



# Mallinckrodt Pharmaceuticals


J.P. Morgan Healthcare Conference  
January 8, 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:

- 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;
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# 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.

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 30, 2016, as well as such sections of Ocera Therapeutics' Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and Sucampo Pharmaceuticals' SEC filings, including its Annual Report on Form 10-K for the fiscal year ended December 31, 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.





**Mallinckrodt**  
Pharmaceuticals

# Mark Trudeau

President and Chief Executive Officer



# Mallinckrodt Pharmaceuticals: Managing complexity. Improving lives.



**Strategic Vision:**  
Innovation-driven specialty  
pharmaceutical growth  
company focused on  
improving outcomes for  
patients with severe and  
critical conditions

## Patients

- Neonates / infants to adults
- Refractory and critically ill

## Diseases / Therapeutic Areas

- Immunologic / autoimmune
- Critical care
- Rare diseases

## Technologies

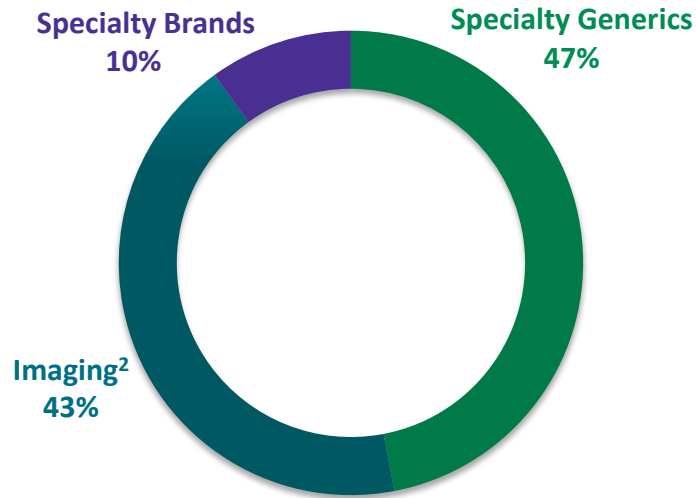
- Small molecules, biologics, large molecules, peptides, proteins, complex naturally derived products
- Synthetic and analytical chemistry, formulation sciences
- Regenerative cell- and tissue-based therapies
- Drug-device combinations

## Capabilities / Strengths

- Science and technology
- Commercial
- Manufacturing and supply chain
- Business development and licensing
- Financial

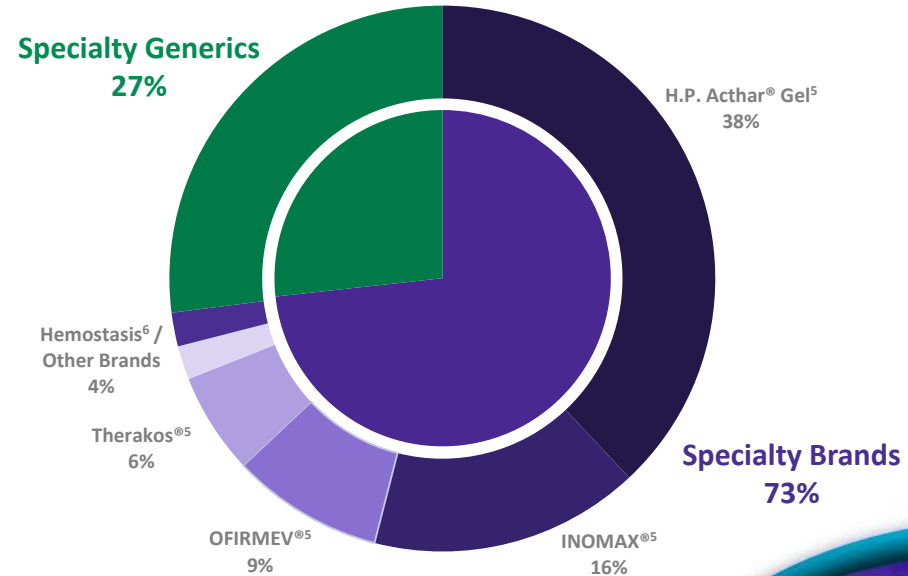
# Portfolio transformation has enhanced financial strength, broadened future opportunities

## FY2013<sup>1,2</sup> Net Sales



**Net Sales - \$2.2 billion**

## LTM Sept. 2017<sup>1,3,4</sup> Net Sales



**Net Sales - \$3.2 billion<sup>6</sup>**

<sup>1</sup> Percentage calculation excludes sales to related parties

<sup>2</sup> Includes Contrast Media and Delivery Systems (CMDS) and Nuclear Imaging (NI) sales

<sup>3</sup> Excludes CMDS and NI sales due to discontinued operations classification upon announcement of the divestitures on 7/27/15 and 8/24/16, respectively

<sup>4</sup> Presentation reflects last twelve months (LTM) ending September 29, 2017, including results from the nine months ended September 29, 2017 and three months ended December 30, 2016

<sup>5</sup> H.P. Acthar Gel (repository corticotropin); INOMAX<sup>®</sup> (nitric oxide) gas, for inhalation; OFIRMEV<sup>®</sup> (acetaminophen) injection; Therakos<sup>®</sup> immunology platform

<sup>6</sup> Hemostasis products include \$56.2 million for the LTM Sept. 2017

# Diversified, inline portfolio focused on patients with significant unmet medical needs

## SPECIALTY BRANDS



Therapeutic Areas:

- Neurology
- Nephrology
- Rheumatology
- Pulmonology
- Ophthalmology

H.P. Acthar<sup>®</sup> Gel



INOMAX<sup>®</sup>



Therakos<sup>®</sup>



OFIRMEV<sup>®</sup>

HEOR<sup>1</sup>

Generate comprehensive value evidence

Medical Affairs

Develop and publish compelling scientific communications

Research & Development

Sponsor controlled trials, advance organic pipeline, and support life-cycle management

Manufacturing Modernization

Strengthen supply chain capabilities

Business Development & Licensing

Focus on growth and pipeline opportunities

# Strong history of execution with clear long-term strategy

Product	Net Sales: Fiscal Year Prior to Acquisition	Net Sales: LTM Sept. 2017	Absolute Growth	CAGR <sup>1</sup>	Long-Term Strategy
H.P. Acthar® Gel	\$761mm	\$1,225mm	~60%	~14%	<ul style="list-style-type: none"> <li>• Advance payer engagement and contracting</li> <li>• Complete six clinical trials and expand label in ALS<sup>2</sup></li> <li>• Develop new product presentation – pre-filled injector</li> </ul>
INOMAX®	\$396mm	\$498mm	~26%	~9%	<ul style="list-style-type: none"> <li>• Defend IP through rigorous appeal</li> <li>• Expand label and develop next generation device</li> <li>• Manage hospital relationships – flexible, multi-year contracts</li> </ul>
OFIRMEV®	\$111mm	\$297mm	~168%	~30%	<ul style="list-style-type: none"> <li>• Generate and communicate HEOR<sup>3</sup> data</li> <li>• Address LOE<sup>4</sup> through pipeline and business development</li> </ul>
Therakos®	\$174mm	\$205mm	~18%	~6%	<ul style="list-style-type: none"> <li>• Complete conversion to advanced Cellex devices</li> <li>• Expand label in chronic and acute GVHD<sup>5</sup></li> <li>• Enlarge footprint and extend geographic focus</li> </ul>

1 Compound Annual Growth Rate

2 Amyotrophic Lateral Sclerosis





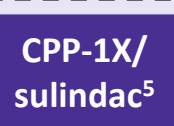
3 Health Economic Outcomes Research

4 Loss of exclusivity

5 Graft versus Host Disease



# Sucampo acquisition will provide commercial and pipeline diversification

	Indication(s) <sup>1</sup>	Status	LTM Sept. 17 Net Sales / Peak Annual Net Sales Opportunity
Marketed	 <ul style="list-style-type: none"> <li>Chronic idiopathic constipation, adults</li> <li>Opioid-induced constipation (OIC) in chronic, non-cancer pain, adults<sup>2</sup></li> <li>Irritable bowel syndrome with constipation, women 18+</li> </ul>	<ul style="list-style-type: none"> <li>Marketed<sup>1</sup> <ul style="list-style-type: none"> <li>Takeda: U.S.; U.K. &amp; Switzerland</li> <li>Mylan N.V.: Japan</li> <li>U.S. (Endo / Par, 2021 start)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Product sales: \$137mm</li> <li>Royalty: \$88mm</li> </ul>
	 <ul style="list-style-type: none"> <li>Ocular hypertension and open-angle glaucoma</li> </ul>	<ul style="list-style-type: none"> <li>Marketed                             <ul style="list-style-type: none"> <li>Santen: Japan</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Product sales: \$10mm</li> </ul>
Pipeline	 <ul style="list-style-type: none"> <li>Pediatric functional constipation</li> </ul>	<ul style="list-style-type: none"> <li>FDA<sup>6</sup> reviewing sNDA<sup>3</sup>, ages 6-17</li> <li>PDUFA<sup>4</sup> date 1H 2018</li> </ul>	<ul style="list-style-type: none"> <li>TBD – label dependent</li> </ul>
	 <ul style="list-style-type: none"> <li>Niemann-Pick Type C (NPC)</li> </ul>	<ul style="list-style-type: none"> <li>Phase 3</li> <li>FDA &amp; EMA Orphan Designation</li> <li>FDA Breakthrough Designation</li> </ul>	<ul style="list-style-type: none"> <li>Net sales: &gt;\$150mm</li> </ul>
	 <ul style="list-style-type: none"> <li>Familial Adenomatous Polyposis (FAP)</li> </ul>	<ul style="list-style-type: none"> <li>Phase 3</li> <li>FDA &amp; EMA<sup>7</sup> Orphan Designation</li> <li>FDA Fast Track Status</li> <li>Developed in collaboration with CPP</li> </ul>	<ul style="list-style-type: none"> <li>Net sales: &gt;\$300mm</li> </ul>

<sup>1</sup> Products are marketed through commercial partners, in various geographic markets. Indications approved/marketed may vary by market. Gloria is responsible for development, commercial, and regulatory activities in China for AMITIZA; <sup>2</sup> OIC includes patients with chronic pain related to prior cancer or its treatment who don't require frequent opioid dosage escalation; <sup>3</sup> supplemental New Drug Application; <sup>4</sup> Prescription Drug User Fee Act; <sup>5</sup> In development and owned by Cancer Prevention Pharma (CPP); <sup>6</sup> Food and Drug Administration; <sup>7</sup> European Medicines Agency

# Specialty Brands pipeline provides long-term organic growth and diversification

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

1 Graft vs Host Disease  
2 Deep Partial Thickness  
3 Hepatorenal Syndrome  
4 Amyotrophic Lateral Sclerosis

5 Full Thickness  
6 Diabetic Foot Ulcers  
7 Duchenne Muscular Dystrophy  
8 Vascular Endothelial Growth Factor

9 Interleukin  
10 Toll-like Receptor  
11 Acute Pancreatitis

Subject to close of Sucampo transaction

# Key pipeline products in mid- to late-stage expected to deliver significant value

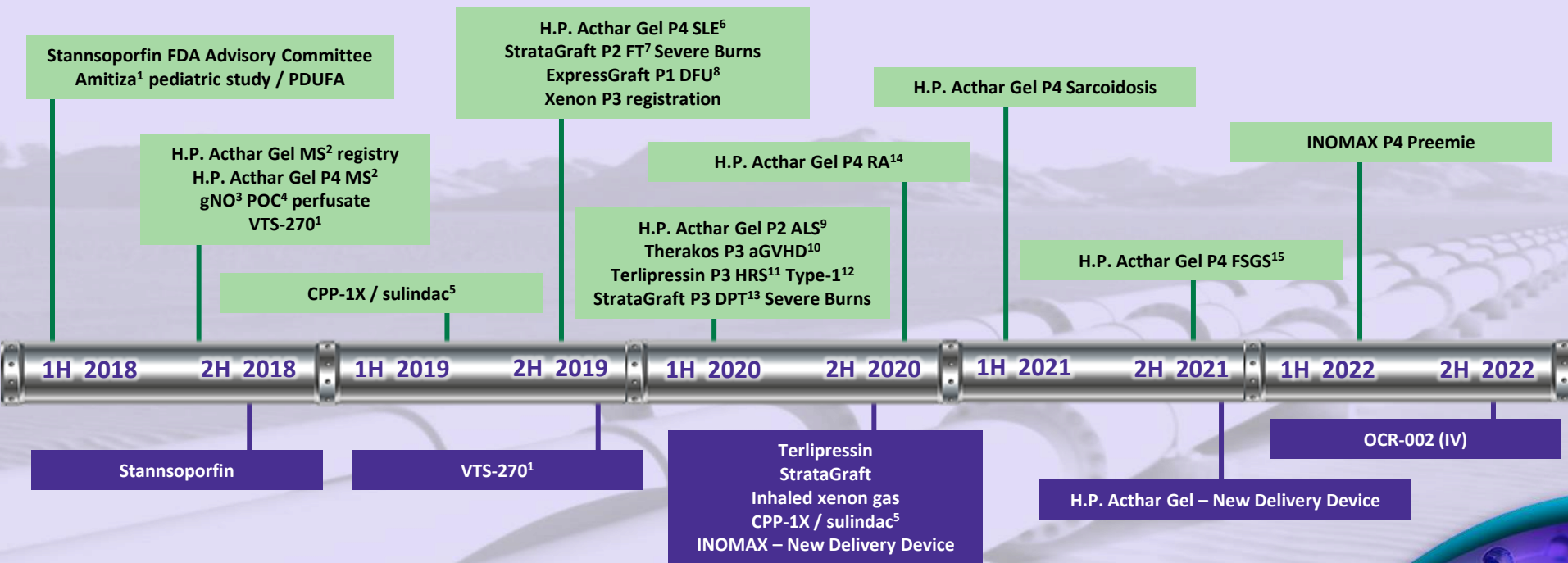
Program	Clinical Status	Est. Launch	Est. Exclusivity	Est. Global Peak Net Sales <sup>1</sup>
Stannsoporfin	Registration	2018	2032	>\$125mm
VTS-270 <sup>2</sup>	Phase 3	2019	2026	>\$150mm
Terlipressin	Phase 3	2020	2027	>\$300mm
StrataGraft	Phase 3	2020	2032	>\$125mm
Inhaled xenon gas	Phase 3	2020	2027	>\$125mm
CPP-1X / sulindac <sup>3</sup>	Phase 3	2020	2027	>\$300mm
OCR-002 (IV / oral)	Phase 2 / Phase 2	2022 / 2024	2030	>\$500mm
Mid- and late-stage pipeline: Net sales opportunity (annual at peak)				>\$1,625mm

<sup>1</sup> Peak net sales estimates are annual, and assume regulatory and commercial success as planned

<sup>2</sup> Subject to close of Sucampo transaction – launch could be as early as 2019

<sup>3</sup> Subject to close of Sucampo transaction and exercising CPP option agreement – launch could be as early as 2020

# Development catalysts and product launches over next five years



1 Subject to close of Sucampo transaction  
2 Multiple Sclerosis  
3 Gaseous Nitric Oxide  
4 Proof of Concept  
5 Subject to close of Sucampo transaction and exercising CPP option agreement

6 Systemic Lupus Erythematosus  
7 Full Thickness  
8 Diabetic Foot Ulcers  
9 Amyotrophic Lateral Sclerosis  
10 Graft versus Host Disease  
11 Hepatorenal Syndrome

12 Interim analysis targeted 1H2018  
13 Deep Partial Thickness  
14 Rheumatoid arthritis  
15 Focal Segmental Glomerulosclerosis

Scientific Catalyst / Data Release

Expected Product Launch

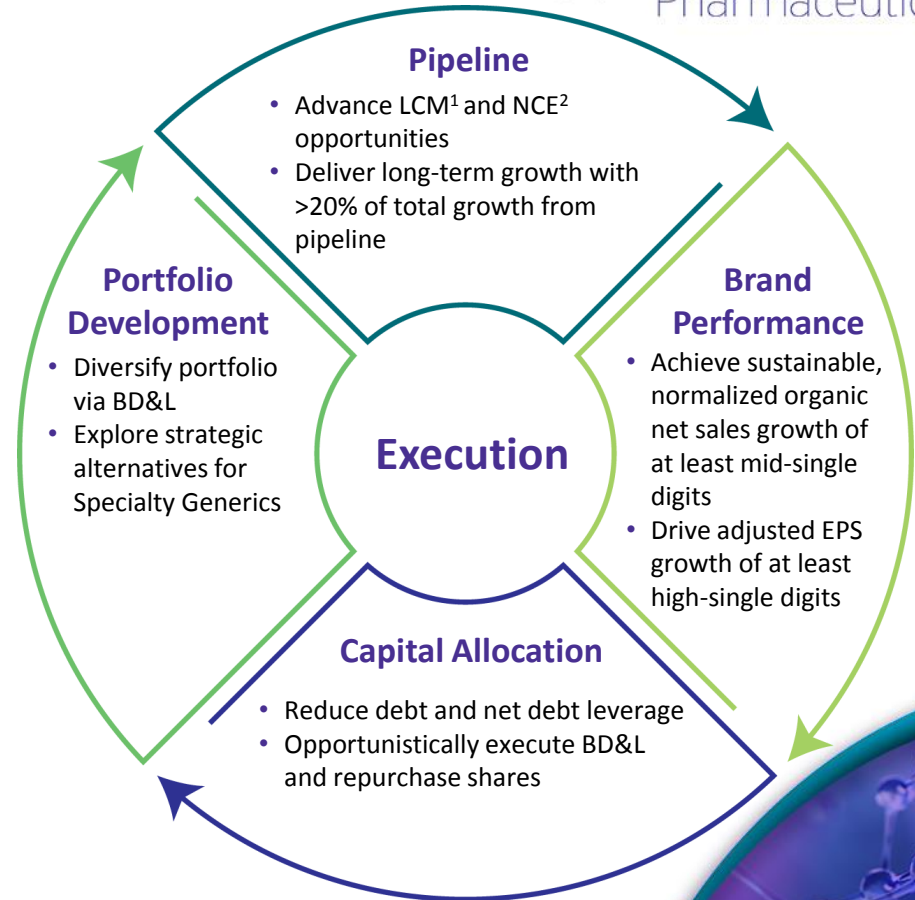
# Create stakeholder value via sustainable organic growth

## Strategic vision:

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

### Recent Events

- Announced planned:
  - **acquisition** of Sucampo Pharmaceuticals, Inc. for \$18 per share (enterprise value of ~\$1.2 billion)
  - **divestiture** of two hemostasis products for \$185 million, comprised of upfront consideration of \$153 million and potential future milestones
- Reduced interest bearing deferred tax liability to less than \$600 million, a greater than \$1 billion reduction in the obligation since the third quarter



# Thank You