### 2006-2010 Medium-term Management Plan

Santen s Global Development: Creating New Drug Candidates and Generating Growth in Promising Regions by Leveraging Strengths

> July 25, 2006 Santen Pharmaceutical Co., Ltd.

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### **Forward-Looking Statements**

- 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 sale 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.

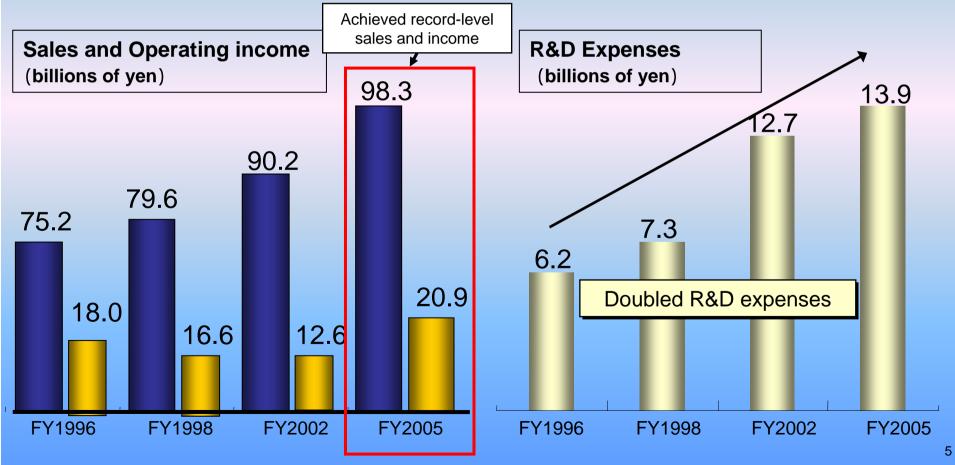
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## **1.10-Year Historical Overview**

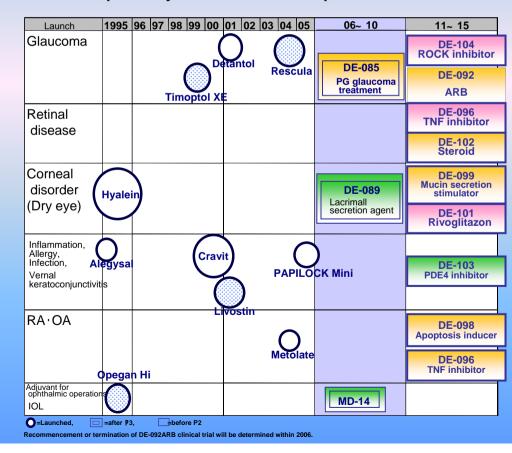
#### Changes in Sales, Income and R&D Expenses Over the Past 10 Years

- -1998-2002 Plan; Enhance sales and marketing capabilities in Japanese prescription ophthalmics business Develop our operations in Europe and the U.S. Enhance product pipeline
- -2003-2005 Plan; Improve Profitability Strengthen R&D Reinforce Organizational Strength



#### Increased Strength Over the Past 10 Years – R&D

- 1. Robust R&D pipeline, led by drugs for glaucoma, corneal and retinal diseases
  - Concentrate resources in core therapeutic areas
  - Emphasis on faster drug discovery and development



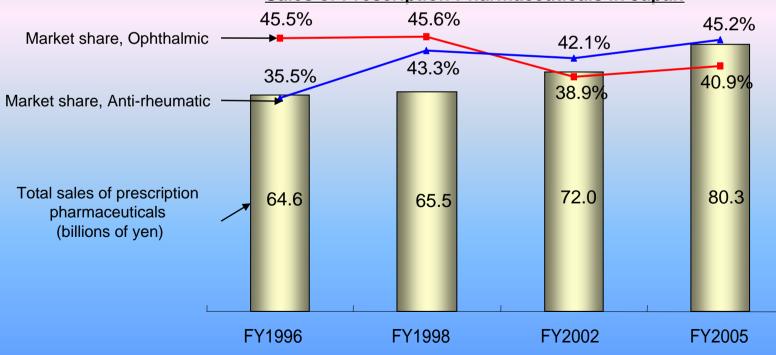
Products launched in the past 10 years and the future products



#### Our Strength Upgraded over the Past 10 Years - Japan -

### 2.Strengthen domestic prescription drug sales and capabilities and recovery of market share in Japan

- Strong promotional platform built for prescription drugs through focus on customer satisfaction and upgrading of product lineup
- Achieved profitability in OTC business

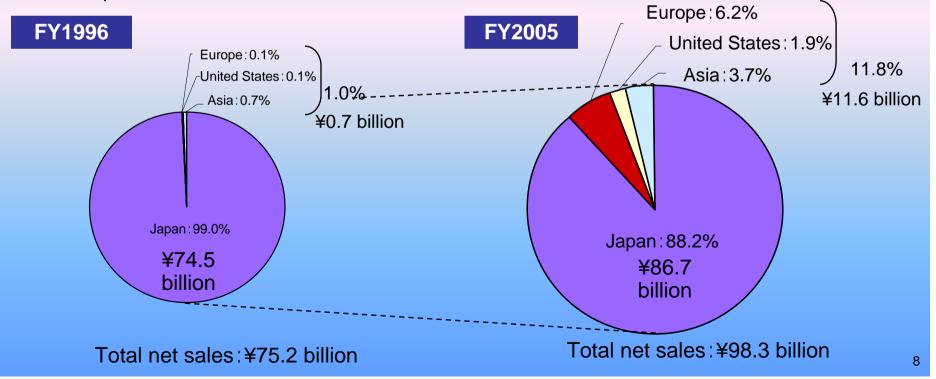


#### Sales of Prescription Pharmaceuticals in Japan

#### Our Strength Upgraded over the Past 10 Years - Overseas -

#### 3. Start of global sales and marketing activities

- **Europe**: Direct entry into ophthalmic drug markets in Northern/Eastern Europe and Russia; market presence secured
- Asia: Market presence secured in China and S. Korea; Santen Pharmaceutical (China) established in 2005 to initiate shift toward own local manufacturing, sales and marketing operation
- USA: In-house clinical development base developed since 1993; approval secured for three drugs; making use of sales partnerships as most efficient option.



#### Increase Strength over the Past 10 Years - Manufacturing/QC, Organization -

### 4. Development of a competitive production function

- Manufacturing of ophthalmic solutions at world-class quality and cost
- New containers with distinctive features resulting in higher convenience, recognition and manufacturing productivity
- Costs reduced due to relentless focus on cost-reduction initiatives

# 5.Implementation of strong corporate governance and organizational controls

- Development and reinforcement of corporate governance:
  - System of outside directors introduced; director terms shortened to one year

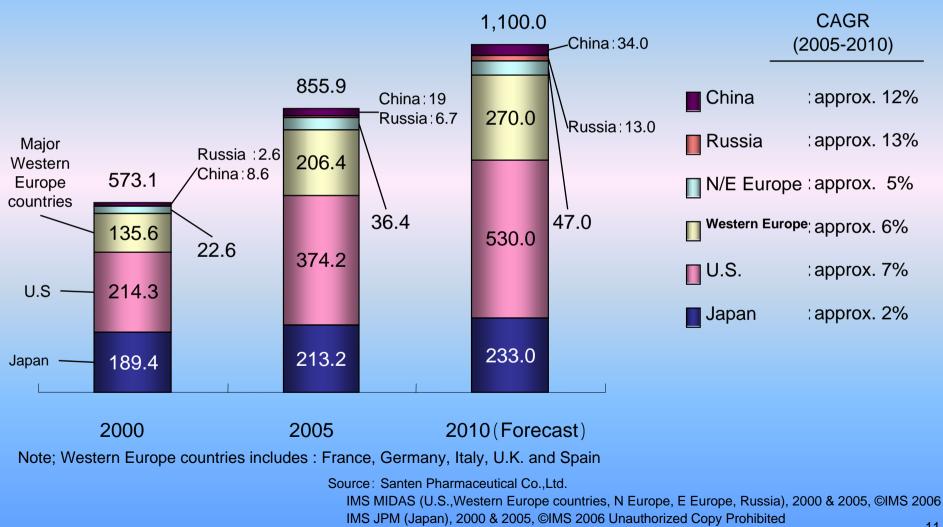
- Voluntary committee system reorganized; several voluntary committees established

- Human resource development programs upgraded and strengthened
- Expanded programs in leadership development, skills training and internal recruitment
- Increased capability for internal process reform

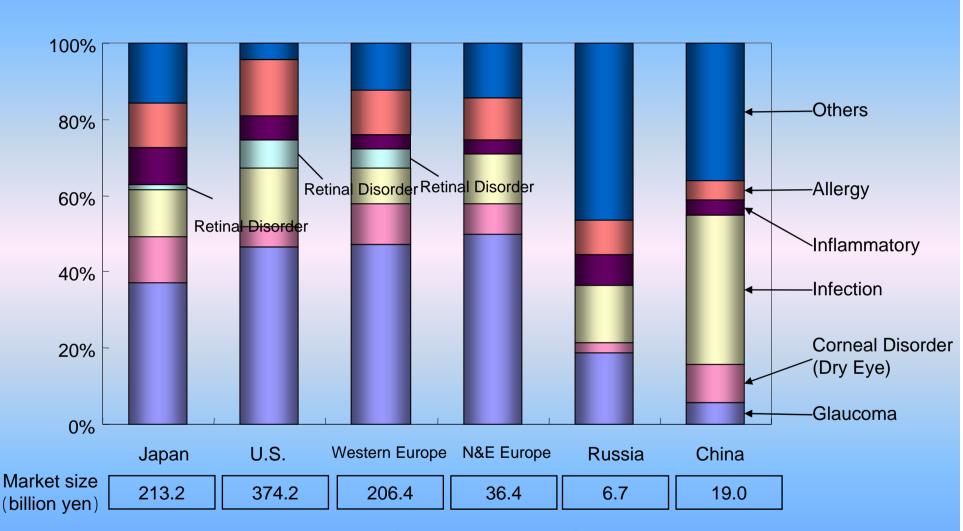
### 2.Medium-term Outlook

### **Global Ophthalmic Market Outlook by Region**

**Prescription Ophthalmics Market (billions of yen)** 



#### Global Ophthalmic Market Outlook by Region, Segment (Japan, U.S. Western Europe, Northern/Eastern Europe, Russia, China in 2005)



Note; Western Europe countries includes : France, Germany, Italy, U.K. and Spain

Source: Santen Pharmaceutical Co.,Ltd.

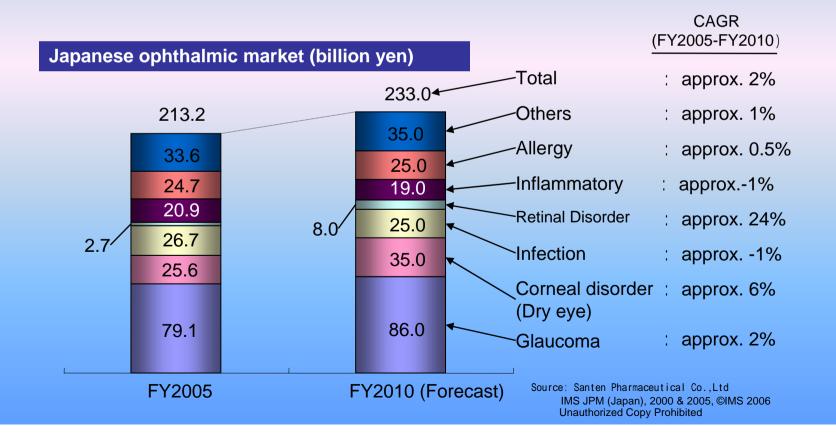
IMS MIDAS (U.S.,Western Europe countries, N Europe, E Europe, Russia), 2000 & 2005, ©IMS 2006IMS JPM (Japan), 2000 & 2005, ©IMS 2006 Unauthorized Copy Prohibited12

### **Growth Opportunities and Risks in Operating Markets**

### Japanese ophthalmic market

Growth opportunities: Age-related demand growth in glaucoma / corneal disorder treatments

Risks: Higher than forecast NHI drug price cuts



### **Growth Opportunities and Risks in Operating Markets**

#### Northern/Eastern Europe & Russia

#### **Growth opportunities:**

- Double-digit market expansion expected in Russia
- Opportunity to boost market presence using current products for cataracts and glaucoma

#### **Risks**:

- Economic change in Russia and Eastern Europe
- Rapid change in drug regulation and related pricing systems

#### <u>China</u>

#### **Growth opportunities:**

- Market expansion forecast as ranks of medically insured grow
- Increased market presence and profits expected based on local manufacturing and sales

#### **Risks:**

-- Rapid change in drug regulation and related pricing systems

### 3. 2006-2010 Medium-term Management Plan

### **Our Basic Core Value**

### "Tenki ni sanyo suru"

- We always ask ourselves what is central to us, clearly decide the action to be taken, and act quickly
- "We are focused on specific areas of expertise, such as eye care, developing our unique capabilities and technologies, and contributing to the health and quality of life of patients and their loved ones, and society as a whole"

### **Long-term Vision**

- World-class company
- Leader in ophthalmic and anti-rheumatic fields
- R&D-oriented pharmaceutical company specializing in ophthalmology and other areas where we can leverage our strengths

### **Plans to Achieve Long-term Vision**

- Santen plans to achieve "World-class Company" by FY2015
- We plan to take the following two steps
  - During the next five years, Santen will continue to grow our business in Japan, Northern/Eastern Europe, Russia and China and will continue to invest in R&D to insure future growth.
  - The R&D investment will generate products that will allow Santen to accelerate global growth and expand in the U.S. and EU during the following five years (FY2011-2015).

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

### **Medium-term Performance Targets**

#### Performance target in FY2010

- Sales: 115 billion yen + (CAGR 3%+)
- Operating income: 32 billion yen + (CAGR 8%+)
- Net income: 22 billion yen +
- ROE: 13% +
- R&D expenses: approx. 16 billion yen

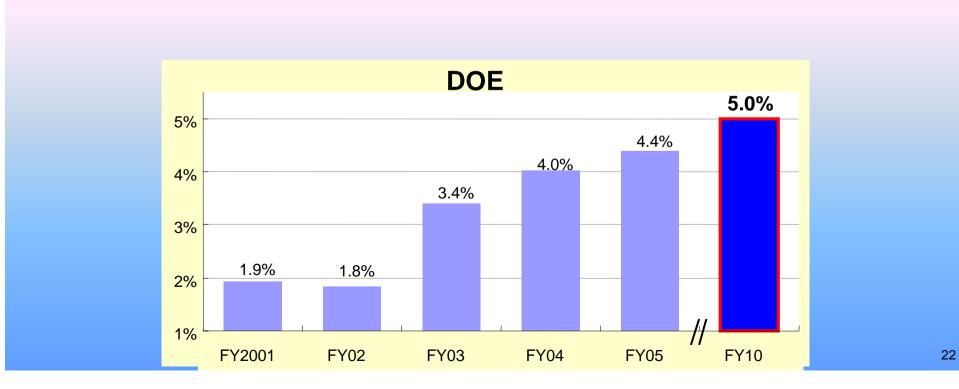
\*Compound annual growth rate from FY2005 to FY2010

### Medium-term Sales Outlook (Reference)

	FY2	FY2005 FY2010		C A G R	
	Billons of yen	%	Billons of yen	%	(2005- 2010)
Japan	86.7	88%	96.6	84%	2%
Europe	6.0	6%	9.0	8%	8%
U.S.	1.9	2%	2.3	2%	5%
Asia and others	3.6	4%	7.1	6%	15%
Total	98.3	100%	115.0	100%	3%

#### **Policy for Return to Shareholders**

- Seek to improve Dividend-on-equity (DOE) ratio to 5% by fiscal 2010, while maintaining capital efficiency and keeping a sound and flexible financial position that will allow us to pursue product acquisition, licensing and alliance activities.
- Make effective use of share buybacks/retirements in flexible manner in addition to dividends.



# **R&D Strategy**

### **R&D** Policy

### • Drug discovery

 Construct an internationally competitive pipeline centered on next-generation drugs in therapeutic areas where Santen is competitive in research and where medical demand is expected to be high.

### Development (FY2006-2010)

 Continue development of key drugs to ensure growth of prescription pharmaceutical business.

Glaucoma; DE-085(Prostaglandin glaucoma treatment), DE-104(ROCK inhibitor)

Corneal; DE-089(lacrimal secretion agent), DE-101(Rivoglitazone)

Retinal; DE-102(Steroid), DE-096(TNF inhibitor)

### **R&D Strategy**

### Strategy

- Focus on core therapeutic areas: glaucoma, corneal disorders and retinal diseases
- Conduct network-based drug discovery, utilize competitive internal resources along with the latest technology from external sources where necessary
- Create a strong development pipeline including backup candidates to strengthen our global portfolio
- Continue improvement of R&D processes

### **Drug Discovery Policies by Therapeutic Field**

### **Ophthalmology**

Glaucoma, retinal diseases and corneal disorders

•Strategic resource allocation for our current drug discovery targets.

•Make active use of relationships with external firms and research institutions

#### •Inflammation/Allergy and Infection

•Build on accumulated compound evaluation expertise

### Anti-rheumatic

•Emphasize drug discovery programs that have some degree of overlap with ophthalmology

•Identify drug discovery targets jointly with external research institutions

•Successful innovative drug discovery outcomes

•Emphasize efficiency in drug development

•Develop high value-added products by reformulating existing drugs

•Realize development efficiencies

### Drug Discovery Approach (Network-based drug discovery)

Drug discovery by linking Santen's accumulated expertise with advanced external technology primary utilizing Santen's strong relationships with other Japanese firms and institutions

#### **Obtaining drug discovery targets**

#### In-house resource

Leverage in-house knowledge and abundant evaluation models for ophthalmic drugs



**Resource from external companies and institutions** 

Expand and utilize access to compound libraries owned by pharmaceutical firms and other partners

#### Potent drug discovery targets; 2 glaucoma, 2 retinal, 2 corneal

Leverage results of in-house genomics and proteomics research programs



Specific technologies owned by external research institutions for identifying groups of disease-related gene target candidates using clinical samples and high-throughput screening for narrowing gene target searches

**Co-development with 3 institutions and** *CytoPathfinder* 

### Drug Discovery Approach (Network-based drug discovery)

Acquisition of development compounds

- Gain strategic access to compounds owned by other companies

**Rivoglitazone etc.** 

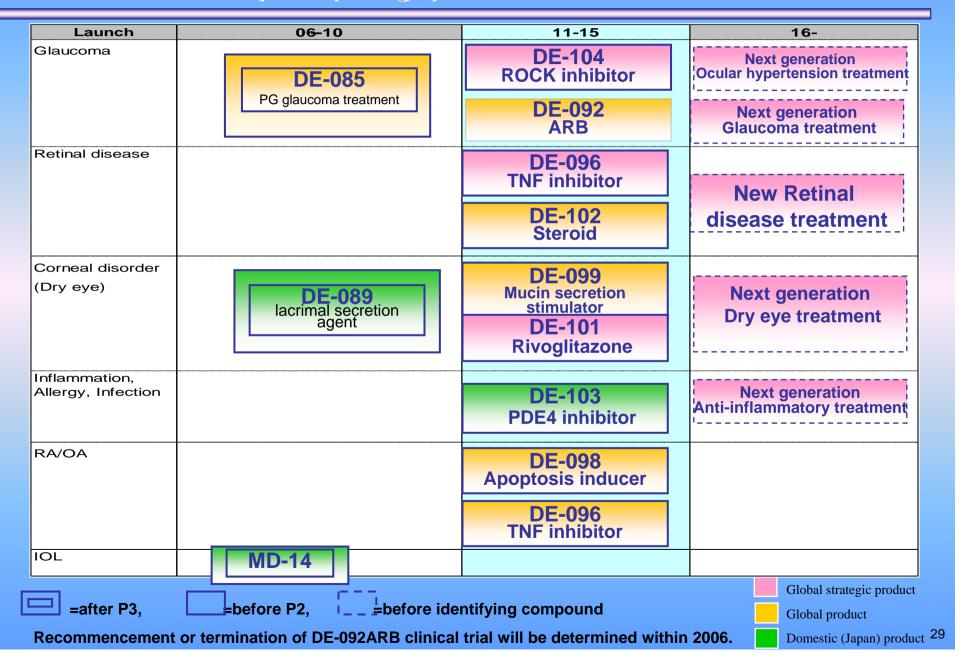
- Co-development programs with chemical companies and other entities

Asahi Glass (DE-085), Ube Industries (DE-104) etc.

- In-house drug discovery

DE-096 etc.

#### **Blueprint(image)of Product Launches**



### **Ongoing R&D Process Improvement**

#### Improvement to accelerate R&D

- Clinical trial phase approx. 5 years (to date: approx. 7–8 years)
- Pre-clinical study phase approx. 1.5 years (to date: approx. 3 years): acceleration of pre-clinical studies to result in two projects entering clinical development per year

#### Expand parallel development process to include all major markets

- Global information sharing for Phase I and Phase IIa (proof of concept trial)
- Integrate development from Phase IIb onward for Europe/U.S. and for Japan/Asia

Overseas Business Strategy - Prescription Pharmaceutical in Northern Europe, Eastern Europe, Russia and Germany -

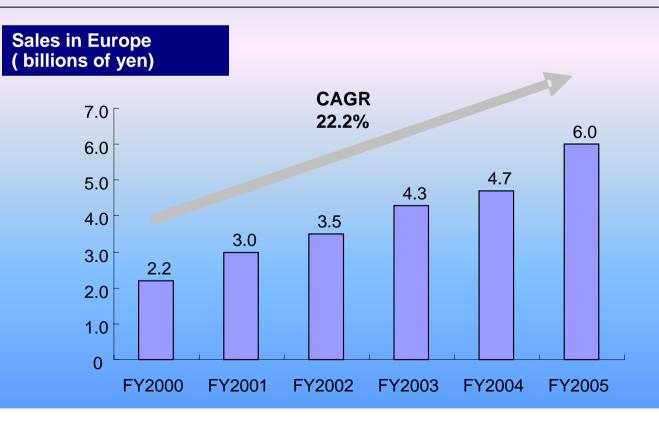
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#### Achievement during the 2003-2005 medium-term plan

Launched Oftaquix (Anti-infective), in-licensed local European products and expanded sales of existing products



Sales increased from ¥2.2 billion (FY2000) to ¥6.0 billion (FY2005)



	Northern Europe Eastern Europe Russia an German
Ophthalmic drugs market	<ul> <li>Northern Europe/Germany: Primary medium-term focus on therapeutic fields of glaucoma and corneal disorders</li> <li>Russia: Ophthalmic drug market expanding in line with economic growth</li> </ul>
Regulatory	<ul> <li>Major differences among countries in terms of drug approval systems, price levels, pricing and reimbursement mechanisms in national medical insurance are expected to continue</li> </ul>
Competition	<ul> <li>Competitors are expected to introduce new glaucoma products (combination drugs) and strengthen sales forces</li> </ul>

**Mid-term Strategy and Objectives** 

Aim to steadily increase our market presence through the sales of existing drugs and launch of local European products.

•Russia:

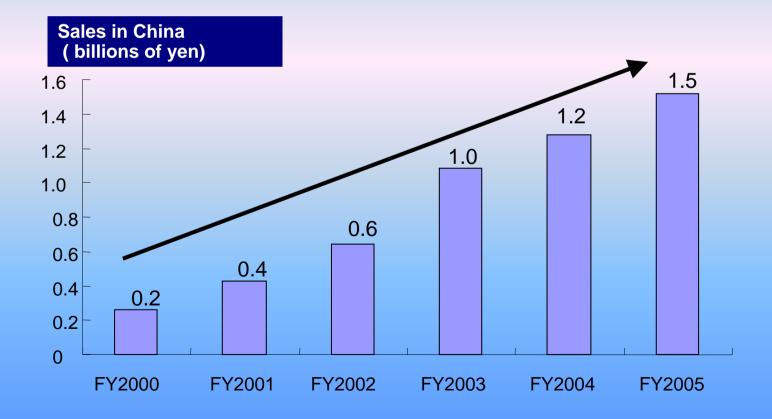
Growth led by cataract and anti-infective ophthalmics through increased promotional activities

- Northern/Eastern Europe, Germany: Aiming to boost market presence through increased promotional activities
- Anti-infective ophthalmics (Oftaquix): Plans to boost brand across entire region by focusing on market for cataract and refractive surgery patients as key target segment

Sales target for fiscal 2010 is ¥9.0 billion (equivalent to a CAGR of approx. 8%)

### Overseas Business Strategy - China -

- First exports in 1988; representative offices opened in Beijing (1995), Guangzhou (2000) and Shanghai (2005)
- Leading market share in hospital market (approx. 25%, according to IMS) and reputation for product quality achieved
- Three year annual average growth in sales of over 20% (export base)

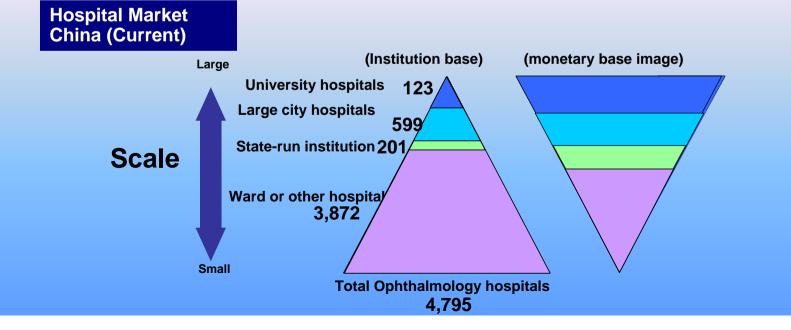


China

#### **China**

### **Characteristics and Changes in Chinese Market**

	Current status	Goal
Focus on large hospitals	<ul> <li>University hospitals are a small proportion of the total hospital base but account for 80% of the total market</li> </ul>	<ul> <li>Continue to focus on large hospitals unchanged</li> </ul>
Sales promotion	<ul> <li>Local companies: Sales activities mainly driven by personal relationships</li> <li>Western companies: academic medical sales approach</li> </ul>	<ul> <li>Shift to more academic medical sales approach</li> </ul>
Products	<ul> <li>Low cost /quality production and low price with domestic products</li> </ul>	Improve quality



## **Market Prospects**

Ophthalmic drug market	<ul> <li>Ophthalmic prescription drug market forecast to achieve CAGR of 12% (value base)</li> <li>Glaucoma market experiencing strong growth (CAGR 35%), but anti-infective segment expected to remain largest part of market in 2010 (approx. 30% share)</li> <li>Rapidly aging population due to constraints on population growth</li> </ul>	
Regulatory	<ul> <li>Regulatory environment unfavorable to imports (regulations/pricing)</li> <li>Market expansion due to fast economic growth and increasing medical insurance coverage likely to be offset by drug price reductions due to constraints in state healthcare finances</li> <li>Regulatory transparency improving since WTO accession</li> </ul>	
Competition	<ul> <li>Local firms emphasizing low price</li> <li>New products from Western firms expected to enter the market</li> </ul>	

<u>China</u>

## **Mid-term Strategy and Objectives**

We are currently the number one ophthalmic company in China, and we will improve our competitiveness and growth by shifting to operations through a local manufacturing and sales subsidiary.

#### **Business strategy**

- Sales method: Academic medical sales approach
- Regional strategy: Targeting large hospitals in major cities Gradually expanding target to local hospitals
- Product strategy: Make *Cravit* and *Hyalein* first-choice drugs



Our sales target for fiscal 2010 is ¥4.5 billion (equivalent to a CAGR of approx. 25%), with sales reaching ¥10.0 billion by fiscal 2015.

# Domestic Business Strategy - Prescription Pharmaceuticals and Intraocular lens Business in Japan -

## Achievements During 2003-2005 Mid-term Plan

#### 2003-2005 Mid-term plan: major implementations

-Focused allocation of resources on high growth therapeutic areas (glaucoma, corneal and conjunctival disorders, allergy)

- -Continued improvement of sales and marketing function
- -Employee education and reinforcement of organizational strength



Established promotional platform and efficient organizational structure for the new growth stage after 2006

## Japan **Market Prospects** •Ophthalmic prescription drug market forecast to achieve CAGR of around 2% •Strong growth expected in glaucoma and corneal markets •Market for disease-modifying anti-rheumatic drugs Market (DMARDs) expected to achieve volume growth of approx. 4% CAGR Intraocular lens market expected to achieve volume growth of approx. 2% CAGR Ongoing changes include revisions of treatment Regulatory reimbursement, NHI drug price reduction and government promotion of generic usage • Launch of competitors new products and expansion of rival Competition sales forces

## **Mid-term Strategy and Objectives**

Building on a strong promotional platform, we aim to introduce new products for glaucoma and corneal disorder as well as new intraocular lenses, while also generating growth through promotion of existing products.

- Glaucoma: Smooth market introduction of new products to maximize product value
- Corneal disorders: Conduct disease-awareness campaigns targeting patients and introduce new product
- Increase numbers of MRs for ophthalmics and rheumatoid arthritis
- Market introduction of new intraocular lens product (MD-14)

Our fiscal 2010 sales target for prescription pharmaceutical and intraocular lens operations in Japan is ¥90.0 billion (equivalent to a CAGR of approx. 2%).

### Smooth Market Introduction of New Products to Maximize Product Value

Japan

Glaucoma market expected to achieve volume growth of about 5% CAGR due to emergence of demand for untreated conditions such as NTG (normal tension glaucoma)

•Launch Prostaglandin anti-glaucoma agent DE-085 (plan to file NDA in FY2006)

•Marketing to maximize the new product value in early stage

•Utilize our strong presence in the ophthalmic market to gain early awareness and maximize prescriptions for our new products

Maximize early sales of DE-085, maintain and improve market share in the glaucoma segment

Corneal disorder: Expand the market through disease-awareness campaigns targeting patients and introducing a new product

The market for corneal disorders is expected to grow due to increased use of contact lenses, and increased prevalence of dry eye rising use of visual display terminals, an aging population as well as increased awareness of dry eye

- Conduct disease awareness campaigns to patients
- Launch a new drug for corneal disorder(DE-089)
- Utilize strong market presence to rapidly achieve high market share of new product. Promote concomitant use with *Hyalein*

#### Further expand dry eye market

Maintain and improve high market share by rapid market penetration

### Realize Strong Promotional Platform by Increasing Specialist MRs for Ophthalmics and RA

Further improvement of MR activities is required to address the diverse needs of medical professionals, intensified competition and to support new product launches (DE-085,DE-089)

- Construct system of specialist MRs for ophthalmics and rheumatoid arthritis

   (420 for ophthalmology / 60 for rheumatoid arthritis )
- Enhance training programs focused on scientific knowledge and professional skills.

Enhance knowledge and skills and improve productivity in ophthalmology and RA Further enhance promotional platform

## **Other Measures to be Implemented**

### 1. Launch new intraocular lens (MD-14):

- Market introduction of a foldable intraocular lens developed by our subsidiary Advance Vision Science.
- Realize synergies between ophthalmic pharmaceuticals and medical device operations
- 2. Maximize existing drugs' value ( ophthalmics and anti-rheumatic):
  - Maintain and improve sales and market share by maximizing existing product value based on expanded sales coverage and improved marketing campaigns.

## **Production Strategy**

Strengthen the manufacturing base over the medium and long term by reorganizing production lines on a global basis while seeking to maintain and improve quality and reduce costs thoroughly.

- Reorganize production lines: Reduce costs and promote global site-planning strategies, including new facility in China.
- Develop strong, autonomous production facilities: Ensure supply capacity for overseas markets, shorten lead times, while maintaining and improving product quality.
- •Focus on strategic manufacturing planning and technology development : Maintain and improve product quality and increase production capacity for new products.

## **HR and Organization Strategy**

#### **HR Strategy**

Strengthen core personnel

Develop HR on a global basis through unified approach

#### **Organizational Strategy**

•R&D:

- Integrate functions across regions (Japan, Europe, U.S. and Asia) to promote high-quality, time-efficient global clinical development
- Strengthen integration of regulatory affairs function in global development
- Production: Optimize production bases in Japan, Finland and China via integrated utilization of global production function
- Strategic marketing: Establish global marketing function

### **Ongoing Major Issues**

- Pursue in-license and alliance opportunities in core areas where internal resources and strengths can be maximized
- Clarify clinical and commercial development strategies for DE-092 through full consideration of future development options