IRONWOOD PHARMACEUTICALS INC
Form 8-K
January 08, 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):

January 8, 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 2.02 Results of Operations and Financial Condition.

On January 8, 2018, Ironwood Pharmaceuticals, Inc. (Ironwood) posted a presentation in the Investors section of its website at www.ironwoodpharma.com detailing its corporate strategy. Although it has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2017, Ironwood disclosed, as part of the presentation, for the full year ended December 31, 2017, expected United States (U.S.) net sales of LINZESS® (linaclotide) of approximately $700 million, expected LINZESS U.S. commercial margin of approximately 60%, and expected Ironwood revenue from linaclotide active pharmaceutical ingredient (API) sales to Astellas Pharma Inc. (Astellas), Ironwood s licensing partner for linaclotide in Japan, of greater than $20 million.

In addition, Ironwood disclosed, as part of the presentation, expected Ironwood revenue compound annual growth rate (CAGR) from the LINZESS U.S. collaboration with Allergan plc (Allergan) of approximately 75% for the year ended December 31, 2014 to the year ended December 31, 2017, expected LINZESS U.S. net sales CAGR of greater than 30% for the year ended December 31, 2014 to the year ended December 31, 2017, and expected Ironwood revenue from linaclotide API sales to Astellas of greater than $100 million for the period beginning on January 1, 2017 and ending on December 31, 2019.

LINZESS U.S. net sales are reported in the financial statements of Allergan and LINZESS U.S. commercial costs incurred by each of Allergan and Ironwood are reported in their respective financial statements. Allergan is Ironwood s collaboration partner for linaclotide in the U.S. and certain other territories.

LINZESS U.S. commercial margin is defined as commercial profit on sales of LINZESS as a percent of total LINZESS U.S. net sales. Commercial profit on sales of LINZESS is equal to LINZESS U.S. net sales less LINZESS U.S. commercial costs, such costs including (a) cost of goods sold incurred by Allergan and (b) selling, general and administrative expenses incurred by Allergan and Ironwood that are attributable to the cost-sharing arrangement between the parties. For purposes of calculating LINZESS U.S. commercial margin, the LINZESS commercial costs utilized assume the midpoint of Ironwood s previously guided range.

The information in this Item 2.02 and the presentation is unaudited, preliminary and based on estimates, and does not present all information necessary for an understanding of Ironwood s financial condition as of December 31, 2017 and its results of operations for the three months and year ended December 31, 2017. The audit of Ironwood and Allergan s respective financial statements for the year ended December 31, 2017 is ongoing and could result in changes to the information in this Item 2.02 and the presentation.

Further, the information in this Item 2.02 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 information 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. In addition, the contents of Ironwood s website, including the presentation, are not incorporated by reference into this Current Report on Form 8-K and you should not consider information provided on Ironwood s website to be part of this Current Report on Form 8-K.

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 Ironwood s expected revenue from linaclotide API sales to Astellas. 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 LINZESS demand in Japan and the effectiveness of commercialization efforts by Astellas; clinical development, manufacturing and formulation development; the risk that findings from Ironwood s completed nonclinical and clinical studies may not be replicated in later studies; efficacy, safety and tolerability of linaclotide; decisions by regulatory authorities; developments in the intellectual property landscape; challenges from and rights of competitors or potential competitors; and the risks listed under the heading Risk Factors and elsewhere in Ironwood s Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, and in Ironwood s subsequent SEC filings. These forward-looking statements (except as otherwise noted) speak only as of the date of this Current Report on Form 8-K, and Ironwood undertakes no obligation to update these forward-looking statements.

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.

Dated: January 8, 2018	By:	/s/ Gina Consylman
	Name:	Gina Consylman
	Title:	Senior Vice President, Chief Financial Officer