

ENDO PHARMACEUTICALS HOLDINGS INC

Form 8-K

January 08, 2003

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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): January 8, 2003 (December 31, 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)

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DEVELOPMENT AND MARKETING STRATEGIC ALLIANCE AGRMT

PRESS RELEASE

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Item 5. Other Events.

On December 31, 2002, Endo Pharmaceuticals Inc. (Endo), a subsidiary of the Registrant, entered into a Development and Marketing Strategic Alliance Agreement (the Agreement) with SkyePharma, Inc. and SkyePharma Canada, Inc. (collectively, SkyePharma), a copy of which is attached as Exhibit 10.43 to this Report and is incorporated herein by reference.

The Agreement relates to two of SkyePharma's patented development products, DEPOMORPHINE[™] and Propofol IDD-D[™] (collectively, the Products). Under the terms of the Agreement, Endo will receive an exclusive license to the U.S. and Canadian marketing and distribution rights for the Products, with options for other development products. In return, SkyePharma will receive a \$25 million upfront payment. In addition, SkyePharma may receive further milestone payments totaling \$95 million which includes total milestones of \$10 million for DEPOMORPHINE through FDA approval. The milestone payments also include \$50 million for Propofol IDD-D, payable when the product successfully achieves certain regulatory milestones, including FDA approval. The total further comprises a \$15 million milestone payment receivable when net sales of DEPOMORPHINE reach \$125 million in a calendar year, and a \$20 million milestone payment when net sales of DEPOMORPHINE reach \$175 million in a calendar year. SkyePharma will also receive a share of each product's sales revenue that will increase from 20% initially, to a maximum of 60%, of net sales as the Products' combined sales achieve certain thresholds.

The Agreement provides for the parties to work together to complete the necessary clinical, regulatory and manufacturing work for North American regulatory approval of the Products. SkyePharma will be primarily responsible for clinical development up to final U.S. Food and Drug Administration (FDA) approval, and for the manufacture of the Products, including all associated costs. Upon approval, Endo will market each Product in the U.S. and Canada, with SkyePharma as the supplier. Endo will be responsible for funding and conducting any post-marketing studies and for all selling and marketing expenses.

Under the Agreement, Endo obtained options on other SkyePharma development products, including DEPOBUPIVACAINE , a long-acting, sustained release formulation of the local anesthetic bupivacaine. Endo has the option to obtain commercialization rights for this product when SkyePharma successfully completes its Phase II trials, as well as any further SkyePharma products formulated using the

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DEPOFOAM technology successfully developed for the prophylaxis or treatment of pain.

In addition, the 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 Agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay SkyePharma \$5.0 million.

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 |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.43 | Development and Marketing Strategic Alliance Agreement, dated as of December 31, 2002, by and among Endo Pharmaceuticals Inc., SkyePharma, Inc. and SkyePharma Canada, Inc.* |
| 99.1 | Press Release of Endo Pharmaceuticals Holdings Inc. and SkyePharma PLC dated January 3, 2003 |

* 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.

Item 9. Regulation FD Disclosure.

On January 3, 2003, the Registrant and SkyePharma issued a press release pertaining to the Agreement, a copy of which is attached as Exhibit 99.1 to this Report is incorporated herein by reference.

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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: January 8, 2003

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