IRONWOOD PHARMACEUTICALS INC
Form 8-K
August 06, 2018

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):

July 31, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Item 1.02 Termination of Material Definitive Agreement.

In July 2018, Ironwood Pharmaceuticals, Inc. (the Company) obtained and analyzed the results from the lesinurad franchise test markets. Data from the test markets did not meet expectations. In connection with the results, the Company s Board of Directors determined on July 31, 2018 to terminate the License Agreement, dated as of April 26, 2016, by and among the Company and Ardea Biosciences, Inc. (AstraZeneca), an indirect wholly-owned subsidiary of AstraZeneca PLC and, solely with respect to Section 13.1 of such License Agreement, Zeneca, Inc. (as amended, the License Agreement).

On August 2, 2018, the Company delivered to AstraZeneca notice of termination (the Notice) of the License Agreement, which termination is made with respect to all products under the License Agreement and expected to be effective 180 days from the Notice (the Termination). Under the License Agreement, AstraZeneca granted the Company an exclusive license to develop, manufacture, and commercialize in the U.S. products containing lesinurad as an active ingredient, including ZURAMPIC® and DUZALLO®.

Upon termination of the License Agreement, the Commercial Supply Agreement between AstraZeneca Pharmaceuticals LP and the Company, dated as of April 26, 2016 (the Commercial Supply Agreement), will terminate in accordance with its terms.

The foregoing description of the License Agreement and Commercial Supply Agreement do not purport to be complete; a summary of the material terms of the License Agreement and Commercial Supply Agreement were included in the Company s Current Report on Form 8-K filed on June 3, 2016, which is incorporated herein by reference and is qualified in its entirety by the full text of the License Agreement and Commercial Supply Agreement, copies of which were filed as Exhibits 10.1 and 10.2, respectively, to the Company s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2016.

Item 2.02 Results of Operations and Financial Condition.

On August 6, 2018, the Company issued a press release containing an update on its recent business activities as well as those for the quarter ended June 30, 2018. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The press release is being furnished pursuant to Item 2.02 of this Current Report on Form 8-K and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that Section, nor shall such document be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as shall be expressly set forth by specific reference in such filing.

Item 2.05 Costs Associated with Exit or Disposal Activities

In connection with the analysis of the data from the test markets and the Notice, the Company has reduced its projected revenue and net cash flow assumptions associated with its developed technology ZURAMPIC and developed technology DUZALLO intangible assets, as well as its

contingent consideration liability. Accordingly, the Company expects to record, during the three months ending September 30, 2018, a full intangible asset impairment of approximately $150.0 million and a gain on fair value remeasurement of contingent consideration of approximately $30.0 million.

As a result of the Termination, the Company expects to reduce its workforce by approximately 125 employees, primarily consisting of field-based sales employees. The Company estimates that it will incur aggregate charges in connection with the reduction in its workforce of approximately $9.0 million to $11.0 million for one-time employee severance and benefit costs, and approximately $1.0 million to $2.0 million for termination fees and other contract-related costs, primarily in 2018, nearly all of which are expected to result in cash expenditures.

The Company is continuing to review the potential impact of the Termination, and is unable to estimate any additional significant costs or charges at this time. If the Company subsequently determines that it will incur additional significant costs or charges, it will amend this Current Report on Form 8-K to disclose such information.

Item 2.06 Material Impairments

The information required by this Item 2.06 is included under Item 2.05 of 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 statements about the Company s expectations regarding the timing and financial impact to be incurred in connection with the Notice and Termination, as well as the timing of the completion of all impacts of the Termination. 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 those related to the difficulty of predicting the financial impact or timing of the Notice and Termination, including the risk that the actual financial and other impacts of the termination could vary materially from the outcomes anticipated; and the risks listed under the heading Risk Factors and elsewhere in the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, and in the Company s subsequent SEC filings. These forward-looking statements speak only as of the date of this Current Report on Form 8-K, and the Company 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 August 6, 2018

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.

Ironwood Pharmaceuticals, Inc.

Dated: August 6, 2018

By: /s/ Gina Consylman

Name: Gina Consylman

Title: Senior Vice President, Chief Financial Officer