IRONWOOD PHARMACEUTICALS INC
Form 10-Q
May 10, 2016
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2016

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 001-34620

IRONWOOD PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**04-3404176**
(State or other jurisdiction of incorporation or organization)	(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)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): o Yes x No

As of May 2, 2016, there were 128,478,166 shares of Class A common stock outstanding and 16,126,146 shares of Class B common stock outstanding.

Table of Contents

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including the sections titled Management s Discussion and Analysis of Financial Condition and Results of Operations and Risk Factors , contains forward-looking statements. All statements contained in this Quarterly Report on Form 10-Q other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words may, continue, estimate, intend, plan, will, believe, project, expect, seek, anticipate and similar expressions may identify forward-looking statem absence of these words does not necessarily mean that a statement is not forward-looking.

These forward-looking statements include, among other things, statements about:

- the demand and market potential for linaclotide in the United States, or the U.S. (LINZESS®), in the European Union, or the E.U. (CONSTELLA®), and in other countries where it is approved for marketing, as well as the revenues therefrom;

- the timing, investment and associated activities involved in commercializing LINZESS by us and Allergan plc in the U.S.;

- the timing and execution of the launches and commercialization of CONSTELLA in the E.U.;

- the timing, investment and associated activities involved in developing, launching, and commercializing linaclotide by us and our partners worldwide;

- our ability and the ability of our partners to secure and maintain adequate reimbursement for linaclotide;

- the ability of our partners and third-party manufacturers to manufacture and distribute sufficient amounts of linaclotide active pharmaceutical ingredient, or API, drug product and finished goods on a commercial scale;

- our expectations regarding U.S. and foreign regulatory requirements for linaclotide and our product candidates, including our post-approval, nonclinical and clinical post-marketing plan with the Food and Drug Administration, or the FDA;

- our partners ability to obtain foreign regulatory approval of linaclotide and the ability of all of our product candidates to meet existing or future regulatory standards;

- the safety profile and related adverse events of linaclotide and our product candidates;

- the therapeutic benefits and effectiveness of linaclotide and our product candidates and the potential indications and market opportunities therefor;

- our ability to obtain and maintain intellectual property protection for linaclotide and our product candidates and the strength thereof;

- the ability of our partners to perform their obligations under our collaboration, license and other agreements with them, and our ability to achieve milestone and other payments under such agreements;

- our plans with respect to the development, manufacture or sale of our product candidates and the associated timing thereof, including the design and results of pre-clinical and clinical studies;

- the in-licensing or acquisition of externally discovered businesses, products or technologies, including expectations relating to the completion of, or the realization of the expected benefits from, such transactions;

- our expectations as to future financial performance, revenues, expense levels, payments, cash flows, profitability, tax obligations, capital raising and liquidity sources, and real estate needs, as well as the timing and drivers thereof;

- our ability to repay our outstanding indebtedness when due, or redeem or repurchase all or a portion of such debt, as well as the potential benefits of the note hedge transactions described herein;

- inventory levels and write downs and the drivers thereof, and inventory purchase commitments;

Table of Contents

- our ability to compete with other companies that are or may be developing or selling products that are competitive with our products and product candidates;

- the status of government regulation in the life sciences industry, particularly with respect to healthcare reform;

- trends and challenges in our potential markets;

- our ability to attract and motivate key personnel; and

- other factors discussed elsewhere in this Quarterly Report on Form 10-Q.

Any or all of our forward-looking statements in this Quarterly Report on Form 10-Q may turn out to be inaccurate. These forward-looking statements may be affected by inaccurate assumptions or by known or unknown risks and uncertainties, including the risks, uncertainties and assumptions identified under the heading Risk Factors in this Quarterly Report on Form 10-Q. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report on Form 10-Q may not occur as contemplated, and actual results could differ materially from those anticipated or implied by the forward-looking statements.

You should not unduly rely on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the U.S. Securities and Exchange Commission, or the SEC, after the date of this Quarterly Report on Form 10-Q.

NOTE REGARDING TRADEMARKS

LINZESS® and CONSTELLA® are trademarks of Ironwood Pharmaceuticals, Inc. Any other trademarks referred to in this Quarterly Report on Form 10-Q are the property of their respective owners. All rights reserved.

Table of Contents

IRONWOOD PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2016

TABLE OF CONTENTS

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. ***Financial Statements***

Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

(unaudited)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 280,926	$ 261,287
Available-for-sale securities	153,526	178,107
Accounts receivable	908	2,884
Related party accounts receivable, net	52,110	51,634
Prepaid expenses and other current assets	7,731	6,293
Restricted cash, current portion	500	
Total current assets	495,701	500,205
Restricted cash, net of current portion	8,247	8,747
Property and equipment, net	19,446	21,075
Convertible note hedges	77,688	86,466
Other assets	2,243	2,628
Total assets	$ 603,325	$ 619,121
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and related party accounts payable, net	$ 4,741	$ 8,589
Accrued research and development costs	6,625	4,245
Accrued expenses and other current liabilities	19,065	23,301
Current portion of capital lease obligations	2,447	2,631
Current portion of deferred rent	7,684	5,544
Current portion of deferred revenue	9,309	7,191
Current portion of PhaRMA notes payable	28,242	24,964
Total current liabilities	78,113	76,465
Capital lease obligations, net of current portion	253	306
Deferred rent, net of current portion	7,131	6,395
Deferred revenue, net of current portion		1,798
Note hedge warrants	68,193	75,328
Convertible senior notes	223,908	220,620
PhaRMA notes payable, net of current portion	124,672	132,964
Other liabilities	10,120	10,120
Commitments and contingencies		
Stockholders equity:		

Preferred stock, $0.001 par value, 75,000,000 shares authorized, no shares issued and outstanding		
Class A common stock, $0.001 par value, 500,000,000 shares authorized and 128,372,191 and 127,371,478 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	128	127
Class B common stock, $0.001 par value, 100,000,000 shares authorized and 16,126,146 and 15,870,356 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	16	16
Additional paid-in capital	1,214,174	1,205,183
Accumulated deficit	(1,123,412)	(1,110,115)
Accumulated other comprehensive income (loss)	29	(86)
Total stockholders equity	90,935	95,125
Total liabilities and stockholders equity	$ 603,325	$ 619,121

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2016	**2015**
Collaborative arrangements revenue	$ 66,042	$