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ENDO PHARMACEUTICALS HOLDINGS INC

Form 8-K

July 25, 2002

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):  
July 25, 2002 (July 25, 2002)

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  
(Address of principal executive offices)

19317  
(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 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 of Endo Pharmaceuticals Holdings Inc. dated July 25, 2002

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Item 9. Regulation FD Disclosure.

On July 25, 2002, the Registrant issued a press release, a copy of which is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

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: July 25, 2002

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press Release of Endo Pharmaceuticals Holdings Inc. dated July 25, 2002

Exhibit 99.1

[ENDO LOGO]

For Immediate Release

CONTACTS:  
Bill Newbould  
Endo Pharmaceuticals  
(610) 558-9800

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Jeremy Fielding/Jon Morgan  
Kekst & Company  
(212) 521-4800

Endo Pharmaceuticals Reports Strong Second Quarter Results  
- Continued Growth of Lead Products Drives Performance -  
- Company Raises 2002 Guidance -

CHADDS FORD, Pa., July 25, 2002 -- Endo Pharmaceuticals Holdings Inc. (Nasdaq: ENDP; ENDPW), a market leader in pain management, today reported its financial results for the second quarter and six months ended June 30, 2002.

Net sales grew by 59% to \$107.9 million in the second quarter of 2002 compared with \$67.9 million for the same period in 2001. For the quarter, net income rose to \$22.0 million, or \$0.22 per diluted share, in 2002 versus \$2.7 million, or \$0.03 per diluted share, in the year-ago second quarter. On a pro forma basis, excluding the amortization of goodwill and workforce-in-place to reflect new accounting standards adopted on January 1, 2002, net income in the second quarter of 2001 was \$9.6 million, or \$0.11 per diluted share. Consolidated EBITDA for the three months ended June 30, 2002 rose 70% to \$45.1 million from \$26.6 million in the comparable period a year ago.

"These outstanding top- and bottom-line results continue to be driven by the strong growth of our core product line, reflecting our leadership position in pain management," said Carol A. Ammon, chairman and chief executive officer. She noted that sales of Percocet(R) have continued to accelerate following the successful introduction of two new strengths in November 2001. Also showing excellent growth during the quarter were Lidoderm(R), the first FDA-approved product for the treatment of pain associated with post-herpetic neuralgia, and Endo's generic extended-release morphine sulfate product. "As a result of this performance, combined with our continued confidence in the underlying strength of our business, we are raising our previous guidance for 2002 net sales from \$300 million to \$350 million, and for consolidated EBITDA from \$100 million to \$125 million. Of course, there can be no assurance of the company achieving these numbers," Ammon said.

## Year-to-Date Results

For the six months, net sales were \$174.9 million in 2002, up 63% from \$107.2 million in 2001. Net income was \$27.4 million, or \$0.27 per diluted share, versus a net loss of \$11.5 million, or \$0.13 per diluted share, in the first half of 2001. On a pro forma basis, excluding the amortization of goodwill and workforce-in-place to reflect new accounting standards adopted on January 1, 2002, the six-month results in 2001 reflect net income of \$8.0 million, or \$0.09 per diluted share. Consolidated EBITDA of \$60.9 million for the first half of 2002 was nearly double the \$31.2 million reported in the same period of 2001.

## Supplemental Financial Information

The following table presents a reconciliation of operating income as determined by GAAP to consolidated EBITDA the three months ended June 30, 2002 and June 30, 2001:

	(Unaudited) Three Months Ended June 30,	
	2002	2001
	----	----
	(in thousands)	
GAAP operating income	\$36,702	\$6,659

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Depreciation and amortization	691	12,377
Non-cash manufacturing charges	6,384	7,554
Non-recurring manufacturing transfer costs	1,301	-
	-----	-----
Consolidated EBITDA	\$45,078	\$26,590
	=====	=====

The following table presents a reconciliation of operating income as determined by GAAP to consolidated EBITDA the six months ended June 30, 2002 and June 30, 2001:

	(Unaudited)	
	Six Months Ended	
	June 30,	
	2002	2001
	----	----
	(in thousands)	
GAAP operating income (loss)	\$47,073	\$(4,071)
Depreciation and amortization	1,476	24,776
Non-cash manufacturing charges	11,081	10,471
Non-recurring manufacturing transfer costs	1,301	-
	-----	-----
Consolidated EBITDA	\$60,931	\$31,176
	=====	=====

### Product Review

Percocet(R). Sales of Percocet(R) were \$40.6 million for the three months ended June 30, 2002, a gain of 12% from \$36.2 million in the same period of 2001. For the first half, sales were \$64.1 million in 2002 versus \$56.4 million in 2001, a 14% increase. "Driving this growth was the continued success of Percocet's(R) most recent formulations, 7.5/325 and 10/325, which provide effective pain management at a reduced dose of acetaminophen," Ammon noted.

Lidoderm(R). For the second quarter of 2002, sales of Lidoderm(R) grew to \$25.8 million from \$7.0 million in the 2001 second quarter, and rose to \$35.8 million for the six months in 2002 versus \$10.7 million in the same period a year ago. "Lidoderm continues to grow at an impressive rate, reflecting broad market acceptance of the product's clinical utility," said Ammon.

Other branded products. Combined sales of all other branded products were \$4.3 million and \$9.6 million for the quarter and six months in 2002 compared with \$3.6 million and \$8.6 million in the respective periods of 2001.

Generic products. Led by growth in morphine sulfate extended-release tablets and Endocet(R), sales from generic products rose to \$37.2 million in the second quarter, up 77% from \$21.0 million in the year-ago quarter, and increased to \$65.4 million for the first six months, a 107% increase from \$31.6 million in the first half of 2001.

As previously announced, Endo has exercised its option to convert its specialty sales force to Endo employees from the contract sales organization Ventiv Health US Sales Inc., effective July 1, 2002. "Based on the success of Lidoderm(R) and our new strengths of Percocet(R), we've strengthened our internal sales capabilities, bringing in-house 70 representatives and seven district managers from the Ventiv sales force," Ammon said. For the remainder of its sales force, which is composed of 160 pharmaceutical sales

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representatives as well as their management, Endo continues to contract with Ventiv.

### Note to Investors

Endo will conduct a conference call with financial analysts to discuss this news release today at 11:00 a.m. EDT. Investors and other interested parties may access the conference call by dialing (800) 474-8920 (domestic) or (719) 457-2727 (international). Please dial in 10 minutes prior to the scheduled start time. A replay of the call will be available from July 25, 2002 at 2:00 p.m. by dialing (888) 203-1112 (domestic) or (719) 457-0820 (international), passcode 795907, and will run until 12:00 a.m. on August 1, 2002.

A simultaneous webcast of the call for interested investors and others may be accessed by visiting [www.endo.com](http://www.endo.com). In addition, a replay of the webcast will be available until August 4, 2002. The replay can be accessed by clicking on "Events" in the Investor Relations section of the company's web site.

### About Endo

Endo Pharmaceuticals is a fully integrated specialty pharmaceutical company with market leadership in pain management products. The company researches, develops, produces and markets a broad product offering of both branded and generic pharmaceuticals, meeting the needs of healthcare professionals and consumers alike. More information about the company, including this and past press releases of Endo Pharmaceuticals Holdings Inc., is available online at [www.endo.com](http://www.endo.com).

### 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

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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.

(Tables Attached)

The following table presents Endo's unaudited net sales for the three months and six months ended June 30, 2002 and June 30, 2001:

Endo Pharmaceuticals Holdings Inc. Net Sales (unaudited) (in thousands)			
		Three Months Ended June 30, -----	
	2002 ----	2001 ----	2002 ----
Percocet (R)	\$40,610	\$36,242	\$64,078
Lidoderm(R)		7,022	35,836
	25,834		
Other Brands	4,295	3,589	9,621
	-----	-----	-----
Total Brands	\$70,739	\$46,853	\$109,535
Total Generics	\$37,163	\$21,004	\$65,393
	-----	-----	-----
Total Net Sales	\$107,902 =====	\$67,857 =====	\$174,928 =====

The following table presents Endo's consolidated statements of operations for the three months and six months ended June 30, 2002 and June 30, 2001:

Endo Pharmaceuticals Holdings Inc.  
Consolidated Statements of Operations (unaudited)  
(in thousands, except per share data)

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	2002	Three Months Ended June 30, 2001
	----	----
NET SALES	\$107,902	\$67,857
COST OF SALES	27,805	21,032
	-----	-----
GROSS PROFIT	80,097	46,825
COSTS AND EXPENSES:		
Selling, general and administrative	27,562	19,453
Research and development	15,142	8,336
Depreciation and amortization	691	12,377
	-----	-----
OPERATING INCOME (LOSS)	36,702	6,659
INTEREST EXPENSE, Net	1,649	2,903
	-----	-----
INCOME (LOSS) BEFORE INCOME TAX	35,053	3,756
	-----	-----
INCOME TAX	13,052	1,025
	-----	-----
NET INCOME (LOSS)	\$22,001	\$2,731
	=====	=====
NET INCOME (LOSS) PER SHARE:		
Basic	\$.22	\$.03
Diluted	\$.22	\$.03
NET INCOME		
Pro Forma to Exclude Amortization of Goodwill and Workforce-in-Place	\$22,001	\$9,554
	=====	=====
NET INCOME PER SHARE		
Pro Forma to Exclude Amortization of Goodwill and Workforce-in-Place:		
Basic	\$.22	\$.11
Diluted	\$.22	\$.11
WEIGHTED AVERAGE SHARES:		
Basic	102,064	89,139
Diluted	102,271	89,213

The following table presents the Endo's unaudited condensed consolidated balance sheet data at June 30, 2002 and December 31, 2001:

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

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	June 30, 2002 ----
ASSETS	
Cash and cash equivalents	\$151,835
Other current assets	182,407
	-----
Total current assets	334,242
Property and equipment, net	9,590
Goodwill	181,079
Other Intangibles, net	12,125
Deferred income taxes	17,167
Restricted cash	150
Other assets	1,764
	-----
TOTAL ASSETS	\$556,117 =====
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current portion of long-term debt	\$94,707
Other current liabilities	145,421
	-----
Total current liabilities	240,128
Long-term debt, less current portion	-
Other liabilities	217
	-----
Total stockholders' equity	315,772
	-----
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$556,117 =====

The following table presents condensed consolidated cash flow data for the six months ended June 30, 2002 and June 30, 2001:

Endo Pharmaceuticals Holdings Inc.  
Condensed Consolidated Cash Flow Data (unaudited)  
(in thousands)

	Six Months Ended June 30, 2002 ----
Net cash provided by operating activities	\$64,031
Net cash used in investing activities	(827)
Net cash used in financing activities	(6,726)
	-----
Net increase in cash and cash equivalents	\$56,478
Cash and cash equivalents, beginning of period	\$95,357
	-----
Cash and cash equivalents, end of period	\$151,835



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=====

Effective January 1, 2002, Endo adopted the new goodwill accounting standards and will no longer amortize goodwill and workforce-in-place. The pro forma effect of the adoption of these new accounting standards, including the pro forma effect on income taxes for the three months ended June 30, 2002 and June 30, 2001, is as follows:

	(Unaudited Three Months June 30 2002 ---- (in thousands, except data))
Reported net income	\$22,001
Add back: Goodwill amortization	-
Add back: Amortization of workforce-in-place	-
Less: Pro forma income tax	-
	-----
Adjusted net income	\$22,001 =====
Basic earnings per share:	
Reported net income	\$.22
Add back: Goodwill amortization	-
Add back: Amortization of workforce-in-place	-
Less: Pro forma income tax	-
	-----
Adjusted net income	\$.22 =====
Diluted earnings per share:	
Reported net income	\$.22
Add back: Goodwill amortization	-
Add back: Amortization of workforce-in-place	-
Less: Pro forma income tax	-
	-----
Adjusted net income	\$.22 =====

Effective January 1, 2002, Endo adopted the new goodwill accounting standards and will no longer amortize goodwill and workforce-in-place. The pro forma effect of the adoption of these new accounting standards, including the pro forma effect on income taxes for the six months ended June 30, 2002 and June 30, 2001, is as follows:

(Unaudited  
Six Months  
June 30  
2002  
----  
(in thousands, except  
data))

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Reported net income (loss)	\$27,377
Add back: Goodwill amortization	-
Add back: Amortization of workforce-in-place	-
Less: Pro forma income tax	-
	-----
Adjusted net income	\$27,377
	=====
Basic earnings (loss) per share:	
Reported net income (loss)	\$.27
Add back: Goodwill amortization	-
Add back: Amortization of workforce-in-place	-
Less: Pro forma income tax	-
	-----
Adjusted net income	\$.27
	=====
Diluted earnings (loss) per share:	
Reported net income (loss)	\$.27
Add back: Goodwill amortization	-
Add back: Amortization of workforce-in-place	-
Less: Pro forma income tax	-
	-----
Adjusted net income	\$.27
	=====

### Definition of Consolidated EBITDA

Endo's amended and restated 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 Endo 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 Endo and its subsidiaries in accordance with generally accepted accounting principles.

### Operating Income (Loss) to Consolidated EBITDA Reconciling Items:

Non-cash manufacturing charges reflect the present value of non-interest bearing promissory notes issued annually to Bristol-Myers Squibb Pharma Company ("BMS") (formerly the DuPont Pharmaceuticals Company) over the initial five-year term of the manufacturing and supply agreement with BMS. Non-recurring manufacturing transfer costs represent the costs incurred to transfer certain products from BMS to alternative manufacturers. Endo anticipates incurring these costs during 2002 and 2003.

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