

ALEXION PHARMACEUTICALS INC
Form 8-K
August 20, 2013

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): August 19, 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.

On August 19, 2013, Alexion Pharma International Srl, a subsidiary of Alexion Pharmaceuticals, Inc., initiated a voluntary recall and replacement of the remaining vials of a single lot of Soliris® (eculizumab) due to the presence of visible particles in a limited number of vials in this single lot. Alexion estimates that the portion of the current affected lot being replaced in hospitals represents approximately 1-2% of the monthly vial consumption. The particles were recently observed by Alexion as part of its routine testing of retained samples following vial filling, packaging, and labeling by a third party contract vialer that began performing services for Alexion in 2012.

Based on current information, Alexion believes that the supply of Soliris to patients will not be interrupted. Alexion continues to use its other third party contract vialer, as it has since 2009, for worldwide distribution of Soliris. Visible particles have not been observed in lots filled at this other third party contract vialer. Alexion has also initiated filling, packaging, and labeling with another contract vialer which is expected to be approved for distribution later in 2013. In addition, Alexion has engaged a fourth contract vialer for filling, packaging, and labeling of Soliris, which is expected to be approved in 2014.

Alexion continues to analyze the relevant information to investigate the cause of this observation. To date, there has not been any identifiable safety concern attributed to this single lot. Prior to the recent observation, post-release testing from the affected lot met quality specifications. All other lots from the same third party contract vialer continue to meet quality specifications in post-release testing. Alexion is not planning to fill new vials with this third party contract vialer at this time, but may do so in the future.

Alexion has voluntarily instructed its distributors to withhold and replace the remaining vials of the affected lot. The affected lot was filled in June 2012, and first distributed in December 2012 in countries outside the United States. Alexion estimates that vials from this lot on the market immediately prior to notifying distributors represent less than 1% of Alexion's total inventory.

Alexion has notified the European Medicines Agency and other health authorities as required.

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, that are subject to risks, uncertainties and other factors, including risks related to continuous product inventory and supply, the uncertainties involved in manufacturing, performance 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. 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 rely on these forward-looking statements. These and other risks are described in detail in Alexion's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, as filed with the U.S. Securities and Exchange Commission. 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.

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: August 20, 2013

ALEXION PHARMACEUTICALS, INC.

By: /s/ Michael V. Greco

Name: Michael V. Greco

Title: Vice President of Law and Corporate Secretary