

# Review of FY2014-2017 Medium-term Management Plan

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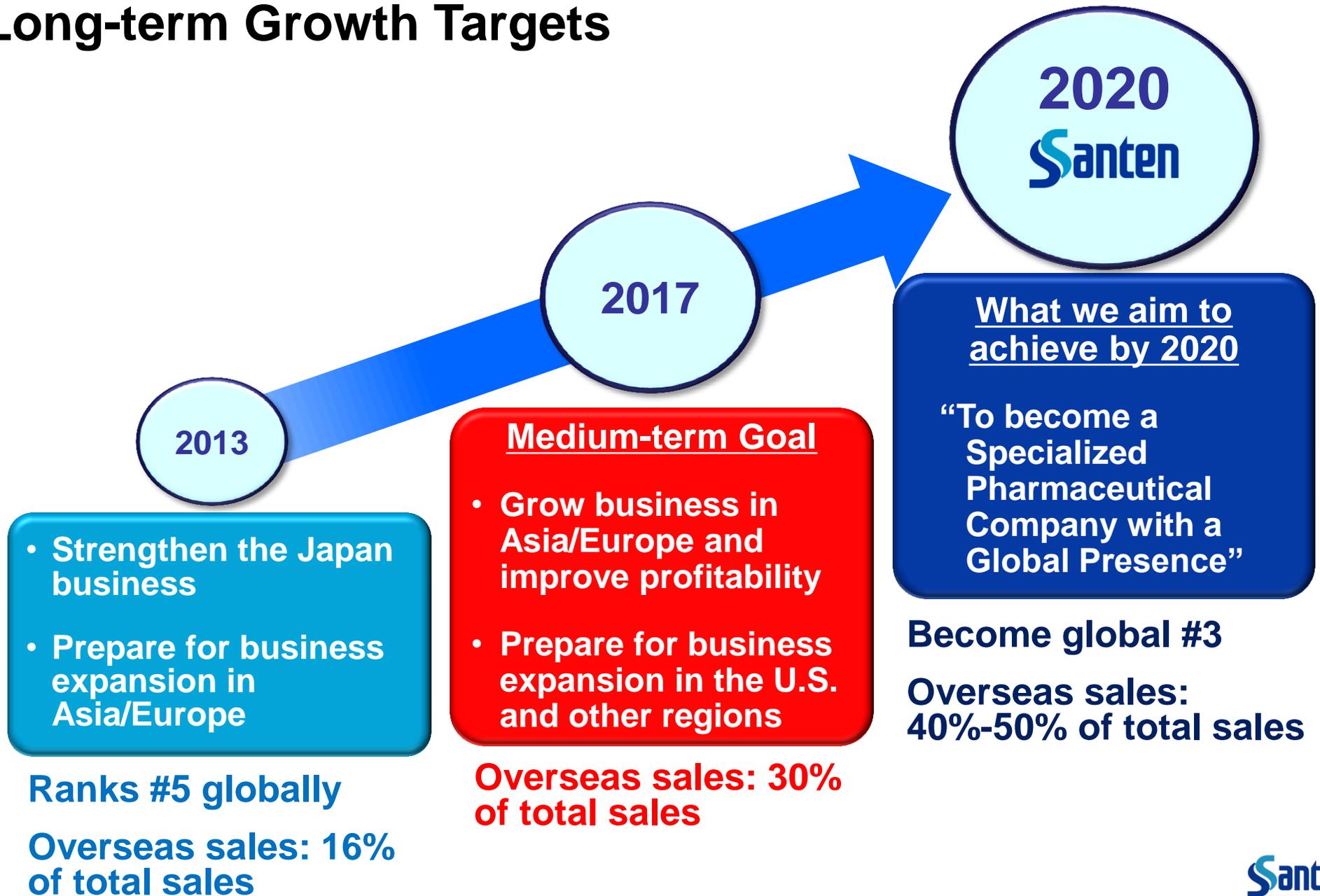
**Akira Kurokawa**

President & CEO

May 2016

**SANTEN PHARMACEUTICAL CO., LTD.**

# Long-term Growth Targets



# Basic Policy of FY2014-2017 Medium-term Management Plan

## Product development

Transform product development to realize enhanced productivity and achieve sustained growth

Active investment in sustainable growth

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## Business expansion

Grow business in Asia/Europe and strengthen market presence by entering into new markets

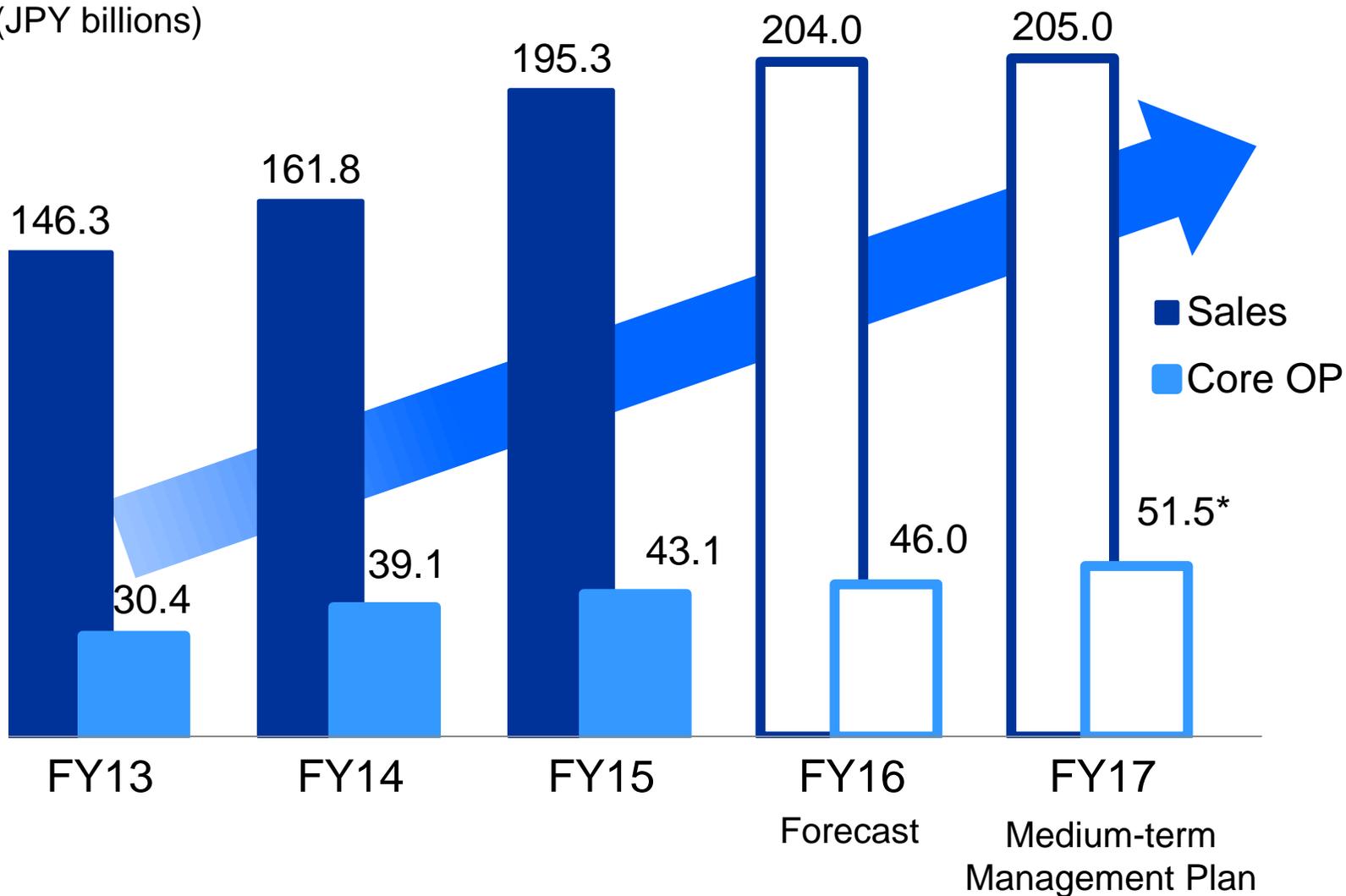
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## Organization and talent

Develop talent and organization to realize sustained growth and strengthen the global management system

# Grow steadily toward Medium-term Management Plan

(JPY billions)



\*FY17 OP: 51.5 billion yen used on IFRS core basis, 45.0 billion yen used on J-GAAP.

# Review of Medium-term Management Plan

- Realized markets expansion in Asia and Europe by leverage from acquisition of US-based Merck's ophthalmic products, Improving structure of business foundation
- Developed globalization and increased overseas sales ratio. (FY13: 17% → FY15: 27%)
- Revenue headwinds, such as NHI drug price revisions in Japan, have become apparent; Accelerating business monetization overseas is a key issue

Review of FY14 - FY15	
<b>R&amp;D</b>	<b>Overseas</b>
<ul style="list-style-type: none"> <li>• Launched new drugs/enhanced pipeline               <ul style="list-style-type: none"> <li>• Launched Ikervis in Europe</li> <li>• Increased the number of LCM/GE applications</li> <li>• In-licensed: DE-122, DE-126</li> </ul> </li> <li>• Strengthened global R&amp;D management</li> <li>• Human resources, Speed-up of decision-making</li> <li>• Structured Global organization               <ul style="list-style-type: none"> <li>• Reorganized Medical Affairs function</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b><u>Strengthened Asian business</u></b> (FY13→FY15 CAGR 39%)               <ul style="list-style-type: none"> <li>• Developed business for expanding Chinese and other markets</li> <li>• Established subsidiary that strengthen business promotion functions in the ASEAN region and local subsidiaries in each countries</li> </ul> </li> <li>• <b><u>Structured business foundation and executed strategies in Europe</u></b> <ul style="list-style-type: none"> <li>• Geographically expended to major countries</li> <li>• Launched new medicine (Ikervis approved/launched)</li> </ul> </li> <li>• <b><u>Has considered strategy of U.S. business expansion</u></b></li> </ul>
<b>Japan</b>	<b>Product supply</b>
<p><b><u>Prescription Pharmaceuticals</u></b> :</p> <p>Increased new drug ratio (FY13: 44%→FY15: 63%)</p> <ul style="list-style-type: none"> <li>• High customer satisfaction by doctors</li> <li>• Expanded promotion to non-ophthalmic clinical departments</li> <li>• Assigned anti-rheumatic pharmaceutical business, established Santen Business Services Co., Ltd.</li> </ul> <p><b><u>OTC</u></b>: Maximized opportunity of inbound demand Strengthened domestic demand</p>	<ul style="list-style-type: none"> <li>• Global product supply               <ul style="list-style-type: none"> <li>• Prepared to manufacture ophthalmic products of US-based Merck (Japan) in domestic plant</li> <li>• Restructured organization</li> </ul> </li> </ul>
	<b>Organization/Talent</b>
	<ul style="list-style-type: none"> <li>• Strengthened global management organization</li> </ul>

# Change of External Factor during Medium-term Management Plan

## Government and Economy

- Japan: Possibility of NHI drug price revisions for three consecutive years due to possible consumption tax increase
  - China: Possibility of price cuts due to new drug price management system
  - Foreign exchange: Increase in foreign exchange rate volatility
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## Market

- Global ophthalmic market: Retina, glaucoma and dry eye areas drive growth
  - Japan: Possibility of ophthalmic market shrinking due to annual NHI drug price revisions, re-calculation of market expansion and generic promotion
  - Medical needs: Diversifying and advancing technology
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## Competition

- Competitive environment change
- Penetration of generic products due to government promotions

# Plan to Medium-term Management Plan

- Contribute to ophthalmic treatment that satisfy customer needs as a global specialized ophthalmic pharmaceutical company
- Strengthen competitive edge led by the development of differentiated products and business expansion
- Accelerate further globalization and preparation for business entry in the U.S.

Plan to FY16 - FY17	
<b>R&amp;D</b>	<b>Overseas</b>
<ul style="list-style-type: none"> <li>• Strengthen pipeline including in-licensing new drugs</li> <li>• Life cycle management</li> <li>• Regional project execution</li> <li>• Expand function of medical affairs (drug evolution) and pharmaceutical affairs (drug regulatory) overseas and strategy</li> </ul>	<ul style="list-style-type: none"> <li>• Strengthen medium and long-term business foundation in China</li> <li>• Further growth in mature markets such as the Big Five of Europe</li> <li>• Strengthen to work in emerging markets</li> <li>• Maximize market value of Ikervis</li> <li>• Continuously consider strategy for U.S. business expansion</li> </ul>
<b>Japan</b>	<b>Product supply</b>
<ul style="list-style-type: none"> <li>• Further increase new drug ratio and market share</li> <li>• Further enhance customer satisfaction</li> </ul>	<ul style="list-style-type: none"> <li>• Reorganize global manufacturing</li> <li>• Transfer technology to manufacture ophthalmic products of US-based Merck (overseas)</li> </ul>
	<b>Organization/Talent</b>
	<ul style="list-style-type: none"> <li>• Globally develop talent</li> </ul>

# Forward-Looking Statements

- Information given in this document 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.
- Business performance and financial conditions could be affected significantly by a substantial drop in sales of a major drug, either currently marketed or expected to be launched, due to termination of sales as a result of factors such as patent expiry and complications, product defects or unforeseen side effects. Santen Pharmaceutical also sells numerous products under sales and/or manufacturing license from other companies. Business performance could be affected significantly by changes in the terms and conditions of agreements and/or the non-renewal of agreements.
- 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 an event were to adversely affect supply capabilities for related final products.

The logo for Santen features a stylized 'S' on the left, composed of two overlapping curved shapes in light blue and dark blue. To the right of the 'S' is the word 'anten' in a bold, dark blue, sans-serif font. The 'a' is lowercase, while 'n', 't', 'e', and 'n' are uppercase.

**Santen**

*A Clear Vision For Life*