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

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

Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Endo Pharmaceuticals Holdings Inc.

(Exact name of Registrant as specified in its charter)

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

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

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Senior Vice President, General Counsel and Secretary
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

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

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

reinvestment plans, check the following box. o

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

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

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

CALCULATION OF REGISTRATION FEE

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

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

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

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

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

SUBJECT TO COMPLETION, DATED SEPTEMBER 7, 2001

PRELIMINARY PROSPECTUS

11,400,000 Shares

[ENDO PHARMACEUTICALS HOLDINGS LOGO]

Endo Pharmaceuticals Holdings Inc.

Common Stock

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

Our common stock is traded on the Nasdaq National Market under the symbol ENDP. On September 6, 2001, the last reported sale price of our common stock was $11.00 per share.

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

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

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

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

Joint Book-Running Managers

JPMorgan **Salomon Smith Barney**

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

, 2001

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

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PROSPECTUS SUMMARY

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

Endo Pharmaceuticals Holdings Inc.

We are a specialty pharmaceutical company with market leadership in pain management. We are engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat

and manage pain. According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totalled $13 billion for the 12 months ended May 2001. Our primary area of focus is analgesics, which according to IMS Health data were the fourth most prescribed class of medication in the United States in 2000.

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

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

Our Strategy

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

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

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

Developing and marketing product line extensions for our existing brands. We plan to continue to develop and market extensions of existing products through new formulations, dosages and delivery platforms. During the fourth quarter of 1999, we complemented the existing Percocet® 5.0/325 with three new formulations: Percocet® 2.5/325, Percocet® 7.5/500 and Percocet® 10.0/650.

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

neuralgia, a chronic, painful condition that often follows an attack of shingles.

Our Competitive Strengths

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

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

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

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

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

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

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

defined targets. These options are exercisable for shares currently held by our controlling stockholder, Endo Pharma LLC, and their exercise will not dilute your ownership of our common stock.

Our Industry

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

fractures and sprains, back injuries, migraines, joint diseases, cancer and various surgical procedures.

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

Product Overview

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

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

(1) ER means extended release.

(2) IR means immediate release.

(3) ANDA means abbreviated new drug application.

(4) See Business Legal Proceedings.

About Our Company

Our wholly-owned subsidiary, Endo Pharmaceuticals Inc., commenced operations in 1997 by acquiring certain pharmaceutical products, related rights and assets of The DuPont Merck Pharmaceutical Company, which subsequently became DuPont Pharmaceuticals Company. Endo Pharmaceuticals Inc. was formed by certain affiliates of Kelso & Company and members of the then-existing management of DuPont Merck, who were also parties to the purchase agreement under which we acquired these initial assets. We were incorporated in Delaware as a holding company on November 18, 1997.

On July 17, 2000, we completed our acquisition of Algos, now a wholly-owned subsidiary named Endo Inc. In connection with this acquisition, our common stock began trading publicly on the Nasdaq National Market under the symbol ENDP. Prior to the acquisition, Algos developed proprietary pain management products, combining existing analgesics, drugs designed to reduce or eliminate pain, with NMDA-receptor antagonist drugs, drugs that block a

specific type of pain receptor in human cells, in an attempt to improve the pain relief efficacy of existing drugs such as morphine. For more information about our acquisition of Algos, see Management s Discussion and Analysis of Financial Condition and Results of Operations Overview and Description of Capital Stock Warrants.

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

The Offering

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

Unless otherwise indicated, all share information in this prospectus is based on the number of shares outstanding as of August 24, 2001, and:

- excludes up to 34,412,836 shares of common stock issuable upon the exercise of warrants issued in connection with our acquisition of Algos Pharmaceutical Corporation and up to 21,580 shares of common stock issuable upon the exercise of our Series A warrants;
- excludes up to 942,134 shares of common stock issuable by us upon the exercise of options granted to our employees, of which 87,246 will be exercisable by November 30, 2001; and
- assumes no exercise by the underwriters of the over-allotment option.

Summary Consolidated Financial Data

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

	Six Months Ended

	Year Ended December 31,			June 30,	
	1998	1999	2000	2000	2001
	(in thousands, except per share data)				
Statement of Operations Data:					
Net sales	$108,370	$138,546	$197,429	$68,934	$107,239
Cost of sales	54,731	58,263	63,041	28,333	33,681
Gross profit	53,639	80,283	134,388	40,601	73,558
Selling, general and administrative	25,540	42,921	56,537	26,138	35,343
Research and development	5,893	9,373	26,012	7,696	17,510
Depreciation and amortization	7,373	8,309	27,624	4,326	24,776
Compensation related to stock options			15,300		
Purchased in-process research and development			133,200		
Merger and other related costs			1,583		
Separation benefits			22,034		22,034
Operating income (loss)	14,833	19,680	(147,902)	(19,593)	(4,071)
Interest expense, net	14,451	14,347	15,119	7,718	6,443

Income (loss) before income tax (benefit)	382	5,333	(163,021)	(27,311)	(10,514)
Income tax (benefit)	181	2,073	(6,181)	(10,325)	993
Net income (loss)	$201	$3,260	$(156,840)	$(16,986)	$(11,507)
Net income (loss) per share					
Basic	$0.00	$0.05	$(1.97)	$(0.24)	$(0.13)
Diluted	$0.00	$0.05	$(1.97)	$(0.24)	$(0.13)
Shares used to compute net income (loss) per share(1)					
Basic	71,307	71,332	79,454	71,327	89,139
Diluted	71,307	71,332	79,454	71,327	89,139

	As of December 31,			As of June 30,
	1998	1999	2000	2001
	(in thousands)			
Consolidated Balance Sheet Data:				
Cash and cash equivalents	$17,367	$22,028	$59,196	$67,027
Working capital	37,676	49,541	72,759	86,198
Total assets	287,618	329,436	467,840	441,157

Total debt
170,544 191,203 198,525 171,408
Other long-term obligations
6,352 6,745 7,218 18,009
Stockholders equity
75,358 78,587 198,173 186,666

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

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

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

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

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

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

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

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

Our credit facility defines consolidated EBITDA as consolidated net income for the applicable period plus, without duplication and to the extent deducted from revenues in determining consolidated net income for that period, the sum of (a) the aggregate amount of consolidated cash interest expense for the period, (b) the aggregate amount of letter of credit fees paid during the period, (c) the aggregate amount of income tax expense for the period, (d) all amounts attributable to depreciation and amortization for the period, (e) all extraordinary charges during the period and (f) all other non-cash charges during the period; and minus, without duplication and to the extent added to revenues in determining consolidated net income for such period, the sum of (i) all extraordinary

gains during the period and (ii) all other non- cash gains during such period, all as determined on a consolidated basis with respect to us and our subsidiaries in accordance with generally accepted accounting principles. The reconciliation of operating income (loss) (as deter-

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

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

Compensation related to stock options is the non-cash charge resulting from the vesting of stock options pursuant to the Endo Pharma LLC stock option plans. Stock options granted pursuant to the Endo Pharma LLC stock

option plans vest if our common stock reaches certain defined thresholds. These options are exercisable for shares currently held by Endo Pharma LLC, and their exercise will not dilute the ownership of other holders of our common stock.

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

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

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

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

RISK FACTORS

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

Risks Related to Our Business

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

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

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

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

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

in regulatory approval.

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

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

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

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

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

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

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

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

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

Even if we obtain regulatory