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ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
November 16, 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 16, 2000
(November 15, 2000)

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 16, 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.

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Not applicable.

(c) Exhibits.

| Exhibit Number | Description |
|----------------|---------------------------------------------------------------------------------|
| 99.1 | Press release issued by Endo Pharmaceuticals Holdings Inc. on November 16, 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 16, 2001

INDEX TO EXHIBITS

| Exhibit No. | Description |
|-------------|---------------------------------------------------------------------------------|
| 99.1 | Press release issued by Endo Pharmaceuticals Holdings Inc. on November 16, 2001 |

Exhibit 99.1

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

ENDO PHARMACEUTICALS CHALLENGES SMITHKLINE BEECHAM'S
PAXIL(R) (PAROXETINE HYDROCHLORIDE, 40 mg) PATENTS

Chadds Ford, PA, November 16, 2001 - Endo Pharmaceuticals Holdings Inc. (NASDAQ: ENDP and ENDPW), a fully integrated, specialty pharmaceutical company with market leadership in pain management, announced today that, on November 15, 2001, SmithKline Beecham Corporation (and related companies) filed suit against its subsidiary, Endo Pharmaceuticals Inc., in the U.S. District Court for the Eastern District of Pennsylvania alleging that Endo's bioequivalent version of SmithKline's Paxil(R), 40 mg strength, infringes five of its patents. The United States Food and Drug

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Administration (FDA) accepted Endo's Abbreviated New Drug Application (ANDA) submission, including the required Paragraph IV certification, for a bioequivalent version of SmithKline's Paxil(R), 40 mg strength, earlier this year. Paxil(R) is indicated for the treatment of depression, obsessive compulsive disorder and panic disorder, and is one of the most widely prescribed prescription drugs in the United States. Although Endo believes the patents asserted by SmithKline Beecham are invalid and/or not infringed, no assurance can be given as to the outcome of the patent challenge process.

Endo, through its wholly owned subsidiaries Endo Pharmaceuticals Inc. and Endo Inc., is a fully integrated specialty pharmaceutical company with market leadership in pain management. The company is engaged in the research, development, sales and marketing of 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 for the relief of moderate-to-moderately severe pain.

To the extent any statements made in this release contain information that is not historical, these statements are essentially forward-looking and are subject to risks and uncertainties. As a result of such risks and uncertainties, which include, but are not limited to, 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 and other risks discussed from time to time in Endo's filings with the Securities and Exchange Commission, actual results may differ materially from those expressed or implied by such forward-looking statements.

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