

ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
January 05, 2009

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): January 5, 2009 (January 5, 2009)

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 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)

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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.

Agreement and Plan of Merger

On January 5, 2009, Endo Pharmaceuticals Holdings Inc. ("Endo"), BTB Purchaser Inc. ("Purchaser"), a wholly-owned subsidiary of Endo, and Indevus Pharmaceuticals, Inc., ("Indevus") entered into an Agreement and Plan of Merger (the "Merger Agreement"), pursuant to which Endo will acquire Indevus.

Pursuant to the terms of the Merger Agreement, and subject to the conditions thereof, Endo (through Purchaser) has agreed to commence a cash tender offer (the "Offer") to purchase all of the issued and outstanding shares of the common stock, par value \$0.001 per share, of Indevus (the "Shares") at a price of \$4.50 per Share, net to the seller in cash (less any required withholding taxes and without interest), plus contractual rights to receive up to an additional \$3.00 per Share in contingent cash consideration payments (the "Offer Price"), which will be payable upon certain drug approval and sales milestones being achieved. The Offer will expire at midnight New York time on the 45th day following and including the commencement date, unless extended in accordance with the terms of the Merger Agreement and the applicable rules and regulations of the Securities and Exchange Commission (such time, the "Offer Closing").

The Offer, if successful, will be followed by a merger (the "Merger") of Purchaser with and into Indevus, with Indevus as the surviving corporation and a wholly owned subsidiary of Endo. In the Merger, any Shares not tendered into the Offer, other than Shares held by Indevus, Endo, Purchaser or shareholders who have validly exercised their appraisal rights under the General Corporate Law of the State of Delaware, will be cancelled and automatically converted into the right to receive the same per share consideration paid to Indevus shareholders in the Offer.

The consummation of the Offer is subject to the satisfaction or waiver of certain conditions, including: (i) a minimum of the majority of outstanding Shares on a fully diluted basis having been tendered into the Offer, (ii) the expiration or termination of the waiting period under the Hart Scott Rodino Antitrust Improvements Act, (iii) the absence of litigation or governmental action challenging or seeking to prohibit the Offer or the Merger, (iv) there not having been a Material Adverse Effect with respect to Indevus, and (v) other customary conditions.

Pursuant to the Merger Agreement and subject to certain exceptions, Indevus granted to Purchaser an irrevocable option (the "Top-up Option") to purchase, at a per Share price equal to the Offer Price, newly issued Shares in an amount up to the lowest number of Shares that, when added to the number of Shares owned by Endo and its Subsidiaries (including Purchaser) at the time of exercise of the Top-Up Option, will constitute one Share more than 90% of the total Shares outstanding on a fully diluted basis. The price per share to be paid in the Top-Up shares will be the Offer Price.

The Merger Agreement contains certain termination rights of Endo and Indevus and provides that, upon the termination of the Merger Agreement under particular circumstances, Indevus would be required to pay Endo a termination fee equal to \$20 million.

The foregoing description of the Offer, the Merger and the Merger Agreement does not purport to be complete and is qualified in its entirety by reference to the Merger Agreement, which is attached hereto as Exhibit 2.1 and incorporated herein by reference.

The Merger Agreement has been included to provide investors with information regarding its terms. It is not intended to provide any other factual information about Endo and Indevus. The Merger

Agreement contains representations and warranties that each of Endo and Indevus made to the other. The assertions embodied in those representations and warranties are qualified by information in confidential disclosure schedules that the parties have exchanged in connection with signing the Merger Agreement. The disclosure schedules contain information that modifies, qualifies and creates exceptions to the representations and warranties set forth in the Merger Agreement. Accordingly, investors should not rely on the representations and warranties as characterizations of the actual state of facts at the time they were made or otherwise.

On January 5, 2009, Indevus and Endo issued a joint press release relating to the Merger Agreement. A copy of the press release is attached hereto as Exhibit 99.1.

Contingent Cash Consideration Agreements

Pursuant to the Merger Agreement, prior to the Offer Closing, Endo will enter into two separate agreements with American Stock Transfer & Trust Company (the "Paying Agent"), for the purpose of establishing the terms, policies and procedures by which those stockholders entitled to any of the Contingent Cash Consideration Payments (as defined below) will be paid.

In accordance with 21 C.F.R. Part 314, and all supplements filed pursuant to the requirements of the U.S. Food and Drug Administration (the "FDA"), Indevus intends to file certain new drug applications for the right to market and sell (i) a certain octreotide implant currently under development for the treatment of acromegaly and carcinoid syndrome, which is a soft, flexible 6-month hydrogel implant based on the patented HYDRON Polymer Technology that delivers octreotide, a somatostatin analogue (such octreotide implant, "Octreotide" and such new drug application, the "Octreotide NDA") and (ii) a certain long-acting intramuscular depot injection of testosterone undecanoate currently under development for the treatment of male hypogonadism (such injection, "NEBIDO®" and such new drug application, the "NEBIDO® NDA" or, together with the Octreotide NDA, the "NDAs").

In the event that Indevus receives an approval letter from the FDA with respect to the NEBIDO® NDA on or before the third anniversary of the time at which we purchase Shares in the Offer (such time, the "Offer Closing"), then Purchaser will, subject to the terms described below, (i) pay an additional \$2.00 per Share to stockholders of Indevus whose Shares are accepted for payment in connection with the Offer, if such approval letter grants the right to market and sell NEBIDO® immediately and provides labeling for NEBIDO® that does not contain a "boxed warning" (as defined in 21 C.F.R. 201.57(c)(1)) (such approval letter, the "NEBIDO® With Label Approval" and such payment, the "NEBIDO® With Label Approval Contingent Cash Consideration Payment") or alternatively, (ii) pay an additional \$1.00 per Share to stockholders of Indevus whose Shares are accepted for payment in connection with the Offer, if such approval letter grants the right to market and sell NEBIDO® immediately and provides labeling for NEBIDO® that contains a "boxed warning" (as defined in 21 C.F.R. 201.57(c)(1)) (such approval letter, the "NEBIDO® Without Label Approval" and such payment, the "NEBIDO® Without Label Contingent Cash Consideration Payment"). In the event that either a NEBIDO® With Label Approval or a NEBIDO® Without Label Approval has not been obtained prior to the third anniversary of the Effective Time, then Purchaser will not pay, and tendering stockholders shall not receive, the NEBIDO® With Label Contingent Cash Consideration Payment or the NEBIDO® Without Label Contingent Cash Consideration Payment, as applicable.

A boxed warning is ordinarily used to highlight for prescribers one of the following situations: (1) there is an adverse reaction so serious in proportion to the potential benefit from the drug (e.g., a fatal, life-threatening or permanently disabling adverse reaction) that it is essential that it be considered in assessing the risks and benefits of using a drug, (2) there is a serious adverse reaction that can be prevented or reduced in frequency or severity by appropriate use of the drug (e.g., patient selection, careful monitoring, avoiding certain concomitant therapy, addition of another drug or managing patients in a specific manner, avoiding use in a specific clinical situation), or (3) the FDA approved the drug with restrictions to assure safe use because the FDA concluded that the drug can be safely used only if distribution or use is restricted. A boxed warning can also be used in other situations to highlight warning information that is especially important to the prescriber.

Further, in the event that the NEBIDO® Without Label Approval is received and subsequently, Endo and its subsidiaries publicly report audited financial statements which reflect that Net Sales (as defined below) of NEBIDO® of at least \$125,000,000, on or prior to the fifth anniversary of the date of the first commercial sale of NEBIDO® (such event, the "NEBIDO® Net Sales Event"), then Purchaser will, subject to the terms described below, pay an additional \$1.00 per Share to stockholders of Indevus whose Shares are accepted for payment in connection with the Offer (such payment, the "NEBIDO® Net Sales Contingent Cash Consideration Payment" and, together with the NEBIDO® Without Label Approval Contingent Cash Consideration Payment, the NEBIDO® With Label Approval Contingent Cash Consideration Payment and the Ocreotide Contingent Cash Consideration Payment, the "Contingent Cash Consideration Payments"). In the event that the NEBIDO® Net Sales Event does not occur prior to the fifth anniversary of the date of the first commercial sale of NEBIDO® then Purchaser will not pay, and tendering stockholders shall not receive, the NEBIDO® Net Sales Contingent Cash Consideration Payment.

"Net Sales" means, with respect to NEBIDO®, the gross amount invoiced by or on behalf of Endo or its affiliates, licensees or sublicensees for NEBIDO® sold to third parties other than licensees or sublicensees in bona fide, arm's-length transactions, less the following deductions, determined in accordance with Endo's standard accounting methods as generally and consistently applied by Endo, to the extent included in the gross invoiced sales price of the product or otherwise directly paid or incurred by Endo, its affiliates, licensees or sublicensees acting on its behalf with respect to the sale of such product:

- (1) normal and customary trade and quantity discounts actually allowed and properly taken directly with respect to sales of the product;
- (2) amounts repaid or credited by reasons of defects, recalls, returns, rebates and allowances of goods or because of retroactive price reductions specifically identifiable to the product;
- (3) chargebacks, rebates (or the equivalent thereof) and other amounts paid on sale or dispensing of the product;
- (4) rebates (or the equivalent thereof) and administrative fees paid to medical healthcare organizations, to group purchasing organizations or to trade customers in line with approved contract terms or other normal and customary understandings and arrangements;
- (5) amounts payable resulting from governmental (or agency thereof) mandated rebate programs or chargeback programs;
- (6) tariffs, duties, excise, sales, value-added and other taxes (other than taxes based on income) and charges of Governmental Authorities;
- (7) cash discounts for timely payment;
- (8) rebates paid to wholesalers for inventory management programs;

- (9) amounts repaid or credited or provisions made for uncollectible amounts on previously sold products; and
- (10) required distribution commissions and fees (such as fees related to services provided pursuant to distribution service agreements with major wholesalers) payable to any third party providing distribution services to Endo so long as such commissions and fees are consistent with the distribution commissions and fees payable in respect to other branded prescription products commercialized by Endo;

all as determined in accordance with Endo's usual and customary accounting methods, which shall be in accordance with U.S. Generally Accepted Accounting Principles; or in accordance with International Financial Reporting Standards "IFRS", should Endo be required to, or elect to maintain records and books of accounts in accordance with IFRS. Sales from Endo to its affiliates, licensees or sublicensees shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are charged to third parties shall not be deducted from the invoice price in the calculation of Net Sales. Further: (1) In the case of any sale or other disposal of a product between or among Endo and its affiliates, licensees and sublicensees, for resale, Net Sales shall be calculated as above only on the value charged or invoiced on the first arm's-length sale thereafter to a third party; (2) In the case of any sale which is not invoiced or is delivered before invoice, Net Sales shall be calculated at the time of shipment or when the product is paid for, if paid for before shipment or invoice; and (3) In the case of any sale or other disposal for value, such as barter or counter-trade, of any product, or part thereof, other than in an arm's-length transaction exclusively for money and excluding any patient assistance programs, Net Sales shall be calculated as above on the value of the non-cash consideration received or the fair market price (if higher) of the product in the country of sale or disposal.

Endo has agreed to deposit \$175,000,000 in cash with a paying agent pursuant to the terms of the NEBIDO® Contingent Cash Consideration Agreement, which amount is equal to the aggregate amount payable to Indevus stockholders if the NEBIDO® approval is obtained and is not subject to a "boxed warning" label (described above) by the FDA, and will be paid to the Indevus stockholders under the terms of the NEBIDO® Contingent Cash Consideration Agreement.

Similarly, in the event that an approval letter from the FDA is received with respect to the Octreotide NDA (such approval letter, the "Octreotide Approval") on or before the fourth anniversary of the Offer Closing, then Purchaser will, subject to the terms described below, pay an additional \$1.00 per Share to stockholders of Indevus whose Shares are accepted for payment in connection with the Offer (such payment, the "Octreotide Contingent Cash Consideration Payment"). In the event that an Octreotide Approval has not been obtained prior to the fourth anniversary of the Offer Closing, then Purchaser will not pay, and tendering stockholders shall not receive, the Octreotide Contingent Cash Consideration Payment.

Pursuant to the Nebido Contingent Cash Consideration Agreement, within five business days of the NEBIDO® With-Label Approval, the NEBIDO® Without-Label Approval or NEBIDO® Net Sales Event, as applicable, Endo will provide the Paying Agent with a certificate stating that such approval or event has occurred and the payment date with respect on which such Contingent Cash Consideration Payment shall be made, which shall be within five business days of the date of such certificate. The Paying Agent will pay the applicable Contingent Cash Consideration Payment to the stockholders who tendered their Shares in the Offer or who are entitled to receive the Merger Consideration (as defined in the Merger Agreement) on the payment date specified in the certificate. Such Contingent Cash Consideration Payment will be equal to (i) \$2.00, in the case of the NEBIDO® With Label Approval, (ii) \$1.00, in the case of the NEBIDO® Without Label Approval or (iii) \$1.00, in the case of the NEBIDO® Net Sales Event. Endo has agreed to deposit \$175,000,000 in cash with a paying agent pursuant to the terms of the NEBIDO® Contingent Cash Consideration Agreement, which amount is equal to the aggregate amount payable to Indevus stockholders if the NEBIDO® approval is obtained and is not subject to a "boxed warning" label (described above) by the FDA, and will be paid to the Indevus stockholders under the terms of the NEBIDO® Contingent Cash Consideration Agreement. The foregoing summary is qualified in its entirety by reference to the complete text of the form of NEBIDO® Contingent Cash Consideration Agreement, which is attached hereto as Exhibit 10.3, and which is incorporated herein by reference.

Pursuant to the Octreotide Contingent Cash Consideration Agreement, within five business days of the Octreotide Approval, Endo will provide the Paying Agent with a certificate stating that such approval or event has occurred and the payment date with respect on which the applicable \$1.00 Contingent Cash Consideration Payment shall be made, which shall be within five business days of the date of such certificate. The Paying Agent will pay the \$1.00 Contingent Cash Consideration Payment to the stockholders who tendered their Shares in the Offer or who are entitled to receive the Merger Consideration (as defined in the Merger Agreement) on the payment date specified in the certificate. The foregoing summary is qualified in its entirety by reference to the complete text of the form of Octreotide Contingent Cash Consideration Agreement, which is attached hereto as 10.4, and which is incorporated herein by reference.

Stockholder Tender Agreements

In connection with the Merger Agreement, Endo and Purchaser have entered into certain Stockholder Tender Agreements with certain directors and executive officers of Indevus, pursuant to which, among other things, each such director or executive officer agreed to irrevocably tender (and deliver any certificates evidencing) its Shares, or cause its Shares to be irrevocably tendered, into the Offer promptly following, and in any event no later than the fifth business day following, the commencement of the Offer. Such directors and executive officers are: Glenn L. Cooper, M.D., James C. Gale, Malcolm Morville, Noah D. Beerman, Mark S. Butler, Michael W. Rogers and Bobby W.

Sandage, Jr., Ph.D. The foregoing description of the Stockholder Tender Agreements does not purport to be a complete description and is qualified in its entirety by reference to the text of each Stockholder Tender Agreement, the form of which is attached hereto as Exhibits 10.2 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

| Exhibit No. | Description |
|-------------|--|
| 10.1 | Agreement and Plan of Merger, dated January 5, 2009, by and among Endo, Purchaser, and Indevus |
| 10.2 | Form of Stockholder Tender Agreement |
| 10.3 | Form of NEBIDO® Contingent Cash Consideration Agreement |
| 10.4 | Form of Octreotide Contingent Cash Consideration Agreement |
| 99.1 | Press Release of Endo, dated January 5, 2009 |

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: January 5, 2009

EXHIBIT LIST

| Exhibit No. | Description |
|-------------|--|
| 10.1 | Agreement and Plan of Merger dated January 5, 2009, by and between Endo, Merger Sub, and Indevus |
| 10.2 | Form of Stockholder Tender Agreement |
| 10.3 | Form of NEBIDO® Contingent Cash Consideration Agreement |
| 10.4 | Form of Octreotide Contingent Cash Consideration Agreement |
| 99.1 | Press Release of Endo, dated January 5, 2009 |