ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
May 14, 2001

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): May 14, 2001 (May 14, 2001)

ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

DELAWARE	39040	13-4022871
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

223 Wilmington-West Chester Pike Chadds Ford, Pennsylvania	19317
(Address of principal executive offices)	(Zip Code)

(610) 558-9800

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Item 5. Other Events.

On May 14, 2001, the Registrant issued a press release, a copy of which is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 7. Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.

Not applicable

(b) Pro Forma Financial Information.

Not applicable.

(c) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Endo Pharmaceuticals Holdings Inc. on May 14, 2001

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

ENDO PHARMACEUTICALS HOLDINGS INC.
(Registrant)

By: /s/ CAROL A. AMMON

Name: Carol A. Ammon
Title: President & Chief Executive Officer

Dated: May 14, 2001

INDEX TO EXHIBITS

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99.1	Press release issued by Endo Pharmaceuticals Holdings Inc. on May 14, 2001

Exhibit 99.1

Contact: Robert Siegfried/Jeremy Fielding
Kekst and Company
212-521-4800

Endo Pharmaceuticals Reports First Quarter 2001 Financial Results
-- Net Sales Increase 46% and Gross Profit Rises by 79% for the Period --

CHADDS FORD, PA, May 14,2001 -- Endo Pharmaceuticals Holdings Inc. (Nasdaq: ENDP; ENDPW), a market leader in pain management, today reported its financial results for the three months ended March 31, 2001. The

Company, which completed its merger with Algos Pharmaceutical Corporation on July 17, 2000, increased net sales by 46% for the quarter ended March 31, 2001 to $39.4 million from $27.0 million in the same period in 2000. Gross profit for the three months ended March 31, 2001 grew by 79% to $26.7 million from $14.9 million over the comparable 2000 period.

Carol A. Ammon, President and Chief Executive Officer of Endo Pharmaceuticals, said, "Our results further underscore the continuing development and growth of our business. In the first quarter, we deployed our full-time dedicated contract specialty and primary care sales forces to promote both Percocet(R) and Lidoderm(R), as well as other products in our portfolio. We continue to significantly increase investment in Research & Development to advance several products in the clinical development stage. We believe that our pipeline, supported by our increased investment in Research & Development, clinical development and education, is enhancing Endo's position as a market leader in pain management."

First Quarter Results

Net sales for the three months ended March 31, 2001 increased by 46% to $39.4 million from $27.0 million in the comparable 2000 period. This increase in net sales was primarily due to the increase in net sales from several new products. In November 1999, the Company launched Percocet(R) 2.5/325, Percocet(R) 7.5/500 and Percocet(R) 10.0/650 to complement the existing Percocet(R) 5.0/325 for the relief of moderate-to-severe pain. In September 1999, the Company launched Lidoderm(R), the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia. In November 1998, the Company launched Morphine Sulfate Extended Release Tablets, the therapeutic equivalent version of MS Contin(R), for moderate-to-severe pain.

Gross profit for the three months ended March 31, 2001 increased by 79% to $26.7 million from $14.9 million in the comparable 2000 period. Gross profit margins increased to 68% from 55% due to the Company's continued focus on a more favorable mix of higher margin products both through product launches as 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 the Company's manufacturing relationship with DuPont Pharmaceuticals, currently the Company's most significant contract manufacturing relationship. Cash Gross Profit (defined in the merger agreement with Algos as equal to gross profit as determined by generally accepted accounting principles (GAAP) excluding non-cash charges) for the three months ended March 31, 2001 increased by 61% to $29.7 million from $18.4 million in the comparable 2000 period. Cash Gross Profit margins increased to 75% from 68%. A reconciliation of gross profit as determined by GAAP to Cash Gross Profit is as follows:

	(Unaudited) Three Months Ended March 31,	
	2001	2000
GAAP Gross Profit	$ 26,733	$ 14,938
Non-cash manufacturing charges	2,917	3,497
Cash Gross Profit	$ 29,650	$ 18,435

Selling, general and administrative expenses for the three months

ended March 31, 2001 increased by 31% to $15.9 million from $12.1 million in the comparable 2000 period. This increase resulted from a $2.3 million increase in sales and promotional efforts in 2001 over the comparable 2000 period in order to support Lidoderm(R) and Percocet(R). The increase in sales and promotional efforts was primarily due to the first quarter 2001 deployment of a dedicated contract sales force of 230 full-time representatives comprised of 70 full-time specialty representatives and 160 full-time primary care representatives as compared to 300 part-time representatives in the comparable 2000 period. In addition, the Company experienced an increase in personnel-related costs in the general and administrative functions in order to support its growth.

Research and development expenses for the three months ended March 31, 2001 increased by 207% to $9.2 million from $3.0 million in the comparable 2000 period. This increase was due to the Company's increased spending on 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 the Company's financial statements prospectively for reporting periods beginning July 17, 2000.

Operating Loss for the three months ended March 31, 2001 decreased to $10.7 million from $24.4 million in the comparable 2000 period. Pro Forma Consolidated EBITDA (as defined in footnote (1) below) for the three months ended March 31, 2001 increased to $4.6 million from a negative $1.2 million in the comparable 2000 period. A reconciliation of Operating Loss as determined by GAAP to Pro Forma Consolidated EBITDA is as follows:

	(Unaudited) Three Months Ended March 31,	
	2001	2000
GAAP Operating Loss	$ (10,730)	$ (24,348)
Depreciation and amortization	12,399	2,151
Non-cash manufacturing charges	2,917	3,497
Non-cash separation benefits	-	20,782
Subtotal: Consolidated EBITDA	$ 4,586	$ 2,082
Operating loss of Algos	-	(3,321)
Depreciation and amortization of Algos	-	55
Pro Forma Consolidated EBITDA	$ 4,586	$ (1,184)

The assets acquired and liabilities assumed, results of operations and cash flows of Algos have been included in the Company's financial statements and Management's Discussion and Analysis of Financial Conditions and Results of Operations prospectively for reporting periods beginning July 17, 2000. The Company's 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 the Company's customers, market acceptance of the Company's products and the impact of competitive products and pricing. On January 3, 2001, Watson Pharmaceuticals, Inc. announced that the Food and Drug Administration had approved Watson's abbreviated new drug application (ANDA) for a generic equivalent to Percocet(R) 7.5/500 and Percocet(R) 10.0/650. The launch of these generics may have a material impact on the results of operations and cash flows of the Company in the future.

Forward Looking Statements

This press release contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on management's beliefs and assumptions, current expectations, estimates and projections. Statements that are not historical facts, including statements which are preceded by, followed by, or that include, the words "believes," "anticipates," "plans," "expects" or similar expressions and statements. Endo's estimated or anticipated future results, product performance or other non-historical facts are forward-looking and reflect Endo's current perspective on existing trends and information. Many of the factors that will determine the Company's future results are beyond the ability of the Company to control or predict. These statements are subject to risks and uncertainties and, therefore, actual results may differ materially from those expressed or implied by these forward-looking statements. The reader should not rely on any forward-looking statement. The Company undertakes no obligations to update any forward-looking statements whether as a result of new information, future events or otherwise. Several important factors, in addition to the specific factors discussed in connection with these forward-looking statements individually, could affect the future results of the Endo and could cause those results to differ materially from those expressed in the forward-looking statements contained herein. Important factors that may affect future results include, but are not limited to: market acceptance of the Company's products and the impact of competitive products and pricing; dependence on sole source suppliers; the success of the Company's product development activities and the timeliness with which regulatory authorizations and product launches may be achieved; successful compliance with extensive, costly, complex and evolving governmental regulations and restrictions; the availability on commercially reasonable terms of raw materials and other third party manufactured products; exposure to product liability and other lawsuits and contingencies; dependence on third party suppliers, distributors and collaboration partners; the ability to timely and cost effectively integrate acquisitions; uncertainty associated with pre-clinical studies and clinical trials and regulatory approval; uncertainty of market acceptance of new products; the difficulty of predicting FDA approvals; risks with respect to technology and product development; the effect of competing products and prices; uncertainties regarding intellectual property protection; uncertainties as to the outcome of litigation; changes in operating results; impact of competitive products and pricing; product development; changes in laws and regulations; customer demand; possible future litigation; availability of future financing and reimbursement policies of government and private health insurers and others; and other risks and uncertainties detailed in Endo's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on June 9, 2000, as amended. Readers should evaluate any statement in light of these important factors.

The following table presents the Company's consolidated statements of operations for the three months ended March 31, 2001 and 2000:

Endo Pharmaceuticals Holdings Inc.

Consolidated Statements of Operations (unaudited)

(in thousands, except share and per share data)

Three Months Ended

March 31,

	2001	2000
NET SALES	$39,382	$27,000
COST OF SALES	12,649	12,062
GROSS PROFIT	26,733	14,938
COSTS AND EXPENSES:		
Selling, general and administrative	15,890	12,073
Research and development	9,174	3,028
Depreciation and amortization	12,399	2,151
Separation benefits	-	22,034
OPERATING LOSS	(10,730)	(24,348)
INTEREST EXPENSE, Net	3,540	3,937
LOSS BEFORE INCOME TAX BENEFIT	(14,270)	(28,285)
INCOME TAX BENEFIT	32	10,691
NET LOSS	$(14,238)	$(17,594)
NET LOSS PER SHARE:		
Basic and Diluted	$(.16)	$(.25)
Weighted average shares (Basic and Diluted)	89,138,950	71,324,957

The following table presents the Company's unaudited condensed consolidated balance sheet data at March 31, 2001 and December 31, 2000:

Endo Pharmaceuticals Holdings Inc.
Condensed Consolidated Balance Sheet Data (unaudited)

(in thousands)

	March 31, 2001	December 31, 2000
ASSETS		
Total current assets	$165,760	$173,054
Property and equipment, net	6,479	5,742
Goodwill and other intangibles, net	272,663	284,560
Deferred income taxes	844	736
Restricted cash	150	150
Other assets	3,050	3,598
TOTAL ASSETS	$448,946	$467,840
LIABILITIES AND STOCKHOLDERS' EQUITY		
Total current liabilities	$ 94,118	$100,295
Long-term debt, less current portion	158,234	162,154
Other liabilities	12,659	7,218

Total Stockholders' Equity	183,935	198,173

The following table presents the Company's unaudited net sales for the three months ended March 31, 2001 and 2000:

Endo Pharmaceuticals Holdings Inc.

Net Sales (unaudited)

(in thousands)

	Three Months Ended March 31,	
	2001	2000
Percocet(R)	$20,159	$ 12,295
Lidoderm(R)	3,643	1,484
Other Brands	5,002	5,603
Total Brands	$28,804	$19,382
Total Generics	$10,578	$ 7,618
Total Net Sales	$39,382	$27,000

Endo is a fully integrated specialty pharmaceutical company with market leadership in pain management. The company researches, develops, produces and markets both branded and generic pharmaceutical products primarily for the treatment of pain. Endo has a portfolio of thirteen branded products that includes established brands such as Percocet(R) and Percodan(R), opioid analgesics. This and past press releases of Endo Pharmaceuticals Holdings Inc. are available at Endo's web site at http://www.endo.com.

(1) Endo's 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 Endo and subsidiaries in accordance with generally accepted accounting principles.

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