



# **Mallinckrodt Pharmaceuticals**

## **JP Morgan Healthcare Conference**

**Mark Trudeau, President & CEO**

**January 12, 2015**

# Forward-Looking Statements



*Statements in this presentation that are not strictly historical, including statements regarding, future financial condition and operating results, economic, business, competitive and/or regulatory factors affecting our business and any other statements regarding events or developments that we believe or anticipate will or may occur in the future, may be “forward-looking” statements within the meaning of the Private Securities Litigation Reform Act of 1995, and involve a number of risks and uncertainties. There are a number of important factors that could cause actual events to differ materially from those suggested or indicated by such forward-looking statements and you should not place undue reliance on any such forward-looking statements. These factors include risks and uncertainties related to, among other things:*

- ▶ general economic conditions and conditions affecting the industries in which we operate;*
- ▶ changes in laws and regulations;*
- ▶ our ability to identify, acquire or close acquisitions;*
- ▶ our ability to successfully integrate acquisitions of operations, technology, products and businesses generally and to realize anticipated growth, synergies and cost savings;*
- ▶ our ability to successfully develop or commercialize new products;*
- ▶ our ability to protect intellectual property rights;*
- ▶ our ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration;*
- ▶ customer concentration;*
- ▶ our reliance on certain individual products that are material to our financial performance;*
- ▶ cost containment efforts of customers, purchasing groups, third-party payers and governmental organizations;*

# Forward-Looking Statements



- ▶ *the reimbursement practices of a small number of public or private insurers;*
- ▶ *limited clinical trial data for H.P. Acthar® Gel;*
- ▶ *complex reporting and payment obligations under healthcare rebate programs;*
- ▶ *our ability to achieve anticipated benefits of price increases;*
- ▶ *our ability to achieve expected benefits from restructuring activities;*
- ▶ *complex manufacturing processes;*
- ▶ *competition;*
- ▶ *product liability losses and other litigation liability;*
- ▶ *ongoing governmental investigations;*
- ▶ *material health, safety and environmental liabilities;*
- ▶ *retention of key personnel;*
- ▶ *conducting business internationally;*
- ▶ *and the effectiveness of information technology infrastructure.*

*These and other factors are identified and described in more detail in the “Risk Factors” section of Mallinckrodt’s Annual Report on Form 10-K for the fiscal year ended September 26, 2014. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt does not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law.*

# Mallinckrodt – Transformative growth built on a solid foundation



## We are:

Well-diversified Specialty Biopharmaceutical company with focus in Brands and Specialty Generics, mix shift to 80% Specialty Pharmaceuticals by end of FY2015

## Focus on:

Growth, profitability to drive value for shareholders and deliver solutions for patients

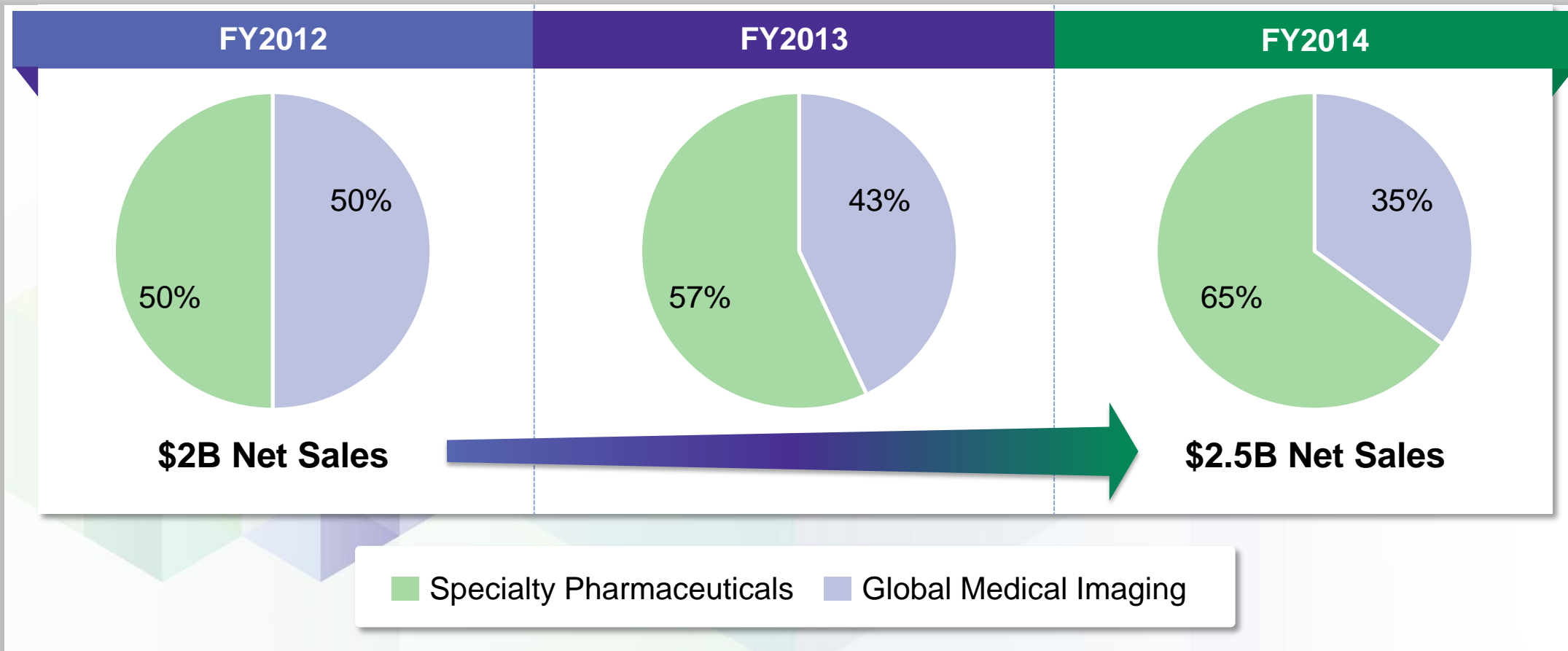
## Our Core Strength:

Mastering Complexity

- ▶ Execution of concurrent transformational initiatives
- ▶ Management of highly regulated raw materials
- ▶ Experience in regulatory, formulation, manufacturing processes
- ▶ Development of complicated products

**Our Goal: Top quartile performance based on total shareholder return**

# Two years of double-digit growth creates the foundation for robust specialty pharmaceuticals business



**In FY2015, Specialty Pharmaceuticals business to be ~80% of portfolio**

# Diversified, durable portfolio of brands and specialty generic products in key growth platforms



**Autoimmune &  
Rare Diseases  
(ARD) Brands**

H.P. **Acthar**<sup>®</sup> GEL  
(repository corticotropin injection) 80 U/mL

**Hospital Brands**

**OFIRMEV**<sup>®</sup>  
(acetaminophen) injection  
1000 mg/100 mL (10 mg/mL)

**Office Brands**

**XARTEMIS**<sup>™</sup> XR  
oxycodone HCl/acetaminophen extended-release (II)

**Specialty Controlled  
Substance Generics<sup>1</sup>**

**HYDROCODONE** (II)  
**BITARTRATE**  
**AND ACETAMINOPHEN**  
TABLETS USP

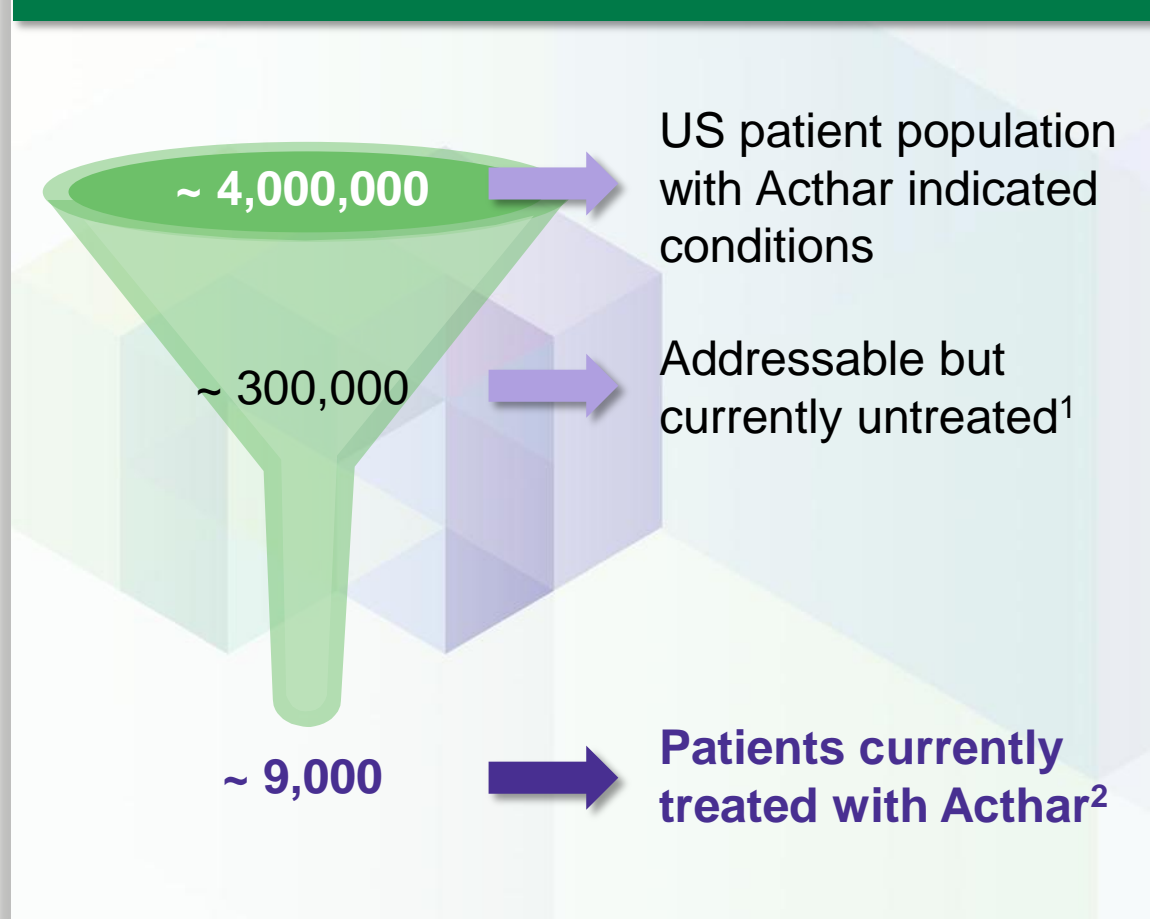
**Create Sustainable Value for Patients and Shareholders**

- ▶ Acquire and develop durable, late-stage, complex products
- ▶ Invest in pipeline and commercial infrastructure

# Acthar® strategy: Increase utilization in appropriate patient populations



**In 9 currently promoted indications, only 3% of addressable Acthar patients are now treated**



## Acthar Strategic Foundation

- ▶ Document current clinical experience
- ▶ Initiate health economic studies
- ▶ Expand into other approved indications
- ▶ Build payer engagement
- ▶ Increase R&D & commercial investment

## Acthar Progress

- ▶ 15% growth in prescriptions shipped (FY15Q1 vs. FY14Q1)
- ▶ Integration complete, synergies realized, commercial retention high

# Surgical pain management strategy: Continuum of care



OFIRMEV®

XARTEMIS™XR

## Location

▶ Inpatient Facilities

▶ Outpatient Facilities

▶ Physician Practices

## Call Point

▶ Surgeons  
▶ Pharmacy  
▶ Anesthesiology

▶ Infusion Clinics  
▶ Rehab Centers  
▶ Surgery Centers  
▶ Emergency Medicine

▶ Surgical Specialties

**Maximize value of surgical pain management business**

▶ Continue strong OFIRMEV® revenue growth

▶ Capitalize on new inpatient and outpatient volume opportunities



# Portfolio development is a key priority to drive sustainable growth



## Objectives for portfolio development

- ▶ Diversify commercial growth platforms
- ▶ Build long-term pipeline with sustainable, durable assets
- ▶ Maximize current R&D and commercial core strengths and capabilities

### BD&L

- ▶ Enhance growth platforms via:
  - Currently commercialized products
  - Late-stage developmental assets
- ▶ Seek strategic options for non-core businesses

### R&D

- ▶ Leverage complex formulations expertise to extend product offerings
- ▶ Support Acthar and OFIRMEV with new efficacy, safety and health economic data
- ▶ Develop novel 505(b)(2) and ANDA products

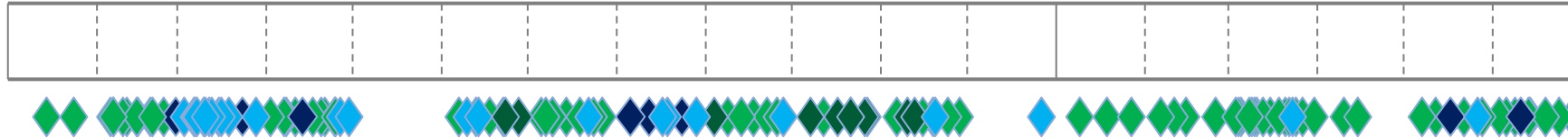
**Portfolio development fueled by financial and organizational capacity**

# Investment in Science and Technology to build our future



Fiscal Year  
2015

2016



- ◆ Branded Pain Study
- ◆ OFIRMEV Study
- ◆ Acthar Study
- ◆ Intrathecal Study

**> 100 publications planned to be submitted through Q2 2016**

## New and ongoing development strategy

### Acthar:

Support on-label indications with new efficacy and safety data  
Differentiate from steroids and synthetic melanocortins  
Demonstrate healthcare economic value proposition

### OFIRMEV:

Expand surgical product presentation options  
Explore intravenous (IV) combinations with acetaminophen

### Pipeline:

Pursue:

- ▶ Depot, IV and abuse deterrent formulations
- ▶ Innovative 505(b)2s and ANDAs

# Mallinckrodt – Where we're going



- ▶ Leverage commercial platforms to accelerate growth
  - ▶ Drive volume growth for Acthar and OFIRMEV
  - ▶ Invest in R&D, medical affairs and commercial
- ▶ Advance pipeline, seek BD&L opportunities in core business and growth platforms
- ▶ Continue successful execution of our growth and profitability strategy
  - ▶ Operate a lean and efficient business model
  - ▶ Drive continuous improvement

**Our Goal: Top quartile performance based on total shareholder return**



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