

# **EXAMPLE 1 EXAMPLE 1 EXAMP**

SANTEN PHARMACEUTICAL CO., LTD. Annual Report 2014 Year Ended March 31, 2014

# Our Values

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## NOTE ON ACCOUNTING STANDARDS

The Santen Group has unified the accounting period from the fiscal year ended March 31, 2014. The results given in this annual report are based on this unified fiscal year, if no note is specified. Results given for fiscal years up to the previous fiscal year have not been calculated on the basis of this unified fiscal year, but on their existing 12-month basis.

## NOTE CONCERNING GRAPHS

Graphs in this annual report are based on fiscal years ended March 31, if no note is specified.

# NOTE CONCERNING DATA

Some information in this annual report is based on IMS data (JPM). Source: ©2014 IMS Health Santen analysis is based on IMS-JPM data from April 2009 to March 2014. All rights reserved.

# CAUTION CONCERNING FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements regarding the Company's plans, outlook, strategies and results for the future. All forward-looking statements are based on judgments derived from the information available to the Company at the time of publication. Certain risks and uncertainties could cause the Company's actual results to differ materially from any projections presented in this report. These risks and uncertainties include, but are not limited to, the economic circumstances surrounding the Company's businesses, competitive pressures, changes in related laws and regulations, status of product development programs and changes in exchange rates. Core Value

# Tenki ni sanyo suru

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

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."

> Santen's Values embody what the Company has continued to recognize as important since its foundation in 1890. Based on Santen's Values— the essence of which is *"tenki ni sanyo suru"*—we have put in place a virtuous cycle of creation and innovation while contributing to the protection and improvement of eyesight and health as a specialty company in the ophthalmic and anti-rheumatic fields. Building on the scientific knowledge and organizational capabilities that Santen has nurtured for over 120 years, the Company will continue to contribute to society, working primarily for the benefit of patients and their loved ones.

# Our Vision

Long-Term Strategic Vision through 2020

# Aiming to Become a Specialized Pharmaceutical Company with a Global

A company possessing a deep understanding of true customer needs, together with a distinct advantage against competitors, and a global competitiveness and presence



# 5 Policies toward the Achievement of Our Long-Term Strategic Vision

- 1. Develop products that meet true customer needs swiftly
- 2. Transform domestic business for further growth
- 3. Accelerate business expansion in Asia and promote market entry in Western Europe/the U.S.
- 4. Establish competitive global product supply and quality assurance systems
- 5. Strengthen talents and organizational capabilities to promote "Creation and Innovation"



# Presence

# Fiscal 2014-2017 Medium-Term Management Plan

# **Basic Policies**



Transform product development to realize enhanced productivity and achieve sustained growth



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



Develop talents and organization to realize sustained growth

# **Strategic Vision**

Santen is working to become a specialized pharmaceutical company with a global presence, in order to realize its long-term strategic vision through 2020. The first step was our Fiscal 2011-2013 Medium-Term Management Plan, which stipulated the plan's period as the time for making investments for medium- and long-term growth, and during which we took a variety of steps such as the promotion of globally oriented research and development. The next step is our newly formulated Fiscal 2014-2017 Medium-Term Management Plan, which calls for two strategies of ongoing product launches and the achievement of growth and profitability in Asia and Europe. At Santen, we are working across the organization to drive our business forward, capitalizing on our strengths to maintain market leadership.

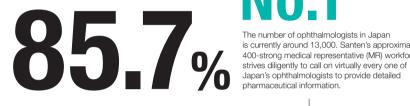


Further Information P.10 President and CEO's Message



# )Ur

Prescription Ophthalmic Pharmaceuticals (Sales Composition)



Share of Japanese Market

is currently around 13,000. Santen's approximately 400-strong medical representative (MR) workforce

**Over-the-Counter** Pharmaceuticals Share of Japanese Market

**No.2** 

Prescription Anti-Rheumatic Pharmaceuticals Share of Japanese Market Disease-Modifying

Anti-Rheumatic Drugs **No.2** 

Others -

Medical Devices -

**Business Domains** 

We channel management resources into the specialized fields of ophthalmology and anti-rheumatics to create innovative drugs sought by the medical community and provide high-quality medical information based on market needs. In this way, we have enhanced Santen's market reputation.



Further Information P.30 Review of Operations

Fiscal 2013 Net Sales ¥148.7 billion

# Advantage

# **Global Business Expansion**

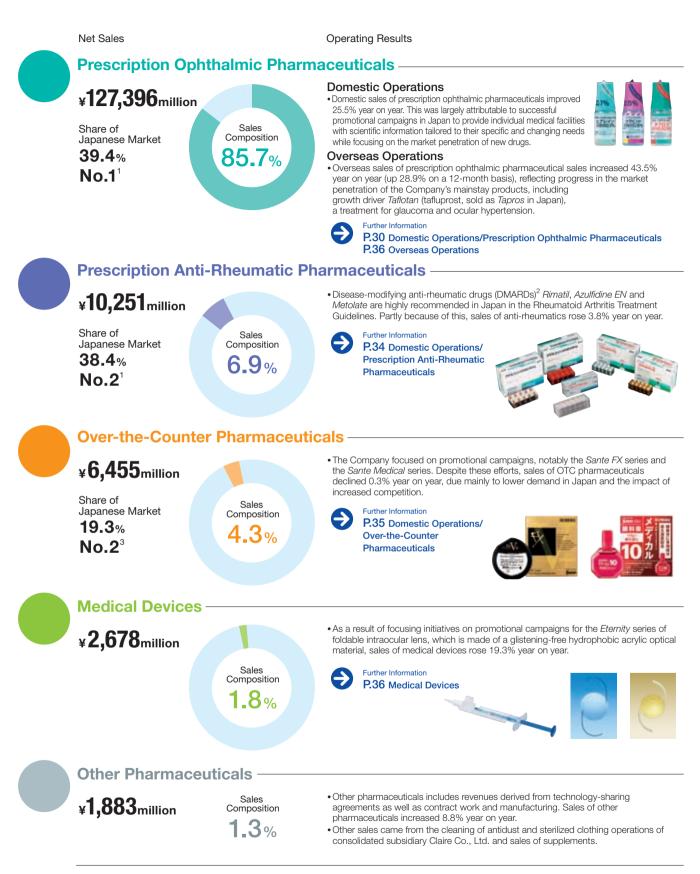
Santen maintains 15 bases spread across 12 countries, and its products are sold in over 50 countries worldwide. Santen produces around 300 million bottles<sup>1</sup> of ophthalmic solutions each year at four plants—in Noto, Shiga, Suzhou (China) and Tampere (Finland). That makes us a world leader in the production of ophthalmic solutions. 1. On a 5 mL bottle conversion basis

Further Information P.18 Feature P.36 Overseas Operations Annual Production Capacity of Ophthalmic Solutions

Approx. **300** million bottles

Countries in Which Products Are Sold





Notes: 1. Market share and market position in Japan for the fiscal year ended March 31, 2014. The share and position for anti-rheumatic pharmaceuticals represent those in the DMARDs segment. Source: Santen analysis based on IMS-JPM data.

2. A class of medicines that are used not only to alleviate symptoms but also to treat the causes of disease. The anti-rheumatic effect works by calming inflammation through the correction of immune abnormalities, which are considered a cause of RA.

3. Market share and market position in the Japanese OTC eye drop market for the fiscal year ended March 31, 2014. Source: Santen Pharmaceutical Co., Ltd.

# October 2013

# Launch in Japan of *Tapros Mini*, a treatment for glaucoma and ocular hypertension

Tapros Mini offers the same intraocular pressure-reducing effect of the original *Tapros* in a preservative-free solution in single-dose disposable containers.

# November 2013

# Launch in Japan of anti-allergy ophthalmic solution *Alesion*

Alesion is an ophthalmic solution licensed from Nippon Boehringer Ingelheim Co., Ltd. and then developed by Santen as a treatment for allergic conjunctivitis. It provides relief from allergic conjunctivitis symptoms such as itching and redness.

Annual net sales<sup>4</sup> of targeted products (2013)



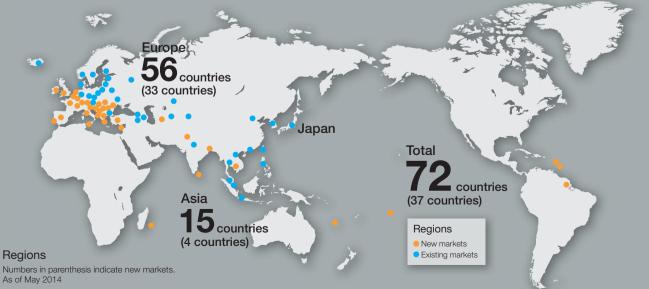
4. Includes sales of COSOPT which was jointly promoted with Santen in Japan.

## May 2014

# Acquisition of ophthalmology assets from U.S.-based Merck & Co., Inc.

The Company entered into an agreement with Merck & Co., Inc. for Santen to purchase Merck's ophthalmology products<sup>5</sup>. The annual sales for 2013 associated with these ophthalmic products are approximately US\$400 million, covering 72 countries. Leveraging this opportunity and with the long-term business vision to become a specialized pharmaceutical company with a global presence, Santen is further accelerating the development of its business operations.

5. COSOPT, COSOPT PF, TRUSOPT, TRUSOPT PF, TIMOPTIC, TIMOPTIC PF, TIMOPTIC-XE, SAFLUTAN, TAPTIQOM



# **Consolidated Financial Highlights**

Santen Pharmaceutical Co., Ltd. and Subsidiaries Years ended March 31, 2014, 2013, 2012, 2011 and 2010

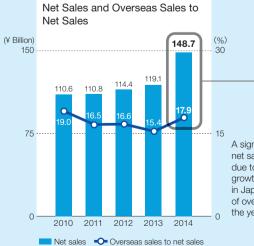
					Millions of yen	Thousands of U.S. dollar	rs Change
	2010	2011	2012	2013	2014	2014	2014/2013
For the year:							
Net sales	¥ 110,594	¥ 110,812	¥ 114,416	¥ 119,066	¥ 148,663	\$ 1,444,456	24.9%
Operating income	29,640	30,739	26,732	24,681	27,414	266,363	11.1
Net income	18,723	21,333	17,161	16,521	17,109	166,239	3.6
Comprehensive income	18,826	19,797	16,966	21,729	25,379	246,585	16.8
R&D expenditures	14,123	13,221	17,225	16,720	19,040	184,998	13.9
Capital expenditures	1,315	1,651	3,281	3,609	4,786	46,502	32.6
Depreciation and amortization	3,421	2,976	2,949	3,291	3,927	38,155	19.3
At year-end:							
Total assets	¥ 166,878	¥ 184,801	¥ 198,801	¥ 199,641	¥ 231,106	\$ 2,245,489	15.8%
Long-term debt	75	152	179	145	102	991	(29.7)
Equity	137,343	156,099	164,514	164,808	180,811	1,756,804	9.7
Per share data (yen and U.S. dollars):							
Net income – basic	¥ 220.10	¥ 249.71	¥ 196.96	¥ 195.81	¥ 207.29	\$ 2.01	5.9%
Net income – diluted	219.85	249.42	196.76	195.51	206.65	2.01	5.7
Equity	1,614.08	1,793.15	1,887.81	1,998.44	2,189.50	21.27	9.6
Cash dividends, applicable to the period	80.00	90.00	100.00	100.00	100.00	0.97	0.0
Other financial data:							
Operating income margin (%)	26.8	27.7	23.4	20.7	18.4		
Overseas sales to net sales (%)	19.0	16.5	16.6	15.4	17.9		
R&D expenditures to net sales (%)	12.8	11.9	15.1	14.0	12.8		
Return on equity (ROE) (%)	14.3	14.5	10.7	10.0	9.9		
Dividend on equity (DOE) (%)	5.2	5.3	5.4	5.1	4.8		
Number of employees	2,756	2,867	3,053	3,050	3,072		

Notes: 1. The Santen Group has unified the accounting period from the fiscal year ended March 31, 2014. Results given for fiscal years up to the fiscal year ended March 31, 2013 have not been calculated on the basis of this unified fiscal year, but on their existing 12-month basis.

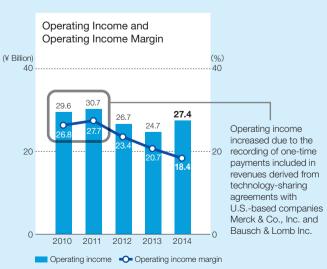
2. U.S. dollar amounts have been translated from yen, solely for the convenience of the reader, at the rate of ¥102.92 to US\$1.00, the exchange rate prevailing on March 31, 2014. 3. See Notes 2. 17) and 13 of Notes to Consolidated Financial Statements in respect of per share data.

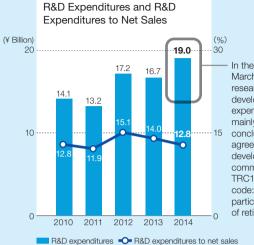
4. Figures in parentheses indicate a decrease.

5. Equity comprises shareholders' equity and accumulated other comprehensive income.

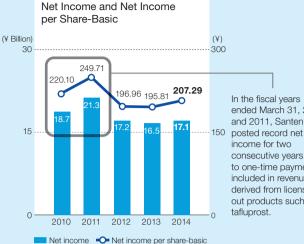








In the fiscal year ended March 31, 2014, research and development expenditures increased mainly due to the concluding of a licensing agreement related to the development and commercialization of TRC105 (development code: DE-122) focusing particularly on the field of retinal disorders.

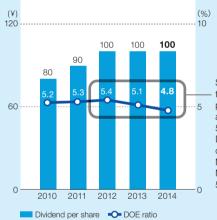


# In the fiscal years ended March 31, 2010 and 2011, Santen income for two consecutive years due to one-time payments included in revenues derived from licensing out products such as

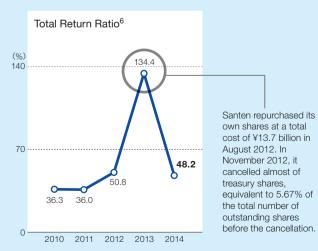


ROE significantly increased in the fiscal vears ended March 31. 2010 and 2011 due to one-time payments included in revenues derived from licensing out products such as tafluprost.

Dividend per Share and DOE



Santen is committed to the stable return of profits to shareholders and a DOE of around 5.0%. The average DOE ratio for the years of the Fiscal 2011-2013 Medium-Term Management Plan was 5.1%



6. The sum of dividends and the cost of share buybacks divided by net income

**Further Information** 

P.50 Report and Analysis of Operating **Results and Financial Condition** 

P.54 Risk Related to Our Business

P.56 Eleven-year Summary of Selected **Financial Data** 

# President and CEO's Message

Santen is making significant strides toward realizing its long-term strategic vision through 2020 of becoming a specialized pharmaceutical company with a global presence. By focusing our efforts on ophthalmology and related areas, we will develop scientific knowledge and organizational capabilities that are unique and original to Santen. We will use these unique capabilities to contribute to society. We kindly ask for the continued support of all our stakeholders.

September 2014

hunchave

Akira Kurokawa President and Chief Executive Officer

# **Fiscal 2013 Overview**

We posted record net sales. We expanded our presence further in both the Japanese and overseas markets, thanks to our focus on sales promotion activities for key products, including new products.

Fiscal 2013, the fiscal year ended March 31, 2014, was the final year of the Fiscal 2011-2013 Medium-Term Management Plan. During fiscal 2013, net sales rose 24.9% year on year to a record ¥148.7 billion. This result reflected significant sales growth in both the Japanese and overseas markets. Operating income was up 11.1% to ¥27.4 billion and net income rose 3.6% to ¥17.1 billion.

In the domestic prescription ophthalmic business, we saw steady growth in sales of key products such as our glaucoma and ocular hypertension treatments Tapros (tafluprost) and Cosopt (dorzolamide hydrochloride/timolol maleate), as well as our dry eye treatment Diguas (diguafosol sodium). Launched in Japan in November 2012, the intravitreal VEGF inhibitor EYLEA (aflibercept [genetical recombination]) continued to grow rapidly, contributing immensely to sales. The anti-allergy ophthalmic solution Alesion (epinastine hydrochloride), which was launched in Japan in November 2013, is steadily penetrating the market. In the overseas business, Santen posted higher sales of the glaucoma and ocular hypertension treatment Taflotan (tafluprost, sold as Tapros in Japan), one of its growth drivers. Taflotan is now available in more than 60 countries worldwide<sup>1</sup>.

Turning to R&D, under a new framework aimed at strengthening global R&D capabilities, we are working to create highly competitive new products based on the medical needs of the world's patients. In December 2013, we applied in Europe for marketing approval of *lkervis* (generic name: ciclosporin, development name: Cyclokat), a treatment for dry eye. We also met the primary endpoint of a Global Phase 3 study of DE-109 (sirolimus) for the treatment of non-infectious uveitis of the posterior segment. This study is being carried out at approximately 150 sites in Europe, the U.S. and Asia.

Furthermore, in May 2014, we entered into an agreement with U.S.-based Merck & Co., Inc. to purchase Merck's ophthalmology products in Japan, Europe and Asia Pacific. Through these initiatives, we intend to enhance our range of glaucoma and ocular hypertension treatment products, with the aim of improving patient's quality of life (QOL). At the same time, we are convinced that we can accelerate our progress toward realizing our long-term strategic vision. 1. As of March 31, 2014

# **Enhancing Shareholder Returns**

Santen has positioned the stable return of profits to shareholders as a key management priority.

For fiscal 2013, we paid a full-year dividend of ¥100 per share, the same amount as for the previous fiscal year. This resulted in a dividend payout ratio of 48.2%. Going forward, we remain committed to the stable return of profits to shareholders. At the same time, we will continue to retain funds primarily for R&D investments, while adopting a flexible stance that includes the acquisition of treasury stock.

# Summary of the Fiscal 2011–2013 Medium-Term Management Plan

# By steadily executing our growth strategy based on Santen's Values, we accelerated our progress toward realizing our long-term strategic vision.

Santen positioned fiscal 2011 to fiscal 2013 as a period to invest in growth. We steadily implemented a number of measures to bring our business strategies to fruition. Notably, we actively invested in R&D to accelerate the creation of new products, enhance our competitiveness in Europe and Asia, and spur growth in our business in Japan. With the aim of making an even greater contribution to patients worldwide, we put a global manufacturing system in place while pursuing efficiency. We also made tremendous progress on building a stronger organization and developing human resources. Both of these initiatives will enable us to realize our long-term strategic vision.

Santen made a Company-wide effort to pursue business activities aimed at achieving sustained growth. As a result, we delivered significantly higher net sales than our target in the previous medium-term management plan. On the other hand, operating income and net income were both below target, mainly due to the impact of upfront investments primarily in R&D. This included the acquisition of Santen S.A.S. of France (formerly Novagali Pharma S.A.S.). Building on the results of the previous medium-term management plan, Santen intends to execute new business strategies with the aim of becoming a specialized pharmaceutical company with a global presence.

# FY2011-2013 Medium-Term Management Plan Financial Targets and Results

	FY2013 Targets	FY2013 Results
Net Sales	Over ¥ <b>121</b> billion	¥ <b>148.7</b> billion
Operating Income	Over ¥ <b>31</b> billion	¥27.4billion
Net Income	Over ¥ <b>20</b> billion	¥ <b>17.1</b> billion
R&D Expenditures	Around ¥ <b>15.5</b> billion	¥19.0billion
ROE	10%	<b>10.2</b> % <sup>1</sup>

1. Three-year average for FY2011-2013

strategic Objective	s	Najor Achievements
Product Development	Promote globally oriented research and development.	<ul> <li>Established a global clinical development system.</li> <li>Reinforced product pipeline through business development and acquisitions.</li> </ul>
Domestic Operations	Obtain high domestic market share and achieve growth through the promotion of new products and implementation of marketing strategies.	<ul> <li>Long-listed drugs ratio declined due to new product<sup>3</sup> growth.</li> </ul>
Overseas Operations	Accelerate growth in both Asia and Europe by reinforcing marketing platforms.	<ul> <li>Accelerated sales growth in China.</li> <li>Asia business turned to profitability.</li> </ul>
Product Supply	Establish a global product supply system with our existing four plants <sup>2</sup> , which enable us to meet emerging market needs.	<ul> <li>Executed measures to reduce manufacturing cost.</li> <li>Structural reforms were conducted in Europe in order to enhance efficient global product supply system.</li> </ul>
Organization and Talents	Develop talents and organizational capabilities to promote "creation and innovation" on a global level.	<ul> <li>Implemented an organizational management system in line with business globalization.</li> </ul>

# Strategic Objectives and Results for Fiscal 2011-2013 Medium-Term Management Plan

# Formulation of the Fiscal 2014-2017 Medium-Term Management Plan

We will further sharpen our competitiveness as a specialty company by achieving ongoing product launches, along with growth and improved profitability in Asia and Europe.

Santen has formulated the Fiscal 2014-2017 Medium-Term Management Plan, with a view toward realizing its long-term strategic vision through 2020 of becoming a specialized pharmaceutical company with a global presence. A set of strategic goals have been formulated in the new plan. Among such goals are the drastic reform of Santen's research and development system to enable sustainable development of new products, accelerated business operations in the Asian market that is expected to grow rapidly, business expansion and early improvement of earnings in Europe where Santen has been solidifying its business foundation. In doing so, Santen aims to achieve a compound annual growth rate (CAGR) of 8%. In addition, the Company will focus on human resources development and establishment of a solid organizational structure aimed at achieving sustainable growth.

By making a Company-wide effort to implement this medium-term strategy, Santen will ensure steady progress on the five policies toward achieving its long-term strategic vision. Santen has set the goal of becoming one of the top three ophthalmic pharmaceutical companies in the world by 2020, a goal the Company has prescribed under its long-term strategic vision.

# Long-Term Strategic Vision through 2020

# To Become a Specialized Pharmaceutical Company with a Global Presence

# 5 Policies toward the Achievement of Our Long-Term Strategic Vision

- 1. Develop products that meet true customer needs swiftly
- 2. Transform domestic business for further growth
- 3. Accelerate business expansion in Asia and promote market entry in Western Europe/the U.S.
- 4. Establish competitive global product supply and quality assurance systems
- 5. Strengthen talents and organizational capabilities to promote "Creation and Innovation"

# Basic Policies of the Fiscal 2014-2017 Medium-Term Management Plan



Transform product development to realize enhanced productivity and achieve sustained growth



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



Develop talents and organization to realize sustained growth

# Fiscal 2017 Financial Targets

Net Sales	Over ¥205 billion
Operating Income	Over $45$ billion
Net Income	Over ¥ <b>31</b> billion
ROE	Over <b>13</b> %
R&D Expenditures	Around ¥ <b>21</b> billion
Operating Income before Amortization	Over ¥ <b>54.5</b> billion
Dividend Payout Ratio	Around <b>40</b> %

# **R&D Strategy**

- Ensure the launch of existing products in the pipeline and improve productivity.
- Enhance the pipeline for differentiated products based on customer needs.

In R&D, Santen is working to ensure commercialization of products under development and further strengthen product pipelines for sustainable growth in order to rapidly develop differentiated products that satisfy unmet medical needs.

In particular, Santen will concentrate on fields that make the most of the Company's strengths, primarily in the fields of dry eye, glaucoma, and retinal disorders. Furthermore, Santen seeks to increase the probability of success for products in late-stage clinical development by promoting "Network Product Development<sup>1</sup>," which actively utilizes compounds and technologies available outside the Company, and by stepping up translational research<sup>2</sup>. Moreover, we plan to continue implementing life cycle management<sup>3</sup>, in order to maximize the value of our existing products. Looking ahead, we will continue to strengthen coordination between our R&D bases in Japan, the U.S. and Europe, as we endeavor to accelerate global clinical development and improve productivity.

- 1. An approach of proactively utilizing compounds and technologies available outside the Company in product development.
- Multi-disciplinary research that links basic research, clinical research, and medical examinations and utilizes the findings from this for effective and efficient practical applications to contribute to healthcare development.
- Aligning one compound to treatment needs over the long term and augmenting through additional indication, dosage, formulation and combination products to increase product value.

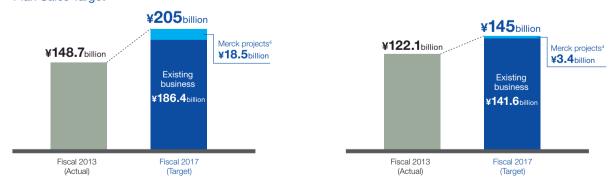
# **Domestic Business Strategy**

 Achieve business growth by contributing to the treatment of patients with new products and innovative services.

In the prescription pharmaceutical business, Santen will promote reforms to build an even stronger sales organization as it works to increase the market penetration of new products. Meanwhile, Santen has fully entered the field of back-of-the-eye diseases, where there are substantial unmet medical needs.

Guided by the new medium-term management plan, Santen will endeavor to enhance competitive advantages by maximizing values of new products such as *Tapros*, *Diquas* and *EYLEA*. The Company also aims to attain sustainable business growth and maintain a strong business presence in the domestic market by enhancing its ability to respond to unmet medical needs. It also seeks to achieve business growth by strengthening coordination among the prescription pharmaceutical, OTC and medical devices business categories by taking advantage of its strength as a specialized pharmaceutical company with a strong presence in Japan.

**Domestic Business Sales Target** 



# Fiscal 2014-2017 Medium-Term Management Plan Sales Target

## 4. The contribution from acquisition of U.S.-based Merck's ophthalmology assets, which Santen acquired in May 2014.

President and CEO's Message

# **Overseas Business Strategy [Asia Business]**

- Strengthen the business platform in order to expand market shares in key countries.
- Achieve sales and market share growth exceeding the market growth rate, and enhance profit contribution.

In the Asian business, Santen strove to expand business in the fast-growing Chinese market, and delivered significant growth in sales.

Under the new medium-term management plan, Santen positioned China, Korea, and Vietnam as key countries. The Company intends to continue to drive sustained growth in the Asian market. The Company aims to capture the top share in major markets in Asia, especially China and Korea, by fiscal 2020, by attaining higher growth than the market average. It will also accelerate business expansion in other ASEAN markets such as Vietnam.

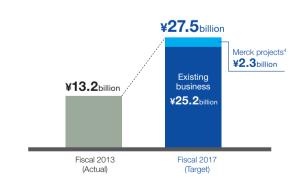
To drive earnings, Santen will work to maximize sales through new products, while strengthening sales and marketing capabilities. Additionally, the Company will reinforce its business platform based on products acquired from U.S.-based Merck in the glaucoma and ocular hypertension fields. In parallel, we will strive to enhance our development pipeline to fit local needs in Asian countries and leverage competitive new products to enter growing markets.

# Overseas Business Strategy [European Business]

- Become a "Value Player" with a unique presence in specific treatment categories such as dry eye and glaucoma.
- Achieve sustained growth and improve profitability.

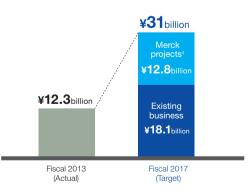
In the European business, higher market penetration of the glaucoma and ocular hypertension treatment *Taflotan*, one of the Company's growth drivers, has contributed to sales growth.

Under the new medium-term management plan, Santen will make the most of that achievement to attain sustained growth and improve profitability in combination with the launch of new products. Furthermore, we believe that the European market is the most promising region for realizing the benefits of increased sales due to the ophthalmology products acquired from Merck. Santen will strive to enhance its lineup of products in the glaucoma field in addition to spurring further growth in sales of existing products, with the aim of achieving sustainable growth and improved profitability.



Asian Business Sales Target

# European Business Sales Target



# **Product Supply Strategies**

 Establish a product supply system with global competitiveness.

In regard to product supply, Santen will strive to enhance price competitiveness and pursue high product quality, in order to continue growing amid a variety of changes in the global pharmaceutical market. Santen will continue to make efforts to reduce cost of sales significantly, for the purpose of ensuring a cost structure that is acceptable to emerging countries.

In more specific terms, our global production system is spread over four plants: the Noto Plant, our main plant, which is seeking to achieve improved productivity; the Shiga Product Supply Center, our core global facility responsible for technological innovation and strategic planning; the Suzhou Plant (China), where we are boosting production capacity; and the Tampere Plant (Finland), which serves as a supply center mainly for markets in Europe. We will maintain and enhance quality, while also ensuring stable supplies, with the aim of optimizing the global supply chain to fulfill our customers' needs.

# **Organization and Talent Strategy**

• Establish organization and strengthen the human resources pipeline towards the realization of sustainable growth.

We believe that developing talent and building a solid organization that can drive "creation and innovation" are crucial to realizing our long-term strategic vision through 2020. With this in mind, we will develop innovative leaders who will be responsible for medium- and long-term business growth. At the same time, we will endeavor to strengthen our global management system, focusing on primary functions such as R&D, product supply, and finance, in an effort to facilitate global decision-making and execution of strategies.

With the view of making its strategic vision a reality, Santen will remain focused on developing and enhancing the organizational management system and its employees to ensure sustained growth.

# Acquisition of Ophthalmology Assets from Merck & Co., Inc.

# To become a specialized pharmaceutical company with a global presence, we are strengthening the domestic prescription pharmaceutical business, along with accelerating growth in Asia and Europe and improving profitability.

In May 2014, Santen entered into an agreement with Merck & Co., Inc. for Santen to purchase Merck's nine ophthalmology products<sup>1</sup> in Japan, Europe, and Asia Pacific, along with product manufacturing and marketing rights.

Through this agreement, Santen has added highly regarded glaucoma and ocular hypertension treatment products to its lineup. In doing so, Santen will reinforce its presence in the domestic prescription ophthalmic business as it strives to achieve growth in the Asian and European business and improve profitability, thereby aiming at realizing our long-term strategic vision through 2020. Under the agreement, Santen will acquire the rights to drugs in 72 countries worldwide, including 37 new countries, positioning the Company to accelerate business expansion overseas.

1. COSOPT, COSOPT PF, TRUSOPT, TRUSOPT PF, TIMOPTIC, TIMOPTIC PF, TIMOPTIC-XE, SAFLUTAN, TAPTIQOM

# Fiscal 2017 Sales Outlook for Merck Projects by Region

Merck Project Sales	¥18.5billion
European business	¥12.8billion
Asian business	¥2.3billion
Domestic business	¥ <b>3.4</b> billion

# Corporate Social Responsibility (CSR) Activities

Based on Santen's Values, we are working as one team to enhance CSR activities integrated with our management strategies, pursuing a true customer focus.

The Santen Group considers it essential to integrate CSR into its management strategies on the basis of Santen's Values. We believe that our mission in society is to contribute to the eyesight and health of patients worldwide.

In order to promote CSR activities, on the basis of the three perspectives of "customers," "employees" and "society" stated in the Santen Code of Practice, as well as the core subjects of ISO 26000<sup>2</sup>, we defined 7 Core Subjects of CSR, for each of which a basic policy has been established. To become a specialized pharmaceutical company with a global presence, as outlined in our long-term strategic vision through 2020, we seek to not

only expand the Company and grow earnings, but also to achieve these goals through the pursuit of CSR.

By promoting business and CSR activities in a holistic and consistent manner, Santen intends to contribute primarily to the welfare of patients and their loved ones, as well as to society at large.

 ISO 26000 was issued by the International Organization for Standardization (ISO) to provide guidance on social responsibility. It is applicable not only to corporations but also to all organizations, including governments, schools, and NGOs.



# Feature

**Capturing the No. 1 Position across Asia by Contributing to Ophthalmic Treatment** 

# Expanding

# Operations in Asia

Santen continues to take the initiative in bold new projects, to realize its long-term strategic vision through 2020, and to meet its goal of becoming the leading contributor to ophthalmic treatments in Asia.

# Asia Business: Results and Strategies

Santen has greatly expanded its business in Asia while striving to contribute to improving the lives of patients in the region.

# Expanding Our Presence across the Entire Asian Market as a Specialized Ophthalmic Pharmaceutical Company

Aiming to become a specialized pharmaceutical company with a global presence and realizing its long-term strategic vision, Santen is working to become the market leader in Asia. Under the new medium-term management plan, we have positioned China, Korea and Vietnam as key countries and are seeking to attain sales growth that is higher than the market growth, while also expanding profits, by strengthening our marketing capabilities.



Akihiro Tsujimura Corporate Officer, Head of Asia Division

During the period covered by the previous medium-term management plan, the Company worked to strengthen its operating platform to support future growth, while focusing on promotional campaigns centered on the dissemination of medical information. As a result, in Asia, sales on a yen basis grew significantly, up 53.9% year on year to ¥13.2 billion in fiscal 2013 (up 31.1% to ¥11.2 billion on a 12-month basis), and we project growth in excess of 12% for fiscal 2014 (in excess of 32% compared to the previous year on a 12-month basis). As Asian economies expand further and levels of medical care improve, there will likely be a market expansion centered on drugs for dry eye and glaucoma. Emerging markets and others will also have significant needs in the field of ocular infection. Focusing on drugs for the treatment of glaucoma and ocular hypertension that were acquired from Merck & Co., Inc., Santen aims to further raise its profile in the Asian market by greatly expanding its product portfolio in the field of glaucoma, and by making a full-scale entry into growth markets through the launch of competitive new pharmaceuticals that meet local needs.



Countries and Regions Undergoing Business Development



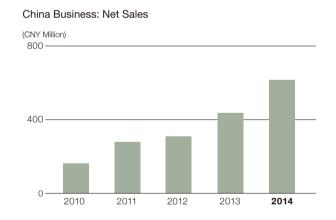
# **Business Development in China**

With the start of integrated production at the Suzhou Plant and the establishment of a new sales company, Santen is now in a position to supply a variety of products that address China's medical needs.

# Strengthening Our Business Platform in China, the Driving Force Behind Growth in the Asian Market

Santen began exporting to China in the 1980s and entered the local market in 1989, launching the anti-infective ophthalmic *Tarivid* (ofloxacin). The Company has steadily added to its product lineup and now markets 10 prescription ophthalmic pharmaceuticals in China, including *Cravit* (levofloxacin), anti-infective eye drops, and *Hyalein* (sodium hyaluronate), a treatment for corneal and conjunctival epithelial disorders.

As in other markets, Santen believes that gaining a competitive edge in China hinges on providing products and services that deliver value to patients, and on offering high-quality drug information. The Company has been bolstering its business platform through integrated production at its Suzhou Plant and through direct marketing. It was in 2005 that the Company established its first Chinese subsidiary, Santen Pharmaceutical (China) Co., Ltd. This was followed in 2007 by the startup of the Suzhou Plant, where the manufacturing environment is on par with that in Santen's domestic plants. In 2012, the Suzhou Plant was licensed for integrated production covering everything from formulation and filling through packaging, creating a system capable of supplying in a timely manner products meeting Chinese market needs. Santen Pharmaceutical (China)



commenced direct marketing in 2009, and now conducts educational and promotional activities using an in-house sales force.

In September 2013, Santen established a second local subsidiary, Santen Pharmaceutical Sales & Marketing (Suzhou) Co., Ltd., to better meet the market's diverse needs. This new subsidiary is seeking certification under China's Good Supply Practice (GSP) guidelines, to support the distribution of imported products. Together with Santen Pharmaceutical (China), which sells in-house products, Santen Pharmaceutical Sales & Marketing (Suzhou) will offer a range of products geared toward China's medical needs, in pursuit of the top market share.

1. On a local currency basis

# Aiming to Contribute Further to Addressing China's Healthcare Needs

Santen Pharmaceutical (China) currently has over 200 MRs, the Company's second-largest sales force after Japan. Over the course of 10 years we have trained our Chinabased MRs to the point where they are now highly regarded by customers for providing information based on local therapeutic needs. Going forward, we will work to strengthen our organizational capabilities with a view to further elevating the caliber of our MRs.

By also enriching our product lineup, we have increased our penetration of the Santen brand in the Chinese market, garnering a particularly large market share among China's urban hospitals. In January 2011 and January 2012, respectively, the Company filed for manufacturing and marketing approval of the glaucoma and ocular hypertension treatment *Tapros* (tafluprost), and the dry eye treatment *Diquas* (diquafosol sodium). We are hopeful that these products will evolve into new growth drivers, helping Santen to capture the No. 1 position in China.

A good deal more growth is forecasted for China's



Rong Weijie Head of Marketing Division Santen Pharmaceutical (China) Co., Ltd.

prescription ophthalmic pharmaceutical market, which is expected to continue growing at around 20% per annum through 2020. Santen Pharmaceutical (China) seeks to grow sales and profits at a rate exceeding growth in the broader market, and to this end is stepping up business development.





# Aiming to Realize World-Class Ophthalmic Treatment as Santen's Contribution Raises Expectations

Of all China's fields of medical practice, ophthalmology can boast of being the second largest. Naturally, there are large numbers of ophthalmologists, and the size of the ophthalmological society is also significant. Ophthalmology has been regarded for decades as being the most advanced field within Chinese medicine, and recent progress has been remarkable. I want to accelerate that progress, and strongly hope that Chinese ophthalmology will grow to become world class. To achieve that, we have been engaged in activities focused on increasing the knowledge of ophthalmologists, training human resources, and conducting international exchanges. Santen's activities for the Chinese Ophthalmology Scholarship Program are extremely useful, and we are deeply grateful.

As an ophthalmologist, I find Santen products to be highly dependable in terms of the quality, efficacy and safety, and I am extremely satisfied with the products. Santen does not merely seek profits, but must be highly regarded for its manufacture and delivery of pharmaceuticals vital for Chinese ophthalmological treatment. Going forward, I expect Santen to continue the high quality activities of developing pharmaceuticals from the viewpoint of Chinese ophthalmological treatment, and improving the quality of life for patients.

## Li Xiaoxin, M.D.

Former President of the Chinese Ophthalmological Society, Director of Ophthalmology Department of People's Hospital of Peking University, Director of Ophthalmic Sciences of Peking University Health Science Center

# Korea, the ASEAN Nations and India



In 2010 Santen Pharmaceutical Korea Co., Ltd. commenced direct marketing. Santen is strengthening its presence in the region by expanding its network of ophthalmologists across Asia.

# Targeting the No. 1 Position in Korea's Prescription Ophthalmic Pharmaceutical Market

Santen Pharmaceutical Korea Co., Ltd. is engaged in the development and sale of prescription ophthalmic pharmaceuticals, with a focus on sales and marketing. The Korean unit began direct marketing in 2010, coinciding with the launch of *Taflotan* (tafluprost, sold as *Tapros* in Japan), the glaucoma and ocular hypertension treatment. Its lineup of ophthalmic drugs now encompasses three therapeutic categories: glaucoma, dry eye, and ocular infection.

Korea's aging population is rapidly growing, and the government views the provision of healthcare as a public service and accordingly is tightening regulations governing drug prices and medical fee reimbursement. However, the medical environment in Korea is highly advanced, and is quick to introduce the latest drugs, treatments and technologies. Pharmaceutical companies must therefore strive constantly to develop the best possible

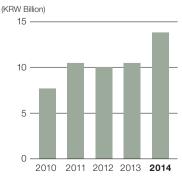


Han-Woong Lee O' Senior Corporate Officer Head of Prescription Pharmaceutical Division Santen Pharmaceutical Korea Co., Ltd.

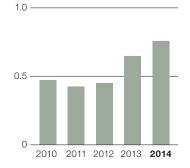
medicines, and provide quality medical information. With the added challenge of competition from generic drug makers, Santen is operating in a challenging market environment.

It is against this backdrop that Santen has set the medium-term goal of becoming No. 1 in Korea's prescription ophthalmic pharmaceutical market. To that end, the Company aims to establish an overwhelming competitive advantage in

Korea Business: Net Sales



ASEAN Nations Business: Net Sales





Dry Eye Leader's Meeting (Held in May 2014 in Seoul, Korea)

the glaucoma field, by pursuing further market penetration for *Taflotan*, and rapidly adding value to the ophthalmology products inherited from Merck, including the glaucoma and ocular hypertension treatment, *Cosopt*. We also think it important to become a leading company in the field of dry eye by achieving rapid market penetration for *Diquas*, launched in October 2013. The Company will also look at diversifying into new domains, taking a proactive approach to developing and licensing products that are outside the fields of glaucoma, dry eye, and ocular infection, and for which there is an identifiable market need.

# Expanding Operations in the ASEAN Nations and India

Santen has positioned Vietnam as a third area of strategic focus after China and Korea. Sales in Vietnam already exceed those in any other ASEAN nations, and in October 2013 Santen opened a representative office in Ho Chi Minh City, to further consolidate its business foundations. In December 2013, the Company also set up a subsidiary in Singapore, Santen Pharmaceutical Asia Pte. Ltd. This new subsidiary is charged with strengthening Santen's business execution capabilities in the ASEAN nations by speeding up approval for manufacturing and marketing and developing products to meet the region's medical needs.

Besides Singapore, the Company is also considering expansion into countries such as Thailand, India, the Philippines, and Malaysia. Santen will steadfastly implement measures designed to realize its goal of becoming the No. 1 ophthalmic company in Asia.



The 28th Asia-Pacific Academy of Ophthalmology (APAO) Congress (Held in January 2013 in Hyderabad, India)



# High Expectations Held for Santen to Conduct Sustained Activities that Help to Improve QOL for Patients in Korea

Santen is a global specialty company in the field of ophthalmology. It contributes to the improving the lives of patients who have ophthalmologic disorders through research and development activities focused on creating high-quality prescription ophthalmic pharmaceuticals such as *Cravit*, *Taflotan*, and *Diquas*. Santen is also helping to advance ophthalmology in Korea by vigorously supporting academic and research activities.

Korea's population is aging at one of the fastest rates in the world. For this reason, the incidence of severe chronic disorders such as glaucoma and retinal disorders is increasing rapidly every year, in addition to external eye diseases, such as dry eye, as a natural consequence of the aging population. Unless these sorts of ophthalmologic disorders are accurately diagnosed and treated at an early stage, patients run the risk of serious deterioration in vision and blindness. Therefore, I believe that we must establish clear guidelines for diagnosis and treatment of ophthalmologic disorders, and explore new treatment methods through continuous research and development activities, in order to safeguard the health of people's eyes and enhance their Quality of Vision (QOV) and Quality of Life (QOL). I believe that this is a common priority shared by all ophthalmologists.

Based on these perspectives, I hold high expectations for Santen to make sustained contributions in areas ranging from the development of innovative new pharmaceuticals devoted to the increasingly specialized field of ophthalmologic disorders, to participation by Korean ophthalmologists in clinical research, and basic research and academic activities.

Man Soo Kim, M.D. President of the Korean Ophthalmological Society, Professor of the Catholic University of Korea

# Santen is working to develop products that meet the unmet medical needs of patients around the world.

Naveed Shams, M.D., Ph.D. Senior Corporate Officer, Chief Scientific Officer, Head of Global Research and Development, President & CEO of Santen Inc.

# Pursuing R&D in Accordance with Santen's Values

Santen is committed to developing innovative medicines that contribute to the improvement of QOL (Quality of Life) of patients around the world. Focusing on developing products in ophthalmology, the Company is creating competitive therapies by selectively channeling resources into three therapeutic categories—corneal and conjunctival epithelial disorders, glaucoma and ocular hypertension, and retinal disorders—as we deem these markets to have high unmet medical needs and strong growth prospects.

The promotion of globally oriented R&D was a strategic objective of the previous medium-term management plan. Under this plan, Santen transformed its R&D structure in order to raise the Proof of Concept<sup>1</sup> success rate and speed up clinical development. In April 2013, we

succeeded in launching a new framework aimed at accelerating global R&D activities. Under this new framework, we are working to enhance strategic planning functions and maximize product value based on treatment needs in each market.

# Product Development to Satisfy the Needs of Patients

Guided by the new medium-term management plan, we aim to enhance the pipeline, raise the probability of success, and boost productivity to shorten development times, for the purpose of rapidly developing differentiated products that satisfy unmet medical needs. To increase the probability of success for late-stage clinical development products, we are promoting "Network Product Development<sup>2</sup>," a best-in-class strategy, and accelerating

Research and Development

Research and Development



translational research<sup>3</sup>. Furthermore, we have drawn up strategies for each therapeutic category where we can leverage Santen's strengths, focusing on dry eye, glaucoma, and retinal diseases. In doing so, we are working to discover and develop differentiated products that fit the treatment needs of patients. Additionally, we aim to maximize the market value of our current portfolio of products through life cycle management<sup>4</sup> using the Company's unique drug formulation technologies. Moreover, we will strengthen collaboration among R&D bases in Japan, the U.S. and Europe, and we will accelerate our global product development.

# **Progress on Global R&D**

We are making steady progress in late-stage clinical development, which we consider essential to achieving sustained growth. For example, the primary endpoint<sup>5</sup> was met in the SAKURA<sup>6</sup> Study 1, the first of two Global Phase 3 studies held at approximately 150 sites across Europe, the U.S. and Asia to evaluate intravitreal injections of sirolimus (development code: DE-109) in patients with non-infectious uveitis of the posterior segment. Also, in

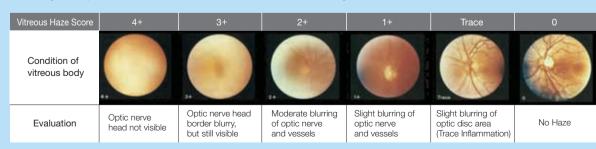
December 2013 the Company filed a European Marketing Authorization Application (MAA) for *Ikervis* (generic name: ciclosporin, development name: Cyclokat), for the treatment of severe dry eye. Currently, there are no prescription treatments for dry eye available in Europe and other do not deliver sufficient treatment satisfaction for patients. We therefore hold high hopes for *Ikervis* as a drug that will fulfil an unmet medical need in the treatment of dry eye disease. In October 2013, we launched the preservative-free and single-dose *Tapros Mini* (tafluprost) in Japan, an achievement made possible by product life cycle management.

In March 2014, TRACON Pharmaceuticals, Inc. and Santen entered into an exclusive agreement for the development and global commercialization of TRACON's anti-endoglin antibodies, including TRC105 (development code: DE-122), in ophthalmology. TRACON's ongoing development of DE-122 in combination with anti-VEGF products in oncology indicate the potential to show advantages over inhibiting VEGF alone in the treatment of conditions such as wet age-related macular degeneration (wet AMD).

By making the most of these accomplishments, we intend to make every effort to rapidly develop differentiated products that satisfy the unmet medical needs of patients worldwide.

Notes:

- 1. Proof of Concept (POC) is the realization of a certain method or idea to demonstrate efficacy or safety in clinical trials.
- An approach of proactively utilizing compounds and technologies available outside the Company in product development.
- Multi-disciplinary research that links basic research, clinical research and medical examinations and utilizes the findings from this for effective and efficient practical applications to contribute to healthcare development.
- Aligning one compound to treatment needs over the long term and augmenting through additional indication, dosage, formulation and combination products to increase product value.
- 5. Main indicator used to evaluate efficacy and safety in clinical trials
- 6. Study Assessing double-masKed Uveitis tReAtment
- Standardization of Uveitis Nomenclature Working Group: A team of specialists charged with standardizing the approach to reporting clinical data in uveitis research.



# Primary Endpoint Met in DE-109 Trial, SAKURA Study 1

Non-infectious uveitis of the posterior segment can cause cloudiness in the vitreous gel that fills the eye, creating what is known as the vitreous haze. The vitreous haze is graded on a photographic vitreous haze grading scheme standardized by the Standardization of Uveitis Nomenclature (SUN) Working Group<sup>7</sup> (where a score of zero means no haze). In SAKURA Study 1, 347 eligible patients were randomized into three treatment arms, each receiving different doses of DE-109. The primary endpoint was the proportion of patients achieving a vitreous haze score of zero at month five. The study met its primary endpoint with statistically significant results.

# **Corneal and Conjunctival Epithelial Disorders**

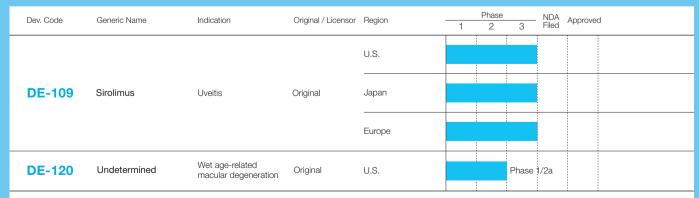


Dev. Code	Generic Name	Indication	Original / Licensor	Region	1	Phase 2	3	NDA Filed	Approved	d
			Korea						Launched, October 2013	
	Merck Sharp &									
DE-089 Diquafosol sodium Dry eye Dohme Corp.	-									
		(U.S.)	(U.S.)	China					January	2012

# Glaucoma

Dev. Code	Generic Name	Indication	Original / Licensor	Region	1	Phase 2	3	NDA Filed	Approve	d
DE-085	Tafluprost	Glaucoma	Co-development	Asia (excluding Japan)						Launched, March 2010
Ocular hypertension with Asahi Glass	China					Januar	2011			
	Tafluprost/	Glaucoma	Co-development	Japan						September 2013
DE-111		with Asahi Glass	Europe					June 2	013	
DE-117	Undetermined	Glaucoma Ocular hypertension	Co-development with Ube Industries	U.S.			Phase	2b		
DE-118	Tafluprost	Glaucoma	Co-development	Japan						Launched, October 2013
DE-110	Tanuprosi	Ocular hypertension	with Asahi Glass	Asia					March	2014
DE-090	Lomerizine HCI	Glaucoma	MSD	Japan						

# Retinal and Uveal Disorders



# Corneal and Conjunctival Epithelial Disorders

# DE-089 (generic name: diquafosol sodium)

A treatment for dry eye that stimulates the ocular surface to secrete mucin and tear fluid, DE-089 offers a different mechanism of action from *Hyalein* (sodium hyaluronate), a treatment for corneal and conjunctival epithelial disorders. DE-089 was launched as a dry eye treatment in Japan under the name *Diquas* in December 2010, and then launched in Korea in October 2013. An NDA has been filed in China.

# Glaucoma

# DE-085 (generic name: tafluprost)

A prostaglandin derivative for the treatment of glaucoma and ocular hypertension, DE-085 increases uveoscleral outflow of the aqueous humor and shows a potent and stable IOP-lowering effect. DE-085 was launched in Japan as *Tapros* in December 2008, and in Germany and some other European countries in 2008. It is also currently marketed in six countries in Asia. An NDA has been filed in China.

# **DE-111** (generic name: tafluprost/timolol maleate)

DE-111 is a combination drug of tafluprost, a prostaglandin derivative and timolol maleate, a beta-adrenergic receptor blocker drug for the treatment of glaucoma and ocular hypertension. Approval for the manufacturing and marketing of the treatment of glaucoma and ocular hypertension was granted in Japan in September 2013, and applications have been filed in Europe.

# DE-117 (generic name: undetermined)

A prostaglandin EP2 agonist with a new mechanism of action. In June 2014, Phase 2b clinical trials started in the U.S.

# DE-118 (generic name: tafluprost)

A prostaglandin derivative for the treatment of glaucoma and ocular hypertension, DE-118 is a preservative-free, unit-dose, single-use type product. It was launched in Japan in October 2013.

# DE-090 (generic name: Iomerizine HCI)

A new type of glaucoma treatment which inhibits the progression of visual field defects, DE-090 is in Phase 2 clinical trials being conducted in Japan. It is the only calcium antagonist being developed as an oral glaucoma treatment. Compared to NMDA receptor antagonists, systematic adverse drug reactions are mild, offering an excellent safety profile. The compound is also marketed by MSD K.K. in Japan as a migraine treatment drug.

# **Retinal and Uveal Disorders**

# DE-109 (generic name: sirolimus)

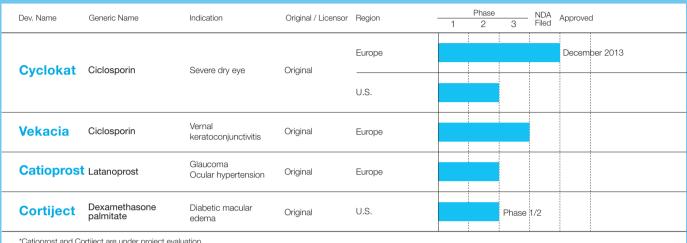
An intravitreal injection with immunoregulatory and anti-angiogenic effects. Phase 3 clinical trials are underway for uveitis in the U.S., Japan and Europe.

# DE-120 (generic name: undetermined)

An intravitreal injection with a dual inhibitor of Vascular Endothelial Growth Factor (VEGF) and Platelet-Derived Growth Factor (PDGF). Phase 1/2a clinical trials started in January 2014 in the U.S.

# Santen S.A.S.'s Pipeline of Prescription Pharmaceuticals

Global product Japan (Asia) product

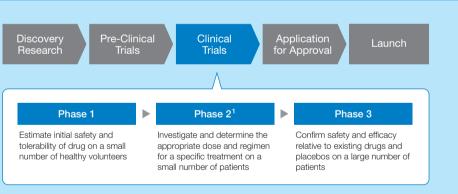


\*Catioprost and Cortiject are under project evaluation

As of August 5, 2014

# **About Research and Development**

After passing pre-clinical trials for safety and efficacy, new drug candidates are put through the clinical trial phases outlined on the right. Upon receiving manufacturing and marketing approval, they can be sold as prescription pharmaceuticals.



1. In the initial stage of Phase 2, POC (Proof of Concept) is tested and safety and efficacy evaluated.

# Santen S.A.S.'s Pipeline of Prescription Pharmaceuticals

# Cyclokat (generic name: ciclosporin)

A topical ophthalmic emulsion which improves signs and symptoms of severe dry eye by immunosuppressive effect. Novasorb technology (cationic emulsion technology) has enhanced ocular tissue absorption. Applications for manufacturing and marketing approval were filed in Europe in December 2013, and Phase 2 clinical trials have been completed in the U.S.

# Vekacia (generic name: ciclosporin)

A topical ophthalmic emulsion which improves vernal keratoconjunctivitis symptoms by immunosuppressive effect. Novasorb technology has enhanced ocular tissue absorption. It is in Phase 3 clinical trials in Europe.

# Catioprost (generic name: latanoprost)

A topical ophthalmic emulsion of a prostaglandin  $F_{2\alpha}$  derivative, for the treatment of glaucoma and ocular hypertension. It is currently under project evaluation.

# Cortiject (generic name: dexamethasone palmitate)

An intravitreal injection with anti-inflammatory effect. It is currently under project evaluation.



# Creation of New Pharmaceutical Carries Hope of Fulfilling Unmet Medical Needs for Orphan Drugs

My relationship with Santen Pharmaceutical Co., Ltd. has spanned over more than 10 years, but became even much closer with the introduction of DE-109 (sirolimus) in 2008. In 2011, Santen employed the data I had accumulated in investigating the role of locally delivered sirolimus in patients with non-infectious uveitis to start the Phase 3 clinical trials of DE-109. It is quite challenging for an ophthalmologist to advance independently on development of an orphan drug, but the fruitful collaboration with Santen has enabled this project to take significant steps forward.

Uveitis is a vision-robbing disease that, if not managed properly, could lead to serious complications including cataracts, glaucoma and other optic neuropathy, maculopathy, retinopathy, among others, and eventual total blindness in some cases. Current uveitis treatment choices are limited to such means as systemic steroid therapy and immunosuppressive therapy, which causes many patients to worry about significant side effects. I wish to improve the mental, social, and physical burden on patients who are on systemic therapy, and have great hope and expectations for local therapy using DE-109 to be effective across a large and protean spectrum of patients and diseases. Initial results of Study 1 in the phase 3 clinical trials were presented at the World Ophthalmology Congress in April 2014, and were very promising. Thus, I truly hope that the development of DE-109 will continue to make steady progress.

# Quan Dong Nguyen, M.D., M.Sc.

Professor and Chair of Ophthalmology McGaw Memorial Endowed Chair in Ophthalmology Inaugural Director of the Stanley M. Truhlsen Eye Institute University of Nebraska Medical Center

# [Domestic Operations] Delivering Needed Pharmaceuticals to Patients and Their Loved Ones

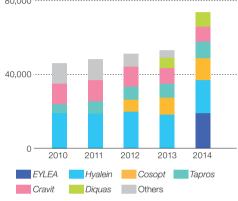
# **Prescription Ophthalmic Pharmaceuticals**

Fiscal 2013 Sales

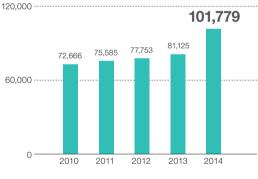
# ¥101,779million+25.5%

The Japanese prescription ophthalmic pharmaceuticals market grew 10.2%, to ¥301,339 million in fiscal 2013, due to growth in sales of products for retinal disorders and corneal and conjunctival epithelial disorders. Santen's domestic prescription ophthalmic pharmaceutical sales increased 25.5%, to ¥101,779 million. This increase was due to our advancement of promotional activities in which our MRs provided individual doctors and medical facilities with scientific information tailored to their changing needs. Based on these results, Santen maintained its top share of the domestic prescription ophthalmic pharmaceutical market, which currently stands at 39.4%.

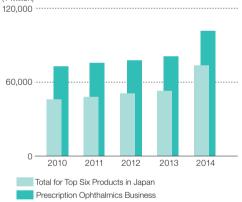




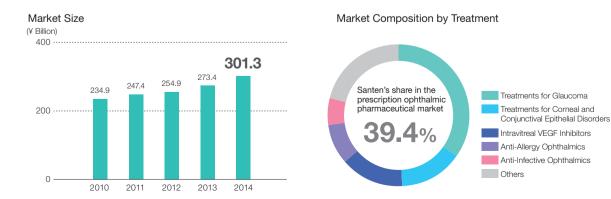
Sales of Prescription Ophthalmic Pharmaceuticals



Sales of Top Six Products in Japanese Prescription Ophthalmics Business (Y Million)



# **Prescription Ophthalmic Pharmaceutical Market Trends**



# Treatments for Corneal and Conjunctival Epithelial Disorders

# **Market Trends**

The market for corneal and conjunctival epithelial disorder treatments associated with dry eye expanded 11.5%, to ¥44,201 million, in fiscal 2013. Dry eye is a disorder caused by inadequate tear fluid volume or a change in tear fluid composition that can result in corneal damage. Proper treatment is dependent upon proper diagnosis through regular consultations with an ophthalmologist. As this disorder is not widely recognized, many patients with obvious symptoms do not receive medical treatment. In addition, the number of people suffering from dry eye is trending upward with increased use of digital devices, increased use of contact lenses and the aging of Japan's population. Based on the aforementioned, the market is expected to continue growing.

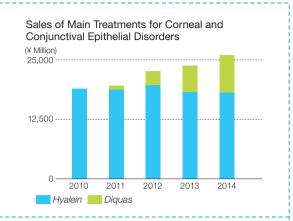
# **Operating Results**

In fiscal 2013, sales of *Hyalein*, a key Santen product, decreased 0.5% year on year to ¥18,178 million, but were robust due to Santen's aggressive dry eye awareness campaign targeting patients and medical professionals. Sales of *Diquas*, which was launched in December 2010, grew sharply by 40.8%, to ¥7,831 million. Santen maintained a firm 70.5% share of the



Treatments for Corneal and Conjunctival Epithelial Disorders Market Share

corneal and conjunctival epithelial disorder treatment market. This good market share was attributable to Santen providing more options for treating dry eye, for which there are high unmet medical needs. Santen plans to continue promoting a greater understanding toward the diagnosis and treatment of dry eye. In strongly advocating that new patients—there are estimated to be at least 8 million in



# Hyalein (Launched in 1995)

*Hyalein* was Japan's first corneal and conjunctival epithelial disorder treatment. It is a highly water-retentive ophthalmic solution that increases tear film stability. *Hyalein* accelerates corneal epithelial bonding and migration, which in turn helps repair corneal epithelial damage.



# Diquas (Launched in 2010)

*Diquas* is the first approved P2Y<sub>2</sub> receptor agonist in the world to be formulated as an ophthalmic pharmaceutical and has a new mechanism of action for the treatment of dry eye. *Diquas* promotes the secretion of mucin<sup>1</sup> and tear fluid, helping to heal damage to the ocular surface by improving the condition of tears.



1. The surface of the cornea contains an aqueous layer and a mucin layer containing complex glycoproteins.

Japan alone—and existing patients consult their doctors to receive proper and continuous treatment, Santen will link efforts to further enhance awareness toward the treatment of dry eye with aims to strengthen the Company's presence and standing further within the corneal and conjunctival epithelial disorder field.

# TOPICS



Osaka Study press seminar (March 25, 2014 at The Tokyo Station Hotel)

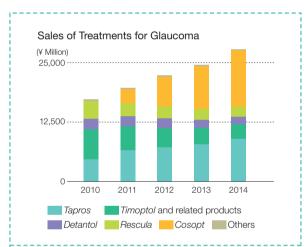
# **Osaka Study Shows Dry Eye Disease Lowers Work Productivity**

In 2011, Santen teamed up with the Dry Eye Society, an organization headed by Dr. Kazuo Tsubota, Professor and Chairperson, Department of Ophthalmology, Keio University School of Medicine, to conduct a large-scale epidemiological study called the Osaka Study, which attempted to assess the status of dry eye among office workers. The study discovered a range of intriguing findings such as: about 65% of office workers were found to actually or potentially suffer from dry eye; business productivity is lower among those with dry eye; and dry eye impacts sleep quality and levels of happiness. Starting autumn 2013, prominent medical journals around the world began to publish the results of the Osaka Study one after another.

# **Treatments for Glaucoma**

# **Market Trends**

The glaucoma treatment market grew 10.5%, to ¥104,725 million. Treatments for glaucoma represent the largest segment of Japan's prescription ophthalmic pharmaceutical market, accounting for approximately 35% of the total. Increased intraocular pressure is a significant risk factor resulting in damage to the optic nerve. This can lead to visual field loss and in some cases blindness. Glaucoma is the most common cause of blindness in people with ophthalmic disease in Japan. According to epidemiological studies, there are a large number of individuals with glaucoma who have not been diagnosed by doctors. A key issue remains early detection and treatment of this disorder. The glaucoma market is expected to expand going forward, mainly due to the increase in patient numbers owing to population aging.



# *Tapros* (Launched in 2008)

Tapros is a prostaglandin-related glaucoma treatment with strong intraocular pressure-reduction properties. It is the first product of its kind to undergo clinical trials as a treatment for normal tension glaucoma, the most common glaucoma disorder among Japanese people.



# Cosopt (Launched in 2010)

*Cosopt* is a leading treatment for glaucoma that combines dorzolamide hydrochloride and timolol maleate, delivering a significant reduction in ocular pressure in a single agent.

# *Mini*, a new preservative-free, unit-dose, single-use formulation. As a result, the Company's share of the glaucoma treatment market was 30.5% in fiscal 2013, as

**Operating Results** In December 2008, Santen

introduced Tapros, which meets the

glaucoma and ocular hypertension.

Reflecting steady market penetra-

tion, Tapros sales grew 17.8% year

on year in fiscal 2013, to ¥8,956

million. In June 2010, Santen

launched Cosopt Combination

Ophthalmic Solution. Sales of this

Santen maintained the top market share.

treatment needs of patients with

In fiscal 2014, Santen will push ahead with efforts to maximize the market value and achieve greater market penetration of mainstay products *Tapros*, *Tapros Mini* and *Cosopt Combination Ophthalmic Solution*. Santen will also continue to highlight the particular benefits of *Rescula* and *Detantol*, while upgrading and expanding its product lineup in the glaucoma field. Looking ahead, we will increase our presence in the glaucoma market by actively providing the latest glaucoma-related information and advice on prescribing pharmaceuticals as well as medical information that meets the needs of medical professionals.

product have also climbed significantly to reach ¥11,846

million, up 31.5%. In October 2013, Santen launched Tapros

# **Treatments for Retinal Disorders**

# **Market Trends**

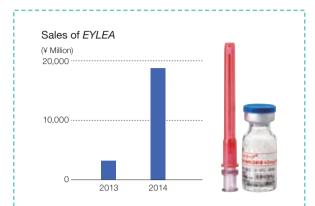
There are unmet medical needs for the field of retinal disorders, including wet age-related macular degeneration (wet AMD), diabetic retinopathy, and macular edema. The Japanese market for retinal disorder treatments has grown at an accelerated pace against the backdrop of the aging of Japan's population and other factors. The market for intravitreal VEGF inhibitors for wet AMD and other disorders expanded 52.6%, to ¥43,188 million, in fiscal 2013.

# **Operating Results**

In November 2012, Santen launched the intravitreal VEGF inhibitor, *EYLEA Solution for Intravitreal Injection*, to meet the need for a new therapeutic option for wet AMD. The sales have grown much faster than we expected to reach ¥18,756 million in fiscal 2013, and our market share in the intravitreal VEGF inhibitor market reached 48.7% in just over a year

30.5% Treatments for

Treatments for Glaucoma Market Share



# EYLEA Solution for Intravitreal Injection (Launched in 2012)

*EYLEA* is an intravitreal injection that inhibits the action of VEGF that is one of the causes of wet AMD. Intravitreal injections of *EYLEA* improve symptoms by suppressing the growth of the new blood vessels.

after the launch. In fiscal 2014 we will continue to vigorously provide high-quality pharmaceutical information, working together with our partner Bayer Yakuhin, Ltd. to penetrate the market further.



Intravitreal VEGF Inhibitors Market Share

# **Anti-Infective Ophthalmics**

# **Market Trends**

The overall scale of the anti-infective ophthalmic market contracted 3.0%, to ¥18,336 million, continuing the declining trend over recent years. One reason is the shortening of the duration of treatment for anti-infective ophthalmic products after cataract and other ocular surgeries.

# **Operating Results**

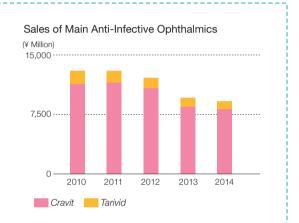
In fiscal 2013, sales of the Company's two key products, *Cravit* and *Tarivid*, declined 4.7% year on year, to ¥9,130 million, due to the market's contraction and the impact of competitor products. Santen's share of the anti-infective ophthalmic market fell to 58.5% year on year. However, the Company continues to maintain a dominant position in this market.

In June 2011, amid strong demand for higher concentration anti-infective ophthalmic pharmaceuticals in step with advances in pharmacokinetics research, Santen launched the higher concentration *Cravit Ophthalmic Solution 1.5%*, which leverages the high solubility of levofloxacin. Clinical trials have confirmed significant efficacy. *Cravit* 



Anti-Infective Ophthalmics Market Share

*Ophthalmic Solution 1.5%* has won high marks in clinical settings since its launch for the early dissipation of major symptoms.



# *Cravit* (Launched in 2000)

*Cravit* is a fluoroquinolone antibacterial agent. Its active ingredient, levofloxacin, is an optically active isomer of ofloxacin, the active ingredient of *Tarivid Ophthalmic Solution. Cravit* offers strong antibacterial properties and intraocular penetration.



# *Tarivid* (Launched in 1987)

*Tarivid* is the world's first fluoroquinolone anti-infective ophthalmic pharmaceutical. It is a synthetic antibacterial drug containing the active ingredient ofloxacin that was developed by Daiichi Sankyo Company, Limited. With a broad spectrum coverage, *Tarivid Ophthalmic Solution* displays strong antibacterial activity.



# Anti-Allergy Ophthalmics

# **Market Trends**

In fiscal 2013, the anti-allergy ophthalmic pharmaceutical market decreased 9.7%, to ¥27,897 million. This was mainly attributable to cedar pollen levels, a major cause of allergic conjunctivitis, which were lower in Japan during the fiscal year under review.

# **Operating Results**

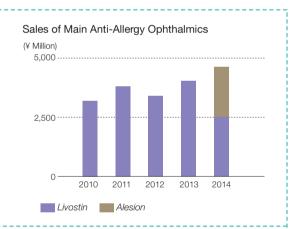
In fiscal 2013, Santen focused on enhancing the market penetration of the mainstay *Livostin* as well as *Alesion*, which was launched in November 2013. As a result, combined sales of the two products increased 14.9%, to ¥4,637 million.

Santen's share of the anti-allergy



Anti-Allergy Ophthalmics Market Share

ophthalmic pharmaceutical market increased to 21.2%.



# *Livostin* (Launched in 2001)



*Livostin* is an H1 blocker ophthalmic solution that has high and selective binding affinity for histamine H1 receptors and a long duration of antihistaminic action.

# Alesion (Launched in 2013)

Alesion is an H1 receptor antagonist with a membrane-stabilizing function used as a treatment for allergic conjunctivitis. It provides relief from eye itching and redness, which are major symptoms of allergic conjunctivitis.

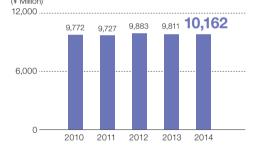
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In fiscal 2014, we will make full use of the strengths of *Livostin* and *Alesion* in being able to provide new treatment options. They provide relief from year-round and seasonal allergy symptoms such as itching and redness and thus contribute to an improved patient's QOL. By continuing to emphasize these product characteristics, we aim to expand both sales and market share of these products.

# Prescription Anti-Rheumatic Pharmaceuticals

Fiscal 2013 Sales ¥10,162 million +3.6%

Sales of Prescription Anti-Rheumatic Pharmaceuticals



# **Market Trends**

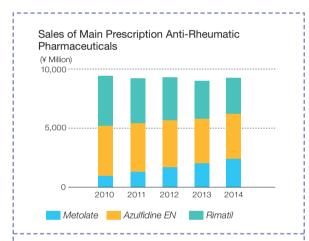
The Japanese market for disease-modifying anti-rheumatic drugs (DMARDs)<sup>1</sup> expanded 5.5% year on year, to ¥28,748 million. Although the causes of rheumatoid arthritis (RA) are yet to be fully identified, it has the appearance of an immune disorder that causes inflammation in the joints and pain and swelling. It is estimated that there are approximately 700,000 people with RA in Japan today. The number of RA patients is expected to rise in the future in line with the nation's aging population. The overall size of the market is also projected to increase for this reason.

 A class of medicines that are used not only to alleviate symptoms but also to treat the causes of disease. The anti-rheumatic effect works by calming inflammation through the correction of immune abnormalities, which are considered a cause of RA.

# **Operating Results**

*Rimatil, Azulfidine EN* and *Metolate* are all recommended in the Rheumatoid Arthritis Treatment Guidelines, and recently there are many cases of them being prescribed in combination treatments. As a result, fiscal 2013 sales of prescription anti-rheumatic pharmaceuticals increased 3.6% compared with the previous fiscal year, to ¥10,162 million. Santen continues to maintain its position as leader of the traditional DMARDs market, excluding biological drugs (biologics), with a 38.4% share.

The introduction of biologics has brought about a significant change in the market environment for RA treatments. The treatment goal has now become achieving remission close to a cure. However, this goal cannot be achieved only with biologics, meaning that traditional DMARDs have an important role to play. *Rimatil* and *Azulfidine EN* are the first-choice drugs for the early treatment of RA, and are used in combination with methotrexate drug formulations and as a controller medication for low disease activity. Meanwhile, *Metolate* is a first-choice drug for patients with high activity and plays a central role in treating rheumatism. Santen will therefore work hard to achieve greater penetration of these three drugs, so as to contribute to even higher QOL for patients.



#### *Rimatil* (Launched in 1987) *Azulficine EN* (Launched in 1995)

Rimatil and Azulfidine EN are standard treatments for RA. These products help improve symptoms as well as the QOL of many patients.



#### Metolate (Launched in 2004)

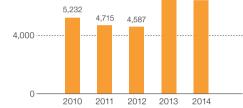
Metolate is a methotrexate drug formulation that plays a central role in the treatment of RA. Offering the improved dividing property of a scored tablet, Metolate has received positive acclaim for its ease of consumption.



(¥ Million)

8 000

Fiscal 2013 Sales



6,459 6,418

¥6,418 million -0.6%

Sales of Over-the-Counter Pharmaceuticals

**Over-the-Counter Pharmaceuticals** 

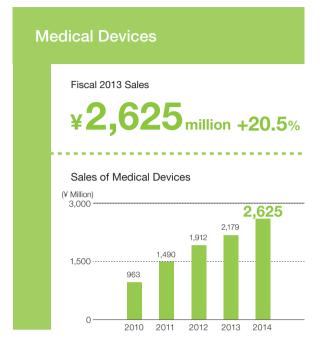
#### **Market Trends**

In fiscal 2013, the OTC pharmaceuticals market contracted 3.1% year on year, to ¥56,007 million, partially due to declining demand.

#### **Operating Results**

The Company's OTC business is centered on a range of ophthalmic products, including the *Sante FX* series, one of Japan's top-selling ophthalmic solution brands, and the *Sante 40* series, which is highly effective in improving blurred vision. In fiscal 2013, OTC pharmaceutical sales declined by 0.6%, to ¥6,418 million, despite a focus on promotional campaigns, particularly for the *Sante FX* series and the *Sante Medical* series. With fierce competition set to continue in the market, Santen will aim to carve out new markets and grow sales by vigorously implementing promotional campaigns, particularly for *Sante Beautéye* and *Sante PC*, both of which were launched in fiscal 2013.





#### **Market Trends**

Santen's medical device business specializes in intraocular lenses (IOLs) in the cataract surgery field. In recent years, demand for IOLs has shifted primarily to foldable lenses that can be inserted through a small incision.

#### **Operating Results**

Since 2008, Santen has been selling the Eternity series of foldable IOLs, which are made of a new glistening-free hydrophobic acrylic material manufactured by Advanced Vision Science, Inc., a U.S. subsidiary of Santen. Thereafter, Santen has worked to enhance its lineup of products. In 2009, the Company launched Eternity Natural, an IOL that blocks harmful light known to damage retina. Then in 2011, Santen launched Accuject, an injector that achieves a smaller incision size. In 2013, the Company launched Eternity Natural Uni, a novel IOL with an original design. Thanks to greater market penetration based on product development aimed at making surgery easier for physicians and patients, sales of medical devices were up 20.5%, to ¥2,625 million in fiscal 2013. Santen will continue to target growth in its medical device business by leveraging its strengths in the Eternity series product concept of "highquality IOLs with outstanding transparency."

#### [Overseas Operations]



Aiming to become a specialized pharmaceutical company with a global presence, Santen is accelerating the development of overseas operations. In Europe, Santen achieved market penetration of its new treatment for glaucoma and ocular hypertension, *Taflotan* (tafluprost, sold as *Tapros* in Japan) as a result of concentrating on promotion activities such as providing pharmaceutical information. In Asia, Santen grew sales in China and increased market share in Korea. As a result, on a yen basis, overseas sales of prescription ophthalmic pharmaceuticals increased 43.5%, to ¥25,617 million (up 28.9% to ¥23,011 million on a 12-month basis). This included an impact of ¥2,606 million due to unification of the accounting period. Overall, overseas sales rose 44.6% to ¥26,550 (up 30.4% to ¥23,932 million on a 12-month basis).



#### Europe

The European market for prescription ophthalmic pharmaceuticals has been growing at an annual rate of approximately 8% (monetary basis), supported by a combination of rising numbers of patients diagnosed with glaucoma and dry eye syndrome as well as increasing economic prosperity in Eastern Europe and Russia. At the same time, the European market is characterized by its diversity—each country in the region has a different health insurance system and different medical treatment practices. Under these circumstances, the Company is engaging in sales and marketing activities that capture the specific characteristics of each country.

Review of Operations

Santen is advancing its sales and marketing activities in over 30 European countries, including Russia, Germany and countries in Northern and Eastern Europe. The anti-infective ophthalmic solution *Oftaquix* (levofloxacin, sold as *Cravit* in Japan) has gained an excellent reputation for preventing and healing eye infections and is now available in 27 countries. Additionally, Santen has already obtained approval for *Taflotan*, a treatment for glaucoma and ocular hypertension, in at least 40 countries throughout Europe. Currently, we market this product directly in 24 countries including Germany. Following Santen's acquisition of the ophthalmology products of U.S.-based Merck & Co., Inc., the Company will work to expand business to 56 countries throughout Europe, including Western Europe, an area in which Santen previously did not have a sales platform.

The Company's subsidiary in Finland, Santen Oy, manufactures pharmaceuticals for the European and the U.S. markets at its Tampere Plant, and is one of Santen's global R&D bases.

#### Asia

The Company's vision for the Asian market is to become the top specialized ophthalmic pharmaceutical company. Accordingly, Santen is striving to enhance long-term relationships with patients and medical professionals, thereby contributing to the improvement of ophthalmic treatment in the region. Santen is conducting business in China, Korea and the ASEAN nations guided by this vision.

Santen began exporting to China, which is driving growth

Santen

in Asia, in the 1980s and since then has established the Santen brand in this market. In 2005, the Company established Santen Pharmaceutical (China) Co., Ltd., which commenced operations at the Suzhou Plant in 2008 and began marketing using its own MRs in 2009. Santen Pharmaceutical (China) is currently providing pharmaceutical information through its own MRs in 305 cities across 31 provinces, mainly focusing on China's major metropolitan cities, and selling prescription ophthalmic pharmaceutical products including *Cravit* (levofloxacin), anti-infective eye drops, and *Hyalein* (sodium hyaluronate), a corneal and conjunctival epithelial disorder treatment.

Also, Santen is working to increase market awareness and penetration of the Santen brand in the Korean and ASEAN markets through Santen Pharmaceutical Korea Co., Ltd. in conjunction with local distributors and agents. Taflotan, a glaucoma and ocular hypertension treatment, and Diguas, a dry eye treatment, were launched in Korea in May 2010 and October 2013, respectively. Meanwhile, Santen has commenced direct marketing through Santen Pharmaceutical Korea and is providing pharmaceutical information on ophthalmic disease through its own MRs. In 2012, approval was obtained for integrated production operations covering everything from formulation and filling through packaging at the Suzhou Plant, and in September 2013, Santen established a second local subsidiary, Santen Pharmaceutical Sales & Marketing (Suzhou) Co., Ltd., and has been working to expand the lineup of products handled. In December 2013, Santen established a local subsidiary in Singapore and is strengthening its strategies for becoming No. 1 in Asia in the field of ophthalmic treatment.

### TOPICS

### Supported the 34th World Ophthalmology Congress "WOC2014 TOKYO" as a Diamond Partner–Held in Japan for the First Time in 36 Years

dNto

WOC2014 TOKYO was held in April 2014 in Tokyo. The congress was attended by approximately 20,000 members, the highest attendance to date, and will be remembered for disseminating a large amount of state-of-the-art ophthalmic medical knowledge and technologies. Santen saw its presence at

> the event increase significantly as its 10 sponsored seminars drew a greater-than-anticipated cumulative attendance of some 5,000 participants. In one of the largest exhibition booths in the hall, a Paper Airplane Project was held, where a multitude of paper airplanes folded by colleagues including congress participants and Santen employees were used to complete a large paper airplane artwork featuring dreams for the future. For Santen, the dreams we have shared with the congress participants through WOC2014 TOKYO are also our motivation for realizing our long-term strategic vision.

#### **CSR Integrated into Business Conduct**

Santen's Values—*"Tenki ni sanyo suru"*—embody what the Company has continued to recognize as important over 120 years since its foundation in 1890. Our mission is to benefit patients and their loved ones, and thereby contribute to society, by always pursuing creation and innovation.

To ensure that all business activities are consistent with our company values and mission, we have established "Organizational Principles" to articulate the ideal state of our organization and "Individual Action Principles" to guide how employees should act and behave. To provide more specific action guidelines, we also formulated the "Santen Code of Practice," which comprises "Declaration of Corporate Behavior" and "Code of Conduct." Focusing on the three perspectives of "customer trust," "employee responsibility and growth" and "harmonization with society," the Santen Code of Practice requires employees not only to comply with all applicable laws and regulations, but also to observe the highest standards of ethics and integrity in their conduct. We are working to disseminate and promote adherence to Santen Code of Practice throughout the Group.

As its long-term strategic vision through 2020, Santen aims to become a specialized pharmaceutical company with a global presence. To achieve this aim, Santen formulated the new medium-term management plan, which is guiding the development of our business activities. Our basic policy is to continue contributing to the improvement of QOL (Quality of Life) of patients around the world by providing valuable products and services and conducting business activities consistent with Santen's Values.

We believe that by conducting business activities and CSR activities in an integrated and continuous manner, we can contribute to a sustainable society and environment, leading to the realization of our long-term strategic vision.

Guided by Santen's Values —"Tenki ni sanyo suru"—Santen continues to help enrich QOL (Quality of Life) of patients around the world through the provision of valuable products and services via its business activities.

#### 7 Core Subjects of CSR

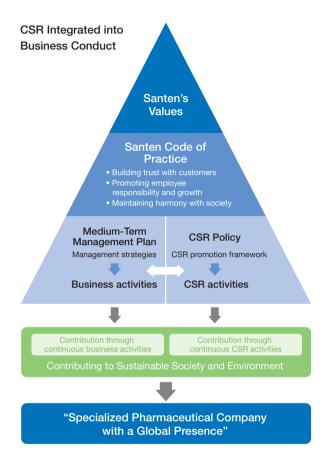
Santen considers it essential to integrate CSR into its management strategies, and to practice CSR as part of its business operations. In line with this, on the basis of Santen's Values and the three perspectives of "customers," "employees" and "society" stated in the Santen Code of Practice, as well as the core subjects of ISO 26000<sup>1</sup>, we defined 7 Core Subjects of CSR, for each of which a basic policy has been established. We also developed a conceptual framework for CSR initiatives that gives an overview of the CSR issues that we will address.

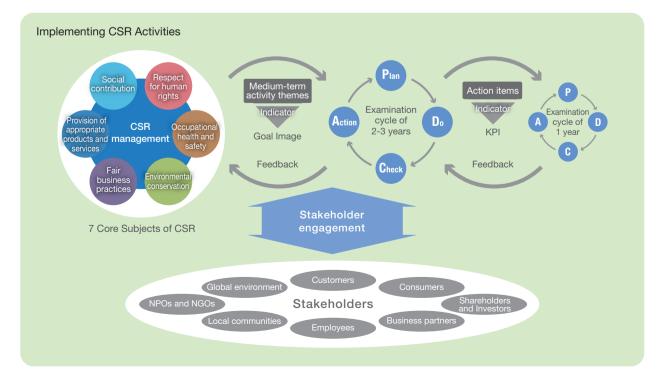
Furthermore, Santen receives various opinions from the dialogue it conducts with stakeholders defined in 7 Core Subjects of CSR. Santen believes that it is important to use evaluations of its CSR activities in examining how future activities should be implemented in order to raise the level of those activities.

 ISO 26000 was issued by the International Organization for Standardization (ISO) to provide guidance on social responsibility. It is applicable not only to corporations but also to all organizations, including governments, schools, and NGOs.

#### **CSR Management**

For each of the 7 Core Subjects of CSR, we have defined medium-term activity themes and specific action items to be carried out. We strive to implement the medium-term activity themes and action items through the steady operation of the Plan-Do-Check-Action (PDCA) cycle both in the short- and medium-term time frame. Based on the state of progress of these activities and any changes in the activities' environment, we will set the goals of each of our medium-term activity themes, and we will define key performance indicators (KPIs) for each action item, to improve and enhance our CSR activities.





#### Provision of Appropriate Products and Services

#### **Developing and Providing Appropriate Products**

The Quality Compliance Division is deeply involved in such wide-ranging processes as product research and development, manufacture and sales. In addition to adhering to the Pharmaceutical Affairs Law in Japan, which stipulates strict standards governing pharmaceutical quality control and post-marketing safety supervision, Santen has established a world-class quality assurance system based on its own specifications and standards.

From a manufacturing perspective, Santen maintains a domestic plant network encompassing Noto and Shiga. Overseas, the Company operates plants in Tampere in Finland and Suzhou in China. Collectively, this represents a structure that ensures the stable manufacture of approximately 300 million bottles per year of ophthalmic solutions to patients worldwide.

### Providing Information and Services Related to Products and Disorders

Providing medical professionals with information about indications, side effects, and methods of use is essential to ensuring the safe and proper use of products. Santen accordingly has a sales force of MRs across Japan who provide accurate information in a timely manner. In order to maintain and enhance the quality of this flow of information, we continuously update MR training with specialized education.

Our Customer Service Center deals comprehensively with customer inquiries on a centralized basis, and we channel customer feedback to the product development process to improve our products and enhance our information services.

We also disseminate information through our websites to the public and medical professionals about eye diseases, the proper use of ophthalmic solutions, rheumatoid arthritis, and pharmaceuticals and medical devices.



Information services on the Company's website

http://www.santen.com

#### Fair Business Practices

Santen recognizes that ensuring compliance in business activities is also an important issue. As such, Santen works to foster compliance awareness among employees, to revise its information security measures, to rigorously enforce personal information protection, and to properly operate and refine its internal control system. Moreover, Santen strives to build sound and constructive relationships with business partners.

#### Respect for Human Rights

Santen has formulated a policy on human rights education and action plans, as well as promoting human rights awareness. Specifically, we work to foster an awareness of respect for human rights through training based on rank and position within ordinary training programs, the issuance of news related to human rights, solicitation of human rights slogans and other actions.

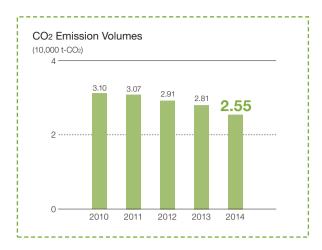
#### Occupational Health and Safety

Based on its CSR policy concerning occupational health and safety, Santen has built a related management system that is customized for the characteristics and scale of each workplace. At each workplace we regularly identify and address hazards inherent at facilities and in workplace practices. In this manner, we implement various measures in order to maintain a safe, clean and comfortable workplace environment while promoting improved employee health.

We are also promoting the employment of people with disabilities. In 1997, we established Claire Co., Ltd., a specified subsidiary, for this purpose. In order to provide a workplace in which people with disabilities can work with vigor and enthusiasm, we consistently improve conditions while encouraging the development of competencies.

#### Environmental Conservation

Santen, recognizing that the nature created by the biodiversity is an essential foundation for the earth's environment, sees the conducting of environmental conservation activities as important management issues based on the theme of handing down a beautiful earth to future generations. As an organization, Santen engages in various environmental issues in order to contribute to the creation of low-carbon society and recycling-oriented society. This is why Santen is building an environmental conservation system that is integrated with its business activities, and is implementing a variety of other environmental initiatives. Moreover, employees engage in voluntary activities to conserve the environment, and promote activities to reduce Santen's environmental load and conserve the earth's natural



environment. All plants in Japan and overseas subsidiary Santen Oy have obtained ISO 14001 environmental management system certification. In fiscal 2013, the Noto Plant received "22nd Reduce Reuse Recycle Assembly Chairperson's Award" in recognition of its initiatives to reduce waste.

Santen assesses its impact on the environment in terms of inputs and outputs. The former refers to the input of energy, materials and water resources associated with business activities, while the latter refers to emissions into the air and water of industrial waste. Furthermore, Santen assesses costs related to environmental conservation measures (investments and expenses) and benefits (economic and environmental preservation effects) with reference to the Environmental

Accounting Guideline (2005) issued by the Ministry of the Environment and continuously implements measures to reduce its environmental load.



22nd Reduce Reuse Recycle Assembly Chairperson's Award Ceremony

#### Social Contribution

Santen engages in social contribution activities centered on medical care and welfare connected with its business domains and on local communities.

In the medical care and welfare fields, Santen continuously donates to a number of organizations including Helen Keller International, an NGO that is devoted to fighting and treating preventable blindness in developing countries, as well as the Japan Eye Bank Association and the Japan National Society for the Prevention of Blindness. Furthermore, a joint lecture program was formed with the Nara Institute of Science and Technology to develop personnel who will advance leading-edge science and technology in the future. In this program, researchers from the Nara Research and Development Center instruct students at research facilities. We also support the Chinese Ophthalmology Scholarship Program in China and the Ophthalmology Training Fund in Korea in support of the education of ophthalmologists. Furthermore, we work together with a support group for visually impaired people so that our employees can act as volunteers when needed, for example when the group holds special events.

In addition, Santen contributes to local communities through concerted efforts to implement clean-up activities and promote the greening of the areas surrounding its headquarters, research facilities, manufacturing plants, and other main business sites while actively participating in crime prevention campaigns.

We also make donations, provide free supplies of pharmaceuticals and other items, and engage in other activities as a corporate citizen in response to relief efforts for large-scale disasters.

Raising awareness of children and their families about keeping eyes healthy in conjunction with Benesse's *Kodomo Challenge* program

From April 2013, Santen has been working to raise the awareness of children and their families about the importance of keeping eyes healthy. We have been doing this in conjunction with *Kodomo Challenge*, which is an educational correspondence course for children conducted by Benesse Corporation. As the main activities of this initiative, we distributed an "Eyecare kit" with a booklet and a poster to about 700,000 members of *Kodomo Challenge* in the June 2013 issue, and provided the following three pieces of information.

- Information about how children can look after the health of their eyes by developing good lifestyle habits and by the correct use of digital devices
- 2) Information related to the early-stage discovery of amblyopia in children aged 3-4
- Information for families about the dry eye condition and methods of caring for one's eyes

In addition to distributing booklets to about 36,000 kindergartens and nursery schools across Japan, we have distributed posters and leaflets to about 9,000 ophthalmic medical institutions.



Please refer to Santen's Corporate Social Responsibility (CSR) section on the Company's website for details.

http://www.santen.com/en/csr

## Corporate Governance

#### **Basic Policy**

Santen recognizes that it is vital to upgrade and strengthen corporate governance systems in order to achieve and enhance corporate value, and thus returns to shareholders. Accordingly, Santen is working to raise business performance while maintaining transparent and sound management practices through the development of effective corporate governance systems.

Santen has already taken some specific steps such as appointing several outside directors to strengthen management supervision; establishing the Corporate Strategy Committee, the Nominating Committee and the Executive Compensation Committee, which are all voluntary committees made up of inside and outside directors; and introducing a corporate officer system to strengthen management and improve the speed of business execution. Santen will continue to strengthen corporate governance further going forward to improve management transparency and objectivity.

Santen has adopted a "Company with Auditors" system as defined in Japan's Companies Act. Santen has enhanced the functions of the corporate auditors by setting up a Corporate Auditor's Group with staff dedicated to assisting with the duties of the corporate auditors, and by promoting collaboration with the Internal Auditing Group and Accounting Auditors, among other measures.

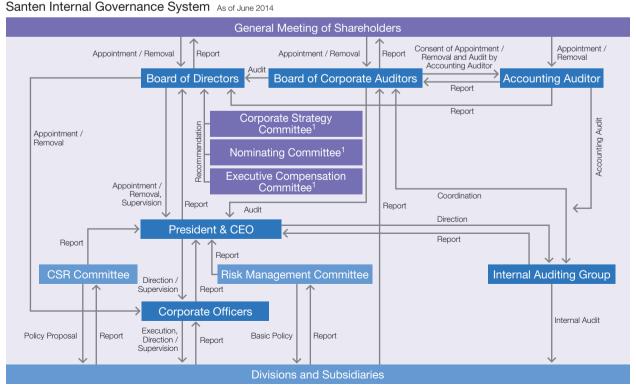
#### Governance Systems

#### Board of Directors

In addition to various statutory functions, the Board of Directors formulates management policies, strategies, and business plans for Santen. The Board of Directors makes decisions relating to the acquisition or disposal of major financial assets and important organizational or personnel-related matters, and also oversees the execution of business at Santen and its subsidiaries. The Board convenes once a month in principle. As of June 2014, the Board comprised five members including three outside directors. The Board of Directors convened 13 times during fiscal 2013.

#### Board of Corporate Auditors

The Board of Corporate Auditors consists of four members, including three outside corporate auditors. Corporate auditors formulate auditing policies and plans, and attend meetings of the Board of Directors and other important business meetings. In addition, corporate auditors audit the execution of duties by directors through overseeing the operational and financial status of Santen's headquarters, major operating sites, and subsidiaries. The Board of Corporate Auditors convened 10 times during fiscal 2013.



1. These committees are voluntary and not part of any statutory "Company with Committees" system under the Japanese Companies Act.

Corporate Governance

#### Voluntary Committees

Santen has established the following three committees composed of inside and outside directors as deliberative bodies to further strengthen corporate governance and to improve management transparency and objectivity. Note that these committees are not part of any statutory "Company with Committees" system under the Japanese Companies Act.

0		
Committee	Role	Members
Corporate Strategy Committee	The Corporate Strategy Committee deliberates on key strategic issues such as business strategies.	All directors
Nominating Committee	The Nominating Committee deliberates on the selection of candidates for directors and submits recommendations to the Board of Directors, and also deliberates on the selection of candidates for corporate officers and corporate auditors and submits recommendations to the Board of Directors.	President and outside directors
Executive Compensation Committee	The Executive Compensation Committee deliberates on the compensation of directors and corporate officers and submits recommendations to the Board of Directors. It also provides the Board of Corporate Auditors with information and advice on such matters as the compensa- tion level for corporate auditors.	President and outside directors

#### Corporate Officer System

Santen has introduced a corporate officer system to strengthen management while improving the quality and speed of strategic decision-making processes. There were 13 corporate officers as of June 2014, excluding some serving concurrently as directors.

### Relationships between the Outside Directors and Outside Corporate Auditors and the Company

In selecting outside directors and outside corporate auditors, Santen applies the independence standards of stock exchanges in Japan, in addition to its own internal standards. Specifically, Santen specifies standards deemed to generally ensure independence in terms of relationships with the Santen Group (duties, transactions, stockholding, etc.) and decides on candidates after evaluating them in accordance with these standards.

None of the three outside directors or three outside corporate auditors are appointees from Santen's subsidiaries or affiliates, major shareholders or leading business partners. Each maintains a degree of independence to avoid conflicts of interest with ordinary shareholders. Outside director Akihiro Okumura is Professor Emeritus of Keio University, with which Santen conducts joint research and has other dealings, and to which it also makes donations. However, these activities are medical related and are not related to management studies, Okumura's area of specialization.

### Reasons for Selection of Outside Directors and Outside Corporate Auditors

Noboru Kotani Outside Director	Noboru Kotani has extensive knowledge and experience in corporate management as a management consultant, and will be able to reflect this knowledge and experience in the Company's management.
Akihiro Okumura Outside Director	Akihiro Okumura has extensive knowledge and experience amassed through the long years of his professorship of business administration at the undergraduate and graduate schools of several universities, and will be able to reflect this knowledge and experience in the Company's management.
<b>Takayuki Katayama</b> Outside Director	Takayuki Katayama has extensive knowledge and experience amassed through long years of involvement in management in the country and overseas, and will be able to reflect his knowledge and experience in the Company's management.
Yasuaki Tsuchiya Outside Corporate Auditor	Yasuaki Tsuchiya has a global perspective amassed through his managerial experience in an American-affiliated company and expertise as a corporate auditor of a listed company, and will be able to reflect his perspective and expertise in auditing the Company.
Yutaka Mizuno Outside Corporate Auditor	Yutaka Mizuno has extensive knowledge and experience amassed through long years of involvement in management in the country and overseas, and will be able to reflect his knowledge and experience in auditing the Company.
Koichi Matsuzawa Outside Corporate Auditor	Koichi Matsuzawa has extensive knowledge and experience amassed through long years of involvement in management in the country and overseas, and will be able to reflect his knowledge and experience in auditing the Company.

#### Directors' and Corporate Auditors' Compensation

Position	Total	Tot	No. of			
		Basic Compensation (Annual)	Stock Compensation- Type Stock Options	Bonus	Retirement Benefits	Eligible People
Directors (Excl. Outside Directors)	165	116	45	-	2	3
Corporate Auditors (Excl. Outside Corporate Auditors)	25	25	_	_	_	1
Outside Directors and Outside Corporate Auditors	63	63	_	_	-	6

Note: In addition to the above, the Company paid ¥45 million in retirement and severance benefits for directors to one director based on a resolution of the Annual General Meeting of Shareholders held on June 25, 2013. This amount includes accrued retirement and severance benefits for directors from prior years. As of June 2013, the retirement benefit program was abolished.

Please refer to Santen's Corporate Governance Report (Japanese only) posted on the Company's website for details. http://www.santen.co.jp

### Cooperation between Corporate Auditors and Accounting Auditors

The corporate auditors hold a meeting with the accounting auditors at the beginning of each fiscal year to receive presentations on the financial auditing plans for the year and any key audit-related issues as well as to exchange opinions, including requests from the corporate auditors. The accounting auditors present audit findings to the corporate auditors at meetings three times a year to exchange opinions.

In addition, the corporate auditors attend an audit review meeting with the accounting auditors after the conclusion of the quarterly and year-end audit reviews to exchange opinions on audit results and procedures. During the fiscal year, the corporate auditors perform audits of the auditing methods of the accounting auditors and exchange information with the accounting auditors as necessary.

### Cooperation between Corporate Auditors and the Internal Auditing Group

Corporate auditors and the Internal Auditing Group cooperate closely at all times. For instance, they hold regular meetings at which they share progress with their respective audit plans and audits, and new points to be aware of, while also simultaneously visiting business sites and subsidiaries to conduct audits as necessary.

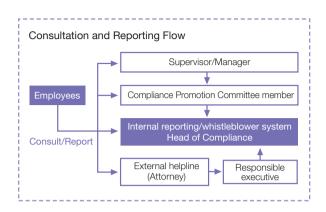
#### Compliance

#### Internal Governance System

Santen benefits society through its business activities, with a particular focus on contributing to patients and their loved ones—which incorporates *"Tenki ni sanyo suru"* that is in the Santen's Values—as a company active in the pharmaceutical industry. At the same time, aiming to heighten society's recognition of our value to society and achieve sustainable growth, we are developing the following internal control systems.

Our compliance system, the Santen Code of Practice, which was formulated in December 1999 and revised in line with changing social conditions, consists of the Declaration of Corporate Behavior and the Code of Conduct that defines strict ethical standards governing corporate activities. The Santen Code of Practice stipulates that the Company will not respond to any demands whatsoever made by antisocial forces that threaten the order and stability of civil society.

In addition, we have appointed a director and department responsible for internal governance, and established the CSR Committee to ensure rigorous compliance. Further, we maintain an internal system for compliance-related inquiries and an external helpline to an independent attorney, which



enables employees to report any suspected compliance violations directly or to receive compliance-related advice.

Santen aims to increase the appropriateness of Santen's operations by building a control system in which the Company provides recommendations and guidance on increasing appropriateness, developing regulations for the control of Group companies to clarify their roles and responsibilities, and strengthening audit functions at major Group companies.

As a department independent from operating divisions, the Internal Auditing Group—comprised of four people including the general manager—verifies that the above internal control systems work efficiently. The Internal Auditing Group reports directly to the president of Santen.

Regarding internal control related to the reliability of financial reports, Santen has established a system whereby divisions and principal subsidiaries check the appropriateness of their systems, while the Internal Auditing Group checks the suitability of these self-checks. In fiscal 2013, Santen did not discover any significant deficiencies or omissions that could undermine the reliability of its financial reports. Santen will continue to develop and maintain systems that consistently meet the requirements of the internal control reporting system, which is based on Japan's Financial Instruments and Exchange Act.

#### **Guidelines Concerning Transparency**

Santen has established "Guidelines Concerning Transparent Relations with Medical Institutions, etc." and "Guidelines Concerning Relations with Patient Groups" in accordance with various rules and regulations, including "Transparency Guideline for the Relation between Corporate Activities and Medical Institutions" and "Transparency Guideline for the Relation between Corporate Activities and Patient Groups" issued by the Japan Pharmaceutical Manufacturers Association. Information on the provision of funds and other related matters is made widely available to the public via the Company's website.

Please refer to Santen's Guidelines Concerning Transparency (Japanese only) posted on the Company's website for details. http://www.santen.co.jp

#### **Risk Management**

#### **Risk Management Promotion Framework**

Santen has built a system for responding appropriately to major risks related to its business activities, which is based on a Risk Management Procedure Manual that sets out basic policies and a code of conduct for crisis management. Operating divisions and headquarters avoid or minimize risk by routinely gathering information and preparing risk management policies and countermeasures for their operations. Further, the Risk Evaluation Committee discusses risk management policies and countermeasures for significant risks that transcend several divisions. An emergency situation affecting Santen beyond a certain level triggers the operation of the Crisis Response Committee headed by a representative director. Based on Santen's Risk Management Procedure Manual, the committee coordinates efforts to minimize any losses or damages and ensure a quick recovery, and institutes measures to prevent a recurrence. As regards the status of such risk management efforts, the Company has a permanent secretariat in place with designated executives. The secretariat checks the status of risk management efforts from a Companywide viewpoint, while the Internal Auditing Group examines them from an independent standpoint.

#### **Business Continuity Management**

Medicines are high-priority necessities for people affected by natural disasters or other emergencies. Santen believes it is essential to maintain supplies of drugs to patients and healthcare workers in affected areas. To this end, Santen has analyzed business continuity-related risks, clarified policies and identified those areas critical to maintaining product supplies. Detailed plans have been formulated to guide the response to an emergency, including the necessary organizational actions. To ensure systems will work, business continuity and disaster preparedness planning and activities are also part of the PDCA<sup>1</sup>-based management cycle.

1. A method to facilitate the smooth management of business activities through a P (Plan), D (Do), C (Check) and A (Action) business activity cycle.

#### Information Security

Regarding information control systems, Santen safely stores and controls information based on in-house rules such as for basic information security and document control. Furthermore, Santen has established personal information protection guidelines and a compliance program regarding personal information protection, which are explained to corporate officers and employees at training events. The Company also works to ensure that they are working properly.



#### Information Disclosure

#### **Investor Relations Activities**

Santen's basic policy is to ensure swift, accurate and fair disclosure of corporate information, taking the viewpoint of shareholders and investors. Under this policy, Santen strives to actively provide disclosure of information in an easy-tounderstand manner.

Santen holds financial results meeting presentations after the release of interim and full-year results for analysts and institutional investors, and also conducts conference calls for them after its first- and third-quarter results are announced. Furthermore, Santen participates in conferences hosted by securities companies around the world and visits overseas shareholders and investors. Moreover, Santen conducts presentations for individual investors and other events such as small meetings, with the aim of explaining corporate information to a wide range of investors.

Santen's website carries a host of information, including flash reports, data books, financial result meeting presentations, and video of financial result meeting



Financial result meeting presentation (May 2014)

presentations. The website also carries annual securities reports (Japanese only), annual reports, and convocation notices, resolution notices, and other materials for the general meetings of shareholders.



Santen's website has been commended highly by third-party institutions. Notably, it was selected as an Excellent Corporate Website in the overall ranking of all listed companies in Japan based on a 2013 survey of corporate websites performed by Nikko Investor Relations Co., Ltd. Santen's website also received the Internet IR Commendation Award 2013 from Daiwa Investor Relations Co., Ltd.

Santen's website: http://www.santen.com

### Message

Realizing Santen's Vision for Becoming a Specialized Pharmaceutical Company with a Global Presence



Noboru Kotani Outside Director

#### **Eyeing Sustainable Growth**

Companies are living organisms that will wither unless they grow. It is crucial for companies to set long-term management objectives that embody management's resolve to achieve this growth. These objectives serve as milestones for the entire company, reminding it to keep growth foremost in mind in all of its activities. Unlike short-term plans, however, the roadmap is obviously unclear. In the course of executing a long-term plan, relationships both within and outside the company can become increasingly complex in step with a shifting business and competitive landscape changes, particularly as globalization continues unabated. This ever increasing complexity can complicate decision-making and execution. Business seldom proceeds exactly as we expect. Companies must rise above challenges of this sort to achieve sustainable growth. In the process, I believe that the important thing is to continuously take on business risks appropriately. Decision-making mistakes and excessive risk-taking must certainly be avoided. However, companies cannot achieve growth unless they take on risks appropriately.

I believe that a crucial role of outside directors is to check whether the operating divisions are continuing to take on risks appropriately, and to encourage them to do so. In doing so, I intend to do my utmost to help Santen achieve sustainable growth.

Yutaka Mizuno Outside Corporate Auditor

#### **Global Governance**

In recent years, Japanese listed companies have been compelled to establish corporate governance structures that can be readily understood internationally, from the standpoint of earning the trust of investors worldwide, particularly overseas investors. This trend comes as no surprise when considering the overseas investor ratios of Japanese listed companies, and the steps taken by these companies to become global enterprises. Clearly, this trend is linked to recent moves by major Japanese companies to appoint outside directors and corporate auditors. Surveys show that highly independent outside directors account for around 70% of the boards of directors of companies in the U.S., Germany and other Western countries. In contrast, Japan has a ratio of only around 15%, even when outside corporate auditors are included. This is extremely low, even in comparison to other Asian countries.

In this respect, Santen has made efforts to put a global governance framework in place. Indeed, the ratio of outside directors and corporate auditors at Santen has already reached the global standard at 67%. Santen has set forth the goal of becoming a specialized pharmaceutical company with a global presence as its long-term strategic vision through 2020. To this end, the Company is accelerating efforts to become a global enterprise. As an outside corporate auditor, I will continue working to ensure that Santen's global governance functions effectively.



(Front row, from left) Akihiro Okumura, Sadatoshi Furukado, Akira Kurokawa, Noboru Kotani, Takayuki Katayama (Back row, from left) Yutaka Mizuno, Yoshihiro Noutsuka, Yasuaki Tsuchiya, Koichi Matsuzawa

#### **Directors**

#### Akira Kurokawa

President and Chief Executive Officer

- 1977 Joined the Company 1997 Director General Manager Office of the Head of Sales and Marketing Division, Prescription Pharmaceuticals Corporate Officer, Head of Sales and Marketing
- 2001 Division, Prescription Pharmaceuticals
- 2004 Senior Corporate Officer, Head of Sales and Marketing Division, Prescription Pharmaceuticals 2006 President & COO
- 2008 President & CEO (incumbent)

#### Noboru Kotani

- Outside Director
- 2000 Representative Director, Dream Incubator Inc.
- 2005 Representative Director, Vehicle Inc. (incumbent)
- 2005 Outside Director of the Company (incumbent)
- 2005 Outside Director, Combi Corporation (incumbent)
- 2006 Outside Director, JIN CO., LTD. (incumbent)

#### Sadatoshi Furukado

Director

Vice President, Executive Corporate Officer

Japan Business and Human Resources Development

- 1977 Joined the Company 2005 Corporate Officer, Head of Prescription Pharmaceuticals Sales Department
- Senior Corporate Officer, Head of Sales and Marketing Division, Prescription Pharmaceuticals Executive Corporate Officer, Japan and Asia Business and Head of Sales and Marketing Division,
- 2011
- Prescription Pharmaceuticals 2011 Director (incumbent)
- Executive Corporate Officer, Japan Business and Human Resources Development, 2013
- Head of Sales and Marketing Division, Prescription Pharmaceuticals
- 2014 Vice President Corporate Officer (incumbent)

#### Akihiro Okumura

Outside Director

- 1988 Professor, Keio Business School, Keio University2008 Professor Emeritus, Keio University (incumbent)
- 2011 Outside Director of the Company (incumbent) 2014 Special Appointed Professor, Graduate School of Management and Information of Innovation,
- University of Shizuoka (incumbent)

#### Takayuki Katayama

Outside Director

- 2006 Executive Vice-President and Representative Director, Teijin Limited
- 2011 Senior Advisor to CEO, Teijin Limited (incumbent)
- 2012 Outside Director of the Company (incumbent)
- Outside Corporate Auditor, 2012
  - Toyo Seikan Group Holdings, Ltd. (incumbent)

#### **Corporate Auditors**

#### Yoshihiro Noutsuka

Standing Corporate Auditor

- 1976 Joined the Company 1999 General Manager, Accounting & Finance Group
- 2006 Corporate Officer,
- Head of Planning & Control Division Corporate Officer, Corporate, 2008 Community and Environment Relations
- 2010 Standing Corporate Auditor (incumbent)

#### Yasuaki Tsuchiya

Outside Corporate Auditor

- 1999 Primary Vice President, General Electric Japan, Ltd. 2004 Corporate Auditor, Information Services International-Dentsu, Ltd.
- Senior Adviser, Permira 2010 Advisers KK (incumbent)
- 2011 Outside Corporate Auditor of the Company (incumbent)

- 2004 Executive Officer, Matsushita Electric Industrial Co., Ltd. 2009 Outside Director,
- Optrex Corporation 2011 Outside Corporate Auditor of the Company (incumbent)
- 2013 Outside Audit & Supervisory Board Member. KOKUYO Co., Ltd. (incumbent)

#### Koichi Matsuzawa

Outside Corporate Auditor

- 1996 President & CEO Kirin Europe GmbH 2008 Representative Director &
  - Managing Director, Kirin Holdings Company, Limited
- 2009 President & CEO, Kirin Brewery Company, Limited
- 2014 Outside Corporate Auditor of the Company (incumbent)

Yutaka Mizuno Outside Corporate Auditor

#### Corporate Officers As of August 2014



(Front row, from left) Akihiro Tsujimura, Naveed Shams, Masamichi Sato, Takeshi Ito, Kenji Morishima, Atsutoshi Ota (Back row, from left) Hiroyuki Yamazaki, Takashi Kaneko, Akio Kimura, Kazuo Koshiji, Noriaki Yamamoto, Keizo Nakada (Insert) Jyrki Liljeroos

#### Corporate Officers (Not including directors who also serve as corporate officers)

Masamichi Sato Senior Corporate Officer Head of Santen European Group President of Santen Holdings EU B.V.

Jyrki Liljeroos Corporate Officer President of Santen Oy

Akio Kimura

Corporate Officer Head of Global Quality Compliance

Hiroyuki Yamazaki Corporate Officer Head of Japan Prescription Pharmaceutical Sales Takeshi Ito Senior Corporate Officer Head of Japan Sales and Marketing, Prescription Pharmaceuticals

Kenji Morishima Corporate Officer Head of Global Pharmaceutical Technology Development

Kazuo Koshiji Corporate Officer Chief Financial Officer Head of Finance and Administration Division

Keizo Nakada Corporate Officer Head of Global Product Supply

#### Naveed Shams, M.D., Ph.D.

Senior Corporate Officer Chief Scientific Officer Head of Global Research and Development, President & CEO of Santen Inc.

Akihiro Tsujimura Corporate Officer Head of Asia Division

Takashi Kaneko, M.D., Ph.D.

Corporate Officer Head of Global Clinical Development & Medical Affairs, Representative, Japan Research & Development

#### Atsutoshi Ota

Corporate Officer Head of Human Resources Development and CSR Division

#### Noriaki Yamamoto

Corporate Officer Chief Information Officer Head of Information Systems Division

# Financial Section

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#### [OPERATING RESULTS]

#### Net Sales

Santen's activities essentially encompass the pharmaceuticals and other businesses. At 98.0%, the vast majority of sales come from the pharmaceuticals segment. In fiscal 2013, ended March 31, 2014, sales from the pharmaceuticals segment rose 24.7% compared with the previous year, to ¥145,713 million. Sales from the other segment rose 30.8%, to ¥2,950 million. On this basis, total net sales for the fiscal year under review rose 24.9%, to ¥148,663 million.

#### **Pharmaceuticals Business**

#### **Prescription Pharmaceuticals**

Santen's prescription pharmaceuticals are divided into three categories: ophthalmics, anti-rheumatics and other pharmaceuticals. In fiscal 2013, sales of ophthalmics, antirheumatics and other pharmaceuticals all increased. The overall result therefore was that prescription pharmaceutical sales increased 26.2%, to ¥139,258 million, representing 93.7% of consolidated net sales.

#### Ophthalmics

Domestic sales of prescription ophthalmic pharmaceuticals improved 25.5%, to ¥101,779 million. This was largely attributable to successful promotional campaigns in Japan to provide individual medical facilities with scientific information tailored to their specific and changing needs. Overseas, prescription ophthalmic pharmaceutical revenues were up 43.5%, to ¥25,617 million, after conversion to yen. In Europe, our concentration on promotional campaigns centered on providing medical and other information saw Taflotan (sold as Tapros in Japan), a new glaucoma and ocular hypertension treatment, increase its market share in Germany and elsewhere. In Asia, market penetration of the Company's products also progressed mainly in China and Korea. This was again attributable to successful promotional campaigns. As a result, total prescription ophthalmic pharmaceutical sales increased 28.7%, to ¥127,396 million.

#### Anti-Rheumatics

*Rimatil, Azulfidine EN* and *Metolate* are highly recommended in Japan in the Rheumatoid Arthritis Treatment Guidelines. Partly because of this, sales of anti-rheumatics rose 3.8%, to ¥10,251 million.

#### **OTC Pharmaceuticals**

The Company focused on promotional campaigns, notably the *Sante FX* series and the *Sante Medical* series. Despite these efforts, sales of OTC pharmaceuticals declined 0.3%, to ¥6,455 million, due mainly to lower demand in Japan and the impact of increased competition.

#### **Other Businesses**

#### **Medical Devices**

As a result of focusing initiatives on promotional campaigns for the *Eternity* foldable intraocular lens, which is made of a glistening-free hydrophobic acrylic optical material, sales of medical devices rose 19.3% year on year, to ¥2,678 million.

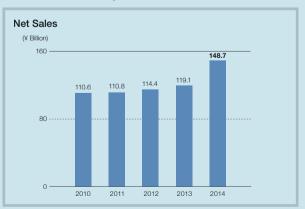
#### Others

Other sales totaling ¥272 million came from the cleaning of antidust and sterilized clothing operations of consolidated subsidiary Claire Co., Ltd. and sales of supplements.

#### Net Sales by Business Segment

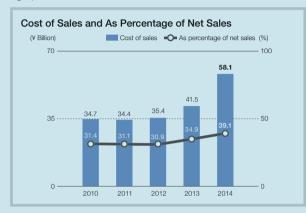
	Millions	s of yen	%
	2014	2013	Change
Pharmaceuticals Business	¥145,713	¥116,810	24.7
Prescription pharmaceuticals	139,258	110,336	26.2
Ophthalmics	127,396	98,981	28.7
Anti-rheumatics	10,251	9,874	3.8
Other pharmaceuticals	1,611	1,481	8.8
OTC pharmaceuticals	6,455	6,474	(0.3)
Other Businesses	2,950	2,256	30.8
Medical devices	2,678	2,246	19.3
Others	272	10	_
Total	¥148,663	¥119,066	24.9

Note: Net sales for each segment refer to sales to outside customers.



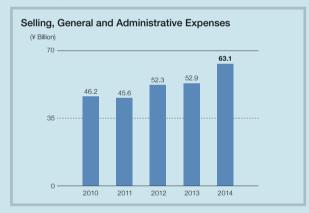
#### **Cost of Sales**

Cost of sales increased 40.0%, to ¥58,104 million. The cost of sales as a percentage of net sales increased 4.2 percentage points, to 39.1%.



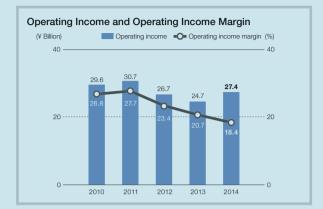
#### Selling, General and Administrative Expenses

Selling, general and administrative expenses increased 19.4%, to ¥63,145 million, which included a 13.9% increase in R&D expenditures, to ¥19,040 million.



#### **Operating Income**

Operating income was up 11.1%, to ¥27,414 million. The operating income margin was 18.4%, down from 20.7% in the previous fiscal year.



#### Other Income and Expenses

Net other expenses for the fiscal year ended March 31, 2014 were ¥521 million.

Other income was up ¥424 million, to ¥1,450 million. This mainly reflected the recording of ¥474 million in gain on sale of investment securities.

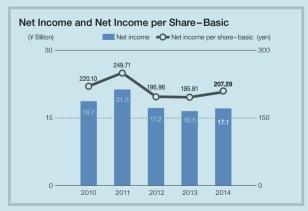
Other expenses increased ¥1,856 million, to ¥1,971 million. This was mainly attributable to the recording of business structure improvement expenses of ¥1,381 million and exchange losses.

#### **Income Taxes**

Income taxes totaled ¥9,784 million. The effective tax rate increased from 35.4% to 36.4%.

#### **Net Income**

Net income was up 3.6%, to ¥17,109 million. The ratio of net income to net sales was 11.5%, down from 13.9% in the previous fiscal year. Basic net income per share was ¥207.29, up from ¥195.81, and diluted net income per share was ¥206.65, up from ¥195.51 in the previous fiscal year.

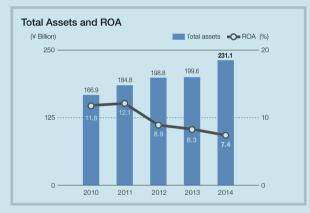


#### [FINANCIAL CONDITION]

#### Assets

As of March 31, 2014, total assets stood at ¥231,106 million, up ¥31,465 million, or 15.8%, compared with the previous fiscal year-end. Cash and cash equivalents, trade receivables, short-term investments and investment securities increased. Return on total assets (ROA) was 7.4%, down from 8.3% in the previous fiscal year.

Total current assets were ¥156,006 million, and the ratio of total current assets to total assets rose from 66.4% as of the previous fiscal year-end to 67.5%. Net property, plant and equipment totaled ¥27,629 million, and total investments and other assets amounted to ¥47,471 million.



#### Liabilities

Total liabilities as of March 31, 2014 were ¥49,896 million, up ¥15,387 million compared with the previous fiscal yearend. Trade accounts payable, income taxes payable, and net defined benefit liability increased due mainly to application of the accounting standard for retirement benefits. The Company abolished its retirement benefit program for directors in June 2013, and therefore retirement and severance benefits for directors were transferred to other liabilities.

Total current liabilities were ¥39,094 million, and total non-current liabilities were ¥10,802 million. Interest-bearing debt was ¥60 million, a decline of ¥27 million, or 31.4%, compared with the previous fiscal year-end.

#### **Net Assets**

Total net assets amounted to ¥181,210 million, up ¥16,078 million compared with the end of the previous fiscal year. While remeasurements of defined benefit plans, net of taxes due mainly to application of the accounting standard for retirement benefits, declined, there was an increase in retained earnings, unrealized gains on securities, net of taxes and foreign currency translation adjustment.

The equity ratio declined from 82.6% to 78.2%. Equity per share was ¥2,189.50, an increase of ¥191.06, or 9.6%, compared with the end of the previous fiscal year. Return on equity (ROE) decreased from 10.0% to 9.9%.



#### **Capital and Liquidity**

Santen strives to maintain a healthy balance sheet and to ensure an appropriate level of liquidity and sufficient resources to fund its business activities.

Cash and cash equivalents as of the end of the fiscal year under review amounted to ¥72,397 million, up ¥12,600 million compared with the previous fiscal year-end. Net cash provided by operating activities was ¥25,958 million. Of this, ¥6,695 million was used in investing activities and ¥7,953 million in financing activities.

#### **Cash Flows**

Net cash provided by operating activities was ¥25,958 million, which mainly resulted from income before income taxes of ¥26,893 million, an increase in account receivables of ¥7,672 million, income taxes paid of ¥7,067 million and trade accounts payable of ¥4,927 million.

Net cash used in investing activities was ¥6,695 million. While ¥2,520 million in cash was provided by proceeds from sale of short-term investments, the main outflows were ¥4,786 million for capital expenditures and ¥4,221 million for the purchase of investment securities.

Net cash used in financing activities was ¥7,953 million. The principal cash outflows were ¥8,247 million for dividends paid. As a result, cash and cash equivalents as of the end of the fiscal year amounted to ¥72,397 million, an increase of ¥12,600 million.

#### **Cash Flows Summary**

	Millions of yen				
	2014	2013	Change		
Cash flows from operating activities	¥25,958	¥ 9,943	¥16,015		
Cash flows from investing activities	(6,695)	(4,596)	(2,099)		
Cash flows from financing activities	(7,953)	(21,557)	13,604		
Cash and cash equivalents at end of year	¥72,397	¥ 59,797	¥12,600		

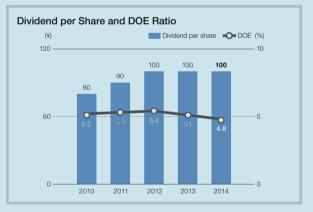
Note: Figures in parentheses indicate a decrease.

#### **Distribution of Profits**

Santen views returns to shareholders as one of its most important management goals and has instituted the following fundamental policies for the distribution of profits:

- We will implement an appropriate dividend policy based on the Company's operating results while taking into consideration the need to secure sufficient internal reserves to fund R&D and the implementation of growth strategies for the purposes of enhancing capital efficiency and expanding corporate value.
- We will strive to increase the level of dividends in line with such factors as the Company's demand for funds and the Company's financial position.
- We will consider the repurchase and retirement of treasury stock as a flexible method of providing a return to shareholders.

To maintain a stable level of dividends, we target a dividend on equity (DOE) ratio, which combines the dividend payout ratio and ROE. Taking into consideration returns to shareholders through dividends and the improvement of capital efficiency, under the Company's Fiscal 2011–2013 Medium-Term Management Plan, our DOE target is 5.0%. On this basis, the annual dividend per share was ¥100, the same as the previous fiscal year, resulting in a DOE ratio of 4.8%. The average DOE ratio for the years of the Fiscal 2011–2013 Medium-Term Management Plan was 5.1%.



#### [FORWARD-LOOKING INFORMATION AND FACTORS THAT MIGHT AFFECT FUTURE RESULTS]

Any statements that we make, other than historical facts, contain forward-looking information based on our business plans and assumptions at the time of disclosure. Such forward-looking information includes, but is not limited to, our expected growth strategies, projected operating results, market forecasts and anticipated timing for developing, obtaining approval and bringing products to market. Our business, as well as each product we develop and market, is subject to various risks and uncertainties beyond our control. Therefore, these forward-looking statements might differ substantially from actual results. Risks and uncertainties that could affect the Company's future results and financial condition include, but are not limited to, the factors described below.

#### **External Factors**

#### **Regulatory Controls**

Our prescription pharmaceutical business is subject to government regulatory controls regarding healthcare programs and drug prices in Japan and other countries. Although our current operating and/or financial projections were made in full consideration of drug price revisions in Japan to the best extent possible, those revisions that may take place beyond the scope of our anticipated projections or other revisions in healthcare programs might also affect our operating and/or financial results. In other countries and markets where we manufacture and sell our products, we continue to face a variety of regulatory controls over prices of prescription pharmaceuticals and government pressure for drug price reduction.

### Social and Economic Conditions and Changes in the Law

The Company's future results might be affected by political and economic changes in key markets worldwide in which we operate. Our anticipated performance and financial condition might also be affected by changes in applicable accounting principles, and laws and regulations concerning taxes, the Product Liability Law, the Antitrust Law, environmental laws and regulations and other factors.

#### Foreign Exchange

Overseas sales and expenses, as well as the assets of overseas subsidiaries, affect our sales, profits and financial condition depending on foreign exchange rate fluctuations. Overseas sales for the fiscal year ended March 31, 2014 accounted for 17.9% of our consolidated net sales.

#### **Competitive Factors**

#### **Generic Products**

The sale of generic products both in and outside Japan has the potential of impacting the Company's performance.

Other companies have already launched generic products in Japan for such items as *Hyalein* and *Cravit*. Looking ahead, the impact from generic products is projected to grow.

### Dependency on Specific Products and Business Partners

#### **Dependency on Mainstay Products**

Total sales of *Hyalein* and *Cravit* accounted for 23% of Santen's consolidated net sales for the fiscal year ended March 31, 2014. Should any sales suspension or a decline in sales occur due to any unanticipated negative influences, such as potential product defects or newly discovered side effects, our business results and financial performance might be negatively affected.

#### **Dependency on In-Licensed Products**

Many products that the Santen Group sells are licensed by other companies. We hold exclusive rights to manufacture and sell ophthalmic formulations such as *Cravit, Detantol, Tapros* and *Diquas*. We also have sales rights in Japan for *Timoptol, Timoptol XE* and *Livostin*, and exclusive sales rights in Japan for *Cosopt, Azulfidine EN, Rescula* and *EYLEA*. Should changes be made in the terms and conditions after the expiration of such contracts or should the agreements not be renewed, our business performance might be affected.

#### Dependency on Specific Business Partners

We depend on specific business partners for the supply of certain raw materials such as the active pharmaceutical ingredient for *Cravit* and containers for our OTC pharmaceuticals. If supply of these materials is interrupted or discontinued for any reason, our pharmaceutical production might be adversely affected. Should it subsequently affect the supply of our products and cause any interruption or discontinuance, it would adversely affect our business performance.

The percentage of our business conducted with the top 10 wholesalers in Japan has reached 70% of our consolidated net sales. If our wholesale partners experience bankruptcy leading to bad debts, our business performance might be adversely affected.

#### **R&D** Activities

#### Uncertainties in New Product Development

Years are required to bring new drugs from initial R&D to final approval and marketing. Various uncertainties exist at every stage in the development process that could sidetrack a new product, such as discontinuance of development or rejection after the application is filed. It is difficult for us to accurately predict when new products, new indications or formulations under development will reach the approval stage and be ready for launch.

Forecasting a precise timeline for project development and completion depends on a number of variable factors, including, but not limited to, delayed government reviews, conflicting or unusable clinical data that does not indicate significant differences in relation to competitor products, safety and efficacy concerns and unexpected side effects which might lead to discontinued development or delayed product launch and thereby negatively affect projected sales of new drugs.

### Potentially Insufficient Returns on R&D Investment

The creation and development of new pharmaceuticals, as well as the development of new indications and formulations, are critical for the future growth of the Company. Every year we invest significantly in R&D, and there is a possibility that future investments will not result in sales of new products sufficient to provide an adequate return.

#### **Issues with Alliances**

Forecasts for new pharmaceuticals include various assumptions of alliances in development and/or sales. Actual results of these alliances might affect our overall sales and financial condition.

#### **Other Factors**

#### Production Interruptions or Delays

The interruption or delay of production activities due to natural disasters or other catastrophes such as fire might affect our financial performance and condition. Certain products are only manufactured at one location. If a specific plant is forced to halt production, supply of some products might be interrupted or delayed.

#### Cancellation of Sales and Product Withdrawals

If sales of certain products are cancelled, or if we withdraw products due to product quality defects, unexpected side effects, tampering or other causes, our overall financial results might be negatively affected.

#### Litigation

Our main business involves the production and sales of prescription pharmaceuticals. The nature of our business makes us vulnerable to litigation related to patents, the Product Liability Law, violation of the Antitrust Law and consumer-related and environmental lawsuits. If such legal actions take place, the proceedings might affect our overall performance and financial condition. Currently, we are involved in no litigation that substantially impacts the management of the Company.

#### **Risk Related to Asset Acquisition**

In the course of developing our global business to achieve sustained growth, we are conducting asset acquisition. The nature of our business activities in countries around the world makes us vulnerable to risks arising from changes in laws or regulations, the instability of a political situation, uncertainty in economic trends, differences in business practices, and other circumstances. As a result, the Company might not achieve the benefits and earnings from any given asset acquisition that we had initially anticipated. Years ended March 31

	2004	2005	2006	2007	
For the year:					
Net sales	¥ 89,858	¥ 92,696	¥ 98,398	¥ 100,486	
Cost of sales	31,859	33,710	34,535	35,484	
Selling, general and administrative expenses	43,475	40,004	42,868	44,590	
Operating income	14,524	18,982	20,995	20,412	
Interest expense	366	182	94	91	
Income before income taxes	13,775	18,436	20,342	21,039	
Income taxes	7,454	7,413	7,319	7,891	
Net income	6,321	11,023	13,023	13,148	
Capital expenditures	3,226	4,907	2,106	3,556	
Depreciation and amortization	4,521	4,750	4,824	4,761	
R&D expenditures	11,853	12,620	13,971	13,663	
Per share data (yen and U.S. dollars):					
Net income – basic	¥ 71.65	¥ 125.85	¥ 150.26	¥ 151.58	
Net income – diluted	71.64	125.71	150.01	151.31	
Equity	1,176.83	1,249.32	1,368.27	1,481.83	
Cash dividends, applicable to period	40.00	50.00	60.00	65.00	
Cash flows:					
Net cash provided by operating activities	¥ 23,196	¥ 6,619	¥ 20,879	¥ 14,959	
Net cash (used in) provided by investing activities	5,246	(2,907)	(1,330)	(5,846)	
Net cash used in financing activities	(12,122)	(12,712)	(5,900)	(5,691)	
Interest coverage ratio (times)	70.6	36.1	218.7	164.3	
Debt to cash flow ratio (%)	54.7	104.0	26.9	36.4	
At year-end:					
Total current assets	¥ 91,231	¥ 82,735	¥ 93,893	¥ 100,820	
Net property, plant and equipment	37,237	32,676	30,395	30,485	
Total assets	150,238	139,980	150,458	159,099	
Long-term debt	12,686	6,882	5,614	5,446	
Equity	103,500	108,240	118,637	128,587	
Return on equity (ROE) (%)	6.3	10.4	11.5	10.6	
Return on total assets (ROA) (%)	4.3	7.6	9.0	8.5	
Equity ratio (%)	68.9	77.3	78.9	80.8	
Equity ratio on stock price basis (%)	101.8	142.3	163.0	165.3	
Price earnings ratio (PER) (times)	24.3	18.3	18.8	20.0	
Dividend on equity (DOE) (%)	3.5	4.1	4.6	4.6	
Issued shares (thousands)	87,963	86,659	86,751	86,825	
Number of employees	2,335	2,308	2,312	2,409	

Notes: 1. U.S. dollar amounts have been translated from yen, solely for the convenience of the reader, at the rate of ¥102.92 to U.S.\$1.00, the exchange rate prevailing on March 31, 2014.

2. See Notes 2. 17) and 13 of Notes to Consolidated Financial Statements in respect of per share data.

3. Equity comprises shareholders' equity and accumulated other comprehensive income.

Millions of yen							Thousands of U.S. dollars
2008	2009	2010	2011	2012	2013	2014	2014
¥ 103,394	¥ 101,619	¥ 110,594	¥ 110,812	¥ 114,416	¥ 119,066	¥ 148,663	\$1,444,456
36,513	35,947	34,710	34,437	35,385	41,501	58,104	564,564
46,510	50,178	46,244	45,636	52,299	52,884	63,145	613,529
20,371	15,494	29,640	30,739	26,732	24,681	27,414	266,363
97	65	53	36	23	7	6	55
20,483	15,824	28,610	31,074	27,791	25,592	26,893	261,302
7,832	5,701	9,887	9,741	10,630	9,071	9,784	95,063
12,651	10,123	18,723	21,333	17,161	16,521	17,109	166,239
3,151	2,953	1,315	1,651	3,281	3,609	4,786	46,502
4,593	4,210	3,421	2,976	2,949	3,291	3,927	38,155
12,942	18,458	14,123	13,221	17,225	16,720	19,040	184,998
¥ 146.15	¥ 119.08	¥ 220.10	¥ 249.71	¥ 196.96	¥ 195.81	¥ 207.29	\$ 2.01
145.94	118.97	219.85	249.42	196.76	195.51	206.65	2.01
1,494.48	1,472.32	1,614.08	1,793.15	1,887.81	1,998.44	2,189.50	21.27
80.00	80.00	80.00	90.00	100.00	100.00	100.00	0.97
¥ 15,468	¥ 11,849	¥ 26,110	¥ 17,768	¥ 21,483	¥ 9,943	¥ 25,958	\$ 252,218
(2,083)	(5,619)	(829)	(7,676)	(10,273)	(4,596)	(6,695)	(65,049)
(11,415)	(11,373)	(6,753)	(1,570)	(8,559)	(21,557)	(7,953)	(77,276)
163.6	165.5	558.1	488.5	1,285.0	3,037.8	9,020.2	
34.1	5.5	2.5	1.1	1.1	1.9	0.6	
¥ 102,754	¥ 101,053	¥ 118,832	¥ 137,668	¥ 140,288	¥ 132,583	¥ 156,006	\$1,515,803
29,849	28,665	26,574	24,957	25,523	27,420	27,629	268,448
156,547	151,012	166,878	184,801	198,801	199,641	231,106	2,245,489
5,278	154	75	152	179	145	102	991
126,998	125,181	137,343	156,099	164,514	164,808	180,811	1,756,804
9.9	8.0	14.3	14.5	10.7	10.0	9.9	
8.0	6.6	11.8	12.1	8.9	8.3	7.4	
81.1	82.9	82.3	84.5	82.8	82.6	78.2	
126.2	154.3	143.1	156.2	155.0	183.8	163.7	
15.9	23.0	12.7	13.3	17.9	22.7	22.1	
5.4	5.4	5.2	5.3	5.4	5.1	4.8	
86,867	86,916	86,992	87,053	87,147	82,469	82,583	
2,483	2,690	2,756	2,867	3,053	3,050	3,072	
2,700	2,000	2,100	2,001	0,000	0,000	0,012	

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### **Consolidated Balance Sheets**

Santen Pharmaceutical Co., Ltd. and Subsidiaries At March 31, 2014 and 2013

	Millions	Millions of yen		
ASSETS	2014	2013	2014	
Current assets:				
Cash and cash equivalents (Note 6)	¥ 72,397	¥ 59,797	\$ 703,425	
Short-term investments (Notes 6 and 7)	4,225	2,094	41,048	
Trade receivables (Note 6):				
Notes	470	763	4,571	
Accounts	51,616	43,078	501,511	
Allowance for doubtful receivables	(4)	(2)	(36)	
Net trade receivables	52,082	43,839	506,046	
Inventories (Note 8)	20,031	20,949	194,630	
Deferred tax assets (Note 17)	2,346	1,880	22,796	
Other current assets	4,925	4,024	47,858	
Total current assets	156,006	132,583	1,515,803	
Property, plant and equipment (Notes 9 and 10):				
Land	8,266	8,241	80,315	
Buildings and structures	45,033	42,807	437,554	
Machinery and equipment	13,347	11,818	129,684	
Tools, furniture and vehicles	12,910	11,936	125,445	
Lease assets	286	252	2,775	
Construction in progress	817	2,455	7,937	
Total	80,659	77,509	783,710	
Accumulated depreciation and impairment loss	(53,030)	(50,089)	(515,262)	
Net property, plant and equipment	27,629	27,420	268,448	
Investments and other assets:				
Investments in affiliates	—	16	_	
Investment securities (Notes 6 and 7)	21,740	18,158	211,229	
Goodwill	6,298	5,936	61,193	
In-process research and development	8,357	6,768	81,202	
Other intangible assets	1,930	1,420	18,751	
Deferred tax assets (Note 17)	5,488	4,460	53,327	
Other assets	3,658	2,880	35,536	
Total investments and other assets	47,471	39,638	461,238	
Total assets	¥231,106	¥199,641	\$2,245,489	

	Million	Millions of yen		
LIABILITIES AND NET ASSETS	2014	2013	2014	
Current liabilities:				
Trade accounts payable (Note 6)	¥ 14,270	¥ 9,266	\$ 138,655	
Other payables (Note 6)	9,696	9,868	94,207	
Accrued expenses	5,459	4,202	53,039	
Income taxes payable (Notes 6 and 17)	8,170	3,039	79,379	
Other current liabilities	1,499	636	14,568	
Total current liabilities	39,094	27,011	379,848	
Non-current liabilities:				
Long-term debt (Note 11)	102	145	991	
Retirement and severance benefits (Note 12)		3,664	_	
Retirement and severance benefits for directors (Note 12)		249	_	
Net defined benefit liability (Note 12)	5,401		52,473	
Deferred tax liabilities (Note 17)	2,796	2,269	27,171	
Asset retirement obligation	221	160	2,150	
Provision for business structure improvement	802		7,797	
Other liabilities	1,480	1,011	14,376	
Total non-current liabilities	10,802	7,498	104,958	
Contingent liabilities (Note 18) Total liabilities	49,896	34,509	484,806	
Net assets (Note 13):				
Shareholders' equity:				
Common stock (Note 13): Authorized – 220,000,000 shares (220,000,000 shares in 2013) Issued – shares 82,582,903 (82,469,103 shares in 2013)	7,264	7,081	70,581	
Capital surplus (Note 13)	7,959	7,775	77,327	
Retained earnings	160,116	151,002	1,555,728	
Treasury stock, at cost: 2,324 shares (900 shares in 2013)	(9)	(2)	(90)	
Total shareholders' equity	175,330	165,856	1,703,546	
Accumulated other comprehensive income (loss):				
Unrealized gains on securities, net of taxes (Note 7)	4,036	1,920	39,214	
Foreign currency translation adjustments	2,574	(2,968)	25,010	
Remeasurements of defined benefit plans, net of taxes	(1,129)		(10,966)	
Total accumulated other comprehensive income (loss)	5,481	(1,048)	53,258	
Stock subscription rights (Note 14)	399	324	3,879	
Total net assets	181,210	165,132	1,760,683	
Total liabilities and net assets	¥231,106	¥199,641	\$2,245,489	

Santen Pharmaceutical Co., Ltd. and Subsidiaries For the years ended March 31, 2014, 2013 and 2012

		Millions of yen		Thousands of U.S. dollars (Note 3)
	2014	2013	2012	2014
Net sales	¥148,663	¥119,066	¥114,416	\$1,444,456
Cost of sales	58,104	41,501	35,385	564,564
Gross profit	90,559	77,565	79,031	879,892
Selling, general and administrative expenses	63,145	52,884	52,299	613,529
Operating income	27,414	24,681	26,732	266,363
Other income (expenses):				
Interest and dividend income	602	522	529	5,848
Dividends income of insurance	148	158	143	1,438
Exchange gains (losses), net	(223)	92	107	(2,163)
Interest expense	(6)	(7)	(23)	(55)
Gain on sale of investment securities	474		42	4,605
Business structure improvement expenses (Note 16)	(1,381)		—	(13,415)
Loss on impairment of fixed assets (Note 10)	(94)	—	(19)	(916)
Other, net	(41)	146	280	(403)
Income before income taxes	26,893	25,592	27,791	261,302
Income taxes (Note 17):				
Current	11,763	7,908	9,912	114,291
Deferred	(1,979)	1,163	718	(19,228)
	9,784	9,071	10,630	95,063
Income before minority interests	17,109	16,521	17,161	166,239
Net income	17,109	16,521	17,161	166,239
	,	,	,	,
Income before minority interests	17,109	16,521	17,161	166,239
Other comprehensive income (loss) (Note 4):				
Unrealized gains (losses) on securities, net of taxes	2,143	1,869	494	20,816
Foreign currency translation adjustments	5,542	3,339	(689)	53,844
Remeasurements of defined benefit plans, net of taxes	585			5,686
Other comprehensive income (loss)	8,270	5,208	(195)	80,346
Total comprehensive income	25,379	21,729	16,966	246,585
Total comprehensive income attributable to:				
Owners of the parent	¥ 25,379	¥ 21,729	¥ 16,966	\$ 246,585
Minority interests	—			_
		Yen		U.S. dollars (Note 3)
Per share data:	2014	2013	2012	2014
Net income – basic	¥207.29	¥195.81	¥196.96	\$2.01
Net income – diluted	206.65	195.51	196.76	2.01
Cash dividends, applicable to the period	100.00	100.00	100.00	0.97

# Consolidated Statements of Changes in Net Assets Santen Pharmaceutical Co., Ltd. and Subsidiaries For the years ended March 31, 2014, 2013 and 2012

		Millions of yen							
	Common stock	Capital surplus	Retained earnings			Unrealized gains (losse on securities net of taxes		Remeasure- ments of defined benefit plans, net of taxes	Stock subscription rights
Balance at April 1, 2011	¥6,615	¥7,969	¥147,578	¥	(2)	¥ (443	) ¥(5,618)	¥ —	¥305
Exercise of stock options	80	80							
Cash dividends			(8,709)						
Net income			17,161						
Repurchase of treasury stock, net					(2)				
Disposal of treasury stock		0			0				
Other, net						494	(689)		42
Balance at March 31, 2012	¥6,695	¥8,049	¥156,030	¥	(4)	¥ 51	¥(6,307)	¥ —	¥347
Exercise of stock options	386	386							
Cash dividends			(8,469)						
Net income			16,521						
Repurchase of treasury stock, net				(13	8,738)				
Retirement of treasury stock		(660)	(13,080)	13	3,740				
Other, net						1,869	3,339		(23)
Balance at March 31, 2013	¥7,081	¥7,775	¥151,002	¥	(2)	¥1,920	¥(2,968)	¥ —	¥324
Cumulative effect of change in accounting policies			228					(1,714)	
Balance at April 1, 2013 as restated	7,081	7,775	151,230		(2)	1,920	(2,968)	(1,714)	324
Exercise of stock options	183	184							-
Cash dividends			(8,250)			<u> </u>			
Net income			17,109						
Repurchase of treasury stock, net					(7)				
Disposal of treasury stock		0			0				
Other, net			27			2,116	5,542	585	75
Balance at March 31, 2014	¥7,264	¥7,959	¥160,116	¥	(9)	¥4,036	¥ 2,574	¥(1,129)	¥399

	Thousands of U.S. dollars (Note 3)							
	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Unrealized gains (losses) on securities, net of taxes	Foreign currency translation adjustments	Remeasure- ments of defined benefit plans, s net of taxes	Stock subscription rights
Balance at April 1, 2013	\$68,800	\$75,547	\$1,467,178	\$ (25)	\$18,656	\$(28,834)	\$ —	\$3,155
Cumulative effect of change in accounting policies			2,214				(16,652)	
Balance at April 1, 2013 as restated	68,800	75,547	1,469,392	(25)	18,656	(28,834)	(16,652)	3,155
Exercise of stock options	1,781	1,780						
Cash dividends			(80,161)					
Net income			166,239					
Repurchase of treasury stock, net				(65)				
Disposal of treasury stock		0	·	0				
Other, net			258		20,558	53,844	5,686	724
Balance at March 31, 2014	\$70,581	\$77,327	\$1,555,728	\$ (90)	\$39,214	\$ 25,010	\$(10,966)	\$3,879

#### **Consolidated Statements of Cash Flows**

Santen Pharmaceutical Co., Ltd. and Subsidiaries For the years ended March 31, 2014, 2013 and 2012

		Millions of yen		Thousands of U.S. dollars (Note 3)
	2014	2013	2012	2014
Cash flows from operating activities:				
Income before income taxes	¥26,893	¥ 25,592	¥ 27,791	\$261,302
Depreciation and amortization	2,914	2,657	2,787	28,314
Amortization of goodwill	1,013	634	162	9,841
Gain on sale of investment securities	(474)		(42)	(4,605)
Loss on impairment of fixed assets (Note 10)	94		19	916
Business structure improvement expenses	1,381			13,415
Increase in retirement and severance benefits	_	187	179	_
Increase in net defined benefit liability	313			3,045
Interest and dividend income	(602)	(522)	(529)	(5,848)
Interest expense	6	7	23	55
(Increase) decrease in trade receivables	(7,672)	(5,560)	1,037	(74,547)
Decrease (increase) in inventories	1,650	(2,589)	(3,294)	16,033
Increase in trade accounts payable	4,927	1,170	2,034	47,875
Other, net	1,970	(1,790)	52	19,136
Subtotal	32,413	19,786	30,219	314,932
Interest and dividend income received	615	532	549	5,972
Interest expense paid	(3)	(3)	(17)	(28)
Income taxes paid	(7,067)	(10,372)	(9,268)	(68,658)
Net cash provided by operating activities	25,958	9,943	21,483	252,218
	,	,		,
Cash flows from investing activities:				
Capital expenditures	(4,786)	(3,609)	(3,281)	(46,502)
Proceeds from sale of property, plant and equipment	11	37	6	108
Purchase of investment securities	(4,221)	(4,883)	(2,420)	(41,008)
Proceeds from sale of investment securities	524	1	377	5,096
Purchase of short-term investments	(734)	(807)	(1,783)	(7,135)
Proceeds from sale of short-term investments	2,520	4,680	7,632	24,483
Acquisition of subsidiary, net of cash acquired	—	—	(10,804)	_
Increase in loans receivable	(3)		(7)	(26)
Proceeds from collection of loans receivable	_	3	8	_
Other, net	(6)	(18)	(1)	(65)
Net cash used in investing activities	(6,695)	(4,596)	(10,273)	(65,049)
Cash flows from financing activities:				
Repurchase of treasury stock	(7)	(13,763)	(2)	(66)
Disposal of treasury stock	0		0	1
Dividends paid	(8,247)	(8,469)	(8,706)	(80,134)
Other, net	301	675	149	2,923
Net cash used in financing activities	(7,953)	(21,557)	(8,559)	(77,276)
Effect of exchange rate changes on cash and cash equivalents	1,290	972	(98)	12,526
Net increase (decrease) in cash and cash equivalents	12,600	(15,238)	2,553	122,419
Cash and cash equivalents at beginning of year	59,797	75,035	72,482	581,006
Cash and cash equivalents at end of year	¥72,397	¥ 59,797	¥ 75,035	\$703,425

		Millions of yen		Thousands of U.S. dollars (Note 3)
	2014	2013	2012	2014
Additional cash flow information				
Assets and liabilities increased by acquisition of shares of subsidiary				
Current assets	¥—	¥—	¥ 1,171	\$—
Non-current assets	_		6,251	—
Goodwill	_	_	6,195	—
Current liabilities	_		(340)	—
Non-current liabilities	_		(2,320)	—
Foreign currency translation adjustments	_	_	(2)	—
Acquisition price	_	_	10,955	_
Other payables	_	_	(32)	_
Cash and cash equivalents	_		(119)	—
Payments for purchases of shares of subsidiary	¥—	¥—	¥10,804	\$—

Santen Pharmaceutical Co., Ltd. and Subsidiaries

#### 1. Basis of Presentation of Consolidated Financial Statements

The consolidated financial statements of Santen Pharmaceutical Co., Ltd. (the "Company") have been prepared in accordance with the provisions set forth in the Japanese Financial Instruments and Exchange Act and its related accounting regulations, and in conformity with accounting principles generally accepted in Japan ("Japanese GAAP"), which are different in certain respects as to application and disclosure requirements from International Financial Reporting Standards.

The accounts of consolidated overseas subsidiaries have been prepared in accordance with either International Financial Reporting Standards or U.S. generally accepted accounting principles, as required under "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements" (Practical Issues Task Force No. 18) issued and revised by the Accounting Standards Board of Japan ("ASBJ"). In this case, adjustments for the following five items are required in the consolidation process so that their impact on net income is accounted for in accordance with Japanese GAAP unless the impact is not material.

- (a) Goodwill not subject to amortization
- (b) Actuarial gains and losses of defined benefit plans recognized outside profit and loss
- (c) Capitalized expenditures for research and development activities
- (d) Fair value measurement of investment properties and revaluation of property, plant and equipment and intangible assets
- (e) Accounting for net income attributable to minority interests

The consolidated financial statements have been restructured and translated into English (with certain expanded disclosures) from the consolidated financial statements of the Company prepared in accordance with Japanese GAAP and filed with the appropriate Local Finance Bureau of the Ministry of Finance as required by the Financial Instruments and Exchange Act. Certain supplementary information included in the statutory Japanese language consolidated financial statements is not presented in these consolidated financial statements.

#### 2. Summary of Significant Accounting Policies

#### 1) Principles of consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries (the "Companies"). All significant intercompany balances and transactions are eliminated on consolidation.

During the year ended March 31, 2012, the Company established two new subsidiaries (Santen India Private Limited, Santen Holdings EU B.V.) and acquired one subsidiary (Novagali Pharma S.A.S.).

During the year ended March 31, 2014, the Company established two new subsidiaries (Santen Pharmaceutical Sales & Marketing (Suzhou) Co., Ltd., Santen Pharmaceutical Asia Private Limited).

Before the year ended March 31, 2013, Investment in an affiliated company is stated at cost due to immateriality.

Note: In April, 2013, Novagali Pharma S.A.S. changed its name to Santen S.A.S.

2) Information regarding the unification of fiscal year end From the year ended March 31, 2014, the fiscal year end of Santen Oy, Santen Pharma AB, Santen GmbH, Taiwan Santen Pharmaceutical Co., Ltd. and Santen Pharmaceutical Korea Co., Ltd. was changed from February 28 to March 31, and the fiscal year end of Santen S.A.S. was changed from December 31 to March 31.

The fiscal year end of Santen Pharmaceutical (China) Co., Ltd. and Santen Pharmaceutical Sales & Marketing (Suzhou) Co., Ltd. was December 31. Effective from the year ended March 31, 2014, however, the fiscal year end of Santen Pharmaceutical (China) Co., Ltd. and Santen Pharmaceutical Sales & Marketing (Suzhou) Co., Ltd have been consolidated using provisional financial statements at March 31, 2014.

As a result of these changes, Consolidated Statements of Income and Comprehensive Income for the fiscal year ended March 31, 2014 includes 13 months (from March 1, 2013 to March 31, 2014) of 5 subsidiaries and 15 months (from January 1, 2013 to March 31, 2014) of 3 subsidiaries.

The effects of these changes were that net sales, operating loss, loss before income taxes and net loss increased by ¥2,791 million (\$27,119 thousand), ¥327 million (\$3,173 thousand), ¥1,042 million (\$10,123 thousand) and ¥1,057 million (\$10,271 thousand), respectively.

#### 3) Use of estimates

The preparation of the consolidated financial statements in conformity with Japanese GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities. Actual results could differ from those estimates.

### 4) Short-term investments, investment securities and golf membership rights (see Notes 6 and 7)

The Company and its domestic subsidiary have adopted the "Accounting Standard for Financial Instruments" which was issued and revised by the Business Accounting Council in Japan. In accordance with this standard, securities are classified into three categories; trading, held-to-maturity, or other securities.

Based on this classification, all trading securities and any held-to-maturity and other securities with a maturity of less than one year are included in current assets. All other securities are included in investment securities as noncurrent assets.

Those classified as other securities with an available market value are reported at fair value with unrealized holding gains (losses), net of related taxes, as a separate component of accumulated other comprehensive income.

Realized gains and losses on sales of such securities are determined by the moving average cost method. Other securities with no available market value are carried at cost, which is determined by the moving average cost method.

In addition, this standard also requires the recognition of an impairment loss on golf membership rights, included in other assets, on the consolidated balance sheets, when the market value declines substantially and the decline is not expected to recover.

#### 5) Derivative instruments (see Note 6)

Derivatives are initially measured at fair value and are subsequently remeasured to fair value at each reporting date. Apart from those derivatives designated as gualifying hedging instruments, all changes in carrying value are recognized in profit and loss. The Company utilizes derivatives for hedging the risk arising from fluctuation in foreign currency exchange rates and interest rates and does not enter into derivatives for trading or speculative purposes. Derivatives that are designated as qualifying hedging instruments are accounted for using deferred hedge accounting. Recognition of gains or losses resulting from changes in fair values of derivative financial instruments are deferred until the related losses or gains on the hedged items are realized if the derivative financial instruments are used as hedges and meet certain hedging criteria. Foreign exchange contracts that meet the criteria are accounted for under the allocation method. The allocation method requires recognized foreign currency receivables or payables to be translated using the corresponding foreign exchange contract rates. Interest rate swaps that meet the criteria are accounted for under the special method, as regulated in the accounting standard, as if the interest rates under interest rate swaps were originally applied to underlying borrowings.

The Company has also developed a hedging policy to control various aspects of derivative instruments including authorization levels and transaction volumes. Based on this policy, the Company hedges the risk arising from fluctuations in foreign currency exchange rates, interest rates, and prices of securities. The Company evaluates hedge effectiveness by comparing the cumulative changes in cash flows from hedged items and corresponding changes in hedging derivative instruments. With respect to interest rate swap under the special method, the evaluation of hedge effectiveness is omitted.

#### 6) Allowance for doubtful receivables

Allowance for doubtful receivables is provided principally at an amount determined based on the historical experience of bad debts and the estimated uncollectible amounts based on the specific analysis of receivables with default possibility.

#### 7) Inventories (see Note 8)

Inventories of the Company and its domestic subsidiary are stated at the lower of average cost or net realizable value under the "Accounting Standard for Measurement of Inventories" which was issued by ASBJ.

Inventories of consolidated foreign subsidiaries are principally stated at the lower of first-in, first-out cost or net realizable value.

### 8) Property, plant and equipment (excluding lease assets)

Property, plant and equipment is stated at cost.

Before the year ended March 31, 2013, for the Company and its domestic subsidiary, depreciation of buildings acquired prior to April 1, 1998, and other property, plant and equipment is computed over the estimated useful lives of the assets using the declining-balance method. And buildings (other than leasehold improvements) which were acquired on or after April 1, 1998, are depreciated using the straight-line method. For all overseas subsidiaries, depreciation is computed over the estimated useful lives of the assets using the straight-line method.

From the year ended March 31, 2014, for the Company and its subsidiaries, depreciation of property, plant and equipment is computed over the estimated useful lives of the assets using the straight-line method.

The principal estimated usefu	I lives are as follows
Buildings and structures	31 to 50 years
Machinery and equipment	7 to 8 years
Tools, furniture and vehicles	4 to 10 years

### 9) In-process research and development and other intangible assets (excluding lease assets)

In-process research and development resources acquired through a business combination are capitalized as intangible assets at the fair value allocated in the acquisition accounting. In-process research and development and other intangible assets are amortized over their useful lives on a straight-linemethod from the point when they are available for use.

#### 10) Leases (see Note 9)

Finance leases, except for certain immaterial leases, are capitalized and depreciated over the leased property's

estimated useful lives or lease terms, in accordance with the "Accounting Standard for Lease Transactions" and the "Guidance on Accounting Standard for Lease Transactions" which were issued by ASBJ. As permitted under the accounting standard, the Company and its domestic subsidiary account for finance leases commencing prior to April 1, 2008 which do not transfer ownership of the leased property to the lessee as operating leases with disclosure of certain "as if capitalized" information.

#### 11) Goodwill

Goodwill recognized through the acquisition of Santen S.A.S. is amortized using the straight-line method over the period of expected benefit (10 years).

#### 12) Impairment of fixed assets (see Note 10)

In accordance with the "Accounting Standards for Impairment of Fixed Assets" which was issued by the Business Accounting Council in Japan, fixed assets, such as property, plant and equipment and intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Recoverability of assets to be held and used is measured by comparing the carrying amount of an asset, or group of assets, to the estimated undiscounted future cash flows expected to be generated. If the carrying amount of an asset, or group of assets, exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the greater of its net realizable value or value in use.

**13) Retirement and severance benefits** (see Note 12) Employees of the Company and certain subsidiaries are generally entitled to lump-sum severance and, in certain cases, annuity payments on retirement, based on current rates of pay, length of service and certain other factors.

The Companies have adopted the "Accounting Standard for Retirement Benefits" which was issued by the Business Accounting Council. In accordance with this standard, the allowance for retirement benefits for employees is provided based on the estimated retirement benefit obligation and the plan assets, and from April 1, 2013, the benefit formula was adopted for attributing the amount of expected retirement benefit in each period in calculating projected obligation. Actuarial gains and losses are amortized from the year in which the actuarial gains and losses are incurred, using the straight-line method over the estimated average remaining service years of employees.

The Company has a retirement benefit scheme, which is a combination of lump-sum severance plan, cash balance and defined contribution pension plan. The Company also has a retirement benefits trust.

Certain overseas subsidiaries have a retirement benefit scheme which is a combination of a cash balance and

defined contribution pension plan, and other overseas subsidiaries have defined contribution pension plans. The amounts contributed under the plans are charged to income.

Certain subsidiaries provide an allowance for payments of employees' retirement and severance benefits at 100% of the required benefit amount at the fiscal year-end calculated using the simplified method.

During the year ended March 31, 2014, the Company abolished an unfunded retirement benefit plan for directors. The remaining amounts were transferred to other liabilities of non-current liabilities.

Before the year ended March 31, 2013, the Company had an unfunded retirement benefit plan for directors. The amounts required under the plan had been fully accrued according to internal regulations.

Before the year ended March 31, 2013, the straight-line basis was adopted for attributing the amount of expected retirement benefit in each period to calculating projected obligation.

#### 14) Provision for business structure impairment

Provision for business structure impairment is provided at the estimate of the expenditure related to execution of business restructuring measures.

#### 15) Foreign currency translation

All monetary assets and liabilities denominated in foreign currencies are translated at the rate of exchange prevailing on the balance sheet date, except for those items covered by forward exchange contracts.

The Company and its domestic subsidiary have adopted the "Accounting Standard for Foreign Currency Transactions" which was issued by the Business Accounting Council in Japan.

Financial statements of overseas subsidiaries are translated into yen at year-end rates for all assets and liabilities and at weighted average rates for income and expense accounts. Adjustments resulting from the translation of financial statements are reflected under the caption, "Foreign currency translation adjustments," in net assets.

**16) Research and development** (see Note 15) Research and development expenditures are charged to income when incurred.

17) Net income and dividends per share (see Note 13) The computation of basic net income per share is based on the weighted average number of shares of common stock outstanding during each period. The average number of shares used in the computation for the years ended March 31, 2014, 2013 and 2012 was 82,537 thousand, 84,368 thousand and 87,127 thousand, respectively.

The diluted net income per share assumes the dilution that could occur if securities or other contracts to issue

common stock were exercised or converted into common stock or resulted in the issuance of common stock. The average number of shares used in the computation for the years ended March 31, 2014, 2013 and 2012 was 82,790 thousand, 84,500 thousand and 87,214 thousand, respectively.

Cash dividends per share shown in the accompanying Consolidated Statements of Income and Comprehensive Income are the amounts applicable to the respective years.

#### 18) Income taxes (see Note 17)

Income taxes are accounted for by the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating loss carryforwards, R&D tax credit and foreign tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities resulting from a change in tax rates is recognized in income in the period that includes the enactment date.

#### 19) Cash and cash equivalents

Cash and cash equivalents mainly include cash on hand, readily available deposits and all highly liquid debt investments, generally with a maturity of three months or less, that are readily convertible to known amounts of cash and are so near maturity that they present insignificant risk of changes in value.

#### 20) Reclassifications

Certain reclassifications have been made to prior years' consolidated financial statements to conform with the presentation used for the year ended March 31, 2014.

#### 21) Changes in accounting policies

#### Application of "Accounting Standard for Accounting Changes and Error Corrections"

Effective April 1, 2011, the Company and its domestic subsidiary adopted the "Accounting Standard for Accounting Changes and Error Corrections" (ASBJ Statement No. 24 issued on December 4, 2009) and the "Guidance on Accounting Standard for Accounting Changes and Error Corrections" (ASBJ Guidance No. 24 issued on December 4, 2009).

#### Change of depreciation method

Effective the year ended March 31, 2014, the Company and its domestic subsidiary have adopted the straight-line method for depreciation of property, plant and equipment.

Previously, the Company and its domestic subsidiary

calculated depreciation of property, plant and equipment primarily by the declining-balance method (except for buildings, excluding structures attached to the buildings, acquired on or after April 1, 1998 to which the straight-line method is applied).

The Company made the goal in medium-term management plan for 2011–2013 that it made the system to provide the competitive products from the mid-to-long term viewpoint by improving the management of productivity and quality, and effectiveness of global product line. To achieve that goal, the Company has reviewed the product system such as function and technique of Osaka plant, the function of supply of raw materials in Shiga Product Supply Center.

Since the year ended March 31, 2013, the Company made the new production systems and stable product supply system, for example, Shiga Product Supply Center began to make operation as a core of the productivity.

As a result of this optimization of the global production system, it is prospective that property, plant and equipment operates stably, the company can allocate the resource effectively and stably, so the Company decided to revise the previous depreciation method and adopt the straight-line method effective the year ended March 31, 2014 because the allocation of expenses among the group is considered appropriate to reflect the actual usage conditions of the Group's property, plant and equipment.

The change of depreciation method resulted in a ¥746 million (\$7,247 thousand), lower depreciation and operating income and income before income taxes during the year ended March 31, 2014 have increased by ¥603 million (\$5,856 thousand) and ¥614 million (\$5,965 thousand), respectively.

The effect of this change on segmented information is stated in Note 19. Segment Information.

#### Application of "Accounting Standard for Retirement Benefits"

As applications of the "Accounting Standard for Retirement Benefits" (ASBJ Statement No. 26, May 17, 2012 (hereinafter, the "Statement No. 26")) and "Guidance on Accounting Standard for Retirement Benefits" (ASBJ Guidance No. 25, May 17, 2012 (hereinafter, the "Guidance No. 25")) are permitted for the fiscal year beginning on or after April 1, 2013, the Company has applied the Statement No. 26 and the Guidance No. 25 effective April 1, 2013. Due to this application, actuarial gains and losses that are yet to be recognized have been recognized and the difference between retirement benefit obligations and plan assets has been recognized as a liability for retirement benefits. In addition, the Company has reviewed the determination of retirement benefit obligations and current service costs and has changed the method of attributing expected benefit to periods from a straight-line basis to a benefit formula basis. Along with this, the Company has changed the method used to determine discount rates based on the average

remaining service period for employees to a method that uses a single weighted average discount rate reflecting the expected payment period as well as the amount for each payment period.

In accordance with the article 37 of the Statement No. 26, the effect of recognizing the difference between retirement benefit obligations and plan assets as a liability for retirement benefits at the beginning of the year ended March 31, 2014 has been recognized in accumulated other comprehensive income. And the effect of changing the determination of retirement benefit obligations and current service costs has been recognized in retained earnings at the beginning of the year ended March 31, 2014.

As a result of the application, a liability for retirement benefits in the amount of ¥5,966 million (\$57,969 thousand) has been recognized, accumulated other comprehensive income has decreased by ¥1,714 million (\$16,652 thousand) and retained earnings has decreased by ¥228 million (\$2,214 thousand), at the beginning of the year ended March 31, 2014. There were no material effects on operating income and income before income taxes for the year ended March 31, 2014.

The effect of this change on the reporting segment profit (loss) for the year ended March 31, 2014 was also immaterial.

#### 3. Translation into United States Dollars

The accompanying consolidated financial statements are expressed in Japanese yen and, solely for the convenience of the reader, have been translated into United States dollars at the rate of ¥102.92 to U.S.\$1.00, the exchange rate prevailing on March 31, 2014. The translation should

not be construed as a representation that the Japanese yen have been, could have been, or could in the future be converted into United States dollars at that rate or any other rate.

#### 4. Other Comprehensive Income (Loss)

Amounts reclassified to net income in the current period that were recognized in other comprehensive income (loss) in the current or previous periods and the tax effects for each component of other comprehensive income (loss) for the three years ended March 31, 2014 were as follows:

		Thousands of U.S. dollars		
	2014	2013	2012	2014
Unrealized gains (losses) on securities:				
Increase during the year	¥ 3,316	¥ 2,896	¥ 881	\$ 32,218
Reclassification adjustments	—	—	(57)	—
Sub-total, before tax	3,316	2,896	824	32,218
Tax (expense)	(1,173)	(1,027)	(330)	(11,402)
Sub-total, net of tax	2,143	1,869	494	20,816
Foreign currency translation adjustments:				
Increase (decrease) during the year	5,542	3,339	(689)	53,844
Remeasurements of defined benefit plans				
Increase (decrease) during the year	637	—	—	6,187
Reclassification adjustments	269	—	_	2,612
Sub-total, before tax	906	—	—	8,799
Tax (expense)	(321)		_	(3,113)
Sub-total, net of tax	585		_	5,686
Total other comprehensive income (loss)	¥ 8,270	¥ 5,208	¥(195)	\$ 80,346

#### 5. Business Combination

#### During the year ended March 31, 2012

#### 1) Overview of the business combination

- Name and business of the acquired company Name of the acquired company: Novagali Pharma S.A. Business of the acquired company: Development and commercializing of ophthalmic products
- ii. Main reasons for the business combination Novagali is a pharmaceutical company that develops ophthalmic products in the dry eye domain and it also commercializes OTC pharmaceuticals. The Company believes that Novagali will play an important role with its outstanding R&D capability as well as its unique pharmaceutical technologies.

Especially, Novasorb technology will enhance the Companies' drug formulation ability as a whole. Based on Novasorb technology, Cyclokat (generic name: ciclosporin) is currently undergoing development. This is a development product in late stage pipeline in the dry eye domain. When Cyclokat is approved for production and marketing, it will be released as Europe's first prescription pharmaceutical for the treatment of dry eye and it will be also able to strengthen the Companies' global business.

- iii. Date of the business combination October 11, 2011
- iv. Legal format of the business combination Acquisition of the shares for cash consideration
- v. Name of the company after business combination Novagali Pharma S.A.
- vi. Shareholding status after business combination Wholly owned subsidiary of the Company
- vii. Main basis behind the determination of the acquiring company Acquired 100% of the shares of Novagali for cash

consideration

### 2) Operating result of the acquired company for the year ended March 31, 2012

Operating results of the acquired company from October 11, 2011 to December 31, 2011 were included in the consolidated results of the Company for the year ended March 31, 2012.

# 3) Acquisition cost of the acquired companyCash payment for acquisition¥10,402 millionOther direct costs for the acquisition¥553 millionTotal acquisition cost¥10,955 million

- 4) Goodwill recognized and method and period of amortization
- i. Goodwill recognized at the date of the business combination

¥6,195 million

#### ii. Method and period of amortization

The excess of cost over the fair value of the underlying net assets at fair value at the date of the acquisition was recognized as goodwill. The goodwill is being amortized using the straight-line method over 10 years.

5) Breakdown of acquired assets and liabilities as of date of business combination

Current assets	¥1,171 million
Fixed assets	¥12,446 million
Total assets	¥13,617 million
Current liabilities	¥340 million
Fixed liabilities	¥2,320 million
Total liabilities	¥2,660 million

- Significant intangible assets other than goodwill acquired in the business combination included in the acquisition cost
- In-process research and development

¥6,170 million

This intangible asset is amortized over the estimated useful life.

7) Estimated impact on the consolidated statements of income and comprehensive income for the year ended March 31, 2012 if the business combination had been completed as of the beginning of the year ended March 31, 2012

Since estimated impact is minimal, it is omitted.

Note: In March, 2012, Novagali changed its company form, and it became Novagali Pharma S.A.S. under the French regulation.

#### 6. Financial Instruments

The Companies have adopted the "Accounting Standard for Financial Instruments" and the "Guideline on Disclosures about Fair Value of Financial Instruments."

Information on Financial instruments for the year ended March 31, 2014, 2013 and 2012 are as follows:

#### 1) Policies for financing activities

The Companies principally use highly liquid and safe financial instruments in financing activities. The Companies basically rely on their own resources to finance operations and use derivative financial instruments only to hedge foreign exchange rate risk for foreign currency denominated assets and liabilities and do not use derivative financial instrument for speculative purposes.

#### 2) Risk management

Trade receivables are exposed to customer credit risk. To manage this risk, the Company performs due date and credit limit controls in accordance with the Companies' credit management rules and periodically assesses the financial reliability of each customer taking into account the customer's financial position and other factors. Bonds in short-term investments are exposed to the credit risk of the issuing institution. The Company invests only in high-rated bonds.

Investment securities are exposed to market risk, most of which are stocks of companies with which the Company has business relationships. The Company periodically reviews the fair market values of these securities and reports on them at the Company's board meeting.

Trade accounts payable, other payables and income taxes payable (the "operating payables") are due within one year.

Bank loans in short-term borrowings and long-term debt do not occur regularly. The Companies use them as short-term funding for business necessities according to the situation.

Operating payables and the bank loans are exposed to liquidity risk. The Company manages the risk by monitoring the monthly cash flows of each group company.

To reduce credit risk, the Company uses derivative instruments according to its policies for hedging, including rules for authorization levels, transaction volumes and entering into transactions only with highly rated banks.

The book value and fair value of the financial instruments on the consolidated balance sheet at March 31, 2014 and 2013 were as follows:

	Millions of yen							
	2014							
	Book value	Fair value	Difference	Book value	Fair value	Difference		
Cash and cash equivalents	¥ 72,397	¥ 72,396	¥ (1)	¥59,797	¥59,797	¥ (0)		
Trade receivables	52,085	52,085	_	43,841	43,841	_		
Short-term investments and Investment securities:								
Time deposits	113	113	—	86	86	_		
Held-to-maturity	4,112	4,111	(1)	4,218	4,218	(0)		
Other securities	21,235	21,235	_	15,477	15,477	_		
Trade accounts payable	(14,270)	(14,270)	—	(9,266)	(9,266)	_		
Other payables	(9,696)	(9,696)	—	(9,868)	(9,868)	_		
Income taxes payable	(8,170)	(8,170)	_	(3,039)	(3,039)	_		
Derivatives	_	_	_	_	_	_		

**Financial Section** 

	Book value	Fair value	Difference
Cash and cash equivalents	\$ 703,425	\$ 703,420	\$ (5)
Trade receivables	506,082	506,082	
Short-term investments and Investment securities:			
Time deposits	1,094	1,094	
Held-to-maturity	39,954	39,947	(7)
Other securities	206,321	206,321	
Trade accounts payable	(138,655)	(138,655)	
Other payables	(94,207)	(94,207)	
Income taxes payable	(79,379)	(79,379)	
Derivatives	_		

Notes: 1. Instruments with no fair market value are excluded in the table above.

2. Figures in parentheses indicate a liability or a decrease.

3. The following methods and assumptions were used to estimate fair value:

Cash and Trade receivables

 As these assets are settled in a short period of time, the fair value approximates book value. Cash equivalents

 The fair values of held-to-maturity debt securities included in Cash and cash equivalents are based on the quoted market prices or the prices provided by corresponding financial institutions.

Thousands of U.S. dollars 2014

Short-term investments and Investment securities

- The fair values of listed stocks are based on year-end quoted stock market prices and those of bonds are based on the quoted market prices or the prices provided by corresponding financial institutions.

- The fair value of time deposits approximates the book value.

Short-term borrowings, Trade accounts payable, Other payables and Income taxes payable

- As these liabilities are settled in a short period, fair value approximates book value.

Derivatives

- There were no outstanding transactions at March 31, 2014 and 2013.

4. Financial Instruments with no fair market value at March 31, 2014 and 2013 were as follows:

	Million	s of yen	Thousands of U.S. dollars
	2014	2013	2014
Other securities:			
Unlisted securities	¥488	¥468	\$4,741
Investment limited partnerships	17	19	167
	¥505	¥487	\$4,908

These instruments are excluded from investment securities in the table above since there are no fair market values available for these instruments.

5. The maturity profile of the anticipated future contractual cash flows in relation to the Companies' financial assets at March 31, 2014 and 2013 were as follows:

		Million	Thousands of	f U.S. dollars		
	201	4	201	3	2014	
	Due within one year	Due after one year	Due within one year	Due after one year	Due within one year	Due after one year
Cash and cash equivalents	¥ 72,397	¥—	¥ 59,797	¥ —	\$ 703,425	\$—
Trade receivables	52,085	_	43,841	_	506,082	_
Short-term investments and invest- ment securities:						
Time deposits	113	_	86	_	1,094	—
Held-to-maturity	4,100	_	2,000	2,200	39,837	_
Other securities	_			_	_	
	¥128,695	¥—	¥105,724	¥2,200	\$1,250,438	\$—

6. See Note 11 of Notes to Consolidated Financial Statements in respect to maturities of long-term debt at March 31, 2014 and 2013.

# 7. Short-term Investments and Investment Securities

The following was a summary of held-to-maturity at market value at March 31, 2014 and 2013:

	Millions of yen						
		2014			2013		
	Book value	Fair value	Difference	Book value	Fair value	Difference	
Securities with fair values exceeding book values:							
Corporate bonds	¥1,000	¥1,000	¥ 0	¥1,704	¥1,705	¥ 1	
Securities with fair values not exceeding book values:							
Corporate bonds	3,112	3,111	(1)	2,514	2,513	(1)	
	¥4,112	¥4,111	¥(1)	¥4,218	¥4,218	¥(0)	

	Thousands of U.S. dollars				
	2014				
	Book value Fair value Differ				
Securities with fair values exceeding book values:					
Corporate bonds	\$ 9,718	\$ 9,720	\$ 2		
Securities with fair values not exceeding book values:					
Corporate bonds	30,236	30,227	(9)		
	\$39,954	\$39,947	\$(7)		

The following was a summary of other securities at market value at March 31, 2014 and 2013:

		Millions of yen					
		2014		2013			
	Acquisition cost	Book value	Difference	Acquisition cost	Book value	Difference	
Securities with book values exceeding acquisition costs:							
Equity securities	¥10,244	¥16,597	¥6,353	¥12,012	¥15,061	¥3,049	
Other	0	0	_	0	0	_	
Securities with book values not exceeding acquisition costs:							
Equity securities	4,776	4,638	(138)	500	416	(84)	
Other					_	_	
	¥15,020	¥21,235	¥6,215	¥12,512	¥15,477	¥2,965	

	Thousands of U.S. dollars				
	2014				
	Acquisition cost Book value Difference				
Securities with book values exceeding acquisition costs:					
Equity securities	\$ 99,532	\$161,263	\$61,731		
Other	0	0	_		
Securities with book values not exceeding acquisition costs:					
Equity securities	46,409	45,058	(1,351)		
Other					
	\$145,941	\$206,321	\$60,380		

The market prices in the table above do not include the unlisted securities. The book value of the unlisted securities at March 31, 2014 and 2013 were ¥505 million (\$4,908 thousand) and ¥471 million, respectively.

	Millions of yen		U.S. dollars
	2014	2013	2014
Proceeds from sales	¥40	¥1	\$389
Gain on sales	—	—	—
Loss on sales			_

Proceeds from sales of investment securities and gain and loss on these sales, computed by the moving-average method, for

During the year ended March 31, 2014, investment in affiliates were reclassified as available for sale securities, due to a decrease in shareholdings as a result of the sale of securities.

If the year-end value of an investment security has declined by more than 50% of its acquisition cost, an impairment loss is recognized. When the year-end value has declined by less than 50% but more than 30%, an impairment loss is recognized if there is no possibility that the security will recover its value.

# 8. Inventories

Inventories at March 31, 2014 and 2013 consisted of the following:

the years ended March 31, 2014 and 2013, were as follows:

	Million	s of yen	Thousands of U.S. dollars
	2014	2013	2014
Merchandise and finished goods	¥16,222	¥16,703	\$157,628
Work in process	391	625	3,796
Raw materials and supplies	3,418	3,621	33,206
	¥20,031	¥20,949	\$194,630

# 9. Leases

Finance leases, commenced prior to April 1, 2008, which did not transfer ownership of the leased assets to the lessees, are accounted for as operating leases.

#### Finance leases

Lease payments, equivalent depreciation and equivalent interest expense for the three years ended March 31, 2014 were as follows:

	Millions of yen			Thousands of U.S. dollars
	2014	2013	2012	2014
Lease payments	¥—	¥—	¥13	\$—
Equivalent depreciation	¥—	¥—	¥12	\$—
Equivalent interest expense	¥—	¥—	¥Ο	\$—

#### **Operating leases**

Future minimum rents under non-cancellable operating leases at March 31, 2014 and 2013 consisted of the following:

	Million	s of yen	Thousands of U.S. dollars
	2014	2013	2014
Due within one year	¥ 489	¥ 428	\$ 4,748
Due after one year	733	847	7,124
	¥1,222	¥1,275	\$11,872

## 10. Impairment of Fixed Assets

The Company and its domestic subsidiary account for impairment of fixed assets in accordance with the "Accounting Standard for Impairment of Fixed Assets."

The Company and its domestic subsidiary review the

recorded value of their property, plant and equipment and intangible assets to determine if the future cash flows from these properties will be sufficient to support the asset's recoverable amount.

Impairment loss recognized for the three years ended March 31, 2014 was as follows:

		Millions of yen		Thousands of U.S. dollars
	2014	2013	2012	2014
Buildings and structures	¥—	¥—	¥19	\$ —
Machinery and equipment	50	—	_	488
Tools, furniture and vehicles	24	—		236
Others	20			192
	¥94	¥—	¥19	\$916

For the year ended March 31, 2012, the Company recorded impairment loss related to building and structures for its plant due to the decision to stop the use of a generator. Recoverable amounts were measured by the fair value less costs to sell using expected sales value. For the year ended March 31, 2014, the Company recorded impairment loss related to machinery and equipment, tools, furniture and vehicles and lease assets for its plant due to the decrease of the profitability. Recoverable amounts were measured by the value in use.

#### 11. Long-term Debt

Long-term debt at March 31, 2014 and 2013 consisted of the following: Long-term borrowings are executed by Santen S.A.S.

	Millions	Thousands of U.S. dollars	
	2014	2013	2014
Unsecured loan from governmental institution, due in installments by September 30, 2015, no interest	¥ 42	¥ 58	\$410
Lease obligations	60	87	581
	¥102	¥145	\$991

The aggregate annual maturities of long-term debt at March 31, 2014 were as follows:

Years ending March 31	Millions of yen	Thousands of U.S. dollars
2016	¥ 58	\$559
2017	20	193
2018	7	67
2019	7	66
2020 and thereafter	10	106
	¥102	\$991

### 12. Retirement and Severance Benefits

During the years ended March 31, 2013 and 2012 As discussed in Note 2. 13), the Company has a retirement benefit scheme, which is a combination of lump-sum severance plan, cash balance and defined contribution pension plan. The Company has a retirement benefit trust for such defined benefit corporate pension plans and lump-sum severance plan. Certain overseas subsidiaries

also have a retirement benefit scheme, which is a combination of cash balance and defined contribution pension plan and other overseas subsidiaries have defined contribution pension plans. The Company has an unfunded retirement benefit plan for directors. The amounts required under the plan have been fully accrued based on internal regulations.

The following table sets forth the details of the benefit obligation, plan assets and funded status of the Companies at March 31, 2013.

	Millions of yen
	2013
For employees:	
Benefit obligation at end of year	¥(17,372)
Fair value of plan assets at end of year	11,053
Funded status (benefit obligation in excess of plan assets)	(6,319)
Unrecognized actuarial loss	2,655
For directors:	

Accrued retirement benefit	(249)
Retirement and severance benefits recognized in the consolidated balance sheets	¥ (3,913)

Retirement and severance costs of the Companies included the following components for the fiscal year ended March 31, 2013 and 2012.

	Millions of	Millions of yen	
	2013	2012	
For employees:			
Service cost	¥ 989	¥ 896	
Interest cost	294	279	
Expected return on plan assets	(208)	(198)	
Recognized actuarial loss	309	182	
Contribution to defined contribution pension plan	928	862	
Net periodic benefit cost	¥2,312	¥2,021	

#### For directors:

Accrual for retirement benefit	¥	52	¥	69

Assumptions used in the accounting for retirement and severance benefits were as follows:

	2013	2012
Method of attributing benefit to period of service	Straight-line basis	Straight-line basis
Discount rate	mainly, 0.99%	mainly, 2.00%
Expected return on plan assets	mainly, 2.00%	mainly, 2.00%
Amortization period for actuarial losses*	mainly, 14 years	mainly, 14 years

\* Amortized on a straight-line basis over the average remaining service period for employees in service starting from the year in which the losses occur.

#### During the year ended March 31, 2014

1) Outline of the adopted retirement benefit plans

In order to provide for retirement benefits for employees, the Company and consolidated subsidiaries have adopted funded and unfunded defined benefit plans and defined contribution plans.

With defined benefit corporate pension plans (all constitute funded plans), a lump-sum payment or pension will be provided according to wage and service length.

A retirement benefit trust has been set up for some defined benefit corporate pension plans.

For retirement lump-sum plans, a lump sum (originally unfunded, however, it became funded as a result of contribution of securities to a retirement benefit trust) will be provided as a retirement benefit according to wage level and service length.

For defined benefit corporate pension plans and retirement lump-sum plans offered by some consolidated subsidiaries, net defined benefit liability and retirement benefit costs are calculated according to a simple method.

The Company abolished an unfunded retirement benefit plan for directors. The remaining amounts were transferred to other liabilities of non-current liabilities.

#### 2) Defined benefit plans

#### (i) Movement in retirement benefit obligations

	Millions of yen	Thousands of U.S. dollars
	2014	2014
Present value of obligation at April 1, 2013	¥17,372	\$168,789
Cumulative effect of changes in accounting polices	(353)	(3,431)
Present value of obligation at April 1, 2013 as restated	17,019	165,358
Service cost	1,069	10,384
Interest cost	199	1,938
Actuarial loss (gain)	(190)	(1,844)
Benefits paid	(916)	(8,903)
Other	36	348
Present value of obligation at March 31, 2014	¥17,217	\$167,281

Note: Includes plan applied simplified method.

#### (ii) Movements in plan assets

	Millions of yen	Thousands of U.S. dollars
	2014	2014
Fair value of plan assets at April 1, 2013	¥11,052	\$107,389
Expected return on plan assets	222	2,159
Actuarial gain (loss)	447	4,343
Contributions paid by the employer	438	4,251
Benefits paid	(351)	(3,415)
Other	8	81
Fair value of plan assets at March 31, 2014	¥11,816	\$114,808

#### (iii) Reconciliation from retirement benefit obligations and plan assets to liability (asset) for retirement benefits

	Millions of yen	Thousands of U.S. dollars
	2014	2014
Funded retirement benefit obligations	¥17,036	\$165,523
Plan assets	11,816	114,808
	5,220	50,715
Unfunded retirement benefit obligations	181	1,758
Total Net liability (asset) for retirement benefits at March 31, 2014	5,401	52,473
Net defined benefit liability	5,401	52,473
Total Net liability for retirement benefits at March 31, 2014	5,401	52,473

Note: Includes plan applied simplified method.

#### (iv) Retirement benefit costs

	Millions of yen	Thousands of U.S. dollars
	2014	2014
Service cost	¥1,069	\$10,384
Interest cost	199	1,938
Expected return on plan assets	(222)	(2,159)
Net actuarial loss amortization	269	2,612
Total retirement benefit costs for the fiscal year ended March 31, 2014	¥1,315	\$12,775

Note: Includes plan applied simplified method.

# (v) Remeasurements of defined benefit plans

	Millions of yen	Thousands of U.S. dollars
	2014	2014
Actuarial gains and losses	¥906	\$8,799
Total	¥906	\$8,799

#### (vi) Accumulated remeasurements of defined benefit plans

	Millions of yen	Thousands of U.S. dollars
	2014	2014
Actuarial gains and losses that are yet to be recognized	¥1,749	\$16,997
Total	¥1,749	\$16,997

# (vii) Plan assets

1. Plan assets comprise:

	2014
Equity securities	34%
Debt securities	50%
Other	16%
Total	100%

Note: Retirement benefit trusts set up for corporate pension plans account and lump-sum severance plan for 35 percent of total plan assets. Others include mainly life insurance company general accounts.

#### 2. Long-term expected rate of return

Current and target asset allocations, historical and expected returns on various categories of plan assets have been considered in determining the long-term expected rate of return.

#### (viii) Actuarial assumptions

The principal actuarial assumptions at March 31, 2014 were as follows:

	2014
Discount rate	mainly, 1.22%
Long-term expected rate of return	mainly, 2.0%

#### 3) Defined contribution plans

The amount of required contributions to the defined contribution plans of the Company and consolidated subsidiaries was ¥1,190 million (\$11,558 thousand).

#### 13. Net Assets

Under the Japanese laws and regulations, the entire amount paid for new shares is required to be designated as common stock. However, a company may, by a resolution of the Board of Directors, designate an amount not exceeding one-half of the price of the new shares as additional paid-in capital, which is included in capital surplus.

Under the Japanese Corporate Law ("The Law"), in cases where dividend distribution of surplus is made, the smaller of an amount equal to 10% of the dividend and the excess, if any, of 25% of common stock over the total of additional paid-in capital and legal earnings reserve must be set aside as additional paid-in capital or legal earnings reserve. Legal earnings reserve is included in retained earnings in the accompanying consolidated balance sheets and amounted to ¥1,551 million (\$15,074 thousand) and ¥1,551 million at March 31, 2014 and 2013, respectively.

The Law also provides for companies to purchase treasury stock and to dispose and cancel of such treasury stock by resolution of the Board of Directors.

For the year ended March 31, 2013, the Company

acquired shares of the Company's common stock under its acquisition plan by the Company's Board of Directors on August 1, 2012. As a result, treasury shares increased by ¥13,739 million for the year ended March 31, 2013.

For the year ended March 31, 2013, the Company canceled 4,938,500 shares on November 16, 2012 in accordance with board resolutions on November 1, 2012. As a result, capital surplus, retained earnings and treasury stock decreased by ¥660 million, ¥13,080 million, and ¥13,740 million, respectively.

As a result, treasury stock at March 31, 2013 amounted to ¥2 million.

Cash dividends charged to retained earnings during the three years ended March 31, 2014 represent dividends paid out during the periods. The accompanying consolidated financial statements do not include any provision for the year-end dividend of ¥50 (\$0.49) per share, aggregating ¥4,129 million (\$40,120 thousand) which was approved at the Company's shareholders' meeting on June 25, 2014 in respect of the year ended March 31, 2014.

# 14. Stock Options

The Company has stock-based compensation plans under which stock options are granted annually to directors and corporate officers at the market price on the date of the grant. The stock options granted before 2012 are fully exercisable after two years and expire ten years from the date of grant.

Stock options existing at March 31, 2014 were as follows:

Stock options granted	2013	2012	2011	2010
Persons granted	Directors and corporate officers: 9	Directors and corporate officers: 10	Directors and corporate officers: 10	Directors and corporate officers: 10
Number of shares	Common Stock 30,600	Common Stock 124,300	Common Stock 114,500	Common Stock 120,500
Date of grant	August 31, 2013	July 4, 2012	July 5, 2011	July 6, 2010
Vesting conditions	No provisions	No provisions	No provisions	No provisions
Service period	No provisions	No provisions	No provisions	No provisions
Exercise period	From September 1, 2016 to September 1, 2023	From June 23, 2014 to June 20, 2022	From June 24, 2013 to June 22, 2021	From June 25, 2012 to June 23, 2020
Stock options granted	2009	2008	2007	2006
Persons granted	Directors and corporate officers: 12	Directors and corporate officers: 12	Directors and corporate officers: 12	Directors and corporate officers: 15
Number of shares	Common Stock 168,400	Common Stock 161,700	Common Stock 99,300	Common Stock 102,700
Date of grant	July 3, 2009	July 2, 2008	July 3, 2007	July 4, 2006
Vesting conditions	No provisions	No provisions	No provisions	No provisions
Service period	No provisions	No provisions	No provisions	No provisions
Exercise period	From June 27, 2011 to June 24, 2019	From June 28, 2010 to June 25, 2018	From June 27, 2009 to June 26, 2017	From June 28, 2008 to June 24, 2016
Stock options granted	2005	2004	2003	
Persons granted	Directors and corporate officers: 15	Directors and corporate officers: 11	Directors and corporate officers: 12	
Number of shares	Common Stock 129,200	Common Stock 78,200	Common Stock 137,600	
Date of grant	July 4, 2005	July 5, 2004	July 4, 2003	
Vesting conditions	No provisions	No provisions	No provisions	
Service period	No provisions	No provisions	No provisions	
Exercise period	From June 25, 2007 to June 23, 2015	From June 26, 2006 to June 24, 2014	From June 27, 2005 to June 25, 2013	

Number, movement and price of stock options for the year ended March 31, 2014 were as follows:

Stock options granted	2013	2012	2011	2010	2009	2008
Balance at April 1, 2013						
Granted	30,600					
Vested	30,600	_				
Balance at March 31, 2014	_	_	_	_	_	_
Stock options granted	2007	2006	2005	2004	2003	
Balance at April 1, 2013	_	_	_	_		
Granted	_	_	_	_		
Vested						
Balance at March 31, 2014	_	_	_	_	_	
After vesting options (Number	of shares):					
Stock options granted	2013	2012	2011	2010	2009	2008
Balance at April 1, 2013		124,300	114,500	91,700	110,800	104,000
Vested	30,600					
Exercised		_	5,800	3,100	700	21,900
Balance at March 31, 2014	30,600	124,300	108,700	88,600	110,100	82,100
Stock options granted	2007	2006	2005	2004	2003	
Balance at April 1, 2013	89,500	70,800	38,900	2,300	900	
Vested						
Exercised	33,000	27,800	18,300	2,300	900	
Balance at March 31, 2014	56,500	43,000	20,600	_	_	
Price information (yen):						
Stock options granted	2013	2012	2011	2010	2009	2008
Option price	1	3,315	3,230	3,170	2,920	2,734
Weight-average stock price		_	4,747	4,425	4,425	4,506
Fair value at grant date	4,049.52	439.00	402.99	403.71	427.73	423.16
Stock options granted	2007	2006	2005	2004	2003	
Option price	3,050	2,715	2,480	1,743	1,176	
Weight-average stock price	4,446	4,500	4,648	4,525	4,555	
Fair value at grant date*	609.45	579.05	,	,	,	

\* Omitted due to stock options which had been granted before the Law became effective on May 1, 2006.

#### 15. Research and Development Expenditures

Research and development expenditures charged to income as incurred for the years ended March 31, 2014, 2013 and 2012 were ¥19,040 million (\$184,998 thousand), ¥16,720 and ¥17,225 million, respectively.

# 16. Business Structure Improvement Expenses

Business structure improvement expenses allocated in the year ended March 31, 2014 were attributable to improving the business structure and organization in the Companies.

# 17. Income Taxes

The Company and its domestic subsidiary are subject to a number of taxes based on earnings which, in the aggregate, resulted in an average normal tax rate of approximately 37.9%, 37.9% and 40.4% for the years ended March 31, 2014, 2013 and 2012, respectively. Overseas subsidiaries are subject to income taxes of the countries in which they operate.

The reasons for the effective rates for the years ended March 31, 2014, 2013 and 2012 differ from the normal tax rates were as follows:

	2014	2013	2012
Normal tax rate	37.9%	37.9%	40.4%
Expenses not deductible for tax purposes	2.6	1.5	1.1
Change in valuation allowance allocated to income tax expenses	0.9	2.8	(0.3)
Lower tax rates of subsidiaries	0.9	(0.5)	0.3
The effect from change in tax rates by tax reform	0.7	(0.5)	2.7
Tax credit for research and development expenses	(5.0)	(5.1)	(6.2)
Others	(1.6)	(0.7)	0.2
Effective tax rate	36.4%	35.4%	38.2%

The tax effects of temporary differences and tax loss carryforwards that gave rise to significant portions of the deferred tax assets and deferred tax liabilities at March 31, 2014 and 2013 were as follows:

	Million	Millions of yen		
	2014	2013	2014	
Deferred tax assets:				
Tax loss carryforwards	¥ 7,294	¥ 5,842	\$ 70,873	
Net defined benefit liability	3,298		32,046	
Advance payment	1,166	821	11,330	
Depreciation and amortization	1,116	1,037	10,842	
Accrued expenses	852	882	8,276	
Deferred assets for tax purposes	712	626	6,922	
Accrued enterprise taxes	610	321	5,928	
Loss on impairment of golf membership rights	59	58	569	
Loss on valuation of securities	57	57	552	
Loss on impairment of fixed assets	53	18	519	
Loss on valuation of inventories	25	43	240	
Retirement and severance benefits	—	2,562		
Retirement and severance benefits for directors	_	88		
Other	3,028	1,837	29,417	
Subtotal	18,270	14,192	177,514	
Valuation allowance	(8,188)	(6,764)	(79,559)	
Total gross deferred tax assets	10,082	7,428	97,955	
Deferred tax liabilities:				
In-process research and development	(2,786)	(2,256)	(27,065)	
Net unrealized holding gains on securities	(2,225)	(1,057)	(21,616)	
Reserve for special depreciation	(11)	(18)	(109)	
Other	(22)	(26)	(213)	
Total gross deferred tax liabilities	(5,044)	(3,357)	(49,003)	
Net deferred tax assets	¥ 5,038	¥ 4,071	\$ 48,952	

Net deferred tax assets at March 31, 2014 and 2013 were reflected in the accompanying consolidated balance sheets under the following captions:

	Million	Thousands of U.S. dollars	
	2014	2013	2014
Current assets – deferred tax assets	¥ 2,346	¥ 1,880	\$ 22,796
Investments and other assets – deferred tax assets	5,488	4,460	53,327
Non-current liabilities – deferred tax liabilities	(2,796)	(2,269)	(27,171)
Net deferred tax assets	¥ 5,038	¥ 4,071	\$ 48,952

Adjustment of deferred tax assets and liabilities for enacted changes in tax laws and rates

During the year ended March 31, 2012, according to the promulgation of the "Act for Partial Revision of the Income Tax Act, etc. for the Purpose of Creating Taxation System Responding to Changes in Economic and Social Structures" (Act No. 114 of 2011) and the "Act on Special Measures for Securing Financial Resources Necessary to Implement Measures for Reconstruction Following the Great East Japan Earthquake" (Act No. 117 of 2011), effective from the fiscal year beginning on and after April 1, 2012, the corporate tax rate will be reduced and a special recovery tax will be imposed.

In accordance with this reform, the effective statutory tax rates which are used to calculate deferred tax assets and deferred tax liabilities will be reduced to 37.86% from 40.44% for temporary differences expected to be reversed on or after April 1, 2012, and to 35.48% for temporary differences expected to be recovered or settled on or after April 1, 2015.

During the year ended March 31, 2014, according to the promulgation of change in "Act on Special Measures for Securing Financial Resources Necessary to Implement Measures for Reconstruction Following the Great East Japan Earthquake" (Act No. 117 of 2011), effective from the fiscal year beginning on and after April 1, 2014, the effective statutory tax rate will be reduced from 37.86% to 35.48%.

The effect of this change on the financial report for the year ended March 31, 2014, was also immaterial.

#### **18. Contingent Liabilities**

The Company has provided guarantees to financial institutions covering employee loans. At March 31, 2014, the total amount of outstanding guarantees was ¥103 million (\$1,005 thousand).

#### **19. Segment Information**

General information about reportable segments

The determination of the Companies' operating segments is based on the organization units for which information is reported to the Company's chief operating decision making body, the Board of Directors. The Board of Directors reviews the internal report in order to assess performance and allocate resources. "Pharmaceuticals" is the Companies' only one reportable segment and includes manufacturing and distribution of prescription and OTC pharmaceuticals.

Basis of measurement about reported segment profit or loss, segment assets, segment liabilities and other material items The accounting policies for the reportable segments are basically the same as those described in Note 2, Summary of Significant Accounting Policies. Performance is measured based on segment operating profit. Transfer pricing between reportable segments are determined on an arm's length basis.

# Change in depreciation method of property, plant and equipment

As discussed in Note 2. 21) previously, the Company and its domestic subsidiaries calculated depreciation of property, plant and equipment primarily by the declining-balance method (except for buildings, excluding structures attached to the buildings, acquired on or after April 1, 1998 to which the straight-line method is applied). Effective the year ended March 31, 2014, however, the Company and its domestic subsidiaries have adopted straight-line method for depreciation of property, plant and equipment.

As a result, segment profit has increased by ¥602 million (\$585 thousand) in "Pharmaceuticals" and there are no material effect on segment profit in "Other."

			Millions of yen		
For the year ended March 31, 2014	Pharmaceuticals	Other	Total	Adjustments	Consolidated
Net Sales:					
External customers	¥145,713	¥2,950	¥148,663	¥ —	¥148,663
Intersegment	—	124	124	(124)	—
Total	145,713	3,074	148,787	(124)	148,663
Segment profit (loss)	27,828	(414)	27,414	_	27,414
Segment assets	138,283	3,466	141,749	89,357	231,106
Other items:					
Depreciation and amortization	2,861	53	2,914	—	2,914
Amortization of goodwill	1,013	_	1,013	_	1,013
Increase in property, plant and equipment and intangible assets	3,816	54	3,870	_	3,870
			Millions of yen		
For the year ended March 31, 2013	Pharmaceuticals	Other	Total	Adjustments	Consolidated
Net Sales:					
External customers	¥116,810	¥2,256	¥119,066	¥ —	¥119,066
Intersegment		114	114	(114)	
Total	116,810	2,370	119,180	(114)	119,066
Segment profit (loss)	25,354	(673)	24,681	_	24,681
Segment assets	120,546	2,444	122,990	76,651	199,641
Other items:					
Depreciation and amortization	2,607	50	2,657	—	2,657
Amortization of goodwill	634	—	634	—	634
Increase in property, plant and equipment and intangible assets	5,198	45	5,243	_	5,243
			Millions of yen		
For the year ended March 31, 2012	Pharmaceuticals	Other	Total	Adjustments	Consolidated
Net Sales:					
External customers	¥111,846	¥2,570	¥114,416	¥ —	¥114,416
Intersegment		113	113	(113)	
Total	111,846	2,683	114,529	(113)	114,416
Segment profit	26,684	48	26,732	_	26,732
Segment assets	106,535	2,126	108,661	90,140	198,801
Other items:					
Depreciation and amortization	2,718	69	2,787	_	2,787
Amortization of goodwill	162	_	162		162
Increase in property, plant and equipment and intangible assets	15,902	69	15,971		15,971

Information about reported segment profit (loss), segment assets, segment liabilities and other material items was as follows:

	Thousands of U.S. dollars				
For the year ended March 31, 2014	Pharmaceuticals	Other	Total	Adjustments	Consolidated
Net Sales:					
External customers	\$1,415,789	\$28,667	\$1,444,456	\$ —	\$1,444,456
Intersegment	—	1,196	1,196	(1,196)	—
Total	1,415,789	29,863	1,445,652	(1,196)	1,444,456
Segment profit (loss)	270,381	(4,018)	266,363	_	266,363
Segment assets	1,343,598	33,675	1,377,273	868,216	2,245,489
Other items:					
Depreciation and amortization	27,802	512	28,314	—	28,314
Amortization of goodwill	9,841		9,841		9,841
Increase in property, plant and equipment and intangible assets	37,081	522	37,603	_	37,603

Notes: 1. "Other" mainly includes the medical device business segments.

2. "Segment profit" is reconciled for operating income described in the Consolidated Statements of Income and Comprehensive Income.

3. "Adjustments" represents unallocated corporate assets which principally include surplus operating capital (cash and cash equivalents,

short-term investments and investment securities) and deferred tax assets.

4. "Depreciation and amortization" and "Increase in property, plant and equipment and intangible assets" include long-term prepaid expenses and its amortization.

Information about products and services was as follows:

		Thousands of U.S. dollars		
	2014	2013	2012	2014
Pharmaceuticals:				
Prescription pharmaceuticals:				
Ophthalmic	¥127,396	¥ 98,981	¥ 93,620	\$1,237,814
Anti-rheumatic pharmaceuticals	10,251	9,874	9,987	99,605
Other prescription pharmaceuticals	1,611	1,481	3,642	15,649
OTC pharmaceuticals	6,455	6,474	4,597	62,721
Other:				
Medical devices	2,678	2,246	2,558	26,023
Other	272	10	12	2,644
Total	¥148,663	¥119,066	¥114,416	\$1,444,456

Information about geographic areas was as follows:

	Millions of yen			Thousands of U.S. dollars
	2014	2013	2012	2014
Net Sales:				
Japan	¥122,113	¥100,712	¥ 95,374	\$1,186,486
Europe	12,295	9,202	8,880	119,459
North America	1,073	582	3,451	10,428
Asia	13,174	8,560	6,706	127,999
Other	8	10	5	84
Total	¥148,663	¥119,066	¥114,416	\$1,444,456
Property, plant and equipment:				
Japan	¥ 22,826	¥ 22,560	¥ 21,157	\$ 221,785
Europe	2,106	2,597	2,245	20,460
North America	644	710	635	6,259
Asia	2,053	1,553	1,486	19,944
Total	¥ 27,629	¥ 27,420	¥ 25,523	\$ 268,448

Information about major customers was as follows:

	Millions of yen			Thousands of U.S. dollars	Related business
	2014	2013	2012	2014	segment
Suzuken Co., Ltd.	¥32,546	¥25,486	¥23,297	\$316,230	Pharmaceuticals
Mediceo Corporation	26,334	21,716	20,392	255,873	Pharmaceuticals

Information about loss on impairment of fixed assets by reportable segment was as follows:

	Millions of yen			Thousands of U.S. dollars
	2014	2013	2012	2014
Pharmaceuticals	¥—	¥—	¥19	\$ —
Other	94			916
Total	¥94	¥—	¥19	\$916

Information about amortization of goodwill and unamortized balances by reportable segment was as follows:

	Millions of yen		Thousands of U.S. dollars
	2014	2013	2014
Amortization of goodwill:			
Pharmaceuticals	¥1,013	¥634	\$9,841
Other	—		_
Total	¥1,013	¥634	\$9,841
Balance at end of period:			
Pharmaceuticals	¥6,298	¥5,936	\$61,193
Other	—		—
Total	¥6,298	¥5,936	\$61,193

#### 20. Subsequent Events

#### Significant asset purchase

On May 13, 2014, The Company's Board of Directors made a resolution to purchase ophthalmology assets from Merck & Co., Inc. ("Merck"), and the Company entered into an Agreement with Merck on the same day. On July 1, 2014, the Company acquired assets related to Japan, Asia Pacific and Europe excluding some countries.

#### 1) Purpose of the purchase

The Company has been taking steps to become "A Specialized Pharmaceutical Company with a Global Presence" based on the long-term corporate vision for 2020. This transaction strengthens Santen's line of glaucoma products and allows us to further meet the medical needs of patients suffering from various eye diseases.

As a result of the purchase, the Company will strengthen its glaucoma business in Japan, accelerate overseas growth by accessing new markets in Asia and Europe and enhance its business platform.

#### 2) Overview of seller

- i. Company name: Merck & Co., Inc.
- ii. Location: New Jersey, U.S.A
- iii. Name of representative: Kenneth C. Frazier
- iv. Paid-in capital: \$1,778 million
- Main business: Research and development, production and marketing of prescription pharmaceuticals, vaccines, biologic pharmaceuticals and consumer health and animal health products

#### 3) Overview of the purchase

The patents, trademarks, domain names, health registrations and others related to Merck's ophthalmology products (COSOPT, COSOPT PF, TRUSOPT, TRUSOPT PF, TIMOPTIC, TIMOPTIC PF, TIMOPTIC XE, SAFLUTAN and TAPTIQOM) in Japan, Europe and Asia Pacific

#### 4) Purchase price

The purchase price for ophthalmology assets, for Japan, Asia Pacific and Europe excluding some countries, was \$548 million. Another purchase in the amount of approximately \$50 million is planned for some European countries. The Company may need to make additional payments based on defined sales milestones.

#### 5) Closing date

The closing date was July 1, 2014 for the asset purchase for Japan, Asia Pacific and Europe excluding some countries. A closing date of October 2014 is planned for some European countries.

#### Large-sum borrowings

On May 13, 2014, the Company's Board of Directors made a resolution to partly finance the asset purchase from Merck. On June 20, 2014, the Company entered into an agreement the terms of which are outlined below and conducted the borrowing transaction on June 27, 2014.

- 1) Purpose of the borrowing Fund asset purchase from Merck
- Name of lenders The Bank of Tokyo-Mitsubishi UFJ, Ltd.
- 3) Aggregate borrowing limit ¥45 billion (\$437,233 thousand)
- 4) Commitment line period From June 20, 2014 to June 20, 2015
- 5) Rate

Base rate and spread

- 6) The due date of repayment June 20, 2015
- 7) Collateral and guarantees None
- 8) Borrowing amount ¥35 billion (\$340,070 thousand) Conducted date: June 27, 2014

#### 1 Framework of internal control over financial reporting

We, as President and CEO of Santen Pharmaceutical Co., Ltd. (the Company) and CFO of the Company, are responsible for the design and operation of internal controls over financial reporting ("ICOFR") and establishing and maintaining an ICOFR based on the framework of ICOFR in Japan in accordance with "On the Setting of the Standards and Practice Standards for Management Assessment and Audit concerning Internal Control Over Financial Report (Business Accounting Council (Council Opinions), February 15, 2007)."

Internal control aims at achieving the objectives to a reasonable extent with the organized and integrated function of individual component as a whole. Therefore ICOFR does not provide an absolute assurance for preventing and detecting all errors to consolidated financial statements.

#### 2 Assessment Scope, Timing and Procedures

#### Basis of Presenting Internal Control Report

The report on ICOFR of the consolidated financial statements of the Company ("Internal Control Report") is prepared on the basis of generally accepted assessment standards of internal control over financial reporting in Japan ("Assessment Standards") and is compiled from the Internal Control Report prepared by the Company as required by the Financial Instruments and Exchange Law of Japan ("Law").

The Assessment Standards require management to assess ICOFR, which consists of the internal controls over the consolidated financial statements included in the Annual Securities Report filed under the Law and the internal control over disclosure information and others included in the Annual Securities Report that materially affects the reliability of the financial statements.

The scope of management's assessment of ICOFR in this annual report is different from the scope required by the Assessment Standards. Management assessment of ICOFR in this annual report covers the ICOFR with respect to the accompanying consolidated financial statements only. In addition, as explained in Note 1 on the basis of presentation of consolidated financial statements, the accompanying consolidated financial statements are reclassified and modified from the consolidated financial statements prepared for the purpose of the Law. Supplementary information is also added to the consolidated financial statements. The process of making reclassifications and modifications and the addition of certain information is for the convenience of readers outside Japan. Management voluntarily includes the process in its assessment of ICOFR, even though it is outside the scope of the Assessment Standards.

#### Scope of Assessment

Management's assessment of ICOFR was conducted as of March 31, 2014 in accordance with the Assessment Standards.

In evaluating internal controls, management first assessed internal controls that have a material impact on overall consolidated financial reporting ("company-level controls") and, based on the results, selected business process to be assessed. For assessment of process level controls management analyzed the selected business processes, identify a key control that would have a material impact on the reliability of financial reporting, and assessed effectiveness of internal controls through assessing design and operation of the key controls.

Management assessed the effectiveness of the ICOFR applicable for the Company and its subsidiaries, to extent necessary in light of their degree of impact on the reliability of financial reporting. Management determined materiality for reliability of financial reporting in light of their degree of quantitative and qualitative impact on financial reporting. From the results of the company-level controls assessment of the Company and two subsidiaries, management determined a reasonable scope for process level controls to be assessed.

Management selected the Pharmaceuticals business unit of the Company as the significant business unit for assessing process level controls, as its sales was more than 80% of the previous fiscal year's consolidated net sales. The process related to net sales, account receivables and inventories from the Pharmaceuticals business unit of the Company was selected for process level control assessment as they have significant relation to the business objectives of the Company. Apart from selected significant business units, including other business units, processes whose accounts were determined to have a high risk of misstatement and involves significant use of management estimate and projection, and processes whose businesses or operations included high risk transactions were additionally selected for controls assessment.

#### 3 Results of assessment

Based on our assessment procedures noted above, I concluded the Company's internal control over financial reporting was effective as of March 31, 2014.

#### 4 Supplementary information

No subsequent events have arisen that has caused to materially effect our evaluation of the effectiveness on the internal control over financial reporting as of March 31, 2014.

5 Other None.

hushava

Akira Kurokawa President & CEO

August 8, 2014

arter:

Kazuo Koshiji CFO

# Independent Auditor's Report



To the Board of Directors of Santen Pharmaceutical Co., Ltd.:

#### **Report on the Consolidated Financial Statements**

We have audited the accompanying consolidated financial statements of Santen Pharmaceutical Co., Ltd. and its consolidated subsidiaries, which comprise the consolidated balance sheets as at March 31, 2014 and 2013, and the consolidated statements of income and comprehensive income, statements of changes in net assets and statements of cash flows for each of the three-year in the period ended March 31, 2014, and a summary of significant accounting policies and other explanatory information.

Management's Responsibility for the Consolidated Financial Statements Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in Japan, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatements, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in Japan. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on our judgement, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, while the objective of the financial statement audit is not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### Opinion

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Santen Pharmaceutical Co., Ltd. and its consolidated subsidiaries as at March 31, 2014 and 2013, and their financial performance and cash flows for each of the three-year in the period ended March 31, 2014, in accordance with accounting principles generally accepted in Japan.

#### Emphasis of Matter

Without qualifying our opinion, we draw attention to the following:

- As described in Note 2 to the consolidated financial statements, effective April 1, 2013, the Company has applied the Accounting Standard for Retirement Benefits (ASBJ Statement No. 26, May 17, 2012) and Guidance on Accounting Standard for Retirement Benefits (ASBJ Guidance No. 25, May 17, 2012).
   As described in Note 20 to the consolidated financial statements, on May 13, 2014, the Company's Board of Directors made a resolution to purchase ophthalmology assets from Merck & Co., Inc. ("Merck"), and the Company entered into an Agreement with Merck on the same day. On July 1, 2014, the Company acquired assets related to Japan, Asia Pacific and Europe excluding some countries.
   As described in Note 20 to the consolidated financial statements, on May 13, 2014, the Company's Board of Directors made a resolution to partly finance the asset is purchased from Merck Account on the company acquired assets related to a partly financial statements, on May 13, 2014, the Company's Board of Directors made a resolution to partly
- finance the asset purchase from Merck. On June 20, 2014, the Company entered into an Agreement and conducted the borrowing transaction on June 27, 2014.

#### **Convenience Translation**

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended March 31, 2014 are presented solely for convenience. Our audit also included the translation of yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 3, to the consolidated financial statements.

#### Report on the Internal Control Report

We also have audited the accompanying report on internal control over financial reporting of the consolidated financial statements of Santen Pharmaceutical Co., Ltd. as at March 31, 2014 ("Internal Control Report").

Management's Responsibility for the Internal Control Report Management is responsible for the design and operation of internal control over financial reporting and the preparation and fair presentation of the internal control report in conformity with assessment standards for internal control over financial reporting generally accepted in Japan. Internal control over financial reporting may not completely prevent or detect financial statement misstatements.

#### Auditor's Responsibility

Our responsibility is to express an opinion on the internal control report based on our internal control audit. We conducted our internal control audit in accordance with auditing standards for internal control over financial reporting generally accepted in Japan. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the Internal Control Report is free from material misstatement.

An internal control audit involves performing procedures to obtain audit evidence about the assessment of internal control over financial reporting in the Internal Control Report. The procedures selected depend on the auditor's judgement, including significance of effect on the reliability of financial reporting. Also, an internal control audit includes evaluating the appropriateness of the scope, procedures and result of the assessment determined and presented by management, and the overall internal control report presentation. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Opinion

In our opinion, the Internal Control Report, in which Santen Pharmaceutical Co., Ltd. states that internal control over financial reporting was effective as at March 31, 2014, presents fairly, in all material respects, the assessment of internal control over financial reporting in conformity with assessment standards for internal control over financial reporting generally accepted in Japan.

KPMG AZSA LLC

August 8, 2014 Osaka, Japan

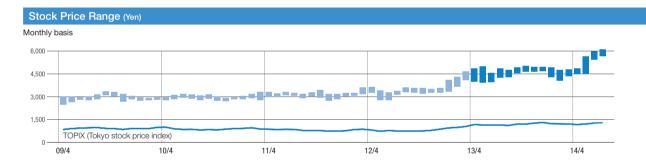
# Corporate Information / Stock Information

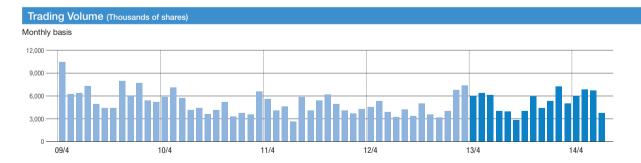
As of March 31, 2014

Corporate Headquarters	Santen Pharmaceutical Co., Ltd. Grand Front Osaka Tower A, 4-20 Ofuka-cho, Kita-ku, Osaka 530-8552, Japan URL: http://www.santen.com Investor relations contact: TEL: +81-6-6321-7000 (Main) +81-6-4802-9360 (IR) E-MAIL: ir@santen.co.jp
Established	1890
Paid-in Capital	¥7,264 million
Number of Shareholders	7,780
Stock Exchange Listings	Tokyo * The cash equity markets of the Tokyo Stock Exchange and the Osaka Securities Exchange were integrated on July 16, 2013.
Ticker Code	4536
Transfer Agent	Osaka Corporate Agency Division, Mitsubishi UFJ Trust and Banking Corporation 6-3, Fushimi-cho 3-chome, Chuo-ku, Osaka 541-8502, Japan
Major Offices	Sendai, Tokyo, Nagoya, Osaka and Fukuoka
Manufacturing Plants	Noto and Shiga
Research Laboratory	Nara Research and Development Center
Number of Employees	3,072 (non-consolidated: 1,878)
Number of Shares Issued	82,582,903



Major Shareholders		
Name	Number of shares held	Percentage of investment
Japan Trustee Service Bank, Ltd.	5,516 Thousands of shares	6.7%
State Street Bank and Trust Company 505223	5,463	6.6
Development Bank of Japan Inc.	3,310	4.0
The Master Trust Bank of Japan, Ltd.	2,794	3.4
Nippon Life Insurance Company	2,398	2.9
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	2,120	2.6
Ono Pharmaceutical Co., Ltd.	1,861	2.3
Daiichi Sankyo Company, Ltd.	1,836	2.2
Gic Private, Ltd.	1,568	1.9
National Mutual Insurance Federation of Agricultural Cooperatives	1,438	1.7





Yearly High and Low Prices					
	2010	2011	2012	2013	2014
High (yen)	3,195	3,445	3,655	5,050	6,150
Low (yen)	2,694	2,731	2,778	3,330	4,065

Notes 1: Calendar years.

2: Stock prices for 2014 are for the period to the end of July.

3: Stock price and trading volume from July 16, 2013 are those listed on the Tokyo Stock Exchange; prior to this date are those listed on the Osaka Securities Exchange.

# Plants and Laboratory



#### **1** Noto Plant

2-14, Shikinami, Houdatsushimizu-cho, Hakui-gun, Ishikawa 929-1494, Japan TEL: +81-767-29-2666 FAX: +81-767-29-4233



Shiga Product Supply Center 348-3, Aza-suwa, Oaza-shide, Taga-cho, Inukami-gun, Shiga 522-0314, Japan TEL: +81-749-48-2900 FAX: +81-749-48-2901



Tampere Plant
 Niittyhaankatu 20, P.O. Box 33,
 FIN-33721 Tampere, Finland
 TEL: +358-3-284-8111 FAX: +358-3-318-1900





Suzhou Plant
 No. 169 Tinglan Road, Suzhou Industrial Park,
 Jiangsu Province 215026, P.R.C.
 TEL: +86-512-6295-7500 FAX: +86-512-6295-7800



S Nara Research and Development Center 8916-16, Takayama-cho, Ikoma-shi, Nara 630-0101, Japan TEL: +81-743-79-4501 FAX: +81-743-79-4521



Corporate Headquarters and Su	ubsidiaries	Business
<ol> <li>Corporate Headquarters</li> </ol>	Grand Front Osaka Tower A, 4-20 Ofuka-cho, Kita-ku, Osaka 530-8552, Japan TEL: +81-6-6321-7000 FAX: +81-6-6328-5082	Research, development, production, marketing of pharmaceuticals and medical devices
2 Claire Co., Ltd.	348-3, Aza-suwa, Oaza-shide, Taga-cho, Inukami-gun, Shiga 522-0314, Japan TEL: +81-749-48-2234 FAX: +81-749-48-2239	Cleaning of antidust and sterilized clothing
Santen Holdings U.S. Inc.	2100 Powell Street, Suite 1600, Emeryville, California 94608, U.S.A.	Holding company for North American businesses and business development
9 Santen Inc.	2100 Powell Street, Suite 1600, Emeryville, California 94608, U.S.A. TEL: +1-415-268-9100 FAX: +1-510-655-5682	Clinical development of pharmaceuticals and business development
Advanced Vision Science, Inc.	5743 Thornwood Drive, Goleta, California 93117, U.S.A. TEL: +1-805-683-3851 FAX: +1-805-964-3065	Development, production, marketing of medical devices
Santen Holdings EU B.V.	Herikerbergweg 238, 1101CM Amsterdam Zuidoost, Netherlands	Centralization of financial controls for European operations
Santen Oy	Niittyhaankatu 20, P.O. Box 33, FIN-33721 Tampere, Finland TEL: +358-3-284-8111 FAX: +358-3-318-1900	Research, development, production, marketing of pharmaceuticals
8 Santen S.A.S.	1 rue Pierre Fontaine, Genavenir IV, F-91058 Evry cedex, France TEL: +33-1-69-87-40-20 FAX: +33-1-69-87-40-30	Research, development, marketing of pharmaceuticals and medical devices
9 Santen GmbH	Erika-Mann-Strasse 21 80636 Munchen, Germany TEL: +49-89-848078-0 FAX: +49-89-848078-60	Business development, product planning, marketing of pharmaceuticals
SantenPharma AB	Solna torg 3, SE-17145 Solna, Sweden TEL: +46-8-83-4140 FAX: +46-8-83-4145	Marketing support of pharmaceuticals
<ol> <li>Santen Pharmaceutical (China) Co., Ltd.</li> </ol>	No.169 Tinglan Road, Suzhou Industrial Park, Jiangsu Province 215026, P.R.C. TEL: +86-512-6295-7500 FAX: +86-512-6295-7800	Production, marketing, clinical development of pharmaceuticals
Santen Pharmaceutical Korea Co., Ltd.	KCUBE Tower 3F, 35, Yeoksam-ro 25-gil, Yeoksam-dong, Gangnam-gu, Seoul, 135-921, Korea TEL: +82-2-754-1434 FAX: +82-2-754-2929	Marketing, clinical development of pharmaceuticals
Taiwan Santen Pharmaceutical Co., Ltd.	16F, No. 57, Sec. 2, Tun-Hwa South Rd., Taipei 10681, Taiwan, R.O.C. TEL: +886-2-2700-1553  FAX: +886-2-2700-1730	Marketing of pharmaceuticals
Santen India Private Limited	No. 216, Raheja Chambers, 12 Museum Road, Bangalore 560 001, India TEL: +91-80-4932-3700  FAX: +91-80-4932-3799	Pharmaceutical market research
Santen Pharmaceutical Asia Pte. Ltd. Other Office	One Raffles Place, Level 24 Tower 1, 1 Raffles Place 048616, Singapore TEL: +65-6408-0573 FAX: +65-6408-0601	Administration of pharmaceutical affairs and business promotion for the Santen Group within the ASEAN region
Beijing Representative Office	Suit 1206B, TOWER W3, Oriental Plaza, No. 1, East Chang An Ave., Dong Cheng District, Beijing 100738, P TEL: +86-10-8515-1515 FAX: +86-10-8515-1020	P.C.
Ho Chi Minh City Representative Office	Unit 1406, Fl.14, Empress Tower, 138-142 Hai Ba Trung, Dakao Ward, District 1, HCMC, Vietnam TEL: +84-8-3824-2585 FAX: +84-8-3824-2586	

# **Company History**

### 1890

Founder Kenkichi Taguchi opens Taguchi Santendo in Kitahama, Osaka

### 1925

Operations incorporated as Santendo Co., Ltd.

# 1935

Yodogawa Plant established in Higashiyodogawa-ku, Osaka

#### 1944

Head Office transferred to Yodogawa Plant (Higashiyodogawa-ku, Osaka)

#### 1945

Company name changed to Santendo Pharmaceutical Co., Ltd.

### 1958

Company name changed to current form of Santen Pharmaceutical Co., Ltd.

Santen enters prescription pharmaceutical business

# 1977

Stock listed on First Section of Tokyo Stock Exchange and Osaka Securities Exchange

Production system introduced to allow filling of solution into molded containers to make bottle-packed eye drops

### 1982

Central Research Laboratories established 1985

Noto Plant established

#### 1990

Long-term business vision formulated to mark centenarv

#### 1993

Subsidiary Santen Inc. established in the U.S.

1970

1975

1978

1981

1987

Launch of antibiotic

ophthalmic Ecolicin

medical devices

Launch of anti-inflammatory

Santen commences sales of

ophthalmic Flumetholon

### 1994

Subsidiary Santen GmbH established in Germany

# 1996

Representative office established in Beijing, China

Nara Research and Development Center and Shiga Plant (currently Shiga Product Supply Center) established

#### 1997

Finnish ophthalmics pharmaceutical company acquired and Santen Oy established

Subsidiary Taiwan Santen Pharmaceutical Co., Ltd. established

# 1998

Medium-term Plan "Hitomi 21" formulated

# 2000

Subsidiary Santen Pharmaceutical Korea Co., Ltd. established

Representative office established in Guangzhou, China

#### 2001

U.S.-based Advanced Vision Science, Inc. acquired

# 1900

# **Product History**

### 1890s

Launch of Heburin-gan, a cold medicine



# 1899 Launch of Daigaku Eye



1952 Launch of Daigaku Penicillin Eye Drops

1954 Launch of Daigaku Super

Launch of Mydrin-P, a mydriatic drug (for pupil dilation)

Launch of Super Sante marks first use of plastic eye drop containers

Launch of Thiola, an original liver detoxification agent



1965

Note: Based on the years when sales were launched by Santen Pharmaceutical

1953 Launch of Daigaku Mycillin Eye Drops



MYDRIN-D

in Japan

# 1963



Launch of Sante de U

# 1990

1991 Launch of Sante FX



# 1992

Launch of BSS PLUS, an ophthalmic perfusion and bathing solution

Launch of Kary Uni, a treatment for early-stage senile cataracts



# 1995

Launch of sodium hyaluronate (sold as Hyalein in Japan), a treatment for corneal and conjunctival epithelial disorders

ophthalmic Alegysal



Launch of anti-rheumatic Azulfidine EN

Launch of Opegan Hi, an adjuvant for ophthalmic operations

# 1999

Launch of *Timoptol XE*, a treatment for glaucoma and ocular hypertension

Launch of Sante FX Neo

Launch of anti-allergy



Launch of *Timoptol*, a treatment for glaucoma and ocular hypertension



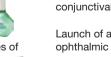
1986 Santen commences sales of intraocular lenses

Launch of anti-rheumatic Rimatil

Launch of anti-infective ophthalmic Tarivid







# 2002

Introduced Dimple Bottle, an innovative patient-oriented container for ophthalmic solutions

#### 2003

2003-2005 Medium-Term Management Plan formulated

ISO 14001 certification acquired by Noto Plant

Santen Activity Improved Navigator (SAIN) medical information support system developed

#### 2004

U.S. sales partnership with Johnson & Johnson Vision Care, Inc. (currently VISTAKON Pharmaceuticals, LLC) started

#### 2005

Representative office established in Shanghai, China

Subsidiary Santen Pharmaceutical (China) Co., Ltd. established

#### 2006

2006-2010 Medium-Term Management Plan formulated

#### 2007

Representative office established in Shenyang, China

Santen Pharmaceutical (China) Co., Ltd. established Suzhou Plant

#### 2008

Completion of pharmaceutical development building and ancillary building at Nara **Research and Development Center** 

#### 2009

Santen Pharmaceutical (China) Co., Ltd. commenced direct marketing

#### 2010

Santen Pharmaceutical Korea Co., Ltd. commenced direct marketing

### 2011

2011-2013 Medium-Term Management Plan formulated

Subsidiary Santen India Private Limited established in India

#### 2012

Acquired Novagali Pharma S.A.S. of France (currently Santen S.A.S.) and made it a wholly owned subsidiary

Established Santen Holdings EU B.V. in the Netherlands as a holding company

Started integrated production at the Suzhou Plant

### 2013

Head Office transferred to Kita-ku. Osaka

Established Santen Pharmaceutical Asia Pte. Ltd. in Singapore

#### 2014

Acquired ophthalmology assets from U.S.-based Merck & Co., Inc

2014-2017 Medium-Term Management Plan formulated

# 2000

### 2000

Launch of anti-infective ophthalmic solution levofloxacin (sold as Cravit in Japan)



### 2001

Launch of Detantol. a treatment for glaucoma and ocular hypertension

Launch of anti-allergy ophthalmic Livostin

# 2002

Launch of Sante de U Plus E Alpha Launch of Sante 40

### 2003

Launch of ClariFlex foldable intraocular lenses

### 2004

Launch of Rescula, a treatment for glaucoma and ocular hypertension Launch of anti-rheumatic Metolate

### 2006

Launch of Papilock Mini, a treatment for vernal keratoconjunctivitis Launch of Sante Medical 10

Launch of Sante AL Cool II

Launch of Sante Uruoi Contact

Launch of nutritional

foldable intraocular lens

Launch of tafluprost (sold as Tapros in Japan), a treatment for glaucoma and ocular hypertension

# 2009

Launch of Sante FX V Plus Launch of Eternity Natural foldable intraocular lens



2010

2010 Launch of Cosopt, a treatment for glaucoma and ocular hypertension

Launch of diquafosol sodium



Launch of Sante Medical Guard

Launch of Intravitreal VEGF Inhibitor EYLEA

Launch of Sante 40 series

# 2013

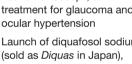
Launch of Sante Beautéye



Launch of Tapros Mini, a treatment for glaucoma and ocular hypertension

Launch of anti-allergy ophthalmic solution Alesion







### 2007

# 2008

supplement Sante Lutax Launch of Sante 40i





Launch of Eternity













www.santen.com



vegetable oil ink.

The following are registered trademarks of Santen's alliance partners: Cravit, Tarivid and Oftaquix (Dalichi Sankyo Company, Limited); Azulfidine (Pfizer Inc.); Detantol (Eisai Co., Ltd.); Livostin (Johnson & Johnson); Rescula (R-Tech Ueno, Ltd.); EYLEA (Bayer AG); and Alesion (Boehringer Ingelheim)