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 22, 2014

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.

From August 18 through August 22, 2014 the U.S. Food and Drug Administration (FDA) inspected Alexion's Smithfield, Rhode Island manufacturing facility. As previously disclosed, Alexion Pharmaceuticals, Inc. had earlier received an FDA Warning Letter, dated March 22, 2013, regarding compliance with current Good Manufacturing Practices at the Rhode Island facility. At the conclusion of the August 2014 inspection, the FDA issued a Form 483 with three inspectional observations, none of which was designated as a repeat observation to the March 22, 2013 Warning Letter. These observations are inspectional, and do not represent a final FDA determination of compliance. The three observations include a need for enhanced training around gowning procedures, more frequent environmental monitoring, and processes related to identification of the definitive root cause of a prior bioburden excursion.

Addressing FDA observations and advancing quality initiatives has been a key priority for Alexion and the company has enhanced and expects to continually enhance its overall quality program. The company will continue to work diligently to address the observations identified in the Form 483.

Alexion continues to manufacture products, including Soliris® (eculizumab), in this facility. Based on current information, Alexion believes that the supply of Soliris to patients will not be interrupted.

Based on current information, Alexion does not believe there will be any material financial impact to address the observations and resolve outstanding FDA concerns.

Unless and until Alexion is able to correct outstanding issues to the FDA’s satisfaction, the FDA may withhold approval of requests for export certificates for certain countries.

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 and Form 483 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, 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: August 25, 2014

ALEXION PHARMACEUTICALS, INC.

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