ALEXION PHARMACEUTICALS INC
Form 8-K
November 12, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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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): November 6, 2013

ALEXION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	000-27756	13-3648318
(State or other jurisdiction of of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

352 Knotter Drive, Cheshire, Connecticut 06410

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (203) 272-2596

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))

Item 8.01 Other Events.

Alexion Pharmaceuticals, Inc. is initiating a voluntary recall and replacement of a limited number of vials of Soliris® (eculizumab) due to the presence of visible particles observed as part of Alexion's periodic testing of retained samples. Alexion estimates that these replaced vials represent less than 1% of Alexion's total inventory, and Alexion does not anticipate any interruption to patient supply. Post-release testing from the two affected lots met quality specifications prior to the recent observations. There have been no identifiable safety concerns attributed to the product consumed from these lots to date.

In August 2013, Alexion reported that its subsidiary initiated a voluntary recall and replacement of a single lot of Soliris due to the presence of similar visible particles. The lot recalled in August 2013, and the two current affected lots, were filled by the same contract vialer prior to August 2013. Following investigation, Alexion now believes that it has identified the filling process step that resulted in the presence of the visible particles and implemented the change necessary to correct the issue.

Alexion continues to use a second contract vialer, as it has since 2009, for distribution of Soliris. This second vialer has not used the process step at issue. In addition, a third contract vialer, who uses the same corrected process step as the second vialer, was validated by Alexion in October 2013 and Alexion is now awaiting approval by the European Medicines Agency (EMA). Alexion expects to request approval from additional health authorities during the fourth quarter of 2013 and in 2014. In addition, Alexion has engaged a fourth contract vialer for Soliris, using the corrected process step, which is expected to be approved in 2014.

Following approval of the corrected process step with additional vialers, Alexion plans to commence the voluntary transition away from any remaining inventory produced using the process step at issue. A health authority, however, may require Alexion to discontinue use of any remaining inventory prior to approval of the corrected process step. Further, Alexion may decide in the future, based on the results of periodic testing, to initiate another voluntary recall, or it may be required to recall, one or more additional lots already filled using the process at issue.

During the fourth quarter of 2013, Alexion expects to record an additional expense in cost of goods sold in the range of $10 million to $25 million resulting from replacement of existing inventory. Alexion is reiterating its 2013 non-GAAP EPS guidance of $3.02 to $3.04, as provided in its press release dated October 24, 2013.

The replacement is taking place in the U.S. only. Alexion has notified the U.S. Food and Drug Administration (FDA), the EMA and other health authorities as required. Alexion cannot guarantee that it will resolve any matter involving the voluntary recall to the satisfaction of FDA, EMA or any other international regulatory authority.

Forward looking statements:

This report on Form 8-K includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, relating to continued adequacy of supply of Soliris, identification and correction of the cause of the visible particles, approval by regulatory authorities of additional vialers, additional expense for cost of goods, and EPS guidance. These statements are subject to risks, uncertainties and other factors, including risks related to continuous product inventory and supply, the uncertainties involved in manufacturing of biologic products, performance of and reliance on third party service providers, whether additional third parties will be approved to and capable of providing services to Alexion, and whether the FDA, EMA or other international regulatory authorities decide to take corrective or disciplinary actions against Alexion, as well as the risks that are described in detail in Alexion's Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, as filed with the U.S. Securities and Exchange Commission. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to place undue reliance on these

forward-looking statements. All forward-looking statements are based on information currently available to Alexion, and Alexion assumes no duty or obligation to update or revise any such forward-looking statements or any other statement in this report.

Signature

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.

Date: November 12, 2013

ALEXION PHARMACEUTICALS, INC.
By: /s/ Michael V. Greco
Name: Michael V. Greco
Title: Vice President of Law and Corporate Secretary