

ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
July 12, 2007

UNITED STATES
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): July 12, 2007 (July 11, 2007)

Endo Pharmaceuticals Holdings Inc.

(Exact name of registrant as specified in its charter)

| | | |
|----------------------------------------------------------------------|-------------------------------------------------|--------------------------------------------------------------|
| Delaware (State or other jurisdiction of incorporation) | 001-15989 (Commission File Number) | 13-4022871 (I.R.S. Employer Identification No.) |
|----------------------------------------------------------------------|-------------------------------------------------|--------------------------------------------------------------|

| | |
|----------------------------------------------------------------------------------------|----------------------------|
| 100 Endo Boulevard, Chadds Ford, PA (Address of principal executive offices) | 19317 (Zip Code) |
|----------------------------------------------------------------------------------------|----------------------------|

Registrant's telephone number, including area code (610) 558-9800

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

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Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure.

On July 11, 2007, the Registrant's wholly-owned subsidiary Endo Pharmaceuticals Inc. (Endo) issued a press release announcing that it has withdrawn its guidance pertaining to the anticipated first-half 2008 filing date of its New Drug Application (NDA) for the topical ketoprofen patch, its development product being studied for the treatment of soft-tissue injuries. Endo's decision regarding the ketoprofen patch is based on the outcome of two Phase III double-blind, placebo-controlled clinical trials. One study evaluated the ketoprofen patch as a treatment for ankle sprains and strains, and the second was targeted at treating the pain associated with tendonitis or bursitis of the shoulder, elbow or knee. No statistically significant difference was observed in either trial in the primary endpoint average pain intensity during daily activities between patients treated with the ketoprofen patch and patients using a placebo patch. A third Phase III study, evaluating the ketoprofen patch in the treatment of pain associated with tendonitis or bursitis of the shoulder, elbow or knee, is ongoing. An open-label, Phase III long-term (three months) study evaluating the safety of the ketoprofen patch in patients with osteoarthritis flare in the knee is also ongoing.

This delay has no impact on the Registrant's previously issued 2007 financial guidance.

A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(a) *Financial Statements of Business Acquired.*
Not applicable.

(b) *Pro Forma Financial Information.*
Not applicable.

(c) *Shell Company Transactions*
Not applicable.

(d) *Exhibits.*

| Exhibit Number | Description |
|-----------------------|----------------------------------------------------------------|
| 99.1 | Press Release of Endo Pharmaceuticals Inc. dated July 11, 2007 |

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/ CAROLINE B. MANOGUE

Name: Caroline B. Manogue

Title: Executive Vice President, Chief Legal
Officer & Secretary

Dated: July 12, 2007

INDEX TO EXHIBITS

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