IRONWOOD PHARMACEUTICALS INC
Form 10-Q
August 08, 2013
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# 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 June 30, 2013**

**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 July 30, 2013, there were 95,321,057 shares of Class A common stock outstanding and 25,472,529 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 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 market potential for LINZESS® (linaclotide) in the U.S. and CONSTELLA® (linaclotide) in the E.U.;

- the timing, investment and associated activities involved in commercializing linaclotide by us and Forest Laboratories, Inc. in the U.S. and by our partners in other countries in the world;

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

- 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, 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;

- the safety profile and related adverse events of linaclotide;

- the ability of our partners to perform their obligations under our collaboration and license agreements with them;

- the therapeutic benefits and effectiveness of linaclotide and our product candidates;

- our plans with respect to the development, manufacture or sale of our product candidates, as well as the in-licensing or acquisition of externally discovered programs;

- our expectations as to future financial performance, expense levels, capital raising and liquidity sources;

- 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.

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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**

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**IRONWOOD PHARMACEUTICALS, INC.**

**QUARTERLY REPORT ON FORM 10-Q**

**FOR THE QUARTER ENDED JUNE 30, 2013**

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## 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, 2013 | December 31, 2012 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 219,461 | $ 136,700 |
| Available-for-sale securities | 81,077 | 31,528 |
| Accounts receivable | | 457 |
| Related party accounts receivable, net | 5,298 | 1,030 |
| Inventory | 20,379 | 6,699 |
| Prepaid expenses and other current assets | 9,565 | 8,026 |
| Total current assets | 335,780 | 184,440 |
| Restricted cash | 8,147 | 7,647 |
| Property and equipment, net | 35,013 | 37,537 |
| Other assets | 5,091 | 283 |
| Total assets | $ 384,031 | $ 229,907 |
| **Liabilities and Stockholders Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 6,569 | $ 14,217 |
| Related party accounts payable, net | 7,268 | 7,509 |
| Accrued research and development costs | 4,946 | 5,664 |
| Accrued expenses | 17,124 | 21,171 |
| Current portion of capital lease obligations | 223 | 261 |
| Current portion of deferred rent | 2,762 | 2,735 |
| Current portion of deferred revenue | 5,074 | 3,381 |
| Total current liabilities | 43,966 | 54,938 |
| Capital lease obligations, net of current portion | 198 | 308 |
| Deferred rent, net of current portion | 10,218 | 11,593 |
| Deferred revenue, net of current portion | 13,952 | 18,024 |
| Notes payable | 174,628 | |
| Other liabilities | 1,653 | 992 |
| Commitments and contingencies | | |
| Stockholders equity: | | |
| Preferred stock, $0.001 par value, 75,000,000 shares authorized, no shares issued and outstanding at June 30, 2013 and December 31, 2012 | | |
| Class A common stock, $0.001 par value, 500,000,000 shares authorized and 95,257,389 and 78,253,074 shares issued and outstanding at June 30, 2013 and December 31, 2012, | 96 | 78 |

| | | | | |
|---|---|---|---|---|
| respectively | | | | |
| Class B common stock, $0.001 par value, 100,000,000 shares authorized and 25,395,947 and 29,512,253 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively | | 25 | | 30 |
| Additional paid-in capital | | 803,363 | | 648,955 |
| Accumulated deficit | | (664,067) | | (505,016) |
| Accumulated other comprehensive income (loss) | | (1) | | 5 |
| Total stockholders equity | | 139,416 | | 144,052 |
| Total liabilities and stockholders equity | $ | 384,031 | $ | 229,907 |

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

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**Ironwood Pharmaceuticals, Inc.**

**Condensed Consolidated Statements of Operations**

**(In thousands, except share and per share amounts)**

**(unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2013** | **2012** | **2013** | **2012** |
| Collaborative arrangements revenue | $ 9,663 | $ 14,604 | $ 12,918 | $ 26,852 |
| Cost and expenses: | | | | |
| Cost of revenue | 3,418 | | 4,649 | |