# Specialized in Ophthalmology

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Information given in presentation contains certain forward-looking statements concerning forecasts, projections and plans whose realization is subject to risk and uncertainty from a variety of sources. Actual results may differ significantly from forecasts.

Business performance and financial condition are subject to the effects of medical regulatory changes made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.

The process of drug research and development from discovery to final approval and sales is long, complex and uncertain. Individual compounds are subject to a multitude of uncertainties, including the termination of clinical development at various stages and the non-approval of products after a regulatory filing has been submitted. Forecasts and projections concerning new products take into account assumptions concerning the development pipelines of other companies and any co-promotion agreements, existing or planned. The success or failure of such agreements could affect business performance and financial condition significantly.

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Santen Pharmaceutical is reliant on specific companies for supplies of certain raw materials used in production. Business performance could be affected significantly by the suspension or termination of supplies of such raw materials if such and event were to adversely affect supply capabilities for related final products.

This presentation includes discussions of certain Santen products marketed in certain markets and compounds in clinical trials, as well as competitors and their products and compounds in clinical trials which are given for illustrative purposes only. Such discussions may include views subject to data interpretation that may or may not be views shared by regulatory authorities in the various regions in which the Company operates.



### Santen's Core Values

# 天機に参与する Tenki ni sanyo suru

By focusing on ophthalmology, Santen develops unique scientific knowledge and organizational capabilities that contribute to the well-being of patients, their loved ones and consequently to society.



### Santen is Specialized in Ophthalmology



Growing ophthalmology market



Specialized in ophthalmology



Santen's growth strategy



Focus on unmet medical needs in ophthalmology



### Santen is Specialized in Ophthalmology



Growing ophthalmology market



Specialized in ophthalmology



Santen's growth strategy

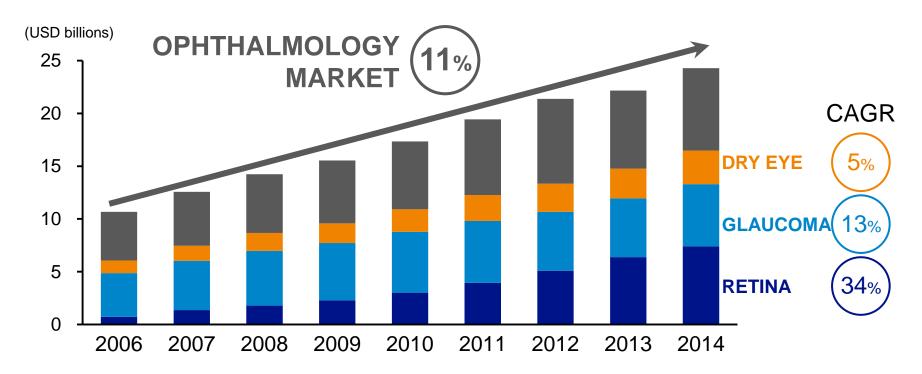


Focus on unmet medical needs in ophthalmology



### **Sustained Growth in Ophthalmology Worldwide**

World Ophthalmology Market by Therapeutic Category

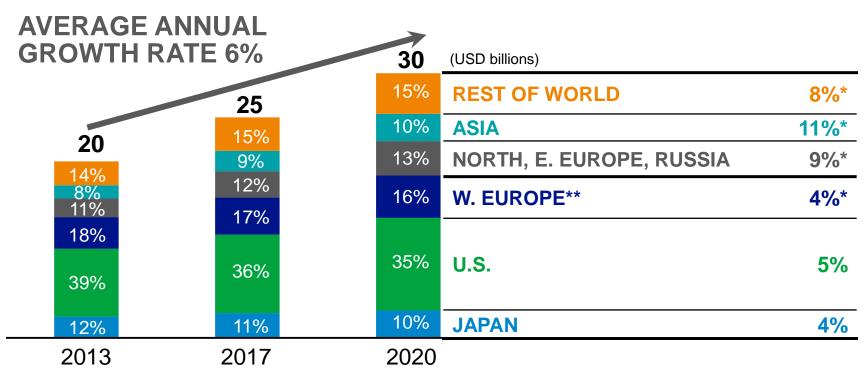


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### **Market Outlook: Continuing Growth**

Global Prescription Ophthalmic Market



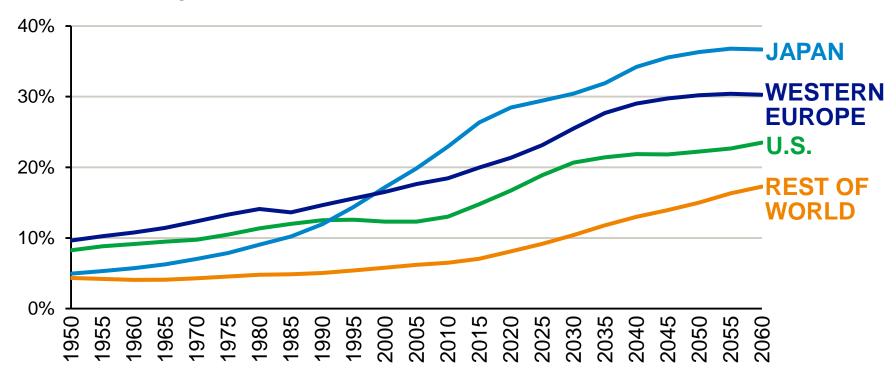
Source: Santen estimation



<sup>\*</sup>Compound annual growth rate, \*\*UK, France, Germany, Spain, Italy

### The Population is Aging Worldwide

Population Aged 65+



Source: United Nations, World Population Prospects: 2015 Revision



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### **Focused on All Ophthalmic Therapeutic Areas**

Santen offers a full range of ophthalmology treatments, including areas with high unmet medical needs.

Company	Retina	Glaucoma	Dry eye	Infection	Allergy	Cataract
Santen	1	✓	<b>√</b>	<b>✓</b>	✓	<b>✓</b>
Alcon/Novartis	<b>√</b>	✓	✓	<b>√</b>	✓	✓
B&L/Valeant	✓	✓	✓	<b>✓</b>	✓	✓
Allergan	<b>✓</b>	✓	✓	<b>✓</b>	✓	
Pfizer	<b>✓</b>	<b>√</b>				
Genentech	<b>✓</b>					
Regeneron/Bayer	<b>✓</b>					
Abbott/Solvay	<b>✓</b>		✓			<b>✓</b>
Sanofi	<b>✓</b>				<b>✓</b>	

Source: Publicly available information



# **Specializing Our Business and R&D in Ophthalmology**

#### 2012

### Novagali Pharma acquisition

- Strengthened R&D, including Novasorb<sup>®</sup> formulation technology
- IKERVIS (now launched in several European countries)

### 2014

# MSD ophthalmology product acquisition

- Acquired product sales:
  21.5b yen (FY15 FCT)
- Reinforced global presence
- Accelerated EU and Asia growth
- Increased profitability

### 2015

Anti-rheumatic (RA) pharmaceutical business divestment

7% RA 93% Op 100% Ophthalmology

 45b yen received to support future investment



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# VISION 2020: Establishing a Global Presence as a Specialized Pharmaceutical Company

- **©** Global Top 3
- (in Asia by 2020)

Maximize new product value globally

Establish and reinforce overseas business platforms

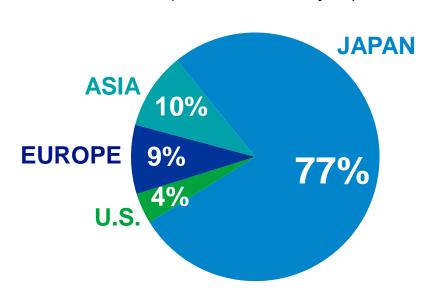
Strengthen domestic business platform and competitiveness

2011 2020



### Santen is the Market Leader in Japan

### \$1.29 Billion, Sales Composition (FY14\*, \$1=125yen)



\*FY14: Fiscal year ended March 31, 2015

### Market Share Leader in Japan



Source: ©2015 IMS Health, Calculated based on IMS-JPM 2001-2015 data, reprinted with permission

### **Driving Sales Growth in Europe and Asia**



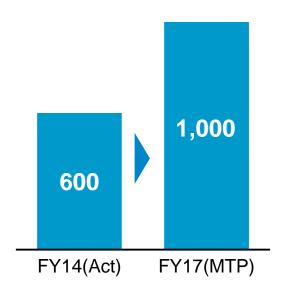
- ASIA: Growth led by China +19% in 1H FY15 (local currency)
- EUROPE: Sales boosted by ophthalmic products from MSD since FY14



### Gaining Share in High-Growth Asia Region

#### **Sales Target China**

(CHY Millions)

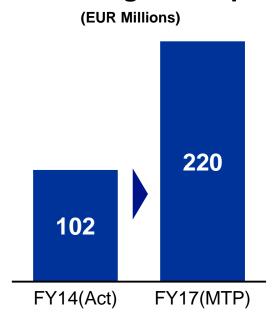


- China: over 60% of Asia revenue
- Building out own-sales in ASEAN countries
- Above-market growth toward goal to become Asia #1
- Growth drivers: CRAVIT (anti-infection) and HYALEIN (dry eye)
- Growth from pipeline: TAPROS (glaucoma) and IKERVIS (severe keratitis with dry eye)



## **Expanded European Operations** is a Growth Driver

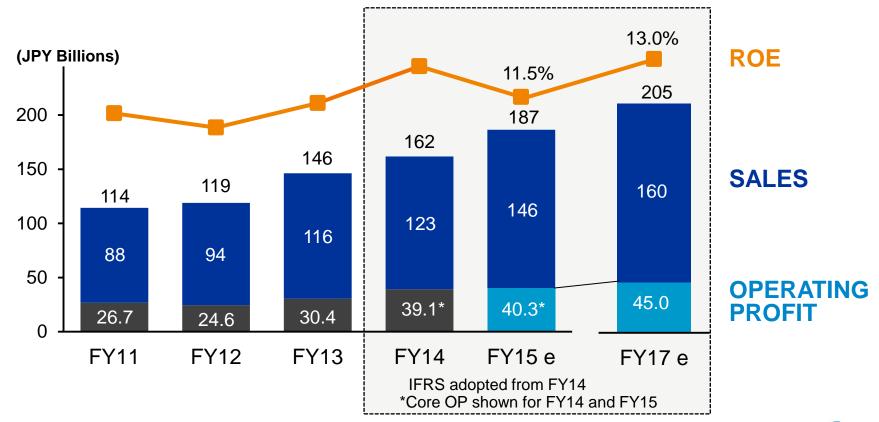
#### **Sales Target Europe**



- Establishing position as differentiated player / best-partner
- New regional HQ in Geneva leading pan-European business platform
- Accelerating new product growth and success with acquired MSD products
- Successful launches and further rollout of IKERVIS across Europe



### Mid-Term Plan to Achieve Above-Market Growth





### **Coming Products to Drive Growth**

Santen Products Targeting Unmet Medical Needs

### **IKERVIS**



- Treatment for severe keratitis in patients with dry eye disease
- First to market in Europe
- Received positive recommendation from NICE (1st HTA authority in Europe)

**DE-109** 



- Treatment for patients with chronic noninfectious uveitis of the posterior segment (NIU-PS)
- Pre-launch initiatives underway
- EMA now reviewing EU submission
- US Phase 3 clinical trials ongoing

NICE: The National Institute for Health and Clinical Excellence; HTA: Health Technology Assessment authority



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### **R&D** for the Next Decade

Santen's R&D Transformation

Target and address region-specific unmet medical needs

**UMN** 

Reduce **time to launch**; Faster with focus on the right products to the right patients

TTL

Significantly improve probability of technical success in all target disease areas

PTS



# R&D Strategy: Raise Competitiveness in Specialty Area of Ophthalmology



**Focus** on differentiated life-cycle management



Improve PTS with pathobiology and unmet needs through translational research, biomarkers and diagnostics



**Boost productivity** by prioritizing Best-in-Class\* programs



Pursue partnered R&D through clearly defined business development and in-licensing



<sup>\*</sup>Any new product candidate that has POC in human with ophthalmic or other systemic indications

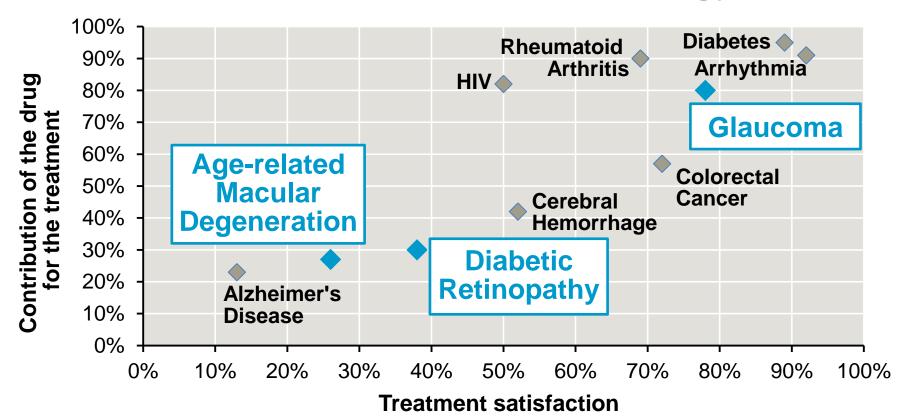
# Addressing the Unmet Needs of a Changing World

### Disease areas with region-specific needs

Asia	Developing World	Developed World	Worldwide
Myopia	Infectious disease	Age related diseases, Dry eye, Chronic illness, Complications of diabetes	Orphan diseases



### **Unmet Medical Needs in Ophthalmology**



Source: Office of Pharmaceutical Industry Research in Japan



### Santen Pipeline Targeting Unmet Needs

	Launched in FY2011-13	Approval Timing FY2014-17	To be Approved FY2018-
Glaucoma	TAPROS Mini	DE-111 (Tafluprost / Timolol	DE-117 (EP2 Agonist)
		(combination))	DE-090 (Lomerizine HCI)
Corneal and Conjunctival Disease (Dry Eye)		IKERVIS (Cyclosporin)	
Retinal Disease, Uveitis	EYLEA	Opsiria (Sirolimus)	DE-120 (VEGF/PDGF inhibitor)
			DE-122 (Anti-endoglin antibodies)
Other Infection,	ALESION CRAVIT 1.5%	VEKACIA	
Allergy		(Cyclosporin)	

Excludes GE products. LCM products includes those to be launched in multiple regions. Feasibility of clinical trials of Santen S.A.S. is being assessed.



### **Expanding Global Partnership Alliances**

Working closely with excellent companies, institutes, and academia to meet unmet medical needs









**UBE** /UBE INDUSTRIES.LTD.



Eisai







































### In Conclusion, Santen Is...



Specialized in ophthalmology



Targeting and addressing unmet medical needs



Geographic and product growth drivers in place



Focused R&D strategy with a strong late-stage pipeline



Ready to make investments for further growth





A Clear Vision For Life®