DEPOMED INC
Form 8-K
June 17, 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): **June 17, 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

Glumetza® 500mg Recall

Depomed, Inc. (the Company) is conducting a voluntary recall from wholesalers of fifty-two lots of Glumetza® 500mg (metformin hydrochloride extended release) tablets due to the presence of trace amounts of a chemical called 2,4,6-tribromoanisole (TBA) in bottles containing 500mg Glumetza tablets. The recall follows an investigation of a single product complaint of a smell and taste consistent with TBA, which may cause temporary, non-serious gastrointestinal upset when present in amounts detectable by smell.

Each lot of Glumetza 500mg tablets includes approximately 4,000 bottles containing 100 Glumetza 500mg tablets per bottle. The Company estimates that wholesalers in the aggregate typically hold approximately 10,000 to 15,000 bottles of Glumetza 500mg tablets.

The recall does not impact the 1000mg formulation of Glumetza, which currently constitutes approximately 40% of total Glumetza net product sales.

The recall is precautionary and is not due to risks to patient health. The health effects of TBA have not been well studied, but TBA has been found in food products (such as wine and milk) at levels greater than those detected in the Glumetza tablet bottles and no serious events associated with TBA have been documented in the medical literature.

The Company is cooperating with the U.S. Food and Drug Administration (FDA) on the recall, which is currently being carried out to the wholesaler level.

The Company believes the presence of TBA in Glumetza 500mg bottles may have resulted from the breakdown of a chemical sometimes applied to wood in pallets previously used to transport Glumetza product bottles to the Company s Glumetza 500mg tablet contract manufacturer in Puerto Rico. The Company has taken numerous corrective actions related to this matter, including ceasing shipment of Glumetza 500mg tablets produced using materials that may been shipped on these wood pallets and requiring the Glumetza 500mg bottle supplier to discontinue the use of these pallets.

Although the Company has confirmed the presence of TBA in an amount detectable by smell in only a single Glumetza bottle associated with a product complaint, the Company has suspended product shipments of 500mg Glumetza to its customers pending further investigation and discussions with the FDA. The Company currently expects to resume shipments of Glumetza 500mg tablets to its customers in four to eight weeks. The Company believes it has sufficient inventory of Glumetza 1000mg and will continue to ship that product to its customers. Santarus, Inc., the Company s promotion partner for Glumetza, has indicated that it plans to focus its promotional efforts on Glumetza 1000mg until the supply of Glumetza 500mg is resumed.

Recall-related administrative fees and manufacturing costs associated with replacing recalled product are expected to be up to $2.0 million.

The supply disruption described above is expected to adversely affect the Company s Glumetza product revenues in the second and third fiscal quarters of 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: the scope of the Glumetza 500mg recall and any additional actions that the FDA may require the Company to take; the duration of the Glumetza 500mg supply disruption; the effect of the supply disruption on the Company s future financial results; the Company s ability to continue to supply Glumetza 1000mg and the success of Santarus promotional activities for that product; changes in the Company s understanding of the circumstances causing the presence of TBA in the Glumetza 500mg bottles; the potential health effects of TBA; 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: June 17, 2010	By:	/s/ Matthew M. Gosling Matthew M. Gosling Vice President and General Counsel