SANTEN PHARMACEUTICAL CO., LTD.



# Annual Report 2016



Annual Report 2016 Year Ended March 31, 2016 (Santen's Values)

Core Value

# Tenki ni sanyo suru

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

### Mission Statement

By focusing on ophthalmology,

Santen develops unique scientific knowledge and organizational capabilities that contribute to the well-being of patients, 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."



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### NOTE ON ACCOUNTING STANDARDS

The Santen Group has adopted International Financial Reporting Standards (IFRS) from the fiscal year ended March 31, 2015, for the purpose of enhancing the international comparability of its financial information. Figures for the fiscal year ended March 31, 2014 have been restated to conform to IFRS for comparison and analysis purposes.

### NOTE CONCERNING GRAPHS

Unless otherwise noted, graphs in this annual report are based on fiscal years ended March 31.

### NOTE CONCERNING DATA

Some information in this annual report is based on IMS data (JPM). Source: ©2016 IMS Health Santen analysis based on IMS-JPM data from April 2011 to March 2016. Reprinted with permission.

### CAUTION CONCERNING FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements regarding the Company's plans, strategies and results for the future. All forwardlooking 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, adverse economic conditions, delays in new products launch, currency exchange rate, legislative and regulatory developments.

The following are registered trademarks of Santen's alliance partners: Cravit and Tarivid (Daiichi Sankyo Company, Limited); Azulfidine (Pfizer Inc.); Detantol (Eisai Co., Ltd.); Livostin (Johnson & Johnson); Rescula (R-Tech Ueno, Ltd.); Eylea (Bayer AG); Alesion (Boehringer Ingelheim); and Rimatil and Metolate (AYUMI Pharmaceutical Corporation) Santen's Values embody what the Company has continued to recognize as important since its foundation in 1890. Based on Santen's Values, 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 specialized ophthalmic pharmaceutical company. Building on the scientific knowledge and organizational capabilities that Santen has nurtured for over 125 years, the Company will continue to contribute to society, working primarily for the benefit of patients and their loved ones.



Guided by Santen's Values, we will fully harness our strengths as a specialized ophthalmic pharmaceutical company to contribute to patients around the world.



Guided by Santen's Values, Santen has continuously implemented a cycle of creation and innovation since its founding in 1890, focusing its efforts on ophthalmology and related areas. Today, Santen has grown into a company that is able to demonstrate unique strengths. Santen is channeling resources into the field of ophthalmology to create outstanding products that satisfy unmet medical needs. Concurrently, through activities to provide high-quality pharmaceutical information, Santen is focusing on assisting medical professionals and contributing to the treatment of their patients.

**Thorough customer focus** 

Specialized expertise in the field of ophthalmology

Accumulated knowledge and experience over 125 years

### Business Domains and Presence in the Global Market

Revenue Composition by Operation

Others -

Medical Devices

Over-the-Counter (OTC) · Pharmaceuticals

Prescription Anti-Rheumatic Pharmaceuticals

> Revenue for the Fiscal Year Ended March 31, 2016 ¥**195.3** billion

Prescription Ophthalmic Pharmaceuticals
 Share of Japanese Market



Over

The number of ophthalmologists in Japan is currently around 14,000. Santen's approximately 400-strong medical representative (MR) workforce strives diligently to call on virtually every one of Japan's ophthalmologists to provide detailed pharmaceutical information.

Ocuntries in Which Products Are Sold

Further Information

Prescription Ophthalmic Pharmaceuticals Revenue Composition



P.28 Review of Operations

P.22 Research and Development

countries

We are working to create new value to drive sustainable growth, with the aim of achieving our long-term strategic vision.



Santen is working to become a "Specialized Pharmaceutical Company with a Global Presence," in order to realize its long-term strategic vision toward 2020. Under the Fiscal 2014-2017 Medium-Term Management Plan, we are aiming to increase Santen's presence in the global market based on strategies focused on the themes of Product Development, Business Expansion, and Organization and Talent.



P.10 Top Message

### Long-Term Strategic Vision toward 2020

## Aiming to Become a "Specialized Pharmaceutical Company with a Global Presence"

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

Fiscal 2014-2017	Medium-Term Mana	gement Plan Basic Policies

Product	Transform product development to realize
Development	enhanced productivity and achieve sustained growth
Business Expansion	Grow business in Asia/EMEA <sup>1</sup> and strengthen market presence by entering into new markets
Organization and Talent	Develop talent and organization to realize sustained growth
Activities to	Strengthen corporate governance/
Support	Promote CSR activities integrated
Sustained Growth	into business conduct

1. Europe, the Middle East and Africa

### Long-Term Growth Targets toward 2020

Prescription Ophthalmic Businesses



in Japan and Asia



Overseas Sales in Fiscal 2020

40%-50%

### Financial and Non-Financial Highlights

Santen Pharmaceutical Co., Ltd. and Its Subsidiaries Years ended March 31

					Millions of yen	Thousands of U.S. dollars	Change
-	2012	2013	2014	2015	2016	2016	2016/2015
	J-GAAP	J-GAAP	IFRS	IFRS	IFRS	IFRS	
For the year:							
Net sales/Revenue	¥ 114,416	¥ 119,066	¥146,260	¥ 161,831	¥195,291	\$1,733,149	20.7%
Core operating profit	_	_	30,403	39,088	43,067	382,205	10.2
Core net profit for the year	_	_	19,813	25,948	29,163	258,809	12.4
R&D expenses	17,225	16,720	16,862	17,477	19,990	177,401	14.4
At year-end:							
Total assets	¥198,801	¥ 199,641	¥237,640	¥304,200	¥355,399	\$3,154,060	16.8%
Net assets/Total equity	164,861	165,132	187,210	211,779	260,009	2,307,498	22.8
Interest-bearing debt	157	133	153	37,161	22,484	199,538	(39.5)
Per share data (yen and U.S. dollars):							
Core EPS (Core basic earnings)	¥ _	¥ _	¥ 48.01	¥ 62.82	¥ 70.48	\$ 0.63	12.2%
Equity/Equity attributable to	1.887.81	1.998.44	452.43	511.14	627.78	5.57	22.8
owners of the company Cash dividends, applicable to the period	,	20.00	20.00	22.00	25.00	0.22	13.6
Financial data:							
Core operating profit margin (%)	_	_	20.8	24.2	22.1		
Overseas sales to net sales/ Overseas sales to revenue (%)	16.6	15.4	16.5	22.9	27.4		
R&D expenditures to net sales/ R&D expenses to revenue (%)	15.1	14.0	11.5	10.8	10.2		
Core ROE (Core return on equity attributable to owners of the company)	—	—	11.2	13.0	12.4		
Core dividend payout ratio (%)	_	—	41.7	35.0	35.5		
Dividend payout ratio (%)	50.8	51.1	41.9	37.8	19.4		
Non-financial data:							
Total energy usage (GJ)	738,375	738,340	698,207	731,381	617,922		(15.5) %
Total water usage (km <sup>3</sup> )	618	562	489	516	519		0.6
CO2 emissions volume (tons)	35,811	35,573	33,210	34,650	31,840		(8.1)
SOx emissions volume (tons)	9.6	9.1	8.4	8.0	10.1		26.3
NOx emissions volume (tons)	8.6	9.2	7.1	10.8	7.9		(26.9)
VOC emissions volume (tons)	71.5	80.8	85.8	64.8	64.7		(0.2)
Final waste disposal ratio (%)	1.16	1.39	1.16	0.50	0.02		

Notes:

1. Please see P.56 for differences between IFRS and Japanese GAAP.

2. Core in the table above shows the figures on a core basis. Please see P.7 for the definition.

3. Santen conducted a five-for-one share split of ordinary shares on the effective date of April 1, 2015. Per share data other than dividends for the fiscal year ended March 31, 2014 and the subsequent fiscal years are calculated under the assumption that the share split took effect at the beginning of the fiscal year ended March 31, 2014. Dividends per share have been retrospectively adjusted to reflect the impact of the share split.

4. The table above shows both IFRS and Japanese GAAP accounts, whereas the graphs show only IFRS accounts.

5. U.S. dollar amounts have been translated from yen, solely for the convenience of the reader, at the rate of ¥112.68 to US\$1.00, the exchange rate prevailing on March 31, 2016.

6. Figures in parentheses indicate a decrease.

7. Equity is calculated by deducting stock subscription rights from net assets under J-GAAP.

8. Target volumes have been set for energy usage, water usage, and CO<sub>2</sub> emissions for all business bases including domestic offices, and for all overseas production bases. The CO<sub>2</sub> emission coefficient uses the country-specific coefficients of the IEA. Target figures have been set for NOx, SOx, and VOC emissions for the business bases in Japan and overseas targeted to be measured excluding the Suzhou Plant. Target figures have been set for the final waste disposal ratio for Japan, where rigorous final disposal is required. The final waste disposal ratio represents the ratio of the total amount of final waste disposal to the total amount of waste emissions.

### Further Information

P.42 Summary of CSR Activities in the Fiscal Year Ended March 31, 2016 P.56 Report and Analysis of Operating Results and Financial Condition P.62 Eleven-year Summary of Selected Financial Data





**Operating profit** 

Profit before tax

Income tax expenses

Net profit for the year

Finance income

Finance expenses

excluded income and

expenses

excludes certain gains and expenses from IFRS results on a full basis. The definition of core basis is shown on the right.

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Core income tax expenses

Core net profit

for the year







### **Non-Financial Data**





Aggregate target: Domestic business bases

Implemented the 3R initiative of reduce, reuse and recycle, and achieved a level of less than our goal of 0.07% for the final waste disposal ratio target for the fiscal year ended March 31, 2016.

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**Operating Results** 

### **Prescription Ophthalmic Pharmaceuticals**



2. Market share and market position in Japan for the fiscal year ended March 31, 2016. Source: Santen analysis based on IMS-JPM data from April 2015 to March 2016. ©2016 IMS Health. Reprinted with permission.

3. Market share and market position in the Japanese OTC eye drop market for the fiscal year ended March 31, 2016. Source: Santen Pharmaceutical Co., Ltd.



Overview of the Fiscal Year Ended March 31, 2016

### Revenue and operating profit both reached all-time highs. We are accelerating growth to realize our long-term strategic vision toward 2020.

Santen has grown tremendously in an effort to realize our long-term strategic vision toward 2020 of becoming a "Specialized Pharmaceutical Company with a Global Presence." During the fiscal year ended March 31, 2016, revenue rose 20.7% year on year to an all-time high of ¥195.3 billion. On the earnings front, core operating profit was up 10.2% to ¥43.1 billion and core net profit for the year rose 12.4% to ¥29.2 billion. Earnings increased even more markedly on an IFRS basis which includes the gain from the assignment of the anti-rheumatic pharmaceuticals business.

In the domestic prescription ophthalmic business, the intravitreal VEGF inhibitor Eylea (aflibercept [genetical recombination]) posted growth in sales. Eylea is a treatment for retinal disorders that have high unmet medical needs. Tapros (tafluprost), a treatment of glaucoma and ocular hypertension, and Diquas (diquafosol sodium), a treatment of dry eye, also contributed to sales. Dry eye is becoming increasingly prevalent particularly among office workers. In addition, the anti-allergy ophthalmic solution Alesion (epinastine hydrochloride) also contributed to higher revenue. Seasonal factors, including pollen allergy, tend to increase the number of patients using Alesion.

In the EMEA<sup>1</sup> business, one of our current areas of focus,

Santen expanded its presence supported by growth in products such as the glaucoma and ocular hypertension treatment Taflotan/Saflutan (tafluprost). Other contributors included ophthalmology products in the glaucoma field taken over from U.S.-based Merck & Co., Inc. and Ikervis (ciclosporin), a new product that addresses the unmet medical needs of adult patients with severe keratitis associated with dry eye disease, which has not improved despite treatment with tear substitutes. In the fast-growing Asian business, sales grew primarily in China, Korea and Vietnam, which are positioned as key countries. In ASEAN countries, Santen focused on bolstering sales activities in addition to laying a strong business foundation.

Under the basic policies of the Fiscal 2014-2017 Medium-Term Management Plan, Santen is steadily executing strategies focused on the themes of Product Development, Business Expansion, and Organization and Talent, with a view to realizing the Company's long-term strategic vision toward 2020. Looking ahead, we will accelerate these activities even more.

In particular, in R&D, the cornerstone of the Product Development theme, we launched the glaucoma and ocular hypertension treatment Tapros in China in March 2016. In

The Santen Group is making significant strides toward realizing our long-term strategic vision toward 2020 of becoming a "Specialized Pharmaceutical Company with a Global Presence" by continuing to focus our efforts on the specialized area of ophthalmology. Looking ahead, we will continue to extend our strengths further, with the aim of supporting the treatment of patients around the world and contributing to society. We kindly ask for the continued support of all of our stakeholders.

a. Muchaur

Akira Kurokawa President and Chief Executive Officer

addition, we are making steady progress on Global Phase 3 studies of DE-109 (sirolimus) for the treatment of non-infectious uveitis of the posterior segment (hereinafter, "NIU-PS"), with the aim of obtaining regulatory approval around the world. Moreover, in August 2016 Santen strengthened its glaucoma pipeline through the acquisition of InnFocus, Inc., a glaucoma implant device developer. We will continue to develop and bolster our pipeline of new products that satisfy unmet medical needs.

Looking at the Business Expansion theme, Santen aims to drive further growth in the EMEA and Asian businesses by leveraging sales growth from ophthalmology products taken over from U.S.-based Merck & Co., Inc. and business expansion in new regions. To make this happen, we will work to strengthen our global product supply and sales organizations.

In terms of the Organization and Talent theme, we will develop innovative leaders who will be responsible for medium- and long-term business growth, as we steadily strengthen our global management systems.

1. Europe, the Middle East and Africa

### **Enhancing Shareholder Returns**

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

year ended March 31, 2016, we paid full-year dividends of ¥25 per share. This resulted in a dividend payout ratio of 35.5% on a core basis, which excludes factors such as the earnings contribution from the assignment of the anti-rheumatic pharmaceuticals business.

Going forward, we remain committed to providing stable shareholder returns. At the same time, we will continue to retain funds primarily for R&D investments, while examining the adoption of a flexible stance that includes the acquisition of treasury stock, as necessary.

### Fiscal 2014-2017 Medium-Term Management Plan Progress of Financial Figures

	Results for the Fiscal Year Ended March 31, 2016	Fiscal 2017 Medium-Term Management Plan <sup>2</sup>
Revenue	¥195.3 billion	Over ¥205 billion
Core operating profit	¥43.1 billion	Over ¥51.5 billion
Core net profit for the year	¥29.2 billion	Over ¥35 billion
Core ROE	12.4%	<b>Over 14</b> %
R&D expenses	¥20.0 billion	Around ¥21 billion

 Financial figures have been restated on an IFRS basis from the Japanese GAAP figures issued when the Medium-Term Management Plan was announced. Under Japanese GAAP, operating income is over ¥45.0 billion, net income is over ¥31.0 billion, and ROE is over 13.0%.

### Medium-Term Management Plan

### Product Development R&D

### Leveraging our global R&D network, we are pursuing product development in ophthalmology fields that make the most of our strengths.

Santen is concentrating on product development in fields that make the most of the Company's strengths, primarily in the fields of corneal and conjunctival epithelial disorders, glaucoma and ocular hypertension, and retinal and uveal disorders. This is to satisfy the unmet medical needs of patients around the world, thereby contributing to further advances in ophthalmic treatment. The Product Development theme is set forth as a basic policy of the Fiscal 2014-2017 Medium-Term Management Plan. Under this theme, Santen has three basic strategies: (1) reduce time to launch, (2) improve the probability of technical success, and (3) target and address unmet medical needs. Guided by those strategies, Santen is undertaking a range of activities on a global basis.

Santen developed *lkervis* using its proprietary Novasorb technology<sup>1</sup>. *lkervis* is approved for treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes. Since July 2015, Santen has sequentially started sales of *lkervis* in European countries and is working to achieve market penetration. In Asia, Santen has also successively filed for marketing approval of *lkervis* to meet the unmet medical needs of patients with dry eye. In Korea, Santen filed for marketing approval in December 2015.

Santen is also advancing life cycle management<sup>2</sup> to maximize the value of its existing products. DE-111 (tafluprost/timolol maleate), a combination ophthalmic solution for the treatment of glaucoma and ocular hypertension that is marketed in Japan and EMEA, was launched in Korea in April 2016, and obtained marketing approval in Thailand in March 2016. Moreover, in December 2015, Phase 2b/3 trials of DE-117 for the treatment of glaucoma and ocular hypertension were initiated in Japan.

In April 2015, Santen filed for marketing approval in Asia of DE-109, for which it is conducting Global Phase 3 studies for the treatment of NIU-PS. As regards filing with the European Medicines Agency for Marketing Authorization Application of DE-109, we plan to file again based on the results of the second Global Phase 3 study that is currently underway.

In addition, Santen is concentrating on business development activities such as "Network Product Development<sup>3</sup>" to strengthen its pipeline. As part of these efforts, in March 2016, Santen licensed and obtained the global development rights to DE-126 (sepetaprost) from ONO PHARMACEUTICAL CO., LTD. DE-126 is an FP/EP3 dual agonist for the treatment of glaucoma and ocular hypertension that has completed Phase 2 clinical trials in the U.S. Moreover, in August 2016, Santen acquired InnFocus, Inc., a developer of glaucoma devices for implant surgery to lower and sustain intraocular pressure.

By strengthening coordination between its R&D bases in Japan, the U.S. and Europe, Santen will continue working to rapidly develop differentiated products that address unmet medical needs.

- Novasorb aids widespread absorption of ophthalmic solutions over the ocular surface by applying a positive electric charge to an ophthalmic emulsion. This causes the drug to be attracted to the negatively charged ocular tissues
- Aligning one compound to treatment needs over the long term and augmenting through additional indication, dosage, formulation and combination products to increase product value
- 3. An approach of proactive use of compounds and technologies from outside the company in product development

### New Growth Drivers to Fulfill the Unmet Medical Needs of Patients around the World

*Ikervis*, a treatment for severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes



In Europe, only over-the-counter drug treatments for dry eye were previously available, making it difficult for patients to receive appropriate treatment for severe keratitis with dry eye. Against this backdrop, *lkervis* is now steadily penetrating the European market as a new prescription pharmaceutical that satisfies the unmet medical needs of patients with dry eye disease in the region.

### DE-109, a treatment for NIU-PS

Currently, only limited treatment options are available for NIU-PS, which is a leading cause of blindness. Therefore, a novel treatment that has minimal local and systemic side effects is desired. Santen expects to satisfy the unmet therapeutic needs of patients through DE-109, a non-steroidal treatment. Business Expansion Domestic Business We are targeting sustained growth by contributing to the treatment of patients through our strong presence, acquired knowledge and expertise in Japan.

In Japan, Santen must address changes at the therapeutic frontlines as needs surrounding ophthalmic treatment become increasingly sophisticated. Accordingly, we intend to supply pharmaceuticals that satisfy the unmet medical needs of patients, in conjunction with strengthening our initiatives in response to government policies to promote the use of generics to reduce medical expenditures. With this in mind, Santen conducted promotion activities, including the provision of pharmaceutical information that accurately reflects each medical facility's unmet needs and changes in those needs. As a result, revenue for the fiscal year ended March 31, 2016 in the domestic prescription pharmaceutical business rose sharply by 17.9% year on year to ¥124.2 billion.

Guided by its Fiscal 2014-2017 Medium-Term Management Plan, Santen is working to enhance its competitive advantages by maximizing the value of new products such as *Eylea* and *Alesion* and that of mainstay products such as *Tapros*. Santen is also seeking to achieve growth by supplying products and services that take advantage of its acquired knowledge and expertise as a specialized pharmaceutical company with a strong presence in Japan. Looking ahead, we will endeavor to achieve business growth by further strengthening coordination among the prescription pharmaceutical, OTC and medical devices business categories. Domestic Business Sales Results and Medium-Term Management Plan



Business Expansion Asian Business

### We are working to expand our market share in key countries, as we accelerate business expansion in the ASEAN region.

Aiming to become #1 in Asia as set forth in our long-term strategic vision toward 2020, we are putting emphasis on business activities that help to advance ophthalmic treatment in Asia by supplying outstanding products and conducting activities to provide pharmaceutical information. We have positioned China, Korea and Vietnam as key countries. By accurately fulfilling the therapeutic needs of patients in the region, we are striving to achieve sales growth exceeding the market growth rate and to maximize profits.

In the Asian business, revenue in the fiscal year ended March 31, 2016 grew substantially by 35.6% to ¥22.6 billion, as mainstay products steadily penetrated the market as a result of concentrating on promotion activities for those products. Notably, in China, Santen announced the establishment of a joint venture through a collaboration with Chongqing Kerui Pharmaceutical (Group) Co., Ltd., a state-owned company with more than 100 years of history. The goal of this collaboration is to supply ophthalmic pharmaceuticals to even more Chinese patients. We will continue to steadily strengthen business expansion in Asian countries, with the aim of contributing further to ophthalmic treatment.

Asian Business Sales Results and Fiscal 2017 Medium-Term Management Plan



### Medium-Term Management Plan

### Business Expansion EMEA Business

### We aim to further contribute to the treatment of patients by taking full advantage of our acquired knowledge and expertise in the glaucoma and dry eye fields.

One of the key priorities of the Fiscal 2014-2017 Medium-Term Management Plan is to accelerate business expansion in EMEA. The EMEA area is home to numerous countries, and regulations, laws and other rules differ by country and region. Therefore, it will be crucial for Santen to take appropriate measures to ensure a steady supply of pharmaceuticals as it seeks to enhance its presence in each country. The transfer of ophthalmology products taken over from U.S.-based Merck & Co., Inc. had been completed in 23 countries as of March 2016, including new countries such as Italy and Spain. We have thus established a framework for ensuring the stable supply of Santen's pharmaceuticals to many more patients.

In the EMEA business, revenue increased dramatically by 80.6% to ¥25.6 billion in the fiscal year ended March 31, 2016. We are strengthening our organization to address our

expanded geographical reach in terms of countries and regions, and our larger product lineup. In addition, we are working to offer comprehensive proposals in the glaucoma field, including those involving Santen's mainstay product *Taflotan/Saflutan*. From July 2015, *Ikervis* has been successively launched in European countries including the U.K. and Germany. Santen is working to maximize the value of *Ikervis* by fully leveraging its sales network, which has expanded as a result of taking over ophthalmology products from U.S.-based Merck & Co., Inc., in conjunction with harnessing our knowledge and expertise as Japan's foremost pioneer in the treatment of dry eye disease.

Looking ahead, we will harness our acquired knowledge and expertise in ophthalmology fields, with the aim of making an even greater contribution to ophthalmic treatment in EMEA.





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Organization and Talent Building a Solid Organization and Developing Talent

We are advancing global initiatives with the aim of strengthening talent and organizational capabilities, enhancing specialization and pursuing a true customer focus.

Aiming to realize our long-term strategic vision toward 2020, we are developing innovative leaders who will be responsible for sustained growth, in conjunction with strengthening our global management system, focusing on primary functions such as R&D, product supply, and sales and marketing.

In April 2015, we established Santen Leadership Competency (SLC), a framework that conveys our expectations for personnel based on Santen's Values, along with a new personnel system based on SLC. SLC is being rolled out globally, particularly in Asia and EMEA spearheaded by Santen Corporate Headquarters. As a basic guideline for developing the capabilities and formulating the career plans of each employee, SLC will support employees who are motivated to grow and provide them with growth opportunities. To achieve sustained growth, Santen will continue the pursuit of each employee honing his or her specialization and true customer focus by leveraging Santen's strengths developed as a specialized ophthalmic pharmaceutical company. Moreover, we will push ahead with activities guided by Santen's Values. In doing so, we will bring together our employees as "One Santen, One Team," even as they become increasingly diverse. In this manner, we will further strengthen the Group's collective capabilities to achieve our strategic vision.

Strengthening Corporate Governance and Enhancing Corporate Social Responsibility (CSR) Activities Corporate Governance and CSR

### Santen is pursuing a true customer focus, thereby contributing primarily to the welfare of patients and their loved ones, as well as to society at large.

We believe that enhancing and strengthening corporate governance is essential to maintaining and improving corporate value and the common interests of our shareholders. While ensuring transparent and sound management practices, we are focusing on improving our business performance in tandem with pushing ahead with measures to mitigate risk. Moreover, we place particular importance on our compliance system in order to fulfill our social mission of providing appropriate products and services to patients around the world. The Santen Code of Practice, which was established by the Company, has been made known to all employees to ensure that we advance business activities based on high standards of ethics by sharing Santen's Values throughout the Group. With the awareness that the fulfillment of CSR by Santen forms the basis of management, we have defined 7 Core Subjects of CSR for promoting CSR activities. Based on the three perspectives of "customers," "employees" and "society" stated in the Santen Code of Practice, we have formulated a CSR Policy and are working to enhance our activities.

Looking ahead, we will continue to promote business activities based on Santen's Values, with a view to realizing the goals of the long-term strategic vision. By doing so, Santen will continue to contribute to the welfare of patients and their loved ones, as well as to society at large.

# Accelerate Business Development Feature Contributing to Further Enhance Ophthalmic Treatment in Asia

Based on our long-term strategic vision toward 2020, our goal is to become #1 in Asia in terms of our contribution to ophthalmic treatment by enhancing Quality of Life (QOL) for patients.





Satoshi Suzuki Corporate Officer, Head of Asia Division

### **Expanding Our Presence in Asian Markets to Realize Our Long-Term Strategic Vision**

As part of Santen's long-term strategic vision toward 2020 of becoming a "Specialized Pharmaceutical Company with a Global Presence," we are placing emphasis in our business activities on responding to the unmet medical needs of patients in Asia and contributing to the development of ophthalmic treatment in the region. We have designated China, Korea and Vietnam as key countries under our Fiscal 2014–2017 Medium-Term Management Plan. We are also developing operations in ASEAN countries and India with the aim of achieving sales growth exceeding the market growth rate while maximizing profits.

In the fiscal year ended March 31, 2016, revenue in Asia increased significantly by 35.6% year on year to ¥22.6 billion, reflecting increased market penetration primarily in China, as a result of concentrating on promotion activities for mainstay products. We have established in-house sales and marketing capabilities in China, Korea and Vietnam, and are developing business through local subsidiaries in Thailand, Malaysia, Philippines, Taiwan and Singapore. We are also targeting the huge Indian market and we will contribute further to ophthalmic treatment in Asia.

### Track Record and Strategy for the Asian Business

Our contribution as a specialized ophthalmic pharmaceutical company focuses on catering to the different medical needs in each country.

### Expanding Product Lineups to Fulfill Customer Needs and Promoting Services

Demographic aging and the lifestyle changes due to economic development are expected to increase the demand across Asia in therapeutic areas such as dry eye and glaucoma. There is also high demand in emerging countries for drugs to treat patients with ocular infections. While some countries and regions such as Korea, Taiwan and Singapore have advanced healthcare systems, there are some emerging countries where disparity in access to healthcare<sup>1</sup> is an issue. It is vital that we take a tailored approach to customer needs in each country as we strive to become #1 in Asia as a specialized ophthalmic pharmaceutical company.

In March 2016, we launched *Tapros* (tafluprost) in China for treatment of glaucoma and ocular hypertension. We also announced a new joint venture between Santen Pharmaceutical (China) Co., Ltd. and Chongqing Kerui Pharmaceutical (Group) Co., Ltd. with the aim to supply ophthalmics to more patients in China. In other Asian markets, we are accelerating efforts to gather intelligence and provide information to customers, with a view to supplying highly competitive new products that meet the needs of local patients. Through these measures, Santen will help to enhance the QOL of patients in Asia.

1. Patient access to appropriate medicines and therapies

Fiscal Year Ended March 31, 2016 Asian Business Revenue Results

¥22.6 billion

Fiscal Year Ended March 31, 2016 Year-on-Year Growth of Asian Business

35.6%

Growing in

# Message



 
 Fung-Rong Hu, M.D.
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 President of the Corneal Society of Taiwan Academy of Ophthalmology
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 Professor of Ophthalmology, Chief of Corneal Service

Department of Ophthalmology, National Taiwan University Hospital

# High Hopes for Santen to Contribute to Further Advances in Ophthalmic Treatment in Asia

In recent years, ophthalmic treatment in Taiwan has made dramatic advances. However, patients still have unmet needs for treatment in certain therapeutic categories. In addition, I recognize that Taiwan faces issues such as restrictions on the drugs and medical devices that could be reimbursed by the National Health Insurance healthcare system, as well as regional disparities in healthcare. In this environment, I believe it is important for doctors, government, research institutions, pharmaceutical companies and other parties to work closely together with the aim of contributing to the welfare of patients, as part of efforts to achieve further advances in ophthalmic treatment.

As an ophthalmologist, I place significant trust in the quality, efficacy, and safety of the pharmaceuticals supplied by Santen. Moreover, I highly appreciated Santen's commitment to proactively contributing to advances in ophthalmic treatment in Asia, including its substantial support for the 31st Asia-Pacific Academy of Ophthalmology Congress (APAO) held in Taiwan in March this year.

Going forward, I expect Santen to leverage its expertise as a specialized ophthalmic pharmaceutical company that has established the leading position in Japan and to become the best partner of ophthalmologists by supplying even better products, information, and services that aid the treatment of patients throughout Asia, including Taiwan.

**SIA** 

### **Progress on the Chinese Business**

We are contributing to enhanced patient QOL in China with an expanded product lineup.

### Fulfill Local Medical Needs in China to Realize Goal of Attaining Market Leadership

At Santen Pharmaceutical (China) Co., Ltd. ("Santen China"), we see our primary sources of competitive advantage as the provision of valuable products and services alongside our activities to provide high-quality pharmaceutical information. After establishing our local subsidiary, Santen China, in 2005, and starting operations at our local production plant in Suzhou in 2007, we have an integrated manufacturing and marketing set-up in China. We have grown sales of products meeting local medical needs, notably Cravit (levofloxacin), anti-infective eye drops, and Hyalein (sodium hyaluronate), a corneal and conjunctival epithelial disorder treatment. In March 2016, we launched Tapros (tafluprost) for the treatment of glaucoma and ocular hypertension in China, which expanded our local lineup to 11 products. Society's aging means the market for treating glaucoma is expanding steadily. By



Ye Liu Corporate Officer General Manager, Santen Pharmaceutical (China) Co., Ltd.

establishing *Tapros* as a mainstay product, we hope to make a significant contribution to higher QOL for patients in China.



Fiscal Year Ended March 31, 2016 Year-on-Year Growth of Chinese Business



### **Revenue from Chinese Business**



# Growing in Asia

# China

### A Stronger Business Base and Organization

Today, Santen China has a medical representative (MR) force of around 280, which is second only to Santen's MR force in Japan. Santen China is engaged in activities to provide pharmaceutical information in line with unique local needs. In 2013, we established Santen Pharmaceutical Sales & Marketing (Suzhou) Co., Ltd. as a second local Chinese subsidiary to drive higher market penetration of Santen products and brands.

In March 2016, we announced a new joint venture for prescription ophthalmics as part of an alliance with Chongqing Kerui Pharmaceutical (Group) Co., Ltd., a state-owned company with more than 100 years of history. The joint venture is building a production plant according to the high quality requirements of Santen, with plans by Kerui to commercialize ophthalmic medicines under license. This venture will aim to provide a reliable supply of high-quality products to many local patients using our core technology and expertise.

By reinforcing our business base and organization, Santen China is striving to achieve sales growth exceeding the market growth rate and to improve profits to achieve the ultimate goal of market leadership.



# Message



# Focusing on Proposing Comprehensive Solutions from the Customer's Perspective

In addition to providing pharmaceutical information about its products, since the fiscal year ended March 31, 2016, Santen China has been developing promotional campaigns through multiple products that focus on comprehensive disease solutions. For example, Santen China has been building e-promotion platform (such as the e-communication platform and the strategies platform) and is achieving rapid information exchange and communication among its Marketing Division, MRs and ophthalmologists. Market share of key product *Cravit* continues to expand (in value and volume), and sales of *Hyalein* are growing steadily in line with its market penetration. Santen China achieved strong sales growth that exceeded market growth, leading the overall market of ophthalmology with an overwhelming advantage and laying a solid foundation for achieving our long-term strategic vision toward 2020.

Zhendong Li Director, Marketing Department Santen Pharmaceutical (China) Co., Ltd.



### Business Development in ASEAN Countries, Vietnam and Korea

We are working to boost Santen's presence further so we can contribute to ophthalmic treatment in Asian countries.

# Business Development in ASEAN Countries and India

To reinforce the Asian business, Santen is steadily developing operations across ASEAN countries. In 2013, we established Santen Pharmaceutical Asia Pte. Ltd. in Singapore as a regional headquarters for the business in Southeast Asia and India to help accelerate the acquisition of regulatory approvals and product development for the region. The mainstay product that we seek to launch in these markets is the dry eye treatment *Diquas* (diquafosol sodium). We are working to gain regulatory approval for this, other mainstay Santen products, and ophthalmology products transferred from U.S.-based Merck & Co., Inc. Over time, we plan to successively launch prescription ophthalmics tailored to the specific needs of each market. Reinforcing sales activities by local subsidiaries, we are targeting further growth for Santen in the ASEAN region, where the market for prescription ophthalmics is forecast to grow at around 10% per year. The Indian market also possesses exceptional potential and we are preparing to enter this market, which we consider to be important, as part of our aim to become #1 in Asia.

### **Progress on the Vietnamese Business**

Having opened a representative office in Ho Chi Minh City in 2013, Santen currently has around 50 staff working in this important market to improve ophthalmic treatment in Vietnam. We are working to raise awareness of glaucoma and dry eye through ophthalmological society meetings and in partnership with local medical institutions, with plans to expand Santen's market presence in Vietnam by launching new products such as the dry eye treatment *Diquas*.

# Message



### Aiming to Become #1 in the Korean Market

Santen Korea celebrated its 16th anniversary in 2016. We initially developed the business in Korea selling through agencies, but our direct sales have grown to account for more than 85% of the total. Focusing on relationships and partnerships built on trust has enabled Santen to achieve market-leading customer satisfaction in Korea. We aim to make our organization strong, adaptable to changing conditions, possessing an overwhelming competitive advantage, and trusted as the leading specialist in the ophthalmology field dedicated to patient care. By realizing such aims, we will contribute to better ophthalmic treatment in Korea and embody Santen's Values. By sharing our experiences and know-how with other Santen operations in Asia to help the Group in realizing its long-term strategic vision toward 2020, we also believe that Santen Korea has a valuable role to play in the success of the Asian business.

### Han-Woong Lee

Vice President, Head of Prescription Pharmaceutical Division Santen Pharmaceutical Korea Co., Ltd.



Seminar on dry eye treatment Diquas (Vietnam)

Santen's market share in Vietnam has already risen to rank third in Asia behind China and Korea. By launching new products continually, we aim to realize our goal of market leadership by the final year of the Fiscal 2014–2017 Medium-Term Management Plan to drive the growth of Santen's business within the ASEAN region.

### **Progress on the Korean Business**

Santen Pharmaceutical Korea Co., Ltd. ("Santen Korea") started direct marketing activities in 2010. We have launched products in Korea to treat glaucoma, dry eye and ocular infections. Santen's local product lineup has expanded to include the treatment for glaucoma and ocular hypertension *Taflotan* (tafluprost), the dry eye treatment *Diquas* (launched in 2013), along with a range of ophthalmology products taken over from U.S.-based Merck & Co.,

Inc. We continue to work on enhancing Santen's local market presence.

Korea is a technically advanced market in terms of ophthalmic diagnostics and therapies. Chronic eye conditions are increasing continually as its society ages. Meanwhile, the market has increasingly strict rules in terms of its regulatory approval requirements, drug-pricing constraints and pharmaceutical sales-related compliance, and there is also fierce generic competition. Responding to changes in market conditions, Santen Korea is focused on contributing to the development of ophthalmic treatment in Korea in line with local medical needs.

# TOPICS

### Supporting the Research Activities of Dry Eye Specialists in Asia

The Asia Dry Eye Society was founded in 2012 by dry eye specialists in Japan, China, and Korea to activate studies of dry eye and share a common understanding of this condition in the Asian region, thereby contributing to the better treatment of patients in Asia.

As the concept of pathology and the diagnostic criteria of dry eye differ in each country, the dissemination of effective treatment methods had become a pressing issue. Thanks to a lively exchange of opinions in the Asia Dry Eye Society, the definition and diagnostic

criteria of dry eye were stipulated in 2014. Currently, the society holds annual meetings, and its proactive activities are continuing, including the networking of the researchers in this field in each country.



Asia Dry Eye Society members

# Asia Dry Eye Society

Research and Development

Santen is advancing ophthalmic R&D in order to improve the Quality of Life (QOL) of patients around the world. The Company is concentrating efforts on developing products that will satisfy unmet medical needs in ophthalmology.

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Basic Strategies for Transforming Santen's Global R&D

### Accelerating Product Development by Leveraging a Global R&D Network

As a specialized ophthalmic pharmaceutical company, Santen is pushing ahead with R&D activities by selectively channeling resources into corneal and conjunctival epithelial disorders and glaucoma and ocular hypertension as well as retinal and uveal disorders, as we deem these markets to have high unmet medical needs and strong growth prospects.

Guided by the Fiscal 2014-2017 Medium-Term Management Plan, in order to rapidly develop differentiated products that satisfy the unmet medical needs of patients around the world, we are accelerating drug and device development by leveraging our global R&D network. These efforts, while emphasizing strict cost control, are focused on (1) targeting and addressing unmet medical needs, (2) reducing time to launch, and (3) improving the probability of technical success.

For example, we aim to increase the probability of success of projects in late-stage clinical development and achieve early approval. To this end, we are concentrating our efforts on promoting "Network Product Development<sup>1</sup>," and accelerating translational research<sup>2</sup>, which seeks to improve productivity by linking basic research and clinical research. Additionally, we have drawn up strategies for each therapeutic category where we can leverage Santen's strengths in



# Santen's Global R&D Network

### Santen is transforming global R&D to accelerate the development of products eagerly awaited by patients.

Naveed Shams, M.D., Ph.D. Senior Corporate Officer Chief Scientific Officer (CSO) Head of Global Research and Development

conjunction with advancing product development to address the constantly changing treatment needs of patients and region-specific unmet medical needs. Furthermore, we are also carrying out life cycle management<sup>3</sup> aimed at maximizing the market value of our current portfolio of products using the Company's unique drug formulation technologies, such as drug delivery systems<sup>4</sup>. We are also exploring biomarkers<sup>5</sup> to facilitate the development of optimal pharmaceuticals for patients.

### **Progress on Global R&D**

Santen has been accelerating global product development in tandem with strengthening collaboration among R&D bases in Japan, the U.S. and Europe, in order to satisfy unmet medical needs for ophthalmic treatment around the world by focusing on biomarkers and translational research.

In the field of corneal and conjunctival epithelial disorders, that is, ocular surface diseases, Santen has launched *lkervis* (ciclosporin) in European countries from July 2015. *lkervis* is a treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes. In Asia, Santen has successively filed for marketing approval of *lkervis* from November 2015. In Korea, Santen filed for marketing approval in December 2015.

In the field of retinal and uveal disorders, Santen is conducting Global Phase 3 studies of DE-109 (sirolimus). In April 2015, Santen filed for marketing approval in Asia of DE-109 for non-infectious uveitis of the posterior segment (hereinafter, "NIU-PS"), which is a leading cause of blindness. DE-109 has received a positive recommendation from Subject Expert Committee (SEC) of the Indian Central Drugs Standard Control Organization (CDSCO), early in 2016. Santen is looking forward to filing an NDA for DE-109 in the U.S. in the first half of 2017 followed by filing in Europe. In the field of glaucoma and ocular hypertension, Santen received an import drug license in China of Tapros (generic name: tafluprost, development code: DE-085) in July 2015 and commenced sales in March 2016. In June 2015, Santen received an import drug license in Korea of the combination ophthalmic solution DE-111 (tafluprost/timolol maleate), which is marketed in Japan and Europe. In March 2016, Santen licensed and obtained the global development rights to DE-126 (sepetaprost), an FP and EP3 receptors dual agonist that has completed Phase 2 clinical trials in the U.S., from ONO PHARMACEUTICAL CO., LTD. Furthermore, in August 2016 Santen acquired InnFocus, Inc., developer of glaucoma implant devices. This acquisition will complete Santen's treatment offering in the ocular hypertension and glaucoma space.

By steadily pushing ahead with these R&D activities, Santen aims to further accelerate the development of differentiated products that satisfy patients' unmet needs.

- 1. An approach of proactive use of compounds and technologies from outside the company in product development
- Multi-disciplinary research that links basic research, clinical research, and medical care and utilizes such findings for effective and efficient practical applications to contribute to healthcare advancement
- 3. Formulation technologies engineered to deliver the right amount of the drug to the right target at the right time
- 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. Indicators that quantify or measure biometric information to identify medical states including the onset or severity of disease

### NDA Filed Phase Dev. Code / Dev. Name Generic Name Indication Original / Licensor Region Approved 1 2 3 Launched, Europe July 2015 U.S. Severe keratitis Cyclokat Ciclosporin Original with dry eye December 2015 Korea November 2015 Asia January 2012 China Merck Sharp & Dohme Corp. (U.S.) **DE-089** Diquafosol sodium Dry eye Launched, Asia February 2016

### Corneal and Conjunctival Epithelial Disorders

### Glaucoma

DE-085	Tafluprost	Glaucoma Ocular hypertension	Co-development with Asahi Glass	China				Launched, March 2016
DE-111 Tafluprost/ timolol maleate		Glaucoma	Co-development	Korea				Launched, April 2016
	Ocular hypertension	with Asahi Glass	Asia	:			March 2016	
DE-117 Undetermined		Glaucoma	Co-development	U.S.				
	Ocular hypertension	with Ube Industries	Japan		Phase 2	2b/3		
DE-118	Tafluprost	Glaucoma Ocular hypertension	Co-development with Asahi Glass	Asia				Launched, April 2016

As of August 2, 2016

### Corneal and Conjunctival Epithelial Disorders

### Cyclokat (generic name: ciclosporin)

A topical ophthalmic emulsion which improves signs and symptoms of severe dry eye by the immunosuppressive effect. Novasorb technology has enhanced ocular tissue absorption. Cyclokat was launched under the name of *lkervis* in Europe in July 2015 as a topical treatment for severe keratitis in adult patients with dry eye disease, which does not improve despite treatment with tear substitutes. In Asia, Santen has successively filed applications for *lkervis* from November 2015. An application was filed in Korea in December 2015.

### DE-089 (generic name: diquafosol sodium)

As 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 application for approval has been filed in China. Sales commenced in Thailand in February 2016, and in Vietnam in April 2016. Applications have been successively filed in other Asian countries.

### 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 some countries in Asia. Sales commenced in China in March 2016.

### 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 for the treatment of glaucoma and ocular hypertension. DE-111 was launched in Japan as a glaucoma and ocular hypertension treatment called *Tapcom* in November 2014. DE-111 was launched as a treatment for glaucoma and ocular hypertension under the name of *Taptiqom* in Europe in January 2015. In Korea, DE-111 was launched in March 2016, and applications have been successively filed in other Asian countries.

### DE-117 (generic name: undetermined)

An EP2 receptor agonist with a new mechanism of action. In February 2015, Phase 2b clinical trials were completed in the U.S., and in December 2015 Phase 2b/3 clinical trials were initiated in Japan.

### DE-118 (generic name: tafluprost)

A prostaglandin derivative for the treatment of glaucoma and ocular hypertension, DE-118 is a preservative-free, single-dose type product. It was launched in Japan as *Tapros Mini* in October 2013. Sales commenced in Singapore and another country in April 2016, and applications have been successively filed in other Asian countries.

# Topics

INNFOCUS

# Acquisition of InnFocus, Inc.

# Santen to Provide a New Treatment Option by Acquiring InnFocus, Developer of Glaucoma Implant Devices

Santen acquired InnFocus, Inc. in August 2016. InnFocus is developing InnFocus MicroShunt ("MicroShunt"), which is an implant device used in implant surgery to lower and sustain intraocular pressure for the treatment of primary open-angle glaucoma from mild to severe stage disease. In clinical trials carried out in various countries outside the U.S., MicroShunt has shown lowering of intraocular pressure by helping effectively drain the aqueous humor when used alone or in combination with cataract surgery. By developing MicroShunt as a new treatment option, we aim to further contribute to the treatment of glaucoma patients around the world.

### Glaucoma

Dev. Code / Dev. Name	Generic Name	Indication	Original / Licensor	Region	1	Phase 2	3	NDA Filed	Approved
DE-126	Sepetaprost	Glaucoma Ocular hypertension	ONO PHARMA- CEUTICAL	U.S.					
Catioprost	Latanoprost	Glaucoma Ocular hypertension	Original	Europe					
DE-090	Lomerizine HCI	Glaucoma	MSD	Japan		;			

### Retinal and Uveal Disorders

DE-109 Sirolimus	Simlimus	Uveitis		U.S.	
			Original	Japan	
	Sironnus			Europe	
				Asia	April 2015
DE-120	Undetermined	Wet age-related macular degeneration	Original	U.S.	
DE-122	Undetermined	Wet age-related macular degeneration	TRACON	U.S.	Phase 1/2
Cortiject	Dexamethasone palmitate	Diabetic macular edema	Original	Europe	Phase 1/2

### Allergy

Vekacia	Ciclosporin	Vernal	Original	Europe	:	:	1	
Veracia	Cloropoint	keratoconjunctivitis	ongina					

As of August 2, 2016

### About Research and Development



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

### Glaucoma

### DE-126 (generic name: sepetaprost)

A prostaglandin eye drop drug product with a novel, mode of action that is both FP and EP3 receptors dual agonist for the treatment of glaucoma and ocular hypertension.

### Catioprost (generic name: latanoprost)

A topical ophthalmic emulsion of a prostaglandin  $F_{2\alpha}$  derivative, for the treatment of glaucoma and ocular hypertension. Phase 2 clinical trials are underway in Europe.

### DE-090 (generic name: lomerizine HCl)

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 effects. An application for approval was filed in Asia in April 2015 for the use of intravitreal sirolimus for the treatment of NIU-PS. In Europe, Santen has withdrawn its Marketing Authorization Application (MAA) and plans to resubmit it later. Phase 3 clinical trials are underway in the U.S. and Japan.

### **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 2a clinical trials are underway in the U.S.

### **DE-122** (generic name: undetermined)

An intravitreal injection of anti-endoglin antibody. Phase 1/2 clinical trials are underway in the U.S.

### Cortiject (generic name: dexamethasone palmitate)

An intravitreal injection with anti-inflammatory effect. Phase 1/2 clinical trials are underway in Europe.

### Allergy

### Vekacia (generic name: ciclosporin)

A topical ophthalmic emulsion which improves vernal keratoconjunctivitis symptoms by immunosuppressive effect. Novasorb technology has enhanced ocular tissue absorption. Phase 3 clinical trials were completed in Europe in March 2016.





# FP/EP3 Dual Agonist **DE-126**

### Accelerating the Development of New Drugs That Satisfy Unmet Medical Needs in Glaucoma Treatment by Promoting "Network Product Development"

Santen is promoting "Network Product Development<sup>2</sup>," which actively utilizes compounds and technologies available outside the Company, in order to accelerate the development of products that satisfy unmet needs for ophthalmic treatment. In March 2016, Santen entered into a licensing agreement with ONO PHARMA-CEUTICAL CO., LTD. for DE-126 (sepetaprost) for the treatment of glaucoma and ocular hypertension. DE-126 is a prostaglandin eye drop drug product with a novel, mode of action that is both FP and EP3 receptors dual agonist. DE-126 is expected to show a superior intraocular pressure lowering effect compared to tafluprost, an FP receptor agonist. Phase 2 clinical trials have been completed in the U.S. In future, Santen will seek manufacturing and marketing approval for DE-126 on a worldwide basis.

An approach of proactive use of compounds and technologies from outside the company in product development

### **Review of Operations**



# omestic Operations

Diquas

Cosopt Hyalein

Eylea

Tapros

### **Prescription Ophthalmic Pharmaceuticals**

Revenue for the Fiscal Year Ended March 31, 2016

¥124,165 million +17.9%

### Revenue from Prescription Ophthalmic Pharmaceuticals and Revenue Trends for the Top Six Products in Japan



The Japanese prescription ophthalmic pharmaceuticals market grew 7.3%, to ¥347.5 billion in the fiscal year ended March 31, 2016, driven by growth in sales of products for retinal disorders. Santen's domestic prescription ophthalmic pharmaceutical revenue increased 17.9%, to ¥124,165 million. This increase was due to our advancement of promotion activities in which our medical representatives provided medical professionals, including 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 44.0%.

> Share in the Japanese Prescription Ophthalmic Pharmaceutical Market (Fiscal Year Ended March 31, 2016) 44.0%

Prescription Ophthalmic Pharmaceutical Market Trends



Market Composition by Treatment (Fiscal Year Ended March 31, 2016)



# Treatments for Corneal and Conjunctival Epithelial Disorders

### **Market Trends**

The market for corneal and conjunctival epithelial disorder treatments associated with dry eye was ¥46.4 billion in the fiscal year ended March 31, 2016, an increase of 4.9% year on year. Dry eye is a chronic disorder caused by instability of tear film attributed to a variety of factors 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 mainly owing to factors such as 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 the fiscal year ended March 31, 2016, revenue from *Diquas*, a key Santen product, continued to experience significant growth, increasing by 19.7% year on year to ¥8,880 million. Revenue from *Hyalein* decreased 5.4% year on year to ¥14,491 million, mainly due to promotions for generic drugs. Santen maintained a firm 63.4% share of the corneal and Revenue from Main Treatments for Corneal and Conjunctival Epithelial Disorders



conjunctival epithelial disorder treatment market. Under challenging market conditions, this strong market share was attributable to Santen providing more options for treating dry eye, for which there are high unmet medical needs, along with continuously implementing activities to raise awareness of dry eye among patients and medical professionals. Santen plans to continue promoting greater awareness of dry eye. By doing so, Santen will strongly advocate that new patients—there are estimated to be 22 million in Japan—and existing patients consult their doctors to receive proper and continuous treatment. In the process, 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.

### 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



### 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.



Treatments for Corneal and Conjunctival Epithelial Disorders Market Share



# Domestic Operations

Revenue from Treatments for Glaucoma

(¥ Billion) 40 Others Detantol Tapcom Rescula 20 Trusopt Timoptol and related products Tapros Cosopt 0 2012 2013 2014 2015 2016

### Revenue from Eylea



### **Treatments for Glaucoma**

### **Market Trends**

The glaucoma treatment market grew 6.5%, to ¥112.6 billion. Treatments for glaucoma represent the largest segment of Japan's prescription ophthalmic pharmaceutical market, accounting for approximately 32% 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.

### **Operating Results**

Mainstay products *Tapros* and *Cosopt Combination Ophthalmic Solution* made steady progress in market penetration. *Tapros* revenue increased 10.1% year on year to ¥9,168 million, and revenue from *Cosopt Combination Ophthalmic Solution* rose 4.9% to ¥11,214 million. Launched in November 2014, *Tapcom Combination Ophthalmic Solution* delivers two agents in the form of a single agent to help improve convenience for patients, as part of efforts to further address patient needs. As a result, the Company's share of the glaucoma treatment market was 32.6% in the fiscal year ended March 31, 2016, as Santen retained the top market share.

In the fiscal year ending March 31, 2017, Santen will push ahead with efforts to maximize the market value and drive market penetration of mainstay products *Tapros*, *Cosopt Combination Ophthalmic Solution* and *Tapcom Combination Ophthalmic Solution*. Meanwhile, by leveraging its expansive product lineup, Santen will vigorously step up activities to provide medical information that meets the needs of medical professionals, such as the latest glaucoma-related information and advice on prescribing pharmaceuticals. Through these and other activities, Santen will continue working to enhance its presence in the glaucoma field.

### **Treatments for Retinal Disorders**

### **Market Trends**

There are unmet medical needs in 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 20.9%, to ¥74.5 billion, in the fiscal year ended March 31, 2016.

### *Tapros* (Launched in 2008)

Tapros is a prostaglandin-derivative 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 Combination Ophthalmic Solution (Launched in 2010)

Cosopt Combination Ophthalmic Solution is a leading treatment for glaucoma that combines dorzolamide hydrochloride and timolol maleate, delivering a significant reduction in intraocular pressure in a single agent.



### Tapcom Combination Ophthalmic Solution (Launched in 2014)

Tapcom Combination Ophthalmic Solution contains tafluprost, which is the active ingredient of Tapros, as well as timolol maleate. This combination delivers a significant reduction in intraocular pressure in a single agent.



Revenue from Main Anti-Allergy Ophthalmics



 Treatments for<br/>Glaucoma Market Share
 Intravitreal VEGF<br/>Inhibitors Market Share
 Anti-Allergy<br/>Ophthalmics

 32.6%
 65.7%
 36.3%

### **Operating Results**

The intravitreal VEGF inhibitor, *Eylea Solution for Intravitreal Injection*, which was launched in November 2012, is growing fast as a product that meets the need for a new therapeutic option for retinal disorder. In the fiscal year ended March 31, 2016, *Eylea* revenue rose 60.7% year on year to ¥39,988 million, due partly to the positive impact of the expansion of indications to four retinal disorders. *Eylea's* market share in the intravitreal VEGF inhibitor market reached 65.7%, spearheading market growth. In the fiscal year ending March 31, 2017, we will continue to vigorously provide high-quality pharmaceutical information, working together with our partner Bayer Yakuhin, Ltd. to penetrate the market further.



### **Anti-Allergy Ophthalmics**

### **Market Trends**

The anti-allergy ophthalmic pharmaceutical market increased 5.7%, to ¥35.8 billion. This was mainly attributable to cedar pollen levels, a major cause of allergic conjunctivitis, which were high in Japan during the fiscal year under review.

### **Operating Results**

In the fiscal year ended March 31, 2016, Santen focused on activities to provide pharmaceutical information centered on *Alesion*, which was launched in November 2013. As a result, combined revenue from *Alesion* and *Livostin* was up sharply by 16.4% to ¥10,431 million. Santen's share of the anti-allergy ophthalmic pharmaceutical market steadily increased to 36.3%.

In the fiscal year ending March 31, 2017, we will continue to focus on enhancing the market penetration of *Alesion*. *Alesion* and *Livostin* provide relief from year-round and seasonal allergy symptoms such as itching and redness and thus contribute to an improved patient's Quality of Life (QOL). By continuing to emphasize these product characteristics, we aim to expand both sales and market share of these products.

### 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.



### Alesion (Launched in 2013)

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



### *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.



# Domestic Operations

Revenue from Main Anti-Infective Ophthalmics



### **Anti-Infective Ophthalmics**

### Market Trends

The overall scale of the anti-infective ophthalmic market contracted 2.5%, to ¥16.4 billion, 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 the fiscal year ended March 31, 2016, revenue from the Company's two key products, *Cravit* and *Tarivid*, declined 9.2% year on year, to ¥6,591 million, mainly due to the impact of promotions for generic drugs. Santen's share of the anti-infective ophthalmic market fell to 49.8% 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 Ophthalmic Solution 1.5%* has won high marks in clinical settings since its launch for the early dissipation of major symptoms.

# Message

Strong Expectations for Pharmaceuticals That Relieve Patients' Troublesome Symptoms, Leading to Improved QOL

The incidence of allergic conjunctival diseases has continued to increase in recent years, with at least 20 million people out of Japan's population of 130 million estimated to be affected by these diseases. In most cases, the cause is believed to be pollen allergy. In the course of treatment, it is crucial to suppress itchiness of the eyes, one of pollen allergy's most troublesome symptoms. Under clinical practice guidelines, the recommended treatment is to provide "early stage therapy" by treating patients before airborne pollination begins in earnest. Early stage therapy will help to delay the onset of symptoms and help to suppress symptoms during the peak pollen season, thereby improving patients' QOL and raising their satisfaction with the treatment regimen. Santen has been undertaking initiatives based on an accurate grasp of treatment needs. For example, it has developed anti-allerov eve drops that do not contain benzalkonium chloride, a preservative that could possibly cause corneal and conjunctival epithelial disorders, with a pH and osmotic pressure that is closer to human tear drops. Through these initiatives, Santen has expanded the range of prescription options for treating allergic conjunctival diseases in patients who, for example, are also suffering from dry eye symptoms or who wear contact lenses. Looking ahead, I have strong expectations for Santen to continue to develop new pharmaceuticals that offer outstanding efficacy and safety.



Hiroshi Fujishima M.D., Ph.D. Professor, Department of Ophthalmology Tsurumi University Dental Hospital

### 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. 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* displays strong antibacterial activity.



Anti-Infective Ophthalmics Market Share





### Revenue from Medical Devices



### **Over-the-Counter Pharmaceuticals**

Revenue for the Fiscal Year Ended March 31, 2016 ¥10,918 million +64.5%

### **Market Trends**

In the fiscal year ended March 31, 2016, the OTC pharmaceuticals market expanded 10.6% year on year, to ¥65.1 billion, primarily due to an increase in eyestrain and blurred vision, plus expansion of the contact lens market, along with the impact of purchases by foreign tourists visiting Japan.

### **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 the fiscal year ended March 31, 2016, OTC pharmaceutical revenue increased significantly by 64.5%, to ¥10,918 million, mainly due to a focus on promotional campaigns to enhance the brand value of the entire *Sante* series and growth in demand from inbound foreign tourists, as well as a strong performance by higher priced products. Santen will continue aiming to carve out new markets and grow sales by vigorously implementing promotional campaigns for mainstay products, including *Sante Beautéye* and *Sante PC*, which were launched in 2013, and *Soft Santear Hitomi Stretch*, which was launched in 2014, as well as the *Sante Medical* series.



### **Medical Devices**

Revenue for the Fiscal Year Ended March 31, 2016 ¥2,323 million +2.4%

### **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 should provide more natural visibility, and in 2013, launched Eternity Natural Uni, a novel IOL with an original design. Another priority has been injectors for the insertion of IOLs. In 2011, Santen launched Accuject, an injector that achieves a smaller incision size, followed in 2015 by the launch of Access and Access Ease, both of which make setting easier. Revenue from medical devices was up 2.4%, to ¥2,323 million in the fiscal year ended March 31, 2016, mainly due to a focus on promotion activities. Santen will continue to target growth in its medical device business by leveraging its strengths in the product concept of "high quality IOLs with outstanding transparency" in the Eternity series.



# **Overseas** Operations

### **Overseas Operations Overall**

Revenue for the Fiscal Year Ended March 31, 2016

¥53,442 million +44.5%



In the fiscal year ended March 31, 2016, overall overseas revenue rose 44.5% to ¥53,442 million on a yen basis, due to accelerated growth both in the EMEA and Asian businesses. Overseas revenue from prescription ophthalmic pharmaceuticals increased 57.5%, to ¥48,379 million.

### **EMEA Business**

Revenue from EMEA Business

(¥ Billion)



### **Market Trends**

The EMEA market for prescription ophthalmic pharmaceuticals, the second largest after the U.S., has been growing supported by a combination of rising numbers of patients diagnosed with glaucoma and dry eye syndrome as well as economic growth in Eastern Europe. At the same time, the EMEA 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, in conjunction with enhancing its organizational management systems for EMEA operations.
#### [Product Supply and Quality Assurance]

# Supply Globally Competitive, High-Quality Products

Santen will strive to pursue globally competitive costs and high product quality to continue growing in step with changes in the global pharmaceutical market. We will provide a stable supply of products to the markets. In addition, we will maintain and enhance our quality assurance system. We thereby aim to optimize the global supply chain in order to fulfill our customers' needs.



## **Operating Results**

To become a "Specialized Pharmaceutical Company with a Global Presence," as outlined in our long-term strategic vision toward 2020, we have positioned enhancing profitability through accelerated expansion of the EMEA business as a key strategy. To date, Santen has been advancing its sales and marketing activities in over 30 countries centered on the EMEA region, including Russia, Germany and countries in Northern and Eastern Europe. After taking over the ophthalmology products of U.S.-based Merck & Co., Inc. and launching new products, Santen's geographic reach in terms of countries and regions and its product portfolio have expanded significantly, laying an even stronger foundation for future growth. As a result, in the fiscal year ended March 31, 2016, revenue from the EMEA business rose sharply by 80.6% to ¥25.6 billion.

Taflotan/Saflutan (tafluprost), a treatment for glaucoma and ocular hypertension, has been driving global business expansion. Santen has obtained approval for *Taflotan/Saflutan* in more than 40 countries centered on the EMEA region, and we market this product directly in 31 countries and regions including Germany. In January 2015, we launched *Taptiqom* (tafluprost/timolol maleate), a combination ophthalmic solution for treatment of glaucoma and ocular hypertension, and our efforts are now focused on achieving rapid market penetration of this product.

The transfer of ophthalmology products taken over from U.S.-based Merck & Co., Inc. had been completed in 23 countries as of March 2016, including new countries such as Italy and Spain, and Santen has successively commenced sales of these items as its own products.

# Message



# Great Expectations for Santen to Improve Glaucoma Patient Care

The mainstay of treatment remains pharmaceutical lowering of intraocular pressure. One of the main barriers to patient acceptance of treatment remains the ocular redness and irritation caused by the drops. This more likely affects the aging population in whom there is increasing frequency and severity of ocular surface disease; this is also the group most likely to be affected by glaucoma. The use of preservatives, particularly benzalkonium chloride, compounds the damage to the ocular surface. Santen have been at the forefront of the 'preservative free' revolution in glaucoma care with the development of *Saflutan*. Furthermore, another issue affecting adherence<sup>1</sup> to glaucoma medications is polypharmacy<sup>2</sup>. Simpler approaches that minimize the number of drops are predicted to increase adherence and therefore efficacy. Once again Santen are applauded for introducing *Taptiqom* which is not only a combination drop (containing two powerful IOP-lowering agents) but a preservative free one; in doing so Santen gives the opportunity for the standard of care and Quality of Life (QOL) of glaucoma patients to be improved.

- 1. Adherence refers to the patients likelihood to maintain correct and sustained use of a prescribed medication as directed by their physician
- 2. Polypharmacy relates to the use of multiple medications to treat the same condition

## Nicholas G Strouthidis, MBBS, M.D., Ph.D., FRCS, FRCOphth, FRANZCO

Consultant Ophthalmic Surgeon and Director of Glaucoma Service, Moorfields Eye Hospital NHS Foundation Trust, London, UK Clinical Associate Professor, Discipline of Clinical Ophthalmology and Eye Health, University of Sydney, Australia

# OVERSEAS Operations

Since July 2015, Santen has been selling the new product *lkervis* (ciclosporin), a treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes, in European countries including Germany and the U.K. Santen is fully leveraging its sales network, which has expanded as a result of taking over ophthalmology products from U.S.-based Merck & Co., Inc., in conjunction with working to maximize the value of *lkervis* by harnessing Santen's knowledge and expertise as Japan's foremost pioneer in the treatment of dry eye syndrome.

Looking ahead, Santen will supply an expansive range of products that match local needs, along with expanding activities to provide high-quality pharmaceutical information. By doing so, Santen will accelerate its activities to contribute to ophthalmic treatment in EMEA.



The 6th World Glaucoma Congress (WGC 2015) (Held in June 2015 in Hong Kong)

# **Asian Business**

Revenue from Asian Business



## **Market Trends**

The Asian market for prescription ophthalmic pharmaceuticals has been growing at an annual rate of more than 10% in line with economic development and improvement in healthcare standards. In particular, further market expansion is being projected in the dry eye, glaucoma, and retinal disorders fields, and there are strong needs in the ocular infection field primarily in emerging countries. Santen is working to upgrade and expand product lineups according to conditions in each country, in tandem with bolstering sales activities by local subsidiaries.

# Topics



# Santen Exhibits at the 119th American Academy of Ophthalmology (AAO) 2015 Annual Meeting, the World's Largest Academic Meeting in the Ophthalmology Field

In November 2015, the 119th American Academy of Ophthalmology (AAO) 2015 Annual Meeting was held in Las Vegas, Nevada in the U.S. The event attracted some 18,000 registered AAO members, as well as more than 600 companies exhibiting from around the world. Santen's exhibition booth showcased the Company's innovative activities in terms of its business expansion, and current products and development pipeline, drawing tremendous attention from eventgoers. At the Ophthalmology Innovation Summit, a peripheral event that was held ahead of AAO 2015, panel discussions were held by management of the world's leading ophthalmology-related companies. Naveed Shams, M.D., Ph.D., Santen's Chief Scientific Officer and Senior Corporate Officer, also took the stage as a panelist. The meeting was a lively event with a record-high attendance of 975 participants.

# **Operating Results**

Santen is working to expand its presence throughout the Asian market, with China, Korea and Vietnam positioned as key countries. Our goal is to become #1 in Asia in terms of our contribution to ophthalmic treatment. In the fiscal year ended March 31, 2016, as a result of efforts focused on increasing the market penetration of core products, revenue from the Asian business rose 35.6% to ¥22.6 billion.

In China, which is driving growth in the Asian region, Santen began exporting to the country in the 1980s and has successfully promoted the Santen brand in this market since establishing Santen Pharmaceutical (China) Co., Ltd. in 2005. In 2013, Santen established a second local subsidiary in China, Santen Pharmaceutical Sales & Marketing (Suzhou) Co., Ltd., and has been working to penetrate the market with its products with a view to achieving sustained growth in the country. In March 2016, Santen announced the establishment of a joint venture to engage in prescription ophthalmic pharmaceuticals through a collaboration with Chongging Kerui Pharmaceutical (Group) Co., Ltd., a state-owned company with more than 100 years of history. The goal of this collaboration is to supply ophthalmic pharmaceuticals to even more Chinese patients.

In Korea, Santen commenced direct marketing in 2010 and is providing pharmaceutical information through its own medical representatives. Santen is adding a glaucoma and ocular hypertension treatment taken over from the U.S.-based Merck & Co., Inc. to its mainstay products, *Taflotan*, a treatment for glaucoma and ocular hypertension,



and *Diquas*, a treatment for dry eye. By expanding its lineup, the Company aims to increase its market presence even further.

In the ASEAN region, Santen has already captured a high market share in Vietnam, one of the region's key countries, on a par with its market shares in China and Korea. In 2013, Santen established a local subsidiary in Singapore to bolster the Company's local management capabilities, with a view to strengthening its business in the ASEAN region. Santen is positioning Thailand, Malaysia, the Philippines and Taiwan as countries marked for intensive development, alongside the major countries of China, Korea and Vietnam, and is bolstering sales activities by local subsidiaries in these countries.

Santen successively commenced direct sales in Thailand, Malaysia, the Philippines, Taiwan and Singapore, and is penetrating these markets through the provision of scholarly information about various products, including the glaucoma and ocular hypertension treatments *Taflotan* and *Cosopt*, and the dry eye treatments *Diquas* and *Cationorm*. Santen will accelerate its activities in every country and region with the goal of making an even greater contribution to improving the QOL of patients in Asia.



# Santen Supports the 31st Asia-Pacific Academy of Ophthalmology Congress (APAO 2016) as a Diamond Sponsor

APAO 2016 was held in March 2016 in Taipei, Taiwan. The event was an academic conference appropriate for being the largest ophthalmology congress in Asia, attended by more than 4,500 ophthalmic-related professionals, who came not only from Asian countries but also Europe and the U.S. Large numbers of ophthalmologists were drawn to Santen's exhibition booth, where we shared information about the Company's current products and development pipeline designed to meet the treatment needs of patients in Asia. Additionally, academic symposiums were held every day throughout the event by specialists in the dry eye, glaucoma, ocular infection and other fields, providing an invaluable opportunity to supply information on the diagnosis and treatment of these diseases. Going forward, Santen will continue to support activities aimed at spurring the development of ophthalmic treatment in Asia.

# **Corporate Social Responsibility (CSR)**

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



# **CSR Integrated into Business Conduct**

Santen has placed importance on and cherished Santen's Values—"*Tenki ni sanyo suru*"—since its foundation in 1890. Our mission is to benefit patients and their loved ones, and thereby contribute to society, by pursuing creation and innovation.

To fulfill its social responsibilities through its business activities, Santen has established "Organizational Principles" and "Individual Action Principles" based on Santen's Values. To provide more specific action guidelines, we also formulated the "Santen Code of Practice," which comprises the "Declaration of Corporate Behavior" and "Code of Conduct." Focusing on the three perspectives of "customers," "employees" and "society," the Code of Practice requires all 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.

As its long-term strategic vision toward 2020, Santen aims to become a "Specialized Pharmaceutical Company with a Global Presence." To achieve this aim, the Santen Group is making a concerted effort to push ahead with its business activities. Our basic policy on CSR activities is to contribute to the improvement of QOL of patients around the world by



Santen will endeavor to enhance its CSR activities on a global basis, aiming to be a company that fully responds to the needs and expectations of patients worldwide.

Masamichi Sato Senior Corporate Officer Head of CSR and General Affairs Division

providing valuable products and services that reflect Santen's Values. Santen believes that by conducting business activities and CSR activities in an integrated and continuous manner, the Company can contribute to society and the environment. Ultimately, we believe that this will lead to the realization of our long-term strategic vision.

As the globalization of our operations gathers pace, we believe that it is crucial to strengthen compliance in conjunction with rigorously sharing Santen's Values throughout the organization. Accordingly, we will continue to build frameworks that address each issue on a Group-wide basis.

# Conceptual Framework for CSR Initiatives and Implementation of Activities

Based on 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>, Santen has defined 7 Core Subjects of CSR, for each of which a basic policy has been established. We have defined them as a conceptual framework for CSR initiatives. Furthermore, Santen believes that it is important to achieve stakeholder engagement by appropriately evaluating its CSR activities based on opinions obtained through dialogue with stakeholders, and putting these evaluations to good use in enhancing its activities. For each of the 7 Core Subjects of CSR, we have defined medium-term activity themes. Additionally, 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 our short-term activity items and our key performance indicators (KPIs). We then run the PDCA cycle<sup>2</sup> for these items in the medium-term and short-term time frames, thereby objectively evaluating our CSR activities, and working to further improve and enhance our CSR activities.

Moreover, in order to explain the value creation activities of Santen from both the financial and non-financial aspects, we are strengthening our information disclosure as regards CSR activities, and we are actively striving to enhance the provision of information, and to conduct information disclosure on a global scale, together with other similar 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.

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

Please refer to the CSR section on the Company's website for details. http://www.santen.com/en/csr

## 7 Core Subjects of CSR





Stakeholder Dialogue 7 Core Subjects of CSR: Provision of Appropriate Products and Services

# Working with Business Partners to Fulfill Our Social Responsibilities as a Global Pharmaceutical Company

# Basic Stance on Collaboration with Business Partners

Santen is committed to fulfilling its social responsibilities as a pharmaceutical company. Accordingly, we emphasize stakeholder engagement to enhance CSR activities that take into account the opinions of stakeholders. We engage in stakeholder dialogue as an effective means to that end.

Santen has designated the provision of appropriate products and services as one of the 7 Core Subjects of CSR. We see cooperative frameworks with business partners and collaboration leveraging other companies' strengths as crucial to continuous, stable provision of high quality products.

Here, we introduce dialogue from our discussion about collaboration with Santen with two representatives from Yamasa Corporation ("Yamasa"), our manufacturer and supplier for the dry eye treatment *Diquas*'s active ingredient, diquafosol sodium.

Dialogue Participants	<ul> <li>YAMASA CORPORATION Biochemicals Division</li> <li>Koji Amari, General Manager, Sales &amp; Marketing</li> <li>Eri Arakawa, Pharmaceuticals Chemicals Section</li> <li>Santen Pharmaceutical Co., Ltd. Supply Chain Group, Product Supply Division</li> </ul>
	Yoshio Kitamura, General Manager
	Daisuke Wada,
	Team Manager, Manufacturing Procurement & Sourcing Team

# Collaboration with Yamasa, Supplier of the Dry Eye Treatment *Diquas*'s Active Ingredient

Amari: Yamasa leverages its technology to degrade nucleic acids and produce "umami" seasoning, the fifth taste sensation, delivering various nucleic acid-related compounds for an array of industries to markets around the world. We are especially proud of our world-class supply capacity, production technology, and quality. Our collaboration on Santen's dry eye treatment *Diquas* began from the initial R&D and we have been supplying its active pharmaceutical ingredient since its launch in 2010.

**Kitamura:** When we launched *Diquas* in Japan in 2010, we enlisted Yamasa to establish a robust framework to support stable supply including by building a manufacturing facility for the active pharmaceutical ingredient. For our part, we share long-term manufacturing plans with Yamasa and adjust the production cycle and manufacturing plans and make other alterations as appropriate in line with changes in demand for the active pharmaceutical ingredient.

Wada: Demand for diquafosol sodium, the active ingredient of *Diquas*, has been rising every year since the treatment's debut in Japan and subsequent launch in Korea in 2013. Our alliance leveraging both companies' strengths in areas such as shortening the production cycle and increasing manufacturing volume has enabled us to respond to changing demand and keep supply stable since the product's launch.

# Taking Steps to Meet the Needs of Patients around the World

**Kitamura:** *Diquas* is an important growth driver for reaching our goal of becoming #1 in Asia. We are steadily working toward taking the product beyond Japan and Korea to countries throughout Asia and achieving rapid market penetration, for which Yamasa's cooperation is vital. **Arakawa:** To help ensure we can meet the needs of Santen's global business development, Yamasa's quality assurance framework is based not only on Japan's GMP<sup>1</sup> standards, but also global standards—ICH<sup>2</sup> guidelines and PIC/S<sup>3</sup> GMP guidelines.

Wada: Following the guidelines of global standards is imperative for supplying products to the global market. We must also meet the regulatory requirements of relative countries to expand our sales reach in Asia. Along with enlisting Yamasa to provide us with information on pharmaceutical affairs in various regions and countries, we aim to effectively utilize the networks and expertise we have built up through our Asian business activities. Amari: Price competitiveness is also important for the Asian business, not just quality and stable supply. Yamasa is taking measures now to reduce costs including capitalizing on its proprietary technologies to improve manufacturing processes.

Arakawa: Making our business collaboration even smoother is crucial to contributing to patients in Asia. In particular, I really sense a need for closer communication in terms of keeping abreast of global supply and demand conditions to ensure that supply remains stable. **Kitamura:** We are working to build on our win-win relationship unifying Santen's expertise and Yamasa's unique strengths under Yamasa's robust framework. I am confident that doing that will give us the fuel to propel *Diquas* into a global brand. Going forward, we look to further evolve the ways in which we collaborate based on our shared desire to contribute to patients' eye health.

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3. Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme

2. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

For details on stakeholder dialogues, please read our CSR Report 2016 (Japanese language only) on the Company's website.

1. Good Manufacturing Practice: Standards relating to pharmaceutical production management and guality

http://www.santen.co.jp/ja/csr

(From left) Yoshio Kitamura, Daisuke Wada, Ms. Eri Arakawa, Mr. Koji Amari

# Message



# Joining Forces with Santen to Contribute to Patients Worldwide

I have consistently been involved in diquafosol sodium's manufacture and supply since the very start of our collaboration on *Diquas*. Over the course of my involvement, I have sensed Santen accelerating its global development in light of changing business conditions. In addition, I feel that the manner in which individuals from various departments carry out their business activities as professionals from a specialized ophthalmic pharmaceutical company has been instrumental in making collaboration leveraging both our companies' strengths a reality. Moving ahead, we look to remain united with Santen in helping improve QOL for patients around the world by supplying the active pharmaceutical ingredient.

#### Koji Amari General Manager, Sales & Marketing, Biochemicals Division YAMASA CORPORATION

# Summary of CSR Activities in the Fiscal Year Ended March 31, 2016 (Evaluation against KPIs<sup>1</sup> and Policy for Activities in the Fiscal Year Ending March 31, 2017)

7 Core Subjects of CSR		Goal	Plan Action items	Check KPI	Target	
			•Enhance stakeholder dialogue	Continuous holding of stakeholder dialogues	100%	
	Establishing of stakeholder engagement	Systems are in place to gather opinions from many stakeholders and reflect them in CSR activities	•Enhance information disclosure	Year on year increase in respondents to external questionnaires	20% increase	
CSR management			•Aim to disseminate the conceptual framework for CSR initiatives among employees	Conduct training on induction and promotion to management	100%	
CSR man	Operating the risk management system efficiently A risk management system based on PDC cycles <sup>2</sup> is operating properly, centered on the CSR Committee, and all CSR activities are being promoted	system based on PDCA cycles <sup>2</sup> is operating properly, centered on	•Properly apply PDCA cycles for compliance, health and safety, fire and disaster readiness, and environmental conservation	CSR Committee meeting held (Five CSR-related committees)	Twice a year	
		and all CSR activities	<ul> <li>Promote due diligence<sup>3</sup> on the supply chain</li> </ul>	Due diligence carried out (vs plan)	100%	
	Developing and providing appropriate products are developed in response to medical needs and supplied stably	in response to medical needs and	•Develop and provide valuable products	Progress stage <sup>4</sup> in product development	100%	
Provision of appropriate products and services			•Supply products stably	Continuous stable supply	100%	
		•Ensure product reliability	Number of product recalls	Zero incidents		
	Providing information and		•Provide useful information for patients and consumers	Continuous provision of information	100%	
	services related to products and diseases identification and appropriate treatment of disease	appropriate treatment	•Supply useful information for healthcare professionals	Continuous provision of information	100%	
	Ensuring compliance across relationships with healthcare professionals and with patients' organizations	Zero incidents of compliance violations with healthcare professionals and patients' organizations	•Establish and operate systems for ensuring compliance	Number of incidents	Zero incidents	

Key Performance Indicators: Indicators for measuring the attainment of targets. Targets for qualitative KPIs are assumed to be 100%.
 A method to facilitate the smooth management of business activities through a P (Plan), D (Do), C (Check) and A (Action) business activity cycle.

Due diligence in CSR is a process for identifying both actual and potential negative effects on society related to an organization's decisions and activities.

4. Refers to product development moving to the next stage.

European Union – Good Manufacturing Practice: Standards relating to production management and quality control of pharmaceuticals and quasi-drugs within the European Union.
 Medical Representative: A person responsible for providing pharmaceutical information.

Performance	Performance and self-evaluation		Activities planned for the fiscal year ending March 31, 2017
100%	<ul> <li>We conducted dialogues with stakeholders in our business activities, such as when providing information to healthcare professionals and responding to customer inquiries. This enhanced our activities.</li> <li>We provided opportunities for dialogue with shareholders and investors, such as the General Meeting of Shareholders and the Financial Results Announcement meeting.</li> <li>We conducted a questionnaire on our CSR Report through a dedicated website and other means, using the results as a reference for our activities.</li> </ul>	0	•Continue and enhance dialogue with stakeholders
35% increase	<ul> <li>We conducted timely disclosure of information affecting our operating results and financial reports, and posted our financial results presentation materials, videos, and other information on the Company website.</li> <li>We disseminated information through our activity reports and the Company website, as well as publishing a CSR Report covering all our activities for the year. This was posted on a dedicated website and distributed to national libraries throughout Japan.</li> </ul>	0	•Enhance information disclosure throughout the Santen Group, including overseas subsidiaries
100%	<ul> <li>We conducted CSR training for all eligible employees on induction and on promotion to management.</li> <li>We continuously disseminated information on CSR activities by posting it on the Intranet noticeboard.</li> <li>We distributed CSR Reports to all employees and conducted a questionnaire to check their level of understanding.</li> </ul>	0	•Continue activities for disseminat- ing information, including increasing opportunities for employee dialogue
Twice a year	<ul> <li>Each CSR Committee met twice during the year, and implemented PDCA cycles to decide on policies, establish action plans, and monitor progress, etc., in order to promote CSR activities.</li> <li>Based on a risk evaluation result on the 7 Core Subjects of CSR, we formulated and executed countermeasures at the Company, Division, and individual levels.</li> </ul>	0	•Maintain and enhance the level of initiatives in each of the 7 Core Subjects through the continued use of PDCA cycles
91%	<ul> <li>To fulfill our social responsibility not only within the Company but also in the sphere of the Company's influence, we checked our pharmaceutical ingredient suppliers and manufacturing outsources to confirm the status of their initiatives on aspects such as legal and regulatory compliance systems, environmental conservation, and occupational health and safety.</li> <li>We did not achieve our planned target, but we checked 15 companies in Japan and 4 companies overseas.</li> </ul>		•Continue to check suppliers based on the plan
100%	<ul> <li>In prescription pharmaceuticals in Japan, we launched one product and obtained approval for an additional indication for one product.</li> <li>In prescription pharmaceuticals overseas, in Europe we launched one product. In Asia we launched two products, obtained marketing approval for two development products, and filed for approval for two products.</li> <li>In OTC pharmaceuticals, we launched one product.</li> </ul>	0	•Provide patients with the pharmaceuticals and treatments they need by developing new products in Japan, as well as in Asia and EMEA
94%	<ul> <li>Due to an increase in demand from overseas visitors, we experienced a shortage of several OTC pharmaceutical products. Moreover, we temporarily halted shipments of one ethical pharmaceutical product to inspect the manufacturing line.</li> <li>We strengthened the production facilities at each plant for launching new products and expanding in new geographical areas, and rebuilt our global logistics and supply system.</li> </ul>	$\bigtriangleup$	•Continue to build a system for stable supply in line with the regional expansion of business development
Zero incidents	<ul> <li>We set global quality targets and made continuous improvements.</li> <li>We put safety monitoring systems in place in regions where we are developing new business.</li> <li>The Suzhou Plant complied with EU-GMP<sup>5</sup>.</li> </ul>	0	•Continue to enhance the system for guaranteeing reliability to ensure product quality and safety
100%	<ul> <li>We aimed to enhance our information provision through the Company website and distribution of leaflets, and so forth, aiming to promote correct understanding of eye disease and facilitate early discovery and treatment.</li> <li>We provided information on daily eye-care methods for preventing eye disease and relieving eye fatigue, and provided information on correct application of ophthalmic solution.</li> </ul>	0	•Strive to enhance and continue providing useful information for patients and consumers
100%	<ul> <li>We continued to provide information on products and diseases through healthcare information provision activities by MRs<sup>6</sup>, seminars, and so forth.</li> <li>We renewed our website for healthcare professionals and aimed to enhance provision of information related to products, disease, and healthcare.</li> </ul>	0	•Strive to enhance and continue providing useful information for patients and healthcare professionals
Zero incidents	<ul> <li>We conducted continuous education on discretionary industry standards and the Company's internal rules relating to information provision and related activities.</li> <li>We disclosed information regarding the Company's relationships with healthcare professionals and patients' organizations.</li> </ul>	0	•Strengthen the system for ensuring compliance by providing educational opportunities, enhancing the educational content and putting it into practice

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# Summary of CSR Activities in the Fiscal Year Ended March 31, 2016 (Evaluation against KPIs<sup>1</sup> and Policy for Activities in the Fiscal Year Ending March 31, 2017)

7 Core

7 Core Subjects of CSR	Medium-term CSR activity themes	Goal	Plan Action items	Check KPI	Target	
siness ices	Ensuring compliance	Achieve zero compliance	•Raise compliance awareness	Employee training implementation rate	100%	
Ensuring compliance across all business transactions	across all business	incidents in business activities with business partners	•Establish and operate systems for ensuring compliance	Number of incidents	Zero incidents	
Respect for human rights	Respecting human rights in business activities	Contribute to realizing a prejudice-free society where human rights are respected across all business activities	•Raise human rights awareness	Number of incidents	Zero incidents	
safety	Creating a great working	Give all employees fair opportunities to grow regardless of age, gender, nationality,	•Promote diversity	Employment rate of people with disabilities	2.1% or higher	
ealth and	environment	mode of employment, and disability, and create a great working environment	Promote human resources     development	Training implementation rate	100%	
Occupational health and safety	Ensuring	vorkplace health working environment	•Ensure employee safety	Number of lost-worktime accidents excluding negligence accidents <sup>1</sup>	Zero incidents	
Occup	and safety		•Ensure employee health	Eye examination rate	100%	
ation	Preventing global warming	Contribute to reducing the environmental load through global warming countermeasures that are compatible with business activities	•Promote measures for reducing CO <sub>2</sub> emissions	CO <sub>2</sub> emission volume	24,311 t-CO2 or lower	
conservation	d and waste	conservation and waste appropriate management	•Promote zero-emission activities	Final waste disposal ratio	0.07% or lower	
Environmenta			•Prevent environmental pollution	Legal and regulatory compliance rate	100%	
Envi	Protecting environment	Contribute to maintaining biodiversity	•Conduct environmental conservation activities	Continuous execution of contribution activities	100%	
Social contribution	in fields related care	are and welfare n fields related to the Company's Contribute to medical care and welfare in the field of ophthalmology	•Bolster activities that contribute to patients, support organizations, and others	Continuous execution of contribution activities	100%	
			•Conduct activities for contributing to healthcare professionals	Continuous provision of assistance, etc.	100%	
Soci	Activities as a corporate citizen Establish relationship of trust with local communities through communication and cooperation		•Conduct social contribution activities	Continuous execution of contribution activities	100%	

1. Traffic accidents not due to human negligence or negligence by the Company, including rear-end collisions when stopped.

Performance	Performance and self-evaluation		Activities planned for the fiscal year ending March 31, 2017
100%	<ul> <li>We conducted education and training for all eligible employees on induction and promotion to management.</li> <li>We continuously conducted education and training tailored to business activities for each division.</li> <li>We raised awareness among all executives and employees through messages from top management and other means.</li> <li>We conducted risk assessments for the entire Company and conducted education, training, and related activities based on the results.</li> </ul>	0	<ul> <li>Provide educational opportunities for raising compliance awareness and enhance the educational content</li> </ul>
Zero incidents	<ul> <li>We established and revised internal regulations in response to changes in the business environment.</li> <li>We continuously conducted monitoring through audits and other means to confirm that compliance was observed.</li> </ul>	0	•Strengthen systems by revising the internal regulations and rules for all Group companies in line with the globalization of business activities
Zero incidents	<ul> <li>We conducted training for all eligible employees on induction and promotion to management.</li> <li>We collected human rights slogans from all employees and used the best ones to create posters to be hung in all business sites, in order to provide opportunities to think about human rights during daily activities.</li> <li>We continuously issued newsletters and promoted dialogue in the workplace.</li> </ul>	0	•Enhance educational content and opportunities, including dialogue- type training, to raise the ethical standards and respect for human rights of each employee
2.06%	<ul> <li>The employment rate of people with disabilities increased 0.1 of a percentage point year on year, almost achieving the target.</li> <li>Following the revision of the Act on Employment Promotion, etc., of Persons with Disabilities, we conducted in-house education and established a counseling function.</li> <li>All employees eligible for taking childrearing leave returned to work after taking it. The ratio of female managers also rose 1.1 percentage points year on year to 9.7%.</li> </ul>	0	•Continue to steadily promote various measures, such as employing people with disabilities and implementing the plan formulated for complying with the Act to Advance Women's Success in Their Working Life
100%	<ul> <li>We defined the desired qualities of personnel based on Santen's Values and we are currently promoting introduction and development of a new human resource system in coordination with this.</li> <li>We enhanced level-specific training and skill training. We established an environment that made it easier to engage in skill based training by including online courses and so forth.</li> </ul>	0	•Strive to develop talent by continually implementing and disseminating the new human resource system and enhancing various types of training
3 incidents	<ul> <li>We conducted health and safety management initiatives such as proposing targets and plans for the entire Company and each business site, conducting onsite visits, and implementing education, training and related activities tailored to work environments. However, we did not achieve the target.</li> <li>We implemented disaster readiness measures based on our plan for preparing against the event of a disaster and conducted disaster readiness drills.</li> <li>We took continuous measures to prevent and reduce traffic rule violations and accidents.</li> </ul>	$\triangle$	•Strive to further ensure employee safety, including by actively incorporating the exemplary initiatives of other companies
69%	<ul> <li>As a specialized ophthalmic pharmaceutical company, we conducted eye examinations for all employees.</li> <li>We formulated an action plan and took measures based on guidance from the Ministry of Health, Labour and Welfare and internal policies.</li> <li>For employees who had been on leave due to mental health issues, we provided continuous support through internal personnel who had taken specialist courses and kept the number of people going back on leave after returning to work to a low level.</li> </ul>	$\bigtriangleup$	•Regularly monitor stress in the workplace in response to the Revised Industrial Safety and Health Act while enhancing support for new employees and marketing offices
23,751 t-CO2	<ul> <li>We continuously promoted energy-saving measures at major business sites such as plants.</li> <li>We conducted continuous electricity saving measures at all business sites.</li> <li>As a result of the above measures, we achieved our CO<sub>2</sub> emission volume reduction target.</li> </ul>	0	•Continue to promote the measures for the entire Santen Group in recognition that reducing CO <sub>2</sub> emissions is a social issue
0.02%	<ul> <li>We processed waste correctly in accordance with laws, regulations and ordinances.</li> <li>We advanced our implementation of the 3R initiatives of reduce, reuse and recycle for resources used and beat our final waste disposal target for the fiscal year ended March 31, 2016 of 0.07% or lower.</li> </ul>	0	•Establish a plan for attaining a 0% final waste disposal ratio and implement it
100%	<ul> <li>We continuously monitored atmospheric pollution, water quality pollution, noise, vibrations and so forth in accordance with laws, regulations and ordinances, and kept to the required standards.</li> <li>At each business site, we implemented a chemical substance management system and worked to manage chemical substances appropriately. We also systematically conducted drills to prepare for preventing pollution in the event of an accident.</li> </ul>	0	•Develop and establish a manage- ment system for the entire Santen Group, including the overseas subsidiaries
100%	<ul> <li>At major business sites, we cooperated with local communities on neighborhood beautification activities. 527 people participated in these environmental beautification activities in the neighborhoods and communities around the business sites.</li> <li>We continuously supported forest protection activities, as they also help to preserve biodiversity.</li> </ul>	0	•Continue to raise employee awareness of environmental protection and beautification and to promote activities linked to business sites and their surroundings
100%	<ul> <li>We continued to support public lectures to help raise awareness of disease.</li> <li>Santen employees continued to participate as volunteers in events held by groups that support visually impaired people.</li> <li>We cooperated with dog training groups to provide opportunities for people to learn about guide dogs.</li> <li>We continued to support events held by guide dog training operations and groups for visually impaired people.</li> </ul>	0	•Continue to support patient groups and groups for visually impaired people, as well as initiatives for raising disease awareness
100%	<ul> <li>To support advances in medicine and pharmacology, mainly in the area of ophthalmology, we continued to support research activities and the nurturing of researchers.</li> <li>We continued to support the popularization of corneal transplants in Japan and activities to prevent blindness, mainly in developing countries, as well as programs to nurture ophthalmologists.</li> </ul>	0	•Continue to support activities for advancing medicine, pharmacology, and treatment, mainly in the area of ophthalmology
100%	<ul> <li>We teamed up with local communities around our main business sites to promote disaster readiness and crime prevention activities, and so forth.</li> <li>The Company's subsidiary contributed NT\$1 million to assist areas affected by the 2016 Taiwan Earthquake.</li> <li>The Company's employees union led efforts to continue supporting the recovery of areas affected by the Great East Japan Earthquake.</li> </ul>	0	<ul> <li>Continue to engage in social contribution activities, including in communities surrounding business sites, as a responsible corporate citizen</li> </ul>

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Evaluations:  $\bigcirc$ : Target achieved  $\triangle$ : Target not completely achieved  $\times$ : Target not achieved

# **Corporate Governance**

# Overview of the Corporate Governance System

# **Basic Views on Corporate Governance**

The Santen Group believes that it is vital to upgrade and strengthen corporate governance system in order to achieve and enhance corporate value, and thus returns to shareholders.

Santen has adopted a "Company with Board of Corporate Auditors" system as defined in Japan's Companies Act. Santen will continuously be working to upgrade and strengthen corporate governance by making the most of the current system.

First, the function of the Board of Directors is to make decisions concerning the vital execution of the business as well as to monitor the execution of the business by the Officers and Directors. Santen will operate with a focus on swift and appropriate managerial decision-making.

Santen expects its Outside Directors to be actively involved in the Board of Directors in decision-making on individual managerial issues, taking advantage of their wide range of experience and knowledge. Santen will also ask for their opinions from the view of strengthening the function of monitoring Santen's management.

Furthermore, Santen has taken some specific steps such as establishing the Corporate Strategy Committee, the Nominating Committee and the Executive Compensation Committee, which are all voluntary committees comprised of Inside and Outside Directors, and introducing a corporate officer system to strengthen management and improve the speed of business execution. Santen will go forward with the aim of improving management transparency and objectivity.

Corporate Auditors audit the Board of Directors and operating divisions by utilizing the Corporate Auditor's Group and collaborating with the Internal Auditing Group, bringing into view not only the legality but also the appropriateness and effectiveness of the performance of their duties, and Santen will endeavor to strengthen their function.





1. These committees are voluntary and not part of the statutory "Company with a Nominating Committee, etc., System" under the Japanese Companies Act.

# **Current Structure**

Santen's management structure after the close of the Annual General Meeting of Shareholders held in June 2016 comprised of five (5) Directors (i.e. four (4) males and one (1) female) including three (3) Outside Directors, four (4) Corporate Auditors (i.e. four (4) males) including three (3) Outside Corporate Auditors, and thirteen (13) Corporate Officers excluding some serving concurrently as Directors.

Santen's Board of Directors features well-balanced knowledge, experience and the ability to effectively fulfill its roles and responsibilities with a structure that satisfies both diversity and an adequate number of the members. Moreover, Santen has appointed Corporate Auditors with the expertise necessary to properly perform audits, including financial affairs and accounting.

All of Santen's Outside Directors and Outside Corporate Auditors are independent officers who maintain neutrality as they are independent from Santen and its subsidiaries and affiliates.

The term of office of Directors and Corporate Officers is one year.

The number of meetings of the Board of Directors convened during the fiscal year ended March 31, 2016, including extraordinary meetings, was 14. The average attendance rate of both the Outside Directors and Outside Corporate Auditors was 100% as of March 31, 2016. To promote meaningful discussions at the meetings of the Board of Directors, and for important agenda items to be resolved at the meetings of the Board of Directors, materials for the meeting and the relevant information were provided to the Outside Directors and Outside Corporate Auditors in advance and thereafter, sufficient explanations were made to them prior to such meetings concerning the background, purposes and details of the agenda of the said meetings.

The purpose and members of the Corporate Strategy Committee, the Nominating Committee and the Executive

Compensation Committee are shown in the following table. These voluntary committees were established with the aim of improving management transparency and objectivity.

Purpose and Members of the Voluntary Committee
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Committee	Purpose	Members
Corporate Strategy Committee	The Corporate Strategy Committee deliberates on key strategic issues such as business strategies.	Five Directors, including three Outside Directors
Nominating Committee	The Nominating Committee deliberates on the selection of candidates for Directors and submits recommendations, and also submits recommendations in response to consultations concerning the selection of candidates for Corporate Officers and Corporate Auditors.	Four Directors including three 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, and also submits recommendations to the Board of Corporate Auditors with respect to the policy on determining the compensation of Corporate Auditors with reference to market level.	Four Directors, including two Outside Directors

# Reasons for Adoption of Current Corporate Governance System

The Santen Group's governance is based on the corporate organizational form of a "Company with Board of Corporate Auditors" as defined in Japan's Companies Act. This structure enables us to have objective audits by Corporate Auditors who are in independent positions of the execution of the business by the Directors. Furthermore, to secure transparency, objectivity and appropriateness of management, Santen believes that making the most of systems such as the voluntary committees on business strategy, nomination of officers, executive compensation and the like will contribute to the strengthening of the current corporate governance system. As a material management matter, Santen commits to continuously review the improvement and strengthening of the said system.

Key Milestones in St Corporate Governan		2000	2005	2010	2015
Management Plan	"Н	edium-term Plan litomi 21" usiness vision formulated	Fiscal 2003-2005 Medium-Term Management Plan I to mark centenary ©2011	n Medium-Ter	m Medium-Term Plan Management Plan
Strengthen management supervision	Outside Directors		From 2003 1 individual	From 2005 <b>3 individ</b>	uals
Strengthen decision-making and business execution functions	Corporate officer system	1999 Introduced			
	Corporate Strategy Committee	1999 Management Adv Committee estab	isory ished 2005 Establis	hed	
Strengthen management	Nominating Committee		2005 Establis	hed	
transparency and soundness	Executive Compensation Committee	Established Compensation Committee	2003 Established		

# Development and Implementation of the Internal Control System

In accordance with Japan's Companies Act and the Ordinance of Enforcement of the Companies Act, the Santen Group has passed a resolution regarding the development of a system to ensure appropriate operations (Basic Policy on Internal Control). The operating divisions regularly report on the status of the development and implementation of the system to the Board of Directors, while the Board of Directors gives instructions and makes course corrections as necessary, in order to qualitatively enhance the development and implementation of the internal control system and expand its scope.

Furthermore, in May 2015, Santen revised the internal control system in line with amendments to the Companies Act. At a meeting held on June 24, 2016, the Board of Directors passed a resolution regarding the partial amendment of the Basic Policy on Internal Control to develop and promote an appropriate internal control system for the entire Group in response to the globalization of Santen's management. For details, please refer to the Corporate Governance Report at Santen's official corporate website.

The implementation status of Santen's internal control system is as follows.

#### [Implementation Status]

System to Ensure that the Execution of Duties of the Directors and Employees of Santen Group Complies with Laws, Regulations and the Articles of Incorporation Santen's Values are encapsulated in the phrase *"Tenki ni sanyo suru*," meaning *"exploring the secrets and*  mechanisms of nature in order to contribute to people's health." Guided by Santen's Values, the Santen Group promotes the Santen Code of Practice, which provides the behavioral guidelines for conducting corporate activities from a shared perspective, by rigorously enforcing the Code through awareness-building activities, including providing information and training. Santen routinely monitors trends concerning anti-social forces and cooperates with the relevant authorities to eliminate any relationship with anti-social forces that threaten the order and stability of civil society.

Santen handles consultation and reporting through points of contact both inside and outside Santen, responding appropriately by conducting the necessary surveys, including interviews, in cooperation with internal and external experts.

To strengthen the function of monitoring management, Santen has appointed three highly independent Outside Directors and four Corporate Auditors, comprising three highly independent Outside Corporate Auditors and one Standing Corporate Auditor. Moreover, Corporate Auditors monitor management. In addition, the Internal Auditing Group established under the direct control of the President also conducts internal audits, and the members of this group strive to enhance their expertise.

# System on Retention and Management of Information on the Execution of Duties of the Directors

The Santen Group appropriately retains and administers records, documents and other information concerning the execution of the duties of the Directors based on rules for information security, internal approvals and document control.

# Risk Assessment

# **Risk Assessments Implemented to Grasp Global Business Risks**

The Santen Group has seen significant growth in its business fields overseas in step with the ophthalmology products taken over from U.S.-based Merck & Co., Inc., and is expected to see rapid growth in sales going forward. In these unprecedented circumstances, the materialization of unforeseen critical risks could have a tremendous impact on the Company's sustained growth. With this in mind, a risk assessment was conducted by an outside research company of subsidiaries and key business bases worldwide from August to December 2015, for the purpose of

comprehensively and objectively surveying the risks faced by the entire Group. As a result, the survey did not identify any evidence of serious compliance violations or misconduct, and it confirmed that Santen's corporate culture and environment for preventing those contingencies were largely satisfactory. Going forward, the Santen Group will continue working to develop an optimal risk management system in line with advances in the globalization of its businesses.

# Rules on the Management of Risk of Loss of Santen Group and Other Systems

The Santen Group routinely implements preventive measures in preparation for the materialization of risks in accordance with risk management rules. Following a risk assessment of the entire Santen Group, it has been determined that Santen's corporate culture for preventing misconduct and compliance breaches is largely satisfactory.

Santen has established a Risk Evaluation Committee as a system to manage risks in normal circumstances. The committee evaluates the impacts of risks, and reports the details to the Board of Directors and others. The Internal Auditing Group verifies the risk management status through operational audits undertaken from its independent viewpoint.

# System to Ensure the Efficient Execution of Duties of the Directors of Santen Group

As part of efforts to ensure efficient decision-making, the Santen Group has introduced a corporate officer system to enhance the quality and speed of decision-making concerning operation and management.

The Board of Directors convened 10 ordinary meetings and 4 extraordinary meetings. The average attendance rate of both the Outside Directors and Outside Corporate Auditors was 100%. In addition, the Corporate Strategy Committee, the Nominating Committee and the Executive Compensation Committee, which are all voluntary committees comprised of Inside and Outside Directors, each convened four meetings for deliberations.

Santen has established the Rules of the Board of Directors and the rules for Corporate Officers to clarify their duties and powers, and operates both of these bodies appropriately. Santen revises its personnel and organizational systems to ensure that operations are executed effectively and efficiently. Santen makes timely changes as necessary. One example of these changes was the conversion of global and regional functions into a matrix-based organization.

# System to Ensure Proper Operating Controls within Santen Group

The Santen Group implements a Basic Policy on Internal Control at Group companies. In an effort to strengthen the auditing function of subsidiaries, Santen has appointed the Head of the Finance Division as an officer of its principal subsidiaries and key management personnel in finance and accounting divisions as officers of other subsidiaries. At the same time, these officers of subsidiaries work to develop a shared understanding of issues by attending the Santen Group's Corporate Auditors' meeting based on the audit plans of the Board of Corporate Auditors.

To enhance the appropriateness of corporate activities

throughout the Group, Santen has built and operates a control system in which the Company provides recommendations and guidance, led by Santen's relevant divisions. In addition, to ensure the credibility of financial reports, Santen conducts internal audits that involve Santen's relevant divisions and Group companies performing a self-check of the development and implementation status of their systems.

# Matters Regarding an Employee, When the Board of Corporate Auditors Seeks to Adopt Him or Her as an Assistant, Matters Regarding the Independence of Such Employee from Directors, and Matters Regarding Ensuring the Effectiveness of Directions to Such Employee

The Santen Group has set up a Corporate Auditor's Group that does not belong under the line of supervision and direction of management, and has appointed three full-time staff, including the General Manager of Corporate Auditor's Group. The staff assist with the duties of the Corporate Auditors and discharge other duties as necessary.

In regard to personnel transfers and performance reviews of the Corporate Auditors' staff, the evaluations of the Corporate Auditors are duly respected in accordance with internal rules.

System for Directors and Employees of Santen Group to Report to Corporate Auditors, System Regarding Other Reports to Corporate Auditors, and System to Ensure That the Person Who Reported to Corporate Auditors Will Not Receive Any Adverse Treatment for the Reason of Such Reporting

The Santen Group develops and operates systems for reporting on important matters to the Corporate Auditors and the Board of Corporate Auditors.

The Internal Auditing Group holds regular monthly meetings with the Standing Corporate Auditor to report on audit results. Internal rules call for the protection of whistleblowers who report possible internal compliance violations, and Santen ensures that no disadvantageous treatment will be suffered by such whistleblowers.

# Other Systems to Ensure the Effective Conduct of the Audit by the Corporate Auditors

The Santen Group's Corporate Auditors and Board of Corporate Auditors hold meetings regularly or as needed with the Directors, Corporate Officers and others to exchange opinions on substantial issues and other matters. The Corporate Auditors attend important internal meetings and state their opinions on procedures regarding substantial decision-making and the state of the conduct of the business.

Santen bears the expenses necessary for Santen's Corporate Auditors to perform their duties.

# Status of Outside Directors and Outside Corporate Auditors

At the Santen Group, three of its five Directors are Outside Directors and three of its four Corporate Auditors are Outside Corporate Auditors. In addition, all of the Outside Directors and Outside Corporate Auditors satisfy the criteria for the independence of Outside Directors and Outside Corporate Auditors established by the Company, in addition to meeting the requirements of the Companies Act and the Tokyo Stock Exchange. There are no personal, capital, or business relationships or other conflicts of interest between the Company and its Outside Directors and Outside Corporate Auditors that would have an impact on their independence from the Company. The Outside Directors and Outside Corporate Auditors do not hold shares of Santen.

# Reasons for Appointing Outside Directors and Outside Corporate Auditors

Akihiro Okumura Outside Director	Considering that he has extensive knowledge and experience amassed through long years of professorship in business administration at the undergraduate and graduate schools of several universities, and that he has contributed to enhance the quality of the discussions in the Board of Directors by expressing his opinions actively throughout the proceedings at meetings, the Board of Directors believes that he is well-qualified to be an Outside Director, and Santen has appointed him as such. His term of office as an Outside Director of Santen is five years at the close of this year's Annual General Meeting of Shareholders.
Takayuki Katayama Outside Director	Considering that he has extensive knowledge and experience amassed through long years of involvement in management in the country and overseas, and that he has contributed to enhance the discussions in the Board of Directors by expressing his opinions actively throughout the proceedings at meetings, the Board of Directors believes that he is well-qualified to be an Outside Director, and Santen has appointed him as such. His term of office as an Outside Director of Santen is four years at the close of this year's Annual General Meeting of Shareholders.
Kanoko Dishi Dutside Director	Considering that she has extensive knowledge and experience amassed through long years of involvement in management in the country and overseas, and that she has contributed to enhance the discussions in the Board of Directors by expressing her opinions actively throughout the proceedings at meetings, the Board of Directors believes that she is well-qualified to be an Outside Director, and Santen has appointed her as such. Her term of office as an Outside Director of Santen is one year at the close of this year's Annual General Meeting of Shareholders.

Yutaka Mizuno Outside Corporate Auditor	Considering that he has extensive knowledge and experience amassed through long years of involvement in management in the country and overseas, it is promising that, at meetings of the Board of Corporate Auditors and the Board of Directors, he will express appropriate audit opinions in line with the managerial viewpoint from the standpoint of Santen as a whole, and Santen has appointed him as its Outside Corporate Auditor. His term of office as an Outside Corporate Auditor of Santen is five years at the close of this year's Annual General Meeting of Shareholders.
Koichi Matsuzawa Outside Corporate Auditor	Considering that he has extensive knowledge and experience amassed through long years of involvement in management in the country and overseas, it is promising that, at the meetings of the Board of Corporate Auditors and the Board of Directors, he will express appropriate audit opinions in line with the managerial viewpoint from the standpoint of Santen as a whole, and Santen has appointed him as its Outside Corporate Auditor. His term of office as an Outside Corporate Auditor of Santen is two years at the close of this year's Annual General Meeting of Shareholders.
Seiichiro Adachi Outside Corporate Auditor	Considering that he has extensive knowledge and experience amassed through long years of involvement in management in the country and overseas, and he has been involved in auditing services as a standing corporate auditor of a company listed on the First Section of the Tokyo Stock Exchange, Inc., it is promising that, at the meetings of the Board of Corporate Auditors and the Board of Directors, he will express appropriate audit opinions in line with the managerial viewpoint from the standpoint of Santen as a whole, and Santen has appointed him as its Outside Corporate Auditor of Santen is one year at the close of this year's Annual General Meeting of Shareholders.

## Directors' and Corporate Auditors' Compensation

	Total	То	No. of Elizible			
Position	Compensation (Millions of yen)	Basic Compensation (Annual)	Stock Compensation- Type Stock Options	Bonus	Retirement Benefits	No. of Eligible People
Directors (Excl. Outside Directors)	208	155	53	_	_	2
Corporate Auditors (Excl. Outside Corporate Auditors)	27	27	_	_	_	1
Outside Directors and Outside Corporate Auditors	65	65	_	_	_	8

Note: The number of Directors and Corporate Auditors shown above represents the total number of individuals appointed in the fiscal year ended March 31, 2016, including one Director and one Corporate Auditor who resigned upon the expiry of their terms of office at the close of the Annual General Meeting of Shareholders held on June 24, 2015.



## **Timely Disclosure System**

The Santen Group has established the Santen Code of Practice that stipulates the corporate ethics as the base of corporate activities for all of officers and company members in order to conduct such corporate activities from a standpoint shared by all.

The Santen Code of Practice stipulates its basic approach to the disclosure of information whereby Santen is to not only disclose reports and information prepared regularly concerning its business, but also to timely and appropriately disclose corporate information, as well as handle formalities, such as those concerning permits or approvals by, reports to or filings with governmental authorities, without any false representation or causing any misunderstanding. Based on the foregoing, Santen commits to make a proactive, fair, easily understandable and accurate disclosure of information.

Furthermore, the Santen Code of Practice has been posted at Santen's internal portal site, and concurrently, it has been distributed to all officers and company members to ensure the proper recognition and thorough compliance thereof.

# **Investor Relations Activities**

The Santen Group has established a Disclosure Policy around a fundamental policy of providing its shareholders and investors with information concerning its management policies, business strategies and financial performance in a coherent, fair and accurate manner. With this in mind, we are working to proactively disclose our corporate information.

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

Santen's website carries a host of information, including performance reports, data books, financial result meeting presentations, and video of financial result meeting presentations. The website also carries annual securities reports (Japanese language only), annual reports, and convocation notices, resolution notices, and other materials for the general meetings of shareholders.

# Corporate Governance Code

# Addressing the Corporate Governance Code

The Santen Group plans to implement all of the principles of the Corporate Governance Code of the Tokyo Stock Exchange with the exception of the supplementary principles shown on the right. In November 2015, Santen stated the Basic Policy on Corporate Governance based on the five General Principles of the Corporate Governance Code (Ensuring the Right and Equality of Shareholders, Cooperation with Stakeholders Other Than Shareholders, Ensuring Appropriate Disclosure of Information and Transparency, Responsibilities of the Board of Directors, etc., Dialogue with Shareholders and Other Persons), and disclosed the policy on its official corporate website.

## Reasons for Non-Compliance with the Principles of the Corporate Governance Code

[Supplementary Principle 4.8.2] Santen will not appoint a "lead independent outside director" for the reason described below.

• Considering that each of the Independent Outside Directors has a variety of experience and knowledge, and hence, the appropriate opinion and advice of each of them can be sought at the Board of Directors, Santen believes that it is not indispensable to confer upon the Outside Directors the task of providing a unified opinion.

For details, please refer to the Basic Policy on Corporate Governance and the Corporate Governance Report at the Company's website. http://www.santen.com

# / Message



Takayuki Katayama Outside Director

# **Issues Currently Facing Management**

In order for Santen to achieve sustainable growth over the medium- and long-term, the Company must develop a growth strategy and improve governance.

As a specialized ophthalmic pharmaceutical company, in recent years Santen has been achieving steady results as the Company focused on core domestic operations, and on expanding business in EMEA and Asia. In 2014, some products of the U.S.-based Merck & Co., Inc. were transferred to the Company, and in 2015 Santen transferred its anti-rheumatic pharmaceuticals business. These are examples of the Company's strategic efforts to perpetuate growth.

As regards Santen's governance, our basic stance has been to adopt a very precise management stance, and place emphasis on measures to return value to shareholders. The Company operates very open Board of Directors' meetings, where questions and opinions are shared freely. Naturally, this process is vital in ensuring sound decisionmaking. Meanwhile, the Company has set a target ROE<sup>1</sup> of over 13.0% and a target dividend payout ratio of 40%. In this way, management conveys its objectives to shareholders, and is tackling the challenge of meeting its ambitious goals in each fiscal year. I consider this to be very commendable.

In order for Santen to continue growing in the future, it is vital that the Company accelerates management decisionmaking and strategy implementation, and further improves governance. As an Outside Director, I believe I can contribute to meeting all of these goals.

1. Return on equity attributable to owners of the company



Seiichiro Adachi Outside Corporate Auditor

# Governance Directed at Enhancing Corporate Value

Santen is accelerating efforts to expand global operations while continuing to solidify its domestic business. Santen's goal is to become a "Specialized Pharmaceutical Company with a Global Presence," in accordance with the essence of its values: *Tenki ni sanyo suru*. This means "exploring the secrets and mechanisms of nature in order to contribute to people's health," as Santen does by contributing to the health of people's eyes.

According to a saying by Sontoku Ninomiya, an 19th-century Japanese philosopher, "economics without morality is crime, whereas morality without considering the economic aspects is just empty talk." Companies that lack morals will face sanctions from society and eventually fail, whereas companies that advocate only morals will also find it hard to operate as a company and will not be able to contribute to its customers, employees and society as Santen strives to do. It is vital that companies develop growth strategies and implement them effectively in order to continually evolve and enhance their corporate value.

Outside Directors account for over half of the members of Santen's Board of Directors, and I am one of three Outside Corporate Auditors on the company's Board of Corporate Auditors. Our role is to make sure that the Company operates a sound business expansion and pursues sound global business growth in consideration of the interests of stakeholders.

From rigorous and objective viewpoints of stakeholders, I intend to continue increasing the depth of my communication with Santen management, and visiting the business frontlines, thereby helping Santen to contribute to the health of people's eyes around the world.

# Board of Directors and Corporate Auditors

As of August 2016



(Front row, from left) Takayuki Katayama, Sadatoshi Furukado, Akira Kurokawa, Akihiro Okumura, Kanoko Oishi (Back row, from left) Koichi Matsuzawa, Masashi Murata, Yutaka Mizuno, Seiichiro Adachi

#### Akira Kurokawa

Representative Director President and Chief Executive Officer

- 1977 Joined the Company1997 Director, General Manager, Head of the Office of Sales and Marketing Division,
- Prescription Pharmaceuticals Corporate Officer, Head of Sales and Marketing Division, 2001 Prescription Pharmaceuticals
- Senior Corporate Officer, Head of Sales and Marketing Division, Prescription Pharmaceuticals 2004
- 2006 President & COO 2008 President & CEO (incumbent)

#### Akihiro Okumura

Outside Director

- 1988 Professor, Keio Business School, Keio University
- 2008 Professor Emeritus, Keio University (incumbent) 2011
- Outside Director of the Company (incumbent) Special Appointed Professor, Graduate School of 2014
- Management and Information of Innovation,
- University of Shizuoka (incumbent) 2015 Vice President, University of Shizuoka (incumbent)

# Directors Sadatoshi Furukado

# Director

Vice President, Executive Corporate Officer

Human Resources Development and Corporate Administration

- 1977 Joined the Company
- Corporate Officer, Head of Prescription Pharmaceuticals Sales Department 2005
- Senior Corporate Officer, Head of Sales and Marketing Division, Prescription Pharmaceuticals Executive Corporate Officer, Japan and Asia Business and Head of Sales and 2007
- 2011
- Marketing Division, Prescription Pharmaceuticals
- 2011 Director (incumbent)
- Executive Corporate Officer, Japan Business and Human Resources Development, 2013 Head of Sales and Marketing Division, Prescription Pharmaceuticals Vice President, Executive Corporate Officer, Japan Business and Human Resources Development
- 2014 Vice President, Executive Corporate Officer 2016
  - Human Resources Development and Corporate Administration (incumbent)

#### Takayuki Katayama Outside Director

- 2006 Executive Vice-President and
- Representative Director, Teijin Limited 2011 Senior Advisor to CEO, Teijin Limited
- (incumbent) Outside Director of the Company 2012
- (incumbent) Outside Corporate Auditor, Toyo Seikan 2012
- Group Holdings, Ltd. (incumbent) 2016 Outside Director, Olympus Corporation
  - (incumbent)

# **Corporate Auditors**

# Masashi Murata

- Standing Corporate Auditor 1999 Joined the Company
- General Manager, Corporate Planning Group 2007
- 2011 Chief Administrative Officer
- (CAO), Santen Inc. General Manager, Corporate 2014 Auditor's Group
- 2016 Standing Corporate Auditor (incumbent)

#### Seiichiro Adachi Outside Corporate Auditor

2008 Managing Director, Toyota Tsusho

Outside Director, SUBUGA bank Ltd. (incumbent)

- Corporation President, NV Toyota Tsusho Europe SA 2010
- 2013 Full-time Audit & Supervisory
- Board Member, Toyota Tsusho Corporation Advisor, Toyota Tsusho Corporation 2015 (incumbent)
- 2015 Outside Corporate Auditor of the Company (incumbent)
- 2016 Professor, Yokohama College of Commerce (incumbent)

Yutaka Mizuno

# Outside Corporate Auditor

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

#### Koichi Matsuzawa Outside Corporate Auditor 1996 President & CEO, Kirin Europe

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

#### External Director, Shiseido Company, Limited 2016 (incumbent)

(incumbent)

(incumbent)

Kanoko Oishi

1993 Partner, McKinsey & Company, Inc.

Outside Director

2015

2015

2000 Established Mediva, Inc. Chief Executive Officer (incumbent) Established Platanus Medical Corporation, COO 2004 Outside Director of the Company (incumbent) External Board Director, Ezaki Glico Co., Ltd. 2015

of the Company (incumbent)



(Front row, from left) Kazuo Koshiji, Naveed Shams, Akihiro Tsujimura, Takeshi Ito, Masamichi Sato, Atsutoshi Ota (Back row, from left) Satoshi Suzuki, Noriaki Yamamoto, Kenji Morishima, Shigeo Taniuchi, Akio Kimura, Hiroyuki Yamazaki, Ye Liu

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

#### Takeshi Ito

Executive Corporate Officer Japan Business Head of Japan Sales and Marketing, Prescription Pharmaceuticals

## Atsutoshi Ota

Senior Corporate Officer Head of Human Resources Development Division

#### Akio Kimura

Corporate Officer Head of Global Product Supply Head of Global Quality Compliance

## Ye Liu

Corporate Officer General Manager, Santen Pharmaceutical (China) Co., Ltd.

## Akihiro Tsujimura

Executive Corporate Officer Head of Corporate Development Division Asia and North America Businesses President & CEO of Santen Inc.

Kazuo Koshiji Senior Corporate Officer Chief Financial Officer (CFO) Head of Finance Division

## Noriaki Yamamoto

Corporate Officer Chief Information Officer (CIO) Head of Information Systems Division

## Masamichi Sato

Senior Corporate Officer Head of CSR and General Affairs Division CEO of Santen Business Service Co., Ltd.

# Shigeo Taniuchi

Senior Corporate Officer Head of Santen EMEA President of Santen Holdings EU B. V.

#### Hiroyuki Yamazaki

Corporate Officer Head of Japan Prescription Pharmaceutical Sales

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

Senior Corporate Officer Chief Scientific Officer (CSO) Head of Global Research and Development

## Kenji Morishima

Corporate Officer Head of Pharmaceutical Technology Development

#### Satoshi Suzuki

Corporate Officer Head of Asia Division

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# **OPERATING RESULTS**

# Adoption of International Financial Reporting Standards (IFRS)

The Santen Group conducts business internationally in countries and regions such as Japan, Asia, and EMEA. Moreover, the composition of Santen Pharmaceutical Co., Ltd. shareholders is notable for its high shareholding of foreign investors, who own more than 40% of the shares of Santen Pharmaceutical Co., Ltd. Considering these factors, Santen has adopted International Financial Reporting Standards (IFRS) effective from the fiscal year ended March 31, 2015, for the purpose of improving the international comparability of its financial information in the capital markets. Figures for the fiscal year ended March 31, 2014 have been restated to conform to IFRS to facilitate comparison and analysis.

The main differences between IFRS and Japanese GAAP are as follows.

# [Presentation of Accounts]

- Revenue under IFRS is equivalent to net sales under Japanese GAAP.
- Operating profit under IFRS differs from operating income under Japanese GAAP. Operating profit includes profits derived from ordinary operating activities, as well as non-operating income, non-operating expenses, extraordinary income and extraordinary losses under Japanese GAAP. However, interest income, interest expense, exchange gains (losses) and other items included in those accounts are classified as finance income and finance expenses, and are not included in operating profit under IFRS.

## [Supplemental Notes]

- Under Japanese GAAP, lump-sum payments and other expenses that were incurred in connection with product and technology licensing agreements that had arisen primarily before the approval of the authorities could be obtained were expensed as research and development expenses. Of these expenses, those that are eligible due to meeting certain requirements are carried as intangible assets under IFRS. These intangible assets are amortized on a straight-line method over their estimated useful lives from the date the assets are available for use.
- In regard to goodwill, under Japanese GAAP, the Santen Group amortized goodwill over the period of expected benefit. Under IFRS, goodwill is not amortized.
- Under Japanese GAAP, the Santen Group amortized actuarial gains and losses on retirement benefits over a certain number of years within the average remaining service period for employees when the actuarial gains and losses were incurred. Under IFRS, the Santen Group must recognize the amount of the re-measurement of net defined benefit liability in other comprehensive income when it occurs, and immediately transfer it to retained earnings.

# **Adoption of Core Basis Indicators**

In line with the adoption of IFRS, Santen discloses financial information on a core basis to better express its recurring business performance, along with IFRS results on a full basis. Financial information on a core basis excludes certain gains and expenses from IFRS results on a full basis.

Please see P.7 for a definition of the core basis.

# Revenue

Santen's activities essentially encompass the pharmaceuticals and other businesses. At 98.6%, the vast majority of revenue comes from the pharmaceuticals segment. In fiscal 2015, ended March 31, 2016, revenue from the pharmaceuticals segment rose 20.9% compared with the previous year, to ¥192,554 million. Revenue from the other segment increased 6.5%, to ¥2,737 million. On this basis, total revenue for the fiscal year rose 20.7%, to ¥195,291 million.

# Pharmaceuticals Business

# [Prescription Pharmaceuticals]

Santen's ophthalmics, anti-rheumatics and other pharmaceuticals saw revenue increase 19.0%, to ¥181,550 million, representing 93.0% of consolidated revenue.

# Ophthalmics

Domestic revenue from prescription ophthalmic pharmaceuticals improved 17.9%, to ¥124,165 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 revenue was up 57.5%, to ¥48,379 million, after conversion to yen. In EMEA, after taking over the ophthalmology products of U.S.-based Merck & Co., Inc. and launching new products, Santen's geographic reach in terms of countries and regions and its product portfolio have expanded significantly, resulting in business growth. 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 revenue increased 26.8%, to ¥172,545 million.

## Anti-Rheumatics

Revenue from anti-rheumatics was down 63.7%, to ¥3,495 million. These results were for the period from April 2015 until the following July. Santen completed the assignment of its anti-rheumatic pharmaceuticals business to AYUMI Pharmaceutical Corporation in August 2015.

## Other Pharmaceuticals

Other pharmaceuticals includes revenues derived from technology-sharing agreements as well as contract work and manufacturing. In addition, certain profits generated by U.S.-based Merck & Co., Inc. were transferred to Santen in accordance with an agreement between the two companies. These profits were generated by Merck & Co., Inc. during the period from the completion of legal procedures in connection with Santen's taking over of ophthalmic products from Merck & Co., Inc. until the start of sales of these products by the Santen Group in various countries and regions. With these revenues amounting to ¥4,277 million, revenue in other pharmaceuticals was ¥5,510 million.

# [OTC Pharmaceuticals]

OTC pharmaceuticals revenue increased 64.1%, to ¥11,004 million, mainly due to a focus on promotional campaigns to enhance the brand value of the entire *Sante* series as well as growth in demand from inbound foreign tourists and a strong performance by higher priced products.

# Other Businesses

## [Medical Devices]

Revenue from medical devices rose 3.5% year on year, to ¥2,394 million, due to focusing initiatives on promotional campaigns for the *Eternity* foldable intraocular lens, which is made of a glistening-free hydrophobic acrylic optical material.

#### Revenue by Business Segment

	Millions	of yen	%
	2016	2015	Change
Pharmaceuticals Business	¥192,554	¥159,262	20.9
Prescription pharmaceuticals	181,550	152,556	19.0
Ophthalmics	172,545	136,059	26.8
Anti-rheumatics	3,495	9,629	(63.7)
Other pharmaceuticals	5,510	6,868	(19.8)
OTC pharmaceuticals	11,004	6,706	64.1
Other Businesses	2,737	2,569	6.5
Medical devices	2,394	2,313	3.5
Others	343	256	33.8
Total	¥195,291	¥161,831	20.7

Notes: 1. Santen completed the assignment of its anti-rheumatic pharmaceuticals business to AYUMI Pharmaceutical Corporation in August 2015. 2. Revenue for each segment refers to revenue to outside customers.





# [Others]

Revenue in Others totaled ¥343 million. This revenue came from sales of supplements, together with the cleaning of antidust and sterilized clothing operations of consolidated subsidiary Claire Co., Ltd.

# **Cost of Sales**

Cost of sales increased 29.2%, to ¥72,829 million. The cost of sales as a percentage of revenue increased from 34.8% to 37.3%.

# Selling, General and Administrative Expenses, Research and Development Expenses, and Amortization on Intangible Assets Associated with Products

Selling, general and administrative expenses increased 21.5%, to ¥59,406 million, mainly due to higher expenses related to selling activities associated with the ophthalmology assets taken over from U.S.-based Merck & Co., Inc. Research and development expenses rose 14.4% to ¥19,990 million. Amortization on intangible assets associated with products amounted to ¥6,205 million, mainly due to the recording of amortization on intangible assets in connection with the aforementioned ophthalmology assets taken over from U.S.-based Merck & Co., Inc., and to the start of amortization on intangible assets associated with beginning marketing the new product *lkervis* (ciclosporin).

# **Other Income and Other Expenses**

Other income was ¥44,999 million. This mainly reflected a gain recognized in conjunction with the assignment of the Company's anti-rheumatic pharmaceuticals business to AYUMI Pharmaceutical Corporation. Other expenses were ¥1,681 million. This was mainly attributable to the recording of a loss on sales of property, plant and equipment.

# **Operating Profit**

Operating profit was up 126.7%, to ¥80,180 million. The operating profit margin to revenue was 41.1%, up from 21.9% in the previous fiscal year. The core operating profit, excluding the contribution of revenue associated with the assignment of Santen's anti-rheumatic pharmaceuticals business, was up 10.2%, to ¥43,067 million. The core operating profit margin to revenue was 22.1%, down from 24.2% in the previous fiscal year.

#### Core Operating Profit and Core Operating Profit Margin



# **Finance Income and Finance Expenses**

Finance income increased 1.8% year on year, to ¥782 million. Finance expenses soared 434.1%, to ¥1,492 million, reflecting the impact of exchange losses.

# **Income Tax Expenses**

Income tax expenses totaled ¥26,097 million. The ratio of income tax expenses to profit before tax decreased from 33.0% to 32.8%.

# Net Profit for the Year

Net profit for the year was up 122.1%, to ¥53,373 million. The ratio of net profit for the year to revenue was 27.3%, up from 14.9% in the previous fiscal year. The core net profit for the year was up 12.4%, to ¥29,163 million, and the core net profit margin to revenue was 14.9%, down from 16.0% in the previous fiscal year.

Basic earnings per share (EPS) was ¥128.99, up from ¥58.18, and diluted earnings per share (diluted EPS) was ¥128.41, up from ¥57.93 in the previous fiscal year. Core basic earnings per share (Core EPS) was ¥70.48, up from ¥62.82.

Santen conducted a five-for-one share split of ordinary shares on the effective date of April 1, 2015. The EPS, the diluted EPS and the Core EPS for the fiscal year ended March 31, 2014 and the subsequent fiscal years were calculated under the assumption that the share split took effect at the beginning of the fiscal year ended March 31, 2014.



#### Core Net Profit for the Year and Core EPS

# **FINANCIAL CONDITION**

# Assets

As of March 31, 2016, total assets stood at ¥355,399 million, up ¥51,200 million, or 16.8%, compared with the previous fiscal year-end. The main contributing factors were the increase in cash and cash equivalents provided by the assignment of the anti-rheumatic pharmaceuticals business, and increases in trade and other receivables due to the increase in revenue and in financial assets. Return on total assets (ROA) was 16.2%, and core return on total assets (Core ROA) was 8.8%. Current assets were ¥194,739 million, and the ratio of current assets to total assets rose from 49.5% as of the previous fiscal year-end to 54.8%. Property, plant and equipment totaled ¥27,991 million, intangible assets were ¥83,681 million, and financial assets amounted to ¥44,535 million.

#### Total Assets and Core ROA



# Equity

Total equity amounted to ¥260,009 million, up ¥48,229 million compared with the end of the previous fiscal year. This was mainly due to an increase in retained earnings associated with the assignment of the anti-rheumatic pharmaceuticals business. The equity attributable to owners of the company ratio rose from 69.6% to 73.2%. Equity attributable to owners of the company per share was

#### Core ROE



¥627.78, an increase of ¥116.64, or 22.8%, compared with the end of the previous fiscal year. Return on equity attributable to owners of the company (ROE) increased from 12.0% to 22.6%. Core return on equity attributable to owners of the company (Core ROE) declined from 13.0% to 12.4%.

# Liabilities

Liabilities as of March 31, 2016 were ¥95,391 million, up ¥2,970 million compared with the previous fiscal year-end. The main contributing factor was an increase in income tax payable due to an increase in revenue associated with the assignment of the anti-rheumatic pharmaceuticals business, despite a decrease in financial liabilities mainly due to repayments of loans payable. Current liabilities were ¥73,230 million, and non-current liabilities were ¥22,161 million.

# **Cash Flows**

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

Net cash provided by operating activities was ¥22,525 million. The main components were net profit for the year of ¥53,373 million, income tax expenses of ¥26,097 million, depreciation and amortization of ¥9,338 million, and an increase in trade and other payables of ¥4,376 million. These were partially offset by earnings of ¥44,477 million due to the assignment of the anti-rheumatic pharmaceuticals business, income tax paid of ¥13,067 million, an increase in inventories of ¥5,388 million, an increase in trade and other receivables of ¥4,799 million, and a decrease in provisions and net defined benefit liabilities of ¥3,974 million mainly due to contributions to the retirement benefit trust.

Net cash provided by investing activities was ¥37,052 million. This mainly reflected cash inflows of ¥45,000 million due to the assignment of the anti-rheumatic pharmaceuticals business, and ¥2,682 million from proceeds from the sale and redemption of investments. These were partially offset by

#### **Cash Flows Summary**

		Millions of yen	
	2016	2015	Change
Cash flows from operating activities	¥22,525	¥25,386	¥(2,861)
Cash flows from investing activities	37,052	(61,709)	98,761
Cash flows from financing activities	(24,066)	28,960	(53,026)
Cash and cash equivalents at end of period	99,798	65,923	33,875

Note: Figures in parentheses indicate a decrease.

cash outflows of ¥4,793 million for payments for acquisition of intangible assets, ¥4,299 million for payments for acquisition of property, plant and equipment, and ¥2,210 million for payments for acquisition of investments.

Net cash used in financing activities was ¥24,066 million. The principal cash outflows were repayments of long-term loans of ¥15,133 million and dividends paid of ¥9,923 million.

As a result, cash and cash equivalents as of the end of the fiscal year amounted to ¥99,798 million, an increase of ¥33,875 million.

# **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, under the Company's Fiscal 2014–2017 Medium-Term Management Plan, Santen is targeting an ROE of more than 13.0%, and a dividend payout ratio of 40%. On this basis, the annual dividend per share for the fiscal year ended March 31, 2016 was ¥25. The dividend payout ratio stood at 19.4% and core dividend payout ratio stood at 35.5%.



# Dividend per Share, Core Dividend Payout Ratio, and Dividend Payout Ratio

Note: Dividends per share have been retrospectively adjusted to reflect the impact of the share split conducted on the effective date of April 1, 2015.

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

Any statements that Santen Group makes, 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 Santen Group's future results might be affected by political and economic changes in key markets worldwide in which it operates. Our anticipated business 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**

Since the Santen Group conducts operations in countries throughout the world, foreign exchange rate fluctuations affect its business performance and financial condition. Overseas revenue for the fiscal year ended March 31, 2016 accounted for 27.4% of our consolidated revenue.

# **Competitive Factors**

# **Generic Products**

The sale of generic products both in and outside Japan has the potential to impact the Santen Group's performance. Some of our products have already been launched as generic products by other companies. Looking ahead, the impact from generic products could increase.

# Dependency on Specific Products and Business Partners

# **Dependency on Mainstay Products**

Total revenue of *Eylea* and *Cosopt* accounted for more than 30% of the Santen Group's consolidated revenue for the fiscal year ended March 31, 2016. Should any sales suspension or a decline in revenue occur due to unanticipated negative influences, such as potential product defects or newly discovered side effects, our business performance and financial condition might be negatively affected.

# **Dependency on In-Licensed Products**

Many products that the Santen Group sells are manufactured or sold under license from other companies. We hold exclusive rights to manufacture and sell ophthalmic formulations such as *Cravit*, *Detantol*, *Tapros*, *Diquas* and *Alesion*. We also have sales rights in Japan for *Livostin*, and exclusive sales rights in Japan for *Rescula* and *Eylea*. Should changes be made in the contract period or conditions of such contracts, or should the agreements not be renewed, our business performance might be affected.

# **Dependency on Specific Business Partners**

The Santen Group depends on specific business partners for the supply of certain raw materials such as active pharmaceutical ingredients and containers. 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 the Santen Group's business conducted with the top 10 wholesalers in Japan has reached almost 65.0% of its consolidated revenue. 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 the Santen Group to accurately predict when new products, or 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 launches and thereby negatively affect projected revenue from 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 Santen Group. Every year we invest significantly in R&D, and there is a possibility that future investments will not result in revenue from 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 Santen Group's business performance and financial condition.

# **Other Factors**

## **Intellectual Property Rights**

The Santen Group's businesses are protected by various patents relating to substances and manufacturing methods. We manage such intellectual property rights appropriately and maintain vigilance against third-party infringements; however, if a third-party infringement were to occur, our business performance might be affected. Moreover, we take care to ensure that our business activities do not infringe on the intellectual property rights of third parties; however, if such an infringement were to occur, it might affect our business performance, such as receiving compensation claims for damages.

## **Production Interruptions or Delays**

The interruption or delay of production activities due to natural disasters or other catastrophes such as fire might affect the Santen Group's business performance and financial condition. Certain products are only manufactured at one location or outsourced to external manufacturers. If a specific plant or the external manufacturers are forced to halt production, supply of some products might be interrupted or delayed.

#### **Cancellation of Sales and Product Withdrawals**

If sales of the Santen Group's certain products are cancelled, or if the Group withdraws products due to product quality defects, unexpected side effects, tampering or other causes, its overall business performance might be negatively affected.

#### Litigation

The Santen Group's 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 business performance and financial condition. Currently, we are involved in no litigation that substantially impacts the management of the Group.

## **Risk Related to Global Business Expansion**

The Santen Group sells pharmaceutical products and conducts research and development in countries all over the world. In the course of developing our global business to achieve sustained growth, we are conducting asset transfers and company acquisitions. The nature of these kinds of 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, we might not achieve the benefits and earnings that we had initially anticipated.

# Eleven-year Summary of Selected Financial Data

Years ended March 31

	2006	2007	2008	2009	
	J-GAAP	J-GAAP	J-GAAP	J-GAAP	
For the year:					
Net sales/Revenue	¥ 98,398	¥100,486	¥103,394	¥101,619	
Cost of sales	34,535	35,484	36,513	35,947	
Selling, general and administrative expenses <sup>2</sup>	28,897	30,926	33,569	31,720	
Research and development expenses	13,971	13,663	12,942	18,458	
Operating profit	20,995	20,412	20,371	15,494	
Core operating profit	-	-	-	_	
Income taxes/Income tax expenses	7,319	7,891	7,832	5,701	
Net income/Net profit for the year	13,023	13,148	12,651	10,123	
Core net profit for the year	-	-	-	-	
Capital expenditures/Payments for acquisition of property, plant and equipment, and intangible assets	2,106	3,556	3,151	2,953	
Depreciation and amortization	4,824	4,761	4,593	4,210	
At year-end:					
Total assets	¥150,458	¥159,099	¥156,547	¥151,012	
Net assets/Total equity	118,637	128,646	127,118	125,369	
Liabilities	31,821	30,453	29,429	25,643	
Per share data (yen and U.S. dollars):					
EPS (Net income – basic/Basic earnings) <sup>3</sup>	¥ 150.26	¥ 151.58	¥ 146.15	¥ 119.08	
Core EPS <sup>3</sup>	-	-	_	-	
Equity/Equity attributable to owners of the company <sup>3, 4</sup>	1,368.27	1,481.83	1,494.48	1,472.32	
Cash dividends, applicable to the period <sup>3</sup>	12.00	13.00	16.00	16.00	
Cash flows:					
Net cash flows from (used in) operating activities	¥ 20,879	¥ 14,959	¥ 15,468	¥ 11,849	
Net cash flows from (used in) investing activities	(1,330)	(5,846)	(2,083)	(5,619)	
Net cash flows from (used in) financing activities	(5,900)	(5,691)	(11,415)	(11,373)	
Free cash flow <sup>5</sup>	18,773	11,403	12,317	8,896	
Interest coverage ratio (times)	218.7	164.3	163.6	165.5	
Financial data:					
ROE (Return (Net income) on equity/Return (Net profit for the year) on equity attributable to owners of the company) $(\%)^4$	11.5	10.6	9.9	8.0	
Core ROE (%)	-				
ROA (Return (Net income/Net profit for the year) on total assets) (%)	9.0	8.5	8.0	6.6	
Equity ratio/Equity attributable to owners of the company ratio (%) <sup>4</sup>	78.9	80.8	81.1	82.9	
Debt equity ratio (Interest-bearing debt to equity ratio/Interest-bearing debt to equity attributable to owners of the company ratio) (times) <sup>4</sup>	0.0	0.0	0.0	0.0	
PER (Price earnings ratio) (times)	18.8	20.0	15.9	23.0	
Dividend payout ratio (%)	39.9	42.9	54.7	67.2	
Core dividend payout ratio (%)	-	-	-	-	
Issued shares (thousands)	86,751	86,825	86,867	86,916	
Number of employees	2,312	2,409	2,483	2,690	

1. U.S. dollar amounts have been translated from yen, solely for the convenience of the reader, at the rate of ¥112.68 to U.S.\$1.00, the exchange rate prevailing on March 31, 2016.

Research and development expenses are excluded under J-GAAP.
 Research and development expenses are excluded under J-GAAP.
 The Company conducted a five-for-one share split of ordinary shares on the effective date of April 1, 2015. Per share data other than cash dividends, applicable to the period for the fiscal year ended March 31, 2014 and the subsequent fiscal years are calculated under the assumption that the share split took effect at the beginning of the fiscal year ended March 31, 2014. Cash dividends, applicable to the period have been retrospectively adjusted to reflect the impact of the share split.

4. Equity is calculated by deducting stock subscription rights from net assets under J-GAAP.
5. Free cash flow = (Net cash flows from operating activities) - (Capital expenditures/Payments for acquisition of property, plant and equipment, and intangible assets)

Millione of use							Thousands of
Millions of yen	2011	2012	2013	2014	2015	2016	U.S. dollars <sup>1</sup> 2016
J-GAAP	J-GAAP	J-GAAP	J-GAAP	IFRS	IFRS	IFRS	IFRS
J-GAAP	J-GAAP	J-GAAP	J-GAAP	IFR3	IFRO	IFRO	IFRO
¥110,594	¥110,812	¥114,416	¥119,066	¥146,260	¥161,831	¥195,291	\$1,733,149
34,710	34,437	35,385	41,501	57,353	56,373	72,829	646,332
32,121	32,415	35,073	36,164	41,642	48,893	59,406	527,211
14,123	13,221	17,225	16,720	16,862	17,477	19,990	177,401
29,640	30,739	26,732	24,681	29,878	35,374	80,180	711,572
_	_	_	_	30,403	39,088	43,067	382,205
9,887	9,741	10,630	9,071	10,643	11,831	26,097	231,601
18,723	21,333	17,161	16,521	19,718	24,032	53,373	473,671
_	_	_	_	19,813	25,948	29,163	258,809
1.015	1 651	0.001	2,600	5 970	66 440	0.002	90.696
1,315	1,651	3,281	3,609	5,879	66,440	9,092	80,686
3,421	2,976	2,949	3,291	2,841	6,958	9,338	82,874
¥166,878	¥184,801	¥198,801	¥199,641	¥237,640	¥304,200	¥355,399	\$3,154,060
137,603	156,404	164,861	165,132	187,210	211,779	260,009	2,307,498
29,275	28,397	33,940	34,509	50,430	92,421	95,391	846,562
		,		,	- ,		
¥ 220.10	¥ 249.71	¥ 196.96	¥ 195.81	¥ 47.78	¥ 58.18	¥ 128.99	\$ 1.14
				48.01	62.82	70.48	0.63
1,614.08	1,793.15	1,887.81	1,998.44	452.43	511.14	627.78	5.57
16.00	18.00	20.00	20.00	20.00	22.00	25.00	0.22
¥ 26,110	¥ 17,768	¥ 21,483	¥ 9,943	¥ 26,686	¥ 25,386	¥ 22,525	\$ 199,899
(829)	(7,676)	(10,273)	(4,596)	(7,847)	(61,709)	37,052	328,827
(6,753)	(1,570)	(8,559)	(21,557)	(7,954)	28,960	(24,066)	(213,583)
24,795	16,117	18,202	6,334	20,807	(41,054)	13,433	119,213
558.1	488.5	1,285.0	3,037.8	2,855.4	309.8	230.9	
14.3	14.5	10.7	10.0	11.1	12.0	22.6	
	-			11.2	13.0	12.4	
11.8	12.1	8.9	8.3	8.9	8.9	16.2	
82.3	84.5	82.8	82.6	78.8	69.6	73.2	
0.0	0.0	0.0	0.0	0.0	0.2	0.1	
12.7	13.3	17.9	22.7	19.2	30.1	13.1	
36.3	36.0	50.8	51.1	41.9	37.8	19.4	
_	_	_	_	41.7	35.0	35.5	
86,992	87,053	87,147	82,469	82,583	82,653	414,192	
2,756	2,867	3,053	3,050	3,072	3,230	3,463	

# Consolidated Statement of Profit or Loss and Other Comprehensive Income

Santen Pharmaceutical Co., Ltd. and Its Consolidated Subsidiaries For the year ended March 31, 2016

		Millions	of yen	Thousands of U.S. dollars	
	Note	2015	2016	2016	
Revenue	6, 7	¥161,831	¥195,291	\$1,733,14	
Cost of sales	9	(56,373)	(72,829)	(646,33)	
Gross profit		105,458	122,463	1,086,81	
Selling, general and administrative expenses	8, 9	(48,893)	(59,406)	(527,21	
Research and development expenses	9	(17,477)	(19,990)	(177,40	
Amortization on intangible assets associated with products	17	(3,979)	(6,205)	(55,07	
Other income	10	723	44,999	399,38	
Other expenses	11	(458)	(1,681)	(14,91	
Operating profit		35,374	80,180	711,57	
Finance income	12	768	782	6,93	
Finance expenses	12	(279)	(1,492)	(13,24	
Profit before tax		35,863	79,470	705,27	
Income tax expenses	13	(11,831)	(26,097)	(231,60	
Net profit for the year		24,032	53,373	473,67	
Items that will not be reclassified subsequently to profit or loss Remeasurements of defined benefit plans Net gain or loss on financial assets measured at fair value through other comprehensive income tems that may be reclassified subsequently to profit or loss	14 14	303 7,863	(1,007) 7,395	(8,93	
Foreign currency translation adjustments					
	14	248	(2,389)	(21,20	
Other comprehensive income	14 14	248 8,414	(2,389) 4,000	-	
Total comprehensive income for the year				(21,20 35,49 509,16	
Total comprehensive income for the year Profit attributable to		8,414 32,446	4,000 57,373	35,49 509,16	
Total comprehensive income for the year Profit attributable to Owners of the company		8,414	4,000	35,49 509,16	
Total comprehensive income for the year  Profit attributable to Owners of the company Non-controlling interests		8,414 32,446 24,032 —	4,000 57,373 53,373 –	35,49 509,10 473,67	
Total comprehensive income for the year  Profit attributable to Owners of the company Non-controlling interests Net profit for the year  Total comprehensive income attributable to		8,414 32,446 24,032 — 24,032	4,000 57,373 53,373  53,373	35,49 509,16 473,67 473,67	
Total comprehensive income for the year  Profit attributable to Owners of the company Non-controlling interests Net profit for the year  Total comprehensive income attributable to Owners of the company		8,414 32,446 24,032 —	4,000 57,373 53,373 –	35,49 509,16 473,67	
Total comprehensive income for the year  Profit attributable to Owners of the company Non-controlling interests Net profit for the year  Total comprehensive income attributable to		8,414 32,446 24,032 — 24,032	4,000 57,373 53,373  53,373	35,49 509,10 473,67 473,67	

		Yer	U.S. dollars	
Earnings per share		2015	2016	2016
Basic earnings per share	15	¥ 58.18	¥ 128.99	\$ 1.14
Diluted earnings per share	15	57.93	128.41	1.14

# Consolidated Statement of Financial Position

Santen Pharmaceutical Co., Ltd. and Its Consolidated Subsidiaries As of March 31, 2016

Assets Non-current assets Property, plant and equipment Intangible assets Financial assets Deferred tax assets Other non-current assets Total non-current assets Current assets Inventories	Note 16 17 18 13	Millions of         2015         ¥ 29,104         84,433         34,725         2,978         2,288	2016 ¥ 27,991 83,681 44,535 2,345	2016 <b>\$ 248,408</b> 742,643 395,233
Property, plant and equipment Intangible assets Financial assets Deferred tax assets Other non-current assets Total non-current assets Current assets	17 18	84,433 34,725 2,978 2,288	83,681 44,535 2,345	742,643
Property, plant and equipment         Intangible assets         Financial assets         Deferred tax assets         Other non-current assets         Total non-current assets         Current assets	17 18	84,433 34,725 2,978 2,288	83,681 44,535 2,345	742,643
Intangible assets Financial assets Deferred tax assets Other non-current assets Total non-current assets Current assets	17 18	84,433 34,725 2,978 2,288	83,681 44,535 2,345	742,643
Financial assets Deferred tax assets Other non-current assets Total non-current assets Current assets	18	34,725 2,978 2,288	44,535 2,345	
Deferred tax assets Other non-current assets Total non-current assets Current assets		2,978 2,288	2,345	000,200
Other non-current assets Total non-current assets Current assets	10	2,288		20,808
Total non-current assets Current assets			2,109	18,718
Current assets		153,528	160,660	1,425,810
		100,020	100,000	1,420,010
	19	20,133	24,996	221,828
Trade and other receivables	20	61,701	65,998	585,708
Other financial assets	18	187	234	2,079
Other current assets	10	2,728	3,714	32,962
	01			
Cash and cash equivalents	21	65,923	99,798	885,672
Total current assets		150,672	194,739	1,728,250
Total assets		304,200	355,399	3,154,060
Equity and liabilities				
Equity				
Share capital	22	7,383	7,695	68,291
Capital surplus	22	8,077	8,389	74,454
Treasury shares	22	(18)	(24)	(216)
Retained earnings	22	178,840	221,945	1,969,696
Other components of equity	22, 23	17,497	22,003	195,273
Total equity attributable to owners of the company		211,779	260,009	2,307,498
Total equity		211,779	260,009	2,307,498
Liabilities				
Non-current liabilities				
Financial liabilities	24	25,351	12,944	114,875
Net defined benefit liabilities	25	5,459	2,556	22,687
Provisions	26	1,444	1,629	14,457
Deferred tax liabilities	13	2,874	3,988	35,392
Other non-current liabilities		953	1,043	9,259
Total non-current liabilities		36,081	22,161	196,670
Current liabilities				
Trade and other payables	27	20,250	24,504	217,465
Other financial liabilities	24	19,298	19,881	176,437
Income tax payable		6,729	20,431	181,320
Provisions	26	1,197	1,276	11,320
Other current liabilities	20	8,866	7,138	63,351
Total current liabilities		56,340	73,230	649,892
Total liabilities		92,421	95,391	846,562
Total equity and liabilities		¥304,200	¥355,399	\$3,154,060

# Consolidated Statement of Changes in Equity Santen Pharmaceutical Co., Ltd. and Its Consolidated Subsidiaries For the year ended March 31, 2015

			Millions of yen						
						Other com	ponents of equity		
	Note	Share capital	Capital surplus	Treasury shares	Retained earnings	Remeasurements of defined benefit plans	Net gain or loss on financial assets measured at fair value through other comprehensive income		
Balance at April 1, 2014		¥7,264	¥7,959	¥ (9)	¥162,727	¥ —	¥ 4,118		
Comprehensive income									
Net profit for the year					24,032				
Other comprehensive income	14					303	7,863		
Total comprehensive income for the	e year	_	_	—	24,032	303	7,863		
Transactions with owners									
Issuance of new shares	22	119	118						
Acquisition of treasury shares	22			(9)					
Dividends	22				(8,259)				
Share-based payments	22, 23								
Other					340	(303)	(37)		
Total transactions with owners		119	118	(9)	(7,919)	(303)	(37)		
Balance at March 31, 2015		¥7,383	¥8,077	¥(18)	¥178,840	¥ —	¥11,944		

			en			
		Other com	ponents of equity			
	Note		Foreign currency translation Subscription adjustments rights to shares		Total equity attributable to owners of the company	Total equity
Balance at April 1, 2014		¥4,752	¥399	¥ 9,269	¥187,210	¥ 187,210
Comprehensive income						
Net profit for the year				_	24,032	24,032
Other comprehensive income	14	248		8,414	8,414	8,414
Total comprehensive income for th	e year	248	—	8,414	32,446	32,446
Transactions with owners						
Issuance of new shares	22		(32)	(32)	205	205
Acquisition of treasury shares	22			_	(9)	(9)
Dividends	22			_	(8,259)	(8,259)
Share-based payments	22, 23		186	186	186	186
Other				(340)	_	_
Total transactions with owners		_	154	(186)	(7,877)	(7,877)
Balance at March 31, 2015		¥5,000	¥553	¥17,497	¥211,779	¥211,779

				Millions	of yen	
					Other com	ponents of equity
Not	Share capital	Capital surplus	Treasury shares	Retained earnings	Remeasurements of defined benefit plans	Net gain or loss on financial assets measured at fair value through other comprehensive income
Balance at April 1, 2015	¥7,383	¥8,077	¥(18)	¥178,840	¥ —	¥11,944
Comprehensive income						
Net profit for the year				53,373		
Other comprehensive income 14					(1,007)	7,395
Total comprehensive income for the year	-	_	-	53,373	(1,007)	7,395
Transactions with owners Issuance of new shares 22	312	2 312				
Acquisition of treasury shares 22			(5)			
Dividends 22				(9,925)		
Share-based payments 22, 2	3					
Other				(343)	1,007	(664)
Total transactions with owners	312	. 312	(5)	(10,268)	1,007	(664)
Balance at March 31, 2016	¥7,695	¥8,389	¥(24)	¥221,945	¥ —	¥18,676

				Millions of ye	n	
		Other comp	onents of equity			
	Note	Foreign currency translation adjustments	Subscription rights to shares	Total	Total equity attributable to owners of the company	Total equity
Balance at April 1, 2015		¥ 5,000	¥553	¥17,497	¥211,779	¥211,779
Comprehensive income						
Net profit for the year				-	53,373	53,373
Other comprehensive income	14	(2,389)		4,000	4,000	4,000
Total comprehensive income for the year		(2,389)	-	4,000	57,373	57,373
Transactions with owners						
Issuance of new shares	22		(86)	(86)	538	538
Acquisition of treasury shares	22			_	(5)	(5)
Dividends	22			_	(9,925)	(9,925)
Share-based payments 2	22, 23		249	249	249	249
Other				343	-	_
Total transactions with owners		-	163	506	(9,143)	(9,143)
Balance at March 31, 2016		¥ 2,611	¥716	¥22,003	¥260,009	¥260,009

# Consolidated Statement of Changes in Equity Santen Pharmaceutical Co., Ltd. and Its Consolidated Subsidiaries For the year ended March 31, 2016

				Т	housands of U.S	6. dollars		
							Other comp	oonents of equity
	Note	Share capital	Capital surplus	Treasury shares	Retained earnings		urements of benefit plans	Net gain or loss on financial assets measured at fair value through other comprehensive income
Balance at April 1, 2015		\$65,522	\$71,685	\$(168)	\$1,587,152	\$	—	\$106,004
Comprehensive income								
Net profit for the year					473,671			
Other comprehensive income	14					(8	,938)	65,632
Total comprehensive income for the	e year	-	_	_	473,671	(8	,938)	65,632
Transactions with owners Issuance of new shares	22	2,769	2,769					
Acquisition of treasury shares	22			(48)				
Dividends	22				(88,079)			
Share-based payments	22, 23							
Other					(3,048)	8	3,938	(5,889)
Total transactions with owners		2,769	2,769	(48)	(91,127)	8	3,938	(5,889)
Balance at March 31, 2016		\$68,291	\$74,454	\$(216)	\$1,969,696	\$	—	\$165,747

			Thou	isands of U.S.	dollars	
		Other co	omponents of equity			
	Note	Foreign currency translation adjustments	Subscription rights to shares	Total	Total equity attributable to owners of the company	Total equity
Balance at April 1, 2015		\$ 44,374	\$4,906	\$155,285	\$1,879,476	\$1,879,476
Comprehensive income						
Net profit for the year				_	473,671	473,671
Other comprehensive income	14	(21,200)		35,494	35,494	35,494
Total comprehensive income for th	ne year	(21,200)	-	35,494	509,165	509,165
Transactions with owners						
Issuance of new shares	22		(765)	(765)	4,773	4,773
Acquisition of treasury shares	22			-	(48)	(48)
Dividends	22			-	(88,079)	(88,079)
Share-based payments	22, 23		2,210	2,210	2,210	2,210
Other				3,048	_	_
Total transactions with owners		_	1,445	4,494	(81,144)	(81,144)
Balance at March 31, 2016		\$ 23,174	\$6,352	\$195,273	\$2,307,498	\$2,307,498

# Consolidated Statement of Cash Flows

Santen Pharmaceutical Co., Ltd. and Its Consolidated Subsidiaries For the year ended March 31, 2016

	Millions of yen		s of ven	Thousands of U.S. dollars	
	Note –	2015	2016	2016	
Cash flows from operating activities					
Net profit for the year		¥ 24,032	¥ 53,373	\$ 473,671	
Depreciation and amortization		6,958	9,338	82,874	
Impairment losses		290	395	3,505	
Finance income and expenses		(529)	(545)	(4,837)	
Income tax expenses		11,831	26,097	231,601	
Gain on transfer of disposal group	33	_	(44,477)	(394,718)	
Decrease (increase) in trade and other receivables		(7,701)	(4,799)	(42,588)	
Decrease (increase) in inventories		(521)	(5,388)	(47,816)	
Increase (decrease) in trade and other payables		1,251	4,376	38,838	
Increase (decrease) in provisions and net defined benefit liabilities		761	(3,974)	(35,271)	
Other		2,554	653	5,793	
Subtotal		38,926	35,049	311,049	
Interest received		81	67	598	
Dividends received		548	573	5,082	
Interest paid		(82)	(98)	(866)	
Income tax paid		(14,087)	(13,067)	(115,964)	
Net cash flows from (used in) operating activities		25,386	22,525	199,899	
Payments into time deposits Proceeds from withdrawal of time deposits		(84) 184	(21) 21	(185) 185	
Payments for acquisition of investments		(114)	(2,210)		
Proceeds from sale and redemption of investments		( )	( ) · · · /	(19.010)	
Payments for acquisition of property, plant and equipment		4,149	2,682		
Proceeds from sales of property, plant and equipment		4,149	2,682 (4,299)	23,805	
ribbeeds norrisales of property, plant and equipment		4,149 (2,972) 656	2,682 (4,299) 696	23,805 (38,151)	
Payments for acquisition of intangible assets		(2,972)	(4,299)	23,805 (38,151)	
	33	(2,972) 656	(4,299) 696	23,805 (38,151) 6,177	
Payments for acquisition of intangible assets	33	(2,972) 656	(4,299) 696 (4,793)	23,805 (38,151) 6,177 (42,535)	
Payments for acquisition of intangible assets Proceeds from transfer of disposal group	33	(2,972) 656 (63,468) —	(4,299) 696 (4,793) 45,000	23,805 (38,151) 6,177 (42,535) 399,361 (220)	
Payments for acquisition of intangible assets Proceeds from transfer of disposal group Other Net cash flows from (used in) investing activities	33	(2,972) 656 (63,468) — (60)	(4,299) 696 (4,793) 45,000 (25)	399,361	
Payments for acquisition of intangible assets Proceeds from transfer of disposal group Other Net cash flows from (used in) investing activities Cash flows from financing activities	33	(2,972) 656 (63,468) — (60) (61,709)	(4,299) 696 (4,793) 45,000 (25)	23,805 (38,151) 6,177 (42,535) 399,361 (220)	
Payments for acquisition of intangible assets Proceeds from transfer of disposal group Other Net cash flows from (used in) investing activities Proceeds from short-term loans	33	(2,972) 656 (63,468) — (60) (61,709) 35,000	(4,299) 696 (4,793) 45,000 (25)	23,805 (38,151) 6,177 (42,535) 399,361 (220)	
Payments for acquisition of intangible assets Proceeds from transfer of disposal group Other Net cash flows from (used in) investing activities ash flows from financing activities Proceeds from short-term loans Repayments of short-term loans	33	(2,972) 656 (63,468) — (60) (61,709) 35,000 (35,000)	(4,299) 696 (4,793) 45,000 (25) 37,052 —	23,805 (38,151) 6,177 (42,535) 399,361 (220) 328,827	
Payments for acquisition of intangible assets Proceeds from transfer of disposal group Other Net cash flows from (used in) investing activities Cash flows from financing activities Proceeds from short-term loans Repayments of short-term loans Proceeds from long-term loans	33	(2,972) 656 (63,468) — (60) (61,709) 35,000 (35,000) 40,000	(4,299) 696 (4,793) 45,000 (25) 37,052  - 500	23,805 (38,151) 6,177 (42,535) 399,361 (220) 328,827 — — 4,437	
Payments for acquisition of intangible assets         Proceeds from transfer of disposal group         Other         Net cash flows from (used in) investing activities         Eash flows from financing activities         Proceeds from short-term loans         Repayments of short-term loans         Proceeds from long-term loans         Repayments of long-term loans	33	(2,972) 656 (63,468) — (60) (61,709) 35,000 (35,000) 40,000 (2,970)	(4,299) 696 (4,793) 45,000 (25) 37,052   500 (15,133)	23,805 (38,151) 6,177 (42,535) 399,361 (220) 328,827 	
Payments for acquisition of intangible assets         Proceeds from transfer of disposal group         Other         Net cash flows from (used in) investing activities         Cash flows from financing activities         Proceeds from short-term loans         Repayments of short-term loans         Proceeds from long-term loans         Repayments of long-term loans         Dividends paid	33	(2,972) 656 (63,468) — (60) (61,709) 35,000 (35,000) (35,000) 40,000 (2,970) (8,264)	(4,299) 696 (4,793) 45,000 (25) 37,052   500 (15,133) (9,923)	23,805 (38,151) 6,177 (42,535) 399,361 (220) 328,827 	
Payments for acquisition of intangible assets         Proceeds from transfer of disposal group         Other         Net cash flows from (used in) investing activities         Cash flows from financing activities         Proceeds from short-term loans         Repayments of short-term loans         Proceeds from long-term loans         Proceeds from long-term loans         Other         Net cash flows from (used in) financing activities	33	(2,972) 656 (63,468) — (60) (61,709) 35,000 (35,000) (35,000) 40,000 (2,970) (8,264) 194	(4,299) 696 (4,793) 45,000 (25) 37,052   500 (15,133) (9,923) 489	23,805 (38,151) 6,177 (42,535) 399,361 (220) 328,827 	
Payments for acquisition of intangible assets         Proceeds from transfer of disposal group         Other         Net cash flows from (used in) investing activities         Cash flows from financing activities         Proceeds from short-term loans         Repayments of short-term loans         Proceeds from long-term loans         Proceeds from long-term loans         Dividends paid         Other         Net cash flows from (used in) financing activities	21	(2,972) 656 (63,468) — (60) (61,709) (61,709) (35,000) (3	(4,299) 696 (4,793) 45,000 (25) 37,052   500 (15,133) (9,923) 489 (24,066)	23,805 (38,151) 6,177 (42,535) 399,361 (220) 328,827 	
Payments for acquisition of intangible assets         Proceeds from transfer of disposal group         Other         Net cash flows from (used in) investing activities         Cash flows from financing activities         Proceeds from short-term loans         Repayments of short-term loans         Proceeds from long-term loans         Repayments of long-term loans         Dividends paid         Other		(2,972) 656 (63,468) — (60) (61,709) (61,709) (35,000) (35,000) (35,000) (35,000) (35,000) (2,970) (8,264) 194 28,960 (7,363)	(4,299) 696 (4,793) 45,000 (25) 37,052  500 (15,133) (9,923) 489 (24,066) 35,510	23,805 (38,151) 6,177 (42,535) 399,361 (220) 328,827 	

Santen Pharmaceutical Co., Ltd. and Its Consolidated Subsidiaries

# 1. Reporting Entity

Santen Pharmaceutical Co., Ltd. and its consolidated subsidiaries (the "Santen Group") conduct businesses centered on the production and sale of prescription pharmaceuticals.

Santen Pharmaceutical Co., Ltd. (the "Company") is a company incorporated in Japan. The addresses of the

Company's headquarters and its major operating sites are disclosed on its corporate website

(http://www.santen.com/en/).

The shares of the Company are listed on the Tokyo Stock Exchange.

# 2. Basis of Preparation

#### 1) Compliance with IFRS

The Santen Group has prepared its consolidated financial statements under International Financial Reporting Standards ("IFRS").

#### 2) Basis of Measurement

The Santen Group's consolidated financial statements have been prepared on a historical cost basis, except for the financial instruments stated in Note 3 "Significant Accounting Policies."

#### 3) Functional Currency and Presentation Currency

The Santen Group's consolidated financial statements are presented in Japanese yen, which is the Company's functional currency. All financial information presented in Japanese yen has been rounded to the nearest million, except when otherwise indicated.

For the convenience of readers outside Japan, the accompanying consolidated financial statements are also presented in U.S. dollars by translating Japanese yen amounts at the exchange rate of ¥112.68 to US \$1.00, the approximate rate of exchange at the end of March 31, 2016. Such translations should not be construed as representations that the Japanese yen amounts could be converted into U.S. dollars at the above or any other rate.

#### 4) Early Adoption of New Standards

The Santen Group has early adopted IFRS 9 *Financial Instruments* ("IFRS 9") (amended in October 2010 and December 2011) since the transition date (April 1, 2013).

IFRS 9 replaces IAS 39 *Financial Instruments: Recognition and Measurement* and divides financial instruments into two classifications: those measured at amortized cost and those measured at fair value. Changes in the fair value of financial assets measured at fair value are recognized in profit or loss. Changes in fair value with respect to investments in equity instruments are recognized in other comprehensive income, except for equity instruments held for trading purposes.

#### 5) Approval of Consolidated Financial Statements

The Santen Group's consolidated financial statements for the fiscal year ended March 31, 2016 were approved by President and CEO Akira Kurokawa and Senior Corporate Officer, Chief Financial Officer (CFO) and Head of Finance Division Kazuo Koshiji on August 5, 2016.

## 3. Significant Accounting Policies

Unless otherwise stated, the Santen Group has consistently applied the accounting policies set forth below to all periods presented on the consolidated financial statements.

#### 1) Basis of Consolidation

The Santen Group's consolidated financial statements have been prepared based on the financial statements of the Company, subsidiaries and associates.

#### A. Subsidiaries

Subsidiaries are entities controlled by the Santen Group.

Control means that the Santen Group has power over the investee, has exposure to variable returns from involvement with the investee and has the ability to use its power over the investee to affect the amount of the investors' returns.

The financial statements of subsidiaries are included in the consolidated financial statements from the date that control commences until the date that control is lost. When the end of the reporting period of a subsidiary is different from that of the Company, the subsidiary prepares its financial statements for consolidation purpose based on the
provisional accounting as of the Company's closing date.

In the case of changes in the ownership interest in subsidiaries, if the Company retains control over the subsidiaries, they are accounted for as equity transactions. Any difference between the adjustment to the non-controlling interests and the fair value of the consideration transferred or received is recognized directly in equity attributable to owners of the company.

All intra-group balances and transactions, and any unrealized income and expenses arising from intra-group transactions are eliminated in preparing consolidated financial statements.

The financial statements of subsidiaries that have different fiscal year-ends than the Santen Group are consolidated using financial statements based on a provisional closing as of the Santen Group's fiscal year-end.

#### **B.** Associates

Associates are entities over which the Santen Group has significant influence over the financial and operating policies, but does not have control or joint control over it.

Investments in associates are accounted for using the equity method, from the date on which the Group obtains significant influence to the date on which the Santen Group loses significant influence.

#### 2) Business Combinations

Business combinations are accounted for using the acquisition method.

The identifiable assets acquired and the liabilities assumed are measured at the fair values at the acquisition date.

The Santen Group measures the consideration for an acquisition as the sum of (1) the consideration transferred in a business combination, (2) the amount of any non-controlling interest and (3) in a business combination achieved in stages, the acquisition-date fair value of the acquirer's previously held equity interest in the acquiree. The Santen Group recognizes goodwill as any excess of this consideration for acquisition over the net amount of the identifiable assets acquired and the liabilities assumed at the acquisition date. If the net amount of the identifiable assets and liabilities of the acquiree exceeds the consideration for acquisition, the acquirer recognizes the excess amount as profit or loss on the acquisition date. The consideration transferred in the business combination is calculated as the sum of the acquisition-date fair values of the assets transferred by the acquirer, the liabilities incurred by the acquirer to former owners of the acquiree and the equity interests issued by the acquirer.

Any expenses arising in connection with business combinations are accounted for as cost when incurred.

#### 3) Foreign Currency Translation

Foreign currency transactions are translated into the functional currency using exchange rates at the dates of transactions or rates that approximate the exchange rates at the dates of the transactions.

Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency using the exchange rate at the fiscal year-end, and exchange differences are recognized as profit or loss.

Assets and liabilities of foreign operations are translated into the presentation currency using the exchange rate at the fiscal year-end. Income and expenses of foreign operations are translated into the presentation currency using the average exchange rate during the fiscal year, except for cases of significant exchange rate movements. Exchange differences are recognized in other comprehensive income. If a foreign operation is discontinued, the cumulative exchange differences of the relevant foreign operation are reclassified to profit or loss when it is discontinued.

#### 4) Revenue

#### A. Revenue

Revenue is measured at the fair value of the consideration received or receivable, less trade discounts, returns and taxes such as consumption taxes. The Santen Group primarily recognizes the following as revenue:

#### i. Sale of goods

Revenue from the sale of goods is recognized when all the following conditions have been satisfied:

- (a) The Santen Group has transferred to the buyer the significant risks and rewards of ownership of the goods;
- (b) The Santen Group retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold;
- (c) The amount of revenue can be measured reliably;
- (d) It is probable that the economic benefits associated with the transaction will flow to the entity;
- (e) The costs incurred or to be incurred in respect of the transaction can be measured reliably.

#### ii. Intellectual property

Revenue from intellectual property is recognized on an accrual basis in accordance with the substance of the relevant agreement.

#### B. Other Income

Revenue that is based on factors other than the aforementioned revenue and finance income is recognized as other income.

#### C. Finance Income

#### i. Interest

Interest is recognized using the effective interest method. **ii. Dividend** 

Dividend is recognized when the Group's right to receive dividend is established.

#### 5) Research and Development Expenses

Internally generated development expenses are recognized as an intangible asset only if capitalization criteria under IAS 38 *Intangible Assets* ("IAS 38") are satisfied.

Expenditure on research and development of an internal project is fully expensed as "Research and development expenses" when incurred.

#### 6) Government Grants

Government grants are recognized at fair value when there is a reasonable assurance that the Santen Group will comply with the conditions attached to them and receive the grants.

Government grants related to income are recognized in profit or loss on a systematic basis over the periods in which the entity recognizes as expenses the related costs for which the grants are intended to compensate.

Government grants related to assets are recognized as deferred income that is recognized in profit or loss on a systematic basis over the useful life of the asset.

#### Income Taxes

Income taxes consist of current income taxes and deferred taxes.

Current income tax is measured at the amount that is expected to be paid to or recovered from the taxation authorities using the tax rates enacted or substantively enacted at the end of the reporting period. Current income tax is recognized in profit or loss, except for taxes that arise from transactions or events that are recognized in other comprehensive income or directly in equity as well as those that arise from business combinations.

Deferred taxes are calculated based on the temporary differences between the carrying amounts for financial reporting purposes and the amounts used for taxation purposes at the end of the reporting period. Deferred tax assets are recognized for deductible temporary differences, unused tax credits and unused tax losses to the extent that it is probable that future taxable profit will be available against which they can be utilized. Deferred tax liabilities are basically recognized for taxable temporary differences.

Deferred tax assets and deferred tax liabilities are not recognized for temporary differences on the initial recognition of assets or liabilities in a transaction that is not a business combination and affects neither accounting profit nor taxable profit on the transaction date. Deferred tax liabilities are not recognized for taxable temporary differences on initial recognition of goodwill.

Deferred tax liabilities are not recognized for taxable temporary differences associated with investments in subsidiaries and associates when the parent company is able to control the timing of the reversal of the temporary difference and it is probable that the temporary difference will not reverse within the foreseeable future. Moreover, deferred tax assets are not recognized for deductible temporary differences when the temporary difference will reverse in the foreseeable future or taxable profit will be available against which the temporary difference can be utilized.

Deferred tax assets and liabilities are calculated based on the tax rates that are expected to apply to the period when the deferred tax assets will be realized or the deferred tax liabilities will be settled.

Deferred tax assets and deferred tax liabilities are offset when there is a legally enforceable right to offset current tax assets and current tax liabilities and the deferred tax assets and liabilities are related to income taxes levied by the same taxation authority on the same taxable entity.

#### 8) Property, Plant and Equipment

Property, plant and equipment is recognized at cost, which includes any costs directly attributable to the acquisition of the asset and dismantlement, removal and restoration costs as well as borrowing costs eligible for capitalization.

After recognition, property, plant and equipment is measured by using the cost model and is stated at cost less accumulated depreciation and accumulated impairment losses.

Property, plant and equipment other than land are depreciated using the straight-line method over the estimated useful lives of each item from the date the assets are available for use. The estimated useful lives of major property, plant and equipment are as follows:

Buildings and structures:	3 to 50 years
Machinery and vehicles:	3 to 10 years
Tools, furniture and fixtures:	4 to 10 years

The depreciation methods, residual values and estimated useful lives are reviewed annually and adjusted as necessary. Impairment losses are stated in "10) Impairment of Property, Plant and Equipment and Intangible Assets."

#### 9) Intangible Assets

Intangible assets are identifiable non-monetary assets without physical substance and have been acquired individually or through business combinations. The major intangible assets are goodwill, intangible assets associated with products and software.

#### A. Goodwill

The measurement of goodwill on initial recognition is stated in "2) Business combinations." After initial recognition, goodwill is not amortized and is measured at cost less any accumulated impairment losses. Goodwill is allocated to the cash-generating units that are expected to benefit from synergies derived from business combinations.

#### B. Intangible Assets Other than Goodwill

Intangible assets other than goodwill that are acquired individually are recognized at cost, specifically any cost directly attributable to the acquisition of the asset. Intangible assets other than goodwill that are acquired through business combinations are recognized based on the fair value at the business combination date.

After recognition, intangible assets are measured using the cost model and are stated at cost less accumulated amortization and accumulated impairment losses.

These intangible assets are amortized using the straight-line method over the estimated useful lives (within approximately 20 years) from the date the assets are available for use. The estimated useful lives are calculated based on the term of legal protection or the economical life, and are regularly reviewed.

Impairment losses are shown in "10) Impairment of Property, Plant and Equipment and Intangible Assets." The treatment of expenditures related to research and development incurred within the Santen Group is shown in "5) Research and Development Expenses."

# 10) Impairment of Property, Plant and Equipment and Intangible Assets

At the end of each reporting period, the Santen Group assesses whether there is any indication of impairment that property, plant and equipment and intangible assets available for use may be impaired for each asset or cash-generating unit. If there is an indication of impairment, the Santen Group performs impairment test and assesses the recoverability of each asset or cash-generating unit.

Goodwill and intangible assets that are not yet available for use are performed impairment test annually, irrespective of whether there is any indication of impairment.

The cash-generating unit is the smallest identifiable

group of assets that generates cash inflows that are largely independent of the cash inflow from other assets or groups of assets.

The recoverable amount of an asset or a cash-generating unit is determined at the higher of its fair value less cost of disposal or its value in use. In determining the value in use, the estimated future cash flow is discounted to the present value using a discount rate that reflects the time value of money and the risks specific to the asset. If the carrying amount of the asset or cash-generating unit exceeds the recoverable amount, impairment loss is recognized in profit or loss and the carrying amount is reduced to the recoverable amount.

An asset or a cash-generating unit other than goodwill for which impairment loss was recognized in prior years is assessed at the end of the reporting period to determine whether there is any indication that the impairment loss recognized in prior periods may no longer exist or may have decreased. If any such indication exists, the recoverable amount of the asset or cash-generating unit is estimated. In cases in which the recoverable amount exceeds the carrying amount of the asset or cash-generating unit, the impairment loss is reversed up to the lower of the estimated recoverable amount or the carrying amount that would have been determined if no impairment loss had been recognized in prior years.

#### 11) Leases

Leases are classified as finance leases when substantially all the risks and rewards incidental to ownership of an asset are transferred to the lessee. Leases other than finance leases are classified as operating leases.

At the commencement of the lease term, the Companies recognize finance leases as assets and liabilities in the consolidated statement of financial position at amounts equal to the fair value of the leased property or, if lower, the present value of the minimum lease payments, each determined at the inception of the lease. The lease assets that have been recognized are depreciated on a straight-line basis over the shorter of the estimated useful life and the lease term of the asset.

Lease payments under an operating lease shall be recognized as an expense on a straight-line basis over the lease term unless another systematic basis is more representative of the time pattern of the user's benefit.

#### 12) Financial Instruments

#### A. Financial Assets

#### i. Initial recognition and measurement

The Santen Group recognizes financial assets on the trade date when the Group becomes party to the contractual provisions of the financial asset.

If the following conditions (a) and (b) are met, the financial assets that have been initially recognized are classified as financial assets measured at amortized cost; otherwise, they are classified as financial assets measured at fair value. Equity investment other than held for trading is measured at fair value through other comprehensive income.

- (a) The asset is held within a business model whose objective is to hold assets in order to collect contractual cash flows;
- (b) The contractual terms of the instrument give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Financial assets are initially measured at fair value plus transaction costs directly attributable to the financial assets, except for financial assets measured at fair value through profit or loss.

#### ii. Subsequent measurement

The financial assets measured at amortized cost are calculated using the effective interest method.

The financial assets measured at fair value are measured with any changes in fair value recognized through profit or loss. In addition, changes in the fair value of equity instruments other than held for trading are recognized through other comprehensive income and presented as "Financial assets measured at fair value through other comprehensive income" in other components of equity. The amount of other components of equity is transferred directly to retained earnings, not to profit or loss, when the equity investment is derecognized or the decline in its fair value compared to its acquisition cost is significant and other-than-temporary.

#### iii. Impairment losses

Financial assets that are measured at amortized cost are assessed whether there is any objective evidence of impairment at the end of each reporting period. If there is objective evidence of impairment, impairment loss is recognized in profit or loss as the difference between the financial asset's carrying amount and the present value of estimated future cash flows discounted at the financial asset's original effective interest rate.

If an impairment loss is reduced by an event occurring after the recognition of impairment losses, the reduction

in the impairment loss is reversed through profit or loss.

#### iv. Derecognition

The Santen Group derecognizes a financial asset only when the contractual right to receive the cash flows from the asset expires or when the Companies transfer the financial asset and substantially all the risks and rewards of ownership of the asset to another entity. On derecognition of a financial asset, the difference between the carrying amount and the consideration received or receivable is recognized in profit or loss, and the cumulative gain or loss that was previously accumulated in other comprehensive income (loss) is reclassified to retained earnings.

#### **B. Financial Liabilities**

#### i. Initial recognition and measurement

The Santen Group recognizes financial liabilities on the trade date when the Group becomes a party to the contractual provisions of the financial liability.

Financial liabilities that have been initially recognized are classified as financial liabilities measured at amortized cost, except for financial liabilities measured at fair value through profit or loss.

Financial liabilities except for financial liabilities at fair value through profit or loss are initially measured at fair value less transaction costs that are directly attributable to the issuance.

#### ii. Subsequent measurement

The financial liabilities measured at amortized cost are measured using the effective interest method.

The financial liabilities measured at fair value through profit or loss are measured at fair value and any gains or losses arising on remeasurement are recognized in profit or loss.

#### iii. Derecognition

The Santen Group derecognizes financial liabilities when the obligation specified in the contract is exempted, cancelled or expired.

#### C. Offsetting of Financial Assets and Financial Liabilities

Financial assets and financial liabilities are offset and the net amount presented in the statement of financial position when, and only when, the Santen Group:

- (a) Currently has a legally enforceable right to set off the recognized amounts;
- (b) Intends either to settle on a net basis or realize the asset and settle the liability simultaneously.

#### D. Derivatives

The Company utilizes derivatives for hedging the risk arising from fluctuation in foreign currency exchange rates,

interest rates and share price. Derivatives are initially measured at fair value on the date when the derivative contracts are entered into and are subsequently remeasured to fair value at each reporting date. The Santen Group does not enter into derivatives for trading or speculative purposes.

#### E. Hedge Accounting

The Santen Group designates certain derivatives as cash flow hedges and adopts hedge accounting for the derivatives.

At the inception of the hedge, the Santen Group documents the relationship between the hedging instrument and the hedged item, and the risk management objectives and strategies for undertaking the hedge. The Santen Group also assesses whether the derivatives used in hedging transactions are highly effective in achieving offsetting changes in cash flows of hedged items both at the hedge inception and on an ongoing basis. When a hedging instrument is designated as a cash flow hedge and meets the criteria for hedge accounting, the effective portion of the gains or losses on the hedging instrument is recognized in other comprehensive income. The ineffective portion of gains or losses on the hedging instrument is recognized in profit or loss.

The cumulative gain or loss that was previously recognized in other comprehensive income is reclassified to profit or loss in the same period when the cash flows of the hedged items are recognized in profit or loss and at the same line item in the consolidated statement of profit or loss and other comprehensive income.

Hedge accounting is discontinued when the Santen Group revokes the hedge designation, when the hedging instrument expires or is sold, terminated or exercised, or when the hedge no longer qualifies for hedge accounting.

#### 13) Inventories

Inventories are measured at the lower of cost and net realizable value.

The cost of inventories is calculated based on the weighted-average cost method, including raw materials, direct labor and other direct costs as well as relevant overhead expenses. The net realizable value is determined based on the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

#### 14) Cash and Cash Equivalents

Cash and cash equivalents consist of cash on hand, demand deposits and short-term highly liquid investments that are subject to insignificant risk of change in value, due within three months from the date of acquisition and readily convertible to known amounts of cash.

#### 15) Assets Held for Sale

The Santen Group classifies a non-current asset or disposal group, which must be available for immediate sale in its present condition and its sale must be highly probable as held for sale if its carrying amount will be recovered principally through a sale transaction rather than through continuing use.

The Santen Group measures a non-current asset or disposal group classified as held for sale at the lower of its carrying amount and fair value less costs to sell.

#### 16) Capital

#### A. Ordinary Shares

Proceeds from the issuance of ordinary shares are included in share capital and capital surplus. The transaction cost (net of tax) of equity transactions is deducted from capital surplus.

#### B. Treasury Shares

Treasury shares purchased by the Company are measured as the amount of the consideration paid for the shares and are recognized as a deduction from capital. The Company does not recognize any gains or losses on the acquisition, sale or cancellation of treasury shares. If the Company sells treasury shares, any differences between the carrying amount and the sales amount are recorded under capital surplus.

#### 17) Share-based Payments

The Santen Group has a share option plan as equity-settled share-based payments for its directors and corporate officers. Share options are measured at fair value on the grant date and the fair value is calculated using the Black-Scholes model. The fair value of share options is recognized as expenses and the corresponding amount as an increase in equity on the grant date.

#### 18) Employee Benefits

#### A. Post-employment Benefits

The Santen Group has adopted defined benefit plans and defined contribution plans as post-employment benefit plans for employees.

#### i. Defined benefit plans

The present value of defined benefit obligation and the related current service costs and past service cost are calculated based on the projected unit credit method.

The discount rates are determined with reference to the market yields of high-quality corporate bonds at the end of each reporting period. Service cost and net interest on the net defined benefit liabilities are recognized in profit or loss.

Actuarial gains and losses, return on plan assets excluding amounts included in net interest on the net defined benefit liabilities, and changes in the effect of the asset ceiling are recognized in other comprehensive income and reclassified to retained earnings in the period in which they are recognized.

#### ii. Defined contribution plans

Costs for defined contribution plans are recognized as expenses when they are paid.

#### B. Short-term Employee Benefits

The undiscounted amount of short-term employee benefits expected to be paid in exchange for that service are recognized as expenses when employees have rendered services to the Santen Group.

#### 19) Provisions

A provision is recognized when the Santen Group has a legal or constructive obligation as a result of a past event, and it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation, and the amount of the obligations can be estimated reliably. When the effect of the time value of money is material, the amount of a provision shall be the present value of the expenditures expected to be required to settle the obligation.

## 4. Use of Judgments, Estimates and Assumptions

In preparing the Santen Group's consolidated financial statements, management makes judgments, estimates and assumptions that affect the adoption of accounting policies and the reported amounts of assets and liabilities, and income and expenses. Actual results may differ from these estimates.

Judgments, estimates and assumptions made by management that may have a significant effect on the amounts recognized in the consolidated financial statements are as follows:

- Impairment of property, plant and equipment and intangible assets
- Recoverability of deferred tax assets
- Provisions
- Measurement of defined benefit obligations
- Fair value of financial instruments
- Share-based payments

### 5. New Standards and Interpretations Not Yet Adopted

The new standards, interpretations and amendments that have been issued for the consolidated financial statements, which the Santen Group has not yet adopted as of the approval date of the consolidated financial statements are set forth in the table below. The Santen Group is currently estimating the possible impact the application will have on the consolidated financial statements.

	IFRS	Mandatory adoption (From the fiscal year beginning on or after)	To be adopted by the Santen Group	Description of new standards, interpretations and amendments
IAS 16	Property, Plant and Equipment	January 1, 2016	Fiscal year ending March 2017	Amendment to the clarification of acceptable methods of depreciation
IAS 38	Intangible Assets	January 1, 2016	Fiscal year ending March 2017	Amendment to the clarification of acceptable methods of amortization
IFRS 15	Revenue from Contracts with Customers	January 1, 2018	Fiscal year ending March 2019	New revenue standards which supersedes IAS 18 "Revenue," IAS 11 "Construction Contracts" and a number of revenue-related interpretations
IFRS 9	Financial Instruments	January 1, 2018	Fiscal year ending March 2019	Amendment to classification, measurement, impairment and hedge accounting of financial instruments
IFRS 16	Lease	January 1, 2019	Fiscal year ending March 2020	Amendments to accounting treatment for lease arrangements

# 6. Operating Segments

#### 1) Reportable Segments

The reportable segment of the Santen Group brings together the components of the Group that are related to the Group's pharmaceuticals segment, which is centered on the manufacturing and distribution of prescription pharmaceuticals. These components of the Group are those for which separate financial information is available, and are evaluated regularly by the Board of Directors in order to decide on resource allocation and assess performance.

The pharmaceuticals segment conducts the manufacturing and distribution of prescription and OTC pharmaceuticals. Performance is measured based on segment operating profit. Transfer pricing between reportable segments is determined on an arm's length basis.

			Millions of yen		
For the year ended March 31, 2015 (April 1, 2014 to March 31, 2015)	Reportable segment Pharmaceuticals	Other*1	Total	Adjustments	Consolidated financial statements
Revenue from external customers	¥159,262	¥2,569	¥161,831	¥ —	¥161,831
Revenue from other operating segments	—	623	623	(623)	—
Total	159,262	3,192	162,454	(623)	161,831
Segment profit (loss)	35,976	(602)	35,374	—	35,374
				Finance income	768
			_	Finance expenses	(279)
				Profit before tax	¥ 35,863

			Millions of yen		
Segment assets and other items	Reportable segment Pharmaceuticals	Other*1	Total	Adjustments*2	Consolidated financial statements
Segment assets	¥218,206	¥3,477	¥221,683	¥82,517	¥304,200
Other items:					
Depreciation and amortization	6,906	52	6,958	—	6,958
Impairment losses	_	290	290	_	290
Additions to non-current assets*3	¥ 66,312	¥ 183	¥ 66,495	¥ —	¥ 66,495

Notes: 1. "Other" comprises operating segments other than the reportable segment, including the medical device operating segments. 2. "Adjustments" of ¥82,517 million for segment assets refer to corporate assets unallocated to the reportable segment, and principally

comprise the Company's surplus operating capital (stocks, cash and cash equivalents).

3. "Additions to non-current assets" exclude increases in financial assets and deferred tax assets.

		Millions of yen				
For the year ended March 31, 2016 (April 1, 2015 to March 31, 2016)	Reportable segment Pharmaceuticals	Other*1	Total	Adjustments	Consolidated financial statements	
Revenue from external customers	¥192,554	¥2,737	¥195,291	¥ —	¥195,291	
Revenue from other operating segments	-	655	655	(655)	-	
Total	192,554	3,392	195,946	(655)	195,291	
Segment profit (loss)	81,159	(979)	80,180	-	80,180	
				Finance income	782	
			_	Finance expenses	(1,492)	
				Profit before tax	¥ 79,470	

			Millions of yen		
Segment assets and other items	Reportable segment Pharmaceuticals	Other*1	Total	Adjustments*2	Consolidated financial statements
Segment assets	¥226,779	¥3,416	¥230,196	¥125,204	¥355,399
Other items:					
Depreciation and amortization	9,325	13	9,338	-	9,338
Impairment losses	234	160	395	-	395
Additions to non-current assets*3	¥ 8,255	¥ 852	¥ 9,107	¥ —	¥ 9,107

		Thousands of U.S. dollars				
For the year ended March 31, 2016 (April 1, 2015 to March 31, 2016)	Reportable segment Pharmaceuticals	Other*1	Total	Adjustments	Consolidated financial statements	
Revenue from external customers	\$1,708,861	\$24,288	\$1,733,149	\$ -	\$1,733,149	
Revenue from other operating segments	-	5,814	5,814	(5,814)	-	
Total	1,708,861	30,102	1,738,963	(5,814)	1,733,149	
Segment profit (loss)	720,259	(8,687)	711,572	—	711,572	
				Finance income	6,939	
			-	Finance expenses	(13,240)	
				Profit before tax	\$ 705,271	

	Thousands of U.S. dollars					
Segment assets and other items	Reportable segment Pharmaceuticals	Other*1	Total	Adjustments*2	Consolidated financial statements	
Segment assets	\$2,012,594	\$30,320	\$2,042,914	\$1,111,146	\$3,154,060	
Other items:						
Depreciation and amortization	82,760	114	82,874	-	82,874	
Impairment losses	2,081	1,424	3,505	-	3,505	
Additions to non-current assets*3	\$ 73,260	\$ 7,562	\$ 80,821	\$ —	\$ 80,821	

Notes: 1. "Other" comprises operating segments other than the reportable segment, including the medical device operating segments.
2. "Adjustments" of ¥125,204 million (\$1,111,146 thousand) for segment assets refer to corporate assets unallocated to the reportable segment, and principally comprise the Company's surplus operating capital (stocks, cash and cash equivalents).
3. "Additions to non-current assets" exclude increases in financial assets and deferred tax assets.

#### 2) Products and Services Information

				Millions of yen			
		Pharma	ceuticals		Ot	her	_
	Presc	ription pharmace	euticals				- Total
For the year ended March 31, 2015 (April 1, 2014 to March 31, 2015)	Ophthalmic	Anti-rheumatic pharmaceuticals	Other	OTC pharmaceuticals	Medical devices	Other	Total
Revenue from external customers	¥136,059	¥9,629	¥6,868	¥6,706	¥2,327	¥242	¥161,831
				Millions of yen			
		Pharma	ceuticals		Ot	her	_
	Presc	ription pharmace	euticals				Total
For the year ended March 31, 2016 (April 1, 2015 to March 31, 2016)	Ophthalmic	Anti-rheumatic pharmaceuticals	Other	OTC pharmaceuticals	Medical devices	Other	TOLAI
Revenue from external customers	¥172,545	¥3,495	¥5,510	¥11,004	¥2,394	¥343	¥195,291
			Thou	isands of U.S. dollars	6		
		Pharmaceuticals		Ot	her		
	Presc	ription pharmace	euticals				- Total
For the year ended March 31, 2016 (April 1, 2015 to March 31, 2016)	Ophthalmic	Anti-rheumatic pharmaceuticals	Other	OTC pharmaceuticals	Medical devices	Other	TOTAL
Revenue from external customers	\$1,531,281	\$31,021	\$48,895	\$97,659	\$21,248	\$3,045	\$1,733,149

Note: The Company assigned its anti-rheumatic pharmaceuticals business to AYUMI Pharmaceutical Corporation in August 2015.

#### 3) Geographical Areas Information

Non-current assets\*2

For the year ended March 31, 2015 –	Millions of yen						
(April 1, 2014 to March 31, 2015)	Japan	Europe	North America	Asia	Other	Total	
Revenue from external customers*1	¥124,836	¥14,156	¥6,169	¥16,668	¥2	¥161,831	
Non-current assets*2	100,991	10,889	459	3,486	_	115,825	

Notes: 1. Revenue is classified into countries or regions based on customer location.

2. Non-current assets are classified into countries or regions based on the asset location. Financial instruments and deferred tax assets are excluded.

For the year ended March 31, 2016	Millions of yen						
(April 1, 2015 to March 31, 2016)	Japan	Europe	North America	Asia	Other	Total	
Revenue from external customers*1	¥141,849	¥25,562	¥5,265	¥22,601	¥14	¥195,291	
Non-current assets*2	99,452	10,207	475	3,647	_	113,781	
For the year ended March 31, 2016	Thousands of U.S. dollars						
(April 1, 2015 to March 31, 2016)	Japan	Europe	North America	Asia	Other	Total	
Revenue from external customers*1	\$1,258,869	\$226,852	\$46,723	\$200,578	\$127	\$1,733,149	

90,588

Notes: 1. Revenue is classified into countries or regions based on customer location.

882,604

 Non-current assets are classified into countries or regions based on the asset location. Financial instruments and deferred tax assets are excluded.

4,215

32,362

1,009,769

4) Information on Major Customers	Millions of yen	
For the year ended March 31, 2015 (April 1, 2014 to March 31, 2015)	Revenue	Reportable segment
Major customers		
Suzuken Co., Ltd.	¥32,774	Pharmaceuticals
Mediceo Corporation	27,491	Pharmaceuticals
	Millions of yen	
For the year ended March 31, 2016 (April 1, 2015 to March 31, 2016)	Revenue	Reportable segment
Major customers		
Suzuken Co., Ltd.	¥37,592	Pharmaceuticals
Mediceo Corporation	30,850	Pharmaceuticals
	Thousands of U.S. dollars	
For the year ended March 31, 2016 (April 1, 2015 to March 31, 2016)	Revenue	Reportable segment
Major customers		
Suzuken Co., Ltd.	\$333,616	Pharmaceuticals
Mediceo Corporation	273,788	Pharmaceuticals

# 7. Revenue

	Millions	Thousands of U.S. dollars	
	2015	2016	
Sale of goods	¥155,785	¥190,343	\$1,689,239
Other	6,046	4,948	43,910
Total	¥161,831	¥195,291	\$1,733,149

# 8. Selling, General and Administrative Expenses

	Millions	Thousands of U.S. dollars	
	2015	2016	2016
Wages and bonuses	¥14,663	¥17,447	\$154,837
Advertising and sales promotion expenses	12,223	15,238	135,235
Legal welfare expenses	2,201	2,521	22,377
Post-employment benefit cost	901	1,161	10,299
Depreciation and amortization	819	1,024	9,088

# 9. Employee Benefit Expenses

	Millions	Thousands of U.S. dollars	
-	2015	2016	2016
Wages and bonuses	¥25,389	¥29,205	\$259,181
Legal welfare expenses	3,788	4,179	37,087
Post-employment benefit cost (defined contribution plan)	1,107	989	8,778
Post-employment benefit cost (defined benefit plan)	1,075	1,186	10,521
Share-based payment	186	249	2,210
Other	919	1,148	10,185
Total	¥32,464	¥36,955	\$327,963

Note: Employee Benefit Expenses are included in "Cost of sales," "Selling, general and administrative expenses" and "Research and development expenses."

# 10. Other Income

	Millions	Millions of yen		
	2015	2015 2016		
Gain on disposal of non-current assets	¥155	¥ 2	\$ 18	
Government grants	323	260	2,309	
Gain on transfer of disposal group*1	—	44,477	394,718	
Other	245	260	2,309	
Total	¥723	¥44,999	\$399,355	

Note 1: Gain on transfer of disposal group is a gain recognized in conjunction with the assignment of the Company's anti-rheumatic pharmaceuticals business to AYUMI Pharmaceutical Corporation.

# 11. Other Expenses

	Millions of yen		Thousands of U.S. dollars
	2015	2016	2016
Loss on disposal of non-current assets	¥ 54	¥ 495	\$ 4,390
Impairment losses*1	290	395	3,505
Extraordinary expense in connection with the transfer of disposal groups	_	431	3,824
Other	114	360	3,198
Total	¥458	¥1,681	\$14,917

Note 1: Impairment losses are stated in "16. Property, Plant and Equipment 2)" and "17. Intangible Assets 2)."

12. Finance Income and Expenses			
1) Finance Income	ncome Millions of yen		
	2015	2016	2016
Interest income			
Financial assets measured at amortized cost	¥ 72	¥ 70	\$ 618
Dividends income			
Financial assets measured at fair value through other comprehensive	e income 548	573	5,082
Life insurance	144	140	1,238
Total dividend income	692	712	6,321
Other	4	-	-
Total	¥768	¥782	\$6,939

2) Finance Expenses	Millions	Thousands of U.S. dollars	
	2015	2016	2016
Interest expense			
Financial liabilities measured at amortized cost	¥ 88	¥ 94	\$ 837
Other	3	1	11
Total interest expense	91	96	848
Foreign exchange losses	23	1,352	11,994
Net interest related to post-employment benefits	65	43	381
Other	100	2	16
Total	¥279	¥1,492	\$13,240

# 13. Deferred Taxes and Income Taxes

1) Deferred Taxes

i. Major items and changes in deferred tax assets and liabilities

	Millions of yen				
-	As of April 1, 2014	Recognized through profit or loss	Recognized in other comprehensive income	As of March 31, 2015	
Deductible temporary differences					
Retirement benefit liabilities	¥ 3,296	¥ (105)	¥ (177)	¥ 3,014	
Research and development expenses	1,271	458	_	1,729	
Accrued enterprise taxes	610	(125)	_	485	
Depreciation and amortization	1,155	149	_	1,304	
Accrued bonus	947	(81)	_	866	
Inventories	454	(10)	_	444	
Paid absences	157	(11)	_	146	
Unearned revenue	246	(4)	_	242	
Impairment losses	16	72	_	88	
Other	1,098	40	_	1,138	
Subtotal	9,250	383	(177)	9,456	
Taxable temporary differences					
Financial assets measured at fair value through					
other comprehensive income	(2,433)	4	(3,380)	(5,809)	
Intangible assets associated with products	(5,074)	171	_	(4,903)	
Reserve for special depreciation	(11)	6	_	(5)	
Other	(40)	6	_	(34)	
Subtotal	(7,558)	187	(3,380)	(10,751)	
Unused tax losses and tax credits					
Unused tax credits	307	497	_	804	
Unused tax losses	421	174	—	595	
Subtotal	728	671	_	1,399	
Net amount	¥ 2,420	¥1,241	¥(3,557)	¥ 104	

The difference between the net amount of temporary differences recognized through profit or loss in the table above and the total deferred income taxes stated in "2) Income Tax Expenses i. Income Taxes Recognized through Profit or Loss" is attributable to foreign exchange fluctuations.

	Millions of yen			
	As of March 31, 2015	Recognized through profit or loss	Recognized in other comprehensive income	As of March 31, 2016
Deductible temporary differences				
Retirement benefit liabilities	¥ 3,014	¥(192)	¥ 420	¥ 3,243
Research and development expenses	1,729	205	-	1,934
Accrued enterprise taxes	485	792	-	1,277
Depreciation and amortization	1,304	(187)	-	1,116
Accrued bonus	866	(78)	-	788
Inventories	444	2	-	447
Paid absences	146	(10)	-	136
Unearned revenue	242	(143)	-	100
Impairment losses	88	(15)	-	73
Other	1,138	84	-	1,221
Subtotal	9,456	457	420	10,334
Taxable temporary differences				
Financial assets measured at fair value through	ı			
other comprehensive income	(5,809)	-	(2,526)	(8,335)
Intangible assets associated with products	(4,903)	307	_	(4,596)
Reserve for special depreciation	(5)	5	_	_
Other	(34)	1	_	(33)
Subtotal	(10,751)	312	(2,526)	(12,965)
Unused tax losses and tax credits				
Unused tax credits	804	129	-	933
Unused tax losses	595	(541)	-	54
Subtotal	1,399	(412)	-	987
Net amount	¥ 104	¥ 358	¥(2,106)	¥ (1,643)

The difference between the net amount of temporary differences recognized through profit or loss in the table above and the total deferred income taxes stated in "2) Income Tax Expenses i. Income Taxes Recognized through Profit or Loss" is attributable to foreign exchange fluctuations.

	Thousands of U.S. dollars			
	As of March 31, 2015	Recognized through profit or loss	Recognized in other comprehensive income	As of March 31, 2016
Deductible temporary differences				
Retirement benefit liabilities	\$ 26,751	\$(1,705)	\$ 3,731	\$ 28,778
Research and development expenses	15,341	1,822	—	17,162
Accrued enterprise taxes	4,301	7,029	-	11,330
Depreciation and amortization	11,570	(1,663)	-	9,907
Accrued bonus	7,688	(693)	-	6,995
Inventories	3,947	17	-	3,964
Paid absences	1,296	(92)	-	1,204
Unearned revenue	2,150	(1,266)	_	884
Impairment losses	783	(133)	-	650
Other	10,091	741	-	10,831
Subtotal	83,917	4,058	3,731	91,707
Taxable temporary differences				
Financial assets measured at fair value through	1			
other comprehensive income	(51,551)	-	(22,416)	(73,967)
Intangible assets associated with products	(43,513)	2,721	_	(40,792)
Reserve for special depreciation	(46)	46	_	_
Other	(292)	(2)	_	(294)
Subtotal	(95,402)	2,766	(22,416)	(115,052)
Unused tax losses and tax credits				
Unused tax credits	7,133	1,148	-	8,281
Unused tax losses	5,280	(4,801)	_	479
Subtotal	12,413	(3,653)	_	8,760
Net amount	\$ 928	\$ 3,177	\$(18,684)	\$ (14,581)

The difference between the net amount of temporary differences recognized through profit or loss in the table above and the total deferred income taxes stated in "2) Income Tax Expenses i. Income Taxes Recognized through Profit or Loss" is attributable to foreign exchange fluctuations.

ii. Deductible temporary differences, unused tax losses and unused tax credits for which no deferred tax assets are recognized in the statement of financial position

	Millions	Thousands of U.S. dollars	
	2015 2016		2016
Deductible temporary differences	¥ 265	¥ 574	\$ 5,092
Carry-forwards of unused tax losses	6,651	7,093	62,945
Carry-forwards of unused tax credits	1,401	1,114	9,888

iii. The expiry schedule for unused tax losses for which no deferred tax assets are recognized in the statement of financial position

	Millions	Thousands of U.S. dollars	
	2015	2016	2016
1st year	¥ 21	¥ 39	\$ 342
2nd year	36	2	13
3rd year	2	18	157
4th year	28	46	406
5th year onward	6,564	6,989	62,027
Total	¥6,651	¥7,093	\$62,945

iv. In the fiscal years ended March 31, 2016 and 2015, there were subsidiaries that recognized carry-forwards of unused tax losses. In the fiscal year ended March 31, 2016, deferred tax assets of ¥54 million (\$479 thousand) were recognized to the extent that future taxable profit is expected (¥595 million as of March 31, 2015). The recoverability of deferred tax assets depends on future taxable profit. The future taxable profit used to recognize these deferred tax assets has been projected in line with business plans approved by management, and is highly likely to be achieved based on a comparison of actual performance trends against previous plans. Accordingly, management believes that the recoverability of deferred tax assets no particular issues.

v. In the fiscal years ended March 31, 2016 and 2015, the Company did not recognize deferred tax liabilities related to the taxable temporary differences associated with investment in subsidiaries, because the Company was able to control the timing of the reversal of the temporary differences and it was probable that such differences would not reverse in the foreseeable future. The taxable temporary differences associated with investments in subsidiaries for which deferred tax liabilities have not been recognized amounted to ¥4,480 million (\$39,759 thousand) as of March 31, 2016, and ¥2,481 million as of March 31, 2015.

#### 2) Income Tax Expenses

#### i. Income Taxes Recognized through Profit or Loss

	Millions	Thousands of U.S. dollars	
	2015	2016	2016
Current income taxes			
Current	¥12,688	¥26,506	\$235,231
Subtotal	12,688	26,506	235,231
Deferred income taxes			
Occurrence and reversal of temporary differences	(1,323)	(708)	(6,283)
Change in tax rate	466	299	2,654
Subtotal	(857)	(409)	(3,630)
Total income tax expenses	¥11,831	¥26,097	\$231,601

Current income taxes include tax benefits arising from previously unrecognized carry-forwards of unused tax losses, tax credits or temporary differences of a prior period. As a result, current income taxes were reduced by ¥666 million (\$5,911 thousand) in the fiscal year ended March 31, 2016 and ¥558 million in the fiscal year ended March 31, 2015. Deferred taxes include tax benefits arising from previously unrecognized carry-forwards of tax losses, tax credits or temporary differences of a prior period, as well as deferred tax expenses arising from the write-down, or reversals of previous write-down of deferred tax asset. As a result, deferred taxes decreased by ¥11 million (\$94 thousand) in the fiscal year ended March 31, 2016 and ¥830 million in the fiscal year ended March 31, 2015.

#### ii. Reconciliation of Applicable Income Tax Rate

The Company is subject mainly to corporate tax, inhabitant tax and enterprise tax, and the effective statutory tax rate calculated on those taxes was 32.9% and 35.5% for the

fiscal years ended March 31, 2016 and 2015, respectively. Foreign subsidiaries are subject to income taxes in their respective countries.

	2015	2016
Effective statutory income tax rate	35.5%	32.9%
Non-deductible items / non-taxable income	0.8%	0.6%
Tax credit for research, development expenses and others	(3.6%)	(2.4%)
Differences in tax rates applied to subsidiaries	(0.2%)	(0.2%)
Effect of changes in tax rates	1.3%	0.4%
Movements in unrecognized deferred tax assets	(0.6%)	1.0%
Other	(0.2%)	0.5%
Actual tax rate	33.0%	32.8%

On March 29, 2016, amendments to the Japanese tax regulations were enacted into law. Based on the amendments, the statutory income tax rates utilized for the measurement of deferred tax assets and liabilities expected to be settled or realized from April 1, 2016 to March 31, 2018 and on or after April 1, 2018 were changed from 32.18% to 30.76% and 30.52%, respectively, as of March 31, 2016.

Due to these changes in statutory income tax rates, net deferred tax assets (after deducting deferred tax liabilities) increased by ¥154 million (\$1,367 thousand) as of March 31, 2016, deferred income tax expense recognized for the fiscal year ended March 31, 2016 increased by ¥299 million (\$2,654 thousand), net unrealized gains on securities increased by ¥454 million (\$4,029 thousand) and remeasurements of defined benefit plans decreased by ¥1 million (\$9 thousand).

#### 14. Other Comprehensive Income

			Thousands of
	Millions	s of yen	U.S. dollars
	2015	2016	2016
Remeasurement of defined benefit plans			
Amounts arising during the year	¥ 480	¥(1,428)	\$(12,669)
Reclassification adjustments to profit or loss	—	—	—
Before tax effects	480	(1,428)	(12,669)
Tax effects	(177)	420	3,731
Remeasurement of defined benefit plans	303	(1,007)	(8,938)
Net gain or loss on financial assets measured at fair value			
through other comprehensive income			
Amounts arising during the year	11,243	10,247	90,941
Reclassification adjustments to profit or loss	—	-	-
Before tax effects	11,243	10,247	90,941
Tax effects	(3,380)	(2,852)	(25,308)
Net gain or loss on financial assets measured at fair value			
through other comprehensive income	7,863	7,395	65,632
Foreign currency translation adjustments			
Amounts arising during the year	248	(2,389)	(21,200)
Reclassification adjustments to profit or loss	_	-	_
Before tax effects	248	(2,389)	(21,200)
Tax effects	_	—	_
Foreign currency translation adjustments	248	(2,389)	(21,200)
Total other comprehensive income	¥ 8,414	¥ 4,000	\$ 35,494

# 15. Earnings per Share

	Millions	of yen	Thousands of U.S. dolla	
	2015	2016	2016	
Profit attributable to owners of the company	¥24,032	¥ 53,373	\$473,671	
Profit not attributable to ordinary shareholders of the company	_	-	-	
Profit used to calculate basic earnings per share	24,032	53,373	473,671	
Basis of calculating diluted earnings per share				
Profit used to calculate basic earnings per share	¥24,032	¥ 53,373	\$473,671	
Adjustment	—	-	-	
Profit used to calculate diluted earnings per share	24,032	53,373	473,671	
		Thousand	ls of shares	
		2015	2016	
Weighted-average number of shares during the year		413,056	413,786	
Subscription rights to shares		1,799	1,864	
Weighted-average number of diluted ordinary shares during the	year	414,855	415,650	

(attributable to owners of the company):	Ye	U.S. dollars		
	2015	2016	2016	
Basic	¥ 58.18	¥ 128.99	\$ 1.14	
Diluted	57.93	128.41	1.14	

Note: On April 1, 2015, the Company completed a five-for-one share split at the Board of Directors meeting held on February 24, 2015. Basic earnings per share and diluted earnings per share were calculated under the assumption that the share split took effect at the beginning of the previous fiscal year.

# 16. Property, Plant and Equipment

1) Statements of Changes in Acquisition Cost, Accumulated Depreciation and Accumulated Impairment Losses and the Carrying Amount by Category

#### A. Acquisition Cost

	Millions of yen					
	Buildings and structures	Machinery, equipment and vehicles	Tools, fixtures and fittings	Land	Construction in progress	Total
Balance as of April 1, 2014	¥44,635	¥13,453	¥12,908	¥ 8,078	¥ 816	¥79,890
Additions	196	87	642	_	3,496	4,421
Transfers	275	748	324	—	(1,347)	_
Disposals	(54)	(118)	(523)	—	_	(695)
Foreign currency translation differences	84	47	(14)	(5)	72	184
Balance as of March 31, 2015	¥45,136	¥14,217	¥13,337	¥ 8,073	¥ 3,037	¥83,800
Additions	217	180	664	_	2,077	3,137
Transfers	1,010	645	199	_	(1,854)	-
Disposals	(54)	(169)	(929)	(1,133)	-	(2,284)
Foreign currency translation differences	(437)	(204)	(163)	(1)	(154)	(959)
Balance as of March 31, 2016	¥45,872	¥14,669	¥13,107	¥ 6,939	¥ 3,106	¥83,693

	Thousands of U.S. dollars					
	Buildings and structures	Machinery, equipment and vehicles	Tools, fixtures and fittings	Land	Construction in progress	Total
Balance as of March 31, 2015	\$400,564	\$126,173	\$118,357	\$ 71,643	\$ 26,957	\$743,695
Additions	1,925	1,596	5,890	-	18,430	27,841
Transfers	8,966	5,725	1,765	-	(16,456)	-
Disposals	(477)	(1,499)	(8,243)	(10,055)	-	(20,274)
Foreign currency translation differences	(3,877)	(1,810)	(1,449)	(11)	(1,364)	(8,510)
Balance as of March 31, 2016	\$407,102	\$130,185	\$116,321	\$ 61,578	\$ 27,567	\$742,753

#### **B.** Accumulated Depreciation and Impairment Losses

	Millions of yen					
	Buildings and structures	Machinery, equipment and vehicles	Tools, fixtures and fittings	Land	Construction in progress	Total
Balance as of April 1, 2014	¥(30,616)	¥(11,242)	¥(10,857)	¥—	¥ —	¥(52,715)
Depreciation	(1,203)	(550)	(667)	—	—	(2,420)
Impairment losses	(10)	(16)	(147)	_	(30)	(203)
Disposals	45	20	509	_	_	574
Foreign currency translation differences	28	13	27	_	_	68
Balance as of March 31, 2015	¥(31,756)	¥(11,775)	¥(11,135)	¥—	¥(30)	¥(54,696)
Depreciation	(1,113)	(567)	(708)	_	-	(2,388)
Impairment losses	(15)	(47)	(65)	-	(0)	(127)
Disposals	33	139	913	_	-	1,085
Foreign currency translation differences	185	153	86	-	0	423
Balance as of March 31, 2016	¥(32,666)	¥(12,098)	¥(10,909)	¥—	¥(31)	¥(55,703)

	Thousands of U.S. dollars					
	Buildings and structures	Machinery, equipment and vehicles	Tools, fixtures and fittings	Land	Construction in progress	Total
Balance as of March 31, 2015	\$(281,822)	\$(104,504)	\$(98,810)	\$—	\$(272)	\$(485,408)
Depreciation	(9,874)	(5,028)	(6,288)	_	-	(21,189)
Impairment losses	(136)	(418)	(575)	_	(2)	(1,130)
Disposals	295	1,231	8,101	_	-	9,627
Foreign currency translation differences	1,638	1,355	760	_	2	3,755
Balance as of March 31, 2016	\$(289,899)	\$(107,364)	\$(96,811)	\$—	\$(273)	\$(494,345)

#### C. Carrying Amount

	Millions of yen					
	Buildings and structures	Machinery, equipment and vehicles	Tools, fixtures and fittings	Land	Construction in progress	Total
As of April 1, 2014	¥14,019	¥2,211	¥2,051	¥8,078	¥ 816	¥27,175
As of March 31, 2015	13,380	2,442	2,202	8,073	3,007	29,104
As of March 31, 2016	¥13,206	¥2,572	¥2,198	¥6,939	¥3,076	¥27,991

	Thousands of U.S. dollars					
	Buildings and structures	Machinery, equipment and vehicles	Tools, fixtures and fittings	Land	Construction in progress	Total
As of March 31, 2016	\$117,203	\$22,822	\$19,510	\$61,578	\$27,296	\$248,408

#### 2) Impairment Losses

In the fiscal year ended March 31, 2016, the Santen Group recorded impairment losses of ¥127 million (\$1,130 thousand) for that period, along with ¥203 million for the period ended March 31, 2015. Impairment losses are included in other expense in the statements of income and comprehensive income.

The major assets for which impairment losses were recognized for the year ended March 31, 2015 were mainly "Tools, fixtures and fittings" in the "Other" segment. The carrying amounts of these assets were written down to the recoverable amounts due to the decline in expected profitability. Those recoverable amounts were measured at the value in use. The major assets for which impairment losses were recognized for the year ended March 31, 2016 were mainly "Tools, fixtures and fittings" in the "Other" segment. The carrying amounts of these assets were written down to the recoverable amounts due to the significant decline in expected profitability. Those recoverable amounts were measured at the value in use.

#### 3) Other Disclosures

The Santen Group has contractual commitments for the acquisition of property, plant and equipment as of March 31, 2016 totaling ¥1,380 million (\$12,247 thousand) and ¥1,535 million as of March 31, 2015.

# 17. Intangible Assets

1) Statements of Changes in Acquisition Cost, Accumulated Amortization and Accumulated Impairment Losses and the Carrying Amount by Category

A. Acquisition Cost	Millions of yen							
	Goodwill	Intangible assets associated with products	Software	Other	Total			
Balance as of April 1, 2014	¥7,172	¥24,172	¥8,107	¥ 844	¥ 40,295			
Additions	—	62,639	226	891	63,756			
Transfers	_	_	548	(548)	_			
Disposals	—	(601)	(427)	—	(1,028)			
Foreign currency translation differences	(594)	(668)	(7)	65	(1,204)			
Balance as of March 31, 2015	6,578	85,542	8,447	1,252	101,819			
Additions	-	5,401	344	993	6,738			
Transfers	-	-	1,018	(1,018)	_			
Disposals	-	-	(55)	(3)	(58)			
Foreign currency translation differences	(137)	(161)	(28)	(45)	(371)			
Balance as of March 31, 2016	¥6,440	¥90,782	¥9,726	¥ 1,181	¥108,128			

	Thousands of U.S. dollars				
	Goodwill	Intangible assets associated with products	Software	Other	Total
Balance as of March 31, 2015	\$58,374	\$759,157	\$74,964	\$11,121	\$903,615
Additions	-	47,928	3,053	8,815	59,795
Transfers	-	-	9,034	(9,034)	-
Disposals	-	-	(486)	(27)	(513)
Foreign currency translation differences	(1,219)	(1,427)	(249)	(396)	(3,291)
Balance as of March 31, 2016	\$57,155	\$805,658	\$86,315	\$10,478	\$959,606

## B. Accumulated Amortization and Accumulated Impairment Losses

			Millions of yen		
	Goodwill	Intangible assets associated with products	Software	Other	Total
Balance as of April 1, 2014	¥—	¥ (6,664)	¥(6,280)	¥(741)	¥(13,685)
Amortization	_	(3,979)	(551)	(8)	(4,538)
Impairment losses	_	_	(87)	_	(87)
Disposals	_	601	378	_	979
Foreign currency translation differences	_	_	13	(68)	(55)
Balance as of March 31, 2015	¥—	¥(10,042)	¥(6,527)	¥(817)	¥(17,386)
Amortization	-	(6,205)	(740)	(5)	(6,951)
Impairment losses	_	(234)	(31)	(2)	(268)
Disposals	-	-	55	3	58
Foreign currency translation differences	-	30	32	37	99
Balance as of March 31, 2016	¥—	¥(16,452)	¥(7,212)	¥(784)	¥(24,447)

	Thousands of U.S. dollars				
	Goodwill	Intangible assets associated with products	Software	Other	Total
Balance as of March 31, 2015	\$—	\$ (89,118)	\$(57,924)	\$(7,256)	\$(154,298)
Amortization	_	(55,071)	(6,566)	(48)	(61,685)
Impairment losses	-	(2,081)	(279)	(15)	(2,375)
Disposals	-	-	488	27	515
Foreign currency translation differences	_	268	281	331	880
Balance as of March 31, 2016	\$—	\$(146,002)	\$(64,000)	\$(6,961)	\$(216,963)

#### C. Carrying Amount

			Millions of yen		
	Goodwill	Intangible assets associated with products	Software	Other	Total
As of April 1, 2014	¥7,172	¥17,508	¥1,827	¥103	¥26,610
As of March 31, 2015	6,578	75,500	1,920	435	84,433
As of March 31, 2016	¥6,440	¥74,330	¥2,514	¥396	¥83,681

	Thousands of U.S. dollars				
	Goodwill	Intangible assets associated with products	Software	Other	Total
As of March 31, 2016	\$57,155	\$659,655	\$22,315	\$3,517	\$742,643

#### 2) Impairment Losses

In the fiscal year ended March 31, 2016, the Santen Group recorded impairment losses of ¥268 million (\$2,375 thousand) for that period, along with ¥87 million for the period ended March 31, 2015. Impairment losses are recognized in other expense in the statements of income and comprehensive income.

The intangible assets for which impairment losses were recognized for the year ended March 31, 2015 were "Software" in the "Other" segment. The carrying amounts of these intangible assets were written down to the recoverable amounts due to the decline in expected profitability. Those recoverable amounts were measured at the value in use.

The intangible assets for which impairment losses were recognized for the year ended March 31, 2016 were mainly "Intangible assets associated with products" in the Pharmaceuticals segment. The carrying amounts of these intangible assets were written down to the recoverable amounts due to the decline in expected profitability. Those recoverable amounts were measured at the value in use.

#### 3) Impairment Test for Goodwill

In the fiscal year ended March 31, 2016, the Santen Group recorded goodwill of  $\pm$ 6,440 million (57,155 thousand) for that period, along with  $\pm$ 6,578 million for the period ended March 31, 2015.

This goodwill was recognized as a result of the acquisition of Santen S.A.S. This goodwill is allocated to the Pharmaceuticals segment and impairment testing is performed annually.

The recoverable amount in the impairment test for goodwill was measured using the market value of the share price of the Company.

In the fiscal year ended March 31, 2016, the Santen Group did not recognize an impairment loss on goodwill, because the recoverable amount exceeded the carrying amount.

#### 4) Other Disclosures

i. Amortization of intangible assets associated with products is recorded as amortization of intangible assets associated with products in the consolidated statement of profit or loss and other comprehensive income. Amortization associated with other intangible assets is included in cost of sales, selling, general and administrative expenses and research and development expenses in the consolidated statement of profit or loss and other comprehensive income.

 ii. The Santen Group did not recognize any internally generated intangible assets as of March 31, 2016 and as of March 31, 2015.

#### iii. Significant Intangible Assets

The significant product marketing and distribution rights recognized in the consolidated statement of financial position were mainly composed of the patents, trademarks, domain names, health registrations and others related to Merck's ophthalmology products. The carrying amount of these intangible assets was ¥54,158 million (\$480,639 thousand) as of March 31, 2016 and ¥58,257 million as of March 31, 2015.

The Santen Group recorded rights associated with Cyclokat (ciclosporin) that were recognized in conjunction with the acquisition of Santen S.A.S., and the rights associated with DE-109 (sirolimus) that were acquired by contract from MacuSight, Inc. as intangible assets associated with products. The carrying amount of these intangible assets was ¥6,932 million (\$61,515 thousand) and ¥6,420 million (\$56,984 thousand), respectively, as of March 31, 2016 and ¥7,688 million and ¥6,420 million, respectively, as of March 31, 2015.

The remaining amortization period of product marketing and distribution rights associated with Merck's ophthalmology products is mainly 9 to 15 years. Additionally, from the fiscal year ended March 31, 2016, the Santen Group has begun amortizing intangible asset associated with products for the rights of Cyclokat and its remaining amortization period is 10 years. DE-109 is not yet being amortized because this intangible asset is not yet available for use.

#### iv. Commitments

	Millions	Millions of yen	
	2015	2016	2016
Research and development milestone	¥22,765	¥33,009	\$292,947
Sales target milestone	38,262	39,310	348,867
Total	¥61,027	¥72,319	\$641,814

The amounts shown in the table above represent the maximum payments to be made when all milestones are achieved, and they are undiscounted and not risk adjusted. Since the achievement of the conditions for payment is

highly uncertain, it is unlikely that they will all fall due and the amounts of the actual payments may vary considerably from those stated in the table.

## 18. Financial Assets (Non-current) and Other Financial Assets (Current)

#### 1) Components

#### A. Non-current Assets

	Millions	Thousands of U.S. dollars	
	2015	2016	2016
Financial assets measured at amortized cost			
Other	¥ 928	¥ 962	\$ 8,535
Financial assets measured at fair value through other comprehensive income			
Stock	33,634	43,413	385,277
Financial assets measured at fair value through prof	ït or loss		
Golf membership rights, etc.	163	160	1,421
Total	¥34,725	¥44,535	\$395,233

#### **B.** Current Assets

	Millions	Thousands of U.S. dollars	
	2015	2016	2016
Financial assets measured at amortized cost			
Other	¥187	¥234	\$2,079
Total	¥187	¥234	\$2,079

#### 2) Financial Assets Measured at Fair Value through Other Comprehensive Income

Equities are held mainly for the purpose of strengthening business relationships with investees, and not for the purpose of obtaining gains through short-term trading. Accordingly, they are designated as financial assets measured at fair value through other comprehensive income.

#### A. Fair Value

The main components of financial assets measured at fair value through other comprehensive income and those fair value are as follows:

	Millions	Thousands of U.S. dollars	
	2015	2016	2016
ONO PHARMACEUTICAL CO., LTD.	¥14,085	¥24,711	\$219,305
Eisai Co., Ltd.	8,104	6,428	57,048
Daiichi Sankyo Company, Ltd.	4,005	5,255	46,640

#### B. Other

Dividend income related to financial assets measured at fair value through other comprehensive income held by the Company was ¥534 million (\$4,739 thousand) as of March 31, 2016 and ¥548 million as of March 31, 2015.

Financial assets measured at fair value through other comprehensive income that were disposed of during the fiscal years were as follows:

	Millions	Thousands of U.S. dollars	
	2015	2016	2016
Fair value at date of sale	¥40	¥2,682	\$23,804
Cumulative gains (losses)	37	990	8,782
Dividend income	-	39	343

Note: These financial assets were sold for the purpose of liquidating certain assets held. Cumulative gains (net of tax) of ¥664 million (\$5,889 thousand) in the fiscal year ended March 31, 2016 and ¥37 million in the fiscal year ended March 31, 2015 were reclassified from other components of equity to retained earnings.

# 19. Inventories

	Millions	Thousands of U.S. dollars	
	2015	2016	2016
Merchandise and finished goods	¥16,036	¥20,036	\$177,812
Work in process	585	516	4,583
Raw materials and supplies	3,512	4,443	39,433
Total	¥20,133	¥24,996	\$221,828

# 20. Trade and Other Receivables

	Millions	Thousands of U.S. dollars	
	2015	2016	2016
Notes and accounts receivables	¥59,611	¥63,954	\$567,570
Other	2,094	2,048	18,174
Allowance for doubtful receivables	(4)	(4)	(36)
Total	¥61,701	¥65,998	\$585,708

# 21. Cash and Cash Equivalents

	Millions	Thousands of U.S. dollars	
	2015	2016	2016
Cash on hand and balances with banks	¥65,945	¥99,817	\$885,847
Time deposits over three months	(22)	(20)	(175)
Total cash and cash equivalents in consolidated statement of financial position	65,923	99,798	885,672
Cash and cash equivalents in consolidated statement of cash flows	¥65,923	¥99,798	\$885,672

# 22. Equity and Other Equity Items

#### 1) Share Capital and Treasury Shares

	Stocks		
	2015	2016	
Type of shares*	Ordinary shares	Ordinary shares	
Number of authorized shares*5	220,000,000	1,100,000,000	
Number of issued shares*2			
Beginning of year	82,582,903	82,653,103	
Change during year*3*5	70,200	331,538,412	
End of year	82,653,103	414,191,515	
Treasury shares			
Beginning of year	2,324	3,845	
Change during year*4*5	1,521	18,524	
End of year	3,845	22,369	

Notes: 1. The ordinary shares have no par value.

- 2. The issued shares are fully paid.
- 3. The changes in the number of issued shares during the fiscal years were attributable to share split and the issuance of new shares upon the exercise of subscription rights to shares.
- 4. The changes in the number of treasury shares during the fiscal years were due to share split and fulfillment of requests to additionally purchase such shares.
- 5. The Company conducted a five-for-one share split of ordinary shares on the effective date of April 1, 2015. As a result, the number of authorized shares rose by 880,000,000 to 1,100,000,000, the number of issued shares rose by 330,612,412 to 413,265,515, and the number of treasury shares rose by 15,380 to 19,225.

#### 2) Capital Surplus

Capital surplus consists of additional paid-in capital not included in share capital upon the ordinary issuance of new shares and the issuance of new shares due to the exercise of subscription rights to shares, as well as other capital surplus.

#### 3) Other Components of Equity

#### A. Remeasurements of Defined Benefit Plans

These are changes caused by remeasurements of defined benefit plans.

#### B. Net Gain or Loss on Financial Assets Measured at Fair Value through Other Comprehensive Income

This includes the cumulative amount of net changes in the fair value of financial assets measured at fair value through other comprehensive income until the recognition of the asset is cancelled or an impairment loss on the asset is booked.

#### C. Foreign Currency Translation Adjustments

These are exchange differences arising from the translation of the financial statements of foreign operations.

#### **D. Subscription Rights to Shares**

The Company has adopted a stock option plan based on subscription rights to shares. In accordance with rules set forth primarily by Article 361 and Article 238 of the Japanese Companies Act, the Company grants subscription rights to shares. The amount of subscription rights to shares recorded in other components of equity is based on the fair value thereof. In addition, the contractual conditions and other details of the subscription rights to shares are stated in "23. Share-based Payments."

#### 4) Retained Earnings and Dividends

#### A. Retained Earnings

These are earnings recognized as profit or loss in or before the fiscal year ended March 31, 2016, and earnings reclassified from other comprehensive income.

#### **B.** Dividends

#### i. Dividends paid

Year ended March 31, 2015 Resolution date	Total dividends (Millions of yen)		Dividends per share (Yen)		Record date	Effective date
Annual General Meeting of Shareholders						
(June 25, 2014)	¥4,129		¥50.00		Mar. 31, 14	Jun. 26, 14
Board of Directors Meeting						
(November 5, 2014)	4,130		50.00		Sep. 30, 14	Nov. 28, 14
Year ended March 31, 2016 Resolution date	Total dividends (Millions of yen)	Total dividends (Thousands of U.S. dollars)	Dividends per share (Yen)	Dividends per share (U.S. dollars)	Record date	Effective date
Annual General Meeting of Shareholders						
(June 24, 2015)	¥4,959	\$44,009	¥60.00	\$0.53	Mar. 31, 15	Jun. 25, 15
Board of Directors Meeting						
(November 4, 2015)	4,966	44,070	12.00	\$0.11	Sep. 30, 15	Nov. 30, 15

Note: The Company completed a five-for-one share split with an effective date of April 1, 2015. "Dividends per share" whose record date is on or before March 31, 2015 shows the amount of dividends paid before the share split.

#### ii. Dividends whose effective date is in the following fiscal year

Year ended March 31, 2015 Resolution date	Total dividends (Millions of yen)		Dividends per share (Yen)		Record date	Effective date
Annual General Meeting of Shareholders						
(June 24, 2015)	¥4,959		¥60.00		Mar. 31, 15	Jun. 25, 15
Year ended March 31, 2016		Total dividends	Dividends	Dividends		
Resolution date	Total dividends (Millions of yen)	(Thousands of U.S. dollars)	per share (Yen)	per share (U.S. dollars)	Record date	Effective date
Annual General Meeting of Shareholders						
(June 24, 2016)	¥5,384	\$47,783	¥13.00	\$0.12	Mar. 31, 16	Jun. 27, 16

Note: The Company completed a five-for-one share split with an effective date of April 1, 2015. "Dividends per share" whose record date is on March 31, 2015 shows the amount of dividends paid before the share split.

# 23. Share-based Payments

1) Contractual Conditions for Share Options <u>A. Eligible Persons</u> Directors and Corporate Officers of the Company

# D. Settlement Method

Settled in shares

For 10 years from grant date

C. Exercise Period for Share Options Granted

**B. Vesting Conditions** No provisions

#### 2) Number and Weighted-average Exercise Price of Share Options

	20	015	2016		
	Number of shares	Weighted-average exercise price	Number of shares		ed-average cise price
	(stocks)	(Yen)	(stocks)	(Yen)	(U.S. dollars)
Balance at the beginning of the year	664,500	¥2,905	3,144,000	¥549	\$4.87
Granted	34,500	1	141,800	1	0.01
Exercised*1	70,200	2,931	926,000	581	5.16
Expired	_	—	48,000	496	4.40
Balance at the end of the year	628,800	2,742	2,311,800	503	4.46
Balance of exercisable stock options, end of year	563,700	3,059	1,844,500	630	5.59

Notes: 1. The weighted-average share price of stock options at the time of exercise was ¥1,748 (\$15.51) in the fiscal year ended March 31, 2016 and ¥6,663 in the fiscal year ended March 31, 2015.

2. The Company has conducted a five-for-one share split with an effective date of April 1, 2015. However, the impact of this share split is not reflected in the information for the previous fiscal year.

#### 3) Range and Weighted-average Remaining Contractual Life of Share Options at the Fiscal Year-End

The exercise price of share options ranged from ¥1 (\$0.01) to ¥663 (\$5.88) as of March 31, 2016 and ¥1 to ¥3,315 as of March 31, 2015. The weighted-average remaining life was 5.4 years as of March 31, 2016 and 5.3 years as of March 31, 2015. Furthermore, the Company has conducted a five-for-one share split with an effective date of April 1, 2015. However, the impact of this share split is not reflected in the information for the previous fiscal year.

#### 4) Fair Value and Fair Value Measurement Method of Share Options Granted During the Year

#### A. Measurement Method

Black-Scholes model

#### B. Fair Value and Primary Base Assumptions and Measurement Method

		2016	
Resolution date		August 4, 2015	
Expected volatility*1 (%)		28.6	24.2
Option life (years)		6.5	
Expected dividend yield (%)		1.16	
Risk-free interest rate (%)		0.120	
	Ye	U.S. dollars	
	2015	2016	2016
Fair value	¥5,382.98	¥1,756.27	\$15.59
Weighted-average share price	6,000	1,895	16.82
Exercise price	1	1	0.01

Note 1: The expected volatility is estimated by calculating the volatility of the share price at the end of each month relative to the end of the previous month, and determining the annualized standard deviation of the volatility for the past 6.5 years.

#### 5) Expenses Recognized in Consolidated Statement of Income

Expense related to share-based payments was ¥249 million (\$2,210 thousand) in the fiscal year ended March 31, 2016, and ¥186 million in the fiscal year ended March 31, 2015.

# 24. Financial Liabilities (Non-current) and Other Financial Liabilities (Current)

#### 1) Components

#### A. Components of Non-current Liabilities

	Millions	Thousands of U.S. dollars	
	2015 2016		2016
Long-term loans payable			
(excluding the current portion of long-term loans payable)	¥25,304	¥12,914	\$114,608
Finance lease obligations	47	30	267
Total	¥25,351	¥12,944	\$114,875

## **B.** Components of Current Liabilities

	Millions	Thousands of U.S. dollars	
	2015	2016	2016
Current portion of long-term loans payable	¥11,767	¥ 9,524	\$ 84,525
Finance lease obligations	43	16	138
Other payables	6,525	8,511	75,532
Other	963	1,830	16,242
Total	¥19,298	¥19,881	\$176,437

# 25. Post-employment Benefits

0) Defined Depetit Diene

1) Outline of Post-employment Benefit Plans In order to provide for post-employment benefits for employees, the Company and its 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 and pension will be provided according to wage and service length. However, the Company and some of its consolidated

subsidiaries have introduced cash balance plans to defined benefit corporate pension plans.

A retirement benefit trust has been set up for some defined benefit corporate pension plans. With post-employment lump-sum payment plans (unfunded, but some are funded as a result of setting up a retirement benefit trust), a lump-sum payment is provided as a post-employment benefit according to wage and service length.

	ofined benefit	Fair value of	
	obligationio	plan assets	Net defined benefit liabilities
Balance as of April 1, 2014	¥17,217	¥(11,816)	¥ 5,401
Current service cost	1,010	_	1,010
Interest (income) expense	210	(145)	65
Remeasurement of the net defined benefit liabilities			
Return on plan assets excluding amounts included in interest income			
on plan assets	_	(1,157)	(1,157)
Actuarial gains and losses arising from changes in demographic assumption	ons 227	—	227
Actuarial gains and losses arising from changes in financial assumptions	686	—	686
Experience adjustments	(236)	_	(236)
Total remeasurement of the net defined benefit liabilities	677	(1,157)	(480)
Foreign currency translation differences	(11)	6	(5)
Employer contributions to plan	_	(422)	(422)
Benefits paid by plan	(529)	270	(259)
Other	165	(16)	149
Balance as of March 31, 2015	¥18,739	¥(13,280)	¥ 5,459
Current service cost	1,143	_	1,143
Interest (income) expense	163	(120)	43
Remeasurement of the net defined benefit liabilities			
Return on plan assets excluding amounts included in interest income			
on plan assets	—	282	282
Actuarial gains and losses arising from changes in demographic assumption	ons (61)	_	(61)
Actuarial gains and losses arising from changes in financial assumptions	1,272	—	1,272
Experience adjustments	(66)	_	(66)
Total remeasurement of the net defined benefit liabilities	1,145	282	1,428
Foreign currency translation differences	(34)	16	(18)
Employer contributions to plan	_	(4,795)	(4,795)
Benefits paid by plan	(1,104)	401	(703)
Other	341	(341)	-
Balance as of March 31, 2016	¥20,394	¥(17,837)	¥ 2,556

	Thousands of U.S. dollars			
	Defined benefit obligations	Fair value of plan assets	Net defined benefit liabilities	
Balance as of March 31, 2015	\$166,302	\$(117,852)	\$ 48,450	
Current service costs	10,140	—	10,140	
Interest (income) cost	1,443	(1,061)	381	
Remeasurement of the net defined benefit liabilities				
Return on plan assets excluding amounts included in interest income				
on plan assets	—	2,504	2,504	
Actuarial gains and losses arising from changes in demographic assur	mptions (539)	_	(539)	
Actuarial gains and losses arising from changes in financial assumption	ns 11,290	_	11,290	
Experience adjustments	(586)	—	(586)	
Total remeasurement of the net defined benefit liabilities	10,165	2,504	12,669	
Foreign currency translation differences	(300)	144	(156)	
Employer contributions to plan	_	(42,557)	(42,557)	
Benefits paid by plan	(9,799)	3,559	(6,240)	
Other	3,031	(3,031)	-	
Balance as of March 31, 2016	\$180,989	\$(158,302)	\$ 22,687	

#### B. Components of Plan Assets

	Presence of	Millions	of yen	Thousands of U.S. dollars
	quoted market prices in active markets	2015	2016	2016
Equities	Yes	¥ 6,696	¥ 3,450	\$ 30,621
Bonds	Yes	3,741	9,853	87,440
General account of life insurance companies	No	1,540	1,681	14,914
Other	No	1,303	2,854	25,327
Total		¥13,280	¥17,837	\$158,302

Plan assets are invested with the aim of securing the required overall returns over the long term with an acceptable risk exposure, in order to ensure the payment of pensions and other benefits in the future. To achieve this goal, the Santen Group selects assets that are suitable for investment along with determining the optimal combination of assets for the future based on consideration of the expected rate of return, risk and other factors. In addition, the composition of assets is revised as necessary.

#### C. Actuarial Assumptions

	2015	2016
Discount rate (%)	0.93	0.41

## D. Sensitivity Analysis

A 0.5% change in significant actuarial assumption would affect the present value of defined benefit obligations by the amounts shown below: Thousands of

SHOWH DEIGW.		Millions	s of yen		U.S. dollars			
	2015 2016				16 2016			
Discount rate (%)	0.5% Increase	0.5% Decrease	0.5% Increase	0.5% Decrease	0.5% Increase	0.5% Decrease		
	¥(1,159)	¥1,279	¥(1,226)	¥1,352	\$(10,877)	\$12,001		

Note: In this analysis, the other variables are assumed to be fixed.

#### E. Impact of the Defined Benefit Plan on Future Cash Flows

The estimated contribution amount for the fiscal year ending March 31, 2017 is ¥451 million (\$4,005 thousand). The weighted-average duration of the defined benefit obligation for the fiscal year ended March 31, 2016 is 13.9 years (for the fiscal year ended March 31, 2015, 14.4 years).

# 26. Provisions

#### 1) Statements of Changes in Provisions

·,	Millions of yen						
	Asset retirement obligations	Provision for restructuring	Provision for paid absence	Other	Total	Breakdown on consolidated statement of financial position	
	(Note A)	(Note B)	(Note C)			Non-current	Current
Balance as of April 1, 2015	¥224	¥766	¥1,198	¥453	¥2,641	¥1,444	¥1,197
Additional provision made in the period	11	—	774	793	1,578	—	—
Amounts used during the period	10	—	781	267	1,058	—	—
Unused amounts reversed during the period	—	—	—	186	186	—	—
The increase during the period in the discounted							
amount arising from the passage of time	3	—	3	—	6	—	—
Foreign currency translation differences	—	(15)	(33)	(28)	(76)	—	—
Balance as of March 31, 2016	¥228	¥751	¥1,160	¥765	¥2,905	¥1,629	¥1,276

			Thousands of	U.S. dollar	S		
	Asset retirement obligations	Provision for restructuring	Provision for paid absence	Other	Total	Breakdown or statement of fir	nancial position
	(Note A)	(Note B)	(Note C)			Non-current	Current
Balance as of April 1, 2015	\$1,988	\$6,800	\$10,628	\$4,023	\$23,438	\$12,814	\$10,624
Additional provision made in the period	100	—	6,865	7,036	14,002	—	—
Amounts used during the period	87	—	6,934	2,369	9,390	—	—
Unused amounts reversed during the period	—	—	—	1,654	1,654	—	—
The increase during the period in the discounted							
amount arising from the passage of time	25	—	27	_	52	—	—
Foreign currency translation differences	—	(135)	(291)	(246)	(671)	—	—
Balance as of March 31, 2016	\$2,026	\$6,665	\$10,295	\$6,791	\$25,777	\$14,457	\$11,320

#### Note A

Asset retirement obligations are recorded to provide for the removal of hazardous substances from plant equipment and other facilities and the fulfillment of obligations to restore leased buildings and other facilities to their original state. To this end, the amount expected to be payable in the future is discounted according to the expected period of use based on estimates and other information obtained from construction contractors.

The Santen Group predicts that the timing of the outflow of economic benefits will primarily be after over one year has passed from each fiscal year-end.

#### Note B

The provision for restructuring provides for expenditures to be incurred in the course of implementing business

restructuring measures. It is provided for in the estimated amount of the related expenses. Furthermore, the Santen Group predicts that the timing of the outflow of economic benefits will primarily be after over one year has passed from each fiscal year-end.

#### Note C

The provision for paid absence recognizes a liability for the unused portion of paid absence granted to employees based on the paid absence system. The Santen Group predicts that the timing of the outflow of economic benefits will primarily be after over one year has passed from each fiscal year-end.

# 27. Trade and Other Payables

	Millions	Thousands of U.S. dollars	
	2015	2016	2016
Trade accounts payable	¥14,330	¥17,225	\$152,869
Other payables	5,920	7,279	64,595
Total	¥20,250	¥24,504	\$217,465

## 28. Financial Instruments

#### 1) Capital Management

The Santen Group considers the equity attributable to owners of the company ratio and profit ratio to equity attributable to owners of the company to be important management indicators. The Group monitors these indicators closely, and conducts purchases of treasury stock on the market and new share issuances as necessary. In doing so, the Group aims to maintain the trust of investors, creditors and the markets and sustain a strong capital base to support continued development of its business into the future.

#### 2) Outline of Financial Risk Management

The risks arising from financial instruments held by the Santen Group are as follows:

#### A. Credit Risk

#### 1) Outline

Credit risk is the risk of financial loss borne by the Santen Group if a customer or a counterparty to a financial instrument is unable to meet its contractual obligations. The main sources of credit risk are customer receivables and investments.

#### i. Trade and other receivables

The Santen Group performs due date and credit limit controls in accordance with its credit management rules

and periodically assesses the financial reliability of each customer taking into account the customer's financial position and other factors.

The percentage of the Santen Group's business conducted with the top 10 wholesalers in Japan reached 65.0% of consolidated revenue in the fiscal year ended March 31, 2016, compared with 68.3% in the fiscal year ended March 31, 2015. If the Santen Group's wholesale partners experience bankruptcy leading to credit losses, its business performance might be adversely affected.

#### ii. Financial assets (investments)

The Santen Group purchases bonds issued only by issuers that have high credit ratings.

#### 2) Credit exposure

The maximum amount of exposure to credit risks for financial assets is the carrying amount after considering impairment in the consolidated statement of financial position.

#### 3) Aging analysis

The analysis of the aging of trade and other receivables that were not impaired as of the end of the reporting period is as follows:

	Millions	s of yen	Thousands of U.S. dollars
	2015	2016	2016
Not past due	¥61,705	¥64,764	\$574,764
Past due			
30 days or less	_	604	5,358
Over 30 days but within 90 days	_	404	3,589
Over 90 days	—	229	2,034
Total past due	_	1,237	10,981
Allowance for doubtful receivables	(4)	(4)	(36)
Total trade and other receivables	¥61,701	¥65,998	\$585,708

#### **B. Liquidity Risk**

#### 1) Outline

Liquidity risk is the risk that the Santen Group will encounter difficulty in fulfilling obligations related to the financial liabilities it must settle using cash or other financial assets. The main sources of liquidity risk are trade payables and loans payable. The Santen Group manages liquidity risk primarily by monitoring monthly cash flows.

# 2) Maturity analysis

The contractual maturities of financial liabilities are as follows.

		Millions of yen						
Year ended March 31, 2015 (as of March 31, 2015)	Carrying amount	Contractual cash flows	Within 1 year	Between 1 year and 2 years	Between 2 years and 3 years	Between 3 years and 4 years	Between 4 years and 5 years	Over 5 years
Trade and other payables	¥20,250	¥20,250	¥20,250	¥ —	¥ —	¥ —	¥—	¥—
Other financial liabilities								
Loans payable	37,071	37,243	11,867	11,698	9,575	4,103	_	—
Other payables	6,525	6,525	6,525	_	_	_	_	_
Other	1,053	1,053	1,007	16	14	10	3	3
Total	¥64,899	¥65,071	¥39,649	¥11,714	¥9,589	¥4,113	¥З	¥З

		Millions of yen						
Year ended March 31, 2016 (as of March 31, 2016)	Carrying amount	Contractual cash flows	Within 1 year	Between 1 year and 2 years	Between 2 years and 3 years	Between 3 years and 4 years	Between 4 years and 5 years	Over 5 years
Trade and other payables	¥24,504	¥24,504	¥24,504	¥ —	¥ —	¥ —	¥—	¥—
Other financial liabilities								
Loans payable	22,438	22,519	9,574	8,340	4,104	501	—	—
Other payables	8,511	8,511	8,511	—	—	—	—	—
Other	1,876	1,876	1,846	15	10	3	3	—
Total	¥57,329	¥57,411	¥44,435	¥8,355	¥4,114	¥504	¥З	¥—

		Thousands of U.S. dollars						
	Carrying amount	Contractual cash flows	Within 1 year	Between 1 year and 2 years	Between 2 years and 3 years	Between 3 years and 4 years	Between 4 years and 5 years	Over 5 years
Trade and other payables	\$217,465	\$217,465	\$217,465	\$ —	\$ -	\$ —	\$ —	\$—
Other financial liabilities								
Loans payable	199,133	199,847	84,963	74,017	36,421	4,446	_	_
Other payables	75,532	75,532	75,532	_	_	_	_	_
Other	16,647	16,647	16,380	134	87	24	22	_
Total	\$508,776	\$509,490	\$394,339	\$74,150	\$36,508	\$4,471	\$22	\$—

The Company has entered into a short-term loan agreement with The Bank of Tokyo-Mitsubishi UFJ, Ltd. Details as of the end of each fiscal year are as follows:

	Millions	Thousands of U.S. dollars	
	2015	2016	
Total amount of loan agreement	¥45,000	-	-
Execution amount	35,000	-	-
Difference	¥10,000	-	-

The execution amount of ¥35,000 million based on the above short-term loan agreement was refinanced as long-term loans payable in October 2014. The total amount of long-term loans payable was ¥40,000 million and is based on long-term loan agreements with The Bank of Tokyo-Mitsubishi UFJ, Ltd. and Development Bank of Japan Inc.

# C. Market Risk

# 1) Outline

The risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk comprises foreign currency risk, interest rate risk and other price risks.

The Santen Group responds to currency risk by adjusting the balance of outstanding foreign currency denominated financial assets and liabilities in the same currency.

With no floating interest rate financial instruments in its portfolio, the Santen Group has judged that it has no exposure to significant interest rate risk. Other price risks primarily have an impact on stocks of companies with which the Company has business relationships. The Company periodically reviews the fair market values of these stocks and reports on them at the Company's Board of Directors meeting.

#### 2) Foreign currency risk

#### i. Foreign currency risk exposure

The following is a summary of the quantitative currency risk exposure data provided to the Santen Group's management based on its risk management policy:

	Thousands of U.S. dollars				
	2015	2016			
Trade and other receivables	\$ 8,560	\$ 9,872			
Trade and other payables	(4,553) (2,4				
Net exposure amount	\$ 4,007	\$ 7,469			

#### ii. Sensitivity analysis of foreign currency risk

The tables below show the increase (decrease) in profit or loss for the year that would result from the yen's depreciation against the euro or U.S. dollar at the rates indicated below at fiscal year-end.

This analysis is based on foreign exchange rate variables that the Santen Group believes to be

reasonably possible as of the fiscal year-end. The analysis assumes that all other variables (particularly interest rates) are held constant. It was conducted on the same basis as the analysis for the year ended March 31, 2015. The yen's appreciation at the same rate would have the opposite effect, in the same amount, on profit (loss) for the year.

	Millions	Thousands of U.S. dollars	
	2015	2016	
	Profit (loss)	Profit (loss)	Profit (loss)
U.S. dollar (5% appreciation)	¥24	\$373	

#### 3) Fair Value of Financial Instruments

## A. Fair Value and Carrying Amount

The carrying amount and fair value of financial instruments are shown below. Financial instruments measured at fair value, and financial instruments whose carrying amounts and fair values are reasonable approximation, are not included in the following table.

		Millions		Thousands of U.S. dollars		
	20	15	2016		20	16
	Carrying amount	Fair value	Carrying amount	Fair value	Carrying amount	Fair value
Loans payable	¥37,071	¥36,992	¥22,438	¥22,452	\$199,133	\$199,253

#### <u>B. Approaches and Valuation Techniques Applied to</u> <u>Measure Fair Value</u>

The valuation techniques for measuring the fair value of financial instruments are as follows:

#### i. Loans payable

Loans payable with floating interest rates have fair values that approximate their carrying amounts because market interest rates are reflected in a short period. The fair value of loans payable with fixed interest rates are measured by the total sum of the principal and interest discounted by the interest rates that would apply if similar borrowings were conducted anew.

#### C. Fair Value Hierarchy

The following table is an analysis of financial instruments carried at fair value by valuation method.

The levels of the fair value hierarchy are defined as follows: Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities

Level 2: Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either

directly (i.e., as a price) or indirectly (i.e., derived from price)

Level 3: Inputs for the asset or liability that are not based on observable market data (unobservable inputs)

						Millions	of yen	
Year ended March 31, 2015				L	evel 1	Level 2	Level 3	Total
Financial assets measured at fair value t	hrough othe	er compreh	ensive incor	ne				
Stock				¥3	32,664	¥—	¥970	¥33,634
Financial assets measured at fair value t	hrough pro	fit or loss						
Golf membership rights, etc.					—	21	142	163
		Millions	s of yen			Thousand	ls of U.S. dolla	ars
Year ended March 31, 2016	Level 1	Level 2	Level 3	Total	Level	1 Level 2	2 Level 3	Total

Year ended March 31, 2016	Lever	Level 2	Level 3	TOLAI	Level I	Level 2	Level 3	TOLA
Financial assets measured at fair value through other comprehensive income								
Stock	¥41,206	¥ —	¥2,207	¥43,413	\$365,690	\$ -	\$19,587	\$385,277
Financial assets measured at fair value through profit or loss								
Golf membership rights, etc.	-	20	141	160	-	174	1,247	1,421

The presence of any financial instruments subject to significant transfers between the fair value hierarchy levels is determined at the end of every fiscal year.

There were no financial instruments subject to significant transfers between the fair value hierarchy levels in the years ended March 31, 2015 and 2016.

The change in carrying values associated with Level 3 financial instruments using significant unobservable inputs.

	Millions of yen		Thousands of U.S. dollars	
	2015	2016	2016	
Balance, beginning of year	¥1,236	¥1,112	\$ 9,864	
Purchases	105	1,205	10,698	
Other comprehensive income	(225)	32	288	
Sales	(2)	(1)	(11)	
Other	(2)	(1)	(4)	
Balance, end of year	¥1,112	¥2,348	\$20,835	

Securities categorized into Level 3 are measured using the market values of comparable companies, valuation models

based on net assets of investees and other valuation approaches.

# 29. Operating Leases

#### 1) The Total of Future Minimum Lease Payments under Non-cancellable Operating Leases

	Millions of yen		Thousands of U.S. dollars	
	2015	2016	2016	
Not later than 1 year	¥2,047	¥1,907	\$16,925	
Later than 1 year and not later than 5 years	2,108	1,299	11,531	
Later than 5 years	_	10	92	
Total	¥4,155	¥3,217	\$28,548	

#### 2) Lease Payments Recognized as Expenses

	Millions of yen		Thousands of U.S. dollars
	2015	2016	2016
Lease payments	¥2,128	¥2,329	\$20,673

# 30. Subsidiaries

#### 1) Structure of the Santen Group

All subsidiaries (23 companies) are consolidated. The names of the major consolidated subsidiaries are shown in "Business Bases."

#### 31. Related Parties

#### 1) Related Party Transactions

Year ended March 31, 2015 (April 1, 2014 to March 31, 2015) There were no significant transactions.

Year ended March 31, 2016 (April 1, 2015 to March 31, 2016) There were no transactions to report.

#### 2) Compensation for Key Management Personnel

The key management personnel of the Company refers to all of its directors, including outside directors.

	Millions of yen		Thousands of U.S. dollars	
	2015	2016	2016	
Compensation	¥187	¥193	\$1,713	
Share-based payment	55	53	472	
Total	¥242	¥246	\$2,185	

# 32. Contingencies

#### 1) Contingent Liabilities

#### A. Guarantees

The Company has provided guarantees to financial institutions covering employee loans.

These are not recognized as liabilities in the consolidated statement of financial position because the possibility of loss from contingent liabilities was remote.

	Millions of yen		Thousands of U.S. dollars	
	2015	2016	2016	
Employees (loan guarantees)	¥76	¥43	\$382	

# 33. Disposal Group Held for Sale

The Company has resolved at its Board of Directors meeting held on May 12, 2015 to assign its anti-rheumatic pharmaceuticals business to AYUMI Pharmaceutical Corporation (formerly Hyperion Pharma Co., Ltd.) ("AYUMI Pharmaceutical") ("Transaction"). On the same date, the Company entered into an absorption-type company split agreement in connection with the Transaction. On August 3, 2015, the Company completed an absorption-type company split (simplified absorption-type company split) based on the agreement.

#### 1) Outline of the Transaction A. Purpose of the Transaction

# As a result of the Transaction, the Company will focus completely on the ophthalmic pharmaceutical business and become much more specialized to meet patients' needs for advanced medical care, and by doing so, the Company is aiming to become one of the top three ophthalmic pharmaceutical companies in the world by 2020. At the same time, the Company has established a strong presence in the field of the anti-rheumatic pharmaceuticals business by gaining the largest share in the market in Japan for disease-modifying anti-rheumatic drugs (DMARDs). The Company believes that the Transaction, through which its anti-rheumatic pharmaceuticals business is succeeded to by AYUMI Pharmaceutical, which aims to become a pharmaceutical company specializing in orthopedics and rheumatism, will make a further contribution to the improvement of patients' quality of life.

#### B. Overview of the Transaction

1) Counterparty to the Company Split AYUMI Pharmaceutical Corporation

#### 2) Overview of Business to Be Split Off

Business relating to distribution, marketing, research and development of anti-rheumatic pharmaceuticals

#### 3) Date of the Company Split

August 3, 2015

#### 4) Method of the Company Split

The company split was an absorption-type company split (simplified absorption-type company split) in which the Company is the splitting company and AYUMI Pharmaceutical is the succeeding company.

#### 5) Consideration Pertaining to the Company Split

As consideration for the succession of rights and obligations regarding the anti-rheumatic pharmaceuticals business, the Company, which is the splitting company, received ¥45 billion (\$3,994 million) in cash from AYUMI Pharmaceutical, the succeeding company.

2) Outline of Accounting Treatment A. Amount of Gain on Business Transfer ¥44,477 million (\$394,718 thousand)

#### B. Appropriate Carrying Amounts of Assets and Liabilities Related to the Transferred Business and the Main Components

The carrying amounts of the assets and liabilities split off from the Company through the Transaction are immaterial.

#### C. Accounting Treatment

The difference between the consolidated carrying amount of the anti-rheumatic pharmaceuticals business and the amount of cash received by the Company as consideration for the Transaction, after deducting the amount of remuneration paid to external advisors, is recorded as a gain on business transfer under other income.

#### 3) Name of the Reportable Segment in Which the Split-off Business Was Included Pharmaceuticals segment

4) Estimate of Profit or Loss Associated with the Split-off Business That Was Recorded in the Consolidated Statement of Profit or Loss and Other Comprehensive Income for the Fiscal Year Ended March 31, 2016

- Revenue: ¥3,495 million (\$31,017 thousand)
- Operating Profit: ¥1,916 million (\$17,004 thousand)

## 34. Subsequent Events

#### Acquisition of InnFocus, Inc.

July 19, 2016, the Company and InnFocus, Inc. (hereinafter, "InnFocus") entered into a definitive agreement under which the Company will acquire privately held InnFocus, developer of the InnFocus MicroShunt<sup>®</sup> (hereinafter, "MicroShunt") glaucoma implant device.

#### 1) Purpose of the Acquisition

InnFocus is developing the MicroShunt implant to lower and sustain intraocular pressure (IOP) for the treatment of primary open-angle glaucoma (mild to severe stage disease). The MicroShunt has shown significant and sustainable lowering of IOP when used alone or in combination with cataract surgery in clinical trials outside of the U.S. Late stage clinical studies are underway in the U.S. and Europe in advance of PMA (Pre-Market Approval) application to the U.S. Food and Drug Administration (FDA) planned in the near future. The MicroShunt has received CE Mark in Europe.

With this acquisition, the Company will strengthen its glaucoma pipeline and stay at the forefront of innovation in ophthalmology. This agreement is in line with the Company's long-term vision to become a "Specialized Pharmaceutical Company with a Global Presence." The Company is excited about the MicroShunt as a new and effective treatment option that should significantly improve patient outcomes.

#### 2) Overview of the Acquiree

- i. Company Name: InnFocus, Inc.
- ii. Location: Miami, Florida, U.S.A.
- iii. Name of representative: Randy Lindholm, Executive Board Chair
- iv. Main business: Development and provision of next generation products for glaucoma surgery
- v. Paid in capital: \$0.9 thousand (as of December 31, 2015)

#### 3) Purchase Price

The Company will acquire InnFocus for an upfront payment of \$225 million, plus performance based consideration upon achievement of certain development, regulatory and commercial milestones.

#### 4) The Percentage of Voting Equity linterests to Be Acquired

The percentage before acquisition: 9.56% The percentage after acquisition: 100.00%

#### 5) Closing Date

To be determined.

Acquisition procedure will be completed by executing the contract after we obtain permission based on Hart-Scott-Rodino Antitrust Improvements Act of the U.S.

#### 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

#### 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, 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, 2016 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, identified 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 seven 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 revenue was more than 80% of the previous fiscal year's consolidated revenue. The process related to revenue, 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, we concluded the Company's internal control over financial reporting was effective as of March 31, 2016.

#### **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, 2016.

5 Other None.

a. Kinchawa

Akira Kurokawa President & CEO

August 5, 2016

arter:

Kazuo Koshiji CFO



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

We have audited the accompanying consolidated financial statements of Santen Pharmaceutical Co., Ltd. and its consolidated subsidiaries, which comprise the consolidated statement of profit or loss and other comprehensive income, statement of financial position, statement of changes in equity and statement of cash flows for the year ended March 31, 2016, 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 International Financial Reporting Standards, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit 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, 2016, and their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards.

#### Emphasis of Matter

Without qualifying our opinion, we draw attention to Note 34 to the consolidated financial statements, on July 19, 2016, Santen Pharmaceutical Co., Ltd. and InnFocus, Inc. entered into a definitive agreement under which Santen Pharmaceutical Co., Ltd. will acquire privately held InnFocus, Inc., developer of the InnFocus MicroShunt® glaucoma implant device.

#### **Convenience Translation**

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended March 31, 2016 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 2 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, 2016 ("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 materia 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, 2016, 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 5, 2016 Osaka, Japan

# Corporate Information / Stock Information

As of March 31, 2016

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 TEL: +81-6-6321-7000 (Main) +81-6-4802-9360 (PR and IR) E-MAIL: ir@santen.co.jp
Established	1890
Paid-in Capital	¥7,695 million
Number of Employees	3,463 (non-consolidated: 1,891)
Number of Shares Issued	414,191,515
Number of Shareholders	23,533
Stock Exchange Listings	Токуо
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



# Stock Price Range (Yen)

Monthly basis





Yearly High	and Low Pr	ices			
	2012	2013	2014	2015	2016
High (yen)	731	1,010	1,230	2,163	2,064
Low (yen)	555.6	666	813	1,262	1,423

Notes: 1. Calendar years.

- 2. Stock prices for 2016 are for the period to the end of June.
- 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.
- 4. Santen conducted a five-for-one share split of ordinary shares on the effective date of April 1, 2015. Figures for stock price and trading volume from before the share split have been adjusted using the share split ratio.

<ul> <li>Corporate Headquarters</li> <li>Claire Co., Ltd.</li> <li>Santen Business Services Co., Ltd.</li> <li>Santen Eye Care Co., Ltd.</li> <li>Santen Holdings U.S. Inc.</li> <li>Santen Inc.</li> <li>Advanced Vision Science, Inc.</li> <li>Santen Holdings EU B.V.</li> <li>Santen Oy</li> </ul>	Japan Japan Japan Japan U.S.A. U.S.A. U.S.A. U.S.A. S.A. U.S.A.
<ul> <li>Santen Business Services Co., Ltd.</li> <li>Santen Eye Care Co., Ltd.</li> <li>Santen Holdings U.S. Inc.</li> <li>Santen Inc.</li> <li>Advanced Vision Science, Inc.</li> <li>Santen Holdings EU B.V.</li> </ul>	Japan Japan U.S.A. U.S.A. U.S.A. U.S.A. Netherlands
<ul> <li>Santen Eye Care Co., Ltd.</li> <li>Santen Holdings U.S. Inc.</li> <li>Santen Inc.</li> <li>Advanced Vision Science, Inc.</li> <li>Santen Holdings EU B.V.</li> </ul>	Japan U.S.A. U.S.A. U.S.A. U.S.A. Netherlands
<ul> <li>Santen Holdings U.S. Inc.</li> <li>Santen Inc.</li> <li>Advanced Vision Science, Inc.</li> <li>Santen Holdings EU B.V.</li> </ul>	U.S.A. U.S.A. U.S.A. Netherlands
<ul> <li>Santen Inc.</li> <li>Advanced Vision Science, Inc.</li> <li>Santen Holdings EU B.V.</li> </ul>	U.S.A. U.S.A. Netherlands
<ul> <li>Advanced Vision Science, Inc.</li> <li>Santen Holdings EU B.V.</li> </ul>	U.S.A. Netherlands
Santen Holdings EU B.V.	Netherlands
Santen Oy	Finland
Santen S.A.S.	France
Santen GmbH	Germany
SantenPharma AB	Sweden
B Santen Switzerland SA	Switzerland
Ø Santen Italy S.r.I.	Italy
Santen UK Limited	U.K.
6 Santen Pharmaceutical Spain, S.L.	Spain
Santen Pharmaceutical (China) Co., Ltd.	China
Santen Pharmaceutical Sales & Marketing (Suzhou) Co., Ltd.	China
Santen Pharmaceutical Korea Co., Ltd.	Korea
Taiwan Santen Pharmaceutical Co., Ltd.	Taiwan
3 Santen India Private Limited	India
2 Santen Pharmaceutical Asia Pte. Ltd.	Singapore
3 SANTEN (THAILAND) CO., LTD.	Thailand
🥸 SANTEN PHARMA MALAYSIA SDN. BHD.	Malaysia
3 SANTEN PHILIPPINES INC.	Philippines

# Other Office

28 Ho Chi Minh City Representative Office

Vietnam

# Plants and Laboratories



1 Noto Plant (Japan)



2 Shiga Product Supply Center (Japan)







**3** Tampere Plant (Finland)



**4** Suzhou Plant (China)



S Nara Research and Development Center (Japan)

#### 1890

Founder Kenkichi Taguchi opened 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 entered prescription pharmaceutical business

#### 1977

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

1900

1962

Launch of Super Sante

marks first use of

plastic eye drop

containers

in Japan

1963

agent

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 centenary

#### 1993

Subsidiary Santen Inc. established in the U.S.

#### 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

1981

1987

Rimatil

1991

1992

Launch of

Sante FX

early-stage

senile cataracts

I aunch of

anti-rheumatic

# 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

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

#### 2002

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

#### 2003

Fiscal 2003-2005 Medium-Term Management Plan formulated

# 2000

#### 1995

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

Launch of anti-allergy 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

#### 2000

Launch of anti-infective ophthalmic solution Cravit (levofloxacin)

## 2001

Launch of Detantol, a treatment for glaucoma and ocular hypertension

Launch of anti-allergy ophthalmic Livostin



Launch of BSS PLUS, an ophthalmic perfusion and bathing solution



1970 Launch of antibiotic ophthalmic Ecolicin



1978



# ophthalmic Flumetholon





#### 1965 Launch of Sante de U





Launch of Kary Uni, a treatment for

Company History

Product History

#### 1890s Launch of Heburin-gan, a cold medicine

1899



Daigaku Eye Drops



# 1952

1 Launch of Daigaku Penicillin Eye Drops

#### 1953

Launch of Daigaku Mycillin Eye Drops

#### 1954

Launch of Daigaku Super Eye Drops

#### 1962

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



114 Santen Pharmaceutical Co., Ltd. Annual Report 2016 Launch of Timoptol, a treatment for glaucoma and ocular hypertension 1985

1990

Launch of Sante 40 NE



of intraocular lenses

Launch of anti-infective

ophthalmic Tarivid

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

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

#### 2006

Fiscal 2006-2010 Medium-Term Management Plan formulated

#### 2007

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

Fiscal 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

#### Representative office established in Ho Chi Minh City, Vietnam

Established Santen Pharmaceutical Asia Pte. Ltd. in Singapore

#### 2014

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

Fiscal 2014-2017 Medium-Term Management Plan formulated

Established subsidiaries in Switzerland, Italy, the U.K., Spain, Thailand, Malaysia and the Philippines

#### 2015

Assigned anti-rheumatic pharmaceuticals business to AYUMI Pharmaceutical Corporation

#### 2016

Established Santen Business Services Co., Ltd.

Established Santen Eye Care Co., Ltd. Acquired U.S.-based InnFocus, Inc.

#### 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

#### 2007

Launch of Sante Uruoi Contact a

#### 2008

Launch of nutritional supplement Sante Lutax

Launch of Sante 40i

Launch of Eternity foldable intraocular lens



Launch of Tapros (tafluprost), a treatment for glaucoma and ocular hypertension

2010

# 2009

Launch of Sante FX V Plus

Launch of Eternity Natural foldable intraocular lens

#### 2010

Launch of Cosopt. a treatment for glaucoma and ocular hypertension

Launch of Diquas, a treatment for dry eye

#### 2012

Launch of Sante Medical Guard

Launch of Intravitreal VEGF Inhibitor Eylea

Launch of Sante 40 series



2013

Launch of Eternity Natural Uni

Launch of Sante Beautéye Launch of Sante PC

a treatment for glaucoma and ocular hypertension

Launch of anti-allergy ophthalmic solution Alesion

#### 2014

Launch of Tapcom (tafluprost/timolol maleate), a treatment for glaucoma and ocular hypertension

Launch of Soft Santear Hitomi Stretch

#### 2015

Launch of nutritional supplement Sante Lutax 20 +Vitamin & Mineral

Launch of New Sante de U a

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



Launch of Ikervis, a treatment for severe keratitis in adult patients with dry eye disease





















SANTEN PHARMACEUTICAL CO., LTD.

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