Ironwood Pharmaceuticals Provides Third Quarter 2010 Investor Update

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

Third Quarter 2010 Highlights

Linaclotide

- Ironwood and its U.S. partner, Forest Laboratories, Inc., announced positive top-line results in both of their confirmatory Phase 3 clinical trials assessing the efficacy and safety of linaclotide in patients with irritable bowel syndrome with constipation (IBS-C). In both trials, linaclotide met all primary and secondary endpoints, including multiple endpoints assessing linaclotide's effect on abdominal pain. Diarrhea was the most common adverse event in linaclotide-treated patients in these trials. The top-line results from these trials were consistent with the results from the previous clinical trials of linaclotide in patients with IBS-C and chronic constipation. For more detailed information on the top-line results from the Phase 3 IBS-C clinical trials, please refer to Ironwood and Forest's joint press releases issued on September 13, 2010 and November 1, 2010; and for more information on the results from the Phase 3 chronic constipation clinical trials, please refer to Ironwood and Forest's joint press release issued on May 3, 2010. Ironwood and Forest are targeting a New Drug Application (NDA) submission for linaclotide to the U.S. Food and Drug Administration (FDA) in the third quarter of calendar year 2011.
- Ironwood and its European partner, Almirall, S.A., also announced positive top-line results from the above Phase 3 IBS-C clinical trials for the E.U. efficacy endpoints. For more detailed information, please refer to Ironwood and Almirall's joint press releases issued on September 13, 2010 and November 1, 2010. Based on the positive top-line results, Almirall will make a one-time $20 million milestone payment, less applicable taxes, to Ironwood. Almirall is targeting a Market Authorization Application (MAA) submission for linaclotide to the European Medicines Agency (EMA) in the second half of 2011.
- Ironwood's Asian partner, Astellas Pharma Inc., recently dosed the first patient in its Phase 1, single-dose clinical study to assess the tolerability of linaclotide in healthy volunteers in Japan. Astellas anticipates completing the study in 2011.

Corporate

- In September, Ironwood sold its interest in its subsidiary, Microbia, Inc., to DSM Holding Company USA, Inc. in exchange for cash proceeds of $9.5 million, payment of $1.1 million for Microbia's remaining debt, and future contingent consideration based on the sale of products incorporating Microbia's technology.
- At the end of October, Ironwood was awarded four federal grants under the Qualifying Therapeutic Discovery Project program for linaclotide and Ironwood's next three most-advanced clinical and pre-clinical candidates. Ironwood received the maximum grant for each of the four applications. This initiative was part of the Patient Protection and Affordable Care Act that was signed into law in March 2010.
- Based on its current operating plan, Ironwood reaffirms its prior guidance that it anticipates ending fiscal year 2010 with greater than $220 million of cash, cash equivalents, and available-for-sale securities.

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 has been shown to reduce visceral pain, increase fluid secretion, and accelerate 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. Linaclotide is in Phase 3 clinical development for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation. An issued composition of matter patent for linaclotide provides protection to 2025. Ironwood and Forest are co-developing and 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.

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. There is a high rate of dissatisfaction 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. 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, our top-line assessment of our Phase 3 IBS-C clinical trial data and its implications for the future development of linaclotide, linaclotide's potential as a treatment for IBS-C or chronic constipation, the successful completion of our long-term safety studies, our ability to produce an adequate commercial supply of linaclotide, the timing of the filing of a New Drug Application or a Marketing Authorization Application for linaclotide, and the potential size of linaclotide's target patient population. 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 our other linaclotide development activities do 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 we are unable to produce an adequate commercial supply of linaclotide, as well as risks related to the difficulty of predicting regulatory approvals, the acceptance of and demand for new pharmaceutical products, the impact of competitive products and pricing, and whether linaclotide will ever be commercialized successfully. Applicable risks also include those that are listed in our Quarterly Report on Form 10-Q for the three months ended June 30, 2010, 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)

	September 30, 2010	December 31, 2009
Assets		
Cash, cash equivalents and available-for-sale securities	$ 250,831	$ 122,306
Accounts receivable, net	5,049	5,219
Prepaid expenses and other assets	7,402	2,673
Current assets of discontinued operations	—	1,250
Total current assets	263,282	131,448
Property and equipment, net	33,286	21,754
Other assets	7,964	8,153
Long-term assets of discontinued operations	—	1,096
Total assets	$ 304,532	$ 162,451
Liabilities and Stockholders' Equity (Deficit)		
Accounts payable and accrued expenses	$ 17,758	$ 21,454
Current portion of long-term debt and capital lease obligations	227	1,079
Current portion of deferred rent	2,374	180

Current portion of deferred revenue	35,490	32,360
Current liabilities of discontinued operations	—	1,364
Total current liabilities	55,849	56,437
Long-term debt and capital lease obligations	429	939
Deferred rent	15,772	10,486
Deferred revenue	64,415	93,642
Long-term liabilities of discontinued operations	—	937
Convertible preferred stock	—	298,350
Total stockholders' equity (deficit)	168,067	(298,340)
Total liabilities and stockholders' equity (deficit)	$ 304,532	$ 162,451

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenue	$ 9,059	$ 15,257	$ 27,085	$ 25,917
Operating expenses:				
Research and development	18,742	18,603	56,188	51,918
General and administrative	6,482	4,941	18,868	13,448
Total operating expenses	25,224	23,544	75,056	65,366
Loss from operations	(16,165)	(8,287)	(47,971)	(39,449)
Other income (expense), net	107	(44)	267	(144)
Net loss from continuing operations before income tax benefit	(16,058)	(8,331)	(47,704)	(39,593)
Income tax benefit	—	(153)	—	(153)
Net loss from continuing operations	(16,058)	(8,178)	(47,704)	(39,440)
Net income (loss) from discontinued operations	9,311	(3,243)	7,495	(9,298)
Net loss	(6,747)	(11,421)	(40,209)	(48,738)
Net (income) loss from discontinued operations attributable to noncontrolling interest	(1,523)	519	(1,121)	1,483
Net loss attributable to Ironwood Pharmaceuticals, Inc.	$ (8,270)	$ (10,902)	$ (41,330)	$ (47,255)
Net loss per share attributable to Ironwood Pharmaceuticals, Inc.—basic and diluted:				
Continuing operations	$ (0.16)	$ (1.15)	$ (0.55)	$ (5.59)
Discontinued operations	0.08	(0.38)	0.07	(1.11)
Net loss per share	$ (0.08)	$ (1.53)	$ (0.48)	$ (6.70)
Weighted average number of common shares used in net loss per share attributable to Ironwood Pharmaceuticals, Inc.—basic and diluted	97,925,657	7,118,345	86,633,080	7,054,291

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