DEPOMED INC
Form 8-K
July 06, 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): **July 6, 2010**

DEPOMED, INC.

(Exact name of registrant as specified in its charter)

001-13111

(Commission File Number)

California	**94-3229046**
(State or other jurisdiction of incorporation)	(I.R.S. Employer Identification No.)

1360 O Brien Drive, Menlo Park, California 94025

(Address of principal executive offices, with zip code)

(650) 462-5900

(Registrant s telephone number, including area 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 (*see* General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

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

Item 8.01 Other Events

Serada® Special Protocol Assessment; Breeze 3 Clinical Trial

As previously disclosed, in March 2010, Depomed, Inc. (the Company) received initial comments from the United States Food and Drug Administration (the FDA) on the Company s protocol for its planned Phase 3 trial for Serada® (Breeze 3), the Company s extended release gabapentin product candidate under study for the treatment of menopausal hot flashes. The FDA s comments were provided in response to a request the Company submitted for feedback from the FDA under the FDA s Special Protocol Assessment (SPA) program. Through the SPA program, companies may reach agreement with the FDA that a proposed trial protocol design, clinical endpoints and statistical analyses are acceptable to support a product candidate s regulatory approval.

Following receipt of the FDA s initial comments, the Company resubmitted the proposed Breeze 3 protocol for a further assessment after modifying the protocol to address the FDA s initial feedback. On April 30, 2010, the Company received the FDA s further guidance on the protocol. The guidance included three minor comments related to the Company s proposed statistical analysis of a secondary endpoint, the Patient Global Impression of Change (PGIC). The PGIC will be used in conjunction with a responder analysis that may be required to assess the clinical meaningfulness of any reduction in the frequency of hot flashes in the active arm relative to the placebo arm.

On June 29, 2010, the Company held a meeting with the FDA to discuss the FDA s further guidance received on April 30, 2010. Following the meeting, the Company resubmitted the protocol for Breeze 3 to the FDA pursuant to the SPA program. Because the resubmitted Breeze 3 protocol reflects the FDA s two prior reviews of the Breeze 3 protocol under the SPA program and guidance from the FDA received at the meeting, the Company does not anticipate any further comments from the FDA on the Breeze 3 protocol. Accordingly, the Company expects to receive a final assessment of the Breeze 3 protocol in August 2010 and begin enrolling patients in Breeze 3 trial in September 2010.

Forward-Looking Statements

The statements that are not historical facts contained in this Form 8-K are forward-looking statements that involve risks and uncertainties including, but not limited to, those related to the Company s expectations regarding the SPA related to Serada; enrollment of patients in the Breeze 3 clinical trial; and other risks detailed in the Company s Securities and Exchange Commission filings, including the Company s Annual Report on Form 10-K and most recent Quarterly Report on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements which speak only as of the date hereof. The Company undertakes no obligation to publicly release the result of any revisions to these forward-looking statements that may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

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.

DEPOMED, INC.

Date: July 6, 2010	By:	/s/ Matthew M. Gosling Matthew M. Gosling Vice President and General Counsel