ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
December 07, 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): December 4, 2009 (December 2, 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)

¨ 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 8.01 Other Events.

On December 2, 2009, the Registrant (or Endo) received a complete response letter from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for its extended-duration testosterone undecanoate injection, AVEED™, for men diagnosed with low testosterone. Low testosterone is also known as hypogonadism. In the complete response letter, the FDA has requested information from Endo to address the agency s concerns regarding very rare but serious adverse events, including post-injection anaphylactic reaction and pulmonary oil microembolism. The letter also specified that the proposed Risk Evaluation and Mitigation Strategy (REMS) is not sufficient. Endo is currently evaluating the FDA s complete response letter.

On December 3, 2009, the Registrant announced the receipt of this complete response letter, and a copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Endo Pharmaceuticals Holdings Inc. Press Release dated December 3, 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: December 4, 2009

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Endo Pharmaceuticals Holdings Inc. Press Release dated December 3, 2009