



## **Second Quarter 2011 Investor Update**

**August 11, 2011**

# Introduction

**Halley Gilbert**  
General Counsel

# Safe Harbor Statement

This presentation contains forward looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including, but not limited to, the timing of the filing of a Marketing Authorization Application for linaclotide, linaclotide's potential as a treatment for IBS-C or chronic constipation, our recent collaboration with Depomed and its potential benefit to our development pipeline, and our targeted cash-on-hand for 2011. 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 risks that our linaclotide development activities do not progress as expected, serious adverse events arise in patients that are deemed to be definitely or probably related to linaclotide treatment, the incidence or severity of diarrhea in patients treated with linaclotide is higher than expected, and advancements in our development pipeline do not proceed as expected, as well as risks related to the difficulty of predicting regulatory approvals, the acceptance of and demand for new pharmaceutical products, the potential prescribing habits of doctors, the impact of competitive products and pricing, and whether linaclotide will ever be commercialized successfully. Applicable risks also include those that are listed in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, in addition to the risk factors that are listed from time to time in Ironwood Pharmaceuticals' Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and any subsequent SEC filings. We undertake no obligation to update these forward-looking statements to reflect events or circumstances occurring after this presentation. These forward-looking statements speak only as of the date of this presentation. All forward-looking statements are qualified in their entirety by this cautionary statement.

# Overview

**Peter Hecht**

Chief Executive Officer

# Agenda

- **Introduction** (Peter Hecht)
- **R&D Update** (Mark Currie)
- **Manufacturing Update** (Michael Higgins)

# Second Quarter 2011 and Recent Highlights

## Linaclotide

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- ✓ NDA submission with FDA in 3Q11
- On track for MAA submission with EMA in 2H11
- Continued progress in preparation for global commercial launch
- ✓ Phase 3 CC publication in *NEJM*

## Pipeline

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- **Advancing pipeline**
  - Gastrointestinal, pain & inflammation, respiratory, cardiovascular
  - Depomed technology enables early stage development program to advance

## Corporate

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- **Cash, cash equivalents and available-for-sale securities**
  - Ended Q2 2011 with ~\$201 million
  - Target ending 2011 with >\$150 million

# R&D Update

**Mark Currie**

SVP, Research & Development

# Linacлотide NDA Submission

## Our Linacлотide Submission Contains:

- **Data from 4 Phase 3 trials**
  - Supporting the safety and efficacy of linacлотide for 2 indications: IBS-C and CC
  - >2,800 patients enrolled in Phase 3 placebo controlled trials
- **Over 3,200 patients enrolled in long-term safety studies**
  - >1,100 patients treated with linacлотide for over 1 year
- **Three drug substance suppliers enabling robust API supply network**
- **Data supporting commercially suitable RT stability for drug product**

# Manufacturing Update

**Michael Higgins**

Chief Operating Officer and  
Chief Financial Officer

# Manufacturing Update

## Goal

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- To consistently and reliably produce and supply the highest quality drugs to our patients on a worldwide basis, with redundancy built into each critical step of the manufacturing process.

## API (Drug Substance)

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- North America: PolyPeptide (June 2010) & Roche Colorado (March 2011)
- ROW: PolyPeptide (May 2011) & Roche Colorado (April 2011)

## Drug Product

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- North America: Forest
- Europe: Almirall
- Japan and certain other Asian countries: Astellas
- ROW and back-up in partnered territories: Almac (May 2011)



Ironwood