

IRONWOOD PHARMACEUTICALS INC

Form 10-Q

August 05, 2014

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**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, 2014

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

Smaller reporting company

(Do not check if a 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 25, 2014, there were 120,866,472 shares of Class A common stock outstanding and 18,491,673 shares of Class B common stock outstanding.

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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 Actavis plc in the U.S., including our direct-to-consumer education program;
- 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, to understand linaclotide's efficacy and safety in pediatric patients;
- 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;

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- the safety profile and related adverse events of linaclotide and our product candidates;
- the therapeutic benefits and effectiveness of linaclotide and our product candidates;
- our ability to obtain and maintain intellectual property protection for linaclotide and our product candidates;
- 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, as well as the in-licensing or acquisition of externally discovered programs;
- our expectations as to future financial performance, expense levels and payments, capital raising and liquidity sources, and real estate needs, as well as the timing 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;
- 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.

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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 United States 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.

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FOR THE QUARTER ENDED JUNE 30, 2014

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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)**

	June 30,		December 31,
	2014		2013
Assets			
Current assets:			
Cash and cash equivalents	\$ 95,357	\$	75,490
Available-for-sale securities	206,621		122,112
Accounts receivable			513
Related party accounts receivable, net	4,455		2,700
Inventory	12,989		22,145
Prepaid expenses and other current assets	6,338		6,168
Total current assets	325,760		229,128
Restricted cash	8,147		8,147
Property and equipment, net	33,560		37,376
Other assets	3,597		4,311
Total assets	\$ 371,064	\$	278,962
Liabilities and Stockholders Equity			
Current liabilities:			
Accounts payable	\$ 3,393	\$	10,139
Related party accounts payable, net	5		48
Accrued research and development costs	2,235		3,412
Accrued expenses	19,048		18,438
Current portion of capital lease obligations	1,104		1,139
Current portion of deferred rent	2,817		2,790
Current portion of deferred revenue	6,447		5,074
Current portion of notes payable	6,577		
Total current liabilities	41,626		41,040
Capital lease obligations, net of current portion	3,158		3,134
Deferred rent, net of current portion	7,431		8,822
Deferred revenue, net of current portion	8,879		11,416
Notes payable, net of current portion	168,139		174,672
Other liabilities			1,653
Commitments and contingencies			
Stockholders' equity:			
Preferred stock, \$0.001 par value, 75,000,000 shares authorized, no shares issued and outstanding			
	120		103

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Class A common stock, \$0.001 par value, 500,000,000 shares authorized and 120,635,892 and 102,803,093 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively

Class B common stock, \$0.001 par value, 100,000,000 shares authorized and 18,497,673 and 18,362,037 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively

Additional paid-in capital	18	18
	1,029,501	815,930
Accumulated deficit	(887,811)	(777,828)
Accumulated other comprehensive income	3	2
Total stockholders' equity	141,831	38,225
Total liabilities and stockholders' equity	\$ 371,064	\$ 278,962

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		Six Months Ended	
	June 30,		June 30,	
	2014	2013	2014	2013
Collaborative arrangements revenue	\$ 6,840	\$ 9,663	\$ 21,445	\$ 12,918
Cost and expenses:				
Cost of revenue	10,518	3,418	12,442	4,649
Research and development	22,142	24,093	49,286	56,846
Selling, general and administrative	29,299	30,870	59,223	64,244
Collaboration expense		11,162		35,892
Total cost and expenses	61,959	69,543	120,951	161,631
Loss from operations	(55,119)	(59,880)	(99,506)	(148,713)
Other income (expense):				
Interest expense	(5,303)	(5,318)	(10,586)	(10,439)
Interest and investment income	65	49	109	101
Other expense, net	(5,238)	(5,269)	(10,477)	(10,338)
Net loss	\$ (60,357)	\$ (65,149)	\$ (109,983)	\$ (159,051)
Net loss per share - basic and diluted	\$ (0.44)	\$ (0.57)	\$ (0.82)	\$ (1.44)
Weighted average number of common shares used in net loss per share basic and diluted:	138,315	113,441	134,053	110,772

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)**

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2014	2013	2014	2013
Net loss	\$ (60,357)	\$ (65,149)	\$ (109,983)	\$ (159,051)
Other comprehensive income (loss):				
Unrealized gains (losses) on available-for-sale securities	15	(13)	1	(6)
Total other comprehensive income (loss)	15	(13)	1	(6)
Comprehensive loss	\$ (60,342)	\$ (65,162)	\$ (109,982)	\$ (159,057)

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)**

	Six Months Ended	
	June 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$ (109,983)	\$ (159,051)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6,211	5,577
Share-based compensation expense	12,086	10,092
Write-down of inventory to net realizable value	8,894	
Accretion of discount/premium on investment securities	466	887
Non-cash interest expense	788	937
Changes in assets and liabilities:		
Accounts receivable and related party accounts receivable	(1,242)	(3,811)
Restricted cash		(500)
Prepaid expenses and other current assets	(84)	(3,447)
Inventory	272	(10,197)
Other assets	(116)	72
Accounts payable and accrued expenses	(7,691)	(10,098)
Accrued research and development costs	(1,177)	(718)
Deferred revenue	(1,164)	(2,379)
Deferred rent	(1,364)	(1,348)
Other liabilities		661
Net cash used in operating activities	(94,104)	(173,323)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(206,943)	(144,584)
Sales and maturities of available-for-sale securities	121,969	94,142
Purchases of property and equipment	(2,023)	(4,890)
Net cash used in investing activities	(86,997)	(55,332)
Cash flows from financing activities:		
Proceeds from issuance of common stock	190,428	137,766
Proceeds from issuance of notes payable		175,000
Costs associated with issuance of notes payable		(7,717)
Proceeds from exercise of stock options and employee stock purchase plan	11,064	6,515
Payments on capital leases	(524)	(148)
Net cash provided by financing activities	200,968	311,416
Net increase in cash and cash equivalents	19,867	82,761
Cash and cash equivalents, beginning of period	75,490	136,700
Cash and cash equivalents, end of period	\$ 95,357	\$ 219,461

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

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Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of Business

Overview

Ironwood Pharmaceuticals, Inc. (the Company) is an entrepreneurial pharmaceutical company focused on creating medicines that make a difference for patients, building value to earn the continued support of its fellow shareholders, and empowering its team to passionately pursue excellence. The Company's core strategy is to establish a leading gastrointestinal (GI) therapeutics company, leveraging its development and commercial capabilities in addressing GI disorders as well as its pharmacologic expertise in guanylate cyclase (GC) pathways.