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ENDO PHARMACEUTICALS HOLDINGS INC

Form 8-K

November 13, 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): November 13, 2001
(November 13, 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.)

100 Painters Drive
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 Matters.

On November 13, 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.

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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 November 13, 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: November 13, 2001

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press release issued by Endo Pharmaceuticals Holdings Inc. on November 13, 2001

Exhibit 99.1

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

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Endo Pharmaceuticals Achieves Strong Third Quarter and Year-to-Date 2001 Financial Results

-- Net Sales Increase 30% and Consolidated EBITDA
Rises by 58% for the Period --

CHADDS FORD, PA, November 13, 2001 -- Endo Pharmaceuticals Holdings Inc. (Nasdaq: ENDP; ENDPW), a market leader in pain management, today reported its financial results for the three months and nine months ended September 30, 2001.

For the third quarter ended September 30, 2001, Endo's net sales grew 30% to \$66.3 million from \$50.9 million for the same period in 2000. Consolidated EBITDA increased by 58% to \$24.7 million from \$15.6 million over the comparable 2000 period. Earnings per share, excluding the impact of non-cash compensation charges related to the vesting of non-dilutive stock options, increased to \$.03 per diluted share for the third quarter of 2001 compared to a net loss per diluted share of (\$.04) in the comparable 2000 period, excluding the impact of in-process research and development. Results for the 2001 periods reflect the company's merger with Algos Pharmaceutical Corporation, which was completed on July 17, 2000.

Carol A. Ammon, President and Chief Executive Officer of Endo Pharmaceuticals, said, "Endo's performance reflects the strength of our established portfolio of products in the fast growing pain management market. We are particularly pleased with the continued growth of Lidoderm(R) and our extended-release morphine sulfate. As a result of the strong performance of these products, we are revising upward for 2001 the net sales and consolidated EBITDA projections contained in Endo's recent S-3 filing made in connection with the company's recent and successful public offering. We anticipate net sales for 2001 to be between \$235 million to \$240 million and consolidated EBITDA for 2001 to be between \$75 million to \$77 million."

Carol Ammon further stated, "We are also pleased about the continued advancement of our three Phase III NDA pipeline products. Specifically, we are on track to file the amendment to the MorphiDex(R) NDA in mid-2002 and file NDAs for both an oral extended-release version and an immediate-release version of our oxymorphone product in the second half of 2002. Although there can be no assurance, we also currently anticipate the approval and launch of our line extension of Percocet(R) by the end of this year.

"In addition, on October 29, 2001, we used the \$84.9 million net proceeds from our recent public offering plus \$16.1 million from our cash balance to repay in full the term loans under our existing credit facility. We are negotiating the terms of a new senior secured credit facility to replace our existing credit agreement. We, therefore, expect to be in an advantageous position to pursue acquisitions and other strategic alliances, which would, we believe, accelerate our growth as a premier specialty pharmaceutical company."

Third Quarter Results

Net sales for the three months ended September 30, 2001 increased by 30% to \$66.3 million from \$50.9 million in the comparable 2000 period. Operating loss for the three months ended September 30, 2001 decreased to \$31.5 million from \$132.7 million in the comparable 2000 period. Consolidated EBITDA (as defined in footnote (1) below) for the three months ended September 30, 2001 increased to \$24.7 million from \$15.6 million in the comparable 2000 period. A reconciliation of Operating Income as determined by GAAP to Consolidated EBITDA is as follows:

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	(Unaudited) Three Months Ended September 30, (in thousands) -----	
	2001 ----	2000 ----
GAAP operating loss	\$ (31,475)	\$ (132,729)
Depreciation and amortization	12,394	10,715
Non-cash manufacturing charges	6,539	4,364
Non-cash compensation charges	37,253	-
Purchased in-process R&D	-	133,200
	-----	-----
Consolidated EBITDA	\$24,711 =====	\$15,550 =====

Net loss for the three months ended September 30, 2001 decreased to \$33.0 million from \$136.5 million in the comparable 2000 period. Net loss per diluted share for the three months ended September 30, 2001 decreased to \$.37 from \$1.59 in the comparable 2000 period. Excluding non-cash compensation charges related to the vesting of non-dilutive stock options recorded in the three months ended September 30, 2001 and purchased in-process research and development recorded in connection with the Algos acquisition in the three months ended September 30, 2000, the Company recorded net income in the three months ended September 30, 2001 of \$2.4 million and \$.03 per diluted share compared to a net loss in the comparable 2000 period of \$3.3 million and \$.04 per diluted share. A reconciliation of net income (loss) is as follows:

	(Unaudited) Three Months Ended September 30, (in thousands) -----	
	2001 ----	2000 ----
GAAP net loss	\$ (32,993)	\$ (136,548)
Non-cash compensation charges (net of tax)	35,394	-
Purchased in-process R&D (net of tax)	-	133,200
	-----	-----
Adjusted net income (loss)	\$2,401 =====	\$ (3,348) =====
Diluted weighted average shares outstanding	89,292	89,139
Diluted earnings (loss) per share	\$.03	\$ (.04)

Year-to-Date Results

Net sales for the nine months ended September 30, 2001 increased by 45% to \$173.5 million from \$119.8 million in the comparable 2000 period. Operating loss for the nine months ended September 30, 2001 decreased to \$35.5 million from \$152.3 million in the comparable 2000 period. Pro Forma Consolidated EBITDA (as defined in footnote (1) below) for the nine months ended September 30, 2001 increased to \$55.9 million from \$22.2 million in the comparable 2000 period. A reconciliation of operating loss as determined by GAAP to Pro Forma Consolidated EBITDA is as follows:

(Unaudited)

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	Nine Months Ended September 30, (in thousands)	
	2001	2000
GAAP operating loss	\$ (35,546)	\$ (152,322)
Depreciation and amortization	37,170	15,041
Non-cash manufacturing charges	17,010	13,921
Compensation related to stock options	37,253	-
Purchased in-process R&D	-	133,200
Non-cash separation benefits	-	20,782
Subtotal: Consolidated EBITDA	\$55,887	\$30,622
Operating loss of Algos	-	(8,525)
Depreciation and amortization of Algos	-	128
Pro Forma Consolidated EBITDA	\$55,887	\$22,225

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.

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. 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. Forward-looking statements are not historical facts and include information regarding the Company's possible or assumed results of operations. Also, statements or expressions that are preceded by, followed by, or that include, the words "believes," "anticipates," "plans," "expects," "intends," "estimates" or similar expressions are forward-looking 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. 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

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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 and in Endo's Registration Statement on Form S-3 dated October 17, 2001. 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 and nine months ended September 30, 2001 and 2000:

Endo Pharmaceuticals Holdings Inc.			
Consolidated Statements of Operations (unaudited)			
(in thousands, except per share data)			
	Three Months Ended		
	September 30,		
	2001	2000	
	----	----	
NET SALES	\$66,268	\$50,902	\$1
COST OF SALES	20,622	15,254	---
	-----	-----	
GROSS PROFIT	45,646	35,648	1
COSTS AND EXPENSES:			
Selling, general and administrative	19,588	14,564	
Research and development	7,886	8,315	
Depreciation and amortization	12,394	10,715	
Compensation related to stock options	37,253	-	
Purchased in-process research and development	-	133,200	

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Merger and other related costs	-	1,583	
Separation benefits	-	-	
	-----	-----	
OPERATING LOSS	(31,475)	(132,729)	(3)
INTEREST EXPENSE, Net	2,686	3,672	
	-----	-----	
LOSS BEFORE INCOME TAX BENEFIT	(34,161)	(136,401)	(4)
	-----	-----	
INCOME TAX (BENEFIT)	(1,168)	147	
	-----	-----	
NET LOSS	\$ (32,993)	\$ (136,548)	\$ (4)
	=====	=====	=====
NET LOSS PER SHARE:			
Basic	\$ (.37)	\$ (1.59)	
Diluted	\$ (.37)	\$ (1.59)	
Weighted average shares			
Basic	89,139	85,848	
Diluted	89,139	85,848	

The following table presents the Company's unaudited condensed consolidated balance sheet data at September 30, 2001 and December 31, 2000:

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

(in thousands)

	September 30,	D
	2001	

ASSETS		
Cash and cash equivalents	\$ 89,309	
Other current assets	104,568	

Total current assets	193,877	
Property and equipment, net	9,086	
Goodwill and other intangibles, net	245,519	
Deferred income taxes	1,979	
Restricted cash	150	
Other assets	5,571	

TOTAL ASSETS	\$456,182	

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LIABILITIES AND STOCKHOLDERS' EQUITY

Total current liabilities	\$88,557
Long-term debt, less current portion	174,516
Other liabilities	2,183
Total stockholders' equity	190,926

The following table presents the Company's unaudited net sales for the three months and nine months ended September 30, 2001 and 2000:

Endo Pharmaceuticals Holdings Inc.				
Net Sales (unaudited)				
(in thousands)				
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
	----	----	----	----
Percocet (R)	\$16,430	\$23,379	\$72,831	\$54,251
Lidoderm(R)	16,268	7,343	26,933	12,833
Other Brands	8,087	8,330	16,678	21,311
	-----	-----	-----	-----
Total Brands	\$40,785	\$39,052	\$116,442	\$88,395
Total Generics	\$25,483	\$11,850	\$57,065	\$31,441
Total Net Sales	\$66,268	\$50,902	\$173,507	\$119,836
	=====	=====	=====	=====

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)

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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.