Ironwood Pharmaceuticals Provides Second Quarter 2010 Investor Update

CAMBRIDGE, Mass., Aug 05, 2010 (BUSINESS WIRE) -- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) today provided an update on its business activities for the second quarter of 2010.

Second Quarter 2010 Highlights

Linaclotide

- Both confirmatory Phase 3 clinical trials being carried out by Ironwood and its U.S. partner, Forest Laboratories, Inc., assessing the efficacy and safety of linaclotide in patients with irritable bowel syndrome with constipation (IBS-C), are fully enrolled. Ironwood and Forest anticipate reporting top-line results from the two trials separately in the fourth quarter of 2010. Subsequent to each top-line data release, Ironwood and its European partner, Almirall, S.A., will report top-line results on the same data measured against the E.U. co-primary efficacy endpoints which evaluate abdominal pain/ abdominal discomfort and IBS degree of relief. Ironwood and Forest are targeting a New Drug Application submission to the U.S. Food and Drug Administration (FDA) in the middle of 2011.
- The FDA issued draft guidance earlier this year on the design of clinical trials for IBS-C. Among other recommendations, the draft guidance recommends primary efficacy endpoints assessing abdominal pain (greater-than or equal to 30 percent average weekly reduction vs. baseline) and stool frequency (increase of one or more complete spontaneous bowel movements (CSBMs) per week vs. baseline). Ironwood and Forest are amending the clinical trial protocols in both ongoing Phase 3 IBS-C clinical trials and have proposed to the FDA to add an additional primary efficacy endpoint that is consistent with the draft FDA guidance. This additional endpoint is as follows:
    - **Six out of 12-week abdominal pain and CSBM responder**: a patient who, for at least six of the 12 weeks of the treatment period, (a) has at least a 30 percent average weekly reduction in abdominal pain from baseline and (b) has an increase of one or more CSBMs per week from baseline.

Adding this endpoint to the clinical trial protocols will ensure that the studies include analyses that conform to the FDA's most current thinking as reflected in the draft guidance. This endpoint is in addition to the original primary efficacy endpoints, which are as follows:

- **Nine out of 12-week abdominal pain and CSBM responder**: a patient who, for at least nine of the 12 weeks of the treatment period, meets the both the abdominal pain and CSBM responder criteria listed below;
- **Nine out of 12-week CSBM responder**: a patient who, for at least nine of the 12 weeks of the treatment period, has three or more CSBMs per week and an increase of one or more CSBMs per week from baseline; and
- **Nine out of 12-week abdominal pain responder**: a patient who, for at least nine of the 12 weeks of the treatment period, has at least a 30 percent average weekly reduction in abdominal pain from baseline.

Corporate

- 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 5:30 p.m. Eastern Time today to discuss its business activities. Individuals interested in participating in the call should dial (877) 312-5420 (U.S. and Canada) or (970) 315-0261 (international) using conference ID number 91630665. 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 8:30 p.m. Eastern Time, running through 11:59 p.m. Eastern Time on August 19, 2010. To listen to the replay, dial (800) 642-1687 (U.S. and Canada) or (706) 645-9291 (international) using conference ID number 91630665. 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 the guanylate cyclase type-C (GC-C) receptor located on the luminal surface of the intestine. In preclinical models, activation of GC-C leads to increases in intracellular and extracellular cyclic guanosine monophosphate (cGMP), resulting in anion secretion, fluid secretion, and accelerated intestinal transit. In addition, both linaclotide and cGMP have reduced visceral pain in several preclinical models. 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. Linaclotide is in Phase 3 clinical development for the treatment of IBS-C and chronic constipation. An issued composition of matter patent for linaclotide provides protection to 2025. Ironwood and Forest are co-developing and co-promoting linaclotide in the United States. Ironwood has out-licensed linaclotide to Almirall, S.A. 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, 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 irritable bowel syndrome with constipation (IBS-C) and chronic constipation. 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 Phase 3 IBS-C clinical trials and the effects on such trials of adding a fourth primary efficacy endpoint. 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, and that we fail to meet any or all of the endpoints in our Phase 3 IBS-C clinical trials, as well as the risks that are identified under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the three months ended March 31, 2010. 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)

	June 30, 2010
Assets	
Cash, cash equivalents and available-for-sale securities	$271,605
Accounts receivable, net	6,352
Prepaid expenses and other assets	4,202
Total current assets	282,159
Property and equipment, net	29,117
Other assets	10,808
Total assets	$322,084
Liabilities and Stockholders' Equity	
Accounts payable and accrued expenses	$ 19,298

Current portion of long-term debt and capital lease obligations	1,263
Current portion of deferred rent	1,150
Current portion of deferred revenue	35,490
Total current liabilities	57,201
Long-term debt and capital lease obligations	1,715
Deferred rent	16,330
Deferred revenue	73,288
Total stockholders' equity	173,550
Total liabilities and stockholders' equity	$322,084

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

	Three Months Ended June 30, 2010	Six Months Ended June 30, 2010
Revenue	$ 10,959	$ 20,011
Operating expenses:		
Research and development	20,953	39,590
General and administrative	7,325	13,968
Total operating expenses	28,278	53,558
Loss from operations	(17,319)	(33,547)
Other income, net	110	85
Net loss	(17,209)	(33,462)
Net loss attributable to noncontrolling interest	73	402
Net loss attributable to Ironwood Pharmaceuticals, Inc.	$ (17,136)	$ (33,060)
Net loss per share attributable to Ironwood Pharmaceuticals, Inc.--basic and diluted	$ (0.18)	$ (0.41)
Weighted average number of common shares used in net loss per share attributable to Ironwood Pharmaceuticals, Inc.--basic and diluted	97,642,330	80,893,200

SOURCE: Ironwood Pharmaceuticals, Inc.

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