ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
March 10, 2008

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): March 10, 2008 (March 4, 2008)

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. Company Identification No.)**

100 Endo Boulevard, Chadds Ford, PA	**19317**
(Address of principal executive offices)	**(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))

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

Item 1.01 Entry into a Material Definitive Agreement.

On March 4, 2008, the Registrant s wholly owned subsidiary, Endo Pharmaceuticals Inc. (Endo) entered into a license and supply agreement (Agreement) with and among Novartis AG, a Swiss corporation (Novartis AG) and Novartis Consumer Health, Inc., a Delaware corporation (Novartis), to obtain the exclusive U.S. marketing rights for the prescription medicine Voltaren® Gel (diclofenac sodium topical gel) 1% (Voltaren Gel or Licensed Product).

Voltaren Gel received regulatory approval in October 2007 from the U.S. Food and Drug Administration (FDA), becoming the first topical prescription treatment for use in treating pain associated with osteoarthritis and the first new product approved in the U.S. for osteoarthritis since 2001. Voltaren Gel has been granted marketing exclusivity in the U.S. as a prescription medicine until at least October 2010.

Under the terms of the five-year Agreement, Endo made an upfront cash payment of $85 million. Endo has agreed to pay royalties to Novartis AG on annual Net Sales of the Licensed Product, subject to certain thresholds as defined in the Agreement. In addition, Endo has agreed to make certain guaranteed minimum annual royalty payments beginning in the fourth year of the Agreement, subject to certain limitations as defined in the Agreement. These guaranteed minimum royalties will be creditable against royalty payments on an Agreement-year basis such that Endo s obligation with respect to each Agreement year is to pay the greater of (i) royalties payable based on annual net sales of the Licensed Product or (ii) the guaranteed minimum royalty for such Agreement year. Novartis is also eligible to receive a one-time milestone payment of $25 million if annual sales exceed $300 million.

Endo shall be solely responsible to commercialize the Licensed Product during the term the Agreement. With respect to each year during the term of the Agreement, Endo is required to expend a minimum amount of annual advertising and promotional expenses on the commercialization of the Licensed Product, subject to certain limitations as provided for under the Agreement. In addition, Endo will be required to perform a minimum number of face-to-face one-on-one discussions with physicians and other health care practitioners (referred to as Details) for the purpose of promoting the Licensed Product within its approved indication during each year of the Agreement, subject to certain provisions under the Agreement. Further, during the term of the Agreement, Endo will share in the costs of certain clinical studies and development activities initiated at the request of the FDA or as deemed appropriate by Novartis and Endo.

During the term of the Agreement, Endo has agreed to purchase all of its requirements for the Licensed Product from Novartis. The price of product purchased under the Agreement is fixed for the first year and subject to annual changes based upon changes in the producer price index and raw materials as set forth in the Agreement. Endo has an existing long-term manufacturing and development agreement with Novartis Consumer Health, Inc. whereby Novartis has agreed to manufacture certain of our commercial products and products in development.

Novartis has the exclusive right, at its sole discretion, to effect a switch of the Licensed Product from a prescription product to an over-the-counter (OTC) product in the United States (an OTC Switch) by filing an amendment or supplement to the Licensed Product New Drug Application or taking any other action necessary or advisable in connection therewith to effect the OTC Switch, and thereafter to commercialize such OTC product. Notwithstanding the foregoing, Novartis shall not launch an OTC equivalent product prior to a time specified in the Agreement, and Novartis shall not take any action that results in the loss of the prescription product status for the Licensed Product prior to such time. Novartis will notify Endo if it submits a filing to the FDA in respect of an OTC equivalent product. In the event that Novartis gains approval of an OTC equivalent product that results in the Licensed Product being declassified as a prescription product, then Novartis will make certain royalty payments to Endo on net sales of such OTC equivalent product in the United States by Novartis, its affiliates and their respective licensees or sublicensees as set forth in the Agreement, provided that, and subject to certain limitations and provisions as set forth in the Agreement, as a condition to the payment of any and all such royalties, net sales of the Licensed Product in the United States must have exceeded a certain threshold as defined in the Agreement prior to the Launch of the OTC equivalent product by Novartis or its affiliates.

The Initial Term of the Agreement will expire on June 30, 2013. Endo has the option to extend the Agreement for two successive one (1) year terms (each, a Renewal Term) beyond the Initial Term. The Agreement will remain in place after the first two Renewal Terms unless either Party provides written notice of non-renewal to the other Party at least six (6) months prior to the expiration of any Renewal Term after the first Renewal Term or the Agreement is otherwise terminated in accordance with its terms.

Among other standard and customary termination rights granted under the Agreement, the Agreement can be terminated by either party upon reasonable written notice, if either party has committed a material breach that has not been remedied within ninety (90) days from the giving of written notice. Endo may terminate the Agreement by written notice upon the occurrence of several events, including the launch in the United States of a generic to the Licensed Product. Novartis may terminate the Agreement upon reasonable written notice (1) if Endo fails to deliver a set percentage of the minimum Details in any given six (6) month period under the Agreement; or (2) on or after the launch in the United States of an OTC equivalent product by Novartis, its affiliates or any third party that does not result in the declassification of the Licensed Product as a prescription product, following which net sales in any six month period under the Agreement are less than a certain defined dollar amount.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety to the full text of the Agreement, a copy of which will be filed with the exhibits to the Company s quarterly report on Form 10-Q for the three months ended March 31, 2008.

A copy of the press release, announcing the execution of the Agreement, 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 Holdings Inc., dated March 4, 2008.

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: March 10, 2008

INDEX TO EXHIBITS

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