HORIZON PHARMA, INC.
Form 8-K
November 19, 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): November 18, 2013

Horizon Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35238**	**27-2179987**
(State of incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**

520 Lake Cook Road, Suite 520, Deerfield, Illinois	**60015**
(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 November 18, 2013, we entered into an asset purchase agreement with AstraZeneca AB, or AstraZeneca, pursuant to which we will acquire from AstraZeneca and its affiliates certain intellectual property and other assets, and assume from AstraZeneca and its affiliates certain liabilities, each with respect to VIMOVO®, and obtain rights to develop other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with non-steroidal anti-inflammatory drug, or NSAIDs, in the United States. VIMOVO (naproxen/esomeprazole magnesium), a proprietary fixed-dose multi-layer delayed-release tablet combining an enteric-coated naproxen, an NSAID, core and an immediate-release esomeprazole, a proton pump inhibitor, layer surrounding the core, was approved by the U.S. Food and Drug Administration in 2010 for the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis, and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

Upon closing of the transactions contemplated by the asset purchase agreement, we will acquire certain existing assets and rights necessary to commercialize VIMOVO in the United States including, among other things, the investigational new drug application, or IND, and new drug application, or NDA, for VIMOVO in the United States, AstraZeneca s interest in certain patents covering VIMOVO in the United States and certain promotional materials and records related to VIMOVO in the United States. Under the asset purchase agreement, we will also be entitled to the benefit of a covenant not to sue granted by Merck Sharp & Dohme Corp. and certain of its affiliates, or collectively Merck, to AstraZeneca, with respect to certain patents owned by AstraZeneca but exclusively licensed to Merck, that cover the manufacture and commercialization of VIMOVO in the United States. In addition, under the asset purchase agreement, upon the closing of the transactions contemplated by the asset purchase agreement, AstraZeneca will assign to us its amended and restated collaboration and license agreement for the United States with Pozen Inc., or Pozen, pursuant to which AstraZeneca has in-licensed from Pozen certain patents and know-how of Pozen covering VIMOVO in the United States. The terms of the amended and restated collaboration and license agreement for the United States with Pozen, or the Pozen license agreement, are described below.

In connection with the closing of the transactions contemplated by the asset purchase agreement, we will also enter into a license agreement with AstraZeneca, a supply agreement with AstraZeneca s affiliate, AstraZeneca LP, and certain other agreements that are described below.

In connection with the closing of the transactions contemplated by the asset purchase agreement, we will also execute a transition agreement with AstraZeneca pursuant to which we and AstraZeneca will coordinate to transition to us regulatory and commercial responsibility for VIMOVO in the United States by December 31, 2013. During this transition period, AstraZeneca will continue to commercialize VIMOVO in the United States under AstraZeneca s existing pricing and will pay to us the net profits recognized on sales of VIMOVO in the United States. Following December 31, 2013, we will commence commercialization of VIMOVO in the United States on our own behalf and under new pricing for VIMOVO.

In consideration for the U.S. rights to VIMOVO, upon closing of the transactions contemplated by the asset purchase agreement, we will pay to AstraZeneca a one-time upfront cash payment of $35.0 million. The closing of the transactions contemplated under the asset purchase agreement will be subject to certain customary closing conditions.

Following the closing, we will be responsible for and will control matters relating to VIMOVO in the United States, including responsibility for commercialization of VIMOVO in the United States (subject to the activities contemplated by the transition agreement as described above), responsibility for ongoing developmental and regulatory activities with respect to VIMOVO in the United States and responsibility for the current VIMOVO litigation with respect to the patents we will be purchasing under the asset purchase agreement and the patents we will be licensing from Pozen under the Pozen license agreement. AstraZeneca will be responsible for and will retain control of VIMOVO outside the United States.

The asset purchase agreement may be terminated prior to closing of the transactions contemplated thereby upon mutual written agreement of the parties, by either party upon written notice if the closing has not occurred on or prior to December 31, 2013 or by either party upon written notice of a material misrepresentation or material breach by the other party of the asset purchase agreement, subject to certain exceptions.

Upon closing of the transactions contemplated by the asset purchase agreement, we will enter into a license agreement with AstraZeneca, or the AstraZeneca license agreement, pursuant to which AstraZeneca will grant to us an exclusive license under certain intellectual property (including patents, know-how, trademarks, copyrights and domain names) of AstraZeneca and its affiliates to develop, manufacture and commercialize VIMOVO in the United States. AstraZeneca will also grant to us a non-exclusive license under certain intellectual property of AstraZeneca and its affiliates to manufacture, import, export and perform research and development activities with respect to VIMOVO outside the United States but solely for purposes of commercializing VIMOVO in the United States. In addition, AstraZeneca will grant to us a non-exclusive right of reference and use under certain regulatory documentation controlled by AstraZeneca and its affiliates to develop, manufacture and commercialize VIMOVO in the United States and to manufacture, import, export and perform research and development activities with respect to VIMOVO outside the United States but solely for purposes of commercializing VIMOVO in the United States.

Under the AstraZeneca license agreement, we will grant to AstraZeneca a non-exclusive sublicense under such licensed intellectual property and a non-exclusive right of reference under certain regulatory documentation controlled by us to manufacture,

import, export and perform research and development activities with respect to VIMOVO in the United States but solely for purposes of commercializing VIMOVO outside the United States.

Under the AstraZeneca license agreement, we and our affiliates will be subject to certain limitations and restrictions on our ability to develop, commercialize and seek regulatory approval with respect to VIMOVO or other products that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs (excluding DUEXIS). These limitations and restrictions include, among other things, restrictions on indications for which we may commercialize VIMOVO or any such other products, restrictions on our ability to develop or seek regulatory approval with respect to such other products that contain esomeprazole, restrictions on our ability to develop or seek regulatory approval for VIMOVO for any indications other than the indications for which NSAIDs are indicated, and restrictions on our marketing activities with respect to VIMOVO and any such other products.

The AstraZeneca license agreement continues in full force and effect until terminated in accordance with its terms. Under the AstraZeneca license agreement, the parties may terminate upon mutual written agreement by the parties, or either party may terminate rights granted to us with respect to licensed trademarks and licensed domain names under the AstraZeneca license agreement upon uncured material breach by the other party of certain specified provisions of the AstraZeneca license agreement.

Under the Pozen license agreement, Pozen will grant to us an exclusive, royalty-bearing license under certain of Pozen s intellectual property in the United States to manufacture, develop and commercialize VIMOVO and other products controlled by us that contain gastroprotective agents in a single fixed combination oral solid dosage form with NSAIDs, in the United States.

Under the Pozen license agreement, we will be required to pay Pozen a 10% royalty on net sales of VIMOVO and such other product sold by us, our affiliates or sublicensees during the royalty term, subject to minimum annual royalty obligations of $5.0 million in 2014 and $7.5 million each year thereafter, which minimum royalty obligations will continue for each year during which one of Pozen s patents covers such products in the United States and there are no competing products in the United States. The royalty rate may be reduced to a mid-single digit royalty rate as a result of loss of market share to competing products. Our obligation to pay royalties to Pozen will expire upon the later of (a) expiration of the last-to-expire of certain patents covering such products in the United States, and (b) ten years after the first commercial sale of such products in the United States. In addition, we will be obligated to reimburse Pozen for costs, including attorneys fees, incurred by Pozen in connection with VIMOVO patent litigation moving forward, subject to agreed caps.

We will be responsible for and will be required to use diligent and reasonable efforts to commercialize VIMOVO or another qualified product in the United States. We will also own and maintain all regulatory filings and marketing approvals in the United States for any such products, including all INDs and NDAs for VIMOVO. Pozen will covenant that it will not at any time prior to the expiration of the royalty term, and will ensure that its affiliates do not, directly or indirectly, develop or commercialize or license any third party to develop or commercialize certain competing products in the United States.

The Pozen license agreement, unless earlier terminated, will expire upon expiration of the royalty term for all such products in the United States. Either party will have the right to terminate the agreement upon uncured material breach by the other party or upon the bankruptcy or similar proceeding of the other party. We will also be able to terminate the Pozen license agreement for cause upon certain defined product failures.

In connection with the asset purchase agreement and the Pozen license agreement, we, AstraZeneca and Pozen entered into a letter agreement in which Pozen consented to AstraZeneca s assignment of the Pozen license agreement to us and that addresses the rights and responsibilities of the parties in relation to the Pozen license agreement and the amended and restated collaboration and license agreement between Pozen and AstraZeneca for outside the United

States. Under the letter agreement, we and AstraZeneca agreed to pay Pozen milestone payments upon the achievement by us and AstraZeneca, collectively, of certain annual aggregate global sales thresholds ranging from $550.0 million to $1.25 billion with respect to products licensed by Pozen to us under the Pozen license agreement and to AstraZeneca under the amended and restated collaboration and license agreement for outside the United States. The aggregate milestone payment amount that may be owed by AstraZeneca and us, collectively, under the letter agreement is $260.0 million, with the amount payable by each of us and AstraZeneca with respect to each milestone to be based upon the proportional sales achieved by each of us and AstraZeneca, respectively, in the applicable year.

The letter agreement will terminate with respect to Pozen and us upon the termination of the Pozen license agreement and will terminate with respect to Pozen and AstraZeneca upon the termination of the amended and restated collaboration and license agreement between AstraZeneca and Pozen for outside the United States.

In connection with the asset purchase agreement, we will enter into a supply agreement with AstraZeneca pursuant to which AstraZeneca will agree to supply VIMOVO to us for commercialization in the United States through December 31, 2014. Under the supply agreement, AstraZeneca will supply the quantity of VIMOVO that we order, both for our own use and for use by our sublicensees, on a transitional basis through December 31, 2014. We will pay a set transfer price agreed by us and AstraZeneca for quantities of VIMOVO supplied by AstraZeneca under the supply agreement.

The supply agreement will expire on December 31, 2014, unless terminated earlier as described herein. 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 at any time upon 120 days prior written notice to AstraZeneca or immediately upon written notice if the existing regulatory approval of VIMOVO is suspended for any reason or if any regulatory authority provides a warning letter or other official documentation expressing major and significant concerns from a regulatory perspective with AstraZeneca s or its affiliates or third party manufacturer s manufacturing of VIMOVO. Additionally, the supply agreement will automatically terminate upon any termination of the AstraZeneca license agreement.

On November 19, 2013, we issued a press release announcing our agreement to acquire the U.S. rights to VIMOVO. A copy of this press release is attached hereto as Exhibit 99.1.

Item 2.04 Triggering Events That Accelerate or Increase a Direct Financial Obligation or an Obligation under an Off Balance Sheet Arrangement.

Also on November 18, 2013, we entered into a consent with the group of institutional lenders under our existing $60.0 million senior secured loan facility. Under the consent, the lenders consented to our consummation of the transactions contemplated by the asset purchase agreement with AstraZeneca and we irrevocably agreed to prepay all outstanding obligations under our existing senior secured loan, including make-whole payments, on or before the earlier of November 26, 2013 or the date we make payments in relation to the acquisition of the U.S. rights to VIMOVO, including the contemplated payment of $35.0 million to AstraZeneca. The amounts owed by us to the lenders will consist of the repayment of approximately $58.3 million, representing all outstanding amounts (including principal and interest), and the payment of $12.2 million for make-whole payments, each assuming a payment date of November 22, 2013.

We expect to finance the payments to our existing lenders and the $35.0 million payment to AstraZeneca with the net proceeds from our proposed private placement of convertible senior unsecured notes that we announced on November 19, 2013.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(e) On November 16, 2013, our board of directors approved, contingent and effective upon the closing of our acquisition of the U.S. rights to VIMOVO, an amendment to our 2011 equity incentive plan, or 2011 EIP, to reserve an additional 800,000 shares of our common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of ours (or following a bona fide period of non-employment with us), as an inducement material to the individual s entry into employment with us within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules, or Rule 5635(c)(4). The 2011 EIP was amended by our board of directors without stockholder approval pursuant to Rule 5635(c)(4).

A complete copy of the 2011 EIP, as amended, is filed herewith as Exhibit 99.2. The above summary of the amendment to the 2011 EIP does not purport to be complete and is qualified in its entirety by reference to such exhibit.

Item 8.01 Other Events.

We are filing certain information for the purpose of updating various aspects of the descriptions of our business and risk factors contained in our other filings with the Securities and Exchange Commission. A copy of this additional disclosure is attached as Exhibit 99.3 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.
(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Horizon Pharma, Inc. dated November 19, 2013.
99.2	2011 Equity Incentive Plan, as amended, and Form of Option Agreement and Form of Stock Option Grant Notice thereunder.
99.3	Company Disclosure.

Forward-Looking Statements

Any statements in this Current Report on Form 8-K, including the documents that we incorporate by reference herein, about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. In some cases, you can identify forward-looking statements by the following words: may, will, could, would, should, expect, intend, plan, anticipate, believe, estin potential, continue, ongoing or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Current Report on Form 8-K, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Many important factors affect our ability to achieve our objectives, including:

our ability to successfully execute our sales and marketing strategy, including continuing to successfully recruit and retain sales and marketing personnel in the United States, and to successfully build the market for DUEXIS, VIMOVO and RAYOS in the United States;

the rate and degree of market acceptance of, and our ability and our distribution and marketing partners ability to obtain reimbursement for, any of our products, including VIMOVO;

our need for and ability to obtain additional financing;

our ability to maintain regulatory approvals for DUEXIS, VIMOVO and RAYOS/LODOTRA;

the accuracy of our estimates regarding expenses, future revenues, and time to profitability;

whether we will be able to realize the expected benefits of our planned acquisition of the U.S. rights to VIMOVO, including whether and when the acquisition will be accretive to our net income;

our ability to manage our anticipated future growth;

the ability of our products to compete with generic products, especially those representing the active pharmaceutical ingredients in DUEXIS, VIMOVO and RAYOS/LODOTRA, as well as new products that may be developed by our competitors;

our ability and our distribution and marketing partners ability to comply with regulatory requirements regarding the sales, marketing and manufacturing of our products and product candidates;

the performance of our third-party distribution partners, co-promoters, licensees and manufacturers, over which we have limited control;

our ability to obtain and maintain intellectual property protection for our products;

our ability to defend our intellectual property rights with respect to our products and otherwise prevent the entry of generic versions of our products;

our ability to operate our business without infringing the intellectual property rights of others;

the loss of key commercial or management personnel;

regulatory developments in the United States and foreign countries; and

our ability to either acquire or develop and commercialize other product candidates in addition to DUEXIS, VIMOVO and RAYOS/LODOTRA.

In addition, you should refer to the Risk Factors section of Exhibit 99.3 of this Current Report on Form 8-K for a discussion of other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Current Report on Form 8-K will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

The information contained in or incorporated by reference in this Current Report on Form 8-K is accurate only as of the date of this Current Report on Form 8-K. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as 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 19, 2013

Horizon Pharma, Inc.

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

EXHIBIT INDEX

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