

# Santen Pharmaceutical Co., Ltd.

### Medium-term Management Plan FY2011-2013

May 11th, 2011 Akira Kurokawa President & CEO



#### **Core Value**

Tenki ni sanyo-suru\*

「天機に参与する」

We think carefully about what is essential, decide clearly what we should do, and act quickly.

#### **Mission Statement**

By focusing our efforts on ophthalmology and related areas, we develop scientific knowledge and organizational capabilities which are unique and original to Santen. We use our unique capabilities to contribute to patients and their loved ones, and consequently to society.

\*Santen's original interpretation of a passage from chapter 22 of Zhongyong (The Doctrine of the Mean) by Confucius, meaning "exploring the secrets and mechanisms of nature in order to contribute to people's health"



- Medium-term Management Plan FY2006-2010
   Overview
- 2. Long-term Strategic Vision toward FY2020
- 3. Medium-term Management Plan FY2011-2013
- 4. Return to Shareholders Policy



## 1. Medium-term Management Plan FY2006-2010 Overview



### **Santen's Global Development:**

Creating new drug candidate and generating growth in promising regions by leveraging strength

- 1. Enhance the global strategic product pipeline through internal discovery and development, joint development projects and in-licensing efforts
- 2. Generate growth mainly in Japan, Northern/Eastern Europe, Russia and China. Focus U.S. activities on clinical and business development
- 3. Strengthen manufacturing bases
- 4. Strengthen human resources and organizational capabilities on a global basis

## **Sales and Operating Income for FY2006-2010**



\* Financial figures mentioned in this slide are consolidated basis.



Launched three new products as planned in MTP FY2006-2010 and succeeded an in-licensing product development.

Global product
Japan (Asia)

			Product
Domain	Launched in FY2006-2010	Development in Process	Status
Glaucoma	Tapros/Taflotan	<b>DE-112</b> Adenosine A <sub>2A</sub> Agonist	Phase1/2
	Cosopt (in-licensing)	<b>DE-111</b> Tafluprost/Timolol (combination)	Phase3
		DE-090 Lomerizine HCI	Phase2
Corneal Disease (Dry Eye)	Diquas	DE-101 Rivoglitazone	Phase1/2-2
		<b>DE-105</b> Combination of peptides	Phase2
		DE-110 SEGRA	Phase2
Retinal Disease		DE-109 Sirolimus	Phase3
		DE-102 Steroid DDS	Phase1/2
Infection, Allergy, RA		DE-108 Levofloxacin 1.5%	Approved
		DE-114 Epinastine HCI	Phase3
		DE-098 Apoptosis inducer	Phase2
IOL	Eternity		



	Target	FY2010 Results
ROE:	13%	14.5%
DOE:	5%	5.3%

**ROE** (Return on Equity) / **DOE** (Dividend on Equity)



\*Dividend assumption: 90 yen per share for FY2010

## **Summary in FY2006-2010 Period**

Enhanced revenue base through new product launches in global markets.

		<u>Target</u>	<u>Results</u>	Achievement %
1.	- Sales in FY2010:	Yen 115 billion	→ Yen 110.8 billi	on 96%
	- Operating income:	Yen 32 billion	→ Yen 30.7 billi	on 96%

- 2. Three new products were launched as originally planned in FY2006-10 medium-term management plan.
- **3.** Overseas businesses especially in Europe and China grew to deliver incomes.
- 4. Licensing-out initiatives to global companies such as Merck/MSD and Bausch & Lomb improved profitability.
- 5. Global product supply capability was strengthened by starting production at new Suzhou plant in China.
- 6. ROE and DOE were 14.5% and 5.3% respectively in FY2010.



- Revenue base expands out to East Asia and Eastern Europe
   R&D capability for new product development to meet unmet medical needs
- 1. Unique expertise and high productivity as a specialized pharmaceutical company.
- 2. Leading positions in prescription ophthalmics markets in Japan and China.
  - Dominant sales and marketing base and competitiveness in Japan
  - Leading position in the fast growing Chinese market
- 3. Establish profitable business platforms in China and Europe.
- 4. Product pipeline in fast growing corneal, glaucoma and retinal segments.



## 2. Long-term Strategic Vision toward FY2020



### To become a specialized pharmaceutical company with global presence

- Specialize in eye care and related categories in the fields where Santen has competitive advantage.
- Focus on R&D based on true customer needs\* and contribute to innovation in therapeutic development.
- Establish our competitiveness and presence in global markets.

<sup>\*</sup>Customer Needs: Unmet medical needs of patients, consumers, doctors and healthcare professionals.





\* UK, France, Germany, Spain, Italy

## **Sustained Business Growth toward FY2020**

Prescription Ophthalmics Business in Market

- #1 in Japan and Asia
- Top 3 position globally

Overseas sales in 2020

 Up to 40 - 50% of Total Sales

> Maximize New Product Value Globally

Establish & Reinforce Overseas Business Platform

Strengthen Domestic Business Platform and Competitiveness

2011



## **S** Long-term Growth Scenario

- Demonstrate our presence in global prescription ophthalmic markets as a specialized pharmaceutical company
- Expand customer base and improve capabilities for product development to drive long-term growth





### 3.Medium-term Management Plan FY2011-2013

## **S** Medium-term Policies FY2011-2013

To become a specialized pharmaceutical company with global presence;

- 1. Promote global oriented research and development operation.
- 2. Boost domestic business by maximizing new product value and implementation of sales/marketing strategies.
- 3. Accelerate growth in both Asia and Europe by reinforcing marketing platform.
- 4. Establish global product supply system with existing 4 plants which enables to meet the emerging market needs.
- 5. Develop talents and organizational capabilities to promote "Creation and Innovation" on a globally level.



Enrich a new product pipeline which drives mid to long term business growth

**Growth in Japan, Asia and Europe** 

Increased investment for sustainable growth



### **Performance Target for FY2013**

- Consolidated sales
  JPY 121 billion +
- Operating income JPY 31 billion +
- Net income
  JPY 20 billiion +
- R&D Expenses
  Approx. JPY 15.5 billion

**DOE** (Dividend on Equity)

Around 5%



#### Increased investment for sustainable business growth

#### 1. Invest strategically in late stage clinical trials

- Succeed in Phase-3 clinical trials.
- Establish a US-centered global clinical operation system.
- Extend product lines to meet local customer needs.

#### 2. Expand sales coverage in growing regions.

- Asia: primarily in China and Korea.
- Europe: primarily in Germany, eastern Europe and Russia.

#### 3. Focused investment in business development.

Enhance licensing and M&A activities.



### Improve R&D capabilities to meet global market needs

#### **1. Clinical Development**

- 1. Improve the probability of success and accelerate the speed of developments.
  - Transfer main process in establishing POC primarily in the US to prompt expansion of late stage trials in Europe and Japan, etc.
  - Fully reflect opinions/advices of clinical practitioners.
- 2. Invest strategically in clinical trials.
  - R&D budget increased to JPY 14-16 billion; in response to increased number of late stage clinical trials.

#### 2. Formulation/New Drug Discovery

- 1. Life cycle management using Santen's unique drug formulation technologies.
- 2. Further strengthen capability for new drug discovery.
  - Focus on business development and new compound research functions.



*Red Letters: Planned phase 3 trials during 2011-2013. Global Product Japan (As Product				
Domain	Launched in FY2006-2010	Launch Planned in FY2011-2013	Launch Planned after FY2014*	
Glaucoma	Tapros/Taflotan	DE-085 Tafluprost (China)	DE-112 Adenosine A <sub>2A</sub> Agonist	
	Cosopt (in-licensing)		DE-111 Tafluprost/Timolol (combination)	
			DE-090 Lomerizine HCI	
Corneal Disease (Dry Eye)	Diquas	DE-089 Diquafosol (China/Korea)	DE-101 Rivoglitazone	
			<b>DE-105</b> Combination of peptides	
			DE-110 SEGRA	
Retinal Disease			DE-109 Sirolimus	
			DE-102 Steroid DDS	
Infection, Allergy, RA		DE-108 Levofloxacin 1.5%	DE-114 Epinastine HCI	
			DE-098 Apoptosis inducer	
IOL	Eternity	Eternity Single piece/pre-loaded		

## **S** Japanese Prescription Ophthalmics: Strategy & Target

#### Drive business by new products value maximization

Maximize product values in Glaucoma.

- Tapros as a NTG\* standard drug.
- Cosopt as the best partner with PG\*\*.
- Maintain the leading position in dry eye with

various therapeutic proposals.

- Hyalein as a standard drug for dry eye.
- Diquas for stabilizing tear film.



\* NTG: Normal Tension Glaucoma.

\*\* PG: Prostaglandin Analogues, a type of glaucoma drugs including Tapros



# **S** Asian Business: Strategy & Target

### **Growth in fast growing markets**

#### Increase sales by +15%

(FY2011-2013, local currency basis)

#### China

- Strengthen marketing platform
- Take advantage of fast growing market with new product launch such as Tafluprost
- Reduce manufacturing costs by commencing a full-line operation at Suzhou plant

#### Korea

- Growth by Tapros, Cravit and Hyalein
- Improve profitability by shifting to a direct promotion system and expanding sales coverage

#### Explore a new business base in Asia



# **S** European Business: Strategy & Target

### Sustained growth with Taflotan family

- Increase sales by +10% in CAGR basis (FY2011-2013, at local currency)
- Business in Germany, Northern and Eastern European countries and Russia
  - Taflotan-driven business growth with launch of combination drugs
  - Strengthen in-licensing and local product development
  - Improve productivity by through combined cooperating manufacturing and sales efforts



# **S** Product Supply Strategy

Develop an efficient global supply chain by optimizing the functions of 4 plants, and establish competitive cost structure

#### Improve production capability based on global site planning.

- Drive innovation in technology and process at Shiga plant as a core plant.
- Improve the efficiency of production at Noto plant as a mother plant.
- Start integrated production at Suzhou Plant in FY2012.
- Increase capacities for new product supply to European markets and improve efficiency at the Tampere plant.

#### Design an optimal global supply chain system from long term point of view.

- Meet market needs, supply new products and realize competitive cost structure in emerging markets.
- Explore candidates of new plants and review the functions of existing plants.





### 4. Return to Shareholders Policy

# **S** Policy for Return to Shareholders

- Stable return to shareholders
- Maintain sound and flexible financial position to enable product acquisitions and M&As for future growth
  - Continue stable return per share
  - Seek to maintain Dividend-on-equity (DOE) at around 5%, along with the income growth
  - Effective use of share buybacks in flexible manner



- Forecast or target figures in this material are not official earnings guidance but present the mediumterm policies, etc.. Official earnings guidance should be referred to in the disclosure of the annual financial report (Kessan Tanshin) in accordance with the rules set by Tokyo Stock Exchange.
- Information given in this announcement and accompanying documentation 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 copromotion 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 and event were to adversely affect supply capabilities for related final products.

