

Horizon Pharma plc
Form 8-K
September 15, 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): September 9, 2015

Horizon Pharma Public Limited Company

(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction

001-35238
(Commission

Not Applicable
(IRS Employer

of incorporation)

File No.)

Identification No.)

Connaught House, 1st Floor, 1 Burlington Road, Dublin 4, Ireland

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(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 September 9, 2015, certain subsidiaries of Horizon Pharma Public Limited Company (collectively, the Horizon Subsidiaries) entered into a Settlement and License Agreement (the Settlement Agreement) with Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (collectively, Taro) relating to the Horizon Subsidiaries on-going patent infringement litigation against Taro in the U.S. District Court for the District of New Jersey (the Litigation). In the Litigation, the Horizon Subsidiaries allege that a generic version of PENNSAID[®] (diclofenac sodium topical solution) 2% w/w, for which Taro is seeking approval to market in the United States pursuant to an Abbreviated New Drug Application (ANDA), infringes certain U.S. patents owned by Horizon that cover PENNSAID[®] 2%.

In accordance with legal requirements, the Horizon Subsidiaries and Taro have agreed to submit the Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The Horizon Subsidiaries and Taro have agreed to file stipulations of dismissal with the courts regarding the Litigation. The Settlement Agreement provides for a full settlement and release by both the Horizon Subsidiaries and Taro of all claims that were or could have been asserted in the Litigation and that arise out of the issues that were the subject of the Litigation or Taro s generic version of PENNSAID[®] 2%.

Under the Settlement Agreement, the Horizon Subsidiaries granted Taro a non-exclusive license to manufacture and commercialize Taro s generic version of PENNSAID[®] 2% in the United States after the License Effective Date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Taro s generic version of PENNSAID[®] 2% during certain limited periods prior to the License Effective Date.

Under the Settlement Agreement, the License Effective Date is January 10, 2029; however, Taro may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of any other third party PENNSAID[®] 2% patent litigation, the entry of other third party generic versions of PENNSAID[®] 2% or certain substantial reductions in Horizon s PENNSAID[®] 2% shipments over specified periods of time.

Under the Settlement Agreement, the Horizon Subsidiaries also agreed not to sue or assert any claim against Taro for infringement of any patent or patent application owned or controlled by the Horizon Subsidiaries during the term of the Settlement Agreement based on the manufacture, use, sale, offer for sale, or importation of Taro s generic version of PENNSAID[®] 2% in the United States.

The Horizon Subsidiaries also agreed that if they enter into any similar agreements with other parties with respect to generic versions of PENNSAID[®] 2%, they will amend the Settlement Agreement to provide Taro with terms that are no less favorable than those provided to the other parties.

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 Quarterly Report on Form 10-Q for the quarter ending September 30, 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

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to market generic versions of PENNSAID 2% and the results of any litigation that Horizon files to defend and/or assert its patents against such third parties. For a further description of these and other risks facing Horizon, please see the risk factors described in Horizon'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 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.

Date: September 15, 2015

**HORIZON PHARMA PUBLIC LIMITED
COMPANY**

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