

ENDO PHARMACEUTICALS HOLDINGS INC

Form 424B4

July 03, 2003

PROSPECTUS

**15,000,000 Shares**

**Endo Pharmaceuticals Holdings Inc.**

**Common Stock**

**\$15.50 per share**

The selling stockholders named in this prospectus are selling 15,000,000 shares. We will not receive any proceeds from the sale of shares offered by the selling stockholders. The selling stockholders have granted the underwriters an option to purchase up to 2,250,000 additional shares of common stock to cover over-allotments.

Our common stock is quoted on the Nasdaq National Market under the symbol ENDP. The last reported sale price of our common stock on the Nasdaq National Market on July 1, 2003 was \$16.07 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.

	<u>Per Share</u>	<u>Total</u>
Public Offering Price	\$ 15.5000	\$232,500,000
Underwriting Discount	\$ 0.73625	\$ 11,043,750
Proceeds to Selling Stockholders (before expenses)	\$ 14.76375	\$221,456,250

The underwriters expect to deliver the shares to purchasers on or about July 8, 2003.

**Joint Book-Running Managers**

**Citigroup**

**Bear, Stearns & Co. Inc.**

**Jefferies & Company, Inc.**  
July 1, 2003

**SG Cowen**

**You should rely only on the information contained in or incorporated by reference 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.**

---

**TABLE OF CONTENTS**

Summary	1
Risk Factors	9
Forward-Looking Statements	23
Use of Proceeds	24
Price Range of Common Stock	24
Dividend Policy	24
Capitalization	25
Selected Historical Consolidated Financial Data	26
Management's Discussion and Analysis of Financial Condition and Results of Operations	27
Business	45
Management	66
Principal and Selling Stockholders	69
Certain Relationships and Related Transactions	73
Description of Capital Stock	76
Shares Eligible for Future Sale	78
Certain U.S. Federal Tax Consequences to Non-U.S. Holders of Common Stock	81
Underwriting	84
Legal Matters	86
Experts	86
Where You Can Find More Information	87
Incorporation of Certain Documents by Reference	87

---

## 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 in this prospectus. 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, totaled \$15 billion in 2002. This represents an approximately 23% compounded annual growth rate since 1998. Our primary area of focus within this market is in the opioid analgesics segment. Total U.S. sales for this segment were \$4.6 billion in 2002, representing a compounded annual growth rate of 25% since 1998.

We have a portfolio of branded products that includes established brand names such as Lidoderm®, Percocet®, Percodan® and Zydone®. Branded products comprised approximately 63% of our net sales in 2002. Our generic portfolio, which accounted for 37% of net sales in 2002, currently consists of products that cover a variety of indications, most of which are focused in pain management. We focus on generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing.

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

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

### **Our Competitive Strengths**

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

*Established portfolio of branded products.* We have assembled a portfolio of branded pharmaceutical products to treat and manage pain, including:

Lidoderm®, a topical patch product containing lidocaine, is the first product approved by the U.S. Food and Drug Administration, or the FDA, to treat the pain relating to post-herpetic neuralgia, pain commonly associated with shingles. The FDA has granted Lidoderm® orphan drug status, which means, generally, that no other lidocaine-containing product can be approved for this indication until March 2006. Additionally, Lidoderm® is protected by certain patents until 2015; and

Percocet®, our oxycodone/acetaminophen combination product, and Percodan®, our oxycodone/aspirin combination product, which we consider to be gold standards of pain management.

*Substantial pipeline focused on pain management with a balanced focus on complementary therapeutic areas.* As a result of our focused research and development efforts, we filed two NDAs with the FDA in December 2002 for oxymorphone ER, or extended-release, and oxymorphone IR, or immediate-release, which the FDA accepted for substantive review in February 2003. In addition, we have

two products in Phase III clinical trials and three products in Phase II clinical trials. If the FDA's review of oxymorphone ER and IR progresses as we anticipate, we expect to receive the first action letters, stating whether the products are approvable or not approvable and possibly identifying further requirements, from the FDA by the end of 2003. If the current clinical trials for DepoMorphine™ progress as we expect, we anticipate that an NDA will be filed with the FDA by mid-2003.

*Research and development expertise.* Our research and development effort is focused on expanding our product portfolio by capitalizing on our core expertise with analgesics. We believe this expertise allows for timely FDA approval of our products. We have launched a number of new products and product line extensions since August 1997, which, in the aggregate, contributed approximately 56% of our net sales in 2002.

*Targeted national sales and marketing infrastructure.* We market our products directly to physicians through an internal sales force of 70 specialty/ institutional representatives and a dedicated contract sales force of approximately 160 community-based field representatives. Through our sales force, we market our branded pharmaceutical products to approximately 35,000 physicians, including specialists who write approximately 80% of the specialist prescriptions for oxycodone/ acetaminophen. Furthermore, we maintain an internal sales management infrastructure to direct and focus these sales efforts, targeting primary care providers and specialists that frequently prescribe opioid analgesics.

*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 our generic product development strategy successfully to date with products such as morphine sulfate extended-release tablets, which we introduced in November 1998 as a bioequivalent version of MS Contin, a product of the Purdue Frederick Company. In addition, we believe we are the first company to have filed an abbreviated new drug application, or ANDA, with the FDA for the bioequivalent version of the 10mg, 20mg and 40mg strengths of Purdue Frederick's OxyContin. In July 2002, we received tentative approval from the FDA for all four strengths (10mg, 20mg, 40mg and 80mg) of our generic OxyContin. We are currently in litigation with Purdue Frederick regarding our generic version of OxyContin. See Business Legal Proceedings.

*Experienced and dedicated management team.* With an average of approximately 20 years of experience in the pharmaceutical industry, our senior management team has a proven track record of building our business through internal growth as well as through acquisitions and licensing. Members of our senior management led the purchase of the company from The DuPont Merck Pharmaceutical Company in August 1997 as well as the licensing of Lidoderm®, CHRONOGESIC™, DepoMorphine™ and Propofol IDD-D™ and the acquisition of the oral rinse (0.1% triclosan) for oral mucositis. After this offering, senior management will continue to have a significant ownership in our business including vested stock options to acquire up to 18% of our common stock and the potential to receive up to an additional 3% of our common stock through options that will vest if the price of our common stock reaches a specified, defined target. All of these options are exercisable solely for shares currently held by Endo Pharma LLC, a limited liability company holding the majority of our common stock, in which affiliates of Kelso & Company and certain other members of management have an interest, and their exercise will not dilute the ownership of our other existing common stockholders. In this offering, senior management will be selling less than 5% of its aggregate ownership in Endo.

## **Our Strategy**

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

Capitalizing on our established brand names and brand awareness through focused marketing and promotional efforts;

Leveraging our pain management expertise by developing proprietary products and generic products with significant barriers to market entry;

Acquiring and in-licensing complementary products, compounds and technologies; and

Developing and marketing product line extensions of our existing brands.

**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, which was subsequently purchased by the Bristol-Myers Squibb Pharma Company in 2001. Endo Pharmaceuticals Inc. was formed by members of the then-existing management of DuPont Merck and an affiliate of Kelso & Company 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. Our common stock is quoted on the Nasdaq National Market under the symbol ENDP.

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](http://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 by the selling stockholders 15,000,000 shares

Common stock to be outstanding after this offering 131,746,568 shares

Use of proceeds We will not receive any proceeds from the sale of shares offered by the selling stockholders

Nasdaq National Market Symbol ENDP

Unless otherwise indicated, all share information in this prospectus is based on the number of shares outstanding as of June 9, 2003 and:

excludes up to 1,987,846 shares of common stock issuable by us upon the exercise of options granted to our employees, of which 363,330 are currently exercisable; and

excludes up to 9,149 shares of common stock issuable by us upon the exercise of warrants, all of which are exercisable until July 8, 2003, at which time they expire.

## Summary Consolidated Financial Data

The summary consolidated financial data for the three months ended March 31, 2002 and 2003 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 related notes included or incorporated by reference in this prospectus.

	Year Ended December 31,			Three Months Ended March 31,	
	2000	2001	2002	2002	2003
(in thousands, except per share data)					
<b>Statement of Operations Data:</b>					
Net sales	\$ 197,429	\$ 251,979	\$ 398,973	\$ 67,026	\$ 152,274
Cost of sales	63,041	74,891	98,857	18,891	27,577
Gross profit	134,388	177,088	300,116	48,135	124,697
Selling, general and administrative	56,537	79,505	110,907	23,583	36,116
Research and development	26,012	38,994	56,823	13,396	12,064
Depreciation and amortization	27,624	49,234	3,142	785	1,352
Compensation related to stock options	15,300	37,253	34,659		48,514
Purchased in-process research and development	133,200		20,300		
Manufacturing transfer fee			9,000		
Merger and other related costs	1,583				
Separation benefits	22,034				
Operating income (loss)	(147,902)	(27,898)	65,285	10,371	26,651
Interest expense, net	15,119	13,290	4,391	1,622	131
Income (loss) before income tax (benefit)	(163,021)	(41,188)	60,894	8,749	26,520
Income tax (benefit)	(6,181)	(4,646)	30,081	3,373	10,161
Net income (loss)(1)	\$ (156,840)	\$ (36,542)	\$ 30,813	\$ 5,376	\$ 16,359
Net income (loss) per share					
Basic	\$ (1.97)	\$ (0.40)	\$ 0.30	\$ 0.05	\$ 0.14
Diluted(2)	\$ (1.97)	\$ (0.40)	\$ 0.30	\$ 0.05	\$ 0.12
Shares used to compute net income (loss) per share					
Basic	79,454	91,505	102,064	102,064	118,217
Diluted	79,454	91,505	102,126	102,281	131,987



(1) Net income (loss) includes charges, net of tax, as follows:

	Year Ended December 31,			Three Months Ended March 31,	
	2000	2001	2002	2002	2003
	(in thousands)				
Net income (loss)	\$ (156,840)	\$ (36,542)	\$ 30,813	\$ 5,376	\$ 16,359
Amortization of goodwill and workforce-in-place	\$ 24,877	\$ 39,745			
Non-cash compensation related to stock options	14,535	22,985	\$ 21,384		\$ 29,937
Purchased in-process research and development	133,200		20,300		
Manufacturing transfer fee			5,553		
Inventory write-down for extended-release oxycodone			4,959		
Debt extinguishment		1,436			
Merger and other related costs	1,504				
Separation benefits	20,932				

(2) Diluted net income (loss) per share includes charges, net of tax, as follows:

	Year Ended December 31,			Three Months Ended March 31,	
	2000	2001	2002	2002	2003
Net income (loss)	\$ (1.97)	\$ (0.40)	\$ 0.30	\$ 0.05	\$ 0.12
Amortization of goodwill and workforce-in-place	\$ 0.31	\$ 0.43			
Non-cash compensation related to stock options	0.18	0.25	\$ 0.21		\$ 0.23
Purchased in-process research and development	1.68		0.20		
Manufacturing transfer fee			0.05		
Inventory write-down for extended-release oxycodone			0.05		
Debt extinguishment		0.02			
Merger and other related costs	0.02				
Separation benefits	0.26				

	As of December 31,			As of
	2000	2001	2002	March 31, 2003
(in thousands)				
<b>Consolidated Balance Sheet Data:</b>				
Cash and cash equivalents	\$ 59,196	\$ 95,357	\$ 56,902	\$ 96,483
Working capital	72,759	65,259	105,058	168,858
Total assets	467,840	470,995	512,972	574,341
Total debt	198,525	91,259		
Other long-term obligations	7,218	207	7,851	7,788
Stockholders equity	198,173	295,122	352,692	416,980

	Year Ended December 31,			Three Months Ended March 31,	
	2000	2001	2002	2002	2003
(in thousands)					
<b>Other Data:</b>					
Credit facility EBITDA	\$67,687	\$79,523	\$158,142	\$15,853	\$79,508

Our credit facility requires us to maintain minimum EBITDA of \$50 million over the prior four-quarter period. Our credit facility defines consolidated EBITDA as consolidated net income for the applicable period plus, without duplication and to the extent deducted from revenues in determining consolidated net income for that period, the sum of (a) the aggregate amount of consolidated cash interest expense for the period, (b) the aggregate amount of letter of credit fees paid during the period, (c) the aggregate amount of income tax expense for the period, (d) all amounts attributable to depreciation and amortization for the period, (e) all extraordinary and non-recurring charges during the period (provided that the amount of charges added to consolidated net income pursuant to this clause (e) that are incurred in connection with any transfer of manufacturing operations shall not exceed \$10 million during any fiscal year of ours or \$20 million in the aggregate) 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.

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

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

Credit facility EBITDA may not be comparable to similarly titled measures reported at other companies.

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 424B4

The calculation of credit facility EBITDA is as follows:

	Year Ended December 31,			Three Months Ended March 31,	
	2000	2001	2002	2002	2003
	(in thousands)				
Net income (loss)	\$ (156,840)	\$ (36,542)	\$ 30,813	\$ 5,376	\$ 16,359
Interest expense, net	15,119	13,290	4,391	1,622	131
Income tax (benefit)	(6,181)	(4,646)	30,081	3,373	10,161
Plus: depreciation and amortization	27,624	49,234	3,142	785	1,352
Plus: purchased in-process research and development	133,200		20,300		
Plus: non-cash compensation charges related to stock options	15,300	37,253	34,659		48,514
Plus: non-cash manufacturing charges	18,683	20,934	22,213	4,697	1,356
Plus: manufacturing transfer fee			9,000		
Plus: manufacturing transfer costs			3,543		1,635
Plus: non-cash separation benefits	20,782				
<b>Credit facility EBITDA</b>	<b>\$ 67,687</b>	<b>\$ 79,523</b>	<b>\$ 158,142</b>	<b>\$ 15,853</b>	<b>\$ 79,508</b>

Descriptions of items excluded from net income in the definition of credit facility EBITDA in our credit facility are as follows:

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

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

Non-cash manufacturing charges reflect the present value of non-interest bearing promissory notes that were issued annually to DuPont Pharmaceuticals Company (n/k/a Bristol-Myers Squibb Pharma Company) over the initial five-year term (August 1997-August 2002) of our manufacturing and supply agreement with DuPont Pharmaceuticals.

Manufacturing transfer fee is the one-time payment made to Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals Company) in the third quarter of 2002 in connection with the August 2002 amendment to the manufacturing and supply agreement we have in place with Bristol-Myers Squibb Pharma Company. This amendment permitted us to transfer up to 100% of any of our products out of any Bristol-Myers facility at any time and compensated Bristol-Myers for its assistance to us in the transfer. See Business Service Agreements - Third Party Manufacturing/ Supply Agreements; Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals).

Manufacturing transfer costs represent the costs incurred to transfer certain of our products from Bristol-Myers to alternative manufacturers. We incurred these manufacturing transfer costs in 2002 and the first quarter of 2003 and anticipate incurring additional costs in 2003.

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.



## 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

***We face intense competition, in particular from companies that develop rival products to our branded products and from manufacturers of generic versions of our branded 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, Elan Corporation plc, Johnson & Johnson, Ligand Pharmaceuticals Incorporated, Mallinckrodt Inc., Pfizer, Inc., 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 safety, development and efficacy, other competitive factors in the branded pharmaceutical market include product quality and price, reputation, service and access to scientific and 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 products business requires an ongoing, extensive search for medical and 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 2002, generic versions of Percocet® were used to fill approximately 86% of the approximately 13.9 million new prescriptions for this drug. Percocet® 10/325 and Percocet® 7.5/325, which currently represent approximately 70% of our dispensed Percocet® prescriptions currently have no generic competition. We believe these formulations may be subject to generic competition late in the third quarter of 2003 and that generic competition with our products will have a material adverse effect on our net sales, gross profit, operating income, net income and cash flows during the remainder of 2003.

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.

***We face intense competition from other manufacturers of generic versions of our generic products.***

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 product on the market, although we believe the introduction of at least one generic competitor may occur early in the third quarter of 2003. The introduction of third-party generic versions of this product will have a material adverse effect on our net sales, gross profit, operating income, net income and cash flows during the remainder of 2003.

***Our first quarter results for 2003 may not be indicative of future quarters or our full year results.***

In the first quarter of 2003, sales of Lidoderm® and Percocet® increased significantly as a result of our customers returning their inventories back to normalized levels compared to the relatively low levels that were maintained at the end of 2002. We believe that the impact of the normalization of our customers' inventory levels during the first quarter of 2003 and expected generic competition with certain of our products will have a material adverse effect on our net sales, gross profit, operating income, net income and cash flows during the remainder of 2003.

***Timing and results of clinical trials to demonstrate the safety and efficacy of products as well as the FDA's approval 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. Preclinical and clinical studies may fail to 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, including Lidoderm®, for chronic low back pain, and two products in Phase III, or the final stage of clinical trials. We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, including oxymorphone ER or oxymorphone IR on a timely basis, if at all, or, if granted, that such approval will not subject the marketing of our products to certain limits on indicated use. Any delay or limitation 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. In addition, we rely on collaboration partners that may control or make changes in trial protocol and design enhancements which may also delay clinical trials. We cannot assure you that we will not experience delays or undesired results in these or any other of our clinical trials.

Before obtaining regulatory approvals for certain generic products, we must conduct limited clinical trials to show comparability to the branded products. A failure to obtain satisfactory results in these trials would prevent us from obtaining required regulatory approvals.

***Our growth and development will depend on developing, commercializing and marketing new products, including both our own products and those developed with our collaboration partners. 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 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 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. Some of our collaboration partners may decide to make substantial changes to a product's formulation or design, may experience financial difficulties or have limited financial resources, any of which may delay the development, commercialization and/or marketing of new products. In addition, if a co-developer on a new product terminates our collaboration agreement or does not perform under the agreement, we may experience delays and, possibly, additional costs in developing and marketing that product. 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.

***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. If an advance is made that qualifies as a joint invention, the joint inventor or his or her employer may have rights in the invention. We cannot assure you that a third party will not infringe upon, design around or develop uses not covered by 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. Various countries limit the subject matter that can be patented and limit the ability of a patent owner to enforce patents in the medical field. This may limit our ability to obtain or utilize those patents internationally. Patent applications in the United States are maintained in secrecy until at least 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. Several drug companies and research and academic institutions have developed technologies, filed patent applications or received patents for technologies that may be related to our business. Others may file patent applications and may receive patents that may conflict with patents or patent applications we have obtained or licensed for our use, either by claiming the same methods or compounds or by claiming methods or compounds that could dominate those owned by or licensed to us. 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.

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

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



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

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, or the manufacturing contract applicable thereto terminates, 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 core products contain narcotic ingredients. As a result of reports of misuse or 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 narcotic ingredients. Misuse or abuse of such drugs can lead to physical or other harm. In the past two years, reportedly widespread misuse or 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 numerous lawsuits, including class action lawsuits, related to OxyContin misuse or abuse. We have received tentative approval from the FDA for bioequivalent versions of the 10mg, 20mg, 40mg and 80mg strengths of OxyContin. We may be subject to litigation similar to the OxyContin suits related to our generic version of OxyContin or any other narcotic-containing product we market, including one case that was recently commenced against us and other manufacturers. See Business Legal Proceedings John Fontenot et al. v. Able Laboratories, Inc. et al., No. 98-845 (34th Judicial District Court for the Parish of St. Bernard, State of Louisiana).

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.

***If the efforts of manufacturers of branded pharmaceuticals to use litigation and legislative and regulatory efforts to limit the use of generics and certain other products are successful, our sales 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 and certain other products to which we do not have a right of reference to all necessary preclinical and clinical data. Opposing such measures can be costly and time-consuming and result in delays in the introduction of our products.

The products for which we are developing generic versions may be claimed by their manufacturer to be protected by one or more patents. If we file an abbreviated new drug application, or an ANDA, to seek FDA approval of our generic version of such a drug, we are required to certify that any patent or patents listed as covering the approved listed drug are invalid, unenforceable or will not be infringed by our generic version. Similar certification and notification requirements apply to new drug applications filed under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, where we rely on information to which we do not have a right of reference. Once the FDA accepts our ANDA or section 505(b)(2) NDA 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 or section 505(b)(2) NDA until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in favor of us or expiration of the patent(s).

In some cases, we may qualify for the 180-day market exclusivity period for generic products. However, we cannot assure you that we will be prepared, authorized or willing (depending on the circumstances) to commercialize our product when the 180-day period begins to run or at any time during that period.

We are currently subject to patent litigation and related delay in our ability to obtain final FDA approval of our tentatively approved extended-release oxycodone product.

***The Purdue Frederick Company has filed suit against us. If we receive an unfavorable ruling by the district or appeals court, the price of our common stock may decline.***

The Purdue Frederick Company filed suit against us in October 2000 (and again in March 2001 and August 2001) alleging that our bioequivalent versions of OxyContin, for which we have filed an ANDA, violate three of their patents. The trial of the patent claims began on June 2, 2003. We can make no prediction as to how the district court will rule at the trial, nor can we predict the effect of the ruling on the price of our common stock or on our generic strategy. If we receive a favorable ruling from the district court and launch our versions of generic OxyContin and the district court's ruling is overturned on appeal, we may be liable for lost profits and damages to Purdue and costs associated with the launching of our products. If we receive an unfavorable ruling from the district or appeals court, we will be unable to sell our generic OxyContin and the price of our common stock may be adversely affected. In addition, if the district court finds that we acted willfully in pursuing the ANDA, the district court may order us to pay Purdue Frederick's legal fees which may be substantial. Our payment of Purdue Frederick's legal fees may adversely affect our business and our results of operations.

***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.

***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.

***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.

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

During 2002, 36% of our net sales came from sales of the Percocet® franchise, 22% came from sales of morphine sulfate extended-release tablets and 21% 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 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 24%, 24%, 23% and 11% respectively, of net sales in 2002, 28%, 24%, 19% and 10%, respectively of net sales in 2001, and 26%, 16%, 12% and 10%, respectively, of net sales in 2000. 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.

***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 Safety and Health Administration, or OSHA, 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, Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals Company) manufactures a significant number of our products. The contract that governs this manufacturing arrangement had an initial five-year term that expired August 2002. On August 27, 2002, we entered into an amendment to the agreement, which provided that Bristol-Myers Squibb would continue to manufacture our products until August 26, 2003 (at which time the manufacturing agreement will expire) and that we would be permitted to transfer up to 100% of our products to another manufacturer at any time. If, prior to August 26, 2003, Bristol-Myers Squibb determines to sell or otherwise transfer either the Garden City plant facility or the Manati plant facility, at which various of our products are manufactured, and we determine that the acquirer of such facility would not be an acceptable manufacturer of our products, Bristol-Myers Squibb will implement, at its cost, appropriate arrangements for the manufacture and supply of the products elsewhere. We may experience an interruption in our manufacturing if we are unable to produce validated batches or receive FDA approval of our products at alternate facilities. We will 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 Bristol-Myers Squibb.

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

In addition, we have entered into minimum purchase requirement contracts with some of our third party manufacturers. If the market for the products manufactured by these third parties substantially contracts or disappears, we will continue to be financially obligated under these contracts, an obligation which could have a material adverse effect on our business.

***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 manufacturers, 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.

In addition, we have entered into minimum purchase requirement contracts with some of our third party suppliers. If the market for the products that utilize these raw materials substantially contracts or disappears, we will continue to be financially obligated under these contracts, an obligation which could have a material adverse effect on our business.

***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.

***Sales of our products may be adversely affected by the consolidation of the wholesale drug distribution and retail pharmacy industries, a trend which may continue.***

The network through which we sell our products has undergone 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.

***We may not be able to maintain our current insurance policies covering our business, assets, directors and officers and product liability claims and we may not be able to obtain new policies in the future.***

Property, product liability, directors and officers and general liability insurance represent significant costs to us. Since the events of September 11, 2001, and due to recent concerns over corporate governance in the U.S., corporate accounting scandals and product liability lawsuits related to pharmaceuticals, liability and other types of insurance have become more difficult and costly to obtain. Unanticipated additional insurance costs could have a material adverse effect on our results of operations and cash flows. There can be no assurance that we will be able to maintain our existing insurance policies or obtain new policies in meaningful amounts or at a reasonable cost. Any failure to obtain or maintain any necessary insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

***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 regularly evaluate selective acquisitions and 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 decrease our income 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 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.

***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, potential impairment of goodwill and other intangibles may significantly impact our profitability.***

Effective January 1, 2002, we adopted the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, and will no longer amortize goodwill. Goodwill and other intangibles represents a significant portion of our assets and stockholders' equity. As of December 31, 2002, goodwill and other intangibles comprised approximately 42% of our total assets and 62% of our stockholders' equity. We assess the potential impairment of goodwill by comparing the fair value of goodwill to its carrying value for our one reporting unit. An impairment loss would be recognized when the estimated fair value is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

***Our 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, including maintaining a specific level of EBITDA, as defined therein. Our ability to comply with these may be affected by matters beyond our control. A breach of any of these covenants would prevent us from being able to draw under our revolving loan and will result in a default under our credit agreement.

***We have entered into a tax sharing agreement with Endo Pharma LLC pursuant to which we may have to make large cash payments to them.***

Upon the exercise of the stock options granted under the Endo Pharma LLC stock option plans, only currently outstanding shares of our common stock held by Endo Pharma LLC will be issued. Endo Pharma LLC was formed in connection with the acquisition of Algos Pharmaceutical Corporation in July 2000 to ensure that the stock options granted pursuant to the Endo Pharma LLC stock option plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we will be required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of March 31, 2003, approximately 1.4 million of these stock options had been exercised by former employees into shares of our common stock held by Endo Pharma LLC. The exercise of any of these Endo Pharma LLC stock options generally will permit us to deduct as a compensation charge, for federal income tax purposes, an amount equal to the difference between the market price of our common stock and the exercise price paid upon exercise of these options (as of March 31, 2003, approximately \$11 million), which is estimated to result in a tax benefit amount of approximately \$4 million. Under the tax sharing agreement, we are required to pay this \$4 million to Endo

Pharma LLC upon the occurrence of a liquidity event, as described further below, to the extent that a compensation charge deduction is usable to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto.

Using a weighted average exercise price of \$2.61 per share and an assumed tax rate of 38.3%, if all 36.3 million stock options under the Endo Pharma LLC stock options plans were vested and exercised (including the 1.4 million stock options already exercised as discussed above), and assuming the market price of our common stock was \$15.00 per share, then, we generally would be able to deduct, for income tax purposes, compensation of approximately \$450 million, which could result in a tax benefit amount of approximately \$172 million payable to Endo Pharma LLC. Under the terms of the tax sharing agreement, we must pay all such tax benefit amounts to Endo Pharma LLC to the extent these tax benefits are usable by us as described above. However, these payments need only be made to Endo Pharma LLC upon the occurrence of a liquidity event, which is generally defined as a transaction or series of transactions resulting in (a) a sale of greater than 20% on a fully diluted basis of our common equity (either through (i) a primary offering by us, (ii) a secondary sale by Endo Pharma LLC or other holders of common stock pursuant to a registration rights agreement or (iii) a combination of both such primary and secondary offerings), (b) a change in control of Endo or (c) a sale of all or substantially all of our assets. In accordance with the tax sharing agreement, no payments have been made or accrued to date. This offering, which represents a sale of approximately 11% of our common equity, or approximately 13% if the underwriters overallotment is exercised, does not by itself trigger a payment under the tax sharing agreement, and no liquidity event will result from this offering. This offering may, however, be combined with future offerings to result in a series of transactions that will trigger a payment obligation pursuant to the tax sharing agreement. We cannot assure you that we will not trigger, or an event outside of our control will not trigger, a large cash payment under the tax sharing agreement in the future which could adversely affect our financial condition and our results of operations.

***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, future net income and future earnings per share 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 incorporated by reference 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 anticipated timing of generic competition and the continued growth in net sales of our 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 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.

***Our revenues and operating results may fluctuate in future periods and we may fail to meet expectations, which may cause the price of our common stock to decline.***

Variations in our quarterly operating results are difficult to predict and may fluctuate significantly from period to period. We cannot predict with certainty the timing or level of sales of our products in the future. If our quarterly sales or operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Our operating results may fluctuate due to various factors including those set forth above in Risk Factors Risks Related to Our Business. As a result of these factors, we believe that period-to-period comparisons of our operating results are not a good indication of our future performance.

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

After this offering, Endo Pharma LLC will own approximately 64% of our common stock. Endo Pharma LLC is, in turn, controlled by affiliates of Kelso & Company who currently own 83.6% of Endo Pharma LLC. 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 therefore direct 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.

***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 \$19.19 and \$4.98 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 change:

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 our or others' 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 June 9, 2003, approximately 100,872,126 million shares of common stock, representing approximately 76.6% 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 of 1933, or the Securities Act.

Of the 1,987,846 shares that may be issued upon the exercise of options outstanding as of June 9, 2003, 363,330 are vested, currently exercisable and eligible for sale. The sale of these shares will be unrestricted, subject to any lock-up agreements with the underwriters in this offering.

All of the 9,149 shares that may be issued upon the exercise of warrants outstanding as of June 9, 2003 were exercisable as of that date and are exercisable until July 8, 2003, at which time they expire.

While the holders of approximately 65.2% 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, Citigroup Global Markets Inc. and Bear, Stearns & Co. 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. Endo Pharma LLC has informed us that, subject to a variety of factors, including market conditions and stock price levels, it may initiate additional secondary offerings in the future.

***We have not paid, and may not 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 our inception. Furthermore, our existing credit facility limits our ability to pay dividends. We may not pay cash dividends in the 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.

### FORWARD-LOOKING STATEMENTS

We have made forward-looking statements in this document within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. These statements, including estimates of future net sales, future net income and future earnings per share, contained in the section titled Management's Discussion and Analysis of Financial Condition and Results of Operations, are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. Also, statements including words such as believes, expects, anticipates, intends, estimates, or similar expressions are forward-looking statements. We have based these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described in 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 preclinical and 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 certain 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 and in-licensing strategy;

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

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

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

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

**USE OF PROCEEDS**

All of the shares of common stock offered hereby are being sold by the selling stockholders. We will not receive any proceeds from this offering.

**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 January 1, 2001.

	<u>High</u>	<u>Low</u>
<b>2003</b>		
Second Quarter	\$ 19.45	\$ 12.72
First Quarter	\$ 14.10	\$ 7.49
<b>2002</b>		
Fourth Quarter	\$ 9.50	\$ 5.90
Third Quarter	\$ 9.56	\$ 5.81
Second Quarter	\$ 13.05	\$ 4.98
First Quarter	\$ 13.31	\$ 8.80
<b>2001</b>		
Fourth Quarter	\$ 12.00	\$ 7.32
Third Quarter	\$ 12.15	\$ 7.24
Second Quarter	\$ 11.65	\$ 6.00
First Quarter	\$ 7.13	\$ 5.13

As of June 11, 2003, we had approximately 127 shareholders of record of our common stock. The closing sale price of our common stock on July 1, 2003 was \$16.07 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 depend 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.

**CAPITALIZATION**

The following table sets forth our capitalization as of March 31, 2003 on an actual basis. 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 or incorporated by reference in this prospectus.

	<b>As of March 31, 2003</b>
	<b>(in thousands, except share and per share data)</b>
Cash and cash equivalents	\$ 96,483
<b>Debt:</b>	
Long-term debt, including current portion	\$
<b>Stockholders' equity:</b>	
Preferred stock, \$.01 par value; 40,000,000 shares authorized; none issued	
Common stock, \$.01 par value, 175,000,000 shares authorized, 131,715,622 shares issued	1,317
Additional paid-in capital	595,468
Accumulated deficit	(178,043)
Accumulated other comprehensive loss	(1,762)
Total stockholders' equity	416,980
Total capitalization	\$ 416,980

## SELECTED HISTORICAL CONSOLIDATED FINANCIAL DATA

The selected historical consolidated financial data for the three months ended March 31, 2002 and 2003 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 and Management's Discussion and Analysis of Financial Condition and Results of Operations included or incorporated by reference in this prospectus. The selected data in this section is not intended to replace the consolidated financial statements.

	Year Ended December 31,					Three Months Ended March 31,	
	1998	1999	2000	2001	2002	2002	2003
(in thousands, except per share data)							
<b>Statement of Operations Data:</b>							
Net sales	\$ 108,370	\$ 138,546	\$ 197,429	\$ 251,979	\$ 398,973	\$ 67,026	\$ 152,274
Cost of sales	54,731	58,263	63,041	74,891	98,857	18,891	27,577
Gross profit	53,639	80,283	134,388	177,088	300,116	48,135	124,697
Selling, general and administrative	25,540	42,921	56,537	79,505	110,907	23,583	36,116
Research and development	5,893	9,373	26,012	38,994	56,823	13,396	12,064
Depreciation and amortization	7,373	8,309	27,624	49,234	3,142	785	1,352
Compensation related to stock options			15,300	37,253	34,659		48,514
Purchased in-process research and development			133,200		20,300		
Manufacturing transfer fee					9,000		
Merger and other related costs			1,583				
Separation benefits			22,034				
Operating income (loss)	14,833	19,680	(147,902)	(27,898)	65,285	10,371	26,651
Interest expense, net	14,451	14,347	15,119	13,290	4,391	1,622	131
Income (loss) before income tax (benefit)	382	5,333	(163,021)	(41,188)	60,894	8,749	26,520
Income tax (benefit)	181	2,073	(6,181)	(4,646)	30,081	3,373	10,161
Net income (loss)	\$ 201	\$ 3,260	\$ (156,840)	\$ (36,542)	\$ 30,813	\$ 5,376	\$ 16,359
Net income (loss) per share							
Basic	\$ 0.00	\$ 0.05	\$ (1.97)	\$ (0.40)	\$ 0.30	\$ 0.05	\$ 0.14
Diluted	\$ 0.00	\$ 0.05	\$ (1.97)	\$ (0.40)	\$ 0.30	\$ 0.05	\$ 0.12
Shares used to compute net income (loss) per share							
Basic	71,307	71,332	79,454	91,505	102,064	102,064	118,217
Diluted	71,307	71,332	79,454	91,505	102,126	102,281	131,987

	As of December 31,					As of
	1998	1999	2000	2001	2002	March 31, 2003

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 424B4

(in thousands)

**Consolidated Balance Sheet Data:**

Cash and cash equivalents	\$ 17,367	\$ 22,028	\$ 59,196	\$ 95,357	\$ 56,902	\$ 96,483
Working capital	37,676	49,541	72,759	65,259	105,058	168,858
Total assets	287,618	329,436	467,840	470,995	512,972	574,341
Total debt	170,544	191,203	198,525	91,259		
Other long-term obligations	6,352	6,745	7,218	207	7,851	7,788
Stockholders equity	75,358	78,587	198,173	295,122	352,692	416,980

**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, future net income and future earnings per share, that involve risks, uncertainties and assumptions. In particular, our estimates of future net sales, future net income and future earnings per share are based on assumptions regarding the anticipated timing of generic competition and the continued growth in net sales of our 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.*

**Overview**

We, through our wholly owned subsidiary, Endo Pharmaceuticals Inc., are engaged in the research, development, sales and marketing of branded and generic prescription pharmaceuticals used primarily for the treatment and management of pain. Branded products comprised approximately 67%, 63% and 69% of net sales for the years ended December 31, 2001, 2002 and the three months ended March 31, 2003, respectively.

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

On July 17, 2000, we completed our merger with Algos and effected a recapitalization of the Company. In the merger, we issued to the former Algos stockholders, in the aggregate, 17.8 million shares of our common stock and 17.8 million warrants to purchase in the aggregate up to 20.6 million additional shares of our common stock in certain circumstances as more fully described under footnote 14 to the consolidated financial statements. As we have previously disclosed, these warrants, known as the Class A Transferable Warrants and the Class B Non-Transferable Warrants, expired on March 31, 2003. Accordingly, we have de-listed the Class A Transferable Warrants.

In the Algos merger, we also issued to our pre-merger stockholders, in the aggregate, 71.3 million warrants to purchase in the aggregate up to 29.7 million additional shares of common stock in certain other circumstances as more fully described under footnote 14 to the consolidated financial statements incorporated herein by reference. On January 8, 2003 we announced that the outstanding warrants that were issued to our pre-merger stockholders became exercisable. Each of these outstanding 71.3 million warrants is exercisable into 0.416667 shares of our common stock. These warrants are exercisable at an exercise price of \$0.01 per share into a maximum of 29.7 million shares of Common Stock on account of MorphiDex® not having been approved by the FDA for any pain indication prior to December 31, 2002. As of March 31, 2003, 71.2 million of these warrants had been exercised into 29,651,172 shares of our common stock.

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

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



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

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

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

We allocated fair value to one project of BML Pharmaceuticals, an oral rinse (0.1% triclosan) for oral mucositis. The development program for a new pharmaceutical substance involves several different phases prior to drug application. Further, drug applications must be approved by the FDA prior to marketing a new drug. Despite our commitment to completion of this research and development project, many factors may arise that could cause the project to be withdrawn or delayed, including the inability to prove the safety and efficacy of the drug during the development process. Upon withdrawal of an application, it is unlikely that the development activities will have alternative use. If this project is not successfully developed, our results of operations and financial position in a future period could be negatively impacted.

In May 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc., whereby Novartis has agreed to manufacture certain of our commercial products and products in development. We have incurred and expect to continue to incur significant costs associated with the preparation of Novartis' manufacturing operations under this agreement. These costs primarily relate to the preparation of test batches of drug product for FDA approval and our own quality assessment and administrative costs relating to the shifting of existing production to Novartis. During 2002, we

incurred approximately \$3.5 million of these costs which are reflected in research and development expense.

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

### **Critical Accounting Policies**

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

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

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

***Amortizable Intangibles: Licenses***

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

***Goodwill and Other Intangibles***

Effective January 1, 2002, we adopted the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, and will no longer amortize goodwill and workforce in place. Goodwill and other intangibles represents a significant portion of our assets and stockholders' equity. As of December 31, 2002, goodwill and other intangibles comprised approximately 42% of our total assets and 62% of our stockholders' equity. We assess the potential impairment of goodwill by comparing the fair value of goodwill to its carrying value for our one reporting unit. An impairment loss would be recognized when the estimated fair value is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

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

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 424B4

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

	December 31, 2002	March 31, 2003
		(unaudited)
Goodwill	\$ 181,079	\$ 181,079
Amortizable Intangibles:		
Licenses	\$ 36,000	\$ 36,000
Patents	3,200	3,200
	39,200	39,200
Less accumulated amortization	(2,445)	(3,015)
Other Intangibles, net	\$ 36,755	\$ 36,185

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

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

	Year Ended December 31,		
	2000	2001	2002
	(in thousands, except per share data)		
Reported net income (loss)	\$(156,840)	\$(36,542)	\$30,813
Add back: Goodwill amortization	22,494	40,431	
Add back: Amortization of workforce-in-place	2,711	5,948	
Less: Pro forma income (tax) benefit	46,603	(6,634)	
Adjusted net income (loss)	\$ (85,032)	\$ 3,203	\$30,813
<b>Basic earnings (loss) per share:</b>			
Reported net income (loss)	\$ (1.97)	\$ (0.40)	\$ 0.30
Add back: Goodwill amortization	0.28	0.44	
Add back: Amortization of workforce-in-place	0.03	0.07	
Less: Pro forma income (tax) benefit	0.59	(0.07)	
Adjusted net income (loss)	\$ (1.07)	\$ 0.04	\$ 0.30
<b>Diluted earnings (loss) per share:</b>			
Reported net (loss) income	\$ (1.97)	\$ (0.40)	\$ 0.30
Add back: Goodwill amortization	0.28	0.44	
Add back: Amortization of workforce-in-place	0.03	0.07	
Less: Pro forma income (tax) benefit	0.59	(0.07)	
Adjusted net income (loss)	\$ (1.07)	\$ 0.04	\$ 0.30

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 424B4

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

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

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

In our 2000 fiscal year we incurred a non-cash charge of \$15.3 million, in our 2001 fiscal year we recorded a non-cash charge of \$37.3 million and in our 2002 fiscal year we recorded a non-cash charge of \$34.7 million, in each case for stock-based compensation relating to the vesting of options that were issued under the Endo Pharma LLC 1997 Amended and Restated Executive Stock Option Plan and the Endo Pharma LLC 1997 Amended and Restated Employee Stock Option Plan (together, the Endo Pharma LLC 1997 Stock Option Plans). Under the Endo Pharma LLC 1997 Stock Option Plans, tranches of options vest when we attain certain stock price targets. As each tranche vests, we incur a non-cash charge representing the difference between the market price of the shares underlying the options and the exercise price of such options.

In connection with the Algos merger and our related recapitalization on July 17, 2000, the Endo Pharma LLC 2000 Supplemental Employee Stock Option Plan and the Endo Pharma LLC 2000 Supplemental Executive Stock Option Plan (collectively, the Endo Pharma LLC 2000 Supplemental Stock Option Plans) and, together with the Endo Pharma LLC 1997 Stock Option Plans, the Endo Pharma LLC Stock Option Plans) were established. The Endo Pharma LLC 2000 Supplemental Stock Option Plans reserve an aggregate of 10.7 million shares of our common stock that is held by Endo Pharma LLC for issuance. The Endo Pharma LLC 2000 Supplemental Stock Option Plans were not effective until January 1, 2003. The Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective on January 1, 2003, resulting in the issuance of approximately 10.7 million stock options to certain employees and members of management. Because approximately 9.2 million of these stock options were immediately vested upon their issuance, we recorded a non-cash compensation charge of approximately \$48.5 million in the first quarter of 2003 representing the difference between the market price of the common stock of \$7.70 and the weighted average exercise price of these stock options of \$2.42. Upon exercise, no additional shares of our common stock will be issued, however, because these stock options are exercisable only into shares of our common stock that are held by Endo Pharma LLC. Accordingly, these stock options do not dilute the public shareholders. In addition, Endo Pharma LLC, and not us, will receive the exercise price payable in connection with these options. Further, the shares of common stock that individuals receive upon exercise of stock options granted pursuant to the Endo Pharma LLC 2000 Supplemental Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

The remaining unvested class of performance-based stock options (Class C4) under the Endo Pharma LLC Stock Option Plans will vest upon (i) our common stock exceeding an average closing price threshold of \$17.29 for ninety consecutive trading days, (ii) the closing price of our common stock on the last trading day of such ninety consecutive trading day period being greater than or equal to \$14.70 and (iii) the holder being a director, officer or employee of the Company or any of our subsidiaries on such date. If this vesting occurs, this charge will be substantial. For example, the vesting of the approximately 5.0 million outstanding Class C4 stock options will result in an additional compensation charge to us, which would be approximately \$75 million if the market price of our stock is \$17.29 on the date the vesting occurs. As stated above, these options are exercisable solely into shares of our common stock that are presently held by Endo Pharma LLC. As a result, the exercise of these options will not result in the issuance of additional shares of common stock and will not dilute the ownership of our other public stockholders. Further, the shares of common stock that individuals receive upon exercise of stock options granted pursuant to the Endo Pharma LLC Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements. For a discussion of the tax sharing agreement between the Company and Endo Pharma LLC relating to the Endo Pharma LLC Stock Options, see Liquidity and Capital Resources; Tax Sharing Agreement.

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

All the stock options we have granted pursuant to the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan have exercise prices equal to the market price of our stock on the date granted and,

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 424B4

under generally accepted accounting principles, a measurement date occurs on the date of each grant. Consequently, we do not expect to incur a charge upon the vesting or exercise of those options.

**Net Sales**

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

The following table presents our unaudited net sales by product category for the years ended December 31, 2000, 2001 and 2002 and the three months ended March 31, 2002 and 2003:

	Year Ended December 31,			Three Months Ended March 31,	
	2000	2001	2002	2002	2003
	(in thousands)				
Percocet®	\$ 92,366	\$ 100,967	\$ 144,623	\$ 23,468	\$ 55,459
Lidoderm®	22,539	40,878	83,218	10,002	41,490
Other brands	35,375	25,824	22,046	5,326	7,379
Total brands	150,280	167,669	249,887	38,796	104,328
Total generics	47,149	84,310	149,086	28,230	47,946
Total net sales	\$ 197,429	\$ 251,979	\$ 398,973	\$ 67,026	\$ 152,274

The following table presents our unaudited net sales as a percentage of total net sales for select products for the years ended December 31, 2000, 2001 and 2002 and the three months ended March 31, 2002 and 2003:

	Year Ended December 31,			Three Months Ended March 31,	
	2000	2001	2002	2002	2003
Percocet®	47%	40%	36%	35%	37%
Lidoderm®	11%	16%	21%	15%	27%
Other brands	18%	11%	6%	8%	5%
Total brands	76%	67%	63%	58%	69%
Total generics	24%	33%	37%	42%	31%
Total net sales	100%	100%	100%	100%	100%

**Results of Operations**

*Three Months Ended March 31, 2003 Compared to the Three Months Ended March 31, 2002*

**Net Sales.** Net sales for the three months ended March 31, 2003 increased by 127% to \$152.3 million from \$67.0 million in the comparable 2002 period. This increase in net sales was primarily due to the increase in the net sales of the new strengths of Percocet®, Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, and certain generic products. Percocet® net sales increased to \$55.5 million from \$23.5 million in the comparable 2002 period due to the new strengths of Percocet® launched in November 2001. In April 2001, generic equivalents of Percocet® 7.5/500 and Percocet® 10.0/650 were introduced. In November 2001, we launched Percocet® 7.5/325 and Percocet® 10.0/325 which do not currently have generic equivalents. Net sales of Lidoderm® increased to \$41.5 million from \$10.0 million in the comparable 2002 period. In September 1999, we launched Lidoderm®, which continues to gain market share due to our ongoing promotional and educational efforts. Net sales of our generic products increased 70% to \$47.9 million from \$28.2 million in the comparable 2002 period primarily due to the growth of our generic morphine sulfate extended-release tablets and Endocet®. In November 1998, we launched the 15mg, 30mg and 60mg strengths, in May 2001, we



launched the 100mg strength and in September 2001, we launched the 200mg strength of our generic morphine sulfate extended-release tablets. These products continue to gain market share. In April 2001, we launched two new strengths of our generic product Endocet®. In addition, Percocet® and Lidoderm® were favorably impacted from our customers' increasing their inventories back to normalized levels from the relatively low levels that were maintained at the end of 2002. Generic competition with our products may have a material impact on our results of operations and cash flows in the future. Although there can be no assurance, due to the expected continued growth in net sales of Lidoderm® and based on our assumptions regarding the timing of generic competition with Percocet® 7.5/325 and Percocet® 10/325 late in the third quarter of 2003 and our assumptions regarding the timing of generic competition with our extended-release morphine sulfate early in the third quarter of 2003, for the year ended December 31, 2003, we anticipate achieving total net sales of approximately \$520 million, including net sales of Lidoderm® of approximately \$175 million.

**Gross Profit.** Gross profit for the three months ended March 31, 2003 increased by 159% to \$124.7 million from \$48.1 million in the comparable 2002 period. Gross profit margins increased to 82% from 72% due to a more favorable mix of higher margin brand and generic products resulting from the products discussed above. In addition, the increase in gross profit margins was also due to the existing fixed cost nature of our manufacturing relationship with Bristol-Myers Squibb Pharma Company (f/k/a The DuPont Merck Pharmaceutical Company), currently one of our most significant contract manufacturing relationships.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the three months ended March 31, 2003 increased by 53% to \$36.1 million from \$23.6 million in the comparable 2002 period. This increase was due to a \$8.0 million increase in sales and promotional efforts in 2003 over the comparable 2002 period to support Lidoderm® and Percocet® and in preparation of new product launches. In addition, we experienced an increase in costs in the general and administrative functions in order to support our new product marketing and new product development.

**Research and Development Expenses.** Research and development expenses for the three months ended March 31, 2003 decreased by 10% to \$12.1 million from \$13.4 million in the comparable 2002 period. This decrease reflects the overall stage of development of our development portfolio. During 2002, we were performing clinical trials on our extended-release and immediate-release oxymorphone products and MorphiDex®. During 2003, our development efforts are focused on our oral mucositis product which is currently in Phase III clinical trials as well as other earlier stage projects focused in the area of pain management.

**Depreciation and Amortization.** Depreciation and amortization for the three months ended March 31, 2003 increased to \$1.4 million from \$0.8 million in the comparable 2002 period primarily due to an increase in amortization of license fees arising from the SkyePharma license entered into on December 31, 2002.

**Compensation Related to Stock Options.** Compensation related to stock options was \$48.5 million during the three months ended March 31, 2003. Effective January 1, 2003, the Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective resulting in the issuance of approximately 10.7 million stock options to certain employees and members of management. Because approximately 9.2 million of these stock options were immediately vested upon their issuance, we recorded a non-cash compensation charge of approximately \$48.5 million in the first quarter of 2003 representing the difference between the market price of the common stock of \$7.70 and the exercise price of these stock options of \$2.42. No additional shares of our common stock will be issued, however, because these stock options are exercisable only into shares of our common stock that are held by Endo Pharma LLC. Accordingly, these stock options do not dilute the ownership of our other public stockholders.

**Interest Expense, Net.** Interest expense, net for the three months ended March 31, 2003 decreased to \$0.1 million from \$1.6 million in the comparable 2002 period. This decrease is substantially due to the repayment on August 26, 2002 of the promissory notes issued to Bristol-Myers Squibb in connection with

our 1997 acquisition from Bristol-Myers Squibb Pharma Company (f/k/a The Dupont Merck Pharmaceutical Company).

**Income Tax (Benefit).** Income tax for the three months ended March 31, 2003 increased to \$10.1 million from \$3.4 million in the comparable 2002 period. This increase is due to the increase in income before income tax for the three months ended March 31, 2003.

**Net Income.** For the reasons set forth above, net income for the three months ended March 31, 2003 was \$16.4 million, which included a non-cash compensation charge, net of tax, of approximately \$30 million. Although there can be no assurance, we anticipate net income for the year ended December 31, 2003 to be approximately \$92 million, which includes the non-cash compensation charge, net of tax, of \$30 million as recorded in the first quarter of 2003, currently anticipated milestone payments to partners for successful achievement of regulatory milestones, net of tax, of approximately \$7 million and, currently anticipated manufacturing transfer costs, net of tax, of approximately \$4 million. These amounts do not include the non-cash compensation charge that may arise as a result of the vesting of the approximately 5.0 million outstanding Class C4 stock options. If this vesting occurs, this charge will be substantial. For example, the vesting of the approximately 5.0 million outstanding Class C4 stock options will result in an additional pre-tax compensation charge to us, which would be approximately \$75 million, if the market price of our stock is \$17.29 on the date vesting occurs.

**Earnings Per Share.** Earnings per share for the three months ended March 31, 2003 was \$.12 per diluted share, which included a non-cash compensation charge, net of tax, of \$.23 per share. Although there can be no assurance, we anticipate earnings per share for the year ended December 31, 2003 to be approximately \$.70 per diluted share, which includes the non-cash compensation charge, net of tax, of \$.23 per diluted share as recorded in the first quarter of 2003, currently anticipated milestone payments to partners for successful achievement of regulatory milestones, net of tax, of approximately \$.05 per diluted share and, currently anticipated manufacturing transfer costs, net of tax, of approximately \$.03 per diluted share. These amounts do not include the non-cash compensation charge that may arise as a result of the vesting of the approximately 5.0 million outstanding Class C4 stock options. If this vesting occurs, this charge will be substantial. For example, the vesting of the approximately 5.0 million outstanding Class C4 stock options will result in an additional pre-tax compensation charge to us, which would be approximately \$75 million, if the market price of our stock is \$17.29 on the date vesting occurs.

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

**Net Sales.** Net sales for the year ended December 31, 2002 increased by 58% to \$399.0 million from \$252.0 million in the comparable 2001 period. This increase in net sales was primarily due to the increase in net sales of Percocet®, Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia and certain generic products. Percocet® net sales increased 43% to \$144.6 million from \$101.0 million in the comparable 2001 period. In April 2001, generic equivalents of Percocet® 7.5/500 and Percocet® 10.0/650 were introduced. In November 2001, we launched Percocet® 7.5/325 and Percocet® 10.0/325 which do not currently have generic equivalents. Prescriptions for these new strengths of Percocet® have continued to grow based on our sales and promotional efforts. In September 1999, we launched Lidoderm®, which continues to gain market share due to our ongoing promotional and educational efforts. Net sales of Lidoderm® increased 103% to \$83.2 million from \$40.9 million in the comparable 2001 period. Generic products increased 77% to \$149.1 million from \$84.3 million in the comparable 2001 period primarily due to the growth of our generic morphine sulfate extended release tablets and Endocet®. In November 1998, we launched the 15mg, 30mg and 60mg strengths, in May 2001, we launched the 100mg strength and in September 2001, we launched the 200mg strength of our generic morphine sulfate extended release tablets. These products continue to gain market share. In April 2001, we launched two new strengths of our generic product Endocet®. Generic competition with our products may have a material impact on our results of operations and cash flows in the future.

**Gross Profit.** Gross profit for the year ended December 31, 2002 increased by 69% to \$300.1 million from \$177.1 million in the comparable 2001 period. Gross profit margins increased to 75% from 70% in the comparable 2001 period due to a more favorable mix of higher margin brand and generic products

resulting from the product launches discussed above, and the discontinuation of some lower margin non-core products. In addition, the increase in gross profit margins was also due to the existing fixed cost nature of our manufacturing relationship with Bristol-Myers Squibb Pharma Company (formerly DuPont Pharmaceuticals), currently our most significant contract manufacturing relationship. Further, during the fourth quarter of 2002, we substantially completed the manufacture of the estimated launch quantities of our extended-release oxycodone tablets. Due to the uncertainty surrounding the ultimate timing of this product's final approval and launch, however, an \$8.0 million reserve was recorded in the 2002 fourth quarter to fully reserve for this inventory. See Business Legal Proceedings. If we achieve our forecast for revenue and product mix, we expect the increase in gross profits and gross profit margins to continue.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the year ended December 31, 2002 increased by 39% to \$110.9 million from \$79.5 million in the comparable 2001 period. This increase was due to a \$15.0 million increase in sales and promotional efforts in 2002 over the comparable 2001 period to support Lidoderm® and Percocet®. In addition, we experienced an increase in personnel-related costs in the general and administrative functions in order to support our new product marketing and new product development. During 2003, we anticipate increasing our investment in sales, promotional efforts and support of our business over 2002 levels. This anticipated increase is primarily attributable to increased spending on Lidoderm® and Percocet® as well as preparing for the anticipated launches in 2004 of extended-release and immediate-release oxymorphone, DepoMorphine™ and our oral mucositis product.

**Research and Development Expenses.** Research and development expenses for the year ended December 31, 2002 increased by 46% to \$56.8 million from \$39.0 million in the comparable 2001 period. This increase was due to our increased spending on new products under development that are focused in pain management and complementary areas. During 2003, we anticipate decreasing our research and development spending compared to 2002 to reflect the overall stage of development of our development portfolio. During 2002, we completed the clinical trials of and subsequently filed the New Drug Applications relating to the extended-release and immediate-release oxymorphone products and additionally substantially concluded three Phase III clinical trials of Morphidex®. During 2003, we will focus our development efforts on our oral rinse (0.1% triclosan) for oral mucositis product which is currently in Phase III clinical trials as well as other projects focused in the area of pain management. In addition, we anticipate the restart by our partner DURECT Corporation of the clinical trials of CHRONOGESIC™ in the second half of 2003. If the clinical trials are restarted during 2003, we will fund 50% of the ongoing development costs.

**Depreciation and Amortization.** Depreciation and amortization for the year ended December 31, 2002 decreased to \$3.1 million from \$49.2 million in the comparable 2001 period. Effective January 1, 2002, we have adopted the provisions of SFAS No. 142, Goodwill and Other Intangible Assets, and will no longer amortize goodwill unless evidence of an impairment exists. If SFAS No. 142 had been adopted as of January 1, 2001, depreciation and amortization for the year ended December 31, 2001 would have been \$2.9 million. We expect depreciation and amortization expense to increase in 2003 as a result of the marketing rights acquired from SkyePharma in December 2002.

**Compensation Related to Stock Options.** For the year ended December 31, 2002, compensation related to stock options decreased to \$34.7 million from \$37.3 million in the comparable 2001 period. Compensation related to stock options reflects the charge arising from the vesting of performance-based stock options granted pursuant to the Endo Pharma LLC Stock Option Plans. Under these plans, tranches of options vest when we attain certain common stock price targets. As each tranche vests, we incur a non-cash charge representing the difference between the market price of the shares of common stock underlying these options and the exercise price of such options. The decrease in compensation related to stock options is due to the decrease in the market price of our common stock as of the measurement date to \$7.70 in 2002 from \$10.80 in 2001. This is offset in part due to an increase in the number of Endo Pharma LLC stock options that vested in 2002 as compared to 2001. During 2002, 6.9 million of these stock options vested, and during 2001, 4.6 million stock options vested. The weighted average exercise price of these stock options that vested in 2002 and 2001 was \$2.69. On January 1, 2003, the Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective resulting in the issuance of

approximately 10.7 million stock options to certain employees and members of management. Because approximately 9.2 million of these stock options were immediately vested upon their issuance, we recorded a non-cash compensation charge of approximately \$48.5 million during the first quarter of 2003 for the difference between the market price of our common stock as of the measurement date of \$7.70 and the weighted average exercise price of these stock options of \$2.42. The exercise of these stock options will not result in the issuance of any additional shares of our common stock, however, because these stock options are exercisable only into shares of our common stock that are held by Endo Pharma LLC. Accordingly, these stock options do not dilute the public shareholders. The remaining unvested class of performance-based stock options (Class C4) under the Endo Pharma LLC Stock Option Plans vest upon (i) our common stock exceeding an average closing price threshold of \$17.29 for ninety consecutive trading days, (ii) the closing price of our common stock on the last trading day of such ninety consecutive trading day period being greater than or equal to \$14.70 and (iii) the holder being a director, officer or employee of us or any of our subsidiaries on such date. The vesting of the approximately 5.0 million outstanding Class C4 stock options will result in an additional compensation charge to us, which would be approximately \$75 million if the market price of our stock on the date the vesting occurs is \$17.29. If this vesting occurs, this charge will be substantial. As stated above, these options are exercisable solely into shares of our common stock that are presently held by Endo Pharma LLC. As a result, the exercise of these options will not result in the issuance of additional shares of common stock and will not dilute the ownership of our other public stockholders. Further, the shares of common stock that individuals receive upon exercise of stock options granted pursuant to the Endo Pharma LLC Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements. For a discussion of the tax sharing agreement between us and Endo Pharma LLC relating to the Endo Pharma LLC Stock Options, see Liquidity and Capital Resources; Tax Sharing Agreement.

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

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

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

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

reduction of goodwill. The reversal of the reserves recorded subsequent to the Algos acquisition was recorded as an increase to income tax benefit. The estimated fair value of the purchased in-process research development of \$20.3 million is not a tax deductible item and, therefore, increases our effective income tax rate in 2002.

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

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

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

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

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

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

***Compensation Related to Stock Options.*** For the year ended December 31, 2001, compensation related to stock options increased to \$37.3 million from \$15.3 million in the comparable 2000 period. Compensation related to stock options reflects the charge arising from the vesting of performance-based

stock options granted pursuant to the Endo Pharma LLC 1997 Stock Option Plans. Under these plans, tranches of options vest when we attain certain common stock price targets. As each tranche vests, we incur a non-cash charge representing the difference between the market price of the shares of common stock underlying the options and the exercise price of such options. We may in the future incur an additional compensation charge on account of the Endo Pharma LLC Stock Option Plans as a result of the attainment of this common stock price target. These charges may be substantial. These options are exercisable solely into shares of our 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 our common stock and will not dilute the ownership of our other public stockholders. Further, the shares of common stock that individuals receive upon exercise of stock options granted pursuant to the Endo Pharma LLC Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements. For a discussion of the tax sharing agreement between us and Endo Pharma LLC relating to the Endo Pharma LLC Stock Options, see [Liquidity and Capital Resources; Tax Sharing Agreement](#).

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

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

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

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

***Income Tax (Benefit).*** We recorded an income tax benefit for the year ended December 31, 2001 of \$4.6 million compared to an income tax benefit for the year ended December 31, 2000 of \$6.2 million. During the fourth quarter of 2001, we evaluated our anticipated future taxable income based upon the repayment of our outstanding term loans, new product approvals and other existing and estimated future product performance and determined that it is more likely than not that we will utilize our deferred tax benefits. Accordingly, we reversed our valuation reserves that had been recorded against those deferred tax assets. The reversal of the reserves established in connection with the acquisition of Algos was recorded as a reduction of goodwill. The reversal of the reserves recorded subsequent to the Algos acquisition was recorded as an increase to income tax benefit.

## **Liquidity and Capital Resources**

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

***Net Cash Provided by Operating Activities.*** Net cash provided by operating activities increased by \$36.0 million to \$65.1 million for the three months ended March 31, 2003 from \$29.1 million for the three months ended March 31, 2002. This increase was due to the cash provided by the increase in net sales and gross profit for the three months ended March 31, 2003 compared to the three months ended March 31, 2002, offset by an increase in selling, general and administrative expenses for the three months ended March 31, 2003 as compared to the three months ended March 31, 2002. Net cash provided by operating activities increased by \$29.1 million to \$109.6 million for the year ended December 31, 2002 from

\$80.5 million for the year ended December 31, 2001. This increase was due to the cash provided by the increase in net sales and gross profit for the year ended December 31, 2002 compared to the year ended December 31, 2001 offset by an increase in selling, general and administrative expenses and research and development expenses for the year ended December 31, 2002 as compared to the year ended December 31, 2001.

**Net Cash Used in Investing Activities.** Net cash utilized in investing activities increased by \$25.4 million to \$25.4 million for the three months ended March 31, 2003. During the three months ended March 31, 2003, the Company paid a \$25.0 million license fee to SkyePharma, Inc. for the marketing rights to DepoMorphine™ and Propofol IDD-D™. Net cash used in investing activities was \$22.3 million for the year ended December 31, 2002 compared to \$6.5 million for the year ended December 31, 2001. The increase is substantially due to the \$14.2 million used to acquire BML Pharmaceuticals in 2002 and the \$5.0 million used to purchase of DURECT Corporation common stock. Capital expenditures decreased in 2002 to \$3.1 million from \$6.5 million. This decrease in capital expenditures was due to the purchase in 2001 of leasehold improvements and other furniture and fixtures related to our new principal executive offices, the lease of which commenced in the third quarter of 2001 and the implementation of an electronic document management system during 2001.

**Net Cash Utilized in Financing Activities.** Net cash utilized in financing activities decreased by \$6.6 million to \$.1 million for the three months ended March 31, 2003 from \$6.7 million for the three months ended March 31, 2002. During the three months ended March 31, 2002, we utilized \$6.7 million of cash, including fees, to repurchase 8.6 million of our Class A Transferable Warrants and Class B Non-Transferable Warrants. Net cash utilized in financing activities increased by \$88.0 million to \$125.8 million for the year ended December 31, 2002 from \$37.8 million for the year ended December 31, 2001. During the 2002 fiscal year, we repaid all of the promissory notes issued to Bristol-Myers Squibb which totaled \$118.9 million, and we utilized \$6.7 million of cash, including fees, to repurchase 8.6 million Class A Transferable Warrants and Class B Non-Transferable Warrants. During the year ended December 31, 2001, we repaid in full the term loans under our old senior secured credit facility. Additionally, in October of 2001, we completed a public offering of 12.9 million primary shares of common stock that provided net proceeds of \$96.2 million.

**Credit Facility.** In December 2001, we amended and restated our senior secured credit facility with a number of lenders. This amended and restated credit facility provides us with a line of credit of \$75.0 million. The line of credit matures on December 21, 2006. Any loans outstanding under the amended and restated credit facility are secured by a first priority security interest in substantially all of our assets. The credit facility contains representations and warranties, covenants, including a covenant requiring us to maintain minimum EBITDA of \$50 million over the prior four-quarter period, events of default and other provisions customarily found in similar agreements. Our ability to borrow under the credit facility is dependent, among other things, on our compliance with those provisions. As of June 13, 2003, we have not borrowed any amounts under our credit facility.

**Tax Sharing Agreement.** On July 14, 2000, Endo Pharma LLC was formed in connection with the Algos merger to ensure that the stock options granted pursuant to the Endo Pharma LLC Stock Option Plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC will be delivered. Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we will be required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of March 31, 2003, approximately 1.4 million of these stock options had been exercised by former employees into shares of our common stock held by Endo Pharma LLC. The exercise of any of these Endo Pharma LLC stock options generally will permit us to deduct as a compensation charge, for federal income tax purposes, an amount equal to the difference between the market price of our common stock and the exercise price paid upon exercise of these options (as of March 31, 2003, approximately \$11 million).

which is estimated to result in a tax benefit amount of approximately \$4 million. Under the tax sharing agreement, we are required to pay this \$4 million to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, to the extent that a compensation charge deduction is usable to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto.

Using a weighted average exercise price of \$2.61 per share and an assumed effective tax rate of 38.3%, if all 36.3 million stock options under the Endo Pharma LLC Stock Option Plans were vested and exercised (including the 1.4 million stock options already exercised as discussed above):

assuming the market price of our common stock was \$10.00 per share, then, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$268 million, which could result in a tax benefit amount of approximately \$103 million payable to Endo Pharma LLC.

assuming the market price of our common stock was \$15.00 per share, then, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$450 million, which could result in a tax benefit amount of approximately \$172 million payable to Endo Pharma LLC.

assuming the market price of our common stock was \$20.00 per share, then, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$631 million, which could result in a tax benefit amount of approximately \$242 million payable to Endo Pharma LLC.

Under the terms of the tax sharing agreement, we must pay all such tax benefit amounts to Endo Pharma LLC to the extent these tax benefits are usable by us, as described above. However, these payments need only be made to Endo Pharma LLC upon the occurrence of a liquidity event, which is generally defined as a transaction or series of transactions resulting in (a) a sale of greater than 20% on a fully diluted basis of our common equity (either through (i) a primary offering by us, (ii) a secondary sale by Endo Pharma LLC or other holders of common stock pursuant to a registration rights agreement or (iii) a combination of both such primary and secondary offerings), (b) a change in control of Endo or (c) a sale of all or substantially all of our assets. In accordance with the tax sharing agreement, no payments have been made or accrued to date. This offering, which represents a sale of, on a fully diluted basis, approximately 11% of our common equity or approximately 13% if the underwriters' overallotment is exercised, does not, by itself, trigger a payment under the tax sharing agreement, and no liquidity event will result from this offering. This offering may, however, be combined with future offerings to result in a series of transactions that will trigger a payment obligation pursuant to the tax sharing agreement. Endo Pharma LLC has informed us that, subject to a variety of factors, including market conditions and stock price levels, it may initiate additional secondary offerings in the future.

**Fluctuations.** Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations are primarily due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products and the impact of competitive products and pricing. As an example, in the first quarter of 2003, our customers increased their inventories back to normalized levels from the relatively low levels that were maintained at the end of 2002, contributing to increased sales of a number of our products, as described above. Further, a substantial portion of our net sales are through wholesale drug distributors who in turn supply our products to pharmacies, hospitals and physicians. Accordingly, we are potentially subject to a concentration of credit risk with respect to our trade receivables.

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

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

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



**Expected Cash Requirements for Contractual Obligations.** The following table presents our expected cash requirements for contractual obligations outstanding as of December 31, 2002 (in thousands):

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

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

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

In addition, we agreed to certain contingent payments in certain of our acquisitions and licenses entered into during 2002. See Business Service Agreements and Business Licenses and Collaboration Agreements. Specifically:

**BML Pharmaceuticals.** Upon FDA approval of our development oral rinse product (0.1% triclosan) for oral mucositis, we will pay the former shareholders of BML Pharmaceuticals a \$32.0 million payment in addition to an earn-out based on a percentage of net sales of this and certain other products that we acquired when we purchased BML on July 26, 2002.

**DURECT Corporation.** On November 8, 2002, we entered into a license agreement with DURECT Corporation to exclusively develop and commercialize DURECT's CHRONOGESIC™ (sufentanil) Pain Therapy System for the U.S. and Canada. In August 2002, at the request of the FDA, DURECT delayed enrolling new patients in the Phase III clinical trial of CHRONOGESIC™, which it had initiated in June 2002, until the clinical trial had been revised and approved by the FDA to provide for additional patient monitoring and data collection. These requested protocol changes were not in response to any observed patient safety or adverse event. Once the clinical trials of CHRONOGESIC™ have restarted or beginning on June 30, 2004 (whichever is earlier), Endo will be obligated to fund 50% of the ongoing development costs of CHRONOGESIC™. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under this agreement could total up to \$52.0 million. In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. With respect to termination rights, this agreement permits Endo to terminate its continued participation under a number of

circumstances, one of which could require Endo to pay DURECT \$10.0 million. Endo and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC™.

*SkyePharma, Inc.* On December 31, 2002, we entered into a development and commercialization agreement under which we received an exclusive license to the U.S. and Canadian marketing and distribution rights for two of SkyePharma's patented development products, DepoMorphine™ and Propofol IDD-D™, with options for certain other development products. In return, SkyePharma received a \$25.0 million upfront payment from Endo, which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We are amortizing this intangible asset over its estimated useful life of 17 years. Milestone payments made by Endo may total up to \$95.0 million which includes total milestones of \$10.0 million for DepoMorphine™ through FDA approval. The milestone payments also include \$50.0 million for Propofol IDD-D™, payable when the product successfully achieves certain regulatory milestones, including FDA approval. The total further comprises a \$15.0 million milestone payable when net sales of DepoMorphine™ exceed \$125.0 million in a calendar year and a \$20.0 million milestone payable when net sales of DepoMorphine™ exceed \$175.0 million in a calendar year.

**Collaboration Agreements.** We have entered into certain collaboration agreements with third parties for the development of pharmaceutical products. These agreements may require us to share in the development costs of such products, make payments to these third parties upon the achievement of certain defined milestones, make payments to such third parties based on a percentage of the net sales of such products and generally grant marketing rights to us for such products. If any of our third party partners are unable or unwilling to fund their portion of the particular collaboration project with us, this may adversely affect our results of operations and cash flows in the foreseeable future. On March 18, 2003, we received notice from Penwest Pharmaceuticals Co. (a collaboration partner of Endo with which Endo has an alliance agreement and with which Endo is developing its pipeline project, oxymorphone ER) that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of oxymorphone ER on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we will now be responsible for funding 100% of these remaining costs until such time as the FDA approves oxymorphone ER, at which time we will recoup from the royalties due to Penwest the full amount of what Penwest should have contributed had it not exercised such right. We believe that our cash and cash equivalents and cash flow from operating activities will be more than sufficient to meet our normal operating, investing and financing activities in the foreseeable future, including the funding of 100% of the costs to bring our pipeline products, including oxymorphone ER, to market.

**Cash and Cash Equivalents.** Our cash and cash equivalents totaled \$96.5 million at March 31, 2003. We believe that our (a) cash and cash equivalents, (b) cash flow from operations and (c) our credit facility (which has an available unused line of credit of \$75.0 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 or unwilling to fund their portion of any particular project. We may use a portion of our cash and cash equivalents for possible acquisitions.

#### **Recent Accounting Pronouncements**

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

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

from goodwill. SFAS No. 142 establishes revised reporting requirements for goodwill and other intangible assets. See Critical Accounting Policies; Goodwill and Other Intangibles.

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

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

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

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

## BUSINESS

We are a specialty pharmaceutical company with market leadership in pain management. We are engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat and manage pain. According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$15 billion in 2002. This represents an approximately 23% compounded annual growth rate since 1998. Our primary area of focus within this market is in the opioid analgesics segment. Total U.S. sales for this segment were \$4.6 billion in 2002, representing a compounded annual growth rate of 25% since 1998.

We have a portfolio of branded products that includes established brand names such as Lidoderm®, Percocet®, Percodan® and Zydone®. Branded products comprised approximately 63% of our net sales in 2002. Our generic portfolio, which accounted for 37% of net sales in 2002, currently consists of products that cover a variety of indications, most of which are focused in pain management. We focus on generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing.

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

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

### Our Competitive Strengths

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

***Established portfolio of branded products.*** We have assembled a portfolio of branded pharmaceutical products to treat and manage pain. These products include Lidoderm®, a topical patch containing lidocaine, which is the first FDA-approved product to treat the pain relating to post-herpetic neuralgia. The FDA has granted Lidoderm® orphan drug status, which means, generally, that no other lidocaine-containing product can be approved for this indication until March 2006. Additionally, Lidoderm® is protected by certain patents until 2015. Net sales of Lidoderm® increased 103% from \$40.9 million in 2001 to \$83.2 million in 2002. We consider Percocet®, our oxycodone/ acetaminophen combination product and Percodan®, our oxycodone/ aspirin combination product, which have been marketed since 1976 and 1950, respectively, to be gold standards of pain management based on their long history of demonstrated product safety and effectiveness. According to IMS Health data, approximately 84% of prescriptions written for oxycodone with acetaminophen are in fact written as Percocet. We believe our close relationships with physicians who are considered to be pain management thought leaders in pain centers, hospitals, and other pain management institutions enable us to improve our market penetration. We believe this interaction with the thought leaders and our track record of developing and launching new products has allowed us to pursue, through in-licensing and acquisitions, novel products for the treatment of pain and complementary therapeutic areas.

***Substantial pipeline focused on pain management with a balanced focus on complementary therapeutic areas.*** As a result of our focused research and development efforts, we filed two NDAs with the FDA in December 2002 for oxymorphone ER and oxymorphone IR, which the FDA accepted for substantive review in February 2003. In addition, we have two products in Phase III clinical trials and three products in Phase II clinical trials. If the FDA's review of oxymorphone ER and oxymorphone IR progresses as we anticipate, we expect to receive the first action letters, stating whether the products are approvable or not approvable and possibly identifying further requirements, from the FDA by the end of 2003. If the

current clinical trials for DepoMorphine™ progress as we expect, we anticipate that an NDA will be filed with the FDA by mid-2003. In addition, if the clinical trials progress as we expect, we anticipate filing an NDA with the FDA for our oral rinse product (0.1% triclosan) for oral mucositis by late 2003 or early 2004.

**Research and development expertise.** Our research and development effort is focused on expanding our product portfolio by capitalizing on our core expertise with analgesics. We have assembled an experienced and multi-disciplined research and development team of scientists and technicians with a proven expertise working with analgesics and complex formulations. We believe this expertise allows for timely FDA approval of our products. We have demonstrated our ability to commercialize our research and development efforts during the last five years through the launch of a number of new products and product line extensions since August 1997, which, in the aggregate, contributed approximately 56% of our net sales in 2002.

**Targeted national sales and marketing infrastructure.** We market our products directly to physicians through an internal sales force of 70 specialty/institutional representatives and a dedicated contract sales force of approximately 160 community-based field representatives. Through our sales force, we market our branded pharmaceutical products to approximately 35,000 physicians, including specialists who write approximately 80% of the specialist prescriptions for oxycodone/acetaminophen. Furthermore, we maintain an internal sales management infrastructure to direct and focus these sales efforts, targeting primary care providers and specialists that frequently prescribe opioid analgesics. The contract sales force is provided exclusively to us pursuant to an agreement with Ventiv Health U.S. Sales Inc., or Ventiv. In 2002, we exercised our option to convert the 70 specialty/institutional sales representatives and their managers to Endo employees effective July 1, 2002. We have a flexible arrangement with Ventiv, whereby we have the option to hire all of the 160 community-based field representatives and their managers as our full time employees at any time.

**Selective focus on generic products.** Our generic product portfolio includes products focused on pain management. Development of these products involves barriers to entry such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. We believe products with these characteristics will face a lesser degree of competition and therefore provide longer product life cycles and higher profitability than commodity generic products. We have executed our generic product development strategy successfully to date with products such as morphine sulfate extended-release tablets, which we introduced in November 1998 as a bioequivalent version of MS Contin, a product of the Purdue Frederick Company. In addition, we believe we are the first company to have filed an ANDA with the FDA for the bioequivalent version of the 10mg, 20mg and 40mg strengths of Purdue Frederick's OxyContin. For several reasons, including potential marketing exclusivity, we believe it is a significant advantage to be the first successful filer of an ANDA for a generic drug. In July 2002, we received a tentative approval from the FDA for all four strengths (10mg, 20mg, 40mg and 80mg) of our generic OxyContin. We currently are in litigation with Purdue Frederick regarding our generic version of OxyContin. See Legal Proceedings.

**Experienced and dedicated management team.** With an average of approximately 20 years of experience in the pharmaceutical industry, our senior management team has a proven track record of building our business through internal growth as well as through acquisitions and licensing. Members of our senior management led the purchase of the company from The DuPont Merck Pharmaceutical Company in August 1997 as well as the licensing of Lidoderm®, CHRONOGESIC™, DepoMorphine™ and Propofol IDD-D™ and the acquisition of the oral rinse (0.1% triclosan) for oral mucositis. Management has received FDA approval on more than fifteen new products and product line extensions since 1997, and as a result of several successful product launches, has grown Endo's net sales from approximately \$108.4 million in 1998 to approximately \$399.0 million in 2002. In addition, management has vested stock options to acquire as much as 19% of our common stock and has the potential to receive as much as an additional 3% of our common stock through options that will vest if the price of our common stock reaches a specified defined target. After this offering, senior management will have vested stock options to acquire up to 18% of our common stock and will have the potential to receive up to an additional 3% of our common stock through options that will vest if the price of our common stock

reaches a specified, defined target. All of these options are exercisable solely for shares currently held by Endo Pharma LLC, and their exercise will not dilute the ownership of our other existing common stockholders. In this offering, senior management will be selling less than 5% of its aggregate ownership in Endo. See Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies; Compensation Related to Stock Options Endo Pharma LLC Stock Option Plans.

## Our Strategy

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

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

***Leveraging our pain management expertise by developing proprietary products and generic products with significant barriers to market entry.*** To capitalize on our expertise in pain management, we are developing new products to address acute, chronic and neuropathic pain conditions. We are developing new patent-protected products that may substantially improve the treatment of pain. Recently, we co-developed an oral extended-release (ER) version of oxymorphone with Penwest Pharmaceuticals Co. and developed an oral immediate-release (IR) version of oxymorphone. The NDAs for oxymorphone ER and IR were filed with the FDA in December 2002 and were accepted for substantive review in February 2003. We are also developing a patented prescription oral rinse (0.1% triclosan) for the management of oral mucositis, painful mouth sores that often occur in patients undergoing cancer treatment. Currently, no product is approved for either the prevention or treatment of oral mucositis; accordingly, the FDA has agreed to grant fast-track review to this product. We expect to be in a position to file an NDA for this product by late 2003 or early 2004. In addition, we are developing with our partner, SkyePharma, Inc., two of SkyePharma's patent-protected development products, DepoMorphine™ and Propofol IDD-D™. DepoMorphine™, a sustained-release injectable formulation, and Propofol IDD-D™, administered intravenously, are our first post-surgical, critical-care drugs. If the clinical trials progress as we expect, we anticipate the DepoMorphine™ NDA to be filed with the FDA by mid 2003. Further, together with DURECT Corporation, we are developing DURECT's patent-protected product, CHRONOGESIC™ (sufentanil) Pain Therapy System to treat patients with chronic pain resulting from a variety of malignant and non-malignant causes. If approved, this product would represent the first systemic medication that provides patients with uninterrupted pain treatment for three months from a single application.

We have also developed an extended-release version of oxycodone, a generic version of OxyContin, a product of The Purdue Frederick Company. According to IMS Retail Provider Perspective data, OxyContin generated U.S. sales of approximately \$1.6 billion in 2002. We have received tentative approval from the FDA for bioequivalent versions of the 10mg, 20mg, 40mg and 80mg strengths of OxyContin. We believe we are the first company to have filed an ANDA with the FDA for the bioequivalents of the 10mg, 20mg and 40mg strengths of OxyContin, thereby potentially entitling us to 180 days of generic product marketing exclusivity with respect to these strengths of this product. We currently are in litigation with Purdue Frederick regarding our generic version of OxyContin. See Legal Proceedings.

**Acquiring and in-licensing complementary products, compounds and technologies.** We look to continue to enrich our product line through selective product acquisitions and in-licensing, or acquiring licenses to products, compounds and technologies from third parties. During 2002, we added four patent-protected products to our research and development pipeline. Specifically, in July 2002, we acquired BML Pharmaceuticals, which provided us with the opportunity to gain access to the palliative care side of oncology, which we see as a natural extension of our pain management franchise. In November 2002, we entered into an agreement whereby we received the exclusive promotional rights to the development product CHRONOGESIC™ in the U.S. and Canada. Under this agreement, we will be responsible for marketing, sales and distribution. In December 2002, we entered into a development and commercialization agreement and received an exclusive license to the U.S. and Canadian marketing and distribution rights for DepoMorphine™ and Propofol IDD-D™. If approved, these medications would expand our presence in the hospital-based setting, consistent with our strategy of growing our franchise in pain management and complementary therapies.

**Developing and marketing product line extensions of our existing brands.** We plan to continue to develop and market extensions of existing products through new formulations, dosages and delivery platforms. During the fourth quarter of 1999, we complemented the existing Percocet® 5.0/325 with three new formulations: Percocet® 2.5/325, Percocet® 7.5/500 and Percocet® 10.0/650. Additionally, during the fourth quarter of 2001, we launched two new formulations: Percocet® 7.5/325 and Percocet® 10.0/325, providing physicians with ever greater flexibility when treating their patients who are in pain. Led by the performance of Percocet® 7.5/325 and Percocet® 10.0/325, net sales of the Percocet® family of products increased 43% from \$101.0 million in 2001 to \$144.6 million in 2002.

## **Our Industry**

According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$15.0 billion in 2002. This represents an approximately 23% compounded annual growth rate since 1998. Our primary area of focus within this market is analgesics. In 2002, analgesics were the fourth most prescribed medication in the United States with over 249 million prescriptions written for this classification. These products are used primarily for the treatment of pain associated with orthopedic fractures and sprains, back injuries, migraines, joint diseases, cancer and various surgical procedures.

Opioid analgesics comprised approximately 74% of the analgesics prescriptions in 2002. This market segment has grown to \$4.6 billion in 2002, representing a compounded annual growth rate of 25% since 1998. If branded products were substituted for generic products, we believe the dollar value of this market segment would be substantially larger. The growth in this segment has been primarily attributable to:

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

aging population (according to the U.S. Census Bureau, in 2000 the population aged 65 and older reached 35 million people and is expected to grow to 40 million people by 2010, representing 14% growth over this period);

introduction of new and reformulated branded products; and

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

**Product Overview**

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

<b>Product</b>	<b>Active Ingredient(s)</b>	<b>Branding</b>	<b>Status</b>
Lidoderm®	lidocaine 5%	Branded	Marketed
Percocet®	oxycodone and acetaminophen	Branded	Marketed
Percodan®	oxycodone and aspirin	Branded	Marketed
Zydone®	hydrocodone and acetaminophen	Branded	Marketed
Morphine Sulfate ER	morphine sulfate	Generic	Marketed
Oxymorphone ER(1)	oxymorphone hydrochloride	Branded	NDA filed; under FDA review
Oxymorphone IR	oxymorphone hydrochloride	Branded	NDA filed; under FDA review
DepoMorphine™(2)	morphine sulfate	Branded	Phase III
Oral Rinse (0.1% triclosan) for Oral Mucositis	triclosan 0.1%	Branded	Phase III
CHRONOGESIC™(3)	sufentanil	Branded	Phase II
Propofol IDD-D™(2)	propofol	Branded	Phase II
Lidoderm® (chronic low back pain)	lidocaine 5%	Branded	Phase II
Oxycodone ER(4)	oxycodone	Generic	Tentatively approved; subject to ongoing litigation

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

**Branded Products**

**Lidoderm®.** Lidoderm® was launched in September 1999. A topical patch product containing lidocaine, it is the first FDA-approved product for the relief of the pain relating to post-herpetic neuralgia. There are approximately 200,000 patients per year who suffer from this condition in the United States, the majority of whom are elderly. The FDA has granted Lidoderm® orphan drug status, generally meaning that no other lidocaine-containing patch product can be approved for this indication until March 2006. Certain exceptions apply (for example, a product shown to be clinically superior may be approved); however, we are unaware that any such product has been, or is being, developed. Lidoderm® is also currently protected by patents for, among other things, treating post-herpetic neuralgia and the composition of the lidocaine-containing patch. The last of these patents will expire in 2015. In 2000, 2001, 2002 and the three months ended March 31, 2003, Lidoderm® net sales were \$22.5 million, \$40.9 million, \$83.2 million and \$41.5 million, respectively. Lidoderm® accounted for approximately 21% of our 2002 net sales.

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

**Percocet®.** We consider Percocet® to be a gold standard of pain management. Launched in 1976, Percocet® is approved for the treatment of moderate-to-moderately severe pain. Although Percocet® has



faced generic competition for nearly 20 years, in 2002, according to the IMS National Prescription Audit, approximately 13.9 million new prescriptions for this combination of oxycodone hydrochloride and acetaminophen were written for the brand name Percocet, of which, due to generic substitution, only approximately 14% were filled by pharmacists with our brand Percocet®.

During the fourth quarter of 1999, we introduced three new strengths of Percocet®: Percocet® 2.5/325, Percocet® 7.5/500 and Percocet® 10.0/650, complementing the existing Percocet® 5.0/325. Prior to the launch of these products, physician prescribing practices had indicated that over 80% of prescriptions were written for amounts other than the label amount. As an example, the current prescription information for the original Percocet®, Percocet® 5.0/325, calls for one tablet every six hours. Approximately 30% of prescriptions written directed patients to take two tablets every four hours, translating into a dosage of 10mg every four hours. By offering new prescription strengths, we have enabled physicians to prescribe one tablet of the proper dose for their patients, facilitating greater ease of administration and compliance. On January 3, 2001, the Food and Drug Administration approved another manufacturer's ANDA for a generic equivalent to Percocet® 7.5/500 and Percocet® 10.0/650. This generic equivalent became available in April 2001. During the fourth quarter of 2001, we launched two new formulations: Percocet® 7.5/325 and Percocet® 10.0/325. These new dosage strengths allow physicians the flexibility of increasing the dose of opioid while still maintaining a low level of acetaminophen. There is currently no generic equivalent available for these new dosage forms; however, we believe that generic competition may be introduced late in the third quarter of 2003. The Percocet® family of products had net sales of \$92.4 million, \$101.0 million, \$144.6 million and \$55.5 million in the years 2000, 2001, 2002 and the three months ended March 31, 2003, respectively. The Percocet® franchise accounted for approximately 36% of our 2002 net sales.

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

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

**Other.** The balance of our branded portfolio consists of a number of products, none of which accounted for more than 5% of our total net sales in the 2002 fiscal year.

### **Generic Products**

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

Our generic portfolio is currently comprised of products that cover a range of indications, most of which are focused in pain management. Our primary generic product is morphine sulfate extended-release tablets, which accounted for 22% of our total net sales in 2002. Launched in November 1998, morphine sulphate extended-release tablets are a bioequivalent of Purdue Frederick's MS Contin. In November 1998, we launched the 15mg, 30mg and 60mg strengths, in May 2001, we launched the 100mg strength and in September 2001, we launched the 200mg strength, thereby completing the product line. In addition, we have a generic oxycodone hydrochloride and acetaminophen product, Endocet®, which accounted for 9% of our total net sales in 2002. We also offer a generic of Sinemet® (carbidopa/levodopa) for the

treatment of the symptoms of idiopathic Parkinson's disease. The balance of our generic portfolio consisted of a few other products, none of which accounted for more than 5% of our total net sales for 2002.

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

complex formulation or development characteristics;

regulatory or legal challenges; or

difficulty in raw material sourcing.

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

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

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

***Oxymorphone ER.*** In December 2002, we filed an NDA for oxymorphone ER with the FDA and in February 2003, this NDA was accepted for substantive review. If approved, oxymorphone ER is intended to treat moderate-to-severe pain in patients requiring continuous, around-the-clock opioid therapy for an extended period of time. In Phase III clinical studies in each of osteoarthritis pain, chronic low back pain, cancer pain, and post-surgical pain, patients taking oxymorphone ER demonstrated statistically significant pain relief. We co-developed this oral extended-release version of oxymorphone with Penwest Pharmaceuticals and currently expect to receive a first action letter from the FDA by the end of 2003. If approved, we expect oxymorphone ER will compete in the approximately \$3 billion U.S. strong opioid market.

***Oxymorphone IR.*** In December 2002, we filed an NDA for oxymorphone IR with the FDA and in February 2003, this NDA was accepted for substantive review. If approved, oxymorphone IR is intended to treat acute moderate-to-severe pain. In Phase III clinical studies in post-surgical pain, patients taking oxymorphone IR demonstrated statistically significant pain relief. We currently expect to receive a first action letter from the FDA by the end of 2003.

***Oral Rinse (0.1% triclosan) for oral mucositis.*** We are currently in Phase III clinical trial development for a patented prescription oral rinse for the management of oral mucositis, painful mouth sores that often occur in patients undergoing cancer treatment. Currently, no product is approved for either the prevention or treatment of oral mucositis; accordingly, the FDA has agreed to grant fast-track review status to this product. We expect to be in a position to file an NDA for this product by late 2003 or early 2004.

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

***CHRONOGESIC™.*** Currently in Phase II clinical trial development, CHRONOGESIC™ is intended to target patients with opioid responsive chronic pain that results from a variety of causes. CHRONOGESIC™ is designed to deliver sufentanil continuously for three months of pain therapy. CHRONOGESIC™ is a miniature, self-driven titanium pump that is placed just under the skin, similar in size to a matchstick, from which drug is dispensed by the natural process of osmosis at a highly controlled

rate. The CHRONOGESIC™ clinical development program is on temporary hold pending agreement between DURECT and the FDA regarding additional monitoring and data collection. These protocol changes requested by the FDA were not in relation to any observed safety issue or adverse event. In addition, DURECT is implementing some necessary design and manufacturing enhancements to the CHRONOGESIC™ product. DURECT anticipates that the changes to the existing clinical protocol, and the implementation of these design and manufacturing enhancements, will delay the restart of clinical trials until the second half of 2003.

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

**Oxycodone ER.** We have also developed an extended-release version of oxycodone, a generic version of OxyContin, a product of The Purdue Frederick Company. According to IMS Retail Provider Perspective data, OxyContin generated U.S. sales of approximately \$1.6 billion in 2002, up from approximately \$1.5 billion in 2001. We have received tentative approval from the FDA for bioequivalent versions of the 10mg, 20mg, 40mg and 80mg strengths of OxyContin. We believe we are the first company to have filed an ANDA with the FDA for the bioequivalents of the 10mg, 20mg and 40mg strengths of OxyContin, thereby potentially entitling us to 180 days of generic product marketing exclusivity with respect to these strengths of this product. We currently are in litigation with Purdue Frederick regarding our generic version of OxyContin. See Legal Proceedings. The rules governing market exclusivity are complex and may be affected by factors outside our control. In addition, these rules are currently undergoing reconsideration. Accordingly, even assuming we otherwise qualify for 180-day marketing exclusivity, we cannot guarantee that we will be able or willing to market our product during the relevant period.

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

## Competition

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

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

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

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

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

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

### **Research and Development**

We devote significant resources to research and development. At April 30, 2003, our research and development staff consisted of 57 employees, primarily based in Garden City, New York and at our corporate headquarters in Chadds Ford, Pennsylvania. On January 6, 2003, we entered into an agreement with Dawson Holding Company to lease a facility in Hicksville, New York, which will become our new research and development facility in late 2003 or early 2004. For fiscal years 2001 and 2002 and the three months ended March 31, 2003, our expenditures on research and development were \$39.0 million, \$56.8 million and \$12.1 million, respectively. In addition to our internal research and development staff, we have agreements and arrangements with various contract research organizations to conduct and coordinate our toxicology and clinical studies. In addition, many of the research and development activities of products that we have licensed the marketing rights to are performed by our partners.

### **Seasonality**

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

### **Customers**

We sell our products directly to a limited number of large pharmacy chains and through a limited number of wholesale drug distributors that, in turn, supply products to pharmacies, hospitals, governmental agencies and physicians. Three distributors and one pharmacy chain individually accounted for 26%, 16%, 12% and 10%, respectively, of our net sales in 2000. Three distributors and one pharmacy chain individually accounted for 28%, 24%, 19% and 10%, respectively, of our net sales in 2001. Three distributors and one pharmacy chain individually accounted for 24%, 24%, 23% and 11%, respectively, of our net sales in 2002.

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

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

As of June 9, 2003, we held 21 U.S. issued patents and 17 foreign issued patents, approximately 20 U.S. patent applications pending and approximately 52 foreign patent applications pending with respect to our products. In addition, as of June 9, 2003, we have licenses for approximately 41 U.S. issued patents, 4 U.S. patent applications pending, 71 foreign issued patents and 28 foreign patent applications pending.

The effect of these issued patents is that they provide us with patent protection for the claims covered by the patents. The coverage claimed in a patent application can be significantly reduced before the patent is issued. Accordingly, we do not know whether any of the applications we acquire or license will result in the issuance of patents, or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because unissued U.S. patent applications are maintained in secrecy for a period of 18 months and U.S. patent applications filed prior to November 29, 2000 are not disclosed until patents issue, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference

proceedings declared by the United States Patent and Trademark Office to determine priority of invention, or in opposition proceedings in a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued, would be held valid by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology.

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

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

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

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

***Bristol-Myers Squibb Pharma Company (f/k/a DuPont Pharmaceuticals).*** Bristol-Myers Squibb currently manufactures a number of our brand and generic pharmaceutical products. Bristol-Myers Squibb manufactures certain of the products that we purchased from DuPont Pharmaceuticals as a result of our August 1997 acquisition from DuPont Pharmaceuticals, as well as some of our new products. The products are manufactured at either the Bristol-Myers Squibb facility in Garden City, New York or the Bristol-Myers Squibb facility in Manati, Puerto Rico. Both of these facilities are FDA- and DEA-approved. For

these manufacturing services, we currently pay Bristol-Myers Squibb compensation in the form of (1) a fixed amount to cover Bristol-Myers Squibb's fixed manufacturing costs for both manufacturing facilities and (2) an amount, adjusted on an annual basis, to cover Bristol-Myers Squibb's variable manufacturing costs plus a reasonable profit.

In addition to manufacturing services, Bristol-Myers Squibb currently provides other ancillary services to us in connection with the manufacture of our products such as raw material procurement, inventory management and quality control services. Compensation for these services is included in the compensation for manufacturing services. The initial term of this agreement was five years, expiring on August 26, 2002. On August 27, 2002, we entered into an amendment to the agreement, which provided that Bristol-Myers Squibb would continue to manufacture our products until August 26, 2003, at which time the agreement will expire, and that we would be able to transfer up to 100% of our products to another manufacturer at any time. If, prior to August 26, 2003, Bristol-Myers Squibb determines to sell or otherwise transfer either the Garden City plant facility or the Manati plant facility and we determine that the acquirer of such facility would not be an acceptable manufacturer of our products, Bristol-Myers Squibb is required to implement, at its cost, appropriate arrangements for the manufacture and supply of the products elsewhere.

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

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

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

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

**Other Service Agreements**

In addition to the material long-term manufacturing agreements described above, we have agreements with (1) UPS Supply Chain Management, Inc. (f/d/b/a Livingston Healthcare Services, Inc.) for customer service support, warehouse and distribution services and certain financial functions, (2) Kunitz and Associates Inc. for medical affairs and (3) Ventiv Health U.S. Sales Inc. for sales promotion. We also have agreements and arrangements with various contract research organizations for our toxicology and clinical studies. Although we have no reason to believe that these agreements will not be honored, failure by any of these third parties to honor their contractual obligations may have a materially adverse effect on our business, financial condition and results of operations.

A description of the material terms of these agreements follows:

**UPS Supply Chain Management, Inc. (f/k/a Livingston Healthcare Services Inc.)** Under the terms of this agreement, we appointed UPS Supply Chain Management to provide customer service support, chargeback processing, accounts receivables management and warehouse and distribution services for our products in the United States. During the term of the agreement, the UPS personnel responsible for providing our customer service, chargeback processing and accounts receivable management services may not provide these services to any third party for any third party products which directly compete with our products covered under the agreement. We currently pay UPS (1) a fixed monthly fee for all services and (2) certain out-of-pocket expenses, which, in the aggregate, may, depending on the facts and circumstances at the time, represent material costs to us. For the year ended December 31, 2002, these fees and expenses were approximately \$5.0 million. The current term of the agreement for all services provided thereunder expires on February 28, 2005. The agreement may be renewed upon mutual agreement of the parties. The agreement may be terminated for material breach and by us, with prior notice: (1) for a sale of our company or a sale of substantially all of our business; (2) for a change in our stock ownership or company control; (3) if we decide to have these services provided in-house or by an affiliate; or (4) if UPS fails to provide additional storage space for our products upon request. In the event of termination under certain circumstances, we are required to pay UPS for certain capital investments and wind-down expenses.

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

**Ventiv Health U.S. Sales Inc.** Under the terms of this agreement, a team of Ventiv professional sales representatives, under our management's direction, exclusively promotes certain of our products to healthcare professionals in the United States. The term of this agreement is until December 31, 2003, but will automatically renew for one-year periods thereafter. The agreement may be terminated (1) by either party for material breach, (2) by us with 90 days' notice, for no reason or (3) by Ventiv with 180 days' notice, for no reason. Under the agreement, we reserve the option to hire all of these sales representatives and managers as our full-time employees at any time.

**Licenses and Collaboration Agreements**

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

**DURECT Corporation.** On November 8, 2002, we entered into a Development, Commercialization and Supply License Agreement with DURECT Corporation, which relates to DURECT's development

product, CHRONOGESIC™. CHRONOGESIC™'s clinical development program is on temporary hold pending agreement between DURECT and the FDA regarding additional monitoring and data collection. These protocol changes requested by the FDA were not in relation to any specific safety issue or adverse event. In addition, DURECT is currently implementing some necessary design and manufacturing enhancements to CHRONOGESIC™. The changes to the existing clinical protocol, and the implementation of these design and manufacturing enhancements, will delay the restart of the development program until the second half of 2003. Under the terms of this agreement, we will have no obligation to fund any of the development costs of CHRONOGESIC™ until the clinical trial restarts (which is currently anticipated to begin in the second half of 2003). In the event that the clinical trial has not restarted by December 31, 2003, then during the six-month period from January 1, 2004 until the earlier of (1) the recommencement of the clinical trial and (2) June 30, 2004, we will be responsible for 25% of the development costs of CHRONOGESIC™ actually incurred each month, up to an aggregate of \$3.0 million of development costs for such period. Once the particular clinical trial of CHRONOGESIC™ has restarted or beginning on June 30, 2004 (whichever is earlier), unless the agreement is earlier terminated, we will be obligated to fund 50% of the ongoing development costs of CHRONOGESIC™. We will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under this agreement could total up to \$52.0 million.

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

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

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

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

This agreement provides for the parties to work together to complete the necessary clinical, regulatory and manufacturing work for North American regulatory approval of the Skye Products. SkyePharma will be primarily responsible for clinical development up to final FDA approval, and for the manufacture of the



Skye Products, including all associated costs. Upon approval, Endo will market each Skye Product in the U.S. and Canada, with SkyePharma as the supplier. We will be responsible for funding and conducting any post-marketing studies and for all selling and marketing expenses. Under this agreement, we also obtained options on other SkyePharma development products, including DepoBupivacaine™, a long-acting, sustained release formulation of the local anesthetic bupivacaine. We have the option to obtain commercialization rights for this product when SkyePharma successfully completes its Phase II trials, as well as any further SkyePharma products formulated using the DepoFoam™ technology successfully developed for the prophylaxis or treatment of pain.

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

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

**Hind Healthcare Inc.** In November 1998, we entered into a license agreement with Hind Healthcare Inc. for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in the United States. We paid Hind up-front fees and milestone payments on the occurrence of certain events. From now until the shorter of (1) the life of the last-to-expire patent license pursuant to this license agreement and (2) November 20, 2011, we will pay Hind non-refundable royalties of 10% of net sales of the product, including a minimum annual royalty of at least \$500,000 per year. Because these royalty payments are based on the net sales of the product, the maximum cost of these royalty payments is uncertain at this time. During 2002, we accrued \$9.1 million for this royalty, which is recorded as a reduction of net sales due to the unique nature of the license agreement and the characteristics of the involvement by Hind in Lidoderm®. Either party may terminate this agreement for material breach, and we may terminate it immediately upon termination of our supply agreement with Teikoku. In September 1999, we launched Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

## Environmental Matters

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

## Employees

As of April 30, 2003, we had 286 employees, of which 57 are engaged in research and development, 24 in regulatory work, 112 in sales and marketing, 21 in quality assurance and 72 in general and administrative capacities. Our employees are not represented by unions, and we believe that our relations with our employees are good.

## Legal Proceedings

*Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 00 Civ. 8029 (SHS) (S.D.N.Y.); Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 01 Civ. 2109 (SHS) (S.D.N.Y.); Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 01 Civ. 8177 (SHS) (S.D.N.Y.)*

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

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

The district court began the trial of the patent claims in all three of the suits against EPI on June 2, 2003. By an earlier order, the judge bifurcated the antitrust counterclaims for a separate and subsequent trial.

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

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

On June 17, 2002, EPI was named, along with ten other pharmaceutical companies, as a defendant in four lawsuits filed by groups of 28, 34, 37, and 43 individual plaintiffs, respectively, in the United States District Court for the Eastern District of Louisiana. On June 18, 2002, EPI was named, along with ten other pharmaceutical companies, as a defendant in a lawsuit filed by Ellen McCullough and Brenda Businelle in the United States District Court for the Western District of Louisiana. On June 21, 2002, EPI was named, along with ten other pharmaceutical companies, as a defendant in a lawsuit filed by Joyce Ashton and Bernadine Johnson in the United States District Court for the Middle District of Louisiana. According to each of these six complaints, each of the defendant pharmaceutical companies allegedly manufactured and sold products containing phenylpropanolamine (PPA). Each complaint alleges that the defendants failed to adequately warn plaintiff of the hazards of the use of the subject products containing PPA and that as a result of this failure to warn, plaintiffs suffered injury. Each of these six cases has been transferred to the United States District Court for the Western District of Washington by order of the United States Judicial Panel on Multidistrict Litigation, where fact and expert discovery is underway. EPI intends to defend itself vigorously in each of these cases.

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

On May 7, 2003, EPI was named, along with thirteen other pharmaceutical companies, as a defendant in a lawsuit filed by John Fontenot, Helen Fontenot Serpas and Andre Paul Fontenot in the 34th Judicial District Court for the Parish of St. Bernard, State of Louisiana. According to the complaint, each of the pharmaceutical companies manufactured or distributed the drugs oxycodone, hydrocodone and/or OxyContin. The complaint alleges that the defendants failed to adequately warn physicians and their patients of the dangers involved with these drugs and that as a result of this failure to warn, plaintiffs suffered injury. EPI intends to defend itself vigorously in this case.

#### *General*

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

#### **Governmental Regulation**

The manufacture, development, testing, packaging, labeling, distribution, sales and marketing of our products and our ongoing product development activities are subject to extensive and rigorous regulation at both the federal and state levels. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal and state statutes and regulations govern or influence the testing, manufacture, safety, packaging, labeling, storage, record keeping, approval, advertising, promotion, sale and distribution

of pharmaceutical products. Noncompliance with applicable requirements can result in fines, recall or seizure of products, total or partial suspension of production and/or distribution, refusal of the government to enter into supply contracts or to approve NDA and ANDAs, civil sanctions and criminal prosecution.

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

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

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

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

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

#### ***NDA Process***

FDA approval is typically required before any new drug can be marketed. An NDA is a filing submitted to the FDA to obtain approval of new chemical entities and other innovations for which thorough applied research is required to demonstrate safety and effectiveness in use. The NDA must contain complete preclinical and clinical safety and efficacy data or a reference to such data. Before the dosing of a new drug in healthy human subjects or patients may begin, stringent government requirements for preclinical data must be satisfied. The preclinical data, typically obtained from studies in animals, as

well as from laboratory studies, are submitted in an Investigational New Drug application, or IND, or its equivalent in countries outside the United States where clinical trials are to be conducted. The preclinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initiation of clinical trials.

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

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

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

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

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

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

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

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

#### ***ANDA Process***

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

reference drugs are the same, the two drugs are bioequivalent and regarded as therapeutically interchangeable.

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

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

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

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

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

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

***Quality Assurance Requirements***

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

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

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

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

***Other FDA Matters***

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

***Drug Enforcement Administration***

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

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

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

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

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

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

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



## MANAGEMENT

## Officers and Directors

The following table sets forth certain information regarding our executive officers and directors (as of June 9, 2003):

Name	Age	Position
Carol A. Ammon	52	Chief Executive Officer, Chairman and Director
Peter A. Lankau	50	President and Chief Operating Officer
Mariann T. MacDonald	55	Executive Vice President, Operations
David A. H. Lee, M.D. Ph.D.	53	Executive Vice President, Research & Development and Regulatory Affairs
Jeffrey R. Black	39	Senior Vice President, Chief Financial Officer and Treasurer
Caroline B. Manogue	34	Senior Vice President, General Counsel and Secretary
Brian T. Clingen	43	Director
Michael B. Goldberg	56	Director
Michael Hyatt	57	Director
Roger H. Kimmel	56	Director
Frank J. Loverro	34	Director
Clive A. Meanwell, M.D. Ph.D	46	Director
Michael W. Mitchell	65	Director
Joseph T. O'Donnell, Jr.	55	Director
David I. Wahrhaftig	46	Director

**Carol A. Ammon** has served as our Chairman, Chief Executive Officer and Director since April 2003, as our President, Chief Executive Officer and a Director since our inception in 1997 and as our Chairman since February 2002. 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.

**Peter A. Lankau** has served as our President and Chief Operating Officer since April 2003 and as our Senior Vice President, U.S. Business since June 2000. Prior to joining us in June 2000, Mr. Lankau was Vice President, Sales and Marketing for Alpharma USPD, Inc. in Baltimore, Maryland. He was Vice President, Sales U.S. Pharmaceuticals for Aventis Pharmaceuticals (f/k/a Rhone Poulenc Rorer, Inc.) from 1996 to 1999, based in Collegeville, Pennsylvania. Prior to 1996, Mr. Lankau was Executive Director, Strategy and Development for 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.

**Mariann T. MacDonald** has served as our Executive Vice President, Operations since our inception in 1997. Prior to founding Endo, Ms. MacDonald was Vice President of Business Information, Training, Administration & Technology for the U.S. Pharmaceuticals Division of DuPont Merck from 1996 to 1997 and Vice President of Operations for Endo Laboratories, L.L.C. from 1995 to 1996. From 1993 to 1995, Ms. MacDonald held various management positions in DuPont Merck. Ms. MacDonald has announced her intention to retire at the end of 2003.

**David A. H. Lee, M.D. Ph.D.** has served as our Executive Vice President, Research and Development and Regulatory Affairs since April 2003 and 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.

**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.

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

**Brian T. Clingen** has served as a Director since December 2002. Mr. Clingen is Founder and President of BP Capital Management, an investment management company based in Oak Brook, IL. Previously, he served as Vice President and Chief Financial Officer of Universal Outdoor (which, until 1997, was an affiliate of Kelso & Company), an outdoor advertising company, from December 1987 and as a Director from 1990, in each case until its purchase by Clear Channel Communication in 1998. From 1983 to 1987, Mr. Clingen was Chief Financial Officer for a subsidiary of Elmore Group, a diversified property and service company. Mr. Clingen serves on the Company's Audit Committee.

**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 Armkel LLC, Consolidated Vision Group, Inc., HCI Direct, Inc. and Hilite International, 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. and Haleko, Inc., a subsidiary 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.

**Clive A. Meanwell, M.D., Ph.D.** has served as a Director since January 2003. Dr. Meanwell has been the Executive Chairman and a Director of The Medicines Company since September 2001. Previously, he served as Chief Executive Officer, President and Director since the inception of The Medicines Company in 1996. From 1995 to 1996, Dr. Meanwell was a partner and Managing Director at MPM Capital L.P., a venture capital firm. Prior to that, he held various positions of increasing scope and responsibility at Hoffmann-La Roche, Inc. from 1986 to 1995, most recently Senior Vice President.

**Michael W. Mitchell** has served as a Director since July 2000. Mr. Mitchell has been a member of Shapiro, Mitchell, Forman, Allen & Miller LLP since September 2002. Previously, Mr. Mitchell had 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 a director of Metzler North America Corp. and President of Van Beuren Capital, L.L.C., a private merchant banking and advisory firm. Until December 31, 2002, Mr. O'Donnell was 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 BWAY Corporation.

We have employment agreements with each of our executive officers.

## PRINCIPAL AND SELLING STOCKHOLDERS

The following table sets forth, as of June 9, 2003, 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 June 9, 2003, the amount of common stock beneficially owned by each of our directors and executive officers. The following table also sets forth, as of June 9, 2003, the amount of common stock beneficially owned by all of our current directors and executive officers as a group. This table assumes the over-allotment option granted to the underwriters is not exercised. All selling stockholders, other than Mr. Hyatt, will participate in the over-allotment option.

Name of Beneficial Owner	Amount and Nature of Beneficial Ownership(a)	Number of Shares Being Offered	Percentage Beneficially Owned	
			Before Offering	After Offering
<b>Directors and Executive Officers:</b>				
Carol A. Ammon(b)(d)	(c)	587,003		
Brian T. Clingen (e)	5,000		*	*
Michael B. Goldberg(f)(g)				
Michael Hyatt(h)	1,724,024	250,000	1.3%	1.1%
Roger H. Kimmel(i)	838,525	200,000	*	*
Frank J. Loverro(f)(j)				
Clive A. Meanwell, M.D., Ph.D(k)	5,000			
Michael W. Mitchell(l)	20,000		*	*
Joseph T. O'Donnell, Jr.(m)	20,000		*	*
David I. Wahrhaftig(f)(g)				
Peter A. Lankau(b)	526,519(n)	4,700	*	*
Mariann T. MacDonald(b)(d)	(o)	492,486	*	*
David A. H. Lee, M.D., Ph.D.(b)(d)	(p)	166,503		
Jeffrey R. Black(b)(d)	(q)	169,474	*	*
Caroline B. Manogue(b)	59,660(r)	4,700	*	*
All current directors and executive officers of Endo Pharmaceuticals Holdings Inc. as a group (15 persons)	2,661,535	450,000(w)	2.0%	1.7%
<b>Other Principal and Selling Stockholders:</b>				
Endo Pharma LLC(d)(f)	98,886,770	13,051,465	75.1%	64.1%
Kelso Investment Associates V, L.P.(d)(f)(s)		10,065,974		
Kelso Equity Partners V, L.P.(d)(f)(s)		846,987		
Kelso Partners V, L.P.(d)(f)(t)		10,065,974		
Joseph S. Schuchert(f)(g)				
Frank T. Nickell(f)(g)				
Thomas R. Wall, IV(f)(g)				
George E. Matelich(f)(g)				
Frank K. Bynum, Jr.(f)(g)				
Philip E. Berney(f)(g)				
Greenwich Street Capital Partners, L.P.(d)(u)		1,289,771		
Greenwich Street Capital Offshore Fund, Ltd.(d)(u)		80,053		
Citigroup GSP Employees Fund, L.P.(d)(u)		313,448		
The Travelers Insurance Company(d)(u)		66,538		
The Travelers Life and Annuity Company(d)(u)		32,772		
Other selling stockholders representing in the aggregate less than 1% of our common stock	(v)	165,770	*	*

\* Represents less than 1%.

## Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 424B4

- (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) The shares to be sold by Ms. Ammon include 47,536 shares, which represent Ms. Ammon's pro rata portion of Endo Pharma LLC's shares being offered, and 539,467 shares, which represent the shares of common stock underlying her Endo Pharma LLC employee stock options that she intends to exercise and sell in the offering. Ms. Ammon owns 0.36% of Endo Pharma LLC and may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of her status as a member of Endo Pharma LLC. Ms. Ammon shares voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities except to the extent of her pecuniary interest. Ms. Ammon's beneficial ownership does not include 10,934,387 shares underlying options that she holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans that she is not exercising and selling in the offering.
- (d) Members of Endo Pharma LLC will receive a pro rata distribution of the net proceeds of this offering received by Endo Pharma LLC based on the number of Endo Pharma LLC units held by each such member. Affiliates of Kelso & Company own 83.6% of Endo Pharma LLC; Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd., Citigroup GSP Employees Fund, L.P., The Travelers Insurance Company and The Travelers Life and Annuity Company own 13.7% of Endo Pharma LLC; management, in the aggregate, owns 0.7% of Endo Pharma LLC; and certain other outside investors own 2.0% of Endo Pharma LLC. The number of shares shown as being offered by Endo Pharma LLC does not include 1.5 million shares of common stock underlying the Endo Pharma LLC employee stock options being exercised and sold in the offering.
- (e) The business address for Mr. Clingen is c/o BP Capital Management, 2215 York Rd, Suite 510, Oak Brook, Illinois 60523. Mr. Clingen's beneficial ownership represents options to purchase 5,000 shares of Common Stock under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.
- (f) The business address for this person is c/o Kelso & Company, 320 Park Avenue, 24th Floor, New York, NY 10022.
- (g) 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.
- (h) The business address for Mr. Hyatt is c/o Bear, Stearns & Co. Inc., 383 Madison Avenue, New York, NY 10179. Mr. Hyatt's beneficial ownership includes (i) 829,551 shares of common stock owned directly by Mr. Hyatt, (ii) 874,473 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 (including 537,193 shares with respect to which beneficial ownership is shared with Mr. Kimmel) and (iii) options to purchase 20,000 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.
- (i) The business address for Mr. Kimmel is c/o Rothschild, Inc., 1251 Avenue of the Americas, New York, NY 10022. Mr. Kimmel's beneficial ownership includes (i) 60,000 shares owned directly by Mr. Kimmel, (ii) 758,525 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

## Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 424B4

(including 537,193 shares with respect to which beneficial ownership is shared with Mr. Hyatt) and (iii) options to purchase 20,000 shares of common stock under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan. Excludes a total of 316,530 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.

- (j) 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.
- (k) The business address for Dr. Meanwell is c/o The Medicines Company, 5 Sylvan Way, Parsippany, New Jersey 07054. Dr. Meanwell's beneficial ownership represents options to purchase 5,000 shares of Common Stock granted under the Endo Pharmaceuticals Holdings, Inc. 2000 Stock Incentive Plan.
- (l) The business address for Mr. Mitchell is c/o Shapiro, Mitchell, Forman, Allen & Miller LLP, 380 Madison Avenue, New York, NY 10017. Mr. Mitchell's beneficial ownership represents options to purchase 20,000 shares of our common stock under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.
- (m) The business address for Mr. O'Donnell is Van Beuren Capital, L.L.C., Van Beuren Road, Morristown, New Jersey 07960. Mr. O'Donnell's beneficial ownership represents options to purchase 20,000 shares of our common stock under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.
- (n) The 4,700 shares to be sold by Mr. Lankau represent the shares of common stock underlying Mr. Lankau's Endo Pharma LLC employee stock options that he intends to exercise and sell in the offering. Mr. Lankau's beneficial ownership represents 526,519 options that Mr. Lankau holds in the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan. This amount does not include 235,211 options that Mr. Lankau holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans that he is not exercising and selling in the offering.
- (o) The shares to be sold by Ms. MacDonald include 35,652 shares, which represent Ms. MacDonald's pro rata portion of her Endo Pharma LLC's shares being offered, and 456,834 shares, which represent the shares of common stock underlying Endo Pharma LLC employee stock options that she intends to exercise and sell in the offering. Ms. MacDonald owns 0.27% of Endo Pharma LLC and may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of her status as a member of Endo Pharma LLC. Ms. MacDonald shares voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities except to the extent of her pecuniary interest. Ms. MacDonald's beneficial ownership does not include 9,214,739 shares underlying options that she holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans that she is not exercising and selling in the offering.
- (p) The shares to be sold by Dr. Lee include 2,971 shares, which represent Dr. Lee's pro rata portion of Endo Pharma LLC's shares being offered, and 163,532 shares, which represent the shares of common stock underlying his Endo Pharma LLC employee stock options that he intends to exercise and sell in the offering. Dr. Lee owns 0.02% of Endo Pharma LLC and may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of his status as a member of Endo Pharma LLC. Dr. Lee shares voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities except to the extent of his pecuniary interest. Dr. Lee's beneficial ownership does not include 4,064,222 shares underlying options that he holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans that he is not exercising and selling in the offering.
- (q) The shares to be sold by Mr. Black include 5,942 shares, which represent Mr. Black's pro rata portion of Endo Pharma LLC's shares being offered, and 163,532 shares, which represent his shares of common stock underlying his Endo Pharma LLC employee stock options that he intends to exercise and sell in the offering. Mr. Black owns 0.05% of Endo Pharma LLC and may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by

virtue of his status as a member of Endo Pharma LLC. Mr. Black shares voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities except to the extent of his pecuniary interest. Mr. Black's beneficial ownership does not include 3,602,948 shares underlying options that he holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans that he is not exercising and selling in the offering.

- (r) The 4,700 shares to be sold by Ms. Manogue represent the shares of common stock underlying Ms. Manogue's Endo Pharma LLC employee stock options that she intends to exercise and sell in the offering. Ms. Manogue's beneficial ownership includes 59,660 options that Ms. Manogue holds in the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan. These amounts do not include 235,211 options that she holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans that she is not exercising and selling in the offering.
- (s) 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.
- (t) Kelso Partners V, L.P., or KP V, 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.
- (u) The business address for these persons is 500 Campus Drive, Suite 220, Florham Park, New Jersey 07932. Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd., Citigroup GSP 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. None of these entities is a managing member of Endo Pharma LLC. 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. These entities 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.
- (v) The 165,770 shares to be sold by the selling stockholders represent the shares of common stock underlying Endo Pharma LLC employee stock options that they intend to exercise and sell in the offering and other shares of common stock owned by the selling stockholders.
- (w) These shares represent 450,000 shares held by Messrs. Hyatt and Kimmel. This number does not include an aggregate of 92,101 shares of common stock reflecting the executive officers' pro rata portion of Endo Pharma LLC shares being offered and an aggregate of 1,332,765 shares of common stock underlying Endo Pharma LLC employee stock options that they will exercise and sell in the offering.

## 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, on a national securities exchange or in a public offering 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 86% of the common stock originally contributed to Endo Pharma LLC, and they continue to have an approximately 86% interest in Endo Pharma LLC. Endo Pharma LLC now owns approximately 75% 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 connection with the Algos merger and our related recapitalization on July 17, 2000, the Endo Pharma LLC 2000 Supplemental Employee Stock Option Plan and the Endo Pharma LLC 2000 Supplemental Executive Stock Option Plan (collectively, the Endo Pharma LLC 2000 Supplemental Stock Option Plans) and, together with the Endo Pharma LLC 1997 Stock Option Plans, the Endo Pharma LLC Stock Option Plans) were established. The Endo Pharma LLC 2000 Supplemental Stock Option Plans reserve an aggregate of 10.7 million shares of our common stock that is held by Endo Pharma LLC for issuance. The Endo Pharma LLC 2000 Supplemental Stock Option Plans were not effective until January 1, 2003. The Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective on January 1, 2003, resulting in the issuance of approximately 10.7 million stock options to certain employees and members of management. Because approximately 9.2 million of these stock options were immediately vested upon their issuance, we recorded a non-cash compensation charge of approximately \$48.5 million in the first quarter of 2003 representing the difference between the then market price of the common stock of \$7.70 and the weighted average exercise price of these stock options of \$2.42. Upon exercise, no additional shares of our common stock will be issued, however, because these stock options are exercisable only into shares of our common stock that are held by Endo Pharma LLC.



Accordingly, these stock options do not dilute the public shareholders. In addition, Endo Pharma LLC, and not us, will receive the exercise price in connection with these options. Further, the shares of common stock that individuals receive upon exercise of stock options granted pursuant to the Endo Pharma LLC 2000 Supplemental Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

***Tax Sharing Agreement***

On July 14, 2000, Endo Pharma LLC was formed in connection with the Algos merger to ensure that the stock options granted pursuant to the Endo Pharma LLC Stock Option Plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC will be delivered. Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we will be required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of March 31, 2003, approximately 1.4 million of these stock options had been exercised by former employees into shares of our common stock held by Endo Pharma LLC. The exercise of any of these Endo Pharma LLC stock options generally will permit us to deduct as a compensation charge, for federal income tax purposes, an amount equal to the difference between the market price of our common stock and the exercise price paid upon exercise of these options (as of March 31, 2003, approximately \$11 million), which is estimated to result in a tax benefit amount of approximately \$4 million. Under the tax sharing agreement, we are required to pay this \$4 million to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, to the extent that a compensation charge deduction is usable to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto.

Using a weighted average exercise price of \$2.61 per share and an assumed effective tax rate of 38.3%, if all 36.3 million stock options under the Endo Pharma LLC Stock Options Plans were vested and exercised (including the 1.4 million stock options already exercised as discussed above):

assuming the market price of our common stock was \$10.00 per share, then, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$268 million, which could result in a tax benefit amount of approximately \$103 million payable to Endo Pharma LLC.

assuming the market price of our common stock was \$15.00 per share, then, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$450 million, which could result in a tax benefit amount of approximately \$172 million payable to Endo Pharma LLC.

assuming the market price of our common stock was \$20.00 per share, then, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$631 million, which could result in a tax benefit amount of approximately \$242 million payable to Endo Pharma LLC.

Under the terms of the tax sharing agreement, we must pay all such tax benefit amounts to Endo Pharma LLC to the extent these tax benefits are usable by us, as described above. However, these payments need only be made to Endo Pharma LLC upon the occurrence of a liquidity event, which is generally defined as a transaction or series of transactions resulting in (a) a sale of greater than 20% on a fully diluted basis of our common equity (either through (i) a primary offering by us, (ii) a secondary sale by Endo Pharma LLC or other holders of common stock pursuant to a registration rights agreement or (iii) a combination of both such primary and secondary offerings), (b) a change in control of Endo or (c) a sale of all or substantially all of our assets. In accordance with the tax sharing agreement, no payments have been made or accrued to date. This offering, which represents a sale of approximately 11% of our common equity, or approximately 13% if the underwriters over-allotment is exercised, will not, by itself, trigger a payment under the tax sharing agreement, and no liquidity event will result from this offering. This offering may, however, be combined with future offerings to result in a series of transactions

that will trigger a payment obligation pursuant to the tax sharing agreement. Endo Pharma LLC has informed us that, subject to a variety of factors, including market conditions and stock price levels, it may initiate additional secondary offerings in the future.

***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. None of these three as individuals currently receive directors fees.

**Other Matters**

Mr. Hyatt, a director, is a Senior Managing Director of Bear, Stearns & Co. Inc., an investment bank that performs services for us from time to time. However, no payment was due to, or received by, Bear, Stearns & Co. Inc. in fiscal 2002 for these services. Bear, Stearns & Co. Inc. is an underwriter in this offering.

Mr. Mitchell, a director, currently performs legal services for us and we expect to pay him in excess of \$60,000 for these services for the current fiscal year. Mr. Mitchell also invests in Kelso transactions from time to time.

Mr. Lyle, a former 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 June 9, 2003, there were 131,746,568 shares of common stock outstanding. As of June 11, 2003, we had approximately 127 shareholders of record of our common stock.

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 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 \$.01 per share, into a specified number of shares of common stock if the FDA did not approve MorphiDex® for any pain indication prior to December 31, 2002.

**Exercisability and Expiration.** As the FDA did not approve MorphiDex® before December 31, 2002, these warrants became exercisable. Each of these outstanding 71.3 million warrants is exercisable into 0.416667 shares of our common stock. These warrants are exercisable at an exercise price of \$.01 per share into a maximum of 29.7 million shares of our common stock. As of June 9, 2003, 71.3 million of these warrants had been exercised into 29,678,455 shares of our common stock. The warrants are exercisable until July 8, 2003, at which time they will expire.



**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.

#### **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 June 9, 2003, we will have an aggregate of 131,746,568 outstanding shares of common stock, excluding up to 1,996,995 shares underlying outstanding warrants and options exercisable for shares to be issued by us. Of the outstanding shares, a total of 45,874,442 shares, or 48,124,442 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 subject to the volume and manner of sale limitations 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 85,872,126 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.

#### *Lock-Up Agreements*

Endo Pharma LLC, our executive officers and our 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 Citigroup Global Markets Inc. and Bear, Stearns & Co. Inc. Immediately following this offering, these stockholders will own 85,872,126 shares, representing approximately 65.2% of the then outstanding shares of common stock, or approximately 63.5% 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 1,317,466 shares upon completion of this offering; 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 29.7 million shares of common stock. As of June 9, 2003, 71.3 million of these warrants had been exercised into 29,678,455 shares of our common stock. If all of the outstanding warrants are exercised, a maximum of 29,687,604 shares of our common stock would be freely tradable upon exercise of these warrants, the majority of which would be subject to Rules 144 and 145(d).

**Stock Options**

As of the date of this prospectus, options to purchase a total of 1,987,846 shares of common stock were outstanding, of which 363,330 are currently exercisable. 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 freely tradable, 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 33.1 million 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. This offering is the result of Endo Pharma LLC having exercised one of its demand registration rights.

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 249,438 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.

Endo Pharma LLC has informed us that, subject to a variety of factors, including market conditions and stock price levels, it may initiate additional secondary offerings in the future.



**CERTAIN U.S. FEDERAL 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 calendar year, one-third of the days present in the immediately preceding calendar year and one-sixth of the days present in the second preceding calendar 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 OUR COMMON STOCK.**

**Dividends**

We may not pay 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 are not subject to the U.S. withholding tax, but, unless otherwise provided in an applicable income tax treaty, 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, and such non-U.S. holder held more than 5 percent of our common stock, at any time during the shorter of the five-year period ending on the date of disposition or the period that such non-U.S. holder held our common stock.

We have determined that we are not, and we do not anticipate that we will 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%, or at a lower rate if provided by an applicable income tax treaty. Other non-U.S. holders who are subject to U.S. federal income tax on gain from the disposition of our common stock will be taxed on such gain in the same manner in which citizens or residents of the U.S. would be taxed, and if such non-U.S. holder is a foreign corporation such gain may also be subject to a branch profits tax at a 30% rate, or at a lower rate if provided by an applicable income tax treaty. 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.

### ***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.

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.

***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 by the U.S. Internal Revenue Service 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, if to or through its U.S. offices, 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**

Citigroup Global Markets Inc. and Bear, Stearns & Co. Inc. are acting as joint book-running managers of the offering and, together with Jefferies & Company, Inc. and SG Cowen Securities Corporation, 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 the selling stockholders have agreed to sell to that underwriter, the number of shares set forth opposite the underwriter's name.

Underwriter	Number of Shares
Citigroup Global Markets Inc.	6,375,000
Bear, Stearns & Co. Inc.	6,375,000
Jefferies & Company, Inc.	1,125,000
SG Cowen Securities Corporation	1,125,000
Total	15,000,000

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 \$0.44200 per share. The underwriters may allow, and the dealers may reallow, a concession not to exceed \$0.10 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.

The selling stockholders, other than Mr. Hyatt, have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 2,250,000 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 executive officers, our 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 Citigroup and Bear, Stearns & Co. 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. Citigroup 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.

Each underwriter has represented, warranted and agreed that:

It has not offered or sold and, prior to the expiry of a period of six months from the closing date, will not offer or sell any shares included in this offering to persons in the United Kingdom except to persons whose ordinary activities involve them in acquiring, holding, managing or disposing of investments (as principal or agent) for the purposes of their businesses or otherwise in circumstances which have not resulted and will not result in an offer to the public in the United Kingdom within the meaning of the Public Offers of Securities Regulations 1995;

It has only communicated and caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 (FSMA)) received by it in connection with the issue or sale of any shares included in this offering in circumstances in which section 21(1) of the FSMA does not apply to us;

## Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 424B4

It has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares included in this offering in, from or otherwise involving the United Kingdom; and

The offer in The Netherlands of the shares included in this offering is exclusively limited to persons who trade or invest in securities in the conduct of a profession or business (which include banks, stockbrokers, insurance companies, pension funds, other institutional investors and finance companies and treasury departments of large enterprises).

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

The following table shows the underwriting discounts and commissions that the selling stockholders 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 Selling Stockholders	
	No Exercise	Full Exercise
Per share	\$ 0.73625	\$ 0.73625
Total	\$ 11,043,750	\$ 12,700,313

In connection with the offering, Citigroup 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 Citigroup 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.

In addition, in connection with this offering, some of the underwriters (and selling group members) may engage in passive market making transactions in the common stock on the Nasdaq National Market, prior to the pricing and completion of the offering. Passive market making consists of displaying bids on the Nasdaq National Market no higher than the bid prices of independent market makers and making purchases at prices no higher than those independent bids and effected in response to order flow. Net purchases by a passive market maker on each day are limited to a specified percentage of the passive market maker's average daily trading volume in the common stock during a specified period and must be

discontinued when that limit is reached. Passive market making may cause the price of the common stock to be higher than the price that otherwise would exist in the open market in the absence of those transactions. If the underwriters commence passive market making transactions, they may discontinue them at any time.

We will pay our and the selling stockholders' expenses for this offering, pursuant to the registration rights agreement. We estimate that the total expenses of this offering will be approximately \$1.3 million.

Because affiliates of Citigroup beneficially own more than 10% of our common stock prior to the closing of this offering through their ownership of membership interests in Endo Pharma LLC, they may be deemed to have a conflict of interest with us under Rule 2720 of the National Association of Securities Dealers, Inc. In addition, more than 10% of the net proceeds of this offering, not including underwriting compensation, will be paid to these affiliates as unit holders of Endo Pharma LLC. Accordingly, this offering is being conducted in compliance with Rules 2710(c)(8) and 2720, Conflicts of Interest, of the NASD Conduct Rules. Pursuant to these rules, the appointment of a qualified independent underwriter is not necessary in connection with this offering, as a bona fide independent market (as defined in the NASD Conduct Rules) exists in the common stock.

The underwriters have performed investment banking and advisory services for us from time to time for which they have received customary fees and expenses. 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 Citigroup and SG Cowen Securities Corporation are lenders under our credit agreement, for which they received customary fees. Mr. Hyatt, one of our directors, is a Senior Managing Director of Bear, Stearns & Co. Inc. Bear, Stearns & Co. Inc. is one of the underwriters for this offering, for which it will receive customary fees. In addition, Mr. Nickell, President and Chief Executive Officer of Kelso & Company, is an outside director of The Bear Stearns Companies Inc.

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters. The representatives may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. The representatives will allocate shares to underwriters that may make Internet distributions on the same basis as other allocations. In addition, shares may be sold by the underwriters to securities dealers who resell shares to online brokerage account holders.

We and the selling stockholders 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, 2002 and 2001 and for each of the three years in the period ended December 31, 2002 of Endo Pharmaceuticals Holdings Inc. and subsidiaries (the Company) and the related financial statement schedule incorporated in this prospectus by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2002 have been audited by Deloitte & Touche LLP, independent auditors, as stated in their report, which is incorporated herein by reference (which report expresses an unqualified opinion and includes an explanatory paragraph referring to the Company's adoption of Statement of Financial Accounting Standards No. 142, *Goodwill*

*and Other Intangible Assets*, effective January 1, 2002), and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

The valuation appraisal of certain intangible assets acquired in 2000 by Endo Pharmaceutical Holdings Inc. and referenced in the Annual Report on Form 10-K of Endo Pharmaceuticals Holdings Inc. and subsidiaries for the year ended December 31, 2002, has been performed by Murray, Devine & Co., Inc., an independent valuation advisor, as indicated in its report dated October 31, 2000 with respect thereto, which is incorporated herein by reference, and has been so incorporated in reliance upon the report of such firm upon their authority as experts in giving said report.

#### **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. 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](http://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, 2002;

our information statement on Schedule 14C for our 2003 annual stockholders' meeting;

our quarterly report on Form 10-Q for the quarterly period ended March 31, 2003; and

our current reports on Form 8-K filed January 8, 2003 (not including the information in Item 9), January 15, 2003 and April 10, 2003.

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 or may be incorporated by reference in 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.

**15,000,000 Shares**

**Endo Pharmaceuticals**

**Holdings Inc.**

**Common Stock**

---

**PROSPECTUS**  
July 1, 2003

---

**Citigroup**  
**Bear, Stearns & Co. Inc.**

---

**Jefferies & Company, Inc.**  
**SG Cowen**

---

---