

## Ironwood Pharmaceuticals Provides Fourth Quarter and Full Year 2015 Investor Update

- Key advancements within three blockbuster opportunities: IBS-C/CIC, vascular/fibrotic diseases and refractory GERD -
- LINZESS<sup>®</sup> (linaclotide) U.S. net sales increased ~53% to \$455 million in 2015; on track to exceed \$1 billion in net sales by 2020 -
- Ironwood revenue increased > 95% to \$150 million in 2015, primarily driven by continued growth in LINZESS net sales and expansion in commercial margin to ~46% -
- Delivered on 2015 financial guidance with strong business execution -

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Ironwood Pharmaceuticals, Inc.](#) (NASDAQ: IRWD), a commercial biotechnology company, today provided an update on its fourth quarter and full year 2015 results and recent business activities.

"Ironwood delivered strong performance in 2015, leveraging a platform of great scientific innovation to advance multiple blockbuster opportunities in areas such as IBS-C/CIC, vascular and fibrotic diseases and refractory GERD," said Peter Hecht, chief executive officer of Ironwood. "We are very proud that more than one million patients have now been treated with our first product, LINZESS, an accomplishment that few biotech companies ever achieve. Continued LINZESS growth, excellent development execution and our strong financial profile positions us well in 2016 to continue building a top-performing commercial biotechnology company with rapid, sustainable, high-margin growth."

### Fourth Quarter 2015 and Recent Highlights

#### Gastrointestinal (GI) Platform

Ironwood is leveraging its GI expertise to advance multiple product candidates in areas with high unmet need in which patients are motivated to seek relief. The development and commercialization of linaclotide products in the U.S. is jointly funded by Ironwood and Allergan plc, with both companies sharing equally in any profits or losses. All other GI development programs are wholly-owned by Ironwood. Highlights during the fourth quarter and recent period include:

#### **Irritable Bowel Syndrome with Constipation (IBS-C) / Chronic Idiopathic Constipation (CIC)**

Ironwood estimates its IBS-C/CIC franchise, including LINZESS and linaclotide colonic release (if approved), may represent a peak U.S. sales opportunity exceeding \$2 billion, with additional global potential.

- | LINZESS U.S. net sales, as provided by Allergan, were \$129.7 million in the fourth quarter of 2015, an approximately 38% increase compared to the fourth quarter of 2014, and \$454.8 million for the full year 2015, an increase of approximately 53% compared to full year 2014.
  - | More than 585,000 total LINZESS prescriptions were filled in the fourth quarter of 2015, an approximately 30% increase compared to the fourth quarter of 2014, according to IMS Health.
  - | Net profit for the LINZESS U.S. brand collaboration, including commercial costs and expenses and research and development (R&D) expenses, was \$66.8 million and \$132.8 million in the fourth quarter and full year 2015, respectively.
  - | LINZESS commercial margin was approximately 65% and 46% in the fourth quarter and full year 2015, respectively, compared to approximately 36% and 10% in the fourth quarter and full year 2014, respectively.
  - | Ironwood and Allergan are finalizing the supplemental new drug application (sNDA) for a 72 mcg dose of linaclotide, expected to be submitted to the U.S. Food & Drug Administration (FDA) early in the second quarter of 2016. If approved, the companies expect the 72 mcg dose to accelerate physician prescribing of LINZESS within the large, heterogeneous adult CIC patient population.
  - | FDA approved the sNDA to include labeling instructions in the LINZESS Prescribing Information allowing adult

IBS-C and CIC patients with swallowing difficulties the option to administer the contents of LINZESS capsules in applesauce or water.

- | *Linacotide Colonic Release*. A second-generation guanylate cyclase-C (GC-C) agonist product candidate with the potential to provide greater and faster abdominal pain relief in adult IBS-C patients. A Phase IIb clinical trial is ongoing, with data expected in the second half of 2016.

### **Refractory GERD**

- | *IW-3718*. Preparing to initiate a dose-ranging Phase IIb clinical trial with IW-3718 for the potential treatment of refractory GERD. The Phase IIb trial is expected to start in the first quarter of 2016. If approved, Ironwood estimates peak sales for IW-3718 may exceed \$2 billion.

### **Diabetic Gastroparesis**

- | *IW-9179*. Completed enrollment of a Phase IIa clinical study evaluating the ability of IW-9179 to provide relief of diabetic gastroparesis symptoms. Data from this study are expected in the first half of 2016.

### **Vascular and Fibrotic Platform**

Ironwood is leveraging its pharmacologic expertise in guanylate cyclases to advance soluble guanylate cyclase (sGC) stimulators for the potential treatment of vascular and fibrotic diseases. Ironwood believes this platform has the potential to deliver multiple products, a number of which could generate peak sales exceeding \$1 billion if approved. All vascular and fibrotic development programs are wholly-owned by Ironwood. Highlights during the fourth quarter and recent period include:

- | *IW-1701*. Announced positive top-line results from a Phase Ia study of IW-1701. Data demonstrated the expected cardiovascular pharmacodynamics effects, proof of mechanism for sGC stimulation, a dose range that was well tolerated in healthy volunteers as a single dose, and a pharmacokinetic profile suitable for once-daily dosing and consistent with distribution into tissues. Ironwood intends to initiate a Phase Ib multiple ascending dose study with IW-1701 in the first half of 2016.
- | *IW-1973*. Currently enrolling healthy volunteers in a Phase Ib clinical study with IW-1973, designed to assess its safety, pharmacokinetic profile and pharmacodynamics effects. Data from this study are expected in the second half of 2016.

### **Global Collaborations and Partnerships**

Ironwood's strong U.S. commercial organization successfully introduced LINZESS to the market with its partner Allergan and expects to commercialize multiple important products in the U.S. over time. Ironwood expects to out-license ex-U.S. commercialization rights to its pipeline product candidates. Highlights during the fourth quarter and recent period include:

- | Ironwood and AstraZeneca AB filed for approval with the China Food and Drug Administration to market linaclotide in China for IBS-C.
- | Astellas Pharma Inc. is preparing to submit an NDA in the first quarter of 2016 to the Ministry of Health, Labor and Welfare for approval to market linaclotide for IBS-C in Japan. Under the terms of Ironwood's license agreement with Astellas, Ironwood will earn a \$15 million development milestone payment upon filing of the NDA.
- | Allergan acquired Almirall S.A.'s exclusive rights to develop and commercialize linaclotide in the European Union, Switzerland, Turkey and the Commonwealth of Independent States for the treatment of IBS-C, CIC and other GI conditions. Allergan also reacquired all rights from Almirall to LINZESS in Mexico.
- | Ironwood and Allergan began co-promoting VIBERZI™ (eluxadoline) in the U.S., Allergan's new treatment for adults suffering from IBS with diarrhea (IBS-D).
- | Ironwood and Exact Sciences Corp. continued co-promoting Cologuard®, Exact Sciences' noninvasive stool DNA screening test for colorectal cancer, in the U.S. As of January 2016, approximately 5,000 healthcare practitioners on whom the Ironwood clinical sales specialists have called have ordered a Cologuard test kit, as provided by Exact Sciences.

### **Corporate and Financials**

#### **Collaborative Arrangements Revenue.**

- | Collaborative arrangements revenue was approximately \$53.3 million in the fourth quarter of 2015 compared to

approximately \$38.1 million in the fourth quarter of 2014. Revenue primarily consisted of approximately \$49.3 million in revenue associated with Ironwood's share of the net profits and losses from the sales of LINZESS in the U.S. compared to \$23.9 million in the fourth quarter of 2014.

For the full year 2015, collaborative arrangements revenue was approximately \$149.6 million compared to approximately \$76.4 million in 2014.

#### **Write-down of Inventory to Net Realizable Value and Loss on Non-cancelable Purchase**

**Commitments.** There was no write-down of inventory or loss on non-cancelable purchase commitments in the fourth quarter 2015 and approximately \$17.6 million in inventory related charges for the full year 2015, compared to approximately \$11.4 million and \$20.3 million in the fourth quarter and full year 2014, respectively. The 2015 charges primarily relate to a write-down of existing linaclotide API and a charge for excess purchase commitments recorded in the second quarter, as well as a charge recorded in the third quarter primarily related to the amended European license arrangement with Allergan, as Allergan assumed responsibility for the manufacturing and costs of linaclotide API for Europe.

#### **Operating Expenses.**

Operating expenses were approximately \$59.1 million in the fourth quarter of 2015 as compared to approximately \$58.1 million in the fourth quarter of 2014. Operating expenses in the fourth quarter of 2015 consisted of approximately \$27.6 million in R&D expenses, and approximately \$31.5 million in selling, general and administrative (SG&A) expenses. Non-cash share-based compensation expenses recorded in R&D and SG&A expenses in the fourth quarter of 2015 were approximately \$2.7 million and \$3.8 million, respectively.

For the full year 2015, operating expenses were approximately \$233.9 million as compared to approximately \$220.2 million in 2014. Operating expenses in 2015 consisted of approximately \$108.7 million in R&D expenses, and approximately \$125.2 million in SG&A expenses. Non-cash share-based compensation expenses recorded in R&D and SG&A expenses in 2015 were approximately \$10.1 million and \$15.4 million, respectively.

#### **Other Expense.**

**Interest Expense.** Net interest expense was approximately \$9.8 million and \$30.7 million in the fourth quarter and full year 2015, respectively, in connection with the company's \$175 million debt financing executed in January 2013 and the approximately \$336 million convertible debt financing executed in June 2015. Net interest expense recorded in the fourth quarter of 2015 includes approximately \$6.4 million in cash expense and approximately \$3.5 million in non-cash expense. Net interest expense recorded in the full year 2015 includes approximately \$23.0 million in cash expense and approximately \$8.1 million in non-cash expense.

**Gain/Loss on Derivatives.** Ironwood records a gain/loss on derivatives related to the change in fair value of the convertible note hedges and note hedge warrants issued in connection with the convertible debt financing in June 2015. A gain on derivatives of approximately \$1.6 million was recorded in the fourth quarter of 2015 and a loss on derivatives of approximately \$9.9 million was recorded for the full year 2015.

#### **Net Loss.**

GAAP net loss was approximately \$14.0 million, or \$0.09 per share, in the fourth quarter of 2015, as compared to approximately \$37.6 million, or \$0.27 per share, in the fourth quarter of 2014. For the full year 2015, GAAP net loss was approximately \$142.7 million, or \$1.00 per share, as compared to approximately \$189.6 million, or \$1.39 per share, in 2014.

Non-GAAP net loss excludes the impact of mark-to-market adjustments on the derivatives related to Ironwood's convertible debt. Non-GAAP net loss was approximately \$15.7 million, or \$0.10 per share, in the fourth quarter of 2015, and approximately \$132.7 million, or \$0.93 per share, for the full year 2015. See *Non-GAAP Financial Measures* below.

**Cash Position.** Ironwood ended 2015 with approximately \$439 million of cash, cash equivalents and available-for-sale securities. Ironwood used approximately \$19 million and \$107 million of cash for operations during the fourth quarter and full year 2015, respectively, as compared to approximately \$23 million in the fourth quarter of 2014 (which included a \$15 million dollar milestone payment from Astellas) and \$156 million in the full year 2014.

#### **2015 Financial Guidance.**

Total 2015 operating expenses were \$233.9 million, consisting of approximately \$108.7 million in R&D expenses and \$125.2 million in SG&A expenses.

2015 total operating expenses were expected to be in the range of \$220 million to \$250 million. This included \$105 million to \$120 million in R&D expenses and \$115 million to \$130 million in SG&A expenses.

Total 2015 marketing and sales expenses for LINZESS were \$230.9 million.

Allergan and Ironwood total 2015 marketing and sales expenses for LINZESS were expected to be in the range of \$230 million to \$260 million.

#### **2016 Financial Guidance.**

- | Ironwood expects to use less than \$60 million in cash for operations in 2016.
- | Ironwood expects its 2016 total operating expenses to be in the range of \$255 million to \$285 million, which includes \$130 million to \$145 million in R&D expenses and \$125 million to \$140 million in SG&A expenses.
- | Ironwood expects the combined Allergan and Ironwood total 2016 marketing and sales expenses for LINZESS to be in the range of \$230 million to \$260 million.

| **Non-GAAP Financial Measures.** The company presents non-GAAP net loss and non-GAAP net loss per share to exclude the impact of net gains and losses on the derivatives related to our convertible notes that are required to be marked-to-market. These gains and losses may be highly variable, difficult to predict and of a size that could have a substantial impact on the company's reported results of operations in any given period. Management believes this non-GAAP information is useful for investors, taken in conjunction with Ironwood's GAAP financial statements, because it provides greater transparency and period-over-period comparability with respect to Ironwood's operating performance. These measures are also used by management to assess the performance of the business. Investors should consider these non-GAAP measures only as a supplement to, not as a substitute for or as superior to, measures of financial performance prepared in accordance with GAAP. In addition, these non-GAAP financial measures are unlikely to be comparable with non-GAAP information provided by other companies. For a reconciliation of these non-GAAP financial measures to the most comparable GAAP measures, please refer to the table at the end of this press release.

#### Conference Call Information

Ironwood will host a conference call and webcast at 4:30 p.m. Eastern Time, on Thursday, February 18, to discuss its fourth quarter and full year 2015 results 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 35561077. To access the webcast, please visit the Investors section of Ironwood's website at [www.ironwoodpharma.com](http://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 at approximately 7:30 p.m. Eastern Time, on February 18, running through 11:59 p.m. Eastern Time on February 25, 2016. To listen to the replay, dial (855) 859-2056 (U.S. and Canada) or (404) 537-3406 (international) using conference ID number 35561077. 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 and is indicated 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 accelerated transit and a decrease in the activity of pain-sensing nerves in the intestine. The clinical relevance of the effect on pain fibers, which is based on 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 under 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 due to dehydration in young juvenile mice. The safety and efficacy of LINZESS in pediatric patients under 18 years of age have not been established. In adults with IBS-C or CIC treated with LINZESS, the most commonly reported adverse event was diarrhea.

Ironwood and Allergan plc are co-promoting LINZESS in the United States. Linaclotide is marketed by Allergan for the treatment of adults with moderate to severe IBS-C in Europe under the brand name CONSTELLA®. Ironwood also has partnered with Astellas Pharma Inc. for development and commercialization of linaclotide in Japan and with AstraZeneca AB for development and commercialization in China.

#### About CONSTELLA (linaclotide)

Linaclotide is a guanylate cyclase-C receptor agonist (GCCA) with visceral analgesic and secretory activities. Linaclotide is a 14-amino acid synthetic peptide structurally related to the endogenous guanylin peptide family. Both linaclotide and its active metabolite bind to the guanylate cyclase-C receptor, on the luminal surface of the intestinal epithelium. Through its action at GC-C, linaclotide has been shown to reduce visceral pain and increase GI transit in animal models and increase colonic transit in humans. Activation of GC-C results in an increase in concentrations of cyclic guanosine monophosphate (cGMP), both extracellularly and intracellularly. Extracellular cGMP decreases pain-fiber activity, resulting in reduced visceral pain in animal models. Intracellular cGMP causes secretion of chloride and bicarbonate into the intestinal lumen, through activation of the cystic fibrosis transmembrane conductance regulator (CFTR), which results in increased intestinal fluid and accelerated transit.

Linaclotide was discovered by scientists at Ironwood and is marketed by Allergan plc for the treatment of adults with moderate to severe IBS-C in Europe under the brand name CONSTELLA.

#### About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ: IRWD) is a commercial biotechnology company focused on creating medicines that make a difference for patients, building value for our fellow shareholders, and empowering our passionate team. We are advancing an innovative pipeline of medicines in multiple areas of significant unmet need, including irritable bowel syndrome with constipation (IBS-C)/chronic idiopathic constipation (CIC), vascular and fibrotic diseases, and refractory gastroesophageal reflux disease, among others. We discovered, developed and are commercializing linaclotide, the U.S. branded prescription market leader in the IBS-C/CIC category, and we are applying our proven R&D and commercial capabilities to advance multiple internally-developed and externally-accessed product opportunities. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. For more information, please visit [ironwoodpharma.com](http://ironwoodpharma.com) or follow @ironwoodpharma on Twitter; information that may be important to investors will be routinely posted in both these locations.

LINZESS® and CONSTELLA® are trademarks owned by Ironwood Pharmaceuticals, Inc. Any other trademarks referred to in this press release are the property of their respective owners. All rights reserved.

#### LINZESS Important Safety Information

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##### **WARNING: PEDIATRIC RISK**

**LINZESS is contraindicated in pediatric patients under 6 years of age. In nonclinical studies, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths due to dehydration in young juvenile mice. Use of LINZESS should be avoided in pediatric patients 6 through 17 years of age. The safety and efficacy of LINZESS has not been established in pediatric patients under 18 years of age.**

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#### Contraindications

- | LINZESS is contraindicated in pediatric patients under 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 children under 6 years of age. The safety and effectiveness of LINZESS in pediatric patients under 18 years of age have not been established. In neonatal mice, increased fluid secretion as a consequence of GC-C agonism resulted in mortality within the first 24 hours due to dehydration. Due to increased intestinal expression of GC-C, children under 6 years of age may be more likely than older children and adults to develop significant diarrhea and its potentially serious consequences.
- | Use of LINZESS should be avoided in pediatric patients 6 through 17 years of age. 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. The healthcare provider should consider dose suspension and rehydration.

## Adverse Reactions

- | In IBS-C clinical trials, the most common adverse reactions in LINZESS-treated patients (incidence  $\geq 2\%$  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  $\geq 2\%$  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](http://www.frx.com/pi/linzess_pi.pdf)

## VIBERZI Important Safety Information

### Contraindications

- | Known or suspected biliary duct obstruction, or sphincter of Oddi disease or dysfunction; a history of pancreatitis; structural diseases of the pancreas.
- | Alcoholism, alcohol abuse, alcohol addiction, or drink more than 3 alcoholic beverages per day.
- | Severe hepatic impairment.
- | A history of chronic or severe constipation or sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction.

### Warnings and Precautions

#### *Sphincter of Oddi Spasm:*

- | There is a potential for increased risk of sphincter of Oddi spasm, resulting in pancreatitis or hepatic enzyme elevation associated with acute abdominal pain (eg, biliary-type pain) with VIBERZI. These events were reported in less than 1% of patients receiving VIBERZI in clinical trials.
- | Patients without a gallbladder are at increased risk. Consider alternative therapies before using VIBERZI in patients without a gallbladder and evaluate the benefits and risks of VIBERZI in these patients.
- | Inform patients without a gallbladder that they may be at increased risk for symptoms of sphincter of Oddi spasm, such as elevated liver transaminases associated with abdominal pain or pancreatitis, especially during the first few weeks of treatment. Instruct patients to stop VIBERZI and seek medical attention if they experience symptoms of sphincter of Oddi spasm.

#### *Pancreatitis:*

- | There is a potential for increased risk of pancreatitis not associated with sphincter of Oddi spasm; such events were reported in less than 1% of patients receiving VIBERZI in clinical trials, and the majority were associated with excessive alcohol intake. All pancreatic events resolved upon discontinuation of VIBERZI.
- | Instruct patients to avoid chronic or acute excessive alcohol use while taking VIBERZI. Monitor for new or worsening abdominal pain that may radiate to the back or shoulder, with or without nausea and vomiting, associated with elevations of pancreatic enzymes. Instruct patients to stop VIBERZI and seek medical attention if they experience symptoms suggestive of pancreatitis.

### Adverse Reactions

- | The most commonly reported adverse reactions (incidence  $> 5\%$  and greater than placebo) were constipation, nausea, and abdominal pain.

Please see full Prescribing Information for VIBERZI.

*This press release contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about the development, launch and commercial potential of linaclotide, our*

product candidates and the other products that we promote and the drivers, timing, impact and results thereof; our corporate goals; market size, growth and opportunity, including peak sales and the potential demand for linaclotide and our product candidates, as well as their potential impact on applicable markets; the potential indications for, and benefits of, linaclotide and our product candidates; the anticipated timing of preclinical, clinical and regulatory developments and the design, timing and results of clinical and preclinical studies; the potential for, and timing of, regulatory submissions and approvals for linaclotide and our product candidates; expected periods of patent exclusivity; the strength of the intellectual property protection for our product and product candidates; potential business development activity and the timing and impact thereof; our potential for rapid, sustainable, high-margin growth; and 2016 financial performance and results, and guidance and expectations related thereto, including expectations regarding the need for future financings, cash flows (including cash use for operations), LINZESS profitability, operating expenses, revenue growth, operating leverage, commercial margin and LINZESS net sales and marketing and sales expense. 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 those related to the effectiveness of commercialization efforts by us and our partners; preclinical and clinical development, manufacturing and formulation development; the risk that findings from our completed nonclinical and clinical studies may not be replicated in later studies; efficacy, safety and tolerability of linaclotide and our product candidates; decisions by regulatory authorities; the risk that we may never get sufficient patent protection for linaclotide and our product candidates; developments in the intellectual property landscape; challenges from and rights of competitors or potential competitors; the risk that our planned investments do not have the anticipated effect on our company revenues, linaclotide or our product candidates; the risk that we are unable to manage our operating expenses or cash use for operations, or are unable to commercialize LINZESS, within the guided ranges; and the risks listed under the heading "Risk Factors" and elsewhere in Ironwood's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, and in our subsequent SEC filings. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and Ironwood undertakes no obligation to update these forward-looking statements. Further, Ironwood considers the net profit for the U.S. LINZESS brand collaboration with Allergan in assessing the product's performance and calculates it based on inputs from both Ironwood and Allergan. This figure should not be considered a substitute for Ironwood's GAAP financial results. An explanation of our calculation of this figure is provided in the U.S. LINZESS Brand Collaboration table and related footnotes accompanying this press release.

**Condensed Consolidated Balance Sheets**  
(In thousands)  
(unaudited)

	December 31, 2015	December 31, 2014
<b>Assets</b>		
Cash, cash equivalents and available-for-sale securities	\$ 439,394	\$ 248,334
Accounts receivable, net	54,518	25,839
Inventory	-	4,954
Prepaid expenses and other current assets	6,293	9,180
Total current assets	500,205	288,307
Property and equipment, net	21,075	29,826
Convertible note hedges	86,466	-
Other assets	11,375	11,189
Total assets	<u>\$ 619,121</u>	<u>\$ 329,322</u>
<b>Liabilities and Stockholders' Equity</b>		
Accounts payable, accrued expenses and other current liabilities	\$ 36,135	\$ 35,948
Current portion of capital lease obligations	2,631	1,152
Current portion of deferred rent	5,544	4,992
Current portion of deferred revenue	7,191	7,191
Current portion of long-term debt	24,964	11,258
Total current liabilities	76,465	60,541
Capital lease obligations	306	2,571
Deferred rent	6,395	10,522
Deferred revenue	1,798	8,989
Other liabilities	10,120	-
Note hedge warrants	75,328	-
Convertible notes	220,620	-
Long-term debt	132,964	158,147
Total stockholders' equity	<u>95,125</u>	<u>88,552</u>

Total liabilities and stockholders' equity

\$ 619,121 \$ 329,322

**Condensed Consolidated Statements of Operations**  
(In thousands, except per share amounts)  
(unaudited)

	<b>Three Months Ended December 31,</b>		<b>Twelve Months Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Collaborative arrangements revenue	\$ 53,307	\$ 38,073	\$ 149,555	\$ 76,436
Cost and expenses:				
Cost of revenue	—	1,743	12	5,291
Write-down of inventory to net realizable value and loss on non-cancellable purchase commitments	—	11,398	17,638	20,292
Research and development	27,627	27,482	108,746	101,890
Selling, general and administrative	31,507	30,575	125,247	118,333
Total cost and expenses	<u>59,134</u>	<u>71,198</u>	<u>251,643</u>	<u>245,806</u>
Loss from operations	(5,827)	(33,125)	(102,088)	(169,370)
Other (expense) income:				
Interest expense, net	(9,830)	(5,183)	(30,653)	(20,909)
Gain (Loss) on derivatives	1,620	—	(9,928)	—
Other income	—	661	—	661
Other expense, net	<u>(8,210)</u>	<u>(4,522)</u>	<u>(40,581)</u>	<u>(20,248)</u>
GAAP net loss	<u>\$ (14,037)</u>	<u>\$ (37,647)</u>	<u>\$ (142,669)</u>	<u>\$ (189,618)</u>
GAAP net loss per share—basic and diluted	\$ (0.09)	\$ (0.27)	\$ (1.00)	\$ (1.39)

	<b>Three Months Ended December 31,</b>		<b>Twelve Months Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Non-GAAP net loss	\$ (15,657)	\$ (37,647)	\$ (132,741)	\$ (189,618)
Non-GAAP net loss per share (basic and diluted)	\$ (0.10)	\$ (0.27)	\$ (0.93)	\$ (1.39)
Weighted average number of common shares used in net loss per share—basic and diluted	142,751	139,815	142,155	136,811

**Reconciliation of GAAP Results to Non-GAAP Financial Measures**  
(In thousands, except per share amounts)  
(unaudited)

A reconciliation between net loss on a GAAP basis and on a non-GAAP basis is as follows:

	<b>Three Months Ended December 31,</b>		<b>Twelve Months Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
GAAP net loss	\$ (14,037)	\$ (37,647)	\$ (142,669)	\$ (189,618)
Adjustments:				
Mark-to-market adjustments on the derivatives related to convertible notes, net	(1,620)	—	9,928	—
Non-GAAP net loss	<u>\$ (15,657)</u>	<u>\$ (37,647)</u>	<u>\$ (132,741)</u>	<u>\$ (189,618)</u>



A reconciliation between diluted net loss per share on a GAAP basis and on a non-GAAP basis is as follows:

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
GAAP net loss per share - Basic and Diluted	\$ (0.09)	\$ (0.27)	\$ (1.00)	\$ (1.39)
Adjustments to GAAP net loss per share (as detailed above)	(0.01)	—	0.07	—
Non-GAAP net loss per share - basic and diluted	\$ (0.10)	\$ (0.27)	\$ (0.93)	\$ (1.39)

**U.S. LINZESS Brand Collaboration<sup>1</sup>**  
**Revenue/Expense Calculation**  
(In thousands)  
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
LINZESS U.S. net sales	\$ 129,726	\$ 93,752	\$ 454,769	\$ 296,980
Commercial costs and expenses <sup>2</sup>	45,963	60,050	247,236	268,414
Net profit on sales of LINZESS	\$ 83,763	\$ 33,702	\$ 207,533	\$ 28,566
<i>Commercial Margin<sup>3</sup></i>	65%	36%	46%	10%
Ironwood's share of net profit	\$ 41,882	\$ 16,851	\$ 103,767	\$ 14,283
Ironwood's selling, general and administrative expenses <sup>4</sup>	7,381	7,654	32,028	31,646
Profit share adjustment <sup>5</sup>	—	(622)	(2,370)	1,689
Ironwood's collaborative arrangement revenue	\$ 49,263	\$ 23,883	\$ 133,425	\$ 47,618

<sup>1</sup> Ironwood collaborates with Allergan on the development and commercialization of linaclotide in North America. Under the terms of the collaboration agreement, Ironwood 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 Ironwood's share of net profit (loss) generated from the sales of LINZESS in the U.S. and Ironwood's collaboration revenue/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. For the three months ended December 31, 2015, net profit for the U.S. LINZESS brand collaboration with Allergan was \$66.8 million, calculated by subtracting \$46.0 million in commercial costs and expenses and \$16.9 million in research and development expenses, from LINZESS U.S. net sales of \$129.7 million. For the full year 2015, net profit for the U.S. LINZESS brand collaboration with Allergan was \$132.8 million, calculated by subtracting \$247.2 million in commercial costs and expenses and \$74.8 million in research and development expenses, from LINZESS U.S. net sales of \$454.8 million.

<sup>2</sup> Includes cost of goods sold incurred by Allergan as well as selling, general and administrative expenses incurred by Allergan and Ironwood that are attributable to the cost-sharing arrangement between the parties.

<sup>3</sup> Commercial margin is defined as net profit on sales of LINZESS as a percent of total LINZESS U.S. net sales.

<sup>4</sup> Includes Ironwood's selling, general and administrative expenses attributable to the cost-sharing arrangement with Allergan.

<sup>5</sup> Ironwood or Allergan may incur additional expenses related to certain contractual obligations, resulting in an adjustment to the company's share of the net profits as stipulated by the collaboration agreement.

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