ENDO PHARMACEUTICALS HOLDINGS INC
Form S-3/A
September 28, 2001

**As filed with the Securities and Exchange Commission on September 28, 2001**

**Registration No. 333-69136**

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

**AMENDMENT NO. 1**
**TO**
# FORM S-3
**REGISTRATION STATEMENT**
**UNDER**
**THE SECURITIES ACT OF 1933**

# Endo Pharmaceuticals Holdings Inc.

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

**Delaware**
**13-4022871 (State or other jurisdiction of**
**incorporation or organization) (I.R.S. Employer Identification No.)**

**100 Painters Drive**

**Chadds Ford, Pennsylvania 19317**
**(610) 558-9800**
**(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant s Principal Executive Offices)**

**Caroline E. Berry, Esq.**
**Senior Vice President, General Counsel and Secretary**
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**Chadds Ford, Pennsylvania 19317**
**(610) 558-9800**
**(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)**

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. o

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

**The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any state where the offer or sale is not permitted.**

SUBJECT TO COMPLETION, DATED SEPTEMBER 28, 2001

**PRELIMINARY PROSPECTUS**

## 11,400,000 Shares

# Endo Pharmaceuticals Holdings Inc.

## Common Stock

We are selling 11,400,000 shares of our common stock. We have granted the underwriters an option to purchase up to 1,710,000 additional shares of common stock to cover over-allotments. All of the shares of common stock in this offering are being issued and sold by us.

Our common stock is traded on the Nasdaq National Market under the symbol ENDP. On September 27, 2001, the last reported sale price of our common stock was $10.85 per share.

**Investing in our common stock involves risks. See Risk Factors beginning on page 9.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

| | Per Share | Total |
|---|---|---|
| Public offering price | $ | $ |
| Underwriting discount | $ | $ |
| Proceeds to Endo Pharmaceuticals Holdings Inc., before expenses | $ | $ |

The underwriters expect to deliver the shares to purchasers on or about , 2001.

*Joint Book-Running Managers*

**JPMorgan** **Salomon Smith Barney**

**SG Cowen** **First Union Securities, Inc.**

, 2001

**You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.**

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## PROSPECTUS SUMMARY

*The following summary highlights selected information from this prospectus and may not contain all of the information that is important to you. For a more complete understanding of this offering, you are encouraged to read this entire prospectus and the documents incorporated by reference. Unless otherwise indicated, we, us, our or Endo refer to Endo Pharmaceuticals Holdings Inc. and its subsidiaries.*

### Endo Pharmaceuticals Holdings Inc.

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, totalled $13 billion for the 12 months ended May 2001. Our primary area of focus is analgesics, which according to IMS Health data were the fourth most prescribed class of medication in the United States in 2000.

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 71% of net sales for fiscal years 1999 and 2000 and the six months ended June 30, 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 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. 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 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. These products include MorphiDex®, a patented combination of morphine and the NMDA (N-methyl-D-aspartate) receptor antagonist, dextromethorphan, which is currently in Phase III clinical trials. We anticipate resubmitting a new drug application, or NDA, with the U.S. Food and Drug Administration, or FDA, in mid-2002. In addition, we are co-developing an oral extended-release version of oxymorphone with Penwest Pharmaceuticals. This product is currently in Phase III clinical trials, and we anticipate filing an NDA with the FDA in the second half of 2002. We also selectively develop generic pharmaceuticals.



*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. We currently have on file with the FDA a line extension of Percocet®, which we anticipate launching by the end of the first quarter of 2002.

*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 Pharmaceutical Corporation and the rights to the development-stage product MorphiDex®. We also acquired rights to a portfolio of other 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 often follows an attack of shingles.

**Our Competitive Strengths**

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

*Established portfolio of branded products.* We have assembled a core portfolio of branded pharmaceutical products to treat and manage pain, including Percocet®, that have a long history of demonstrated product safety and effectiveness.

*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 include MorphiDex® and our oral extended-release version of oxymorphone.

*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 believe this expertise allows for timely FDA approval of our products. We have launched more than 10 products and product extensions during the last three years, contributing approximately 42% of our net sales in 2000.

*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 have executed this strategy successfully with products such as morphine sulfate extended release tablets, which we introduced in November 1998 as a bioequivalent of MSContin®, a Purdue Frederick product.

*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 targeting high-prescribing physicians. 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 addition, management has vested stock options to acquire up to 12% of our common stock and has the potential to receive as much as an additional 10% of our



common stock through options which vest if the price of our common stock reaches specified defined targets. These options are exercisable for shares currently held by our controlling stockholder, Endo Pharma LLC, and their exercise will not dilute your ownership of our common stock.

**Our Industry**

According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled $13 billion for the 12 months ended May 2001. This represents an approximately 30% compound annual growth rate since May 1999. Our primary area of focus within this market is analgesics. In 2000, analgesics were the fourth most prescribed medication in the United States with over 220 million prescriptions written for this classification. These products are used primarily for the treatment of pain associated with orthopedic fractures and sprains, back injuries, migraines, joint diseases, cancer and various surgical procedures.

Opioid analgesics comprised approximately 75% of the analgesics prescriptions in 2000. This market segment has grown to $3.4 billion for the 12 months ended May 2001, representing a compound annual growth rate of 28% since 1997. If branded products were substituted for generic products, we believe this market segment would be substantially larger.

**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(1) | morphine sulfate | Generic | Marketed |
| MorphiDex® | morphine and dextromethorphan | Branded | Phase III |
| Oxymorphone ER(1) | oxymorphone hydrochloride | Branded | Phase III |
| Oxymorphone IR(2) | 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(1) | oxycodone | Generic | ANDA filed(3); subject to litigation(4) |

(1) ER means extended release.

(2) IR means immediate release.

(3) ANDA means abbreviated new drug application.

(4) See Business Legal Proceedings.

**About Our Company**

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



Pharmaceuticals Inc. was formed by certain affiliates of Kelso & Company and members of the then-existing management of DuPont Merck, who were also parties to the purchase agreement under which we acquired these initial assets. We were incorporated in Delaware as a holding company on November 18, 1997.

On July 17, 2000, we completed our acquisition of Algos, now a wholly-owned subsidiary named Endo Inc. In connection with this acquisition, our common stock began trading publicly on the Nasdaq National Market under the symbol ENDP. Prior to the acquisition, Algos developed proprietary pain management products, combining existing analgesics, drugs designed to reduce or eliminate pain, with NMDA-receptor antagonist drugs, drugs that block a specific type of pain receptor in human cells, in an attempt to improve the pain relief efficacy of existing drugs such as morphine. For more information about our acquisition of Algos, see Management s Discussion and Analysis of Financial Condition and Results of Operations Overview and Description of Capital Stock Warrants.

Our executive offices are located at 100 Painters Drive, Chadds Ford, Pennsylvania 19317. Our telephone number is (610) 558-9800. The address of our website is www.endo.com (this is an inactive textual reference only). The information on our website is not part of this prospectus.



**The Offering**

| | |
|---|---|
| Common stock offered | 11,400,000 shares |

| | |
|---|---|
| Common stock outstanding after the offering | 100,538,950 shares |
| Use of proceeds | Our net proceeds from this offering will be approximately $117.3 million. We expect to use the net proceeds from this offering to repay in full the term loans under our existing credit agreement and for general corporate purposes. See Use of Proceeds. |
| Nasdaq National Market symbol | ENDP |

Unless otherwise indicated, all share information in this prospectus is based on the number of shares outstanding as of September 21, 2001, and:

- excludes up to 34,412,836 shares of common stock issuable upon the exercise of warrants issued in connection with our acquisition of Algos Pharmaceutical Corporation and up to 21,580 shares of common stock that were issuable upon the exercise of our Series A warrants;
- excludes up to 915,149 shares of common stock issuable by us upon the exercise of options granted to our employees, of which 87,246 will be exercisable by December 31, 2001; and
- assumes no exercise by the underwriters of the over-allotment option.



## Summary Consolidated Financial Data

The summary consolidated financial data for the six months ended June 30, 2000 and 2001 have been derived from our unaudited interim financial statements. All other summary consolidated financial data presented below have been derived from our audited financial statements. See Selected Historical Consolidated Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations, as well as our audited financial statements and unaudited interim financial statements and related notes included elsewhere in this prospectus.

| | Year Ended December 31, | | | Six Months Ended June 30, | |
|---|---|---|---|---|---|
| | 1998 | 1999 | 2000 | 2000 | 2001 |
| | (in thousands, except per share data) | | | | |
| **Statement of Operations Data:** | | | | | |
| Net sales | $108,370 | $138,546 | $197,429 | $68,934 | $107,239 |
| Cost of sales | 54,731 | 58,263 | 63,041 | 28,333 | 33,681 |

| | | | | | |
|---|---|---|---|---|---|
| Gross profit | 53,639 | 80,283 | 134,388 | 40,601 | 73,558 |
| Selling, general and administrative | 25,540 | 42,921 | 56,537 | 26,138 | 35,343 |
| Research and development | 5,893 | 9,373 | 26,012 | 7,696 | 17,510 |
| Depreciation and amortization | 7,373 | 8,309 | 27,624 | 4,326 | 24,776 |
| Compensation related to stock options | | | 15,300 | | |
| Purchased in-process research and development | | | 133,200 | | |
| Merger and other related costs | | | 1,583 | | |
| Separation benefits | | | 22,034 | 22,034 | |
| Operating income (loss) | 14,833 | 19,680 | (147,902) | (19,593) | (4,071) |
| Interest expense, net | 14,451 | 14,347 | 15,119 | 7,718 | 6,443 |
| Income (loss) before income tax (benefit) | 382 | 5,333 | (163,021) | (27,311) | (10,514) |
| Income tax (benefit) | 181 | 2,073 | (6,181) | (10,325) | 993 |

| | | | | |
|---|---|---|---|---|
| Net income (loss) | $201 | $3,260 | $(156,840) | $(16,986) | $(11,507) |
| Net income (loss) per share | | | | | |
| Basic | $0.00 | $0.05 | $(1.97) | $(0.24) | $(0.13) |
| Diluted | $0.00 | $0.05 | $(1.97) | $(0.24) | $(0.13) |
| Shares used to compute net income (loss) per share(1) | | | | | |
| Basic | 71,307 | 71,332 | 79,454 | 71,327 | 89,139 |
| Diluted | 71,307 | 71,332 | 79,454 | 71,327 | 89,139 |

| | As of December 31, | | | As of June 30, |
|---|---|---|---|---|
| | 1998 | 1999 | 2000 | 2001 |
| | (in thousands) | | | |
| **Consolidated Balance Sheet Data:** | | | | |
| Cash and cash equivalents | $17,367 | $22,028 | $59,196 | $67,027 |
| Working capital | 37,676 | 49,541 | 72,759 | 86,198 |
| Total assets | 287,618 | 329,436 | 467,840 | 441,157 |
| Total debt | 170,544 | 191,203 | 198,525 | 171,408 |
| Other long-term obligations | 6,352 | 6,745 | 7,218 | 18,009 |
| Stockholders equity | 75,358 | 78,587 | 198,173 | 186,666 |



| | Year Ended December 31, | | | Six Months Ended June 30, | |
|---|---|---|---|---|---|
| | 1998 | 1999 | 2000 | 2000 | 2001 |
| | (in thousands) | | | | |

**Other Financial Data**:

| | | | | | |
|---|---|---|---|---|---|
| Net cash provided by operating activities | $20,932 | $13,766 | $35,069 | $18,004 | $39,342 |
| Net cash provided by (used in) investing activities | (3,537) | (9,074) | 18,077 | (507) | (2,000) |
| Net cash provided by (used in) financing activities | (14,549) | (31) | (15,978) | (9,667) | (29,511) |
| Consolidated EBITDA(2) | 40,726 | 47,232 | 67,687 | 15,072 | 31,176 |

(1) Excludes any shares of common stock issuable upon exercise of warrants issued in connection with our acquisition of Algos.

(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 deter-



mined by generally accepted accounting principles) to consolidated EBITDA (as defined in our credit facility) is as follows:

| | Year Ended December 31, | | | Six Months Ended June 30, | |
|---|---|---|---|---|---|
| | 1998 | 1999 | 2000 | 2000 | 2001 |

| | | | | | **(in thousands)** |
|---|---|---|---|---|---|
| Operating income (loss) | $14,833 | $19,680 | $(147,902) | $(19,593) | $(4,071) |
| Plus: purchased in-process research and development | | | 133,200 | | |
| Plus: depreciation and amortization | 7,373 | 8,309 | 27,624 | 4,326 | 24,776 |
| Plus: compensation related to stock options | | | 15,300 | | |
| Plus: non-cash manufacturing charges | 14,228 | 19,135 | 18,683 | 9,557 | 10,471 |
| Plus: purchase accounting changes | 4,292 | 108 | | | |
| Plus: non-cash separation benefits | | | 20,782 | 20,782 | |
| Consolidated EBITDA | $40,726 | $47,232 | $67,687 | $15,072 | $31,176 |

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 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.



## RISK FACTORS

*You should carefully consider the following risk factors in addition to the other information in this prospectus before investing in our common stock.*

### Risks Related to Our Business

**Our growth and development will depend on developing, commercializing and marketing new products. If we do not do so successfully, our growth and development will be impaired.**

Our future revenues and profitability will depend, to a significant extent, upon our ability to successfully commercialize new branded and generic pharmaceutical products in a timely manner. As a result, we must continually develop, test and manufacture new products and, in addition, these new products must meet regulatory standards and receive requisite regulatory approvals. Products we are currently developing may or may not receive the regulatory approvals necessary for us and our third party partners to market them. Furthermore, the development and commercialization process is time-consuming and costly, and we cannot assure you that any of our products, if and when developed and approved, can be successfully commercialized. Risk particularly exists with respect to the development of proprietary products, because of the uncertainties and higher costs associated with research and development of these products.

**Results of clinical trials to demonstrate the safety and efficacy of products are uncertain.**

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

The rate of patient enrollment sometimes delays completion of clinical studies. There is substantial competition to enroll patients in clinical trials for pain management products, and such competition has delayed clinical development of our products in the past. Delays in planned patient enrollment can result in increased development costs and delays in regulatory approval.

We presently have three products in Phase II of clinical trials and three in Phase III, or the final stage of clinical trials, including MorphiDex® and an oral extended release version of oxymorphone. We have experienced slower than anticipated patient enrollment into the MorphiDex® clinical studies and we cannot assure you that we will not experience future delays in these or other of our present or future clinical trials.

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

The pharmaceutical industry is intensely competitive, and we face competition across the full range of our activities. If we fail to compete successfully in any of these areas, our business, profitability and cash flows could be

adversely affected. Our competitors include the major brand name and generic manufacturers of pharmaceuticals, especially those doing business in the United States, and include Abbott Laboratories, Johnson & Johnson, The Purdue Frederick Company, Roxane Laboratories, Inc. and Watson Pharmaceuticals, Inc.



In the market for branded pharmaceutical products, our competitors vary depending on product category, dosage strength and drug-delivery systems. In addition to product development and efficacy, other competitive factors in the branded pharmaceutical market include product quality and price, reputation, service, and access to technical information. It is possible that developments by our competitors will make our products or technologies uncompetitive or obsolete. Because we are smaller than many of our national competitors in the branded pharmaceutical products sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector.

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

Our branded products face competition from generic versions. Generic versions are generally significantly cheaper than the branded version, and, where available, may be required or encouraged in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies. The entrance of generic competition to our branded products generally reduces our market share and adversely affects our profitability and cash flows. According to the IMS National Prescription Audit, in 2000, generic versions of Percocet® were used to fill approximately 81% of the approximately 11 million prescriptions for this drug. In April 2001, Watson Pharmaceuticals, Inc. introduced the first generic versions of our Percocet® 7.5/500 and Percocet® 10.0/650 products. We expect that these generics will have a material adverse effect on our sales of Percocet® 7.5/500 and Percocet® 10.0/650.

Our generic products compete with generic versions made by other manufacturers, such as Mallinckrodt Inc., Roxane Laboratories, Inc. and Watson Pharmaceuticals, Inc. When additional versions of one of our generic products enter the market, we generally lose market share and our margins on the product decline. Because we are smaller than many of our national competitors in the generic pharmaceutical products sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector. Presently, one of our generic products, morphine sulfate extended release tablets, is the sole generic alternative to the innovator s products although we anticipate the introduction of a generic competitor in the near future. The introduction of third-party generic versions of this product could have a material adverse impact on our profitability and cash flows.

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

**Once approved, there is no guarantee that the market will accept our future products, and this may have an adverse effect on our profitability and cash flows.**

Even if we obtain regulatory approvals, uncertainty exists as to whether the market will accept our products. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, the price of our products relative to alternative products, the availability of third-party reimbursement and the extent of marketing efforts by third-party

distributors or agents that we retain. We cannot assure you that our products will receive market acceptance in a commercially viable period of time, if at all. In addition, many of our products contain narcotic ingredients that carry stringent record-keeping obligations, strict storage requirements and other limitations on these products availability, which could limit the commercial usage of these products.



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

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

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

We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, including MorphiDex® and our oral extended release version of oxymorphone, on a timely basis, if at all, or, if granted, that approval will not entail limiting the indicated uses for which we may market the product, which could limit the potential market for any of these products. Any delay of this nature in obtaining, or failure to obtain, these approvals would adversely affect the marketing of our products and our ability to generate product revenue.

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

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

could result in production delays, which could adversely affect our business, profitability and cash flows.

The stringent DEA regulations on our use of controlled substances include restrictions on their use in research, manufacture, distribution and storage. A breach of these regulations could



result in imposition of civil penalties, refusal to renew or action to revoke necessary registrations, or other restrictions on operations involving controlled substances.

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

During 2000, 47% of our net sales came from sales of Percocet®, 12% came from sales of morphine sulfate extended release tablets and 11% came from sales of Lidoderm®. If we were unable to continue to market any of these products, if any of them lost market share, for example, as the result of the entry of new competitors, or if the prices of any of these products declined significantly, our net sales, profitability and cash flows would be materially adversely affected.

**We are dependent on outside manufacturers for the manufacture of our products; therefore, we will have limited control of the manufacturing process and related costs.**

Third-party manufacturers currently manufacture all of our products pursuant to contractual arrangements. Accordingly, we have a limited ability to control the manufacturing process or costs related to this process. Increases in the prices we pay our manufacturers, interruptions in our supply of products or lapses in quality could adversely impact our margins, profitability and cash flows. We are reliant on our third-party manufacturers to maintain the facilities at which they manufacture our products in compliance with FDA, DEA, state and local regulations. If they fail to maintain compliance with FDA, DEA or other critical regulations, they could be ordered to cease manufacturing which would have a material adverse impact on our business, profitability and cash flows. In addition to FDA and DEA regulation, violation of standards enforced by the Environmental Protection Agency, or EPA, and the Occupational Health and Safety Administration, or OHSA, and their counterpart agencies at the state level could slow down or curtail operations of third-party manufacturers. Certain of our manufacturers currently constitute the sole source of one or more of our products. Because of contractual restraints and the lead-time necessary to obtain FDA approval, and possibly DEA registration, of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of products to customers.

Currently, DuPont Pharmaceuticals manufactures a significant number of our products. The contract that governs this manufacturing arrangement has a five-year initial term expiring August 2002, and is renewable at our option through 2007, with pricing terms to be negotiated. We have begun discussions with DuPont Pharmaceuticals concerning arrangements to manufacture certain of our products following the expiration of the initial term in August 2002. We cannot be certain what pricing we will be able to negotiate for this subsequent period. Further, if we are unable to negotiate acceptable manufacturing arrangements with DuPont Pharmaceuticals following the expiration of the five-year initial term of our current manufacturing agreement in August 2002, we may be unable to complete the transfer of some of our products from DuPont Pharmaceuticals facilities to alternate facilities before the expiration of our manufacturing arrangement with DuPont. We cannot be sure if or on what terms DuPont Pharmaceuticals would continue to manufacture our products or when the manufacturing of our products could be transferred to another facility. We would expect to incur significant costs in obtaining the regulatory approvals and taking other steps necessary to begin commercial production at other manufacturers of all our products currently manufactured by DuPont.

In June 2001, an agreement for the sale of DuPont Pharmaceuticals to Bristol-Myers Squibb was announced. The sale is subject to government approvals. We are unable to predict the effect of this transaction on our relationship with

DuPont Pharmaceuticals.

In May 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc., pursuant to which Novartis has agreed to manufacture certain of our commercial products in addition to products in development. In addition, we may consider entering into additional manufacturing arrangements with third-party manufacturers. In each case,



we expect to incur significant costs in obtaining the regulatory approvals and taking the other steps necessary to begin commercial production at these manufacturers.

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

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

**Most of our core products contain narcotics. As a result of reports of abuse of prescription narcotics, the sale of such drugs may be subject to new regulation, which may prove difficult or expensive to comply with, and we and other pharmaceutical companies may face lawsuits.**

Most of our core products contain narcotics. Misuse of such drugs can lead to addiction. Recently, reportedly widespread abuse of OxyContin®, a Purdue Frederick product containing the narcotic oxycodone, resulted in the strengthening of warnings on its labeling. In addition, the manufacturer of OxyContin® faces several lawsuits, including class action lawsuits, related to OxyContin® abuse. We have filed and amended an ANDA for bioequivalent versions of the 10mg, 20mg, 40mg and 80mg strengths of OxyContin®. We and other pharmaceutical companies may be subject to litigation similar to the OxyContin® suits.

The FDA or the DEA may impose new regulations concerning the manufacture and sale of prescription narcotics. Such regulations may include new labeling requirements, restrictions on prescription and sale of these products and mandatory reformulation of our products in order to make abuse more difficult. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse. In either case, any such new regulations may be difficult and expensive for us to comply with, may adversely affect our net sales and may have a material adverse effect on our business, profitability and cash flows.

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

Our business exposes us to potential liability risks that arise from the testing, manufacturing and sale of our products. In addition to direct expenditures for damages, settlement and defense costs, there is a possibility of adverse

publicity as a result of product liability claims. Product liability is a significant commercial risk for us. Some plaintiffs have received substantial damage awards in some jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. In addition, it may be necessary for us to recall products that do not meet approved specifications, which would also result in adverse publicity, as well as resulting in costs connected to the recall and loss of revenue.



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

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

Our success, competitive position and amount of potential future income will depend in part on our ability to obtain patent protection relating to the technologies, processes and products we are currently developing and that we may develop in the future. Our policy is to seek patent protection and enforce the intellectual property rights we own and license. We cannot assure you that patent applications we submit and have submitted will result in patents being issued. We cannot assure you that a third party will not infringe upon or design around any patent issued or licensed to us or that these patents will otherwise be commercially viable. In this regard, the patent position of pharmaceutical compounds and compositions is particularly uncertain. Even issued patents may later be modified or revoked by the U.S. Patent and Trademark Office, or PTO, or in legal proceedings. Moreover, we believe that obtaining foreign patents may be more difficult than obtaining domestic patents because of differences in patent laws and, accordingly, our patent position may be stronger in the United States than abroad. Foreign patents may be more difficult to protect and/or the remedies available may be less extensive than in the United States. Patent applications in the United States are maintained in secrecy until 18 months after the filing of the application with the PTO and, since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries, we cannot be certain that we were the first creator of the inventions covered by pending patent applications or the first to file patent applications on those inventions. We cannot assure you that any of our pending patent applications will be allowed, or, if allowed, whether the scope of the claims allowed will be sufficient to protect our products. Litigation to establish the validity of patents, to defend against patent infringement claims of others and to assert patent infringement claims against others can be expensive and time-consuming even if the outcome is favorable to us. If the outcome is unfavorable to us, this could have a material adverse effect on our business. We have taken and may, in the future, take steps to enhance our patent protection, but we cannot assure you that these steps will be successful or that, if unsuccessful, our patent protection will be adequate.

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

If, in the future, we were found to be infringing on a patent, we might have to seek a license to use the patented technology. We cannot assure you that, if required, we would be able to obtain such a license on terms acceptable to

us, if at all. If a third party brought a legal action against us or our licensors, we could incur substantial costs in defending ourself, and we cannot assure you that such an action would be resolved in our favor. If such a dispute were to be resolved against us, we could be subject to significant damages, and the testing, manufacture or sale of one or more of our technologies or proposed products, if developed, could be enjoined.



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

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

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

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

fail to accomplish our strategic objectives;

not be successfully combined with our operations;

not perform as expected; and

expose us to cross border risks.

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

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

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

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our current products and products in development, including oxycodone, oxymorphone, morphine 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 and our quota may not be sufficient to meet commercial demand or complete clinical trials. DEA regulations may limit the supply of the



drugs used in our clinical trials, and in the future, our ability to produce and distribute our products in the volume needed to meet commercial demand.

**The availability of third-party reimbursement for our products is uncertain and thus we may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third-party reimbursement is not adequately provided.**

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

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

the trend toward managed health care in the United States;

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

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

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

**We sell our products to a limited number of large pharmacy chains and wholesale drug distributors, the loss of whose business could materially affect our sales.**

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 our products to pharmacies, hospitals, governmental agencies and physicians. 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 and 26%, 21%, and 14% of net sales in 1998. If we were to lose the business of any of these customers, or if any were to experience difficulty in paying us on a timely basis, our net sales, profitability and cash flows could be materially and adversely affected.

**Sales of our products may be adversely affected by the continuing consolidation of the wholesale drug distribution and retail pharmacy industries.**

The network through which we sell our products is continuing to undergo significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drug store chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. We expect that consolidation of drug wholesalers and retailers will increase pricing and other competitive pressures on drug manufacturers, including us.



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

Pharmaceutical companies that produce patented brand products are increasingly employing a range of legal and regulatory strategies to delay the introduction of competing generics. Opposing such measures can be costly and time-consuming and result in delays in the introduction of generic products.

The products of which we are developing generic versions may be claimed by their manufacturer to be protected by one or more patents. If we file an ANDA with respect to our generic version of such a drug, we are required to certify that the patent or patents listed as covering the generic drug are invalid or will not be infringed by the generic version. Once the FDA accepts our ANDA filing, we are required to notify the brand manufacturer of this fact. The brand manufacturer then has 45 days from the receipt of the notice in which to sue us for patent infringement. If it does so, the FDA is generally prevented from granting approval of the ANDA until the earlier of 30 months from the date the FDA accepted the ANDA for filing and the satisfactory conclusion of the ensuing litigation. The Purdue Frederick Company has filed suit against us alleging that our bioequivalent versions of OxyContin®, for which we have filed an ANDA, violate their patents. We expect to be sued again as early as the fourth quarter of 2001 with respect to another ANDA we have filed.

**Our current credit agreement limits our ability to conduct our business, which could negatively affect our ability to finance future capital needs and engage in other business activities.**

The covenants in our existing credit agreement contain a number of significant limitations on our ability to, among other things:

pay dividends;

incur additional indebtedness;

create liens on our assets; and

acquire or dispose of assets.

These restrictive covenants could negatively affect our ability to finance our future capital needs, engage in other business activities or withstand a future downturn in our business or the economy.

Under our credit agreement, we are required to maintain certain specified financial ratios and meet financial tests. Our ability to comply with these may be affected by matters beyond our control. A breach of any of these covenants will result in a default under our credit agreement.

We are currently negotiating the terms of a new senior secured credit facility that would replace our existing credit agreement. We anticipate that this new credit facility will contain similar restrictions to those in our existing credit agreement.

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

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors will remain highly dependent, in large part, upon our ability to attract and retain qualified scientific and technical personnel. The loss of key scientific and technical personnel or the failure to recruit additional key scientific and technical personnel could have a material adverse effect on our business. While we have consulting agreements with certain key individuals and institutions and have employment



agreements with our key executives, we cannot assure you that we will succeed in retaining this personnel or their services under existing agreements. There is intense competition for qualified personnel in the areas of our activities, and we cannot assure you that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business.

**We have significant goodwill and other intangible assets. Consequently, amortization of goodwill and other intangibles significantly impacts our profitability.**

Goodwill and other intangibles represent a significant portion of our assets and stockholders equity. As of June 30, 2001, goodwill and other intangibles comprised approximately 59% of our total assets and 140% of our 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 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. We use the discounted future expected net cash flows as our estimate of fair value in order 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 profitability. In addition, our profitability in a future period would be further negatively impaired should impairment of goodwill and other intangible assets occur.

Effective January 1, 2002, we will adopt the provisions of a new accounting standard, SFAS No. 142, Goodwill and Other Intangible Assets. Upon adoption, we will no longer amortize goodwill unless evidence of an impairment exists, and we will review for impairment on at least an annual basis. Although we are currently evaluating all of the provisions of SFAS No. 142, we believe that the adoption of SFAS No. 142 will have a material impact on our results of operations. We have $241.7 million of goodwill as of June 30, 2001 and have recorded $20.4 million of goodwill amortization for the six months ended June 30, 2001.

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

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



**Risks Related to this Offering and Ownership of Our Common Stock**

**Our future results could differ significantly from the forward-looking financial information contained in this prospectus.**

This prospectus contains forward-looking financial information, including certain estimates of future net sales and consolidated EBITDA in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations. This information is not fact, and you should not rely upon it as necessarily indicative of actual future results that might be achieved, which may be significantly less favorable than set forth in this prospectus.

*We caution readers of this prospectus not to place undue reliance on our forward-looking financial information.*

Neither our independent auditors, nor any other independent accountants, have compiled, examined or performed any procedures with respect to the prospective financial information contained in this prospectus, nor have they expressed any opinion or any other form of assurance on such information or its achievability, and assume no responsibility for, and disclaim any association with, the prospective financial information. The opinions of the independent auditors included in this prospectus relate to historical financial information only. The opinions of the independent auditors do not extend to prospective financial information and should not be read to do so.

Our assumptions and estimates underlying the prospective financial information in this prospectus are inherently uncertain and are subject to a wide variety of significant regulatory, business, economic, and competitive risks, uncertainties and conditions that could cause actual results to differ materially from those contained in the prospective financial information. In particular, our estimates are based on assumptions regarding the timing of the completion of clinical trials, FDA approval and market acceptance of certain of our new products. Accordingly, we cannot assure you that the prospective results are indicative of our future performance or that actual results will not differ materially from those that the prospective financial information present. You should not regard inclusion of the prospective financial information in the offering as a representation by any person that we will achieve the results that the prospective financial information contains.

We have expressly disclaimed any obligations to update this prospective financial information for any reason, even if new information becomes available or other events occur in the future.

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

We have not paid any cash dividends since inception. We do not anticipate paying cash dividends in the foreseeable future. As a result, investors in this offering will not be able to benefit from owning our stock unless the shares that these investors acquire appreciate in value.

**Our controlling stockholder will continue to control us following the offering.**

After the offering, Endo Pharma LLC will own approximately 69.8% of our common stock. Endo Pharma LLC is, in turn, controlled by Kelso. Two of our directors, Mr. Goldberg and Mr. Wahrhaftig, are Managing Directors of Kelso. Mr. Loverro, another of our directors, is a Vice President of Kelso. Three of our directors, Mr. Goldberg, Mr. Wahrhaftig and Ms. Ammon, serve as members of the Board of Managers of Endo Pharma LLC. These individuals may therefore affect how Endo Pharma LLC votes its shares on corporate matters. As a result, Endo Pharma LLC and Kelso will be able to control the outcome of stockholder votes, including votes concerning the election of the majority of directors, the adoption or amendment of provisions in our charter or by-laws, the approval of mergers, decisions affecting our capital structure and other significant

corporate transactions. Kelso will also have significant control over our management and policies. The interests of Endo Pharma LLC and Kelso may conflict with your interests. Their control could also have the effect of deterring hostile takeovers, delaying or preventing changes in control or changes in management or limiting the ability of our stockholders to approve transactions that they may deem to be in their best interests.

**The exercise of any of our outstanding warrants will dilute your investment. The exercise of some of these warrants may result in our controlling stockholder increasing its percentage ownership.**

In connection with our merger with Algos, we issued two sets of warrants to acquire our common stock. One set of warrants was issued to the persons that held Algos shares prior to the merger and the other set was issued to and continues to be held by Endo Pharma LLC. The exercisability of the warrants and, in the case of the Algos warrants, the number of shares into which the warrants are exercisable, depends on whether and when the FDA approves MorphiDex®, as set forth in the following table:

| | Aggregate number of shares issuable upon exercise of | |
|---|---|---|
| | **Algos warrants** | **Endo warrants** |
| The FDA approves MorphiDex® on or before March 31, 2002 | 20,575,507 | |
| The FDA approves MorphiDex® after March 31, 2002 and on or before September 30, 2002 | 11,302,039 | |
| The FDA approves MorphiDex® after September 30, 2002 and on or before December 31, 2002 | 4,692,659 | |
| The FDA approves MorphiDex® after December 31, 2002 and on or before March 31, 2003 | 4,692,659 | 29,720,177 |
| The FDA does not approve MorphiDex® by March 31, 2003 | | 29,720,177 |

The exercise of any of these warrants will dilute your ownership of common stock. In addition, any delay in the approval of MorphiDex® past December 31, 2002 would result in our controlling stockholder holding a larger stake in us than it would otherwise hold. We anticipate that we will be in a position to file a re-application for FDA approval of MorphiDex® in mid 2002. We cannot predict when or if MorphiDex® will be approved.

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

The market prices for securities of healthcare companies in general have been highly volatile and may continue to be highly volatile in the future. Within the last 12 months, our stock has traded between $5.125 and $12.15 per share. The following factors, in addition to other risk factors described in this section, may cause the market price of our common stock to fall:

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

the success or failure of our clinical trials;

competitors announcing technological innovations or new commercial products;

introduction of generic substitutes for our products;

developments concerning proprietary rights, including patents;

competitors publicity regarding actual or potential products under development;



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

period-to-period fluctuations in our financial results;

litigation; and

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

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

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

At September 21, 2001, approximately 74 million shares of common stock, representing approximately 73% of our common stock outstanding after the offering, were eligible for sale, subject to compliance with Rule 144 or Rule 145(d) under the Securities Act.

None of the 915,149 shares that may be issued upon the exercise of options outstanding as of September 21, 2001 will be vested on the date of this prospectus and eligible for sale. However, options in respect of 87,246 shares of common stock will become exercisable before December 31, 2001. The sale of these shares will be unrestricted, subject to any lock-up agreements with the underwriters in this offering.

Of the 34,434,416 shares that may be issued upon the exercise of warrants outstanding as of September 21, 2001, approximately 21,580 shares were exercisable as of that date.

While the holders of approximately 73% of our outstanding shares of common stock following the offering will be subject to lock-up agreements with the underwriters in this offering for 90 days after the date of this prospectus, Salomon Smith Barney Inc. may release any portion or all of these shares from the lock-up restrictions. In addition, sales of a substantial number of shares could occur at any time after the expiration of the 90-day period. These sales could have an adverse effect on the price of our common stock and could impair our ability to raise capital in the future.

**As a new investor, you will experience immediate and substantial dilution in the net tangible book value of your shares.**

The public offering price of the shares of common stock in this offering will significantly exceed the net tangible book value per share of our common stock. Any shares of common stock that investors purchase in this offering will have a net tangible book value per share of $10.59 per share less than the public offering price paid, assuming an public offering price per share of $11.00 and based on our as adjusted net tangible book value as of June 30, 2001. In addition, investors who purchase shares in the offering will contribute 23.3% of the amount of consideration paid for our outstanding capital stock, but will own only 11.3% of the shares outstanding.

The above discussion does not include the 34,434,416 shares that could, in certain circumstances, be issued on exercise of our outstanding warrants or the 915,149 shares that could be issued on exercise of outstanding stock options. To the extent that any of these shares are issued, you will experience further dilution.

## 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. 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, intend, estimates, or similar expressions are forward-looking statements. We have 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 Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations, Business and elsewhere in this prospectus 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 prospectus. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in this prospectus 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 our 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 prospectus for any reason, even if new information becomes available or other events occur in the future.



## USE OF PROCEEDS

We will receive approximately $117.3 million in net proceeds from this offering, based upon the sale of 11,400,000 shares of common stock at an assumed offering price of $11.00 per share, and after deducting the underwriting discount and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we estimate that our net proceeds will be approximately $135.0 million.

We expect to use $101.1 million of the net proceeds from this offering to repay in full the term loans under our existing credit agreement. For maturity and interest rate information concerning these term loans, see Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources Our Credit Agreement.

The remaining net proceeds from this offering will be available for general corporate purposes, and, together with all or a portion of our available cash and cash equivalents, may be used for the repayment of notes we have issued to DuPont Pharmaceuticals and for possible acquisitions.

## PRICE RANGE OF COMMON STOCK

Our common stock is quoted on the Nasdaq National Market under the symbol ENDP. The following table sets forth the range of high and low sale prices for our common stock on the Nasdaq National Market for the fiscal quarters indicated since July 1, 2000.

| | High | Low |
|---|---|---|
| **2001** | | |
| Third Quarter to September 27, 2001 | $12.15 | $7.24 |
| Second Quarter | $11.65 | $6.00 |
| First Quarter | $7.125 | $5.125 |
| **2000** | | |
| Fourth Quarter | $10.125 | $5.50 |
| Third Quarter | $14.50 | $5.00 |

As of September 21, 2001, we had approximately 100 shareholders of record of our common stock. The closing sale price of our common stock on September 27, 2001 was $10.85 per share.

## DIVIDEND POLICY

We have never declared or 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.



## DILUTION

At June 30, 2001, we had net tangible book deficit of $74.1 million, or $0.83 per share. Net tangible book value per share is equal to our total tangible assets less our total liabilities, divided by the total number of shares of our common stock outstanding. After giving effect to the sale of 11,400,000 shares of our common stock at an assumed offering price of $11.00 per share, and after deducting underwriting discounts and estimated offering expenses payable by us, our as adjusted net tangible book value at June 30, 2001 would have been $41.5 million or $.41 per share. This represents an immediate increase in net tangible book value of $1.24 per share to existing stockholders and an immediate dilution of $10.59 per share to new investors purchasing shares of our common stock in this offering. The following table illustrates the per share dilution to the new investors.

| | |
|---|---|
| Offering price per share | $11.00 |
| Net tangible book value (deficit) per share at June 30, 2001 | $(0.83) |
| Increase per share attributable to this offering | 1.24 |
| As adjusted net tangible book value per share after this offering | 0.41 |
| Dilution per share to new investors in this offering | $10.59 |

The foregoing discussion and table do not take into account:

up to 34,412,836 shares of common stock issuable upon the exercise of the warrants we issued in connection with our acquisition of Algos, which have an exercise price of $0.01 per share;

21,580 shares of common stock issuable upon the exercise of warrants we issued to replace previously outstanding Algos warrants at the time of our acquisition of Algos, which had an exercise price of $1.20 per share; and

915,149 shares of common stock issuable upon the exercise of outstanding stock options, which have a weighted average exercise price of $8.26 per share.

To the extent these options and warrants are exercised, there will be further dilution to new investors.



## CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2001:

on an actual basis; and

as adjusted to give effect to the sale of 11,400,000 shares of our common stock at an assumed public offering price of $11.00 per share, less underwriting discounts and commissions and estimated offering expenses payable by us, and the application of the anticipated proceeds as set forth in Use of Proceeds, and the scheduled repayment on September 30, 2001 of $3.4 million of the term loans under our existing credit agreement.

You should read this information in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations, our financial statements and the related notes appearing elsewhere in this prospectus.

| | As of June 30, 2001 | |
|---|---|---|
| | Actual | As Adjusted |
| | (in thousands, except share data) | |
| Cash and cash equivalents | $67,027 | $79,777 |
| Debt: | | |
| Long-term debt, including current portion | $171,408 | 66,905(1) |
| Stockholders equity: | | |
| Preferred stock, $0.01 par value; 40,000,000 shares authorized; none issued | | |
| Common stock, $0.01 par value, 175,000,000 shares authorized, 89,138,950 shares issued (actual) and 100,538,950 shares issued (as adjusted) | 891 | 1,005 |
| Additional paid-in capital | 385,955 | 503,094 |
| Accumulated deficit | (200,180) | (201,859) |

| | | |
|---|---|---|
| Total stockholders equity | 186,666 | 302,240 |
| Total capitalization | $358,074 | $369,145 |

(1) Gives effect to the use of $101.1 million of the net proceeds from this offering to repay in full the term loans under our existing credit agreement, as described in Use of Proceeds, and the scheduled repayment on September 30, 2001 of $3.4 million of the term loans under our existing credit agreement.



## UNAUDITED PRO FORMA COMBINED FINANCIAL INFORMATION

The following unaudited pro forma combined financial information has been derived by the application of pro forma adjustments to our historical consolidated financial statements included elsewhere in this prospectus. The unaudited pro forma combined statement of operations for the year ended December 31, 2000 gives effect to the Algos merger, which occurred on July 17, 2000, as if it had occurred on January 1, 2000.

You should read the following unaudited pro forma combined financial information together with (1) our historical audited and unaudited financial statements and the related notes and (2) the historical audited and unaudited financial statements of Algos and the related notes, in each case included elsewhere in this prospectus.

In connection with the Algos merger, we issued, in the aggregate, 17,810,526 shares of our common stock and warrants to purchase in the aggregate up to 34,412,836 additional shares of our common stock in certain circumstances as more fully described under the heading Description of Capital Stock Warrants.

We accounted for the merger using the purchase method of accounting. In accordance with the purchase method of accounting, the purchase price was allocated to Algos assets and liabilities based on their respective estimated fair values on the date of the merger. The excess of the purchase price over the fair value of the net tangible assets was allocated to identifiable intangible assets, including intellectual property and in-process research and development, and the remainder to goodwill. Any amounts that were allocable to in-process research and development were recorded as a one-time charge immediately after the completion of the merger. See the notes to the unaudited pro forma combined financial information for a discussion of the changes to earnings that resulted as a result of the final allocation of purchase price.

We have presented these unaudited pro forma combined financial information for illustrative purposes only and are not necessarily indicative of the operating results or financial position that we would have achieved had the merger been completed as of the date indicated.

## UNAUDITED PRO FORMA COMBINED STATEMENT OF OPERATIONS

| | Year Ended December 31, 2000 | | | |
|---|---|---|---|---|
| | Historical | | Adjustments | Pro Forma |
| | Endo | Algos(1) | | |
| | (In thousands, except per share data) | | | |
| Net sales | $197,429 | | | $197,429 |
| Cost of sales | 63,041 | | | 63,041 |
| Gross profit | 134,388 | | | 134,388 |
| Selling, general and administrative | 56,537 | 3,120 | | 59,657 |
| Research and development | 26,012 | 5,278 | | 31,290 |
| Depreciation and amortization | 27,624 | 128 | 21,764(2) | 49,516 |
| Compensation related to stock options primarily selling, general and administrative | 15,300 | | | 15,300 |
| Purchased in-process research and development | 133,200 | | | 133,200 |
| Merger and other related costs | 1,583 | | | 1,583 |
| Separation benefits | 22,034 | | | 22,034 |
| Operating loss | (147,902) | (8,526) | (21,764) | (178,192) |
| Interest expense (income), net | 15,119 | (979) | | 14,140 |

| | | | |
|---|---|---|---|
| Loss before income tax (benefit) | (163,021) | (7,547) | (21,764) | (192,332) |
| Income tax (benefit) | (6,181) | | | (6,181) |
| Net loss | $(156,840) | $(7,547) | $(21,764) | $(186,151) |
| Net loss per share | | | | |
| Basic | $(1.97) | $(0.42) | | $(2.09) |
| Diluted | $(1.97) | $(0.42) | | $(2.09) |
| Shares used to compute net loss per share | | | | |
| Basic | 79,454 | 17,811 | | 89,139 |
| Diluted | 79,454 | 17,811 | | 89,139 |

(1) Represents the results of operations of Algos from January 1, 2000 through July 17, 2000.

(2) Reflects the additional depreciation and amortization arising from the Algos acquisition as if it had occurred on January 1, 2000. Based on the fair value of the assets acquired and liabilities assumed, the adjustment is comprised of an additional $18,470,000 of goodwill amortization and $3,342,000 of other intangible amortization, and less $48,000 of depreciation. Effective January 1, 2002, we will adopt the provisions of SFAS No. 142. Upon adoption, we will no longer amortize goodwill unless evidence of an impairment exists.



## SELECTED HISTORICAL CONSOLIDATED FINANCIAL DATA

The selected historical consolidated financial data for the six months ended June 30, 2000 and 2001 have been

derived from our unaudited interim financial statements. 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 the audited financial statements, unaudited interim financial statements and accompanying notes included in this prospectus and Management s Discussion and Analysis of Financial Condition and Results of Operations. The selected data in this section is not intended to replace the consolidated financial statements.

| | Year Ended December 31, | | | Six Months Ended June 30, | |
|---|---|---|---|---|---|
| | 1998 | 1999 | 2000 | 2000 | 2001 |
| | (in thousands, except per share data) | | | | |
| **Statement of Operations Data:** | | | | | |
| Net sales | $108,370 | $138,546 | $197,429 | $68,934 | $107,239 |
| Cost of sales | 54,731 | 58,263 | 63,041 | 28,333 | 33,681 |
| Gross profit | 53,639 | 80,283 | 134,388 | 40,601 | 73,558 |
| Selling, general and administrative | 25,540 | 42,921 | 56,537 | 26,138 | 35,343 |
| Research and development | 5,893 | 9,373 | 26,012 | 7,696 | 17,510 |
| Depreciation and amortization | 7,373 | 8,309 | 27,624 | 4,326 | 24,776 |
| Compensation related to stock options | | | 15,300 | | |
| Purchased in-process research and development | | | 133,200 | | |
| Merger and other related costs | | | 1,583 | | |
| Separation benefits | | | 22,034 | | 22,034 |

| | | | | | |
|---|---|---|---|---|---|
| Operating income (loss) | 14,833 | 19,680 | (147,902) | (19,593) | (4,071) |
| Interest expense, net | 14,451 | 14,347 | 15,119 | 7,718 | 6,443 |
| Income (loss) before income tax (benefit) | 382 | 5,333 | (163,021) | (27,311) | (10,514) |
| Income tax (benefit) | 181 | 2,073 | (6,181) | (10,325) | 993 |
| Net income (loss) | $201 | $3,260 | $(156,840) | $(16,986) | $(11,507) |
| Net income (loss) per share | | | | | |
| Basic | $0.00 | $0.05 | $(1.97) | $(0.24) | $(0.13) |
| Diluted | $0.00 | $0.05 | $(1.97) | $(0.24) | $(0.13) |
| Shares used to compute net income (loss) per share(1) | | | | | |
| Basic | 71,307 | 71,332 | 79,454 | 71,327 | 89,139 |
| Diluted | 71,307 | 71,332 | 79,454 | 71,327 | 89,139 |

| | **As of December 31,** | **As of June 30,** |
|---|---|---|

| | 1998 | 1999 | 2000 | 2001 |
|---|---|---|---|---|
| | | | (in thousands) | |
| **Consolidated Balance Sheet Data:** | | | | |
| Cash and cash equivalents | $17,367 | $22,028 | $59,196 | $67,027 |
| Working capital | 37,676 | 49,541 | 72,759 | 86,198 |
| Total assets | 287,618 | 329,436 | 467,840 | 441,157 |
| Total debt | 170,544 | 191,203 | 198,525 | 171,408 |
| Other long-term obligations | 6,352 | 6,745 | 7,218 | 18,009 |
| Stockholders equity | 75,358 | 78,587 | 198,173 | 186,666 |



| | Year Ended December 31, | | | Six Months Ended June 30, | |
|---|---|---|---|---|---|
| | 1998 | 1999 | 2000 | 2000 | 2001 |
| | | | (in thousands) | | |
| **Other Financial Data**: | | | | | |
| Net cash provided by operating activities | $20,932 | $13,766 | $35,069 | $18,004 | $39,342 |
| Net cash provided by (used in) investing activities | (3,537) | (9,074) | 18,077 | (507) | (2,000) |
| Net cash provided by (used in) financing activities | (14,549) | (31) | (15,978) | (9,667) | (29,511) |
| Consolidated EBITDA(2) | 40,726 | 47,232 | 67,687 | 15,072 | 31,176 |

(1) Excludes any shares of common stock issuable upon exercise of warrants issued in connection with our acquisition of Algos.

(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 deter-



mined by generally accepted accounting principles) to consolidated EBITDA (as defined in our credit facility) is as follows:

| | Year Ended December 31, | | | Six Months Ended June 30, | |
|---|---|---|---|---|---|
| | 1998 | 1999 | 2000 | 2000 | 2001 |
| | (in thousands) | | | | |
| Operating income (loss) | $14,833 | $19,680 | $(147,902) | $(19,593) | $(4,071) |
| Plus: purchased in-process research and development | | | 133,200 | | |
| Plus: depreciation and amortization | 7,373 | 8,309 | 27,624 | 4,326 | 24,776 |
| Plus: compensation related to stock options | | | 15,300 | | |
| Plus: non-cash manufacturing charges | 14,228 | 19,135 | 18,683 | 9,557 | 10,471 |
| Plus: purchase accounting charges | 4,292 | 108 | | | |
| Plus: non-cash separation benefits | | | 20,782 | 20,782 | |
| Consolidated EBITDA | $40,726 | $47,232 | $67,687 | $15,072 | $31,176 |

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 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.



**MANAGEMENT S DISCUSSION AND ANALYSIS OF**

**FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our financial statements and related notes included elsewhere in this prospectus. This discussion and analysis contains forward-looking statements, including estimates of future net sales and consolidated EBITDA, that involve risks, uncertainties and assumptions. In particular, our estimates of future net sales and consolidated EBITDA are based on assumptions regarding the timing of the completion of clinical trials, FDA approval and market acceptance of certain new products. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of a number of factors, including, but not limited to, those set forth under Risk Factors, Forward-Looking Statements and elsewhere in this prospectus. For a description of the definition of consolidated EBITDA and how it is calculated, see footnote 2 in Selected Historical Consolidated Financial Data.*

**Overview**

We, through our wholly owned subsidiaries, Endo Pharmaceuticals Inc. and Endo 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 69%, 68%, 76% and 71% of net sales for the years ended December 31, 1998, 1999 and 2000 and the six months ended June 30, 2001, respectively.

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. The stock of Endo Pharmaceuticals Inc. and the stock of Endo Inc. are our only assets and we have no other operations or business.

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 the heading Description of Capital Stock Warrants. 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 the heading Description of Capital Stock Warrants.

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 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, sales allowances, the cost of returns and losses. Net sales are recognized when products are shipped.

The following table presents our unaudited net sales by product category for the years ended December 31, 1998, 1999 and 2000 and the six month periods ended June 30, 2000 and 2001.

| | Year Ended December 31, | | | Six Months Ended June 30, | |
|---|---|---|---|---|---|
| | 1998 | 1999 | 2000 | 2000 | 2001 |
| | (in thousands, unaudited) | | | | |
| Percocet® | $44,556 | $51,513 | $92,366 | $30,861 | $56,401 |
| Lidoderm® | 5,695 | 22,539 | 5,490 | 10,665 | |
| Other brands | 28,829 | 36,500 | 35,375 | 12,992 | 8,591 |
| Total brands | 73,385 | 93,708 | 150,280 | 49,343 | 75,657 |
| Total generics | 34,985 | 44,838 | 47,149 | 19,591 | 31,582 |
| Total net sales | | | | | |

$108,370 $138,546 $197,429 $68,934 $107,239



The following table presents our unaudited net sales as a percentage of total net sales for select products for the years ended December 31, 1998, 1999 and 2000 and the six-month periods ended June 30, 2000 and 2001.

| | Year Ended December 31, | | | Six Months Ended June 30, | |
|---|---|---|---|---|---|
| | 1998 | 1999 | 2000 | 2000 | 2001 |
| | (unaudited) | | | | |
| Percocet® | 41% | 37% | 47% | 45% | 53% |
| Lidoderm® | 4 | 11 | 8 | 10 | |
| Other brands | 27 | 26 | 18 | 19 | 8 |
| Total brands | 68 | 68 | 76 | 72 | 71 |
| Total generics | 32 | 32 | 24 | 28 | 29 |

| | | | | | |
|---|---|---|---|---|---|
| Total | 100% | 100% | 100% | 100% | 100% |

*Goodwill and Other Intangibles*

Goodwill and other intangibles represent a significant portion of our assets and stockholders equity. As of June 30, 2001, goodwill and other intangibles comprised approximately 59% of total assets and 140% 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 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 $241.7 million of goodwill as of June 30, 2001 and have recorded $20.4 million of goodwill amortization for the six months ended June 30, 2001. We will adopt 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. These 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.

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.

**Results of Operations**

*Six Months Ended June 30, 2001 Compared to the Six Months Ended June 30, 2000*

*Net Sales.* Net sales for the six months ended June 30, 2001 increased by 56% to $107.2 million from $68.9 million in the comparable 2000 period. This increase in net sales was primarily due to the increase in net sales from several 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 the 15mg, 30mg and 60mg strengths of morphine sulfate extended release tablets, the therapeutic equivalent version of MS Contin®, and in May 2001, we launched the 100mg strength, for the relief of moderate-to-severe pain. On January 3, 2001, Watson Pharmaceuticals, Inc. announced that the FDA had approved Watson s ANDA for a generic equivalent to Percocet® 7.5/500 and Percocet® 10.0/650. These generic equivalents became available in April 2001. We expect that these generics will have a material adverse effect on our net sales of Percocet® 7.5/500 and Percocet® 10.0/650, and may have a material adverse effect on our profitability and cash flows in the future. Although there can be no assurance, we anticipate that the growth in net sales of these products will enable us to achieve total net sales of approximately $225 million to $230 million for the year ended December 31, 2001. For the year ended December 31, 2002, although there can be no assurance, we anticipate achieving total net sales of approximately $245 million to $255 million, primarily as a result of anticipated continued growth in net sales of Lidoderm® and the introduction of a new line extension of Percocet®, primarily offset by anticipated ongoing generic erosion of net sales of Percocet® 5.0/325, Percocet® 7.5/500 and Percocet® 10.0/650.

*Gross Profit.* Gross profit for the six months ended June 30, 2001 increased by 81% to $73.6 million from $40.6 million in the comparable 2000 period. Gross profit margins increased to 69% from 59% due to a more favorable mix of higher margin products resulting from 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 existing 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 six months ended June 30, 2001 increased by 35% to $35.3 million from $26.1 million in the comparable 2000 period. This increase was due to a $5.0 million increase in sales and promotional efforts in 2001 over the comparable 2000 period to support Lidoderm® and Percocet®. The increase in sales and promotional efforts was primarily due to the first quarter 2001 deployment of a dedicated contract sales force of 230 representatives comprised of 70 full-

time specialty representatives and 160 full-time primary care representatives compared to 300 part-time representatives in the comparable 2000 period. In addition, we experienced an increase in personnel-related costs in the general and administrative functions in order to support our growth. Based on our continued promotional efforts and the expected growth in our infrastructure, we anticipate these increases to continue.

*Research and Development Expenses.* Research and development expenses for the six months ended June 30, 2001 increased by 127% to $17.5 million from $7.7 million in the comparable 2000 period. This increase was due to our increased spending on 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 six months ended June 30, 2001 increased to $24.8 million from $4.3 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 merger.

*Separation Benefits.* Separation benefits of $22.0 million for the six months ended June 30, 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 entered into by us. 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 each of the separation and release agreements.

*Consolidated EBITDA.* Consolidated EBITDA for the six months ended June 30, 2001 increased 107% to $31.2 million from $15.1 million in the comparable 2000 period. Although there can be no assurance, we anticipate achieving consolidated EBITDA of approximately $71 million to $75 million for the year ended December 31, 2001 and approximately $80 million to $85 million for the year ended December 31, 2002.

*Interest Expense, Net.* Interest expense, net for the six months ended June 30, 2001 decreased by 17% to $6.4 million from $7.7 million in the comparable 2000 period. The decrease was primarily due to an increase in interest income of $0.8 million due to an increase in the average cash balance for the six months ended June 30, 2001 compared to the comparable 2000 period. The increase in the average cash balance was in part due to the acquisition of $19.6 million in net cash and cash equivalents in our merger with Algos. In addition, the decrease was due to a decrease in interest expense of $0.7 million due to a decrease in interest rates. In addition, due to the adoption of SFAS 133 on January 1, 2001, we recorded a $0.2 million charge for the accumulated transition adjustment relating to derivative instruments that do not qualify as a hedge under SFAS 133.

*Income Tax (Benefit).* Income tax (benefit) for the six months ended June 30, 2001 increased as a result of an increase in taxable income. We have recorded a valuation allowance on our existing deferred tax assets due to the uncertainty of the utilization of such amounts in the foreseeable future.

*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-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.

*Consolidated EBITDA.* Consolidated EBITDA for the year ended December 31, 2000 increased by 43% to $67.7 million from $47.2 million in the comparable 1999 period.

*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.

*Year Ended December 31, 1999 Compared to Year Ended December 31, 1998*

*Net Sales.* Net sales for the year ended December 31, 1999 increased by 28% to $138.5 million from $108.4 million in the comparable 1998 period. This increase in net sales was primarily due to the launch of several new products. In April 1998, we terminated a promotional agreement with a third party regarding Moban® tablets and liquid, and began our own promotion of the product for the management of psychotic disorders. In November 1998, we launched morphine sulfate extended release tablets, the therapeutic equivalent version of MS Contin®, for moderate-to-severe pain. In February 1999, we launched Zydone® tablets, a hydrocodone/acetaminophen offering for moderate-to-moderately-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 1999, we launched Percocet® 2.5/325, Percocet® 7.5/500 and Percocet® 10.0/650 to complement the existing Percocet® 5.0/325.

*Gross Profit.* Gross profit for the year ended December 31, 1999 increased by 50% to $80.3 million from $53.6 million in the comparable 1998 period. Gross profit margins increased to 58% from 49% substantially due to the fixed cost nature of our manufacturing relationship with DuPont Pharmaceuticals, currently our most significant contract manufacturing relationship. In addition, the increase in gross profit margins is due to our continued focus since the asset purchase transaction in August 1997 on a more favorable mix of higher margin products both through product launches, as discussed above, as well as discontinuation of some lower margin non-core products. If we achieve our forecast for net sales and product mix, our management expects the increase in gross profit margins to continue.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses for the year ended December 31, 1999 increased by 68% to $42.9 million from $25.5 million in the comparable 1998 period. This increase was substantially due to the increased sales and promotional efforts to support the launches of Zydone®, 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 February 1999, we deployed a dedicated contract field force of approximately 300 part-time sales representatives to promote these new products, which was an increase from the prior field force of approximately 100 sales representatives.

*Research and Development Expenses.* Research and development expenses for the year ended December 31, 1999 increased by 59% to $9.4 million from $5.9 million in the comparable 1998 period. This increase was due to increased spending on products under development focused in pain management.

*Depreciation and Amortization.* Depreciation and amortization for the year ended December 31, 1999 increased by 13% to $8.3 million from $7.4 million in the comparable 1998 period.

This increase was primarily due to the increase in capital spending required since our inception in August 1997.

*Consolidated EBITDA.* Consolidated EBITDA for the year ended December 31, 1999 increased by 16% to $47.2 million from $40.7 million in the comparable 1998 period.

*Interest Expense, Net.* Interest expense, net for the year ended December 31, 1999 decreased by 1% to $14.3 million from $14.5 million in the comparable 1998 period. The decrease in interest expense of $1.0 million due to lower interest rates applicable to long-term debt was substantially offset by an increase in interest expense of $1.0 million due to an increase in long-term debt during 1999.

*Income Taxes.* Income taxes for the year ended December 31, 1999 increased to $2.1 million from $0.2 million for the comparable 1998 period.

**Liquidity and Capital Resources**

Our principal source of liquidity is cash generated from operations. We also have the ability to borrow on a revolving basis up to $25.0 million under our credit agreement, described below. Our principal liquidity requirements are for working capital for operations, capital expenditures and debt service.

Net cash provided by operating activities increased by $21.3 million to $39.3 million for the six months ended June 30, 2001 from $18.0 million for the six months ended June 30, 2000. This increase was substantially due to reduction in cash flow utilized in inventory. During the six months ended June 30, 2000, we were building up inventories to support the launches of several new products, which utilized a significant amount of cash flow. Net cash provided by operating activities increased by $21.3 million to $35.1 million for the year ended December 31, 2000 from $13.8 million for the comparable 1999 period. This increase was substantially due to the cash provided by the increase in net sales and gross profit for the year ended December 31, 2000 compared to the year ended December 31, 1999 offset by an increase in selling, general and administrative expenses and research and development expenses for the year ended December 31, 2000 compared to the year ended December 31, 1999.

Net cash utilized in investing activities increased by $1.5 million to $2.0 million for the six months ended June 30, 2001 from $0.5 million for the six months ended June 30, 2000 due to an increase in capital expenditures. This increase in capital expenditures was due to the implementation of an electronic document management system during 2001 and the purchase of leasehold improvements and other furniture and fixtures related to our new principal executive offices, the lease of which is expected to commence in the third quarter of 2001. Net cash provided by investing activities increased by $27.2 million to $18.1 million for the year ended December 31, 2000 from $9.1 million of net cash utilized in investing activities for the comparable 1999 period. This increase in net cash was substantially due to the net cash acquired in the merger with Algos of $19.6 million. In addition, this increase in net cash was due to a $6.0 million decrease in license fees we paid due to our payment for our license of Lidoderm® and our $1.0 million payment for its exclusive license of technologies for pain management from Lavipharm Laboratories, Inc. both made in 1999. The remaining increase in cash provided by investing activities is due to a $0.6 million decrease in capital expenditures due to the completion of an enterprise software system implementation during 1999.

Net cash utilized in financing activities increased by $19.8 million to $29.5 million for the six months ended June 30, 2001 from $9.7 million for the six months ended June 30, 2000 due to repayments made on our credit facility. Net cash utilized in financing activities increased by $16.0 million for the year ended December 31, 2000 due to repayments made on our credit facility. No significant net cash was utilized for financing activities in the year ended December 31, 1999.

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.

On March 15, 2001, Penwest Pharmaceuticals Co., a collaboration partner of ours with which we have an alliance agreement and with which we are developing one of our 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 June 30, 2001, Penwest stated that its existing capital resources, including, among other things, the proceeds of the private placement of $30.0 million of common stock, will enable Penwest to maintain currently-planned operations into at least the fourth quarter of 2002 . If Penwest is 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.

Our cash and cash equivalents totaled $67.0 million at June 30, 2001. After giving effect to this offering, the use of $101.1 million of the net proceeds of the offering to repay in full the term loans under our existing credit agreement and the September 30, 2001 scheduled repayment of $3.4 million of the term loans, we would have had $79.8 million of cash and cash equivalents at June 30, 2001. We believe that our (a) cash and cash equivalents, (b) cash flow from operations and (c) existing credit facility, which has an available unused line of credit of $25.0 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 we have issued to DuPont, for possible acquisitions and for possible repurchase of warrants originally issued to the former stockholders of Algos in connection with our acquisition of Algos. We may repurchase these warrants in privately negotiated transactions, open market purchases, tender offers or otherwise. Repurchase of these warrants would be subject to market conditions and receipt of any required third party consents and waivers. In the event that we make any significant acquisitions or other strategic investments, we may be required to raise additional funds, through the issuance of additional debt or equity securities.

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 the financial statements.

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

*Our Credit Agreement*

We entered into a credit agreement on August 26, 1997 with a number of lenders and The Chase Manhattan Bank, as administrative agent. Under this credit agreement, as of June 30, 2001, we had outstanding a Tranche A Term Loan in the amount of $22.6 million and a Tranche B Term Loan in the amount of $81.9 million. Under the credit agreement, we have the ability to borrow on a revolving basis up to $25.0 million, none of which was outstanding as of June 30, 2001. The Tranche A Term Loan amortizes quarterly and has a final maturity date of December 31, 2002. The Tranche B Term Loan also amortizes quarterly and has a final maturity date of June 30, 2004. The revolving loans may be borrowed, repaid and reborrowed and have a final maturity of December 31, 2002.

These loans bear interest at an agreed-upon spread over the applicable base rate (as defined in the credit agreement) or over LIBOR. Currently, the Tranche A Term Loan bears interest at an annual rate of 5%, and the Tranche B Term Loan bears interest at an annual rate of 6%. These rates will be reset based upon the agreed-upon spread over LIBOR on September 30, 2001. 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.

*DuPont Notes*

We financed a portion of the purchase price of the assets we purchased from DuPont at our inception by the issuance of a $3.9 million promissory note that bears no interest and is payable on August 26, 2002. On each of August 26, 1998, August 26, 1999, August 26, 2000 and August 26, 2001, we issued an additional promissory note to DuPont as consideration for manufacturing and supply services under its agreement with us. Each note has a face value of $23.0 million, bears no interest and is due on August 26, 2002. We are entitled to extend the maturity date of these notes until February 26, 2005, provided that we pay interest in cash or additional notes for such extra period at the rate of 16% per annum.

*New Credit Facility*

We are currently negotiating the terms of a new senior secured credit facility with a number of lenders, including affiliates of certain of the underwriters in this offering, to replace our existing credit agreement.

The new credit facility is expected to be in the amount of approximately $100 million and to have a final maturity of five years. Any outstanding loans under the new credit facility may be secured by a first priority security interest in substantially all of our assets. The new credit facility is expected to contain representations and warranties, covenants, events of default and other provisions customarily found in similar agreements.

The closing of the new credit facility is expected to be conditional on the closing of this offering, the repayment of all outstanding indebtedness under our existing credit agreement and the termination of all our guarantees and security agreements in relation to our existing credit agreement prior to or concurrently with the closing of the new credit facility.

We cannot assure you that we will be able to enter into the new credit facility on the terms described above or at all.

*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 $241.7 million of goodwill as of June 30, 2001 and have recorded $20.4 million of goodwill amortization for the six months ended June 30, 2001. We will adopt the provisions of SFAS No. 142 effective January 1, 2002.

**Quantitative and Qualitative Disclosures about Market Risk**

Our primary market risk exposure is to changes in interest rates (LIBOR) on our variable rate borrowings. 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 have entered into an interest rate cap agreement with a notional amount of $82.5 million that sets a maximum LIBOR rate of 8% that we will pay on the related notional amount. This interest rate cap agreement expired on August 27, 2000. Effective August 27, 2000, we entered into a new interest rate cap agreement with a notional amount of $70.0 million that sets a maximum LIBOR

rate of 8% that we will pay on the related notional amount through August 27, 2003.

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, 2000 and



December 31, 1999. You should read Notes 6 and 7 to our consolidated financial statements for the year ended December 31, 2000, together with the tables below.

During the six months ended June 30, 2001, there were no significant changes to our market risk exposure.

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

| | Year of Maturity | | | | | | |
|---|---|---|---|---|---|---|---|
| | 2001 | 2002 | 2003 | 2004 | Thereafter | Total due at Maturity | Fair Value At 12/31/00 |
| | (dollars in thousands) | | | | | | |
| **Interest rate sensitive liabilities:** | | | | | | | |
| **Short-term and variable rate borrowings** | | | | | | | |
| 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% | |
| Total | 36,371 | 16,947 | 37,121 | 43,576 | | 134,015 | 134,015 |
| **Fixed-rate borrowings** | | | | | | | |
| 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%

Total interest rate sensitive liabilities
$36,371 $89,836 $37,121 $43,576 $206,904 $198,525

Weighted average interest rate
8.23% 7.45% 8.75% 8.75% 8.09%

**Interest rate instruments:**

Interest rate cap
$311
Cap rate
8.00%

**Schedule of Interest Rate Sensitive Assets and Liabilities at December 31, 1999**

| | Year of Maturity | | | | | | |
|---|---|---|---|---|---|---|---|
| | 2000 | 2001 | 2002 | 2003 | Thereafter | Total due at Maturity | Fair Value At 12/31/99 |
| | (dollars in thousands) | | | | | | |
| **Interest rate sensitive liabilities:** | | | | | | | |
| **Short-term and variable rate borrowings** | | | | | | | |
| Tranche A term loan | $12,040 | $15,538 | $19,422 | | $47,000 | $47,000 | |
| Average interest rate | 8.40% | 8.40% | 8.40% | | 8.40% | | |
| Tranche B term loan | | | | | | | |

3,945 971 971 $44,672 $52,441 103,000 103,000
Average interest rate
8.90% 8.90% 8.90% 8.90% 8.90% 8.90%

Total
15,985 16,509 20,393 44,672 52,441 150,000 150,000
**Fixed-rate borrowings**

Acquisition note payable
3,889 3,889 3,002
Average interest rate
9.75% 9.75%
Other notes payable
46,000 46,000 38,201
Average interest rate
7.00% 7.00%

Total interest rate sensitive liabilities
$15,985 $16,509 $70,282 $44,672 $52,441 $199,889 $191,203

**Interest rate instruments:**

Interest rate cap
$50
Cap rate
8.00%

The most significant changes to interest rate sensitive assets and liabilities were increases in interest rates from 1999 to 2000, and additional notes issued during 2000.



## 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, totalled $13 billion for the 12 months ended May 2001. Our primary area of focus is analgesics, which according to IMS Health data were the fourth most prescribed class of medication in the United States in 2000.

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 71% of net sales for fiscal years 1999 and 2000 and the six months ended June 30, 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 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 NMDA-receptor antagonists, drugs that block a specific type of pain receptor in human cells. 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 NDA, with the FDA, in mid-2002. In addition, we are co-developing an oral extended-release version of oxymorphone with Penwest Pharmaceuticals. This product is currently in Phase III clinical trials, and we anticipate filing an NDA with the FDA in the second half of 2002.

We have also developed oxycodone ER, a generic version of OxyContin®, a product of The Purdue Frederick Company. According to IMS Health data, OxyContin® generated U.S. sales of approximately $1 billion in 2000, up from approximately $600 million in 1999. We have filed and amended an 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®.

*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. Net sales of Percocet® products increased to $92.4 million in 2000 from $51.5 million in 1999 and to $56.4 million for the six months ended June 30, 2001 from $30.9 million for the six months ended June 30, 2000. We currently have on file with the FDA a line extension of Percocet®, which we anticipate launching by the end of the first quarter of 2002. 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 development-stage product MorphiDex®. We also acquired rights to a portfolio of other 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 often follows an attack of shingles. We launched this product in September 1999. Net sales of Lidoderm® increased to $22.5 million in 2000 from $5.7 million in 1999 and to $10.7 million for the six months ended June 30, 2001 from $5.5 million for the six months ended June 30, 2000. 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. In November 1999, we entered into a collaboration agreement with Lavipharm Laboratories Inc., under which we obtained exclusive worldwide rights to Lavipharm s existing drug-delivery platforms.

**Our Competitive Strengths**

We believe that we have established a position as a market leader among pain-focused pharmaceutical companies by capitalizing on the 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 85% of

oxycodone acetaminophen prescriptions are written as Percocet. We believe our close relationships with physicians we consider to be thought leaders in pain management in pain centers, hospitals, and other pain management institutions enable us to improve penetration in these types of institutions. We believe this interaction has also allowed us to pursue, through in-licensing, products targeted at additional indications such as 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 include MorphiDex® and oxymorphone ER. In addition, we have filed applications with the FDA for several other new products and product extensions, and we believe we will be able to launch at least two of these by early 2002.

*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 three years through the launch of more than 10 products and product extensions during this period. These products and product extensions contributed approximately 42% of our net sales in 2000.

*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 MSContin®, a Purdue Frederick product. Morphine sulfate extended release tablets have been the sole therapeutic equivalent to the Purdue Frederick products on the market, and since the time of their launch have gained significant market share. 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 under an exclusive arrangement with Ventiv Healthcare. We have a flexible arrangement with Ventiv, reserving the option to hire all of these sales representatives and managers as our full time employees. 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 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 ten new products and product extensions since 1997 and has grown net sales from approximately $108.4 million in 1998 to approximately $197.4 million in 2000. In addition, management has vested stock options to acquire up to 12% of our common stock

and has the potential to receive as much as an additional 10% of our common stock through options which vest if the price of our common stock reaches specified defined targets. These options are exercisable for shares currently held by Endo Pharma LLC, and their exercise will not dilute your ownership of our common stock.

**Our Industry**

According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled $13 billion for the 12 months ended May 2001. This represents an approximately 30% compound annual growth rate since May 1999. Our primary area of focus within this market is analgesics. In 2000, analgesics were the fourth most prescribed medication in the United States with over 220 million prescriptions written for this classification. These products are used primarily for the treatment of pain associated with orthopedic fractures and sprains, back injuries, migraines, joint diseases, cancer and various surgical procedures.



Opioid analgesics comprised approximately 75% of the analgesics prescriptions in 2000. This market segment has grown to $3.4 billion for the 12 months ended May 2001, representing a compound annual growth rate of 28% since 1997. If branded products were substituted for generic products, we believe 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 65 and older reached 31 million and is expected to grow to 40 million 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 Legal Proceedings.

*Branded Products*

*Percocet*(R). We consider Percocet(R) to be a gold standard of pain management. Launched in 1971, Percocet(R) is approved for the treatment of moderate-to-severe pain. Although Percocet(R) has faced generic competition for more than 15 years, in 2000, according to the IMS National Prescription Audit, approximately 11 million prescriptions for this combination of oxycodone hydrochloride and acetaminophen were written for the brand name Percocet(R), of which, due to generic substitution, only approximately 19% were filled by pharmacists with our brand Percocet(R).

During the fourth quarter of 1999, we introduced three new strengths of Percocet(R): Percocet(R) 2.5/325, Percocet(R) 7.5/500 and Percocet(R) 10.0/650, complementing the existing Percocet(R) 5.0/325. Physician prescribing practices indicate that over 80% of prescriptions are written for amounts other than the label amount. As an example, the current prescription



information for Percocet(R) 5.0/325 calls for one tablet every six hours. Approximately 30% of prescriptions written direct patients to take two tablets every four hours, translating into a dosage of 10mg every four hours. By creating new prescription strengths, physicians will be able to prescribe one tablet of the proper dose for their patients, facilitating greater ease and compliance. The Percocet® products were responsible for net sales of $44.5 million, $51.5 million, $92.4 million and $56.4 million in the years 1998, 1999 and 2000 and the six months ended June 30, 2001, respectively. Percocet(R) accounted for approximately 47% of our 2000 net sales. 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.

*Lidoderm*®. Lidoderm® was launched in September 1999. A topical patch product containing lidocaine, it is the first FDA-approved product for the relief of the pain 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 2000 and the six months ended June 30, 2001, Lidoderm® net sales were $22.5 million and $10.7 million, respectively.

*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 2000, according to the IMS National Prescription Audit, approximately 489,000 prescriptions for oxycodone hydrochloride and oxycodone terephthalate in combination with aspirin were written for the brand name Percodan®. Due to generic substitution, only approximately 32% 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 2000 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 12% of our total net sales in 2000. Launched in November 1998, morphine sulphate extended release tablets are a bioequivalent of MS Contin®. The balance of our generic portfolio consisted of several products, none of which accounted for more than 5% of our total net sales for 2000.

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.

*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, a not-approvable letter was received from the FDA by Algos. A not-approvable letter is issued by the FDA for various reasons and outlines deficiencies that must be corrected prior to approval. After our meeting with the FDA in September 2000, 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 the NDA reapplication 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 by mid-2002. We expect the FDA to respond within six months after acceptance of the reapplication. 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 the 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. We expect our oral extended-release version of oxymorphone 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 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 cheaper 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 June 30, 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 and 2000 and the six months ended June 30, 2001, our expenditures on research and development were $9.4 million, $26.0 million and $17.5 million, respectively. In addition to our internal research and development staff, we have agreements and arrangements with various contract research organizations to conduct and coordinate our 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 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 and 26%, 21%, and 14% of net sales in 1998.

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 two foreign issued patents, nine U.S. patent applications pending and 49 foreign patent applications pending with respect to our products. We have licenses for 28 U.S. issued patents, three U.S. patent applications pending, 66 foreign issued patents and 25 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, 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 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, quality control. The FDA also has the

authority to revoke previously granted drug approvals. Product development and approval within this regulatory framework requires a number of years and involves the expenditure of substantial resources.

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

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

*NDA Process*

FDA approval is required before any new drug can be marketed. An NDA is a filing submitted to the FDA to obtain approval of new chemical entities and other innovations for which thorough applied research is required to demonstrate safety and effectiveness in use. The NDA must contain complete pre-clinical and clinical safety and efficacy data or a right of reference to such



data sponsored by the applicant. Before dosing a new drug in healthy human subjects or patients may begin, stringent government requirements for preclinical data must be satisfied. The preclinical data, typically obtained from studies in animals, as well as from laboratory studies, are submitted in an Investigational New Drug application, or IND, or its equivalent in countries outside the United States where clinical trials are to be conducted. The preclinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initiation of clinical trials.

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

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

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

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

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

Data from preclinical testing and clinical trials are submitted to the FDA in an NDA for marketing approval and to other health authorities as a marketing authorization application. The process of completing clinical trials for a new drug may take several years and require the expenditures of substantial resources. Preparing an NDA or marketing authorization application involves considerable data collection, verification, analysis and expense, and there can be no

assurance that approval from the FDA or any other health authority will be granted on a timely basis, if at all. The approval process is affected by a number of factors, primarily the risks and benefits demonstrated in clinical trials as well as the severity of the disease and the availability of alternative treatments. The FDA or other health authorities may deny an NDA or marketing authorization application if the regulatory criteria are not satisfied, or such authorities may require additional testing or information.

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

*ANDA Process*

FDA approval of an ANDA is required before a generic equivalent of an existing, or listed drug can be marketed. We usually receive approval for such products by submitting an ANDA to the FDA. The ANDA process is abbreviated in that the FDA waives the requirement of conducting



complete preclinical and clinical studies and instead relies on bioequivalence studies. Bioequivalence compares the rate of absorption and levels of concentration of a generic drug in the body with those of the previously approved drug. When the rate and extent of absorption of the test and reference drugs are the same, the two drugs are bioequivalent and regarded as therapeutically interchangeable.

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

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

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

*Patent and Non-Patent Exclusivity Periods*

A sponsor of an NDA is required to identify in its application any patent that claims the drug or a use of the drug subject to the application. Upon NDA approval, the FDA lists these patents in a publication referred to as the Orange Book. Any person that files an ANDA to secure approval of a generic version of this first, or listed, drug, or an NDA that relies upon the data in the application for which the patents are listed, must make a certification in respect to listed patents. The FDA may not approve such an application for the drug until expiration of the listed patents unless (1) the later applicant certifies that the listed patents are invalid, unenforceable or not infringed by the proposed generic drug and gives notice to the holder 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 could be rejected by U.S. Customs. In respect to domestic establishments, the FDA could initiate product seizures or require product recalls and seek to enjoin a product s manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include preventing the company from receiving the necessary licenses to export its products and classifying the company as an unacceptable supplier , thereby disqualifying the company from selling products to federal agencies.

We believe 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 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, 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. A description of the material terms of the material third party manufacturing/supply contracts follows:

*DuPont Pharmaceuticals.* DuPont Pharmaceuticals currently manufactures a significant number of our brand and generic pharmaceutical products. DuPont Pharmaceuticals 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 new products. The products are manufactured at either the DuPont facility in Garden City, New York or the DuPont



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 DuPont Pharmaceuticals compensation in the form of (1) a fixed amount to cover DuPont s fixed manufacturing costs for both manufacturing facilities, (2) an amount, adjusted on an annual basis, to cover DuPont 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, DuPont Pharmaceuticals 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 DuPont Pharmaceuticals concerning arrangements to manufacture certain of our products following the expiration of the initial term in August 2002. If DuPont 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, DuPont shall implement, at its cost, appropriate arrangements for the manufacture and supply of the products elsewhere.

In June 2001, an agreement for the sale of DuPont Pharmaceuticals to Bristol-Myers Squibb was announced. The sale is subject to government approvals. Upon such a change in control of DuPont Pharmaceuticals, DuPont may assign this agreement, provided that we consent to such assignment, which consent may not be unreasonably withheld. We are unable to predict the effect of this transaction on our relationship with DuPont Pharmaceuticals.

*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 (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, and during the first year, we expect to exceed such minimum levels. 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 DuPont, 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. for customer service support, warehouse and distribution services and certain financial functions and (2) Kunitz and Associates Inc. for medical affairs. We also have an arrangement with Ventiv Healthcare for sales as well as 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.* 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, 2000, these fees and expenses were approximately $4.0 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, 2002; 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 provide these services 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 Healthcare Inc.* We have an arrangement with Ventiv Healthcare whereby a team of Ventiv s professional sales representatives, under our management s direction, exclusively promotes certain of our products to healthcare professionals in the United States. We recently entered into a multi-year agreement with Ventiv to continue to use their sales and promotional services. The term of this agreement is until December 31, 2003 but will automatically renew for one-year periods thereafter. Under the agreement, we reserve the option to hire all of these sales representatives and managers as our full-time employees.

**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 also have an option to extend this license agreement to other territories within a defined period of time. 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 the second quarter of 2001, we accrued $0.6 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.

**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.

**Employees**

As of August 31, 2001, we had 157 employees, of which 49 are engaged in research and development, 17 in regulatory work, 27 in sales and marketing, 19 in quality assurance and 45 in general and administrative capacities. Employees are not represented by unions and we believe that our relations with our employees are good.

**Legal Proceedings**

The 1984 Drug Price Competition and Patent Term Restoration Act, or the Waxman-Hatch Act, provides for a period of 180 days of generic marketing exclusivity for those ANDA applicants that are first to file an ANDA containing a certification of invalidity, non-infringement or unenforceability with respect to the listed patent(s), referred to as Paragraph IV certifications. Once the FDA accepts an ANDA for filing, the ANDA applicant is required to notify the NDA and patent owner(s) of this fact. The patent owner then has 45 days from the receipt of the notice in which to sue the applicant for patent infringement. If it does so, the FDA is generally prevented from granting approval of the ANDA until the earlier of 30 months from the date the FDA accepted the ANDA for filing and the satisfactory conclusion of the ensuing litigation.

On October 20, 2000, The Purdue Frederick Company and related companies ( Purdue Frederick ) filed suit against us and our subsidiary, Endo Pharmaceuticals Inc., in the U.S. District Court for the Southern District of New York alleging that our bioequivalent version of Purdue Frederick s OxyContin® (oxycodone hydrochloride extended-release tablets), 40mg strength, infringes three of its patents. This suit arose after we provided the plaintiffs with notice that our 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 Endo Pharmaceuticals Inc. in the U.S. District Court for the Southern District of New York alleging that our bioequivalent versions of Purdue Frederick s OxyContin®, 10mg and 20mg strengths, infringe the same three patents. This suit arose from Endo Pharmaceuticals Inc. 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 Endo Pharmaceuticals Inc. in the U.S. District Court for the Southern District of New York alleging that our bioequivalent version of Purdue Frederick s OxyContin®, 80mg strength, infringes the same three patents. This suit arose from Endo Pharmaceuticals Inc. 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, we made the required Paragraph IV certification against the patents listed in the FDA s Orange Book as covering these strengths of OxyContin®. We have pleaded counterclaims that the patents asserted by Purdue Frederick are invalid, unenforceable and/or not infringed by our formulation of oxycodone hydrochloride extended-release tablets, 10mg, 20mg and 40mg strengths. We have also counterclaimed for antitrust damages based on our 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. We intend to pursue a similar litigation strategy with respect to the 80mg strength of this product. However, we cannot assure you 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 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.

We expect to be sued again as early as the fourth quarter of 2001 with respect to another ANDA we have filed with the FDA. Similar litigation may also result from products we currently have in development, as well as those which 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.

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



## MANAGEMENT

### Officers and Directors

The following table sets forth certain information regarding our executive officers and directors:

| Name | Age | Position |
|---|---|---|
| Carol A. Ammon | 50 | President and Chief Executive Officer and Director |
| Mariann T. MacDonald | 53 | Executive Vice President, Operations |
| Caroline E. Berry | 33 | Senior Vice President, General Counsel and Secretary |
| Jeffrey R. Black | | |

| | | |
|---|---|---|
| Carol A. Ammon | 37 | Senior Vice President, Chief Financial Officer and Treasurer |
| Peter A. Lankau | 48 | Senior Vice President, U.S. Business |
| David A. H. Lee, M.D. Ph.D. | 51 | Senior Vice President, Research & Development and Regulatory Affairs |
| Michael B. Goldberg | 54 | Director |
| Michael Hyatt | 55 | Director |
| Roger H. Kimmel | 54 | Director |
| Frank J. Loverro | 32 | Director |
| John W. Lyle | 57 | Chairman of the Board and Director |
| Michael W. Mitchell | 64 | Director |
| Joseph T. O Donnell, Jr. | 53 | Director |
| David I. Wahrhaftig | 44 | Director |

*Carol A. Ammon* has served as our President, Chief Executive Officer and a Director since our inception in 1997. Prior to founding 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 Christiana Care of Delaware and the St. Louis College of Pharmacy in St. Louis, Missouri.

*Mariann T. MacDonald* has served as our Executive Vice President, Operations since our inception in 1997. Prior to joining us, 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.

*Caroline E. Berry* has served as our Senior Vice President, General Counsel and Secretary since September 2000. Prior to joining us, Ms. Berry was an Associate at the law firm Skadden, Arps, Slate, Meagher & Flom LLP since 1995.

*Jeffrey R. Black* has served as our Senior Vice President, Chief Financial Officer and Treasurer since our inception in 1997. Prior to joining us, 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* has served as our Senior Vice President, U.S. Business since June 2000. Prior to joining us, 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 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.* has served as our Senior Vice President, Research & Development and Regulatory Affairs since December 1997. Prior to joining us, 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.

*Michael B. Goldberg* has served as a Director since our inception in 1997. Mr. Goldberg has been a Managing Director of Kelso & Company since 1991. Mr. Goldberg is also a director of Consolidated Vision Group, Inc., HCI Direct, Inc., Armkel, LLC and Unilab Inc. He also serves as a member of the Phoenix House Foundation Board of Directors and The Wilson Council of the Woodrow Wilson International Center for Scholars.

*Michael Hyatt* has served as a Director since July 2000. Mr. Hyatt had been a director of Algos Pharmaceutical Corporation since November 1996. For more than five years, Mr. Hyatt has been a Senior Managing Director of Bear Stearns & Co., Inc.

*Roger H. Kimmel* has served as a Director since July 2000. Mr. Kimmel had been a Director of Algos Pharmaceutical Corporation since July 1996. Mr. Kimmel has been Vice-Chairman of Rothschild Inc., an investment banking firm, since January 2001. Previously, Mr. Kimmel was a partner of the law firm of Latham & Watkins for more than five years. Mr. Kimmel is also a director of Weider Nutrition International, Inc.

*Frank J. Loverro* has served as a Director since July 2000. Mr. Loverro has been a Vice President at Kelso & Company since March 1999. Prior to joining Kelso in November 1993, Mr. Loverro was an Associate at the Clipper Group and previously worked in the High Yield Finance Group of Credit Suisse First Boston.

*John W. Lyle* has served as our Chairman of the Board and a Director since July 2000. Mr. Lyle had been President and Chief Executive Officer and a Director of Algos since its formation in January 1992. Mr. Lyle served as President and Chief Executive Officer of OmniCorp Holdings, Inc., in 1991. Prior to founding Algos, Mr. Lyle was one of the founders of Osteotech, Inc., a public orthopedic pharmaceutical company formed in 1986. He served as Osteotech, Inc. s Chairman and Chief Executive Officer from 1989 to 1991 and as President from 1986 to 1989. From 1981 to 1986, Mr. Lyle served as President of CIBA-GEIGY Corporation s Self-Medication Division. From 1975 to 1981, Mr. Lyle held various positions at Johnson & Johnson.

*Michael W. Mitchell* has served as a Director since July 2000. Mr. Mitchell has been Counsel to the law firm Morvillo, Abramowitz, Grand, Iason & Silberberg since November 1991. Mr. Mitchell is currently the Treasurer and a member of the New York Police Athletic League Board of Directors, and from 1997 to 1999 was a member of The Wilson Council of the Woodrow Wilson International Center for Scholars.

*Joseph T. O Donnell, Jr.* has served as a Director since September 2000. Mr. O Donnell is currently the President of Metzler Corporation, New York City. Metzler Corporation is the U.S. based corporate finance affiliate of B. Metzler seel. Sohn & Co., Frankfurt, Germany. Prior to joining Metzler, Mr. O Donnell spent 26 years at various affiliates of Bankers Trust Corporation. From 1986 to 2000, he was involved in the acquisition and leveraged finance business. Prior to 1986, Mr. O Donnell was involved in Banker Trust s global Airline and Aerospace Division and in middle market financing activities in the New York metropolitan area.

*David I. Wahrhaftig* has served as a Director since our inception in 1997. Mr. Wahrhaftig has been a Managing Director of Kelso & Company since April 1997, after joining the firm in 1987. Mr. Wahrhaftig is also a director of Consolidated Vision Group, Inc. and Unilab Inc.

We have employment agreements with each of the executive officers.

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth, as of September 21, 2001, the name, address and holdings of each person, including any group as defined in Section 13(d)(3) of the Exchange Act, known by us to be the beneficial owner of more than 5% of common stock. Footnote (a) below provides a brief explanation of what is meant by the term beneficial ownership. The following table also sets forth, as of September 21, 2001, the amount of common stock beneficially owned by each of our directors and executive officers. The following table also sets forth, as of September 21, 2001, the amount of common stock beneficially owned by all of our current directors and executive officers as a group.

| Name of Beneficial Owner | Amount and Nature of Beneficial Ownership(a) | Percentage Beneficially Owned | |
|---|---|---|---|
| | | Before Offering | After Offering |
| **Directors and Executive Officers:** | | | |
| Carol A. Ammon(b)(c) | (d) | | |
| Michael B. Goldberg(e) | (f) | | |
| Michael Hyatt(g) | 1,844,024 | 2.1% | 1.8% |
| Roger H. Kimmel(h) | 918,525 | 1.0% | * |
| Frank J. Loverro(e) | (i) | | |
| John W. Lyle(b)(j) | 1,344,416 | 1.5% | 1.3% |
| Michael W. Mitchell(k) | 10,000 | * | * |
| Joseph T. O Donnell, Jr.(l) | 10,000 | * | * |
| David I. Wahrhaftig(e) | (f) | | |
| Mariann T. MacDonald(b)(c) | (d) | | |
| Caroline E. Berry(b)(c) | 27,389(m) | * | * |
| Jeffrey R. Black(b)(c) | (d) | | |
| David A. H. Lee, M.D., Ph.D.(b)(c) | (d) | | |
| Peter A. Lankau(b)(c) | 166,519(m) | * | * |
| All current directors and executive officers of Endo Pharmaceuticals Holdings Inc. as a group (14 persons)(c) | 3,663,680 | 4.1% | 3.6% |
| **Other Principal Stockholders:** | | | |
| Endo Pharma LLC(e) | 70,196,017 | 78.7% | 69.8% |

Kelso Investment Associates V, L.P.(e)
(n)
Kelso Equity Partners V, L.P.(e)
(n)
Kelso Partners V, L.P.(e)
(o)
Joseph S. Schuchert(e)
(f)
Frank T. Nickell(e)
(f)
Thomas R. Wall, IV(e)
(f)
George E. Matelich(e)
(f)
Frank K. Bynum, Jr.(e)
(f)
Philip E. Berney(e)
(f)
Greenwich Street Capital Partners, L.P.(p)(q)
(r)
Greenwich Street Capital Offshore Fund, Ltd.(p)(q)
(r)
TRV Employees Fund, L.P.(p)(q)
(r)
The Travelers Insurance Company(p)(q)
(r)
The Travelers Life and Annuity Company(p)(q)
(r)

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* Represents less than 1%.



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(a) Beneficial ownership is a term broadly defined by the Securities and Exchange Commission in Rule 13d-3 under the Exchange Act, and includes more than the typical form of stock ownership, that is, stock held in the person s name. The term also includes what is referred to as indirect ownership, meaning ownership of shares as to which a person has or shares investment power. For purposes of this table, a person or group of persons is deemed to have beneficial ownership of any shares as of a given date that such person has the right to acquire within 60 days after such date.

(b) The business address for these persons is c/o Endo Pharmaceuticals Holdings Inc., 100 Painters Drive, Chadds Ford, Pennsylvania 19317.

(c) These amounts do not include any options that these individuals hold in the Endo Pharma LLC 1997 Stock Option Plans. Options exercised pursuant to the Endo Pharma LLC 1997 Stock Option Plans do not result in the issuance of additional shares of our common stock.

(d) Ms. Ammon, Ms. MacDonald, Mr. Black and Dr. Lee may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of the status of each of them as members of Endo Pharma LLC. Ms. Ammon, Ms. MacDonald, Mr. Black and Dr. Lee share investment and voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaim beneficial ownership of such securities except to the extent of each individual s pecuniary interest.

(e) The business address for this person is c/o Kelso & Company, 320 Park Avenue, 24th Floor, New York, NY 10022.

(f) Messrs. Schuchert, Nickell, Wall, Matelich, Goldberg, Wahrhaftig, Bynum and Berney may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of the status of Kelso Investment Associates V, L.P., or KIA V, and Kelso Equity Partners V, L.P., or KEP V, as members of Endo Pharma LLC. Messrs. Schuchert, Nickell, Wall, Matelich, Goldberg, Wahrhaftig, Bynum and Berney may be deemed to share beneficial ownership of securities owned of record by KIA V and KEP V, by virtue of the status of each of them as a general partner of the general partner of KIA V and as a general partner of KEP V. Messrs. Schuchert, Nickell, Wall, Matelich, Goldberg, Wahrhaftig, Bynum and Berney share investment and voting power along with the other general partners with respect to securities owned by KIA V and KEP V, but disclaim beneficial ownership of such securities except to the extent of each individual s pecuniary interest.

(g) The business address for Mr. Hyatt is c/o Bear, Stearns & Co., Inc., 245 Park Avenue, New York, NY 10167. This amount includes (i) 829,551 shares of common stock owned directly by Mr. Hyatt, (ii) 1,004,473 shares held in trusts for which Mr. Hyatt serves as trustee and as to which shares Mr. Hyatt holds either the sole or the shared power of disposition or the power to vote and (iii) options to purchase 10,000 shares of common stock under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan. Excludes 221,332 shares of common stock held in a trust for the benefit of the children of Mr. Hyatt, as to which shares Mr. Hyatt has neither the power of disposition nor the power to vote.

(h) The business address for Mr. Kimmel is c/o Rothschild, Inc., 1251 Avenue of the Americas, New York, NY 10022. This amount includes (i) 30,000 shares owned directly by Mr. Kimmel, (ii) 878,525 shares held in trusts for which Mr. Kimmel serves as trustee and as to which shares Mr. Kimmel holds either the sole or the shared power of disposition and power to vote and (iii) options to purchase 10,000 shares of common stock under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan. Excludes a total of 326,530 shares of common stock held in trusts for the benefit of Mr. Kimmel s adult children, as to which shares Mr. Kimmel has neither the power of disposition nor the power to vote.

(i) Mr. Loverro may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of the status of KIA V and KEP V, as members of Endo Pharma LLC. Mr. Loverro may be deemed to share beneficial ownership of shares of



common stock owned of record by KIA V and KEP V, by virtue of his status as a limited partner of the general partner of KIA V and as a limited partner of KEP V. Mr. Loverro could be deemed to share investment and voting power along with the other partners with respect to securities owned by KIA V and KEP V, but disclaims beneficial ownership of such securities except to the extent of his pecuniary interest.

(j) This amount includes 1,344,416 shares of common stock owned by Karen Lyle, wife of Mr. Lyle, as to which Mr. Lyle disclaims beneficial ownership. Excludes (i) 38 shares owned by Mr. Lyle s son, as to which Mr. Lyle also disclaims beneficial ownership and (ii) 500,000 shares of common stock held in a trust for the benefit of the children of Mr. and Mrs. Lyle, as to which shares Mr. Lyle has neither the power of disposition nor the power to vote.

(k) The business address for Mr. Mitchell is c/o Morvillo, Abramowitz, Grand, Iason & Silberberg, PC, 565 Fifth Avenue, New York, NY 10017. This amount includes 10,000 options under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.

(l) The business address for Mr. O Donnell is Metzler Corporation, 399 Park Ave., 32nd Floor, New York, NY 10022. This amount includes 10,000 options under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.

(m) This amount includes options that each of Mr. Lankau and Ms. Berry hold in the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.

(n) As part of the 1997 acquisition of Endo from the then DuPont Merck Pharmaceutical Company, KIA V and KEP V acquired respectively 847,028 and 71,722 shares of our common stock, representing 77.0% and 6.5%, respectively of the 1,100,000 shares of our common stock then outstanding. Subsequent to the acquisition, KEP V transferred 500 shares to an affiliate of Kelso. KIA V and KEP V, due to their common control, could be deemed to beneficially own each other s shares, but disclaim this beneficial ownership. KIA V and KEP V may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of their status as members of Endo Pharma LLC. KIA V and KEP V share investment and voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaim beneficial ownership of such securities except to the extent of its pecuniary interest.

(o) Kelso Partners V, L.P. may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of its status as a general partner of KIA V, which is a member of Endo Pharma LLC. KP V shares investment and voting power along with its general partners with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities except to the extent of its pecuniary interest.

(p) The business address for this person is 500 Campus Drive, Suite 220, Florham Park, New Jersey 07932.

(q) Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd., TRV Employees Fund, L.P., The Travelers Insurance Company and The Travelers Life and Annuity Company, could be deemed to beneficially own each other s shares, but disclaim this beneficial ownership.

(r) These entities may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of the status of each of them as members of Endo Pharma LLC, to the extent of each entity s pecuniary interest.



## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

### Stockholders Agreements

Concurrently with the merger with Algos, we, Endo Pharma LLC and the affiliates of Kelso & Company that owned the majority of our common stock prior to the formation of Endo Pharma LLC entered into two stockholders agreements with certain of our non-management employees and substantially all our management employees, respectively. Under these agreements, Endo Pharma LLC has the right to repurchase the common stock held by the employee parties at its fair market value on termination of their employment with us, unless their employment is terminated by us for cause. If their employment is terminated for cause, the repurchase price is the lesser of fair market value and the price such employee paid for the stock. Endo Pharma LLC has a right of first refusal to purchase any shares of common stock that the employee parties wish to transfer.

If Endo Pharma LLC wishes to sell in any transaction or series of transactions more than 25% of the stock it owned at the time of the merger, other than through a broker or on a national securities exchange, it must include in such sale, at the option of each employee party to either of these agreements, the portion of such employee s shares that is equal to the portion the proposed number of sale shares bears to the number of shares then owned by Endo

Pharma LLC and the remaining management or non-management employee stockholders, as the case may be, who are parties to the same agreement.

If Endo Pharma LLC proposes at any time to transfer at least 60% of the common stock it then owns to a third party, it has the right to require employees who are party to either agreement to include in such transfer the portion of such stockholder s shares that is equal to the portion the proposed number of sale shares bears to the number of shares then owned by Endo Pharma LLC and the remaining management or non-management employee stockholders, as the case may be, who are parties to the same agreement.

If Endo Pharma LLC demands that we register any of its shares for resale pursuant to its registration rights (see Endo Pharma LLC ), employee parties are entitled to require us to include their shares in such registration statement, subject to customary cut-backs in the case of an underwritten offering.

**Endo Pharma LLC**

In connection with the Algos acquisition, affiliates and designees of Kelso contributed approximately 85.8% of the common stock originally contributed to Endo Pharma LLC, and they continue to have an approximately 85.8% interest in Endo Pharma LLC. Endo Pharma LLC now owns approximately 78.7% of all of the issued and outstanding common stock. Currently, Messrs. Goldberg and Wahrhaftig and Ms. Ammon serve as members of the Board of Managers of Endo Pharma LLC.

*Option Plans*

In order to ensure that the exercise of employee stock options that were outstanding prior to our merger with Algos would only affect holders of our common stock that held these shares prior to the merger, we agreed with Endo Pharma LLC that those employee stock options would be exercisable only into shares of common stock that are held by Endo Pharma LLC. These plans are titled: Endo Pharma LLC 1997 Amended and Restated Executive Stock Option Plan, Endo Pharma LLC 1997 Amended and Restated Employee Stock Option Plan, Endo Pharma LLC Amended and Restated 2000 Supplemental Executive Stock Option Plan and Endo Pharma LLC Amended and Restated 2000 Supplemental Employee Stock Option Plan. See Management s Discussion and Analysis of Financial Condition and Results of Operations Overview Compensation Related to Stock Options.



*Tax Sharing Agreement*

Under U.S. federal income tax law, the exercise of the options by our employees for our common stock held by Endo Pharma LLC generally will result in compensation deductions to us. In general, to the extent that we are permitted to deduct these amounts in computing our income tax liability, our income tax liability would be reduced. Because Endo Pharma LLC (and not us) will provide the shares issued upon the exercise of the options, we, Endo Inc. and Endo Pharma LLC entered into an agreement under which, in general, we will pay to Endo Pharma LLC the amount of the tax benefits we receive as a result of the exercise of these current stock options into shares of common stock held by Endo Pharma LLC for the years in which these tax benefits arise. This agreement does not apply to the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.

*Registration Rights Agreement*

We have granted Endo Pharma LLC certain registration rights with respect to the common stock contributed to it on formation. See Shares Eligible for Future Sale Registration Rights.

**Kelso & Company**

*Financial Advisory Services Agreement*

Prior to the acquisition of Algos Pharmaceutical Corporation in July 2000, we had a pre-existing agreement with Kelso to:

pay Kelso an annual fee of $347,000 for financial advisory services,

indemnify Kelso in providing its services, and

reimburse Kelso for out-of-pocket expenses incurred.

In connection with the completion of the Algos acquisition, we terminated this agreement to pay an annual fee to Kelso by making a one-time payment to Kelso of $1.5 million in July 2000. However, the arrangements for indemnification and reimbursement of specific expenses survived the termination of this annual fee arrangement. Mr. Goldberg and Mr. Wahrhaftig, two of our directors, are Managing Directors of Kelso. Mr. Loverro, another director of the Company, is a Vice President of Kelso.

*Kelso Side Letter*

Kelso Investment Associates V, L.P. and Kelso Equity Partners V, L.P., which were our majority stockholders prior to the merger with Algos, agreed in a binding letter agreement with Algos and us, dated November 26, 1999, that, until July 17, 2002, they will not, and will not permit any of their affiliates to which they have transferred any of their shares of common stock, including Endo Pharma LLC to, sell their shares except pursuant to:

(a) Rule 144 under the Securities Act,

(b) an effective registration statement filed under the Securities Act,

(c) privately negotiated sales to any person or group of affiliated persons that do not aggregate more than 5.0% of the issued and outstanding common stock at the time of the sale,

(d) a transaction in which all of our stockholders are permitted to participate on equal economic terms and on a pro rata basis in accordance with their ownership, or

(e) any transfer, sale or distribution to any affiliate of these Kelso entities.



In addition, these parties agreed that, until July 17, 2002, they would not engage in any transaction that would be a going private transaction within the meaning of Rule 13e-3 of the Securities Exchange Act of 1934, as amended, unless the holders of the majority of the then outstanding common stock not affiliated with either of these Kelso entities have approved the transaction by a vote or other action.

**Other Matters**

Mr. Kimmel, a director, had been, until January 1, 2001, a partner at the law firm Latham & Watkins LLP, which had performed legal services for Algos Pharmaceutical Corporation from time to time.

Mr. Mitchell, a director, performs legal services for us from time to time and in fiscal year 2000 was paid $117,050 for services rendered. Mr. Mitchell also invests in Kelso transactions from time to time.

Mr. Lyle, a director, currently serves as a consultant to U.S. Dermatologics, Inc., a company in which we own 1,330,000 shares, or less than 10% of the outstanding shares. Our Board of Directors granted Mr. Lyle permission to accept such position, waiving a provision of his current consulting agreement with us that would have precluded him from doing so.



## DESCRIPTION OF CAPITAL STOCK

### Authorized Capital Stock

Under our current charter, we have the authority to issue up to 175,000,000 shares of common stock and 40,000,000 shares of preferred stock.

### Common Stock

*Common Stock Outstanding.* As of September 21, 2001, there were 89,138,950 shares of common stock outstanding, which were held of record by approximately 100 shareholders.

Shares of our common stock are listed on the Nasdaq National Market and trade under the symbol ENDP.

*Dividends.* Owners of shares of common stock are entitled to receive dividends when, as and if declared by our board of directors, out of funds legally available for their payment, subject to the rights of holders of any outstanding shares of preferred stock.

*Voting Rights.* Owners of shares of common stock are entitled to one vote per share. Subject to the rights of the holders of any preferred stock pursuant to applicable law or the provision of any future certificate of designations creating a specific series of preferred stock, all voting rights are vested in the owners of shares of common stock. Owners of shares of common stock have non-cumulative voting rights, which means that the holders of more than 50% of the shares voting for the election of directors can elect 100% of the directors.

*Rights Upon Liquidation.* In the event of our voluntary or involuntary liquidation, dissolution or winding up, the owners of shares of common stock will be entitled to share equally in any assets available for distribution after the payment in full of all debts and distributions and after the owners of any of our outstanding preferred stock have received their liquidation preferences in full.

*Other Rights.* Owners of shares of common stock are not entitled to pre-emptive rights with respect to the future issuances of common stock. We may, however, enter into contracts with stockholders to grant holders pre-emptive rights. Shares of common stock are not convertible into shares of any other class of capital stock. If we merge or consolidate with or into another company and, as a result, the shares of common stock are converted into or exchangeable for other securities or property including cash, all owners of shares of common stock will be entitled to receive the same kind and amount of such consideration for each share of common stock.

### Preferred Stock

No shares of preferred stock are outstanding. Our board of directors may, without further action by our 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.

**Warrants**

*Warrants Issued to Algos Stockholders in the Merger*

*General.* In the merger, former Algos stockholders received, for each of their Algos common shares, one warrant exercisable, for $0.01 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. A total of 17,810,526 warrants were issued and remain outstanding.



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, representing an aggregate of 20,575,507 additional shares.

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, representing an aggregate of 11,302,039 additional shares.

If the FDA approves MorphiDex® after September 30, 2002 and on or prior to March 31, 2003, then upon exercise of these warrants, each warrant will be exercisable into 0.263158 shares of common stock, representing an aggregate of 4,692,659 additional shares.

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.

*Exercisability and Expiration.* 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.

*Transferability.* Each Algos stockholder was able to elect whether to receive transferable or non-transferable warrants. Transferable warrants are listed on the Nasdaq National Market under the symbol ENDPW.

*Dividends and Other Distributions.* If the warrants are exercisable and we have authorized:

- the issuance of subscription rights, options or warrants to all holders of common stock; or
- the distribution of indebtedness or assets or cash to all holders of common stock;

then, upon exercise, each holder of warrants will receive his, her or its pro rata share of such dividends or other distributions.

*Reorganization, Consolidation, Merger or Sale.* In the event of any:

- capital reorganization (other than any capital reorganization that does not result in any reclassification of common stock);
- consolidation or merger of us with and into another corporation (other than a consolidation or merger in which we are the continuing corporation and which does not result in any reclassification of common stock); or

sale of all or substantially all of our assets;

then, upon exercise, each holder of warrants will receive the number of shares of stock or other securities or property to which they would have been entitled upon such event if the warrant had been exercised in full immediately prior to such event.

*Antidilution Provisions.* The number of shares of common stock issuable upon exercise of the warrants and the exercise price of the warrants are subject to adjustment in the event that we:

pay a dividend or make a distribution on the common stock in shares of common stock or other capital stock; or

subdivide, split, combine or reclassify our outstanding shares of common stock into a different number of securities of the same class.



The number of shares of common stock issuable upon exercise of the warrants and the exercise price of the warrants are also subject to adjustment in the event that we:

issue or sell to any of our affiliates shares of common stock at a price per share less than the then current market value of common stock; or

distribute to any of our affiliates any rights, options or warrants entitling them to purchase shares of common stock or securities convertible into or exchangeable for common stock at a price per share less than the then current market value of the common stock,

and prior to such issuance, sale or distribution we did not first offer to issue, sell or distribute such shares, rights, options, warrants or convertible or exchangeable securities to all holders of common stock on the same economic terms and on a pro rata basis with the issuance, sale or distribution to our affiliates.

*No Other Rights.* No holder of a warrant will be entitled to any of the rights of a common stockholder, including, without limitation, the right to vote or to attend or receive any notice of meetings of stockholders or any of our other proceedings.

*Warrants Issued to Endo Stockholders Immediately Prior to the Merger*

*General.* Immediately prior to the merger, our then stockholders received, for each of their common shares, one warrant exercisable, for $0.01 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.

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, representing an aggregate of 29,720,177 additional shares.

*Other Terms.* All of the other terms of these warrants are substantially identical to the warrants that we issued to the Algos stockholders in the merger, described above.

*Series A Warrants*

*General.* Holders of the Series A warrants of Algos that were outstanding at the time of the merger received warrants to purchase common stock with substantially the same terms and conditions as the then-existing Series A warrants. Each warrant was exercisable to purchase one share of common stock with an exercise price of $1.20 per

share. As of September 21, 2001, there were outstanding Series A warrants to purchase 21,580 shares of common stock. The Series A warrants expired if they were not exercised on or before September 25, 2001.

**Directors Liability**

Our certificate of incorporation allows us to eliminate the personal liability of our directors and to indemnify directors and officers to the fullest extent authorized by Delaware Law.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock and transferable warrants is American Stock Transfer & Trust Company. Its address is 40 Wall Street, New York, New York 10005.



## SHARES ELIGIBLE FOR FUTURE SALE

The market price of our common stock could decline as a result of future sales of substantial amounts of our common stock, or the perception that such sales could occur.

**Sale of Restricted Shares**

Upon completion of this offering, based upon the number of shares outstanding as of September 21, 2001, we will have an aggregate of 100,538,950 outstanding shares of common stock, excluding up to 35,376,550 shares underlying outstanding warrants and options exercisable for shares to be issued by us. Of the outstanding shares, a total of 26,913,161 shares, or 28,623,161 shares if the underwriters over-allotment option is exercised in full, will be freely tradable without restriction or further registration under the Securities Act, except that any shares purchased by our affiliates, as that term is defined in Rule 144 under the Securities Act, may generally only be sold in compliance with the limitations of Rule 144 described below. As defined in Rule 144, an affiliate of an issuer is a person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with the issuer. Shares of our common stock which are purchased in the open market by an affiliate will be deemed restricted securities, as that term is defined under Rule 144. Such restricted securities may be sold in the public market only if they qualify for an exemption from registration under Rule 144, including Rule 144(k). The remaining 73,625,789 outstanding shares of our common stock are held by affiliates, including Endo Pharma LLC, and are subject to the resale restrictions of Rule 145(d) or such shares constitute restricted securities subject to Rule 144. In addition, certain affiliates of Kelso & Company, which hold a controlling interest in Endo Pharma LLC, have agreed with us that until July 17, 2002 they will not permit Endo Pharma LLC to sell their shares except pursuant to:

(a) Rule 144 under the Securities Act,

(b) an effective registration statement filed under the Securities Act,

(c) privately negotiated sales to any person or group of affiliated persons that do not aggregate more than 5.0% of the issued and outstanding common stock at the time of the sale,

(d) a transaction in which all of our stockholders are permitted to participate on equal economic terms and on a pro rata basis in accordance with their ownership, or

(e) any transfer, sale or distribution to any affiliate of these Kelso entities.

In addition, these parties agreed that, until July 17, 2002, they would not engage in any transaction that would be a going private transaction within the meaning of Rule 13e-3 of the Securities Exchange Act of 1934, as amended, unless the holders of the majority of the then outstanding common stock not affiliated with Kelso & Company have approved the transaction by a vote or other action.

*Lock-Up Agreements*

Endo Pharma LLC and our officers and directors have agreed, subject to limited exceptions, not to offer, sell, contract to sell, pledge or otherwise dispose of any shares of common stock or any security convertible into or exchangeable for common stock for a period of 90 days from the date of this prospectus without the prior written consent of Salomon Smith Barney Inc. Immediately following this offering, these stockholders will own 73,625,789 shares, representing approximately 73.2% of the then outstanding shares of common stock, or approximately 72.0% if the underwriters over-allotment option is exercised in full.



We have agreed not to issue, sell or otherwise dispose of any shares of common stock during the 90-day period following the date of the prospectus, except we may grant options to purchase shares of common stock under certain stock option plans.

**Rule 144**

In general, under Rule 144 as currently in effect a person who has beneficially owned restricted shares of our common stock for at least one year, including a person who is an affiliate, is entitled to sell within any three-month period a number of shares that does not exceed the greater of:

1% of the number of shares of common stock then outstanding, which is expected to be approximately 1,005,390 shares upon completion of this offering, assuming no exercise of the underwriters over-allotment option; or

the average weekly trading volume of the common stock on the Nasdaq National Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to a sale, subject to restrictions specified in Rule 144.

Sales under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

**Rule 144(k)**

Under Rule 144(k), a person who has not been one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned the restricted shares proposed to be sold for at least two years, is entitled to sell those shares without regard to the volume, manner-of-sale or other limitations contained in Rule 144.

**Rule 145(d)**

An affiliate holding shares of our common stock that are subject to the resale limitations of Rule 145(d) is allowed to sell such shares in the same manner as the persons described under Rule 144 but without being subject to Rule 144 s one-year holding and notice requirements.

**Warrants**

As described in Description of Capital Stock Warrants , we have issued warrants in connection with the Algos merger that are exercisable for up to a maximum of 34,412,836 shares of common stock and Series A warrants that were exercisable for up to 21,580 shares of common stock. A maximum of 20,597,087 shares would be freely tradeable upon exercise of these warrants.

**Stock Options**

As of the date of this prospectus, options to purchase a total of 915,149 shares of common stock were outstanding, of which 87,246 will be exercisable by December 31, 2001. These options were issued under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan and, when exercised, will result in the issuance by us of new shares of Common Stock. We have on file with the SEC a registration statement under the Securities Act covering shares of common stock underlying the options. Shares registered under this registration statement will, subject to Rule 144 limitations applicable to affiliates, be available for sale in the open market, unless such shares are subject to the lock-up agreements described above.

Some of our employees also hold options that may become exercisable for a total of 24,873,326 shares of the common stock currently held by Endo Pharma LLC. Substantially all of these options are governed by stockholders agreements with us and Endo Pharma LLC under



which Endo Pharma LLC has a right of first refusal over any sales of common stock by these employees See Certain Relationships and Related Transactions Stockholders Agreements.

**Registration Rights**

In connection with the formation of Endo Pharma LLC, we and Endo Pharma LLC entered into a registration rights agreement, providing Endo Pharma LLC with registration rights with respect to the shares of common stock owned by Endo Pharma LLC. The registration rights agreement provides, among other things, that Endo Pharma LLC, as a holder of such shares of common stock, is entitled to six demand registrations and, together with its permitted transferees (as defined in the registration rights agreement), unlimited piggyback registrations. No piggyback registrations will be permitted, however, if a managing underwriter (or, in the case of an offering that is not underwritten, a nationally recognized investment banker) determines in good faith and in writing that the participation in an incidental registration would adversely affect the offering, the marketability or the offering price of the securities to be sold by us in such registration. In addition, we are not required to effect any registration of common stock pursuant to the registration rights agreement that is incidental to the registration of any of our securities in connection with mergers, acquisitions, exchange offers, subscription offers, dividend reinvestment plans or any executive, employee benefit or compensation plans.

Pursuant to this registration rights agreement, we will pay all expenses in connection with demand and piggyback registrations other than underwriting discounts, commissions and transfer taxes. This agreement will continue in effect until the earlier of (1) its termination by the consent of us and Endo Pharma LLC or our respective successors in interest and (2) the date on which none of our registrable securities (as to be defined in the registration rights agreement) remain outstanding.

If Endo Pharma LLC demands that we register any of its shares for resale pursuant to its registration rights, certain employees and former employees holding a total of 187,442 shares are entitled to require us to include their shares in such registration statement, subject to customary cut-backs in the case of an underwritten offering.

## CERTAIN U.S. FEDERAL INCOME TAX CONSEQUENCES

## TO NON-U.S. HOLDERS OF COMMON STOCK

The following is a general discussion of the principal United States federal income and estate tax consequences of the ownership and disposition of our common stock by a non-U.S. holder. As used in this discussion, the term non-U.S. holder means a beneficial owner of our common stock that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation or partnership created or organized in or under the laws of the United States or any political subdivision of the United States, other than a partnership treated as a foreign person under U.S. Treasury regulations;
- an estate whose income is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust, in general, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust.

An individual may be treated as a resident of the United States in any calendar year for U.S. federal income tax purposes, instead of a nonresident, by among other ways, being present in the United States on at least 31 days in that calendar year and for an aggregate of at least 183 days during the current calendar year and the two immediately preceding calendar years. For purposes of this calculation, you would count all of the days present in the current year, one-third of the days present in the immediately preceding year and one-sixth of the days present in the second preceding year. Residents are taxed for U.S. federal income purposes as if they were U.S. citizens.

This discussion does not consider:

- U.S. state and local or non-U.S. tax consequences;
- specific facts and circumstances that may be relevant to a particular non-U.S. holder s tax position, including, if the non-U.S. holder is a partnership, that the U.S. tax consequences of holding and disposing of our common stock may be affected by certain determinations made at the partner level;
- the tax consequences for the stockholders, partners or beneficiaries of a non-U.S. holder;
- special tax rules that may apply to particular non-U.S. holders, such as financial institutions, insurance companies, tax-exempt organizations, U.S. expatriates, broker-dealers, and traders in securities; or
- special tax rules that may apply to a non-U.S. holder that holds our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment.

The following discussion is based on provisions of the U.S. Internal Revenue Code of 1986, as amended, applicable U.S. Treasury regulations and administrative and judicial interpretations, all as in effect on the date of this prospectus, and all of which are subject to change, retroactively or prospectively. The following discussion also assumes that a non-U.S. holder holds our common stock as a capital asset. **EACH NON-U.S. HOLDER SHOULD CONSULT ITS TAX ADVISOR REGARDING THE U.S. FEDERAL, STATE, LOCAL, AND NON-U.S. INCOME AND OTHER TAX CONSEQUENCES OF ACQUIRING, HOLDING, AND DISPOSING OF SHARES OF OUR COMMON STOCK.**

**Dividends**

We do not anticipate paying cash dividends on our common stock in the foreseeable future. See Dividend Policy. In the event, however, that we pay dividends on our common stock, we will have to withhold U.S. federal withholding tax at a rate of 30%, or at a lower rate if provided by an applicable income tax treaty and we have received proper certification of the application of such income tax treaty, from the gross amount of the dividends paid to a non-U.S. holder.

Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under an applicable income tax treaty and the manner of claiming the benefits of such treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the U.S. Internal Revenue Service.

Dividends that are effectively connected with a non-U.S. holder s conduct of a trade or business in the United States or, if provided in an applicable income tax treaty, dividends that are attributable to a permanent establishment in the United States, are not subject to the U.S. withholding tax, but are instead taxed in the manner applicable to U.S. persons. In that case, we will not have to withhold U.S. federal withholding tax if the non-U.S. holder complies with applicable certification and disclosure requirements. In addition, dividends received by a foreign corporation that are effectively connected with the conduct of a trade or business in the United States may be subject to a branch profits tax at a 30% rate, or at a lower rate if provided by an applicable income tax treaty.

**Gain on Disposal of Common Stock**

A non-U.S. holder generally will not be taxed on gain recognized on a disposition of our common stock unless:

the non-U.S. holder is an individual who holds our common stock as a capital asset, is present in the United States for 183 days or more during the taxable year of the disposition and meets certain other conditions (though any such person will generally be treated as a resident of the U.S.);

the gain is effectively connected with the non-U.S. holder s conduct of a trade or business in the United States or, in some instances if an income tax treaty applies, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States;

we are or have been a U.S. real property holding corporation for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the non-U.S. holder held our common stock.

We have determined that we are not, and we believe we will not become, a U.S. real property holding corporation.

Individual non-U.S. holders who are subject to U.S. tax because the holder was present in the U.S. for 183 days or more during the year of disposition are taxed on their gains (including gains from sale of our common stock and net of applicable U.S. losses from sale or exchanges of other capital assets incurred during the year) at a flat rate of 30%. Other non-U.S. holders who may be subject to U.S. federal income tax on the disposition of our common stock will be taxed on such disposition in the same manner in which citizens or residents of the U.S. would be taxed. In addition, if any such gain is taxable because we are or were a United States real property holding corporation, the buyer of our common stock will be required to withhold a tax equal to 10% of the amount realized on the sale.

Recently enacted U.S. federal legislation provides for reductions in the U.S. federal estate tax through 2009 and the elimination of the tax entirely in 2010. Under the legislation, the estate tax would be fully reinstated, as in effect

prior to the reductions, in 2011.



*Federal Estate Tax*

Common stock owned or treated as owned by an individual who is a non-U.S. holder at the time of death will be included in the individual s gross estate for U.S. federal estate tax purposes and may be subject to U.S. federal estate tax unless an applicable estate tax treaty provides otherwise.

*Information Reporting and Backup Withholding Tax*

We must report annually to the U.S. Internal Revenue Service and to each non-U.S. holder the amount of dividends paid to that holder and the tax withheld from those dividends. Copies of the information returns reporting those dividends and withholding may also be made available to the tax authorities in the country in which the non-U.S. holder is a resident under the provisions of an applicable income tax treaty or agreement.

Under some circumstances, U.S. Treasury regulations require additional information reporting and backup withholding on payments made with respect to or on our common stock. Under currently applicable law, the gross amount of dividends paid to a non-U.S. holder that fails to certify its non-U.S. holder status in accordance with applicable U.S. Treasury regulations generally will be subject to additional information reporting and backup withholding.

The payment of proceeds on the disposition of common stock by a non-U.S. holder to or through a U.S. office of a broker or a non-U.S. office of a U.S. broker generally will be reported to the U.S. Internal Revenue Service and reduced by backup withholding unless the non-U.S. holder either certifies its status as a non-U.S. holder under penalties of perjury or otherwise establishes an exemption and certain other conditions are met. The payment of proceeds on the disposition of common stock by a non-U.S. holder to or through a non-U.S. office of a non-U.S. broker will not be reduced by backup withholding or reported to the U.S. Internal Revenue Service unless the non-U.S. broker has certain enumerated connections with the United States.

Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder will be refunded, or credited against the holder s U.S. federal income tax liability, if any, provided that certain required information is furnished to the U.S. Internal Revenue Service.



## UNDERWRITING

J.P. Morgan Securities Inc. and Salomon Smith Barney Inc. are acting as joint bookrunning managers of the offering and, together with SG Cowen Securities Corporation and First Union Securities, Inc., are acting as representatives of the underwriters named below. Subject to the terms and conditions of the underwriting agreement dated the date of this prospectus, each underwriter named below has agreed to purchase, and we have agreed to sell to that underwriter, the number of shares set forth opposite the underwriter s name.

| Underwriter | Number of Shares |
|---|---|
| J.P. Morgan Securities Inc. | |
| Salomon Smith Barney Inc. | |
| SG Cowen Securities Corporation | |
| First Union Securities, Inc. | |
| Total | 11,400,000 |

The underwriting agreement provides that the obligations of the underwriters to purchase the shares included in this offering are subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all the shares, other than those covered by the over-allotment option described below, if they purchase any of the shares.

The underwriters propose to offer some of the shares directly to the public at the public offering price set forth on the cover page of this prospectus and some of the shares to dealers at the public offering price less a concession not to exceed $ per share. The underwriters may allow, and the dealers may reallow, a concession not to exceed $ per share on sales to other dealers. If all of the shares are not sold at the public offering price, the representatives may change the public offering price and the other selling terms.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 1,710,000 additional shares of common stock at the public offering price less the underwriting discount. The underwriters may exercise the option solely for the purpose of covering over-allotments, if any, in connection with this offering. To the extent the option is exercised, each underwriter must, purchase a number of additional shares approximately proportionate to that underwriter s initial purchase commitment.

We, our officers, directors, and Endo Pharma LLC have agreed, subject to limited exceptions, that, for a period of 90 days from the date of this prospectus, we and they will not, without the prior written consent of Salomon Smith Barney Inc., offer, sell, contract to sell, pledge or otherwise dispose of any shares of our common stock or any securities convertible into or exchangeable for our common stock. Salomon Smith Barney Inc. in its sole discretion may release any of the securities subject to these lock-up agreements at any time without notice. See Shares Eligible for Future Sale.

Our common stock is traded on the Nasdaq National Market under the symbol ENDP.

The following table shows the underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters option to purchase additional shares of common stock.

| Paid by Us |
|---|

| | No Exercise | Full Exercise |
|---|---|---|
| Per share | $ | $ |
| Total | $ | $ |



In connection with the offering, Salomon Smith Barney Inc. on behalf of the underwriters, may purchase and sell shares of common stock in the open market. These transactions may include short sales, syndicate covering transactions and stabilizing transactions. Short sales involve syndicate sales of common stock in excess of the number of shares to be purchased by the underwriters in the offering, which creates a syndicate short position. Covered short sales are sales of shares made in an amount up to the number of shares represented by the underwriters over-allotment option. In determining the source of shares to close out the covered syndicate short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. Transactions to close out the covered syndicate short involve either purchases of the common stock in the open market after the distribution has been completed or the exercise of the over-allotment option. The underwriters may also make naked short sales of shares in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of bids for or purchases of shares in the open market while the offering is in progress.

The underwriters also may impose a penalty bid. Penalty bids permit the underwriters to reclaim a selling concession from an underwriter when Salomon Smith Barney Inc. repurchases shares originally sold by that syndicate member in order to cover syndicate short positions or make stabilizing purchases.

Any of these activities may have the effect of preventing or retarding a decline in the market price of the common stock. They may also cause the price of the common stock to be higher than the price that would otherwise exist in the open market in the absence of these transactions. The underwriters may conduct these transactions on the Nasdaq National Market or in the over-the-counter market, or otherwise. If the underwriters commence any of these transactions, they may discontinue them at any time.

We estimate that our total expenses attributable to this offering will be approximately $1.25 million, excluding underwriting discounts and commissions. The underwriters have agreed to reimburse us for certain expenses in connection with this offering.

The underwriters may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business. Affiliates of J.P. Morgan Securities Inc., First Union Securities, Inc. and SG Cowen Securities Corp. are lenders under our credit agreement, for which they received customary fees. We are negotiating with affiliates of J.P. Morgan Securities Inc., Salomon Smith Barney Inc., First Union Securities, Inc. and SG Cowen Securities Corp. for a new credit facility, for which we expect to pay customary fees. See Management s Discussion and Analysis of our Financial Condition and Results of Operations Liquidity and Capital Resources New Credit Facility. As discussed under Use of Proceeds, we intend to use a portion of the proceeds from this offering to repay in full the term loans under the existing credit agreement. As of the date of this prospectus, there were outstanding loans of approximately $10.9 million, $4.8 million and $2.3 million to affiliates of J.P. Morgan Securities Inc., First Union Securities, Inc. and SG Cowen Securities Corp., respectively. Accordingly, we expect that more than 10% of the proceeds from this offering, not including underwriting compensation, will be received by entities that are affiliated with members of the National Association of Securities Dealers, Inc. that are participating in this offering.

Additionally, affiliates of Salomon Smith Barney Inc. may be deemed to beneficially own more than 10% of the shares of our common stock through their ownership of membership interests in Endo Pharma LLC. As a result, this offering is being conducted in compliance with NASD Conduct Rules 2710(c)(8) and 2720. Pursuant to those rules, the appointment of a qualified independent underwriter is not required



in connection with this offering, as a bona fide independent market (as defined in the NASD Conduct Rules) exists in the shares of our common stock.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, or to contribute to payments the underwriters may be required to make because of any of those liabilities.

## LEGAL MATTERS

Skadden, Arps, Slate, Meagher & Flom LLP, New York, New York is acting as legal counsel to Endo Pharmaceuticals Holdings Inc. Skadden, Arps, Slate, Meagher & Flom LLP represents Kelso & Company and its affiliates from time to time. Debevoise & Plimpton, New York, New York is acting as legal counsel to the underwriters. Debevoise & Plimpton also represents Kelso and its affiliates from time to time.

## EXPERTS

The financial statements as of December 31, 1999 and 2000 and for each of the three years in the period ended December 31, 2000 of Endo Pharmaceuticals Holdings Inc. included in this prospectus and the related financial statement schedule included elsewhere in the registration statement have been audited by Deloitte & Touche LLP, independent auditors, as stated in their reports, appearing herein and elsewhere in the registration statement, and have been so included in reliance upon the reports of such firm given upon their authority as experts in accounting and auditing.

The financial statements as of December 31, 1999 and 1998 and for each of the two fiscal years in the period ending December 31, 1999 of Algos Pharmaceutical Corporation (a development stage enterprise) included in this prospectus, have been so included in reliance on the report of PricewaterhouseCoopers LLP, independent accountants, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

We file reports and other information with the SEC. We have filed a registration statement on Form S-3 with the SEC regarding this offering. This prospectus, which is part of the registration statement, does not contain all of the information included in the registration statement, and you should refer to the registration statement and its exhibits to read that information. References in this prospectus to any of our contracts or other documents are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract or document.

You may read and copy the registration statement, the related exhibits and the other material we file with the SEC at the SEC s public reference room at 450 Fifth Street, N.W., Washington, D.C. 20549 and at the SEC s regional offices in Chicago, Illinois and New York, New York. You can also request copies of those documents, upon payment of a duplicating fee, by writing to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference rooms. The SEC also maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file with the SEC. The site s address is www.sec.gov. You may also request a copy of these filings, at no cost, by writing or telephoning us as follows: 100 Painters Drive, Chadds Ford, Pennsylvania 19317, Attention: Chief Financial Officer or (610) 558-9800.

## INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we later file with the SEC will automatically update and supersede the information contained or incorporated by reference in this prospectus. Accordingly, we incorporate by reference:

our annual report on Form 10-K for the year ended December 31, 2000;

our information statement on Schedule 14C for our 2001 annual stockholders meeting;

our quarterly reports on Form 10-Q for the three months ended March 31 and June 30, 2001;

our current reports on Form 8-K dated March 15, 2001, March 23, 2001, May 14, 2001, August 31, 2001, September 5, 2001 and September 10, 2001, not including the information in Item 9 of our Form 8-K dated September 10, 2001; and

the description of our common stock contained in our registration statement on Form 8-A dated July 12, 2000, including any amendment or report updating this description.

All documents which we subsequently file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 prior to the termination of this offering shall be deemed to be incorporated by reference into this prospectus from the date of filing of such documents. These documents are or will be available for inspection or copying at the locations identified above under the caption Where You Can Find More Information.

We will provide without charge to each person, including any beneficial owner of common stock, to whom this prospectus is delivered, upon written or oral request, a copy of any and all of the documents that have been incorporated by reference in this prospectus (other than exhibits to such documents unless such exhibits are specifically incorporated by reference but not delivered with this prospectus). You should direct requests for documents to 100 Painters Drive, Chadds Ford, Pennsylvania 19317, attn: Chief Financial Officer. His telephone number is (610) 558-9800.



## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**ALGOS PHARMACEUTICAL CORPORATION**

## INDEPENDENT AUDITORS REPORT

The Board of Directors

Endo Pharmaceuticals Holdings Inc.

We have audited the accompanying consolidated balance sheets of Endo Pharmaceuticals Holdings Inc. and subsidiaries as of December 31, 1999 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, 2000. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements 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, 1999 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2000 in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP

Deloitte & Touche LLP

Philadelphia, Pennsylvania
February 23, 2001



## ENDO PHARMACEUTICALS HOLDINGS INC.

## CONSOLIDATED BALANCE SHEETS

## DECEMBER 31, 1999 AND 2000
**(In thousands, except share data)**

| | 1999 | 2000 |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS: | | |

| | |
|---|---|
| Cash and cash equivalents | $22,028 $59,196 |
| Accounts receivable, net of allowance of $444 and $515 at December 31, 1999 and 2000, respectively | 62,254 78,312 |
| Inventories | 21,269 29,746 |
| Prepaid expenses | 3,356 3,496 |
| Deferred income taxes | 9,520 2,304 |
| Total current assets | 118,427 173,054 |
| PROPERTY AND EQUIPMENT, Net | 5,712 5,742 |
| GOODWILL AND OTHER INTANGIBLES, Net of amortization of $15,625 and $41,468 at December 31, 1999 and 2000, respectively | 192,081 284,560 |
| DEFERRED INCOME TAXES | 8,636 736 |
| RESTRICTED CASH | 150 |
| OTHER ASSETS | 4,580 3,598 |
| TOTAL ASSETS | $329,436 $467,840 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | |
| CURRENT LIABILITIES: | |
| Accounts payable | $19,185 $15,855 |
| Accrued expenses | 33,641 45,520 |
| Income taxes payable | 75 2,549 |
| Current portion of long-term debt | |

| | | |
|---|---|---|
| | 15,985 | 36,371 |
| Total current liabilities | 68,886 | 100,295 |
| LONG-TERM DEBT, Less current portion | 175,218 | 162,154 |
| OTHER LIABILITIES | 6,745 | 7,218 |
| COMMITMENTS AND CONTINGENCIES | | |
| STOCKHOLDERS EQUITY: | | |
| Preferred Stock, $.01 par value; 40,000,000 shares authorized; none issued | | |
| Common Stock, $.01 par value; 175,000,000 shares authorized; 71,323,644 and 89,138,950 shares issued in 1999 and 2000, respectively | 713 | 891 |
| Additional paid-in capital | 109,707 | 385,955 |
| Accumulated deficit | (31,833) | (188,673) |
| Total stockholders equity | 78,587 | 198,173 |
| TOTAL LIABILITIES AND STOCKHOLDERS EQUITY | $329,436 | $467,840 |

See notes to consolidated financial statements.

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**YEARS ENDED DECEMBER 31, 1998, 1999 AND 2000**
**(In thousands, except share and per share data)**

| | 1998 | 1999 | 2000 |
|---|---|---|---|
| NET SALES | $108,370 | $138,546 | $197,429 |
| COST OF SALES | 54,731 | 58,263 | 63,041 |
| GROSS PROFIT | 53,639 | 80,283 | 134,388 |
| COSTS AND EXPENSES: | | | |
| Selling, general and administrative | 25,540 | 42,921 | 56,537 |
| Research and development | 5,893 | 9,373 | 26,012 |
| Depreciation and amortization | 7,373 | 8,309 | 27,624 |
| Compensation related to stock options primarily selling, general and administrative | | | 15,300 |
| Purchased in-process research and development | | | 133,200 |
| Merger and other related costs | | | 1,583 |
| Separation benefits | | | 22,034 |
| OPERATING INCOME (LOSS) | 14,833 | 19,680 | (147,902) |

| | | | |
|---|---|---|---|
| INTEREST EXPENSE, Net of interest income of $838, $1,065 and $2,700, respectively | 14,451 | 14,347 | 15,119 |
| INCOME (LOSS) BEFORE INCOME TAX (BENEFIT) | 382 | 5,333 | (163,021) |
| INCOME TAX (BENEFIT) | 181 | 2,073 | (6,181) |
| NET INCOME (LOSS) | $201 | $3,260 | $(156,840) |
| NET INCOME (LOSS) PER SHARE | | | |
| Basic and Diluted | $0.00 | $0.05 | $(1.97) |
| Weighted average shares (Basic and Diluted) | 71,307,302 | 71,332,266 | 79,454,223 |

See notes to consolidated financial statements.

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**

**YEARS ENDED DECEMBER 31, 1998, 1999 AND 2000**
**(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, 1997 | 71,051,066 | $710 | $109,290 | $(35,294) | $74,706 |
| Issuance of Common Stock | 291,310 | 3 | 448 | | 451 |
| Net Income | | | | 201 | 201 |
| 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

See notes to consolidated financial statements.



**ENDO PHARMACEUTICALS HOLDINGS INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**YEARS ENDED DECEMBER 31, 1998, 1999 AND 2000**
**(In thousands)**

| | 1998 | 1999 | 2000 |
|---|---|---|---|
| OPERATING ACTIVITIES: | | | |
| Net income (loss) | $201 | $3,260 | $(156,840) |
| Adjustments to reconcile net (loss) income to net cash provided by operating activities: | | | |
| Depreciation and amortization | 7,373 | 8,309 | 27,624 |
| Purchased in-process research and development | | | 133,200 |
| Accretion of promissory notes | 675 | 2,001 | 3,579 |
| Deferred income taxes | 164 | 1,998 | (8,732) |
| Amortization of deferred financing costs | | | |

| | | | |
|---|---|---|---|
| | 1,283 | 1,199 | 1,234 |
| Non-cash portion of separation benefits | | | 20,782 |
| Compensation related to stock options | | | 15,300 |
| Other noncash charges | 133 | | |
| Changes in assets and liabilities which provided (used) cash: | | | |
| Accounts receivable | (11,886) | (29,245) | (15,960) |
| Inventories | (1,368) | (6,808) | (8,477) |
| Other assets | | (3,533) | (238) |
| Accounts payable | 5,099 | 7,234 | (6,792) |
| Accrued expenses | 18,758 | 28,958 | 27,367 |
| Income taxes payable | | | 2,549 |
| Other liabilities | 500 | 393 | 473 |
| Net cash provided by operating activities | 20,932 | 13,766 | 35,069 |
| INVESTING ACTIVITIES: | | | |
| Purchase of property and equipment | (1,487) | (2,124) | (1,534) |
| Acquisition of licensing rights | | (2,050) | (6,950) |
| Net cash acquired in the Merger | | | 19,611 |
| Net cash provided by (used in) investing activities | (3,537) | (9,074) | 18,077 |

| | | | |
|---|---|---|---|
| FINANCING ACTIVITIES: | | | |
| Issuance of Common Stock | 451 | | |
| Exercise of stock options | 7 | | |
| Repurchase of Common Stock | (31) | | |
| Repayments of long-term debt | (15,000) | (15,985) | |
| Net cash used in financing activities | (14,549) | (31) | (15,978) |
| NET INCREASE IN CASH AND CASH EQUIVALENTS | 2,846 | 4,661 | 37,168 |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 14,521 | 17,367 | 22,028 |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | $17,367 | $22,028 | $59,196 |
| SUPPLEMENTAL INFORMATION: | | | |
| Interest paid | $14,401 | $12,194 | $13,205 |

| | | | |
|---|---|---|---|
| Income taxes paid | $17 | $75 | |
| | | | |
| SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES: | | | |
| Promissory note issued under Manufacturing and Supply Agreement | $17,397 | $18,655 | $19,727 |
| | | | |
| | | | |
| Fair value of net assets acquired in the Merger, net of cash | $228,941 | | |

See notes to consolidated financial statements.



**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**YEARS ENDED DECEMBER 31, 1998, 1999 and 2000**

## 1. Organization and Acquisitions

Endo Pharmaceuticals Holdings Inc. (the Company ), through its wholly owned subsidiaries, Endo Pharmaceuticals Inc. ( Endo ) and Endo Inc., 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 |
| Total purchase price | $276,961 |

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 the Company s 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 used by the Company 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 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 (dollars in thousands). 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 |
|---|---|---|
| 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 stockholders of the Company, 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 to effect the acquisition of Algos Pharmaceutical Corporation ( Algos ). The stock of Endo and the stock of Endo Inc. are the only assets 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, 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 the Company s financial statements prospectively for reporting periods beginning July 17, 2000.

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 will be amortized over its estimated useful life of two years, patents of $3.2 million which will be amortized over their estimated useful lives of 17 years and goodwill of $104.8 million which will be amortized over its estimated useful life of three years. In addition, the Company recorded estimated liabilities for exit costs of $3.1 million related to non-cancelable lease payments and $1.1 million for employee relocation costs. The balance of the estimated liabilities for exit costs is unchanged as of December 31, 2000. Also, as a result of the Merger, it was determined that the utilization of the Company s federal deferred tax assets is uncertain. Accordingly, a valuation allowance has been recorded to fully reserve its federal deferred tax assets.

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 ( IPRD ) of $133.2 million which was immediately expensed in the consolidated statement of operations on the acquisition date. The methodology used by the Company 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 the Company s 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, it is unlikely that the development activities will have alternative use. If these projects are not successfully developed, the Company s 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 the Company would have achieved had the Merger been completed as of January 1, 1999, or the operating results that the Company may achieve in the future.

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

**2. Summary of Significant Accounting Policies**

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

*Nature of Operations and Customer and Supplier Concentration* The Company, through its wholly owned subsidiaries, is engaged in the marketing and sales of pharmaceuticals. The Company s sales are substantially through wholesale drug distributors who in turn supply products to pharmacies, hospitals and physicians. The Company is potentially subject to a concentration of credit risk with respect to its trade receivables. Three customers individually accounted for 26%, 21% and 14% of net sales in 1998, and 27%, 20%, and 13% of net sales in 1999. Four customers individually accounted for 26%, 16%, 12% and 10% of net sales in 2000. The Company performs ongoing credit evaluations of its customers and maintains sufficient allowances for estimated uncollectible accounts. Generally, the Company does not require collateral from its customers.

The Company has an agreement with DuPont for the manufacture and supply of substantially all of its 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 the Company could make alternative arrangements on a timely basis, if at all. Such interruption could have a material adverse effect on the Company s 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, sales allowances, returns and losses. The Company s 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* The Company considers 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 the Company s lease agreements is included in restricted cash.

*Derivative Financial Instruments* The Company uses an interest rate cap agreement ( Cap ), to manage its exposure to fluctuations in interest rates. This Cap is matched with debt and periodic cash payments and is accrued on a net basis as an adjustment to interest expense. Any fee associated with this instrument is amortized over its term. (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.

*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.

*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.

*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.

*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. The Company assesses 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.

*Long-Lived Assets* The Company reviews 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 they are identifiable cash flows that are largely independent from other asset groups. The Company uses the discounted future expected net cash flows, as its estimate of fair value, to determine the amount of impairment loss. The Company has 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 $8.1 million, $9.0 million and $2.6 million for the years ended December 31, 2000, 1999 and 1998.

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

*Use of Estimates* The preparation of the Company s financial statements in conformity with generally accepted accounting principles requires management 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. Actual results could differ from those estimates.

*Segment Information* The Company reports segment information in accordance with SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*. The Company has one reportable segment, pharmaceutical products.

*Recent Accounting Pronouncements* In June 1998, the Financial Accounting Standards Board (FASB) issued SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, which is effective for all fiscal years beginning after June 15, 1999. SFAS 133 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 on going 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.

Effective January 1, 2001, the Company recorded $228,000 as an accumulated transition adjustment as a reduction to earnings relating to derivative instruments that do not qualify for hedge accounting under SFAS 133.

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 the Company s 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 the Company s financial statements.

*Reclassifications* Certain reclassifications have been made to the prior year s financial statements to conform to classifications used in 2000.

**3. License and Collaboration Agreements**

In November 1998, the Company 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, the Company is required to pay Hind approximately $10 million (the License Fee ) based upon the achievement of certain milestones. During 2000, 1999 and 1998, the Company 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, 2000. In addition, beginning on March 19, 2001, the Company will pay Hind royalties based on net sales of the product.

In November 1999, the Company entered into a collaboration agreement with Lavipharm Laboratories, Inc. pursuant to which the Company obtained exclusive worldwide rights to Lavipharm s existing drug delivery technology platforms. Under the terms of this collaboration agreement, the Company paid an upfront license fee of $1 million.

The Company has licensed from a university certain patents and pending patent applications in the field of pain management. The Company is required to pay royalties equal to 4% of sales of licensed products. In addition, the Company 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)**

## 4. Property and Equipment

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

| | 1999 | 2000 |
|---|---|---|
| Machinery and equipment | $3,993 | $4,202 |
| Computer equipment and software | 3,475 | 4,687 |
| Furniture and fixtures | 489 | 845 |
| | 7,957 | 9,734 |
| Less accumulated depreciation | (2,245) | (3,992) |
| Total | $5,712 | $5,742 |

## 5. Goodwill and Other Intangibles

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

| | 1999 | 2000 |
|---|---|---|
| Goodwill | $196,706 | $299,928 |
| Licenses | 11,000 | 11,000 |

| | |
|---|---|
| Workforce in Place | 11,900 |
| Patents | 3,200 |
| | |
| | |
| 207,706 | 326,028 |
| Less accumulated amortization | |
| (15,625) | (41,468) |
| | |
| | |
| Total | |
| $192,081 | $284,560 |

**6. Long-Term Debt**

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

| | 1999 | 2000 |
|---|---|---|
| Tranche A Term Loan | $47,000 | $34,961 |
| Tranche B Term Loan | 103,000 | 99,054 |
| Notes payable | 41,203 | 64,510 |
| | | |
| | | |
| 191,203 | 198,525 | |
| Less current portion | | |
| (15,985) | (36,371) | |
| | | |
| | | |
| $175,218 | $162,154 | |

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. The Credit Agreement is 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 are segregated into two tranches, Tranche A Term Loan and Tranche B Term Loan. The Tranche A Term Loan is due in quarterly installments ranging from $2 million to $5 million beginning December 31, 1998, with a final payment due December 31, 2002. On June 3, 1998, Endo made an optional prepayment of the Tranche A Term Loan in the amount of $13 million. The Tranche B

Term Loan is due in quarterly installments ranging from $250,000 to $27 million beginning December 31, 1998 with a final payment due



**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

June 30, 2004. On June 3, 1998, Endo made an optional prepayment of the Tranche B Term Loan in the amount of $2 million. The prepayments made for both the Tranche A Term Loan and Tranche B Term Loan were applied to the most current payments due under the original payment schedules. The revolving commitment has availability of $25 million and matures December 31, 2002. No borrowings have been made under the revolving commitment.

Borrowings under the Tranche A Term Loan bear interest, which is payable at least quarterly, at a rate equal to the bank s floating alternate base rate plus a premium ranging from .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 the Company s performance against certain criteria. The effective borrowing rate was 7.8% and 8.4% as of December 31, 2000 and 1999, respectively.

Borrowings under the Tranche B Term Loan bear interest, which is payable at least quarterly, at a rate equal to the bank s floating alternate base rate plus a premium ranging from 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 the Company s performance against certain criteria. The effective borrowing rate was 8.8% and 8.9% as of December 31, 2000 and 1999, respectively.

Additionally, fees are 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 is payable quarterly.

The 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 Credit Agreement requires Endo to maintain certain ratios (as defined therein).

Endo 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 9.75% which approximated Endo s borrowing rate for similar instruments at the time of borrowing. The promissory note has a balance of $3.3 million and $3.0 million at December 31, 2000 and 1999, respectively.

On August 26, 2000, 1999 and 1998, Endo issued promissory notes to Dupont 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%, 7.0% and 7.0%, respectively, which approximates Endo s borrowing rate for similar instruments at the time of borrowing. The promissory notes have a balance of $61.2 million and $38.2 million as of December 31, 2000 and 1999, respectively.

The aggregate annual maturities of long-term debt for the five years subsequent to December 31, 2000 are as follows (in thousands):

| |
|---|
| 2001 |
| $36,371 |

2002
89,836
2003
37,121
2004
43,576

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 which expired August 27, 2000. The agreement set a maximum LIBOR rate Endo will 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. Endo does not enter into such transactions for trading or speculative purposes. The cost of this interest rate cap of $350,000 is being amortized as a component of interest expense over the term of the agreement which expires August 27, 2003. The agreement set a maximum LIBOR rate Endo will pay on the related notional amount of 8.0%. The unamortized cost for such agreement is included in other assets in the accompanying balance sheet (see Note 2 *Recent Accounting Pronouncements*).

**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.

*Other Long-Term Debt Including Current Portion* The carrying amounts reported for other long-term debt approximate fair value because the interest rates on these instruments are subject to changes with market interest rates.

*Interest Rate Cap* The fair value of this item is estimated to be $83,000 at December 31, 2000. The carrying amount of this item at December 31, 2000 was $311,000. Effective January 1, 2001, the carrying value of this derivative financial instrument will be 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*.)

**8. Income Taxes**

Income tax (benefit) consists of the following for 2000, 1999 and 1998 (in thousands):

| | 1998 | 1999 | 2000 |
|---|---|---|---|
| Current: | | | |
| Federal | | $1,578 | |
| State | $17 | $75 | 972 |
| | 17 | 75 | 2,550 |
| Deferred: | | | |
| Federal | 119 | 1,673 | (6,743) |
| State | 45 | 325 | (1,988) |
| | 164 | 1,998 | (8,731) |
| Total income tax (benefit) | $181 | $2,073 | $(6,181) |

A reconciliation of income tax (benefit) at the federal statutory income tax rate to the total income tax provision (benefit) for 2000, 1999 and 1998 is as follows (in thousands):

| | 1998 | 1999 | 2000 |
|---|---|---|---|
| Federal income tax (benefit) at the statutory rate | $130 | $1,813 | $(55,428) |
| State income tax (benefit) | 33 | 215 | (192) |
| Research and development credit utilized | | | (607) |
| Other | 18 | 45 | (210) |
| Effect of permanent items: | | | |
| Purchased in-process research and development | | | 45,288 |
| Goodwill | | | 5,419 |
| Other | | | (451) |
| Total income tax (benefit) | $181 | $2,073 | $(6,181) |

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):

| | 1999 | 2000 |
|---|---|---|
| Deferred tax assets: | | |
| Accrued expenses | $9,479 | $25,931 |
| Purchased in-process research and development | 14,734 | 13,250 |
| Net operating loss carryforward | 1,398 | 16,789 |
| Other | | 2,228 |

| | | |
|---|---|---|
| Total gross deferred income tax assets | 25,611 | 58,198 |
| Deferred tax liabilities: | | |
| Depreciation and amortization | (6,829) | (13,797) |
| Other | (626) | (569) |
| Total gross deferred income tax liabilities | (7,455) | (14,366) |
| Net deferred income tax asset | 18,156 | 43,832 |
| Valuation allowance | | (40,791) |
| | $18,156 | $3,041 |

The Company has evaluated the available evidence about future taxable income and other possible sources of realization of deferred tax assets and believes that a valuation allowance in the amount of $40.8 million is required at December 31, 2000. At December 31, 2000, the Company has $48.4 million in net operating loss carryforwards for tax purposes which expire through 2019.

**9. Service Agreements**

On August 26, 1997, the Company entered into various agreements with Dupont 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 the Company s existing and new pharmaceutical products.

**ENDO PHARMACEUTICALS HOLDINGS INC.**

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

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 the Company s existing and new pharmaceutical products. During 1999, the Company extended the Warehousing and Distribution Agreement through May 31, 2000. The Warehousing and Distribution Agreement expired 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 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 during 1999.

Any interruption or failure by Dupont to meet its obligations under the aforementioned agreements could have a material adverse effect on the Company s business, financial condition and results of operations.

The Company has entered into various service agreements to provide customer service support, warehouse and distribution services, certain financial functions, medical affair services, sales promotion and clinical studies. These agreements expire from 2001 through 2005. Although the Company has no reason to believe that these agreements will not be honored, failure by any of these third parties to honor their contractual obligations could have a material adverse effect on the Company s business, financial condition and results of operations.

**10. Commitments and Contingencies**

**Employment Agreements**

The Company has entered into employment agreements with certain members of management.

**License Agreements**

The Company has licensed from a university certain patents and pending patent applications in the field of pain management. The Company is required to pay royalties equal to 4% of sales of licensed products. In addition, the Company 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.

**Leases**

The Company leases office and laboratory facilities under certain noncancelable operating leases that expire through April 2008. These leases are renewable at the Company s option. A

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

summary of minimum future rental payments required under operating leases as of December 31, 2000 is as follows (in thousands):

| | |
|---|---|
| 2001 | $1,367 |
| 2002 | 1,691 |
| 2003 | 1,417 |
| 2004 | 1,419 |
| 2005 | 1,421 |
| Thereafter | 7,063 |
| Total | $14,378 |

Rent expense incurred under operating leases was $747,000, $523,000 and $452,000 for the years ended December 31, 2000, 1999 and 1998, respectively.

The Company has an option to purchase the office building located in Neptune, N.J. which is exercisable between April 29, 2001 and April 28, 2003.

**Research Contracts**

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

**Collaboration Agreements**

The Company has entered into certain collaboration agreements with third parties for the development of pain management products. These agreements require the Company to share in the development costs of such products and grant marketing rights to the Company for such products.

**Contingencies**

The Company may be subject to various claims arising out of the normal course of business with respect to commercial matters, including product liabilities, patent infringement matters, governmental regulation and other actions. In the opinion of management, the amount of ultimate liability with respect to these actions will not materially affect the financial position, results of operations or liquidity of the Company.

**11. Savings and Investment Plan**

On September 1, 1997, the Company 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 ). The Company matches 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. The Company s contributions are generally fully vested after five years of continuous service. Contributions by the Company amounted to $429,000, $329,000 and $264,000 for the years ended December 31, 2000, 1999 and 1998, 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 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, will not be required to return a portion of its shares in the Company to the Company s treasury so that the percentage ownership of the stockholders will remain 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 will no longer be 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 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, 2000, no shares of Preferred Stock have been issued.

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

The Class A Transferable Warrants and Class B Non-Transferable Warrants are exercisable at an exercise price of $.01 per share into a specified number of shares of Common Stock depending on the timing of the FDA s approval of MorphiDex® for one or more pain indications. As of December 31, 2000, there were outstanding 17,810,526 of these warrants. These warrants become exercisable on the fifth business day following the date on which the Company receives 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.

**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, 2000, there were outstanding 29,720,177 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.

**Series A Warrants**

The Series A Warrants are 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 have 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 expire 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 expire no later than December 31, 2012 unless an initial public offering 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, 1997 through December 31, 2000 is as follows:

| | Number of Shares | Weighted Average Exercise Price |
|---|---|---|
| Outstanding, December 31, 1997 | 17,366,958 | $2.50 |
| Granted | | |
| 1,064,218 $2.51 | | |
| Forfeited | | |
| (51,452) $2.51 | | |
| 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 |

The following table summarizes information about stock options outstanding under the Endo Pharma LLC Stock Option Plans at December 31, 2000:

**Options Outstanding**