Ironwood Pharmaceuticals Provides Second Quarter 2011 Investor Update

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) today provided an update on its second quarter 2011 and recent business activities.

Second Quarter 2011 and Recent Highlights

Linaclotide

- Ironwood and its U.S. partner, Forest Laboratories, Inc., recently submitted a New Drug Application (NDA) for linaclotide to the U.S. Food and Drug Administration (FDA) for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC). The submission includes efficacy and safety data from a Phase 3 program that comprised four double-blind placebo-controlled clinical trials and two open-label long term safety studies. A total of more than 2,800 patients received a once-daily dose of either linaclotide or placebo across the four placebo-controlled clinical trials: two trials in patients with IBS-C and two trials in patients with CC. Over 3,200 patients have enrolled in the long term safety studies, and more than 1,100 of those patients have received linaclotide for at least 12 months.
- Ironwood's European partner, Almirall, S.A., is on track to submit a Market Authorization Application (MAA) for linaclotide to the European Medicines Agency for IBS ‑ C in the second half of 2011.
- The results of the two Phase 3 clinical trials in patients with CC are published in this week's *New England Journal of Medicine.* The published data show that in clinical trials, treatment with once-daily dosing of linaclotide over 12 weeks achieved statistical significance for the primary endpoint of 12-week complete spontaneous bowel movement (CSBM) overall responder. In both trials, statistical significance was achieved for all pre-specified secondary endpoints, which included measures of bloating, abdominal discomfort, and average weekly CSBMs. In these two Phase 3 clinical trials, the most commonly reported adverse event was diarrhea. Most events of diarrhea were reported as mild to moderate. The topline data were first presented at the Digestive Disease Week annual meeting in May 2010.
- Ironwood entered into commercial supply agreements with PolyPeptide Laboratories, Inc. and Polypeptide Laboratories (Sweden) AB and with Roche Colorado Corporation, each for the manufacture of the linaclotide drug substance that will be incorporated into the finished product for commercialization. Ironwood also entered into an agreement with Almac Pharma Services Limited to complete the manufacturing process of linaclotide in the parts of the world outside of the partnered territories of North America, Europe, Japan, and certain other Asian countries and to introduce redundancy into the supply chain within these partnered territories.

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. In July 2011, Ironwood entered into a collaboration with Depomed, Inc. to utilize Depomed's Acuform™ gastric retentive drug delivery technolo to enable an Ironwood early stage, non-GC-C development program directed at a gastrointestinal disorder.

Corporate

- Ironwood ended the second quarter of 2011 with approximately $201 million of cash, cash equivalents, and available-for-sale securities. Ironwood used approximately $42 million of cash for operations for the six months ended June 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 8:30 a.m. Eastern Time today to discuss its business activities. Individuals interested in participating in the call should dial (877) 847-5946 (U.S. and Canada) or (970) 315-0447 (international) using conference ID number 90255369. 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 11:30 a.m. Eastern Time, running through 11:59 p.m. Eastern Time on August 25, 2011. To listen to the replay, dial (855) 859-2056 (U.S. and

Canada) or (404) 537-3406 (international) using conference ID number 90255369. 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. The efficacy portion of linaclotide's development program has been completed and supports the recently submitted NDA for linaclotide for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation, as well as the MAA submission for the IBS-C indication. An issued composition of matter patent for linaclotide provides protection to 2025. Ironwood and Forest are co-developing and, if it is approved, will 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.

Based on improved methods used to measure linaclotide content, the numbers that define the linaclotide dose are being adjusted from 133 mcg to 145 mcg and from 266 mcg to 290 mcg. These methods are based on current industry best practices. The adjustment does not reflect a change in the actual amount of linaclotide used in clinical trials. These 145 mcg and 290 mcg designations are utilized in the recently published *NEJM* article and the recently submitted NDA.

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 an 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. The efficacy portion of linaclotide's development program has been completed and supports the recently submitted NDA for both indications, as well as the MAA submission 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 timing of the filing of a Marketing Authorization Application for linaclotide, linaclotide's potential as a treatment for IBS-C or chronic constipation, our recent collaboration with Depomed and its potential benefit to our development pipeline, and our targeted cash-on-hand for 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 Almirall's MAA submission does not progress as expected, 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, 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 March 31, 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.

Condensed Consolidated Balance Sheets

(in thousands)
(unaudited)

	June 30, 2011	December 31, 2010
Assets		
Cash, cash equivalents and available-for-sale securities	$201,097	$ 248,027
Accounts receivable, net	2,627	2,895
Prepaid expenses and other assets	4,658	8,153
Total current assets	208,382	259,075
Property and equipment, net	33,484	34,369
Other assets	7,861	7,921
Total assets	$249,727	$ 301,365
Liabilities and Stockholders' Equity		
Accounts payable, accrued expenses and other current liabilities	$ 18,778	$ 21,380
Current portion of capital lease obligations	229	197
Current portion of deferred rent	3,282	2,799
Current portion of deferred revenue	48,555	40,050
Total current liabilities	70,844	64,426
Capital lease obligations	540	393
Deferred rent	14,379	14,612
Deferred revenue	33,144	62,383
Other liabilities	703	—
Total stockholders' equity	130,117	159,551
Total liabilities and stockholders' equity	$249,727	$ 301,365

Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenue	$ 11,262	$ 9,188	$ 21,499	$ 18,026
Operating expenses:				
Research and development	19,409	19,897	38,964	37,446
General and administrative	10,805	6,601	20,029	12,386
Total operating expenses	30,214	26,498	58,993	49,832
Loss from operations	(18,952)	(17,310)	(37,494)	(31,806)
Other income (expense), net	108	145	249	160
Net loss from continuing operations	(18,844)	(17,165)	(37,245)	(31,646)
Net loss from discontinued operations	—	(44)	—	(1,816)
Net loss	(18,844)	(17,209)	(37,245)	(33,462)
Net loss from discontinued operations attributable to noncontrolling interest	—	73	—	402
Net loss attributable to Ironwood Pharmaceuticals, Inc.	$ (18,844)	$ (17,136)	$ (37,245)	$ (33,060)
Net loss per share attributable to Ironwood Pharmaceuticals, Inc.—basic and diluted:				
Continuing operations	$ (0.19)	$ (0.18)	$ (0.37)	$ (0.39)
Discontinued operations	—	—	—	(0.02)
Net loss per share	$ (0.19)	$ (0.18)	$ (0.37)	$ (0.41)
Weighted average number of common shares used in net loss per share attributable to Ironwood Pharmaceuticals, Inc.—basic and diluted	99,674,969	97,642,330	99,458,336	80,893,200

Ironwood Pharmaceuticals
Susan Brady, 617-621-8304
sbrady@ironwoodpharma.com

Source: Ironwood Pharmaceuticals, Inc.