Ironwood Pharmaceuticals Provides First Quarter 2012 Investor Update

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) today provided an update on its first quarter 2012 and recent business activities.

First Quarter 2012 and Recent Highlights

Linaclotide

- In April, the U.S. Food and Drug Administration (FDA) notified Ironwood and Forest Laboratories, Inc. that it will require a three-month extension to complete its review of the data supporting the New Drug Application (NDA) for linaclotide for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC). FDA action has been extended to September 2012. Ironwood and Forest continue to plan for a 2012 launch.
- In February, Ironwood and Forest were informed that the FDA will not schedule an advisory committee meeting in connection with its review of the NDA for linaclotide.
- Seventeen abstracts have been accepted for presentation during the 2012 Digestive Disease Week (DDW) annual meeting being held in San Diego from May 19-22, 2012. One abstract will be an oral presentation and 16 will be made available through poster presentations.

Pipeline

- Ironwood continues to advance its pipeline, which includes early development candidates and discovery research efforts focused on gastrointestinal disease, central nervous system disorders, respiratory disease, and cardiovascular disease. Early development candidates include IW-9179 for the treatment of painful disorders of the small intestine and IW-2143 for the treatment of anxiety, and several others.

Corporate

- Ironwood ended the first quarter of 2012 with approximately $202 million of cash, cash equivalents, and available-for-sale securities. This includes approximately $85 million received in February through the sale of its Class A common stock.

Conference Call Information

Ironwood will host a conference call and webcast at 8:30 a.m. Eastern Time, May 1, to discuss its business activities, including its commercial strategy for linaclotide. Individuals interested in participating in the call should dial (877) 643-7155 (U.S. and Canada) or (914) 495-8552 (international) using conference ID number 74951581. 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 May 8, 2012. To listen to the replay, dial (855) 859-2056 (U.S. and Canada) or (404) 537-3406 (international) using conference ID number 74951581. 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 a guanylate cyclase-C agonist (GCCA). 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 GCCA, 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's target action date, linaclotide's potential as a treatment for IBS-C or chronic constipation, and the anticipated use of proceeds from Ironwood's equity offering in February 2012. 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 the FDA further extends its review of the linaclotide NDA, 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 issues a complete response letter for linaclotide, advancements in our development pipeline do not proceed as expected, Ironwood chooses to apply the proceeds from its equity offering in a different manner, 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 Ironwood Pharmaceuticals' Annual Report on Form 10-K for the year ended December 31, 2011, in addition to the risk factors that are listed from time to time in Ironwood Pharmaceuticals' 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)

	March 31, 2012	December 31, 2011
Assets		
Cash, cash equivalents and available-for-sale securities	$ 202,108	$ 164,016
Accounts receivable, net	109	652
Prepaid expenses and other assets	4,048	2,899
Total current assets	206,265	167,567
Property and equipment, net	35,140	33,625
Other assets	7,771	7,785
Total assets	$ 249,176	$ 208,977
Liabilities and Stockholders' Equity		
Accounts payable, net and accrued expenses	$ 22,727	$ 24,568
Current portion of capital lease obligations	271	233
Current portion of deferred rent	4,350	4,042
Current portion of deferred revenue	24,935	36,291
Total current liabilities	52,283	65,134
Capital lease obligations	435	422
Deferred rent	11,964	12,435
Deferred revenue	20,348	21,130

Total stockholders' equity	164,146	109,856
Total liabilities and stockholders' equity	$ 249,176	$ 208,977

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

	Three Months Ended March 31,	
	2012	**2011**
Revenue	$ 12,248	$ 10,237
Operating expenses:		
Research and development	29,510	19,555
General and administrative	18,374	9,224
Total operating expenses	47,884	28,779
Loss from operations	(35,636)	(18,542)
Other income (expense), net	35	141
Net loss	$ (35,601)	$ (18,401)
Net loss per share—basic and diluted:		
Net loss per share	$ (0.34)	$ (0.19)
Weighted average number of common shares used in net loss per share—basic and diluted	103,751,060	99,075,187

Ironwood Pharmaceuticals
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