

ENDO PHARMACEUTICALS HOLDINGS INC

Form 8-K

February 22, 2010

**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): February 22, 2010 (February 17, 2010)**

**Endo Pharmaceuticals Holdings Inc.**

**(Exact name of registrant as specified in its charter)**

**Delaware**  
**(State or other jurisdiction**

**of incorporation)**

**001-15989**  
**(Commission**

**File Number)**

**13-4022871**  
**(I.R.S. Employer**

**Identification No.)**

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**100 Endo Boulevard, Chadds Ford, PA**

(Address of principal executive offices)

**Registrant's telephone number, including area code (610) 558-9800**

**19317**

(Zip Code)

**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 2.02. Results of Operation and Financial Condition.**

On February 22, 2010, the Registrant issued an earnings release announcing its financial results for the three and twelve month periods ended December 31, 2009. A copy of the earnings release is furnished as Exhibit 99.1.

This earnings press release includes financial measures that are not in conformity with accounting principles generally accepted in the United States. We refer to these as non-GAAP financial measures. Specifically, the release refers to adjusted statements of operations and adjusted diluted earnings per share.

The adjusted statements of operations and adjusted diluted earnings per share are non-GAAP financial measures. These non-GAAP financial measures are not prepared in accordance with accounting principles generally accepted in the United States and may be different from non-GAAP financial measures used by other companies. Endo refers to these non-GAAP financial measures in making operating decisions because it believes they provide meaningful supplemental information regarding the company's operational performance. For instance, Endo believes that these non-GAAP financial measures facilitate its internal comparisons to its historical operating results and comparisons to competitors' results. The company includes these non-GAAP financial measures in its earnings announcements because it believes they are useful to investors in allowing for greater transparency related to supplemental information used by Endo in its financial and operational decision-making. In addition, Endo has historically reported similar non-GAAP financial measures to its investors and believes that the inclusion of comparative numbers provides consistency in its financial reporting at this time. Further, Endo believes that these non-GAAP financial measures may be useful to investors as it is aware that certain of its significant stockholders utilize these measures to evaluate its financial performance. Finally, these measures are considered by the Compensation Committee of Endo's Board of Directors in assessing the performance and compensation of substantially all of its employees, including its executive officers. Investors are encouraged to review the reconciliation of the non-GAAP financial measures used in this earnings announcement to their most directly comparable GAAP financial measures as provided with the financial statements included in this press release.

The information in this Item 2.02 and in Exhibit 99.1 shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information contained in this Item 2.02 and in Exhibit 99.1 shall not be incorporated into any registration statement or other document filed with the Securities and Exchange Commission by the company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

**Item 2.06. Material Impairments**

On February 17, 2010, the Registrant concluded that it is required, under generally accepted accounting principles, to record a pre-tax, non-cash impairment charge for the write-down to the estimated fair value of its indefinite-lived intangible asset related to Aveed™, our injectable testosterone product (formerly known as Nebido). In December 2009, we received a complete response letter from the Food and Drug Administration with respect to our new drug application for Aveed. In the complete response letter, the FDA requested information to address the agency's concerns regarding rare but serious adverse events, including post-injection anaphylactic reaction and pulmonary oil microembolism. The letter also specified that our proposed Risk Evaluation and Mitigation Strategy with respect to the product is not sufficient. We believe that significant regulatory uncertainty currently exists with respect to the timing, label and regulatory path forward for Aveed, and accordingly determined that a review for asset impairment was appropriate. While we currently believe that Aveed could ultimately be approved and commercialized in the US, we recorded a \$65 million, non-cash impairment charge reflecting, in part, these heightened regulatory uncertainties with respect to this product. Offsetting this charge is a credit of \$125 million, reflecting a reduction in the liability on our balance sheet associated with contingent consideration payable to former Indevus shareholders in the event that the product is approved by the FDA on or before February 23, 2012, under the Nebido Contingent Cash Consideration Agreement entered into in connection with our acquisition of Indevus. The reduction in the liability on our balance sheet reflects management's current assessment of the decreased probability that we will be obligated to make contingent consideration payments to former Indevus shareholders under the Nebido Contingent Cash Consideration Agreement within the specified contractual timeframe.

**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 February 22, 2010, reporting the Registrant's financial results for the three and twelve month periods ending December 31, 2009
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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/ CAROLINE B. MANOGUE  
Name: **Caroline B. Manogue**  
Title: **Executive Vice President, Chief Legal Officer & Secretary**

Dated: February 22, 2010

**INDEX TO EXHIBITS**

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