



# Mallinckrodt Pharmaceuticals

Planned Spin-Off of Specialty Generics Business  
December 6, 2018

# Forward-looking statements

Statements in this document that are not strictly historical, including statements regarding future clinical trials and commercial launches, 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 the company believes or anticipates 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.

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## These factors include risks and uncertainties related to, among other things:

- The proposed spin-off of the Specialty Generics/API (Specialty Generics) business inclusive of Mallinckrodt's AMITIZA® (lubiprostone) product, including the costs associated with the contemplated separation and spin-off, the expected benefits of the transaction, and the expected timeframe to complete such a transaction;
- General economic conditions and conditions affecting the industries in which Mallinckrodt operates;
- Mallinckrodt's ability to obtain regulatory approval to market its products or the timing of such approval process;
- 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 and Mallinckrodt's licensors' ability to successfully develop or commercialize new products;
- Mallinckrodt's and Mallinckrodt's licensors' 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;
- 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;

# Forward-looking statements

- 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;
- The effectiveness of information technology infrastructure; and
- Cybersecurity and data leakage risks.

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 December 29, 2017. 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.

# Planned spin-off transaction summary

## Transaction Overview

- Separation will create two independent, publicly traded companies – one focused on innovative specialty pharmaceutical brands, the other on niche specialty generics and API manufacturing

## Specialty Generics Company

- Spin-off company expected to include Mallinckrodt's portfolio of niche specialty generic products, active pharmaceutical ingredients (APIs), and non-promoted brands including AMITIZA® (lubiprostone)
- Anticipated that it will assume the Mallinckrodt name and ticker symbol ("MNK")

## Transaction Structure

- Expected to be a pro-rata distribution to Mallinckrodt shareholders, anticipated to be generally tax-free for U.S. federal income tax purposes, of new publicly-traded stock

## Timing

- Expected to be completed in second half 2019 or sooner

## Key Steps To Completion

- Develop detailed separation plans over the coming months; significant separation already complete
- Complete Form 10 registration statement

## Key Closing Conditions

- Final Board of Directors approval and opinion of counsel on tax-free nature of transaction
- Effectiveness of Form 10 registration statement to be filed with the SEC

# Strategic rationale for a proposed separation

Anticipated second half 2019 or sooner



**Creates two independent, publicly traded companies, each with resources to plan for success and be positioned for sustainable growth**

**Reflects two distinct markets and business models with separate fundamental drivers**

**Allows respective management teams to commit to long-term strategic priorities aligned with each company's stakeholders, which is expected to unlock value**

**Enables distinct, focused investment strategies in innovation to drive each company's long-term growth**

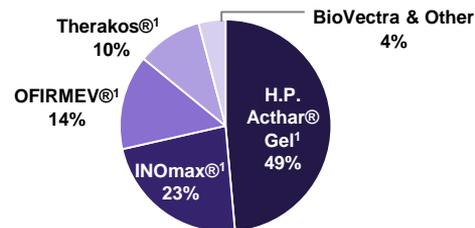
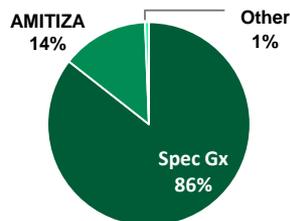
**Provides investors with separate businesses focused on two distinct strategies**

# Expected profiles of two independent, publicly traded companies

## Specialty Generics (Assumes “Mallinckrodt” Name)

## Specialty Pharmaceutical Brands (To Be Named)

Net Sales  
Breakdown



LTM Q3 2018  
Net Sales<sup>2</sup>

\$862mm

\$2,311mm

CEO

Matt Harbaugh

Mark Trudeau

Portfolio

amitiza<sup>®</sup>  
lubiprostone

Rescula<sup>®</sup>  
dihydropyridine, acetaminophen  
combination solution (3/15)

- 26 Product Families
- 150+ SKUs<sup>3</sup>
- 10 Dosage Forms

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

OFIRMEV<sup>®</sup>  
(acetaminophen) injection

BioVectra<sup>®</sup>

INOmax<sup>®</sup>  
(nitric oxide) CASPRA<sup>®</sup>

Therakos<sup>®</sup>  
PHOTOPHERESIS

Expected  
2019  
Milestones

Launch of up to  
five new products

- H.P. Acthar Gel: RA<sup>4</sup> trial and MS<sup>5</sup> registry readouts; complete enrollment in uveitis, lupus and ALS<sup>6</sup> trials
- Phase 3 trial readouts: CPP1-X/sulindac, StrataGraft<sup>®7</sup> and terlipressin

# Overview: Two new companies

## Specialty Generics (Assumes “Mallinckrodt” Name)

- U.S.-based specialty generics player with industry-leading reputation for quality and service
- Integrated supply of products with expertise in complex formulations and specialty chemistry; strong reputation for quality
- Focused R&D<sup>1</sup> investment leveraging core formulation capabilities, targeting complex, differentiated opportunities
- Pipeline selection process focuses on high value projects with a high technical probability of success

## Specialty Pharmaceutical Brands (To Be Named)

- Pure-play, innovation-driven specialty pharmaceutical growth company
- Focus on drug development and commercialization for underserved patients with severe and critical conditions
- Robust pipeline of late-stage developmental assets; potential to launch as many as half a dozen products and product enhancements in next 3 years
- Track record of operational execution, expense control driving increased investments in the company’s innovative pipeline



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# Overview of Specialty Generics

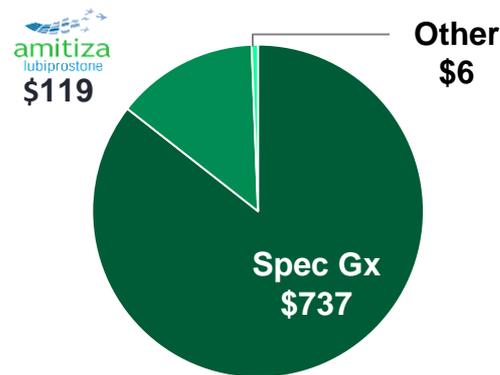


# Overview of Specialty Generics

## Key Attributes

- Vertically integrated specialty generics and APIs
- Robust R&D, manufacturing, and commercial capabilities
- Industry-leading capabilities in formulation, complex chemistry
- Expanding pipeline of complex generics; opportunities to expand product portfolio through business development and licensing
- Enhanced financial profile with the AMITIZA product

## LTM Q3 2018<sup>1</sup> Net Sales by Product (\$ in mm)



**LTM Q3 2018 Net Sales: \$862 mm**

### Portfolio Development



- Industry-leading complex formulation expertise
- Sophisticated product characterization and de-formulation capabilities

### Business Development



- Extend manufacturing capabilities through partnering
- Expand into other near-adjacent areas

# Specialty Generics key investment summary



**Vertically integrated business with strong R&D, manufacturing and commercial capabilities**

**Leading manufacturer of API acetaminophen, and controlled substances in both APIs and finished dosage products**

**Industry-leading formulation capabilities**

**Expanding pipeline in complex generics; focused on business development and licensing effort into near adjacent areas**

**Enhanced financial profile with AMITIZA, a well-established prescription product with manufacturing facilities in Japan**



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# Overview of Innovation-Driven Specialty Pharmaceutical Brands

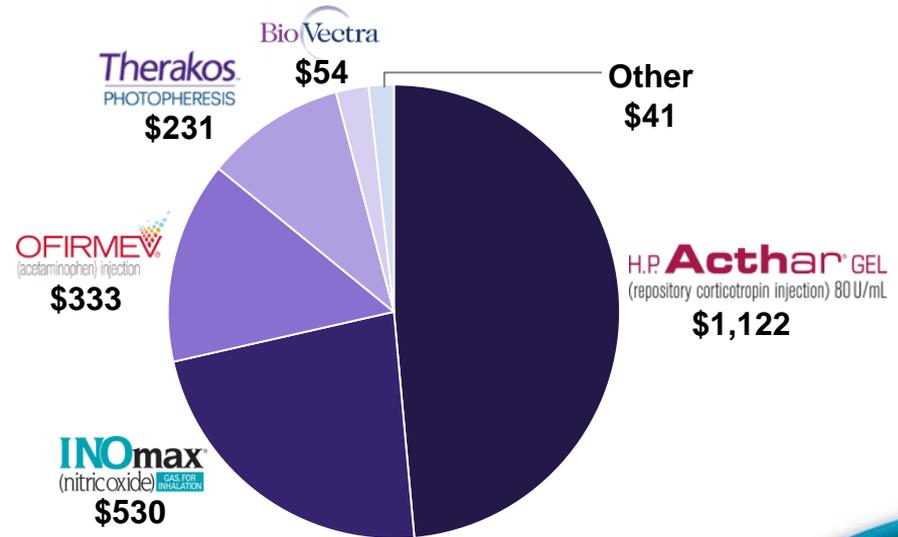


# Overview of the innovation-driven Specialty Pharmaceutical Brands growth company

## Key Attributes

- Well-established commercial hospital portfolio
- Autoimmune and rare disease-focused technology portfolio
- Experienced management team
- Mid- and late-stage pipeline with potential to diversify the business and drive growth, with key programs in hepato-renal, neurology and organ care
- Highly engaged R&D organization
- Defined business development focus on late-stage assets with underserved patient populations
- Emphasis on rapid execution of selected high-value projects

## LTM Q3 2018<sup>1</sup> Net Sales by Product (\$ in mm)



**LTM Q3 2018 Net Sales: \$2,311mm**

# Specialty Brands development pipeline

Product	PreClinical	Phase 1	Phase 2	Phase 3	Registration	Indication Under Study	Diseases/Therapeutic Areas
<b>UVADEX® (methoxsalen) sterile solution (Therakos)</b>						Chronic GVHD <sup>1</sup> (Japan)	Critical Care
<b>STANNSOPORFIN</b> heme oxygenase inhibitor						Neonatal Hyperbilirubinemia	Critical Care
<b>VTS-270</b> (2-hydroxypropyl-β-cyclodextrin (HPβCD mixture))						Niemann-Pick Disease Type C	Rare Disease
<b>CPP-1X-sulindac</b> oral combination						Familial Adenomatous Polyposis	Rare Disease
<b>XENON</b> gas for inhalation						Post Cardiac Arrest	Critical Care
<b>TERLIPRESSIN</b> vasopressin analog						HRS <sup>2</sup> Type-1	Critical Care
<b>STRATAGRAFT®</b> regenerative skin tissue						Severe Burns, DPT <sup>3</sup>	Critical Care
<b>UVADEX (methoxsalen) sterile solution (Therakos)</b>						Acute GVHD (U.S.)	Critical Care
<b>MNK-6105 (OCR-002) (ornithine phenylacetate) intravenous</b>						Hepatic Encephalopathy	Critical Care
<b>STRATAGRAFT</b> regenerative skin tissue						Severe Burns, FT <sup>4</sup>	Critical Care
<b>H.P. ACTHAR® GEL</b> (repository corticotropin injection)						ALS <sup>5</sup>	Immunologic / Autoimmune
<b>MNK-6106 (OCR-002) (ornithine phenylacetate) oral</b>						Hepatic Encephalopathy	Critical Care
<b>MNK-1411</b> (cosyntropin injection)						DMD <sup>6</sup>	Immunologic / Autoimmune
<b>EXPRESSGRAFT™</b> anti-infective (cathelicidin)						DFU <sup>7</sup>	Critical Care
<b>NITRIC OXIDE</b> gas for perfusion						Transplant Organ Perfusate	Critical Care
<b>EXPRESSGRAFT</b> pro-angiogenic (VEGF <sup>8</sup> )						TBD - Chronic Non-healing Wounds	Critical Care
<b>EXPRESSGRAFT</b> anti-tumor (IL-12 <sup>9</sup> )						TBD - Skin Cancer Recurrence	Critical Care
<b>MP-3964</b> (TLR9 <sup>10</sup> antagonist)						Transplant Organ Perfusate & AP <sup>11</sup>	Critical Care

Device	Concept	Planning	Development	Qualification	Registration	Details	Diseases/Therapeutic Areas
<b>INOMAX®</b> (Nitric Oxide) gas						Next Generation Device	Critical Care
<b>H.P. ACTHAR® GEL</b> (repository corticotropin injection)						Alternative Delivery Device	Immunologic / Autoimmune
<b>NITRIC OXIDE</b> gas for perfusion						Organ Transplant Device	Critical Care

1 Graft vs Host Disease  
2 Hepatorenal Syndrome  
3 Deep Partial Thickness  
4 Full Thickness

5 Amyotrophic Lateral Sclerosis  
6 Duchenne Muscular Dystrophy  
7 Diabetic Foot Ulcers  
8 Vascular Endothelial Growth Factor

9 Interleukin  
10 Toll-like Receptor  
11 Acute Pancreatitis

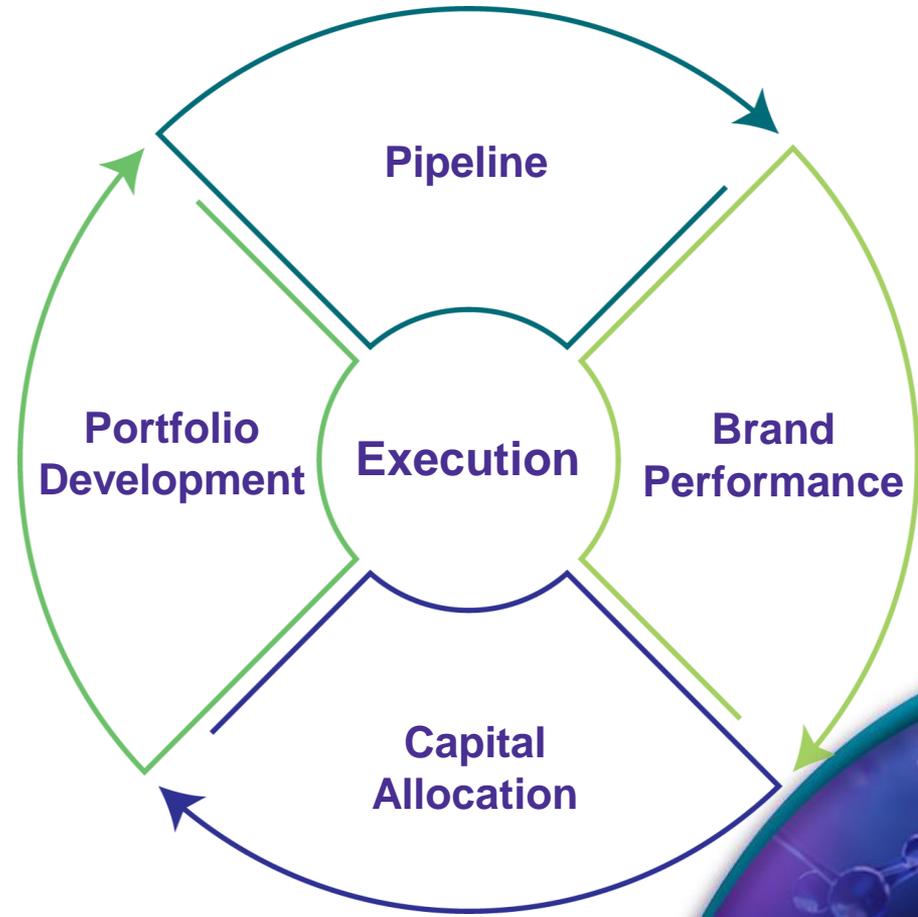
# Focused on increasing stakeholder value via sustainable organic growth

## Strategic vision:

Innovation-driven specialty pharmaceutical growth company focused on improving outcomes for underserved patients with severe and critical conditions

## Strategic Priorities:

- Maximize the value of current diversified, inline portfolio through strong execution and an H.P. Acthar Gel modernization strategy which includes data generation
- Invest in the current pipeline to provide long-term organic growth and diversification
- Execute BD&L to enhance the pipeline and portfolio
- Strengthen the balance sheet and optimize deployment of capital



# Thank You