ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
August 23, 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 23, 2002 (August 21, 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.

(c) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Endo Pharmaceuticals Holdings Inc.

on August 21, 2002

Item 9. Regulation FD Disclosure.

On August 21, 2002, the Registrant issued a press release, a copy of which is filed herewith as Exhibit 99.1 and is incorporated herein by reference. This press release related to presentations made by researchers at the International Association for the Study of Pain's (IASP) 10th World Congress on Pain.

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 23, 2002

INDEX TO EXHIBITS

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99.1	Press release issued by Endo Pharmaceuticals Holdings Inc. on August 21, 2002

Exhibit 99.1

[ENDO LOGO]

For Immediate Release

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DATA FROM STUDIES investigating
extended-RELEASE OXYMORPHONE PRESENTED TODAY
AT 10TH WORLD CONGRESS ON PAIN

SAN DIEGO, August 21, 2002 --- Researchers at the International Association for the Study of Pain's (IASP) 10th World Congress on Pain today presented clinical data from two studies on Endo Pharmaceuticals' investigational drug EN3202, an extended-release (ER) oral form of the opioid oxymorphone.

The first, a Phase III multicenter, randomized, double-blind, parallel group study, compared the safety and efficacy of EN3202, oxycodone ER (Oxycontin(R)), and placebo in patients with moderate-to-severe pain due to osteoarthritis of the hip and/or knee.

Following a two-to-seven day washout period during which all analgesic use was discontinued (except aspirin for cardiovascular prophylaxis), patients experiencing pain in the index joint of at least 40 mm on a visual analog scale (VAS) due to OA of the knee and/or hip were randomized to the following treatment groups: (1) 119 patients received oxymorphone ER, 20 mg, every 12 hours from weeks 1 - 4; (2) 121 patients received oxymorphone ER, 20mg, every 12 hours from weeks 1 - 2, and then increased to 40 mg every 12 hours for weeks 3 and 4; (3) 125 patients received oxycodone ER (Oxycontin(R)) 10 mg every 12 hours from weeks 1 - 2, and then increased to 20 mg every 12 hours for weeks 3 and 4; and (4) 124 patients received placebo every 12 hours from weeks 1 - 4.

The primary endpoint was change in arthritis pain intensity (VAS) from baseline to Week 3 versus placebo. The mean change from baseline in VAS at week 3 in both oxymorphone ER treatment groups was significantly superior compared with the placebo group. The oxycodone ER treatment group did not differ significantly from placebo in this study at Week 3 at the given dose.

The most common adverse events were those typically associated with opioid use (constipation, nausea, somnolence, dizziness, and vomiting), and most were mild-to-moderate in severity. There were no clinically meaningful effects on laboratory test, vital sign, physical examination, or EKG results associated with active treatment.

Data were also presented from a randomized, placebo-controlled, multicenter trial comparing the analgesic efficacy of EN3202 with placebo in a standard model for assessment of analgesic efficacy, postoperative pain associated with unilateral knee arthroplasty.

The study incorporated two measures of analgesic efficacy. The primary outcome measure was a 12-hour standard analgesic evaluation following a single dose of the study drug. A second outcome measure was a patient-controlled analgesia (PCA) opioid dose-sparing evaluation during a 24-hour assessment period associated with two doses of the study drug. A patient who continued to have pain after doses of either EN3202 or placebo could receive "rescue doses" of oxymorphone (0.2 mg) as needed using an intravenous PCA device.

Data from the study demonstrate that oxymorphone ER 20 mg both relieved pain better than placebo in the 12 hours following a single dose, and was more effective than placebo in the 24-hour PCA opioid dose-sparing analgesic evaluation following two doses.

The overall incidence of adverse events in the oxymorphone ER 20 mg group was similar to that for the placebo treatment group. As expected, some patients experienced opioid-related side effects. There were no clinically significant changes in vital signs, laboratory tests, or physical examination findings.

Endo developed oxymorphone ER using Penwest Pharmaceuticals' proprietary time-release technology, TIMERx(R). The two companies provided funding for the studies.

About Endo

A wholly owned subsidiary of Endo Pharmaceuticals Holdings (Nasdaq: ENDP; ENDPW), Endo Pharmaceuticals Inc. 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 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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