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ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
April 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):
April 25, 2002 (April 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 | 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 7. Financial Statements and Exhibits.
- (a) Financial Statements of Business Acquired.
Not applicable.
- (b) Pro Forma Financial Information.
Not applicable.

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(c) Exhibits.

| Exhibit Number ----- | Description ----- |
|-------------------------|---|
| 99.1 | Press release issued by Endo Pharmaceuticals Holdings Inc. on April 25, 2002 |

Item 9. Regulation FD Disclosure.

On April 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: April 25, 2002

INDEX TO EXHIBITS

| Exhibit No. ----- | Description ----- |
|----------------------|---|
| 99.1 | Press release issued by Endo Pharmaceuticals Holdings Inc. on April 25, 2002 |

Exhibit 99.1

Contact: Robert Siegfried/Jeremy Fielding

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Kekst and Company
212-521-4800

Endo Pharmaceuticals Achieves Strong First Quarter 2002 Financial Results

-- Results Reflect Strength of Product Line Including Lidoderm(R),
Extended-Release Morphine Sulfate and the New Strengths of Percocet(R) --
-- 2002 Guidance Raised --

CHADDS FORD, PA, April 25, 2002 -- Endo Pharmaceuticals Holdings Inc. (Nasdaq: ENDP; ENDPW), a market leader in pain management, today announced its financial results for the first quarter ended March 31, 2002.

For the three months ended March 31, 2002, Endo's net sales grew 70% to \$67.0 million from \$39.4 million for the same period in 2001. Gross profits for the three months ended March 31, 2002 increased by 80% to \$48.1 million from \$26.7 million in the comparable 2001 period. Net income increased to \$5.4 million or \$.05 per diluted share from a net loss of \$(14.2) million or \$(-.16) per diluted share in the comparable 2001 period. Excluding the amortization of goodwill and workforce-in-place, net income increased to \$5.4 million or \$.05 per diluted share from a net loss of \$(1.6) million or \$(-.02) per diluted share for the comparable 2001 period. Consolidated EBITDA increased to \$15.9 million from \$4.6 million in the comparable 2001 period.

Carol A. Ammon, Chairman and Chief Executive Officer of Endo Pharmaceuticals, said, "We are extremely pleased with our strong financial performance during the first quarter. We have seen favorable market acceptance of our new strengths of Percocet(R) and are pleased with the consistent growth of Lidoderm(R). As a result of the anticipated continued strength of our product line, we are revising our guidance upward for 2002. We believe that we are well-positioned to achieve net sales in 2002 of approximately \$300 million and consolidated EBITDA of \$100 million. Of course, there can be no assurance of Endo achieving these numbers.

"We are progressing toward our goal of filing three NDA products in 2002. We believe these three products, MorphiDex(R), oxymorphone oral extended-release and oxymorphone immediate release, will enable us to achieve our vision of providing new ways to treat pain. We continue to invest in research and development as we complete Phase III clinical studies and prepare for the NDA filings. Endo anticipates releasing data from the first of three MorphiDex(R) clinical studies late in the second quarter of 2002 and although there can be no assurances, we continue to expect to resubmit an amendment to the existing MorphiDex(R) NDA with the FDA in the late third quarter or during fourth quarter of 2002. In addition, we anticipate releasing data on our two oxymorphone products in development in late summer and to be in a position to file both oxymorphone NDA's in the second half of 2002. We are committed to ongoing investment in research and development as we begin to advance our earlier stage pipeline."

First Quarter Results

Net sales for the three months ended March 31, 2002 increased by 70% to \$67.0 million from \$39.4 million in the comparable 2001 period. This increase in net sales was primarily due to the increase in net sales of Lidoderm(R), the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, certain generic products and the new strengths of Percocet(R). Gross profits for the three months ended March 31, 2002 increased by 80% to \$48.1 million from \$26.7 million in the comparable 2001

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period. Gross profit margins for the three months ended March 31, 2002 improved to 72% from 68% in the comparable 2001 period.

Selling, general and administrative ("SG&A") expenses increased 48% to \$23.6 million as a result of promotional efforts and support provided to our new products, including Lidoderm(R) and the new strengths of Percocet(R). Research and development ("R&D") expenses increased 46% to \$13.4 million as a result of our investment in new product development, including the development of MorphiDex(R) and our extended-release and immediate-release versions of oxymorphone. Operating income increased to \$10.4 million for the three months ended March 31, 2002 compared to an operating loss of \$(10.7) million in the comparable 2001 period. Excluding the amortization of goodwill and workforce-in-place, operating income increased to \$10.4 million from \$1.0 million in the comparable 2001 period. Consolidated EBITDA (as defined in endnote (1) below) for the three months ended March 31, 2002 increased to \$15.9 million from \$4.6 million in the comparable 2001 period. A reconciliation of operating income (loss) as determined by GAAP to Consolidated EBITDA is as follows:

| | (Unaudited) Three Months Ended March 31, ----- | |
|--------------------------------|---|------------------|
| | 2002 ---- | 2001 ---- |
| | (in thousands) | |
| GAAP operating income (loss) | \$10,371 | \$(10,730) |
| Depreciation and amortization | 785 | 12,399 |
| Non-cash manufacturing charges | 4,697 | 2,917 |
| | ----- | ----- |
| Consolidated EBITDA | \$15,853 ===== | \$4,586 ===== |

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 tax benefit, is as follows:

| | (Unaudited) Three Months Ended March 31, ----- | |
|--|---|--------------------|
| | 2002 ---- | 2001 ---- |
| | (in thousands, except per share data) | |
| Reported net income (loss) | \$5,376 | \$(14,238) |
| Add back: Goodwill amortization | - | 10,225 |
| Add back: Amortization of workforce-in-place | - | 1,487 |
| Pro forma income tax benefit | - | 954 |
| | ----- | ----- |
| Adjusted net income (loss) | \$5,376 ===== | \$(1,572) ===== |
| Basic earnings (loss) per share: | | |
| Reported net income (loss) | \$.05 | \$ (.16) |
| Add back: Goodwill amortization | - | .11 |

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| | | |
|--|-------|---------|
| Add back: Amortization of workforce-in-place | - | .02 |
| Pro forma income tax benefit | - | .01 |
| | ----- | ----- |
| Adjusted net income (loss) | \$.05 | \$(.02) |
| | ===== | ===== |
| Diluted earnings (loss) per share: | | |
| Reported net income (loss) | \$.05 | \$(.16) |
| Add back: Goodwill amortization | - | .11 |
| Add back: Amortization of workforce-in-place | - | .02 |
| Pro forma income tax benefit | - | .01 |
| | ---- | ----- |
| Adjusted net income (loss) | \$.05 | \$(.02) |
| | ===== | ===== |

Endo'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 Endo's customers, market acceptance of our 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 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

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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 Endo's consolidated statements of operations for the three months ended March 31, 2002 and March 31, 2001:

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

| | | Three Months En March 31, ----- |
|---|----------|---------------------------------------|
| | 2002 | ----- |
| NET SALES | \$67,026 | |
| COST OF SALES | 18,891 | ----- |
| GROSS PROFIT | 48,135 | |
| COSTS AND EXPENSES: | | |
| Selling, general and administrative | 23,583 | |
| Research and development | 13,396 | |
| Depreciation and amortization | 785 | ----- |
| OPERATING INCOME (LOSS) | 10,371 | |
| INTEREST EXPENSE, Net | 1,622 | ----- |
| INCOME (LOSS) BEFORE INCOME TAX (BENEFIT) | 8,749 | ----- |
| INCOME TAX (BENEFIT) | 3,373 | ----- |
| NET INCOME (LOSS) | \$5,376 | ===== |
| NET INCOME (LOSS) PER SHARE: | | |
| Basic | \$.05 | |
| Diluted | \$.05 | |
| NET INCOME (LOSS) Pro Forma to Exclude Amortization of Goodwill and Workforce-in-Place | \$5,376 | ===== |
| NET INCOME (LOSS) PER SHARE Pro Forma to Exclude Amortization of Goodwill and Workforce-in-Place: | | |

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| | |
|--------------------------|---------|
| Basic | \$.05 |
| Diluted | \$.05 |
| WEIGHTED AVERAGE SHARES: | |
| Basic | 102,064 |
| Diluted | 102,281 |

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

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

| | |
|--|----------------------------|
| | March 31, 2002 ----- |
| ASSETS | |
| Cash and cash equivalents | \$117,695 |
| Other current assets | 132,584 |
| | ----- |
| Total current assets | 250,279 |
| Property and equipment, net | 9,364 |
| Goodwill | 181,079 |
| Other Intangibles, net | 12,311 |
| Deferred income taxes | 20,418 |
| Restricted cash | 150 |
| Other assets | 1,874 |
| | ----- |
| TOTAL ASSETS | \$475,475 ===== |
| LIABILITIES AND STOCKHOLDERS' EQUITY | |
| Current portion of long-term debt | \$92,968 |
| Other current liabilities | 88,521 |
| | ----- |
| Total current liabilities | 181,489 |
| Long-term debt, less current portion | - |
| Other liabilities | 218 |
| | ----- |
| Total stockholders' equity | 293,768 |
| | ----- |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$475,475 ===== |

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The following table presents condensed consolidated cash flow data for the three months ended March 31, 2002 and March 31, 2001:

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

| | Three Months Ended March 31, ----- 2002 ----- |
|---|---|
| Net cash provided by operating activities | \$29,148 |
| Net cash (used in) provided by investing activities | (80) |
| Net cash provided by (used in) financing activities | (6,730) |
| | ----- |
| Net increase in cash and cash equivalents | \$22,338 |
| Cash and cash equivalents, beginning of period | \$95,357 |
| | ----- |
| Cash and cash equivalents, end of period | \$117,695 |
| | ===== |

The following table presents Endo's unaudited net sales for the three months ended March 31, 2002 and March 31, 2001:

Endo Pharmaceuticals Holdings Inc. Net Sales (unaudited) (in thousands)

| | Three Months Ended March 31, ----- | |
|-----------------|--|---------------|
| | 2002 ----- | 2001 ----- |
| Percocet (R) | \$23,468 | \$20,159 |
| Lidoderm (R) | 10,002 | 3,643 |
| Other Brands | 5,326 | 5,002 |
| | ----- | ----- |
| Total Brands | \$38,796 | \$28,804 |
| Total Generics | \$28,230 | \$10,578 |
| | ----- | ----- |
| Total Net Sales | \$67,026 | \$39,382 |
| | ===== | ===== |

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

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professionals and consumers alike. This and past press releases of Endo Pharmaceuticals Holdings Inc. are available at Endo's Web site at <http://www.endo.com>.

- (1) 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.

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