ENDO PHARMACEUTICALS HOLDINGS INC
Form S-3/A
June 16, 2003

As filed with the Securities and Exchange Commission on June 16, 2003
Registration Statement No. 333-105338

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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

Endo Pharmaceuticals Holdings Inc.

(Exact name of Registrant as specified in its charter)

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

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

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

Copies to:

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

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

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

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

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

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

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

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

Subject to Completion. Dated June 16, 2003

PROSPECTUS

15,000,000 Shares

Endo Pharmaceuticals Holdings Inc.

Common Stock

$ 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 June 13, 2003 was $18.60 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 Selling Stockholders (before expenses)	$	$

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

Joint Book-Running Managers

Citigroup Bear, Stearns & Co. Inc.

Jefferies & Company, Inc. SG Cowen

, 2003

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

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 (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 will be exercisable by June 30, 2003; 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)				
Statement of Operations Data:					
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 March 31,
	2000	2001	2002	2003
	(in thousands)			
Consolidated Balance Sheet Data:				
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)				
Other Data:					
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.

The calculation of credit facility EBITDA is as follows:

Three Months