

HORIZON PHARMA, INC.
Form 8-K
February 17, 2012

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): February 15, 2012

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

Edgar Filing: HORIZON PHARMA, INC. - Form 8-K

(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 8.01 Other Events.

On February 15, 2012, we received a Paragraph IV Patent Certification from Par Pharmaceutical, Inc. (Par) advising that Par has filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for a generic version of DUEXIS, containing 800 mg of ibuprofen and 26.6 mg of famotidine. Par has not advised us as to the timing or status of the FDA 's review of its filing, or whether it has complied with FDA requirements for proving bioequivalence.

We are evaluating the Paragraph IV certification and intend to vigorously enforce our intellectual property rights relating to DUEXIS. All of the issued U.S. patents covering DUEXIS are listed in the FDA 's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as 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. In addition to the two issued U.S. patents listed in the Orange Book, Horizon is currently prosecuting additional patent applications that would cover DUEXIS.

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 Par '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: February 16, 2012

Horizon Pharma, Inc.

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