

ENDO PHARMACEUTICALS HOLDINGS INC

Form 8-K

July 19, 2004

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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 19, 2004 (July 14, 2004)

ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

DELAWARE

001-15989

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)

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Item 5. Other Events

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INDEX TO EXHIBITS

EX-10.48: LICENSE AGREEMENT

EX-10.49: LOAN AGREEMENT

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Item 5. Other Events.

We are filing as Exhibits 10.48 and 10.49 hereto a License Agreement and a Loan Agreement, each dated as of July 14, 2004, and each between Vernalis Development Limited (Vernalis) and our wholly owned subsidiary, Endo Pharmaceuticals Inc. (EPI).

On July 14, 2004, EPI entered into a license agreement (the License Agreement) and a loan agreement (the Loan Agreement), and together with the License Agreement, the Vernalis Agreements), each dated as of July 14, 2004, with Vernalis, under which Vernalis agreed to exclusively license to EPI rights to market Vernalis 's Frova (frovatriptan) in North America. In connection with the License Agreement, Endo has agreed to loan Vernalis \$50 million as further described below. Launched in the U.S. in June 2002, Frova is indicated for the acute treatment of migraine headaches in adults. Net sales of Frova in the U.S. were \$37.5 million in 2003.

One of a class of compounds known as triptans (selective serotonin receptor agonists), Frova is also being studied as a potential prophylactic treatment for Menstrually Associated Migraine (MAM). If approved for this indication, the companies believe that Frova would be the first triptan to be indicated for the prevention of any type of migraine. Vernalis anticipates filing a supplemental New Drug Application (sNDA) for this indication following the completion of the second of two Phase III clinical trials.

Under the terms of the License Agreement, Endo will pay Vernalis an upfront fee of \$30 million, anniversary payments for the first two years at \$15 million each year, and a \$40 million milestone payment upon U.S. Food and Drug Administration (FDA) approval for the MAM indication. In addition, Vernalis will receive one-time milestone payments for achievement of defined annual net sales targets. These sales milestone payments increase based on increasing net sales targets ranging from a milestone of \$10 million on \$200 million in net sales to a milestone of \$75 million on \$1.2 billion in net sales. These sales milestones could total up to \$255 million if all of the defined net sales targets are achieved. Endo will also pay royalties to Vernalis based on net sales of Frova .

Endo expects to expand its primary and specialty sales force in early 2005 by approximately one-third to ensure the commercial success of Frova in the U.S., with the possibility for additional expansion in the future based on the product 's growth and the potential approval by the FDA for the MAM indication. Vernalis has retained rights to co-promote Frova in the U.S. Upon Vernalis exercising its co-promotion option, Endo will establish, train and fund a Vernalis sales force for a period of up to five years.

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In addition, the License Agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the License Agreement is essentially for the shorter of the time that (i) there are valid claims of the Vernalis patents covering Frova or there is market exclusivity granted by a regulatory authority, whichever is longer, or (ii) until the date on which a generic version of Frova is first offered, but in no event longer than 20 years. Endo can terminate the License Agreement under certain circumstances, including upon one year's written notice. The License Agreement is subject to a number of closing conditions, including obtaining clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

Under the Loan Agreement, Endo will provide Vernalis with a loan of \$50 million at closing. The loan will primarily be used to pay in full the amounts currently due to Elan Corporation from Vernalis in connection with Vernalis reacquisition of the North American rights to Frova. The balance of the loan will be available for Vernalis' general corporate purposes. The loan will be secured against the revenues receivable by Vernalis under the License Agreement. At Endo's election, Endo is able to offset \$20 million of the \$40 million MAM indication approval milestone and 50 percent of all royalties to be paid to Vernalis to repay the loan. The loan is due in full in five years to the extent it is not previously repaid. Interest is at the rate of five percent per annum, payable semi-annually; however, Vernalis has the option to defer payment of interest and increase the loan outstanding each time an interest payment becomes due.

Item 7. Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.

Not applicable.

(b) Pro Forma Financial Information.

Not applicable.

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(c) *Exhibits.*

| Exhibit Number | Description |
|-----------------------|---|
| 10.48 | License Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited** |
| 10.49 | Loan Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited |

** Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 406 of the Securities Act of 1933.

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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: July 19, 2004

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