

ENDO PHARMACEUTICALS HOLDINGS INC

Form 10-K

March 29, 2002

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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, 2001

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number: 39040

# ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

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

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

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

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

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

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

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**Annual Report for the Year Ended December 31, 2001**

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.

Aggregate market value, as of March 25, 2002, of Common Stock held by non-affiliates of the registrant: \$307,798,000 based on the last reported sale price on the Nasdaq.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of March 25, 2002: 102,063,950.

**Documents Incorporated by Reference**

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

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**ENDO PHARMACEUTICALS HOLDINGS INC.**

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### Forward Looking Statements

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

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

results of clinical trials on new products;

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 strategy;

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

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

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

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

## PART I

### Item 1. *Our 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 \$14 billion for the 12 months ended December 31, 2001. Our primary area of focus is analgesics, which according to IMS Health data was the second most prescribed class of medication in the United States in 2001.

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

We have a portfolio of branded products that includes established brand names such as Percocet®, Lidoderm®, Percodan® and Zydone®. Branded products comprised approximately 68%, 76% and 67% of net sales for fiscal years 1999, 2000 and 2001, respectively. Through a national dedicated contract sales force of approximately 230 sales representatives, we market our branded pharmaceutical products to doctors, retail pharmacies and other healthcare professionals throughout the United States.

We have established research and development expertise in analgesics and devote significant resources to this effort so that we can maintain and develop our product pipeline. We enhance our financial flexibility by outsourcing many of our functions, including manufacturing. Currently, our primary suppliers of contract manufacturing services are Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals), Novartis Consumer Health, Inc. and Teikoku Seiyaku Pharmaceuticals.

#### Our Strategy

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

*Capitalizing on our established brand names through focused marketing and promotion.* We consider two of our brands, Percocet® and Percodan®, to be gold standards of pain management. Percocet® has been prescribed by physicians since 1971, 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, as well as new formulations and dosages of our existing branded products. We also believe that our strong corporate and product reputation leads to more rapid adoption of our new products by physicians.

*Developing proprietary products and selected generics.* To capitalize on our expertise in pain management, we are developing new products to address acute, chronic and neuropathic pain conditions by treating moderate-to-severe pain. We are also developing new patent protected products that leverage our patent portfolio covering the combination of a number of compounds, including opioids and N-methyl-D-aspartate (NMDA)-receptor antagonists, drugs that may substantially improve the treatment of pain by addressing the underlying processes associated with acute and chronic pain, including those processes relating to increased sensitivity to pain signals and the development of analgesic tolerance. These products include MorphiDex®, a patented combination of morphine and the NMDA-receptor antagonist, dextromethorphan, which is currently in Phase III clinical trials. We anticipate resubmitting an amendment to the existing new drug application (also known as an NDA), with the U.S. Food and Drug Administration (or the FDA), in the late third quarter or during the fourth quarter of 2002. In addition, we are co-developing an oral extended-release (ER) version of oxymorphone with Penwest Pharmaceuticals. This product is currently in Phase III clinical trials along with an immediate-release (IR) form of oxymorphone, and we continue to anticipate filing NDAs for both of these products with the FDA in the second half of 2002.

We have also developed extended-release version of oxycodone, an AB-rated generic version of OxyContin®, a product of The Purdue Frederick Company. According to IMS Retail Provider Perspective data, OxyContin® generated U.S. sales of approximately \$1.5 billion in 2001, up from approximately \$1.0 billion in 2000. We have filed and amended an abbreviated new drug application (or ANDA) with the FDA for bioequivalent versions of the 10mg, 20mg, 40mg and 80mg strengths of OxyContin®. We believe we are the first company to have filed an ANDA with the FDA for the bioequivalents of the 10mg, 20mg and 40mg strengths of OxyContin®, thereby entitling us to 180 days of marketing exclusivity with respect to these strengths of this product. See Item 3. Legal Proceedings.

*Developing and marketing product line extensions for 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. Net sales of Percocet® products increased from \$92.4 million in 2000 to \$101.0 million in 2001. We have also implemented this strategy with a line extension of our Zydone® product, a combination of hydrocodone and acetaminophen.

*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 July 2000, we acquired Algos and the rights to the patented development-stage product MorphiDex®. Through this acquisition, we also acquired rights to a portfolio of patents, including those covering the combination of the NMDA-antagonist, dextromethorphan, with opioids. In November 1998, we in-licensed Lidoderm®, which became the first FDA-approved product for the relief of the pain of post-herpetic neuralgia, a chronic, painful condition that may follow an attack of shingles. We launched this product in September 1999. Net sales of Lidoderm® increased from \$22.5 million in 2000 to \$40.9 million in 2001. In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals under which we are co-developing an oral extended-release version of oxymorphone. We also entered into a collaboration agreement with Lavipharm Laboratories Inc., under which we obtained rights to certain of Lavipharm's existing drug-delivery platforms in combination with defined drug substances.

## **Our Competitive Strengths**

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

*Established portfolio of branded products.* We have assembled a core portfolio of branded pharmaceutical products to treat and manage pain. These products include Percocet® and Percodan®, which have been marketed since 1971 and 1950, respectively, and which we consider to be gold standards of pain management based on their long history of demonstrated product safety and effectiveness. According to IMS Health data, approximately 86% of oxycodone with acetaminophen prescriptions are written as Percocet. We believe our close relationships with physicians who we consider to be pain management thought leaders in pain centers, hospitals, and other pain management institutions enable us to improve our penetration in these types of institutions. We believe this interaction has also allowed us to pursue, through in-licensing, products targeted at additional or novel indications, such as Lidoderm® for post-herpetic neuralgia.

*Substantial pipeline focused on pain management.* As a result of our focused research and development effort, we have three products in Phase III and three products in Phase II clinical trials. If clinical studies progress as we anticipate, we expect to file NDAs with the FDA in 2002 for our three products currently in Phase III clinical trials. These are MorphiDex®, oxymorphone ER and oxymorphone IR.

*Research and development expertise.* Our research and development effort is focused on expanding our product portfolio by capitalizing on our core expertise with narcotic analgesics. We have assembled an experienced and multi-disciplined research and development team of scientists and technicians with a proven expertise working with opioids 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 four years through the launch of a number of new products and product extensions all of which, in the aggregate, contributed approximately 54% of our net sales in 2001.

*Selective focus on generic products.* Our generic product portfolio includes products focused on pain management. Development of these products involves barriers to entry such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. We believe products with these characteristics will face a lesser degree of competition and therefore provide longer product life cycles and higher profitability than commodity generic products. We have executed this strategy successfully with products such as morphine sulfate extended-release tablets, which we introduced in November 1998 as a bioequivalent of MS Contin®, a Purdue Frederick product. In addition, we believe we are the first company to have filed an ANDA with the FDA for the bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin®. We believe it is a significant advantage to be the first successful filer of an ANDA for a generic drug. See Governmental Regulation.

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

*Experienced and dedicated management team.* With an average of approximately 20 years of experience in the pharmaceutical industry, our management team has a proven track record of building our business through internal growth as well as acquisitions and licensing. Members of our senior management led the purchase of the company from The DuPont Merck Pharmaceutical Company in August 1997. In September 1999, management in-licensed and launched Lidoderm®, an orphan drug for the treatment of the pain of post-herpetic neuralgia. In July 2000, we acquired Algos to obtain its patent-protected platform and technology. Management has received FDA approval on more than fifteen new products and product extensions since 1997 and has grown net sales from approximately \$108.4 million in 1998 to approximately \$252.0 million in 2001. In addition, management has vested stock options to acquire up to 11% of our common stock and has the potential to receive as much as an additional 9% of our common stock through options that vest if the price of our common stock reaches specified defined targets. These options are exercisable solely for shares currently held by Endo Pharma LLC, and their exercise will not dilute the ownership of our other common stockholders.

## **Our Industry**

According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$14.3 billion for the 12 months ended December 31, 2001. This represents an approximately 28% compounded annual growth rate since 1998. Our primary area of focus within this market is analgesics. In 2001, analgesics were the second most prescribed medication in the United States with over 232 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 76% of the analgesics prescriptions in 2001. This market segment has grown to \$3.6 billion for the 12 months ended December 31, 2001, representing a compound annual growth rate of 31% since 1998. If branded products were substituted for generic products, we believe



the dollar value of this market segment would be substantially larger. The growth in this segment has been primarily fueled by the:

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

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

introduction of new and reformulated branded products; and

increasing number of surgical procedures.

**Product Overview**

The following table summarizes select pain products in our portfolio as well as those in development:

Product	Active ingredient	Branding	Status
Percocet®	oxycodone and acetaminophen	Branded	Marketed
Lidoderm®	lidocaine 5%	Branded	Marketed
Percodan®	oxycodone and aspirin	Branded	Marketed
Zydone®	hydrocodone and acetaminophen	Branded	Marketed
Morphine Sulfate ER	morphine sulfate	Generic	Marketed
MorphiDex®	morphine and dextromethorphan	Branded	Phase III
Oxymorphone ER	oxymorphone hydrochloride	Branded	Phase III
Oxymorphone IR	oxymorphone hydrochloride	Branded	Phase III
HydrocoDex	hydrocodone, acetaminophen, and dextromethorphan	Branded	Phase II
OxycoDex	oxycodone and dextromethorphan	Branded	Phase II
PercoDex	oxycodone, acetaminophen and dextromethorphan	Branded	Phase II
Oxycodone ER	oxycodone	Generic	ANDA filed; subject to litigation(1)

(1) See Item 3. Legal Proceedings.  
*Branded Products*

*Percocet®*. We consider Percocet® to be a gold standard of pain management. Launched in 1971, Percocet® is approved for the treatment of moderate-to-severe pain. Although Percocet® has faced generic competition for more than 15 years, in 2001, according to the IMS National Prescription Audit, approximately 12.5 million prescriptions for this combination of oxycodone hydrochloride and acetaminophen were written for the brand name Percocet®, of which, due to generic substitution, only approximately 14% were filled by pharmacists with our brand Percocet®.

During the fourth quarter of 1999, we introduced three new strengths of Percocet®: Percocet® 2.5/325, Percocet® 7.5/500 and Percocet® 10.0/650, complementing the existing Percocet® 5.0/325. Prior to the launch of these products, physician prescribing practices had indicated that over 80% of prescriptions were written for amounts other than the label amount. As an example, the current prescription information for the original Percocet®, Percocet® 5.0/325, calls for one tablet every six hours. Approximately 30% of prescriptions written directed patients to take two tablets every four hours, translating into a dosage of 10mg every four hours. By offering new prescription strengths, we have enabled physicians to prescribe one tablet of the proper dose for their patients, facilitating greater ease and compliance. On January 3, 2000, the Food and Drug Administration approved another manufacturer's ANDA for a generic equivalent to Percocet® 7.5/500 and

Percocet® 10.0/650. This generic equivalent became available in April 2001. During the fourth quarter of 2001, we launched two new formulations: Percocet® 7.5/325 and Percocet® 10.0/325. These new dosage forms allow physicians the flexibility of increasing the dose of narcotic while still maintaining a low level of acetaminophen. There is currently no generic equivalent available for these new dosage forms. All of the Percocet® products were responsible for net sales of \$51.5 million, \$92.4 million and \$101.0 million in the years 1999, 2000 and 2001, respectively. The Percocet® franchise accounted for approximately 40% of our 2001 net sales.

*Lidoderm®.* Lidoderm® was launched in September 1999. A patented, topical patch product containing lidocaine, it is the first FDA-approved product for the relief of the pain from post-herpetic neuralgia. There are approximately 200,000 patients per year who suffer from this condition in the United States, the majority of whom are elderly. The FDA has granted Lidoderm® orphan status, meaning that no other lidocaine-containing patch product can be approved for this indication until March 2006. In 1999, 2000 and 2001, Lidoderm® net sales were \$5.7 million, \$22.5 million and \$40.9 million, respectively. Lidoderm® accounted for approximately 16% of our 2001 net sales.

*Percodan®.* Launched in 1950 for the treatment of moderate-to-severe pain, we also consider Percodan® to be a gold standard of pain management. In 2001, according to the IMS National Prescription Audit, approximately 398,000 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 Percodan®.

*Zydone®.* In February 1999, we launched Zydone® tablets, branded hydrocodone/acetaminophen products for the relief of moderate-to-severe pain. Zydone® is available in three strengths, 5.0mg, 7.5mg and 10.0mg, each in combination with 400mg acetaminophen.

*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 2001 fiscal year.

#### **Generic Products**

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

Our generic portfolio is currently comprised of products that cover a broad range of indications, most of which are focused in pain management. Our primary generic product is morphine sulfate extended-release tablets, which accounted for 17% of our total net sales in 2001. Launched in November 1998, morphine sulphate extended-release tablets are a bioequivalent of 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. We also have a generic oxycodone hydrochloride and acetaminophen product, Endocet®, which accounted for 9% of our total net sales in 2001. The balance of our generic portfolio consisted of several products, none of which accounted for more than 5% of our total net sales for 2001.

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

complex formulation or development characteristics;

regulatory or legal challenges; or

difficulty in raw material sourcing.

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

## Products in Development

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

*MorphiDex®.* We are currently conducting Phase III clinical trials of MorphiDex®, a patented combination of morphine and the NMDA-receptor antagonist, dextromethorphan. A new drug application was submitted to the FDA by Algos for MorphiDex® in August 1998. In August 1999, Algos received a not-approvable letter received from the FDA. A not-approvable letter is issued by the FDA for various reasons and outlines deficiencies that must be corrected prior to a product's approval. Following our acquisition of Algos in July 2000, we met with the FDA in September 2000 to discuss MorphiDex®. At this meeting, the FDA requested, among other things, the submission of a second pivotal chronic multiple dosing study to support the intended indication of MorphiDex®. We have initiated three chronic multiple dosing studies of MorphiDex®. If successful, these studies will complement the already successful pivotal chronic multiple dosing study previously submitted to the FDA and provide the data necessary for the commercial optimization of the product. We intend to file with the FDA an amendment to the existing NDA for MorphiDex® as soon as possible and, subject to the successful completion of these studies, including successful patient recruitment, currently expect to be in a position to file this reapplication in the late third quarter or during the fourth quarter of 2002. Under the guidelines included in the Prescription Drug User Fee Act of 1992, as amended, we anticipate that the FDA will respond within six months after its acceptance of the reapplication. Once approved, we expect MorphiDex® to compete in the \$2 billion severe pain market.

*Oxymorphone ER.* We are currently conducting Phase III clinical trials of an oral extended-release version of oxymorphone. We have marketed oxymorphone in the U.S. for over 40 years in injection and suppository form. We are co-developing this oral extended-release version of oxymorphone with Penwest Pharmaceuticals and currently expect to be in a position to file the NDA application in the second half of 2002. Once approved, we expect oxymorphone ER will also compete in the \$2 billion severe pain market.

*Other.* In addition to MorphiDex® and our oral extended-release version of oxymorphone, we have a third product in Phase III clinical trials (oxymorphone immediate release (IR)), three in Phase II (HydrocoDex®, Oxycodex® and Percodex®) and other products in various stages of development. 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, especially those doing business in the United States, including, Abbott Laboratories, Johnson & Johnson, The Purdue Frederick Company, Roxane Laboratories, Inc. and Watson Pharmaceuticals, Inc.

We compete principally through our targeted product development strategies. In addition to product development, 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, our branded products not only face competition from other brands, but also from generic versions. Generic versions are generally significantly less expensive than branded versions, and, where available, may be required in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies. The entrance of generic competition to one of our branded products generally reduces our market share and adversely affects our profitability and cash flows.

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

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

### **Research and Development**

We devote significant resources to research and development. At December 31, 2001, our research and development staff consisted of 52 employees, primarily based in Garden City, New York and at our corporate headquarters in Chadds Ford, Pennsylvania. For fiscal years 1999, 2000 and 2001, our expenditures on research and development were \$9.4 million, \$26.0 million and \$39.0 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.

### **Seasonality**

Although our business is affected by the purchasing patterns and concentration of our customers, our business is not materially impacted by seasonality. Generally, the fourth fiscal quarter has relatively higher net sales than each of the first three fiscal quarters.

### **Customers**

We sell our products directly to a limited number of large pharmacy chains and through a limited number of wholesale drug distributors who, in turn, supply products to pharmacies, hospitals, governmental agencies and physicians. Three distributors individually accounted for 27%, 20% and 13% of our net sales in 1999. Three distributors and one pharmacy chain individually accounted for 26%, 16%, 12% and 10%, respectively, of our net sales in 2000. Three distributors and one pharmacy chain individually accounted for 28%, 24%, 19% and 10%, respectively, of our net sales in 2001.

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

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

We currently hold 12 U.S. issued patents and three foreign issued patents, approximately 15 U.S. patent applications pending and approximately 50 foreign patent applications pending with respect to our products. We have licenses for 31 U.S. issued patents, one U.S. patent application pending, 66 foreign issued patents and 26 foreign patent applications pending. The effect of these issued patents is that they provide us patent protection for the claims covered by the patents.

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

We rely on confidentiality agreements with our employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. There can be no assurance that these agreements will not

be breached, that we will have adequate remedies for any breach, or that others will not independently develop equivalent proprietary information or other third parties will not otherwise gain access to our trade secrets and other intellectual property.

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

### **Governmental Regulation**

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

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

We cannot determine what effect changes in regulations or legal interpretations, when and if promulgated, may have on our business in the future. Changes could, among other things, require expanded or different labeling, the recall or discontinuance of certain products, additional record keeping and expanded documentation of the properties of certain products and scientific substantiation. Such changes, or new legislation, could have a material adverse effect on our business, financial condition and results of operations.

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

#### *NDA Process*

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

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

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

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

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

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

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

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

#### *ANDA Process*

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

An ANDA also may be submitted for a drug authorized by approval of an ANDA suitability petition. Such petitions may be submitted to secure authorization to file an ANDA for a product that differs from a previously approved drug in active ingredient, route of administration, dosage form or strength. For example, the FDA has authorized the substitution of acetaminophen for aspirin in certain combination drug products and switching the drug from a capsule to tablet form. Bioequivalence data may be required, if applicable, as in the case of a tablet in place of a capsule, although the two products would not be rated as interchangeable.

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

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

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

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

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

### *Quality Assurance Requirements*

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

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

The FDA also conducts periodic inspections of facilities to assess their cGMP status. If the FDA were to find serious cGMP non-compliance during such an inspection, it could take regulatory actions that could adversely affect our business, results of operations and financial condition. Imported API and other components needed to manufacture our products could be rejected by U.S. Customs. In respect to domestic establishments, the FDA could initiate product seizures or require product recalls and seek to enjoin a product's manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP

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requirements, sanctions may be imposed that include preventing the company from receiving the necessary licenses to export its products and classifying the company as an unacceptable supplier, thereby disqualifying the company from selling products to federal agencies.

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

### *Other FDA Matters*

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

### *Drug Enforcement Agency*

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

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

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

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

### *Government Benefit Programs*

Medicaid, Medicare and other reimbursement legislation or programs govern 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 to the public. We cannot predict the nature of such measures or their impact on our profitability and cash flows.



## Service Agreements

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

### *Third Party Manufacturing/ Supply Agreements*

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

*Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals).* Bristol-Myers Squibb (f/k/a DuPont Pharmaceuticals) currently manufactures a significant number of our brand and generic pharmaceutical products. Bristol-Myers Squibb manufactures certain of the products that we purchased from DuPont Pharmaceuticals as a result of our August 1997 acquisition from DuPont Pharmaceuticals, as well as some of our new products. The products are manufactured at either the Bristol-Myers Squibb facility in Garden City, New York or the Bristol-Myers Squibb facility in Manati, Puerto Rico. Both of these facilities are FDA- and DEA-approved. Under the terms of this agreement, we are able to introduce the manufacture of new products that we have developed in those plants. For these manufacturing services, we currently pay Bristol-Myers Squibb compensation in the form of (1) a fixed amount to cover Bristol-Myers Squibb's fixed manufacturing costs for both manufacturing facilities, (2) an amount, adjusted on an annual basis, to cover Bristol-Myers Squibb's variable manufacturing costs for our products in both facilities and (3) an additional fee, paid annually, based upon a predetermined formula.

In addition to manufacturing services, Bristol-Myers Squibb currently provides other ancillary services to us in connection with the manufacture of our products such as raw material procurement, product development, inventory management and quality control services. Compensation for these services is included in the compensation for manufacturing services. The initial term of this agreement is five years, expiring on August 26, 2002, and is renewable, at our option, for a period of time not to exceed five years (through August 2007) with pricing terms to be negotiated. We have begun discussions with Bristol-Myers Squibb concerning arrangements to manufacture certain of our products following the expiration of the initial term in August 2002. If Bristol-Myers Squibb determines to sell or otherwise transfer either the Garden City plant facility or the Manati plant facility and we determine that the acquirer of such facility would not be an acceptable manufacturer of our products, Bristol-Myers Squibb shall implement, at its cost, appropriate arrangements for the manufacture and supply of the products elsewhere.

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

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

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

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

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

#### *Other Service Agreements*

In addition to the long-term manufacturing agreements described above, we have agreements with (1) Livingston Healthcare Services, Inc. (n/k/a UPS Supply Chain Management, Inc.) for customer service support, warehouse and distribution services and certain financial functions, (2) Kunitz and Associates Inc. for medical affairs and (3) Ventiv Health U.S. Sales Inc. for sales. We also have agreements and arrangements with various contract research organizations for our toxicology and clinical studies. 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 would have a materially adverse effect on our business, financial condition and results of operations.

A description of the material terms of these agreements follows:

*Livingston Healthcare Services Inc. (n/k/a UPS Supply Chain Management, Inc.)* Under the terms of this agreement, we appointed Livingston 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 Livingston personnel responsible for providing our customer service, chargeback processing and accounts receivable management services may not provide these services to any third party for any third party products which directly compete with our products covered under the agreement. We pay Livingston a (1) start-up fee, payable in three installments, (2) a fixed monthly fee for all services and (3) certain miscellaneous 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, 2001, these fees and expenses were approximately \$5.0 million. The term of the agreement for customer service support and chargeback processing services is February 1, 2000 to January 31, 2003; for accounts receivable services, February 1, 2000 to January 31, 2003; and for warehouse and distribution services, February 1, 2000 to February 28, 2005. The agreement may be renewed upon mutual agreement of the parties. The agreement may be terminated for material breach by us, with prior notice: (1) for a sale of our company or a sale of substantially all of our business; by us, with prior notice, for a change in our stock ownership or company control; (2) if we decide to have these services provided in-house or by an affiliate or (3) if Livingston fails to

provide additional storage space for our products upon request. In the event of termination under certain circumstances, we are required to pay Livingston for certain capital investments and wind-down expenses.

*Kunitz and Associates Inc.* Under the terms of the agreement, we appointed Kunitz as our exclusive provider in the United States of pharmacovigilance, medical communications, product information support, adverse drug experience surveillance and medical literature search support, with respect to all of our products. During the term of this agreement, Kunitz may not provide identical or similar services to or for any third party whose products directly compete with our products in the prescription pain management therapeutic category. For these services, we pay Kunitz a fixed amount, in equal monthly installments. This agreement will expire on July 31, 2002, unless we exercise our option to renew the agreement for up to two successive one-year periods through July 31, 2004. The agreement may be terminated by either party for material breach or by us, with notice, for no reason.

*Ventiv Health U.S. Sales Inc.* Under the terms of this agreement, a team of Ventiv professional sales representatives, under our management's direction, exclusively promotes certain of our products to healthcare professionals in the United States. The term of this agreement is until December 31, 2003, but will automatically renew for one-year periods thereafter. The agreement may be terminated by either party for material breach, by us (with 90 days' notice) for no reason or by Ventiv (with 180 days' notice) for no reason. Under the agreement, we reserve the option to hire all of these sales representatives and managers as our full-time employees at any time.

### **Licenses and Collaboration Agreements**

We enter into licenses and collaboration agreements to develop, use, market and promote certain of our products from or with other pharmaceutical companies and universities.

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

*Penwest Pharmaceuticals.* In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals to exclusively co-develop opioid analgesic products for pain management, using Penwest's patent-protected proprietary technology, for commercial sale worldwide. Under the terms of this agreement, we are currently developing an opioid product for the treatment of pain. We currently share on an equal basis the costs and profits of products developed under this agreement. At this point in time, we cannot predict the cost of this agreement. We have exclusive U.S. marketing rights with respect to products developed under this collaboration, subject to the terms and conditions contained in this agreement. See Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources.

*Hind Healthcare Inc.* In November 1998, we entered into a license agreement with Hind Healthcare Inc. for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in the United States. We paid Hind up-front fees and milestone payments on the occurrence of certain events. From now until the shorter of (1) the life of the last-to-expire patent license pursuant to this license agreement and (2) November 20, 2011, we will pay Hind non-refundable royalties, including a minimum annual royalty of at least \$500,000 per year, on net sales of the product in the future. 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 2001, we accrued \$3.3 million for this royalty. Either party may terminate this agreement for material breach and we may terminate it immediately upon termination of our supply agreement with Teikoku. In September 1999, we launched Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

## Environmental Matters

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

## Summary of Recent Transactions

On August 1, 2001, we moved into our new corporate headquarters at 100 Painters Drive, Chadds Ford, Pennsylvania. We lease this space from Painters Crossing One Associates, L.P. See Item 2. Properties.

On October 17, 2001, we sold 11,400,000 additional shares of common stock at a price of \$8.00 per share in a follow-on public offering. On November 16, 2001, we closed the sale of an additional 1,525,000 shares of common stock, at \$8.00 per share, in connection with the exercise by the underwriters of their over-allotment option in connection with this public offering. A total of 12,925,000 shares common stock were issued and sold by the Company in this offering for a total of \$96.2 million in net proceeds.

On October 29, 2001, we used \$84.9 million of the net proceeds from the recently completed public offering plus \$16.1 million from our cash balance to repay in full the term loans under the then current credit facility. On December 21, 2001, we amended and restated our credit facility. The details of this amendment and restatement are set forth below. See Description of Credit Facility.

On December 5, 2001, we commenced a tender offer to purchase up to 13,500,000 of our outstanding Class A Transferable Warrants (Nasdaq: ENDPW) 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 8,576,762 Class A Warrants and 8,500 Class B Warrants for payment at a purchase price of \$0.75 per warrant, or approximately \$6.4 million in the aggregate. We used cash on hand to finance the purchase of tendered warrants. Following of the purchase of these warrants by us, approximately 9.2 million Class A Warrants and approximately 18,500 Class B Warrants remained outstanding as of January 28, 2002.

## 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, 2001, no amounts were outstanding under the credit agreement.

Under the credit agreement, we have the ability to borrow on a revolving basis up to \$75.0 million. The revolving loans have a final maturity of December 21, 2006. The credit agreement also provides for a delayed draw term loan that must be utilized, if at all, by August 26, 2002 solely for the purpose of paying off the outstanding promissory notes that are payable to Bristol-Myers Squibb. The aggregate principal amount of this term loan is \$25.0 million. The term loan, once borrowed and repaid, may not be reborrowed, and it has a final maturity date of December 21, 2006. As of December 31, 2001, we have not borrowed under either the revolving loans or the term loan.

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.

## **Employees**

As of December 31, 2001, we had 167 employees, of which 52 are engaged in research and development, 15 in regulatory work, 30 in sales and marketing, 18 in quality assurance and 52 in general and administrative capacities. Our employees are not represented by unions, and we believe that our relations with our employees are good.

## **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.

## **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. Through the acquisition of Algos in July 2000, we also acquired a lease of the former corporate headquarters of Algos in Neptune, New Jersey. This lease was terminated on April 30, 2001. A description of the material terms of each of the agreements pertaining to these properties follows:

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

*Bristol-Myers Squibb Company (f/k/a DuPont Pharmaceuticals) Lease Agreement.* Under this agreement, we lease a laboratory and office building from Bristol-Myers Squibb, which is located at Bristol-Myers Squibb's Garden City, New York manufacturing facility. We may use these facilities for the research and development of our pharmaceutical products. The lease is not assignable by us without the consent of Bristol-Myers Squibb. The lease may be terminated (1) by us, if substantial premise alteration changes are required in order to comply with government regulations, (2) by Bristol-Myers Squibb, for tenant damage and destruction to the premises and (3) as a result of arbitration between the parties. The term of the lease is five years, expiring August 26, 2002 and is renewable at our option, provided the related manufacturing and supply agreement between the parties has been renewed, for an additional five-year period or successive one-year periods through August 2007.

### **Chadds Ford, Pennsylvania**

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

*Painters Crossing One Associates, L.P. Lease Agreement.* On May 5, 2000, we entered into a ten-year lease with Painters Crossing One Associates, L.P. pursuant to which Painters Crossing leases to us a building comprised of approximately 47,756 square feet located in Chadds Ford, Pennsylvania. By amendment dated February 26, 2001, this lease commenced on August 1, 2001 and will end on August 31, 2010. However, we, at our discretion, have the right to terminate this lease at the end of the fifth year, by providing two years' notice.

and paying a fixed termination fee to Painters Crossing. During the term of the lease, the annual rent is a fixed amount paid in equal monthly installments that increase after the first five years of the lease.

### Neptune, New Jersey

*Commercial Realty & Resources Corp. Lease.* Through our acquisition of Algos in July 2000, we had acquired the lease of the former Algos corporate headquarters in Neptune, New Jersey. On April 30, 2001, we terminated this lease and obtained from the landlord a full and final release from any and all obligations thereunder.

### Item 3. Legal Proceedings

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

For each of the 10mg, 20mg, 40mg and 80mg strengths of this product, EPI made the required Paragraph IV certification against the patents listed in the FDA's Orange Book as covering these strengths of OxyContin®. EPI has pleaded counterclaims that the patents asserted by Purdue Frederick are invalid, unenforceable and/or not infringed by EPI's formulation of oxycodone hydrochloride extended-release tablets, 10mg, 20mg, 40mg and 80mg strengths. EPI has also counterclaimed for antitrust damages based on allegations that Purdue Frederick obtained the patents through fraud on the United States Patent and Trademark Office and is asserting them while aware of their invalidity and unenforceability. However, we cannot make any assurances as to the outcome of this patent challenge. Purdue Frederick was granted a preliminary injunction (*Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 98 F. Supp. 2d 362 (SDNY 2000)), which decision was affirmed on appeal (*Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359 (Fed. Cir. 2001)), against a different manufacturer based on the same patents that are being asserted against us and EPI, and in the same court in which Purdue Frederick sued. We believe the defenses rejected in the preliminary injunction decision and in the appellate decision do not substantially impact the principal defenses raised by us and EPI.

On November 15, 2001, SmithKline Beecham Corporation (and related companies) filed suit against EPI in the U.S. District Court for the Eastern District of Pennsylvania alleging that EPI's bioequivalent version of SmithKline's Paxil®, 40 mg strength, infringes five of its patents. The FDA accepted EPI's ANDA submission for a bioequivalent version of SmithKline's Paxil®, 40 mg strength, earlier in 2001. In this ANDA, EPI made the required Paragraph IV certification against all of the SmithKline patents listed in the FDA's Orange Book as covering Paxil®. Paxil® is indicated for the treatment of depression, obsessive compulsive disorder and panic disorder. Although we believe the patents asserted by SmithKline Beecham are invalid and/or not infringed, no assurance can be given as to the outcome of this patent challenge process.

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.

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On November 15, 2001, EPI was named, along with ten other pharmaceutical companies, as a defendant in a class action lawsuit filed by Bennie Toombs in the United States District Court for the Western District of Louisiana. According to the complaint, each of the defendant pharmaceutical companies had allegedly manufactured and sold products containing phenylpropanolamine (PPA). The 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. The action has been transferred by order of the United States Judicial Panel on Multidistrict Litigation to the Western District of Washington, where it has been consolidated for pretrial proceedings with other cases involving claims against manufacturers of PPA-containing products. EPI is not a party to any of these other actions and intends to vigorously defend itself in the *Toombs* litigation.

In addition to the above, the Company is involved in, or has been involved in, arbitrations or legal proceedings that arise from the normal course of its business. The Company cannot predict the timing or outcome of these claims and proceedings. Currently, the Company is not involved in any arbitration and/or legal proceeding that it expects to have a material effect on its 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, 2001.

#### **Item 4A. Executive Officers of the Registrant**

Set forth below is information regarding each current executive officer of Endo:

<u>Name</u>	<u>Age</u>	<u>Position and Offices</u>
Carol A. Ammon	51	President, Chief Executive Officer, Chairman and Director
Mariann T. MacDonald	54	Executive Vice President, Operations
Jeffrey R. Black	37	Senior Vice President, Chief Financial Officer and Treasurer
Peter A. Lankau	49	Senior Vice President, U.S. Business
David A.H. Lee, M.D., Ph.D.	52	Senior Vice President, Research & Development
Caroline B. Manogue	33	Senior Vice President, General Counsel & Secretary

CAROL A. AMMON, 51, is President, Chief Executive Officer, Chairman and Director of Endo. Prior to joining Endo, Ms. Ammon was the President of DuPont Merck's U.S. Pharmaceuticals Division from 1996 through 1997, and from 1993 through 1995 she was the President of Endo Laboratories, L.L.C. She also serves as a director on the boards of the Christiana Care Health System and the St. Louis School of Pharmacy in St. Louis, Missouri.

MARIANN T. MACDONALD, 54, is Executive Vice President, Operations of Endo. Prior to joining Endo, Ms. MacDonald was Vice President of Business Information, Training, Administration & Technology for the U.S. Pharmaceuticals Division of DuPont Merck from 1996 to 1997 and Vice President of Operations for Endo Laboratories, L.L.C. from 1995 to 1996. From 1993 to 1995, Ms. MacDonald held various management positions in DuPont Merck.

JEFFREY R. BLACK, 37, 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, 49, is Senior Vice President, U.S. Business of Endo. Prior to joining Endo in June 2000, Mr. Lankau was Vice President, Sales and Marketing for Alpharma USPD, Inc. in Baltimore, Maryland. He was Vice President, Sales - U.S. Pharmaceuticals for Rhone Poulenc Rorer, Inc. from 1996 to 1999, based in Collegeville, Pennsylvania. Prior to 1996, Mr. Lankau was Executive Director, Strategy and

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Development for RPR from 1995 to 1996. Prior to 1995, he held various management positions at RPR including business unit management, and had responsibility for RPR's generics business as well as managed care.

DAVID A.H. LEE, M.D. Ph.D., 52, is Senior Vice President, Research & Development and Regulatory Affairs of Endo. Prior to joining Endo in December of 1997, Dr. Lee was Executive Vice President, Research and Development for CoCensys, Inc., an emerging pharmaceuticals company based in Irvine, California, from 1992 through 1997. Prior to joining CoCensys, Dr. Lee held various positions at Solvay Pharmaceuticals in the Netherlands, ranging from head of global clinical development programs to his final position as V.P. Research and Development. Dr. Lee received his M.D. and Ph.D. degrees from the University of London and specialized in internal medicine and gastroenterology, prior to joining the pharmaceutical industry.

CAROLINE B. MANOGUE, 33, 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.

### PART II

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

Our common stock has been traded on the Nasdaq under the symbol ENDP since July 18, 2000. 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, 2001		
1st Quarter	\$ 7.13	\$ 5.13
2nd Quarter	\$ 11.65	\$ 6.00
3rd Quarter	\$ 12.15	\$ 7.24
4th Quarter	\$ 12.00	\$ 7.32
Year Ending December 31, 2000		
3rd Quarter (from July 18, 2000)	\$ 14.50	\$ 5.00
4th Quarter	\$ 10.13	\$ 5.50

As of March 25, 2002, we estimate that there were approximately 116 record holders of our common stock.

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.

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

The consolidated statement of operations data for the period ended August 26, 1997 has been derived from the statements of earnings and statement of assets to be sold audited by PricewaterhouseCoopers LLP, independent accountants. All other selected historical 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



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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.

	Predecessor Company(1)	Endo				
	Period From January 1, 1997 to August 26, 1997	Period From August 26, 1997 (Date of Acquisition) to December 31, 1997	Year Ended December 31,			
			1998	1999	2000	2001
(in thousands, except per share data)						
<b>Consolidated Statement of Operations Data:</b>						
Net sales	\$ 65,077	\$ 39,431	\$ 108,370	\$ 138,546	\$ 197,429	\$ 251,979
Cost of sales	30,551	29,779	54,731	58,263	63,041	74,891
Gross profit	34,526	9,652	53,639	80,283	134,388	177,088
Selling, general and administrative	5,621	8,707	25,540	42,921	56,537	79,505
Research and development	5,253	2,865	5,893	9,373	26,012	38,994
Depreciation and amortization		2,340	7,373	8,309	27,624	49,234
Compensation related to stock options					15,300	37,253
Purchased in-process research and development		46,000			133,200	
Merger and other related costs					1,583	
Separation benefits					22,034	
Operating income (loss)	23,652	(50,260)	14,833	19,680	(147,902)	(27,898)
Interest expense, net		5,352	14,451	14,347	15,119	10,962
Income (loss) before income tax (benefit) and extraordinary item	23,652	(55,612)	382	5,333	(163,021)	(38,860)
Income tax (benefit)		(20,318)	181	2,073	(6,181)	(3,753)
Income (loss) before extraordinary item	23,652	(35,294)	201	3,260	(156,840)	(35,107)
Extraordinary item loss on early extinguishment of debt						(1,435)
Net income (loss)	\$ 23,652	\$ (35,294)	\$ 201	\$ 3,260	\$ (156,840)	\$ (36,542)
<b>Basic and Diluted Net Income (Loss) Per Share:</b>						
Income (loss) before extraordinary item	N/A	\$ (.50)	\$ 0.00	\$ .05	\$ (1.97)	\$ (.38)
Extraordinary item						\$ (.02)
Net income (loss)	N/A	\$ (.50)	\$ 0.00	\$ .05	\$ (1.97)	\$ (.40)
Shares Used to Compute Basic and Diluted Net Income (Loss) Per Share	N/A	71,051	71,307	71,332	79,454	91,505

Endo

Period from  
August 26,  
1997  
(Date of

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	Acquisition) to	Year Ended December 31,			
	December 31,	1998	1999	2000	2001
	1997				
(in thousands)					
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 14,521	\$ 17,367	\$ 22,028	\$ 59,196	\$ 95,357
Working capital	17,659	37,676	49,541	72,759	65,259
Total assets	275,496	287,618	329,436	467,840	470,995
Total debt	167,472	170,544	191,203	198,525	91,259
Other long-term obligations	5,852	6,352	6,745	7,218	207
Stockholders' equity	74,706	75,358	78,587	198,173	295,122
<b>Other Financial Data:</b>					
Net cash provided by operating activities	\$ 15,165	\$ 20,932	\$ 13,766	\$ 35,069	\$ 80,486
Net cash provided by (used in) investing activities	(268,454)	(3,537)	(9,074)	18,077	(6,546)
Net cash provided by (used in) financing activities	267,810	(14,549)	(31)	(15,978)	(37,779)
Consolidated EBITDA(2)	14,025	40,726	47,232	67,687	79,523

- (1) On August 26, 1997, we commenced operations by acquiring certain branded and generic pharmaceutical products, related rights and certain assets of the then DuPont Merck Pharmaceutical Company, or the

predecessor company. The financial information for the predecessor company is not comparable to our financial information as the business was operated within a division of the predecessor company and historical financial statements were not prepared for the Endo business. These products represented less than 10% of the revenues of DuPont Pharmaceuticals Company. The financial information for the predecessor company includes estimates and allocations that may not necessarily be indicative of the costs that would have resulted if the business had been operated as a separate entity. The consolidated statement of operations data include those net sales, other operating revenue, costs and expenses directly related to the manufacture and distribution of the products acquired including the allocation of certain manufacturing and distribution overhead costs. The consolidated statement of operations data also include direct and allocated expenses for marketing and selling, general and administrative and research and development. In connection with the original formation of the predecessor company, no indebtedness was assumed nor any material indebtedness incurred subsequent to formation. Accordingly, no interest expense has been charged in the consolidated statement of operations data. In addition, although depreciation and amortization expense is included in the allocation of expenses to the acquired products, such amount is not compatible to depreciation and amortization expense of Endo.

The predecessor company's sales, manufacturing, research and development and corporate activities were integrated for all products of the predecessor company, not only those products of Endo. We did not acquire the physical assets used to produce the products and these products continue to be manufactured by the predecessor company. Consequently, Endo understands that there has not been a segregation of production assets associated with the products by the predecessor company. Consequently, depreciation and amortization expense of the predecessor company is not comparable to depreciation and amortization expense of Endo.

Due to the August 26, 1997 acquisition, a new basis of accounting has been recorded for the purchase. The predecessor company did not charge to the business interest expense and income taxes, although income tax expense, on a pro forma basis, has been reflected on the face of the predecessor financial statements of \$9,461 for the period ended August 26, 1997.

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

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

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

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

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

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

Our credit facility defines consolidated EBITDA as consolidated net income for the applicable period plus, without duplication and to the extent deducted from revenues in determining consolidated net income for that period, the sum of (a) the aggregate amount of consolidated cash interest expense for the period, (b) the aggregate amount of letter of credit fees paid during the period, (c) the aggregate amount of income tax expense for the period, (d) all amounts attributable to depreciation and amortization for the period, (e) all extraordinary charges during the period and (f) all other non-cash charges during the period; and minus, without duplication and to the extent added to revenues in determining consolidated net income for such period, the sum of (i) all extraordinary gains during the period and (ii) all other non-cash gains during such period, all as determined on a consolidated basis with respect to us and our subsidiaries in accordance with generally accepted accounting principles. The reconciliation of operating income (loss) (as determined by generally accepted accounting principles) to consolidated EBITDA (as defined in our credit facility) is as follows:

	Period From August 26, 1997 (Date of Acquisition) to December 31, 1997	Year Ended December 31,			
		1998	1999	2000	2001
		(in thousands)			
Operating (loss) income	\$(50,260)	\$ 14,833	\$ 19,680	\$ (147,902)	\$ (27,898)
Plus: purchased in-process research and development	46,000			133,200	
Plus: depreciation and amortization	2,340	7,373	8,309	27,624	49,234
Plus: compensation related to stock options				15,300	37,253
Plus: non-cash manufacturing charges	2,701	14,228	19,135	18,683	20,934
Plus: purchase accounting charges	13,244	4,292	108		
Plus: non-cash separation benefits				20,782	
Consolidated EBITDA	<u>\$ 14,025</u>	<u>\$40,726</u>	<u>\$47,232</u>	<u>\$ 67,687</u>	<u>\$ 79,523</u>

Compensation related to stock options is the non-cash charge resulting from the vesting of stock options pursuant to the Endo Pharma LLC stock option plans. Stock options granted pursuant to the Endo Pharma LLC stock option plans vest if our common stock reaches certain defined thresholds. These options are exercisable for shares currently held by Endo Pharma LLC, and their exercise will not dilute the ownership of other holders of our common stock.

Non-cash manufacturing charges reflect the present value of non-interest bearing promissory notes issued annually to DuPont Pharmaceuticals Company (n/k/a Bristol-Myers Squibb Pharma Company) over the initial five-year term of the manufacturing and supply agreement with DuPont Pharmaceuticals. These amounts have been excluded from consolidated EBITDA.

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

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

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

#### **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 68%, 76% and 67% of net sales for the years ended December 31, 1999, 2000 and 2001. On August 26, 1997, an affiliate of Kelso & Company and the then members of management entered into an asset purchase agreement with the then DuPont Merck Pharmaceutical Company to acquire certain branded and generic pharmaceutical products and exclusive worldwide rights to a number of new chemical entities in the DuPont research and development pipeline from DuPont Merck through the newly-formed Endo Pharmaceuticals Inc. On November 19, 1999, we formed Endo Inc. as a wholly owned subsidiary to effect the acquisition of Algos. On December 31, 2001, Endo Inc. was merged with and into Endo Pharmaceuticals Inc. The stock of Endo Pharmaceuticals Inc. is our only asset and we have no other operations or business.

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On July 17, 2000, we completed our merger with Algos. In the merger, we issued to the former Algos stockholders, in the aggregate, 17,810,526 shares of our common stock and 17,810,526 warrants to purchase in the aggregate up to 20,575,507 additional shares of our common stock in certain circumstances as more fully described under footnote 12 to the consolidated financial statements located at the back of this Report. In the merger, we also issued to our pre-merger stockholders, in the aggregate, 71,328,424 warrants to purchase in the aggregate up to 29,720,177 additional shares of common stock in certain other circumstances as more fully described under footnote 12 to the consolidated financial statements located at the back of this Report.

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

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

The merger included various on-going projects to research and develop innovative new products for pain management. As a result, the allocation of the fair value of the assets acquired and liabilities assumed includes an allocation to purchased in-process research and development, or IPRD, of \$133.2 million, which was immediately expensed in the consolidated statement of operations on the acquisition date. The methodology we used on the acquisition date in determining the value of IPRD was to: 1) identify the various on-going projects that we will prioritize and continue; 2) project net future cash flows of the identified projects based on current demand and pricing assumptions, less the anticipated expenses to complete the development program, drug application, and launch the products (significant net cash inflows from Morphidex® were projected in 2003); 3) discount these cash flows based on a risk-adjusted discount rates ranging from 25% to 33% (weighted average discount rate of 27%); and 4) apply the estimated percentage of completion to the discounted cash flow for each individual project ranging from 4% to 81%. The discount rate was determined after considering various uncertainties at the time of the merger, primarily the stage of project completion.

We allocated fair value to the three opioid analgesic projects of Algos: Morphidex®, HydrocoDex™ and Oxycodex™. The development program for a new pharmaceutical substance involves several different phases prior to drug application. Drug applications must be approved by the FDA prior to marketing a new drug. Despite our commitment to completion of the research and development projects, many factors may arise that could cause a project to be withdrawn or delayed, including the inability to prove the safety and efficacy of a drug during the development process. Upon withdrawal of an application, it is unlikely that the development activities will have alternative use. If these projects are not successfully developed, our results of operations and financial position in a future period could be negatively impacted.

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

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.

### *Net Sales*

Our net sales consist of revenues from sales of our pharmaceutical products, less estimates for certain chargebacks, rebates, sales incentives and allowances, royalties and the cost of returns and losses. We estimate the accrual for sales deductions based on historical data, estimated future trends and other competitive factors. Net sales are recognized when products are shipped.

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The following table presents our unaudited net sales by product category for the years ended December 31, 1999, 2000 and 2001.

	Year Ended December 31,		
	1999	2000	2001
	(in thousands, unaudited)		
Percocet®	\$ 51,513	\$ 92,366	\$ 100,967
Lidoderm®	5,695	22,539	40,878
Other brands	36,500	35,375	25,824
	93,708	150,280	167,669
Total brands	93,708	150,280	167,669
Total generics	44,838	47,149	84,310
	138,546	197,429	251,979
Total net sales	\$ 138,546	\$ 197,429	\$ 251,979

The following table presents our unaudited net sales as a percentage of total net sales for select products for the years ended December 31, 1999, 2000 and 2001.

	Year Ended December 31,		
	1999	2000	2001
	(unaudited)		
Percocet®	37%	47%	40%
Lidoderm®	4	11	16
Other brands	27	18	11
	68	76	67
Total brands	68	76	67
Total generics	32	24	33
	100%	100%	100%
Total	100%	100%	100%

### *Goodwill and Other Intangibles*

Goodwill and other intangibles represent a significant portion of our assets and stockholders' equity. As of December 31, 2001, goodwill and other intangibles comprised approximately 41% of total assets and 66% of stockholders' equity. We assess the recoverability and the amortization period of goodwill by determining whether the amount can be recovered through undiscounted net cash flows of the businesses acquired over the remaining amortization period. We review for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable, such as in the event of a significant adverse change in business conditions or a significant change in the intended use of an asset. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset are less than its carrying amount. Assets are grouped at the lowest level for which there are identifiable cash flows that are largely independent from other asset groups. We use the discounted future expected net cash flows, as our estimate of fair value, to determine the amount of impairment loss. As a result of the significance of goodwill and other intangibles, amortization of goodwill and other intangibles will significantly impact our results of operations. In addition, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill and other intangible assets occur.

In June 2001, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS No. 141, Business Combinations, and SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 141 is effective for all business combinations completed after June 30, 2001. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. SFAS No. 141 requires that all

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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. Upon adoption, we will no longer amortize goodwill unless evidence of an impairment exists. Goodwill will be evaluated for impairment on at least an annual basis. Although we are currently evaluating all of the provisions of SFAS No. 141 and

SFAS No. 142 and therefore are not presently able to quantify the impact of adoption, we believe the adoption of SFAS No. 141 and SFAS No. 142 will have a material impact on our results of operations. We have \$179.1 million of goodwill as of December 31, 2001 and have recorded \$40.4 million of goodwill amortization for the year ended December 31, 2001. We have adopted the provisions of SFAS No. 142 effective January 1, 2002.

*Compensation Related to Stock Options*

In the fourth quarter of our 2000 fiscal year we incurred a non-cash charge of \$15.3 million, and in the third quarter of our 2001 fiscal year, we recorded a non-cash charge of \$37.3 million, in each case for stock-based compensation relating to the vesting of options that were issued under the Endo Pharma LLC stock option plans. Under these plans, tranches of options vest when we attain certain stock price targets. As each tranche vests, we incur a non-cash charge representing the difference between the market price of the shares underlying the options and the exercise price of such options. We may in the future incur up to two additional charges in relation to the Endo Pharma LLC options as a result of the attainment of these common stock price targets. These charges may be substantial. 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.

In connection with the Algos merger and our related recapitalization on July 17, 2000, the Endo Pharma LLC 2000 Supplemental Employee Stock Option Plan and the Endo Pharma LLC 2000 Supplemental Executive Stock Option Plan (collectively, the Endo Pharma LLC 2000 Supplemental Stock Option Plans ) were established. The Endo Pharma LLC 2000 Supplemental Stock Option Plans reserve an aggregate of 10,672,314 shares of our common stock that is held by Endo Pharma LLC for issuance. The Endo Pharma LLC 2000 Supplemental Stock Option Plans are only effective on January 1, 2003 in the event that we have not received the approval from the FDA of MorphiDex® for the treatment of pain by December 31, 2002. The exercise of stock options pursuant to the Endo Pharma LLC 2000 Supplemental Stock Option Plans does not result in the issuance of additional shares in the Company, however, may result in additional non-cash compensation charges upon issuance and/or attainment of defined common stock price targets. These charges may be substantial. The Endo Pharma LLC 2000 Supplemental Stock Option Plans are not currently effective, therefore no options have been granted.

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

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

*Net Sales.* Net sales for the year ended December 31, 2001 increased by 28% to \$252.0 million from \$197.4 million in the comparable 2000 period. This increase in net sales was primarily due to the increase in net sales of Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, and certain generic products. In September 1999, we launched Lidoderm®, which continues to gain market share due to our ongoing promotional and educational efforts. Net sales of Lidoderm® increased 82% to \$40.9 million from \$22.5 million in the comparable 2000 period. Percocet® net sales increased 9% to \$101.0 million from \$92.4 million in the comparable 2000 period. In April 2001, generic equivalents of Percocet® 7.5/500 and Percocet® 10.0/650 were introduced. In November 2001, we launched Percocet® 7.5/325 and Percocet® 10.0/325 which do not currently have generic equivalents. Generic products increased 79% to \$84.3 million from \$47.1 million in the comparable 2000 period primarily due to the growth of our generic morphine sulfate extended release tablets and Endocet®. In November 1998, we launched the 15mg, 30mg and 60mg strengths, in May 2001, we launched the 100mg strength and in September 2001, we launched the 200mg strength of our generic morphine sulfate extended release tablets. These products continue to gain market share. In April 2001, we launched two new strengths of our generic product Endocet®. Generic competition with our products may have a material impact on our results of operations and cash flows in the future.



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*Gross Profit.* Gross profit for the year ended December 31, 2001 increased by 32% to \$177.1 million from \$134.4 million in the comparable 2000 period. Gross profit margins increased to 70% from 68% in the comparable 2000 period due to a more favorable mix of higher margin brand and generic products resulting from the product launches discussed above, and the discontinuation of some lower margin non-core products. In addition, the increase in gross profit margins was also due to the existing fixed cost nature of our manufacturing relationship with Bristol-Myers Squibb Pharma Company (formerly DuPont Pharmaceuticals), currently our most significant contract manufacturing relationship. If we achieve our forecast for revenue and product mix, we expect the increase in gross profits and gross profit margins to continue.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses for the year ended December 31, 2001 increased by 41% to \$79.5 million from \$56.5 million in the comparable 2000 period. This increase was due to a \$11.0 million increase in sales and promotional efforts in 2001 over the comparable 2000 period to support Lidoderm® and Percocet®. In addition, we experienced an increase in personnel-related costs in the general and administrative functions in order to support our new product marketing and new product development.

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

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

*Compensation Related to Stock Options.* For the year ended December 31, 2001, compensation related to stock options increased to \$37.3 million from \$15.3 million in the comparable 2000 period. Compensation related to stock options reflects the charge arising from the vesting of performance-based stock options granted pursuant to the Endo Pharma LLC stock option plans. Under these plans, tranches of options vest when we attain certain common stock price targets. As each tranche vests, we incur a non-cash charge representing the difference between the market price of the shares of common stock underlying the options and the exercise price of such options. We may in the future incur up to two additional compensation charges on account of the Endo Pharma LLC stock option plans as a result of the attainment of these common stock price targets. These charges may be substantial. These options are exercisable solely 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 ownership of our other public stockholders.

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

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

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

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*Interest Expense, Net.* Interest expense, net for the year ended December 31, 2001 decreased by 27% to \$11.0 million from \$15.1 million in the comparable 2000 period. The increase was substantially due to a decrease in interest expense of \$2.0 million due to a decrease in long-term debt outstanding and a decrease in interest expense of \$1.6 million due to a decrease in interest rates.

*Income Tax (Benefit).* We recorded an income tax benefit for the year ended December 31, 2001 of \$3.8 million compared to an income tax benefit for the year ended December 31, 2000 of \$6.2 million. During the fourth quarter of 2001, we evaluated our anticipated future taxable income based upon the repayment of our outstanding term loans, new product approvals and other existing and estimated future product performance and determined that it is more likely than not that we will utilize our deferred tax benefits. Accordingly, we reversed our valuation reserves that had been recorded against those deferred tax assets. The reversal of the reserves established in connection with the acquisition of Algos was recorded as a reduction of goodwill. The reversal of the reserves recorded subsequent to the Algos acquisition was recorded as an increase to income tax benefit.

### *Year Ended December 31, 2000 Compared to Year Ended December 31, 1999*

*Net Sales.* Net sales for the year ended December 31, 2000 increased by 43% to \$197.4 million from \$138.5 million in the comparable 1999 period. This increase in net sales was primarily due to the increase in net sales from several recently launched new products. In November 1999, we launched Percocet® 2.5/325, Percocet® 7.5/500 and Percocet® 10.0/650 to complement the existing Percocet® 5.0/325 for the relief of moderate-to-severe pain. In September 1999, we launched Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia. In November 1998, we launched morphine sulfate extended release tablets, the therapeutic equivalent version of MS Contin®, for moderate-to-severe pain.

*Gross Profit.* Gross profit for the year ended December 31, 2000 increased by 67% to \$134.4 million from \$80.3 million in the comparable 1999 period. Gross profit margins increased to 68% from 58% due to our continued focus on a more favorable mix of higher margin products both through product launches as 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 DuPont Pharmaceuticals, currently our most significant contract manufacturing relationship. If we achieve our forecasts for net sales and product mix, our management expects the increase in gross profits and gross profit margins to continue.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses for the year ended December 31, 2000 increased by 32% to \$56.5 million from \$42.9 million in the comparable 1999 period. This increase was due to a \$8.1 million increase in sales, marketing and promotional efforts in 2000 over the comparable 1999 period to support the recent launch of Lidoderm® and the launches of Percocet® 2.5/325, Percocet® 7.5/500 and Percocet® 10.0/650 to complement the existing Percocet® 5.0/325. In addition, we experienced an increase in personnel-related costs in the general and administrative functions in order to support our growth.

*Research and Development Expenses.* Research and development expenses for the year ended December 31, 2000 increased by 177% to \$26.0 million from \$9.4 million in the comparable 1999 period. This increase was due to our increased spending on products under development that are focused in pain management including the products under development in the former Algos pipeline.

*Depreciation and Amortization.* Depreciation and amortization for the year ended December 31, 2000 increased to \$27.6 million from \$8.3 million in the comparable 1999 period. This increase was substantially due to the increase in amortization of goodwill and other intangibles resulting from the intangible assets acquired as a result of the merger.

*Compensation Related to Stock Options.* Compensation related to stock options of \$15.3 million reflects the charge arising from the vesting of performance-based stock options granted pursuant to the Endo Pharma LLC Amended and Restated 1997 Stock Option Plans. The amount represents the estimated difference in the market price and the exercise price of the vested stock options. To the extent that additional performance-

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based stock options vest pursuant to the Endo Pharma LLC Amended and Restated 1997 Stock Option Plans, significant charges may occur in the future. The exercise of stock options pursuant to the Endo Pharma LLC Amended and Restated 1997 Stock Option Plans does not result in the issuance of additional shares of our common stock.

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

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

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

*Interest Expense, Net.* Interest expense, net for the year ended December 31, 2000 increased by 6% to \$15.1 million from \$14.3 million in the comparable 1999 period. The increase was due to an increase in interest expense of \$1.2 million due to an increase in long-term debt outstanding and an increase in interest expense of \$1.2 million due to an increase in interest rates. These increases are offset by an increase in interest income of \$1.6 million due to an increase in the average cash balance for the year ended December 31, 2000 compared to the comparable 1999 period. The increase in the average cash balance was primarily the result of acquiring \$19.6 million in net cash and cash equivalents in the merger with Algos.

*Income Tax (Benefit).* Income tax (benefit) for the year ended December 31, 2000 was \$6.2 million. In the year ended December 31, 2000, 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.

### Liquidity and Capital Resources

Our principal source of liquidity is cash generated from operations. We also have the ability to borrow up to \$75.0 million on a revolving basis and up to \$25.0 million as a delayed draw term loan for certain purposes as described above under Item. 1. Business Description of Credit Facility. Our principal liquidity requirements are for working capital for operations, capital expenditures and debt service.

Net cash provided by operating activities increased by \$44.4 million to \$80.5 million for the year ended December 31, 2001 from \$35.1 million for the year ended December 31, 2000. This increase was due to the cash provided by the increase in net sales and gross profit for the year ended December 31, 2001 compared to the year ended December 31, 2000 offset by an increase in selling, general and administrative expenses and research and development expenses for the year ended December 31, 2001 as compared to the year ended December 31, 2000. In addition, cash provided by working capital increased due to the significant increase in selling, general and administrative expenses and research and development expenses incurred in the fourth quarter of 2001 as compared to the fourth quarter of 2000.

Net cash used in investing activities was \$6.5 million for the year ended December 31, 2001 compared to net cash provided by investing activities of \$18.1 million for the year ended December 31, 2000. The \$19.6 million in net cash acquired from the merger with Algos was offset by an increase in capital expenditures of \$5.0 million. This increase in capital expenditures was due to the purchase of leasehold improvements and other furniture and fixtures related to our new principal executive offices, the lease of which commenced in the third quarter of 2001 and the implementation of an electronic document management system during 2001.

Net cash utilized in financing activities increased by \$21.8 million to \$37.8 million for the year ended December 31, 2001 from \$16.0 million for the year ended December 31, 2000 due to repayment in full of the

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term loans under our old credit facility. During the fourth quarter of 2001, we completed a public offering of 12.9 million primary shares of common stock that provided net proceeds of \$96.2 million. During 2001, we made scheduled payments of \$32.9 million under our term loans. On October 29, 2001, we repaid the remaining outstanding balance of our term loans of \$101.1 million.

On March 15, 2001, Penwest Pharmaceuticals Co., a collaboration partner of Endo with which Endo has an alliance agreement and with which Endo is developing one of its pipeline projects, received a going concern opinion from Ernst & Young LLP, its independent auditors, in connection with Penwest's Annual Report on Form 10-K for the year ended December 31, 2000. Specifically, Ernst & Young stated that they had substantial doubt about Penwest's ability to continue as a going concern in light of its recurring operating losses and negative cash flows from operations in each of the three years in the period ended December 31, 2000. In addition, Penwest's Annual Report indicated that, based on anticipated levels of operations and currently available capital resources, Penwest's management expects continued operating losses and negative cash flows during 2001. On July 10, 2001, Penwest announced that it had entered into definitive agreements for the sale of 2.4 million shares of newly issued common stock to selected institutional and other accredited investors for an aggregate of \$30.0 million. On July 25, 2001, Penwest filed a Report on Form 8-K with the SEC that contained an opinion of Ernst & Young LLP that, on account of this issuance of \$30.0 million of common stock, the conditions that raised substantial doubt about whether Penwest will continue as a going concern no longer exist. In Penwest's quarterly report for the quarter ended September 30, 2001, Penwest stated that its existing capital resources, will enable Penwest to maintain currently planned operations at least through 2002. If Penwest is unable to fund their portion of the collaboration project with Endo, this may adversely affect the Company's results of operations and cash flows in the foreseeable future.

Our cash and cash equivalents totaled \$95.4 million at December 31, 2001. 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 to fund their portion of any particular project. We may use a portion of our cash and cash equivalents to repay all or a portion of the notes that we have issued to Bristol-Myers Squibb Company (formerly DuPont Pharmaceuticals) or for possible acquisitions. In January 2002, we repurchased 8.6 million of our outstanding Class A Transferable Warrants (Nasdaq: ENDPW) and 8,500 of our outstanding Class B Non-Transferable Warrants for a purchase price of \$0.75 per warrant or a total of approximately \$6.4 million.

In December 2001, we amended and restated our senior secured credit facility with a number of lenders, including affiliates of certain of the underwriters of our recent public offering. This amended and restated credit facility provides for a line of credit of \$75.0 million and a delayed draw term loan of \$25.0 million. The line of credit and delayed draw term loan mature December 21, 2006. Any loans outstanding under the credit facility are secured by a first priority security interest in substantially all of our assets. The credit facility contains representations and warranties, covenants, events of default and other provisions customarily found in similar agreements. See Item 1. Business Description of Credit Facility.

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

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

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.

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

### **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. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption made by us, there may also be other estimates or assumptions that are reasonable. We believe, however, that given current facts and circumstances, it is unlikely that applying any such other reasonable judgment would cause a material adverse effect on our consolidated results of operations, financial position or cash flows for the periods represented in this Report. Our most critical accounting policies include the determination of sales deductions for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses and the determination of future net cash flows of businesses and intangible assets acquired and the utilization of deferred tax assets. Note 2 to the consolidated financial statements attached at the back of this Report describes our significant accounting policies.

### **Recent Accounting Pronouncements**

In June 1998, the FASB issued SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, which is effective for all fiscal years beginning after June 15, 2000. SFAS 133, as amended by SFAS 137 and SFAS 138, establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities. All derivatives, whether designated in hedging relationships or not, will be required to be recorded on the balance sheet at fair value. If the derivative is designated in a fair value hedge, the changes in the fair value of the derivative and the hedged item will be recognized in earnings. If the derivative is designated as a cash flow hedge, changes in the fair value of the derivative will be recorded in other comprehensive income (OCI) and will be recognized in the income statement when the hedged item affects earnings. SFAS 133 defines new requirements for designation and documentation of hedging relationships as well as ongoing effectiveness assessments in order to use hedge accounting. A derivative that does not qualify as a hedge will be marked to fair value through earnings.

At January 1, 2001, we recorded \$0.2 million as an accumulated transition adjustment as a reduction to earnings relating to cash flow hedges.

In December 1999, the SEC issued SAB 101, entitled *Revenue Recognition in Financial Statements*, as amended, effective as of October 1, 2000, which summarizes the SEC's views in applying generally accepted accounting principles to revenue recognition. The adoption of this guideline had no effect on our financial statements.

In March 2000, the FASB issued Financial Accounting Series Interpretation No. 44 entitled *Accounting for Certain Transactions Involving Stock Compensation*, which provides clarification to Accounting Principles Board Opinion No. 25 (APB No. 25), *Accounting for Stock Issued to Employees*. The adoption of this interpretation had no effect on our financial statements.

In June 2001, the FASB, issued SFAS No. 141, *Business Combinations*, and SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 141 is effective for all business combinations completed after June 30, 2001. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. SFAS No. 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS No. 142 establishes revised reporting requirements for goodwill and other intangible assets. Upon adoption, we will no longer amortize goodwill unless evidence of an impairment exists. Goodwill will be evaluated for impairment on at least an annual basis. Although we are currently evaluating all of the provisions of SFAS No. 141 and

SFAS No. 142 and therefore are not presently able to quantify the impact of adoption, we believe the adoption of SFAS No. 142 will have a material impact on our results of operations. We have \$179.1 million of goodwill as of December 31, 2001 and have recorded \$40.4 million of goodwill amortization for the year ended December 31, 2001. We have adopted the provisions of SFAS No. 142 effective January 1, 2002.

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

During the fourth quarter of 2001, we repaid the remaining outstanding balance of our variable rate term loans. Prior to the repayment of our variable rate term loans, our primary market risk exposure was to changes in interest rates (LIBOR) on our variable rate borrowings. As of December 31, 2001, we only have outstanding fixed rate borrowings. These fixed rate borrowings are comprised of promissory notes payable to Bristol-Myers Squibb issued in consideration for manufacturing and supply services provided under the Manufacturing and Supply Agreement. The notes have a face value of \$23.0 million and are payable on August 26, 2002. The promissory notes bear no interest and therefore have been discounted in the accompanying financial statements using our borrowing rate for similar instruments at the time of borrowing. We also financed a portion of the purchase price of the Acquisition through the issuance of a promissory note to DuPont. The note has a face value of \$3.9 million and is payable on August 26, 2002. The promissory note bears no interest and therefore has been discounted in the accompanying financial statements using a rate of 9.75%, which approximates our borrowing rate for similar instruments at the time of borrowing. On December 21, 2001, we entered into a new credit facility that provides for a line of credit of \$75.0 million and a delayed draw term loan of \$25.0 million. Borrowings under the new credit facility are variable rate borrowings. There are no amounts outstanding under the new credit facility. We do not utilize financial instruments for trading purposes and hold no derivative financial instruments that could expose us to significant market risk. We monitor interest rates and enter into interest rate agreements as considered appropriate. To manage a portion of our exposure to fluctuations in interest rates, we had entered into an interest rate cap agreement with a notional amount of \$70.0 million. The interest rate cap agreement sets a maximum LIBOR rate of 8% that we would pay on the related notional amounts. The interest rate cap agreement has been extinguished.

To the extent that our financial instruments expose us to interest rate risk, they are presented in the table below. The table presents principal cash flows and related interest rates by year of maturity for our term loans, notes payable and interest rate cap as of December 31, 2001 and December 31, 2000. You should read Notes 6 and 7 to our consolidated financial statements for the year ended December 31, 2001, together with the tables below.

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

(dollars in thousands)

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

## Schedule of Interest Rate Sensitive Assets and Liabilities at December 31, 2000

(dollars in thousands)

	Year of Maturity					Total due at Maturity	Fair Value At 12/31/00
	2001	2002	2003	2004	Thereafter		
<b>Interest rate sensitive liabilities:</b>							
<b>Short-term and variable rate borrowings</b>							
Tranche A term loan	\$ 18,821	\$ 16,140				\$ 34,961	\$ 34,961
Average interest rate	7.75%	7.75%				7.75%	
Tranche B term loan	17,550	807	\$ 37,121	\$ 43,576		99,054	99,054
Average interest rate	8.75%	8.75%	8.75%	8.75%		8.75%	
<b>Total</b>	<b>36,371</b>	<b>16,947</b>	<b>37,121</b>	<b>43,576</b>		<b>134,015</b>	<b>134,015</b>
<b>Fixed-rate borrowings</b>							
Acquisition Note Payable		3,889				3,889	3,308
Average interest rate		9.75%				9.75%	
Other Notes Payable		69,000				69,000	61,202
Average interest rate		7.23%				7.23%	
<b>Total interest rate sensitive liabilities</b>	<b>\$ 36,371</b>	<b>\$ 89,836</b>	<b>\$ 37,121</b>	<b>\$ 43,576</b>		<b>\$ 206,904</b>	<b>\$ 198,525</b>
Weighted average interest rate	8.23%	7.45%	8.75%	8.75%		8.09%	
<b>Interest rate instruments:</b>							
Interest rate cap	\$ 311						
Cap rate	8.00%						

The most significant change to interest rate sensitive assets and liabilities was our repayment of the remaining outstanding balance of our variable rate term loans in 2001.

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

The information required by this item is contained in the financial statements set forth in Item 14(a) under the caption Consolidated Financial Statements as part of this Form 10-K Annual Report.

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

Not applicable.

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

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

(the 2002 Information Statement ).

**Executive Officers**

The information concerning our executive officers required under this item is provided under Item 4A of this Form 10-K Annual Report.



**Item 11. Executive Compensation**

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

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

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

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

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

**PART IV****Item 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K****(a) Documents filed as part of this Annual Report on Form 10-K**

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

**SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS**

(dollars in thousands)

	Balance at beginning of period	Additions	Deductions(1)	Other	Balance at end of period
<b>Allowance For Doubtful Accounts:</b>					
Year Ended December 31, 1999	\$ 315	\$ 150	\$ (21)		\$ 444
Year Ended December 31, 2000	\$ 444	\$ 1,128	\$ (1,057)		\$ 515
Year Ended December 31, 2001	\$ 515	\$ 300	\$ (102)		\$ 713

(1) Accounts written-off.

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

**(b) Reports on Form 8-K.**

We filed the following Current Reports on Form 8-K in the quarter ended December 31, 2001:

Dates	Items
October 18, 2001	Items 5 & 7
November 13, 2001	Items 5 & 7
November 16, 2001	Items 5 & 7
November 20, 2001	Items 7 & 9

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November 27, 2001	Items 7 & 9
December 6, 2001	Items 7 & 9
December 17, 2001	Items 7 & 9

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

**SIGNATURES**

Pursuant to the requirements 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/ CAROL A. AMMON

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Name: Carol A. Ammon  
Title: *Chairman and Chief Executive Officer*

/s/ JEFFREY R. BLACK

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

Date: March 29, 2002

**POWER OF ATTORNEY**

Each of the undersigned, hereby constitutes and appoints each of Carol A. Ammon, James J. Connors, II, 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 Report and Power of Attorney have been signed by the following persons in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
*	Chairman, Chief Executive Officer, President and Director	March 29, 2002
Carol A. Ammon *	Director	March 29, 2002
Michael B. Goldberg *	Director	March 29, 2002
Michael Hyatt *	Director	March 29, 2002
Roger H. Kimmel *	Director	March 29, 2002
Frank J. Loverro *	Director	March 29, 2002
Michael W. Mitchell *	Director	March 29, 2002
Joseph T. O'Donnell, Jr. *	Director	March 29, 2002
David I. Wahrhaftig		
*By: /s/ CAROLINE B. MANOGUE	Attorney-in-fact	March 29, 2002

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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, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. Our audits also included the financial statement schedule listed in Item 14 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, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 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.

/s/ Deloitte & Touche LLP

Deloitte & Touche LLP

Philadelphia, Pennsylvania  
February 20, 2002

## ENDO PHARMACEUTICALS HOLDINGS INC.

## CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2001 AND 2000

(In thousands, except share data)

	2001	2000
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 95,357	\$ 59,196
Accounts receivable, net of allowance of \$713 and \$515 at December 31, 2001 and 2000, respectively	85,329	78,312
Inventories	27,766	29,746
Prepaid expenses	5,527	3,496
Deferred income taxes	26,946	2,304
	<u>240,925</u>	<u>173,054</u>
Total current assets	240,925	173,054
PROPERTY AND EQUIPMENT, Net	9,883	5,742
GOODWILL AND OTHER INTANGIBLES, Net of amortization of \$88,590 and \$41,468 at December 31, 2001 and 2000, respectively	194,813	284,560
DEFERRED INCOME TAXES	23,420	736
RESTRICTED CASH	150	150
OTHER ASSETS	1,804	3,598
	<u>470,995</u>	<u>467,840</u>
TOTAL ASSETS	\$ 470,995	\$ 467,840
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 30,705	\$ 15,855
Accrued expenses	50,176	45,520
Income taxes payable	3,526	2,549
Current portion of long-term debt	91,259	36,371
	<u>175,666</u>	<u>100,295</u>
Total current liabilities	175,666	100,295
LONG-TERM DEBT, Less current portion		162,154
OTHER LIABILITIES	207	7,218
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; 102,063,950 and 89,138,950 shares issued and outstanding in 2001 and 2000, respectively	1,021	891
Additional paid-in capital	519,316	385,955
Accumulated deficit	(225,215)	(188,673)
	<u>295,122</u>	<u>198,173</u>
Total Stockholders Equity	295,122	198,173
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	\$ 470,995	\$ 467,840

See notes to consolidated financial statements.

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## ENDO PHARMACEUTICALS HOLDINGS INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2001, 2000 AND 1999

(In thousands, except per share data)

	2001	2000	1999
NET SALES	\$ 251,979	\$ 197,429	\$ 138,546
COST OF SALES	74,891	63,041	58,263
GROSS PROFIT	177,088	134,388	80,283
COSTS AND EXPENSES:			
Selling, general and administrative	79,505	56,537	42,921
Research and development	38,994	26,012	9,373
Depreciation and amortization	49,234	27,624	8,309
Compensation related to stock options (primary selling, general and administrative)	37,253	15,300	
Purchased in-process research and development		133,200	
Merger and other related costs		1,583	
Separation benefits		22,034	
OPERATING (LOSS) INCOME	(27,898)	(147,902)	19,680
INTEREST EXPENSE, Net of interest income of \$2,830, \$2,700 and \$1,065, respectively	10,962	15,119	14,347
(LOSS) INCOME BEFORE INCOME TAX (BENEFIT) AND EXTRAORDINARY ITEM	(38,860)	(163,021)	5,333
INCOME TAX (BENEFIT)	(3,753)	(6,181)	2,073
NET (LOSS) INCOME BEFORE EXTRAORDINARY ITEM	(35,107)	(156,840)	3,260
EXTRAORDINARY ITEM   Loss on early extinguishment of debt (net of tax benefit of \$893)	(1,435)		
NET (LOSS) INCOME	\$ (36,542)	\$ (156,840)	\$ 3,260
BASIC AND DILUTED NET (LOSS) INCOME PER SHARE:			
(LOSS) INCOME BEFORE EXTRAORDINARY ITEM	\$ (.38)	\$ (1.97)	\$ .05
EXTRAORDINARY ITEM	\$ (.02)		
NET (LOSS) INCOME	\$ (.40)	\$ (1.97)	\$ .05
SHARES USED TO COMPUTE BASIC AND DILUTED NET (LOSS) INCOME PER SHARE	91,505	79,454	71,332

See notes to consolidated financial statements.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

YEARS ENDED DECEMBER 31, 2001, 2000 AND 1999

(In thousands, except share data)

	Number Of Shares	Common Stock at Par Value	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders Equity
BALANCE, DECEMBER 31, 1998	71,342,376	\$ 713	\$ 109,738	\$ (35,093)	\$ 75,358
Repurchase of Common Stock at cost	(18,732)		(31)		(31)
Net income				3,260	3,260
BALANCE, DECEMBER 31, 1999	71,323,644	713	109,707	(31,833)	78,587
Exercise of stock options	4,780		7		7
Compensation related to stock options separation benefits			20,782		20,782
Issuance of Common Stock	17,810,526	178	240,159		240,337
Compensation related to stock options			15,300		15,300
Net loss				(156,840)	(156,840)
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)
BALANCE, DECEMBER 31, 2001	102,063,950	\$ 1,021	\$ 519,316	\$ (225,215)	\$ 295,122

See notes to consolidated financial statements.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2001, 2000 AND 1999

(In thousands)

	2001	2000	1999
<b>OPERATING ACTIVITIES:</b>			
Net (loss) income	\$ (36,542)	\$ (156,840)	\$ 3,260
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation and amortization	49,234	27,624	8,309
Purchased in-process research and development		133,200	
Accretion of promissory notes	5,449	3,579	2,001
Deferred income taxes	(4,701)	(8,732)	1,998
Amortization of deferred financing costs	3,603	1,234	1,199
Non-cash portion of separation benefits		20,782	
Compensation related to stock options	37,253	15,300	
Changes in assets and liabilities which provided (used) cash:			
Accounts receivable	(7,017)	(15,960)	(29,245)
Inventories	1,980	(8,477)	(6,808)
Other assets	(3,546)	(238)	(3,533)
Accounts payable	14,850	(6,792)	7,234
Accrued expenses	25,957	27,367	28,958
Income taxes payable	977	2,549	
Other liabilities	(7,011)	473	393
Net cash provided by operating activities	<u>80,486</u>	<u>35,069</u>	<u>13,766</u>
<b>INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	(6,546)	(1,534)	(2,124)
Acquisition of licensing rights			(6,950)
Net cash acquired in the Merger		19,611	
Net cash provided by (used in) investing activities	<u>(6,546)</u>	<u>18,077</u>	<u>(9,074)</u>
<b>FINANCING ACTIVITIES:</b>			
Issuance of Common Stock	96,238		
Exercise of stock options		7	
Repurchase of Common Stock			(31)
Repayments of long-term debt	(134,017)	(15,985)	
Net cash used in financing activities	<u>(37,779)</u>	<u>(15,978)</u>	<u>(31)</u>
NET INCREASE IN CASH AND CASH EQUIVALENTS	36,161	37,168	4,661
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	59,196	22,028	17,367
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 95,357</u>	<u>\$ 59,196</u>	<u>\$ 22,028</u>
<b>SUPPLEMENTAL INFORMATION:</b>			
Interest paid	\$ 7,065	\$ 13,205	\$ 12,194
Income taxes paid	\$ 3,031	\$ 75	\$ 17

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SCHEDULE OF NON-CASH INVESTING AND FINANCING

ACTIVITIES:

Promissory notes issued under Manufacturing and Supply Agreement	\$ 21,301	\$ 19,727	\$ 18,655
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Fair value of net assets acquired in the Merger, net of cash		\$ 228,941	
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See notes to consolidated financial statements.

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## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2001, 2000 AND 1999

**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 August 26, 1997, Endo commenced operations by acquiring certain branded and generic pharmaceutical products, related rights and certain assets of DuPont Pharmaceuticals Company (DuPont, formerly The DuPont Merck Pharmaceutical Company, DuPont Merck Pharma and Endo Laboratories, L.L.C.) (the Acquisition). The purchase price for the Acquisition of approximately \$277 million (including approximately \$15 million in transaction fees) was financed with approximately \$275 million in cash from (i) borrowings of \$165 million under a credit facility with a group of banks and (ii) the issuance of \$110 million of Common Stock and Class A Common Stock of Endo for cash to certain affiliates and designees of Kelso & Company, Inc. (Kelso), management and certain other investors; and (iii) the issuance of a promissory note to DuPont of approximately \$2 million.

The Acquisition was accounted for using the purchase method of accounting. In accordance with the purchase method of accounting, the purchase price was allocated to the underlying assets of the business acquired based on their estimated fair values at the date of acquisition. The final value of acquired in-process research and development was \$46 million and charged to expense at the date of the Acquisition. The excess of the purchase price over the tangible and identifiable intangible assets was allocated to goodwill. In consideration of services provided by an individual prior to the Acquisition, such individual was granted contingent consideration of \$2 million only upon the occurrence of certain events. This amount will be expensed in the period the contingency is resolved.

The final allocation of the purchase price was as follows (in thousands):

Inventories	\$ 23,642
Property and equipment	3,423
Acquired in-process research and development	46,000
Goodwill	196,706
Debt issuance costs	7,190
	<hr/>
Total purchase price	\$276,961
	<hr/>

The Acquisition included various on-going projects to research and develop innovative new products primarily for pain management. As a result, a portion of the total purchase price for the Acquisition was allocated to these acquired in-process research and development projects (IPRD). At the time of the Acquisition, the total number of projects acquired and in various phases of development was 15. The development program for a new pharmaceutical substance involves several different phases prior to drug application. Generic and branded Phase II projects ranged from 20% to 50% completed at the time of the Acquisition. Branded Phase III projects were approximately 90% completed at the time of the Acquisition. Drug application must be approved prior to marketing a new drug. Despite our commitment to completion of the research and development projects, many factors may arise which could cause a project to be withdrawn, including a drug being shown as ineffective during the development process. Upon withdrawal, it is unlikely that the development activities will have alternative use.

The methodology we used in determining the value of IPRD was: 1) identify the various on-going projects that the Company will prioritize and continue; 2) project net future cash flows of the identified projects based on current demand and pricing assumptions, less the anticipated expenses to complete the development program, drug application, and launch the product (significant net cash inflows were projected to

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

commence in 1999); 3) discount these cash flows based on a risk-adjusted discount rate (17%); and 4) apply the estimated percentage of completion to the discounted cash flow for each individual project. The discount rate was determined after considering various uncertainties at the time of the Acquisition, primarily the stage of project completion.

A summary of the various projects included in IPRD follows. Projects included as IPRD and reflected in the below schedule include Percocet® 2.5/325, Percocet® 7.5/500, Percocet® 10.0/650, Zydone® and Morphine Sulfate Extended Release Tablets, all of which have been subsequently completed and commercially launched by the Company. There can be no assurance that other projects acquired and included in IPRD will prove successful.

	Number of Projects	Estimated Value
		(in thousands)
Generic projects Phase II	9	\$ 13,000
Branded projects Phase II	4	21,000
Branded projects Phase III	2	12,000
	15	\$46,000

On November 18, 1997, the Company, a Delaware corporation, was established for the sole purpose of holding all of the shares of capital stock of Endo. As of December 1, 1998, the stockholders of Endo became the Company's stockholders, owning the same interests in the Company that they formerly owned in Endo.

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 and the 1997 Executive Stock Option Plan (collectively, as amended and restated, the Endo Pharma LLC 1997 Stock Option Plans) diluted only the pre-Merger holders of Endo Common Stock (see Note 12). Subsequent to the Merger, only currently outstanding shares of Common Stock of the Company held by Endo Pharma LLC will be issued upon the exercise of these stock options. Because Endo Pharma LLC, and not the Company, will provide the shares issued upon the exercise of the options, the Company has entered into a tax sharing agreement with Endo Pharma LLC under which the Company will pay to Endo Pharma LLC the amount of the tax benefits it receives as a result of the exercise of these stock options into shares of Common Stock held by Endo Pharma LLC for the years in which these tax benefits arise. No payments have been made or accrued for the year ended December 31, 2001 and 2000.

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

On July 17, 2000, we completed our merger with Algos. In the merger, we issued to the former Algos stockholders, in the aggregate, 17,810,526 shares of our common stock and 17,810,526 warrants to purchase in the aggregate up to 20,575,507 additional shares of our common stock in certain circumstances as more fully described under footnote 12 to these consolidated financial statements. In the merger, we also issued to our



**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

pre-merger stockholders, in the aggregate, 71,328,424 warrants to purchase in the aggregate up to 29,720,177 additional shares of common stock in certain other circumstances as more fully described under footnote 12 to these consolidated financial statements.

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

The Merger included various on-going projects to research and develop innovative new products for pain management. As a result, the allocation of the fair value of the assets acquired and liabilities assumed included an allocation to purchased in-process research and development (IPRD) of \$133.2 million which was immediately expensed in the consolidated statement of operations on the acquisition date. The methodology used by us on the acquisition date in determining the value of IPRD was to: 1) identify the various on-going projects that the Company will prioritize and continue; 2) project net future cash flows of the identified projects based on current demand and pricing assumptions, less the anticipated expenses to complete the development program, drug application, and launch the products (significant net cash inflows from MorphiDex® were projected in 2003); 3) discount these cash flows based on a risk-adjusted discount rates ranging from 25% to 33% (weighted average discount rate of 27%); and 4) apply the estimated percentage of completion to the discounted cash flow for each individual project ranging from 4% to 81%. The discount rate was determined after considering various uncertainties at the time of the Merger, primarily the stage of project completion.

The Company allocated fair value to the three opioid analgesic projects of Algos: MorphiDex®, HydrocoDex™ and OxycoDex™. The development program for a new pharmaceutical substance involves several different phases prior to drug application. Drug application must be approved prior to marketing a new drug. Despite our commitment to the completion of the research and development projects, many factors may arise that could cause a project to be withdrawn or delayed, including the inability to prove the safety and efficacy of a drug during the development process. Upon withdrawal, it is unlikely that the development activities will have alternative use. If these projects are not successfully developed, our results of operations and financial position in a future period could be negatively impacted.

The following unaudited pro forma summary presents the net sales, net loss and net loss per share as if the Merger occurred as of January 1, 1999. This unaudited pro forma summary has been prepared for comparative purposes only and is not necessarily indicative of the operating results that we would have achieved had the Merger been completed as of January 1, 1999, or the operating results that we may achieve in the future.



## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	(Unaudited)	
	2000	1999
	(In thousands, except per share data)	
Net sales	\$ 197,429	\$ 138,546
Net loss	\$ (57,836)	\$ (188,540)
Net loss per share (basic and diluted)	\$ (.65)	\$ (2.12)

**2. Summary of Significant Accounting Policies**

*Principles of Consolidation* The consolidated financial statements include the accounts of Endo Pharmaceuticals Holdings Inc. (the Company) 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 sales 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 28%, 24%, 19% and 10%, respectively, of net sales in 2001. Three distributors and one pharmacy chain individually accounted for 26%, 16%, 12% and 10%, respectively, of net sales in 2000. Three distributors individually accounted for 27%, 20% and 13% of net sales in 1999. We perform ongoing credit evaluations of our customers and maintain sufficient allowances for estimated uncollectible accounts. Generally, we do not require collateral from our customers.

We have an agreement with Bristol-Myers Squibb for the manufacture and supply of substantially all of our existing and new pharmaceutical products (see Note 9). In the event of any interruption in the manufacture and supply of these products due to regulatory or other causes, there can be no assurance that we could make alternative arrangements on a timely basis, if at all. Such interruption could have a material adverse effect on our business, financial condition and results of operations.

*Revenue Recognition* Revenues are recognized when products are shipped. Revenues are recorded net of reserves for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses. We estimate the accrual for sales deductions based on historical data, estimated future trends and other competitive factors. Our revenue recognition policies are in accordance with Staff Accounting Bulletin No. 101 ( SAB 101 ).

*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. A bank certificate of deposit that serves as collateral for an irrevocable letter of credit required by the terms of one of our lease agreements is included in restricted cash.

*Derivative Financial Instruments* 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. (See *Recent Accounting Pronouncements*.)

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

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

*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 three 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 Fees* The cost of license fees is capitalized and amortized on a straight-line basis over their estimated useful life of twenty years. (See *Recent Accounting Pronouncements*.)

*Workforce in Place* The cost of workforce in place acquired in the Merger is capitalized and amortized on a straight-line basis over their estimated useful life of two years. (See *Recent Accounting Pronouncements*.)

*Patents* The cost of patents acquired in the Merger is capitalized and amortized on a straight-line basis over their estimated useful life of seventeen years. (See *Recent Accounting Pronouncements*.)

*Goodwill* Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is amortized on a straight-line basis over its estimated useful life ranging from three to thirty years. We assess the recoverability and the amortization period of the goodwill by determining whether the amount can be recovered through undiscounted net cash flows of the business acquired over the remaining amortization period. (See *Recent Accounting Pronouncements*.)

*Long-Lived Assets* We review for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset are less than its carrying amount. Assets are grouped at the lowest level for which there are identifiable cash flows that are largely independent from other asset groups. We use the discounted future expected net cash flows, as its estimate of fair value, to determine the amount of impairment loss. We have not identified any such impairment losses with respect to long-lived assets for all periods presented.

*Marketing Costs* Marketing costs, including advertising costs, are expensed as incurred. Such costs were \$9.8 million, \$8.1 million and \$9.0 million for the years ended December 31, 2001, 2000 and 1999.

*Deferred Financing Costs* Costs incurred in connection with the issuance of debt 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*.

*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. Significant estimates and assumptions are also required in the determination of future net cash flows of businesses and intangible assets acquired and the utilization of deferred tax 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.

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

*Recent Accounting Pronouncements*

In June 1998, the FASB issued SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, which is effective for all fiscal years beginning after June 15, 2000. SFAS 133, as amended by SFAS 137 and SFAS 138, establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities. All derivatives, whether designated in hedging relationships or not, will be required to be recorded on the balance sheet at fair value. If the derivative is designated in a fair value hedge, the changes in the fair value of the derivative and the hedged item will be recognized in earnings. If the derivative is designated as a cash flow hedge, changes in the fair value of the derivative will be recorded in other comprehensive income (OCI) and will be recognized in the income statement when the hedged item affects earnings. SFAS 133 defines new requirements for designation and documentation of hedging relationships as well as ongoing effectiveness assessments in order to use hedge accounting. A derivative that does not qualify as a hedge will be marked to fair value through earnings.

At January 1, 2001, we recorded \$228,000 as an accumulated transition adjustment as a reduction to earnings.

In December 1999, the SEC issued SAB 101, entitled Revenue Recognition in Financial Statements, as amended, effective as of October 1, 2000, which summarizes the SEC's views in applying generally accepted accounting principles to revenue recognition. The adoption of this guideline had no effect on our financial statements.

In March 2000, the FASB issued Financial Accounting Series Interpretation No. 44 entitled Accounting for Certain Transactions Involving Stock Compensation, which provides clarification to Accounting Principles Board Opinion No. 25 (APB No. 25), Accounting for Stock Issued to Employees. The adoption of this interpretation had no effect on our financial statements.

In June 2001, the FASB, issued SFAS No. 141, Business Combinations, and SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 141 is effective for all business combinations completed after June 30, 2001. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. SFAS No. 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS No. 142 establishes revised reporting requirements for goodwill and other intangible assets. Upon adoption, we will no longer amortize goodwill unless evidence of an impairment exists. Goodwill will be evaluated for impairment on at least an annual basis. Although we are currently evaluating all of the provisions of SFAS No. 141 and SFAS No. 142 and therefore are not presently able to quantify the impact of adoption, we believe the adoption of SFAS No. 141 and SFAS No. 142 will have a material impact on our results of operations. We have \$179.1 million of goodwill as of December 31, 2001 and have recorded \$40.4 million of goodwill amortization for the year ended December 31, 2001. We have adopted the provisions of SFAS No. 142 effective January 1, 2002.

**3. License and Collaboration Agreements**

In November 1998, we entered into a license agreement (the 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 License Agreement, we were required to pay Hind approximately \$10 million (the License Fee) based upon the achievement of certain milestones. During 2000, 1999 and 1998, we paid Hind approximately \$2 million, \$6 million and \$2 million, respectively, in accordance with the terms of the License Agreement. Costs related to the License Agreement are included in Goodwill and Other Intangible Assets at December 31, 2001. In addition, beginning on March 19, 2001, we pay Hind royalties based on net sales of the product. The royalty rate is 8% of net sales from March 19, 2001 through March 18, 2002 and 10% of net sales from March 19, 2002 through the shorter of (1) the expiration of the last licensed patent or November 23, 2011. During 2001, we accrued \$3.3 million for royalties, which

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

were recorded as a reduction to net sales. In March 2002, we extended this license with Hind to cover Canada and Mexico.

In November 1999, we entered into a collaboration agreement with Lavipharm Laboratories, Inc. pursuant to which we obtained exclusive worldwide rights to Lavipharm's existing drug delivery technology platforms. Under the terms of this collaboration agreement, we 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.

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

**4. Property and Equipment**

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

	2001	2000
Machinery and equipment	\$ 5,274	\$ 4,202
Computer equipment and software	6,194	4,687
Furniture and fixtures	3,900	845
	<u>15,368</u>	<u>9,734</u>
Less accumulated depreciation	(5,485)	(3,992)
Total	<u>\$ 9,883</u>	<u>\$ 5,742</u>

**5. Goodwill and Other Intangibles**

Goodwill and other intangible assets consist of the following at December 31 (in thousands):

	2001	2000
Goodwill	\$257,303	\$299,928
Licenses	11,000	11,000
Workforce in Place	11,900	11,900
Patents	3,200	3,200
	<u>283,403</u>	<u>326,028</u>
Less accumulated amortization	(88,590)	(41,468)
Total	<u>\$194,813</u>	<u>\$284,560</u>

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**6. Long-Term Debt**

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

	<u>2001</u>	<u>2000</u>
Tranche A Term Loan		\$ 34,961
Tranche B Term Loan		99,054
Notes payable	\$ 91,259	64,510
	<u>91,259</u>	<u>198,525</u>
Less current portion	(91,259)	(36,371)
	<u>\$ 0</u>	<u>\$ 162,154</u>

On August 26, 1997, Endo entered into a revolving credit and term loan agreement (the "Credit Agreement") with a group of banks to provide funds for the 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, and recognized a \$1.4 million (net of tax) extraordinary charge for the extinguishment of this debt. On December 21, 2001, we amended and restated this credit agreement (the "Amended and Restated Credit Agreement"). As of December 31, 2001, no amounts were outstanding under the Amended and Restated Credit Agreement.

**Credit Agreement**

The Credit Agreement was secured by substantially all of the assets of Endo. The Credit Agreement provided a term loan facility of \$165 million and a revolving commitment of \$25 million. The term loans were segregated into two tranches, Tranche A Term Loan and Tranche B Term Loan. The Tranche A Term Loan was due in quarterly installments ranging from \$2 million to \$5 million beginning December 31, 1998, with a final payment due December 31, 2002. The Tranche B Term Loan was due in quarterly installments ranging from \$250,000 to \$27 million beginning December 31, 1998 with a final payment due June 30, 2004. The revolving commitment had availability of \$25.0 million and matured December 31, 2002. No borrowings were made under the revolving commitment.

Borrowings under the Tranche A Term Loan bore interest, which was payable at least quarterly, at a rate equal to the bank's floating alternate base rate plus a premium ranging from .25% to 1.25%, or at a rate equal to LIBOR plus a premium ranging from 1.25% to 2.25%, depending on the type of borrowing and Endo's performance against certain criteria. The effective borrowing rate was 7.8% as of December 31, 2000.

Borrowings under the Tranche B Term Loan bore interest, which was payable at least quarterly, at a rate equal to the bank's floating alternate base rate plus a premium ranging from 1.25% to 1.75%, or at a rate equal to LIBOR plus a premium ranging from 2.25% to 2.75%, depending on the type of borrowing and Endo's performance against certain criteria. The effective borrowing rate was 8.8% as of December 31, 2000.

Additionally, fees were charged on the average daily unused amount of the revolving commitment at a rate ranging from .375% to .50% depending on Endo's performance against certain criteria. This commitment fee was payable quarterly.

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



**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**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 Amended and Restated Credit Agreement also provides for a delayed draw term loan that must be utilized, if at all, by August 26, 2002 solely for the purpose of paying off the outstanding promissory notes that are payable to Bristol-Myers Squibb. The aggregate principal amount of this term loan is \$25.0 million. The term loan, once borrowed and repaid, may not be reborrowed, and it has a final maturity date of December 21, 2006. As of December 31, 2001, we have not borrowed under the revolving loan or this term loan.

Borrowings under the Amended and Restated Credit Agreement bear interest, which is payable at least quarterly, at a rate equal to the bank 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 Acquisition through the issuance of a promissory note to Bristol-Myers Squibb. The note has a face value of \$3.9 million and is payable on August 26, 2002. This promissory note bears no interest and therefore has been 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. The promissory note has a balance of \$3.6 million and \$3.3 million at December 31, 2001 and 2000, respectively.

On August 26, 2001, 2000, 1999 and 1998, Endo issued promissory notes to Bristol-Myers Squibb in consideration for manufacturing and supply services provided under the Manufacturing and Supply Agreement (see Note 9). The notes have a face value of \$23 million and are payable on August 26, 2002. The promissory notes bear no interest and therefore have been discounted in the accompanying financial statements using 7.7%, 7.7%, 7.0% and 7.0%, respectively, which approximates our borrowing rate for similar instruments at the time of borrowing. The promissory notes have a balance of \$87.7 million and \$61.2 million as of December 31, 2001 and 2000, respectively.

All of our long-term debt outstanding as of December 31, 2001 matures on August 26, 2002.

**Interest Rate Cap**

Effective February 27, 1998, Endo entered into an interest rate cap agreement with a notional amount of \$82.5 million for the purpose of minimizing its exposure to fluctuations in interest rates. The cost of this interest rate cap of \$154,000 was amortized as a component of interest expense over the term of the agreement that expired August 27, 2000. The agreement set a maximum LIBOR rate Endo would pay on the related notional amount of 8.0%.

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

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

**7. 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.

*Notes Payable* The carrying amount of this item is a reasonable estimate of its fair value. The carrying value and the estimate of fair value were determined by discounting the future cash flows using rates currently available to the Company for similar instruments.

*Interest Rate Cap* The fair value of this item is estimated to equal to the carrying amount of this item at December 31, 2001, which was zero. 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. (See Note 2 *Recent Accounting Pronouncements*.) The interest rate cap was extinguished in 2002.

**8. Income Taxes**

Income tax (benefit) consists of the following for 2001, 2000 and 1999 (in thousands):

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Current:			
Federal	\$ 2,653	\$ 1,578	
State	2,248	972	\$ 75
	<u>4,901</u>	<u>2,550</u>	<u>75</u>
Deferred:			
Federal	(5,312)	(6,743)	1,673
State	(3,342)	(1,988)	325
	<u>(8,654)</u>	<u>(8,731)</u>	<u>1,998</u>
Total income tax (benefit)	<u>\$ (3,753)</u>	<u>\$ (6,181)</u>	<u>\$ 2,073</u>



## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A reconciliation of income tax (benefit) at the federal statutory income tax rate to the total income tax provision (benefit) for 2001, 2000 and 1999 is as follows (in thousands):

	2001	2000	1999
Federal income tax (benefit) at the statutory rate	\$(13,209)	\$(55,428)	\$1,813
State income tax (benefit)	(690)	(192)	215
Research and development credit utilized	(1,609)	(607)	
Other		(210)	45
Effect of permanent items:			
Purchased in-process research and development		45,288	
Goodwill	11,517	5,419	
Other	238	(451)	
Total income tax (benefit)	\$ (3,753)	\$ (6,181)	\$2,073

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):

	2001	2000
Deferred tax assets:		
Accrued expenses	\$ 38,451	\$ 25,931
Purchased in-process research and development	12,106	13,250
Net operating loss carryforward	11,987	16,789
Other	2,294	2,228
Total gross deferred income tax assets	64,838	58,198
Deferred tax liabilities:		
Depreciation and amortization	(14,092)	(13,797)
Other	(380)	(569)
Total gross deferred income tax liabilities	(14,472)	(14,366)
Net deferred income tax asset	50,366	43,832
Valuation allowance		(40,791)
	\$ 50,366	\$ 3,041

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 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 were recorded as a reduction of goodwill. The reversal of the reserves recorded subsequent to the Algos acquisition were recorded as an increase to income tax benefit. At December 31, 2001, the Company has \$31.6

million in net operating loss carryforwards for tax purposes which expire through 2019.

**9. 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

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**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

(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.

On August 26, 1997, we entered into various agreements with Bristol-Myers Squibb to provide manufacturing and supply of products (the Manufacture and Supply Agreement ), warehousing and distribution (the Warehousing and Distribution Agreement ), research and development facilities (the R&D Lease ) and certain administrative services (the Administrative Services Agreement ).

The Manufacture and Supply Agreement has an original term of five years through August 26, 2002, with options to renew for up to five additional years in the aggregate. The Manufacture and Supply Agreement currently covers substantially all of our existing and new pharmaceutical products.

The Warehousing and Distribution Agreement had an original term of two years, with options to renew for up to two additional years in the aggregate. The Warehousing and Distribution Agreement covered substantially all of our existing and new pharmaceutical products. During 1999, we extended the Warehousing and Distribution Agreement through May 31, 2000. The Warehousing and Distribution Agreement expired in accordance with its terms during 2000.

The R&D Lease has 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 has been renewed.

The Administrative Services Agreement had a term of up to two years except for those services that relate to the Manufacture and Supply Agreement and the R&D Lease which then correspond to the terms of those respective agreements. The Administrative Services Agreement covered various administrative functions including customer service, certain accounting functions, medical affairs and selected regulatory and research and development functions. The Administrative Services Agreement expired in accordance with its terms during 1999.

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

In addition to the long-term manufacturing agreements described above, we have agreements with (1) Livingston Healthcare Services, Inc. (n/k/a UPS Supply Chain Management, Inc.) for customer service support, warehouse and distribution services and certain financial functions, (2) Kunitz and Associates Inc. for medical affairs and (3) Ventiv Health U.S. Sales Inc. for sales. We also have agreements and arrangements with various contract research organizations for our toxicology and clinical studies. These agreements expire from 2002 through 2005. 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 would have a materially adverse effect on our business, financial condition and results of operations.

## **10. Commitments and Contingencies**

### **Employment Agreements**

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

### **License Agreements**

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

**ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Leases**

We lease office and laboratory facilities under certain noncancelable operating leases that expire through August 2011. These leases are renewable at our option. A summary of minimum future rental payments required under operating leases as of December 31, 2001 is as follows (in thousands):

2002	\$ 1,342
2003	1,008
2004	1,008
2005	1,008
2006	1,067
Thereafter	5,166
	<hr/>
Total	\$ 10,599
	<hr/>

Rent expense incurred under operating leases was \$1,406,000, \$747,000 and \$523,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

**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 the study prior to its 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 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.

**11. 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 \$597,000, \$429,000 and \$329,000 for the years ended December 31, 2001, 2000 and 1999, respectively.



**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

**12. Stockholders Equity**

**Recapitalization**

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

**Adjustment Event**

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

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

**Common Stock**

Prior to July 17, 2000, the Company had Common Stock and Class A Common Stock. Rights and privileges of holders of shares of Class A Common Stock were identical to the rights and privileges of holders of shares of Common Stock, except that the Class A Common Stock was non-voting and convertible into the same number of shares of Common Stock upon or subsequent to any public offering.

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, 2001, no shares of Preferred Stock have been issued.

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

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

The Class A Transferable Warrants and Class B Non-Transferable Warrants are exercisable at an exercise price of \$.01 per share into a specified number of shares of Common Stock depending on the timing of the FDA's approval of MorphiDex® for one or more pain indications. As of December 31, 2001, there were outstanding 17,810,526 of these warrants. These warrants become exercisable on the fifth business day following the date on which we receive approval from the FDA with respect to MorphiDex® for the treatment of one or more pain indications. These warrants will remain exercisable for a period of six months after the exercisability date, at which time they will expire. If the FDA does not approve MorphiDex® by March 31, 2003, each of these warrants expires without any payment therefor.

If the FDA approves MorphiDex® on or before March 31, 2002, then upon exercise of these warrants, each warrant will be exercisable into 1.153846 shares of Common Stock. If the FDA approves MorphiDex® after March 31, 2002 and on or prior to September 30, 2002, then upon exercise of these warrants, each warrant will be exercisable into 0.633803 shares of Common Stock. If the FDA approves MorphiDex® after September 30, 2002 and prior to March 31, 2003, then upon exercise of these warrants, each warrant will be exercisable into 0.263158 shares of Common Stock. If the FDA does not approve MorphiDex® before March 31, 2003, each of these warrants becomes void and all rights in respect of these warrants will cease.

On December 5, 2001, we commenced a tender offer to purchase up to 13,500,000 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 8,585,262 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 9,225,264 of these warrants.

**Pre-Merger Endo Warrants**

The Pre-Merger Endo Warrants are exercisable at an exercise price of \$.01 per share into a specified number of shares of Common Stock if the FDA does not approve MorphiDex® for any pain indication prior to December 31, 2002. As of December 31, 2001, there were outstanding 71,328,424 of these warrants. If the FDA does not approve MorphiDex® before December 31, 2002, then these warrants become exercisable and upon exercise, each warrant will be exercisable into 0.416667 shares of Common Stock for a total of 29,720,177 shares of Common Stock.

**Series A Warrants**

The Series A Warrants were exercisable into (a) one share of Common Stock and (b) one Class A Transferable Warrant or one Class B Non-Transferable Warrant, at the election of the holder. The Series A Warrants had an exercise price of \$1.20 per share. As of December 31, 2000, there were outstanding Series A Warrants to purchase 21,580 shares of Common Stock and 21,580 Class A Transferable Warrants or Class B Non-Transferable Warrants, at the election of the holder. These warrants expired on September 25, 2001.

**Endo Pharma LLC 1997 Executive and Employee Stock Option Plans**

On November 25, 1997, the Company established the 1997 Employee Stock Option Plan and the 1997 Executive Stock Option Plan (collectively, the 1997 Stock Option Plans). Pursuant to the Recapitalization of the Company on July 17, 2000, the 1997 Stock Option Plans were amended and restated. The Endo Pharma LLC Amended and Restated 1997 Employee Stock Option Plan and the Endo Pharma LLC Amended and Restated 1997 Executive Stock Option Plan (collectively, the Endo Pharma LLC 1997 Stock Option Plans) 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

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

expire no later than December 31, 2012 unless an initial public offering of the Company Common Stock held by Endo Pharma LLC occurs, in which case the stock options granted will expire on August 26, 2007. The effect of the Recapitalization has been reflected in the accompanying financial statements. Subsequent to the Merger, the exercise of stock options pursuant to the Endo Pharma LLC 1997 Stock Option Plans does not result in the issuance of additional shares in the Company.

A summary of the activity under the Endo Pharma LLC 1997 Stock Option Plans from December 31, 1998 through December 31, 2001 is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 1998	18,379,724	\$2.50
Granted	416,062	\$2.51
Forfeited	(143,811)	\$2.51
Outstanding, December 31, 1999	18,651,975	\$2.50
Granted	9,625,633	\$3.00
Exercised	(10,892)	\$2.42
Forfeited	(2,998,055)	\$2.44
Outstanding, December 31, 2000	25,268,661	\$2.70
Exercised	(735,901)	\$2.42
Forfeited	(353,734)	\$2.57
Outstanding, December 31, 2001	24,179,026	\$2.71

The following table summarizes information about stock options outstanding under the Endo Pharma LLC Stock Option Plans at December 31, 2001:

## Options Outstanding

Number Outstanding at 12/31/01	Weighted Average Remaining Contractual Life	Exercise Price
13,237,227	11 years	\$2.42
9,525,477	11 years	\$3.00
1,416,322	11 years	\$3.42

Of the outstanding stock options as of December 31, 2001, 1,734,504 shares have vested and are exercisable ratably over service periods of five years and 1,842,815 shares have vested and are exercisable at the end of nine years from the date of grant. The vesting and exercisability of options may be accelerated at the discretion of the Board of Directors or upon the occurrence of certain defined events. The remaining 20,601,707 stock options vest in four discrete tranches contingent upon (i) the Common Stock of the Company exceeding a defined 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





## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

employee of the Company or any of its subsidiaries on such date. The defined closing price thresholds are as follows:

Option Class	MorphiDex® is Approved On or Prior to December 31, 2002 Common Stock Closing Price Threshold	MorphiDex® is Not Approved On or Prior to December 31, 2002 Common Stock Closing Price Threshold
C1A and C1B	\$ 6.06	\$ 4.28
C2	\$ 9.38	\$ 6.62
C3	\$ 14.99	\$ 10.58
C4	\$ 24.50	\$ 17.29

If these share price targets are achieved resulting in the vesting of each tranche of options, the Company will record up to four non-cash compensation charges related to the vesting of certain of the options. Under performance-based options, the measurement of expense is calculated and recorded as a non-cash charge at the time performance is achieved as the difference between the market price of the stock and the exercise price of the options. If these charges are recorded by the Company in connection with the above options, they will be significant. They will, however, not result in the issuance of additional shares of Company Common Stock.

During the year ended December 31, 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. To the extent that additional performance-based stock options vest pursuant to the Endo Pharma LLC 1997 Stock Option Plans, significant charges may occur in the future. Subsequent to the Merger, the exercise of stock options pursuant to the Endo Pharma LLC 1997 Stock Option Plans does not result in the issuance of additional shares in the Company.

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. To the extent that additional performance-based stock options vest pursuant to the Endo Pharma LLC 1997 Stock Option Plans, significant charges may occur in the future. Subsequent to the Merger, the exercise of stock options pursuant to the Endo Pharma LLC 1997 Stock Option Plans does not result in the issuance of additional shares in the Company.

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 ( Transfer ) of Common Stock, after which Kelso no longer owns any shares of Common Stock or (ii) January 1, 2006.

Stock options exercisable pursuant to the Endo Pharma LLC 1997 Stock Option Plans as of December 31, 2001 and 2000 were 2,431,150 and 2,890,260, respectively. The shares of common stock that employees receive upon exercise of stock options pursuant to the Endo Pharma LLC 1997 Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

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

Pursuant to the Merger and Recapitalization of the Company on July 17, 2000, the Endo Pharma LLC 2000 Supplemental Employee Stock Option Plan and the Endo Pharma LLC 2000 Supplemental Executive

**ENDO PHARMACEUTICALS HOLDINGS INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Stock Option Plan (collectively, 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 are only effective on January 1, 2003 in the event that we have 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 exercise of stock options pursuant to the Endo Pharma LLC 2000 Supplemental Stock Option Plans does not result in the issuance of additional shares in the Company, however, may result in additional non-cash compensation charges upon issuance and/or attainment of defined common stock price targets. These charges may be substantial. The Endo Pharma LLC 2000 Supplemental Stock Option Plans are not currently effective, therefore no options have been granted.

**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, 2001, only stock options have been awarded. Stock options granted under the 2000 Stock Incentive Plan expire ten years from the date of grant.

A summary of the activity under our 2000 Stock Incentive Plan from December 31, 1999 through December 31, 2001 is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 1999	0	
Granted	391,250	\$7.20
Forfeited	0	
	<hr/>	
Outstanding, December 31, 2000	391,250	\$7.20
Granted	605,712	\$8.85
Forfeited	(59,351)	\$7.45
	<hr/>	
Outstanding, December 31, 2001	937,611	\$8.25

The following table summarizes information about stock options outstanding under our 2000 Stock Incentive Plan at December 31, 2001:

**2000 Stock Incentive Plan Options Outstanding**

Number Outstanding at 12/31/01	Weighted Average Remaining Contractual Life	Range of Exercise Prices
456,187	9.0	\$6.47-\$ 7.50
41,882	9.7	\$7.51-\$ 8.50
424,421	9.7	\$8.51-\$ 9.50

15,121

9.5

\$9.51-\$10.11

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## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

We have adopted the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, while following APB No. 25, *Accounting for Stock Issued to Employees*, and related interpretations in accounting for its Stock Option Plans. Under APB No. 25, because the exercise price of our stock options equals at least the fair value of the underlying stock at the date of grant or a measurement date has not yet been reached, no compensation expense has been recognized. If we were to have adopted the accounting provisions of SFAS No. 123, it would have been required to record compensation expense based on the fair value of the stock options on the date of grant.

Pro-forma information regarding net income is required as if we had accounted for our stock options under the provisions of SFAS No. 123. We estimated the fair value of our stock options, as of the respective date of grant, using the Black-Scholes option-pricing model. The following assumptions were used for such estimates: no dividend yield; expected volatility of 60% in 2001 and 2000 and no expected volatility in 1999 as our stock was not publicly traded; risk-free interest rate of 5.0%, 6.0% and 6.5% for 2001, 2000 and 1999, respectively; and a weighted average expected life of the options of 5 years. Had the accounting provisions of SFAS No. 123 been adopted, net loss for 2001 and 2000 would have increased and net income for 1999 would have decreased to the pro-forma amounts as follows (in thousands):

	2001	2000	1999
Net (loss) income as reported	\$(36,542)	\$(156,840)	\$3,260
Net (loss) income, pro-forma	\$(38,392)	\$(245,476)	\$3,112

During 1999, the Company repurchased 18,732 shares of Common Stock from former employees for an aggregate of \$31,000.

**13. Earnings Per Share**

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

	2001	2000	1999
<b>Numerator:</b>			
Net (loss) income available to common stockholders	\$(36,542)	\$(156,840)	\$ 3,260
<b>Denominator:</b>			
For basic per share data weighted average shares	91,505	79,454	71,332
Effect of dilutive stock options			
For diluted per share data	91,505	79,454	71,332
Basic (loss) earnings per share	\$ (.40)	\$ (1.97)	\$ .05
Diluted (loss) earnings per share	\$ (.40)	\$ (1.97)	\$ .05

The dilutive effect of stock options outstanding excludes the effect of stock options and warrants exercisable only upon satisfaction of certain defined events as these events have not occurred. For loss periods, weighted average common shares are used for calculating both basic and diluted loss per share as the use of other dilutive securities would be anti-dilutive. Stock options exercisable pursuant to the Endo Pharma LLC 1997 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.

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**14. Separation Benefits**

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

**15. Related Party Transactions**

Prior to July 17, 2000, Kelso & Company provided financial advisory services to us for an annual fee of \$347,000 plus the reimbursement of expenses. Payment for these services and reimbursement of expenses totaled \$366,000 and \$349,000 for the years ended December 31, 2000 and 1999, respectively. In connection with the Merger, which was completed on July 17, 2000, we terminated this agreement by making a one-time payment to Kelso of \$1.5 million, which is included in Merger and other related costs.

On July 14, 2000, Endo Pharma LLC was formed to ensure that the stock options granted pursuant to the 1997 Employee Stock Option Plan and the 1997 Executive Stock Option Plan (collectively, as amended and restated, the Endo Pharma LLC 1997 Stock Option Plans ) diluted only the pre-Merger holders of Endo Common Stock (see Note 12). Subsequent to the Merger, only currently outstanding shares of Common Stock of the Company held by Endo Pharma LLC will be issued upon the exercise of these stock options. Because Endo Pharma LLC, and not the Company, will provide the shares issued upon the exercise of the options, the Company has entered into a tax sharing agreement with Endo Pharma LLC under which the Company will pay to Endo Pharma LLC the amount of the tax benefits it receives as a result of the exercise of these stock options into shares of Common Stock held by Endo Pharma LLC for the years in which these tax benefits arise. No payments have been made or accrued for the years ended December 31, 2001 and 2000.

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

The effect of the Recapitalization has been retroactively reflected in the following quarterly financial data (see Note 12):

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share data)			
<b>2001(1)</b>				
Net sales	\$ 39,382	\$ 67,857	\$ 66,268	\$ 78,472
Gross profit	\$ 26,733	\$ 46,825	\$ 45,646	\$ 57,884
Operating income (loss)	\$(10,730)	\$ 6,659	\$(31,475)	\$ 7,648
Net (loss) income	\$(14,238)	\$ 2,731	\$(32,993)	\$ 7,959
Net (loss) income per share (basic)	\$ (.16)	\$ .03	\$ (.37)	\$ .09
Net (loss) income per share (diluted)	\$ (.16)	\$ .03	\$ (.37)	\$ .09
Weighted average shares (basic)	89,139	89,139	89,139	98,526
Weighted average shares (diluted)	89,139	89,213	89,139	98,649

## ENDO PHARMACEUTICALS HOLDINGS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share data)			
<b>2000(2)</b>				
Net sales	\$ 27,000	\$ 41,934	\$ 50,902	\$ 77,593
Gross profit	\$ 14,938	\$ 25,663	\$ 35,648	\$ 58,139
Operating (loss) income	\$(24,348)	\$ 4,755	\$(132,729)	\$ 4,420
Net (loss) income	\$(17,594)	\$ 608	\$(136,548)	\$ (3,306)
Net (loss) income per share (basic and diluted)	\$ (.25)	\$ .01	\$ (1.59)	\$ (.04)
Weighted average shares (basic and diluted)	71,325	71,328	85,848	89,139

- (1) Operating (loss) income and net (loss) income for the year ended December 31, 2001 include charges of \$37.3 million in the quarter ended September 30, 2001 for compensation related to stock options. The number of weighted average shares outstanding increased in the quarter ended December 31, 2001 due to the shares issued in our secondary offering.
- (2) Operating (loss) income and net (loss) income for the year ended December 31, 2000 include charges of \$22.0 million in the quarter ended March 31, 2000 for separation benefits, \$133.2 million in the quarter ended September 30, 2000 for purchased in-process research and development, \$1.6 million in the quarter ended September 30, 2000 for Merger and other related costs and \$15.3 million in the quarter ended December 31, 2000 for compensation related to stock options. The number of weighted average shares outstanding increased in the quarter ended September 30, 2000 due to the shares issued in the Merger. For this reason, the sum of the quarterly net (loss) income per share does not equal net (loss) income per share for the year.

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## EXHIBIT INDEX

Exhibit No.	Title
2.1	Amended and Restated Agreement and Plan of Merger, dated as of March 3, 2000 (the Merger Agreement ), by and among Endo Pharmaceuticals Holdings Inc. ( Endo ), Endo Inc. and Algos Pharmaceutical Corporation ( Algos ) (incorporated herein by reference to Exhibit 2.1 of the Registration Statement on Form S-4 of the Registrant (Registration No. 333-39040) (the Registration Statement ), filed with the Securities and Exchange Commission (the Commission ) on June 9, 2000)
2.2	Amendment, dated as of April 17, 2000, to the Merger Agreement, by and between Endo, Endo Inc. and Algos (incorporated herein by reference to Exhibit 2.2 of the Registration Statement filed with the Commission on June 9, 2000)
2.3	Asset Purchase Agreement, dated as of August 27, 1997, by and between Endo Pharmaceuticals Inc. ( Endo Pharmaceuticals ) and The DuPont Merck Pharmaceutical Company ( DuPont Merck Pharmaceutical ) (incorporated herein by reference to Exhibit 2.3 of the Registration Statement filed with the Commission on June 9, 2000)
3.1	Amended and Restated Certificate of Incorporation of Endo (incorporated herein by reference to Exhibit 3.1 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
3.2	Amended and Restated By-laws of Endo (incorporated herein by reference to Exhibit 3.2 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.1	Amended and Restated Executive Stockholders Agreement, dated as of July 14, 2000, by and among Endo, Endo Pharma LLC ( Endo LLC ), Kelso Investment Associates V, L.P. ( KIA V ), Kelso Equity Partners V, L.P. ( KEP V ) and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.2	Amended and Restated Employee Stockholders Agreement, dated as of July 14, 2000, by and among Endo, Endo LLC, KIA V, KEP V and the Employee Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.2 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.3	Form of Stock Certificate of Endo Common Stock (incorporated herein by reference to Exhibit 4.3 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.4	Registration Rights Agreement, dated as of July 17, 2000, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 4.4 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
10.1	Endo Warrant Agreement, dated as of July 17, 2000, by and between Endo and United States Trust Company of New York (incorporated herein by reference to Exhibit 10.1 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
10.2	Algos Warrant Agreement, dated as of July 17, 2000, by and between Endo and United States Trust Company of New York (incorporated herein by reference to Exhibit 10.2 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
10.3	Form of Series A Warrant to Purchase Shares of Common Stock and Warrants of Endo (incorporated herein by reference to Exhibit 10.3 of the Registration Statement filed with the Commission on June 9, 2000)
10.4	Letter Agreement, dated as of November 26, 1999, by and among Algos, Endo, KIA V and KEP V (incorporated herein by reference to Exhibit 10.4 of the Registration Statement filed with the Commission on June 9, 2000)



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Exhibit No.	Title
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
10.8	[Intentionally Omitted.]
10.9	[Intentionally Omitted.]
10.10	Sole and Exclusive License Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Hind Health Care, Inc. (incorporated herein by reference to Exhibit 10.10 of the Registration Statement filed with the Commission on June 9, 2000)
10.11	Analgesic License Agreement, dated as of October 27, 1997, by and among Endo Pharmaceuticals, Endo Laboratories, LLC and DuPont Merck Pharmaceutical (incorporated herein by reference to Exhibit 10.11 of the Registration Statement filed with the Commission on June 9, 2000)
10.12	Anti-Epileptic License Agreement, dated as of October 27, 1997, by and among Endo Pharmaceuticals, Endo Laboratories, LLC and DuPont Merck Pharmaceutical (incorporated herein by reference to Exhibit 10.12 of the Registration Statement filed with the Commission on June 9, 2000)
10.13	[Intentionally Omitted.]
10.14	Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd (incorporated herein by reference to Exhibit 10.14 of the Registration Statement filed with the Commission on June 9, 2000)
10.15	Supply Agreement, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt Inc. ( Mallinckrodt ) (incorporated herein by reference to Exhibit 10.15 of the Registration Statement filed with the Commission on June 9, 2000)
10.16	Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt (incorporated herein by reference to Exhibit 10.16 of the Registration Statement filed with the Commission on June 9, 2000)
10.17	Manufacture and Supply Agreement, dated as of August 26, 1997, by and among Endo Pharmaceuticals, DuPont Merck Pharmaceutical and DuPont Merck Pharma (n/k/a Bristol-Myers Squibb Pharma Company) (incorporated herein by reference to Exhibit 10.17 of the Registration Statement filed with the Commission on June 9, 2000)
10.18	Strategic Alliance Agreement, dated as of September 17, 1997, by and between Endo Pharmaceuticals and Penwest Pharmaceuticals Group (incorporated herein by reference to Exhibit 10.18 of the Registration Statement filed with the Commission on June 9, 2000)
10.19	Agreement, dated as of February 1, 2000, by and between Endo Pharmaceuticals and Livingston Healthcare Services Inc. (n/k/a/ UPS Supply Chain Management, Inc.) (incorporated herein by reference to Exhibit 10.19 of the Registration Statement filed with the Commission on June 9, 2000)
10.20	Medical Affairs Support Services Agreement, dated as of June 1, 1999, by and between Endo Pharmaceuticals and Kunitz and Associates, Inc. (incorporated herein by reference to Exhibit 10.20 of the Registration Statement filed with the Commission on June 9, 2000)
* 10.21	Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.21 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)

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Exhibit No.	Title
* 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	Office Lease, dated as of August 26, 1997, by and between Endo Pharmaceuticals and Northstar Development Company (incorporated herein by reference to Exhibit 10.33 of the Registration Statement filed with the Commission on June 9, 2000)
10.34	Lease Agreement, dated as of May 5, 2000, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34 of the Registration Statement filed with the Commission on June 9, 2000)
* 10.35	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo and Caroline B. Manogue (formerly Berry) (incorporated herein by reference to Exhibit 10.35 of the Current Report on Form 8-K dated August 31, 2001)
* 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)

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Exhibit No.	Title
10.37	License Agreement, dated as of August 16, 1993, by and between Endo Pharmaceuticals (as successor in interest to Algos Pharmaceutical Corporation) and The Medical College of Virginia (incorporated herein by reference to Exhibit 10.4.1 of the registration statement on Form S-1 of Algos Pharmaceutical Corporation declared effective on September 25, 1996)
10.38	[Intentionally Omitted.]
10.39	Master Development and Toll Manufacturing Agreement, dated as of May 3, 2001, by and between Novartis Consumer Health, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.39 of the Form 10-Q for the Quarter Ended June 30, 2001 filed with the Commission on August 14, 2001)
10.40	[Intentionally Omitted.]
10.41	Service Agreement, dated as of February 1, 2001, by and between Endo Pharmaceuticals and Ventiv Health U.S. Sales Inc. (incorporated herein by reference to Exhibit 10.41 of the Current Report on Form 8-K dated August 31, 2001)
21	Subsidiaries of the Company
24	Power of Attorney

\* A management contract or compensatory plan or arrangement required to be filed as an Exhibit pursuant to Item 14(c) of Form 10-K.