Ironwood Pharmaceuticals Provides First Quarter 2010 Investor Update

CAMBRIDGE, Mass., May 11, 2010 (BUSINESS WIRE) -- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) today provided an update on its business activities for the first quarter of 2010.

First Quarter 2010 Highlights

Linaclotide

- In March, the final patients were enrolled into each of the two confirmatory Phase 3 clinical trials being carried out by Ironwood and its U.S. partner, Forest Laboratories, Inc., to assess the efficacy and safety of linaclotide in patients with irritable bowel syndrome with constipation (IBS-C). Ironwood and Forest anticipate that the top-line data from the two trials will be reported separately in the fourth quarter of 2010. Ironwood and Forest are targeting a New Drug Application submission for both IBS-C and chronic constipation (CC) in the middle of 2011.
- At the end of March, the U.S. Food and Drug Administration (FDA) issued draft guidance on the design of clinical trials for IBS-C. The draft guidance calls for co-primary efficacy endpoints assessing abdominal pain (greater-than or equal to 30 percent average weekly reduction versus baseline) and stool frequency (increase of one or more complete spontaneous bowel movements per week versus baseline). The co-primary endpoints in the above-mentioned Phase 3 IBS-C clinical trials are closely aligned with the draft guidance.
- The European Medicines Agency (EMA) has indicated that Ironwood's European partner, Almirall, S.A., can utilize the U.S. IBS-C Phase 3 clinical trials as a basis for a Market Authorisation Application. For that reason, no additional E.U. Phase 3 clinical trials are contemplated. The primary endpoint will be different in Europe, but both the EMA and the FDA have agreed to allow separate and independent statistical analysis plans of the primary data sets for the two territories. For the E.U., the co-primary efficacy endpoints will evaluate abdominal pain/abdominal discomfort and IBS degree of relief.

Corporate

- In early February, Ironwood executed the initial public offering (IPO) of its Class A common stock, which raised net proceeds of approximately $203 million with less than 17 percent dilution to its pre-IPO stockholders on a fully-diluted basis. In addition, the IPO provided Ironwood with the opportunity to discuss, with many of the biotechnology industry's most highly-regarded investors, linaclotide's potential to improve the lives of millions of Americans who are suffering from IBS-C or CC. Including proceeds from the IPO, Ironwood closed the first quarter with approximately $299 million of cash, cash equivalents, and available-for-sale securities.
- Based on its current operating plan, Ironwood anticipates ending fiscal year 2010 with greater than $220 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 on Wednesday, May 12, 2010 to discuss its business activities. Individuals interested in participating in the call should dial (888) 686-9681 (U.S. and Canada) or (913) 312-1451 (international) using conference ID number 1030465. 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 May 12, 2010 at 7:30 p.m. Eastern Time, running through 11:59 p.m. Eastern Time on May 26, 2010. To listen to the replay, dial (888) 203-1112 (U.S. and Canada) or (719) 457-0820 (international) using conference ID number 1030465. An archived version of the event 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 guanylate cyclase type-C (GC-C), a receptor found on epithelial cells lining the intestine. In preclinical models, this activation of GC-C leads to increases in cyclic guanosine monophosphate (cGMP), anion secretion, fluid secretion, and intestinal transit. In addition, both linaclotide and cGMP demonstrated anti-nociceptive effects in several preclinical models of visceral pain. Linaclotide is an orally delivered peptide that acts locally in the gut with no detectable

systemic exposure at therapeutic doses and is intended for once-daily administration. Linaclotide is in Phase 3 clinical development for the treatment of IBS-C and CC. In a Phase 2b study in patients with IBS-C, linaclotide statistically significantly reduced abdominal pain, abdominal discomfort, bloating, and severity of straining, and increased complete spontaneous bowel movement frequency, throughout the 12-week treatment period versus placebo. In two Phase 3 trials in patients with CC, statistical significance versus placebo was achieved for the primary endpoint--increasing complete spontaneous bowel movements--and all secondary endpoints, which included measures of straining severity, stool hardness, bloating, and abdominal discomfort. In Phase 2 IBS-C and Phase 3 CC trials, diarrhea was the most common adverse event, and occurred more commonly in linaclotide-treated patients than placebo-treated. Although most events of diarrhea were reported as mild to moderate, diarrhea was the most common cause for discontinuation. Data from the Phase 3 IBS-C trials are expected in the fourth quarter of 2010. An issued composition of matter patent for linaclotide provides protection to 2025. In September 2007, Ironwood and Forest entered into a 50/50 collaboration to co-develop and 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 gastrointestinal disorder characterized by abdominal pain, discomfort, and bloating associated with altered bowel habits, and as many as 11 million people in the U.S. suffer from it. There are currently few available therapies to treat this disorder and there is a high rate of dissatisfaction with available therapies. Patients suffering from IBS-C can be affected physically, psychologically, socially, and economically.

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 discomfort and bloating. This condition significantly affects patients' quality of life by impairing their ability to work and participate in typical daily activities. Half of patients are not satisfied with currently available treatments.

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 being evaluated in a confirmatory Phase 3 program for the treatment of IBS-C and CC. Ironwood also has a growing pipeline of additional drug candidates in earlier stages of development. Ironwood is located in Cambridge, Mass.

This press release includes forward-looking statements. You are hereby cautioned not to place undue reliance on these forward-looking statements, including, but not limited to, statements about the anticipated timing of the release of our Phase 3 IBS-C clinical trial results, the anticipated timing of our regulatory filing in the U.S., Almirall's plan with respect to its regulatory filing in the E.U., and our end-of-year cash, cash equivalents and available-for-sale securities balance. 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, among others, the risks that our clinical studies and other development activities do not progress as predicted, that developments arise that prevent the regulatory filing in the U.S. from being made within the targeted timeline, that developments arise that prevent the regulatory filing in the E.U. from proceeding as planned, and that our actual spend rate does not conform to our current operating plan, as well as the risks that are identified under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2009. For further discussion of risks and uncertainties, individuals should refer to our past and future SEC filings. We undertake no obligation and do not intend 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 Sheet
(in thousands)
(unaudited)

	March 31, 2010
Assets	
Cash, cash equivalents, and available-for-sale securities	$ 298,568
Accounts receivable, net	4,723
Prepaid expenses and other assets	3,107
Total current assets	306,398
Property and equipment, net	23,540

Other assets	8,192
Total assets	$ 338,130
Liabilities and Stockholders' Equity	
Accounts payable and accrued expenses	$ 17,868
Current portion of long-term debt and capital lease obligations	1,313
Current portion of deferred rent	196
Current portion of deferred revenue	35,607
Total current liabilities	54,984
Long-term debt and capital lease obligations	1,603
Deferred rent	10,703
Deferred revenue	82,038
Total stockholders' equity	188,802
Total liabilities and stockholders' equity	$ 338,130

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

	Three Months Ended March 31, 2010
Revenue	$ 9,052
Operating expenses:	
Research and development	18,637
General and administrative	6,643
Total operating expenses	25,280
Loss from operations	(16,228)
Other expense, net	(25)
Net loss	(16,253)
Net loss attributable to noncontrolling interest	329
Net loss attributable to Ironwood Pharmaceuticals, Inc.	$ (15,924)
Net loss per share attributable to Ironwood Pharmaceuticals, Inc.--basic and diluted	$ (0.25)
Weighted average number of common shares used in net loss per share attributable to Ironwood Pharmaceuticals, Inc.--basic and diluted	63,957,966

SOURCE: Ironwood Pharmaceuticals, Inc.

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