

## Ironwood Pharmaceuticals Provides Second Quarter 2017 Investor Update

- LINZESS<sup>®</sup> (linaclotide) expanded IBS-C/CIC branded prescription market leadership in 2Q 2017 with 19% growth in volume year-over-year and \$168 million in U.S. net sales -

- Positive IW-3718 Phase IIb top-line data in uncontrolled GERD support advancement into Phase III -

- Multiple additional catalysts expected in 2H 2017, including DUZALLO<sup>®</sup> (lesinurad and allopurinol) approval and launch, three mid-stage data readouts and four mid- to late-stage trial initiations -

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Ironwood Pharmaceuticals, Inc.](http://www.ironwoodpharm.com) (NASDAQ: IRWD), a commercial biotechnology company, today provided an update on its second quarter 2017 results and recent business activities.

"Our performance in the first half of 2017 reinforces the potential for our commercial products and mid- to late-stage pipeline to efficiently grow large consumer-driven patient categories and help millions of patients for years to come," said Peter Hecht, chief executive officer of Ironwood. "We expect LINZESS and DR1, if approved, to coexist as leading products and grow the IBS-C/CIC category into the 2030s. IW-3718, if approved, has the opportunity to build and grow the uncontrolled GERD market, and is a strong fit with our U.S. commercial capabilities. These assets, combined with DUZALLO, DR2 and our sGC stimulators, position us well to continue to deliver new medicines to patients and accelerate high-margin growth for our fellow shareholders."

### Second Quarter 2017 and Recent Highlights

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

- 1 LINZESS. U.S. net sales, as reported by Ironwood's U.S. collaboration partner Allergan plc, were \$167.8 million in the second quarter of 2017, a 12% increase compared to the second quarter of 2016. Ironwood and Allergan share equally in brand collaboration profits.
  - 1 Total LINZESS prescription volume in the second quarter of 2017 included over 28 million LINZESS capsules, a 19% increase in capsules compared to the second quarter of 2016, per QuintilesIMS.
    - 1 Levels of inventory held in the channel were lower in the second quarter of 2017 compared to the second quarter of 2016, resulting in lower year-over-year growth in LINZESS net sales compared to LINZESS prescription volume. If inventory remains at these levels, we expect there will continue to be a gap between growth in LINZESS net sales and growth in LINZESS prescription volume for the balance of 2017.
  - 1 More than 750,000 total LINZESS prescriptions were filled in the second quarter of 2017, a 15% increase compared to the second quarter of 2016, per QuintilesIMS.
  - 1 Since the launch of LINZESS in December 2012, greater than 1.5 million unique patients have filled more than 8 million prescriptions, per QuintilesIMS.
  - 1 Net profit for the LINZESS U.S. brand collaboration, including commercial and research and development (R&D) expenses, was \$72.2 million in the second quarter of 2017, a 24% increase compared to the second quarter of 2016.
    - 1 LINZESS commercial margin was 52% in both the second quarter of 2017 and of 2016.
  - 1 Ironwood received a U.S. patent covering a component of LINZESS as well as formulations comprising linaclotide and this component. The patent extends the LINZESS patent portfolio into 2033.
- 1 *Linaclotide Delayed Release-1 (DR1)*. Ironwood and Allergan are evaluating DR1 in adult patients with IBS-C. The companies are engaging with the U.S. Food and Drug Administration (FDA) to discuss Phase III development plans, with Phase III IBS-C trials expected to begin in the second half of 2017.
- 1 *Linaclotide Delayed Release-2 (DR2)*. Ironwood and Allergan are evaluating DR2 for the potential to treat patients with disorders where lower abdominal pain is a predominant symptom, such as non-constipated subtypes of IBS. The

companies plan to engage with the FDA to discuss advancing DR2 into Phase IIb dose-ranging clinical trials, expected to begin in 2018.

### **Uncontrolled Gout**

- | *ZURAMPIC*<sup>®</sup> (*lesinurad*). In October 2016, Ironwood began commercializing ZURAMPIC in the U.S. for the treatment of hyperuricemia in patients with uncontrolled gout who are already taking a xanthine oxidase inhibitor (XOI), such as allopurinol or Uloric<sup>®</sup> (febuxostat). ZURAMPIC is not recommended for the treatment of asymptomatic hyperuricemia and should not be used as monotherapy.
  - | ZURAMPIC U.S. net sales were \$0.5 million in the second quarter of 2017.
  - | Approximately 1,500 total ZURAMPIC prescriptions were filled in the second quarter of 2017, per QuintilesIMS.
- | *DUZALLO*. The DUZALLO New Drug Application (NDA) for the treatment of hyperuricemia in patients with uncontrolled gout is currently under FDA review. If approved, DUZALLO is expected to be commercially available early in the fourth quarter of 2017 and would be the first fixed-dose, combination treatment of hyperuricemia in patients with uncontrolled gout.

### **Uncontrolled Gastroesophageal Reflux Disease (GERD)**

- | *IW-3718*. IW-3718 is a wholly-owned asset being developed for the potential treatment of uncontrolled GERD. In July 2017, Ironwood announced positive top-line data from a Phase IIb clinical trial of IW-3718 in adult patients with uncontrolled GERD. The trial met its primary endpoint, indicating that twice-daily, oral dosing of IW-3718 1500 mg plus a proton pump inhibitor (PPI) significantly reduced heartburn severity in patients by 58.0% compared to 46.0% in patients treated with a PPI alone. Further, 52.9% of patients treated with IW-3718 1500 mg plus a PPI achieved a clinically meaningful reduction in heartburn severity, based on patient-reported outcome measures. In the study, IW-3718 1500 mg plus a PPI also showed a 55.4% reduction in regurgitation frequency compared to 37.9% in patients treated with a PPI alone. IW-3718 1500 mg was well tolerated in the trial; the most common adverse event reported overall was constipation. Ironwood plans to have end of Phase II meetings with the FDA, after which the company expects to advance IW-3718 1500 mg into Phase III development in the second half of 2018.

### **Vascular and Fibrotic Diseases**

- | *IW-1973*. Ironwood expects to initiate Phase II trials of IW-1973 during the second half of 2017 in three disease states: heart failure with preserved ejection fraction, diabetic nephropathy, and resistant hypertension.
  - | Data from two Phase IIa studies with IW-1973 in diabetic patients with hypertension are expected in the second half of 2017. The first study is designed to evaluate the effect of IW-1973 on endothelial function and explores its effects on biomarkers. The second study is a fourteen-day study designed to evaluate the tolerability and blood pressure effects of IW-1973.
- | *IW-1701*. Ironwood is enrolling patients with Type II achalasia in a Phase IIa randomized, double-blind, placebo-controlled single-dose study of IW-1701. This study is designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of IW-1701 in these patients. Data from this study are expected in the second half of 2017.

### **Global Collaborations and Partnerships**

- | Ironwood continues to co-promote Allergan's VIBERZI<sup>®</sup> (eluxadoline) in the U.S. for adults suffering from IBS with diarrhea.
- | Ironwood's partner, Astellas Pharma Inc., is commercializing LINZESS for adults with IBS-C in Japan. Astellas also plans to submit a Supplemental New Drug Application with the Pharmaceuticals and Medical Devices Agency in Japan in the second half of 2017 for potential approval for the treatment of chronic constipation.
- | Ironwood expects the China Food and Drug Administration to complete its review of the filing for approval to market linaclotide in China for adult IBS-C patients in the first quarter of 2018. Ironwood is partnered with AstraZeneca AB for development and commercialization of linaclotide in China.

### **Corporate and Financials**

#### **Total Revenues**

- | Total revenues were \$65.1 million in the second quarter of 2017 compared to \$54.4 million in the second quarter of 2016. Included in total revenues was \$56.3 million associated with Ironwood's share of the net profits from the sales of LINZESS in the U.S., as well as sales of linaclotide API, linaclotide royalties, co-promotion

revenue and ZURAMPIC revenue.

#### **Operating Expenses**

- i Operating expenses were \$106.1 million in the second quarter of 2017 as compared to \$69.7 million in the second quarter of 2016. Operating expenses in the second quarter of 2017 consisted of \$3.5 million in cost of revenues, \$37.3 million in R&D expenses, \$57.8 million in selling, general and administrative (SG&A) expenses, \$0.1 million in write-down of lesinurad commercial supply to net realizable value, \$0.4 million in acquired intangible asset amortization expenses, and a \$6.9 million loss on fair value remeasurement of contingent consideration.
- i Contingent consideration and amortization of acquired intangible assets relate to Ironwood's licensing agreement with AstraZeneca for the exclusive U.S. rights to all products containing lesinurad.

#### **Other Expense**

- i **Interest Expense.** Net interest expense was \$8.6 million in the second quarter of 2017, primarily in connection with the \$150 million 8.375% Notes funded in January 2017 and the approximately \$336 million convertible debt financing funded in June 2015. Interest expense recorded in the second quarter of 2017 includes \$5.0 million in cash expense and \$4.0 million in non-cash expense.
- i **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 funded in June 2015. A gain on derivatives of \$5.3 million was recorded in the second quarter of 2017.

#### **Net Loss**

- i GAAP net loss was \$44.2 million, or \$0.30 per share, in the second quarter of 2017, compared to \$21.7 million, or \$0.15 per share, in the second quarter of 2016.
- i Non-GAAP net loss was \$42.2 million, or \$0.28 per share, in the second quarter of 2017, compared to \$23.8 million, or \$0.16 per share, in the second quarter of 2016. Non-GAAP net loss excludes the impact of mark-to-market adjustments on the derivatives related to Ironwood's convertible debt, as well as the amortization of acquired intangible assets and the fair value remeasurement of contingent consideration related to Ironwood's U.S. lesinurad license. See Non-GAAP Financial Measures below.

#### **Cash Position**

- i Ironwood ended the second quarter of 2017 with \$272.9 million of cash, cash equivalents and available-for-sale securities. Ironwood used approximately \$31.3 million of cash for operations during the second quarter of 2017.

#### **2017 Financial Guidance**

- i Ironwood continues to expect:
  - n R&D expenses to be in the range of \$145 million to \$160 million.
  - n SG&A expenses to be in the range of \$235 million to \$250 million.
  - n the combined Allergan and Ironwood total 2017 marketing and sales expenses for LINZESS to be in the range of \$250 million to \$280 million.
  - n net interest expense to be approximately \$40 million.
  - n to use less than \$100 million in cash for operations in 2017.

#### **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, as well as the amortization of acquired intangible assets and the fair value remeasurement of contingent consideration associated with Ironwood's U.S. licensing agreement with AstraZeneca for the exclusive rights to all products containing lesinurad. The derivative 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. The acquired intangible assets are valued as of the date of acquisition and are amortized over their estimated economic useful life, and management believes excluding the amortization of acquired intangible assets provides more consistency with the treatment of internally developed intangible assets for which research and development costs were previously expensed. The contingent consideration balance is remeasured each reporting period, and the resulting change in fair value impacts the company's reported results of operations. The changes in the fair value remeasurement of contingent consideration do not correlate to the company's actual cash payment obligations in the relevant 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, August 3, 2017 to discuss its second quarter of 2017 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 51693981. 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 August 3, 2017 running through 11:59 p.m. Eastern Time on August 10, 2017. To listen to the replay, dial (855) 859-2056 (U.S. and Canada) or (404) 537-3406 (international) using conference ID number 51693981. The archived webcast will be available on Ironwood's website for 14 days beginning approximately one hour after the call has completed.

#### 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 commercializing two innovative primary care products: linaclotide, the U.S. branded prescription market leader for adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC), and lesinurad, which is approved to be taken with a xanthine oxidase inhibitor (XOI) for the treatment of hyperuricemia associated with uncontrolled gout. We are also advancing a pipeline of internally and externally generated innovative product candidates in areas of significant unmet need, including uncontrolled gastroesophageal reflux disease and vascular and fibrotic diseases. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. For more information, please visit [www.ironwoodpharma.com](http://www.ironwoodpharma.com) or [www.twitter.com/ironwoodpharma](https://www.twitter.com/ironwoodpharma); information that may be important to investors will be routinely posted in both these locations.

#### About LINZESS (linaclotide)

LINZESS® is the #1 prescribed brand for the treatment of adult patients with irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC), based on QuintilesIMS data. Since its FDA approval in August of 2012 and subsequent launch in December 2012, greater than 1.5 million unique patients have filled more than 8 million prescriptions for LINZESS, according to QuintilesIMS.

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, straining, and incomplete evacuation associated with CIC. The recommended dose is 290 mcg for IBS-C patients and 145 mcg for CIC patients, with a 72 mcg dose approved for use in CIC depending on individual patient presentation or tolerability. LINZESS should be taken at least 30 minutes before the first meal of the day.

LINZESS is contraindicated in pediatric patients less than 6 years of age. The safety and effectiveness of LINZESS in pediatric patients less than 18 years of age have not been established. In neonatal mice, linaclotide increased fluid secretion as a consequence of GC-C agonism resulting in mortality within the first 24 hours due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than patients 6 years of age and older to develop severe diarrhea and its potentially serious consequences. In adults with IBS-C or CIC treated with LINZESS, the most commonly reported adverse event was diarrhea.

LINZESS is not a laxative; it is the first medicine approved by the FDA in a class called guanylate cyclase-C (GC-C) agonists. LINZESS contains a peptide called linaclotide that activates the GC-C receptor in the intestine. Activation of GC-C is thought to result 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 the United States, Ironwood and Allergan plc co-develop and co-commercialize LINZESS for the treatment of adults with IBS-C or CIC. In Europe, Allergan markets linaclotide under the brand name CONSTELLA® for the treatment of adults with moderate to severe IBS-C. In Japan, Ironwood's partner Astellas markets linaclotide under the brand name LINZESS for the treatment of adults with IBS-C. Ironwood also has partnered with AstraZeneca for development and commercialization of linaclotide in China, and with Allergan for development and commercialization of linaclotide in all other territories worldwide.

#### About ZURAMPIC (lesinurad) 200mg tablets

ZURAMPIC (lesinurad) works in combination with xanthine oxidase inhibitors (XOIs) to treat hyperuricemia associated with

uncontrolled gout. ZURAMPIC is not recommended for the treatment of asymptomatic hyperuricemia and should not be used as monotherapy. XOIs reduce the production of uric acid; ZURAMPIC increases the excretion of uric acid. Together, the combination of ZURAMPIC and an XOI provides a dual mechanism of action that both decreases production and increases excretion of uric acid, thereby lowering serum uric acid (sUA) levels in patients who have not achieved target serum uric acid levels with XOI treatment alone. ZURAMPIC selectively inhibits the function of transporter proteins uric acid transporter 1 (URAT1) and organic anion transporter 4 (OAT4), involved in uric acid reabsorption in the kidney. The safety and efficacy of ZURAMPIC was established in three Phase III clinical trials that evaluated a once-daily dose of ZURAMPIC in combination with the XOI allopurinol or febuxostat compared to XOI alone. The boxed warning for ZURAMPIC states that acute renal failure has occurred with ZURAMPIC and was more common when ZURAMPIC was given alone and reinforces that ZURAMPIC should be used in combination with an XOI.

## LINZESS Important Safety Information

### INDICATIONS AND USAGE

LINZESS (linaclotide) is indicated in adults for the treatment of both irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC).

### IMPORTANT SAFETY INFORMATION

#### WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS

**LINZESS is contraindicated in patients less than 6 years of age. In nonclinical studies in neonatal mice, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths due to dehydration. Use of LINZESS should be avoided in patients 6 years to less than 18 years of age. The safety and effectiveness of LINZESS have not been established in patients less than 18 years of age.**

### Contraindications

- ┆ LINZESS is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
- ┆ LINZESS is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

### Warnings and Precautions

#### *Pediatric Risk*

- ┆ LINZESS is contraindicated in patients less than 6 years of age. The safety and effectiveness of LINZESS in patients less than 18 years of age have not been established. In neonatal mice, linaclotide increased fluid secretion as a consequence of GC-C agonism resulting in mortality within the first 24 hours due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than patients 6 years of age and older to develop severe diarrhea and its potentially serious consequences.
- ┆ Use of LINZESS should be avoided in pediatric patients 6 years to less than 18 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 years to less than 18 years of age.

#### *Diarrhea*

- ┆ Diarrhea was the most common adverse reaction in LINZESS-treated patients in the pooled IBS-C and CIC double-blind placebo-controlled trials. The incidence of diarrhea was similar in the IBS-C and CIC populations. Severe diarrhea was reported in 2% of 145 mcg and 290 mcg LINZESS-treated patients, and in < 1% of 72 mcg LINZESS-treated CIC patients. If severe diarrhea occurs, dosing should be suspended and the patient rehydrated.

### Common Adverse Reactions (incidence $\geq$ 2% and greater than placebo)

- ┆ In IBS-C clinical trials: 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 trials of a 145 mcg dose: 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%). In a CIC trial of a 72 mcg dose: diarrhea (19% vs 7% placebo) and abdominal distension (2% vs < 1%).

Please see full Prescribing Information including Boxed Warning:

## ZURAMPIC Important Safety Information and Limitations of Use

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### **WARNING: RISK OF ACUTE RENAL FAILURE MORE COMMON WHEN USED WITHOUT A XANTHINE OXIDASE INHIBITOR (XOI)**

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- Acute renal failure has occurred with ZURAMPIC and was more common when ZURAMPIC was given alone
  - ZURAMPIC should be used in combination with an XOI
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#### **Contraindications:**

- ┆ Severe renal impairment (eCLcr less than 30 mL/min), end-stage renal disease, kidney transplant recipients, or patients on dialysis
- ┆ Tumor lysis syndrome or Lesch-Nyhan syndrome

#### **Warnings and Precautions:**

- ┆ **Renal events:** Adverse reactions related to renal function have occurred after initiating ZURAMPIC. A higher incidence was observed at the 400-mg dose, with the highest incidence occurring with monotherapy use. Monitor renal function at initiation and during therapy with ZURAMPIC, particularly in patients with eCLcr below 60 mL/min or with serum creatinine elevations 1.5 to 2 times the pre-treatment value, and evaluate for signs and symptoms of acute uric acid nephropathy. Interrupt treatment with ZURAMPIC if serum creatinine is elevated to greater than 2 times the pre-treatment value or if there are symptoms that may indicate acute uric acid nephropathy. ZURAMPIC should not be restarted without another explanation for the serum creatinine abnormalities. ZURAMPIC should not be initiated in patients with an eCLcr less than 45 mL/min.
- ┆ **Cardiovascular events:** In clinical trials, major adverse cardiovascular events (defined as cardiovascular deaths, non-fatal myocardial infarctions, or non-fatal strokes) were observed with ZURAMPIC. A causal relationship has not been established.

#### **Adverse Reactions:**

- ┆ Most common adverse reactions with ZURAMPIC (in combination with an XOI and more frequently than on an XOI alone) were headache, influenza, blood creatinine increased, and gastroesophageal reflux disease

#### **Indication and Limitations of Use for ZURAMPIC**

ZURAMPIC is a URAT1 inhibitor indicated in combination with an XOI for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with an XOI alone.

- ┆ ZURAMPIC is not recommended for the treatment of asymptomatic hyperuricemia
- ┆ ZURAMPIC should not be used as monotherapy

Please see full Prescribing Information, including Boxed Warning, at:

<http://www.azpicentral.com/zurampic/zurampic.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:

[http://www.allergan.com/assets/pdf/viberzi\\_pi](http://www.allergan.com/assets/pdf/viberzi_pi).

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*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, commercial availability and commercial potential of linaclotide, lesinurad, our product candidates and the other products that we promote and the drivers, timing, impact and results thereof (including pipeline catalysts); market size, prevalence, growth and opportunity, including peak sales (and drivers thereof) and the growth in and potential demand for linaclotide, lesinurad and our product candidates, as well as their potential impact on applicable markets; the potential indications for, and benefits of, linaclotide, lesinurad and our product candidates; the anticipated timing of preclinical, clinical and regulatory developments and the design, timing and results of clinical and preclinical studies (including engaging with the FDA and defining primary and secondary endpoints); the potential for, and timing of, regulatory submissions and approvals for linaclotide, lesinurad and our product candidates; expected periods of patent exclusivity and life of the respective patent portfolios for linaclotide, lesinurad and our product candidates; commercial strategy, including market development, the potential for broad access and reimbursement, refreshing our DTC campaign, fit within our U.S. commercial capabilities, and intentions related to commercializing IW-3718 within and outside the U.S.; comparisons related to net sales and volume; the strength of the intellectual property protection for linaclotide, lesinurad and our product candidates and our intentions and efforts to protect such intellectual property; our potential for sustainable, high-margin growth and shareholder returns; and our financial performance and results, and guidance and expectations related thereto (including the drivers and timing thereof), including expectations related to Ironwood revenue CAGR and revenue growth, LINZESS U.S. net sales, growth and net price, R&D, SG&A and marketing and sales expenses, net interest expense and cash used for operations. 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 development and commercialization efforts by us and our partners; preclinical and clinical development, manufacturing and formulation development; our reliance on AstraZeneca to provide critical support services related to lesinurad; the risk that findings from our completed nonclinical and clinical studies may not be replicated in later studies; efficacy, safety and tolerability of linaclotide, lesinurad and our product candidates; decisions by regulatory authorities; the risk that we are unable to successfully integrate lesinurad into our existing business, commercialize lesinurad or realize the anticipated benefits of the lesinurad transaction; the risk that we may never get sufficient patent protection for linaclotide and our product candidates or that we are not able to*

successfully protect such patents; the outcomes in legal proceedings to protect or enforce the patents relating to our products and product candidates, including ANDA litigation; 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, lesinurad 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 our products, within the guided ranges or otherwise as expected; and the risks listed under the heading "Risk Factors" and elsewhere in Ironwood's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, 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)

	June 30, 2017	December 31, 2016
<b>Assets</b>		
Cash, cash equivalents and available-for-sale securities	\$272,895	\$ 305,216
Accounts receivable, net	60,357	64,854
Inventory	-	1,081
Prepaid expenses and other current assets	8,235	9,030
Total current assets	341,487	380,181
Property and equipment, net	17,854	20,512
Convertible note hedges	171,880	132,521
Intangible assets, net	165,278	166,119
Goodwill	785	785
Other assets	7,795	9,703
Total assets	<u>\$705,079</u>	<u>\$ 709,821</u>
<b>Liabilities and Stockholders' Equity</b>		
Accounts payable, accrued expenses and other current liabilities	\$ 59,461	\$ 62,941
Current portion of capital lease obligations	5,097	6,227
Current portion of deferred rent	205	7,719
Current portion of deferred revenue	225	-
Current portion of contingent consideration	14,985	14,244
Total current liabilities	79,973	91,131
Capital lease obligations	-	82
Deferred rent, net of current portion	3,515	557
Other liabilities	8,190	8,190
Contingent consideration, net of current portion	71,213	63,416
Note hedge warrants	149,458	113,237
Convertible notes	241,544	234,243
Long-term debt	146,316	132,249
Total stockholders' equity	4,870	66,716
<b>Total liabilities and stockholders' equity</b>	<u>\$705,079</u>	<u>\$ 709,821</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Total revenues	\$ 65,077	\$ 54,350	\$117,243	\$120,392

Cost and expenses:				
Cost of revenues, excluding amortization of acquired intangible asset	3,502	-	4,033	-
Write-down of lesinurad commercial supply to net realizable value	96	-	96	-
Research and development	37,344	31,682	71,046	63,524
Selling, general and administrative	57,792	36,918	113,396	73,086
Amortization of acquired intangible asset	421	1,065	841	1,065
Loss on fair value remeasurement of contingent consideration	6,933	-	8,547	-
Total cost and expenses	<u>106,088</u>	<u>69,665</u>	<u>197,959</u>	<u>137,675</u>
Loss from operations	(41,011)	(15,315)	(80,716)	(17,283)
Other (expense) income:				
Interest expense, net	(8,550)	(9,532)	(17,138)	(19,218)
Loss on extinguishment of debt	-	-	(2,009)	-
Gain on derivatives	5,337	3,145	3,138	1,502
Other expense, net	<u>(3,213)</u>	<u>(6,387)</u>	<u>(16,009)</u>	<u>(17,716)</u>
GAAP net loss	<u>\$ (44,224)</u>	<u>\$ (21,702)</u>	<u>\$ (96,725)</u>	<u>\$ (34,999)</u>
GAAP net loss per share—basic and diluted	\$ (0.30)	\$ (0.15)	\$ (0.65)	\$ (0.24)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Non-GAAP net loss	\$ (42,207)	\$ (23,782)	\$ (90,475)	\$ (35,436)
Non-GAAP net loss per share (basic and diluted)	\$ (0.28)	\$ (0.16)	\$ (0.61)	\$ (0.25)

Weighted average number of common shares used in net loss per share — basic and diluted	148,778	144,642	148,285	144,118
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**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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
GAAP net loss	\$ (44,224)	\$ (21,702)	\$ (96,725)	\$ (34,999)
Adjustments:				
Mark-to-market adjustments on the derivatives related to convertible notes, net	(5,337)	(3,145)	(3,138)	(1,502)
Amortization of intangible asset	421	1,065	841	1,065
Fair value remeasurement of contingent consideration	6,933	-	8,547	-
Non-GAAP net loss	<u>\$ (42,207)</u>	<u>\$ (23,782)</u>	<u>\$ (90,475)</u>	<u>\$ (35,436)</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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
GAAP net loss per share - Basic and Diluted	\$ (0.30)	\$ (0.15)	\$ (0.65)	\$ (0.24)
Adjustments to GAAP net loss per share (as detailed above)	0.01	(0.01)	0.04	(0.01)

Non-GAAP net loss per share - basic and diluted <sup>1</sup>	<u>\$ (0.28)</u>	<u>\$ (0.16)</u>	<u>\$ (0.61)</u>	<u>\$ (0.25)</u>
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<sup>1</sup> Numbers may not add due to rounding.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
LINZESS U.S. net sales	\$ 167,833	\$ 150,464	\$ 315,448	\$ 287,601
Commercial costs and expenses <sup>2</sup>	80,211	71,556	151,140	133,705
Commercial profit on sales of LINZESS	<u>\$ 87,622</u>	<u>\$ 78,908</u>	<u>\$ 164,308</u>	<u>\$ 153,896</u>
<i>Commercial Margin<sup>3</sup></i>	52%	52%	52%	54%
Ironwood's share of net profit	\$ 43,811	\$ 39,454	\$ 82,154	\$ 76,948
Ironwood's selling, general and administrative expenses <sup>4</sup>	12,496	8,879	23,605	18,032
Ironwood's collaborative arrangement revenue	<u>\$ 56,307</u>	<u>\$ 48,333</u>	<u>\$ 105,759</u>	<u>\$ 94,980</u>

<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 June 30, 2017, net profit for the U.S. LINZESS brand collaboration with Allergan was \$72.2 million, calculated by subtracting \$80.2 million in commercial costs and expenses and \$15.4 million in research and development expenses, from LINZESS U.S. net sales of \$167.8 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 commercial 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.

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