HORIZON PHARMA PLC

FORM 8-K
(Current report filing)

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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): May 15, 2017

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, 1 st 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 8.01. Other Events.

On May 15, 2017, Horizon Pharma plc issued a press release announcing the ruling of the United States District Court for the District of New Jersey in Horizon Pharma Ireland Limited, et al v. Actavis Laboratories UT, Inc., C.A. No. 14-cv-7992-NLH-AMD, following a bench trial. The District Court upheld the validity of Horizon Pharma's patent covering PENNSAID® (diclofenac sodium topical solution) 2% w/w, which Actavis Laboratories UT, Inc. (Actavis) has admitted that its proposed generic diclofenac sodium topical solution product would infringe. A copy of the press release is attached at Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release of Horizon Pharma plc, dated May 15, 2017.

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: May 15, 2017

HORIZON PHARMA PUBLIC LIMITED COMPANY

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

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press release of Horizon Pharma plc, dated May 15, 2017.

Exhibit 99.1

Horizon Pharma plc Announces District Court Decision to Uphold PENNSAID ® (diclofenac sodium topical solution) 2% w/w Patent

- *Patent Covering PENNSAID ® 2% Infringed by a Proposed Generic Developed by Actavis Laboratories UT, Inc.* -

DUBLIN, IRELAND – May 15, 2017 – Horizon Pharma plc (NASDAQ:HZNP), a biopharmaceutical company focused on improving patients' lives by identifying, developing, acquiring and commercializing differentiated and accessible medicines that address unmet medical needs, today announced that the United States District Court for the District of New Jersey upheld the validity of Horizon Pharma's patent covering PENNSAID ® (diclofenac sodium topical solution) 2% w/w, which Actavis Laboratories UT, Inc. (Actavis) has admitted that its proposed generic diclofenac sodium topical solution product would infringe.

On July 6, 2015, Horizon filed a patent infringement lawsuit in District Court against Actavis related to Abbreviated New Drug Applications filed with the U.S. Food and Drug Administration to market a generic version of PENNSAID 2%. The lawsuit claims infringement of Horizon's U.S. Patent No. 9,066,913 ('913 patent) titled "Diclofenac Topical Formulation," which covers PENNSAID 2%. The District Court's decision was made based on the validity of Horizon Pharma's '913 patent for PENNSAID 2% and the Court's judgment will prevent Actavis from launching a generic version of PENNSAID 2% in the United States.

PENNSAID 2% has 18 Orange Book listed patents with terms that extend to 2030.

About PENNSAID 2%

PENNSAID (diclofenac sodium topical solution) 2% w/w is a non-steroidal anti-inflammatory drug (NSAID) indicated for the treatment of pain of osteoarthritis (OA) of the knee(s). PENNSAID 2% contains diclofenac sodium, an NSAID, and also includes dimethyl sulfoxide (DMSO), a powerful penetrating agent that helps ensure that diclofenac sodium is absorbed through the skin to the site of inflammation and pain. PENNSAID 2% is an alternative to oral NSAID treatment, reducing systemic exposure to a fraction of that provided by the oral NSAID diclofenac. The only topical NSAID offered with the convenience of a metered-dose pump, PENNSAID 2% is applied in two pumps, twice daily, to the site of OA knee pain. For more information, please see ***www.PENNSAID.com.***

IMPORTANT SAFETY INFORMATION

WARNING: CARDIOVASCULAR AND GASTROINTESTINAL RISK

Heart Risk

- ***Non-steroidal anti-inflammatory drugs (NSAIDs) may cause an increased risk of serious heart clotting events, heart attack and stroke, which can kill you. This risk may increase with longer use. Patients with heart disease or risk factors for heart disease may be at greater risk.***
- ***PENNSAID 2% should not be used if you are in the hospital for certain heart surgeries.***

Stomach and Intestine Risk

- ***NSAIDs cause an increased risk of serious stomach and intestine events including bleeding, ulcers and holes in the stomach or intestines, which can kill you. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious stomach and intestine events.***

CONTRAINDICATIONS

- DO NOT USE PENNSAID 2% if you:
  - are in the hospital for certain heart surgeries.
  - know you are allergic to diclofenac sodium or any other ingredient of PENNSAID 2%.
  - have experienced asthma, hives, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, allergic reactions that will rarely kill you, to NSAIDs have been reported in such patients.

WARNINGS AND PRECAUTIONS

- To minimize the potential for increased risk of serious heart events while being treated with an NSAID, use the lowest effective dose for the shortest duration possible.
- Elevation of one or more liver tests may occur during therapy with NSAIDs. PENNSAID 2% should be discontinued immediately if abnormal liver tests persist or worsen.
- Use with caution in patients with fluid retention or heart failure.
- Hypertension can occur with NSAID treatment. Monitor blood pressure closely with PENNSAID 2% treatment.
- Long-term use of NSAIDs can result in severe kidney injury. Use PENNSAID 2% with caution in patients at greatest risk of this reaction, including the elderly, those with impaired kidney function, heart failure, liver dysfunction and those taking diuretics and ACE-inhibitors (certain blood pressure medicines).
- Severe allergic reactions may occur without prior use of PENNSAID 2%. NSAIDs can cause serious skin reactions such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN), which can kill you.
- Wash and dry hands before and after use. Avoid contact of PENNSAID 2% with the eyes, nose and mouth.
- PENNSAID 2% was not studied under the conditions of heat application, complete covering bandages or exercise; therefore, concurrent use of PENNSAID under these conditions is not recommended.
- Do not:
  - Apply PENNSAID 2% to open wounds.
  - Shower for at least 30 minutes after applying PENNSAID 2%.

- Wear clothing over the PENNSAID 2% treated knee until the treated knee is dry.

- Protect treated knee(s) from natural or artificial sunlight.
- Protect treated knee(s) from sunlight (real and tanning booths).
- Topicals, such as sunscreen and bug repellent, should not be used until after PENNSAID 2% treated knee(s) are completely dry.
- Do not use with oral NSAIDs unless your doctor says it is OK and you have lab tests to check your progress.
- There is no consistent evidence that regular use of aspirin lessens the increased risk of serious heart events, such as heart clotting, heart attack and stroke associated with NSAID use. As with all NSAIDs, regular administration of PENNSAID 2% and aspirin is not generally recommended because of the potential of increased risks.

ADVERSE REACTIONS

- The most common adverse events in a phase 2 clinical trial of PENNSAID 2% were application site reactions, such as dryness (22%), peeling (7%), redness (4%), itching (2%), pain (2%), skin hardening (2%), rash (2%) and scabbing (< 1%). Other adverse reactions occurring in > 1% of patients receiving PENNSAID 2% included bladder infection (3%), bruising (2%), sinus congestion (2%) and nausea (2%).

USE IN SPECIFIC POPULATIONS

- PENNSAID 2% should not be used in pregnant woman or in women who are breastfeeding and is not approved for use in children.

For more information on PENNSAID 2%, please see the Medication Guide and Full Prescribing Information , available at *www.PENNSAID.com.*

About Horizon Pharma plc

Horizon Pharma plc is a biopharmaceutical company focused on improving patients' lives by identifying, developing, acquiring and commercializing differentiated and accessible medicines that address unmet medical needs. The Company markets 11 medicines through its orphan, rheumatology and primary care business units. For more information, please visit www.horizonpharma.com . Follow @HZNPplc on Twitter or view careers on our LinkedIn page.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the impact of the District Court's ruling on Horizon Pharma's '913 patent. These forward-looking statements are based on management expectations and assumptions as of the date of this press release, and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include risks regarding whether Actavis appeals the District Court's decision and whether the decision is upheld on such an appeal and other factors described in Horizon Pharma's 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 press release and Horizon Pharma does not undertake any obligation to update or revise these statements, except as may be required by law.

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