IRONWOOD PHARMACEUTICALS INC
Form 8-K
April 26, 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):

April 26, 2016

IRONWOOD PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-34620**	**04-3404176**
(State or other jurisdiction of incorporation)	*(Commission file number)*	*(I.R.S. Employer Identification Number)*

301 Binney Street	
Cambridge, Massachusetts	**02142**
(Address of principal executive offices)	*(Zip code)*

(617) 621-7722
(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))

Item 1.01 Entry into a Material Definitive Agreement

On April 26, 2016 (the Execution Date), Ironwood Pharmaceuticals, Inc. (Ironwood) and Ardea Biosciences, Inc. (Ardea), an indirect wholly owned subsidiary of AstraZeneca PLC, 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 will have 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 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 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. Upon termination of the waiting period established by the Hart-Scott-Rodino Antitrust Improvements Act of 1976, the transaction is expected to close in the second quarter of 2016.

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 entry into the License Agreement is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

This Current Report on Form 8-K contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including, but not limited to, statements about the expected timing of closing. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include, but are not limited to, the risk that the transaction does not close or is delayed. Applicable risks also include those that are listed under the heading Risk Factors and elsewhere in Ironwood s Annual Report on Form 10-K for the year ended December 31, 2015 and in our subsequent SEC filings. These forward-looking statements (except as otherwise noted) speak only as of the date of this Form 8-K, and Ironwood undertakes no obligation to update these forward-looking statements.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Ironwood Pharmaceuticals, Inc. Press Release dated April 26, 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:	/s/ Thomas Graney
Name:	Thomas Graney
Title:	Chief Financial Officer and Senior Vice President of Finance and Corporate Strategy

Date: April 26, 2016

EXHIBIT INDEX

Exhibit No.	Description
99.1	Ironwood Pharmaceuticals, Inc. Press Release dated April 26, 2016