ENDO PHARMACEUTICALS HOLDINGS INC
Form S-3
September 07, 2001

**As filed with the Securities and Exchange Commission on September 7, 2001**

**Registration No. 333-**

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# 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)**

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**Senior Vice President, General Counsel and Secretary**
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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

**CALCULATION OF REGISTRATION FEE**

| Title of Each Class of Securities to be Registered | Amount to be Registered(1) | Proposed Maximum Offering Price Per Share(2) | Proposed Maximum Aggregate Offering Price(2) | Amount of Registration Fee |
|---|---|---|---|---|
| Common stock, par value $0.01 per share | 13,110,000 shares | $10.925 | $143,226,750 | $35,806.70 |

(1) Includes 1,710,000 shares that may be issued upon exercise of the underwriters over-allotment option.

(2) Estimated solely for the purpose of determining the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended (the Securities Act ), based on the average of the high and low prices of the common stock on the Nasdaq National Market on September 6, 2001.

**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 7, 2001

**PRELIMINARY PROSPECTUS**

## 11,400,000 Shares

## [ENDO PHARMACEUTICALS HOLDINGS LOGO]

# 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 6, 2001, the last reported sale price of our common stock was $11.00 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 Pharmaceutical 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.



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*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.

*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 $ 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 August 24, 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 issuable upon the exercise of our Series A warrants;
- excludes up to 942,134 shares of common stock issuable by us upon the exercise of options granted to our employees, of which 87,246 will be exercisable by November 30, 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.

| | Six Months Ended |
|---|---|

| | Year Ended December 31, | | | 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.



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**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.



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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.



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**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 70% 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 $5.12 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 August 24, 2001, approximately 74 million shares of common stock, representing approximately 74% 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 942,134 shares that may be issued upon the exercise of options outstanding as of August 24, 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 November 30, 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 August 24, 2001, approximately 21,580 shares are currently exercisable.

While the holders of over 83% of our currently outstanding shares of common stock are 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 $ per share less than the public offering price paid, assuming an public offering price per share of $ and based on our net tangible book value as of June 30, 2001. In addition, investors who purchase shares in the offering will contribute % 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 942,134 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.



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## FORWARD-LOOKING STATEMENTS

We have made forward-looking statements in this document within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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 $ million in net proceeds from this offering, based upon the sale of 11,400,000 shares of common stock at the assumed offering price of $ 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 $ 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 6, 2001 | $12.09 | $7.74 |
| 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 August 24, 2001, we had approximately 100 shareholders of record of our common stock. The closing sale price of our common stock on September 6, 2001 was $11.00 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 the assumed offering price of $ per share, and after deducting underwriting discounts and estimated offering expenses payable by us, our as adjusted net tangible book value (deficit) at June 30, 2001 would have been $ million or $ per share. This represents an immediate increase in net tangible book value of $ per share to existing stockholders and an immediate dilution of $ 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
$
Net tangible book value (deficit) per share at June 30, 2001
$(0.83)
Increase per share attributable to this offering

As adjusted net tangible book value (deficit) per share after this offering

| | |
|---|---|
| Dilution per share to new investors in this offering | $ |

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 have an exercise price of $1.20 per share; and

942,134 shares of common stock issuable upon the exercise of outstanding stock options, which have a weighted average exercise price of $8.22 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 $ 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 | |
| Debt: | | |

| | | |
|---|---|---|
| Long-term debt, including current portion | $171,408 | (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 | |
| Additional paid-in capital | 385,955 | |
| Accumulated deficit | (200,180) | |
| Total stockholders equity | 186,666 | |
| Total capitalization | $358,074 | $ |

(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 | | |
| | (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(1) | 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) 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