

IRONWOOD PHARMACEUTICALS INC

Form 8-K

February 01, 2017

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):

January 31, 2017

IRONWOOD PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-34620
(Commission file number)

04-3404176
(I.R.S. Employer
Identification Number)

301 Binney Street
Cambridge, Massachusetts
(Address of principal
executive offices)

02142
(Zip code)

(617) 621-7722
(Registrant's telephone number,
including area code)

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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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

 - o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

 - o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

 - o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 1.01 Entry into a Material Definitive Agreement

License Agreement Amendment

On January 31, 2017, Ironwood Pharmaceuticals, Inc. (Ironwood) and Allergan Pharmaceuticals International Ltd. (Allergan Pharma) entered into an amendment (the Amendment) to the license agreement, dated April 30, 2009, as amended, between Ironwood and Allergan Pharma (as transferee from Almirall S.A.) relating to the development, manufacture and commercialization of linaclotide in Europe (the License Agreement).

Pursuant to the terms of the Amendment, the license granted to Allergan Pharma was extended to a territory (the Additional Territory) consisting of all countries not previously covered by the License Agreement, other than the People's Republic of China (including Hong Kong and Macau), Japan, and the countries and territories of North America. On a country-by-country and product-by-product basis in the Additional Territory, Allergan Pharma will pay Ironwood an annual royalty as a percentage of net sales of products containing linaclotide as an active ingredient (Linaclotide Products) in the upper-single digits for five years following the first commercial sale of a Linaclotide Product in a country, and in the low-double digits thereafter. The royalty rate for Linaclotide Products in the Additional Territory will decrease, on a country-by-country basis, to the lower-single digits, or cease entirely, following the occurrence of certain specified events.

Allergan Pharma will use commercially reasonable efforts to obtain regulatory approval for and thereafter commercialize the Linaclotide Products in certain countries in the Additional Territory and will assume certain purchase commitments for quantities of linaclotide active pharmaceutical ingredient (API) under Ironwood's agreements with its third-party API suppliers.

In addition to customary termination provisions, Allergan Pharma may terminate the License Agreement with respect to the Additional Territory for convenience on a country-by-country basis. The Amendment includes customary representations and warranties.

Commercial Agreement

Concurrently with entering into the Amendment, on January 31, 2017, Ironwood entered into an agreement (the Commercial Agreement) with subsidiaries of Allergan plc, Allergan USA, Inc. (Allergan) and Forest Laboratories, LLC (Forest). Pursuant to the terms of the Commercial Agreement, the parties have agreed to eliminate, in full, in 2018 and all subsequent years thereafter the adjustments to Ironwood's or Forest's share of the net profits under the share adjustment provision of the collaboration agreement, dated as of September 12, 2007, as amended, between Ironwood and Forest for linaclotide in North America (the Share Adjustment Relief).

In addition, Allergan appointed Ironwood, on a non-exclusive basis, to promote CANASA® and DELZICOL® (the Products) in the United States for approximately two years. Ironwood will perform certain third position details and offer samples of the Products to gastroenterology prescribers who are on the then-current call panel for LINZESS® to which Ironwood provides first or second position details. Ironwood will commence its promotional activities on or about February 27, 2017. On a Product-by-Product basis, Allergan will pay a royalty in the mid-teens to Ironwood on incremental sales of such Product above a mutually agreed upon sales baseline. If Ironwood fails to perform the required third position details in any period, Ironwood will make payments to Allergan, based on the difference between the required third position details for such period and the actual third position details performed by Ironwood in such period multiplied by a specified amount. Allergan will have the right, in certain circumstances, to substitute the Products with another gastrointestinal product, subject to the mutual consent of Ironwood and Allergan to the product and certain related key terms.

Subject to either Ironwood's or Allergan's rights of early termination, the Commercial Agreement will expire on February 26, 2019. Allergan may terminate the Commercial Agreement for convenience. The Share Adjustment Relief will, in the case of Allergan's termination for convenience and certain other specified circumstances, survive termination of the Commercial Agreement. The Commercial Agreement includes customary representations and warranties.

The foregoing summaries are qualified in their entirety by reference to the Amendment and the Commercial Agreement, which Ironwood expects to file as exhibits to its Quarterly Report on Form 10-Q for the quarter ending March 31, 2017.

LINZESS® is a registered trademark of Ironwood Pharmaceuticals, Inc. CANASA® is a registered trademark of Aptalis Pharma Canada ULC and DELZICOL® is a registered trademark of Allergan Pharmaceuticals International Limited. All rights reserved.

SIGNATURE

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.

IRONWOOD PHARMACEUTICALS, INC.

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| By: | /s/ Thomas Graney |
| Name: | Thomas Graney |
| Title: | Chief Financial Officer and Senior Vice President of Finance and Corporate Strategy |

Date: February 1, 2017