IRONWOOD PHARMACEUTICALS INC
Form 10-Q
November 06, 2018
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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 September 30, 2018

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	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 No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files): Yes No

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

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.

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 November 1, 2018, there were 140,082,377 shares of Class A common stock outstanding and 13,976,855 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 but 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 our products in the countries where they are 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 Europe and LINZESS in Japan;
- the timing, investment and associated activities involved in developing, obtaining regulatory approval for, launching, and commercializing our products and product candidates by us and our partners worldwide;
- our ability and the ability of our partners to secure and maintain adequate reimbursement for our products;
- our ability and the ability of our partners and third parties to manufacture and distribute sufficient amounts of linaclotide active pharmaceutical ingredient, drug product and finished goods, as applicable, on a commercial scale;
- our expectations regarding U.S. and foreign regulatory requirements for our products and our product candidates, including our post-approval development and regulatory requirements;
- the ability of our product candidates to meet existing or future regulatory standards;
- the safety profile and related adverse events of our products and our product candidates;
- the therapeutic benefits and effectiveness of our products and our product candidates and the potential indications and market opportunities therefor;

- our and our partners' ability to obtain and maintain intellectual property protection for our products and our product candidates and the strength thereof, as well as Abbreviated New Drug Applications filed by generic drug manufacturers and potential U.S. Food and Drug Administration approval thereof, and associated patent infringement suits that we have filed or may file, or other action that we may take against such companies, and the timing and resolution thereof;

- our and our partners' ability to perform our respective obligations under our collaboration, license and other agreements, 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, as well as partnering arrangements, including expectations relating to the completion of, or the realization of the expected benefits from, such transactions;

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

- 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, or asset impairments, and the drivers thereof, and inventory purchase commitments;

- 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;

- the proposed separation of the Company’s operations into two independent, publicly traded companies, including the completion and timing of the separation, the business and operations of each company and any benefits or costs of the separation, including the tax treatment;

- the timing and benefits and costs associated with the termination of the lesinurad license agreement and the transition of the lesinurad franchise to AstraZeneca; 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

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IRONWOOD PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2018

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June 30,

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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)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 141,562	$ 125,736
Available-for-sale securities	19,836	95,680
Accounts receivable, net	10,193	3,190
Related party accounts receivable, net	55,182	78,967
Inventory, net	76	735
Prepaid expenses and other current assets	21,699	7,288
Total current assets	248,548	311,596
Restricted cash	7,676	7,056
Property and equipment, net	16,161	17,274
Convertible note hedges	142,774	108,188
Intangible assets, net	—	159,905
Goodwill	785	785
Other assets	708	870
Total assets	$ 416,652	$ 605,674
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable and related party accounts payable, net	$ 9,332	$ 15,958
Accrued research and development costs	5,088	7,313
Accrued expenses and other current liabilities	44,958	38,237
Capital lease obligations	171	4,077
Current portion of deferred rent	247	195
Current portion of 2026 Notes	39,191	—
Current portion of contingent consideration	74	247
Deferred revenue	13,521	—
Total current liabilities	112,582	66,027
Deferred rent, net of current portion	6,113	5,449
Contingent consideration, net of current portion	—	31,011
Note hedge warrants	122,778	92,188
Convertible senior notes	261,355	249,193
2026 Notes, net of current portion	108,589	146,898
Other liabilities	2,530	5,060
Commitments and contingencies		

Stockholders' (deficit) 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 139,805,308 and 136,465,526 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	140	137
Class B common stock, $0.001 par value, 100,000,000 shares authorized and 13,976,855 shares issued and outstanding at September 30, 2018 and 13,983,762 shares issued outstanding at December 31, 2017	14	14
Additional paid-in capital	1,378,195	1,318,536
Accumulated deficit	(1,575,635)	(1,308,760)
Accumulated other comprehensive loss	(9)	(79)
Total stockholders' (deficit) equity	(197,295)	9,848
Total liabilities and stockholders' (deficit) equity	$ 416,652	$ 605,674

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 per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Collaborative arrangements revenue	$ 54,194	$ 76,652	$ 188,487	$ 187,156
Product revenue, net	1,235	682	2,966	1,436
Sale of active pharmaceutical ingredient	10,257	9,491	24,494	15,476
Total revenues	65,686	86,825	215,947	204,068
Cost and expenses:				
Cost of revenues, excluding amortization of acquired intangible assets	4,616	6,080	11,288	10,113
Write-down of commercial supply and inventory to net realizable value and (settlement) loss on non-cancellable purchase commitments	(1,589)	71	247	167
Research and development				