

Horizon Pharma plc
Form 8-K
July 03, 2018

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): June 27, 2018

Horizon Pharma Public Limited Company

(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction
of incorporation)

001-35238
(Commission

Not Applicable
(IRS Employer

File No.)

Identification No.)

Connaught House, 1st Floor, 1 Burlington Road, Dublin 4, D04 C5Y6, 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement.

On June 27, 2018, a subsidiary of Horizon Pharma plc (the *Horizon Subsidiary*) entered into a Settlement and License Agreement (the *Settlement Agreement*) with Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, *Lupin*) relating to RAVICTI® (glycerol phenylbutyrate) Oral Liquid, 1.1 gm/mL. Specifically, the Settlement Agreement pertains to on-going patent infringement litigation against Lupin in the U.S. District Court for the District of New Jersey (the *Litigation*), petitions for *Inter Partes* Review with the Patent Trial and Appeal Board with respect to certain U.S. patents covering RAVICTI (the *IPRs*) and an appeal to the Court of Appeals for the Federal Circuit of a prior finding of the Patent Trial and Appeal Board (the *Appeal*). In the Litigation, the Horizon Subsidiary has alleged that a generic version of RAVICTI, for which Lupin is seeking approval to market in the United States pursuant to an Abbreviated New Drug Application (ANDA), infringes certain U.S. patents that are owned by the Horizon Subsidiary.

The parties have agreed to file stipulations of dismissal with the court regarding the Litigation and a joint request for termination in the IPRs. Lupin has further agreed to withdraw from the Appeal. The Settlement Agreement also provides for a full settlement and release by each party of all claims that relate to Lupin's generic version of RAVICTI or the Litigation, the IPRs or the Appeal.

Under the Settlement Agreement, the Horizon Subsidiary granted Lupin a non-exclusive, perpetual, royalty-free license to manufacture and commercialize Lupin's generic version of RAVICTI Oral Liquid 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, Lupin's generic version of RAVICTI during certain limited periods prior to the License Effective Date.

Under the Settlement Agreement, the License Effective Date is July 1, 2026; however, Lupin may be able to enter the market earlier in certain circumstances.

The Horizon Subsidiary also agreed not to sue or assert any claim against Lupin for infringement of any patent or patent application owned or controlled by the Horizon Subsidiary during the term of the Settlement Agreement based on the manufacture, use, sale, offer for sale, or importation of Lupin's generic version of RAVICTI in the United States. In turn, Lupin agreed not to challenge the validity or enforceability of the licensed patents.

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 U.S. Securities and Exchange Commission as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2018.

Forward-Looking Statements

This report contains forward-looking statements, including statements regarding the anticipated results and actions to be taken under the Settlement Agreement. 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 court will grant orders dismissing the Litigation, whether the IPRs will be terminated following the parties' joint request for termination, whether additional third parties may seek to market generic versions of RAVICTI and the results of any litigation that Horizon Pharma plc files to defend and/or assert its patents against such third parties. For a further description of these and other risks facing Horizon Pharma plc, please see the risk factors described in Horizon Pharma plc'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 plc 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: July 3, 2018

**HORIZON PHARMA PUBLIC LIMITED
COMPANY**

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