

HORIZON PHARMA, INC.
Form 8-K
August 22, 2013

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): August 21, 2013

Horizon Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State of incorporation)

001-35238
(Commission File No.)

27-2179987
(IRS Employer Identification No.)

520 Lake Cook Road, Suite 520, Deerfield, Illinois

60015

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(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: (224) 383-3000

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 August 21, 2013, Horizon Pharma, Inc. and Horizon Pharma USA, Inc. (collectively, Horizon) entered into a Settlement Agreement (the Settlement Agreement) and License Agreement (the License Agreement) with Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively, Par) relating to Horizon s on-going patent infringement litigation against Par in the U.S. District Court for the District of Delaware (the Litigation). In the Litigation, Horizon alleges that a generic version of DUEXIS[®] for which Par is seeking approval to market in the U.S. pursuant to an Abbreviated New Drug Application (ANDA), infringes certain U.S. patents owned by Horizon that cover DUEXIS.

In accordance with legal requirements, Horizon and Par have agreed to submit the agreements to the U.S. Federal Trade Commission and the U.S. Department of Justice for review within three business days following the date of their execution. Horizon and Par have agreed to file a stipulation of dismissal with the court within three business days following expiration of the 45-day regulatory review period. The Settlement Agreement provides for a full settlement and release by both Horizon and Par of all claims that were or could have been asserted in the Litigation and that arise out of the specific patent issues that were the subject of the Litigation, including all resulting damages or other remedies, subject to the court s acceptance of the stipulation of dismissal.

Under the License Agreement, Horizon granted Par a non-exclusive license (that is only royalty-bearing in some circumstances) to manufacture and commercialize Par s generic version of DUEXIS in the U.S. after the Generic Entry Date (as defined below) and to take steps necessary to develop inventory of, and obtain regulatory approval for, but not commercialize, Par s generic version of DUEXIS prior to the Generic Entry Date (collectively, the License). The License covers all patents owned or controlled by Horizon during the term of the License Agreement that would, absent the License, be infringed by the manufacture, use, sale, offer for sale, or importation of Par s generic version of DUEXIS in the U.S. Unless terminated sooner pursuant to the terms of the License Agreement, the License will continue until the last to expire of the licensed patents and/or applicable periods of regulatory exclusivity.

Under the License Agreement, the Generic Entry Date is January 1, 2023; however, Par may be able to enter the market earlier in certain circumstances. Such events relate to the resolution of potential future third party DUEXIS patent litigation, the entry of other third party generic versions of DUEXIS or certain specific changes in DUEXIS market conditions. Only in the event that Par enters the DUEXIS market due to the specified changes in DUEXIS market conditions will the license become royalty-bearing, with the royalty obligations ceasing upon the occurrence of one of the other events that would have allowed Par to enter the DUEXIS market.

Under the License Agreement, Horizon also agreed not to sue or assert any claim against Par for infringement of any patent or patent application owned or controlled by Horizon during the term of the License Agreement based on the manufacture, use, sale, offer for sale, or importation of Par s generic version of DUEXIS in the U.S.

The License Agreement may be terminated by Horizon if Par commits a material breach of the agreement that is not cured or curable within 30 days after Horizon provides notice of the breach. Horizon may also terminate the License Agreement immediately if Par or any of its affiliates initiate certain challenges to the validity or enforceability of any of the licensed patents or their foreign equivalents. In addition, the License Agreement will terminate automatically upon termination of the Settlement Agreement or if the Litigation has not been dismissed by the court within 75 days after execution of the License Agreement.

The foregoing description of the Settlement Agreement and License Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the agreements, which will be filed, with confidential terms redacted, with the Securities and Exchange Commission as an exhibit to Horizon s Quarterly Report on Form 10-Q for the quarter ending September 30, 2013.

Forward-Looking Statements

This report contains forward-looking statements, including statements regarding the anticipated results and actions to be taken under the Settlement Agreement and License Agreement, plans to submit the agreements 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 agreements, whether the U.S. District Court will grant an order dismissing the Litigation, whether additional third parties may seek to market generic versions of DUEXIS 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 the 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: August 22, 2013

Horizon Pharma, Inc.

By: /s/ Robert J. De Vaere
Robert J. De Vaere
Executive Vice President and Chief Financial Officer