

# Mallinckrodt Pharmaceuticals: Jefferies London Healthcare Conference

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### **Forward-Looking Statements**

Statements in this document that are not strictly historical, including statements regarding future financial condition and operating results, economic, business, competitive and/or regulatory factors affecting Mallinckrodt's businesses 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:

- ➤ The parties' ability to satisfy the conditions to the divestiture of the Nuclear Imaging business, including approval from the U.S. Nuclear Regulatory Commission and the Committee on Foreign Investment in the United States, and clearance from relevant competition authorities, and complete the divestiture on the anticipated timeline or at all;
- General economic conditions and conditions affecting the industries in which Mallinckrodt operates;
- The commercial success of Mallinckrodt's products;
- Mallinckrodt's ability to realize anticipated growth, synergies and cost savings from acquisitions;
- Conditions that could necessitate an evaluation of Mallinckrodt's goodwill and/or intangible assets for possible impairment;
- Changes in laws and regulations;
- Mallinckrodt's ability to successfully integrate acquisitions of operations, technology, products and businesses generally and to realize anticipated growth, synergies and cost savings;
- Mallinckrodt's ability to successfully develop or commercialize new products;
- Mallinckrodt's ability to protect intellectual property rights;
- Mallinckrodt's ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration;
- Customer concentration;



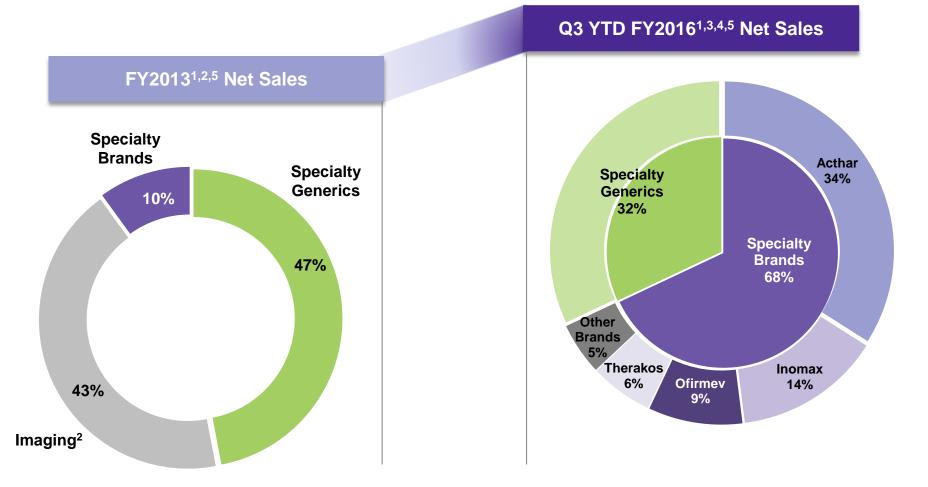
### **Forward-Looking Statements**

- ▶ Mallinckrodt's reliance on certain individual products that are material to its financial performance;
- ▶ Cost containment efforts of customers, purchasing groups, third-party payers and governmental organizations;
- ▶ The reimbursement practices of a small number of public or private insurers;
- Pricing pressure on certain of Mallinckrodt's products due to legal changes or changes in insurers' reimbursement practices resulting from recent increased public scrutiny of healthcare and pharmaceutical costs;
- Limited clinical trial data for H.P. Acthar® Gel;
- Complex reporting and payment obligations under healthcare rebate programs;
- Mallinckrodt's ability to navigate price fluctuations;
- Future changes to U.S. and foreign tax laws;
- Mallinckrodt's 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" sections of Mallinckrodt's Annual Report on Form 10-K for the fiscal year ended September 25, 2015 and Quarterly Report on Form 10-Q for the fiscal quarter ended June 24, 2016. 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.



# "Acquire to Invest" and divestitures of CMDS and Nuclear drive our transformation to a top-quartile global specialty pharmaceutical company



<sup>&</sup>lt;sup>1</sup>Percentage calculation excludes sales to related parties; <sup>2</sup> Includes Contrast Media and Delivery Systems and Nuclear Imaging sales;

<sup>&</sup>lt;sup>3</sup> Excludes Contrast Media and Delivery Systems and Nuclear Imaging sales due to discontinued operations classification upon announcement of the divestitures on July 27, 2015 and August 24, 2016, respectively; <sup>4</sup> Nine months of fiscal 2016; <sup>5</sup> Presentation reflects current fiscal year, transitioning to a calendar year in December 2017



### **Specialty Brands approved and marketed portfolio**

MNK Specialty Brands Primary Indications / Benefits Durability U.S. Penetration <sup>5</sup>				
H.P. <b>Acth</b> ar GEL (repository cardicatropin injection) 80 U/mL	►US¹: 19 indications across a range of autoimmune conditions	Trade secret	~ 4% share	
INOmax (nitricoxide)	<ul> <li>US: Neonatal respiratory failure, delivery system for nitric oxide</li> <li>Japan/Australia: approval for pulmonary HTN² in cardiac surgery</li> </ul>	2031 LOE <sup>4</sup> Commercial model	~ 50% share	
Therakos. PHOTOPHERESIS	<ul> <li>► US: Cutaneous T-cell lymphoma<sup>3</sup></li> <li>► OUS: Photopheresis administration</li> </ul>	2023+ LOE Commercial model	~ 5% share <sup>6</sup>	
OFIRMEV. (acetaminophen) injection	►US: Pain and fever	2020	~ 15% share	
RECOTHROM® THROMBIN,TOPICAL (RECOMBINANT)	► US: Adjunct for surgical hemostasis – for minor bleeding from capillaries, small veins; 1 <sup>st</sup> /only topical synthetic thrombin approved for use in adults, children> 1 month of age	2026		

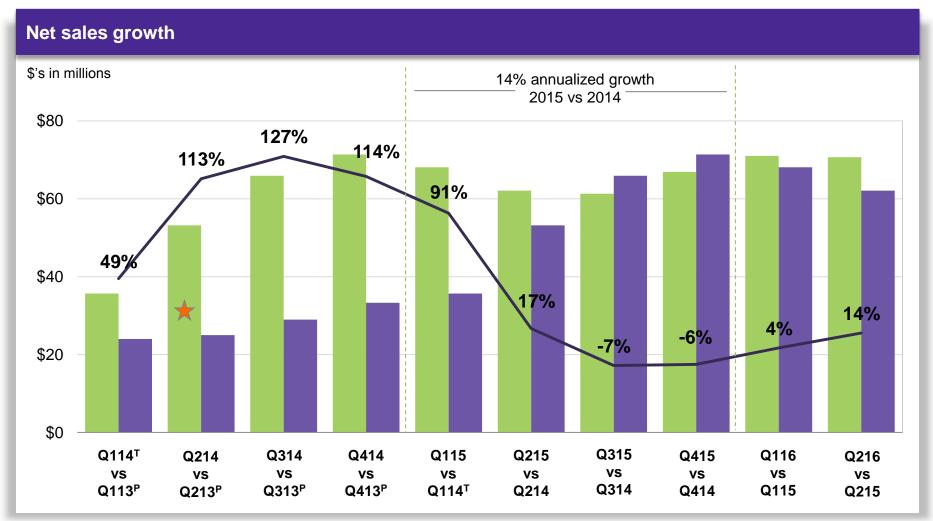


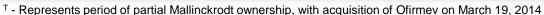
### **Specialty Brands developmental pipeline**

ands Primary Indications / Benefits	Durability	Expected Launch Timing
►US: Adjunct for surgical hemostasis for use in vascular reconstructions; more flexible than hemostasis glue products	2028	2016
US: Adjunct for surgical hemostasis for mild to moderate bleeding in adults	2031	2016 to 2017
➤ US: Phase 3 pivotal registration trial in type 1- hepatorenal syndrome (HRS-1)	Orphan drug	Early 2020s
<ul> <li>StrataGraft – US: Phase 3 regenerative skin tissue for severe burns and other complex skin defects</li> <li>ExpressGraft – US: Phase 1 genetically enhanced tissue for elevated natural wound healing and anti-microbial factors</li> </ul>	2032 regulatory exclusivity	Early 2020s
►US: Phase 1 investigational new drug (IND) with fast track designation for Duchenne muscular dystrophy (DMD)	Orphan drug	Early 2020s
	<ul> <li>US: Adjunct for surgical hemostasis for use in vascular reconstructions; more flexible than hemostasis glue products</li> <li>US: Adjunct for surgical hemostasis for mild to moderate bleeding in adults</li> <li>US: Phase 3 pivotal registration trial in type 1-hepatorenal syndrome (HRS-1)</li> <li>StrataGraft – US: Phase 3 regenerative skin tissue for severe burns and other complex skin defects</li> <li>ExpressGraft – US: Phase 1 genetically enhanced tissue for elevated natural wound healing and anti-microbial factors</li> <li>US: Phase 1 investigational new drug (IND) with fast track designation for Duchenne</li> </ul>	<ul> <li>US: Adjunct for surgical hemostasis for use in vascular reconstructions; more flexible than hemostasis glue products</li> <li>US: Adjunct for surgical hemostasis for mild to moderate bleeding in adults</li> <li>US: Phase 3 pivotal registration trial in type 1-hepatorenal syndrome (HRS-1)</li> <li>StrataGraft – US: Phase 3 regenerative skin tissue for severe burns and other complex skin defects</li> <li>ExpressGraft – US: Phase 1 genetically enhanced tissue for elevated natural wound healing and anti-microbial factors</li> <li>US: Phase 1 investigational new drug (IND) with fast track designation for Duchenne</li> </ul>



## Ofirmev® (acetaminophen injection) has demonstrated positive net sales growth over the prior two quarters driven by volume increases

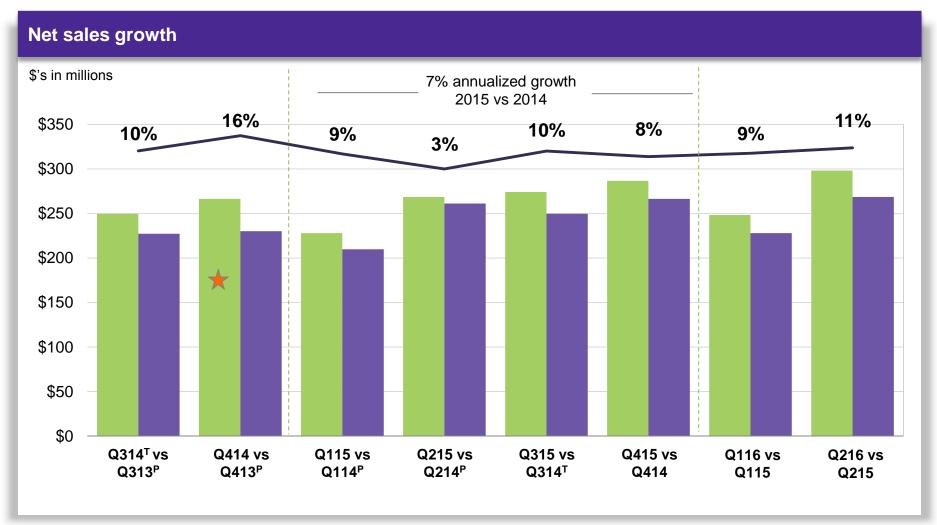


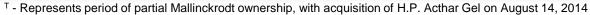


P - Proforma amounts utilized for quarters prior to acquisition



### H.P. Acthar® Gel (repository corticotropin) net sales growth is expected to be in the mid-single to low-double digits per annum

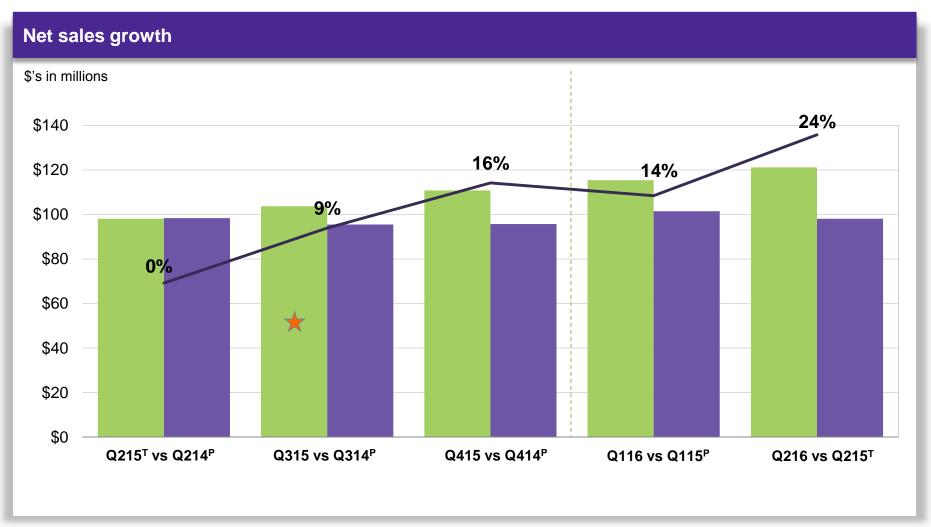




P - Proforma amounts utilized for quarters prior to acquisition



### INOMAX® (gas for inhalation) net sales growth is anticipated to return to mid-single digits per annum over time



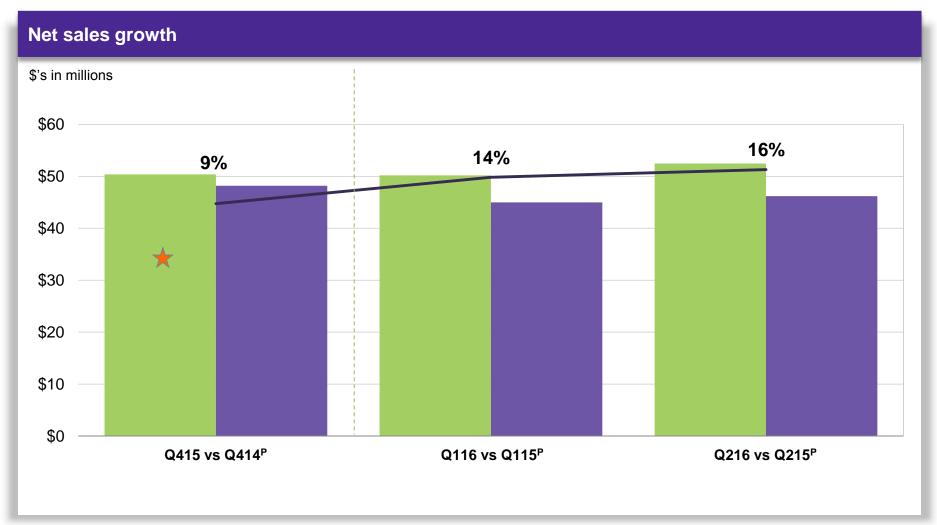


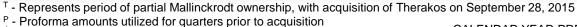
<sup>&</sup>lt;sup>T</sup> - Represents period of partial Mallinckrodt ownership, with acquisition of INOMAX on April 16, 2015

Represents first full quarter under Mallinckrodt's ownership

P - Proforma amounts utilized for quarters prior to acquisition

## Therakos® immunotherapy platform net sales growth is expected to be in the high single digits per annum





Represents first full quarter under Mallinckrodt's ownership





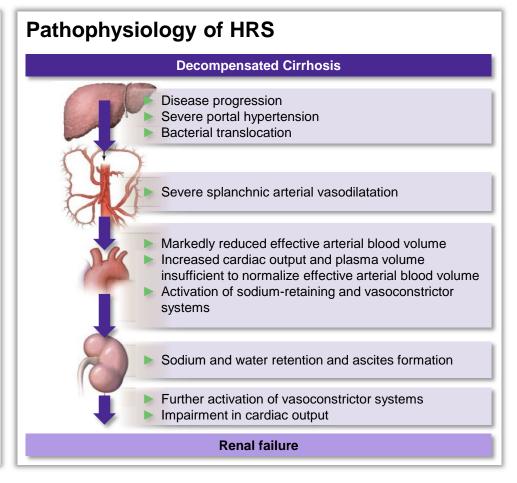
## MNK Development Pipeline - Highlights



### Terlipressin is global standard of care for rare, lifethreatening condition

### Ongoing Phase 3 US development program

- ➤ Type 1-hepatorenal syndrome (HRS-1) is a rare, lifethreatening complication of cirrhosis of the liver
- ▶ Affects >10K patients in US¹-⁴; high mortality rates
- Condition leads to multi-organ failure<sup>5,6</sup> including acute kidney failure<sup>5,6</sup>
- Kidneys appear structurally normal on diagnostic imaging<sup>5,6</sup>
- Survival improves with early diagnosis and treatment<sup>5,6</sup>

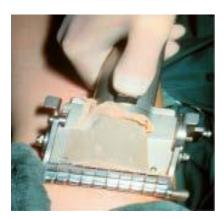


<sup>&</sup>lt;sup>1</sup> Boyer TD et al. Open Access Journal of Clinical Trials. 2012;4:39-49; <sup>2</sup> Marrero J et al. Am J Respir Crit Care Med. 2003;168:1421-1426; <sup>3</sup> Muir AJ et al. Liver Transpl. 2002;8:957-961; <sup>4</sup> Gines A et al. Gastroenterology. 1993;105:229-236; <sup>5</sup> Barbano B et al. Curr Vasc Pharmacol. 2014;12:125-135; <sup>6</sup> Low G et al. Gastroenterol Res Pract. 2015;2015:207012. doi: 10.1155/2015/207012. Epub 2015 Jan 12.



## StrataGraft: potential to be standard of care for severe burn patients; may eliminate the need for autograft

#### Human Skin Autografting: current standard of care for 2<sup>nd</sup>/3<sup>rd</sup> degree



Harvest skin with dermatome





**Donor sites** 

- Current burn management requires autograft & has negative patient impact:
  - painful harvesting of donor skin creates new wound
  - causes extensive scarring
  - multiplies infection risk
  - results in multiple treatments & surgeries; hospitalizations of variable, unknown length



Autograft (3 months)

#### StrataGraft designed to:

- eliminate painful donor site, reduce short- & long-term care
- result in fast coverage & closure
- reduce rate of contracture & scarring
- simplify surgical procedure & shorten surgical time
- eliminate multiple surgeries & reduce costs



StrataGraft (3 months)



### **Capital Allocation and Liquidity**

- Capital allocation priorities
  - 1. Business development
  - 2. Share repurchases
  - 3. Reduction of debt
- ➤ Net debt leverage¹ has ranged between 3.5x and 3.7x over the last four quarters, with net debt leverage at June 2016 of 3.5x
- Significant free cash flow<sup>2</sup> generation
- Proceeds from sale of nuclear imaging business
  - Anticipated to close in first half of 2017
  - Cash proceeds at closing are \$574 million (total consideration \$690 million including earn outs and assumed obligations)
  - Expect minimal tax impact

<sup>&</sup>lt;sup>2</sup> Operating cash flow less capital expenditures



<sup>&</sup>lt;sup>1</sup> Total debt less cash on hand divided by Adjusted EBITDA (defined on our website)

## Mallinckrodt Goal: Become a top-performing Specialty Pharmaceuticals business

Create sustainable long-term value balanced between organic and inorganic growth

### **Organic growth**

- Achieve sustainable normalized revenue growth in mid-single digits
- ▶ Drive EPS higher

### Inorganic growth

- Acquire commercial latestage development assets across Specialty Brands and Specialty Generics
- Leverage significant cash generation capacity

