ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
August 01, 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): August 1, 2002
(August 1, 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 5. Other Events.

On August 1, 2002, 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 August 1, 2002

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: Chairman & Chief Executive Officer

Dated: August 1, 2002

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press release issued by Endo Pharmaceuticals Holdings Inc. on August 1, 2002

Exhibit 99.1

[ENDO LOGO]

For Immediate Release

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

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

ENDO PHARMACEUTICALS ANNOUNCES TENTATIVE FDA APPROVAL OF ITS OXYCODONE EXTENDED-RELEASE PRODUCT

CHADDS FORD, Pa., August 1, 2002 - Endo Pharmaceuticals Holdings Inc. (Nasdaq: ENDP; ENDPW), a market leader in pain management, announced today that the U.S. Food and Drug Administration (FDA) has granted tentative approval of Endo's abbreviated new drug application (ANDA) for Oxycodone Extended-Release Tablets, 10 mg, 20 mg, 40 mg and 80 mg.

Endo's Oxycodone Extended-Release Tablets are AB-rated bioequivalent versions of the 10mg, 20mg, 40mg and 80mg strengths of OxyContin(R), a product of The Purdue Frederick Company that is indicated for the management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. These strengths had combined 2001 U.S. branded sales of approximately $1.5 billion.

In accordance with the Waxman-Hatch Act, Endo made the required paragraph IV certification when it filed and amended an ANDA with the FDA for this product. Endo believes that once final FDA approval is granted, it will have 180 days of marketing exclusivity with respect to the 10 mg, 20 mg and 40 mg strengths of this product since it believes that it was the first company to file an ANDA containing a paragraph IV certification for these strengths.

Since October 2000, Purdue Frederick has filed three lawsuits against Endo in response to its ANDA submission and related amendments alleging that Endo's Oxycodone Extended-Release product infringes three of its patents which cover the 10 mg, 20 mg, 40 mg and 80 mg strengths of OxyContin(R). These patent challenges are currently pending in the U.S. District Court for the Southern District of New York.

Commenting on the tentative FDA approval, Carol A. Ammon, chairman and chief executive officer, said, "We are pleased with the FDA's decision, which reflects our ability to bring products successfully through the regulatory process." She noted that tentative approval such as this indicates that the FDA has made a determination that a generic product meets the substantive requirements for approval, subject to the expiration of all statutorily imposed non-approval periods. A final approval must be granted before Endo is permitted to market Oxycodone Extended-Release Tablets.

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, including this and past press releases of Endo Pharmaceuticals Holdings Inc., is available online at 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. 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 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.

- XXX -