

DEPOMED INC
Form 8-K
March 05, 2012

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 28, 2012**

DEPOMED, INC.

(Exact name of registrant as specified in its charter)

001-13111

(Commission File Number)

California
(State or other jurisdiction of
incorporation)

94-3229046
(I.R.S. Employer Identification No.)

1360 O Brien Drive, Menlo Park, California 94025

(Address of principal executive offices, with zip code)

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(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):

- 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))
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Item 8.01. Other Events

Incepta Pharmaceuticals Paragraph IV Certification Notice

On February 28, 2012, Depomed, Inc. (the Company) received a Paragraph IV certification notice in accordance with 21 U.S.C. §355(j)(2)(B) from Incepta Pharmaceutical Co. Ltd. (Incepta) advising the Company of Incepta's filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (the FDA) for a generic version of Gralise™ (gabapentin), 300 mg and 600 mg tablets.

Incepta's certification notice alleges that U.S. Patent Nos. 6,340,475; 6,635,280; 6,488,962; 6,723,340; 7,731,989; and 7,438,927 (collectively, the Gralise Orange Book Patents) are invalid, unenforceable and/or will not be infringed by Incepta's commercial manufacture, use or sale of the drug products described in Incepta's ANDA. Each of the Gralise Orange Book Patents is listed in the Patent and Exclusivity Information Addendum of the FDA's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book),

U.S. Patent Nos. 6,340,475 and 6,635,280 will expire in 2016, U.S. Patent No. 6,488,962 will expire in 2020, U.S. Patent No. 6,723,340 will expire in 2021, U.S. Patent No. 7,731,989 will expire in 2022, and U.S. Patent No 7,438,927 will expire in 2024

Gralise ANDA Patent Litigation

On March 2, 2012, the Company filed a lawsuit in the United States District Court for the District of New Jersey for infringement of the Gralise Orange Book Patents against the following defendants: Actavis Elizabeth LLC (Actavis) and an affiliated company; Watson Laboratories Inc. Florida (WLF) and two affiliated companies; and Incepta. The lawsuit is in response to the ANDAs filed by each of Actavis, WLF and Incepta to market generic versions of Gralise prior to expiration of the Gralise Orange Book Patents.

The Company has commenced the lawsuit within the 45 days required to automatically stay, or bar, the FDA from approving the Gralise ANDAs for 30 months or until a district court decision that is adverse to the patents, whichever may occur earlier.

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: March 5, 2012

By:

/s/ Matthew M. Gosling
Matthew M. Gosling
Senior Vice President and General Counsel