Ironwood Pharmaceuticals Provides Fourth Quarter 2011 Investor Update

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) today provided an update on its fourth quarter 2011 and recent business activities.

"During 2011, we were focused on preparing linaclotide for successful regulatory submissions in the U.S. and Europe, and we continue to put all of the elements in place for a successful product launch while these submissions are under review, including our recent capital raise of $85 million to strengthen our balance sheet," said Michael Higgins, Ironwood's chief operating officer and chief financial officer. "We believe that linaclotide's product profile is highly appealing for both therapy-seeking patients and physicians and we are committed to a successful product launch, if approved."

Fourth Quarter and Recent Highlights

Linaclotide

- On February 8, Ironwood was informed that the U.S. Food and Drug Administration (FDA) will not schedule an advisory committee meeting in connection with its review of the New Drug Application (NDA) for linaclotide for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC). Under the FDA's Prescription Drug User Fee Act (PDUFA), the companies anticipate action by the FDA in June 2012.
- Fourteen linaclotide-related abstracts have been accepted for presentation during the 2012 Digestive Disease Week (DDW) annual meeting that will be held in San Diego from May 19—22, 2012. One abstract will be discussed in an oral presentation and 13 will be made available through poster presentations.

Pipeline

- Ironwood continues to advance its pipeline, which includes early development candidates and discovery efforts focused on gastrointestinal disease, central nervous system disorders, and respiratory disease.
- In January 2012, Ironwood announced that it entered into a collaboration, research, and licensing agreement for the development and commercialization of Bionomics' investigational anti-anxiety compound BNC210 (renamed as IW-2143) and other related compounds. Ironwood will be responsible for worldwide development and commercialization of all products incorporating IW-2143 or other licensed compounds, including funding of clinical trials. Over the next 24 months, Bionomics may receive up to $13 million in research funding and milestone payments, which includes an initial payment of $3 million.

Corporate

- Ironwood ended 2011 with approximately $164 million of cash, cash equivalents, and available-for-sale securities. Ironwood used approximately $75 million of net cash for operations for the year ended December 31, 2011.
- In February 2012, Ironwood sold 6,037,500 shares of its Class A common stock through a firm commitment, underwritten public offering at a price to the public of $15.09 per share. As a result of the offering, Ironwood received aggregate net proceeds, after underwriting discounts and commissions and other estimated offering expenses, of approximately $85 million. Ironwood intends to use these proceeds for general corporate purposes, including to fund expenses related to the expected market launch of linaclotide (if approved).
- In February, the Massachusetts Life Sciences Center awarded Ironwood tax incentives of $1.8 million based upon Ironwood's plan to increase its Massachusetts-based employees by 75 by the end of 2012.

Conference Call Information

Ironwood will host a conference call and webcast at 4:30 p.m. Eastern Time today to discuss its business activities, including its commercial strategy for linaclotide. Individuals interested in participating in the call should dial (888) 208-1812 (U.S. and Canada) or (719) 457-2702 (international) using conference ID number 3679648. 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 7:30 p.m. Eastern Time, running through 11:59 p.m. Eastern Time on March 13, 2012. To listen to the replay, dial (888) 203-1112 (U.S. and Canada) or (719) 457-0820 (international) using conference ID number 3679648. 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 an agonist of the guanylate cyclase type-C (GC-C) receptor located on the luminal surface of the intestine. 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 GC-C agonist, 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 PDUFA target action date, linaclotide's potential as a treatment for IBS-C or chronic constipation, the potential clinical trials for IW-2143 and Ironwood's obligations to make milestone payments and royalties if products incorporating IW-2143 are successfully developed or commercialized, the anticipated use of proceeds from Ironwood's recent equity offering, and the plan to increase Massachusetts-based employees in 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 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 recommends modifications to the proposed label for linaclotide or issues a complete response letter for linaclotide, the goals of the Bionomics collaboration are never satisfied or take longer than anticipated to achieve, Ironwood chooses not to develop or commercialize a product incorporating IW-2143, advancements in our development pipeline do not proceed as expected, Ironwood chooses to apply the proceeds from its recent equity offering in a different manner, and we are unable to or choose not to hire additional employees at the anticipated rate, 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 our Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, 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)

	December 31, 2011	December 31, 2010
Assets		
Cash, cash equivalents and available-for-sale securities	$ 164,016	$ 248,027
Accounts receivable, net	652	2,895
Prepaid expenses and other current assets	2,899	8,153
Total current assets	167,567	259,075
Property and equipment, net	33,625	34,369
Other assets	7,785	7,921
Total assets	$ 208,977	$ 301,365
Liabilities and Stockholders' Equity		
Accounts payable and accrued expenses	$ 24,568	$ 21,380
Current portion of capital lease obligations	233	197
Current portion of deferred rent	4,042	2,799
Current portion of deferred revenue	36,291	40,050
Total current liabilities	65,134	64,426
Capital lease obligations	422	393
Deferred rent	12,435	14,612
Deferred revenue	21,130	62,383
Total stockholders' equity	109,856	159,551
Total liabilities and stockholders' equity	$ 208,977	$ 301,365

Condensed Consolidated Statements of Operations

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

	Three Months Ended December 31,		Year Ended December 31,	
	2011	2010	2011	2010
Revenue	$ 32,154	$ 16,772	$ 65,871	$ 43,857
Operating expenses:				
Research and development	24,224	21,266	86,093	77,454
General and administrative	14,962	8,301	45,920	27,169
Total operating expenses	39,186	29,567	132,013	104,623
Loss from operations	(7,032)	(12,795)	(66,142)	(60,766)
Other income (expense), net	58	1,144	1,293	1,411
Net loss from continuing operations before income tax expense (benefit)	(6,974)	(11,651)	(64,849)	(59,355)
Income tax expense (benefit)	—	—	3	(2,944)
Net loss from continuing operations	(6,974)	(11,651)	(64,852)	(56,411)
Net income from discontinued operations	—	—	—	4,551
Net loss	(6,974)	(11,651)	(64,852)	(51,860)
Net income from discontinued operations attributable to noncontrolling interest	—	—	—	(1,121)
Net loss attributable to Ironwood Pharmaceuticals, Inc.	$ (6,974)	$ (11,651)	$ (64,852)	$ (52,981)
Net income (loss) per share attributable to Ironwood Pharmaceuticals, Inc.—basic and diluted:				
Continuing operations	$ (0.07)	$ (0.12)	$ (0.65)	$ (0.63)
Discontinued operations	—	—	—	0.04
Net loss per share	$ (0.07)	$ (0.12)	$ (0.65)	$ (0.59)
Weighted average number of common shares used in net income (loss) per share attributable to Ironwood Pharmaceuticals,				

Inc.—basic and diluted	100,394,800	98,615,754	99,874,790	89,653,364

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Source: Ironwood Pharmaceuticals, Inc.