ENDO PHARMACEUTICALS HOLDINGS INC
Form 424B4
October 18, 2001

Filed Pursuant to Rule 424(b)(4)
Registration No. 333-69136

PROSPECTUS

11,400,000 Shares

Endo Pharmaceuticals Holdings Inc.

Common Stock

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

Our common stock is traded on the Nasdaq National Market under the symbol ENDP. On October 17, 2001, the last reported sale price of our common stock was $8.15 per share.

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

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

	Per Share	Total
Public offering price	$8.00	$91,200,000
Underwriting discount	$0.44	$ 5,016,000
Proceeds to Endo Pharmaceuticals Holdings Inc., before expenses	$7.56	$86,184,000

The underwriters expect to deliver the shares to purchasers on or about October 23, 2001.

Joint Book-Running Managers

JPMorgan **Salomon Smith Barney**

SG Cowen **Wachovia Securities**

October 17, 2001

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

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PROSPECTUS SUMMARY

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

Endo Pharmaceuticals Holdings Inc.

We are a specialty pharmaceutical company with market leadership in pain management. We are engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat and manage pain. According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totalled $13 billion for the 12 months ended May 2001. Our primary area of focus is analgesics, which according to IMS Health data were the fourth most prescribed class of medication in the United States in 2000.

We have a portfolio of branded products that includes established brand names such as Percocet®, Lidoderm®, Percodan® and Zydone®. Branded products comprised approximately 68%, 76% and 71% of net sales for fiscal years 1999 and 2000 and the six months ended June 30, 2001, respectively. Through a national dedicated contract sales force of approximately 230 sales representatives, we market our branded pharmaceutical products to doctors, retail pharmacies and other healthcare professionals throughout the United States.

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

Our Strategy

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

Capitalizing on our established brand names through focused marketing and promotion. We consider two of our brands, Percocet® and Percodan®, to be gold standards of pain management. We plan to continue to capitalize on this brand awareness to market new products, as well as new formulations and dosages of our existing branded products. We believe that our strong corporate and product reputation leads to more rapid adoption of our new products by physicians.

Developing proprietary products and selected generics. To capitalize on our expertise in pain management, we are developing new products to address acute, chronic and neuropathic pain conditions by treating moderate-to-severe pain. These products include MorphiDex®, a patented combination of morphine and the NMDA (N-methyl-D-aspartate) receptor antagonist, dextromethorphan, which is currently in Phase III clinical trials. We anticipate resubmitting a new drug application, or NDA, with the U.S. Food and Drug Administration, or FDA, in mid-2002. In addition, we are co-developing an oral extended-release version of oxymorphone with Penwest Pharmaceuticals. This product is currently in Phase III clinical trials, and we anticipate filing an NDA with the FDA in the second half of 2002. We also selectively develop generic pharmaceuticals.

Developing and marketing product line extensions for our existing brands. We plan to continue to develop and market extensions of existing products through new formulations, dosages and delivery platforms. During the fourth quarter of 1999, we complemented the existing Percocet® 5.0/325 with three new formulations: Percocet® 2.5/325, Percocet® 7.5/500 and Percocet® 10.0/650. We currently have on file with the FDA a line extension of Percocet®, which we anticipate launching by the end of the first quarter of 2002.

Acquiring and in-licensing complementary products, compounds and technologies. We look to continue to enrich our product line through selective product acquisitions and in-licensing, or acquiring licenses to products, compounds and technologies from third parties. In July 2000, we acquired Algos Pharmaceutical Corporation and the rights to the development-stage product MorphiDex®. We also acquired rights to a portfolio of other patents including those covering the combination of the NMDA-antagonist, dextromethorphan, with opioids. In November 1998, we in-licensed Lidoderm®, which became the first FDA-approved product for the relief of the pain of post-herpetic neuralgia, a chronic, painful condition that often follows an attack of shingles.

Our Competitive Strengths

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

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

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

Research and development expertise. Our research and development effort is focused on expanding our product portfolio by capitalizing on our core expertise with narcotic analgesics. We believe this expertise allows for timely FDA approval of our products. We have launched more than 10 products and product extensions during the last three years, contributing approximately 42% of our net sales in 2000.

Selective focus on generic products. Our generic product portfolio includes products focused on pain management. Development of these products involves barriers to entry such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. We have executed this strategy successfully with products such as morphine sulfate extended release tablets, which we introduced in November 1998 as a bioequivalent of MSContin®, a Purdue Frederick product.

Targeted national sales and marketing infrastructure. We market our products directly to physicians through a dedicated contract sales force of approximately 160 community-based field representatives and 70 specialty/institutional representatives targeting high-prescribing physicians. We maintain an internal sales management infrastructure to direct and focus these sales force efforts.

Experienced and dedicated management team. With an average of approximately 20 years of experience in the pharmaceutical industry, our management team has a proven track record of building our business through internal growth as well as acquisitions and licensing. Members of our senior management led the purchase of the company from The DuPont Merck Pharmaceutical Company in August 1997. In addition, management has vested stock options to acquire up to 12% of our common stock and has the potential to receive as much as an additional 10% of our

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

Our Industry

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

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

Product Overview

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

Product	Active ingredient	Branding	Status
Percocet®	oxycodone and acetaminophen	Branded	Marketed
Lidoderm®	lidocaine 5%	Branded	Marketed
Percodan®	oxycodone and aspirin	Branded	Marketed
Zydone®	hydrocodone and acetaminophen	Branded	Marketed
Morphine Sulfate ER(1)	morphine sulfate	Generic	Marketed
MorphiDex®	morphine and dextromethorphan	Branded	Phase III
Oxymorphone ER(1)	oxymorphone hydrochloride	Branded	Phase III
Oxymorphone IR(2)	oxymorphone hydrochloride	Branded	Phase III
HydrocoDex	hydrocodone, acetaminophen, and dextromethorphan	Branded	Phase II
OxycoDex	oxycodone and dextromethorphan	Branded	Phase II
PercoDex	oxycodone, acetaminophen and dextromethorphan	Branded	Phase II
Oxycodone ER(1)	oxycodone	Generic	ANDA filed(3); subject to litigation(4)

(1) ER means extended release.

(2) IR means immediate release.

(3) ANDA means abbreviated new drug application.

(4) See Business Legal Proceedings.

About Our Company

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

subsequently became DuPont Pharmaceuticals Company. Endo

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

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

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

The Offering

Common stock offered	11,400,000 shares
Common stock outstanding after the offering	100,538,950 shares
Use of proceeds	Our net proceeds from this offering will be approximately $84.9 million. We expect to use the net proceeds from this offering, together with amounts from existing cash and cash equivalents to repay in full the term loans under our existing credit agreement. See Use of Proceeds.
Nasdaq National Market symbol	ENDP

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

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

Summary Consolidated Financial Data

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

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

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

71,307 71,332 79,454 71,327 89,139

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

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

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

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

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

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

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

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

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

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

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

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

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

Non-cash manufacturing charges reflect the present value of non-interest bearing promissory notes issued annually to DuPont Pharmaceuticals Company over the initial five-year term of the manufacturing and supply agreement with DuPont Pharmaceuticals. These amounts have been excluded from consolidated EBITDA.

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

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

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

RISK FACTORS

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

Risks Related to Our Business

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

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

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

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

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

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

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

The pharmaceutical industry is intensely competitive, and we face competition across the full range of our activities. If we fail to compete successfully in any of these areas, our business, profitability and cash flows could be adversely affected. Our competitors include the major brand name and generic manufacturers of pharmaceuticals, especially those doing business in the United States, and include Abbott Laboratories, Johnson & Johnson, The Purdue Frederick Company, Roxane Laboratories, Inc. and Watson Pharmaceuticals, Inc.

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

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

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

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

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

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

Even if we obtain regulatory approvals, uncertainty exists as to whether the market will accept our products. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, the price of our products relative to alternative products, the availability of third-party reimbursement and the extent of marketing efforts by third-party distributors or agents that we retain. We cannot assure you that our products will receive market acceptance in a commercially viable period of time, if at all. In addition, many of our products contain narcotic ingredients that carry stringent record-keeping obligations, strict storage requirements and other limitations on these products availability, which could limit the commercial usage of these products.

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

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

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

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

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

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

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

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

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

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

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

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

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

On October 1, 2001, Bristol-Myers Squibb completed the acquisition of DuPont Pharmaceuticals. We are unable to predict the effect of this transaction on our relationship with DuPont Pharmaceuticals.

In May 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health,