# News Release



# 2003-2005 Medium-term Management Plan

**Osaka, Japan, February 20, 2003** – Santen Pharmaceutical Co., Ltd. (President and CEO: Takakazu Morita) announces the formulation of a three-year management plan for the period from April 2003 to March 2006.

## [Business Environment]

## I. Previous Medium-Term Management Plan "Hitomi 21"

Santen developed the Medium-term Management Plan "Hitomi 21" (from April 1998 to March 2003) five years ago, assuming 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, dry eye and rheumatic/osteoarthritic treatments, thanks to its reinforced licensing and R&D capabilities. Santen has also developed international clinical development capabilities, an example of which is the fast-track approvals for two ophthalmic pharmaceuticals in the U.S.

As for the Japanese prescription ophthalmic pharmaceuticals business, which accounts for approximately 70 percent of net sales, the market expanded by more than 10 percent over the past five years, despite three revisions of National Health Insurance (NHI) drug prices. During the period, Santen drove the growth of the market for corneal disorder treatments, and is forecast to achieve its sales target for the Japanese prescription ophthalmic business. However, due to Santen's lack of new blockbuster products for the glaucoma market, which grew dramatically by more than 40 percent, combined 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 the domestic ophthalmic-related businesses (*i.e.* over-the-counter eye drops and new business) are expected to be far lower than originally planned. As a result, the Company will not achieve its overall sales and profit targets.

#### **II. Market Environment**

During the period of the new 2003-2005 Medium-term Management Plan that will begin in April 2003, the prescription ophthalmic pharmaceutical market is estimated to grow by an average of 1.5 percent per annum. However, the challenging business environment is expected to continue due to several factors such as ongoing revisions of the health insurance system (workers' co-payments are set to increase in April 2003 and a revision of NHI drug prices is scheduled for April 2004); intensifying competition including foreign-capital pharmaceutical companies entering the Japanese market; and the impact of economic stagnation.

## [Outline of the 2003-2005 Medium-term Management Plan]

To lay the groundwork for significant advances in the year ending March 31, 2007 and beyond, Santen will devote the next three years to thoroughly overhauling its earnings structure and bolstering its R&D capabilities. By doing so, Santen aims to evolve into a company that makes R&D - in the fields of ophthalmic and rheumatic/osteoarthritc treatments - the source of growth, in addition to its existing strength in sales and marketing.

## I. Basic Objectives

- 1. Restoration of Profitability
- 2. Strengthening of R&D
- 3. Reinforcement of Organizational Strength

## **II. Financial Targets**

#### Net Sales, Operating Income, Net Income and ROE

Japanese Yen (JPY) billions, except ROE

		(1 of federalioe)
	Year ending	Year ending March
	March 2006	2003 (est.)
Net sales	93.0	90.4
Operating income	18.0	12.7
Net income	10.0	8.2
Return on equity (ROE)	10.0%	8.5%

(For Reference)

## Net Sales by Business Segment

	Year ending March 2006 (JPY billions)	Percentage of Company sales (%)
Prescription Pharmaceuticals	80.8	86.9
Ophthalmic	71.8	77.2
Anti-rheumatic	8.5	9.2
Others	0.5	0.5
OTC Pharmaceuticals	6.6	7.1
Medical Devices	2.5	2.7
Others	3.1	3.3
Total	93.0	100.0
Overseas Sales	13.7	14.7

(For Reference)		
Year ending	Percentage	
March 2003	of Company	
(est.)	sales (%)	
(JPY billions)		
79.4	87.9	
70.9	78.4	
7.7	8.6	
0.8	0.9	
5.8	6.4	
1.1	1.2	
4.1	4.5	
90.4	100.0	
10.4	11.5	

## III. Key Issues

## 1. Restoration of Profitability

## □ Early profitability of U.S. operations

 We will enter into a sales alliance in order to make our U.S. operations profitable (before R&D expenses on an operating basis) in the year ending March 2005. U.S. operations have been a significant drain on profits over the last few years.

#### □ Reduction of expenses

- We will cut manufacturing costs by introducing new ophthalmic bottles with improved usability, optimizing manufacturing functions and processes, and reducing purchasing expenses.
- We will control R&D expenses (estimate for year ending March 2006: JPY12.5 billion) by integrating R&D functions for rheumatic/osteoarthritic area with part of ophthalmics; prioritizing R&D projects; and streamlining pre-clinical research operations.
- We will reduce selling, general and administrative expenses through measures such as converting sales bases to satellite offices and consolidating sales support.

### □ Maintenance and improvement of domestic earnings base

 Through measures including focused allocation of resources to growth and strong areas (corneal and conjunctiva disorders, glaucoma and allergy), investing in sales force automation to strengthen customer relationships and raising the efficiency of medical representatives' activities, we will minimize market share erosion and maintain and improve our earnings base in the domestic prescription ophthalmic pharmaceutical business.

## 2. Strengthening of R&D

## □ Accelerating new product development

- We will increase our R&D capabilities and development speed, particularly for glaucoma treatments, as an engine for medium- and long-term growth.
- We will shorten the development period from Phase I clinical trials to new drug application (NDA) filing to approximately five years. To achieve this, we will reinforce clinical development by shifting personnel from research sections to clinical development sections, increase clinical trial enrollment through expanding the number of trial sites and improve the workflows.
- In addition, we will implement safety tests focusing on clinical pharmacology tests (Phase IIa) and pharmacology tests that use the evaluation methods focusing on the major indication expected for the drug, in order to shorten the non-clinical trial period to approximately 1.5 years.
- We changed the R&D organization in December 2002, aiming to reinforce planning abilities and leadership in order to shorten the clinical development period and to improve efficiency of R&D operations.

## ☐ Enhancing the pipeline of drug candidates through focused resource allocation

- We will focus resources on promising research themes.
- We will expand opportunities by strengthening domestic and international alliances for rheumatic/osteoarthritic area.
- We will reinforce creation of new drugs in the ophthalmic field by combining know-how of the rheumatic/osteoarthritic research and a part of ophthalmic research.

## 3. Reinforcement of Organizational Strength

#### □ Strengthening of corporate governance

- We will appoint outside directors and shorten the term of directors (from two years to one) in order to strengthen monitoring function towards the Board.
- We will introduce a balance scorecard system and a uniform compensation system for management at major overseas subsidiaries to reinforce overseas business operations.

## □ Employee education and enhancement of organizational management capabilities

- We will retain, systematically train and promote competent employees.
- We will further reinforce employee training programs such as the Santen Innovation Project, an in-house business school program.
- We will facilitate mobility in internal positions through measures such as an in-house recruiting system.

## [About Santen Pharmaceutical Co., Ltd.]

Santen specializes in the research, development, manufacture and marketing of ophthalmic and anti-rheumatic pharmaceuticals to protect and improve people's eyesight and health. Santen has created innovative pharmaceuticals for all types of ophthalmic disorders and provides information tailored to clinical needs. As a result, Santen leads Japan's market for prescription ophthalmics, which represent nearly 80 percent of Company sales.

###

#### Notes:

#### 1. Forward-Looking Statements

This news release 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.

## 2. Assumptions of the Plan

The Plan assumes:

- average annual growth of 1.5 percent in the domestic prescription ophthalmic pharmaceutical market during the period (projected market size in the year ending March 2006: JPY200 billion);
- (2) the impact of NHI drug price revision scheduled for April 2004 on Santen's prescription pharmaceutical sales will be negative 6-8 percent;
- (3) sales alliance for Santen's U.S. operations will begin during the period; and
- (4) average exchange rates of US\$1=JPY120 and 1 euro=JPY117.

#### 3. About the 12-hour Rule

You will be deemed the primary recipient(s) of corporate insider information by virtue of the provisions of Paragraph 3 of Article 166 of the Securities and Exchange Law of Japan and will be subject to insider regulations under such Law and Order until the elapse of twelve hours from the time this news release was made (until 1:00 a.m. of February 21, 2003, JST).