

IRONWOOD PHARMACEUTICALS INC

Form 10-Q

August 07, 2015

Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2015

OR

**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**

(State or other jurisdiction of  
incorporation or organization)

**04-3404176**

(I.R.S. Employer  
Identification Number)

**301 Binney Street**

**Cambridge, Massachusetts**

(Address of Principal Executive Offices)

**02142**

(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  No

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  No

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

Accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Smaller reporting company

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

As of July 31, 2015, there were 126,676,412 shares of Class A common stock outstanding and 15,898,444 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 statements. The 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;
- 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 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;

## Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

- 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 and license agreements with them;
- 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;
- our expectations as to future financial performance, expense levels, payments, tax obligations, capital raising and liquidity sources, and real estate needs, as well as the timing 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;
- 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;

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

- 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.

Table of Contents

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 JUNE 30, 2015**

**TABLE OF CONTENTS**

	<b>Page</b>
	<b><u>PART I FINANCIAL INFORMATION</u></b>
<u>Item 1.</u>	<u>Financial Statements (unaudited)</u>
	<u>Condensed Consolidated Balance Sheets as of June 30, 2015 and December 31, 2014</u> 5
	<u>Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2015 and 2014</u> 6
	<u>Condensed Consolidated Statements of Comprehensive Loss for the Three and Six Months Ended June 30, 2015 and 2014</u> 7
	<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2015 and 2014</u> 8
	<u>Notes to Condensed Consolidated Financial Statements</u> 9
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> 27
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u> 37
<u>Item 4.</u>	<u>Controls and Procedures</u> 38
	<b><u>PART II OTHER INFORMATION</u></b>
<u>Item 1A.</u>	<u>Risk Factors</u> 39
<u>Item 6.</u>	<u>Exhibits</u> 57
	<u>Signatures</u> 58



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)**

	<b>June 30, 2015</b>	<b>December 31, 2014</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 256,450	\$ 74,297
Available-for-sale securities	236,865	174,037
Accounts receivable	1,057	10
Related party accounts receivable, net	25,992	25,829
Inventory		4,954
Prepaid expenses and other current assets	6,595	9,180
Total current assets	526,959	288,307
Restricted cash	8,147	8,147
Property and equipment, net	25,017	29,826
Convertible note hedges	90,314	
Other assets	3,504	3,042
Total assets	\$ 653,941	\$ 329,322
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable and related party accounts payable, net	\$ 6,650	\$ 9,762
Accrued research and development costs	5,530	3,574
Accrued expenses	18,945	22,612
Current portion of capital lease obligations	1,203	1,152
Current portion of deferred rent	5,009	4,992
Current portion of deferred revenue	7,191	7,191
Current portion of PhaRMA notes payable	17,571	11,258
Total current liabilities	62,099	60,541
Capital lease obligations, net of current portion	1,959	2,571
Deferred rent, net of current portion	8,821	10,522
Deferred revenue, net of current portion	5,393	8,989
Note hedge warrants	69,456	
Convertible senior notes	214,292	
PhaRMA notes payable, net of current portion	147,793	158,147
Other liabilities	3,845	
Commitments and contingencies		
Stockholders' equity:		

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form 10-Q

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 126,414,773 and 124,915,658 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively		126	125
Class B common stock, \$0.001 par value, 100,000,000 shares authorized and 16,153,146 and 15,907,272 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively		16	16
Additional paid-in capital		1,188,807	1,055,876
Accumulated deficit		(1,048,688)	(967,446)
Accumulated other comprehensive income (loss)		22	(19)
Total stockholders' equity		140,283	88,552
Total liabilities and stockholders' equity	\$	653,941	\$ 329,322

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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Collaborative arrangements revenue	\$ 27,744	\$ 6,840	\$ 56,676	\$ 21,445
Cost and expenses:				
Cost of revenue	8,150	10,518	8,162	12,442
Research and development	28,648	22,142	55,289	49,286
Selling, general and administrative	32,955	29,299	63,301	59,223
Total cost and expenses	69,753	61,959	126,752	120,951
Loss from operations	(42,009)	(55,119)	(70,076)	(99,506)
Other (expense) income:				
Interest expense	(5,874)	(5,303)	(11,094)	(10,586)
Interest and investment income	71	65	136	109
Loss on derivatives	(208)		(208)	
Other expense, net	(6,011)	(5,238)	(11,166)	(10,477)
Net loss	\$ (48,020)	\$ (60,357)	\$ (81,242)	\$ (109,983)
Net loss per share - basic and diluted	\$ (0.34)	\$ (0.44)	\$ (0.57)	\$ (0.82)
Weighted average number of common shares used in net loss per share basic and diluted:	142,098	138,315	141,690	134,053

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

Table of Contents**Ironwood Pharmaceuticals, Inc.****Condensed Consolidated Statements of Comprehensive Loss****(In thousands)****(unaudited)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Net loss	\$ (48,020)	\$ (60,357)	\$ (81,242)	\$ (109,983)
<b>Other comprehensive income:</b>				
Unrealized gains on available-for-sale securities	19	15	41	1
Total other comprehensive income	19	15	41	1
Comprehensive loss	\$ (48,001)	\$ (60,342)	\$ (81,201)	\$ (109,982)

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

Table of Contents**Ironwood Pharmaceuticals, Inc.****Condensed Consolidated Statements of Cash Flows****(In thousands)****(unaudited)**

	<b>Six Months Ended June 30,</b>	
	<b>2015</b>	<b>2014</b>
Cash flows from operating activities:		
Net loss	\$ (81,242)	\$ (109,983)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6,043	6,211
Share-based compensation expense	12,329	12,086
Change in fair value of note hedge warrants	(1,393)	
Change in fair value of convertible note hedges	1,601	
Write-down of inventory to net realizable value and loss on non-cancelable purchase commitments	8,150	8,894
Accretion of discount/premium on investment securities	298	466
Non-cash interest expense	1,170	788
Changes in assets and liabilities:		
Accounts receivable and related party accounts receivable	(1,210)	(1,242)
Prepaid expenses and other current assets	2,676	(84)
Inventory	4	272
Other assets	(462)	(116)
Accounts payable, related party accounts payable and accrued expenses	(5,978)	(7,691)
Accrued research and development costs	1,956	(1,177)
Deferred revenue	(3,596)	(1,164)
Deferred rent	(1,684)	(1,364)
Net cash used in operating activities	(61,338)	(94,104)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(202,091)	(206,943)
Sales and maturities of available-for-sale securities	139,006	121,969
Purchases of property and equipment	(2,840)	(2,023)
Proceeds from sale of property and equipment	27	
Net cash used in investing activities	(65,898)	(86,997)
Cash flows from financing activities:		
Proceeds from issuance of convertible senior notes	335,699	
Proceeds from issuance of common stock		190,428
Proceeds from issuance of note hedge warrants	70,849	
Purchase of convertible note hedges	(91,915)	
Costs associated with issuance of convertible senior notes	(10,930)	
Proceeds from exercise of stock options and employee stock purchase plan	10,941	11,064
Payments on capital leases	(561)	(524)
Principal payments on PhaRMA notes	(4,694)	
Net cash provided by financing activities	309,389	