

IRONWOOD PHARMACEUTICALS INC
Form 8-K
June 03, 2016

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):

June 2, 2016

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

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(Registrant's telephone number,

including area code)

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 2.01 Completion of Acquisition or Disposition of Assets

On June 2, 2016 (the Effective Date), Ironwood Pharmaceuticals, Inc. (Ironwood) closed its previously announced transaction with Ardea Biosciences, Inc. (Ardea), an indirect wholly owned subsidiary of AstraZeneca PLC. On April 26, 2016 (the Execution Date), Ironwood and Ardea entered into a license agreement (the License Agreement) pursuant to which Ardea granted to Ironwood a license for the commercialization, and the development, manufacture and support of such commercialization, of products containing lesinurad as an active ingredient, including Zurampic® (the Products), in the United States. Subject to the terms of the License Agreement, Ardea will conduct certain development activities on Ironwood's behalf for (i) Zurampic (including the post-marketing requirement activities currently required by the Food and Drug Administration, for which Ironwood will reimburse Ardea up to \$100 million over up to ten years), and (ii) a fixed dose combination product with lesinurad and allopurinol as active ingredients, for which Ironwood will reimburse Ardea up to specified limits. Ironwood is responsible for any additional development of the Products for commercialization in the United States and for commercialization of the Products in the United States. In addition, under the terms of the License Agreement, Ironwood has the right of first negotiation and a right of last refusal with Ardea for the right to commercialize (and develop and manufacture for commercialization) products comprising verinurad as at least one of its active ingredients for the prevention or treatment of gout in the United States.

Pursuant to the terms of the License Agreement, Ironwood will make an upfront payment of \$100 million to Ardea within ten business days of the Effective Date, and will pay a royalty to Ardea in the single digits as a percentage of net sales of the Products in the United States (such royalty rate to be dependent on the aggregate net sales of the Products). Ardea is also eligible to receive \$15 million following approval of the new drug application for the fixed dose combination product with lesinurad and allopurinol as active ingredients, as well as up to an aggregate of \$150 million in additional commercial milestone payments over the term of the License Agreement, contingent on the achievement of certain net sales milestones in the United States. Subject to customary termination provisions, the License Agreement will continue as long as royalties are payable by Ironwood with respect to a Product.

In connection with the License Agreement, on the Execution Date Ironwood and AstraZeneca Pharmaceuticals LP (AZ Pharmaceuticals) entered into a commercial supply agreement, pursuant to which AZ Pharmaceuticals will manufacture and supply commercial supply of Zurampic to Ironwood (the Supply Agreement), and a transitional services agreement, pursuant to which AZ Pharmaceuticals will provide certain support services, including development, regulatory and commercial services, to Ironwood for Zurampic until such activities are transferred to Ironwood.

Ironwood, Ardea and AZ Pharmaceuticals have made customary representations and warranties and have agreed to certain customary covenants.

The foregoing summary is qualified in its entirety by reference to the License Agreement and the Supply Agreement, which Ironwood expects to file as exhibits to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2016.

The full text of the press release issued by Ironwood in connection with the closing of the transaction is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(a) Financial Statements of Business Acquired

If financial statements are required by Item 9.01(a) of Form 8-K, Ironwood will file such financial statements by amendment within 71 calendar days after the date that this Current Report on Form 8-K is required to be filed.

(b) Pro Forma Financial Information

If pro forma financial information is required by Item 9.01(b) of Form 8-K, Ironwood will file such pro forma financial information by amendment within 71 calendar days after the date that this Current Report on Form 8-K is required to be filed.

(d) Exhibits

| Exhibit No. | Description |
|-------------|---|
| 99.1 | Ironwood Pharmaceuticals, Inc. Press Release dated June 3, 2016 |

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.

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

Date: June 3, 2016

EXHIBIT INDEX

| Exhibit No. | Description |
|------------------------|---|
| 99.1 | Ironwood Pharmaceuticals, Inc. Press Release dated June 3, 2016 |