

## Annual Report 2019

Year Ended March 31, 2019





# Ophthalmology is our singular focus.

Santen has conducted business as a specialized pharmaceutical company in ophthalmology since its foundation in 1890. Based on Santen's Values and Mission Statement, we will continue to contribute even further to ophthalmic treatments, working toward better eye health and healthy lives for all.

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# Our History as a Specialized Pharmaceutical Company

In the nearly 130 years since its founding, Santen has conducted business toward improving the quality of life (QOL) for people around the world by focusing on the ophthalmology and developing its business globally.

<u> 1890- 1950- 1990-</u>



#### **Establishment in 1890**

Taguchi Santendo opened in Osaka, Japan in 1890. *Daigaku Eye Drops* launched in 1899

Today, more than 100 years later, these long-selling eye drops remain a favorite for many.

# Business Strategy Focused on Eye Drops, Expansion into Prescription Pharmaceuticals

During the period of recovery following World War II, Santen worked to rebuild around a business strategy focused on eye drops. In 1958, the Company advanced into the prescription pharmaceutical business. *Midorin-P* launched in 1962, and greatly boosted Santen's reputation in the field of prescription ophthalmic pharmaceuticals.

## Taking on Challenges for a Global Rollout

On the centennial of Santen's founding in 1990, the Company announced its long-term vision: "To contribute to society with the best products and services focusing on the eye and health." With the launch of *Hyalein* in 1995, Santen began expanding its product lineup, accelerating its growth in Japan. It also established subsidiaries including Santen Inc. in the U.S. and Santen Oy in Finland and started building a structure for global clinical development and production.

## 2000- 2010-



## **Expanding Solutions and Full-Scale Entry into Asia**

Santen has developed a wide range of products and services that contribute to ophthalmology, including the launch of *Cravit* in 2000, a next-generation "dimple bottle" which is designed to make application easier for patients, and intraocular lenses. The company has also strengthened its global sales base, spreading to new sites and plants primarily in Asia, including China and Korea.

## Accelerating Global Development to Contribute to People's Eye Health Worldwide

Under its long-term strategic vision toward 2020 of becoming a "Specialized Pharmaceutical Company with a Global Presence," Santen is accelerating its global development, taking over the ophthalmology products from U.S.-based Merck & Co., Inc. in 2014. After assigning the anti-rheumatic pharmaceuticals business in 2015, Santen has further concentrated management resources in the ophthalmology field and continued to take on the challenges of contributing to better eye health for people worldwide.

## **Our Strengths**

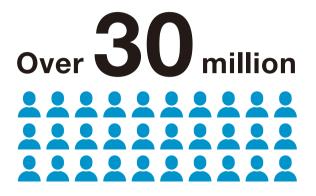
Santen has built its expertise and technical capabilities in the specialized field of ophthalmology through a thorough customer focus for patients and medical professionals. Taking advantage of these strengths, Santen will contribute to enhancing QOL for patients around the world by responding to customer needs in each region and through a product lineup that covers a wide range of ophthalmic disorders.

**Thorough customer focus** 

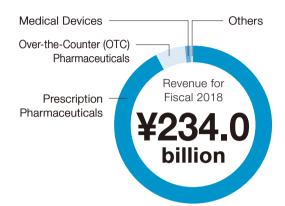
Specialized expertise in the field of ophthalmology

Enhancing QOL for ophthalmic patients around the world

**Number of Patients Benefited from Our Treatments** 



#### **Revenue Composition by Category**



Number of Countries/Regions for Business Development



Share of the Prescription Ophthalmic Pharmaceutical Market (Amount) <sup>1</sup>

Japan/Korea

#2

Annual Production Volume of Ophthalmic Solutions

Approx.

400 million bottles<sup>2</sup>

Primary Ophthalmic Disorders Covered

Disorders Covered

Retinal Disorders

Glaucoma

Dry Eye

Ocular Infections

Allergy

Cataract

Number of Products Sold in Japan

Over **70** 

<sup>1.</sup> Source: Copyright © 2019 IQVIA. Santen analysis based on JPM, MIDAS 2018. Reprinted with permission.

<sup>2.</sup> Ophthalmic solutions packaged in single-dose disposable containers are aggregated by counting 10 single-dose containers as 1 bottle. All other ophthalmic solutions are counted based on the actual number of bottles.

### **CEO Message**



# As a specialized pharmaceutical company, we will continue to contribute to the eye health of people worldwide.

## Supporting the Eye Health of People Worldwide Based on Santen's Values

Santen's Values are embodied in the phrase "Tenki ni sanyo suru," which literally means "exploring the secrets and mechanisms of nature in order to contribute to people's health." Since our founding in 1890, we have continued to contribute to patients and their loved ones in the specialized field of ophthalmology based on the philosophy behind this phrase, from which our company name is also derived. Santen has built its expertise and capabilities in this field based on a thorough customer focus, taking advantage of these strengths to offer products and services aligned with the needs of each region across a wide range of ophthalmic disorders, including retinal disorders, glaucoma, dry eye, ocular infections, allergy and cataracts.

I myself have attached great importance to Santen's Values as a basis for management decision-making, and have focused our resources on ophthalmology as we work to contribute to patients. Under our long-term strategic vision toward 2020 of becoming a "Specialized Pharmaceutical Company with a Global Presence," we will also accelerate our global development. Today, we support the eye health of over 30 million people in over 60 countries and regions.

Further Information ► P.1 Santen's Values

## A Mission to Contribute to Ophthalmology as a Specialized Company

The eyes are an organ of critical importance to daily life. We get over 80% of our information through our vision, and according to a report by the World Health Organization (WHO), those with impaired vision are involved in traffic accidents at a rate triple that of those with healthy vision, reflecting a significant decline in Quality of Life (QOL). Approximately 217 million people suffer from low vision¹ worldwide, while about 36 million people are blind. This means that of the global population, 1 out of 30 people has some kind of problem with eye health.² Meanwhile, it is thought that about 80% of vision impairment worldwide could be prevented through early detection and treatment; providing information on disease and treatment and offering treatment methods is thus critically important.

- 1. The WHO defines low vision as corrected visual acuity of both eyes of 0.05 or greater but less than 0.3.
- 2. Source: Lancet Global Health 2017;5: e888-97

A global increase in the elderly population and the emergence of new diagnostic technologies is expected to drive a further increase in the number of ophthalmic patients. Depending on country and region, there are also many patients without access to appropriate diagnoses and treatment, whether because of problems with local healthcare conditions or for economic reasons. Given these and a variety of other issues surrounding ophthalmology today, we have taken on the challenge of creating an environment in which optimal care reaches as many patients as possible. These efforts include support for glaucoma and dry eve research and patient awareness both inside and outside Japan, development and provision of a glaucoma treatment continuation program package, assistance for the education of ophthalmologists in emerging countries, and improving access to pharmaceuticals. I believe our mission is to contribute to people's eye health through our business as a specialized pharmaceutical company.

Further Information ► P.20 Feature: Contributing to Global Ophthalmology by Developing New Drugs and Treatment Options P.26 Research and Development

P.28 Japan Business P.30 Asia Business P.31 EMEA Business

P.32 Corporate Social Responsibility (CSR)

#### A Strengthened Management Base to Achieve a Sustainable **Society and Enhance Corporate Value**

It is even more important that we contribute to achieving a sustainable society through our business activities while also ensuring our sustainable growth as a company. Santen makes ongoing efforts to strengthen corporate governance for business sustainability. We believe that it is essential not only to have systems for corporate governance in place, but also to implement measures to ensure that those systems function effectively. For example, Outside Directors and Outside Corporate Auditors must engage in prompt, appropriate decision-making, in addition to providing management oversight. To ensure they can perform these duties, we share information about our business strategies, business environment and other issues and create opportunities for interactive communication. We also believe that thorough compliance systems are essential to providing appropriate products and services to patients around the world, and we are thus focused on reinforcing our global compliance systems.



Santen continues to support the United Nations (UN) Global Compact. We have augmented our daily business activities with the UN Global Compact's Ten Principles covering the four areas of human rights, labor, environment, and anti-corruption, and we are working toward the development of a sustainable society. Through these efforts, we will continue to meet the expectations of patients and those involved in

Further Information ► P.32 Corporate Social Responsibility (CSR)

P.38 Corporate Governance

ophthalmology worldwide, contributing to society through our business.

August 2019

Akira Kurokawa Chairman and Chief Executive Officer

a. Thuchava

### **COO Message**



# Contributing to people's eye health worldwide through a wide range of ophthalmic products and services.

#### **Contributing in the Ophthalmology Field Is Our True Mission**

Looking back at fiscal 2018, we made considerable progress in executing our key strategies under MTP2020, the new three-year Medium-Term Plan we announced as the culmination of our long-term vision through 2020.

In our global business strategy, the goal was to achieve Group-wide growth that exceeded that of the market by advancing into the fast-growing Asian market using assets and knowledge from Japan and EMEA. This included focusing on activities deeply rooted in customer needs in each Asian country and rolling out products originally launched in Japan and EMEA such as *Ikervis* and *Diquas* in Asia. In addition, we leveraged our personnel and expertise in medical and regulatory affairs in Japan and EMEA for the Asia business. As a result, sales in Asia grew over 20% year on year, leading sales growth for the Group as a whole. Solid progress was also made in advance of entering the U.S. market, including preparations for a 2019 PMA (premarket approval) application for *PRESERFLO MicroShunt*, a glaucoma treatment device, and the signing of an exclusive distributor agreement for the same device with Glaukos Corporation. During the year, Santen has also expanded lineup of products and services beyond eye drops, including the launch in Japan of *Eybelis*, an intraocular lens for cataract surgery, supplements, and carried out global efforts to enhance patient awareness.

Santen's fundamental policy under MTP2020 is to achieve our long-term strategic vision toward 2020 of becoming a "Specialized Pharmaceutical Company with a Global Presence," and building a pathway to sustained growth in 2020 and beyond. With the expansion of our products and services and through customer-focused activities involving patients and doctors, the ratio of overseas sales reached 31% in fiscal 2018 as our global presence continues to grow.

Going forward, we will continue to leverage our specialization and knowledge in the ophthalmology field to further expand our contributions to patients and their loved ones.

Further Information ▶ P.14 Medium-Term Plan (MTP2020)

## **Contributing to Fulfilling Lives for People through** a **Broad Approach**

As a specialized ophthalmology company, Santen has expanded its efforts to respond to the needs of patients and those involved in medical care. For example glaucoma, which requires lifetime control over intraocular pressure, has few noticeable symptoms, leading many patients to stop treatment which makes continued treatment an issue. In our Japan business, Santen has begun supplying its own developed glaucoma treatment program packages to medical clinics as part of our efforts to support treatment compliance.

As populations age, the number of ophthalmology patients worldwide is expected to increase even further, giving Santen an even greater responsibility for eye health. Looking at conditions surrounding global ophthalmology, some regions in emerging countries may not be able to provide patients with appropriate information and treatment, and offering more people access to high-quality eye care is an issue. Expectations have also grown for innovations in diagnostic technology and qualitative improvements in treatment, including regenerative medicine, gene therapy, IoT and micro-devices.

As a specialized company in the ophthalmic field, Santen approaches these issues from a broad point of view. We hope to continue the challenge of helping patients and others the world over achieve happy lives, while actively incorporating these and other new technologies.

Further Information ▶ P.20 Feature: Contributing to Global Ophthalmology by Developing New Drugs and Treatment Options

## Strengthening Our Organizational Base to Create Sustained Value for Customer

Acceleration of business growth overseas brings with it the globalization of our organization, including a ratio of overseas employees exceeding 50%, as well as increased diversification of needs among patients, medical professionals and other customers. To respond to those diverse needs, Santen undertook a review of its global structure with the goal of strengthening its organizational capabilities, and in April 2019 we conducted major organizational changes. Sales and marketing organizations are now dedicated to customer-facing activities. R&D and other organizations responsible for creating and supplying products and services are focused on providing solutions based on customer needs. Finally, the mission of the corporate organization is to contribute to our customers by promoting our strategies and optimizing operations with a global perspective. We have also begun work on business process reforms across the



entire Group, as well as global standardization and integration of processes and systems centered on mission-critical operations. Through these efforts, we will improve both productivity and organizational collaboration, and focus management resources on activities that generate customer value, while also enhancing the quality of our products and services.

All of us at Santen will continue working together toward sustainable growth as we contribute to better eye health for people the world over.

August 2019

Shigeo Taniuchi

President and Chief Operating Officer Head of North America Business

## **Medium-Term Plan**



We formulated the Medium-Term Plan (MTP2020) covering the period from fiscal 2018 to fiscal 2020 to realize Santen's long-term strategic vision of becoming a "Specialized Pharmaceutical Company with a Global Presence" by 2020 and move toward sustainable growth beyond 2020. With MTP2020, we have set strategic goals to improve customer satisfaction, profitability, and organizational strength. Through steady execution of priority strategies toward achieving these goals, we are aiming to offer products and services of the highest quality that best satisfy actual needs of patients and medical professionals, and sustainably contribute to ophthalmic treatment around the world.

**Fundamental Policy** 

By contributing to the QOL of patients worldwide, Santen will realize its long-term strategic vision through 2020 to become a "Specialized Pharmaceutical Company with a Global Presence" while constructing a path for sustainable growth beyond 2020.

Strategic Goals

Increase customer satisfaction

Increase profitability

Increase organizational strength

#### Key **Strategies**

- (1) Grow faster than the market through progress in global business strategy
- (2) Enhance the product pipeline and develop new treatment options
- (3) Raise the strength and efficiency of business framework as well as boost human resource and organizational capabilities

**Financial Targets** 

Revenue Growth

6%

Core OP Ratio 21%

(MTP average)

ROE 11%

(MTP average)

Under our global business strategy, which is one of the key strategies, we will further accelerate business growth in Japan, Asia and EMEA, while also steadily preparing to enter the U.S. market.

In Japan, Santen has dominant strength in ophthalmic pharmaceutical markets based on sales and production capabilities developed over many years. In addition, we have established a presence in Europe, which has a major influence worldwide including academia, as well as standards and regulatory policies such as GMP1. Under MTP2020, while we make an even greater contribution to ophthalmic care across each region by using the experience and knowledge we have cultivated until now as our strength, we aim to grow faster than the market by

expanding our knowledge in Asia. Asia encompasses a population of over four billion people, and although the region will have a shift in aging populations going forward, it is also expected to continue experiencing high economic growth and therefore greater expansion in the ophthalmic pharmaceutical market.

Our preparations of the U.S. entry will continue with the aim of early contribution to earnings from 2021 onwards. Based on continuous business development, we will work to build a presence in the U.S. market, which drives innovation in life sciences.

 GMP stands for "Good Manufacturing Practice," which is a standard for manufacturing control and quality control for drugs and quasi-drugs

#### Review of Previous Medium-Term Plan

Fiscal 2014-2017 Medium-Term Plan

Priorities and Basic Policies	Major Achievements
Priorities  Grow and improve profitability in Asia and EMEA Prepare for business expansion to the U.S. and other regions Basic Policies Product Development: Transform product development to realize enhanced productivity and achieve sustained growth Business Expansion: Grow business in Asia/EMEA and strengthen market presence by entering into new markets Organization and Talent: Develop talent and organization to realize sustained growth	<ul> <li>Revenue Exceeded 200 Billion Yen: Achieved the Vision 2020 revenue target of 200 billion yen 3 years ahead of the plan</li> <li>Increased Sales Regions/Countries: An increase to approximately 60 from 50 countries and regions due to products acquired through U.Sbased Merck &amp; Co., Inc. and shifting from an agency model to direct selling model</li> <li>Achieved 30% Overseas Revenue Composition: Growth from the launch of new products in addition to organic growth and growth from products acquired through Merck &amp; Co., Inc.</li> <li>Enhanced and Advanced Pipeline: Received approval and launched <i>Ikervis</i> in Europe, filed for DE-117 in Japan, added DE-126 and DE-128 to the pipeline, received approval for <i>Diquas</i> in China, etc.</li> </ul>

#### Fiscal 2011-2013 Medium-Term Plan

Priorities and Basic Policies	Major Achievements
Priorities  Strengthened Japan business Complete preparations for business expansion in Asia and EMEA Basic Policies  Promote globally oriented research and development  Obtain high market share and achieve growth in Japan business through the promotion of new products and implementation of marketing strategies  Accelerate growth in both Asia and Europe by reinforcing marketing platforms  Establish a global product supply system with our existing four plants, which enable us to meet emerging market needs  Develop talents and organizational capabilities to promote "creation and innovation" on a global level	<ul> <li>Product Development: Established a global clinical development system, reinforced product pipeline through business development and acquisitions</li> <li>Japan Business: Achieved sales growth driven by new products (<i>Tapros</i>, <i>Diquas</i>, <i>Eylea</i>, <i>Cosopt</i>, etc.), decline in long-listed drugs ratio</li> <li>Overseas Business: Achieved growth in China, Asia businesses turned to profitability</li> <li>Product Supply: Executed measures to reduce manufacturing cost, implemented structural reforms at production bases in Europe</li> <li>Organization and Talent: Implemented an organizational management system in line with business globalization</li> </ul>

#### Highlights for the First Year of MTP2020

In fiscal 2018 as the first year for MTP2020. Santen moved forward with important steps to complete the plan. We focused particularly on glaucoma, a disease that can lead to blindness, with the launch of sales in Japan in November 2018 for Eybelis, a product with a new mechanism of action as a treatment for glaucoma and ocular hypertension. Santen is also proceeding with development in Asia and the U.S.. Furthermore, in striving to contribute to eye health by a broader range of solutions, we also launched sales in Japan in April 2019 for Lentis Comfort, a new concept for intraocular lenses used as a cataract treatment option. We are also proceeding with development of DE-128 (PRESERFLO MicroShunt), a device used in glaucoma surgery, in the U.S. with the aim of launching sales in 2020. Along with this development, we have concluded an agreement with Glaukos Corporation, a leading company in the field of glaucoma treatment devices, in which Glaukos will become the exclusive distributor of the PRESERFLO MicroShunt solely in the U.S. market. The

agreement allows us to build a sales structure to deliver the product to more patients at an earlier date.

We also began joint research with PeptiDream, Inc. and RIKEN, as well as gene therapy development with Oxford Biomedica plc. We will actively undertake initiatives to introduce new outside technologies to the ophthalmic field, and aim to offer treatment methods that meet the needs of patients.

Due to the impact in Japan business by NHI drug price reductions, the rate of growth in revenue in fiscal 2018 was 4.0%, compared to the target of more than 6% CAGR. However, in Asia, primarily China and South Korea, sales growth exceeded 20% year on year, maintaining a high growth rate. Due to continued growth in priority products in Japan business and significant growth in overseas businesses, we are aiming to achieve more than 6% annual average growth as a target for MTP2020. Core operating profit margin was also 20.6% (with an MTP average target of more than 21%) and ROE was 11.1% (with an MTP average target of more than 11%).

Further Information ▶ P.20 Feature: Contributing to Global Ophthalmology by Developing New Drugs and Treatment Options P.26 Research and Development P.28 Japan Business P.30 Asia Business P.31 EMEA Business



#### **Topics**

### Contributing to Patients' Enhanced QOL with Ophthalmologists from around the World at the World Ophthalmology Congress

During the 36th World Ophthalmology Congress (WOC2018) held in Barcelona, Spain in June 2018, Santen collected messages from visitors to the Santen booth on the theme of aspirations for the future of ophthalmology, in addition to its regular congress activities. Santen donated two euros to provide glasses to people in developing countries for each message received. Contributing to society by enhancing patients' QOL was a wonderful opportunity shared deeply with Santen's corporate values. Also, Santen conducted three sponsored symposiums on the themes of dry eye and glaucoma, attracting a total of over 1,800 people. The congress provided a chance for those involved in the medical field from around the world to engage in cross-border sharing of clinical experience and the latest knowledge.



### Raising Awareness of Early Detection and Continued Treatment of Glaucoma Globally during World Glaucoma Week

World Glaucoma Week is held in March to raise awareness of glaucoma throughout the world. Santen provides its support for these activities every year and cooperated with promoting awareness activities for patients around the world in 2019. In addition, Santen provided make-up lessons to patients so that the side-effects of ophthalmic drops for glaucoma did not stand out, held lectures and distributed a smart phone app in which users can experience a simulation of the visual field impairment caused by glaucoma. The Company also held lectures by ophthalmologist and patient for the purpose of fostering employees' understanding of glaucoma and encouraging employees to spread awareness of the disease to their family and friends.

Glaucoma is a disease in which lifelong blindness can be avoided with early diagnosis and adequate treatment. Santen will continue raising awareness of the disease to reduce instances of blindness through glaucoma.



### Taking Part in Events Marking the 25th Anniversary of the Suzhou Industrial Park in China

Santen's Suzhou Plant, which is located in the Suzhou Industrial Park that commenced development in 1994 as an economic partnership between China and Singapore, held a commemorative ceremony to mark the 25th anniversary of its establishment in April 2019. Representatives of both countries, iconic Chinese IT companies and various companies from around the world participated in the ceremony, which Santen was invited to attend in recognition of its contribution to the medical industry within the park. We aim to continue to contribute to eye health for all and the development of business in the expanding Chinese market.

Further Information ► P.30 Asia Business



#### Developing Activities for Appropriate Ophthalmological Treatment in Japan in Collaboration with External Partners

Santen started initiatives in Japan in 2016 aimed at promoting appropriate ophthalmic treatment with the purpose of preventing eye disease and cessation of treatment.

Currently, Santen is raising awareness of continued treatment through pharmacies and collaborating with companies, organizations and local governments to engage in activities that lead to early detection of disease and medical treatment using Santen OptiNavi¹ and vision loss simulator to experience how vision is affected by ophthalmic diseases. We will raise Santen's activities to a higher level to attract a greater attention throughout society about eye health.

1. A simple, self-check website for eye health developed with ophthalmologists



#### Capital Policy

#### **Financial Strategy**

In seeking to establish competitive superiority in the field of ophthalmology, Santen aims to enhance its profitability in tandem with maximizing its cash generation capability as well as shareholder value. Our basic policy is to maintain the right balance between securing sufficient internal reserves to implement growth strategies and returning profits to shareholders. At the same time, we pursue an optimal capital structure for the Company in terms of capital efficiency, financial soundness and other factors. Santen is working to enhance return on equity attributable to owners of the company (ROE) by optimizing the aforementioned elements of profitability, financial soundness and shareholder returns.

For investment toward company growth, Santen is planning active and efficient investment for strengthening the pipeline, acceleration of global development, new medical technology and production sites, and information systems and other systems to enhance business bases around the world. For profitability, we espouse achieving profit that exceeds capital cost as a basic policy, and judge investments based on evaluation criteria for that purpose. Furthermore, for return on investment, we are undertaking initiatives to maximize cash generation through cash management that includes taxes, in addition

to enhancing a business management system that monitors the status of businesses expanding globally. For capital efficiency, we will proceed with optimization of the debt-to-equity ratio (D/E ratio) and asset downsizing, while considering both growth investments and financial soundness. In fiscal 2018, Santen decided to sell the location of the vacant site of former head office and Osaka plant, and transferred the Tampere Plant (Finland) to NextPharma Technologies Holdings Limited.

#### **Shareholder Returns**

Our basic policy ensures management places greatest importance on shareholder returns. We return profits to shareholders primarily through dividend payments, in tandem with repurchasing treasury shares as a supplemental measure, taking into consideration a comprehensive range of factors, including the medium- to long-term business environment, funding requirements, internal reserves available, and capital structure.

In consideration of spare capital for growth investment, we repurchased 8,144,000 shares in treasury stock in fiscal 2018 (of which, 7.5 million shares were retired on March 29, 2019) to further improve shareholder returns and capital efficiency.

Maximize cash generation to implement effective investments in future growth and stable shareholder return



#### Conduct active and effective investments in future growth

Enhance pipeline
Accelerate development of business globally

Pursue new treatment technologies / innovation

Make capital investment to support future growth

#### Optimize profit and capital efficiency

Strengthen global management framework

Optimize global tax and cash management

Balance investment in future growth and financial soundness

#### Continue stable and sustainable shareholder return

Implement stable and sustainable dividends

#### Strengthening Human Resources and Organizational Capabilities

# Strengthening Human Resources and Organizational Capability to Sustainably Contribute to Patients around the World

At Santen, we believe improvements in human resources (HR) and organizational capability are integral to sustainable contributions to patients as well as company growth. We are focusing on enhancing our ability to promote our global business development by cultivating leadership talent to support sustained growth and strengthening organizational capabilities.

We are building and developing a HR system worldwide for the cultivation of talent pursuing truly customer-focused value creation. This system derives from the Santen Leadership Competencies (SLC) framework as the basis for our expectations for personnel based on Santen's Values. We are undertaking initiatives to strengthen global organizational capabilities underpinned by Santen's Values while cultivating leadership through a systematic approach. We are also focusing our efforts in Japan on strengthening a stable HR base that supports development through job grade-based training and other initiatives.

In striving to strengthen its ability to execute global strategies and further contribute to our customers, Santen reviewed organizational roles from a Group-wide perspective and implemented organizational changes as of April 2019. With these changes, the Group defined the functions that connect to value contribution for our customers by increasing optimization and efficiency in global strategies and operations, as well as functions to face and contribute directly to the customers in each country and region. We are aiming to further contribute to ophthalmic treatments by improving the collaboration across functions and unifying our employees.

#### Santen Leadership Competencies (SLC)

**Expected behaviors of Santen Group employees based on Santen's Values** 

With a mindset and from a perspective unique to Santen

Customer-Focused Value Creation Integrity and Trust Expertise Application outline what should be done

Strategic Planning

and encourage oneself as well as others

Change Leadership Collaboration beyond Boundaries HR and Organizational Development to carry out objectives to the end

Drive for Achievement

Reinforcement of human resources and organizational capabilities based on Santen's Values and SLC

### **Feature**

## Contributing to Global Ophthalmology by Developing New Drugs and Treatment Options

In order to deliver the best treatment for each individual patient, Santen focuses on developing treatment options that meet previously unmet needs by leveraging its expertise and technical abilities in the field of ophthalmology.

## Aiming to Make an Ongoing Contribution to Ophthalmic Treatment around the World

As elderly populations increase around the world, the number of ophthalmic patients is also increasing, and it is thought that one in every 30 people worldwide suffer from some form of visual impairment. In addition to this, the prevalence of computers and mobile devices has led to an increased burden on people's eyes, thus a heightened awareness of eye health regardless of age can be expected going forward. As such, a wide range of treatment options that are suitable not only for a person's ophthalmic symptoms or disorders but also their environment, lifestyle, age, and other such factors is required in order to deliver the best treatment.

At Santen, in addition to building up a strong and varied lineup of products for a range of ophthalmic disorders, we have worked hard to provide products and services that meet a wide range of previously unmet needs by developing preservative-free products, combination ophthalmic solutions incorporating multiple pharmaceuticals, and containers that simplify eye drop application. We are also adopting highly distinguishable packaging among other measures. Currently, in addition to providing products that go beyond eye drops such as surgical devices and supplements, we are now also working to develop a wide range of solutions to meet eye health needs that include programs to encourage the continuation of patient treatment and raising awareness of ophthalmic disorders with the aim of making the kind of contribution to patients that only a company specialized in the field of ophthalmology is capable of providing.

## Providing the Best Treatment to as Many Patients as Possible

#### **Unmet Needs in the Field of Glaucoma**

Glaucoma is the second most common cause of blindness in the world<sup>1</sup>, and the number of those who suffer from glaucoma is expected to reach 150 million by the year 20232. Although it is a serious disorder that leads to blindness if symptoms progress, no permanent cure has been established and it requires treatment over the course of a person's life. However, there are no obvious symptoms and there are many patients who already have a reduced field of vision by the time the disorder is discovered or end up discontinuing treatment, so early diagnosis and continued treatment are issues that must be addressed. In addition to this, there are also cases where existing medicines cannot provide the desired effect and where side effects limit the range of applicable medicines, meaning there is still an insufficient number of options when it comes to treatment. This means that the development of effective drugs and treatments is highly anticipated.

## A New Eye Drop with a World First Action Mechanism

In order to address such unmet needs, Santen launched *Eybelis*, with its world first action mechanism in the field of glaucoma drugs, as a new treatment option for



glaucoma patients. *Eybelis* boasts an excellent intraocular pressure (IOP) lowering action with once-a-day application, and has demonstrated an IOP lowering effect for patients who have been unable to obtain results with prostaglandin-related drugs.

Currently, *Eybelis* is being developed beyond Japan on a global level, with an application for sales approval having been submitted in Asia and Phase 3 trials underway in the U.S. We intend to leverage this product's prescription results and the knowledge gained during rollout domestically, and make use of this knowledge in the treatment of glaucoma globally.

#### PRESERFLO MicroShunt: A Glaucoma Treatment Device That Can Reduce Patient Burden

The current treatments for glaucoma are centered on eye drops, but surgery is necessary in some cases where a sufficient reduction in intraocular pressure cannot be obtained through medication. However, conventional surgery for glaucoma entails a large burden for patients and ophthalmologists that includes, among other things, post-surgery care to prevent complications.

As such, Santen is working on the development of a glaucoma surgery device called *PRESERFLO MicroShunt* as a treatment option for glaucoma patients who require surgery. This device enables a stable reduction in intraocular pressure through the insertion of an

extremely small microtube (around twice the size of an eyelash) made of material with high bioaffinity from the outside of the eye. It can be inserted with the smallest incision, and compared to conventional surgical techniques, it has the potential to reduce the burden of surgery on the patient, starting with minimizing time in surgery.

As well as working on development of this device ahead of a market launch in the U.S. in 2020, we also plan to implement training for surgeons who perform glaucoma surgery using *PRESERFLO MicroShunt* so that it can become a treatment method in which glaucoma patients feel safe and reassured.

- 1. Source: WHO Global Data on Visual Impairments 2010
- 2. Source: Market Scope



## Lentis Comfort: An Intraocular Lens for Cataract Treatment to Enhance Patient QOL

Cataracts cause visual impairments such as deterioration of vision, blurring, and the sensation of brightness from clouding of the eye lens which occurs due to a range of factors. Normally, surgery that involves the replacement of the eye lens with an intraocular lens is performed for cataracts. In order to achieve comfortable long- to mid-range visual acuity, Santen launched the Lentis Comfort intraocular lens for the treatment of cataracts in Japan. With a combination of circular sector-shaped dual monofocal design and mild additional power<sup>1</sup>, it is expected to provide a broader field of focus than conventional monofocal lenses, meaning it can expand the area in which the wearer feels they can see clearly without wearing glasses. It is also thought that this product can suppress noticeable symptoms that cause discomfort such as halos<sup>2</sup> and glare, and after an operation the patient can hope to live a comfortable daily life.

- 1. Additional power added to enable wearers to see nearby objects
- Halo: A phenomenon where a ring of light is seen around an object at night and in dark areas Glare: A phenomenon in which light feels too bright or intense on the eyes

Further Information ► P.28 Japan Business



#### Message



Yuriko Endo Director, Glaucoma Friend Network (general incorporated association)

#### Aiming to Improve the Environment for Glaucoma Patients

The Glaucoma Friend Network is a general incorporated association comprised of patients that was established with the aim of raising awareness in society of glaucoma, for which there is said to be roughly three million latent cases in Japan, providing a venue for interaction between those suffering from glaucoma and their family members, and raising awareness about the early discovery of glaucoma.

There are many glaucoma patients who are concerned by the fact that it can lead to blindness, and relying on primary doctors, we also seek useful information in treatment and interaction with fellow patients. Glaucoma requires ongoing treatment for life, and there is a significant number of patients who use three or four types of eye medicine. While the types of medicine that can be chosen has increased compared to the past, there are cases where patients have to change their medication due to side effects and where the choice of medications is limited due to an existing illness, so we hope to see an increase in options for treatment.

In order to improve the environment that surrounds glaucoma patients going forward, we believe that cooperation between patient groups, medical institutions, and companies is essential. We have high hopes for the development of pharmaceuticals by ophthalmology specialists like Santen, and we hope we can work together on a wide range of initiatives.

## Proactive Collaboration and Joint Research with External Partners for New Treatment

Through regenerative medicine, gene therapy, and the fusion of IT and medicine among other things, medical technology is evolving beyond its traditional boundaries. In order to make a sustained contribution to QOL improvement for people around the world through our value-providing products and services, we are focusing our efforts on proactively using excellent technology and innovation from external sources and fusing it with the ophthalmic expertise and technology we have cultivated to create new approaches.

And that is why Santen is proactively carrying out joint research and collaboration with research institutes and companies that perform cutting edge research, such as the Institute of Physical and Chemical Research (RIKEN), the Singapore Eye Research Institute (SERI), University College London (UCL), Kobe Eye Center, PeptiDream Inc., and the Tokyo Medical and Dental University among others. An example being eye drops that suppress the advancement of myopia in children (DE-127), which we are jointly developing with SERI, and in the first half of FY2019 it commenced Phase 2/3 trials while Phase 2 trials in Asia are planned to be completed in the second

half of FY2019. We are also conducting research into inherited retinal disease, for which the establishment of a method of treatment is highly anticipated, with RIKEN, the Kobe Eye Center, and Oxford Biomedica plc.

Taking maximum advantage of the expertise and technical abilities we have gained through our specialization in ophthalmology and taking a proactive approach to joint research, we aim to create new treatment options to meet treatment needs around the world.

#### Joint research announced from 2018

September 2018	Conclusion of a comprehensive agreement for joint research and development into pharmaceutical creation with PeptiDream Inc.
March/June 2019	Commencement of research and development of gene therapy vectors for inherited retinal disease in collaboration with RIKEN, the Kobe Eye Center, and Oxford Biomedica plc.
March 2019	Commencement of research and development for photo-crosslinking for pathological myopia in collaboration with Tokyo Medical and Dental University and FiberTech Co., Ltd.

Further Information ▶ P.26 Research and Development

#### Message



Aldo Caporossi M.D., Ph.D.
Professor, Institute of Ophthalmology,
Catholic University of the Sacred Heart
Director, Rome Policlinico Gemelli
ophthalmologic Clinic
President, Italian Glaucoma Society, SIGLA
Vice President, Italian Society of
Corneal Transplants, SITRAC

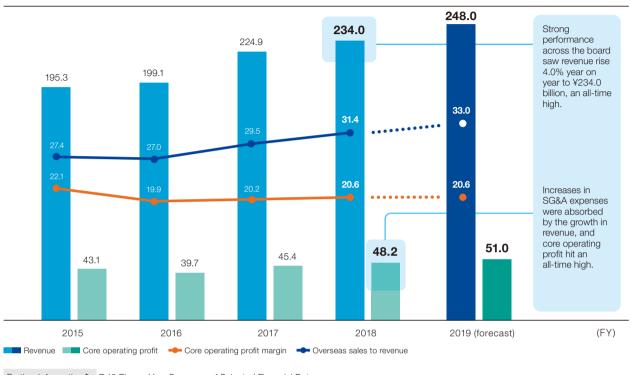
## **Great Expectations for Santen to Develop Safer and More Effective Treatments for Glaucoma**

The recent advancements in glaucoma treatment have gained a lot of interest in Italy and the rest of Europe. It is a common perception among the ophthalmology community that trabeculectomy is a highly risky procedure for glaucoma patients due to the level of care required following surgery. Santen has been at the forefront of offering new hope to our patients in an outstanding effort to develop alternative solutions to minimize the immediate post-operative complications related to lower anterior chamber, hypotonia and bleeding. Since introducing Santen's minimally invasive surgical device, *PRESERFLO MicroShunt*, we have observed post-operative complications almost completely disappear. With these initial positive results, it is important that we continue to monitor the long-term effects of new techniques, like *PRESERFLO MicroShunt*, and I believe Santen will play a fundamental role to validate these findings. By working together with surgeons, Santen's therapies and devices have the potential to complement our ability to treat and radically safeguard glaucoma patients.

## **Facts and Figures**

#### **Financial Data**

Revenue, Core Operating Profit, Core Operating Profit Margin, and Overseas Sales to Revenue (¥ Billion) (%)



Further Information ► P.48 Eleven-Year Summary of Selected Financial Data

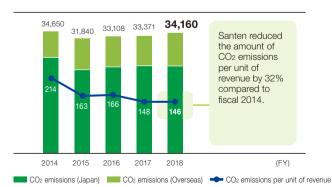
**About Core Basis Results** 

Santen discloses financial information on a core basis to better express its recurring business performance. Financial information on a core basis excludes certain gains and expenses from IFRS results on a reported (full) basis.

#### **Non-Financial Data**

#### CO<sub>2</sub> Emissions

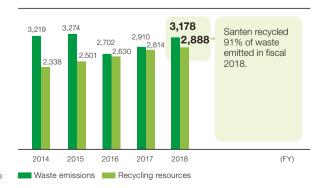
(t-CO<sub>2</sub>) (t-CO<sub>2</sub>/billion yen)



Scope of aggregation: All operational bases in Japan, Tampere Plant, and Suzhou Plant

#### Waste Emissions and Recycling Resources

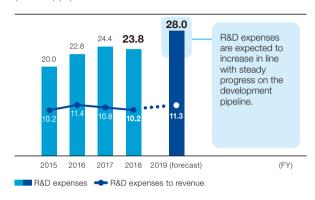
( t`



Scope of aggregation: Shiga Product Supply Center, Noto Plant, Nara Research and Development Center, Shimoshinjo Office, Tampere Plant, and Suzhou Plant

#### R&D Expenses and R&D Expenses to Revenue

(¥ Billion) (%)



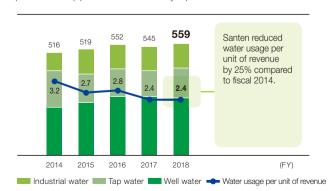
#### **EPS**

(¥)



#### **Total Water Usage**

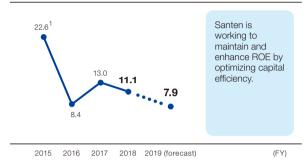
(thousand m³) (thousand m³/billion yen)



Scope of aggregation: Shiga Product Supply Center, Noto Plant, Nara Research and Development Center, Shimoshinjo Office, Tampere Plant, and Suzhou Plant

#### ROE

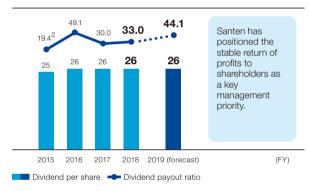
(%)



 ROE increased due to the temporary gains associated with the transfer of Santen's anti-rheumatic pharmaceutical business. Excluding this factor, core ROE was 12.4%.

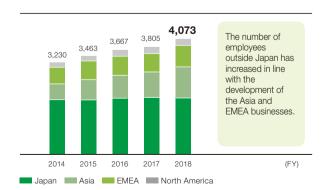
#### Dividend per Share and Dividend Payout Ratio

(¥) (%)



The dividend payout ratio decreased due to the temporary drop in gains associated with the transfer of Santen's anti-rheumatic pharmaceutical business. Excluding this factor, the core dividend payout ratio was 35.5%.

#### **Number of Employees**



## **Research and Development**

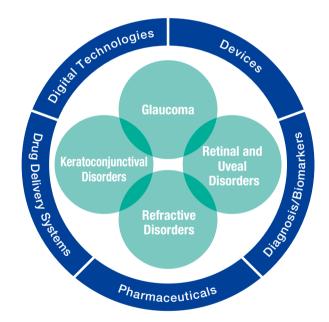
#### **R&D Strategy**

As a pharmaceutical company specialized in ophthalmology, Santen seeks to preserve vision for patients by addressing unmet needs and by developing products that have significant positive impact on the QOL of patients. With an intense focus on patient QOL, we intend to address the needs of not only patients, but also other important stakeholders such as ophthalmologists, caregivers and healthcare providers.

Our Medium-Term Plan (MTP2020) is focused on enhancing our product pipeline and developing new treatment options. We have started to tackle challenging new technologies to optimize treatment outcomes through a "Network Product Development" approach. In March 2019, Santen, together with RIKEN, a national institute, has commenced research and development of gene therapy products for the treatment of inherited retinal disease. This collaboration will also leverage the lentiviral vector platform of Oxford Biomedica plc., with the aim of making new treatment options available to patients. Another example is our partnership with PeptiDream Inc. to develop new treatments by utilizing cyclized/constrained peptides produced by PeptiDream's proprietary Peptide Discovery Platform System Technology. In order to improve the outcomes of clinical research and improve patient care, we are also conducting translational research<sup>2</sup> to identify biomarkers<sup>3</sup> and eventually develop diagnostics. In addition, we are working to create preservative-free formulations leveraging formulation technologies while developing drug-delivery systems<sup>4</sup> and better containers as a way of making these treatments more convenient and less burdensome for our patients.

In November 2018, we launched *Eybelis* as a treatment for glaucoma and ocular hypertension based on a world-first mechanism of action. We are pursuing development activities globally so that we can better satisfy the unmet medical needs of glaucoma patients around the world.

- 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. Indicators that objectively measure and evaluate biometric information to identify medical states including the onset or severity of disease
- 4. Formulation technologies engineered to deliver the right amount of drug to the right target at the right time





## Pipeline of Prescription Pharmaceuticals (Clinical Development)

Alaucoma Dev. Code/ Dev. Name	Generic Name	Indication	Original/Licensor	Region	1	Phase 2	3	NDA Filed	Approved	I
DE-111	Tafluprost/ Timolol maleate	Glaucoma Ocular hypertension	Co-development with AGC Inc.	China					 	
DE-117 Omidenepag isopropyl Glaucoma Ocular hypertension		claucoma Ocular Ocular Opertension  Co-development With Ube Industries	U.S.			1		1		
	Ocular		Japan		1		 	 	Launched November 2018	
			Asia					April	 2019 	
DE-126 Sepetaprost Glaucoma Ocular hypertension		ONO PHARMACEUTICAL CO., LTD.	U.S.			Phase	e 2b			
			Japan			Phase	e 2b			
DE-128 PRESERFLO	Glaucoma	Glaucoma	Original	U.S.				Phase	2/3	
MicroShunt	implant device	Cildadoma	Oliginal .	Europe			1		1	
DE-130A	Latananyaat	Glaucoma	Original	Europe			1 1 1		1	
Catioprost	Latanoprost	Ocular hypertension	Original	Asia			1		1	
eratoconju	nctival Disord	ers					1	1	1	
DE-114A	Epinastine hydrochloride	Allergic conjunctivitis	Nippon Boehringer Ingelheim Co., Ltd.	Japan			1		Septe	mber 2018
DE-076C Vekacia Ciclosporin	Vernal	Original	Europe			1	 		Launched October 2018	
			Asia			1	1	Nove	l mber 2018 	
				Others <sup>5</sup>						December 2018
etinal and	Uveal Disorde	rs								
				U.S.			1		i 	
DE 400	Civalina	l la cellala	Original	Japan						
DE-109 Sirolimus	Uveitis	Original	Europe			1 1 1		 		
				Asia		1	 	 	April :	2015
DE-122	Carotuximab	Wet age-related macular degeneration	TRACON Pharmaceuticals, Inc.	U.S.			Phase	2a		
efractive D	isorders									
DE-127 Atropine sulfate Myopia	Atropine sulfate	Myonia	Singapore Health Services, Nanyang	Japan	Plann	ing to sta	: art Phase :	: e 2/3 in t !	; the first h	 nalf of fiscal 2019 in Ja 
	Technological University	Asia								
thers										
MD-16	Intraocular lens	Cataract	Oculentis BV	Japan			1		May 2	2019
Canada						:	:	:	-	l .

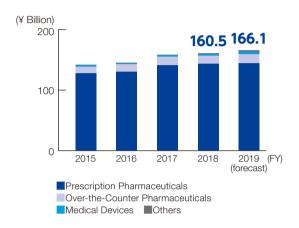
5. Canada As of August 1, 2019

For details on the status of the development pipeline, please refer to "Main Products in Pipeline" on the Company's website. https://www.santen.com

## **Business Review**

#### Japan Business





#### Prescription Ophthalmic Pharmaceutical Market Scale/Santen Product Market Share<sup>1</sup>

	Market scale	Market share		
Prescription Ophthalmic Pharmaceuticals Overall	¥365.2 billion	47.3%	#1	
Glaucoma Treatments	109.8 billion	30.1%	#1	
Corneal Disease Treatments	45.7 billion	61.5%	#1	
Retinal Disorders Treatment <sup>2</sup>	93.6 billion	<b>72.1</b> %	#1	
Anti-Allergy Ophthalmics	47.3 billion	<b>52.2</b> %	#1	
Anti-Infective Ophthalmics	12.6 billion	<b>35.1</b> %	#1	

- Source: Copyright © 2019 IQVIA. Santen analysis based on IMS-JPM 2018.4-2019.3. Reprinted with permission.
- 2. Including co-promoted product of Bayer Yakuhin, Ltd. (MAH) (Anti-VEGF Eylea)

#### **Business Strategy**

Santen is developing three businesses in the ophthalmic field in Japan: prescription pharmaceuticals, OTC pharmaceuticals and medical devices. For over 20 years, we have maintained a strong leading share in the prescription ophthalmic pharmaceutical market, emphatically gaining support from ophthalmologists in terms of customer satisfaction.

Under the Medium-Term Plan (MTP2020), we will take full advantage of the strengths of these businesses with the goal of transforming Santen into an ophthalmic "total solution" provider to achieve eye health for patients and consumers, creating new markets and responding to new needs.

In the prescription ophthalmic pharmaceutical business, we are working toward achieving sustained revenue growth by using strategies for each disease to expand markets and sales, and by developing new businesses. In addition, we not only provide information on individual products, but are also engaged in developing solutions that address the full range of ophthalmic treatment needs, from prevention and diagnosis, to treatment and post-therapeutic follow-up. Our glaucoma treatment continuation program, developed to encourage glaucoma patients to continue treatment, has proven highly effective in early implementation and is currently being offered more widely.

Many patients also struggle to apply eye drops due to shaky hands or for other various reasons. It has been reported that approximately 60% of glaucoma patients fail to accurately apply eye drops on the surface of the eye on their first try.<sup>3</sup> With this in mind, we are working to provide solutions that address the needs of patients and medical professionals, including the launch of *Just in*, an eyedropper aid designed to improve the usability of eye drops. In November 2018, Santen also launched *Eybelis*, a glaucoma treatment agent with a new mechanism of action. We continually provide information on the product in an effort to ensure its proper use and maximize its value.

In the OTC pharmaceutical business, Santen continues to focus on sales of mainstay products such as the Sante FX and Soft Santear series. At the same time, Santen continues working to expand the availability of high-value, high-end brands including the Sante Medical series and the Sante Beautéye series. In December 2018, Santen launched Well Wash Eye, a cleansing eye drop designed to meet the needs of patients suffering from allergic conjunctivitis, and in June 2019, we launched sales for Sante Well Vision, a supplement focused on aging eyes. Aiming to win the support of consumers as the #1 eye care company, Santen is also leveraging specialist and technical expertise cultivated in prescription ophthalmic medicines in its efforts to contribute to eye health through sales of OTC products and other activities.

In the medical device business, Santen has been developing its specialized intraocular lenses (IOLs) in the cataract surgery field. The *Eternity* series, which we have sold since 2008, is based on the concept of offering a high-quality lens with outstanding transparency, a lineup which we have expanded with consideration to visibility and lens shape and design. In April 2019, we introduced

and launched sales for *Lentis Comfort* from Oculentis BV of the Netherlands, which offers a wider range of clear vision compared to mono-focal IOLs. In addition to developing new products, we unified the prescription ophthalmic pharmaceutical business with the organization in April 2019, aiming to contribute even further to the ophthalmic surgical field.

3. Koji Namiguchi, et. al., Atarashii Ganka 34 (9): 1257-1262 (2017)

#### **Business Performance**

Revenue from the prescription pharmaceuticals business increased 1.3% year on year in fiscal 2018 to ¥143.0 billion. Revenue from mainstay products by sector is shown in the table at the right.

Revenue from OTC pharmaceuticals and medical devices in fiscal 2018 were ¥13.9 billion (down 2.6% year on year) and ¥2.6 billion yen (up 2.9% year on year), respectively.

Revenue from Mainstay Products		Revenue (¥ Billion)	Year on Year	
	Tapros	9.6	-0.6%	
Glaucoma Treatments	Tapcom	2.5	+2.8%	
	Cosopt	8.9	-21.8%	
Corneal Disease Treatments	Hyalein	8.8	-18.7%	
	Diquas	13.9	+8.7%	
Retinal Disorders Treatment	Eylea <sup>4</sup>	56.2	+9.0%	
Anti-Allergy Ophthalmics	Alesion	19.4	+15.4%	
Anti-Infective Ophthalmics	Cravit	3.2	-22.7%	

<sup>4.</sup> Co-promoted product (Anti-VEGF Eylea) of Bayer Yakuhin, Ltd. (MAH)

#### Offering Solutions that Address Ophthalmic Treatment Needs

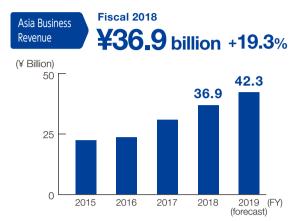
Glaucoma is a disease that narrows the field of vision by causing damage to the optic nerve, due to a rise in intraocular pressure and other factors. Because the optic nerve cannot be restored to a healthy state once it is damaged, lifetime treatment is required to reduce intraocular pressure.

Santen developed *Just in*, an eyedropper aid to improve eye drop usability; the product was launched in April 2019. In-house tests conducted prior to the product's release demonstrated a high application accuracy rate of 84%<sup>5</sup>; we expect this will contribute to continuous treatment through improved patient adherence to eye drop dosage, and the reduction of side effects caused by the drug adhering around the eyes.



5. Based on visual determination by investigators

#### **Asia Business**



#### **Business Strategy**

With a population of more than 4 billion, Asia is expected to see the rapid progression of an aging society in 2020 and beyond. Despite a laudable high economic growth rate, the region includes many countries where medical infrastructure is still developing, and the market for prescription ophthalmic pharmaceuticals in Asia is forecast to see high growth going forward. Santen has built high customer satisfaction and a leading market share in China, Korea and other Asian countries based on a relationship of trust with its customers. As we prepare to expand into India and other countries we have yet to enter, we will work to grow market share to establish a strong position as #1 in Asia.

In China, which represents nearly 60% of Santen's revenue in Asia, we are working to increase customer satisfaction by expanding the number of hospitals we cover, offering a broad product lineup and providing high-quality information. We are also building trust relationships with customers by collaborating with key opinion leaders (KOL) and professional societies, and are

utilizing web channels to expand our information offerings. Current coverage in China that provides advanced medical treatment which focuses primarily on tier 3 hospitals and expanding to a portion of tier 2 hospitals. We have also established a joint venture in Chongqing to expand the supply of products to patients in medical institutions other than these hospitals, and a production facility is also under construction.

Outside of China, we are striving to meet medical needs of each country in Asia through the effective investment of resources, while at the same time continuing to bring new products to market and engaging in activities designed to further their penetration. To accurately capture and respond quickly to the specific needs of customers in countries, Santen is promoting a shift away from our traditional model of using resellers to supply products, and towards sales through our own local representatives. Going forward, we will use the insights we have cultivated in Japan and EMEA to enhance the level of our products and services, with the goal of contributing to the development of eye health and ophthalmic medicine in Asia and continuing to grow faster than the market.

#### **Business Performance**

Revenue from the Asia business increased 19.3% year on year to ¥36.9 billion on a yen conversion basis in fiscal 2018. Growth continued primarily in China and Korea, driven mainly by progress in efforts to encourage the wider use of mainstay products such as the dry eye treatment *Hyalein* and the anti-infective agent *Cravit*. We also maintained strong growth rates throughout the ASEAN region.

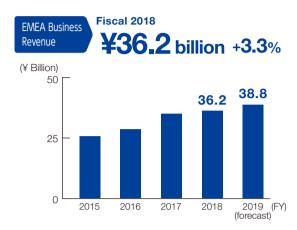
## Meeting of the Santen Asia Scientific Steering Committee Held

Santen established the Santen Asia Scientific Steering Committee (SSC), comprised of ophthalmologists who serve as KOL in the Asia Pacific region, with the goal of identifying unmet needs in ophthalmology throughout Asia and providing a forum for discussion of initiatives to address those needs. Participants include doctors from a



variety of countries and regions, including Singapore, Korea, Thailand, Taiwan, Hong Kong, the Philippines, Indonesia and others. The SSC meeting, held in October 2018, focused on identifying and prioritizing unmet needs by disease field in the countries of Asia that should be addressed in the short and medium term. Working with local doctors, Santen will expand these activities as we pursue the development of ophthalmology in line with individual regional needs.

#### **EMEA Business**



#### **Business Strategy**

The EMEA market for prescription ophthalmic pharmaceuticals is the second largest after the U.S. The market is characterized by its diversity—each country in the region has a different health system and different medical treatment practices, and the maturity of each market also varies. Santen is working to align its business in the region with the specific characteristics and needs of each country in conjunction with enhancing our organizational management systems.

Santen markets several treatments for glaucoma in the EMEA region, starting with *Cosopt*, acquired from Merck & Co., Inc. *Taflotan/Saflutan*, a key product driving our global business expansion, is available in approximately 40 countries in the region. We also offer *Taptiqom*, a combination ophthalmic solution launched in 2015, and

preservative-free eye drops to meet the needs of patients in the EMEA region. In 2018, we began sales of *PRESERFLO MicroShunt*, a medical device for minimally invasive treatment of glaucoma. In the dry eye field, *Ikervis* was launched in 2015 as a treatment for severe keratitis stemming from dry eye, part of an effort to expand development in the regions where we undertake business.

In addition to expanding our product portfolio in the EMEA region, we are moving to strengthen our global product supply system. In 2018, we established an operation center in Almere in the Netherlands which will handle supply chain management for the entire EMEA region. We will continue working to offer a more reliable and efficient supply of products.

#### **Business Performance**

Revenue from the EMEA business increased 3.3% year on year to ¥36.2 billion in fiscal 2018. Focusing on providing medical information and other efforts toward activities that get closer to current needs on the ground, we worked to increase market penetration for products such as *Taflotan/Saflutan* and other glaucoma treatments, and *Ikervis*.

#### **Challenges in the Glaucoma Surgical Field**

PRESERFLO MicroShunt is a minimally invasive surgical device developed in the U.S. by InnFocus, Inc. (a subsidiary) for the treatment of primary open-angle glaucoma (POAG). This represents a new approach to treating glaucoma, an area Santen has been involved in for many years and is also a new challenge in the surgical market in the EMEA regions.



In the EMEA business, we are providing opportunities to practice surgical techniques that use *PRESERFLO MicroShunt* for ophthalmologists specializing in glaucoma from various European countries. We continue to implement activities such as lectures by doctors with extensive surgical experience with *PRESERFLO MicroShunt*, demonstrations of the actual techniques, and question and answer sessions.

## **Corporate Social Responsibility (CSR)**

We will fulfill our responsibilities as a specialized ophthalmic pharmaceutical company, with the aim of further contributing to ophthalmic treatment around the world.

#### CSR Basic Policy

- Guided by Santen's Values "Tenki ni sanyo suru"<sup>1</sup>, Santen Group strives to continue our contribution to society through improving QOL of patients around the world by conducting business activities which provide valuable products and services.
- In a highly ethical manner, we conduct business activities in compliance with applicable laws and international norms, and fulfill our social responsibilities, together with our business partners.
- 1. 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."

## Contributing to Eye Health Worldwide and the Achievement of a Sustainable Society Through Business Activities

Santen positions contributions to society through its business as the central focus of its social responsibility. As a specialized ophthalmic pharmaceutical company, we develop products that can fulfill unmet needs in ophthalmology, and provide products, services and information that can fulfill needs specific to individual countries and regions. We believe that our responsibility as a specialized ophthalmic pharmaceutical company requires us to improve access to treatment by providing affordable drugs to patients who otherwise could not receive ophthalmic treatments for economic reasons, in addition to supporting the widespread adoption of ophthalmic treatments around the world including emerging countries, and develop orphan medicinal products. In carrying out such business activities, we will comply with both legal regulations and international norms in a highly ethical manner, fulfilling our social responsibilities by addressing

issues concerning fair business, human rights, labor, occupational health and safety, the environment, good corporate citizenship and stakeholder engagement.

## Framework to Promote Further Enhanced CSR Activities Across the Santen Group

Santen has established a CSR Committee, which comprises the Santen President and COO as Chair and corporate officers in charge of relevant divisions. Based on Santen's Values, the CSR Basic Policy, the Group's strategies and various social issues, the CSR Committee sets CSR-related policies and targets for the entire Group and monitors the progress of our CSR activities.

Under the leadership of the CSR Committee, we have the Environment, Health and Safety (EHS) Committee in Japan, which comprises the managers of our large-scale business facilities, including plants and research center, and three subcommittees dedicated, respectively, to environmental conservation, health and safety, and fire and disaster risk management.



Fair Business	Comply with laws, regulations, and fair business practices applicable to the countries and territories where we conduct business activities, and work against corruption in all its forms.	
Human Rights	Respect and protect the human rights of all people, including patients and employees.	
Labour, Occupational Health & Safety	Secure the rights and safety of people engaged in our business, promote their better health, and maintain and improve their workplace environments.	
Work on preventing environmental pollution, reducing environmental loads, and utilizing resources effectively.     Strive to protect and preserve the planet in a sustainable manner.		
Good Corporate Citizen	Act as a good corporate citizen to develop medical care and welfare in the ophthalmic field through our business, and to build trust relationships with related communities and contribute to their development.	
Stakeholder Engagement	Actively disclose information about our business activities and have meaningful dialogues, to understand the expectations of stakeholders and reflect them in our efforts.	

#### **Initiatives to Address Priority Issues**

To enhance our global CSR activities, we have been currently focusing on the four priority issues noted below.

#### **Promotion of Group-Wide Mutual Education**

We establish and conduct group-wide mutual educational programs so that all Santen employees can share the same understanding of the Santen Group's essential values and philosophy, represented by Santen's Values and the Santen Code of Practice, and act in a highly ethical manner.

#### **Promotion of Diversity**

With the belief that human resource diversity is essential to a robust organization, we promote diversity based on a full understanding of the realities in the countries and regions where we operate, and work to further enhance our working environment to ensure that diverse personnel can demonstrate the full extent of their abilities.

#### **Efforts to Address Environmental Issues**

To take on environmental issues such as climate change, we are currently working to achieve the environmental targets set for FY2020. We have also begun to set new medium-term targets for 2030 from a longer-term perspective.

#### Involvement of Business Partners in CSR Promotion

In addition to requiring both ourselves and our suppliers to ensure social responsibility in the areas of legal compliance, ethical conduct, environmental preservation and employee health and safety, we are working to build sound relationships with those suppliers. At present, we primarily monitor the status of environmental and health and safety measures implemented by our major suppliers, including suppliers of active pharmaceutical ingredients and contract manufacturers. Going forward, we will broaden the scope of suppliers subject to monitoring, and extend the scope of our monitoring to social issues in general, including human rights and labor issues.

#### **Participating in the United Nations Global** Compact

In October 2017, we announced that Santen had joined the UN Global Compact, Santen intends to support and practice the ten principles of the UN Global Compact in the four areas of human rights, labour, environment, and anti-corruption, which are in line with Santen's Values and



the Santen Code of Practice, in pursuit of a sustainable society.

#### **Efforts to Achieve Sustainable Development** Goals (SDGs)

Santen will continue to contribute to society through its business of providing valuable products and services while striving as a specialized company in the field of ophthalmology to improve access to pharmaceuticals. We will contribute to the achievement of the SDGs adopted by the United Nations, such as Goal 3, to "Ensure healthy lives and promote well-being for all at all ages."































#### **Topics**

#### Santen Included in All Four ESG Investment Indexes Selected by GPIF

Japan's Government Pension Investment Fund (GPIF), the world's largest institutional investor, has selected four environmental, social and governance (ESG) indexes for ESG investment in Japanese companies. These include the FTSE Blossom Japan Index, the MSCI Japan ESG Select Leaders Index, the MSCI Japan Empowering Women Index, and the S&P/JPX Carbon Efficient Index<sup>2</sup>. Santen has been selected as a constituent stock in all four of these indexes. Since 2016, we have also been selected four years in a row for inclusion in the SNAM Sustainability Index, established by Sompo Japan Nipponkoa Asset Management Co., Ltd.

2. (1) FTSE Blossom Japan Index: a broad index incorporating overall ESG considerations based on FTSE Russell, an investment index calculator wholly owned by the London Stock Exchange, (2) MSCI Japan ESG Select Leaders Index; a similar broad index based on MSCI, a U.S. provider of investment indices, (3) MSCI Japan Empowering Women Index (WIN): Another MSCI index targeting companies that excel in gender diversity, (4) S&P/JPX Carbon Efficient Index: Developed by S&P Dow Jones Indices of the U.S. It targets companies that excel in carbon efficiency and other factors.

Further Information ► CSR Website https://www.santen.com/en/csr

#### **CSR Activities through Business** Santen aims to contribute to society by providing valuable products and services.

#### **R&D** to Fulfill Unmet Medical Needs

Santen will promote R&D focused on glaucoma, retinal and uveal disorders, which can cause blindness, and keratoconjunctival disorders, which can be said to lack sufficient treatment globally. We are also working hard to develop new treatment options in refractive disorders.

#### **New Treatment Options that Lead** to Improved QOL for Patients

Santen is working to develop new medical treatment options, such as the world's first anti-glaucoma agent with a mechanism of action and glaucoma surgery devices to reduce the burden placed on patients.

#### Initiatives on Pharmaceuticals for **Orphan Diseases**

Papilock Mini, an orphan medicinal product for treatment of vernal keratoconjunctivitis, is on sale in Japan. In October 2018, vernal keratoconjunctivitis treatment DE-076C (product name: Verkazia) was launched in Europe, and applications will be made in sequence for Asia and other areas.

Further Information ▶ P.20 Feature: Contributing to Global Ophthalmology by Developing New Drugs and Treatment Options P.26 Research and Development

#### Stable Supply of **Ophthalmic Solutions**

To provide a high quality, stable supply of ophthalmic solutions to over 60 countries and regions around the world. Santen has built a global production and supply structure and is building a structure to deal with expansion to even more countries and the future diversification of products other than ophthalmic solutions.

#### **Meticulous Attention** to Quality

Santen maintains safety, efficacy and homogeneity in the manufacturing process in our main area of ophthalmic solutions by insisting on water with high purity equivalent to that used in injections, high purity air equivalent to that used in surgical environments, and the training and development of people to conduct our rigorous quality management.

#### **Product Supply**

#### **Research and Development**

#### **Quality Compliance**

#### **Prevention of Medical Mistakes**

To prevent confusion between different ophthalmic solutions, Santen is working to make improvements including clearly identifiable packaging and information labels on containers. For example, for ophthalmic solutions available in various concentrations with the same active ingredients, we provide highly visible information about the concentration on the shrink label covering the solution container as well as on the top of the cap.





Examples of labeling for ophthalmic solutions available in various concentrations with the same active ingredients (Side and top surface labels)

# Production Site for Improving Access to Pharmaceuticals

To provide quality prescription ophthalmic pharmaceuticals at appropriate prices to even more patients, Santen founded Chongqing Santen Kerui Pharmaceutical Co., Ltd., a joint venture with China's state-owned Chongqing Kerui Pharmaceutical (Group) Co., Ltd., in August 2016 and is currently constructing a manufacturing plant.

# **Raising Disease Awareness**

We will continue to raise disease awareness and encourage correct recognition and understanding of ophthalmic disorders. Through these efforts, we strive to increase QOL for as many patients as possible with early identification and treatment. In Asia, we support lectures by ophthalmic facilities for the general public on glaucoma and free screenings, while in Europe we work together with the World Glaucoma Association to disseminate information to the media. In Japan, we provide medical institutions with program packages to support continued medical treatment.

# Initiatives to Enhance and Develop Ophthalmic Treatment

Santen is continuing initiatives to enhance diagnosis and medical treatment in countries and regions around the world, such as offering training for young ophthalmologists to create environments for patients to receive optimal medical treatment. In Asia, we conduct workshops with patients in attendance to enhance young doctors' knowledge and skills in diagnosis and treatments.

# **Support for Academic Associations and Joint Sponsorship of Seminars**

To enhance the medical treatment environment for patients, Santen supports academic associations in Japan and overseas, such as the World Ophthalmology Congress (WOC), the Asia-Pacific Academy of Ophthalmology (APAO), and the Japanese Ophthalmological Society, and hold joint seminars with those academic associations in which we provide medical professionals with information about the latest research and treatment trends in the field of ophthalmology. Further Information ► P.17 Topics

# Sales and Marketing

# Measures against Counterfeit Medicines and Other Quality Compliance Measures

Santen is promoting measures to ensure traceability<sup>1</sup> and address Good Distribution Practice (GDP), aiming to ensure pharmaceutical product quality during storage and transportation, manage products appropriately, and take measures against counterfeits. In Japan, by the end of March 2021 we will display barcodes on product boxes and transportation packaging indicating product codes, serial numbers and expiration dates.

 Traceability: The ability to track and identify the distribution channels for pharmaceutical products from manufacture to consumption.

# Obtaining Information for Pharmacovigilance

Santen has established internal procedures to ensure that safety information such as side effects is reported quickly and accurately as soon as it is obtained by the department in charge of safety management, and then shared with the relevant departments in Santen. We have also built a system for pharmacovigilance globally to ensure safety and reliability.

Further Information ► CSR Website https://www.santen.com/en/csr

# **CSR Activities**

# Santen will carry out its social responsibilities in a highly ethical manner and in compliance with laws and international norms.

## **Fair Business**

# **Initiatives to Prevent Corruption**

The Santen Code of Practice, which sets out how individual employees are to conduct themselves clearly prohibits bribery and other such activities as follows: "We do not engage in any conduct regarded as bribery or corruption, whether directly or through a third party, that would violate the applicable laws and regulations of the relevant country, including those applicable to other countries." We conduct regular training to promote employee understanding about prevention of corruption in all its forms, including extortion, bribery, and conflict of interest. There were no incidences of corruption in all its forms including bribery, nor cases requiring legal measures be taken in fiscal 2018.

# **Supplier Management**

We aim to fulfill our social responsibilities throughout the entire production and supply of pharmaceuticals, including our suppliers. In fiscal 2018, we found no issues after conducting checks of 28 major suppliers, including pharmaceutical ingredient suppliers and outsourced manufacturers.

# **Human Rights**

# **Initiatives on Respecting Human Rights**

In accordance with the Universal Declaration of Human Rights, the ILO Conventions, the UN Guiding Principles on Business and Human Rights, other international norms, and the spirit behind them, Santen believes in the importance of respecting the rights of each of its employees and acting with the highest ethical standards, and is working to diffuse understanding of these issues through training. In October 2017, we joined the United Nations Global Compact and declared our commitment to support and respect human rights protection, and our commitment not to be complicit in any manner of human rights abuses. The Santen Code of Practice firmly declares, "We do not engage in discrimination against or harassment of individuals based on their nationality, race, skin color, religion, creed, sexual orientation, age, education, family background, place of birth, disability, health problems, social position, etc. We respect individual personalities and do not engage in sexual, moral or any other kind of harassment in the workplace." As global expansion brings increasing diversity to our workforce, we are working to ensure each employee is familiar with and can put our beliefs into practice by translating the Santen Code of Practice into 13 languages. We also carried out global compliance e-learning to promote understanding during an awareness month held in November 2018.

## Labour, Occupational Health & Safety

# **Promoting Diversity**

Santen is working to build an organization that enables employees with different professional and cultural backgrounds to maximize their abilities, regardless of change in life-stage, gender, nationality or presence of disability, with full respect for the diverse values of our employees, and to develop human resources who are able to carry out our work. We also provide our employees with equal opportunities for compensation without discrimination. The ratio of women in the Company is at 42%, and the ratio of female managers is at 33% as of March 31, 2019. We have also accelerated globalization of businesses, with the ratio of overseas employees at 51% as of March 31, 2019, and the number of executive directors employed is also increasing.

#### Number of Employees by Region



## **Health and Safety Management**

We implement a health and safety management system aiming to achieve zero occupational accidents. In fiscal 2018, there were no work-related fatalities across all regions (including contract and temporary employees).

#### **Environment**

# **Environmental Management**

Santen has implemented an environmental management system aimed at realizing a low-carbon, recycling society and we are working to reduce our emissions of greenhouse gas (CO<sub>2</sub>) and waste, as well as our water usage and so forth. The Noto and Shiga operational sites have acquired certification in ISO 14001 for international standards environmental management systems, and conduct environmental audits. The Suzhou Plant in China also acquired ISO 14001 certification and began operations in February 2019. In fiscal 2018, the Group had no environmental accidents that impact the local community, soil, groundwater, or other aspects. There was no deviation of laws, ordinances, etc. that required reporting to the authorities.

# **Climate Change Countermeasures**

The volume of greenhouse gas (CO<sub>2</sub>) emissions in fiscal 2018 in terms of emissions per unit of revenue on a consolidated basis was 146 tons per billion yen, down 32% from fiscal 2014. Our Scope 3<sup>1</sup> emissions in Japan for fiscal 2018 per unit of revenue on a non-consolidated basis were 989 tons per billion yen, up 0.4%, which is about the same level as in fiscal 2016.

 CO<sub>2</sub> emissions across the supply chain including factors such as purchase of raw materials, product distribution, and employee transportation.

# **Reducing Our Environmental Impact**

Final waste disposal volume in fiscal 2018 per unit of revenue on a consolidated basis was 1.1 tons per billion yen, an increase of 366% from fiscal 2014 due to the one-off effects caused by the disposal of residual devices from the sale of the old headquarters and Osaka Plant.

# Conservation of Water Resources and Biodiversity

Water usage in fiscal 2018 in terms of usage per unit of revenue on a consolidated basis was 2.4 thousand m3 per billion yen, a decrease of 25% from fiscal 2014. We also engaged in forest protection activities that help to preserve biodiversity.

#### Per Unit of Consolidated Revenue

	FY2014	FY2018	Rate of change
CO <sub>2</sub> emissions (ton/billion yen)	214	146	-32%
Volume of waste for final disposal (ton/billion yen)	0.3	1.1	+366%
Water usage (thousand m³/billion yen)	3.2	2.4	-25%

# **Good Corporate Citizen**

# **Initiatives as a Good Corporate Citizen**

In addition to enhancing welfare and medical advancements in the ophthalmic field through our business, Santen is also working to build trust with the communities associated with the ophthalmic field and contribute to development, in accordance with Santen's Values. Santen provides grants to research institutions such as universities and academic associations, mainly in the field of ophthalmology, and also makes ongoing donations to organizations involved in activities to raise disease awareness and prevent loss of vision. In fiscal 2018, the total amount of consolidated donations was ¥617 million, which is equivalent to 1.3% of the core operating profit.

# **Support for Improving Access to Healthcare in Developing Countries**

Santen supports the training of those working in ophthalmology in developing countries, helping to alleviate a shortage of ophthalmologists and train ophthalmologists in China. We also provide free pharmaceuticals, intraocular lenses, and other supplies to organizations working to promote ophthalmic treatment in developing countries.

# **Supporting Sports for the Visually Impaired**

Santen supports sports for people with visual impairment to increase understanding of ophthalmic disorders and to foster an awareness of patient perspectives among employees. In Japan, Santen has partnered with the NPO Japan Blind Football Association in activities which allow visually-impaired children who have few opportunities to exercise to engage in sports, as well as supporting diversity education programs for elementary and junior high school students.



Santen Pharmaceuticals Blind Soccer Junior Training Camp 2019

Further Information ► CSR Website https://www.santen.com/en/csr

# **Corporate Governance**

Santen will continue to enhance and strengthen its corporate governance in order to promote business activities based on Santen's Values.

# **Overview of the Corporate Governance System**

# **Basic Views on Corporate Governance**

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

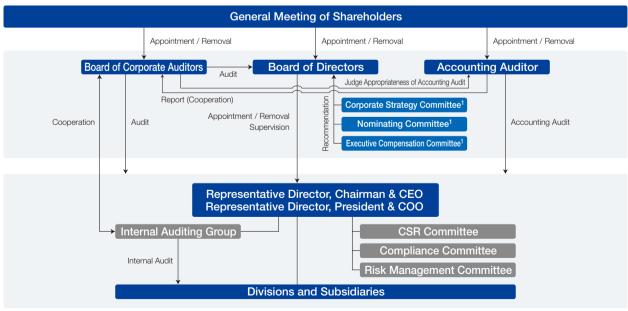
Santen has adopted a "Company with a Board of Company Auditors" system as defined in Japan's Companies Act. Santen will continuously be working to upgrade and strengthen corporate governance by making the most of the current system.

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 management 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 made up of Inside and Outside Directors, and introducing a corporate officer system to strengthen management and improve the speed of business execution. Santen will go forward with the aim of improving management transparency and objectivity.

Corporate Auditors audit the Board of Directors and executive sections by utilizing the Corporate Auditor's Group or 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.

# Santen Internal Governance System (As of June 2019)



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

# **Status of Management Supervision Structure**

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 appropriate number of members. Moreover, Santen has appointed Corporate Auditors with the expertise necessary to properly perform audits from an academic, legal, and accounting perspective. To promote meaningful discussions at Board of Director Meetings, materials for the meetings and the relevant information are provided to the Outside Directors and Outside Corporate Auditors in advance followed by sufficient explanations concerning the background, purpose and details of the agenda of said meetings.

To improve the functions of the Board of Corporate Auditors, each Corporate Auditor regularly attends Board of Directors meetings, exchanges opinions with Chairman, President and

Outside Directors, and conducts interviews with executives and site visits at Group companies in Japan and abroad.

Furthermore, the voluntary committees serve a variety of purposes respectively: the Corporate Strategy Committee aims to deliberate on key strategic issues such as business strategies; the Nominating Committee aims to deliberate on the selection of candidates for Directors and submit recommendations therefor, as well as to provide advice in response to consultations concerning the selection of candidates for Corporate Officers and Corporate Auditors; the Executive Compensation Committee sets compensation policies and designs the compensation system (such as setting performance targets, determining the rationality of performance-based compensation, appropriateness of standards and composition of remuneration, the amount of compensation in accordance with the system, etc.)

#### Corporate Governance Meeting Composition (As of August 2019)

Position	Name	Board of Directors	Board of Corporate Auditors	Corporate Strategy Committee	Nominating Committee	Executive Compensation Committee
	Akira Kurokawa	0		•	0	0
	Shigeo Taniuchi	0		0	0	0
D'andre	Takeshi Ito	0		0		
Directors	Kanoko Oishi Outside Director	0		0	0	0
	Yutaro Shintaku Outside Director	0		0	•	•
	Kunihito Minakawa Outside Director	0		0	0	0
	Masashi Murata	0	0			
Corporate	Yasuyuki Miyasaka Outside Corporate Audi	or O	0			
Auditors	Hirofumi Yasuhara Outside Corporate Audi	or O	0			
Yum	Yumiko Ito Outside Corporate Audi	or O	0			
Meetings	held (April 2018 – March 2019)	17 times	10 times	4 times	5 times	8 times

Chairpersons of voluntary committees

# Attendance of Outside Directors and Outside Corporate Auditors (from April 2018 to March 2019)

Position	Independent Officers	Attendance at Board of Directors Meetings	Attendance at Board of Corporate Auditors Meetings
	Kanoko Oishi	17 out of 17 meetings	_
Outside Directors	Yutaro Shintaku	17 out of 17 meetings	-
	Kunihito Minakawa	14 out of 14 meetings (Appointed June 2018)	-
Outside	Yasuyuki Miyasaka	14 out of 14 meetings (Appointed June 2018)	7 out of 7 meetings (Appointed June 2018)
Corporate	Hirofumi Yasuhara	— (Appointed June 2019)	— (Appointed June 2019)
Auditors	Yumiko Ito	— (Appointed June 2019)	— (Appointed June 2019)

# Reasons for Selecting the Current Corporate Governance System

Santen'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 the Company to have objective audits by Corporate Auditors who are in independent positions from the execution of 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, etc. will contribute to the strengthening of the current corporate governance system. As a material management matter, Santen commits to continuously reviewing the improvement and strengthening of said system.

# Policy for Appointing Directors and Corporate Auditors

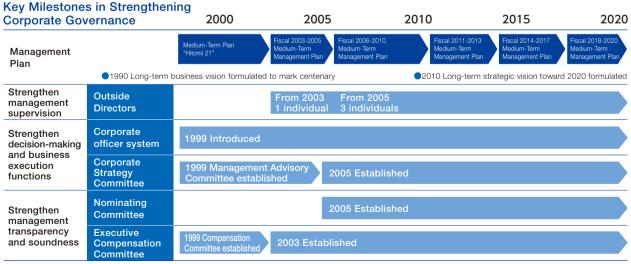
For Directors, the Nominating Committee deliberates on the candidates for Director positions. Based on the results of deliberations, the committee then recommends the candidates to the Board of Directors, which determines the actual nominees. In terms of deliberation by the Nominating Committee, the guiding principle for the selection of Inside Directors is that the nominees must have credentials such as superb expertise, ability to participate in decision-making from a managerial standpoint, and supervise execution of duties, in addition to an understanding of Santen's Values and the underlying ethos. Furthermore, Outside Directors must have credentials such as being capable of contributing to improving the quality of discussions in the Board of Directors, with

experience in managing companies or a specialized understanding of corporate management. They must also satisfy the criteria of independence established by the Company.

The Nominating Committee also discusses the recommendation of candidates for Corporate Auditor positions. Those who have been recommended as a candidate will be determined as actual nominees at the Board of Directors after obtaining consent from the Board of Corporate Auditors. Upon consent by the Board of Corporate Auditors, the guiding principles for judgement are that each nominee must have credentials such as having ethical values and a sense of fairness, in addition to an understanding of Santen's Values and the underlying ethos, while being experienced in performing high-level duties in any field. For Outside Corporate Auditors, each nominee must have credentials such as being experienced in academic, legal, accounting, or management as well as an abundance of experience and expertise in their field. Outside Corporate Auditors must also satisfy the criteria of independence established by the Company.

# **Ensuring Independence of Outside Directors and Outside Corporate Auditors**

Santen has made a concerted effort to nominate Outside Directors and Corporate Auditors, with Outside Directors serving on its Board since June 2003. In a bid to strengthen and enhance management supervision functions, a number of highly independent Outside Directors and Outside Corporate Auditors have been appointed. All of its Outside Directors and Outside Corporate Auditors satisfy the requirements of independent officers as defined by the Companies Act and the Tokyo Stock Exchange, and are registered with the Tokyo Stock Exchange.



For details on the criteria of independence and the reasons for selecting Outside Directors or Outside Corporate Auditors, please refer to Corporate Governance Report on the Company's website.

# **Director and Corporate Auditor Compensation**

Santen is not a "Company with a Nominating Committee, etc.," as defined in Japan's Companies Act, however it has set up an Executive Compensation Committee as one of its voluntary committees. This committee appoints an Outside Director as the chair with a majority of Outside Directors, and makes recommendations and deliberates on policies for compensation received by Directors, Corporate Auditors, and Corporate Officers. The Executive Compensation Committee has determined the basic policies as follows.

- Ensure effectiveness that contributes to Santen's sustainable growth and enhancement of mid-and-long term corporate value to enable them to be engaged in the achievement of Santen's vision and the medium-term management plan with high motivation;
- 2. Deepen the sharing of values with shareholders;
- Objectiveness is secured through a highly transparent process for making decisions on remunerations to ensure high accountability to stakeholders;
- 4. Provide a competitive level of compensation capable of recruiting outstanding human resources; and
- Appropriately encourage the Target Directors to fulfill their respective functions in executing duties and supervising.

# **Director Compensation**

Director compensation (excluding Outside Directors) consists of a fixed basic compensation, an annual bonus tied to Company performance and individual evaluation, and stock-linked remuneration. Of these, stock-linked remuneration was introduced following passage of a resolution at the Annual General Meeting of Shareholders held on June 26, 2018 with the purpose encouraging Directors of Santen, excluding Outside Directors, to proactively engage in achieving Santen's vision and strategy and to promote the further sharing of value with shareholders so that it contributes to Santen's continuous growth and the improvement of corporate value on a medium- to long-term basis. Stock-linked remuneration comprises of "Performance Share Units (PSU)," a performance-linked stock remuneration system that is linked to the achievement rate of numerical targets or the like during a

Compensation Structures

Annual incentives

Annual bonus

Performance-linked remuneration

Performance-linked remuneration

Possible Properties

Performance-linked remuneration

Performance-linked remuneration

certain performance evaluation period, as well as a "Restricted Stock-Linked Remuneration system (RS)," stock-linked remuneration with a transfer restriction that is lifted by satisfying conditions such as holding the target Director position continuously for a certain period. PSU is decided through a stock issuance rate on a scale of 0% to 200% that responds to revenue growth rate, core operating profit margin, and full ROE related to achievement of targets in MTP2020. Assuming basic compensation is at a ratio of 1, annual bonuses and stock-linked remuneration are typically at 0.25 and 0.5 respectively.

Compensation for Outside Directors, who are independent from business execution, consists only of fixed monthly compensation, decided in reference to the results of pharmaceutical company benchmarks. An allowance is paid to the Outside Director who serves as the chair of a voluntary committee, including the Executive Compensation Committee.

# **Corporate Auditor Compensation**

Compensation for Corporate Auditors consists only of fixed monthly compensation, decided in reference to the results of pharmaceutical company benchmarks and in accordance with recommendations from the Executive Compensation Committee through consultations with the Corporate Auditors. Performance-linked remuneration is not paid stemming from the perspective of encouraging proper demonstration of Corporate Auditors' auditing functions.

# **Process to Determine Compensation**

For Director compensation, payment totals for each different type of compensation and individual payment amounts are determined within the scope of each compensation as per resolutions of the General Meeting of Shareholders by the Representative Director as part of the Board of Directors, and upon deliberation by Executive Compensation Committee.

The total amount of Corporate Auditor compensation and individual payments is determined pending consultation with Corporate Auditors and within the scope of Corporate Auditor compensation limits as per resolutions of the General Meeting of Shareholders.

Santen also established the Executive Compensation Committee as an advisory body of the Board of Directors so that it can strengthen the capabilities of the supervisory functions of the Board of Directors and fulfill accountability, along with guaranteeing independence and objectivity in deliberations and determinations on basic policies on compensation for the Board of Directors, the compensation system, levels of compensation, and other matters.

For details on resolutions by the General Meeting of Shareholders on Director and Corporate Auditor compensation, please refer to the Corporate Governance Report on the Company's website.

# Limits on Director and Corporate Auditor Compensation

At the Annual General Meeting of Shareholders held on June 26, 2018, a resolution was passed that limited compensation for Directors (excluding Outside Directors) to ¥600 million and ¥100 million per year in regard to those Directors applicable for the PSU system or the RS system. At that same Annual General Meeting of Shareholders, a resolution was passed that compensation for Outside Directors is limited to ¥60 million per year. At the Annual General Meeting of Shareholders held on June 27, 2006, it was decided that compensation for Corporate Auditors would be limited to ¥80 million per year.

# Analysis and Evaluation of the Board of Directors' Effectiveness

For the purpose of improving the roles and functions of the Board of Directors, Santen assesses the overall effectiveness by implementing surveys for Directors and Corporate Auditors, and individual interviews for Outside Directors and Corporate Auditors. Based on those results, we carry out evaluations and improvements each year toward effectiveness of the entire Board of Directors.

With "further strengthening discussions from the viewpoint of risk management" recognized as an issue for improvement in fiscal 2017, Santen enhanced

discussions about risks by creating materials that clarified risks associated with important matters in terms of regular monitoring of investment projects and important investment projects decided at previous Board of Directors meetings and provided explanations for those materials.

The evaluation for fiscal 2018 determined that the Board of Directors is functioning efficiently. Furthermore, the Board of Directors was found to have facilitated a culture of incorporating the opinions of Outside Directors and Outside Corporate Auditors, and is engaging in free and open discussions. By having the Outside Directors and Outside Corporate Auditors visit business locations inside and outside Japan and participate in operating division meetings, the Company is providing them with information that fosters deeper understanding of business activities.

Further improvement of the Board of Director's role and functions is integral to sustainable growth in our businesses. We recognize that points we should strengthen are focused on monitoring of strategic projects and ascertaining capital costs in particular, and we strive to maximize shareholder and corporate value by further deepening the quantity of these discussions. Moreover, as Santen increases the diversity of the organization and employees in line with globalization of business development, we are considering how to provide opportunities to clearly understand each organization's activities and the comprehension and permeation of Santen's Values for the Board of Directors.

## Director and Corporate Auditor Compensation (Fiscal 2018)

Position	Total Compensation	Total C	Number of			
Position	(Millions of Yen)	Fixed Compensation	Annual Bonus	PSU	RS	Eligible People <sup>1</sup>
Directors (Excluding Outside Directors)	247	169	29	25	23	4
Corporate Auditors (Excluding Outside Corporate Auditors)	27	27	_	-	-	1
Outside Directors	43	43	_	-	-	4
Outside Corporate Auditors	36	36	-	-	_	4

<sup>1.</sup> The number of applicable Directors is the total number of Directors who were appointed during this fiscal year (including those who resigned within the fiscal year).

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

# Addressing the Corporate Governance Code

Santen implements all of the principles of the Corporate Governance Code of the Tokyo Stock Exchange. 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 discloses the policy on its corporate website.

# **Internal Controls**

# **Development of the Internal Control System**

In accordance with Japan's Companies Act and the Ordinance of Enforcement of the Companies Act, Santen 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.

# Compliance

# **Global Compliance Framework**

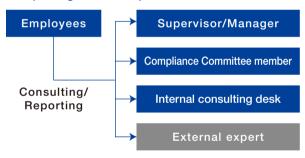
Santen has established a Compliance Committee to promote compliance activities that address globalization. We regularly hold meetings of the Global Compliance Committee, which bring together executives in charge of regions and functional organizations, and Global Meetings of Compliance Administrators, which are attended by in-house compliance administrators in charge of regions and functional organizations.

In fiscal 2018, the Santen Group was not involved in any serious law violations nor litigation.

# **Compliance Consulting & Reporting Desk**

Santen has made it easier for all employees, including contract workers and temporary workers, to consult and report on suspicious actions related to compliance by establishing internal consulting and reporting desks that respond in various languages in its operating countries and regional bases. Additionally, Santen has established external helplines through external third-parties such as lawyers that receive reports anonymously in nearly all of the countries where it develops business. Incoming consultations and reports are appropriately investigated and addressed in a sincere manner, while also being relayed to levels of management regularly. The Compliance Rules that are applied to all Group companies stipulate that there must be adequate measures in place to protect internal whistleblowers in each region.

# Example of Compliance Consulting & Reporting Desk in Japan



For details, please refer to the Corporate Governance Report on the Company's website. https://www.santen.com

# **Risk Management**

Santen has designated crisis report regulations for officers and employees to report to the Crisis Management Secretariat directly if there is a possibility that an incident could become a major crisis. At the Risk Evaluation Committee, which acts in accordance to these crisis management regulations, committee members discuss risk management policies and countermeasures for when a risk incident occurs. Depending on the degree of impact on the Company, an incident may trigger the operation of the Crisis Response Committee headed by a representative director, which will coordinate efforts to minimize any losses or damages and ensure a quick recovery, and institutes

measures to prevent a recurrence. Furthermore, the Risk Management Division serves as a system to manage risks in normal circumstances, and conducts risk assessments every two years to comprehensively ascertain risks facing the Group as a whole, including corruption that infringes on human rights or the use of bribery in addition to risks in production and product quality. In the assessment implemented in collaboration with an outside investigative company in fiscal 2017, it was confirmed that there were no major compliance violations nor misconduct, and that the corporate culture and environment to prevent such incidents was largely satisfactory.

# Key Risks and Status of Response

Matters Assessed	Specific Anticipated Risks	Status of Response
Global Compliance	Risk of decline in compliance awareness due to an inadequate global compliance framework	In conjunction with the progress on the globalization of business activities, we are working on a global level to enhance, develop and administer internal controls, strengthen compliance, and develop a risk management promotion framework in each country.  Please refer to Page 36 for details on initiatives to prevent corruption and Page 43 for details on compliance.
Production/ Supply related	Risk of stagnation in global production and supply     Risk of delayed deliveries due to an increasingly complex supply chain and inaccurate demand forecasts	Having a stable supply of products is one of the missions that pharmaceutical companies should fulfill for patients. Santen has positioned strengthening the global product supply framework as one of its important strategies, and the Company is working to expand the countries it provides products to and construct a framework to respond to a future increase in various products aside from ophthalmic solutions. In addition to establishing processes and systems to ensure a stable supply, Santen is continuously assessing the current state of affairs and addressing issues through initiatives such as monitoring planning and execution, and evaluating risks.  Recently, Santen has also been undertaking initiatives globally in manufacturing and supply systems for quality products that respond to strict regulations related to logistics in Europe, as well as visualizing and centrally managing inventory management, including production plans.
Research and Development related	•Risk of decline in reliability of R&D-related data	Santen is committed to carrying out appropriate R&D, and to ensuring the reliability of R&D data. The Company also addresses the risks of data manipulation or fabrication, as well as the concealment of facts.  Along with establishing an implementation process and procedure manual for R&D, we are continually providing training and education to improve the reliability of R&D data to employees involved in R&D. Another division specializing in guaranteeing reliability also conducts quality checks of R&D data.  In addition, the Research Ethics Committee, which includes outside medical experts and lawyers, checks the appropriateness of research from an ethical perspective. We also thoroughly inform employees about the obligation to report safety information, and we have put in place a system to gather such information.  When selecting contract research organizations (CRO) and other vendors, we choose organizations that satisfy certain criteria, and make sure that vendors comply with the processes and procedures set forth by Santen.
Information Security related	Risk of information leaks and/or system stoppage due to a cyberattack, etc.	In recent years, there has been an increase in cyberattacks and other information security threats. We are working to protect personal information and other information, and to strengthen our system to ensure that the systems remain in operation.  As an information management framework, Santen conducts both technological and physical protection as well as training, based on internal rules for information security and document management.  We have formulated a roadmap for countermeasures based on information security risk analysis that also includes threats other than IT related threats, and each year we review the status of achieving those countermeasures and make necessary revisions. In addition to continuously incorporating the latest security technologies and trends, we regularly conduct vulnerability audits in order to grasp the current situation and promote countermeasures. We have put in place procedures and a BCP to make the IT system more robust, and minimize impacts in the case of an emergency.

# Messages from Outside Director and Outside Corporate Auditor



Kanoko Oishi Outside Director

# **Contributing to Eye Health for All!**

This will be my fifth year as an Outside Director for Santen. People often address me as an executive officer for Santen, and what has especially left an impact on me is the immense trust that ophthalmologists have in Santen and its strong branding power. With Santen's Values embodied in the phrase "Tenki ni sanyo suru" and the mission to contribute to the well-being of patients, their loved ones and consequently to society, Santen is clearly committed to results.

I believe that Santen's Values and Mission Statement will be the keys to its future. While trust from ophthalmologists is a great asset, it is necessary to keep patients at the center of the Company's focus. We must not forget the existence of those who are likely to become patients in the future.

There are many people in the world who do not or cannot receive treatment even though they suffer from an eye disease, or do not realize they have an eye disease. We strive to capture these missed treatment opportunities and achieve eye health for everyone. We want to convey and carry out all sorts of activities related to global eye health to close this treatment gap, and I believe that these activities will increase Santen's value in a sustainable manner. As an Outside Director, I will continue to support Santen as it takes on challenges while contributing to appropriate decision-making for the benefit of patients and other stakeholders.



Hirofumi Yasuhara
Outside Corporate Auditor

# **Toward Healthy Growth for the Company**

I was appointed as an Outside Corporate Auditor at the shareholders meeting in June 2019. As a package of reforms in regulations for corporate governance has recently been put into place in Japan, there has been a significant uptick in social concerns regarding fairness and transparency in the operations of listed companies. In this context, it is necessary for us Corporate Auditor to report to the stakeholders what we have found through the audit more promptly, accurately, and precisely than ever. My first impression of Santen was, as shown in its name, its commitment to Santen's Values.

Santen's Vision which embodies these Values has also clearly stated that it contributes to society in the field of ophthalmology. With activities that coincide with Santen's Values and Mission, the Company is demonstrating steady financial results, particularly with a focus on overseas markets.

However, as it successfully expands its business, every company inevitably faces various risks of internal control, managerial inefficiency, and ineffectiveness, including operational misconduct. I hope I will contribute to Santen overcoming these challenges so that it will stay on the right track toward becoming a "Specialized Pharmaceutical Company with a Global Presence."



Yumiko Ito
Outside Corporate Auditor

# **Addressing Diversity and Governance**

For a company to grow sustainably, it must work to make an even greater contribution to solving social issues through its business. As the number of eye disease patients worldwide continues to grow, Santen's efforts to accelerate its global expansion as a specialized company in the ophthalmology field not only answers society's demand for further contributions to ophthalmology worldwide, but will lead to improved corporate value.

I believe the key to this global expansion is addressing diversity. Patient needs are regionally diverse, and regulations and social norms vary with different historical and cultural backgrounds. Diversity needs to be recognized and handled appropriately in terms of compliance and other so-called "defensive" aspects of business activity.

I think that Santen has a corporate culture that recognizes and incorporates diversity. The Board of Directors consists of individuals with various experiences and specializations, and the members of the Board share a belief that candid discussions lead to the creation of new value. At Santen, for which addressing diversity will be the key to success, I will actively participate as an Outside Corporate Auditor in discussions of the Board, thereby playing a part in the company's global growth and the contributions it can make to ophthalmology worldwide.

# **Directors**



# Corporate **Auditors**









## 1 Akira Kurokawa

Chairman and Chief Executive Officer

1977 Joined the Company

1977 Director, General Manager, Head of the Office of Sales and Marketing Division, Prescription Pharmaceuticals

2001 Corporate Officer, Head of Sales and Marketing Division, Prescription Pharmaceuticals

2004 Senior Corporate Officer, Head of Sales and Marketing Division, Prescription Pharmaceuticals

2006 President & COO

2008 President & CEO

2018 Chairman & CEO (incumbent)

# Shigeo Taniuchi

President and Chief Operating Officer Head of North America Business

1996 Joined the Company

2015 Corporate Officer, Head of Santen Europe (currently EMEA), and President of Santen Holdings EU B.V.

2016 Senior Corporate Officer, Head of Santen Europe (currently EMEA), and President of Santen Holdings EU B.V. 2017 Director. Senior Corporate Officer. Head of Santen

EMEA, President of Santen Holdings EU B.V. 2018 President & COO Head of Asia Division, President & CEO of Santen Inc.

2019 President & COO

Head of North America Business (incumbent)

## 3 Takeshi Ito

Director, Executive Corporate Officer Head of Japan Business, Head of Japan Sales and Marketing Division Head of Sales and Marketing Division – OTC Products

1982 Joined the Company

2012 Corporate Officer, Head of Prescription Pharmaceuticals Sales Department, Sales and Marketing Division, Prescription Pharmaceuticals

2014 Senior Corporate Officer, Head of Japan Sales and Marketing, Prescription Pharmaceuticals 2016 Executive Corporate Officer, Japan Business, Head of Japan Sales

and Marketing, Prescription Pharmaceuticals
2017 Director, Executive Corporate Officer, Japan Business, Head of

Japan Sales and Marketing, Prescription Pharmaceuticals

2019 Director, Executive Corporate Officer, Head of Japan Business Head of Japan Sales and Marketing Division, Head of Sales and Marketing Division - OTC Products (incumbent)

## Kanoko Oishi

Outside Director

1993 Partner, McKinsey & Company, Inc. 2000 Established Mediva, Inc.

Chief Executive Officer (incumbent)

2000 Established Seinan Mediwa Co., Ltd. (currently, Seeds 1 Co., Ltd.) Representative Director (incumbent)

2004 Established Platanus Medical Corporation, COO (incumbent)

2010 Outside Director, Astellas Pharma Inc.

2015 Outside Director of the Company (incumbent)

2015 Outside Director, Ezaki Glico Co., Ltd. (incumbent) 2015 Outside Director, SURUGA bank Ltd.

2016 External Director, Shiseido Company, Limited (incumbent)

## 5 Yutaro Shintaku

Outside Director

2010 Representative Director, President and CEO Terumo Corporation

2017 External Director, J-OIL MILLS, Inc. (incumbent)

2017 Outside Director of the Company (incumbent) 2017 Corporate Advisor, Terumo Corporation

2018 Outside Director, Kubota Corporation (incumbent)

2018 Visiting Professor, Business Administration, Hitotsubashi University Business School

2019 Project Professor, Business Administration Hitotsubashi University Business School (incumbent)

# 6 Kunihito Minakawa

Outside Director

2010 Outside Audit & Supervisory Coard Member

Ricoh Leasing Company, Ltd. 2013 Audit & Supervisory Board Member, Ricoh Company, Ltd.

2017 Outside Director, Sony Corporation (incumbent)

2018 Outside Director of the Company (incumbent)

# 7 Masashi Murata

Standing Corporate Auditor

1999 Joined the Company 2007 General Manager, Corporate Planning Group

2011 Chief Administrative Office (CAO) Santen Inc.

2014 General Manager, Corporate Auditor's Group

2016 Standing Corporate Auditor (incumbent)

# 8 Yasuyuki Miyasaka 9 Hirofumi Yasuhara

Outside Corporate Auditor

2010 Director of Risk Management and Quality Assurance Office of IFRS Deloitte Touche Tohmatsu LLC

Established Yasuyuki Miyasaka Certified Public Accountant Office and assumed the Head thereof (incumbent)

2018 Outside Director, ITOCHU-SHOKUHIN Co., Ltd. (incumbent) 2018 Outside Corporate Auditor of the

Company (incumbent)

#### Outside Corporate Auditor

2008 Director, PanaHome Corporation

(currently, Panasonic Homes Co., Ltd.) 2012 Representative Director, PanaHome Corporation (currently, Panasonic Homes Co., Ltd.)

2014 Senior Audit & Supervisory Officer, Automotive & Industrial Systems Company, Panasonic Corporation

2015 Senior Audit & Supervisory Board Member

Panasonic Corporation 2019 Outside Corporate Auditor of the Company (incumbent)

## 10 Yumiko Ito

Outside Corporate Auditor

2007 Executive Officer, Microsoft Co., Ltd.

(currently Microsoft Japan Co., Ltd.) 2013 Director, Executive Officer, Sharp Corporation

2014 Director, Executive Managing Officer

Sharp Corporation 2019 Established Ito Law Office

Representative (incumbent)

2019 Independent Director, Kobe Steel, Ltd. (incumbent) 2019 Outside Corporate Auditor of the Company

(incumbent)

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





# ■ Naveed Shams, M.D., Ph.D. 12 Kazuo Koshiji

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

Senior Corporate Officer Corporate Administration Chief Financial Officer (CFO) Head of Finance and Administration Division

# 13 Akio Kimura

Senior Corporate Officer Global Product Supply Head of Manufacturing Division

# 14 Satoshi Suzuki

Senior Corporate Officer Head of Corporate Development Division Head of China Business

# 15 Kenji Morishima

Corporate Officer Head of Pharmaceutics & Pharmacology Department

# 16 Noriaki Yamamoto

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

# **Takahiro Morita**

Corporate Officer Head of Sales Department

# 18 Frank Binder

Corporate Officer Head of Supply Chain Division

# 19 Luis Iglesias

Corporate Officer Head of Santen EMEA Business

# 20 Ken Araki

Corporate Officer Head of Global Business Development

## 21 Isao Takahashi

Corporate Officer Head of Asia Business

# 22 Miki Fujima

Corporate Officer Head of Human Resources Division









# Eleven-Year Summary of Selected Financial Data

				Millions of yen	
	FY2008	FY2009	FY2010	FY2011	
	JGAAP	JGAAP	JGAAP	JGAAP	
For the year:					
Net sales/Revenue	¥101,619	¥110,594	¥110,812	¥114,416	
Cost of sales	35,947	34,710	34,437	35,385	
Selling, general and administrative expenses <sup>2</sup>	31,720	32,121	32,415	35,073	
Research and development expenses	18,458	14,123	13,221	17,225	
Operating profit	15,494	29,640	30,739	26,732	
Core operating profit	_	_	_	_	
Income taxes/Income tax expenses	5,701	9,887	9,741	10,630	
Net income/Net profit for the year	10,123	18,723	21,333	17,161	
Core net profit for the year	_	_	_	_	
Capital expenditures/Payments for acquisition of property, plant and equipment, and intangible assets	2,953	1,315	1,651	3,281	
Depreciation and amortization	4,210	3,421	2,976	2,949	
At year-end:	•		·		
Total assets	¥151,012	¥166,878	¥184,801	¥198,801	
Net assets/Total equity	125,369	137,603	156,404	164,861	
Liabilities	25,643	29,275	28,397	33,940	
Per share data (yen and U.S. dollars):				•	
EPS (Net income - basic/Basic earnings) <sup>3</sup>	¥ 119.08	¥ 220.10	¥ 249.71	¥ 196.96	
Core EPS <sup>3</sup>	_	_	_	_	
Equity/Equity attributable to owners of the company <sup>3,4</sup>	1,472.32	1,614.08	1,793.15	1,887.81	
Cash dividends, applicable to the period <sup>3</sup>	16.00	16.00	18.00	20.00	
Cash flows:					
Net cash flows from (used in) operating activities	¥ 11,849	¥ 26,110	¥ 17,768	¥ 21,483	
Net cash flows from (used in) investing activities	(5,619)	(829)	(7,676)	(10,273)	
Net cash flows from (used in) financing activities	(11,373)	(6,753)	(1,570)	(8,559)	
Free cash flow <sup>5</sup>	8,896	24,795	16,117	18,202	
Interest coverage ratio (times)	165.5	558.1	488.5	1,285.0	
Financial data: ROE (Return (Net income) on equity/Return (Net profit for the year) on equity attributable to owners of the company) (%) <sup>4</sup>	8.0	14.3	14.5	10.7	
Core ROE (%)	_	_	_	_	
ROA (Return (Net income/Net profit for the year) on total assets) (%)	6.6	11.8	12.1	8.9	
Equity ratio/Equity attributable to owners of the company ratio (%) <sup>4</sup>	82.9	82.3	84.5	82.8	
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)	23.0	12.7	13.3	17.9	
Dividend payout ratio (%)	67.2	36.3	36.0	50.8	
Issued shares (thousands)	86,916	86,992	87,053	87,147	
Number of employees	2,690	2,756	2,867	3,053	

<sup>1.</sup> U.S. dollar amounts have been translated from yen, solely for the convenience of the reader, at the rate of ¥110.99 to U.S.\$1.00, the exchange rate prevailing on March 29, 2019. (This date was selected because March 30, 31, 2019 was a non-business day for financial institutions.)

<sup>2.</sup> Research and development expenses are excluded under J-GAAP.

<sup>3.</sup> 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 fiscal 2013 and the subsequent fiscal years are calculated under the assumption that the share split took effect at the beginning of fiscal 2013. Cash dividends, applicable to the period have been retrospectively adjusted to reflect the impact of the share split.

<sup>4.</sup> Equity is calculated by deducting stock subscription rights from net assets under J-GAAP.

<sup>5.</sup> Free cash flow = Net cash flows from operating activities minus capital payments for acquisition of property, plant and equipment, and intangible assets

Γhou	san	ds	01
U.S.	dol	lar	s <sup>1</sup>

							o.o. dollaro
FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2018
JGAAP	IFRS						
¥119,066	¥146,260	¥161,831	¥195,291	¥199,096	¥224,942	¥234,026	\$2,108,535
41,501	57,353	56,373	72,829	74,966	86,378	90,764	817,769
36,164	41,642	48,893	59,406	62,193	68,788	71,273	642,158
16,720	16,862	17,477	19,990	22,786	24,398	23,759	214,061
24,681	29,878	35,374	80,180	32,479	38,691	45,098	406,322
_	30,403	39,088	43,067	39,687	45,378	48,230	434,547
9,071	10,643	11,831	26,097	8,331	4,000	11,174	100,679
16,521	19,718	24,032	53,373	21,724	35,261	31,943	287,798
_	19,813	25,948	29,163	29,125	33,458	36,092	325,185
3,609	5,879	66,440	9,092	9,500	9,937	8,332	75,071
3,291	2,841	6,958	9,338	9,882	10,896	10,969	98,831
,	,	,	,	,	,	,	,
¥199,641	¥237,640	¥304,200	¥355,399	¥358,906	¥388,463	¥391,186	\$3,524,516
165,132	187,210	211,779	260,009	255,929	287,557	292,572	2,636,023
34,509	50,430	92,421	95,391	102,977	100,905	98,614	888,493
,	,	,	,	,	,	,	,
¥ 195.81	¥ 47.78	¥ 58.18	¥ 128.99	¥ 52.96	¥ 86.73	¥ 78.67	\$ 0.71
_	48.01	62.82	70.48	70.99	82.29	88.89	0.80
1,998.44	452.43	511.14	627.78	628.09	702.54	728.97	6.57
20.00	20.00	22.00	25.00	26.00	26.00	26.00	0.23
¥ 9,943	¥ 26,686	¥ 25,386	¥ 22,525	¥ 10,843	¥ 42,843	¥ 32,894	\$ 296,368
(4,596)	(7,847)	(61,709)	37,052	(28,201)	(8,259)	(2,935)	(26,444)
(21,557)	(7,954)	28,960	(24,066)	(28,657)	(17,631)	(28,107)	(253,242)
6,334	20,807	(41,054)	13,433	1,342	32,906	24,562	221,298
3,037.8	2,855.4	309.8	230.9	206.6	1,573.6	4,330.0	
10.0	11.1	12.0	22.6	8.4	13.0	11.1	
_	11.2	13.0	12.4	11.3	12.4	12.5	
8.3	8.9	8.9	16.2	6.1	9.4	8.2	
82.6	78.8	69.6	73.2	71.1	73.6	74.4	
0.0	0.0	0.2	0.1	0.1	0.0	0.0	
22.7	19.2	30.1	13.1	30.4	19.8	21.0	
51.1	41.9	37.8	19.4	49.1	30.0	33.0	
82,469	82,583	82,653	414,192	406,173	406,848	399,782	
3,050	3,072	3,230	3,463	3,667	3,805	4,073	
,	,	, -	, -	,	,	,	

# Consolidated Statement of Profit or Loss and Other Comprehensive Income

Santen Pharmaceutical Co., Ltd. and Its Consolidated Subsidiaries

	Millions	Thousands of U.S. dollars <sup>1</sup>	
	FY2017	FY2018	FY2018
5	V004 040	V004 000	<b>#0.400.505</b>
Revenue	¥224,942	¥234,026	\$2,108,535
Cost of sales	(86,378)	(90,764)	(817,769)
Gross profit	138,564	143,262	1,290,766
Selling, general and administrative expenses	(68,788)	(71,273)	(642,158)
Research and development expenses	(24,398)	(23,759)	(214,061)
Amortization on intangible assets associated with products	(6,740)	(6,988)	(62,961)
Other income	417	4,028	36,287
Other expenses	(364)	(172)	(1,552)
Operating profit	38,691	45,098	406,322
Finance income	1,004	901	8,114
Finance expenses	(434)	(2,881)	(25,958)
Profit before tax	39,261	43,117	388,477
Income tax expenses	(4,000)	(11,174)	(100,679)
Net profit for the year	35,261	31,943	287,798
Items that will not be reclassified subsequently to profit or loss  Remeasurements of defined benefit plans	284	9	79
Net gain or loss on financial assets measured at fair value		9	79
through other comprehensive income	5,867	(3,289)	(29,636)
Items that may be reclassified subsequently to profit or loss	5,867	(3,289)	
Items that may be reclassified subsequently to profit or loss	ŕ	, . ,	(29,636)
Foreign currency translation adjustments	(686)	794	(29,636) 7,156
Foreign currency translation adjustments  Other comprehensive income	(686) 5,464	794 (2,486)	(29,636) 7,156 (22,402)
Foreign currency translation adjustments	(686)	794	(29,636) 7,156
Foreign currency translation adjustments  Other comprehensive income	(686) 5,464	794 (2,486)	(29,636) 7,156 (22,402)
Foreign currency translation adjustments  Other comprehensive income  Total comprehensive income for the year	(686) 5,464	794 (2,486)	(29,636) 7,156 (22,402)
Foreign currency translation adjustments  Other comprehensive income  Total comprehensive income for the year  Profit attributable to	(686) 5,464 40,725	794 (2,486) 29,456	7,156 (22,402) 265,396 287,899
Foreign currency translation adjustments  Other comprehensive income  Total comprehensive income for the year  Profit attributable to  Owners of the company	(686) 5,464 40,725 35,247	794 (2,486) 29,456	7,156 (22,402) 265,396 287,899 (100)
Foreign currency translation adjustments  Other comprehensive income  Total comprehensive income for the year  Profit attributable to  Owners of the company  Non-controlling interests	(686) 5,464 40,725 35,247	794 (2,486) 29,456 31,954 (11)	7,156 (22,402) 265,396 287,899 (100)
Foreign currency translation adjustments  Other comprehensive income  Total comprehensive income for the year  Profit attributable to  Owners of the company  Non-controlling interests  Net profit for the year	(686) 5,464 40,725 35,247	794 (2,486) 29,456 31,954 (11)	7,156 (22,402) 265,396 287,899 (100)
Foreign currency translation adjustments  Other comprehensive income  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	(686) 5,464 40,725 35,247 14 35,261	794 (2,486) 29,456 31,954 (11) 31,943	(29,636)  7,156 (22,402) 265,396  287,899 (100) 287,798

	Ye	U.S. dollars <sup>1</sup>		
Earnings per share	FY2017	FY2018	FY2018	
Basic earnings per share	¥ 86.73	¥ 78.67	\$ 0.71	
Diluted earnings per share	86.42	78.43	0.71	

<sup>1.</sup> U.S. dollar amounts have been translated from yen, solely for the convenience of the reader, at the rate of ¥110.99 to U.S.\$1.00, the exchange rate prevailing on March 29, 2019. (This date was selected because March 30, 31, 2019 was a non-business day for financial institutions.)

# Consolidated Statement of Financial Position

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

	Millions	Thousands of U.S. dollars <sup>1</sup>	
Assets	FY2017	FY2018	FY2018
Non-current assets			
Property, plant and equipment	¥ 29,706	¥ 31,699	\$ 285,605
Intangible assets	134,495	131,110	1,181,281
Financial assets	35,775	30,044	270,691
Deferred tax assets	2,264	1,771	15,958
Other non-current assets	2,855	1,819	16,388
Total non-current assets	205,095	196,444	1,769,924
Current assets			
Inventories	30,636	35,235	317,457
Trade and other receivables	78,654	84,618	762,394
Other financial assets	472	267	2,408
Other current assets	4,322	3,826	34,469
Cash and cash equivalents	69,283	70,796	637,863
Total current assets	183,367	194,742	1,754,592
Total assets	388,463	391,186	3,524,516
Equity and liabilities			
Equity			
Equity attributable to owners of the company			
Share capital	8,032	8,252	74,345
Capital surplus	8,657	8,661	78,031
Treasury shares	(11)	(1,131)	(10,193)
Retained earnings	249,225	258,659	2,330,471
Other components of equity	19,921	16,461	148,307
Total equity attributable to owners of the company	285,823	290,900	2,620,961
Non-controlling interests	1,734	1,672	15,063
Total equity	287,557	292,572	2,636,023
Liabilities			
Non-current liabilities			
Financial liabilities	21,244	23,520	211,911
Net defined benefit liabilities	1,804	1,992	17,945
Provisions	1,367	1,255	11,303
Deferred tax liabilities	12,909	9,389	84,597
Other non-current liabilities	1,380	1,795	16,172
Total non-current liabilities	38,704	37,951	341,928
Current liabilities Trade and other payables	29,743	32,079	289,023
Other financial liabilities	14,404	12,116	109,167
Income tax payable	7,656	7,185	64,739
Provisions	1,508	7,165	6,457
Other current liabilities	8,890	8,566	77,180
Total current liabilities	62,201	60,663	546,565
Total liabilities	100,905	98,614	888,493
Total equity and liabilities	¥388,463	¥391,186	\$3,524,516

# Consolidated Statement of Changes in Equity

Santen Pharmaceutical Co., Ltd. and Its Consolidated Subsidiaries Fiscal 2017

				Millions of	yen		
					Other components of equity		
	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, 2017	¥7,792	¥8,417	¥(10)	¥223,283	¥—	¥ 9,470	
Comprehensive income							
Net profit for the year				35,247			
Other comprehensive income					284	5,867	
Total comprehensive income for the year	_	_	_	35,247	284	5,867	
Transactions with owners							
Issuance of new shares	240	240					
Acquisition of treasury shares			(1)				
Dividends				(10,563)			
Changes for equity of subsidiary with non-controlling interests							
Share-based payments							
Other				1,257	(284)	(973)	
Total transactions with owners	240	240	(1)	(9,306)	(284)	(973)	
Balance at March 31, 2018	¥8,032	¥8,657	¥(11)	¥249,225	¥—	¥14,364	

			Milli	ons of yen		
	Other components of equity					
	Foreign currency translation adjustments	Subscription rights to shares			Non-controlling interests	Total equity
Balance at April 1, 2017	¥5,332	¥825	¥15,628	¥255,110	¥819	¥255,929
Comprehensive income						
Net profit for the year			_	35,247	14	35,261
Other comprehensive income	(749)		5,401	5,401	63	5,464
Total comprehensive income for the year	(749)	_	5,401	40,648	77	40,725
Transactions with owners						
Issuance of new shares		(68)	(68)	412		412
Acquisition of treasury shares			_	(1)		(1)
Dividends			_	(10,563)		(10,563)
Changes for equity of subsidiary with non-controlling interests			_	_	838	838
Share-based payments		218	218	218		218
Other			(1,257)	_		_
Total transactions with owners	_	150	(1,107)	(9,934)	838	(9,096)
Balance at March 31, 2018	¥4,583	¥975	¥19,921	¥285,823	¥1,734	¥287,557

				Millions of y	en	
					Other comp	conents of equity
	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, 2018	¥8,032	¥8,657	¥(11)	¥249,225	¥ —	¥14,364
Comprehensive income						
Net profit for the year				31,954		
Other comprehensive income					9	(3,289)
Total comprehensive income for the year	-	_	_	31,954	9	(3,289)
Transactions with owners						
Issuance of new shares	152	152				
Acquisition of treasury shares		(148)	(13,911)			
Retirement of treasury stock		(12,791)	12,791			
Transfer to retained earnings from capital surplus		12,791		(12,791)		
Dividends				(10,581)		
Share-based payments	67	(1)				
Other				853	(9)	(844)
Total transactions with owners	220	4	(1,120)	(22,519)	(9)	(844)
Balance at March 31, 2019	¥8,252	¥8,661	¥(1,131)	¥258,659	¥ —	¥10,230

	Millions of yen						
	Other co	Other components of equity					
	Foreign currency translation adjustments	Subscription rights to shares	Total	Total equity attributable to owners of the company	Non-controlling interests	Total equity	
Balance at April 1, 2018	¥4,583	¥975	¥19,921	¥285,823	¥1,734	¥287,557	
Comprehensive income							
Net profit for the year			_	31,954	(11)	31,943	
Other comprehensive income	845		(2,435)	(2,435)	(51)	(2,486)	
Total comprehensive income for the year	845	_	(2,435)	29,519	(62)	29,456	
Transactions with owners							
Issuance of new shares		(173)	(173)	132		132	
Acquisition of treasury shares			_	(14,059)		(14,059)	
Retirement of treasury stock			_	_		_	
Transfer to retained earnings from capital surplus			_	_		_	
Dividends			_	(10,581)		(10,581)	
Share-based payments			_	67		67	
Other			(853)	_		_	
Total transactions with owners	_	(173)	(1,025)	(24,442)	_	(24,442)	
Balance at March 31, 2019	¥5,428	¥802	¥16,461	¥290,900	¥1,672	¥292,572	

# Consolidated Statement of Changes in Equity

Santen Pharmaceutical Co., Ltd. and Its Consolidated Subsidiaries Fiscal 2018

			Thous	sands of U.S. do	llars <sup>1</sup>	
					Other comp	onents of equity
	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, 2018	\$72,365	\$77,998	\$(101)	\$2,245,468	\$-	\$129,413
Comprehensive income						
Net profit for the year				287,899		
Other comprehensive income					79	(29,636)
Total comprehensive income for the year	_	_	_	287,899	79	(29,636)
Transactions with owners						
Issuance of new shares	1,374	1,374				
Acquisition of treasury shares		(1,335)	(125,336)			
Retirement of treasury stock		(115,244)	115,244			
Transfer to retained earnings from capital surplus		115,244		(115,244)		
Dividends				(95,334)		
Share-based payments	606	(5)				
Other				7,682	(79)	(7,604)
Total transactions with owners	1,980	33	(10,092)	(202,895)	(79)	(7,604)
Balance at March 31, 2019	\$74,345	\$78,031	\$(10,193)	\$2,330,471	\$-	\$92,173

	Thousands of U.S. dollars <sup>1</sup>					
	Other o	omponents of equ				
	Foreign currency translation adjustments	Subscription rights to shares	Total	Total equity attributable to owners of the company	Non-controlling interests	Total equity
Balance at April 1, 2018	\$41,289	\$8,784	\$179,487	\$2,575,218	\$15,624	\$2,590,841
Comprehensive income						
Net profit for the year			_	287,899	(100)	287,798
Other comprehensive income	7,617		(21,941)	(21,941)	(461)	(22,402)
Total comprehensive income for the year	7,617	_	(21,941)	265,958	(561)	265,396
Transactions with owners						
Issuance of new shares		(1,557)	(1,557)	1,190		1,190
Acquisition of treasury shares			_	(126,671)		(126,671)
Retirement of treasury stock			_	_		_
Transfer to retained earnings from capital surplus			_	_		_
Dividends			_	(95,334)		(95,334)
Share-based payments			_	601		601
Other			(7,682)	_		_
Total transactions with owners	_	(1,557)	(9,239)	(220,214)	_	(220,214)
Balance at March 31, 2019	\$48,906	\$7,227	\$148,307	\$2,620,961	\$15,063	\$2,636,023

<sup>1.</sup> U.S. dollar amounts have been translated from yen, solely for the convenience of the reader, at the rate of ¥110.99 to U.S.\$1.00, the exchange rate prevailing on March 29, 2019. (This date was selected because March 30, 31, 2019 was a non-business day for financial institutions.)

# Consolidated Statement of Cash Flows

Santen Pharmaceutical Co., Ltd. and Its Consolidated Subsidiaries

	Millions of yen		Thousands of U.S. dollars <sup>1</sup>
	FY2017	FY2018	FY2018
Cash flows from operating activities			
Net profit for the year	¥ 35,261	¥ 31,943	\$ 287,798
Depreciation and amortization	10,896	10,969	98,831
Impairment losses	150	_	_
Gain on disposal of non-current assets	_	(3,592)	(32,366)
Finance expenses (income)	(327)	(700)	(6,305)
Income tax expenses	4,000	11,174	100,679
Decrease (increase) in trade and other receivables	(7,116)	(6,303)	(56,787)
Decrease (increase) in inventories	(1,435)	(5,000)	(45,047)
Increase (decrease) in trade and other payables	5,697	2,445	22,030
Increase (decrease) in provisions and net defined benefit liabilities	285	(518)	(4,666)
Increase (decrease) in accounts payable-other	961	1,181	10,638
Increase (decrease) in long-term accounts payable-other	17	1,885	16,986
Other	728	2,116	19,064
Subtotal	49,117	45,601	410,854
Interest received	145	187	1,688
Dividends received	598	521	4,694
Interest paid	(27)	(8)	(68)
Income tax paid	(6,990)	(13,408)	(120,800)
Net cash flows from (used in) operating activities	42,843	32,894	296,368
Cash flows from investing activities	(505)	(004)	(0.000)
Payments for acquisition of investments	(565)	(931)	(8,390)
Proceeds from sale of investments	2,879	2,156	19,425
Payments for acquisition of property, plant and equipment	(3,984)	(5,470)	(49,280)
Proceeds from sales of property, plant and equipment		4,338	39,089
Payments for acquisition of intangible assets	(5,953)	(2,863)	(25,791)
Other	(636)	(166)	(1,498)
Net cash flows from (used in) investing activities	(8,259)	(2,935)	(26,444)
Cash flows from financing activities		507	5404
Proceeds from long-term loans	(0.010)	567	5,104
Repayments of long-term loans	(8,316)	(4,098)	(36,922)
Purchase of treasury stock	(1)	(14,124)	(127,258)
Capital contribution from non-controlling interests	838	(4.0.500)	(05.000)
Dividends paid	(10,559)	(10,580)	(95,323)
Other Not and fire a few (and in) few and in its and its a	408	128	1,156
Net cash flows from (used in) financing activities	(17,631)	(28,107)	(253,242)
Net increase (decrease) in cash and cash equivalents	16,953	1,852	16,682
Cash and cash equivalents at the beginning of period	52,282	69,283	624,228
Effect of exchange rate changes on cash and cash equivalents	48	(338)	(3,047)
Cash and cash equivalents at the end of period	¥ 69,283	¥ 70,796	\$ 637,863

# Corporate Information / Stock Information

As of March 31, 2019

Corporate Headquarters Santen Pharmaceutical Co., Ltd.

Grand Front Osaka Tower A,

4-20 Ofuka-cho, Kita-ku, Osaka 530-8552,

Japan

URL: https://www.santen.com TEL: +81-6-6321-7000 (Main) +81-6-4802-9360 (PR and IR)

E-MAIL: ir@santen.com

Established 1890

Paid-in Capital ¥8,252 million

Number of Employees 4,073 (non-consolidated: 1,812)

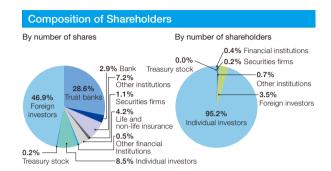
Number of Shares Issued 399,782,354 Number of Shareholders 18,247 Stock Exchange Listings Tokyo Ticker Code 4536

Transfer Agent Osaka Corporate Agency Division,

Mitsubishi UFJ Trust and Banking Corporation

6-3, Fushimi-cho 3-chome, Chuo-ku,

Osaka 541-8502, Japan



Major Shareholders		
Name	Number of shares held	Percentage of ownership
Japan Trustee Service Bank, Ltd. (Trust Account)	33,546 <sup>Thousands</sup>	8.4%
STATE STREET BANK AND TRUST COMPANY		
505223	32,027	8.0
The Master Trust Bank of Japan, Ltd. (Trust		
Account)	28,960	7.3
RBC IST 15 PCT LENDING ACCOUNT - CLIENT		
ACCOUNT	10,786	2.7
Nippon Life Insurance Company	10,662	2.7
MUFG Bank, Ltd.	10,605	2.7
ONO PHARMACEUTICAL Co.,Ltd.	9,307	2.3
Japan Trustee Service Bank, Ltd. (Trust Account 5)	7,438	1.9
Trust & Custody Services Bank.,Ltd.as trustee for		
Eisai Co.,Ltd. Retirement Benefit Trust Account		
re-entrusted by Mizuho Trust and Banking Co.,Ltd	6,863	1.7
Japan Trustee Service Bank, Ltd. (Trust Account 9)	5,958	1.5

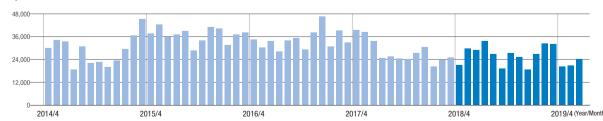
# Stock Price Range (Yen)

Monthly basis



## Trading Volume (Thousands of shares)

Monthly basis



Yearly High and Low Prices							
	2015	2016	2017	2018	2019		
High (yen)	2,163	2,064	1,946	2,061	1,797		
Low (yen)	1,262	1,251	1,343	1,509	1,450		

Notes: 1. Calendar years.

- 2. Stock prices for 2019 are for the period to the end of June.
- 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.

Business Bases			
Group Companies	Location		Location
Claire Co., Ltd.		Santen Pharmaceutical (China) Co., Ltd.	
Santen Business Services Co., Ltd.	Japan	Santen Pharmaceutical Sales and Marketing (Suzhou) Co., Ltd.	China
Santen Eye Care Co., Ltd.		Chongqing Santen Kerui Pharmaceutical Co., Ltd.	1
Santen Holdings U.S. Inc.		Santen Pharmaceutical Korea Co., Ltd.	Korea
Santen Inc.		Taiwan Santen Pharmaceutical Co., Ltd.	Taiwan
Advanced Vision Science, Inc.	U.S.	Santen India Private Limited	India
InnFocus, Inc.		Santen Pharmaceutical Asia Pte. Ltd.	Cingonoro
Santen Ventures, Inc.		Santen Pharmaceutical Asia Pte. Ltd.	Singapore
Santen Canada Inc.	Canada	SANTEN (THAILAND) CO., LTD.	Thailand
Santen Holdings EU B.V.	Netherlands	SANTEN PHARMA MAI AYSIA SDN. BHD.	Malaysia
Santen Oy	Finland	SANTEN FRANKIA WALATSIA SUN. BRU.	
Santen S.A.S.	France	SANTEN PHILIPPINES INC.	Philippines
Santen GmbH	Germany	SANTEN PHARMACEUTICAL (HONG KONG) LIMITED	Hong Kong
SantenPharma AB	Sweden		
Santen SA	Switzerland	Other Office	
Santen Italy S.r.l.	Italy	Ho Chi Minh City Representative Office	Vietnam
Santen UK Limited	U.K.		
Santen Pharmaceutical Spain, S.L.	Spain		

Inclusion in	ESG Indexes			
Index name		Overview	Index name	Overview
FTSE4Good Index Series	FTSE4Good	Index Series developed by FTSE Russell in the U.K. The index series selects companies based on evaluations of their initiatives in the areas of Environmental, Social and Governance(ESG) activities.	MSCI World ESG Leaders Indexes  MSCI 100 Indexes  MSCI 100 Indexes Indexes	An index developed by MSCI in the U.S. The index selects companies from their respective industries based on outstanding ESG performance.
FTSE Blossom Japan Index	FTSE Blossom Japan	A broad index developed by FTSE Russell in the U.K. The index incorporates overall ESG considerations.	MSCI Japan ESG Select Leaders Index MSCI 30 MSCI Japan ESG Select Leaders Index	An index developed by MSCI in the U.S. The index selects companies that rate highly for ESG response from among the top 700 Japanese stocks by market capitalization.

Russia

Please refer to the CSR section on the Company's website for the most recent information about index selection. https://www.santen.com/en/csr

# **Editorial Policy**

SANTEN LIMITED LIABILITY COMPANY

From fiscal 2017, Santen has adopted a policy to integrate its former Annual Report and CSR Report into an integrated report that provides a view of overall business activities based on Santen's Values. The integrated report is edited with the intention to provide customers and society with an understanding of Company values and includes comprehensive coverage of financial information as well as non-financial information such as management strategies, review of operations and CSR activities. Santen has streamlined content and simplified descriptions to allow for easier understanding by a wide range of stakeholders, starting with shareholders and investors. Detailed information is disclosed through the following media.

Corporate Website

https://www.santen.com

- •IR Website ("Investors & Media" on Santen's Corporate Website) https://www.santen.com/en/ir
- •CSR Website ("CSR" on Santen's Corporate Website) http://www.santen.com/en/csr

# Information Provided

Information contained in this report is selected in order of importance from both aspects of value creation for Santen and the impact on stakeholders.

#### Applicable Scope

Santen Pharmaceutical Co., Ltd. and consolidated subsidiaries

## Reporting Period

Fiscal 2018 (April 1, 2018 to March 31, 2019) Certain information is updated after April 1, 2019.

#### Reference Guidelines

The International Integrated Reporting Framework (International Integrated Reporting Council), The GRI Sustainability Reporting Standards (Global Reporting Initiative), and Environmental Reporting Guidelines (Ministry of the Environment)

# Note on Accounting Standards

The Santen Group has adopted International Financial Reporting Standards (IFRS) from fiscal 2014, for the purpose of enhancing the international comparability of its financial information. Figures for fiscal 2013 have been restated to conform to IFRS for comparison and analysis purposes.

## **Caution Concerning Forward-Looking Statements**

This annual report contains forward-looking statements regarding the Company's plans, strategies and results for the future. All forward-looking statements are based on judgments derived from the information available to the Company at the time of publication. Certain risks and uncertainties could cause the Company's actual results to differ materially from any projections presented in this report. These risks and uncertainties include, but are not limited to, adverse economic conditions, delays in new products launch, currency exchange rate, legislative and regulatory developments.



