



Mallinckrodt Pharmaceuticals Investor Briefing

October 14, 2014



John Moten
Vice President, Investor Relations

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;*
- ▶ *The commercial success of our products, including H.P. Acthar® gel (“Acthar”);*
- ▶ *Our ability to protect intellectual property rights;*
- ▶ *Our ability to maintain important business relationships;*
- ▶ *The lack of patent protection for Acthar, and the possible United States Food and Drug Administration (“FDA”) approval and market introduction of additional competitive products;*
- ▶ *Our reliance on certain individual products that are material to our financial performance;*
- ▶ *Our ability to continue to generate revenue from sales of our products to treat on-label indications and to develop other therapeutic uses for them;*
- ▶ *Our ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration;*
- ▶ *Our ability to obtain and/or timely transport molybdenum-99 to our technetium-99m generator production facilities;*
- ▶ *Customer concentration; cost containment efforts of customers, purchasing groups, third-party payers and governmental organizations;*
- ▶ *Our ability to successfully develop or commercialize new products;*
- ▶ *Competition;*

Forward-Looking Statements



- ▶ *Our ability to achieve anticipated benefits of price increases;*
- ▶ *Our ability to successfully integrate acquisitions of operations, technology, products and businesses generally and to realize anticipated growth, synergies and cost savings;*
- ▶ *The reimbursement practices of a small number of large public or private issuers;*
- ▶ *Complex reporting and payment obligations under healthcare rebate programs;*
- ▶ *Changes in laws and regulations;*
- ▶ *Conducting business internationally;*
- ▶ *Foreign exchange rates;*
- ▶ *Material health, safety and environmental liabilities;*
- ▶ *Product liability losses and other litigation liability; and*
- ▶ *Information technology infrastructure and restructuring activities.*

Additional information regarding the factors that may cause actual results to differ materially from these forward-looking statements is available in (i) our SEC filings, including our Annual Report on Form 10-K for the fiscal year ended September 27, 2013 and our Quarterly Reports on Form 10-Q for the quarterly periods ended December 27, 2013, March 28, 2014 and June 27, 2014; (ii) the SEC filings of Cadence Pharmaceuticals, Inc., which was acquired by Mallinckrodt on March 19, 2014, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2013; and (iii) the SEC filings of Questcor Pharmaceuticals, Inc.'s, which was acquired by Mallinckrodt on August 14, 2014, including its Annual Report on Form 10-K for the year ended December 31, 2013 (and the amendment thereto on Form 10-K/A), its Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2014 and June 30, 2014, and its Current Report on Form 8-K filed with the SEC on July 10, 2014. The forward-looking statements made herein speak only as of the date hereof and neither Mallinckrodt nor any of its affiliates 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.

Agenda for our session



- ▶ **Mallinckrodt Business Transformation**
- ▶ **Specialty Pharmaceuticals**
- ▶ **H.P. Acthar Gel**
 - ▶ **Business Background**
 - ▶ **Physician and Patient Experience**
- ▶ **Fiscal Year 2015 Guidance**
- ▶ **Summary**
- ▶ **Investor Q&A**



Mark Trudeau
President and Chief Executive Officer

Mallinckrodt – Transformative growth built on a solid foundation



We are:

Well diversified global Specialty Biopharmaceutical company with focus in Brands and Specialty Generics

Focus:

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

Core Strength:

Mastering Complexity

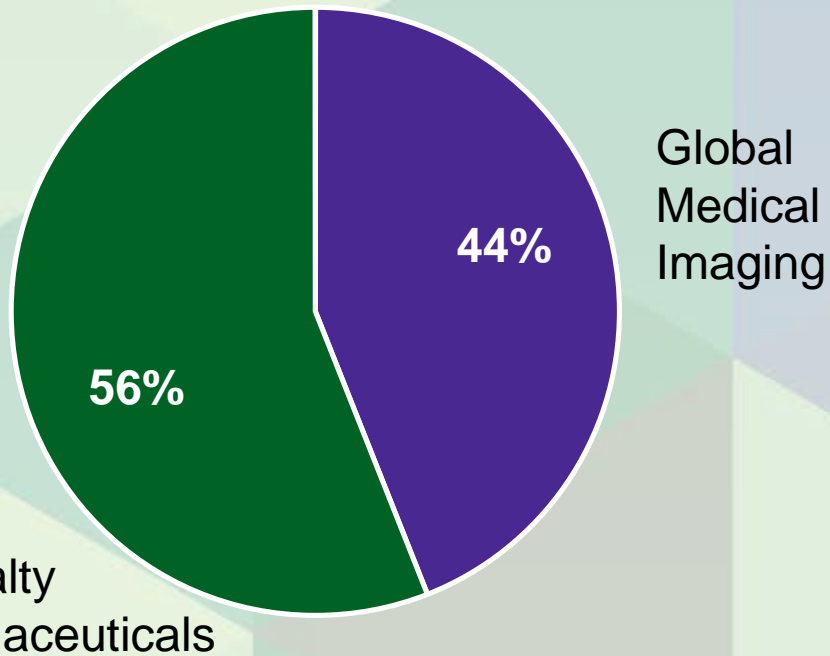
- ▶ Exceptional execution of concurrent transformational initiatives
- ▶ Management of highly regulated raw materials
- ▶ Expertise in regulatory, formulation, manufacturing processes
- ▶ Development of complicated products

Our Goal: Top quartile performance based on total shareholder return

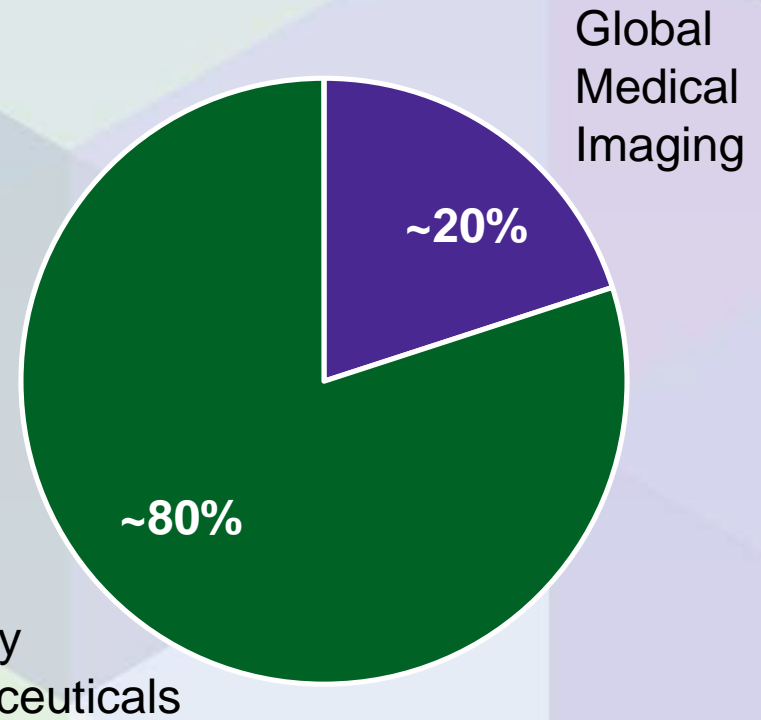
Transforming the portfolio



At Spin¹



FY2015 Guidance



¹ FY2013 Q3 YTD Net Sales, excluding sales to related parties

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



Office Brands

XARTEMIS™ XR
oxycodone HCl/acetaminophen extended-release Ⓢ

Hospital Brands

OFIRMEV®
(acetaminophen) injection
1000 mg/100 mL (10 mg/mL)

Autoimmune &
Rare Diseases
(ARD) Brands

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

Specialty Controlled
Substance Generics¹

METHYLPHENIDATE Ⓢ
HYDROCHLORIDE Ⓢ
EXTENDED-RELEASE TABLETS USP

Goal is straightforward: Create Sustainable Value for Patients and Shareholders

- ▶ Develop and acquire durable, late stage complex products
- ▶ Invest in pipeline extensions of key portfolio assets
- ▶ Divest lower margin, slower growing businesses

¹ Compete in 43 different categories



Hugh O'Neill
Senior Vice President and
President, Specialty Pharmaceuticals

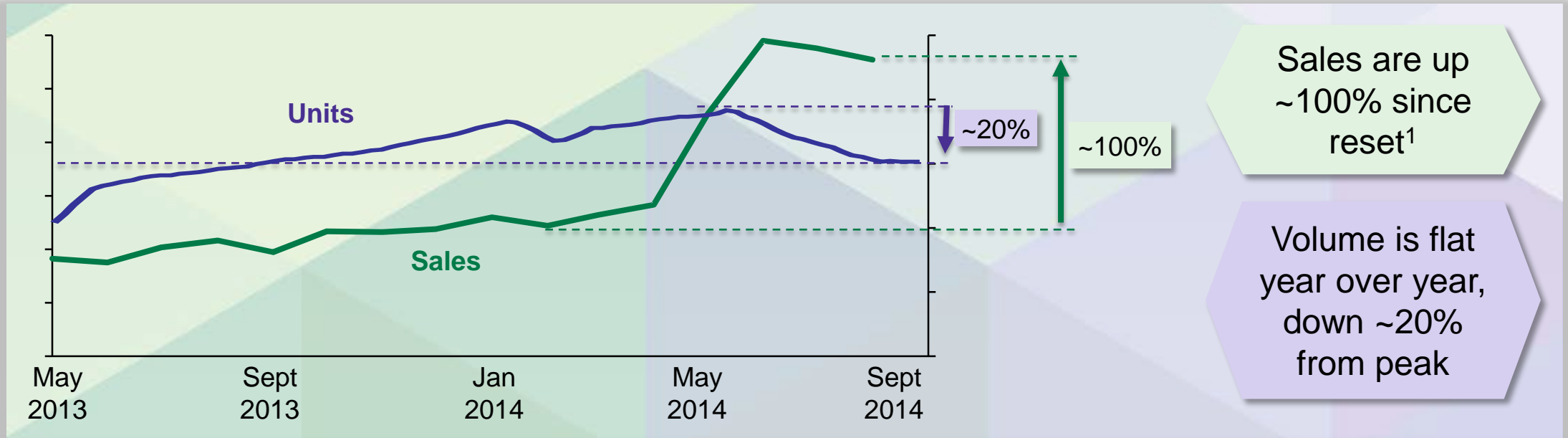
Durable assets and platforms positioned for sustained Specialty Pharmaceuticals growth



	Office Brands <i>Invest for long term growth</i>	Hospital Brands <i>Drive growth and profitability</i>	Specialty Controlled Substance Generics <i>Drive profit and generate cash</i>
Near term	<ul style="list-style-type: none"> ▶ Drive XARTEMIS XR up-take in surgical specialties ▶ Grow Intrathecal 	<ul style="list-style-type: none"> ▶ Expand OFIRMEV volume growth ▶ Drive pharmacoeconomic value 	<ul style="list-style-type: none"> ▶ Continue strong methylphenidate/pain portfolio performance ▶ Optimize hydrocodone rescheduling
Long term	<ul style="list-style-type: none"> ▶ Maximize commercial opportunity for XARTEMIS XR and MNK-155 	<ul style="list-style-type: none"> ▶ Pursue next generation OFIRMEV development 	<ul style="list-style-type: none"> ▶ Advance ANDAs¹ in pipeline ▶ Further Abuse Deterrent Technologies

¹Abbreviated New Drug Application

OFIRMEV is well positioned for growth in 2015 and beyond



OFIRMEV is positioned to return to unit growth

- ▶ OFIRMEV enjoys broad formulary access
- ▶ Opportunity to further penetrate surgical market and increase vials per procedure
- ▶ Synergy of OFIRMEV and XARTEMIS XR as the post-op treatment continuum

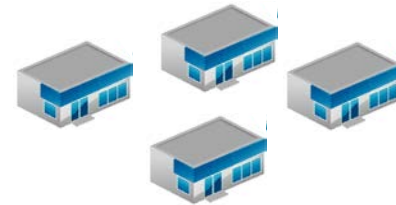
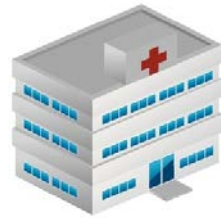
¹ Feb-April vs. May-July

Surgical pain management continuum for multimodal pain treatment



OFIRMEV

XARTEMIS XR



Location

▶ Inpatient Facilities

▶ Outpatient Facilities

▶ Physician Practices

Sales Force

▶ Hospital Specialists

▶ Outpatient Specialists

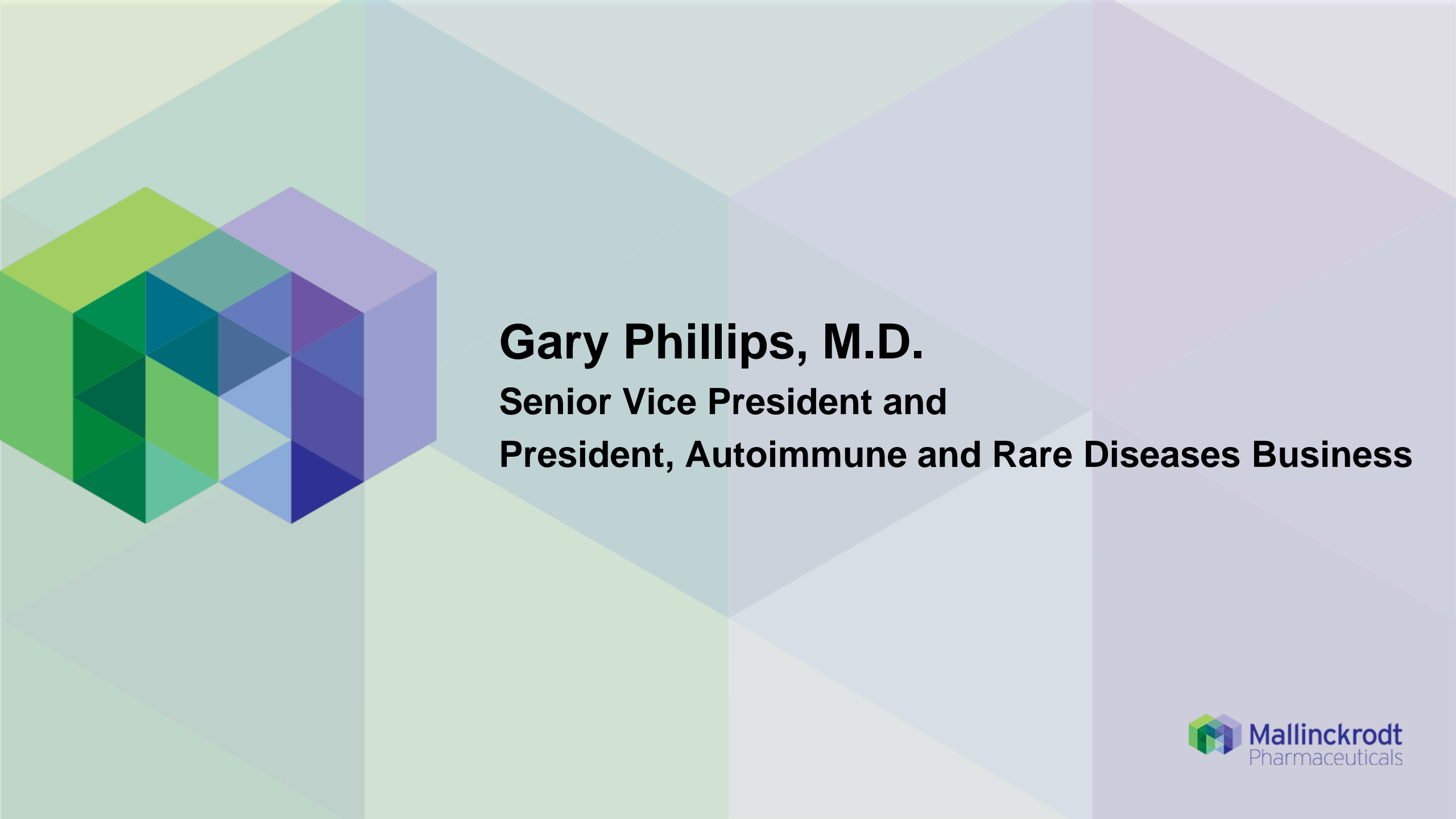
▶ Office Specialists

Call Point

- ▶ Surgeons
- ▶ Pharmacy
- ▶ Anesthesiology

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

▶ Surgical Specialties



Gary Phillips, M.D.
Senior Vice President and
President, Autoimmune and Rare Diseases Business

Acthar is a complex, naturally-derived biological product, mixture of organic molecules



FDA approved in 19 debilitating diseases/conditions; currently marketed in only 9 indications*

Neurology

- ▶ Infantile spasms*
- ▶ Multiple sclerosis flares in adults*

Rheumatology

- Multiple organs (including muscle and joint):
- ▶ Lupus*
 - ▶ Dermatomyositis/polymyositis*
 - ▶ Rheumatoid arthritis flares*
 - ▶ Psoriatic arthritis flares*
 - ▶ Ankylosing spondylitis flares*

Pulmonology

- ▶ Symptomatic sarcoidosis*

Nephrology

- ▶ Edematous state* (remission of proteinuria in nephrotic syndrome)



Ophthalmology

- Eye inflammation such as:
- ▶ Keratitis
 - ▶ Iritis
 - ▶ Iridocyclitis
 - ▶ Diffuse posterior uveitis
 - ▶ Optic neuritis
 - ▶ Chorioretinitis
 - ▶ Anterior segment inflammation

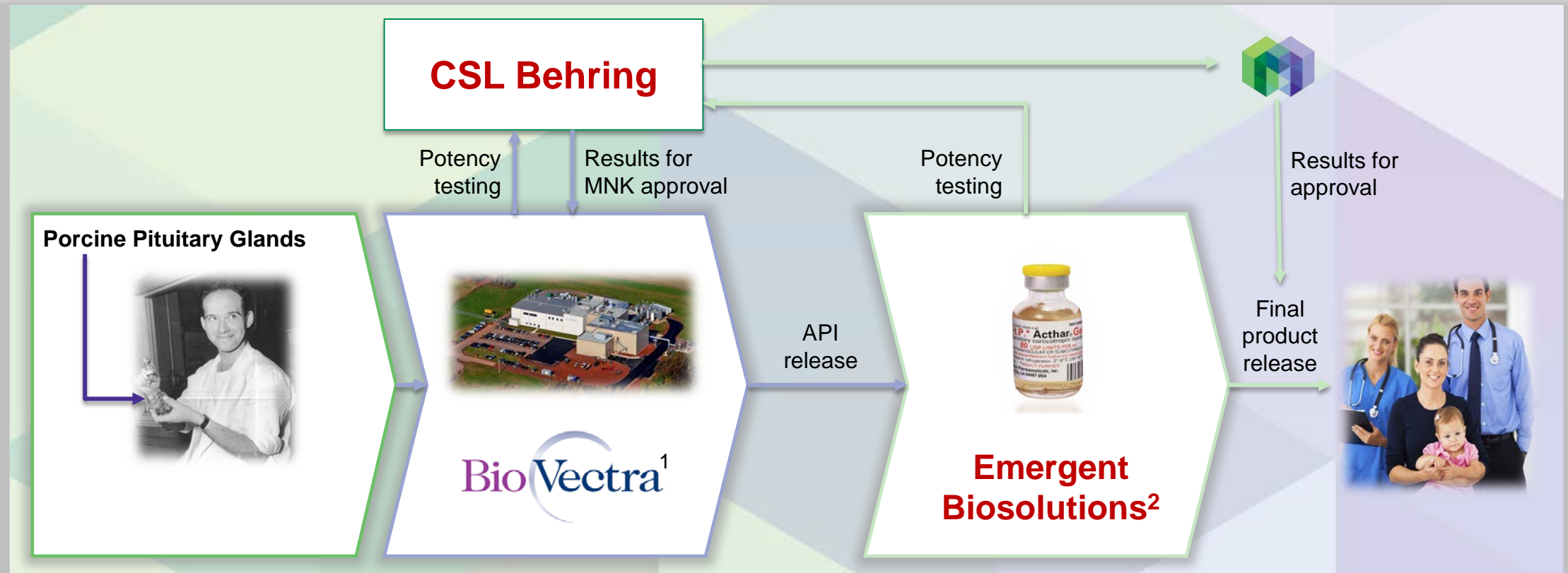
Dermatology

- Rare skin diseases such as:
- ▶ Stevens-Johnson syndrome
 - ▶ Severe erythema multiforme

Allergic States

- ▶ Serum sickness

Acthar manufacturing is well-established and conducted under FDA current Good Manufacturing Practices



- ▶ Quality and potency monitoring throughout all stages of processing
- ▶ Manufacturing and purification process, precise characterization and ratio of organic elements in Acthar remain trade secrets

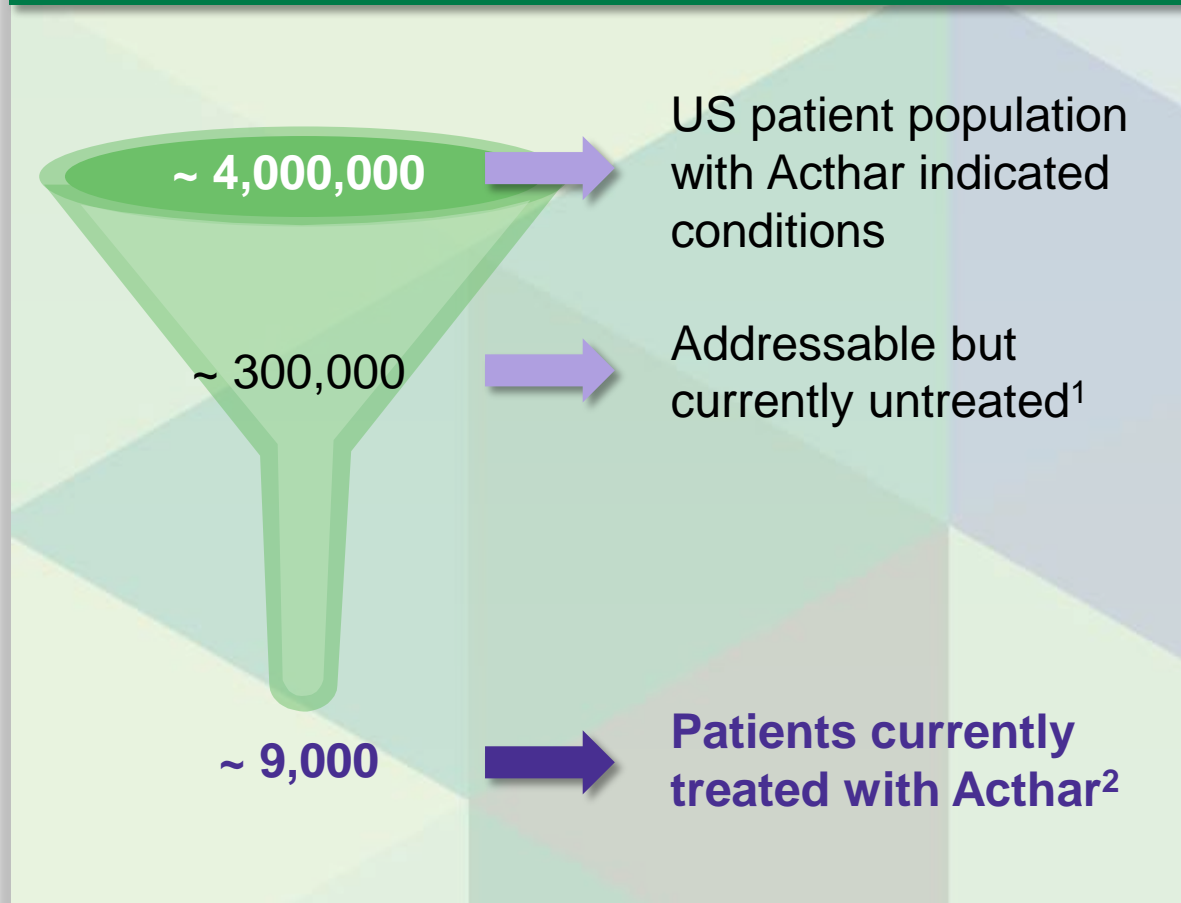
¹ Owned by Mallinckrodt Pharmaceuticals

² Formerly Cangene bioPharma

Acthar is the foundation of our broad Autoimmune and Rare Diseases business



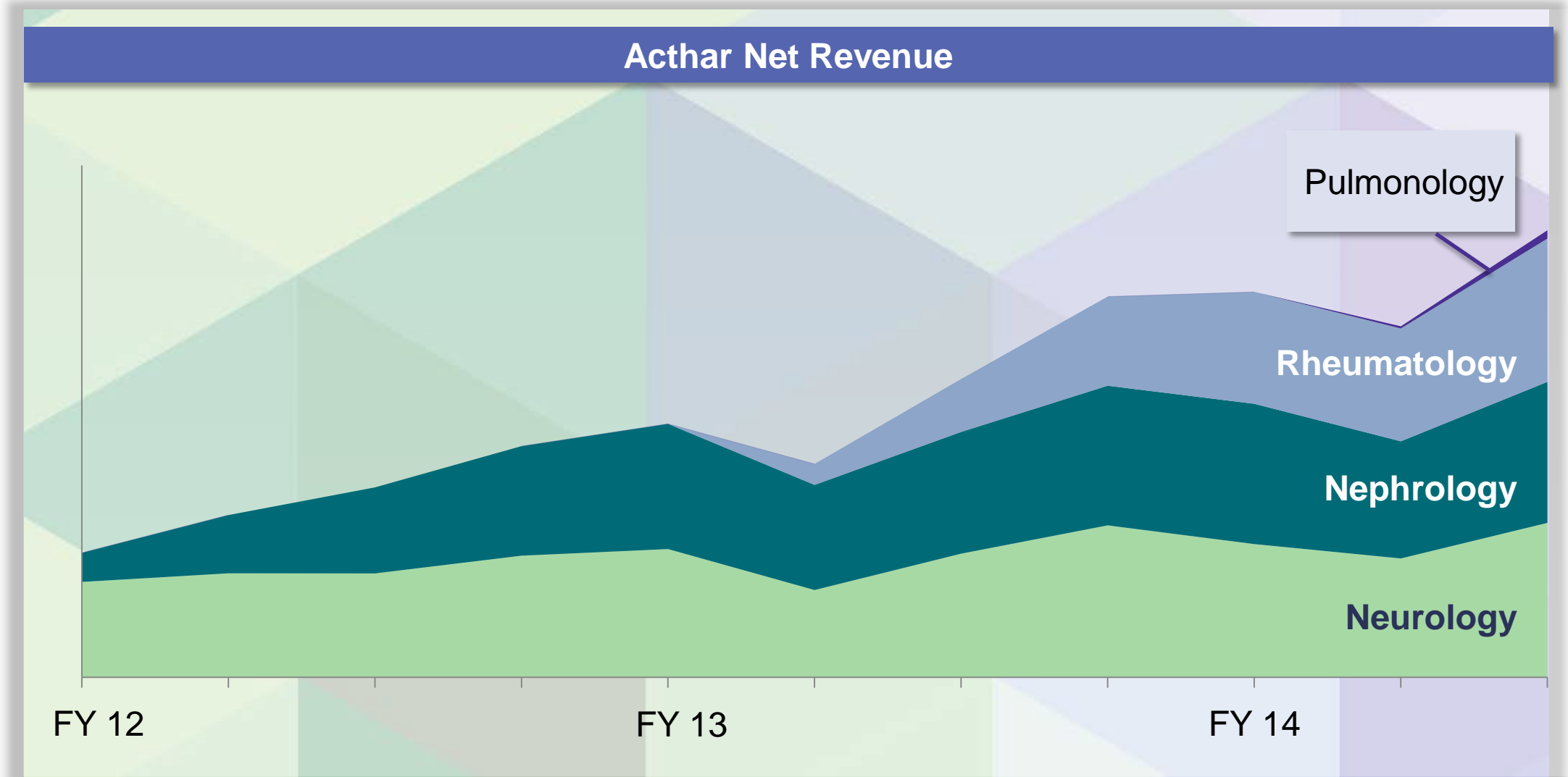
In 9 currently promoted indications, only 3% of addressable Acthar patients are now treated



Mallinckrodt's Strategy

- ▶ Document and publish clinical experience and health economic outcomes
- ▶ Grow utilization of Acthar in appropriate, but underserved, patient populations
- ▶ Initiate commercial efforts in other approved indications with high unmet medical need
- ▶ Increase payer engagement to support reimbursement
- ▶ Focus R&D investment
- ▶ We believe current regulatory guidelines drive complicated development and make a generic unlikely

Acthar growth historically strong; driven by market entry of therapeutic areas



Mallinckrodt plans to enhance Science and Technology investment



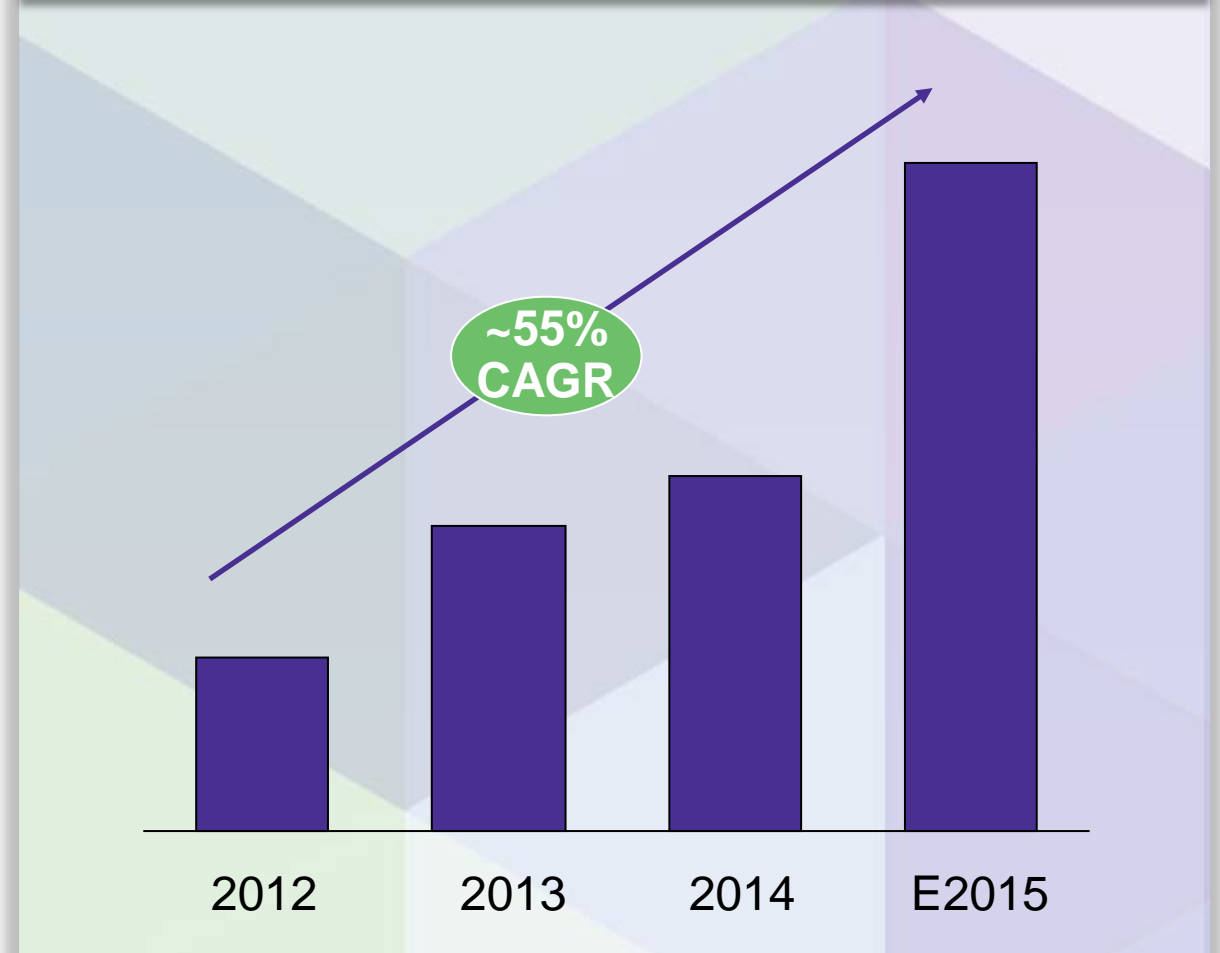
Substantial Historical Investment

- ▶ Well-funded, diverse program
 - ~\$190M invested in company and investigator sponsored research¹
 - ~300 funded studies
- ▶ Publication ramp up planned for 2015

Future Research Focus

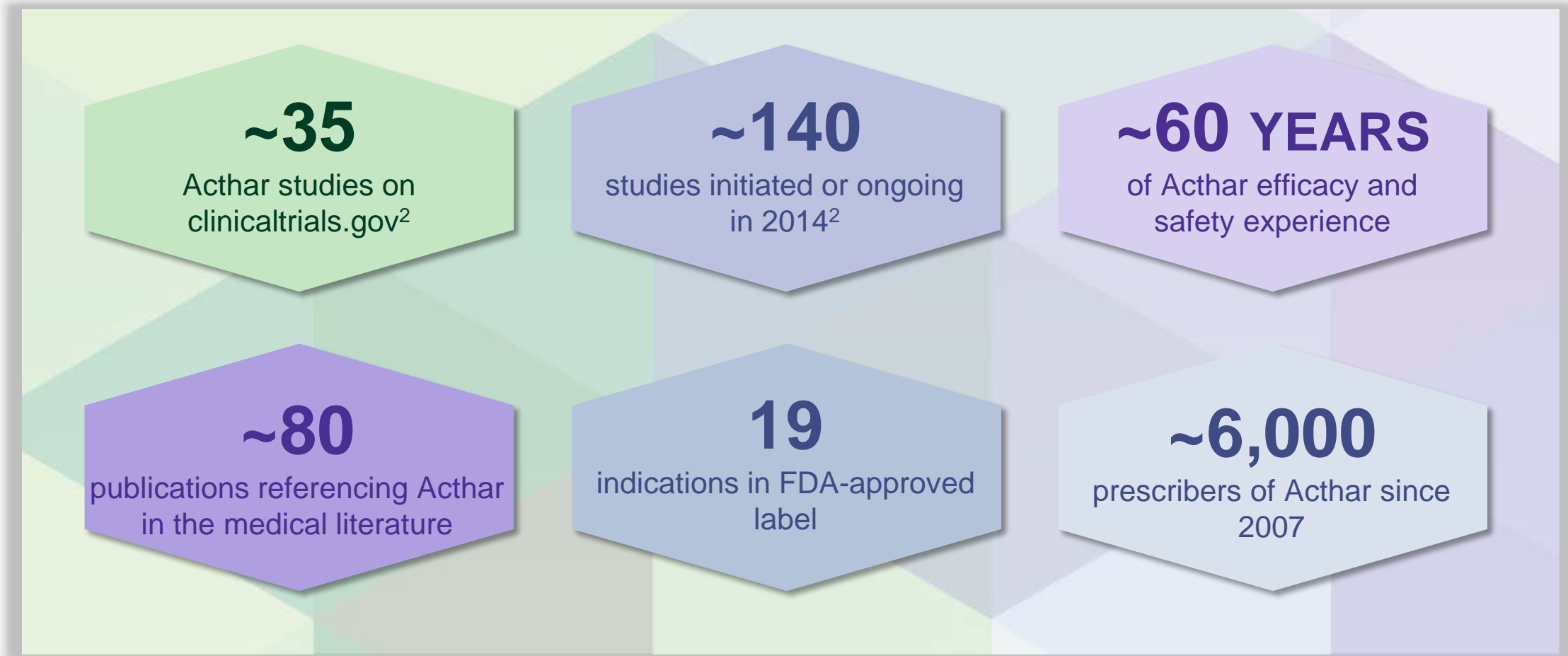
- ▶ Health economic and outcomes research
- ▶ New clinical data in approved indications
- ▶ New clinical indications research
- ▶ Broaden Acthar's scientific foundation

Science and Technology Spending



¹ 2011-2014

Expanding the body of knowledge for Acthar¹

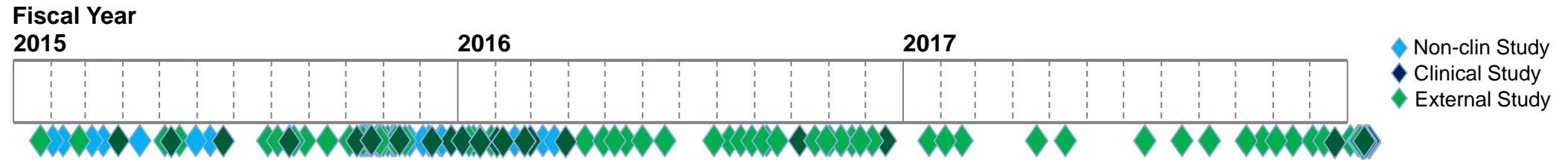


¹Bibliography reference included in presentation appendix

² Includes company and investigator sponsored research



Planned and ongoing studies will provide the basis for potential publications



New and ongoing study strategy

Short-term (1-6 months):

Document **differentiation from steroids** through non-clinical studies in animal models

Medium-term (6-15 months):

Expand on **safety and efficacy data and healthcare economics** with ongoing studies and available data

Long-term (>15 months):

Strengthen **clinical confidence and healthcare economics** with ongoing and new designed clinical studies

Four ongoing in progress company sponsored clinical studies on clinicaltrials.gov

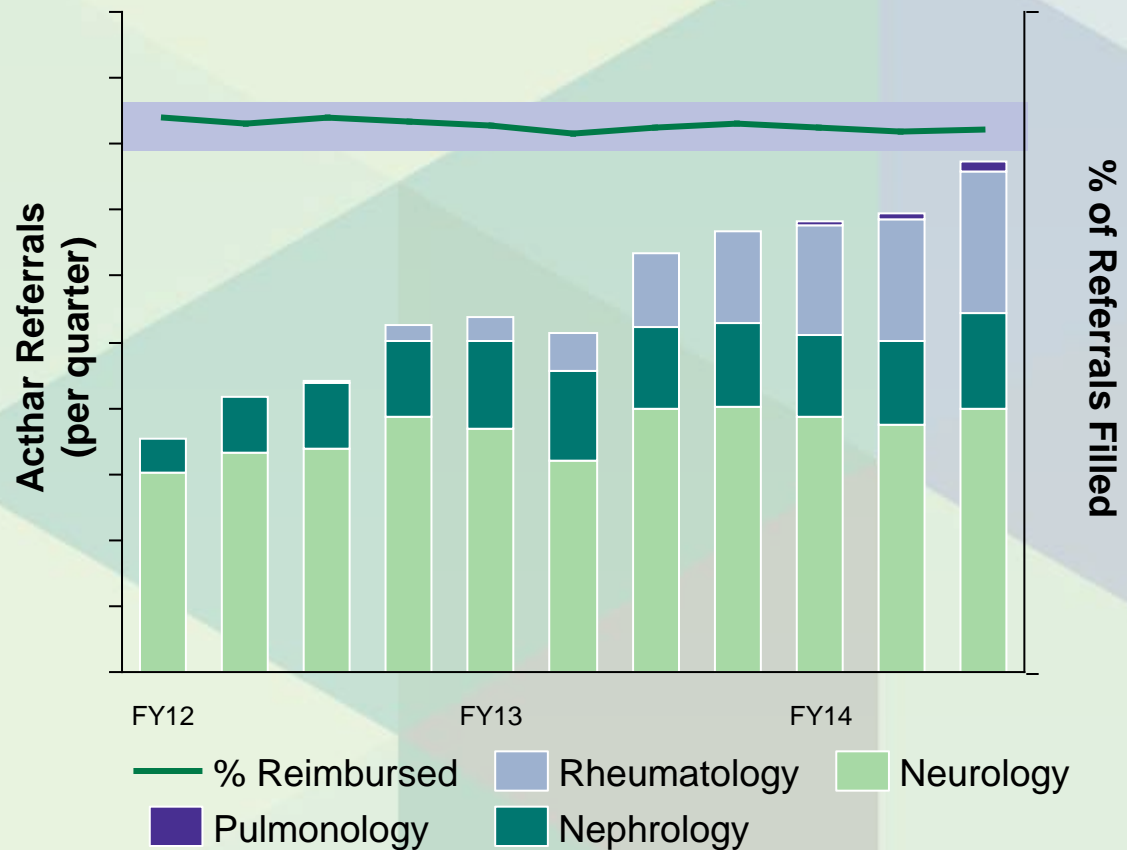


	Study Objective	Study Design	Study Size	Current Status
Amyotrophic Lateral Sclerosis (ALS)	▶ Safety and tolerability	▶ Open label, randomized	▶ 40 patients	▶ Active, not enrolling
Systemic Lupus Erythematosus (SLE)	▶ Efficacy, safety, pharmacodynamics	▶ Double blind, randomized	▶ 36 patients	▶ Active, not enrolling
Membranous Nephropathy	▶ Efficacy and safety	▶ Double blind, randomized	▶ 60 patients	▶ Enrolling
Diabetic Nephropathy	▶ Efficacy and safety	▶ Double blind, randomized	▶ 40 patients	▶ Enrolling

Acthar reimbursement will continue to be important to reach underserved addressable patient populations



Expect growth in appropriate patients to continue to outweigh reimbursement challenges



Strong, established foundation

- ▶ Support network established to help patients with reimbursement process
- ▶ Primary focus: appropriate access and accelerated reimbursement time

Building on this foundation

- ▶ Engage payers at plan-wide policy level
- ▶ Document and communicate patient benefits of Acthar treatment
- ▶ Publish clinical experience and health economic outcomes



James A. Tumlin, M.D.

Professor Medicine/Nephrology

University of Tennessee Chattanooga

Director Southeast Renal Research Institute

Dr. Tumlin is a paid consultant and on the Speakers' Bureau of Mallinckrodt



Nephrotic Syndrome: Definition & Contributing Diseases

**High Grade Loss of Protein in the Urine
>3000 mg/24hrs
(Normal up to 150 mg/24 hrs.)**

Low Serum Albumin < 3.0 mg/dl

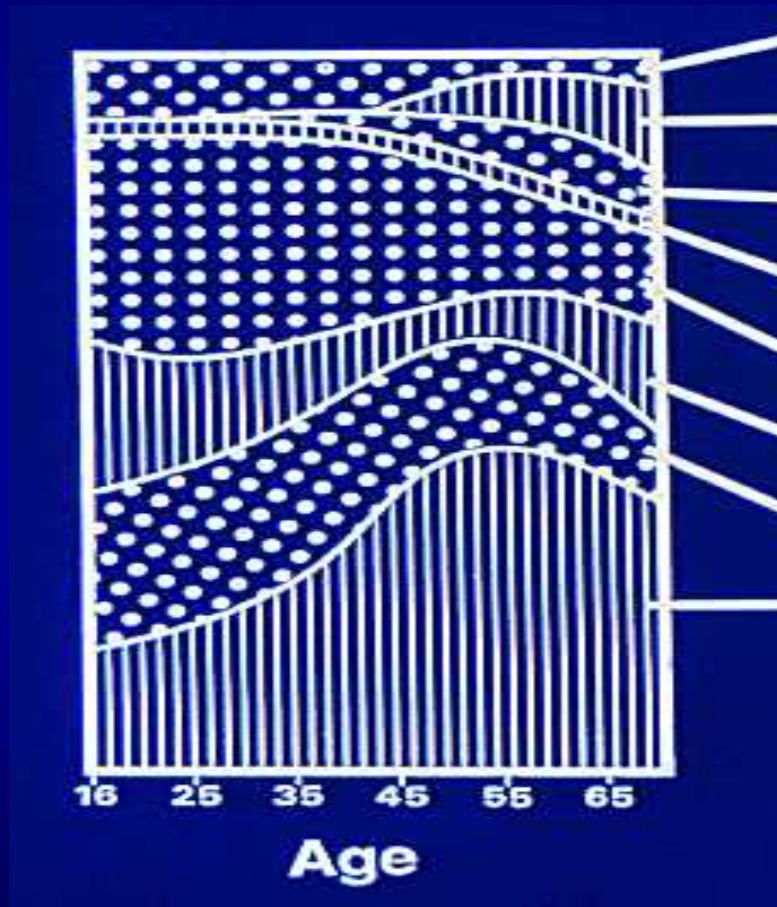
**Hyperlipidemia: Elevated Cholesterol
& Triglycerides**

Anasarca: Total Body Swelling and Edema

Proteinuria: Causes Massive Lower Extremity Swelling & Weight Gain



Nephrotic Syndrome: Definition & Contributing Diseases



Amyloidosis

Diabetic Nephropathy

Membranoproliferative GN

Focal Segmental GN

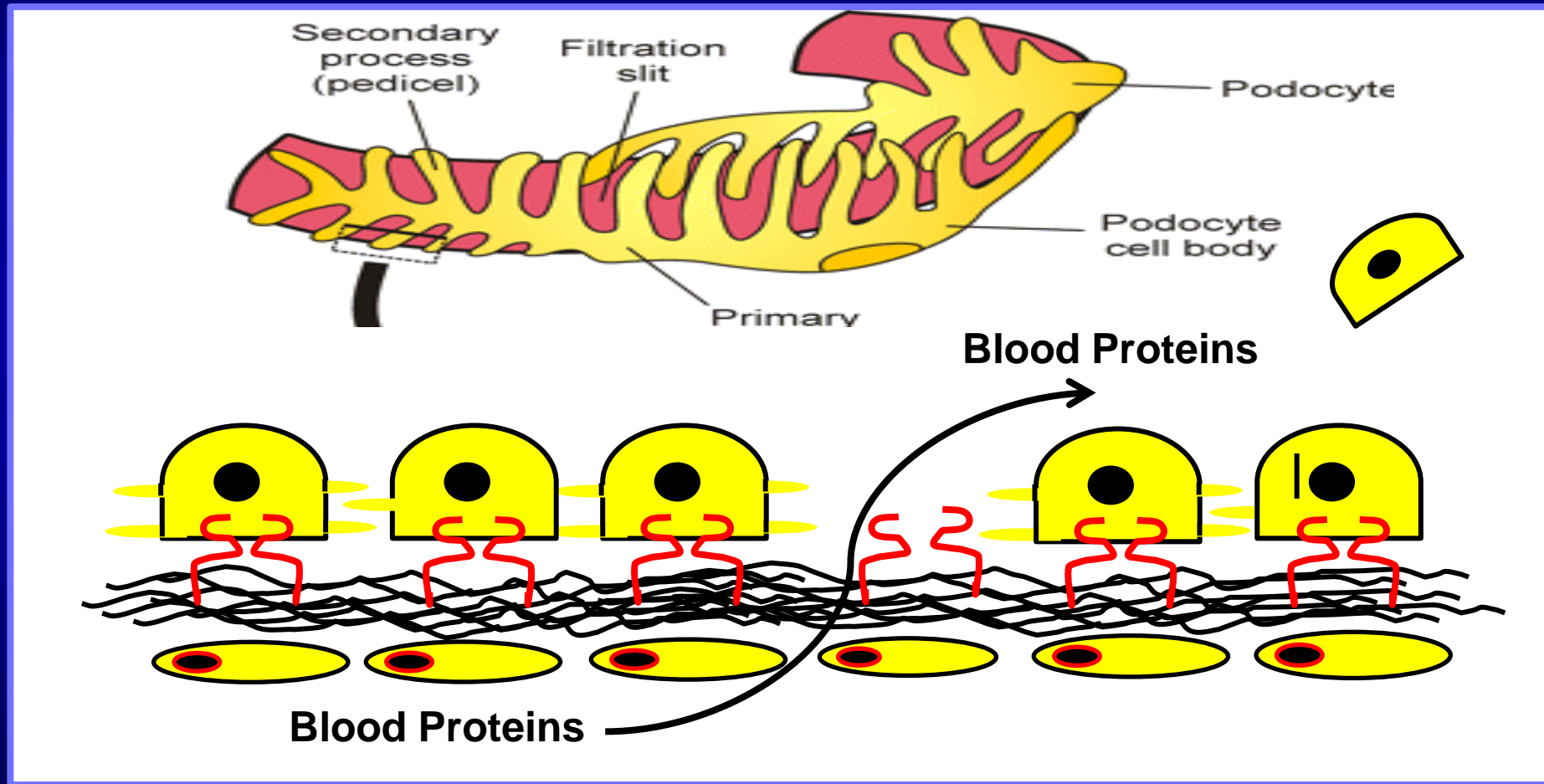
Membranous GN

Lupus Nephritis

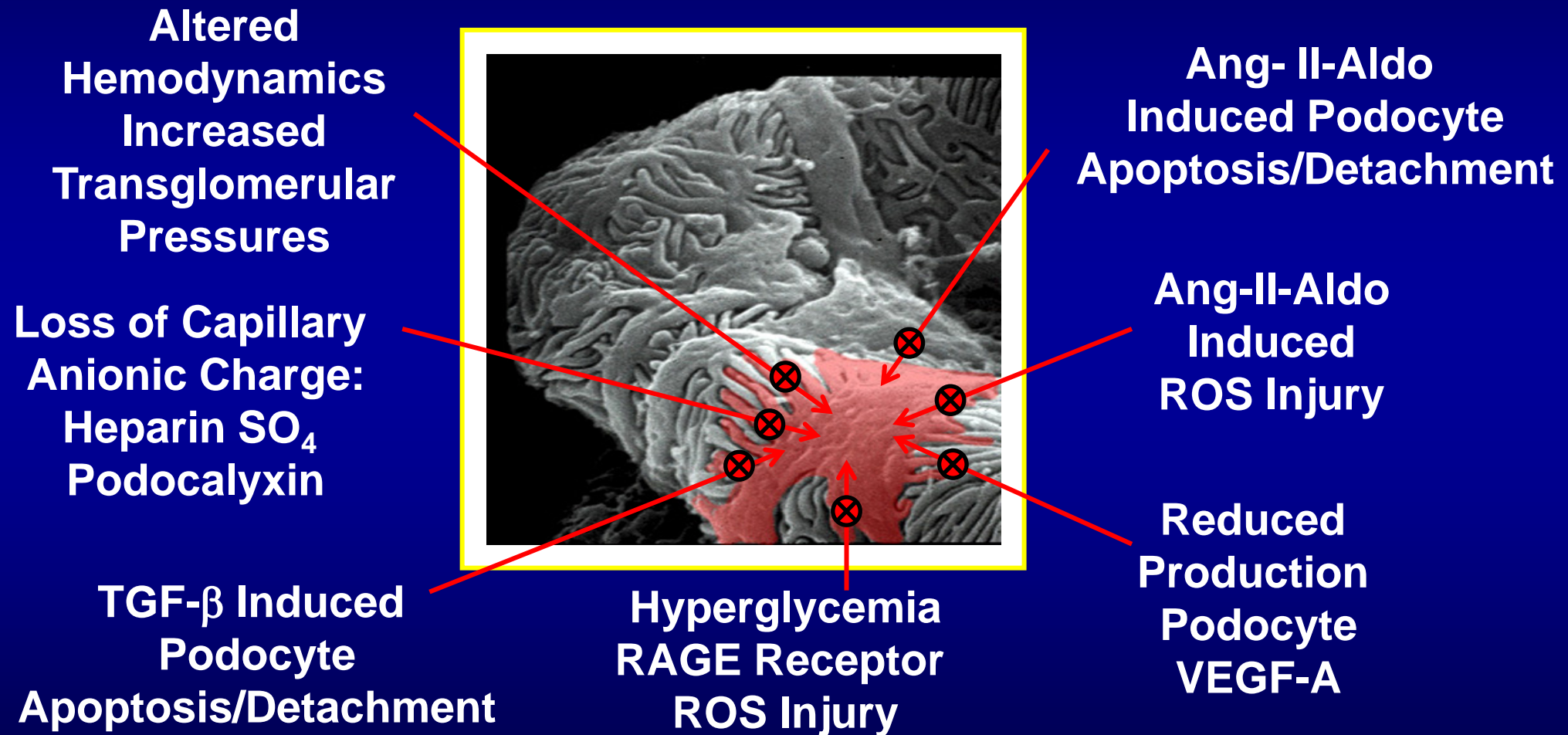
IgA Nephropathy

C1Q Nephropathy

Podocyte Loss Contributes To Protein Losses in Urine

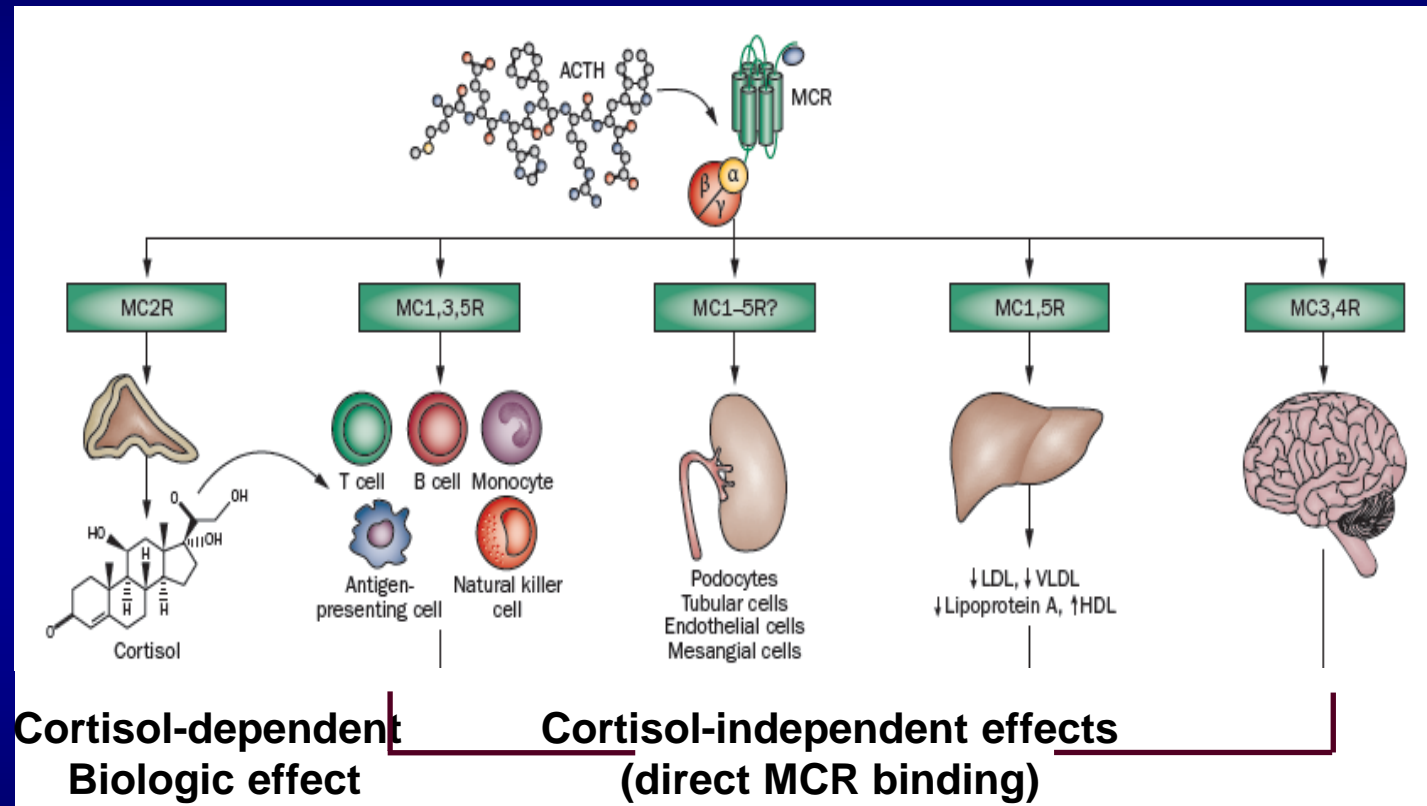


Diabetic Podocytopathy: Cellular Target of Injury and Focus of Therapeutic Interventions



Corticotrophins: Podocyte Stabilizers?

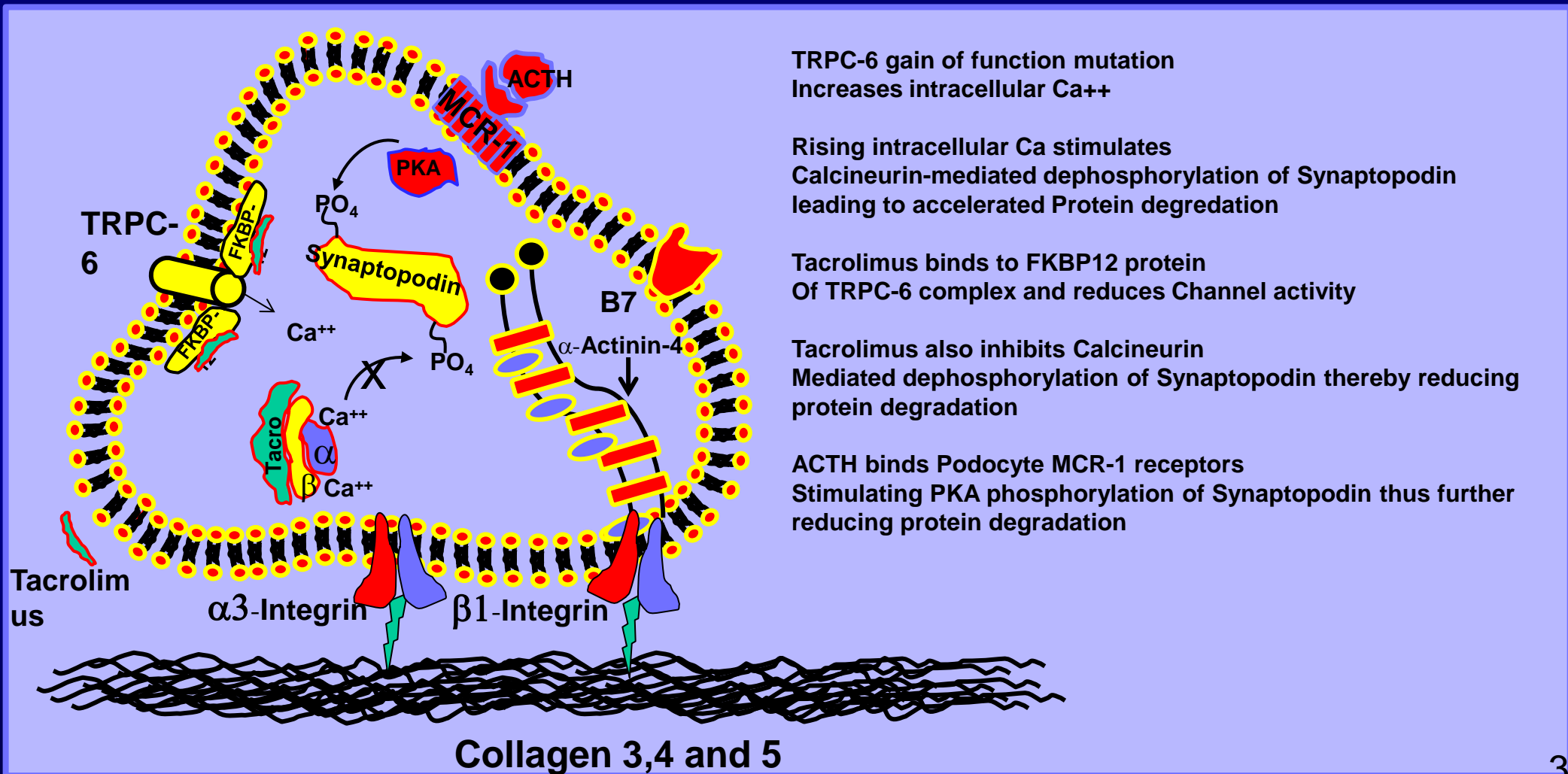
Acthar Binds to Five Different Melanocortin Receptors¹⁻³



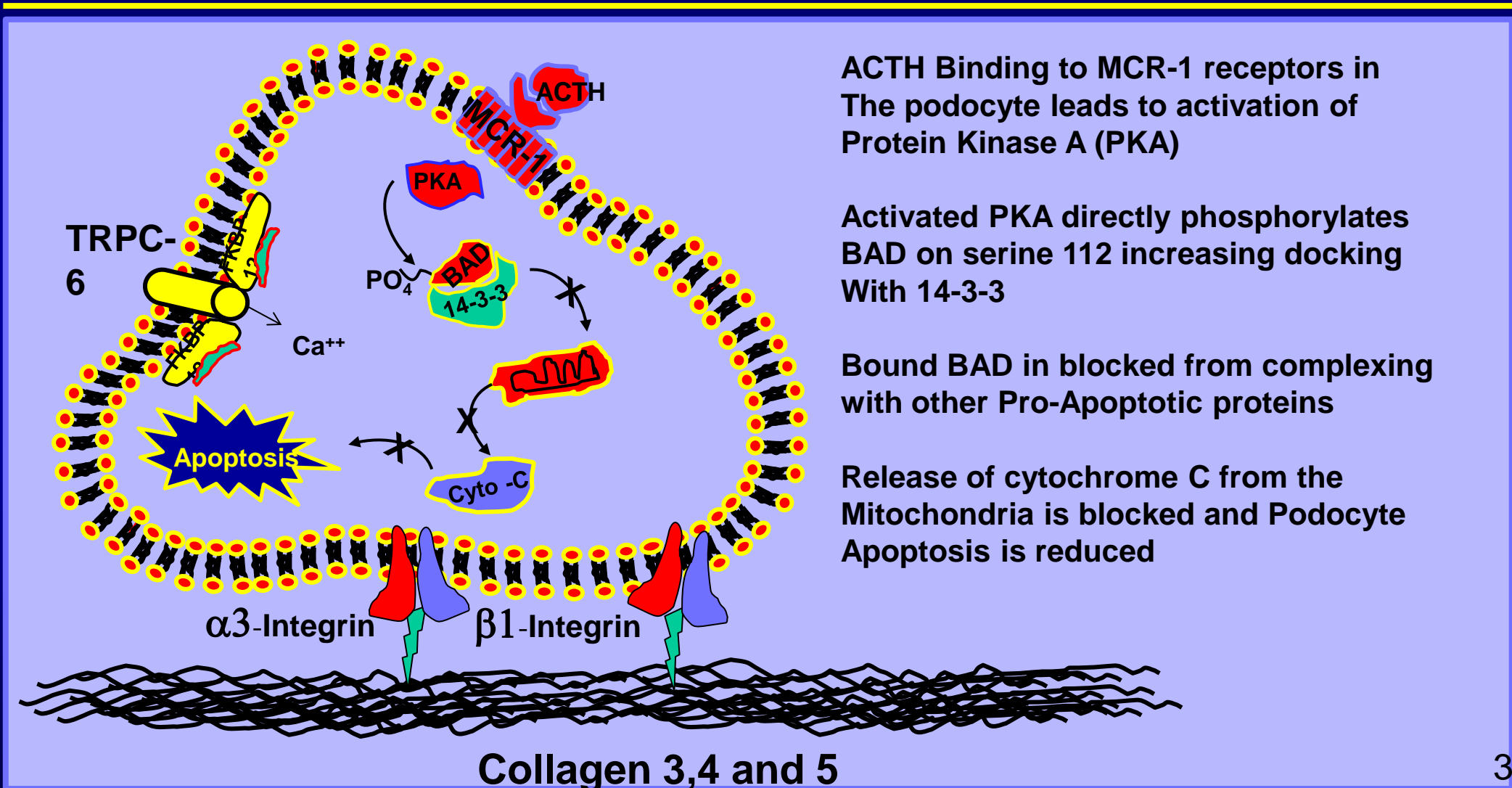
While the exact mechanism of action of Acthar is unknown, further investigation is being conducted. This information is based on nonclinical data, and the relationship to clinical benefit is unknown.

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ACTH & Tacrolimus Blocks Degredation of Podocyte Synaptopodin: Mechanism for Protein Reduction



ACTH and Protein Kinase A Activation Reduces Proteinuria Through Inhibition of Podocyte Apoptosis



Corticotrophin Use in Protein Loosing Renal Diseases

Membranoproliferative GN

Focal Segmental GN

Membranous GN

Lupus Nephritis

IgA Nephropathy

C1Q Nephropathy



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Todd D. Levine, M.D.

**Clinical Assistant Professor
University of Arizona**

**Adjunct Professor
Kansas University**

Dr. Levine is a paid consultant and on the Speakers' Bureau of Mallinckrodt

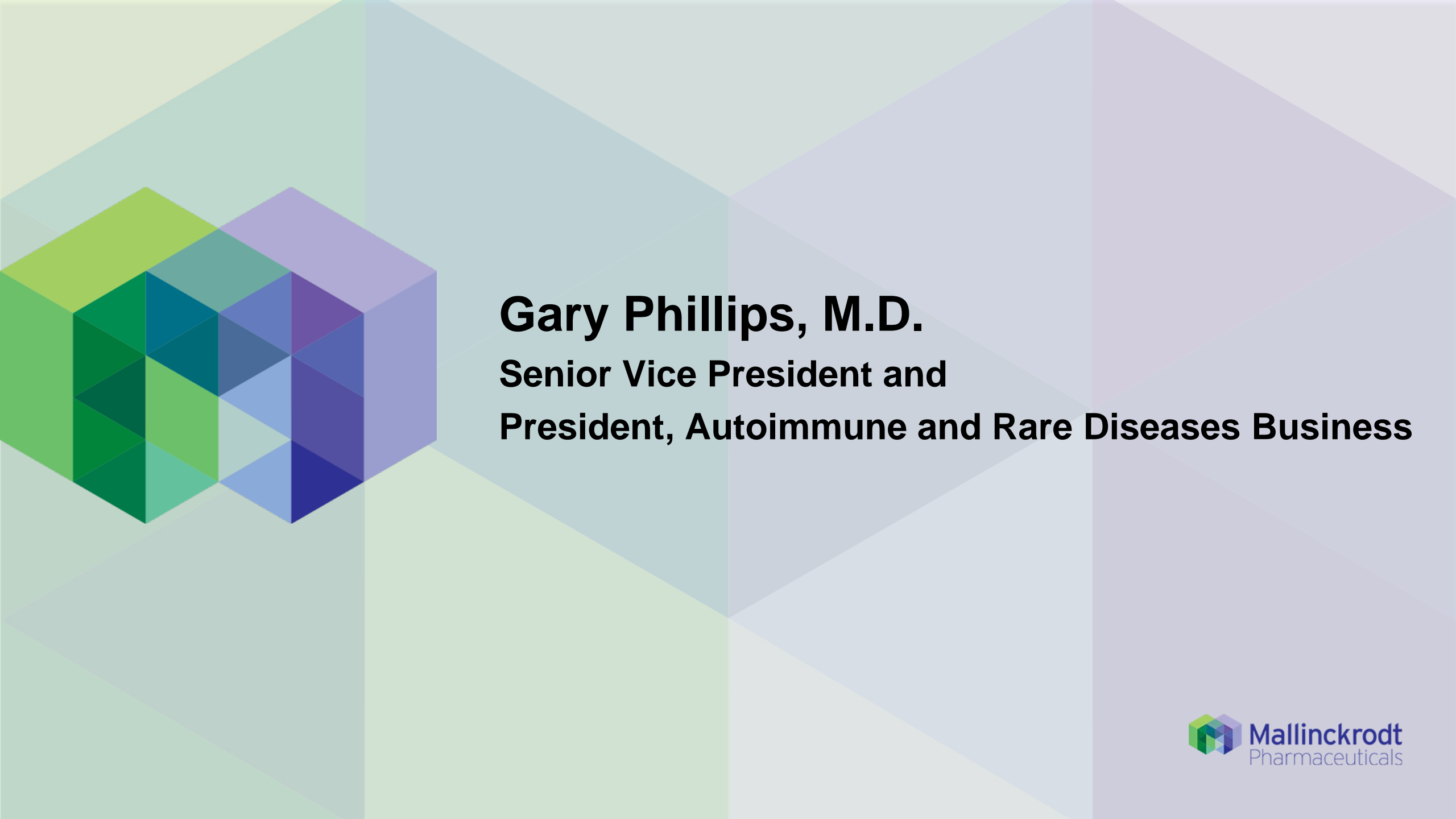




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Physician Q&A



Gary Phillips, M.D.
Senior Vice President and
President, Autoimmune and Rare Diseases Business

Acthar is a durable asset with significant growth potential



- ▶ Reach **underserved patient populations** in current indications, build on near-term **opportunities in rheumatology and pulmonology**
- ▶ Solidify, enhance **publication strategy** to expand Acthar awareness
- ▶ Support **reimbursement access** for appropriate patients in need
- ▶ Invest in **infrastructure** to continue to ensure quality and uninterrupted supply



Matt Harbaugh

Senior Vice President and Chief Financial Officer

Guidance – Fiscal Year 2015



\$ in millions, except per share data

Metric <i>(excluding foreign currency impact)</i>	FY15 Guidance
Adjusted diluted EPS	\$6.70 to \$7.20
Total company net sales	\$3,650 to \$3,750
Specialty Pharmaceuticals net sales	\$2,870 to \$2,930
Global Medical Imaging net sales	\$760 to \$800
Non-GAAP effective tax rate	20% to 23%
Capital expenditures	\$130 to \$150



Mark Trudeau
President and Chief Executive Officer

Mallinckrodt – Where we're going



- ▶ Leverage **four platforms to accelerate growth**
 - ▶ Focus on **integration and expansion of the durable Acthar asset**
 - ▶ Execute on **hospital/surgical specialty/pain synergy**
- ▶ Advance **pipeline**, seek **BD&L opportunities** in core business and growth platforms
- ▶ Continue **flawless execution of our growth and profitability** strategy; operate a **lean and efficient** business model

Our Goal: Top quartile performance based on total shareholder return

Q&A

Thank You



Q&A



Closing Remarks



Thank You

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Appendix

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Infantile Spasms – Manuscripts

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