ALEXION PHARMACEUTICALS INC
Form 8-K
September 23, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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): **September 23, 2011**

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.)**

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. has revised its 2011 revenue and non-GAAP earnings per share (EPS) guidance. Alexion has revised its 2011 revenue guidance from the previous range of $745 to $755 million, to the higher range of $760 to $768 million, and has revised its 2011 non-GAAP EPS guidance from the previous range of $1.10-$1.15, to the higher range of $1.15- $1.20. Alexion s revised 2011 guidance is based on continued strength in the global rollout of Soliris® (eculizumab) for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), which includes sales growth in Alexion s core territories of the U.S., Western Europe and Japan. Alexion is not revising any other items of 2011 financial guidance.

Alexion announced today that the US Food and Drug Administration has approved Soliris for the treatment of patients with atypical hemolytic uremic syndrome (aHUS). 2011 Revenue and EPS guidance provided prior to today s revision anticipated this approval, and today s guidance revision is not based on additional forecasted aHUS sales in 2011. Given the lower prevalence of aHUS than PNH, utilization of Soliris for aHUS is expected to increase more slowly than for PNH in all countries. Further, the large majority of patients in the aHUS registration trials live outside of the United States.

In addition, Alexion announced today that the European Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending that the therapeutic indication for Soliris be extended to include the treatment of patients with aHUS. A decision on final approval for marketing in Europe is now expected in approximately two months and then, if positive, country-by-country reimbursement processes will begin.

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.

ALEXION PHARMACEUTICALS, INC.

Date: September 23, 2011

By: /s/ Michael V. Greco
Name: Michael V. Greco

Title: Associate General Counsel and Corporate Secretary