

# Ironwood 3Q 2016 Investor Update

November 3, 2016

# Introduction

**Meredith Kaya** 

Director, Investor Relations



### Safe Harbor Statement

This presentation 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, lesinurad, our product candidates and the other products that we promote and the drivers, timing, impact and results thereof; market size, growth and opportunity, including peak sales and the 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; the potential for, and timing of, regulatory submissions and approvals for linaclotide, lesinurad and our product candidates; milestone and royalty payments; expected periods of patent exclusivity; the strength of the intellectual property protection for linaclotide, lesinurad and our product candidates and our intentions and efforts to protect such intellectual property; ANDAs filed by generic drug manufacturers and potential FDA approval thereof, and associated patent infringement suits that we may file or other action that we may take against such companies, and the timing thereof; expectations regarding the issuance of our 8.375% notes due 2026 and the redemption of our 11% PhaRMA Notes, and the timing thereof; our potential for rapid, sustainable, high-margin growth and shareholder returns; 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), profitability, operating expenses (including R&D expenses, SG&A expenses and amortization of intangible assets), LINZESS marketing and sales expense, revenue growth, operating leverage, commercial margin, net sales and cash flow accretion. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include the risk that we are unable to successfully integrate lesinurad into our existing business, commercialize lesinurad or realize the anticipated benefits of the lesinurad transaction; those related to the effectiveness of 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 may never get sufficient patent protection for linaclotide and our product candidates or that we are not able to successfully protect such patents; 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; and the risks listed under the heading "Risk Factors" and elsewhere in Ironwood's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, and in our subsequent SEC filings. These forward-looking statements (except as otherwise noted) speak only as of the date of this presentation, 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 on page 14 of this presentation.

# 3Q 2016 Overview

Peter Hecht
Chief Executive Officer



### Ironwood 3Q16: Successful Commercial Biotech

Continued execution; opportunity for sustainable value creation

- Ironwood revenue increased 67% to \$66 million in 3Q 2016 over 3Q 2015
- LINZESS® (linaclotide) growing strongly; on track to exceed \$1 billion in annual net sales by 2020
  - U.S. net sales increased 40% to \$164 million in 3Q 2016 over 3Q 2015
  - >60% commercial margin
- ZURAMPIC® (lesinurad) launched in October 2016
  - Focused salesforce bringing both LINZESS and ZURAMPIC to ~30 thousand high prescribing, primary care physicians
- \$320 million in cash & investments + strong revenue growth → expect to deliver positive cash flow beginning in 2018



# 3Q 2016 Commercial Update

Tom McCourt
Chief Commercial Officer



# Strong LINZESS Demand Reinforces Brand Leadership Position in IBS-C/CIC Market



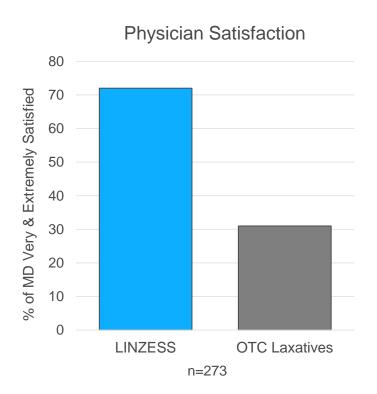
- ~700,000 TRx in 3Q16, 26% growth vs 3Q15<sup>1</sup>
- >5.5 million TRx filled by >1 million unique patients since launch<sup>1,2</sup>
- >17% increase in NRx market share,
   >22% increase in TRx market share YTD through 3Q 2016<sup>1</sup>
- >90% unrestricted access in Medicare
   Part D, >70% in commercial health plans<sup>3</sup>



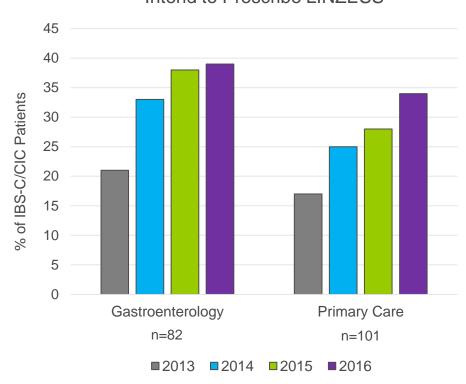


# Most Surveyed Physicians are Highly Satisfied; Intention to Prescribe LINZESS Nearly Doubled since Launch

### Physician Attitude Assessment; September 2016



Percent IBS-C/CIC Patients MDs Intend to Prescribe LINZESS



#### Physician Attitude Assessment, SRI, Sept 2016

Q: Thinking of your experience with each of the following product(s) used to treat IBS-C and/or CIC symptoms, please indicate how satisfied you are with the overall performance of each product used for the treatment of IBS-C and/or CIC.

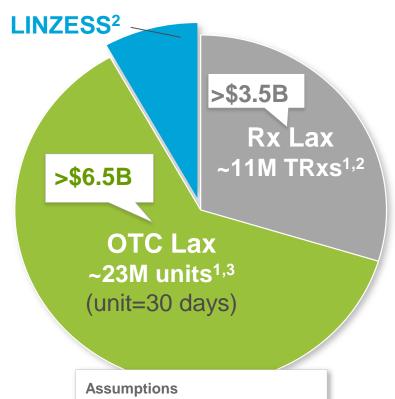
Physician Attitude Assessment, SRI, Sept 2016

Q:Please think of all your IBS-C patients whom you will treat with medication in the next 3 months. For what percent of these patients do you expect to prescribe / recommend the following product(s)?



## Significant Opportunity for Continued LINZESS Growth

>\$6.5B Opportunity in OTC Market; 2/3 of LINZESS NRx from OTC<sup>3</sup>



### **Key drivers of LINZESS growth**

Educate and activate patients through robust DTC campaign

Create urgency for HCPs
to recognize burden of IBS-C/CIC and
to choose LINZESS

Secure broad payer access and reimbursement

by minimizing barriers to access

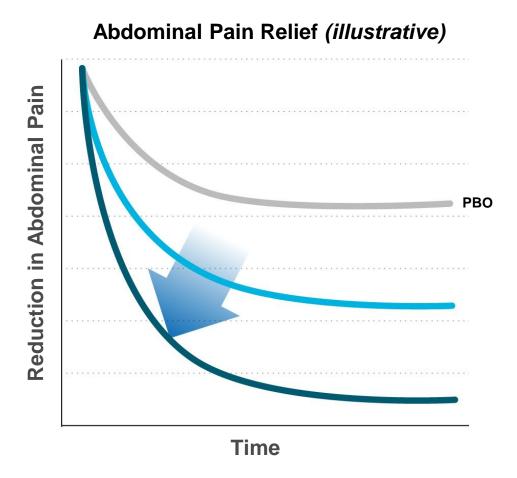
- Branded medication priced \$10.76/day
- TRx (30 day) priced \$322/TRx





# Linaclotide Colonic Release: Continued Innovation Provides Opportunity to Drive Growth and Expand IBS-C/CIC Market

LINZESS + Colonic Release represent >\$2 billion peak U.S. sales opportunity



# If approved, better symptom improvement can drive:

- Healthcare practitioners to choose for more patients
- Patients to be more adherent to treatment

Expected patent protection into mid-2030s

50/50 partnership with Allergan

Phase IIb IBS-C data expected 4Q 2016



# **ZURAMPIC:** Launch Strategy Focused on Key Efforts Necessary to Drive Growth



# MD **URGENCY** to change treatment

- Patients in need easily identified
- Understand need to get uncontrolled patients to sUA goal
- Recognize limited treatment options for patients beyond XOI



# Payer **WILLINGNESS** to serve patient need

- Appreciate level of patient suffering / need
- Agree evidence supports treatment choice
- Reasonable access & reimbursement



# Patients **ACTIVELY** engaged in care

- Proactively describe health problem
- Positive treatment experience
- Advocate efficacy and satisfaction





# 3Q 2016 Financial Summary

**Tom Graney** 

Chief Financial Officer and SVP, Finance and Corporate Strategy



## **3Q 2016 Ironwood Financial Summary**

### Condensed Consolidated Statement of Operations (unaudited)

Three Months Ended September 30, 2016

	000s, except per share amounts		
Total revenue	\$	66,106	
Cost and expenses:			
Cost of revenue		_	
Research and development		37,526	
Selling, general and administrative		44,987	
Amortization of acquired intangible asset		3,213	
(Gain)/Loss on fair value remeasurement of contingent consideration		8,667	
Total cost and expenses		94,393	
Loss from operations		(28,287)	
Other expense, net		(4,917)	
GAAP net loss	\$	(33,204)	
GAAP net loss per share – basic and diluted	\$	(0.23)	
Non-GAAP net loss	\$	(25,865)	
Non-GAAP net loss per share – basic and diluted	\$	(0.18)	



### **3Q 2016 Ironwood Financial Summary**

#### Reconciliation of GAAP Results to Non-GAAP Financial Measures

## Three Months Ended September 30, 2016

(000s, except per share amounts)

	(1111)	
GAAP net loss	\$	(33,204)
Adjustments:		
Mark-to-market adjustments on the derivatives related to convertible notes, net		(4,541)
Amortization of acquired intangible asset		3,213
Fair value remeasurement of contingent consideration		8,667
Non-GAAP net loss	\$	(25,865)
GAAP net loss per share (basic and diluted)	\$	(0.23)
Adjustments to GAAP net loss (detailed above)		0.05
Non-GAAP net loss per share (basic and diluted)	\$	(0.18)

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, the amortization of acquired intangible assets, and the fair value remeasurement of contingent consideration. The company has presented non-GAAP net loss and non-GAAP net loss per share in prior calendar quarters, and this is the first calendar quarter in which the company has the fair value remeasurement of contingent consideration that is excluded from such non-GAAP financial measures. 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 the company's non-GAAP financial measures to the most comparable GAAP measures, please refer to the table above. Additional information regarding the non-GAAP financial measures is included in the company's press release dated November 3, 2016.



## **3Q 2016 LINZESS Financial Summary**

#### LINZESS® U.S. Brand Collaboration

#### **Ironwood Revenue/Expense Calculation**

<u>ommerciai</u>	P00I
	<b>Three Months Ended</b>
	September 30, 2016

	September 30, 2010		
	(000s)		
LINZESS U.S. net product sales	\$	164,379	
Commercial costs and expenses		64,136	
Commercial profit on sales of LINZESS	\$	100,243†	
Commercial Margin		61%	
Ironwood's share of net profit		50,122	
Ironwood's selling & marketing		7,491	
Profit share adjustment		2,370	
Ironwood's collaboration	\$	59,983	

#### R&D Pool

revenue

LINZESS R&D expenses	\$ 18,735 ‡
Ironwood's 50% Share	9,368

#### Ironwood & Allergan Combined U.S. LINZESS P&L

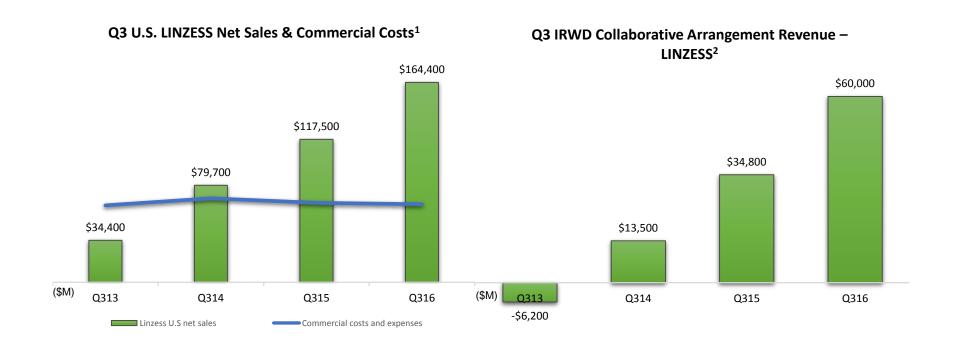
	Three Months Ended September 30, 2016 (000s)
LINZESS U.S. net product sales	\$ 164,379
Commercial costs and expenses	64,136
R&D expenses	18,735 ‡
Net profit on sales of LINZESS	\$ 81,508

	3Q 2015		3Q 2016
LINZESS sales	\$117.5M	+ \$46.9M	\$164.4M
Commercial contribution	\$52.2M	+ \$48.0M	\$100.2M †



# Rapidly Growing LINZESS Sales and Commercial Margin Drive Ironwood Revenue Growth

>\$1B in U.S. Linzess Net Sales Projected by 2020





### **Ironwood 2016 Financial Guidance**

- Ironwood now expects cash used for operations to be less than \$50 million (vs prior guidance of less than \$70 million)
- Ironwood continues to expect:
  - Operating expenses:
    - \$140 million to \$150 million for R&D expenses
    - \$170 million to \$180 million for SG&A expenses
    - expected amortization of intangible assets of \$8 million (not applicable prior to the U.S. lesinurad license)

#### - LINZESS:

 Combined Ironwood and Allergan marketing and sales expense for LINZESS in mid to higher end of \$230 million to \$260 million range

## **Building a Top-Performing Commercial Biotech**

Entering period of expected rapid, sustainable, high-margin growth

#### **2016 Goals**

- ✓ ZURAMPIC U.S. launch
- ✓ Lesinurad Fixed Dose Combination filing
- ✓ sGC: Initiate multiple
  Phase II trials with IW1973 and IW-1701

Colonic Release: Phase IIb data

#### 2017/2018 Goals

Cash flow positive in 2018

Continued expansion of LINZESS commercial margin

≥3 blockbuster opportunities in later-stage development

≥2 major linaclotide launches

#### **2020 Goals**

Rapidly growing cash flows

>\$1B annual LINZESS net sales

≥2 new product launches

≥5 Phase III clinical programs

Potential upside through value-creating acquisitions and licensing



A COMMERCIAL BIOTECHNOLOGY COMPANY