Horizon Pharma plc
Form 8-K
October 07, 2015

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): October 1, 2015

Horizon Pharma Public Limited Company

(Exact name of registrant as specified in its charter)

Ireland	001-35238	Not Applicable
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

Connaught House, 1st Floor, 1 Burlington Road, Dublin 4, Ireland
(Address of principal executive offices)

Registrant s telephone number, including area code: 011-353-1-772-2100

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:

¨ 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 1.01 Entry Into a Material Definitive Agreement.

On October 1, 2015, a subsidiary of Horizon Pharma Public Limited Company (the Horizon Subsidiary), as well as Jagotec AG, entered into a License and Settlement Agreement (the Settlement Agreement) with Actavis Laboratories FL, Inc. (formerly known as Watson Laboratories, Inc. Florida) (Actavis) relating to the Horizon Subsidiary s and Jagotec s on-going patent infringement litigation against Actavis in the U.S. District Court for the District of New Jersey (the Litigation). In the Litigation, the Horizon Subsidiary and Jagotec allege that a generic version of RAYOS® (prednisone) Delayed- Release Tablets in 1 mg, 2 mg and 5 mg dosages, for which Actavis is seeking approval to market in the United States pursuant to an Abbreviated New Drug Application (ANDA), infringe certain U.S. patents that are either owned by the Horizon Subsidiary or licensed to the Horizon Subsidiary by Jagotec.

In accordance with legal requirements, the Horizon Subsidiary, Jagotec and Actavis have agreed to submit the Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The parties have agreed to file stipulations of dismissal with the court regarding the Litigation. The Settlement Agreement provides for a full settlement and release by each party of all claims that relate to the Litigation or under the patents with respect to Actavis generic version of RAYOS® tablets.

Under the Settlement Agreement, the Horizon Subsidiary and Jagotec granted Actavis a non-exclusive license to manufacture and commercialize Actavis generic version of RAYOS® tablets in the United States after the Generic Entry Date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Actavis generic version of RAYOS® tablets during certain limited periods prior to the Generic Entry Date. The Horizon Subsidiary and Jagotec also agreed that during the 180 days after the Generic Entry Date, the license granted to Actavis would be exclusive with respect to any third party generic version of RAYOS® tablets.

Under the Settlement Agreement, the Generic Entry Date is December 23, 2022; however, Actavis may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of any other third party RAYOS® patent litigation, the entry of other generic versions of RAYOS® tablets or certain substantial reductions in RAYOS® prescriptions over specified periods of time.

The Horizon Subsidiary and Jagotec also agreed not to sue or assert any claim against Actavis for infringement of any patent or patent application owned or controlled by the Horizon Subsidiary or Jagotec during the term of the Settlement Agreement based on Actavis generic version of RAYOS® tablets in the United States. In turn, Actavis agreed not to challenge the validity or enforceability of the licensed patents.

If the Horizon Subsidiary or Jagotec enter into any similar agreements with other parties with respect to generic versions of RAYOS® tablets, they agreed to amend the Settlement Agreement to provide Actavis with terms that are no less favorable than those provided to the other parties with respect to the license terms, Generic Entry Date, permitted pre-market activities and notice provisions.

The foregoing description of the Settlement Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the agreement, which will be filed, with confidential terms redacted, with the Securities and Exchange Commission as an exhibit to the Company s Annual Report on Form 10-K for the year ending December 31, 2015.

Forward-Looking Statements

This report contains forward-looking statements, including statements regarding the anticipated results and actions to be taken under the Settlement Agreement, plans to submit the Settlement Agreement for regulatory approval and the potential dismissal of the Litigation. These forward-looking statements are based on management s expectations and assumptions as of the date of this report and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include, but are not limited to risks regarding whether

regulatory authorities challenge the enforceability of or seek to enjoin the entry into the Settlement Agreement, whether the U.S. District Court will grant orders dismissing the Litigation, whether additional third parties may seek to market generic versions of RAYOS® tablets and the results of any litigation that Horizon Pharma files to defend and/or assert its patents against such third parties. For a further description of these and other risks facing Horizon Pharma, please see the risk factors described in Horizon Pharma s filings with the U.S. Securities and Exchange Commission, including those factors discussed under the caption Risk Factors in those filings. Forward-looking statements speak only as of the date of this report and Horizon Pharma undertakes no obligation to update or revise these statements, except as may be required by law.

SIGNATURES

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.

HORIZON PHARMA PUBLIC LIMITED COMPANY

Date: October 7, 2015

By: /s/ Paul W. Hoelscher
Paul W. Hoelscher
Executive Vice President, Chief Financial Officer