ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
November 14, 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):
November 13, 2002 (November 8, 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 November 8, 2002, Endo Pharmaceuticals Inc. ("Endo"), a subsidiary of the Registrant, entered into a Development, Commercialization and Supply License Agreement (the "License Agreement") with DURECT Corporation ("DURECT"), a copy of which is attached as Exhibit 10.42 to this Report and is incorporated herein by reference.

The License Agreement relates to DURECT's development product, ChronogesicTM (the "Product"). The Product's clinical development program is on temporary hold pending agreement between DURECT and FDA regarding additional monitoring and data collection. These protocol changes requested by the FDA were not in relation to any specific safety issue or adverse event. In addition, DURECT is currently implementing some necessary design and manufacturing enhancements to the Product. The changes to the existing

clinical protocol, and the implementation of these design and manufacturing enhancements, will delay the restart of the development program until the second half of 2003.

Under the terms of the agreement, Endo will have no obligation to fund any of the development costs until the clinical trials are restarted (which are currently anticipated to begin in the second half of 2003). In the event that the clinical trials have not restarted by December 31, 2003, then during the six-month period from January 1, 2004 until the earlier of (a) the recommencement of the clinical trials and (b) June 30, 2004, Endo will be responsible for 25% of the development costs actually incurred each month, up to an aggregate of $3.0 million of development costs for such period.

Once the Product's clinical trials have restarted or beginning on June 30, 2004 (whichever is earlier), Endo will be obligated to fund 50% of the Product's ongoing development costs. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the License Agreement could total up to $52.0 million.

In addition, under the License Agreement, DURECT licensed to Endo the exclusive promotional rights to the Product in the U.S. and Canada. Endo will be responsible for marketing, sales and distribution, including providing specialty sales representatives dedicated to supplying technical and training support. DURECT will be responsible for the manufacture of the Product. Endo and DURECT will share profits equally, based on projected financial performance of the Product.

Further, the License Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. With respect to termination rights, the License Agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT $10.0 million.

Finally, in connection with the License Agreement, Endo will purchase approximately $5.0 million of newly issued common shares of DURECT, representing approximately 3% of DURECT's currently outstanding shares.

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
10.42	Development, Commercialization and Supply License Agreement, dated as of November 8, 2002, by and between DURECT Corporation and Endo Pharmaceuticals Inc.*
99.1	Press Release of Endo Pharmaceuticals Holdings Inc. and DURECT Corporation dated November 11, 2002

Item 9. Regulation FD Disclosure.

On November 11, 2002, the Registrant and DURECT issued a press release pertaining to the License Agreement, a copy of which is attached as Exhibit 99.1 to this Report is incorporated herein by reference.

* Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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: November 13, 2002

CONFIDENTIAL

INDEX TO EXHIBITS

Exhibit No.	Description
10.42	Development, Commercialization and Supply License Agreement, dated as of November 8, 2002, by and between DURECT Corporation and Endo Pharmaceuticals Inc.*
99.1	Press Release of Endo Pharmaceuticals Holdings Inc. and DURECT Corporation dated November 11, 2002

* Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.