



# **Medium-term Management Plan 2003-2005**

**Santen Pharmaceutical Co., Ltd.**

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**This document contains forward-looking statements regarding the Company's plans, outlook, strategies and results for the future. All forward-looking statements are based on the judgment of the Company's management derived from the information available at the time of announcement. Certain risks and uncertainties could cause the Company's actual results to differ materially from any projections presented in this news release. These risks and uncertainties include, but are not limited to, changes in the business environment, status of product development programs, exchange rate fluctuations, and changes in related laws and regulations.**



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# **Overview of Hitomi 21 Plan (4/1998 - 3/2003)**



# Overview of Hitomi 21 Plan - Outline -

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## Basic Concepts

1. A global Santen
2. A leader in ophthalmic and related fields and anti-rheumatic medicine

## Key Measures

- In the Japanese prescription pharmaceutical business, maintain earnings through sales and marketing strength
- Achieve moderate growth driven by U.S. business and ophthalmic-related businesses in Japan
- Invest resources in R&D to enhance the pipeline of drug candidates

## Performance Targets

Sales target: ¥110 billion

Net income: ¥12 billion

ROE: 10% or higher

Share of Japanese ophthalmic pharmaceuticals: 50% or more



# Overview of Hitomi 21 Plan - Key Measures 1 -

## ● Japanese Prescription Pharmaceuticals: Maintain earnings through sales and marketing strength

	Hitomi 21 Target, March 2003	Year ending March 2003 (est.)	Notes
Japanese prescription Ophthalmic Pharmaceuticals, Sales	¥ 64.3 billion	¥ 64.1 billion	· NHI drug prices revised three times : 1998 (9.7% on industry average ), 2000 (7.0%), 2002 (6.3%)
Japanese Ophthalmic Pharmaceuticals, Share	50%	39.7%	· Launched no major new anti-glaucoma drugs · <i>Zaditen</i> terminated
Japanese Anti-rheumatic, Share	28%	30.2%	· Expanded market for <i>Rimatil</i> and <i>Azulfidine</i> by clarifying their positioning

## ◎ Status of the Market and Santen's Share

	March 1998		Hitomi 21 Targets		March 2003 (est.)	
	Market (¥ billion)	Santen's share	Market (¥ billion)	Santen's share	Market (¥ billion)	Santen's share
Ophthalmic Pharmaceuticals, Total	166.4	45.7%	139.6	50.0%	191.3	39.7%
Glaucoma	46.6	30.6%	51.2	35.0%	67.1	18.3%
Anti-infective	31.2	76.4%	22.6	84.0%	26.5	80.7%
Anti-allergy	21.2	33.4%	16.0	43.0%	23.8	18.0%
Corneal disorders	10.5	84.1%	13.6	90.0%	18.3	85.4%



# Overview of Hitomi 21 Plan – Key Measures 2 –

## ● Growth of U.S. business and ophthalmic-related businesses in Japan

	<b>Targets*</b> ( ¥ billion)	<b>March 2003</b> (est.) (¥ billion)	<b>Notes</b>
<b>U.S. Ophthalmic Pharmaceuticals, Sales</b>	<b>5.4</b>	<b>2.4</b>	<ul style="list-style-type: none"><li>· Fast-track approvals for 2 items in 2000</li><li>· Direct marketing started for 3 items in 2001</li></ul>
<b>OTC Pharmaceuticals</b>	<b>11.9</b>	<b>5.8</b>	<ul style="list-style-type: none"><li>· Slumping market</li><li>· Product planning delayed</li></ul>
<b>New Business</b>	<b>8.8</b>	<b>—</b>	<ul style="list-style-type: none"><li>· Abandoned</li></ul>

\* U.S. Ophthalmic: sales target at start of direct marketing  
OTC and New Business: sales target from Hitomi 21



# Overview of Hitomi 21 Plan – Key Measures 3 –

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## ● Enhancing the pipeline of drug candidates

### ◆ Strategies

- Reinforce licensing and R&D capabilities
- Enhance strategies to compete with global rivals
  - Increase the number of ophthalmic researchers
- Specify areas/technologies of focus and allocate resources in these areas (glaucoma, DDS etc.)
- Expand clinical development platform in Japan and overseas and increase R&D capabilities and development speed

### ◆ Results

- Pipeline additions
  - Prescription ophthalmic pharmaceuticals : 6 items
  - Anti-rheumatic pharmaceuticals: 3 items ( 2 original compounds)
  - Intraocular lenses : 2 items
- Increased employees / organized areas of focus
  - From 303 (March '98) to 487 (January '03)
- Promoted clinical development in the U.S. and Europe
  - Fast-track approvals: Alamast and Quixin
- Reformed R&D organization (Dec. 2002)



# Overview of Hitomi 21 Plan - Key Measures 3 -

- Enhancing the pipeline of drug candidates

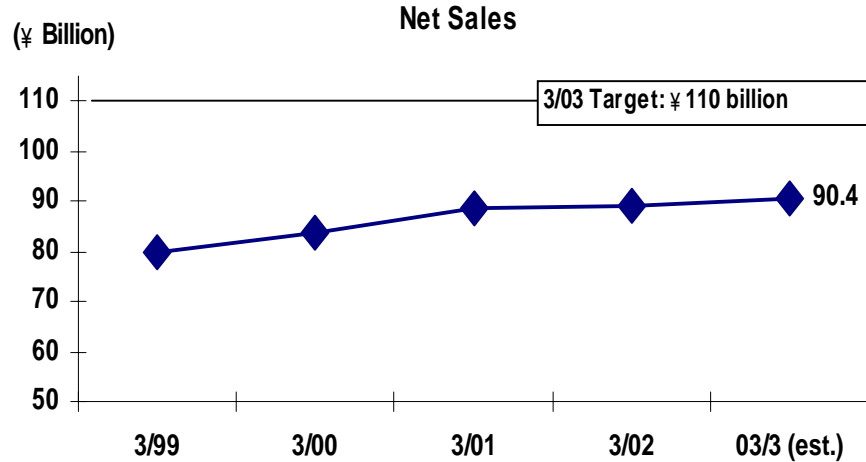
- **Candidates for Prescription Drugs Added to Pipeline Since 1998**

		3/99	3/00	3/01	3/02	3/03
Pipeline additions	Ophthalmics	DE-085 (PG derivative) (PG-based glaucoma treatment) DE-087 (Brimonidine) (Glaucoma treatment)	DE-089 (INS365) (Dry eye treatment)  Lactoferrin (Dry eye treatment)	DE-090 (Iomerizine hydrochloride) (Visual field improving agent for glaucoma)  ADL2-1294 (Analgesic ophthalmic)	DE-092 (CS088)  (New glaucoma treatment)	
	Anti-rheumatic			Anti-APO-1 antibody  (Anti-rheumatic)	DE-096 (TNF inhibitor)  (Original anti-rheumatic)	Original OA  Indication expansion
	Intraocular lens				MD-13  (IOL)	MD-14  (IOL)
Discontinued				DE-087 (Brimonidine)  (Glaucoma treatment)		

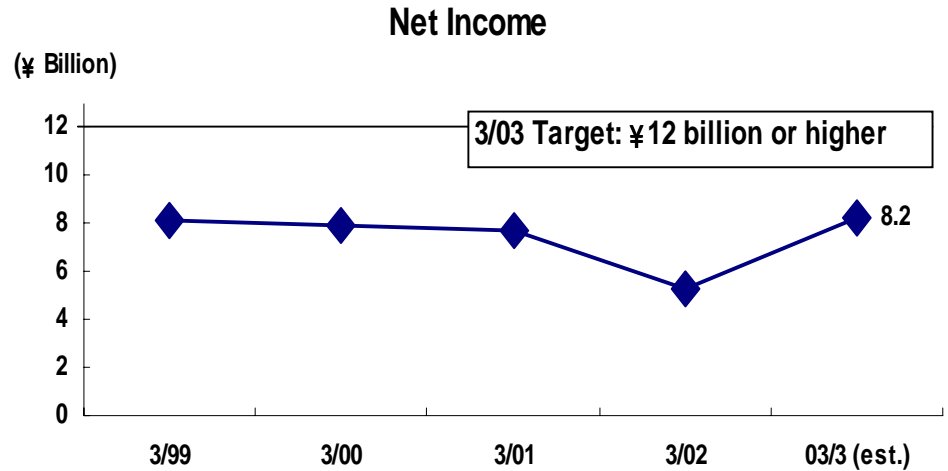




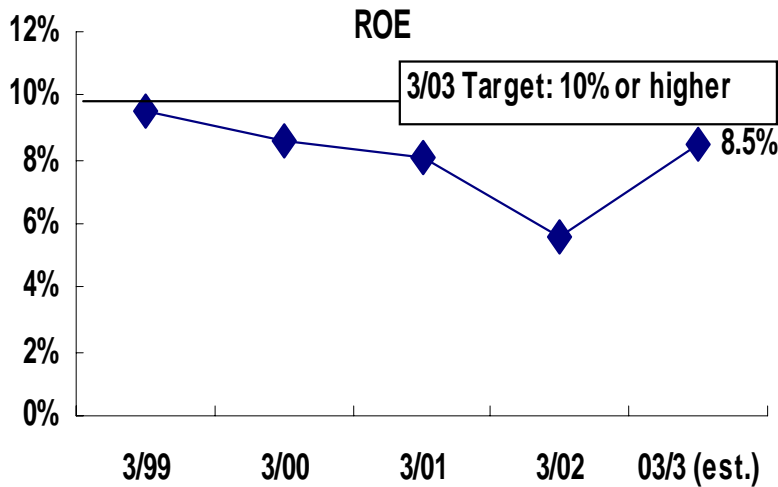
# Overview of Hitomi 21 Plan – Numbers



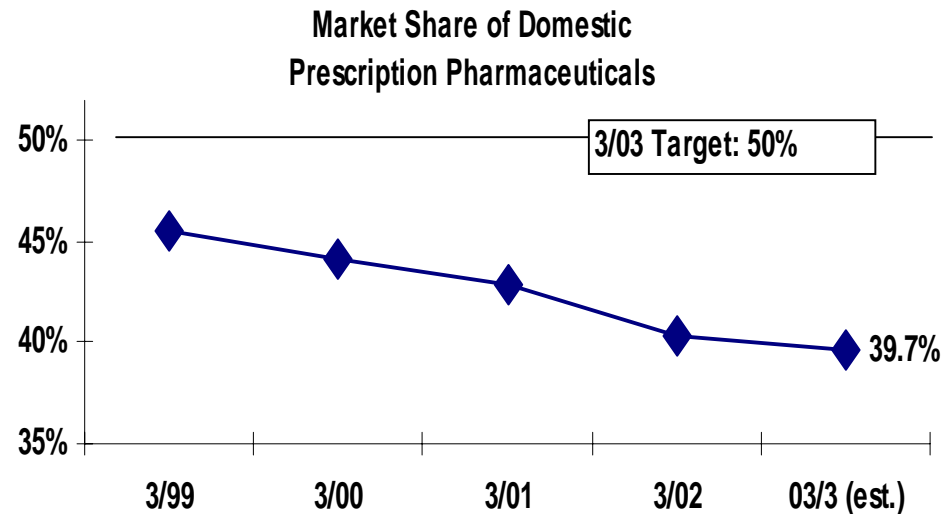
- OTC and Medical devices fell short of the target



- Sales expenses increased for the direct U.S market



- 3/01, 3/02: Share repurchases in 2 consecutive years  
- Net income fell short of the target



- Glaucoma treatments share declined  
- *Zaditen* terminated



# Summary of Hitomi 21 Plan

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●Santen devised the Medium-term Management Plan “Hitomi 21” (from April 1998 to March 2003) five years ago, assuming a decelerated growth of the Japanese prescription pharmaceutical market and fewer sales and development alliance opportunities for ophthalmic pharmaceuticals. The Plan aimed at bolstering profits in the Japanese prescription pharmaceutical business; enhancing the Company’s research and development (R&D) capabilities; and achieving growth in U.S. operations and ophthalmic-related areas.

●As a result, Santen successfully enhanced its new product pipeline for glaucoma and dry eye thanks to our reinforced licensing and R&D capabilities. Santen has also acquired international clinical development capabilities, an example of which is the fast-track approvals for two ophthalmic pharmaceuticals in the U.S. Also in the rheumatism/osteoarthritic area, a number of candidate compounds are ready to start clinical stages.

●Santen achieved its domestic prescription pharmaceutical sales target. However, due to Santen’s lack of new blockbuster drugs for the glaucoma area, together with the impact of intensifying competition, Santen is not expected to reach its planned market share, either in the overall prescription ophthalmic market or in key therapeutic areas. Additionally, U.S. sales and marketing results and results in domestic ophthalmic-related businesses are expected to be far lower than originally planned. The Company will not achieve its overall profit target as a result.



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# **2003-2005 Medium-Term Management Plan**



# Basic Philosophy

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- **Basic philosophy: “Santen applies its unique capabilities and technologies in its areas of expertise to contribute to the health and quality of life of patients and their loved ones, and society as a whole.”**  
**(Organizational capabilities – process renovation –customer solutions – financial performance)**
- **To “see” and to “move” are fundamental functions in people’s lives, and there are unmet needs relevant to their improvement. For medium- and long-term growth, we will continue to accelerate development and enhance research in areas related to these functions.**
- **The domestic market is stagnating due to deflation and the changes in the health insurance system. Moreover, Santen has no blockbuster new products that will be launched in three years. Santen will reinforce sales and marketing to gain the maximum profit from its existing products.**
- **Santen will overhaul its investment in U.S. sales and marketing, which have been a major factor in the low profits in recent years. Overseas investments with long-term growth potential will be evaluated in terms of competitiveness and time to profitability.**



# Basic Objectives of 2003-2005 Medium-Term Plan

- **Restoration of Profitability**
  - ◆ Early profitability of U.S. operations
  - ◆ Reduction of expenses
  - ◆ Maintenance and improvement of our domestic earnings base
- **Strengthening of R&D**
  - ◆ Acceleration of new product development
  - ◆ Enhancement of the pipeline of drug candidates through focused resource allocation
- **Reinforcement of Organizational Strength**
- **Financial Targets (JPY billions, except ROE)**

	March 2006	March 2003 (est.)
Net sales	93.0	90.4
Operating income	18.0	12.7
Net income	10.0	8.2
ROE	10.0%	8.5%



# Numerical Targets

## ○ Sales by segment (JPY billions)

	Mar. 2006	Mar. 2003 (est.)
Prescription Pharmaceuticals	80.8	79.4
Ophthalmic	71.8	70.9
Anti-rheumatic	8.5	7.7
Others	0.5	0.8
OTC Pharmaceuticals	6.6	5.8
Medical Devices	2.5	1.1
Others	3.1	4.1
<b>Total</b>	<b>93.0</b>	<b>90.4</b>
Overseas Sales	13.7	10.4

## ○ Income statements (JPY billions)

	Mar. 2006		Mar. 2003 (est.)	
		% Sales		% Sales
Net sales	93.0	100.0%	90.4	100.0%
COGS	31.1	33.4%	32.0	35.4%
SGA expenses	43.9	47.2%	45.6	50.4%
R&D expenses	12.5	13.4%	13.3	14.7%
Operating income	18.0	19.4%	12.7	14.0%
Ordinary income	18.0	19.4%	12.4	13.7%
Net income	10.0	10.8%	8.2	9.1%



## **Restoration of Profitability – Early Profitability of U.S. Operations**

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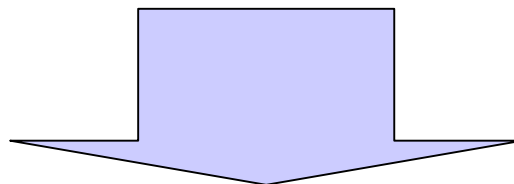
- **Use prescription ophthalmic pharmaceutical sales alliances to make U.S. operations profitable (before R&D expenses on an operating basis) in the year ending March 2005**
  - ◆ **Negotiations under way with several companies**
  - ◆ **Launch of *Quixin 1.5%* scheduled in 2004**
  - ◆ **Profit/loss will increase by approx. JPY2.5 billion**



## ● Manufacturing

### ◆ Reduce costs while maintaining and improving quality

- Improve usability and productivity by introducing new bottles
- Optimize manufacturing functions and processes
- Reduce purchasing expenses



**Expenses for year ending March 2006:  
JPY1.5 billion lower than year ending  
March 2003**



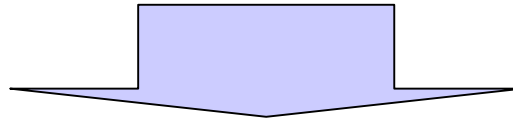


# Restoration of Profitability – Reduction of Expenses

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- **R&D**

- ◆ Integrate R&D functions of rheumatic and osteoarthritic area with a part of ophthalmics to eliminate overlap and inefficiency in research
- ◆ Control costs by prioritizing research project expenditures more thoroughly
- ◆ Reduce R&D expenses from surgical area



**Reduce R&D costs to JPY12.5 billion in the year ending March 2006  
(JPY800 million lower than the year ending March 2003)**

- **Sales and Sales Support**

- ◆ Reduce expenses for sales offices, etc.
  - Convert sales bases into satellite offices and consolidate sales support
  - Expenses for year ending March 2006: JPY500 million lower than the year ending March 2003



## Key Measures

- Focused allocation of resources in growth and strong areas (corneal and conjunctiva disorders, glaucoma, allergies)
  - ◆ Corneal disorders: *Cravit, Hyalein*
  - ◆ Glaucoma: *Detantol*
  - ◆ Allergies: *Livostin*
- Market penetration strategies geared to customer segments through clear segmentation and targeting
- Improvement of customer response and MR efficiency through adoption of SFA (Sales Force Automation)

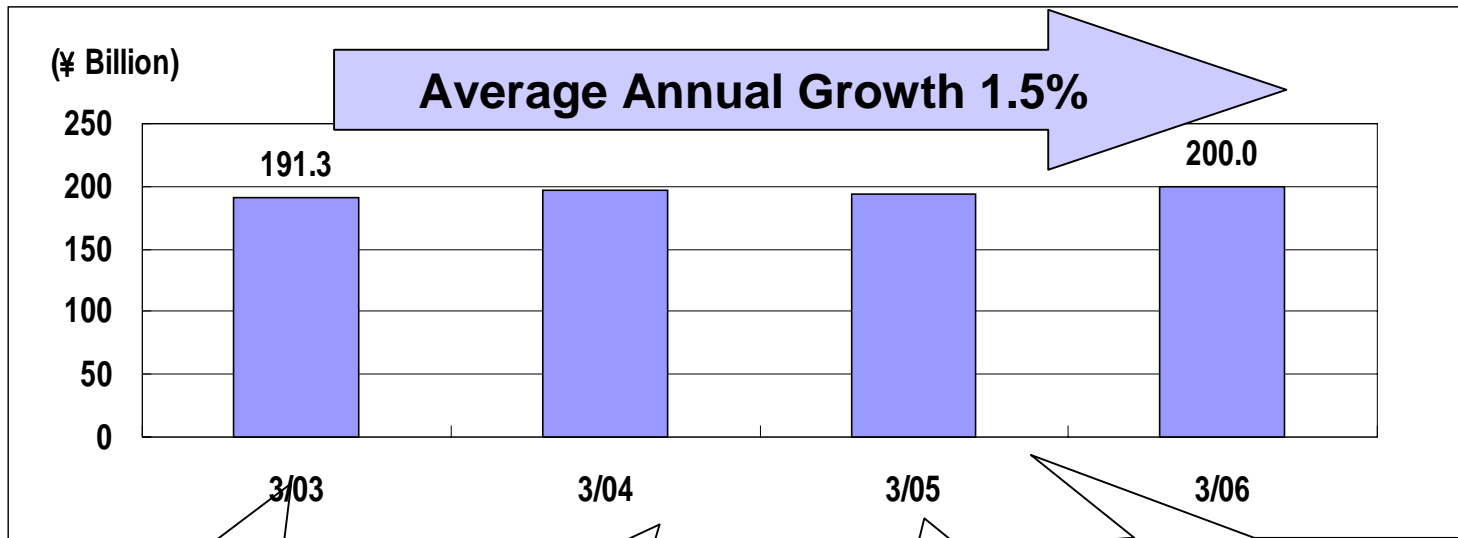


# Restoration of Profitability – Maintenance and Improvement of Domestic Earnings Base

## ● Outlook for Domestic Prescription Ophthalmics

- Despite an increase in patients, the ophthalmic pharmaceutical market is projected to remain flat due to the effect of NHI drug price revisions.
- Although the market for glaucoma treatments will increase, it is expected that the anti-infective ophthalmic market will decline.

## ● Ophthalmic Pharmaceutical Market Forecast



NHI drug price revision: 6%  
10% copayments by elderly

30% copayments by salaried workers

Estimated NHI drug price revision: negative 6-8%

Planned rival product launches:  
Anti-infective (gatifloxacin), glaucoma treatment, generic drugs

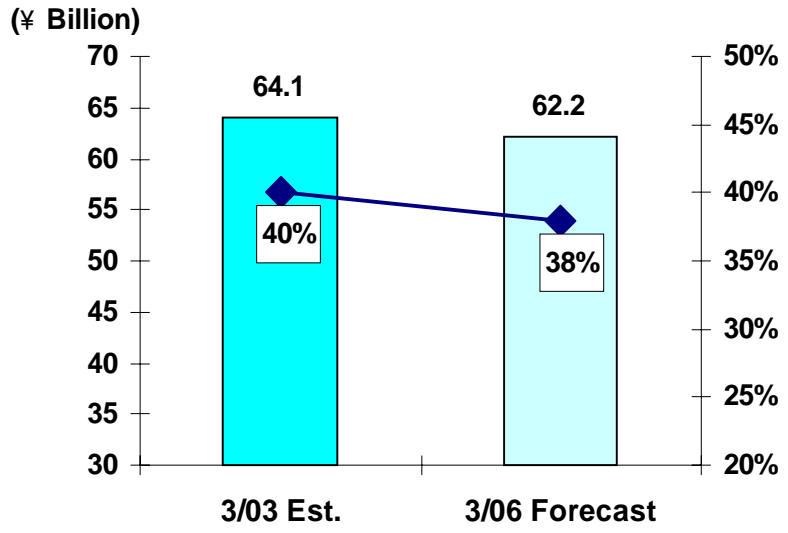


# Restoration of Profitability – Maintenance and Improvement of Domestic Earnings Base

## ● Net Sales & Market Share Forecast

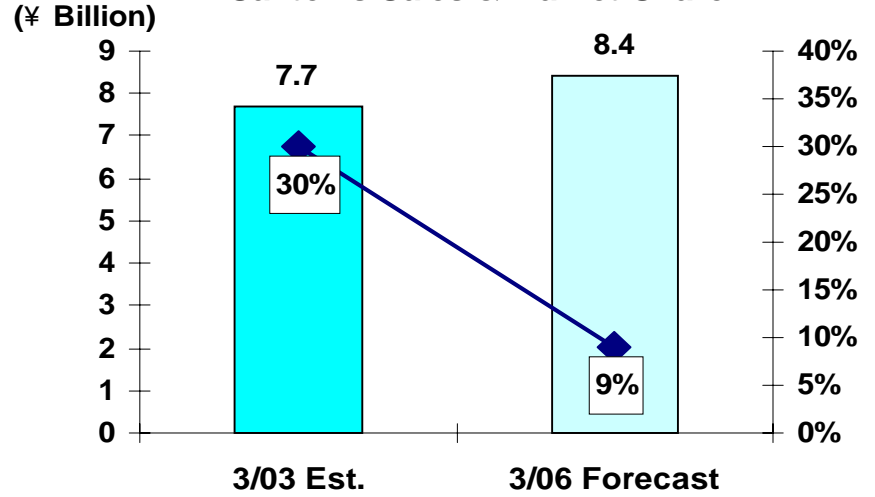
Domestic Prescription Ophthalmic

Pharmaceuticals: Santen's Sales and Market Share

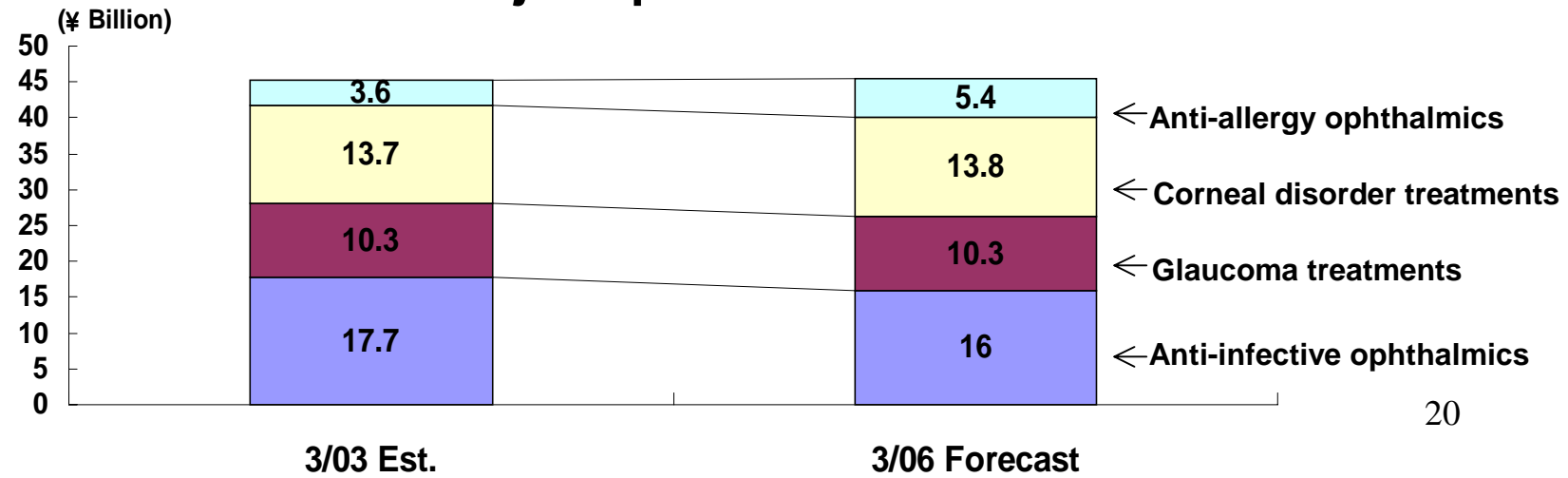


Domestic Anti-rheumatic Pharmaceuticals:

Santen's Sales & Market Share



## ● Sales Forecast for Major Ophthalmic Pharmaceuticals





- **Increase R&D capabilities and development speed, particularly for glaucoma treatments**
  - ◆ **Shorten clinical trial period**  
**Target: 5 years from Phase I to NDA**
    - Bolster clinical development by shifting personnel from research sections to clinical development sections
    - Encourage enrollment of clinical trial subjects by expanding the number of trial sites
    - Improve workflows
  - ◆ **Shorten pre-clinical period**  
**Target: 1.5 years**
    - Safety tests focusing on clinical pharmacology tests (Phase II a)
    - Pharmacology tests that use evaluation system focusing on the major indication expected for the drug
  - ◆ **R&D organization change (December 2002)**
    - Purposes: Shorten the clinical development period; improve efficiency of R&D operations



## **● Focused Resource Allocation**

### **◆ Focus resources on promising themes**

- Reinforce and accelerate the pipeline through concentrated, stronger investment in promising themes**
- Control overall research investment and shift to clinical development**

### **◆ Expand opportunities through alliances**

- Maximize opportunities by strengthening domestic and international alliances for rheumatic and osteoarthritic area**

### **◆ Integrate know-how of rheumatic and osteoarthritic research and a part of ophthalmic research**



# Development Status of Prescription Pharmaceuticals

## ● Glaucoma Treatments

Brand name/ Development code	Generic name	Stage	Planned launch
DE-085	(Undetermined)	Japan: Phase 2 U.S.: Phase 2	Japan: 2007-2008 U.S.: 2006 Europe: 2007
Despite late start of development of this prostaglandin derivative, Santen aims to identify distinct factors that can differentiate from competitors and meet medical needs overseas and in Japan. Co-development with Asahi Glass.			
DE-092 (CS-088)	Olmesartan	Japan: Phase 2	Japan: 2007-2008
The only ophthalmic preparation in the development stage as an angiotensin II receptor antagonist. Has a strong mechanism of action comparable to prostaglandin drugs in reducing intraocular pressure. Assumed to have very few side effects (including conjunctival infection and other topical effects). Especially high potential in Europe and the U.S., where high-pressure glaucoma predominates. In-licensed from Sankyo.			
DE-090	lomerizine hydrochloride	Japan: Phase 2	Japan: 2010 or later
A new type of glaucoma treatment with a mechanism that inhibits progression of visual field loss. The only preparation under development as an oral glaucoma drug based on calcium antagonizing activity. Compared with NMDA receptor antagonists, has been shown to have fewer systemic side effects and has a high degree of safety. High expectations as an oral drug with a broad spectrum of action. Currently marketed by Nippon Organon as a migraine treatment.			



# Development Status of Prescription Pharmaceuticals

## ● Anti-allergy Ophthalmics

Brand name/ Development code	Generic name	Stage	Planned launch
DE-076	cyclosporine	Japan: Phase 2/3	Japan: 2004
Under development as a treatment for vernal keratoconjunctivitis using immunosuppressive action; NDA filing planned this year.			
DE-081	apafant	Japan: Phase 2A	Japan: 2007
Expected to have an effect different from other anti-inflammatory ophthalmic solutions. After studying efficacy based on concept, will be moved into a later stage of Phase 2 this year.			





# Development Status of Prescription Pharmaceuticals

## ● Corneal Disorder Treatments

Brand name/ Development code	Generic name	Stage	Planned launch
Hyalein	sodium hyaluronate	U.S.: Phase 2 (Under preparation)	---
Phase 2 tests showed significant difference in the efficacy between this drug and placebo, but in the Phase 3 tests, both the drug and placebo alleviated symptoms in a number of subjects. Phase 2 tests will be carried out once again after modifying the clinical study model.			
DE-089 (INS365)	diquafosol tetrasodium	Japan: Phase 2	Japan: 2008-2009
Dry eye treatment that promotes secretion of tear components and moisture from the corneal epithelium. Can be used in combination with existing drugs and has potential to be effective where other drugs have not. Developing under license from Inspire Pharmaceuticals of the U.S. NDA filed in the U.S. by Allergan, Inc.			
Lactoferrin	lactoferrin	Japan: nonclinical	---
Stimulates production of tear components to stabilize tear film. Has potential to offer new treatment system with administration method different from ophthalmic solutions. Preparing to begin clinical development this year. In-licensed from Agennix.			



# Development Status of Prescription Pharmaceuticals

## ● Anti-infective Ophthalmics

<b>Brand name/ Development code</b>	<b>Generic name</b>	<b>Stage</b>	<b>Planned launch</b>
<b><i>Quixin 1.5%</i></b>	<b>levofloxacin</b>	<b>U.S.: Phase 3</b>	<b>U.S.: 2004</b>
<b>New quinolone antibacterial agent. The adoption of a more highly concentrated formulation enables stronger antibacterial action. Also expected to be effective for intractable bacterial corneal ulcers.</b>			
<b>DE-094</b>	<b>levofloxacin &amp; prednisolone A</b>	<b>U.S.: Phase 1/2</b>	<b>U.S.: 2008</b>
<b>Ophthalmic combination solution with levofloxacin and steroid.</b>			



# Development Status of Prescription Ophthalmics

## ● Anti-rheumatic pharmaceuticals

Brand name/ Development code	Generic name	Stage
DE-096		Japan: Preparing for clinical trials
TNF inhibitor. Anti-rheumatic effect comparable to oral antibody drugs has been observed in basic research. Will soon begin negotiating with major overseas pharmaceutical company for overseas out-licensing. Also in tie-up negotiations with several companies for domestic development.		
DE-098	—	Japan: Preparing for clinical trials
Joint injection that induces apoptosis in diseased joints of rheumatoid arthritis patients. Bulk pharmaceutical manufacturing process for actual production scale established, and drug development being studied.		
<i>Rimatil</i> (additional indication: OA)	Bucillamine	Japan: Preparing for clinical trials
Shown to be effective on joint inflammation due to osteoarthritis (OA).		



# Other Businesses

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<b>Division</b>	<b>Key Measures</b>	<b>3/06 Sales Target (JPY billion)</b>	<b>3/03 Est. (JPY billion)</b>
<b>OTC Pharmaceuticals</b>	<b>Boost sales with new products and added-value, proposal-based sales activities</b>	<b>6.6</b>	<b>5.8</b>
<b>Medical Devices</b>	<b>Secure profits by launching new products, primarily intraocular lenses</b>	<b>2.5</b>	<b>1.1</b>

<b>Region</b>	<b>Key Measures</b>	<b>3/06 Sales Target (JPY billion)</b>	<b>3/03 Est. (JPY billion)</b>
<b>Europe</b>	<b>Increase sales by expanding sales channels and adding new products</b>	<b>4.8</b>	<b>3.7</b>
<b>Asia</b>	<b>Concentrate resources, with a focus on China and Korea.</b>	<b>2.7</b>	<b>2.2</b>



# Reinforcement of Organizational Strength

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- **Strengthening of Corporate Governance**
  - ◆ **Strengthen monitoring functions of Board of Directors**
    - Planned appointment of outside directors
    - Planned shortening of term of directors (2 years to 1)
  - ◆ **Strengthen management at major overseas subsidiaries**
    - Introduce balance scorecard system
    - Introduce uniform compensation system
  
- **Employee Education and Enhancement of Organizational Management Capabilities**
  - ◆ **Retain, systematically train and promote competent employees**
  - ◆ **Further reinforce employee training programs such as the Santen Innovation Project, an in-house business school program**
  - ◆ **Facilitate mobility in internal positions through measures such as an in-house recruiting system**



# Financial Strategy

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- **Provide necessary funds for business activities and ensure liquidity on hand**
  - ◆ **With the redemption of convertible bonds in Sept. 2003, consider new funding for part of this amount**
  - ◆ **Supplement liquidity with commitment line contracts**
- **Ensure a proper balance sheet**
  - ◆ **Improve capital efficiency**
  - ◆ **Minimize the cost of invested capital**
- **Promote shareholder returns**
  - ◆ **Provide appropriate dividends, giving consideration to overall earnings conditions**
  - ◆ **Make effective use of share buybacks/cancellations**



# Future Developments

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- **4/2003 to 3/2006**

**Preparation period for a new growth stage after 4/2006**

- ◆ **Earnings Structure Reform**
- ◆ **Strengthening of R&D**
- ◆ **Reinforcement of Organizational Strength**

- **4/2006 and Beyond**

**Promote evolution into a company that makes R&D – in the fields of ophthalmic and rheumatic/osteoarthritic treatments – the source of growth, in addition to Santen's existing strength in sales and marketing**