ALEXION PHARMACEUTICALS INC
Form 8-K
March 28, 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
THE SECURITIES EXCHANGE ACT OF 1934
Date of report (Date of earliest event reported): March 27, 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 March 27, 2013, Alexion Pharmaceuticals, Inc. received a Warning Letter from the U.S. Food and Drug Administration (FDA) regarding compliance with current Good Manufacturing Practices (cGMP) at our Rhode Island manufacturing facility. The Warning Letter follows an FDA inspection which concluded on August 6, 2012. At the conclusion of that inspection, the FDA issued a Form 483 Inspectional Observations, to which Alexion responded in August 2012 and provided additional information to the FDA in September and December 2012. The observations concern commercial and clinical manufacture of Soliris at this facility.

Based on current information, we believe that the supply of Soliris to patients will not be interrupted and that the Warning Letter does not restrict production of Soliris or shipment of Soliris from the Rhode Island facility. We continue to manufacture products, including Soliris, in this facility. Additionally, a third party manufacturing facility is currently approved worldwide for production of Soliris. Further, an additional third party manufacturing facility was validated in 2012 for production of Soliris, and we are currently completing our regulatory submissions for this facility. We anticipate first approval for this additional facility to occur in the fourth quarter of 2013. Finally, we estimate that our current inventory of Soliris licensed for commercial sale is sufficient for at least four-thousand patient-years of patient treatment.

The Warning Letter relates to certain observations that the FDA believes were inadequately addressed by our responses to the Form 483. The Warning Letter cites inadequate investigation of bacterial contamination of certain batches, and the failure to ensure compliance with cGMP. The Warning Letter states that deficiencies from a 2011 inspection were also observed in the 2012 inspection, and the FDA expressed a general concern that we have not implemented a robust quality system.

We believe that, since our initial response to the FDA, we have adequately addressed certain of the Form 483 observations, and we will work diligently to resolve outstanding FDA concerns discussed in the Warning Letter. Unless and until we are able to correct outstanding issues to the FDA’s satisfaction, the FDA may withhold approval of requests for export certificates for certain countries. The FDA may also withhold approval of pending drug applications listing the Rhode Island facility. We will notify appropriate international regulatory authorities of the Warning Letter, and it is possible that the letter may impact our ability to supply Soliris manufactured at our Rhode Island facility outside the United States.

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 whether the FDA or other international regulatory authorities will agree that steps taken or to be taken by Alexion to correct matters described in the Warning Letter are adequate, whether Alexion can resolve any continuing concerns that may be expressed by the FDA or other international regulatory authorities in a timely manner and whether the FDA or other international regulatory authorities decide to take further 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 Annual Report on Form 10-K for the quarter and year ended December 31, 2012, 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 obligation to update 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: March 28, 2013

ALEXION PHARMACEUTICALS, INC.
By: /s/ Michael V. Greco
Name: Michael V. Greco
Title: Associate General Counsel and Corporate Secretary