ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
October 28, 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): October 28, 2002 (October 28, 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 October 28, 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 No.	Description
99.1	Press release issued by Endo Pharmaceuticals Holdings Inc. on October 28, 2002
99.2	Slide Presentation of Endo Pharmaceuticals Holdings Inc. dated October 29, 2002

Item 9. Regulation FD Disclosure.

On October 29, 2002, the Registrant intends to make a slide presentation at the Salomon Smith Barney 2002 Global Health Care Conference in New York, New York, a copy of which presentation is filed herewith as Exhibit 99.2 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: Chairman & Chief Executive Officer

Dated: October 28, 2002

INDEX TO EXHIBITS

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Exhibit 99.1

For Immediate Release

CONTACT:
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Endo Pharmaceuticals
(610) 558-9800

ENDO PHARMACEUTICALS ANNOUNCES RESULTS FROM MORPHIDEX(R)PHASE III CLINICAl

TRIAL

Chadds Ford, Pa., October 28, 2002 - Endo Pharmaceuticals Holdings Inc. (Nasdaq: ENDP; ENDPW) today announced results from the second of its three Phase III clinical trials for its development product MorphiDex(R).

The primary endpoint of the study was to demonstrate that MorphiDex(R), administered at a fixed dose throughout the study, provided superior analgesia (pain relief) compared to morphine alone at equivalent morphine doses. No statistically significant difference in analgesia was observed in the MorphiDex(R) group compared to the morphine sulfate alone group. The study also did not meet its secondary endpoint, a reduction in analgesic tolerance for patients administered MorphiDex(R).

"We are disappointed that this study, similar to our previously announced Phase III trial, did not have a positive outcome," said Carol A. Ammon, chairman and chief executive officer. "While we expect the results of the remaining Phase III trial to be available shortly, the company believes that the data that has been generated to date would suggest that we will not have enough evidence to support the filing of an amendment to the MorphiDex(R) NDA," said Ammon.

Trial Summary

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. Chronic pain patients totaling 327 were randomized into this double-blind trial from approximately 30 centers in the United States. In the initial unblinded portion of the study, patients had their level of pain stabilized on MorphiDex(R). If patients were able to attain satisfactory pain control on a stable dose of MorphiDex(R) during this run-in period, they were then randomized in a double-blind fashion to either the same dose of morphine sulfate, either alone or in combination with dextromethorphan (MorphiDex(R)). During the double-blind treatment period, patients were instructed to maintain the same daily dose of study medication throughout the three-month study period and not to take any additional pain medication. If a patient could not maintain the same dose for any reason, they were discontinued from the study.

The trial was designed to demonstrate analgesic superiority of MorphiDex(R) over morphine alone for patients with moderate-to-severe chronic pain as measured by the change in the level of pain reported by patients. In addition, the study examined whether MorphiDex(R) would reduce the rate of opioid analgesic tolerance.

Conference Call Information

Ms. Ammon and Dr. David A.H. Lee, senior vice president, research and development, will be hosting a conference call for the investment community on October 28, 2002 from 9:00 a.m. (ET) to 9:30 a.m. (ET). Those who wish to participate in this conference call should telephone (800) 305-2862 (US/Canada) or (706) 634-1979 (International) approximately 15 minutes before the 9:00 A.M. starting time. There will be a replay of the call from 12:30 P.M. (ET) on October 28, 2002 until 12:00 A.M. (ET) on November 4, 2002. Callers wishing to access the replay should dial (800) 642-1687 (US/Canada) or (706) 645-9291 (International), Passcode: 6386077. The conference call will also be webcast at www.vcall.com.

About Endo

A wholly owned subsidiary of Endo Pharmaceuticals Holdings (Nasdaq: ENDP;

ENDPW), 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.

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Exhibit 99.2