# Mallinckrodt Pharmaceuticals

# J.P. Morgan Healthcare Conference

January 11, 2016

Mallinckrodt Pharmaceuticals

# 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 hemostatis products acquisition and complete the acquisition 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 its 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 identify, acquire or close future acquisitions;*
- *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;*

# Forward-Looking Statements

- *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;*
- *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 25, 2015. 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.*

**Mark Trudeau**
**President and Chief Executive Officer**

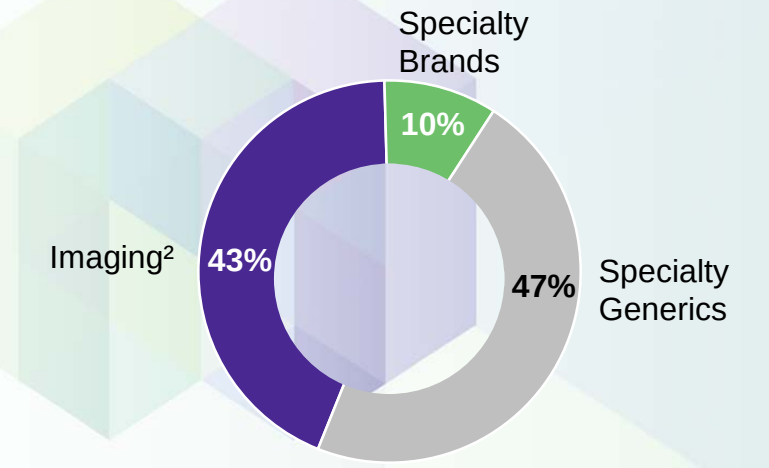
Mallinckrodt Pharmaceuticals

# Acquire to Invest strategy to build a sustainable portfolio

**Patient-centered:**

- **Acquire durable, under-resourced** treatments for underserved patient populations
- **Invest in meeting patient need and achieving products' full potential**

**FY2013[1,2] Net Sales $2.2B**

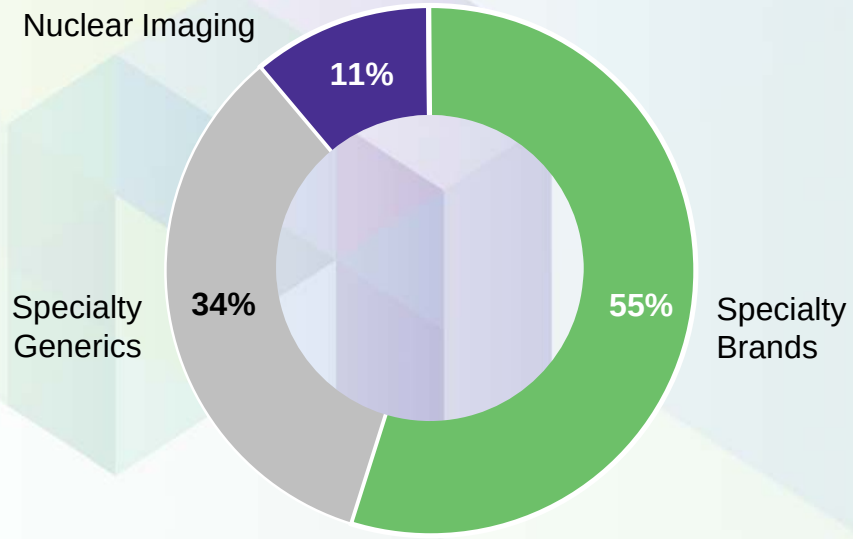



**Adjusted EPS: $3.13**

**Shareholder focused:**

- Provide **immediate/near-term value**
- Create diversified, sustainable **long-term growth potential**

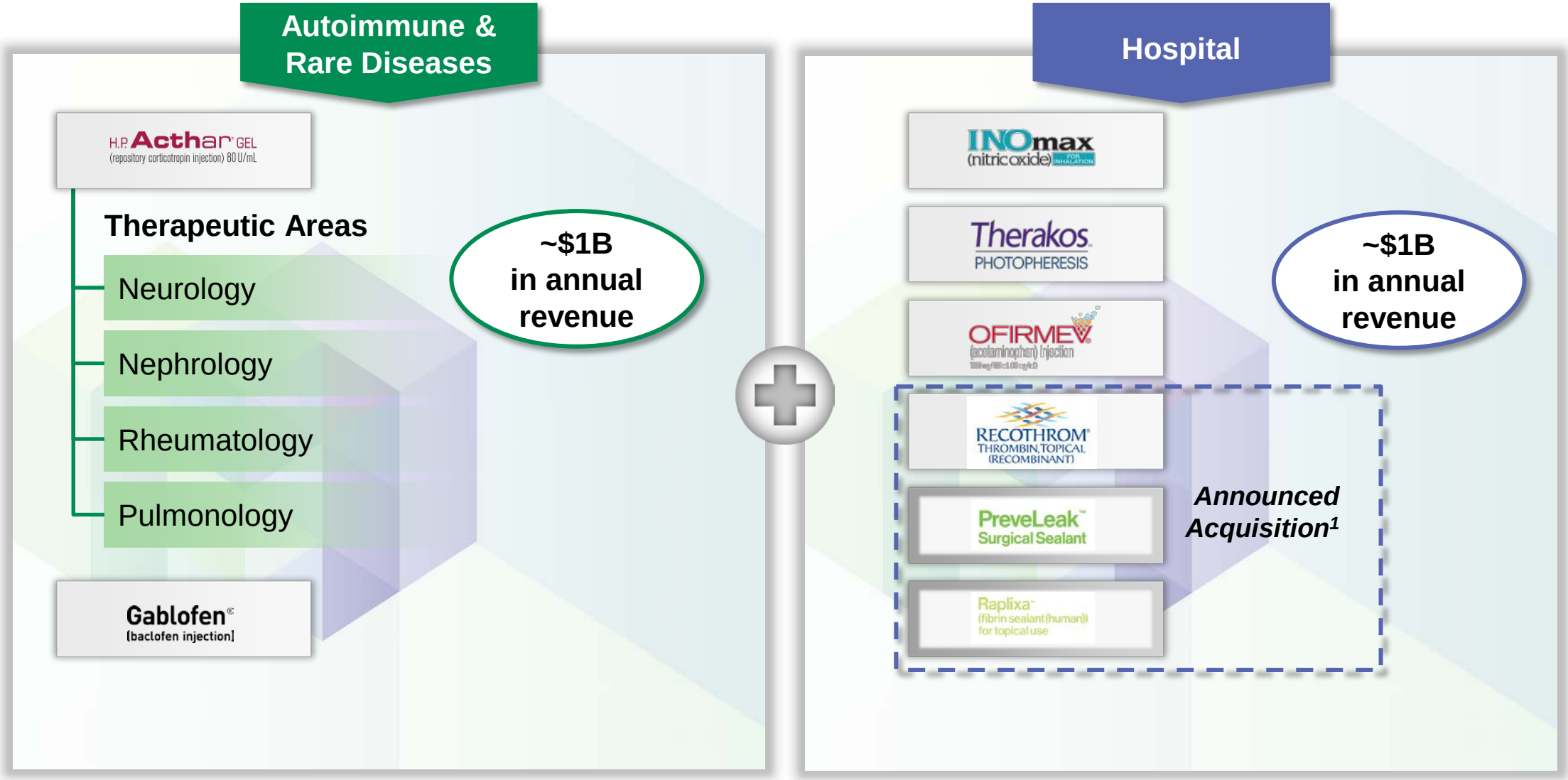
**FY2015[1,3] Net Sales $3.7B**




**Adjusted EPS: $7.37 (CAGR[4]: 53%)**

[1] Percentage calculation excludes sales to related parties; [2] Includes Contrast Media and Delivery Systems and Nuclear Imaging sales;
[3] Percentage calculation includes proforma sales for INOmax® and Therakos®; [4] CAGR: Compounded annual growth rate over FY 2013 – FY 2015

# Announced hemostasis product acquisitions will further diversify Specialty Brands segment




[1] Mallinckrodt has entered into a purchase agreement with The Medicines Company to acquire Recothrom®, PreveLeak™ and Raplixa.™ The acquisition is expected to be completed in the first calendar quarter of 2016, Mallinckrodt's second fiscal quarter.

# Durable Specialty Brands portfolio with attractive long-term growth potential

| | Primary Indications/Benefits | Durability | U.S. Market Size & Penetration[5] | Financial Objectives |
|---|---|---|---|---|
| H.P. Acthar GEL (repository corticotropin injection) 80 U/mL | ▶ 19 FDA-approved autoimmune indications across a wide range of conditions | Trade secret | ~300K patients<br>3% share | Mid-single digit to low-double digit revenue growth |
| INOmax (nitric oxide) FOR INHALATION | ▶ FDA-approved for neonatal respiratory failure and OUS[1] for pulmonary HTN[2] in cardiac surgery;<br>FDA-approved delivery system for nitric oxide | 2031 LOE[4]<br>Commercial model | ~23K patients<br>50% share | Mid-single digit revenue growth |
| Therakos PHOTOPHERESIS | ▶ FDA-approved for cutaneous T-cell lymphoma[3]<br>▶ OUS approval for photopheresis administration | 2023+ LOE<br>Commercial model | ~15K patients<br>5% share[6] | High-single digit revenue growth |
| OFIRMEV (acetaminophen) injection | ▶ FDA-approved for pain and fever | 2020<br>Potential formulation extension | ~20M in-patient procedures<br>15% share | >$500M peak annual revenue |
| RECOTHROM THROMBIN, TOPICAL (RECOMBINANT) | ▶ FDA-approved as adjunct for surgical hemostasis – for minor bleeding from capillaries, small veins<br>▶ 1st/only topical synthetic thrombin approved for use in adults, children > 1 month of age | 2026 | | |
| PreveLeak™ Surgical Sealant | ▶ FDA-approved as adjunct for surgical hemostasis for use in vascular reconstructions<br>▶ More flexible than hemostasis glue products | 2028 | ~$750M U.S. market[7]<br>~8% share | Low-double digit revenue growth from fiscal 2017 |
| Raplixa™ (fibrin sealant (human)) for topical use | ▶ FDA-approved as adjunct for surgical hemostasis for mild to moderate bleeding in adults | 2031 | | |

[1] Outside United States; [2] Hypertension; [3] Approved for palliative treatment of skin manifestations of cutaneous T-cell lymphoma (CTCL); [4] Loss of exclusivity; [5] Penetration rates of currently approved and marketed indications; [6] Includes early-stage CTCL topical non-responders and late-stage CTCL patients; [7] Estimated $750 million U.S., at least $1 billion globally-IMS Health Data

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Announced acquisition

Reflects FY2016 launches

# R&D investment focused on enhancing and expanding Specialty Brands portfolio

| | THERAPY | INDICATION | PHASE 4 |
|---|---|---|---|
| PHASE 4 / MARKETED | H.P. ACTHAR GEL (repository corticotropin injection) | *19 Indications* | *SLE[1], iMN[2], FSGS[3]* |
| | OFIRMEV® (acetaminophen) injection | *Pain, Fever* | *Knee, Burn* |
| | GABLOFLEN® (baclofen injection) | *Spasticity* | |
| | INOMAX® (nitric oxide) for inhalation | *HRF[4] (neonates)* | |
| | UVADEX® (methoxsalen) sterile solution | *CTCL[5]* | |
| PHASE 3 / REGISTRATION | TERLIPRESSIN | *HRS[6] Type-1* | |
| | GABLOFLEN 3000 mg | *Spasticity* | |
| | IT MORPHINE | *Chronic pain* | |
| | IT HYDROMORPHONE | *Chronic pain* | |
| | UVADEX | *Acute GvHD[7] (US), Chronic GvHD (JP)[8]* | |
| P 2 | ACTHAR | *ALS[9], DN[10]* | |
| P1/ PC[12] | SYNACTHEN® (cosyntropin injection) | *(Pre-IND[11])* | |

***Significant investment in HEOR[13] for key in-line brands ongoing***

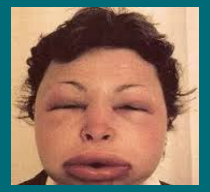
[1] SLE: Systemic Lupus Erythematosus ; [2] iMN: idiopathic Membranous Nephropathy; [3] FSGS: Focal Segmental Glomerulo-sclerosis; [4] HRF: Hypoxic Respiratory Failure;
[5] CTCL: Cutaneous T-Cell Lymphoma; [6] HRS: Hepatorenal Syndrome; [7] GvHD: Graft vs Host Disease; [8] JP: Japan; [9] ALS: Amyotrophic Lateral Sclerosis; [10] DN: Diabetic Nephropathy;
[11] IND: Investigational new drug; [12] Phase 1 / Pre-Clinical; [13]HEOR: Health economic outcomes research

# Acthar® has potential to reach more patients in need of therapeutic options; only ~3% of addressable patients are now treated

| Diagnosis | Share of addressable patients treated |
|---|---|
| Infantile spasms | ~2K |
| Multiple sclerosis | ~25K |
| Proteinuria remission in iMN[1] | ~10K |
| Rheumatoid arthritis | ~85K |
| DM/PM[2] | ~20K |
| Sarcoidosis | ~20K |
| SLE[3] (lupus) | ~75K |
| Psoriatic arthritis | ~30K |
| Ankylosing spondylitis | ~50K |


Rheumatoid Arthritis


Infantile Spasms


Idiopathic Nephrotic Syndrome


Multiple Sclerosis


SLE (Lupus)

[1] iMN: idiopathic Membranous Nephropathy; [2] DM/PM: Dermatomyositis/polymyositis; [3] SLE: Systemic Lupus Erythematosus

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# Building evidence for Acthar with company-sponsored, controlled trials

| | Design | Patients | Status |
|---|---|---|---|
| ON-LABEL | **SLE**[1]: Phase 4, double-blind, placebo-controlled study in steroid-dependent patients followed by open label extension | 36 | ▶ Complete |
| | **iMN**[2]: Phase 4, double-blind, placebo-controlled study in treatment-resistant subjects with iMN | 60 | ▶ Ongoing |
| | **FSGS**[3]: Phase 4, randomized withdrawal study in subjects with treatment resistant or intolerant proteinuria | 210 | ▶ Ongoing |
| EXPLORATORY | **ALS**[4]: Phase 2, randomized, controlled study; explore safety, tolerability in patients with ALS | 40 | ▶ Analysis ongoing |
| | **DN**[5]: Phase 2, double-blind, placebo-controlled study; explore safety, tolerability in patients with DN | 40 | ▶ Ongoing |

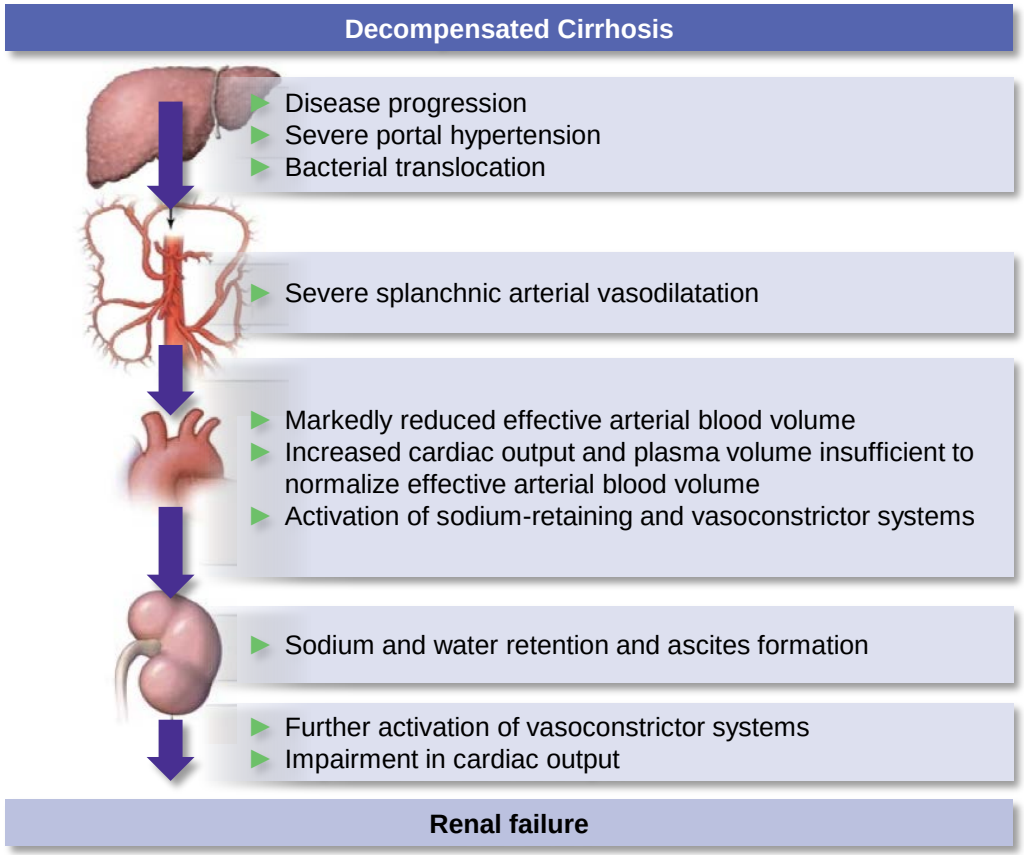
[1] SLE: Systemic Lupus Erythematosus; [2] iMN: idiopathic Membranous Nephropathy; [3] FSGS: Focal Segmental Glomerulo-sclerosis; [4] ALS: Amyotrophic Lateral Sclerosis; [5] DN: Diabetic Nephropathy

# Terlipressin is global standard of care for rare, life-threatening condition

## Ongoing Phase 3 US development program

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

## Pathophysiology of HRS




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

# Mallinckrodt Goal: Become a top-performing Specialty Biopharmaceutical 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 at higher rates

## Inorganic growth

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