

ALEXION PHARMACEUTICALS INC
Form 8-K
August 19, 2010

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, 2010

ALEXION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of

incorporation or organization)

000-27756
(Commission

File Number)

13-3648318
(I.R.S. Employer

Identification No.)

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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 18, 2010, Novartis Institutes for Biomedical Research, Inc, or Novartis, filed an opposition with the European Patent Office, or EPO, to Alexion's European Patent 0758904, or EP 0758904. EP 0758904 is issued and valid in fourteen countries in Europe, including the major market countries of France, Germany, Italy, Spain, and the United Kingdom, and covers, among other matters, Alexion's marketed product Soliris® (eculizumab), which is approved in Europe for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH. EP 0758904 expires on May 1, 2015, and Alexion has applied for Supplementary Protection Certificates, or SPCs, in the fourteen European countries where the patent issued. Together with EP 0758904, issued SPCs would include a prohibition on the sale or use by third parties of Soliris until May 1, 2020 for all approved indications of the drug.

Soliris received orphan drug designation from the European Commission, or E.C., for the treatment of patients with PNH in October 2003 and for the treatment of patients with atypical Hemolytic Uremic Syndrome, or aHUS, in August 2009. E.C. orphan drug designation provides for ten years of marketing exclusivity throughout all countries of the European Union in the designated indication, which in the case of Soliris for PNH is through June 2017, and is not dependent on the status of relevant patents. If the E.C. grants marketing approval for Soliris in the treatment of aHUS, orphan drug designation would provide marketing exclusivity for Soliris for ten years following any such approval for such indication.

EP 0758904 was issued by the EPO after extensive review on November 18, 2009. An invalidation or limitation on the scope of EP 0758904 could affect the value of the patent in preventing other parties from commercializing a competitive product, but would not affect Alexion's right to continue to commercialize Soliris. The foreign equivalent of EP 0758904 has been issued in each country of the world in which Alexion has applied for protection, including after extensive review by the United States Patent and Trademark Office and the Japanese Patent Office. Alexion believes that the EPO properly granted patent protection for Soliris, and we intend to respond vigorously to Novartis' opposition arguments.

We may receive notice that additional opposition proceedings regarding EP 0758904 have been initiated by other parties.

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: August 19, 2010

By: /s/ Thomas I.H. Dubin

Name: Thomas I. H. Dubin

Title: Senior Vice President and Chief Legal Officer