ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
June 24, 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): June 24, 2002 (June 24, 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 June 24, 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 June 24, 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: President &
Chief Executive Officer

Dated: June 24, 2002

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press release issued by Endo Pharmaceuticals Holdings Inc. on June 24, 2002

Exhibit 99.1

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

Endo Pharmaceuticals Announces Results from MorphiDex(R)

Phase III Clinical Trial

CHADDS FORD, PA, June 24, 2002 -- Endo Pharmaceuticals Holdings Inc. (Nasdaq: ENDP; ENDPW), today announced results from the first of its three Phase III clinical trials for its development product, MorphiDex(R).

The primary endpoint of the study was to demonstrate that the average daily dose of morphine given in combination with the N-methyl-D-aspartate (NMDA)-receptor antagonist, dextromethorphan is less than the average daily dose of morphine when given as morphine alone in order to maintain the same degree of pain control over a three-month period. No statistically significant difference in average daily morphine dose was observed in the morphine sulfate:dextromethorphan (MS:DM) group compared to the morphine sulfate group.

A secondary endpoint of the study was to determine if the combination of morphine and dextromethorphan minimizes the rate of escalation of daily morphine dose compared with morphine alone over the study period in order to maintain satisfactory pain control. No statistically significant difference in the percentage change from baseline in daily morphine dose averaged by week from the commencement of the double-blind study period to the completion of the double-blind study period was observed.

Carol A. Ammon, Chairman and Chief Executive Officer of Endo Pharmaceuticals, said, "Although we are disappointed by these study results, we will continue to analyze the data from this study and await the results of our other two ongoing Phase III clinical studies. As you may be aware, this study is the first of Endo's three Phase III clinical trials that we undertook for MorphiDex(R). Enrollment for the second of these trials has recently been completed, and we expect enrollment for the third of these trials to be completed in the next couple of weeks. We expect to be able to announce the results of the second and third of these clinical trials in the fourth quarter of this year. Until we are able to analyze the data from these studies, we will not be in a position to resubmit an amendment to the existing MorphiDex(R) new drug application with the FDA."

This clinical trial compared MorphiDex(R) (morphine and the N-methyl-D-aspartate (NMDA)-receptor antagonist, dextromethorphan) to immediate-release morphine sulfate among chronic pain patients. This pivotal, randomized, double-blind trial enrolled 193 chronic pain patients from 20 centers in the United States of America. The protocol called for patients enrolled in the study to be dosed for a three-month period in a double-blind fashion. Prior to this three-month double-blind period, patients were stabilized at a predefined level of pain control with their current opioid medication during a seven to 21-day run-in period in order to establish the morphine-equivalent daily dose needed to maintain satisfactory pain control. Following this open-label run-in period, patients were randomized to one of two double-blind treatment groups - receiving either MS:DM 15:15mg or immediate-release morphine sulfate 15 mg capsules, both of which are identical in appearance. These patients started this three-month double-blind period with 50% of their morphine-equivalent daily dose that had been established during the run-in period. During the three-month double-blind period, patients were permitted to self-titrate their dose of medication in order to achieve the predefined level of pain control. The study population consisted of 193 patients (101 men and 92 women). The mean age of the patients was 49 years, ranging between 22 and 75 years.

Ms. Carol A. Ammon and Dr. David A.H. Lee will be hosting a conference call for the investment community on June 24, 2002 from 9:30 A.M. (EST) to 10:00 A.M. (EST). Those who wish to participate in this conference call should telephone (800) 946-0712 or (719) 457-2641 approximately 15

minutes before the 9:30 A.M. starting time. There will be a replay of the call from 12:30 P.M. (EST) on June 24, 2002 until 6:00 P.M. (EST) on July 1, 2002. Callers wishing to access the replay should dial (888) 203-1112 or (719) 457-0820, Passcode: 435441. The conference call will also be webcast at www.vcall.com.

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. This and past press releases of Endo Pharmaceuticals Holdings Inc. are available at Endo's Web site at 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. 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.

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