



Ironwood Pharmaceuticals Provides Second Quarter 2012 Investor Update

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

Second 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.
- Ironwood and Forest presented linaclotide-related data in one oral presentation and sixteen poster presentations at the 2012 Digestive Disease Week (DDW) annual meeting held in San Diego from May 19-22, 2012. Included in these presentations were data about the effect of linaclotide on abdominal pain and other symptoms in Phase 3 clinical trials involving patients with IBS- C.
- Ironwood submitted a Clinical Trial Application (CTA) to China's State Food and Drug Administration for a Phase 3 trial of linaclotide in patients with IBS-C. The CTA has been accepted for review.
- As part of the strategy to maximize the utility of linaclotide over time, Ironwood and Forest have initiated a Phase 3b clinical trial to further characterize the effect of linaclotide on abdominal symptoms in patients with chronic constipation.

Research & Development

- 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.

Corporate

- Ironwood ended the second quarter of 2012 with approximately \$158 million of cash, cash equivalents, and available-for-sale securities. Ironwood used approximately \$93 million of cash for operations during the six months ended June 30, 2012.

Conference Call Information

Ironwood will host a conference call and webcast at 8:30 a.m. Eastern Time, July 17, to discuss its second quarter 2012 and recent business activities. 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 98056073. 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 July 31, 2012. To listen to the replay, dial (855) 859-2056 (U.S. and Canada) or (404) 537-3406 (international) using conference ID number 98056073. 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 guanylate cyclase-C agonist (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 submitted NDA 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, our development plans for linaclotide in China, and linaclotide's potential as a treatment for IBS-C or CC. 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, China's State Food and Drug Administration does not grant our request for a Phase 3 clinical trial or we choose not to perform a clinical trial in China, 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 Ironwood Pharmaceuticals' Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, 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, 2012	December 31, 2011
Assets		
Cash, cash equivalents and available-for-sale securities	\$157,653	\$ 164,016
Accounts receivable, net	2,466	652
Prepaid expenses and other assets	5,964	2,899
Total current assets	<u>166,083</u>	<u>167,567</u>
Property and equipment, net	34,859	33,625
Other assets	7,721	7,785
Total assets	<u>\$208,663</u>	<u>\$ 208,977</u>
Liabilities and Stockholders' Equity		
Accounts payable, net and accrued expenses	\$ 30,749	\$ 24,568
Current portion of capital lease obligations	277	233

Current portion of deferred rent	4,517	4,042
Current portion of deferred revenue	<u>13,578</u>	<u>36,291</u>
Total current liabilities	49,121	65,134
Capital lease obligations	364	422
Deferred rent	10,832	12,435
Deferred revenue	19,565	21,130
Total stockholders' equity	<u>128,781</u>	<u>109,856</u>
Total liabilities and stockholders' equity	<u>\$208,663</u>	<u>\$ 208,977</u>

Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenue	\$ 14,604	\$ 11,262	\$ 26,852	\$ 21,499
Operating expenses:				
Research and development	32,238	19,409	61,748	38,964
General and administrative	23,200	10,805	41,574	20,029
Total operating expenses	<u>55,438</u>	<u>30,214</u>	<u>103,322</u>	<u>58,993</u>
Loss from operations	(40,834)	(18,952)	(76,470)	(37,494)
Other income (expense), net	31	108	66	249
Net loss	<u>\$ (40,803)</u>	<u>\$ (18,844)</u>	<u>\$ (76,404)</u>	<u>\$ (37,245)</u>
Net loss per share—basic and diluted	<u>\$ (0.38)</u>	<u>\$ (0.19)</u>	<u>\$ (0.73)</u>	<u>\$ (0.37)</u>
Weighted average number of common shares used in net loss per share - basic and diluted	107,078,150	99,674,969	105,414,607	99,458,336

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