

# **Ironwood 1Q 2017 Investor Update**

May 8, 2017

# Introduction

**Meredith Kaya** 

Senior 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, introduction 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); reduction of a significant risk from IW-3718, if Phase IIb data is positive; market size, prevalence, 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, and the level of risk associated with the path to approval; expected periods of patent exclusivity; commercial strategy, including plans to secure payer access and activate patients; 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 quidance 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 and growth, 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 Annual Report on Form 10-K for the year ended December 31, 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 13 of this presentation.



# 1Q 2017 Overview

**Peter Hecht** 

**Chief Executive Officer** 



## **Ironwood: A Successful Commercial Biotech**

Creating outstanding value for patients and our fellow shareholders



# Rapid growth

Expect >25% Ironwood revenue CAGR (2016-2020)<sup>1</sup>

Two innovative, marketed products









# 1Q 2017 Commercial Update

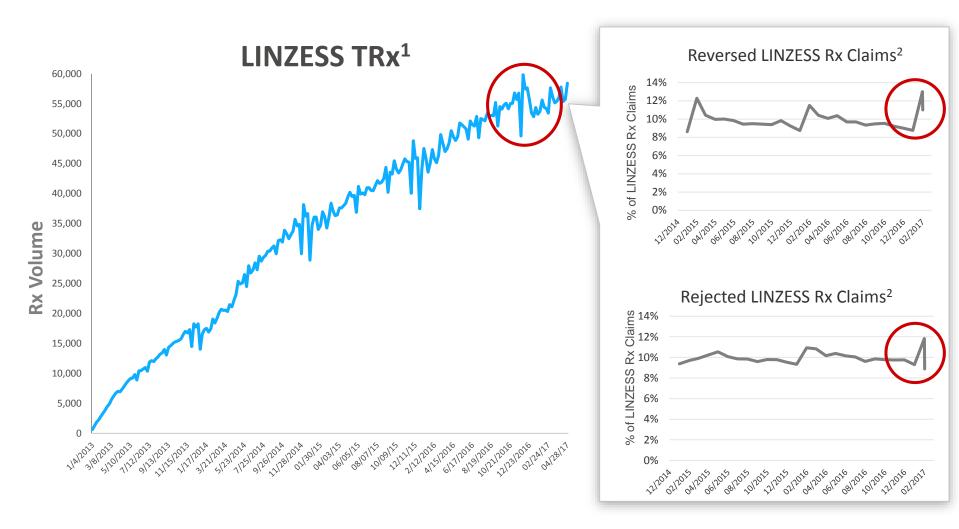
**Tom McCourt** 

**Chief Commercial Officer** 



## LINZESS Demand Grew >20% in 1Q17 over 1Q16

1Q Impacted by Rejections/Reversals Due to High Deductible Plans





# Converting OTC Treated Patients Expected to Fuel Continued Growth of LINZESS

\$7.5B+

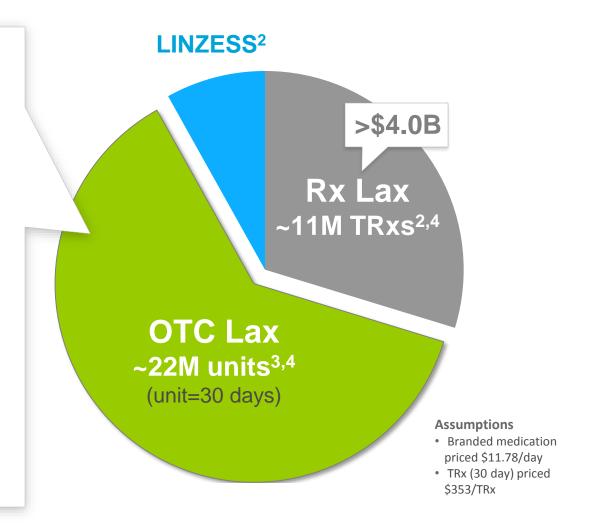
**OTC Lax Market** 

~70% patients dissatisfied

with OTC treatment<sup>5</sup>

2/3 of new LINZESS Rxs

come from OTC<sup>1</sup>





# **ZURAMPIC®** and **DUZALLO™**:

## Opportunity to Get More Uncontrolled Gout Patients to Goal

Estimated 2M Americans not reaching targeted sUA levels of <6mg/dL<sup>1</sup>

>\$300M

Estimated U.S. peak sales opportunity for uncontrolled gout franchise

XOI and Acute Treatment

30+ years



## **Building a Gout Franchise**

**ZURAMPIC + XOI** 

TODAY



DUZALLO (lesinurad + allo FDC)

Expected late 2017  $\rightarrow$ 

Advancement

Acceleration



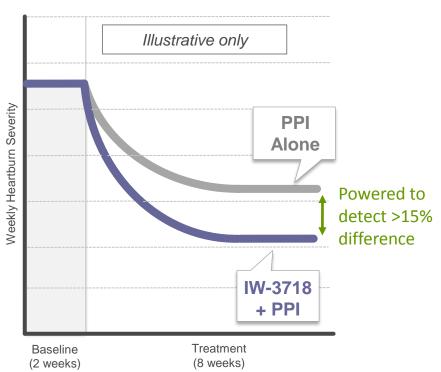
1Q 2017 R&D Update

Mark Currie
Chief Scientific Officer



# Major Phase IIb Objectives: Evaluate Improvement in Heartburn Severity with IW-3718 (+ PPI) vs PPI Alone and Define Clinically Meaningful Response

# **Evaluate Improvement in Heartburn Severity**



# Define Clinically Meaningful Response

Patient-reported outcome data expected to:

- Define clinically meaningful response for *first time* in this category
- Reference with treatment effect
  - Inform Phase III go/no go decision
  - Advise Phase III endpoints, pending FDA discussions and Phase IIb data



# Multiple Pipeline Catalysts Expected in 2017

- ✓ Continued strong LINZESS growth; introduce LINZESS 72mcg dose (1Q 2017)
- ✓ LINZESS IBS-C launch in Japan (1H 2017)
- IW-3718 Phase IIb data in uncontrolled GERD (mid-2017)
- **ZURAMPIC** market development; **DUZALLO** launch, if approved (2H 2017)
- Linaclotide DR1 Phase III initiation in IBS-C (2H 2017)
- IW-1973 Phase IIa data in diabetic hypertension (2H 2017)
- IW-1973 Phase II initiations in rHTN, HFpEF, DN (2H 2017)
- IW-1701 Phase IIa data in achalasia (2H 2017)



# 1Q 2017 Financial Summary

**Tom Graney** 

Chief Financial Officer and SVP, Finance and Corporate Strategy



## 1Q 2017 LINZESS Financial Summary

#### LINZESS U.S. Brand Collaboration

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

Commercial Pool

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

Commercial Pool				
	Three Months Ended March 31, 2017			
_	(000s)			
LINZESS U.S. net product sales	\$	147,615		
Commercial costs and expenses		70,929		
Commercial profit on sales of LINZESS	\$	76,686		
Commercial Margin		52%		
Ironwood's share of net profit	\$	38,343		
Ironwood's selling & marketing		11,109		
Ironwood's collaboration revenue	\$	49,452		
R&D Pool				
LINZESS R&D expenses	\$	14,571		
Ironwood's 50% Share	\$	7,285		

	Three Months Ended March 31, 2017 (000s)	
LINZESS U.S. net product sales	\$ 147,615	
Commercial costs and expenses	70,929	
R&D expenses	14,571	
Net profit on sales of LINZESS	\$ 62,115	



# 1Q 2017 Ironwood Financial Summary

Condensed Consolidated Statement of Operations (unaudited)

#### Three Months Ended March 31, 2017

	(000s, except per share	amounts)
Total revenue	\$	52,166
Cost and expenses:		
Cost of revenue, excluding amortization of acquired intangible asset		531
Research and development		33,702
Selling, general and administrative		55,604
Amortization of acquired intangible asset		420
Loss on fair value remeasurement of contingent consideration		1,614
Total cost and expenses		91,871
Loss from operations		(39,705)
Other expense, net		(12,796)
GAAP net loss	\$	(52,501)
GAAP net loss per share – basic and diluted	\$	(0.36)
Non-GAAP net loss	\$	(48,268)*
Non-GAAP net loss per share – basic and diluted	\$	(0.33)*



# 1Q 2017 Ironwood Financial Summary

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

## Three Months Ended March 31, 2017

(000s, except per share amounts)

	(0003, except per share amounts)
GAAP net loss	\$ (52,501)
Adjustments:	
Mark-to-market adjustments on the derivatives related to convertible notes, net	2,199
Amortization of acquired intangible asset	420
Fair value remeasurement of contingent consideration	1,614
Non-GAAP net loss	\$ (48,268)
GAAP net loss per share (basic and diluted)	\$ (0.36)
Adjustments to GAAP net loss (detailed above)	0.03
Non-GAAP net loss per share (basic and diluted)	\$ (0.33)

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. 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 May 8, 2017.



## On Track to Meet 2017 Financial Guidance

## **Ironwood continues to expect:**

R&D Expenses	\$145 - \$160 million
SG&A Expenses	\$235 - \$250 million
Total LINZESS Marketing & Sales Expenses (IRWD + AGN)	\$250 - \$280 million
Net Interest Expense	~\$40 million
Cash Used for Operations	<\$100 million



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A COMMERCIAL BIOTECHNOLOGY COMPANY