

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

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FILER

IRONWOOD PHARMACEUTICALS INC

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**Current Report Pursuant to
Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported):

November 7, 2011

IRONWOOD PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of incorporation
or organization)

001-34620
(Commission file number)

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)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition.

On November 7, 2011, Ironwood Pharmaceuticals, Inc. issued a press release containing an update on its recent business activities as well as those for the quarter ended September 30, 2011. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The press release is being furnished pursuant to Item 2.02 of this Current Report on Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that Section, nor shall such document be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Ironwood Pharmaceuticals, Inc. Press Release dated November 7, 2011

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Ironwood Pharmaceuticals, Inc.

Dated: November 7, 2011

By: /s/ Michael J. Higgins

Name: Michael J. Higgins

Title: Chief Operating Officer and Chief
Financial Officer

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FOR IMMEDIATE RELEASE

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**IRONWOOD PHARMACEUTICALS PROVIDES
THIRD QUARTER 2011 INVESTOR UPDATE**

CAMBRIDGE, Mass., November 7, 2011 – Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) today provided an update on its third quarter 2011 and recent business activities.

Third Quarter 2011 and Recent Highlights

Linaclotide

- At the end of September, Ironwood's European partner, Almirall, S.A., submitted a Market Authorization Application (MAA) for linaclotide to the European Medicines Agency (EMA) for the treatment of irritable bowel syndrome with constipation (IBS-C). The submission includes efficacy and safety data from a Phase 3 program that comprised two double-blind placebo-controlled clinical trials measured against the endpoints required by the EMA and two open-label long term safety studies. A total of more than 1,600 patients with IBS-C received a once-daily dose of either linaclotide or placebo across the two Phase 3 clinical trials. Additionally, over 3,200 patients have enrolled in the ongoing open-label long term safety studies, and more than 2,000 of those patients have received linaclotide for at least 12 months.
- In October, the U.S. Food and Drug Administration (FDA) accepted for review the New Drug Application (NDA) submitted by Ironwood and its U.S. partner, Forest Laboratories, Inc., for linaclotide for the treatment of IBS-C and chronic constipation (CC). With a standard 10-month review timeline, the FDA Prescription Drug User Fee Act (PDUFA) target action date is expected to occur in June 2012.

Pipeline

- Ironwood continues to advance its pipeline, which includes product candidates and research efforts focused on gastrointestinal disease, pain and inflammation, respiratory disease, and cardiovascular disease.

Corporate

- Ironwood ended the third quarter of 2011 with approximately \$175 million of cash, cash equivalents, and available-for-sale securities. Ironwood used approximately \$68 million of cash for operations for the nine months ended September 30, 2011. Based on its

current operating plan, Ironwood continues to target ending fiscal year 2011 with greater than \$150 million of cash, cash equivalents, and available-for-sale securities.

Conference Call Information

Ironwood will host a conference call and webcast at 4:30 p.m. Eastern Time, November 7, to discuss its business activities, including its commercial strategy for linaclotide. Individuals interested in participating in the call should dial (888) 663-2242 (U.S. and Canada) or (913) 312-1516 (international) using conference ID number 3637845. To access the webcast, please visit the Investors section of Ironwood's website at www.ironwoodpharma.com at least 15 minutes prior to the start of the call to ensure adequate time for any software downloads that may be required. The call will be available for replay via telephone starting today at approximately 7:30 p.m. Eastern Time, running through 11:59 p.m. Eastern Time on November 21, 2011. To listen to the replay, dial (888) 203-1112 (U.S. and Canada) or (719) 457-0820 (international) using conference ID number 3637845. The archived webcast will be available on Ironwood's website for 14 days beginning approximately one hour after the call.

About Linaclotide

Linaclotide, an investigational drug, is an agonist of the guanylate cyclase type-C (GC-C) receptor located on the luminal surface of the intestine. In preclinical models, linaclotide reduced visceral hypersensitivity, increased fluid secretion, and accelerated intestinal transit. The effects on secretion and transit are mediated through cyclic guanosine monophosphate (cGMP), which is also believed to modulate the activity of local nerves to reduce pain. Linaclotide is an orally delivered peptide that acts locally in the gut with no measurable systemic exposure at therapeutic doses and is intended for once-daily administration. An issued composition of matter patent for linaclotide provides protection to 2025 in the United States. Ironwood and Forest plan to co-promote linaclotide in the United States. Ironwood has out-licensed linaclotide to Almirall for European development and commercialization, and to Astellas Pharma Inc. for development and commercialization in Japan, Indonesia, Korea, the Philippines, Taiwan, and Thailand.

About Irritable Bowel Syndrome with Constipation (IBS-C)

IBS-C is a chronic functional gastrointestinal disorder characterized by abdominal pain, abdominal discomfort, and bloating associated with altered bowel habits, and as many as 11 million people in the U.S. suffer from it. IBS-C can have a negative impact on daily living. There are currently few available therapies to treat this disorder.

About Chronic Constipation (CC)

As many as 34 million Americans suffer from symptoms associated with CC and 8.5 million patients have sought treatment. Patients with CC often experience hard and lumpy stools, straining during defecation, a sensation of incomplete evacuation, and fewer than three bowel

movements per week, as well as abdominal discomfort and bloating. There is a high rate of dissatisfaction with currently available treatments for CC.

About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ: IRWD) is an entrepreneurial pharmaceutical company dedicated to the art and science of great drugmaking. Linaclotide, Ironwood's GC-C agonist, is an investigational drug for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC). The efficacy portion of linaclotide's development program has been completed and supports the recently submitted NDA submission for both indications, as well as the MAA submission in Europe for the IBS-C indication. Ironwood also

has a growing pipeline of additional drug candidates in earlier stages of development. Ironwood is located in Cambridge, Mass. To learn more, visit www.ironwoodpharma.com.

This press release contains forward looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including, but not limited to, the FDA PDUFA target action date, linaclotide's potential as a treatment for IBS-C or chronic constipation, and our targeted cash-on-hand for the end of 2011. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include the risks that serious adverse events arise in patients that are deemed to be definitely or probably related to linaclotide treatment, the incidence or severity of diarrhea in patients treated with linaclotide is higher than expected, the FDA convenes an advisory committee that does not recommend approval of linaclotide or that recommends modifications to the proposed label for linaclotide, the FDA issues a complete response letter for linaclotide, and advancements in our development pipeline do not proceed as expected, as well as risks related to the difficulty of predicting regulatory approvals and the acceptance of and demand for new pharmaceutical products. Applicable risks also include those that are listed in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, in addition to the risk factors that are listed from time to time in Ironwood Pharmaceuticals' Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and any subsequent SEC filings. We undertake no obligation to update these forward-looking statements to reflect events or circumstances occurring after this press release. These forward-looking statements speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement.

SOURCE: Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets

(in thousands)
(unaudited)

	September 30, 2011	December 31, 2010
Assets		
Cash, cash equivalents and available-for-sale securities	\$ 175,129	\$ 248,027
Accounts receivable, net	741	2,895
Prepaid expenses and other assets	2,896	8,153
Total current assets	178,766	259,075
Property and equipment, net	32,875	34,369
Other assets	7,839	7,921
Total assets	\$ 219,480	\$ 301,365
Liabilities and Stockholders' Equity		
Accounts payable and accrued expenses	\$ 19,266	\$ 21,380
Current portion of capital lease obligations	228	197
Current portion of deferred rent	3,707	2,799
Current portion of deferred revenue	47,647	40,050
Total current liabilities	70,848	64,426
Capital lease obligations	481	393
Deferred rent	13,308	14,612
Deferred revenue	21,913	62,383
Total stockholders' equity	112,930	159,551
Total liabilities and stockholders' equity	\$ 219,480	\$ 301,365

Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Revenue	\$ 12,218	\$ 9,059	\$ 33,717	\$ 27,085
Operating expenses:				
Research and development	22,905	18,742	61,869	56,188
General and administrative	10,929	6,482	30,958	18,868
Total operating expenses	<u>33,834</u>	<u>25,224</u>	<u>92,827</u>	<u>75,056</u>
Loss from operations	(21,616)	(16,165)	(59,110)	(47,971)
Other income (expense), net	986	107	1,235	267
Net loss from continuing operations before income tax expense (benefit)	(20,630)	(16,058)	(57,875)	(47,704)
Income tax expense (benefit)	3	(2,944)	3	(2,944)
Net loss from continuing operations	(20,633)	(13,114)	(57,878)	(44,760)
Net income from discontinued operations	-	6,367	-	4,551
Net loss	(20,633)	(6,747)	(57,878)	(40,209)
Net income from discontinued operations attributable to noncontrolling interest	-	(1,523)	-	(1,121)
Net loss attributable to Ironwood Pharmaceuticals, Inc.	<u>\$ (20,633)</u>	<u>\$ (8,270)</u>	<u>\$ (57,878)</u>	<u>\$ (41,330)</u>
Net income (loss) per share attributable to Ironwood Pharmaceuticals, Inc.—basic and diluted:				
Continuing operations	\$ (0.21)	\$ (0.13)	\$ (0.58)	\$ (0.52)
Discontinued operations	-	0.05	-	0.04
Net loss per share	<u>\$ (0.21)</u>	<u>\$ (0.08)</u>	<u>\$ (0.58)</u>	<u>\$ (0.48)</u>
Weighted average number of common shares used in net income (loss) per share attributable to Ironwood Pharmaceuticals, Inc.—basic and diluted	100,174,100	97,925,657	99,699,545	86,633,080