

Horizon Pharma plc
Form 8-K
November 13, 2014

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): November 13, 2014

Horizon Pharma Public Limited Company

(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction

of incorporation)

001-35238
(Commission

File No.)

Adelaide Chambers, Peter Street, Dublin 8, Ireland

Not Applicable
(IRS Employer

Identification No.)

(Address of principal executive offices)

Registrant's telephone number, including area code: 011-353-1-649-8521

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 8.01 Other Events.

On November 13, 2014, we received a Paragraph IV Patent Certification from Watson Laboratories, Inc. (Watson) advising that Watson has filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for a generic version of PENNSAID (diclofenac sodium topical solution) 2% w/w (PENNSAID 2%). The Paragraph IV Certification does not state whether or not the FDA has formally accepted the Watson ANDA for review. Additionally, Watson has not advised us as to the timing or status of the FDA 's review of its filing.

We are evaluating the Paragraph IV certification and intend to vigorously enforce our intellectual property rights relating to PENNSAID 2%. There are currently six issued U.S. patents covering PENNSAID 2% that are listed in the FDA 's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. A seventh U.S. patent has recently issued that covers PENNSAID 2%. The Company is in the process of listing this newly issued patent into the Orange Book. Under the FDA 's rules and regulations, if we initiate a patent infringement suit to defend the patents identified in the Paragraph IV notice within 45 days after our receipt of the notice, the FDA would be prevented from approving the ANDA until the earlier of 30 months or a decision in the infringement case that each of the patents is not infringed or invalid. Horizon is currently prosecuting additional patent applications that would cover PENNSAID 2%.

Forward-Looking Statements

This report contains forward-looking statements, including statements regarding our intent to enforce our patents, the possibility of initiating a patent infringement suit and whether the FDA would be prevented from approving Watson 's ANDA filing. 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, whether we would be successful in patent infringement litigation, if initiated. For a further description of these and other risks facing us, please see the risk factors described in our filings with the United States 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 we undertake 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: November 13, 2014

**HORIZON PHARMA PUBLIC LIMITED
COMPANY**

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