Horizon Pharma plc
Form 8-K
October 17, 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): October 17, 2014

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.)**

Adelaide Chambers, Peter Street, Dublin 8, Ireland

(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 1.01 Entry into a Material Definitive Agreement.

On October 17, 2014, we entered into an asset purchase agreement with Nuvo Research Inc., or Nuvo, pursuant to which we acquired from Nuvo certain intellectual property and other assets, and assumed from Nuvo certain liabilities, each with respect to PENNSAID® 2% w/w in the United States. PENNSAID 2% (diclofenac sodium topical solution) is a topical non-steroidal anti-inflammatory drug (NSAID) that is approved by the U.S. Food and Drug Administration (FDA) for the treatment of the pain of osteoarthritis (OA) of the knee(s).

Pursuant to the asset purchase agreement, we acquired the rights and other assets related to PENNSAID 2% in the United States including, among other things, the investigational new drug application, or IND, and new drug application, or NDA, for PENNSAID 2%, Nuvo s interests in patents covering PENNSAID 2% in the United States and certain regulatory documentation, promotional materials and records related to PENNSAID 2% in the United States. We granted back to Nuvo an exclusive, royalty-free, fully paid-up license (with the right to sublicense to Mallinckrodt plc, or Mallinckrodt, and its affiliates) to use the acquired assets and rights until December 31, 2014. Following the date on which the FDA publishes a National Drug Code number indicating that we are the labeler of PENNSAID 2%, we will become responsible for and will control matters relating to PENNSAID 2% in the United States, including its commercialization.

Also pursuant to the asset purchase agreement, Nuvo agreed to discontinue the manufacture, sale and marketing of PENNSAID® 1.5% w/w in the United States and is prohibited, for a period of ten years, from developing, manufacturing or commercializing any diclofenac sodium product for topical uses in humans in the United States. Likewise, we agreed to not manufacture PENNSAID 2% for use outside the United States or to commercialize PENNSAID 1.5% or PENNSAID 2% outside the United States. We are also prohibited, for a period of ten years, from referencing the PENNSAID 2% IND or NDA in order to develop, manufacture or commercialize any diclofenac sodium product for uses in humans outside the United States.

As consideration for the U.S. rights to PENNSAID, we paid Nuvo a one-time upfront cash payment of $45.0 million on October 17, 2014.

In connection with the asset purchase agreement, we also entered into a supply agreement with Nuvo on October 17, 2014 pursuant to which Nuvo agreed to supply PENNSAID 2% to us for commercialization in the United States. Under the supply agreement, Nuvo is obligated to supply PENNSAID 2% based on our purchase orders and rolling forecasts of product needs. We are obligated to obtain 100% of our requirements for PENNSAID 2% from Nuvo and will pay an agreed-upon transfer price under the supply agreement. The transfer price is subject to semi-annual adjustments based on Nuvo s raw material costs and annual adjustments based upon changes in the national manufacturing cost index for pharmaceutical products.

The supply agreement also provides for the selection and qualification of alternate suppliers of PENNSAID 2% and its active pharmaceutical ingredient (API). Following the approval by the FDA of a selected alternate supplier, and subject to certain limitations, Nuvo is required to enter into a supply agreement with the alternate supplier with respect to PENNSAID 2% or its API. To the extent maintaining regulatory approvals for an alternative supplier requires Nuvo to purchase minimum quantities of drug product or API from the alternate supplier, Nuvo is obligated to purchase such minimum quantities, subject to our obligation to reimburse Nuvo for any excess cost compared to Nuvo s cost to otherwise obtain such drug product or API.

The initial term of the supply agreement is through December 31, 2022 and, unless terminated, will automatically renew for successive two-year terms thereafter. The supply agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party. Additionally, we have the right to terminate the supply agreement immediately upon written notice to Nuvo if the existing regulatory approval of PENNSAID 2% is suspended, if a regulatory authority provides a warning letter or otherwise expresses major and significant concerns with Nuvo s or its

third party manufacturer s manufacturing of PENNSAID 2%, or if Nuvo sells its manufacturing facility, including in connection with a merger or acquisition, to a party that has been subject to specified regulatory actions related to that party s ability to perform its obligations under the supply agreement. We may also elect to terminate the supply agreement upon six month s prior written notice if Nuvo sells its manufacturing facility, including as part of a merger or acquisition, to a party that has a material competitive business to our business.

On October 17, 2014, we issued a press release announcing our acquisition of the U.S. rights to PENNSAID 2% and the supply agreement. A copy of this press release is attached hereto as Exhibit 99.1.

Item 8.01 Other Events.

In connection with our acquisition of the U.S. rights to PENNSAID 2%, we also announced plans to increase our primary care sales force by approximately 75 representatives, to a total of approximately 325 representatives.

In January 2013, Nuvo and Mallinckrodt entered into a settlement agreement with a generic drug manufacturer. Under the settlement agreement, the generic drug manufacturer was granted a non-exclusive license to manufacture and commercialize a generic version of PENNSAID 2% in the United States beginning on April 21, 2022 and to take steps necessary to develop inventory of, but not commercialize, a generic version of PENNSAID 2% prior to April 21, 2022. The generic manufacturer may be able to enter the market earlier upon certain events. Such events relate to the entry of other third party generic versions of PENNSAID 2% or the finding that patent claims related to PENNSAID 2% are invalid, unenforceable or not infringed by the manufacture and commercialization of generic versions of PENNSAID 2%.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release dated October 17, 2014.

Forward-Looking Statements

This Current Report contains forward-looking statements, including statements regarding expected timing of certain events contemplated by the asset purchase agreement and Horizon s plans to expand its primary care sales force. These forward-looking statements are based on management s 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, but are not limited to, risks regarding Horizon s ability to complete regulatory activities related to its commercialization of PENNSAID 2% and its ability to successfully hire new sales representatives and retain existing sales representatives. For a further description of these and other risks facing the Company, please see the risk factors described in the Company 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 Current Report and the Company 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: October 17, 2014

HORIZON PHARMA PUBLIC LIMITED COMPANY

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

EXHIBIT INDEX

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