April 23, 2013

Ironwood Pharmaceuticals Provides First Quarter 2013 Investor Update

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) today provided an update on its first quarter 2013 and recent business activities.

"We and Forest have made significant process advancing LINZESS during the first few months of commercialization, and the positive response from patients and physicians is very encouraging," said Tom McCourt, chief commercial officer and senior vice president, marketing and sales. "There have been a number of favorable early decisions made by key national payers, and the integrated Ironwood and Forest sales and marketing team is executing at a high level. While it's still early, and we have more work to do to deliver LINZESS to patients in need, everything we are seeing reinforces the substantial opportunity for LINZESS to treat adults with IBS-C or CIC and to dramatically grow this category over the coming years."

First Quarter 2013 and Recent Highlights

LINZESS™ (linaclotide)

- More than 70,000 LINZESS prescriptions have been filled since the launch of LINZESS on December 17, 2012 through April 12, 2013, according to IMS Health.
- LINZESS net product sales, as reported by Forest Laboratories, Inc., were $4.5 million in the first quarter of 2013.
- Ironwood and Forest continue to introduce LINZESS to the physician community in the U.S. To date, more than 50% of high prescribing gastroenterologists and approximately 20% of high prescribing primary care physicians have prescribed LINZESS.
- The companies have ongoing discussions with payers to seek broad unrestricted access for patients. As of April 2013, approximately 75% of adult IBS-C or CIC patients with commercial insurance have unrestricted access to LINZESS.
- Ironwood and Forest completed enrollment in a Phase IIIb clinical trial to further evaluate the effect of LINZESS on abdominal symptoms in patients with chronic idiopathic constipation (CIC). The companies expect to report data from this trial in the second half of 2013.
- Ironwood and Forest continue to explore development opportunities to strengthen the clinical profile of LINZESS within its indicated population, expand the product label for broader patient populations and indications, as well as explore the potential for linaclotide-based combination products. The companies expect to initiate additional U.S. clinical trials involving linaclotide in the next 12 months.

Constella® (linaclotide)

- Ironwood's European partner, Almirall S.A., intends to initiate launches of Constella in the U.K. and Germany during the second quarter of 2013.

Linaclotide (Rest of World)

- Astellas continues to advance a double-blind, placebo-controlled, dose-ranging Phase II clinical trial of linaclotide in adult patients with irritable bowel syndrome with constipation (IBS-C) in Japan. The study is expected to be completed in the second half of 2013.
- Ironwood received approval from China's State Food and Drug Administration of its Clinical Trial Application (CTA) for a Phase III trial of linaclotide in adult patients with IBS-C. Ironwood and AstraZeneca expect to initiate the Phase III trial in the second half of 2013.

Research & Development

- In addition to exploring additional linaclotide development opportunities, Ironwood continues to advance other programs in its pipeline, which include early development candidates and discovery research efforts focused on gastrointestinal disease, central nervous system disorders, allergic conditions and cardiovascular disease.

Corporate

- Ironwood ended the first quarter of 2013 with approximately $242 million of cash, cash equivalents and available-for-sale securities. Ironwood used approximately $93 million of net cash for operations during the quarter.
- In January, Ironwood completed a debt financing of $175 million.
- Ironwood appointed Edward Owens, retired partner, portfolio manager and global industry analyst with Wellington Management Company, LLP, to its board of directors.
- Ironwood promoted Mark Currie, Ph.D. to senior vice president, chief scientific officer, and president of research & development.

Conference Call Information

Ironwood will host a conference call and webcast at 8:30 a.m. Eastern Time, on Tuesday, April 23, to discuss its first quarter 2013 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 30336328. 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 April 30, 2013. To listen to the replay, dial (855) 859-2056 (U.S. and Canada) or (404) 537-3406 (international) using conference ID number 30336328. The archived webcast will be available on Ironwood's website for 14 days beginning approximately one hour after the call has completed.

About LINZESS (linaclotide)

LINZESS is the first and only guanylate cyclase-C (GC-C) agonist approved by the FDA for the treatment of both irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC) in adults. LINZESS is a once-daily capsule that helps relieve the abdominal pain and constipation associated with IBS-C, as well as the constipation, infrequent stools, hard stools and incomplete evacuation associated with CIC. The recommended dose is 290 mcg for IBS-C patients and 145 mcg for CIC patients. LINZESS should be taken at least 30 minutes before the first meal of the day.

LINZESS is thought to work in two ways based on nonclinical studies. LINZESS binds to the GC-C receptor locally, within the intestinal epithelium. Activation of GC-C results in increased intestinal fluid secretion and transit and a reduction in visceral pain, which is thought to be mediated by decreased activity of pain-sensing nerves. The clinical relevance of the effect on pain fibers in nonclinical studies has not been established.

In placebo-controlled Phase III clinical trials of more than 2,800 adults, LINZESS was shown to reduce abdominal pain in IBS-C patients and increase bowel movement frequency in both IBS-C patients and CIC patients. Improvement in abdominal pain and constipation occurred in the first week of treatment and was maintained throughout the 12-week treatment period. Maximum effect on abdominal pain was seen at weeks 6-9 and maximum effect on constipation occurred during the first week. When a subset of LINZESS-treated patients in the trials were switched to placebo, they reported their symptoms returned toward pretreatment levels within one week, while placebo-treated patients switched to LINZESS reported symptom improvements. LINZESS is contraindicated in pediatric patients up to 6 years of age. The use of LINZESS in pediatric patients 6 through 17 years of age should be avoided. In nonclinical studies, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths in young juvenile mice. LINZESS has not been studied in pediatric patients. In adults with IBS-C or CIC treated with LINZESS, the most commonly reported adverse event was diarrhea.

Ironwood and Forest Laboratories, Inc. are co-promoting LINZESS in the United States. Linaclotide was also approved by the European Commission for the treatment of adults in the European Union with IBS-C and will be marketed under the brand name Constella® through a license agreement between Ironwood and Almirall, S.A. Ironwood also has partnered linaclotide with Astellas Pharma Inc. for development and commercialization in Japan and with AstraZeneca for development and commercialization in China.

About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ: IRWD) is committed to the art and science of making medicines, from discovery through commercialization. We're focused on three goals: transforming knowledge into medicines that make a difference for patients, creating value that will inspire the continued support of our fellow shareholders, and building a team that passionately pursues excellence. Our first product, linaclotide, is approved in the United States and Europe. Our pipeline priorities include exploring further opportunities for linaclotide, leveraging our deep expertise in functional gastrointestinal disorders, and advancing programs in other areas such as allergic conditions, cardiovascular disease, central nervous system disorders and other conditions defined by patient symptoms. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. Connect with us at www.ironwoodpharma.com or on Twitter at www.twitter.com/ironwoodpharma to learn more about Ironwood.

Information that may be important to investors will be routinely posted in both these locations.

Important Safety Information

WARNING: PEDIATRIC RISK

LINZESS is contraindicated in pediatric patients up to 6 years of age. Use should be avoided in pediatric patients 6 through 17 years of age. In nonclinical studies, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths in young juvenile mice.

Contraindications

- LINZESS is contraindicated in pediatric patients up to 6 years of age.
- LINZESS is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions

Pediatric Risk

- LINZESS is contraindicated in pediatric patients up to 6 years of age. In nonclinical studies, deaths occurred within 24 hours in young juvenile mice (1 to 3 week-old mice; approximately equivalent to human pediatric patients less than 2 years of age) following administration of one or two daily oral doses of linaclotide.
- Use of LINZESS should be avoided in pediatric patients 6 through 17 years of age. Linaclotide did not cause deaths in older juvenile mice (approximately equivalent to humans age 12 to 17 years). Although there were no deaths in older juvenile mice, given the deaths in young juvenile mice and the lack of clinical safety and efficacy data in pediatric patients, use of LINZESS should be avoided in pediatric patients 6 through 17 years of age.

Diarrhea

- Diarrhea was the most common adverse reaction of LINZESS-treated patients in the pooled IBS-C and CIC double-blind placebo-controlled trials. Severe diarrhea was reported in 2% of LINZESS-treated patients. The incidence of diarrhea was similar in the IBS-C and CIC populations.
- Patients should be instructed to stop LINZESS if severe diarrhea occurs and to contact their healthcare provider, who should consider dose suspension.

Adverse Reactions

- In IBS-C clinical trials, the most common adverse reactions in LINZESS-treated patients (incidence ≥2% and greater than placebo) were diarrhea (20% vs 3% placebo), abdominal pain (7% vs 5%), flatulence (4% vs 2%), headache (4% vs 3%), viral gastroenteritis (3% vs 1%) and abdominal distension (2% vs 1%).
- In CIC clinical trials, the most common adverse reactions in LINZESS-treated patients (incidence ≥2% and greater than placebo) were diarrhea (16% vs 5% placebo), abdominal pain (7% vs 6%), flatulence (6% vs 5%), upper respiratory tract infection (5% vs 4%), sinusitis (3% vs 2%) and abdominal distension (3% vs 2%).

Please see full Prescribing Information including Boxed Warning:

http://www.frx.com/pi/linzess_pi.pdf.

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 potential for LINZESS as a treatment option for adults in the United States suffering from IBS-C and CIC, Ironwood's and Forest's sales and marketing plans for LINZESS, Ironwood's and Forest's goals with respect to payer reimbursement for appropriate patients, Ironwood's and its partners' anticipated non-clinical and clinical development activities for linaclotide and their associated timelines as well as the timing of reporting of the data from such activities, Ironwood's intended activities for the other product candidates and early development programs in its pipeline, and the anticipated launch timeline for Constella in the European Union. 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 market acceptance of LINZESS in the U.S. is not as anticipated, Ironwood or its partners are unable to manufacture or distribute a sufficient commercial supply of LINZESS, Ironwood and Forest are unable to obtain unrestricted and/or Tier 2 access to LINZESS through commercial payers, Almirall is unable to obtain sufficient pricing

or reimbursement for Constella in countries in the European Union or it chooses to launch Constella on a different timeline, serious adverse events arise in patients that are deemed to be related to linaclotide treatment, the incidence or severity of diarrhea in patients treated with linaclotide is higher than expected, advancements in the further development of linaclotide in additional patient populations or indications or in fixed dose combinations do not proceed as expected, or the development of other products or early development programs in Ironwood's 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's Annual Report on Form 10‑K for the year ended December 31, 2012, in addition to the risk factors that are listed from time to time in Ironwood's Annual Reports on Form 10‑K, Quarterly Reports on Form 10‑Q and any subsequent SEC filings. Ironwood undertakes 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, 2013	December 31, 2012
Assets		
Cash, cash equivalents and available-for-sale securities	$ 242,029	$ 168,228
Accounts receivable, net	48	1,487
Inventory	19,704	6,699
Prepaid expenses and other current assets	13,853	8,026
Total current assets	275,634	184,440
Property and equipment, net	36,100	37,537
Other assets	13,359	7,930
Total assets	$ 325,093	$ 229,907
Liabilities and Stockholders' Equity		
Accounts payable and accrued expenses	$ 56,392	$ 48,561
Current portion of capital lease obligations	242	261
Current portion of deferred rent	2,749	2,735
Current portion of deferred revenue	3,299	3,381
Total current liabilities	62,682	54,938
Capital lease obligations	254	308
Deferred rent	10,907	11,593
Deferred revenue	17,217	18,024
Notes Payable	174,601	—
Other liabilities	909	992
Total stockholders' equity	58,523	144,052
Total liabilities and stockholders' equity	$ 325,093	$ 229,907

Condensed Consolidation Statement of Operations

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

	Three Months Ended March 31,	
	2013	2012
Revenue	$ 3,255	$ 12,248
Cost and expenses:		
Cost of revenue	1,231	—
Research and development (1)	32,753	29,510
Selling, general and administrative (1)	33,374	16,319
Collaboration expense	24,730	2,055

Total cost and expenses	92,088	47,884
Loss from operations	(88,833)	(35,636)
Other income (expense), net	(5,069)	35
Net loss	$ (93,902)	$ (35,601)
Net loss per share —basic and diluted	$ (0.87)	$ (0.34)
Weighted average number of common shares used in net loss per share —basic and diluted	108,072,643	103,751,060
(1) Non-cash share-based compensation expenses included reflected in the condensed consolidated statements of operations are as follows:		
Research and development	$ 2,224	$ 1,951
Selling, general and administrative:	3,051	3,721

LINZESS U.S. Collaboration Expense Calculation[1]

(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2013	**2012**
LINZESS net sales	$ 4,502	$ —
Commercial costs and expenses[2]	71,040	6,474
Net profit (loss) on sales of LINZESS	$ (66,538)	(6,474)
Ironwood's share of net profit (loss)	$ (33,269)	$ (3,237)
Ironwood's selling & marketing[3]	$ 8,539	$ 1,182
Ironwood's collaboration expense	$ (24,730)	$ (2,055)

[1] The Company collaborates with Forest on the development and commercialization of linaclotide in North America. Under the terms of the collaboration agreement, the Company receives 50% of the net profits and bears 50% of the net losses from the commercial sale of LINZESS in the U.S. The purpose of this table is to present calculations of the Company's share of net profit (loss) generated from the sales of LINZESS in the U.S. and the Company's collaboration expense; however, the table does not present the research and development expenses related to LINZESS in the U.S. that are shared equally between the parties under the collaboration agreement.

[2] Includes cost of sales incurred by Forest as well as selling and marketing costs incurred by Forest and Ironwood that are attributable to the cost-sharing arrangement between the parties.

[3] Includes Ironwood's selling and marketing costs attributable to the cost-sharing arrangement with Forest.

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