ALEXION PHARMACEUTICALS INC
Form 8-K
August 08, 2016

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): August 3, 2016

ALEXION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

100 College Street, New Haven, Connecticut 06510

(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.

The U.S. Food and Drug Administration (FDA) recently completed a routine current Good Manufacturing Practice (GMP) inspection of Alexion Pharmaceutical, Inc.'s (Alexion's) Smithfield, Rhode Island manufacturing facility. At the conclusion of the inspection, the FDA issued a Form 483 with three observations. These observations are inspectional, and do not represent a final FDA determination of compliance. The observations pertain to: completion and closure of certain investigations, validation of surface sampling methods, and monitoring of water systems. As previously disclosed, Alexion received an FDA Warning Letter, dated March 22, 2013, regarding compliance with current GMP at the Rhode Island facility. None of the observations in the current Form 483 were designated as a repeat observation.

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

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

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

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, the adequacy of our corrective actions determined by us, the FDA or other international regulatory authorities, and the financial impact of our corrective actions. 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 the risks that are described in detail in Alexion's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, 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: August 8, 2016 ALEXION PHARMACEUTICALS, INC.
By: /s/ Michael V. Greco
Name: Michael V. Greco
Title: Senior Vice President of Law and Corporate Secretary