance with Section 10.02 (the Effective Date until such termination, the "Term").

Section 10.02. Certain Termination Events.

(a) Except as otherwise contemplated by Sections 3.05 and 10.02(c), either Noven or Endo shall have the right to terminate this Agreement if the other commits any continuing or material breach of any of the provisions of this Agreement and (in the case of a breach which is capable of remedy) fails to remedy the same within 60 days after receipt of written notice giving full particulars of the breach and requiring it to be so remedied;

(b) In the event that at any time during the Term Noven shall, (i) during any period of six consecutive months, fail to supply at least \*\*\* of the aggregate number of units of Product (which number of units shall be determined with reference to the number of units estimated to be yielded by each Batch ordered by Endo as reflected in Exhibit A) ordered pursuant to Purchase Orders properly submitted by Endo during such period (other than by reason of the fault of Endo), or (ii) fail to provide \*\*\* of the aggregate number of units of Product ordered during any

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two separate periods of three consecutive months, Endo shall (A) have the right to terminate its obligation to exclusively purchase Product from Noven and have a third party manufacture on its behalf the Product to supply and (B) have the right to withdraw any purchase orders submitted to Noven for amounts in excess of Noven's ability to supply.

(c) Either party may terminate this Agreement with immediate effect if the Product is withdrawn from the market in the Territory for serious adverse health or safety reasons.

(d) Either Noven or Endo may terminate this Agreement with immediate effect in the event a Force Majeure Event as to the other shall exist and be continuing for a period of 120 consecutive days.

(e) Noven may terminate its obligation to supply Endo with its requirements of Product under this Agreement upon twenty-four months notice in the event that Noven's gross margins on the manufacture of Product (taking into account all Endo payments hereunder and under the License Agreement in calculating such margins -- except for the milestone payments) drops to less than\*\*\* of its fully allocated manufacturing cost for the Product in two consecutive calendar quarters. \*\*\*. Noven agrees to provide the technical transfer services set forth in Schedule 10.02 (the "Tech Transfer Services"), including the delivery to Endo of the Technical Transfer Documentation Package within \*\*\* of the termination notice and completion of the transfer of all analytical methods within \*\*\* of the termination notice. The termination by Noven shall become effective \*\*\* following receipt of the notice by Endo, provided, however, that the effective date of the termination shall be extended by each day of delay in excess of the corresponding time periods set forth above which it takes Noven to complete the transfer of the Technical Transfer Documentation Package and the analytical methods. The manufacturing period, however, shall not be extended to the extent such delay occurs through no fault of Noven. To the extent that such alternative manufacturer would need to use technology owned by, or protected by intellectual property owned by, Noven, access to such technology would be provided on limited basis and restricted solely to use for the manufacture of Product.

(f) In the event of a termination by Endo pursuant to Section 10.02 (a), (b) or (d), Noven agrees to work in good faith with Endo to qualify a suitable alternative manufacturer for the Product that has been identified by Endo and that agrees to undertake such manufacturing. Endo agrees to work in good faith with Noven regarding such transfer and ensure that the third party works in good faith with Noven as well. Noven shall, as promptly as is reasonably practicable, perform the Tech Transfer Services. In the event the delivery to Endo of the Technical Transfer Documentation Package is completed within \*\*\* of the termination notice and the transfer of all analytical methods is completed within \*\*\* of the termination notice, or such time periods are exceeded due to no fault of Noven, Endo shall \*\*\*. In the event that such services are not completed within such time periods due to the fault of Noven, Endo will \*\*\*. To the extent that such alternative manufacturer would need to use technology owned by, or protected by intellectual property owned by, Noven, access to such technology would be provided on limited basis and restricted solely to use for the manufacture of Product.

Section 10.04. Obligations on Termination. Within 30 days of any expiration or termination of this Agreement other than a termination by Endo pursuant to Section 10.02 (a), (b) or (d), or a termination by Noven pursuant to Section 10.02 (e), (i) Endo shall cease to use

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and shall deliver to Noven, upon written request, all Confidential Information of Noven, except for any documents or records that Endo is required to retain by Applicable Law, and (ii) Noven shall cease to use and shall deliver to Endo, upon written request, all Confidential Information of Endo except for any documents or records that Noven is required to retain by Applicable Law. In the event of a termination by Endo pursuant to Section 10.02 (a), (b) or (d), a termination by Noven pursuant to Section 10.02 (e), Endo shall be permitted to retain and use the Confidential Information in the manufacture of the Product, and to disclose such Confidential Information to its third party manufacturer, provided that such third party manufacturer is under obligations of confidentiality no less stringent than this Agreement.

Section 10.05. Effect of Termination. Upon termination, this Agreement shall forthwith become void and of no further force or effect, except for the following provisions, which shall remain in full force and effect: (a) Section 7.01 (Confidentiality), (b) this Article 10, (c) Section 11.9 (Governing Law), (d) Section 11.11 (Entire Agreement), and (e) Section 11.12 (Expenses) and any other provisions which expressly survive termination. The rights and remedies provided in this Article X shall be cumulative and not exclusive of any rights or remedies provided by Applicable Law. Any termination of this Agreement shall not affect any right or claim hereunder that arises prior to such termination, which claims and rights shall survive any such termination.

#### ARTICLE XI MISCELLANEOUS

Section 11.01. Notices. All notices, claims, certificates, requests, demands and other communications hereunder shall be in writing and shall be delivered personally or sent by confirmed facsimile transmission, air courier or registered or certified mail, return receipt requested, addressed as follows:

if to Noven:

Noven Pharmaceuticals, Inc.  
11960 S. W. 144th Street Miami, Florida 33186  
Attention: CEO & General Counsel  
Telecopy: 305-964-3340

with copies (which shall not constitute notice) to:

Frommer Lawrence & Haug LLP  
745 Fifth Avenue  
New York, New York 10151  
Attention: Edgar H. Haug, Esq.  
Telecopy: 212-588-0500

if to Endo:

Endo Pharmaceuticals Inc.  
100 Painters Dr.

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Chadds Ford, PA 19317  
Attention: General Counsel  
Telecopy: 610-558-9684

or to such other address as the party to whom notice is to be given may have furnished to the other party in writing in accordance herewith. Any such communication shall be deemed to have been delivered (a) when delivered, if delivered personally, by air courier or by mail, (b) when sent (with written confirmation received), if sent by facsimile transmission on a Business Day, (c) on the first Business Day after dispatch (with written confirmation received), if sent by facsimile transmission on a day other than a Business Day.

Section 11.02. Independent Contractors. In making and performing this Agreement, the parties are acting and shall act as independent contractors. Nothing in this Agreement shall be deemed to create an agency, joint venture or partnership relationship between the parties hereto. No party shall have the authority to obligate another party in any respect, and no party shall hold itself out as having any such authority. All personnel of Noven shall be solely employees of Noven and shall not represent themselves as employees of Endo. All personnel of Endo shall be solely employees of Endo and shall not represent themselves as employees of Noven.

Section 11.03. Assignment. Noven shall not have the right to assign this Agreement or delegate any of its rights, interests duties or obligations hereunder without the prior written consent of Endo, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, at any time during the term of this Agreement either party may assign this Agreement to any of its Affiliates without the prior written consent of the other parties; provided, that no such assignment of this Agreement shall relieve the assignor of any of its obligations or liabilities under this Agreement. Notwithstanding the foregoing, any party may assign this Agreement without the other parties' prior written consent in connection with the transfer or sale of all or substantially all of its assets or business or its merger or consolidation with another Person upon written notice to the other parties. Any attempted assignment in violation of this Section 11.04 shall be void.

Section 11.04. Binding Effect; Benefit. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their successors and permitted assigns. Nothing in this Agreement, express or implied, is intended to confer on any Person other than the parties hereto and their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement.

Section 11.05. Amendments. This Agreement shall not be modified, amended or supplemented except pursuant to an instrument in writing executed and delivered on behalf of each of the parties hereto.

Section 11.06. No Waiver. The failure in any one or more instances of a party to insist upon performance of any of the terms, covenants or conditions of this Agreement, to exercise any right or privilege conferred in this Agreement, or the waiver by said party of any breach of any of the terms, covenants or conditions of this Agreement, shall not be construed as a

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subsequent waiver of any such terms, covenants, conditions, rights or privileges, but the same shall continue and remain in full force and effect as if no such forbearance or waiver had occurred. No waiver shall be effective unless it is in writing and signed by an authorized representative of the waiving party.

Section 11.07. Counterparts. This Agreement shall become binding when any one or more counterparts hereof, individually or taken together, shall bear the signatures of each of the parties hereto. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original as against the party whose signature appears thereon, but all of which taken together shall constitute but one and the same instrument. Each party may execute this Agreement on a facsimile of the Agreement. In addition, facsimile signatures of authorized signatories of any party shall be valid and binding and delivery of a facsimile signature by any party shall constitute due execution and delivery of this Agreement.

Section 11.08. Interpretation. The article and section headings contained in this Agreement are for convenience of reference only and shall not affect the meaning or interpretation of this Agreement. As used in this Agreement, any reference to the masculine, feminine or neuter gender shall include all genders, the plural shall include the singular, and singular shall include the plural. Unless the context otherwise requires, the term "party" when used herein means a party hereto. References herein to a party or other Person include their respective successors and assigns. The words "include," "includes" and "including" when used herein shall be deemed to be followed by the phrase "without limitation" unless such phrase otherwise appears. Unless the context otherwise requires, references herein to Articles, Sections, Exhibits and Schedules shall be deemed references to Articles and Sections of, and Exhibits and Schedules to, this Agreement. Unless the context otherwise requires, the words "hereof," "hereby" and "herein" and words of similar meaning when used in this Agreement refer to this Agreement in its entirety and not to any particular Article, Section or provision hereof. With regard to each and every term and condition of this Agreement, the parties understand and agree that the same have or has been mutually negotiated, prepared and drafted, and that if at any time the parties desire or are required to interpret or construe any such term or condition or any agreement or instrument subject thereto, no consideration shall be given to the issue of which party actually prepared, drafted or requested any term or condition of this Agreement.

Section 11.9. Governing Law. This Agreement and any claims, disputes or causes of action relating to or arising out of this Agreement shall be construed in accordance with and governed by the substantive laws of the State of New York, without giving effect to the conflict of laws principles thereof.

Section 11.10. Unenforceability. If any provisions of this Agreement are determined to be invalid or unenforceable in any jurisdiction, such provisions shall be ineffective to the extent of such invalidity or unenforceability in such jurisdiction, without rendering invalid or unenforceable the remaining provisions hereof or affecting the validity or enforceability of any of such provisions of this Agreement in any other jurisdiction. The parties will use their best efforts to substitute the invalid or unenforceable provision with a valid and enforceable one which conforms, as nearly as possible, with the original intent of the parties.



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Section 11.11. Entire Agreement. This Agreement, together with any and all schedules, exhibits and appendices hereto, embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements, commitments, arrangements, negotiations or understandings, whether oral or written, between the parties hereto and their respective Affiliates with respect thereto. There are no agreements, covenants or undertakings with respect to the subject matter of this Agreement other than those expressly set forth or referred to herein and no representations or warranties of any kind of nature whatsoever, express or implied, are made or shall be deemed to be made herein by the parties hereto, except those expressly made in this Agreement and the other Transaction Documents.

Section 11.12. Expenses. Except as expressly set forth herein, each party hereto shall bear all fees and expenses incurred by such party in connection with, relating to or arising out of the execution, delivery and performance of this Agreement and the consummation of the Contemplated Transactions, including attorneys', accountants' and other professional fees and expenses.

Section 11.13. Force Majeure. If the performance of this Agreement or any obligation hereunder (except the payment of money) by any party is prevented or hindered, by reason of any cause beyond the reasonable control of the affected party, including fire, flood, riot, war, explosions, acts of God (including hurricanes and tropical storms), acts of a public enemy, delay of carrier, shortage or failure in the supply of materials, labor disturbance or acts, regulations or laws of any government adopted after the date of this Agreement or subject to a new interpretation after the date of this Agreement that render impossible or illegal the performance by a Party of its obligations under this Agreement (a "Force Majeure Event"), the party so affected, upon notice to the other parties, shall be excused from such performance, provided that the party so affected shall use diligent effort to avoid or remove such cause or causes of non-performance and shall continue to perform hereunder with the utmost dispatch whenever such cause or causes are removed.

Section 11.14. Insurance. Throughout the Term, each of Noven and Endo shall maintain commercial liability insurance, including blanket commercial liability insurance covering the obligation of that party under this Agreement through the term of this Agreement and for five years thereafter, which insurance shall afford limits of not less than US\*\*\* per occurrence, (and in the aggregate only with respect to personal injury liability) for bodily injury liability, products liability, property damage liability, contractual liability and completed operations liability with an insurance carrier qualified to do business in the United States. Each of Noven and Endo shall promptly furnish to the other evidence of the maintenance of the insurance required hereunder and shall name the other as an "additional insured" under a broad form vendor's endorsement to such insurance policy. In case any such policies are written on a "claims made" basis, such policies shall remain in effect for a period of five years following the expiration or earlier termination of this Agreement. Notwithstanding the foregoing, the obligation of each of Noven and Endo to obtain insurance in accordance with this Section 7.04 is subject to the availability of such insurance from nationally recognized carriers at reasonable rates and on reasonable terms and conditions, which reasonableness shall be determined in the judgment of each party, respectively, in accordance with such party's past practices to the ordinary course of business. In the event either party shall be unable to obtain insurance as contemplated by this Section 7.04,

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such party shall notify the other party as soon as practicable and shall have the right to self-insure such coverage; provided that any party opting to so self-insure shall provide to the other party reasonable information regarding its self-insurance program.

Section 11.15. No Debarred Persons. Each of Noven and Endo covenants and agrees that it has not and will not use in any capacity the services of any Person debarred under subsections (a) or (b) of Section 306 of the FDC Act in connection with its performance of this Agreement.

IN WITNESS WHEREOF, the parties hereto have entered into this Agreement effective as of the Effective Date.

NOVEN PHARMACEUTICALS, INC.

ENDO PHARMACEUTICALS INC.

By: /s/ Robert C. Strauss  
Name: Robert C. Strauss  
Title: President, CEO and Chairman  
Date: February 25, 2004

By: /s/ Peter A. Lankau  
Name: Peter A. Lankau  
Title: President and COO  
Date: February 25, 2004

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SUBSIDIARIES OF THE REGISTRANT

Endo Pharmaceuticals Inc.

BML Pharmaceuticals, Inc. (indirect)

EPI Company (indirect)

Endo Pharma Canada Inc. (indirect)

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**INDEPENDENT AUDITORS' CONSENT**

We consent to the incorporation by reference in Registration Statement No. 333-52648 of Endo Pharmaceuticals Holdings Inc. on Form S-8 of our report dated March 15, 2004, which report expresses an unqualified opinion and includes an explanatory paragraph as to the Company's change in 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, appearing in this Annual Report on Form 10-K of Endo Pharmaceuticals Holdings Inc. for the year ended December 31, 2003.

/s/ Deloitte & Touche LLP

Philadelphia, Pennsylvania  
March 15, 2004

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POWER OF ATTORNEY

Each of the undersigned, hereby constitutes and appoints each of Carol A. Ammon, Jeffrey R. Black and Caroline B. Manogue to be his or her true and lawful attorneys-in-fact and agents, with full power of each to act alone, and to sign for the undersigned and in each of their respective names in any and all capacities stated below, this Annual Report on Form 10-K (and any amendments hereto) and to file the same, with exhibits hereto and thereto and other documents in connection herewith and therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Power of Attorney has been signed by the following persons in the capacities and on the dates indicated.

<TABLE>  
<CAPTION>

SIGNATURE -----	TITLE -----	DATE ----
<S> /s/ CAROL A. AMMON Carol A. Ammon	<C> Chairman, Chief Executive Officer and Director	<C> March 12, 2004
/s/ BRIAN T. CLINGEN Brian T. Clingen	Director	March 12, 2004
/s/ MICHAEL B. GOLDBERG Michael B. Goldberg	Director	March 12, 2004
/s/ MICHAEL HYATT Michael Hyatt	Director	March 12, 2004
/s/ ROGER H. KIMMEL Roger H. Kimmel	Director	March 12, 2004
/s/ FRANK LOVERRO Frank Loverro	Director	March 12, 2004
/s/ CLIVE A. MEANWELL, M.D., PH.D. Clive A. Meanwell, M.D., Ph.D.	Director	March 12, 2004
/s/ MICHAEL W. MITCHELL Michael W. Mitchell	Director	March 12, 2004
/s/ JOSEPH T. O'DONNELL, JR. Joseph T. O'Donnell, Jr.	Director	March 12, 2004
/s/ DAVID I. WAHRHAFTIG David I. Wahrhaftig	Director	March 12, 2004

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CERTIFICATION

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

-----  
Carol A. Ammon  
Chairman and Chief Executive Officer

Date: March 15, 2004

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CERTIFICATION

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

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

Date: March 15, 2004

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CERTIFICATION OF CHAIRMAN AND CHIEF EXECUTIVE OFFICER OF ENDO  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Endo Pharmaceuticals Holdings Inc. (the "Company") for the fiscal year ended December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Carol A. Ammon, as Chairman and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of her knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Carol A. Ammon  
Name: Carol A. Ammon  
Title: Chairman & Chief Executive Officer  
Date: March 15, 2004

This certification accompanies this Quarterly Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that Section.

A signed original of this written statement required by Section 906 has been provided to, and will be retained by, Endo Pharmaceuticals Holdings Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

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CERTIFICATION OF CHIEF FINANCIAL OFFICER OF ENDO  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Endo Pharmaceuticals Holdings Inc. (the "Company") for the fiscal year ended December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Jeffrey R. Black, as Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Jeffrey R. Black  
Name: Jeffrey R. Black  
Title: Chief Financial Officer  
Date: March 15, 2004

This certification accompanies this Quarterly Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that Section.

A signed original of this written statement required by Section 906 has been provided to, and will be retained by, Endo Pharmaceuticals Holdings Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

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**ENDO PHARMACEUTICALS HOLDINGS INC.  
100 Painters Drive  
Chadds Ford, Pennsylvania 19317**

March 15, 2004

VIA EDGAR

Securities and Exchange Commission  
450 Fifth Street, N.W.  
Washington, DC 20549

Re: Annual Report on Form 10-K for  
the Year Ended December 31, 2003 of  
Endo Pharmaceuticals Holdings Inc.

Ladies and Gentlemen:

On behalf of Endo Pharmaceuticals Holdings Inc. ("Endo"), transmitted herewith for filing with the Securities and Exchange Commission, pursuant to Rule 13a-1 of the Securities and Exchange Act of 1934, as amended, is Endo's Annual Report on Form 10-K for the Year Ended December 31, 2003.

If you have any questions or comments concerning the Form 10-K filed herewith, please do not hesitate to contact the undersigned at (610) 558-9800 (ext. 4116).

Very truly yours,

/s/ CAROLINE B. MANOGUE

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

Enclosure