



## Ironwood Pharmaceuticals Provides First Quarter 2015 Investor Update

- LINZESS<sup>®</sup> (linaclotide) U.S. net sales of \$95.5 million in first quarter 2015 -

- Total LINZESS prescriptions increased approximately 90% in first quarter 2015 compared to first quarter 2014 -

- Reported positive top-line data from IW-3718 Phase IIa study for refractory GERD -

- Advanced sGC platform with initiation of first candidate, IW-1973, into Phase I study -

- Established agreement with Exact Sciences to co-promote Cologuard<sup>®</sup> -

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Ironwood Pharmaceuticals, Inc.](http://www.ironwoodpharm.com) (NASDAQ: IRWD) today provided an update on its first quarter 2015 and recent business activities.

"Strong fundamentals continued to fuel LINZESS prescriptions and net sales growth, resulting in another solid quarter of profitability for the LINZESS brand, and we expect at least 16 years of continued expansion ahead for the U.S. linaclotide franchise," said Peter Hecht, chief executive officer of Ironwood. "Our innovative pipeline continues to advance, with positive Phase IIa data for IW-3718 and several important inflection points expected later this year, including up to four additional clinical data readouts. We are also excited to apply our strong commercial capabilities through a collaboration with Exact Sciences to co-promote their innovative colon cancer diagnostic, Cologuard."

### First Quarter 2015 and Recent Highlights

#### **LINZESS<sup>®</sup> (linaclotide)**

- LINZESS U.S. net sales, as provided by Actavis plc, were \$95.5 million in the first quarter of 2015, an approximately 57% increase compared to the first quarter of 2014.
- Approximately 460,000 total LINZESS prescriptions were filled in the first quarter of 2015, an approximately 90% increase compared to the first quarter of 2014, and more than 2.4 million LINZESS prescriptions have been filled since the product's launch in December 2012, according to IMS Health.
  - Higher year over year growth in total LINZESS prescriptions relative to LINZESS net sales was due to (i) a higher build of wholesaler inventory in the first quarter of 2014, and (ii) a previously disclosed change in accounting methodology in the third quarter of 2014 that resulted in certain costs related to LINZESS co-pay assistance programs, previously recognized as sales and marketing expenses, now being recognized as gross-to-net adjustments.
- Net profit for the LINZESS brand collaboration in the U.S., including commercial costs and expenses and research and development (R&D) expenses, was \$15.2 million in the first quarter of 2015. LINZESS U.S. net profit is shared equally with Actavis.
- Greater than 125,000 healthcare practitioners have prescribed LINZESS to nearly 630,000 unique patients since the product's launch, according to IMS Health.
- More than 70% of people with commercial insurance or Medicare Part D plans had unrestricted access to LINZESS as of March 2015. Additionally, as of March 2015, more than 75% of people with commercial insurance had access to LINZESS for a co-pay of \$30 or less through formulary coverage or the LINZESS Instant Savings Program.

#### **Research & Development**

Ironwood continues to advance its innovative pipeline. During 2015, the company expects up to ten ongoing clinical studies and five clinical data readouts, including the recent positive IW-3718 Phase IIa data.

- Ironwood and Actavis continue to evaluate opportunities to strengthen the clinical utility of linaclotide in its indicated

patient population, as well as to develop and seek approval of linaclotide in additional indications, patient populations and formulations. Development highlights during the first quarter and recent period include:

- Faster than anticipated enrollment in the Phase III clinical trial assessing the efficacy and safety of a once-daily 72 mcg dose of linaclotide in adult patients with chronic idiopathic constipation (CIC). If approved, the 72 mcg dose and the currently approved 145 mcg dose would provide a broader range of treatment options to physicians and adult CIC patients. Data from this trial are now expected in the second half of 2015 and a supplemental new drug application is expected to be submitted to the U.S. Food and Drug Administration (FDA) in the first half of 2016.
- Ongoing enrollment in the Phase II clinical study evaluating linaclotide for the treatment of adults suffering from opioid-induced constipation. Data from this study are expected in the second half of 2015.
- Selection of two linaclotide colonic release formulations to be evaluated in a Phase IIb clinical study in adult patients with irritable bowel syndrome with constipation (IBS-C). The Phase IIb study is now expected to initiate in the second half of 2015 with data anticipated in the second half of 2016.
- Ironwood continues to advance its pipeline of gastrointestinal (GI) product candidates and its soluble guanylate cyclase (sGC) program. Development highlights during the first quarter and recent period include:
  - Positive top-line data reported from an exploratory Phase IIa clinical study evaluating IW-3718, Ironwood's investigational gastric retentive bile acid sequestrant. Data from this study demonstrated encouraging improvements in relief of heartburn and certain other symptoms often associated with refractory gastroesophageal reflux disease (GERD). Ironwood intends to advance IW-3718 into a dose-ranging Phase IIb study following development of the commercial-ready formulation.
  - Continued enrollment in a Phase IIa clinical study evaluating the ability of IW-9179 to provide relief of diabetic gastroparesis symptoms. IW-9179 is a guanylate cyclase-C (GC-C) agonist designed to target the upper GI tract. Data from this study are expected in the first half of 2016.
  - Started dosing in a Phase I clinical study of IW-1973 with data expected in the second half of 2015. IW-1973 is the first clinical compound in a broad library of sGC stimulators discovered by Ironwood. The company expects to initiate a Phase I clinical study with its second sGC candidate, IW-1701, in the second half of 2015. Both IW-1973 and IW-1701 are being explored for the potential treatment of cardiovascular diseases.

### **Global Partnerships for Linaclotide**

- Ironwood and AstraZeneca AB completed enrollment in a Phase III clinical trial of linaclotide in adults with IBS-C for China. Data from this trial are expected in the second half of 2015.
- Astellas Pharma Inc. continues to enroll patients in its Phase III clinical trial of linaclotide in adult patients with IBS-C for Japan, and expects to complete the trial in 2016. In addition, Astellas recently initiated a Phase II clinical study of linaclotide in adult patients with chronic constipation for Japan. Astellas expects to complete the Phase II study in 2016.
- Almirall, S.A. continues to commercialize CONSTELLA<sup>®</sup> (linaclotide) in Europe, where it is approved for adult patients with moderate to severe IBS-C and is available in 10 European countries, including the United Kingdom, Italy and Spain.

### **Cologuard<sup>®</sup> Co-Promote**

- Ironwood and Exact Sciences Corp. agreed to co-promote Exact Sciences' Cologuard, the first and only FDA-approved noninvasive stool DNA screening test for colorectal cancer. Ironwood's clinical sales specialists began promoting Cologuard in April 2015. Under the terms of the deal, Ironwood will be compensated from the net sales generated from the physicians on whom it calls. The non-exclusive co-promotion agreement covers an initial one-year term with the opportunity for extension.

### **Corporate and Financials**

- **Collaborative Arrangements Revenue.** Collaborative arrangements revenue was approximately \$28.9 million in the first quarter of 2015 compared to approximately \$14.6 million in the first quarter of 2014. Revenue consisted of approximately \$25.1 million in revenue associated with Ironwood's share of the net profits and losses from the sales of LINZESS in the U.S., as well as approximately \$3.8 million in amortization of deferred revenue associated with consideration received from Ironwood's collaboration with Astellas, revenue recognized in connection with the collaboration with AstraZeneca, sales of linaclotide active pharmaceutical ingredient (API), and royalty payments based on sales of linaclotide in territories outside of the U.S.
- **Cost of revenue.** Cost of revenue is recognized upon shipment of linaclotide API to certain licensing partners outside of the U.S. Actavis records costs associated with linaclotide API in the U.S. Cost of revenue was insignificant in the first quarter of 2015 as compared to \$1.9 million in the first quarter of 2014.
- **Operating Expenses.** Operating expenses were approximately \$57.0 million in the first quarter of 2015 as compared to

approximately \$57.1 million in the first quarter of 2014, which included non-recurring charges totaling \$4.3 million associated with Ironwood's headcount reduction in January 2014. Operating expenses in the first quarter of 2015 consisted of approximately \$26.6 million in R&D expenses, including an approximately \$4.3 million receivable recorded from Actavis for reimbursement of certain prior period manufacturing activities. Operating expenses also consisted of approximately \$30.3 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 first quarter of 2015 were approximately \$2.1 million and \$3.4 million, respectively.

- **Interest Expense.** Interest expense was approximately \$5.2 million in the first quarter of 2015, as compared to approximately \$5.3 million in the first quarter of 2014, in connection with the \$175 million debt financing executed in January 2013.
- **Net Loss.** Net loss was approximately \$33.2 million, or \$0.24 per share, in the first quarter of 2015, as compared to approximately \$49.6 million, or \$0.38 per share, in the first quarter of 2014.
- **Cash Position.** Ironwood ended the first quarter of 2015 with approximately \$216 million of cash, cash equivalents and available-for-sale securities. Ironwood used approximately \$36 million of cash for operations during the first quarter of 2015, as compared to approximately \$58 million in the first quarter of 2014 and approximately \$38 million in the fourth quarter of 2014, excluding the \$15.0 million milestone payment received during the fourth quarter from Astellas upon initiation of a linaclotide Phase III IBS-C trial for Japan.
- **2015 Financial Guidance.**
  - Ironwood continues to expect its 2015 total operating expenses to be in the range of \$220 million to \$250 million, which includes \$105 million to \$120 million in R&D expenses and \$115 million to \$130 million in SG&A expenses.
  - Ironwood continues to expect combined Actavis and Ironwood total 2015 marketing and sales expenses for LINZESS to be in the range of \$230 million to \$260 million.

#### Conference Call Information

Ironwood will host a conference call and webcast at 4:30 p.m. Eastern Time, on Tuesday, May 5, to discuss its first quarter 2015 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 26622828. 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 May 5, running through 11:59 p.m. Eastern Time on May 12, 2015. To listen to the replay, dial (855) 859-2056 (U.S. and Canada) or (404) 537-3406 (international) using conference ID number 26622828. 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<sup>®</sup> 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 Actavis plc are co-promoting LINZESS in the United States. Linaclotide is marketed by Ammirall, S.A. for the treatment of adults with moderate to severe IBS-C in Europe under the brand name CONSTELLA<sup>®</sup>. 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 Almirall, S.A. for the treatment of adults with moderate to severe IBS-C in Europe under the brand name CONSTELLA, through a license agreement between the two companies.

#### About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ: IRWD) is focused on creating medicines that make a difference for patients, building value to earn the continued support of our fellow shareholders, and empowering our team to passionately pursue excellence. We discovered, developed and are commercializing linaclotide, which is approved in the United States and a number of other countries. Our pipeline priorities include exploring further opportunities for linaclotide, as well as leveraging our therapeutic expertise in gastrointestinal disorders and our pharmacologic expertise in guanylate cyclases to address patient needs across the upper and lower gastrointestinal tract. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. Connect with us at [www.ironwoodpharma.com](http://www.ironwoodpharma.com) or on Twitter at [www.twitter.com/ironwoodpharma](https://www.twitter.com/ironwoodpharma); information that may be important to investors will be routinely posted in both these locations.

LINZESS<sup>®</sup> and CONSTELLA<sup>®</sup> 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.

#### 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)

*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, statements about development, launch and commercialization plans for linaclotide and our product candidates; commercial efforts for linaclotide and the drivers, timing, impact and results thereof; market size, growth and opportunity, and potential demand for linaclotide and our product candidates, as well as their potential impact on applicable markets; growth in LINZESS U.S. net sales relative to total LINZESS prescription growth and the drivers thereof; the potential indications for, and benefits of, linaclotide and our product candidates; the anticipated timing of pre-clinical, clinical and regulatory developments; the design, timing and results of clinical and pre-clinical studies; 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; profitability of the U.S. LINZESS brand collaboration with Actavis plc; and our company's financial performance and results, and guidance and expectations related thereto, including our projected 2015 operating expenses, revenue growth, operating leverage, and 2015 marketing and sales expense for LINZESS. 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, but are not limited to, those related to pre-clinical 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; decisions made by U.S. regulatory authorities, the U.S. Patent and Trademark Office and their foreign counterparts; the risk that we may never get sufficient patent protection for linaclotide and our product candidates; intellectual property rights of competitors or potential competitors; efficacy, safety and tolerability of linaclotide and our product candidates; competition in disease states; the commercial potential of linaclotide and our product candidates; 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 identify and execute on business development opportunities in a cost-effective and timely manner or that such opportunities do not have the impact expected; the risk that we are unable to manage our operating expenses over the year due to foreseeable or unforeseeable events or occurrences; and the risk that we and Actavis are unable to commercialize LINZESS within the guided range of expenses. Applicable risks also include those that are listed under the heading "Risk Factors" and elsewhere in Ironwood's Annual Report on Form 10-K for the year ended December 31, 2014, 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 other subsequent SEC filings. Ironwood undertakes no obligation to update these forward-looking statements to reflect events or circumstances occurring after this press release. Except as otherwise noted, 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. Further, Ironwood considers the net profit for the U.S. LINZESS brand collaboration with Actavis in assessing the product's performance and calculates it based on inputs from both Ironwood and Actavis. 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)

	March 31, 2015	December 31, 2014
<b>Assets</b>		
Cash, cash equivalents and available-for-sale securities	\$ 215,865	\$ 248,334
Accounts receivable, net	33,849	25,839

Inventory	4,950	4,954
Prepaid expenses and other current assets	9,212	10,603
Total current assets	<u>263,876</u>	<u>289,730</u>
Property and equipment, net	27,477	29,826
Other assets	14,175	13,957
Total assets	<u>\$ 305,528</u>	<u>\$ 333,513</u>
<b>Liabilities and Stockholders' Equity</b>		
Accounts payable and accrued expenses	\$ 33,232	\$ 35,948
Current portion of capital lease obligations	1,177	1,152
Current portion of deferred rent	5,006	4,992
Current portion of deferred revenue	7,191	7,191
Current portion of long-term debt	<u>13,207</u>	<u>11,258</u>
Total current liabilities	59,813	60,541
Capital lease obligations	2,268	2,571
Deferred rent	9,935	10,522
Deferred revenue	7,191	8,989
Notes payable	158,159	162,338
Total stockholders' equity	<u>68,162</u>	<u>88,552</u>
Total liabilities and stockholders' equity	<u>\$ 305,528</u>	<u>\$ 333,513</u>

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

	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Collaborative arrangements revenue	\$ 28,932	\$ 14,605
Cost and expenses:		
Cost of revenue	12	1,924
Research and development (1)	26,641	27,144
Selling, general and administrative (1)	<u>30,346</u>	<u>29,924</u>
Total cost and expenses	56,999	58,992
Loss from operations	(28,067)	(44,387)
Other expense	<u>(5,155)</u>	<u>(5,239)</u>
Net loss	<u>\$ (33,222)</u>	<u>\$ (49,626)</u>
Net loss per share—basic and diluted	\$ (0.24)	\$ (0.38)
Weighted average number of common shares used in net loss per share — basic and diluted	141,278	129,745

(1) Non-cash compensation expenses reflected in the condensed consolidated statements of operations are as follows:

Research and development	\$ 2,054	\$ 2,690
Selling, general and administrative	\$ 3,372	\$ 3,384

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

<b>Three Months Ended March 31,</b>	
<b>2015</b>	<b>2014</b>

LINZESS U.S. net sales <sup>2</sup>	\$ 95,489	\$ 60,812
Commercial costs and expenses <sup>3</sup>	<u>58,151</u>	<u>59,916</u>
Net profit on sales of LINZESS	<u>\$ 37,338</u>	<u>\$ 896</u>
Ironwood's share of net profit	\$ 18,669	\$ 448
Ironwood's selling, general and administrative expenses <sup>4</sup>	\$ 7,688	\$ 7,999
Profit share adjustment <sup>5</sup>	<u>\$ (1,220)</u>	<u>\$ —</u>
Ironwood's collaborative arrangement revenue	<u>\$ 25,137</u>	<u>\$ 8,447</u>

- 1 Ironwood collaborates with Actavis 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 March 31, 2015, net profit for the U.S. LINZESS brand collaboration with Actavis was \$15.2 million, calculated by subtracting \$58.2 million in commercial costs and expenses and \$22.1 million in research and development expenses, from LINZESS U.S. net sales of \$95.5 million.
- 2 For the three months ended March 31, 2014, certain costs related to the LINZESS co-pay assistance programs were recorded as sales and marketing expenses. Beginning in the third quarter of 2014, and following the integration of Forest Laboratories, Inc. with Actavis plc., these costs are recorded as gross-to-net adjustments.
- 3 Includes cost of goods sold incurred by Actavis as well as selling, general and administrative expenses incurred by Actavis and Ironwood that are attributable to the cost-sharing arrangement between the parties.
- 4 Includes Ironwood's selling, general and administrative expenses attributable to the cost-sharing arrangement with Actavis.
- 5 Ironwood or Actavis 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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