

# Santen Report 2022

Year ended March 31, 2022

Happiness with Vision





1 The Importance of the Eyes and Social Issues







1 The Importance of the Eyes and Social Issues



## The Importance of the Eyes and Social Issues

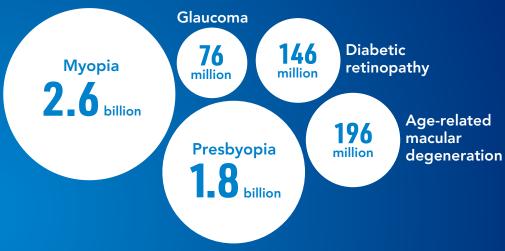
#### **Population with Blindness** or Visual Impairment<sup>1</sup>

Population living with blindness or visual impairment

Population with a visual impairment that could have been prevented or has yet to be addressed

At least 2.2 billion people worldwide live with blindness or a visual impairment. Of these people, at least 1.0 billion have a visual impairment that could have been prevented or has yet to be addressed. This number is expected to increase due to factors such as population growth, aging societies and changing lifestyles.

#### **Number of People Affected** Worldwide<sup>1</sup>



People worldwide live with various eye conditions and diseases, and many of us must deal with an eye heath issue at some point in our lives. Myopia is considered the world's most common eye problem, and the number of people affected is expected to increase to 3.36 billion by 2030.

#### **Economic Losses due to Visual Impairments**

Approx. 410 7 billion annually

Visual impairments, are on the rise globally, are estimated to result in annual economic losses of as much as US\$410.7 billion. Initiatives to address eye health have led to improvements in education and the workforce, making the implementation of such initiatives a key social issue for achieving a sustainable society.

WHO, World report on vision 2 The Lancet Global Health Commission on Global Eye Health: vision beyond 2020

#### **Navigating This Document**

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Published October 2022

#### Note

Particularly important points are underlined.

Representative questions and comments received in IR dialogue can be found on page 69. Pages containing related content are denoted by the letter **Q** and the corresponding number in the upper right corner.

#### **Editorial Policy**

From fiscal 2017, Santen has integrated its former Annual Report and CSR Report into an integrated report that provides a view of overall business activities based on our CORE PRINCIPLE. The integrated report is edited with the intention of informing stakeholders about the value Santen provides to customers and society and includes comprehensive coverage of financial information as well as non-financial information such as management strategies, review of operations and sustainability 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 available on the corporate website.

#### Applicable Scope

Santen Pharmaceutical Co., Ltd. and consolidated subsidiaries

#### Reporting Period

Fiscal 2021 (April 1, 2021 to March 31, 2022). Certain information is updated after April 1, 2022.

## The Santen Report and Santen's Information Disclosure Framework

The Santen Report (this document) contains information based on materialities that we consider particularly useful to investors.



#### Detailed Information

#### Concerning Forward-Looking Statements

This 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 product launches, currency exchange rates, legislative and regulatory developments.

This report contains information about pharmaceutical products (including products under development), but such information is not for the purpose of advertising or medical advice.

The following are registered trademarks of Santen's partner companies

- Alesion (Boehringer Ingelheim)
- · Cravit, Tarivid (Daiichi Sankyo Co., Ltd.)
- · Livostin (Johnson & Johnson)
- LENTIS Comfort, LENTIS Comfort Toric (Teleon Holding B.V.)
- CYBERSIGHT (Project Orbis International, Inc.)

## CORE PRINCIPLE and WORLD VISION

## **Purpose**

4 CORE PRINCIPLE and WORLD VISION



**CORE PRINCIPLE** 

# 天機に参与する Tenki ni sanyo suru

"Exploring the secrets and mechanisms of nature in order to contribute to people's health"

\* Santen's original interpretation of a passage from the Zhongyong (The Doctrine of the Mean) by Confucius

**WORLD VISION** 

## Happiness with Vision

The Happiest Life for every individual, through the Best Vision Experience

5 Santen's History

#### Purpose

## Santen's History

Since its founding in 1890, Santen has contributed to patients and their loved ones. The spirit of our CORE PRINCIPLE, reflected in our company name, has more than 130 years of heritage. We have turned the challenges we have overcome into our strengths, and this continues to pave the way for our next growth trajectory.

A Brief History of Santen's Product Innovation

\* Major products based on year of launch



1890 Heburin-gan (cold medication)



Daigaku Eye Drops



Mydrin-P (mydriatic)

First eye drop in a plastic container in Japan



1962 Super Sante

World's first fluoroguinolone opthlamic



1987 Tarivid



1991 Sante FX



1992
Kary Uni
(treatment for early-stage senile cataracts)



Our first treatment for

2047/01 0.19

1995 Hyalein

#### Growth (1990-2009)

#### 1890

## Santen kicks off by taking the challenge of contributing to people's health

Santen's origins date back to 1890, when Kenkichi Taguchi opened Taguchi Santendo. *Heburin-gan*, a cold medication, was its main product at the time. In the late 19th century, many people in Japan suffered from eye disorders, and demand for eye drops was high. The company launched *Daigaku Eye Drops* in 1899 and the product's popularity spread nationwide. From that point, Santen began taking on the challenge of contributing to eye health.

#### 1950s

Establishment - Laying the Foundation (1890–1989)

## Pursuing a strategy centered on eye drops, and expanding into prescription pharmaceuticals

Due to difficulties encountered from aerial bombings during World War II, Santen shifted its business strategy focusing on eye drops. In 1958, Santen entered the prescription pharmaceutical business and in 1962 launched *Mydrin-P*, which promotes mydriasis, or dilation of the pupil. This groundbreaking eye drop used in ophthalmic surgery and diagnosis contributed significantly to the development of ophthalmology in Japan. Thereafter, product launches included an innovative antibiotic ophthalmic and a glaucoma treatment, laying the foundation to support ophthalmic treatment in Japan.

#### 1990s

## Strengthening the global production system toward internationalization and entering the European market

Upon its centennial in 1990, Santen embarked on a new growth stage with the announcement of a long-term vision to contribute to society with the best products and services focusing on the eye and health. In addition to business growth in Japan on the back of an expanding product lineup, and the completion of the Shiga Plant, Santen entered the European market and emphasized aggressive business development to contribute to patients around the world.





5 Santen's History



#### Santen's History







**Tapros** (treatment for glaucoma and ocular hypertension)



**Cosopt** (treatment for glaucoma and ocular hypertension)



**Diquas** (treatment for dry eye syndrome)



2015

Ikervis

(treatment for severe keratitis in adult patients with dry eye disease)

Transformation (2010-)



Eybelis
(treatment for glaucoma and ocular hypertension)



(intraocular lens)

0.1% フレンテン・レ (1000.015) (1000.01

Alesion LX
(anti-allergy ophthalmic)

#### Growth (1990-2009)

#### 2000s

## Expanding solutions and building a business foundation in Asia

Santen focused on meeting the needs of more people by providing a wide range of treatment options including intraocular lenses and supplements in addition to ophthalmic solutions for eye diseases. At the same time, the Company worked to build a business foundation in Asia, which included building a direct sales network in China as well as completing the Suzhou Plant, and establishing Group company in South Korea.

#### 2010s

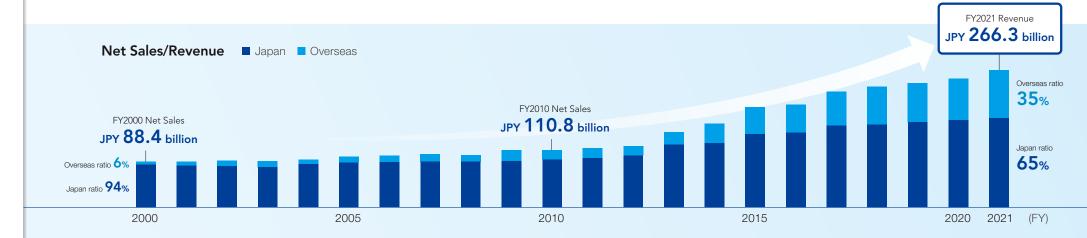
## Rapidly accelerating globalization to contribute to eye health worldwide

Aiming to become a specialized pharmaceutical company with a global presence as its long-term vision up to 2020, Santen rapidly accelerated its globalization, centered on China, Asia and EMEA. In 2015, Santen sold its anti-rheumatic pharmaceuticals business to AYUMI Pharmaceutical Corporation to specialize in ophthalmology and concentrate its management resources in the field.

#### 2020s

## Aspiring to Become A Social Innovator to deliver happiness through vision

Aiming to resolve eye-related social issues, the Company announced Santen 2030, a long-term vision toward 2030 and beyond. To realize "The Happiest Life for every individual through the Best Vision Experience," Santen continues to take on challenges worldwide to provide products and services with true value by bringing together knowhow and expertise through partnerships with external organizations, M&A and other approaches.





7 At a Glance

Purpose

### At a Glance

**Countries/Regions** 

Over **60** 

Number of patients who have benefited from our treatment<sup>1</sup>

48 million

Overseas sales ratio<sup>2</sup>

35%

Japan and China / Asia<sup>3</sup>

No.1

Annual production volume<sup>4</sup>

Approx. 400 million units

Phase III study success rate<sup>5</sup>

Over **83**%

Outside Director ratio

71%

Woman manager ratio

37%

CO<sub>2</sub> emissions (vs. 2019)<sup>7</sup>

**-14**%

<sup>&</sup>lt;sup>1</sup> Estimated total no. of patients to which Santen contributed (disease areas: inflammation/allergies, cornea, glaucoma, cataracts) in FY2020, calculated based on JMDC's estimated total no. of patients for Santen's Rx products and Santen's shipment data <sup>2</sup> Based on FY2021 data <sup>3</sup> Internal estimate based on external data, and research <sup>4</sup> 5mL unit equivalent <sup>5</sup> FY2010–FY2021 results <sup>6</sup> As of September 30, 2022 <sup>7</sup> Scope 1 and 2



8 Value Creation Story



## Value Creation Story (Value Creation Model)

Santen specializes in ophthalmology and develops products and services from the patient's perspective. We will contribute to people's lives and achieve corporate growth, leveraging our strengths in industrialization, commercialization and internationalization, and incorporating digital technologies.

#### Specific strengths



#### **Industrialize**

- Ability to create products through formulation development technologies based on an unparalleled understanding of the characteristics of the eyes as a specialized company with a history of more than 130 years
- Commitment to patient ease of use, from pharmaceuticals to eye drop containers
- World-class manufacturing volume capability of ophthalmic products that have contributed to patients worldwide

## Internationalize

- Rollout of our broad lineup of ophthalmic products, in-depth ophthalmology expertise and thoroughgoing patient perspective to more than 60 countries/regions and covering major cities worldwide
- A network of more than 120,000
   ophthalmologists and wide-ranging partnerships,
   from ophthalmology research institutes to IT companies
- Strong presence as a unique global company specialized in ophthalmology, backed by our track record

Santen

A unique global company specialized in ophthalmology

Panner and stable supply rooted in patient needs

Souten

A unique global company specialized in ophthalmology

Contributed

Synthocite business ialized

Synthocite business ialized

People Glaucoma
who need eye care Other eye diseases

Myopia
Dry eye
Ptosis

Products and services specialized in ophthalmology Contribution to the development of ophthalmology Resolution of eye-related social issues



#### Commercialize

- A broad lineup of more than 70 products,¹ extensive and in-depth expertise in ophthalmology and proposal capabilities based on the patient's perspective
- High customer satisfaction (No. 1 in Japan²), resulting in steady product uptake
- Contribution to the development of ophthalmology in each country and region we serve through measures such as support for the establishment of diagnostic criteria for eye diseases and provision of training for medical professionals

Unmet needs

<sup>&</sup>lt;sup>1</sup>Number of Rx products sold in Japan

<sup>&</sup>lt;sup>2</sup> Percentage of ophthalmologists rating Santen the first among companies providing ophthalmic prescription pharmaceuticals. Santen calculations based on external data.

8 Value Creation Story



### Value Creation Story (Creating Shared Value)

Santen's vision for 2030 and beyond is becoming a Social Innovator that orchestrates and mobilizes key technologies and players around the world to deliver happiness through vision. We are working to create shared value in collaboration with various stakeholders to resolve eye-related social issues and achieve sustainable company growth.

#### Inputs



#### **Social Capital**

- Insights from medical professionals and patients
- Partnerships with medical professionals and suppliers
- Dialogue with capital markets

#### **Human Capital, Intellectual Capital**

- Experienced leadership team
- Approximately 4,300 diverse employees worldwide with expertise in ophthalmology
- Excellent technologies and knowledge from partner companies and organizations
- Data utilization



#### Manufactured Capital, Natural Capital

- A production system specialized in ophthalmology that manufactures high-quality products
- Stable supply through a global product supply network
- Expanding production capacity through construction of new plants and conversion of plants to smart factories
- Use of environmentally friendly water resources and eye drop containers



Social

changes

#### **Financial Capital**

- Robust balance sheet
- · A disciplined capital expenditure investment approach

#### **Specific Activities / Outputs**

Develop and provide products and services that utilize digital and other technologies to meet the needs of people with eye problems



patients and people

"Happiness with Vision" for

**Outcomes** 

Provide solutions to medical issues such as early detection of conditions and patient adherence to treatment, and provide training for medical professionals



**Development and** improvement of ophthalmology

Develop, popularize and conduct an overseas rollout of products and services that leverage the strengths of Santen and its partner companies and organizations



Increased corporate value for Santen and its partners

Provide employees with career realization opportunities, growth opportunities and a digital workplace



Improvement in employee skills and fulfillment in work

Use biomass plastic and other sustainable technologies, and efficiently utilize water resources



Realization of a carbon-free and recycling-oriented society

Engage in dialogue with shareholders and investors toward the realization of a sustainable society and corporate growth



Stable shareholder returns

























**Technological** Increased Diversification Increasing Aging Lifestyle innovation and environmental of needs population society changes evolution awareness

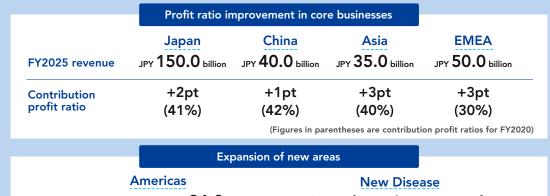
8 Value Creation Story

**Purpose** 

## Value Creation Story (Initiatives for Medium-to-Long-Term Value Creation)

#### **Enhance corporate value**

#### MTP2025



FY2025 revenue JPY 24.0 billion Contribution profit ratio 54%

Start of contribution to profit from new areas including ptosis (STN1013800)

Strengthening of foundation as a global company

ESG

Strengthening of product development capabilities

Strengthening of product supply infrastructure

Reflect strategies in company-wide financial KPIs and business KPIs

Establishing global platform

#### **Encouragement of an Organizational Culture that Promotes Value Creation**

• Promote diversity with a focus on gender, nationality and the visually impaired

#### Strengthening Governance, Contributing to the Realization of Fair and Equal Society

**Development and Stable Supply of** 

**Socially Significant Products and Services** 

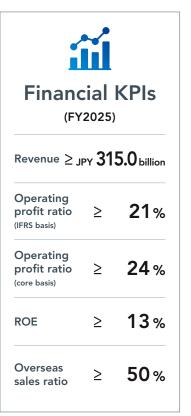
Aiming to reach over 60 million patients

Management effectiveness, diversity, compliance and respect for human rights

#### Conservation of the Global Environment

- Reduction of CO<sub>2</sub> emissions Efficient use of water resources
- · Shift to biomass plastic eye drop containers

Implement strategic investments and shareholder returns of one-third or more of operating cash flow<sup>2</sup>



Santen 2030 **Become A Social** Innovator

Estimated total no. of patients to which Santen has contributed (disease areas: inflammation/allergies, cornea, For details on MTP2025, please see the Company's website. glaucoma, cataracts) in FY2019 was approx. 43 million, calculated based on JMDC's estimated total no. of patients for Santen's Rx products and Santen's shipment data

Secure a dividend payout ratio of at least 40%, and flexibly return surplus funds through share buybacks



11 Materiality



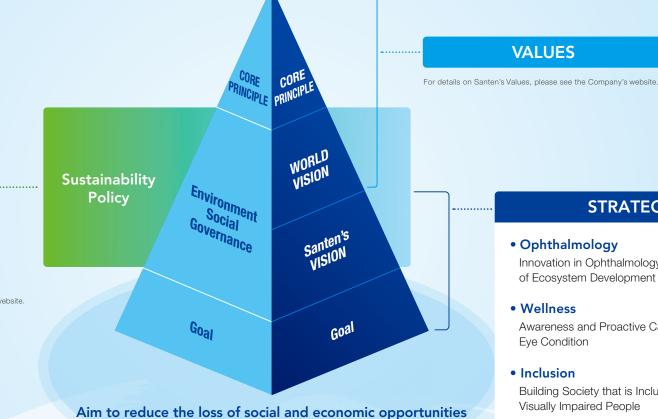
## **Materiality**

Santen is pursuing the three strategies set forth in its STRATEGY to resolve social issues. Additionally, the four ESG materialities aim at improving medium-to-long-term corporate value. These seven areas constitute the key issues and materialities to be addressed by Santen's management.

#### **ESG Materiality**

- Development and Stable Supply of Socially Significant Products and Services ("Happiness with Vision")
- Encouragement of an Organizational Culture that Promotes Value Creation
- Strengthening Governance, Contributing to the Realization of Fair and Equal Society
- Conservation of the Global Environment

For details on Santen's Sustainability Policy, please see the Company's website.



**STRATEGY** 

#### Ophthalmology

Innovation in Ophthalmology and Acceleration of Ecosystem Development

#### Wellness

**VALUES** 

Awareness and Proactive Care toward Better Eye Condition

#### Inclusion

Building Society that is Inclusive of Blind/ Visually Impaired People



















**Relevant SDGs** 

Starting with contributing to achieving Goal 3, "Ensure healthy lives and promote well-being for all at all ages," Santen is contributing to the achievement of the above United Nations' Sustainable Development Goals (SDGs) through its materiality-related initiatives.

for people around the world due to eye conditions



#### 11 Materiality



## **Materiality** (Identification Process)

We have identified Santen's Materiality based on international guidelines and demands from society, taking into account the opinions of experts, investors and other external stakeholders.



## **ESG Materiality**

ESG Materiality	Issue	KPI for FY2025	Progress in FY2021	
Development and Stable Supply of Socially Significant Products and Services	Market Penetration of Products with Social Significance	Aiming to contribute to more than 60 million patients <sup>1</sup>	Contributed to around 48 million patients in FY2020	
	Evaluation and Management of the Supply Chain	CSR survey evaluation rate: 85% or higher Supplier training implementation rate: 80% or higher ESG education in the procurement department: 100%	Conducted a survey of 77 secondary suppliers, resulting in an evaluation rate: 68% (survey of primary suppliers was conducted in the previous year)	
	Assurance of Quality and Safety, and Establishment of an Appropriate Supply System	Production and supply capacity: 500 million or more OTIF (on-time and in-full) shipping <sup>2</sup> : 100% Japan, 97% EMEA, 97% Asia, 97% U.S.	Production and supply results: 390 million     OTIF shipping: 100% Japan, 96% EMEA, 96% Asia, 100% U.S.	
	Providing Appropriate Information on Products and Services	Thorough education of Medical Representatives (MRs): 100%	• Education of MRs: 100%	
Encouragement of an Organizational Culture that Promotes Value Creation	Promoting Diversity, Equity & Inclusion	Increased diverse representation in Senior Management globally     Increase representation percentage of Woman Managers to 25% in Japan	Percentage of Woman Managers in Japan: 15%	
		Philosophy is permeated into all employees by implementation of the BLIND EXPERIENCE	Percentage of taking BLIND EXPERIENCE basic course: 77%	
	Building a High-Value-Added and Highly Productive Work Environment	(Quantitative targets are disclosed from next term on the basis of FY2022 survey.)	Prepared to conduct an engagement survey in FY2022	
	Human Resource Development	• In-house training on ophthalmology knowledge: 100%	• The aggregate length of training sessions in Japan: 48,612 hours	
Strengthening Governance, Contributing to the Realization of Fair and Equal Society	Corporate Governance	Outside Director ratio: Maintain at over 50%	Outside Director ratio: 50%	
	Compliance	<ul> <li>Implementation of annual compliance education: Continue at least 95%</li> <li>Major compliance violations: 0</li> </ul>	Annual compliance education implementation rate: 99%     Major compliance violations: 0	
	Risk Management	<ul> <li>Development of Group risk management system, development and penetration of related regulations, strengthening of cooperation with the risk management department and internal control defense line-related departments</li> <li>Business continuity: Disaster recovery plan (IT area) completed</li> <li>Major information security related incidents to be resolved and controlled with clear SLA/OLA<sup>3</sup> (90% or more)</li> </ul>	The online IT security awareness training completion rate: 96%	
	Respect for Human Rights	• Implementation rate of human rights education: 100% (in-house)	Ongoing survey of human rights initiatives at business partners	
Conservation of the Global Environment	Measures against Climate Change	Shift of company-owned vehicles to electric vehicles (HEVs, PHEVs, EVs, and FCVs): 100%     Facilitating wider use of transportation means with low environmental loads, including railroads, for commuting and business trips, and encouraging remote work and meetings     Reduction of CO₂ emissions (compared to FY2019)     Scope 1 and 2: 25% reduction     Scope 3 Category 1 (non-consolidated): 8% reduction	<ul> <li>Shift of company-owned vehicles to electric vehicles (HEVs, PHEVs, EVs, and FCVs) in Japan: 92.3%</li> <li>Completed conversion to renewable energy at plants and the laboratory in Japa on February 2022</li> <li>CO<sub>2</sub> emissions</li> <li>Scope 1 and 2: 13.7% reduction (30,012 t-CO<sub>2</sub>)</li> <li>Scope 3 Category 1: 12.2% increase (165,569 t-CO<sub>2</sub>)</li> </ul>	
	Environmental Load Reduction	Water consumption per unit of production: 12.4 m³/10,000 bottles or less     Recycling rate: 98% or higher     60% of plastic eye drop containers being produced from biomass plastic in FY2030     10% reduction in plastic used for wrapping and packing materials (compared to FY2019)	Water consumption per unit of production: 13.4 m³/10,000 bottles Recycling rate: 98.5% Replacing to biomass plastic eye drop container: started replacing the container of five eye drop products and three of five products replacement had been completed Investigating alternative means of plastic materials for wrapping and packing materials	

<sup>1</sup> Estimated total no. of patients to which Santen contributed (disease areas: inflammation/allergies, cornea, glaucoma, cataracts) in FY2019 was approx. 43 million, calculated based on JMDC's estimated total no. of patients for Santen's Rx products and Santen's shipment data

<sup>3</sup> SLA/OLA: SLA is a promise made between the service provider and the service recipient; OLA is a promise made between the parties involved in providing the services

<sup>&</sup>lt;sup>2</sup> OTIF (on-time and in-full) shipping: a KPI for logistics or delivery performance within the supply chain, meaning on-time and in-full delivery

14 CEO's Message

**Strategy** 

## **CEO's Message**

On September 12, 2022, I was appointed representative director, president and CEO of Santen Pharmaceutical. I am keenly aware of the magnitude of the responsibility this new role entails, and I intend to dedicate all my time and efforts to the further growth of the Company.

Our CORE PRINCIPLE is *Tenki ni Sanyo Suru* (Exploring the secrets and mechanisms of nature in order to contribute to people's health). Under this principle, we have endeavored to be of service to our patients and their loved ones. And as a specialty company focusing on ophthalmology, we contribute to *Happiness with Vision* by providing valuable products and services to patients and medical professionals around the world.

Takeshi Oto

Takeshi Ito
President & CEO



## **Strategy**

14 CEO's Message

#### Strategy

#### My Approach as President and CEO

I have a deep conviction of the large potential of this company, our capabilities, and the talent that will take Santen to renewed and sustainable growth.

I feel both responsible and capable for putting the company back on a growth trajectory for our investors, for our duty to the long history of Santen, and for the employees who support our company. This is why I accepted this new role, and I believe we can achieve these goals.

I have always considered it my mission to provide ever-higher levels of essential value through our products and services. My belief in this mission is what motivates me and also what has driven my work at Santen.

In 2012, I was appointed as Head of Prescription Pharmaceuticals Sales

Department, Sales and Marketing Division, Prescription Pharmaceuticals, in what

I feel both responsible and capable for putting Santen back on a growth trajectory.

was deemed to be a difficult business environment in Japan. The number of our domestic medical representatives remained at around 400, never varying significantly over time, but I increased Japan ophthalmology business sales from JPY 90 billion to JPY 160 billion by filling our development pipeline, building an efficient and effective sales network, and managing via KPIs and the PDCA (Plan-Do-Check-Action) cycle. And while the global environment of today is challenging, it seems similar to what we experienced in Japan, and we look forward to the many growth opportunities waiting to be exploited.

#### Japan Ophthalmology Business Sales



## **Strategy**

14 CEO's Message



#### Fiscal 2021 Review and of Current Issues

Santen recorded a year-on-year increase in revenue and a decrease in profit for fiscal 2021, the first year of our MTP2025 medium-term management plan. While revenue grew 7% to JPY 266.3 billion, core operating income decreased 7% to JPY 46.3 billion. Rest assured that our management team takes this decrease in profit as a very serious matter.

Sales and profitability in our core overseas businesses are improving. But we still face challenges in productivity and profitability Company-wide. Our business in **China** ( Page 27) experienced a negative impact due to volume-based purchasing mainly with respect to *Cravit*. However, the steady shift to multi-channel sales allowed the business to recover. At the same time, the launch of our business in the **U.S.** ( Page 30) has not progressed as planned due to delays in the development and release of new products. This delay has slowed

our growth momentum temporarily. Therefore, we will place the highest priority on rebuilding profitability. In May, we began selling *Verkazia*, a treatment for vernal keratoconjunctivitis. We also re-submitted an application to the FDA for our glaucoma treatment, STN1011700, which received approval on September 22.

From the viewpoint of sustainability, we added an **ESG indicator as a component of executive compensation** (Page 64). We believe this new component will strengthen our framework for pursuing ESG management as a united company. On the environmental front, we formulated the Santen Vision for the Earth 2050, coinciding with the announcement of MTP2025. And the Company is already engaged in activities to achieve targets related to climate change and reducing our environmental footprint. Santen also began using biomass plastic for eye drop bottles. As of today, we use biomass plastic for seven products.

(JPY billions)

	FY2020	vs. Revenue	FY2021	vs. Revenue	FY2022 (Forecast)	vs. Revenue
Revenue	249.6		266.3		264.0	
Core operating profit	50.1	20%	46.3	17%	45.5	17%
Operating profit	12.2	5%	35.9	13%	34.2	13%
Net profit	9.1	4%	27.2	10%	24.4	<b>9</b> %

## Strategy

14 CEO's Message



#### **Challenges and Risks**

We have taken on a variety of challenges over the past several years. At the same time, we have not considered and evaluated opportunities sufficiently from the perspective of consumers and patients, and we have not prioritized projects sufficiently, either. As a result, our resources have been dispersed, and we have not built a system to properly manage and monitor KPIs, etc., which has kept us from implementing new initiatives consistently.

Given an awareness of these issues, I intend to organize our policies and reiterate our growth plan under my leadership. We will be more consistent in our study and evaluation of the opportunities we face and strengthen prioritization of projects. We must also refine our execution capabilities, mobilizing limited resources and establishing systems to manage and regularly monitor KPIs appropriately.

In terms of risk assumptions, we face the same risks common to the pharmaceutical industry, namely pipeline and geopolitical risks. We intend to build a risk-based portfolio for pipelines, including potential future changes. With regard to geopolitical risk, we plan to study the formation of supply chains tailored to each region as necessary.



We will be more consistent in our study and evaluation of the opportunities we face and strengthen prioritization of projects.

We accept that we have not met your expectations in terms of earnings. I have my own understanding of the challenges Santen faces and I intend to do everything in my power to meet your expectations.

As a first step, we will map out a detailed action plan, evaluate the challenges we faced looking back over the past three years, and assess what we have done well and what we have done poorly. In this way, we will make a course correction to return to a growth trajectory.

#### The Santen Approach to Raising Corporate Value Over the Long Term

Santen also pursues initiatives related to sustainability. On the environmental side, in June this year, we endorsed the Task Force on Climate-related Financial Disclosures (▶Page 49) and began disclosing risk scenarios along with other information. To reduce the environmental impact of our business operations, we use biomass plastic for eye drop bottles. At the same time, we are working toward a 15% reduction in plastic for packaging and packing materials by 2030, compared with 2019 levels. In February 2022, we completed a switchover to renewable energy for electricity used at our plants in Japan. You might not know that steam is essential for the production of eye drops and other products. As the transition to low-carbon energy accelerates, we envision the use of hydrogen boilers and hydrogen fuel storage facilities to transition from fossil-fuel boiler-driven energy to low-carbon energy. Santen is a member of the global community, and we will continue to fulfill our environmental responsibilities to the best of our ability.

## **Strategy**

14 CEO's Message





With employees of the Japan Business at the business division awards

Looking at human resources, I intend to emphasize relationships with our people above all else. I want to share the joy of providing consumers and patients with essential value at a level never-before provided through our products and services, which I view as a personal mission. And together with our people, we will deliver success under our new plan, tying the efforts of all to business results.

At the same time, we continue initiatives to strengthen corporate governance further. In June this fiscal year, we added two Outside Directors. Our Outside Directors now represent over 70%¹ of the Board, and the addition of a woman non-Japanese Director has increased **Board diversity** (▶ Page 59). The business environment will be challenging this fiscal year, and our Board of Directors is engaged in active and in-depth discussions to ensure we steer company management in the right direction.

We have started purchasing shares up to a total payout ratio of 150% this fiscal year.

#### To Our Shareholders

As announced in May this year, we have started to buy back shares as a means of capital allocation, purchasing shares up to a total payout ratio of 150% this fiscal year. Santen will act in a flexible manner, taking into account the stock price, market conditions, and other factors. While our basic policy is to make strategic investments in carefully selected projects based on our medium-term management plan, I will also focus on shareholder returns.

Last, I will say that in this rapidly changing world, it is essential that Santen engages with speed and consistent execution if we are to continue contributing to society as the leader in ophthalmology. Having been a member of the Santen management team for many years, I am convinced we have the talent and skills to accomplish our goals.

We will continue to do our utmost to meet the expectations of our shareholders, investors, and other stakeholders, and we look forward to your continued support.

Takeshi Ito
President & CEO

<sup>&</sup>lt;sup>1</sup> As of September 30, 2022

## CFO's Message (Financial Strategy for Medium-to-Long-Term Growth)

## **Strategy**

19 CFO's Message

#### **Strategy**

#### FY2021 Results and FY2022 Outlook

FY2021 marked the start of our medium-term plan MTP2025 with our share price underperforming the market and industry averages. Revenue was JPY 266.3 billion and grew 7% over the previous year, led by overseas sales, with core operating profit falling 7% to JPY 46.3 billion. The decrease in profit was mainly due to reduced pollen levels in Japan impacting core product line *Alesion* sales in contrast to the previous

year, COVID-19-related impact on certain regions' sales, and a delay in the earnings contribution of U.S.-based Eyevance acquired in FY2020.

For FY2022, the second year of MTP2025, we expect revenue to remain flat at JPY 264.0 billion, and core operating profit to decline 2% to JPY 45.5 billion. While we expect continued growth centered on Asia and EMEA for our overseas business, we project a decline in profit due to substantial impact from NHI drug price revisions in the Japanese market and an increase in upfront investments, including research and development expenses as new drugs in our pipeline advance to the next phase.

Meanwhile, we are making steady progress in the construction of new plants in Japan and China, our first major capital investments in 20 years, funded by a stable FY2021 and FY2022 operating cash flow. In addition, we have strengthened our new products pipeline for future growth through in-house development and in-licensing.

We also acknowledge the capital markets evaluation: we have not delivered one of our most important priorities which is shareholder value maximization.



Kazuo Koshiji Chief Financial Officer (CFO) & Chief Risk Officer

19 CFO's Message



#### **CFO's Message**

#### **FY2022 Financial Approach**

Improving our share price in light of its last 12-month trend remains our priority. While we recognize share price is determined by multiple factors, we intend to take the necessary actions towards (1) Earnings per share (EPS) and return on invested capital (ROIC) improvements and (2) Capital allocation with a greater focus on our shareholders.

Pertaining to our businesses, the previously stated projections are minimum targets. We aim to bring core operating profit to JPY 50 billion levels as early as FY2023. We will focus on improving profit margins across all income streams and taking necessary measures to manage the appropriate size of our balance sheet in a disciplined manner. Consequently, we will conduct a zero-based review of expenses including structural reforms, screen investments based on economic rationale, and improve existing asset turnover. We will also continue to take the necessary measures with a stronger commitment to capital efficiency. For investment in business development, in addition to verifying ROIC, we will control the consolidated intangible assets ratio on our balance sheet, and implement financial discipline to eliminate inefficiencies. We will also continue to optimize working capital.

Our capital policy will support improvements in EPS, ROIC, and consequently ROE by adjusting our outstanding number of shares and total capital through share buybacks. Although the quantitative impact would be limited, we will also promote divestments of cross-shareholdings from the standpoint of balance sheet discipline.

We will continue to prioritize investment for future growth in our cash flow allocation. However, since large-scale investments in business development are contingent on available opportunities, economic conditions and other factors, any resulting surplus funds generated from unrealized investments will be returned to shareholders. For FY2022, we project a cash allocation that would allow a minimum total payout ratio of approximately 150%, factoring in a dividend payout ratio of 40% and share buybacks. This reflects our recognition that the speed with which we have realized returns on upfront investments in recent years has fallen short of capital markets' expectations, whilst also taking into account Santen's minimum required level of working capital.

We will allocate capital in a way that contributes to improved capital efficiency. We will evidently optimize growth investments and shareholder returns while monitoring investment opportunities and profitability.

#### Positioning of Fiscal 2022 in MTP2025: FY2022–2023, Transitioning to a Resilient Financial Structure



19 CFO's Message

**Strategy** 

#### **CFO's Message**

#### **Medium-Term Financial Strategy**

#### 1 Capital Efficiency

Santen seeks to maximize shareholder value by maximizing cash flow and reducing the cost of capital, using return on equity (ROE) as its most important indicator.

Our fundamental approach remains unchanged. We will continue to focus on ophthalmology as we work to increase profitability, maximize cash generation capabilities and improve capital efficiency (ROE) to maximize shareholder value. I will work to optimize Santen's capital structure for financial soundness, while seeking the appropriate balance between upfront investments/retained earnings for future growth, and shareholder returns.

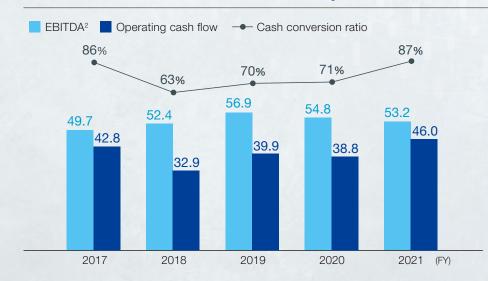
Santen aims to achieve an ROE target of 13% by the end of MTP2025 and 20% in FY2030. As precedently mentioned, although the earnings contribution of our U.S. business was delayed and the impact of drug price revisions in Japan was larger than anticipated, we will transform our earnings structure to be more

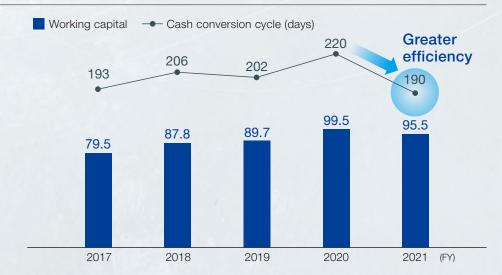
resilient and capable of generating profits irrespective of the business environment. On the basis that there is still ample room to increase profitability by reducing SG&A expenses, we aim to reduce the ratio of SG&A to revenue to a 30% level. We will also reduce the cost of goods sold (COGS) ratio to a 36% level by reducing manufacturing costs as well as changing the product mix. This should improve our core operating profit ratio by about 4 percentage points. We also expect to raise the net profit ratio by 5 percentage points or more by reducing the effective tax rate to the low 20% range by fiscal 2025, and target a compound annual growth rate (CAGR) for revenue of about 5% with an operating profit growth rate of approximately 10%.

We intend also to reduce the cost of capital through financial leverage in conjunction with aiming to maintain an A+ credit rating from R&I as an indication of our financial health and relevant low funding costs, thereby maximizing our ability to make investments.

#### Cash Flow: Stable Cash Generation Ability

(JPY billions)





<sup>&</sup>lt;sup>1</sup> Core basis: Non-recurring charges significantly reduced profit in FY2020.

<sup>&</sup>lt;sup>2</sup> EBITDA = (Operating profit) - (Other income) + (Other expenses) + (Depreciation and amortization)

19 CFO's Message



#### **CFO's Message**

#### Cash Maximization & Capital Cost Reduction

Our sources of cash will principally consist of net operating cash inflows, to be supplemented by external funding whilst maintaining financial health and stability. We will also mitigate long-term funding risk through staggered redemptions and repayments. In addition, we are centralizing financing at our International Financial Head Quarter (IFHQ) in Switzerland, thereby improving capital efficiency by funding respective regional capital needs using a cash management system.

Shareholders and the market expect value creation from investments in business opportunities that only Santen can turn into successes. This is why investment is our top priority in capital allocation. We have entered our first large-scale capital investment cycle in 20 years, which includes expanding production capacity in Japan and China and upgrading to a next-generation ERP system. We will also continue to invest strategically to acquire external resources that contribute to growth in our businesses, taking into account our balance sheet capacity, including intangible assets. We will evaluate investments to ensure that they are accretive in the near term, and enhance

asset turnover in existing businesses, which should mitigate the negative impact on capital efficiency from asset growth.

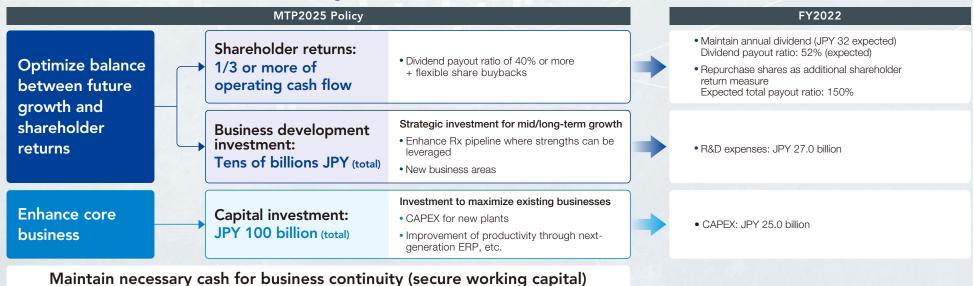
#### 3 Shareholder Returns

Delivering shareholder returns is a priority for Santen's management.

In MTP2025, we are focusing on improving total shareholder return (TSR) through direct distribution of profits and medium-to-long-term share price appreciation.

First, we will maximize profits by enhancing the profitability of the investments previously mentioned. We expect this will contribute to medium-term share price gains. Dividends are the primary form of shareholder returns, but we also intend to deploy our internal capital reserves to further enhance returns through share repurchases, subject to market conditions, in order to reward medium- and long-term shareholders. For FY2022, we are targeting a total payout ratio of approximately 150%, but in the medium term, we plan to return approximately one-third of operating cash flow to shareholders with a dividend payout ratio of 40% as a base.

#### Cash Allocation: Proactive Allocation to Strategic Investments and Shareholder Returns



23 Feature 1: Strengths in Japan





## We will effectively leverage our knowledge and experience in the Japan business, that has driven Santen's growth, to deploy our firmwide business strategies and bolster our competitiveness as a global ophthalmology company.

**Ito:** Japan has been the cornerstone of Santen's business and growth. Its greatest strength consists of its high quality and sophistication in product and marketing strategy followed by a thorough execution yielding results. This is largely the result of many years of changes we have undergone, regardless of the environment.

**Kurihara:** Fundamentally, all products exist to resolve a particular issue in eye care, and our evident objective should be to deliver what allows for a better treatment. Nevertheless, in terms of outcomes, there is a vast difference between product-centric sales promotion, and a set of actions and behavior resulting from a treatment vision-centric strategy. The strength of our Japan business is that we all

<sup>\*</sup> This discussion was held in June 2022.

#### Feature 1

#### Strengths in Japan

## **Strategy**

23 Feature 1: Strengths in Japan

Strategy

seek to propose better treatments from the patients' standpoint.

**Ito:** Our first consideration is the type of therapeutic value and satisfaction this product can bring to the patient. In order to meet this, we need to share the same understanding with doctors on the product's implication for the status quo, and its usage for actual treatment. Naturally, we also place importance on formulating concrete plans to realize our vision.

**Kurihara:** The considerations pertaining to a product launch including its preparations, consist of identifying the effective treatment and laying out the respective scenarios, and set of action plan. As a result of this approach, we have



a number of products that have achieved sales beyond our initial expectations.

**Ito:** Creating a vision for better treatment from the patient's standpoint, mapping out a clear process to reach the objective, and our capabilities for a thorough process implementation is something that is firmly rooted in a variety of our business activities. *Alesion* is a good example.

Kurihara: Conventionally, anti-allergy eye drops were applied once itching is felt, but from the patient's perspective, we thought it would be preferable to avoid any feelings of itchiness during the onset period. We thought on how this itchiness felt by a patient could be reduced which led us to promote proactive application as part of an appropriate eye drop usage. *Alesion* yielded results that greatly surpassed our original expectations. This outcome can be accredited not only to our Marketing Department but also to our medical representatives (MRs) and their entire division's ability to share and work toward the goal of better treatment from the patient's standpoint.

**Ito:** Sharing a picture of better treatment from that standpoint is also starting to make a difference in the activities and mindset of our MRs.

**Teramachi:** Our MRs in Japan share a common mission: To correctly understand and convey the value and potential of products, and to resolve challenges facing both patients and medical professionals. MRs share the same desire to alleviate the symptoms and burden concerning eye-related problems as the medical professionals who engage with patients every day. I believe that thinking from the perspective of patients will make it easier for them to understand the issues patients face. MRs place importance on collecting and providing information based

#### Feature 1

#### Strengths in Japan

## **Strategy**

23 Feature 1: Strengths in Japan

Strategy

on dialogues with medical professionals on how to realize better treatment, and that leads to proposals for solutions from the patients' perspective.

**Ito:** Other strengths of our MRs in Japan include their attention to detail in executing strategies and their thorough implementation of the Plan-Do-Check-Action (PDCA) cycle. We have taken a number of measures to ensure that each MR understands our strategies and incorporates them in their daily activities.

**Teramachi:** A PDCA process has been meticulously designed to maximize the outcomes of strategies. A management plan is established for each product. First, it is important that MRs understand the strategy. We take great care to make sure that they fully understand the significance of what they do. Strategies must be converted into action by MRs. Therefore, in pharmaceutical detailing, <sup>1</sup> for example, we have defined and are sharing the "model" that took shape after examining various ideas for the behavior MRs should adhere to according to our strategies.

<sup>&</sup>lt;sup>1</sup> Provision of pharmaceutical information to medical professionals and pharmacists by MRs of pharmaceutical companies





A systematic structure that includes **training through cooperation between the head office and frontline operations** (Page 47), support, and follow-up has
been established to empower all MRs to take action based on this model. MRs
prepare extensively before meetings and engage with medical professionals. In
addition, the aspects of their activities that have been positively evaluated by
patients and medical professionals, as well as issues that should be addressed, are
quickly shared with the sales organization as well as strategic planning and support
departments to be used for further improvements. These are just examples, but the
PDCA management of our overall sales organization is full of innovation that we put
into practice while making necessary improvements.

Ito: To achieve further global growth, it will be important for Santen to use its creativity to paint a picture for better treatment that fits the specific needs of patients and stakeholders in each region. In pursuing that objective, I think the comprehensive PDCA cycle that we are implementing in Japan can also be applied in other regions to bolster our firmwide results.

# Strategies by Region Japan



- Increase in people with eye problems due to increased use of digital technology and visual display terminals
- Recovery in demand from overseas visitors as Japan relaxes entrance restrictions (OTC pharmaceuticals)
- Discovery of potential patients and improvement in adherence rates as a result of greater disease awareness and understanding
  Expansion of consultations as a result of the availability of online consultations and other services that offer improved
- Increase in eye exams in new patient segments and discovery of potential patients, following the development of drugs in areas that lack widely available treatments, such as myopia, presbyopia and ptosis



• Patent expiration of core products and launch of generics

convenience of medical care

- Reform of National Health Insurance system and drug pricing system (e.g., possible extension of reimbursement pricing revisions to all drugs)
- Replacement with generics to the same degree as in other therapeutic areas (80% or more) due to government policies to promote the use of generics

## **Strategy**

26 Strategies by Region





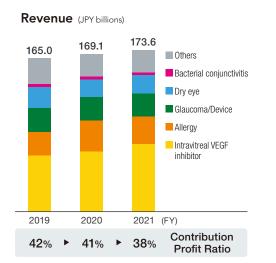
The Japan business, which is mainly centered on the prescription pharmaceuticals, over-the-counter (OTC) pharmaceuticals, and surgical domains, accounts for approximately 65% of consolidated revenue. In prescription pharmaceuticals, which accounts for the bulk of sales, we maintain the top market share<sup>1</sup> and high customer satisfaction. In that regard, our 400 medical representatives nationwide deliver services as an "Ophthalmic Solutions Provider," while focusing on the needs of patients and medical professionals. Sales and marketing, medical affairs, development and other functions cooperate to gain a firm understanding of medical challenges, which they apply in developing high-value-added products and providing information. This has led to business growth and increased productivity. For example, STN1008903, a dry eye treatment approved in June 2022, is an improved formulation of Diquas. It reduces the frequency of application from six times a day to three. One of the challenges in treating dry eye syndrome is poor adherence to the dosing regimen and consequently, the desired therapeutic effect is not obtained.<sup>2</sup> In response, Santen developed a formulation that is expected to improve therapeutic

outcomes by reducing the burden on patients and promoting adherence to the dosing regimen.

In fiscal 2021, although revenue from *Alesion* decreased sharply due to lower-than-average pollen counts, revenue for the Japan business as a whole increased 2.7% over the previous year due to the contribution of other major products. Over the next few years, we expect to face National Health Insurance (NHI) drug price revisions, including a significant reduction in the reimbursement price of *Alesion*, and patent expirations of core products such as *Diquas*, *Tapros* and *Tapcom*. This will make for a difficult operating environment, with sales in fiscal 2022 projected to decline 10% year on year. However, by launching new products and providing tools that support treatment and care for glaucoma and dry eye, we will continue to resolve the challenges faced by patients and eye care professionals, and thereby maintain and improve profitability. We will also put the knowledge we have cultivated in Japan to use in other regions to enhance Group-wide profitability and contribute to better ophthalmic care globally.

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目のかゆみ



.IPY **173.6** hillion

(65%)

#### Value Creation Highlights

#### Using Digital Technology to Provide Information to Patients and Consumers

Santen develops various smartphone apps aimed at improving quality of life for patients and everyday users. Two examples are *Kayumidas* and *Hitomi Ururu Scan* (see images on right). *Kayumidas* targets pollinosis patients.

Based on the daily weather forecast, the app provides users with alerts for eye conditions such as itchiness, as well as precautionary measures they can take. It also comes with a reminder for eye drop application and other functions that support "preemptive instillation" during the onset period. *Hitomi Ururu Scan* promotes care by using image recognition technology to check for low eye moisture, which is closely associated with eye dryness and eye strain, and suggests ways to maintain and improve eye moisture.



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## China



- Market growth driven by increasing number of patients due to aging population and development of ophthalmic ecosystem
- National-level initiatives targeting myopia and other eye conditions
  Rising demand for high-value-added pharmaceuticals and shift of patients to high-end private hospitals, reflecting rapid
- Insurance reimbursement for innovative products and acceleration of new product launches due to evolution of the drug approval system



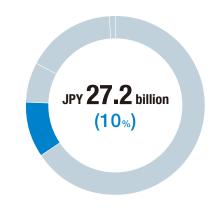
- Drug reimbursement price reductions among existing products and impact on sales due to changes in healthcare policy and the insurance system
- COVID-19-related restrictions in major cities due to renewed outbreak and impacts on business
- Delay in construction of new plant in Suzhou due to the global semiconductor shortage and COVID-19-related restrictions
- · Soaring labor costs amid economic growth and intensifying competition to acquire highly skilled personnel

## **Strategy**

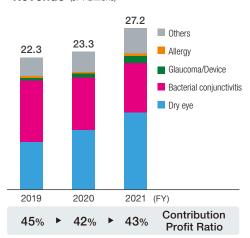
26 Strategies by Region

Strategy









#### **Business Strategy and Overview**

The China business began scientific and marketing activities following the establishment of the Beijing Representative Office (no longer in operation) in 1996. Following the establishment of Santen Pharmaceutical (China) Co., Ltd. in 2005, completion of the Suzhou Plant and the start of integrated production, as well as sales and marketing activities, enabled Santen to further grasp customer needs in China and offer greater value. As a result, we maintain a large market share¹ and high customer satisfaction. In anticipation of continuing reforms to China's healthcare system, we will shift from concentration on large national public hospitals to a multichannel customer strategy. In addition, we will pursue differentiation by strengthening development of the ophthalmic ecosystem (such as through support for the training of eye care professionals and initiatives to identify potential patients), by enhancing research and development functions, and by using digital technology and scientific evidence to expand sales of new products. With this approach, we aim to achieve sustainable growth while unlocking high growth potential.

We expect long-term expansion of product demand in the China market with the emergence of potential patients and new markets in areas such as myopia, reflecting the large population, rapid aging of the population, and the development of the ophthalmic ecosystem. In the context of our operations in

China as a pharmaceutical company specialized in ophthalmology, our Suzhou Plant is unparalleled in its technological capabilities, quality and production capacity for ready-to-sell products. Additionally, our new plant in Suzhou, currently under construction and scheduled to start operations in 2025, will reduce costs through increased automation and labor saving, and incorporate environmental considerations such as  $CO_2$  emission reductions. With a production capacity of up to 840 million units (5mL unit equivalent) per year, it will further solidify our competitive advantage in China.

In fiscal 2021, the China business recovered rapidly from the impact of volume-based purchasing that began in the second half of fiscal 2020, achieving growth of 16.5% year on year driven by expanded sales of new products such as *Diquas* and *Tapros* and the steady implementation of the multichannel approach and other strategies. We have also been taking steps to boost productivity, including efforts to improve sales and marketing efficiency, and ensuring expenditure allocations are fully deployed according to revenue performance. Through the steady implementation of our strategies in fiscal 2022, we aim to expand sales of existing products and advance R&D projects to the next stage. The launch of *Verkazia*, which obtained approval in China in April 2022, will contribute to the treatment of vernal keratoconjunctivitis (VKC) and help improve quality of life for patients and their families.

#### Value Creation Highlights

## Building a Society Inclusive of Blind and Visually Impaired People: Establishment of Education Centers

In April 2021, the Suzhou Industrial Park Youth and Kid Extracurricular Education Center was established by Santen and the Suzhou Industrial Park Education Department. Its purpose is to promote knowledge and management of eye health among young people. On the same day, Santen and the Beijing Hongdandan Cultural Service Center for the Visually Impaired established an education center for visually impaired people with the objective of enhancing social understanding and support for the visually impaired.





<sup>&</sup>lt;sup>1</sup> Copyright © 2022 IQVIA. IQVIA MIDAS 2021, Santen analysis based on IQVIA data. Reprinted with permission.

## **Asia**



- Improved diagnosis and treatment rates for eye conditions as the ophthalmic ecosystem develops
- Increasing interest in eye care in conjunction with economic development and rising household income, primarily in Southeast Asia
- Diversification of sales channels such as e-commerce and online pharmacies in tandem with advances in digital technologies

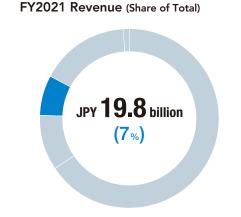


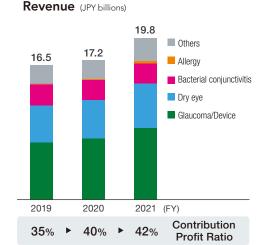
- Drug reimbursement price reductions and accelerated promotion of generics in government hospitals due to deteriorating national health insurance finances
- Improvement in quality of generics
- Stricter regulatory reviews that take cost-effectiveness into consideration in drug approval and insurance coverage

## **Strategy**

26 Strategies by Region







#### **Business Strategy and Overview**

In its Asia business, Santen operates in more than 15 countries and regions, including South Korea, Taiwan and Hong Kong in East Asia, and Vietnam, Thailand and other countries in Southeast Asia. We entered various markets starting in the 1990s, then began our own sales activities in South Korea in 2010 and in Thailand, the Philippines and elsewhere from the mid-2010s. We have steadily implemented strategies geared to needs specific to the Asia region, such as the launch of single-dose products for glaucoma and dry eye. As a result, we hold the top market share in South Korea and the Philippines, and have increased our market share<sup>1</sup> and gained a high level of customer satisfaction in many markets. We will continue to launch new products that accurately address the needs of patients and healthcare professionals, and support the development of the ophthalmic ecosystem to improve diagnosis and treatment rates. In Asia, there are not enough high-quality healthcare professionals to develop the ophthalmic ecosystem, and Santen is taking various measures to address that issue. In 2021, we began educational support for ophthalmic technicians in cooperation with the Singapore National Eye Centre. Such personnel play an important role in ophthalmology; however, in many regions systematic training opportunities are inadequate in comparison to those for ophthalmologists. By supporting training of ophthalmic technicians, we will contribute to the expansion of eye care capacity in Southeast Asia.

In fiscal 2021, although some areas were significantly impacted by COVID-19, revenue increased 15.1% year on year as sales of core products for glaucoma and dry eye outpaced market growth¹ in major markets. The COVID-19 pandemic led us to digitalize and rethink sales activities, which improved the contribution profit ratio. Going forward, we will accelerate our shift in emphasis from expansion of sales volume to enhancement of quality. From the standpoint of providing new value that will support medium- and long-term growth, we will strengthen our business in glaucoma, an important therapeutic area, with the launch of *Eybelis* (in South Korea, Taiwan and Thailand), obtain approval of *PRESERFLO MicroShunt* in Singapore and other markets, and file for approval of ROCK inhibitor STN1013900. In addition, we are developing a treatment for ptosis, a new disease area for us, with the aim of filing an application in fiscal 2022.

#### Value Creation Highlights

#### An App That Provides Eye Care Information

In Asia, we are using digital technology to deepen communication with healthcare professionals. As part of those efforts, we are offering *Santen MD*, an app that provides the latest medical information to eye care professionals. The app features a wide range of content, including educational materials provided by Santen, webinars conducted jointly with academic societies, articles and videos about eye conditions, and columns by key opinion leaders. Approximately 6,800 healthcare professionals have registered for the app since its release in early 2020, representing more than half of the ophthalmologists in the supported area.<sup>2</sup>





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<sup>&</sup>lt;sup>2</sup> Countries and regions where Santen conducts its own sales activities

## **EMEA**



- Opportunity for further penetration of the world's second-largest market<sup>1</sup>
- Increase in glaucoma patient numbers due to aging population, and dry eye patients due to higher disease awareness
- · Economic development and market growth in Middle Eastern and African countries



- Macroeconomic impact resulting from the situation in the Russia-Ukraine region that could affect countries' productivity, interest rates and cost of living
- Changes in insurance reimbursement coverage and reductions in reimbursement prices in response to deteriorating healthcare finances in various countries

## **Strategy**

26 Strategies by Region





The scale of Santen's EMEA business is second only to that of Japan, with operations in about 50 countries and regions. The acquisition of Novagali Pharma S.A. (now Santen S.A.S.) and the ophthalmology assets of Merck & Co., Inc. of the U.S. in the 2010s expanded our product portfolio and geographic reach, and we have continued to strengthen our business foundation in this region. Currently, we are achieving growth in excess of market growth² rates with a product lineup that addresses regional needs, centered on single-dose products and preservative-free multi-dose (PFMD) products in the areas of glaucoma and dry eye. As a result, we achieved the top glaucoma market share in 13 countries.² For PRESERFLO MicroShunt, which was first launched in Europe, we have been providing product training to surgeons and expanding the number of facilities at which it is available since the controlled launch in 2018. We are aiming to grow sales to over JPY 5.0 billion in fiscal 2025.

The EMEA business encompasses many countries and regions, and while this enables us to diversify risk, each country has its own healthcare policies and insurance systems, so precise management is required across the entire region. A market access strategy and marketing strategy for maintaining and improving product value over the medium and long term is especially important, and our diverse team of 26 leaders from 13 countries and regions works in close cooperation on a daily basis to grow and promote the business.

Fiscal 2021 revenue increased 13.2% year on year with growth centered on the core areas of glaucoma and dry eye. At this time, the impact of the situation in the Russia-Ukraine region on the Santen Group is not significant, but we are closely watching developments while ensuring our product supply capabilities, placing top priority on the safety of employees and their families. We are also actively entering new therapeutic areas. In addition to expanding sales of new products such as the antibiotic/steroid combination treatment *Ducressa*, we have in-licensed ROCK inhibitor products for glaucoma and an atropine myopia treatment. Going forward, we will leverage digital technology to increase productivity and share knowledge within the Group, focusing on functions for which we are particularly strong in Europe such as medical affairs and market access, as we continue our transformation into a truly global company.

# Revenue (JPY billions) 42.9 Others Allergy Bacterial conjunctivitis Dry eye Glaucoma/Device

2021 (FY)

2019

2020

27% ▶ 30% ▶ 33%

JPY 42.9 billion

(16%)

# Allergy Bacterial conjunctivitis Dry eye Glaucoma/Device (i) try) Contribution Profit Ratio

#### Value Creation Highlights

#### Next-Generation Ophthalmology Education Platform

Since February 2022, we have been steadily rolling out the Santen Eyecare Education (SEE) portal for healthcare professionals in Europe. As digitalization progresses rapidly, there is a growing need for flexible online education programs. SEE enables European healthcare professionals to access best practices, as well as educational programs that incorporate gamified elements, thereby contributing to the development of ophthalmology healthcare education in the region.





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<sup>&</sup>lt;sup>2</sup> Excluding S01P (retinal diseases)

## **Americas**



- Growth in the world's largest ophthalmic market<sup>1</sup>
- Increase in volume of patients with eye conditions (e.g. glaucoma, etc.) due to an aging population



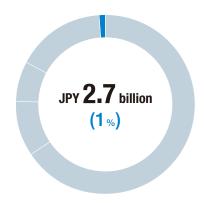
- Decrease in selling prices due to changes in insurance systems and tightening of criteria for formulary<sup>2</sup> listing
- Impacts of product distribution due to issues in the global supply chain
- Decline in competitiveness of existing products due to emergence of OTC products

## **Strategy**

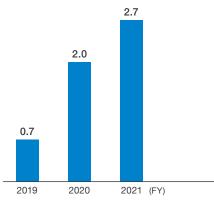
26 Strategies by Region







#### Revenue (JPY billions)



\* Mainly consists of revenue from products of the former Eyevance Pharmaceuticals and *Cationorm*.

The profit contribution is negative.

#### **Business Strategy and Overview**

In the Americas business, 2019 marked the launch of Verkazia for the treatment of vernal keratoconjunctivitis (VKC) in Canada. In addition, we made a full-fledged re-entry into the U.S. market (following market withdrawal in the early 2000s) with the acquisition of Eyevance Pharmaceuticals Holdings Inc. in September 2020. The United States is a large market, accounting for nearly half of the global ophthalmic solutions market, 1 and is a critical market from the perspectives of building our global presence, exploring opportunities for future growth, and research and development. It is also a fiercely competitive market, so we decided on a strategy of pursuing differentiated products, building market understanding and cultivating a customer network. We acquired Eyevance as a base for developing our product pipeline and for sales and marketing infrastructure. Post-acquisition, integration was extremely challenging due to the COVID-19 pandemic, however, we successfully integrated Eyevance with the Santen U.S. business, and our platform for securing U.S. market access is now in place. Nevertheless, achieving profitability has taken longer than expected due to the receipt of a complete response letter from the FDA citing issues with regard to STN1011700, for which we have filed a new drug application,

the removal of core Eyevance products from formularies, and product shortages caused by problems in the global supply chain.

In fiscal 2021, revenue increased 35.0% year on year, but due to the factors mentioned above this figure was significantly lower than the forecast, while profitability was also impacted. Currently, we are working on the normalization of product distribution, as well as measures to improve productivity, rebuilding the organizational structure, and to strengthen R&D functions, which is key to our future growth. We anticipate achieving several major milestones in the United States in fiscal 2022. First, is the launch of VKC treatment, *Verkazia*, in May 2022, following which we will focus on market penetration. The second milestone relates to STN1011700. In response to the complete response letter received in 2021, we implemented remedial measures and refiled the new drug application in May 2022. We believe this formulation with a novel mechanism of action can provide a new therapeutic option to glaucoma patients. For the Americas business, increasing sales and productivity are urgent issues, and we will accelerate our preparations to achieve profitability as early as we can.

#### **Value Creation Highlights**

#### Launch of Verkazia

This product is a prescription treatment for which we have obtained approval in the U.S., and is the only FDA-approved topical immunomodulator for the treatment of VKC in children and adults. The number of patients diagnosed with VKC exceeds 49,000,3 with more cases believed to go undiagnosed or overlooked. By raising awareness and providing treatment options for VKC, a rare disease, we are helping patients affected by this disease achieve greater independence in their daily lives.

- <sup>1</sup> Copyright © 2022 IQVIA. IQVIA MIDAS 2020-2021, Santen analysis based on IQVIA data. Reprinted with permission.
- <sup>2</sup> A list of drugs compiled by the pharmacy benefit manager that are approved for prescription under insurance coverage
- <sup>3</sup> Delvelnsight 2020 Vernal Keratoconjunctivitis (VKC) Epidemiology Forecast—2030.



31 EMEA: Continuing Its Steady

**Growth Trajectory** 

## **EMEA:** Continuing Its Steady Growth Trajectory

By integrating the region's diversity into business strategies, we will raise Santen's presence further as a global ophthalmology company in EMEA.



#### **EMEA Human Capital Diversity**

Our EMEA region extends to around 50 countries with about 750 employees of 45 different nationalities. Our overall regional female-to-male employee ratio stands at 61%:39% with an average age of 45. If you look at gender for medical representatives (MRs) and scientific affairs managers, the

ratio is 58%:42%. The prevailing rich diversity that the EMEA region offers and which we have leveraged is one of the key factors that has enabled us to develop a strong business over the course of the last few years.

#### **Diversity and Business Strength**

The EMEA region consists of a sophisticated network of countries with different healthcare systems and operating and regulatory environments. Our focus on working with this diversity as we pursue full-scale business expansion has allowed us to assess properly the business environment and calibrate the region's strategy accordingly. We leverage this sophisticated level of coordination in the region to achieve a similar level of collaboration internally between various functions ranging from market access to R&D and externally, for example with contract manufacturing organizations (CMOs). This has been fundamental to the execution of our regional business strategy and allowing us to develop our talent with global role opportunities based in EMEA.

Top-line contribution to Santen is at 16% for fiscal 2021, coupled with an increase in productivity in terms of

contribution profit margin that has improved from 27% to 33% since fiscal 2019 due to a disciplined cost-conscious approach. As a result of our penetration in the glaucoma and dry-eye space, which accounts for close to 90% of EMEA sales, our market share is increasing in a number of countries. Our key products are contributing to this growth, resulting in an increase in share in 10 out of 12 key countries in EMEA. In particular, we have the top market share in 13 countries for glaucoma.

Our EMEA Pricing & Market Access team has shown an integral role in optimizing the value of our products to patients, from initial new product planning, to obtaining patient access with successful health technology assessments, showing cost containments and cost-utility and economic studies, all the way down the line to pricing management in light of loss of exclusivity and generic bridging. It is even more exciting to see that this Value & Access approach will be incorporated into our global framework to not only serve patients in the EMEA region, but to optimize and enhance the value and access of our products to patients globally.

The change in environment related to the COVID-19 pandemic also compelled us to accelerate our digital transformation in key areas such as switching to online medical education, direct-to-consumer activation and marketing personalization. The use of data and analytics alongside medical education delivered in novel and relevant ways improved learning accessibility and effectiveness for many.

Strategy



Average 5.7 years

Average 45 years old

45 different nationalities in EMEA

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31 EMEA: Continuing Its Steady Growth Trajectory

#### Strategy

#### **EMEA: Continuing Its Steady Growth Trajectory**

We will continue to grow our business while we constantly calibrate and improve our processes and optimize and leverage our resources. In EMEA, we have also been very keen to take the necessary actions to minimize short- and long-term impacts from change in external operating conditions such as the ongoing situation concerning Russia and Ukraine.

#### **Latest Trends**

Our glaucoma product portfolio has performed with gains in market share. *Tapcom* is one of our key growth drivers with further potential and *Cosopt* preservative-free formulation has fared well, overtaking the preservative formulation. As for *PRESERFLO MicroShunt*, we have a growing number of surgeons using it, with our surgical partners playing a key role in supporting them to get the best outcomes in all of their suitable patients.

The trend of early treatment to stop the vicious cycle of dry eye has strengthened among both healthcare

professionals and patients. COVID-19 created a backlog for ophthalmologists to catch up with after the pandemic. We are working on a patient support program which will not only help patients to better understand their disease and ways of managing it but also to realize why is it important to stay on treatment in order to get better long-term relief from their dry eye.

Despite various hurdles related to the COVID-19 pandemic, clinical activities in EMEA successfully continued in fiscal 2021, including the recent completion of a pivotal trial, in parallel with three other ongoing clinical studies in dry eye and glaucoma. Through our emphasis on People Centricity we aim at better understanding patient needs and expectations to guide R&D directions.

While we will drive new products across the glaucoma and dry eye space in fiscal 2022, leveraging the diversity of our human capital pool will continue to remain the key factor to determine our success as a firm in supporting our customers and patients.

#### **Catherine Curutchet**







#### On Diversity

#### What does diversity mean to you?

Diversity in an organization is multi-faceted, covering such wide angles as gender, professional experience and age. The more diversity you have, the more perspectives you can rely on to anticipate, plan and execute your business strategy wherein you are constantly faced with changes.

#### How have you promoted diversity in the organization?

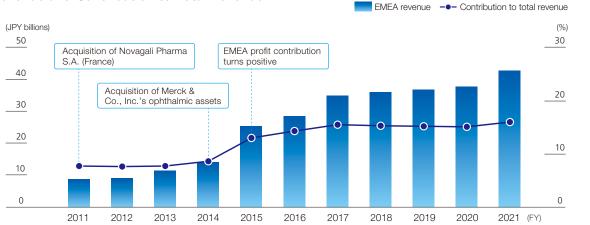
The key is to ensure that there is diversity in your own team. Company-wide quota objectives on specific ratios are good tools to point out which direction the Company is heading, but in terms of effectively promoting a diverse work environment, respective diversities need to have representation. I believe human nature makes it difficult to make bias-free decisions—regardless of good intentions or whether or not you are aware of it.

#### How has acknowledging bias worked for you in promoting diversity at Santen?

I am leveraging my experience in France to be responsible for Benelux and North Africa, in addition to France. I think being aware of your own bias is first and foremost important. I spent the first sixteen years of my career in the consumer products space before spending the other half in the pharmaceutical industry. I believe constantly challenging yourself is important and this is why upon my current appointment I focused on getting the appropriate level of representation of diversity in my team, including but not limited to professional experience, gender, age, and cultural background.

Belgium, the Netherlands and Luxembourg

#### Revenue and Contribution to Total Revenue



33 Product Development

## **Product Development**

Santen is working to support short- and medium-term growth by developing and launching products in its core business areas with a focus on glaucoma, dry eye and allergies. At the same time, we are conducting research and development in new therapeutic areas and treatments that will support future growth. We are stepping up our efforts for innovation in areas such as digital health and cell therapy, and are working on new disease areas including myopia and ptosis with a view to providing value to patients through the out-of-pocket market. Having identified which diseases to target based on unmet needs and the maturity of technologies, Santen formulates disease strategies by comprehensively considering the kinds of therapeutic methods and services we can and should contribute to, taking into account the impact on society and medical care, and the suitability of our technologies and experience.

Key Achievements of Ophthalmology Innovation Center (FY2021)

- STN1010905—Started P2a (meibomian gland dysfunction)
- STN1012700—Confirmed safety and tolerability in P1 (myopia; China)
- STN1013400—Confirmed safety and tolerability in P1 (myopia)
- STN1013600—Confirmed safety and tolerability in P1 (presbyopia)

Key Achievements of Product Development Division (FY2021)

- STN1007603 Obtained approval in U.S. and China
- STN1008903 Filed in Japan
- **STN1013900**—Filed in Asia
- STN2000100 Obtained approval in Japan and Asia



Understand patients' circumstances and address eye diseases in collaboration with external partners

Santen is working to create products by considering patient needs, scientific understanding, and medical perspectives, while continually being people-centric. In order to strategically create new products for target diseases, we, the Ophthalmic Innovation Center, collect patients' real voices and visualize the patient journey1 to accurately grasp the progression of symptoms, treatment methods, and patients' circumstances. This process enables us to clarify the points that should be addressed in each disease and the product concept, and then establish an appropriate disease strategy. In addition, our pipeline in the early stages of research is mapped on two axes: the number of patients with a given disease and the degree of potential therapeutic contribution to the patients. Through this mapping we identify areas in our pipeline to strengthen and focus on. Based on these strategies and priorities, we engage with universities, research institutes, pharmaceutical companies, and startup companies worldwide to strengthen

our networks and collaborations. This approach is one of Santen's strengths, and leads to the development of new drug candidates and therapeutic technologies. We have created a collaborative research and development framework with academic institutions such as the Singapore Eye Research Institute (SERI) and University College of London (UCL). In addition, through our alliances we have been able to find drug candidates for myopia and Fuchs endothelial corneal dystrophy. We are also working toward the objective of increasing the probability of success in product creation, including by increasing the percentage of products that advance to the next stage of clinical trials. For diseases where it is difficult to establish clinical efficacy indicators, we perform biomarker exploration and translational research.<sup>2</sup> In these and other ways, we will contribute to the creation of new products from a scientific standpoint and from the patient's perspective.

Strategy

- 1 A representation of the patient's Behavior, Thoughts, Feelings, and other processes from the patient's recognition of a disease or symptom to the patient's eventual treatment, including hospital visits and medication
- <sup>2</sup> Bridging research that links basic research, clinical research, and medical treatment to efficiently and effectively commercialize results that contribute to medical development

33 Product Development

**⊘** Strategy

#### **Product Development**



Develop products efficiently to meet true unmet needs by strengthening strategies and execution capabilities

The Product Development Division's mission is to develop and deliver products that meet the needs of patients as quickly as possible, without compromising quality. In order to achieve this goal, we maintain the following three deliverables as priorities:

 develop and implement a development strategy that reflects both patient insights and market needs;
 continuously maximize product value through life cycle management;
 strengthen global scientific and operational excellence, supporting our ability to accomplish the development objectives we set.

In fiscal 2021, we achieved several important pipeline milestones. In Japan, examples include filing for approval of STN1008903, a new formulation of *Diquas* that reduces applications needed per day, and obtaining approval for *Eybelis* as a single-dose eye drop with improved safety. In the U.S., we obtained approval for *Verkazia*. At the same time, we filed for approval of *Verkazia* in China as part of our regional expansion. We also refiled STN1011700 in the U.S. in May 2022. These achievements are the result of our efforts to create products that meet the needs of patients by closely communicating with them, as well as with regional health authorities and agencies, and strategically implementing development.

We have been able to minimize delays as well as accelerate the development plans for our late-stage clinical pipeline, despite the COVID-19 pandemic that has been ongoing since



2020. This success can be attributed to our constant efforts to implement new technologies to improve the execution of remote clinical trials, and the close communication between regional clinical development members and study sites. Digitalization is indispensable for the further pursuit of global operational excellence. These technologies are advancing day by day; hence, we are keeping our eyes on the development of new technologies worldwide and will quickly adopt those that are consistent with our clinical trial strategies. We will continue to contribute to Happiness with Vision for our patients by effectively developing a pipeline based on our strategy of continuously delivering products to patients that meet their true needs.



**Kenji Morishima**Head of China Product
Development Department

The mission of the China Product Development Department is to develop and deliver drugs to meet the needs of patients as quickly as possible. Until now, for products already launched outside China, the development process involved bridging studies to demonstrate that there is no significant variation in efficacy of products due to interethnic differences between patients in China and in other regions. The need for this creates a time lag between product launches in other regions and in China. Of course, one of our most important missions to accomplish by 2025 is to obtain early approval in China for products already launched in other regions. However, looking ahead to 2030, we would also like to integrate the pipeline in China with the global pipeline from an early stage, through which China would be able to participate in

multi-regional clinical trials (MRCT) for new products, file for approval and launch products within the same timeframe as other regions. To achieve this, we are working to secure skilled human resources, build a robust development process and construct a framework capable of high-quality development. We will also formulate competitive development strategies that take full advantage of Santen's strengths, i.e., having a development base in China and knowledge of application routes specific to this region. Backed by both an extensive pipeline and operational excellence, we will accelerate innovation at the China Product Development Department in order to bring new products to patients in China faster, and continue to contribute to Happiness with Vision.

33 Product Development

**Strategy** 

#### **Product Development**

Taking on a rare allergy mainly affecting children with our proprietary technology "Novasorb"



Henri Criseo

Director, Project Management Research & Development (Global) Project Management Group Product Development Division

Vernal keratoconjunctivitis (VKC) is a rare allergy mainly affecting children and adolescents. It can feature severe symptoms such as a burning sensation, eye pain and pruritus that can significantly impair patients' quality of life, and may cause corneal damage and loss of vision. If patients develop symptoms at school age, they may need to cool their eyes frequently with a clean towel to relieve symptoms, or wear sunglasses due to photophobia when they go out, which may interfere with their daily life and ability to follow classes.

Before Santen developed *Verkazia*, the only treatments were mainly corticosteroids, which cannot be used over the long term and can include significant side effects, or the empirical use of ciclosporin A through hospital compounded formulations. Santen therefore decided to develop its own formulation of ciclosporin A using *Novasorb*, a cationic emulsion technology that improves the corneal bioavailability of the active ingredients compared to more standard formulations. This is the same innovative technology that is used in *Cationorm*, *Ikervis* and more recently STN1013001. *Novasorb* technology was developed by Novagali Pharma, which Santen acquired in 2011. This technology led to the

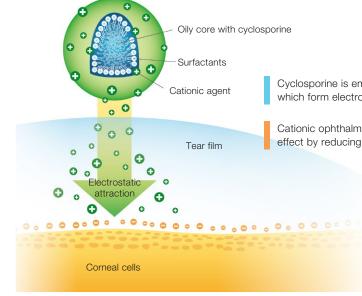
development of *Verkazia* with a specific adapted dosing regimen to treat VKC, keeping in mind that the product had to be well tolerated by the patients as well as being highly effective.

All those medical requirements were engraved in the development team's mind so that each step would be reflected in the final product. *Verkazia* demonstrated rapid improvement in the symptoms of patients with severe VKC in large-scale clinical trials. This resulted in the approval and launch of the first product with a VKC indication in the EU. It was recently approved in Asian countries, Canada, the U.S. and China as well.

At Santen, Patient and People Centricity is at the forefront,

and we truly believed from the beginning of development that bringing an innovative, standardized and effective product to VKC patients and their caregivers would help relieve the effects of this condition. One caregiver provided us with the following message. "The *Verkazia* eye drops are amazing. I would like to thank all of you for coming up with this drug and making it happen. Our lives have changed dramatically, and our family can't thank you enough." It is messages such as these that inspire and drive us forward in developing treatments for patients such as those affected by VKC. We are proud to make available a new and effective therapeutic solution that helps improve the quality of life of patients with this rare and burdensome condition.

#### ■ *Novasorb* Technology



Cyclosporine is embedded in positively-charged nanosized droplets, which form electrostatic attractions with the anionic ocular surface¹

Cationic ophthalmic emulsion provides an additional palliative effect by reducing inflammation and discomfort¹

Verkazia¹ cyclosporine ophthalmic emulsion 0.1 %

Sterile

For topical ophthalmic use

<sup>1</sup> J Drug Deliv. 2012;604204.

Santen Report 2022

# **Strategy**

#### 33 Product Development

# **Strategy**

## **Product Development**

# **Development Status**

Products Launched in FY2021	37 products including STN1011702 (Eybelis Mini, glaucoma, Japan)
Products Approved in FY2021	<b>47</b> products including <b>STN1007603</b> ( <i>Verkazia</i> , vernal keratoconjunctivitis, U.S.) and <b>STN2000100</b> ( <i>PRESERFLO MicroShunt</i> , glaucoma, Japan/Asia)

For the latest development status of main projects in the pipeline, please see the Company's website.

#### Pipeline Development Status (As of May 31, 2022)

	Clinical development plan in preparation <sup>1</sup>	P1	P2	Р3	Filed
	<b>STN1014000</b> (Asia, filing)		<b>STN1012600</b> (JP, EU, U.S.)	<b>STN1011101</b> (CN)	<b>STN1011700</b> (U.S.)
Glaucoma	STN1008507 ( <i>Tapros</i> with new instillation system, JP, filing)			<b>STN1013001</b> (Asia, EU)	<b>STN1013900</b> (Asia)
	STN1011103 ( <i>Tapcom</i> with new instillation system, JP, filing)			STN1013900 (JP)	
					STN1008903 (JP)
Dry eye					<b>STN1013500</b> (JP)
					<b>STN1000501</b> (CN)
Allergies				STN1011402 (JP)	
Fuchs endothelial corneal dystrophy			<b>STN1010904</b> <sup>2</sup> (U.S., France, India)		
Meibomian gland dysfunction			STN1010905 (JP)		
Myonia	STN1013300	<b>STN1012700</b> (CN)	<b>STN1012700</b> (Asia)	STN1012700 (JP)	
Myopia		STN1013400 (JP)		<b>STN1012701</b> <sup>3</sup> (EU)	
Presbyopia	<b>STN1013600</b> (U.S., P2a)	<b>STN1013600</b> (JP)			
Ptosis	<b>STN1013800</b> (JP, P3/Asia, filing)				
Retinitis pigmentosa	STN6000100 (P3)				

Discontinued development of STN1010900 (sirolimus, intravitreal injection) based on a reassessment of its business feasibility Out-licensed STN2000100 (glaucoma implant device) to U.S.-based Glaukos in the Americas, Australia and New Zealand

<sup>1</sup> Includes projects in the non-clinical stage, projects for which clinical trial protocols are being formulated, and projects for which applications are planned.

<sup>&</sup>lt;sup>2</sup> Santen retains the option right for exclusive license for this program. This development code to be formally assigned to the product when Santen obtains exclusive license upon the completion of Phase II trial.

<sup>&</sup>lt;sup>3</sup> Conducted by Sydnexis

# **Strategy**

37 Digital Transformation (DX) Supporting Business and Management

Strategy

# Digital Transformation (DX) Supporting Business and Management

One of the key management strategies at Santen is to enhance digital capabilities from a company-wide perspective. In the global healthcare market, we see an acceleration toward business models that leverage digital technologies to create new products and services. We aim to grow medium- to long-term corporate value by becoming even more competitive and engaging in advanced digital governance.



The Santen digital strategy consists of a three-layered structure: DX for social value creation, DX for operational excellence, and DX for organizational capability.

DX for social value creation means solving social issues by introducing digital health services and optimizing commercial excellence through digitalization.

DX for operational excellence produces cost efficiencies and creates value via global-level process innovation and data utilization. In this way, we facilitate rapid decision making and business development.

DX for organizational capability inspires new work styles in digital workplaces. It also strengthens information security and digital governance against business continuity risks.

The organic integration of these initiatives will ensure the success of Santen business and management.



KGI: Key Goal Indicator
KPI: Key Performance Indicator



# Strengthening Digital Governance

In February 2022, Santen became a certified Digital Transformation Business Operator under the Ministry of Economy, Trade and Industry.

The certification recognized our efforts to meet the certification criteria under the Digital Governance Code, which stipulates actions that business managers are expected to implement in order to boost corporate value, and that the Company conducts appropriate information disclosure to its stakeholders.



# **Strategy**

37 Digital Transformation (DX) Supporting Business and Management

Strategy

## Digital Transformation (DX) Supporting Business and Management

Furthermore, our information security policy conforms to ISO/IEC 27001 and we continue to strengthen initiatives to protect stakeholders. In addition to instituting cybersecurity processes, our response to information security risk also includes global training programs. We gamify these trainings for efficient learning related to cybersecurity in daily work scenarios to maintain a high level of security.

And we are implementing a next-generation enterprise resources planning (ERP) system as one means to enhance internal controls. Santen has created a team of highly specialized personnel in an agile, cross-regional organizational structure. Under the leadership of this team, we pursue a global project aimed at standardizing internal processes and improving transparency to accelerate the transformation of our business model. Leveraging standardized data infrastructure as an important management resource, we will execute more agile management decision-making, improve profitability, and create new value.

Business Model Transformation:

Accelerating Innovations in Ophthalmology

We are transforming our business model through the use of digital technologies across the entire value chain, from R&D and production to sales and marketing. We are converting our plants to smart factories, including in Shiga and at new facilities under construction in Suzhou. These efforts, together with the ongoing introduction of the next-generation ERP platform, are uncovering issues in the value chain, allowing us to optimize costs and create new value.

Santen is also making progress in building out our online platform for healthcare professionals and medical institutions, leading to the further development of an ophthalmic ecosystem. As an example, in February 2022, we launched the Santen Eyecare Education (SEE) portal, beginning in France and the Netherlands, and we are rolling out this program in other countries as well. The environment related to education has undergone changes since the outbreak of COVID-19. These changes include fewer opportunities for medical professionals to interact with each other. However, our new system provides interactive learning opportunities and contributes to the educational needs of local ophthalmologists.

In January 2020, we entered into a partnership with the International Telecommunication Union (ITU), a specialized agency of the United Nations. Our goal in this partnership is to support the *Be He@lthy*, *Be Mobile* initiative between ITU and the World Health Organization. As part of this initiative, we are developing digital health programs for developing countries in Asia and Africa to raise awareness and health literacy about myopia and myopia prevention. As a specialized company dedicated to ophthalmology, we will contribute to the further development of the ophthalmic ecosystem.





# DE&I: Utilizing Human Resources

We were quick in developing a remote work environment in response to COVID-19. Santen aspires to Become A Social Innovator, orchestrating and mobilizing key technologies and players around the world, to deliver happiness through vision, and we will continue to explore new work styles. As our global expansion gains momentum, we adopted a new Work from Anywhere program in fiscal 2021. Under this policy, employees choose where and when to work in a flexible manner, carrying out their duties efficiently, with independence and autonomy. The Company is also improving accessibility to digital tools for visually impaired employees. Santen executes work-style reform and Diversity, Equity & Inclusion (DE&I) through digital means to allow people from diverse backgrounds to participate fully. In this way, we attract and benefit from talented individuals who share our corporate culture. We support each individual to maximize their skills and abilities, thereby raising the overall capability of the organization. We began offering educational programs on Al and data dashboard building, which 350<sup>1</sup> employees have taken and are now using to solve business issues.

39 Improving Access to Healthcare

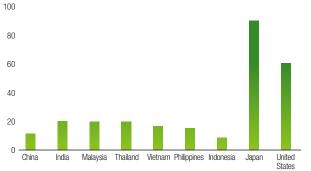
# Improving Access to Healthcare

Santen is helping ophthalmologists to improve their skills in surgery and treatment, and contributing to education of ophthalmic technicians and other professionals to make appropriate care available to the patients who need it.

# Improving Access to Healthcare According to Local Needs

In many emerging economies, there are not enough medical professionals, including ophthalmologists and ophthalmic technicians. This is preventing patients from receiving adequate treatment, or even being correctly diagnosed. The number of ophthalmologists per million people is 89.6 in

#### ■ Number of Ophthalmologists per Million People by Country



<sup>\*</sup> Numbers are estimated by Santen based on information disclosed by academic societies in each country

Japan and 60.3 in the United States, but only 11.3 in China and 16.5 in Vietnam.

Santen develops socially significant products, and is striving to reduce the number of untreated patients in the world by expanding access to ophthalmic care. Our goal is to contribute to more than 60 million<sup>1</sup> patients by 2025.

A particular challenge is disparities in medical care, especially for medical professionals in rural or otherwise remote locations, which lack access to the latest information and surgical training systems. Santen cooperates with external partners to raise the quality of care, such as by providing opportunities for ophthalmologists to improve their skills in cataract surgery and glaucoma treatment. In addition, Santen works to expand access to care by devoting efforts to educating other medical professionals such as ophthalmic technicians.

## Providing Education and Skill Upgrade Opportunities to Eye Care Professionals in Partnership with Orbis

Santen established a partnership in 2020 with Orbis International, a leading global non-governmental organization that has been a pioneer in the prevention and treatment of avoidable blindness for four decades.

### Initiatives to Help Ophthalmologists Develop Their Expertise and Skills in Glaucoma Treatment (China, Vietnam and India)

#### **Online Training**

Cybersight, Orbis's award-winning telemedicine and e-learning platform for eye health professionals, offers opportunities for efficient learning as well as a wide variety of online learning content, including courses on various eye-disease-related topics and the latest medical information,





<sup>&</sup>lt;sup>1</sup> Estimated total no. of patients to which Santen contributed (disease areas: inflammation/allergies, cornea, glaucoma, cataracts) in FY2019 was approx. 43 million, calculated based on JMDC's estimated total no. of patients for Santen's Rx products and Santen's shipment data

39 Improving Access to Healthcare

### Improving Access to Healthcare

thereby contributing to the development of ophthalmologists' expertise. *Cybersight* provides eye health professionals with free access to a standardized educational platform and world-class knowledge, no matter where they are on the planet. The high-quality educational content is available online in multiple languages, enabling local ophthalmologists and other medical professionals to learn effectively in their language of choice.

As of July 2022, *Cybersight* offers six online courses and over 20 educational resources on glaucoma in Chinese, and two online courses and four educational resources in Vietnamese. The number of ophthalmologists using *Cybersight* for their study totals over 1,700 in China, 1,600 in Vietnam, and 5,300 in India. They are among more than 67,000 eye care professionals across many countries and regions globally using the platform.

#### **Development of Diagnostic and Surgical Skills**

Developing skills in diagnosis and surgery requires a suitable learning environment and ample opportunities for training, including access to equipment, educational materials, programs, and skilled trainers. To ensure efficient access to high-level professional training for as many ophthalmologists as possible, Santen has partnered with Orbis to offer innovative training programs whose features include diagnostic support assisted by Al and digital technology, online remote instruction, and surgical training using simulation kits—all through *Cybersight*. Santen will continue helping ophthalmologists in emerging economies to develop their skills in glaucoma diagnosis and surgery.

# Initiative to Help Train Ophthalmology Residents (Vietnam and India)

Another key to making high-quality ophthalmic treatment more accessible is to provide ophthalmology residents with standardized, high-quality education, thereby increasing the number of fully trained ophthalmologists. Santen supports Orbis in developing and offering practical solutions for raising the level of ophthalmic education, including tools for evaluating training programs, instructor training programs, and training tools based on digital technology. These efforts lead to standardized training programs for ophthalmology

residents in Vietnam and India and help local educational institutions enhance their resident training capabilities.

## Strategic Partnership with SNEC to Provide Innovative Educational Programs for Healthcare Professionals

We have entered a strategic partnership with the Singapore National Eye Centre (SNEC), which is widely recognized internationally as a world leader in research and education for eye care professionals. We are working to jointly develop and deploy an internationally accredited educational program that is enhanced to be offered on a combined online and offline platform to address the shortage of trained healthcare professionals, which will contribute to the development of the eye care ecosystem throughout the region.

We have begun offering the Ophthalmic Technician training program from Singapore to the region as the first initiative under the partnership and plan to expand the program to other countries and regions.



Social & Environment



41 Feature 2: Inclusion from the Perspective of Medical Professionals



## Feature 2

# Inclusion from the Perspective of Medical Professionals

## The Social Value of Disabilities

## From the ESG Meeting Keynote Address by Dr. Masayo Takahashi of Vision Care Inc. and Kobe City Eye Hospital

As one of its strategies for 2030 and beyond, Santen aims to help build society that is inclusive regardless of visual impairment. We work to promote awareness and understanding of visual impairments, enable those with and without impairments to share their joys and values, and improve quality of life for people with visual impairments. At the ESG meeting Santen held in March 2022, Dr. Masayo Takahashi of Vision Care Inc. and Kobe City Eye Hospital gave an address on inclusion from an ophthalmological and medical perspective.



# Resolving Issues Relating to Visual Impairment

Vision Care Inc. is engaged in the research and development of retinal regenerative medicine technologies. We consider it essential not simply to use regenerative medicine to make products, but to also link this to treatment. Moreover, resolving issues relating to visual impairment requires consideration of aspects that cannot be addressed through medical care alone.

When considering what kind of corporation we should

be, pursuing a vision that essentially limits ourselves to being a "two-dimensional" company that simply grows cells and makes products will not enable us to realize the potential of regenerative medicine. While we have consequently worked to be a "three-dimensional" company that provides medical care encompassing patient selection, methods for measuring efficacy, and rejection test, we aspire to become a "four-dimensional" company that also resolves issues that go beyond medical care.

### **■** Form of Corporation

	2D	3D	4D
Corporation field	Cell production sales corporation (Pharmaceutical model)	Retinal cell treatment (Medical device model)	Retinal treatment general trading company (Unknown model)
Outcome	Cell	Healthcare	Society

Aiming to become a 4D corporation

#### Feature 2

Kobe City Eye Hospital

### Inclusion from the Perspective of Medical Professionals—The Social Value of Disabilities

# Social & Environment

41 Feature 2: Inclusion from the Perspective of Medical Professionals





Vision Park, 2nd Floor, Kobe City Eye Hospital

City Eye Hospital at the end of 2017. The center uses all methods available to resolve issues relating to visual impairment—it works to resolve issues using not limited to medical treatment but also measures that extend to living and working environments, social awareness and advocacy. It is a one-stop facility specializing in ophthalmology—from research, development of treatments and ophthalmological care, to low-vision care¹ and welfare. Low-vision care is a holistic medical approach² (including the provision of accurate and useful information) that is attuned to a

patient's state of mind and helps that person lead a

fuller life. Rapid advances in devices and technologies

Based on this concept, we established the Kobe

necessitate a comprehensive approach encompassing advanced medical care to low-vision care and welfare.

### **Building a Truly Inclusive Society**

Social attitudes toward people with visual impairments have changed significantly in recent years. Society as a whole is moving away from approaches that could be considered overprotective, toward establishing a truly inclusive era of living happily together. I strongly feel that welfare services should change accordingly. To date, our systems for welfare are structured to focus mainly on people with severe disabilities. However, there are various gradations of disability from mild to severe, and society functions through the

interaction of a wide range of people, with and without disabilities. One other benefit of looking at the world in terms of such gradations is that we can be reminded that, in a sense, everyone has disabilities, for example the inability to use IT or difficulty speaking a second language. With that in mind, I think society is on its way to becoming truly inclusive.

Addressing the needs of people with visual impairments can offer additional value as by doing so we are able to spur advances in society and technological innovation (i.e., transforming barriers into value), but society is not yet aware of this potential. For example, recent advances in technology have facilitated widespread digital low-vision care, which has

Social & Environment

Low-vision care is a general term for multifaceted support for people with low vision (visual function or eyesight that causes some degree of impairment in growth and development or everyday life and social participation). Typically encompassing comprehensive medical, educational, occupational, social, welfare and psychological support, the primary aims of low-vision care are to provide the necessary education and support (i.e., habilitation) for children in developmental and growth stages, and rehabilitation for people who develop impairments as adults.

<sup>&</sup>lt;sup>2</sup> Medical care that not only treats diseases but also provides comprehensive disease prevention, diagnosis and treatment from all angles, including the psychological and social aspects of patients.

#### Feature 2

**■** Disability Gradation

### Inclusion from the Perspective of Medical Professionals—The Social Value of Disabilities

# Social & Environment

41 Feature 2: Inclusion from the Perspective of Medical Professionals

eliminated impediments to work for people with mild

impairments. History has shown that resolving issues relating to visual impairment will help to spread technologies throughout society and make everyone's

lives more convenient.

I usually advise patients that even successful regenerative therapy will not result in complete restoration of sight, and they should prepare to accept some degree of impairment. However, I also tell them that although their vision may not be fully restored, there are things they can change or do to fulfill their desire to be able to enjoy reading again, for example through the use of a magnifying glass or text-to-speech generation. There are often misunderstandings over what is possible in terms of restoration and rehabilitation, so simply resolving these misunderstandings makes a

major difference in patients' lives. Loss of eyesight cannot yet be completely eliminated, but I believe despair can be.

Regenerative medicine is a promising and, at the same time, a highly challenging field that may have the potential to cure central nervous system diseases that have been thought to be incurable. I believe that reaching a point where there is a broad understanding that some fates cannot be changed in spite of these initiatives, and full acceptance that there is nothing unusual about having a disability, will be the most admirable development for society as a whole. With this conviction, I will continue to work with all stakeholders to build a truly inclusive society where everyone can live happily together.







44 Talent Strategy

# **Talent Strategy**

Aiming for sustainable growth founded on high-level talent, leadership for the next decade, and ongoing development of organizational capabilities and culture



# **Strategic Pillars**

Our people are the driving force for achieving growth as a sustainable company and increasing our corporate value. We have set four items as the pillars of our Human Resources Strategy in the runup to 2025 as we evolve into a truly global company.

1	Reinforcement of organizational capabilities

A strong, diverse talent pipeline

3 Common global personnel infrastructure

Corporate brand (EVP: Employee value proposition)

In order to realize true globalization and the deeper potential of the ophthalmology business, ongoing business transformation is necessary.

One pillar of that is <u>strengthening organizational capabilities</u>. This includes establishing a global leadership team, reinforcing corporate headquarters and R&D functions, promoting diversity, equity and inclusion, and building the management skills of those responsible for transformation-related leadership and training.

The second pillar is enhancement of the talent pipeline to support future business. We will develop the human resources necessary to accelerate Santen's next decade of growth by strategically and systematically implementing inclusive development for senior leadership candidates.

Particular focus will be placed on globally-minded leaders, female leaders and local talent familiar with the countries and

regions in which we operate.

The third pillar is building a <u>Group-wide HR infrastructure</u> suitable for an organization that does business globally. Believing that we need a platform that is consistent throughout the world, we introduced a suite of new systems in April 2022 to attract and develop talent. We will also efficiently handle cross-border team management, which has become an increasingly important theme in recent years.

Fourth is the <u>strength of our employer brand</u>. We want Santen to be an attractive proposition for people around the world, not only in terms of the satisfaction of our 4,300 or so employees, but also in terms of our ability to recruit high-level talent. To that end, we will define, visualize and communicate an EVP that leverages Santen's unique strengths, tradition and heritage, and that sets expectations for future growth and evolution.





44 Talent Strategy



## **Talent Strategy**

# Introduction of a Human Resources System Suited to the Changing Business Environment

The COVID-19 pandemic has significantly changed the way we work. With the spread of virtual work, the old idea of working at the office is no longer the de facto standard. Introduced in fiscal 2021, our Work from Anywhere Guideline has already taken root. The globalization of our business has increased the need for a system that enables all employees to work toward stretch goals, be fairly evaluated, recognized and rewarded for high performance, and grow through their work, no matter where in the world they are based. At the same time, in order to accelerate the development of globally

minded talent to support Santen's future growth, a personnel system premised on gaining practical experience across countries and regions has become necessary.

With that in mind, in April 2022, we made our HR systems consistent throughout the world, and introduced new job grading, evaluation and compensation systems. Grade definitions, which varied by country or region, were also clarified, making it possible to quickly determine what talent we have and where.



# Actions to Date and Approach Going Forward

We are making steady progress in promoting diversity. In terms of gender diversity, our global woman manager ratio was 37% as of March 31, 2022. On the other hand, in Japan, where about half of our employees are located, women are still underrepresented in management, although the woman manager ratio has increased from 13% (as of March 2021) to 15%. We have set and are working toward the goal of raising that ratio to 25% by 2025. As for the diversity among senior management, the ratio of women is greater than 20%, and the ratio of non-Japanese nationals is about 50%. The gender pay gap is a social issue that has been receiving attention recently. At the Santen Group, among senior management in particular, there is no significant gap, which reflects the relatively high percentage of women in management outside Japan.

In human resource development, we believe it is necessary to foster an inclusive mindset as the diversity of the organization increases. We implemented neuroscience-based microlearning practices as part of DE&I training for managers worldwide in fiscal 2021, and will roll out a program for all employees, beginning in fiscal 2022. We are also taking action to promote conversations about diversity and inclusion. For example, on International Women's Day, we invited Caroline Casey, President of the International Agency for the Prevention of Blindness (IAPB), for an online session for all employees on intersectionality and inclusion.

44 Talent Strategy



## **Talent Strategy**

Regarding employment of people with disabilities, Santen special subsidiary Claire Co., Ltd.¹ became certified under the Ministry of Health, Labour and Welfare's MONISU Certification System in September 2021. Given our specialization in ophthalmology, we also emphasize employment and occupational development for people with visual impairments. As of March 31, 2022, five employees with visual impairments are active in a variety of roles, including in HR and CSR, with a particular focus on activities to raise awareness within and outside the Company, such as the Blind Experience program, which aims to deepen participants' understanding of visual impairments.

In the process of globalizing our organization, and taking into account current exchange rates, rising prices and other trends, we recognize the need to respond to increased recruiting and labor costs and increased workforce mobility. In addition, we must take a firmer stance in addressing issues such as

consideration for human rights, promotion of health and productivity management, and retention of employees. We are always mindful of the need to secure the best talent, including the recruitment of specialists in digital transformation and new business areas.

In Japan and EMEA in fiscal 2021, we implemented an employee engagement survey, which targeted a narrowed scope of themes, and plan to conduct it worldwide this year. In other achievements, our Netherlands branch (Santen SA) was certified as a top employer by the Top Employer Institute<sup>2</sup> in fiscal 2021, and Santen Pharmaceutical Spain and Santen UK Limited were each certified as a Great Place To Work®.

At Santen, "People Centricity" is the core of our Values, and as such we will continue our transformation into a company that achieves true global growth.



Top Employer certification (Netherlands)



Great Place to Work® certification (UK)



Great Place to Work® certification (Spain)



Operations at Claire Co., Ltd.



Members of Santen UK

<sup>1</sup> Claire's main line of business is cleaning services for clothing used in sterile and dust-free environments. Its main clients are Santen's Shiga Product Supply Center and Noto Plant, but services under contract are also available to companies outside the Group.

<sup>&</sup>lt;sup>2</sup> A European organization headquartered in the Netherlands, recognizes companies that achieve high scores in employee satisfaction based on surveys of workers. It evaluates companies' workplace systems and employment practices across six categories.

44 Talent Strategy



# Talent Strategy (Human Resource Development)



# Professional Development of Medical Representatives

With a history of more than 130 years, Santen has built a strong presence in the field of ophthalmology. That presence is rooted in our culture that emphasizes thorough training and education of medical representatives (MRs).

In fiscal 2020 and 2021, when the COVID-19 pandemic significantly limited our normal business activities and brought changes to the way we work, we set up an online training environment and spent more time than ever on in-house education. In addition to learning the basic conduct and knowledge required to maintain their qualifications and communicate pharmaceutical information, MRs need expertise in ophthalmology as well as wide-ranging knowledge about medicines and eye clinic management. Given our

specialization, our MRs must have the ability to respond to the needs of ophthalmologists and healthcare professionals. This in turn is the source of our competitive advantage.

Particularly in our Japan business, where we hold a market share of more than 50%, throughout the year we provide a wide variety of training to a degree that external parties would find unexpected. In fiscal 2021, the average training per MR totaled about 100 hours. All MRs, whether recent university graduates or mid-career hires, undergo a half year of rigorous training after joining Santen, and even after being assigned to a department they continue to expand their knowledge of diseases, pathophysiology and Santen's products through monthly strategy-based training. In skills development, we provide them with ongoing training on basic mindset as a business person. Moreover, we have been enhancing specialized training based on the type of facility that they are

responsible for, such as for university hospitals. The expanding use of telework due to the pandemic has increased the importance of good communication, so we also conduct one-on-one training to improve dialogue skills for management-level employees. In addition, we place great importance on "people-centric" thinking based on Santen's Values, and are enhancing programs tailored to this approach. For example, role-playing exercises are conducted as part of output-oriented training every month. This practical learning program covers how to correctly convey information to ophthalmologists and what kind of communication is required in interactions with general medical professionals and patients. Through such ongoing training programs, MRs hone these communication skills that enable them to engage deeply with doctors on issues in medical care.



Role-playing as an MR and a doctor



Online training to learn the customer's point of view



Product training at a plant

44 Talent Strategy



## **Talent Strategy (Human Resource Development)**





To promote inclusion in everyday work, we conduct organization-wide learning with a neuroscientific focus that opens up opportunities for all leaders. Santen partnered with the NeuroLeadership Institute (NLI), a global research and consulting firm that provides neuroscientific methodologies and frameworks, to facilitate positive and sustainable behaviors based on "shared everyday habits."

Together with NLI, we launched INCLUDE: The Neuroscience of Smarter Teams®, a learning program for leaders and people managers at Santen. The program focuses on the habits of collaboration and inclusive team interactions with the goal of building high-performing teams. Since its launch in November 2021, 75% of Santen's global leaders and people managers have taken part in the program and learned the habits of inclusion based on the latest neuroscientific research.



# A Skill Development Program on AI in Business

To enhance our customer value proposition and productivity, we promote the use of data in business through online training that teaches the basics of how to leverage data to a wide range of employees at business sites in Japan. In the first two-day session, 247 employees from 18 departments participated. The first day covered the basic history and concepts of digital transformation, Al and other technologies that form the foundation for leveraging data. On the second

day, participants gained a more practical grasp of technologies and deepened related understanding by contributing their own ideas for how to use Al in actual business and engaging in discussions with lecturers.

In fiscal 2022, we are offering similar training at overseas locations, and will strengthen initiatives to promote the use of data in business globally.



# **Strategic Planning Training for Selected Employees**

Santen selected mid-level employees from various divisions, including R&D, marketing and corporate functions, to receive strategic planning training for approximately 60 hours over half

a year. Participants split into five teams to draft new business proposals. As a final report, they made presentations to their supervisors, including the executives.





Strategic planning training

49 Disclosures Based on the TCFD Recommendations



# Disclosures Based on the TCFD Recommendations

Santen has established the "Santen Vision for the Earth 2050" (hereinafter, environmental vision) as its environmental vision toward 2050, and is actively committed to implementing measures against climate change and reducing the environmental load of its business activities. In addition, in June 2022, the Company declared its support for the recommendations of the Task Force on Climate-related Financial Disclosures (hereinafter, TCFD). Since we have conducted scenario analysis and assessed risks and opportunities to measure the financial impact of climate change on us, we will disclose related information appropriately in line with the TCFD recommendations.

#### Governance

Issues of ESG Materiality including climate change are reported to and discussed by the CSR Committee, which is chaired by the President and CEO and usually meets twice a year.

Important discussion contents and decisions are proposed as "Reports & Deliberations" to the Board of Directors.

Since we launched an interdivisional TCFD project in 2021, we have held discussions on the identification of climate-related risks and opportunities, assessment of financial impacts and measures to address to them. After consultation was sought from the CSR Committee regarding discussion contents, they were proposed as "Reports & Deliberations" to the Board of Directors.

After the risks are identified, the department in charge of risk management and the division responsible for addressing the risks hold discussions to devise a policy and specific measures in response to the risks. To address the identified opportunities, we monitor and assess changes in the external and internal environments and incorporate the monitoring and assessment results in our business strategy according to necessity.

We have also included ESG metrics in our evaluation methods used to determine the level of compensation for executives in order to promote and enhance our environmental efforts, including efforts to combat climate change issues.

## Strategy

As a result of analysis and assessment under a 1.5°C scenario and a 4°C scenario,¹ we have identified climate-related risks and opportunities and their financial impacts, and have devised measures to address them as follows.

#### Details about climate-related risks and resilience

We have judged that only the risk entailed by the accelerated shift to low-carbon energy will have a major financial impact. However, for Santen, there is also the risk of plastics such as eye drops which are the core of Santen's business, and water which is indispensable for the production of eye drops. Below are the details of the risks and the countermeasures considered.

#### Accelerated shift to low-carbon energy

The production of eye drops and other products involves the use of steam. Amid the accelerated shift to low-carbon energy, we are planning to introduce hydrogen boilers and hydrogen fuel storage facilities to replace fossil fuel used to fuel the

boilers with a low-carbon energy source. We have estimated the financial impacts on the supposition that hydrogen boilers and hydrogen fuel storage facilities will be installed at the following Santen's production sites: the Noto Plant, the Shiga Product Supply Center (both in Japan), and the Suzhou Plant (in China). Despite many uncertainties, including fluctuations in fuel prices toward 2050, technological issues, and the need to ensure a necessary area of land, we have conservatively calculated that the related financial impacts will be worth JPY 3.0 billion or more, which we have judged as "major" impacts.

To reduce the risk, we will consider minimizing the investment amount by utilizing novel technologies and other means. Through this fuel shift, we also aim to achieve zero greenhouse gas emissions as envisioned in our environmental vision, in order to decarbonize our products and services and contribute to a sustainable society and business.

<sup>4°</sup>C scenario: Scenario postulating the maximum climate-related physical risks for Santen, constructed using the high greenhouse gas emissions scenario RCP8.5 in the IPCC's Fifth Assessment Report (AR5) and other information



<sup>&</sup>lt;sup>1</sup> 1.5°C scenario: Scenario postulating the maximum climate-related transition risks for Santen, constructed using the very low emissions scenario SSP1-1.9 in the Intergovernmental Panel on Climate Change (IPCC) Sixth Assessment Report (AR6), the International Energy Agency (IEA)'s Net Zero Emissions by 2050 Scenario (NZE), and other information

49 Disclosures Based on the TCFD Recommendations



### Disclosures Based on the TCFD Recommendations

### ■ Climate-related risks and opportunities and financial impacts

Scenario	Risks / Opportunities	Change in external environment (from present to around 2050)	Risks / Opportunities for Santen	Financial impacts¹	Method of assessing impacts
		Accelerated shift to low-carbon energy	Experiencing an increase in investments in and the cost of shifting to low-carbon energy	Major	Calculating conservatively in consideration of a certain level of technological uncertainties
1.5°C scenario	Transition risks	Imposition of the obligation to shift to bioplastic and biomass plastic and related regulations	Experiencing an increase in the cost of procuring container and packaging materials	Minor	Assessing the impacts by calculating the cost increase on the supposition of an ambitious sales growth rate
		Sharp rise in ingredient prices due to a decreased supply of plant-based ingredients	Experiencing an increase in the cost of procuring plant-based ingredients	Minor	Judging the price rise risk not to be high because plant-based ingredients, which account for a large part of the ingredient procurement costs, do not rely on particular animals or plants and can be procured easily
	Physical risks	Floods and droughts due to changes in rainfall patterns	Delaying or suspending product supply due to floods or restrictions on water use, which will cause difficulty in plant or laboratory operations	Minor	Judging in consideration of water usage in production processes and other factors based on whether or not rivers exist near each plant or laboratory and the result of the assessment of drought risks at each location using Aqueduct,² which is water risk assessment tools
4°C scenario	Opportunities	Increase in the number of myopia patients due to more frequent indoor activities in extreme weather events	Contributing to treating an increasing number of myopia patients by increasing the production and supply of new myopia and other drugs	Financial impacts are hard to identify at the present.	<ul> <li>Assessing the impact of climate change on eye diseases referring to published research</li> <li>Judging that it is hard to calculate the monetary value of the impact because it is difficult to determine what part of the increase in the number of myopia patients<sup>3</sup> is accounted for by climate change</li> </ul>
		Increase in the number and activity of allergens, such as pollen, and pathogenic organisms due to climate change	Contributing to treating allergies and infectious diseases of the eyes by increasing the production and supply of existing drugs, such as allergy and infectious disease treatments	Financial impacts are hard to identify at the present.	Assessing the impact of climate change on eye diseases referring to published research     Judging that it is hard to calculate the monetary value of the impact because it is difficult to determine what part of the increase in the number of eye allergy and infectious disease patients, which is predicted to occur due to a rise in the average temperature, will be accounted for by climate change

<sup>&</sup>lt;sup>1</sup> Judged by how much the impacts on profits or costs would be worth annually or by the total amount of investments. "Major" impacts are worth JPY 3.0 billion or more, while "Minor" impacts are worth less than JPY 3.0 billion.

<sup>2</sup> Water risk assessment tools made open to public use by the World Resources Institute (WRI)

<sup>3</sup> An article [Ophthalmology, 123; 1036-1042, 2016] estimates that the number of myopia patients will increase to approximately 5.0 billion by 2050, around 3 times higher than the figure for 2000.

49 Disclosures Based on the TCFD Recommendations



### Disclosures Based on the TCFD Recommendations

# Imposition of the obligation to shift to bioplastic and biomass plastic and related regulations

Santen uses plastic as a material of eye drop containers and a wrapping and packaging material for various products. If regulations are imposed on the use of current fossil-based plastic or if the obligation to use bioplastic and biomass plastic is imposed on us, procurement costs will increase because the unit prices of bioplastic and biomass plastic containers and packages are higher than those of conventional plastic containers and packages.

We have assessed the related financial impacts by estimating the cost increase on the supposition of a more ambitious sales growth rate than the current forecast of sales growth rate. We estimate that the impacts will be worth less than JPY 3.0 billion, which we have judged as "minor."

We have already launched an initiative to achieve the target of replacing 60% of conventional plastic eye drop containers with biomass plastic containers by 2030 to realize our environmental vision. By the end of FY2021, we had started replacing the containers of five eye drop products with biomass plastic containers, and three of five products replacement had been completed. We are also striving to achieve the target of reducing the use of plastic as a wrapping and packaging material by 15% from the 2019 level by 2030.

# Floods and droughts due to changes in rainfall patterns

The production of eye drops necessitates the use of water. If climate change causes changes in rainfall patterns or radical changes in weather patterns, floods and droughts will occur more often. Such a weather event is predicted to damage plants physically or lead to restrictions on the use of industrial water and consequently make it difficult for plants to operate, resulting in the suspension or delay of product supply and a resulting decrease in sales and profits. Therefore, we have assessed the risks of our plants and laboratories being affected by floods and droughts.

We have judged flood risks to be low because there are no rivers that could flood the areas near our plants.

Regarding drought, the degree of drought risks at each factory and laboratory specified by Aqueduct, and the opportunity loss (impact on sales) in the event of current and future water usage and water intake restrictions at the site are taken into consideration. As a result, we have determined that the relevant financial impacts of climate change will be minor on our production facilities in the Noto Plant, the Shiga Product Supply Center (both in Japan), the Suzhou Plant (in China) and Advanced Vision Science, Inc. (in the U.S.), and research facilities in Nara Research and Development Center (in Japan) and Santen S.A.S. (in France).

## **Risk Management**

Santen conducts scenario analysis and identifies climate-related risks and opportunities to monitor and assess the impacts of climate change on its business. The identified risks and opportunities are regularly reported to the CSR Committee for discussions. To address a risk that has proven serious based on the results of Company-wide risk assessment, the department in charge of risk management under the leadership of the Chief Risk Officer selects a department to be responsible for addressing the risk by implementing measures to prevent the realization of the risk, formulating a business continuity plan, confirming that the business continuity plan is capable of functioning effectively in the event of an emergency, and reviewing the plan as needed.

## **Metrics and Targets**

Santen has established the "Santen Vision for the Earth 2050" as its environmental vision toward 2050. The Company has also set environmental targets for 2030, including a  $CO_2$  emission reduction target, and is promoting activities to achieve the targets. As a measure to combat climate change, we have set a target of reducing Scope 1 and Scope 2 emissions¹ by 50% on a  $CO_2$ -ton basis from the 2019 level by 2030, and a target of reducing Scope 3 Category 1 emissions² (non-consolidated) by 15% on a  $CO_2$ -ton basis from the 2019 level by 2030. The Science Based Targets initiative (SBTi)³ has approved the former target as a 1.5°C target and the latter as a 2°C target.

<sup>1</sup> Scope 1: Direct greenhouse gas emissions from sources owned or controlled by a company (fuel combustion and industrial processes) / Scope 2: Indirect greenhouse gas emissions from the generation of purchased energy, such as electricity, heat, and steam

<sup>&</sup>lt;sup>2</sup> Indirect greenhouse gas emissions, other than Scope 1 and 2 emissions, resulting from a company's value chain activities, which are not owned or controlled by the company. Among them, Category 1 emissions are emissions from all purchased goods and services.

<sup>3</sup> A joint initiative to encourage companies to set and achieve science-based targets for GHG emissions reduction in line with the Paris Agreement

52 Chairman's Message

## Governance

# Chairman's Message

Fiscal 2021 was a year that caused us to think even more on what we should do to meet the expectations of our customers, shareholders, employees and other stakeholders—but particularly investors, given the current state of our stock price. It is even more important now for the Board of Directors to share with executives their thoughts on the challenges the Company faces to achieve its medium-term plan and targets. Key topics of discussion during the year revolved around the products and services required by Santen's customers, from ophthalmologists and patients to general consumers, expected future changes in the market and competition, and how to develop not only strategies but also the consequent measures and capabilities required to realize them.

Going back to our CORE PRINCIPLE of *Tenki ni sanyo suru*, we need to ensure management transparency, and to make better decisions through objective discussions from the perspectives of customers, shareholders and employees. This is the role and responsibility of the Board of Directors to pursue sustainable growth.

Following the resignation of the former CEO in September 2022, the Board of Directors approved the appointment of Mr. Takeshi Ito as the new Representative Director of the Board, President and CEO based on the proposal from the Nominating Committee. With this new management team, I will work to manage a highly effective Board of Directors to meet the expectations of both internal and external stakeholders.

Akira Kurokawa
Representative Director
Chairman



## Chairman's Message

# Governance

52 Chairman's Message



## Governance

# **Expectations regarding the New Executive Team**

The Board of Directors is responsible for making decisions on key business execution matters, such as the medium-term plan and targets, and monitoring management's execution of business. Members of the Board are elected and approved by the General Meeting of Shareholders, so it is incumbent on us that we discuss various management issues from the standpoint of Santen's sustainable growth and governance as representatives of shareholders. It is important that Santen's Board of Directors serves the two functions mentioned above. For the first, we must deliberate and make decisions from various points of view, including risks, on whether the management plans proposed by the executive team are appropriate for sustainable growth. For the second, we must confirm that approved management plans are being implemented properly and meeting the expectations of customers and investors, and that the Company is steadily contributing to ophthalmology. However, there are also risks in our operating environment that the Company cannot control, including changes in the economic climate due to the weak yen, the COVID-19 pandemic and interregional conflicts. The Board of Directors provides advice and support to executives to enable a flexible response even in these circumstances. Transparency and communication are essential in this

## Chairman's Message

# **Governance**

52 Chairman's Message

kind of business environment. We need to keep an eye on management issues and discuss ways to overcome them. Accordingly, executive management should make proposals to the Board of Directors after they are thoroughly discussed by the Global Executive Committee. In order to realize the medium-term plan, this type of discussion is critical, as is the need to have multifaceted discussions from various perspectives. Needless to say, achievement of the medium-term plan will depend above all on its execution, as well as the people and organizations that are integral to that execution. Today, businesses that do not have the support of customers will be forced to withdraw from the market. Many of the clues to overcoming challenges in execution also reside with customers and the market. If we can mobilize the abilities and motivation of our employees, we will be able to make progress on resolving issues. The Board of Directors has discussions on business issues, and underlying those discussions is a desire to understand customer and market needs, the competition, and employee awareness. Therefore, I expect executives to appropriately lead employees based on a thorough understanding of our business, customers and market to achieve the medium-term plan. If our growth potential as a company specialized in ophthalmology is recognized, we will regain the trust of investors, and I believe that will also be reflected in our stock price.

# Progress in Enhancing the Board's Diversity and Effectiveness

The number of Outside Directors increased from three to five following approval by the General Meeting of Shareholders in June 2022. This decision was made partly in response to feedback from shareholders and investors that we had too few Directors and that we should further increase diversity, but also from our own desire to bring in as many outside views as possible. Outside Directors comprise 71% of the Board as of the end of September 2022 and this has strengthened the Board's diversity in terms of skills, experience, gender and nationality. Going forward, we also want to appoint Board members from within the Company who have experience on the front lines of Santen's business. Age and gender are irrelevant. Most of all, we prefer people who can see things objectively as they are, and who have a clear and unwavering vision.

We have taken various steps to enhance the **Board of Directors' effectiveness** ( Page 56). I intend to fulfill my role and responsibility as Chairman of the Board while maintaining a firm awareness of the issues facing management and continuing to seek better governance.

#### Akira Kurokawa

Representative Director Chairman



55 Messages from Newly Appointed Officers

## Governance

# Messages from Newly Appointed Officers



I supported transformation at a wide range of leading companies in my 19 years at Boston Consulting Group, and helped develop early-stage companies at Dream Incubator Inc. as well as through my later activities. In the life sciences field, I have been involved with companies in various fields. I have known Santen over 20 years, with a thorough understanding of its characteristics, strengths and weaknesses. Based on my "dual-lens" experience, I will promote a growth trajectory factoring-in a balance between its vision and the status quo.

Being in harmony across a broad range of stakeholders and ensuring that governance evolves in coherence with corporate growth are also primordial. Growth necessitates an appropriate amount of risk-taking. I will provide relevant oversight and advice to contribute to Santen's enterprise value enhancement.



I look forward to contributing to the growth of Santen as a member of the Board. My experience in leading organizations across various geographical areas should help support Santen's growth globally.

Driving consistent growth while sustaining uncompromising integrity of the operations in every market around the world requires intimate understanding of local markets as well as strong local leadership teams. Alignment of global organizations with Santen's values, common goals, clear strategies and growth mindset are essential to its accelerated growth globally. Santen's culture which values and promotes diversity and inclusion around the world will attract and retain strong leaders and employees. As our stakeholders expect without any exceptions in every geography, driving Santen's ESG agenda forward as one organization around the world with a clear strategy and roadmap will be a key imperative for sustainable and profitable growth.



Santen's WORLD VISION "The Happiest Life for every individual, through the Best Vision Experience" resonates with me strongly. I am delighted to play a part in the process of realizing the vision through the execution of the long-term vision Santen 2030 and the medium-term plan MTP2025.

For companies pursuing global growth, developing their business alongside the organizational foundation including governance is both a condition to meet and a challenge.

As a management consultant and an executive, I have experience and knowledge from my involvement in the reform and growth of companies including global corporations at various stages of development. I look forward to leveraging my experience for Santen's growth and development in my role as an Outside Corporate Auditor.

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Since 2016, Santen has been making a particular effort to enhance both the depth of information and the quality of discussions at Board of Directors meetings through effectiveness evaluations. We will continue to maintain an environment that facilitates open and constructive discussions as we work toward the higher level of Board performance and effectiveness that Santen requires.

# Previous Initiatives for Enhancing Effectiveness

Masunari: In the years since the Company started conducting evaluations of the Board of Directors' effectiveness in 2016, we have been gradually tackling essential issues. On the administrative side, I feel that steady improvements have been made. Initially, the main

focus was on measures to deepen discussions by helping Outside Directors obtain adequate information about business execution targets and issues—for example, through advance distribution of relevant documents and more thorough explanations, as well as through visits to plants and research centers around the world. Since 2019, we have focused on enhancing strategic decision-making and improving oversight, which are the core functions of

the Board of Directors. The effects of such efforts cannot be expected to show up overnight, but what are your thoughts from your position as an Outside Director?

Oishi: I think both the depth of information and the quality of discussions are improving. Also, information that provides context for agenda items has been enhanced, so I feel that discussions cover more ground than before. The Corporate Strategy Committee has also taken measures such as

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bringing matters to the Board of Directors only after having discussed them in depth. This makes it easier for us to understand the impact of these matters on the relevant projects based on where they fit into the Company's overall strategy, and to monitor the status of priority themes over a longer period of time to ascertain what has and has not been accomplished or improved in the past, and what needs to be done now and in the future.

Masunari: Now that you mention monitoring, I recall that when I was appointed to this position in 2019, I asked the Directors for their thoughts on what kind of Board of Directors we should be aiming for. The general response was that we should strengthen the oversight function, but the Board should also be more deeply involved in and devote sufficient time to strategic decision-making. I found that a bit

surprising because I had imagined they would be more oriented toward being a "monitoring board," given current trends in society.

Oishi: I think that in choosing to be a company specialized in ophthalmology, Santen has entered a turbulent world that requires it to take on many challenges, including the challenge of global markets, and the U.S. market in particular. Preparing for those challenges entails reforming its internal culture with an orientation toward globalization. To serve on the Company's Board of Directors, we should be ready not only to press executive management on how to do their best, but also to take risks and work together with them in making major decisions. I am sure the other Board members feel the same way.



Masunari: While it is important to understand Japan's Corporate Governance Code and prevailing views on how a company should function, we should not simply adopt standard practices wholesale; we need to consider the best governance system for Santen right now, and what role the Board of Directors should play.

(FY)	2016	2017	2018	2019	2020	2021	2022
Key events influencing effectiveness	Japan's Corporate Govern	ance Code	2018 Code Revision			2021 Co	de Revision
	Expansion of overseas	businesses as part o	f Vision 2020	Santen 2030	)		
evaluations						MTP2025	

#### Improvements in operation of Board of Directors

- Distribution of meeting materials in advance
- Information sharing including advance explanations and observation of executive meetings

Key initiatives

to improve

effectiveness

 Preparation and advance sharing of yearly schedule for Board meetings Confirmation of engagement with corporate philosophy and operation of internal controls

- Visits to domestic and overseas plants and research laboratories
- Enhanced internal control reporting

#### Enhancement of strategic decision-making

- Strengthened cooperation between Corporate Strategy Committee (discussion of medium-to-long-term strategy) and Board of Directors (discussion/approval of individual proposals)
- Revised criteria for placing items on Board agenda

#### Improvement of monitoring

- Set a schedule for regular progress reports on important strategic matters (decided matters to report, frequency and content of reporting, etc., and set a regular schedule)
- Set a schedule for regular progress reports on pipeline development projects at meetings of the Corporate Strategy Committee

#### Further enhancement of Board of Directors functions in a timely manner

- Made human resource and IT strategies topics of discussion
- Cooperation between committees and Board of Directors to perform the functions required of the Nominating Committee and Executive Compensation Committee

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From a different angle, Santen has also strengthened the way it conducts and discloses effectiveness evaluations. The Company used to disclose the evaluation results only in the Corporate Governance Report, but in 2020 it was also posted on Santen's website, and in 2021, the Company accelerated internal processes for the effectiveness evaluation and the evaluation results were included in the convocation notice of the General Meeting of Shareholders, enabling evaluations to be considered during voting to elect the Board of Directors. In terms of our approach to effectiveness evaluations, we also enlisted a third-party institution in fiscal 2021. I would like to continue to improve effectiveness by engaging stakeholders in dialogue to get their understanding and feedback on our efforts to enhance the Board's functions.

Oishi: It is important that we Directors stay aware of outside perspectives, and the harshness of those perspectives, when considering strategies. Every autumn, we invite investors to a Board of Directors meeting to get their opinions and advice and provide an opportunity for dialogue, and this is also a good chance to recalibrate our thinking. Communication with outside stakeholders is also essential for managing with an appropriate sense of urgency even in ordinary times.



# Further Enhancing Board of Directors' Functions

Masunari: In the revised 2021 Corporate Governance Code, sustainability is positioned as something to be incorporated into medium-to-long-term strategy and discussed by the Board of Directors. Until now, regular reports on compliance, implementation of digital transformation, and human resource strategy, including diversity, have been discussed in Board meetings, but I would also like to consider measures to deepen the discussion by further integrating sustainability into medium-to-long-term strategies.

Oishi: Because of time constraints, it is difficult to debate everything at a single meeting, nevertheless in the future I want to deepen our discussion of sustainability-related issues. It is important to first begin the discussion and share it with stakeholders, including the things that have yet to be addressed. Masunari: I agree with that. You have a lot of experience as an outside director at other companies. Are there any practices you would like to see adopted at Santen? Oishi: One thing might be the concept of "bad news first." Santen does do this to a degree, but I think it could do more. For instance, it could reinforce a corporate culture of reporting bad news faster to senior management, and thinking about ways to resolve the underlying issues. In terms of how we discuss the Company's strategic direction, I would like to have more discussion of the fundamental origin of problems, without sticking strictly to the agenda. Offsite meetings would also be good. Since the outbreak of COVID-19, I have noticed that we have had fewer opportunities to learn about what is happening on the front lines, which includes hearing the views of employees lower in the hierarchy than Directors and from people working at business sites.

Masunari: I agree with you about offsite meetings. The Corporate Strategy Committee and the Board of Directors

both have lively discussions, but their content is specific to the agenda, and the fact is that there is not enough time to talk about peripheral issues. If we had opportunities to discuss things more freely, Outside Directors could better understand the status of the Company's business execution, which would enhance the quality of discussions.

Oishi: A laudable aspect of Board meetings at Santen is that anything can be put on the agenda and discussed openly, and counterarguments are also heard, without the Chairman steering the discussion to a forced compromise. The number of Outside Directors was increased by two at the General Meeting of Shareholders in June 2022. I think having more diversity in terms of background and other aspects will lead to questions with fresh perspectives that go back to the fundamentals. If Santen aspires to be a global ophthalmology company, it will need non-Japanese and female Directors, including at the very top. As one step toward that, it is necessary to maintain a forum where members with broader backgrounds, and of different genders and nationalities, can have constructive discussions while continuing to deepen their mutual understanding.

Masunari: We have made a number of improvements with the optimal balance between the supervisory function and the strategic decision-making function in mind. Examples include revising the criteria for submitting proposals to the Board of Directors to allow for closer examination and allocation of time to proposals, and introducing regular reporting on strategic matters and pipeline development. I want to continue to be engaged in the operation of the Board of Directors with an eye on the Company's current situation and its future direction. On that basis, in a secretariat role, I will support the Board so that it can make bold management decisions and properly monitor execution, which will contribute to the enhancement of Santen's corporate value.

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## **Corporate Governance Initiatives**

Santen is taking initiatives based on its belief that it is essential to constantly improve and strengthen corporate governance in order to achieve and enhance corporate value, and thus returns to shareholders.

Santen has adopted a "Company with Board of Corporate Auditors" system as defined in Japan's Companies Act. To further improve and strengthen corporate governance, Santen newly elected two Outside Directors at the General Meeting of Shareholders held on June 24, 2022. As a result, Outside Directors constitute a majority of Santen's Board of Directors.

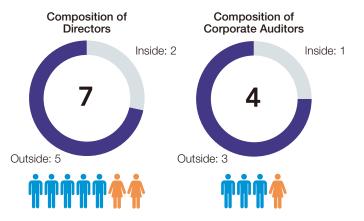
This structure has allowed Santen to further strengthen the Board's supervisory function, and to also bring speed and expediency in management decision-making which has been its priority focus. Santen's Directors consist of five men and two women, including one foreign national, and they have diverse experience, knowledge and backgrounds, as indicated in the skill matrix (see next page). In particular, Outside Directors draw on these attributes to engage actively in decision-making on individual managerial issues and provide opinions and suggestions from the viewpoint of strengthening supervisory functions.

Santen has established the Corporate Strategy
Committee, Nominating Committee and Executive
Compensation Committee, which are all voluntary
committees made up of Inside and Outside Directors.
Outside Directors comprise a majority of each committee,

and the Nominating Committee and Executive
Compensation Committee are chaired by Outside
Directors to improve management transparency and
objectivity. Furthermore, Santen has adopted a corporate
officer system centered on the Executive Management
Team (EMT) to strengthen management and improve the
speed of business execution

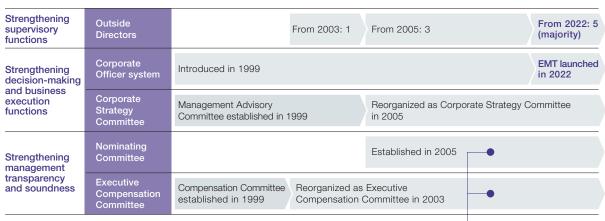
For the Board of Corporate Auditors, Santen has maintained the conventional structure with Outside Corporate Auditors as a majority. The Corporate Auditors fulfill their audit function by collaborating with the Internal Auditing Group to audit the Board of Directors and executive departments, bringing into perspective appropriateness and effectiveness in addition to legality.

# Composition of Directors and Corporate Auditors (As of September 30, 2022)



For more detailed information on Corporate Governance, please see the Company's website.

#### Milestones in Strengthening Corporate Governance



Outside Director appointed as chairperson in 2019 —

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## **Skill Matrix of Directors and Corporate Auditors**

Santen believes that, in addition to planning and carrying out corporate strategies as well as appropriate business administration, the knowledge, experience and abilities described in the chart below are particularly important from the viewpoint of Santen's principles and the future direction of its business. In addition to the life science business and a global perspective, Santen will continue to emphasize aspects such as ESG and service to society. In appointing Directors and Corporate Auditors, Santen shall ensure balance and diversity by appointing individuals from various backgrounds, including areas of expertise and experience, to allow

them to provide advice to and supervision of management from multiple perspectives. Santen shall also place importance on valuing individuals without making distinctions based on characteristics such as gender, age, nationality, race or ethnicity. Moreover, Santen takes into consideration the balance between Inside and Outside Directors to allow for objective discussions. Outside Directors and Outside Corporate Auditors shall respectively constitute a majority of the Board of Directors and the Board of Corporate Auditors, to satisfy the criteria of independence and enhance independence and neutrality.

	Composition of Corporate Governance	ce Organization	ns (©: Chairpers	ons of voluntary	/ committees) (A	s of Sep. 30, 2022)				Skill Matrix <sup>1</sup>			
Position	Name	Board of Directors	Board of Corporate Auditors	Corporate Strategy Committee	Nominating Committee	Executive Compensation Committee	Corporate management	Life science business	Understanding medical field and patients	Global leadership	Finance and accounting	Legal affairs and risk control	ESG and service to society
	Akira Kurokawa (Representative Director)	(Chair)		0	0	0	•	•	•				
	Takeshi Ito (Representative Director)	0		0	0	0		•	•				
	Kanoko Oishi (Outside Director)	0		0	0	0	•		•				•
Director	Yutaro Shintaku (Outside Director)	0		0	0	0	•	•		•			
	Kunihito Minakawa (Outside Director)	0		0	0	0				•	•	•	
	Noboru Kotani (Outside Director)	0		0	0		•	•					
	Tamie Minami (Outside Director) <sup>2</sup>	0		0		0		•		•			
	Hiroshi Isaka (Standing Corporate Auditor)	0	(Chair)			-		•	•				
Corporate	Hirofumi Yasuhara (Outside Corporate Auditor)	0	0				•			•	•		
Auditor	Yumiko Ito (Outside Corporate Auditor)	0	0							•		•	•
	Masahiko Ikaga (Outside Corporate Auditor)	0	0				•				•	•	
Meetings	s (April 2021 – March 2022) <sup>3</sup>	14	10	4	9	8							

<sup>&</sup>lt;sup>1</sup> Among the skills of each person, only two or three skills that are particular strengths or have strong relevance to Santen's businesses are listed. / <sup>2</sup> Australian nationality / <sup>3</sup> In fiscal 2021, there were four written resolutions, in addition to the 14 meetings of the Board of Directors. The average attendance rate of Outside Directors and Outside Corporate Auditors at meetings of the Board of Directors was 100% and 98%, respectively (the rate was 100% for both Inside Directors and the Inside Corporate Auditor). The average attendance rate for Outside Corporate Auditors at meetings of the Board of Corporate Auditors was 100%.

## Reasons for Appointment of New Directors and Corporate Auditors

#### Noboru Kotani (Outside Director)

Having served as an Outside Director of the Company for ten years from 2005 to 2015, Mr. Kotani has in-depth understanding of the Company's ophthalmic business, strategy, governance, and decision-making, and has extensive knowledge and experience concerning corporate management as a management consultant.

#### Tamie Minami (Outside Director)

Ms. Minami has abundant overseas business experience, including experience as a head of businesses in multiple regions at companies with global operations.

#### Masahiko Ikaga (Outside Corporate Auditor)

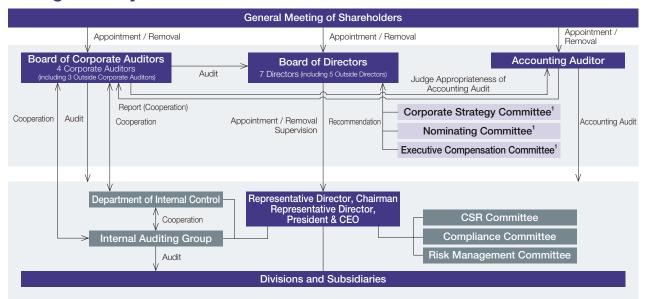
Mr. Ikaga is knowledgeable about finance and accounting as a certified public accountant, and has extensive international experience and knowledge in areas such as promoting globalization as a corporate executive.

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### Management System (As of September 30, 2022)



<sup>&</sup>lt;sup>1</sup> These committees are voluntary and not part of the statutory "Company with a Nominating Committee, etc.," system under Japan's Companies Act.

Corporate Strategy Committee	Deliberates with focus on key strategic issues such as business strategies.
Nominating Committee	Deliberates and makes recommendations on the selection of candidates for the positions of Director and Corporate Auditor, and provides advice in response to requests concerning the selection of candidates for the position of Corporate Officer.
Executive Compensation Committee	Deliberates on the compensation of Directors and Corporate Officers and submits recommendations therefor to the Board of Directors, as well as provides advice to the Board of Corporate Auditors with respect to the compensation of Corporate Auditors with reference to market levels.

#### **Shareholdings of Shares Other Than Unlisted Shares**

	FY2019	FY2020 <sup>2</sup>	FY2021
Number of securities (at end of fiscal year)	14	14	11
Number of securities with a decrease in shares held during the year	1 (sold all shares)	2 (sold all shares of 1 security)	4 (sold all shares of 3 securities)
Amount on balance sheet (Total sale value for number of shares decreased)	JPY 26,840 million (JPY 3,498 million)	JPY 26,098 million (JPY 3,044 million)	JPY 20,866 million (JPY 3,870 million)

<sup>&</sup>lt;sup>2</sup> In fiscal 2020, one unlisted security was listed, and was transferred to shares other than unlisted shares

# Succession Plan for the CEO and Other Top Executives

Our Representative Director recognizes that nurturing succession candidates for the position of Chief Executive Officer (CEO) and other top executives is one of the Representative Director's most important responsibilities, and systematically promotes discovery, selection and cultivation of candidates. The Nominating Committee advises on and oversees the planning and implementation of the succession plan. The Nominating Committee determines the evaluation criteria and methods for the selection of successors. deliberates on whether or not any successor (including those for Outside Officers) holds the appropriate credentials, achievements and other qualifications, and confirms whether or not the plan for the development of succession candidates is appropriately progressing. This is followed by further discussions at the Board of Directors based on the recommendation and advice of the Nominating Committee. In determining the final candidates after this evaluation process, the Nominating Committee makes a recommendation to the Board of Directors, which deliberates on the succession plan and determines successors.

## Strategic-Shareholdings

Santen shall hold shares as strategic-shareholdings only when it determines that doing so will lead to stronger business relationships with the Company over the medium to long term and contribute to enhancing its corporate value. Santen sets a maximum threshold amount for its overall holdings of investment securities, and within that scope, holds only the shares of business partners that are imperative for its business development as strategic-shareholdings. At least once a year, the Board of Directors verifies whether or not such shareholdings are within the threshold based on these criteria, and for each individual security, evaluates the priority placed on the benefit of holding the shares to strengthen business relationships with the Company, taking into account the investment amount and investment risk involved therein. Santen will liquidate securities held as strategic-shareholdings if the rationale of keeping these is deemed to be insufficient.

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## Analysis and Evaluation of the Board of Directors' Effectiveness

The Company's Board of Directors evaluated its effectiveness in fiscal 2021 with the aim of further enhancing the role and function of the Board of Directors. Based on the amendments to Japan's Corporate Governance Code in the previous year, the Board revised the questionnaire items to conduct an evaluation that contributes to the enhancement of governance. The perspective concerning the selection and evaluation of the CEO and other executives who are the main subjects of supervision by the Board of Directors was added, and the questionnaire constituted of viewpoints on the structure of the Board of Directors; decision-making on and supervision of management strategies and business strategies; corporate ethics and risk management; and relationships with shareholders and other stakeholders to

allow for a more comprehensive evaluation. In addition, the Company has taken steps to make qualitative improvements in the evaluation by obtaining the support of third-party organizations in the implementation and analysis of the effectiveness evaluation, including the aforementioned revisions.

The Company's Board of Directors assessed that the effectiveness of the Board of Directors was secured for fiscal 2021. The overall average evaluation mark was "mostly effective," and a high percentage (approximately 90%) of responses for each questionnaire item indicated "effective" and "mostly effective." The Company recognizes that, in addition to continued undertakings, implementations to improve the issues recognized in the evaluation of the

effectiveness of the Board of Directors in the preceding fiscal year contributed to these evaluations. Specifically, in meetings of the Board of Directors, the Company expanded opportunities for reporting on the status of development and the formulation and implementation of human resource, IT, and other strategies, in addition to the progress of material matters, which led to enhancement of opportunities for and the quality of monitoring. Furthermore, the Board of Directors focused on promptly and steadily sharing opinions and recommendations provided by institutional investors and other stakeholders with Outside Directors and Corporate Auditors, and made efforts to ensure that the Board shares a common perception with stakeholders.

Dec. 2021

Questionnaire for all Directors and Corporate Auditors

(Four-level quantitative evaluation and open-ended response)

Jan.-Feb. 2022

Individual interviews with Outside Directors and Outside Corporate Auditors

#### March

Board of Directors discussion based on evaluation results (Identified issues and decided on initiatives) April

Began initiatives based on decisions

#### Results of the Fiscal 2021 Evaluation

#### **Evaluated as Positive**

- Outside Directors are engaging in discussions from multifaceted viewpoints based on sufficient provision of information, and appropriately fulfill their duties.
- Delegation of authority to executive bodies is made in an appropriate manner, and thus the Board of Directors is able to concentrate on its primary role.
- Systems necessary for compliance with corporate ethics have been established, and the whistle-blowing system is effectively functioning as a means for that purpose.

#### Evaluated as Improved

- The progress of projects and other internal strategies the Company is executing is being appropriately monitored.
- The opinions of external stakeholders and other information is appropriately shared with Outside Directors and Corporate Auditors.

#### Issues and Future Initiatives

#### Securing the certainty of implementation when decisions are made on material strategic matters

- Increase opportunities to regularly share the progress, issues and capabilities concerning each business
- Increase opportunities to comprehend conditions at sites where business is conducted as well as the subjects of post-merger integration
- Expand and enhance quantitative metrics for decision-making on strategic matters

#### Strengthening monitoring of planning and implementation of strategies

- Verify the progress of strategic investments and development projects, and the situation, causes and countermeasures when an issue arises in their progress
- Verify the progress of important managerial measures, including human resources, sustainability and digital transformation

# Strengthening of cooperation between the Board of Directors and activities of voluntary committees

- Appropriately share the details of initiatives in the Board of Directors and the Nominating Committee and Executive Compensation Committee
- Further enhance the functions of committees by increasing cooperation of the secretariat functions of both committees

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## **Executive Compensation**

Santen has established the following basic policy for determining the compensation paid to its Directors, Corporate Auditors and Corporate Officers.

#### **Directors (excluding Outside Directors) and Corporate Officers**

- Ensure effectiveness in motivating Directors (excluding Outside Directors) and Corporate Officers to work to achieve Santen's long-term vision "Santen 2030," medium-term plan "MTP2025," and to strengthen ESG management, thereby contributing to Santen's sustainable growth and enhancement of medium-to-long-term corporate value.
- Deepen the alignment of value with a broad range of stakeholders
- Secure objectivity through a highly transparent process for making decisions on compensation to ensure high accountability to stakeholders
- Provide a competitive level of compensation that enables Santen to attract outstanding talent including global talent in various countries and regions
- Under a globally unified system of evaluation and compensation, further foster a highly disciplined performance culture, and share the results with all Executive Management Team (EMT) members including the CEO

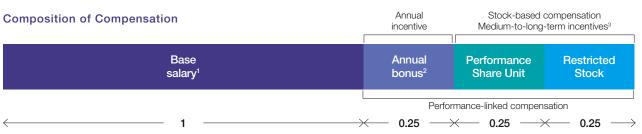
#### **Outside Directors and Corporate Auditors**

• With the aim of supporting Santen's sustainable growth from independent perspectives from those of Directors (excluding Outside Directors) and Corporate Officers, set compensation levels for Outside Directors and Corporate Auditors that are commensurate with the size of their roles, and, through a system that is not dependent on performance results (as opposed to that of Directors [excluding Outside Directors] and Corporate Officers), promote effective supervision of executive management

# Composition of Executive Compensation

Compensation for Directors (excluding Outside Directors) has three components: base salary, annual bonus, and stock-based compensation. Outside Directors and Corporate Auditors receive fixed monthly compensation only, and do not receive performance-linked compensation, so as to promote the appropriate performance of supervisory duties. In addition, allowances are paid to Outside Directors who chair voluntary committees, including the Executive Compensation Committee.

With the introduction of the new leadership structure and a common global HR platform, the basic policy for determining executive compensation and the criteria for determining payout ratio have been revised.



- <sup>1</sup> Base salary: Fixed monthly salary based on grade and job
- <sup>2</sup> Annual bonus (annual incentive): Performance-linked compensation that motivates the steady achievement of business performance targets each year.
- <sup>3</sup> Stock-based compensation (medium-to-long-term incentives): Santen has two stock-based compensation plans (the Performance Share Unit and the Restricted Stock), both of which are designed to encourage executives to proactively work to achieve the Company's vision and strategy, and to promote alignment of value with shareholders.
- ▶ Performance Share Unit: Shares are issued at range of 0% to 200% determined according to the achievement of the performance metrics set for a certain Performance Evaluation Period, such as the period of the medium-term plan. Shares are issued at one time after the Performance Evaluation Period ends, subject to conditions including that the participant remains as an eligible Director at vesting.
- ▶ Restricted Stock: A stock-based compensation plan in which restricted shares are granted each fiscal year. Selling restrictions are lifted three years after the grant, subject to conditions including that the participant remains as an eligible Director at vesting.

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#### **Annual Bonus Performance Metrics and Evaluation Criteria**

Three evaluation factors: Single-year consolidated Financial performance metrics, Non-Financial performance metrics, and Individual metrics based on divisional performance and individual targets. Performance metrics for CEO and Chairman consist of only two evaluation factors: Financial

and Non-Financial. The final payout is calculated by multiplying the target amount for each position by the payout ratio for each evaluation factor; bonuses are paid after the end of each fiscal year. Non-financial performance metrics (ESG-related targets) for fiscal 2022 include strengthening

the system for stable supply, promoting DE&I through wider participation in the Blind Experience program, conducting initiatives to enhance employee engagement, reinforcing global risk management, and reducing environmental impact through measures such as switching to electrified vehicles.

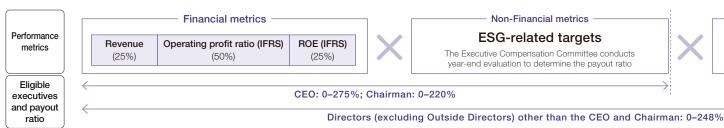
Individual metrics based on divisional

performance and individual targets

Through discussion with each Director (excluding Outside

Directors), the CEO sets targets at the beginning

of the year and conducts year-end review



<sup>\*</sup> Corporate Officers operate under a similar system, with the payout ratio set in the range of 0-248%

#### Performance Metrics and Evaluation Criteria of Performance Share Unit

Perform	nance metrics	Weighting	Evaluation criteria and payout ratio
Relative total shareholder return (TSR)	Comparison and ranking against 21 global healthcare peer companies (seven companies headquartered in each of Japan, Europe and the United States)	80%	Upper ½ (75th percentile): 200% Upper ½ (50th percentile): 100% Upper ¾ (25th percentile): 50% Lowest ½: 0%
ESG-related metrics	Improvement of score on Dow Jones Sustainability Indices	20%	Inclusion in "World Index" or equivalent score: 200% Inclusion in "Asia Pacific Index" or equivalent score: 150% Increase in score of 10 points or more: 100% Increase in score of 5–9 points: 50% Increase in score of 4 points or less: 0%

<sup>\*</sup> Performance Share Unit performance period: 3 years from fiscal 2021 through fiscal 2023

### Executive Compensation (Fiscal 2021)

Type of compensation	Targets	Actual results	Payout ratio
Annual bonus (Company performance portion)	Revenue: JPY 260,000 million Operating profit ratio (IFRS): 16.0% ROE (IFRS): 10.0%	Revenue: JPY 266,257 million Operating profit ratio (IFRS): 13.5% ROE (IFRS): 8.4%	86.9%

Targets related to individual performance (ESG-related metrics) of the CEO for fiscal 2021 included promotion of the transition to biomass plastic eye drop containers, promotion of DE&I with a focus on increasing the diversity of senior management, and enhancing of internal control functions. The evaluation conducted by the Executive Compensation Committee in May 2022 determined performance as "Highly Achieved" (i.e., 150% of target amount).

#### Total Compensation and Eligible Executives (Fiscal 2021)

	Total compensation (JPY millions)	Total by type (JPY millions)						
Position			Annual bonus	Performance Share Unit	Restricted Stock	Non-monetary compensation included at left	Number of individuals	
Directors (excluding Outside Directors)	333	218	48	16	51	59	3	
Corporate Auditors (excluding Outside Corporate Auditors)	25	25	_	_	_	_	1	
Outside Directors	54	54	-	_	_	_	3	
Outside Corporate Auditors	38	38	_	_	_	_	3	

<sup>\*</sup> In fiscal 2021, there was no vesting of Performance Share Unit.

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### **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 modifications as deemed necessary, in order to qualitatively enhance the development and implementation of the internal control system and expand its scope. In addition, Santen develops and uses internal controls related to financial reporting in accordance with assessment and auditing standards and implementation standards for internal controls related to financial reporting based on the Financial Instruments and Exchange Act.

Santen is introducing governance, risk and compliance (GRC) tools in its next-generation enterprise resource planning (ERP) software, which is currently being developed for the purpose of strengthening internal control functions in core systems to respond to the expansion and changes in Santen's global business environment.

### **Compliance Initiatives**

The Company has established a Global Compliance Policy that provides a foundation for business activities based on Santen's CORE PRINCIPLE. In addition to enhancing the structure to promote compliance globally under the Chief Compliance Officer, the Santen Group is devoted to reinforcing compliance awareness and ensuring compliance with laws and regulations. For example, the Group has introduced and is implementing globally organized educational programs for all its employees in the healthcare industry where laws and regulations are becoming more stringent, as well as designates Awareness Month for Santen's Code of Practice, supported by messages from the CEO and regional senior management.

Santen is also introducing integrated Group-wide tools such as a global whistleblowing platform (Santen Speak Up Portal), aiming to accurately grasp Group-wide risks as well as the status of compliance, and to identify issues and ensure to address them appropriately.



# FOCUS: Launch of Speak Up Portal

The Speak Up Portal, a whistleblowing platform partnered with an independent third party organization, was launched globally in November 2021. Its purpose is twofold: to support early detection of concerns about actual or potential violations of laws and regulations, or internal rules and policies including the Santen Code of Practice, and to promote an open and transparent workplace environment in which employees and other parties can speak up in good faith and without fear of retaliation when they are confronted with questionable behavior or violations. This portal enables the reporter to raise concerns with the option of using their name or even remaining anonymously via the web (or via the phone) that are available 24/7/365. It safeguards the safety and confidentiality of reporting based on the Company's zero-tolerance principle toward any acts of retaliation.

By fostering a culture of speaking up, Santen is committed not only to creating work environments in which all employees are treated fairly with respect and dignity, but also to promoting business with the highest level of integrity and ethical behavior.



#### 59 Corporate Governance

## **₫** Governance

## **Corporate Governance**

## **Risk Management**

For Santen to respond appropriately to foreseeable major risks of loss related to its business activities, in accordance with the rules on risk management, each of its operating companies and organizations shall endeavor to comprehend and manage major risks of loss during normal times, construct systems for formulating policies and countermeasures and for gathering information, and endeavor to avoid or minimize major risks of loss.

Santen is expanding its business globally, and the

pharmaceutical industry requires a high level of compliance with various regulations as well as stable product supply. Moreover, Santen must deal with various risks. Santen is strengthening risk management activities under the Chief Risk Officer, clarifying risks that could have serious impact on its businesses, and carrying out ongoing risk management activities toward planning and discussing countermeasures.

When an event that could potentially develop into a

material risk occurs or is reported, the Crisis Management Committee, chaired by Santen's Representative Director, President & CEO, shall be convened, and will endeavor to address and resolve the situation, as well as institute measures to prevent a recurrence.

In addition, the Internal Auditing Group shall conduct internal audits of risk management within the Santen Group from an independent standpoint.

#### Principal Business Risks

Assessment points	Risk scenario	Impacts on corporate value	Relevant issue(s) of ESG materiality <sup>1</sup>	Santen's countermeasures and current progress
Global compliance	• Violations of social norms, laws, regulations, etc.	Decline in public trust and brand image     Damage to corporate value due to a stock price decrease     Decline in Santen's business performance or difficulty in business continuity due to decreased revenue or payment of compensation for damages, etc.	3	Established the Global Compliance Policy; systemically enhance the structure for global compliance     Introduced an organized global education program for all employees; implement the program     Reinforce compliance awareness and ensure compliance with laws and regulations by designating Awareness Month for Santen's Code of Practice, supported by messages from the CEO and regional senior management     Introduced integrate Group-wide tools (global whistleblowing platform etc.) to identify issues and ensure to address them appropriately
Production and Supply	Suspension of operations at a specific plant (the Noto, Shiga or Suzhou Plants, in particular) or at external contractors, or the suspension of raw material supply from a supplier due to a pandemic, natural disaster, fire or other factors	Adverse impacts of disruption or suspension, etc. of production activities on stable product supply, and on Santen's business performance and financial condition	1	Create processes, systems and other mechanisms to ensure stable supply Having continuously a full understanding of actual conditions and respond to issues by planning, monitoring execution, and assessing risk Structure product manufacturing and supply for compatibility with rigorous logistics regulations in Europe Visualize and centralize global inventory management and production planning Establish and strengthen the contract manufacturer management system and backup supplier system
Investment	Failure to realize expectations or profits from proactive investments with the aim of sustainable global growth in the ophthalmic field, due to changes in the external environment or other unfavorable circumstances	Impairment loss on tangible or intangible assets and adverse impacts on Santen's business performance	1,3	Implement investment decisions in line with internal evaluation criteria based on cost of capital     Established the Corporate Strategy Committee to discuss key strategic issues; organically coordinate discussions of medium-to-long-term strategy, businesses and development portfolio with individual projects for submission to the Board of Directors; clarify the position of individual projects in overall strategy and lay out issues for discussion     Introduced a framework of regular, continuous monitoring of Board of Directors' resolved items to obtain steady results

<sup>&</sup>lt;sup>1</sup> 1: Development and Stable Supply of Socially Significant Products and Services ("Happiness with Vision")

For details on risks affecting each business, please see Strategies by Region.

<sup>2:</sup> Encouragement of an Organizational Culture that Promotes Value Creation

<sup>3:</sup> Strengthening Governance, Contributing to the Realization of Fair and Equal Society

<sup>4:</sup> Conservation of the Global Environment

59 Corporate Governance

## Governance

# **Corporate Governance**

Assessment points	Risk scenario	Impacts on corporate value	Relevant issue(s) of ESG materiality <sup>1</sup>	Santen's countermeasures and current progress
IT Security and Information Management	<ul> <li>Malfunction of IT systems used in business activities</li> <li>Cyberattacks, computer virus infection, etc.</li> <li>Leakage of personal or other kinds of information</li> </ul>	Adverse impacts of suspension of or delays in business activities, decline in public trust, etc. on Santen's business performance	3	Operate and maintain an information security management system that meets the ISO/IEC 27001 standard  Established the Global Data Privacy Policy, the Global Information Security Policy, the Document Management Policy, and other policies to address cyber security risks  Enhance security governance through personnel and organizational measures centered around security training and drills and through technical measures (provide global antiphishing training as one measure to enhance cyber security)  Ensure appropriate risk management not only within the Santen Group but also throughout its supply chain and at its business partners  Established a system by which the Chief Digital & Information Officer (CDIO) serves as the Chief Information Security Officer (CISO), who is in charge of formulating and implementing global information security strategies and reports directly to the CEO and the Board of Directors
Pharmaceutical Regulatory Trends	Drug price revisions beyond the scope of those predicted, mainly in the Japanese market     Other revisions to healthcare insurance systems     Measures by governments or revisions to pharmaceutical insurance systems to encourage the use of generic drugs, such as volume-based purchasing in China, and other companies' launch of generic drugs	Adverse impacts on Santen's business performance and financial condition	1	Accelerate the development of new drugs with high added value Pivot from long-listed products to a portfolio centered on new drugs Expand sales channels to include markets for treatments that are not listed under healthcare insurance systems, etc.  Help ensure drug approval and fair pricing by strengthening global regulatory and market access capabilities
Research and Development	<ul> <li>Suspension of or delays in development, refusal of submitted drug approval applications, failure to obtain expected efficacy, etc.</li> <li>Unexpected side effects, leakage of personal information, etc. during clinical trials</li> </ul>	Difficulty in achieving revenue commensurate with research and development investment costs     Decline in public trust and adverse impacts on Santen's business performance	1,3	<ul> <li>Enhance development functions, mainly in the U.S. and China</li> <li>Prioritize and optimize the development pipeline</li> <li>Consult closely with authorities to refine clinical trial design and improve the process for selecting institutions where clinical trials are conducted</li> <li>Establish and hold meetings of the Research Ethics Committee as a deliberating body to ensure scientifically and ethically appropriate research and development</li> <li>Implement necessary measures to ensure patients' participation in clinical trials of their free will, with their fully informed consent, and with the protection of their personal information ensured</li> </ul>
Global Operation	Revisions to laws or regulations in the countries where Santen operates     Political instability and/or economic uncertainties     Cultural differences in business practices	Difficulty in achieving initially expected effects and/or profits	1,2,3,4	Strengthen the crisis management system through global collaboration     Established global policies and operational rules     Ensure continued monitoring
Environment	Occurrence of environmental issues, such as environmental pollution Legal measures or obligations to pay damages due to revisions to environmental laws or regulations, or other circumstances Accelerated shift to low-carbon energy Mandatory or regulatory shift to bioplastic or biomass plastic in materials for eye drop bottles and other packages Decline in the supply of plant-based materials Floods or drought at major production sites due to changes in rainfall patterns, and resulting delays in or suspension of product supply	Adverse impacts on Santen's business performance     Incurrence of countermeasure costs     Increase in capital investment, procurement costs, etc.	4	<ul> <li>Operate an environmental management system that not only complies with environmental laws and regulations but also meets higher in-house standards</li> <li>Formulated the Environmental Vision and set environmental targets; implement the action plan based thereon (including promoting the use of biomass plastic as a material for eye drop bottles)</li> <li>Plan capital investments necessary to realize a low-carbon society, including investments in installing hydrogen boilers and hydrogen fuel storage facilities</li> </ul>

<sup>&</sup>lt;sup>1</sup> 1: Development and Stable Supply of Socially Significant Products and Services ("Happiness with Vision")

<sup>2:</sup> Encouragement of an Organizational Culture that Promotes Value Creation

<sup>3:</sup> Strengthening Governance, Contributing to the Realization of Fair and Equal Society

<sup>4:</sup> Conservation of the Global Environment

**68** Stakeholder Engagement



# Stakeholder Engagement

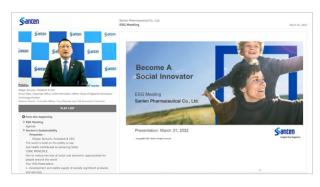
Santen aims to create value shared with its stakeholders by building a relationship based on mutual trust and communication.



# **Shareholders and Investors**

In fiscal 2021, although COVID-related difficulties in holding face-to-face meetings and presentations continued from the previous fiscal year, we were able to maintain or improve the quality and quantity of opportunities for communication by proactively conducting these events online.

We also held a briefing session on our medium-term plan MTP2025 in May 2021, a product development meeting in October 2021, and our first ESG meeting in March 2022. Investors have suggested the need for more detailed numbers in our explanations and target setting, and so in this report we have made particular effort to disclose non-financial KPIs.



For presentation materials and videos, please see the Company's website.



## **Suppliers**

To maintain a stable supply of pharmaceuticals and fulfill our responsibility to society throughout the supply chain, we strive for dialogue with our suppliers through a CSR survey and other means. In fiscal 2021, we expanded the scope of the survey beyond primary suppliers to include secondary suppliers. We also started obtaining declarations of intent to comply with our CSR Procurement Policy and Guidelines in our indirect procurement.



## **Employees**

In 2020, we held the VISION Meeting as an online event for employees worldwide to understand and share in our long-term vision. This was followed by ongoing VISION Talk sessions that provide regular opportunities for dialogue with management. Each session covers different content, with, for example the president sharing the status of initiatives to achieve the long-term vision and his expectations for employees, or regional heads and others introducing initiatives in their particular regions.

For more about communication with stakeholders, please see the Company's website.



# Partners in Building an Inclusive Society

In February 2022, we <u>launched the VISI-ONE Accelerator</u>

<u>Program</u>, which aims to create innovation in "seeing" by providing support to companies and organizations that are trying to create new businesses.

We began by soliciting ideas for commercialization from companies and organizations with the aim of creating new businesses that bring down the walls between those who can see and those who cannot. In working with the applicants we select to create and implement products and services with business potential, we will provide support that is not only financial but also includes cooperation with people with visual impairments, and other companies that agree with the project's aims.



For more about creating innovation in "seeing," please see the Company's website.

68 Stakeholder Engagement



## **Stakeholder Engagement**

### Dialogue with Shareholders and Investors

We proactively exchange opinions with institutional investors and analysts in Japan and overseas at occasions such as financial results presentations, one-on-one meetings and conferences.

Our aim is to help them deepen their understanding of our management, business and ESG initiatives.

In fiscal 2021, the more than 200 occasions that arose for dialogue included IR meetings with top management and IR staff, and ESG-related meetings also attended by the members from sustainability or legal departments, all of which have led to improvements in the quality of our management. Below are some of the questions and opinions we receive most frequently during these exchanges. Click on the page links for content relating to these questions and opinions in this report.

Category		Question/Opinion	Corresponding Pages in Santen Report 2022
Management	Q1	Santen's business execution capabilities will be key to achieving the medium-term plan. What issues do you think lie ahead?	→ CEO's Message (Page 17)  → Initiatives for Medium-to-Long-Term Value Creation (Page 10)
	Q2	What do you consider Santen's path to improved profitability and profit growth?	→ CEO's Message (Page 17) → CFO's Message (Pages 19–22)
	Q3	Impairment loss and delays related to its pipeline in the United States seem to indicate that Santen is experiencing challenges. What is your approach to risk management and how will those factors impact financial soundness? (Examples include impairment loss on glaucoma device STN2000100 and a complete response letter from the FDA for STN1011700.)	<ul> <li>→ CEO's Message (Page 16)</li> <li>→ CFO's Message (Pages 19–22)</li> <li>→ Corporate Governance (Pages 66-67)</li> </ul>
	Q4	Will Santen further enhance its shareholder returns policy? Will you conduct a share buyback?	→ CEO's Message (Page 18) → CFO's Message (Pages 19–22)
Business /R&D	Q5	What is Santen's outlook and response regarding the upcoming NHI drug price revisions and patent expirations in its Japan business?	→ Feature 1: Strengths in Japan (Pages 23–25) → Strategies by Region, Japan Business (Page 26)
	Q6	Although Santen's China business responded promptly to the impact of volume-based purchasing, the delay in ramping up business in the United States is an issue. What is the status of your overseas businesses and what is your strategy going forward?	<ul> <li>→ EMEA: Continuing Its Steady Growth Trajectory (Pages 31–32)</li> <li>→ Strategies by Region, Overseas Businesses (Pages 27–30)</li> <li>→ Product Development (Page 34)</li> </ul>
	Q7	Please explain Santen's progress in its pipeline and initiatives to enhance R&D functions mainly overseas.	→ Product Development (Pages 33–36)
	Q8	Can you describe the current status of initiatives and the outlook in new areas such as myopia, ptosis and cell therapy?	→ Product Development (Pages 33–36)
ESG	Q9	What kind of discussions have taken place about increasing the diversity and effectiveness of the Board of Directors?	<ul> <li>→ Chairman's Message (Page 54)</li> <li>→ Aiming for an Effective Board of Directors Suited to the Business Environment (Pages 56–58)</li> <li>→ Corporate Governance (Pages 59–67)</li> </ul>
	Q10	Please disclose specifics on calculating executive compensation. Although adding ESG-related targets to compensation is a step forward, there is a need for greater detail in your disclosure.	→ Corporate Governance (Pages 63–64)
	Q11	Santen's initiatives for ESG are clearly conveyed but it seems that much of the disclosure is qualitative. Please disclose specific KPIs.	⇒ ESG Materiality (Page 13)
	Q12	What do you expect from your new Executive Management Team?	→ Chairman's Message (Page 53)
	Q13	What risks are you aware of and what actions are you taking with regard to environmental measures, including support for the TCFD recommendations?	<ul> <li>→ CEO's Message (Page 17)</li> <li>→ Disclosures Based on the TCFD Recommendations (Pages 49–51)</li> </ul>
	Q14	As concerns about human resources grow, have you been focusing on human resource development? Do you conduct an employee engagement survey?	→ Talent Strategy (Pages 44–48) → ESG Materiality (Page 13)

70 Corporate Executives





#### Directors

Akira Kurokawa Representative Director

5 Kunihito Minakawa **Outside Director** Independent Officer

2 Takeshi Ito Representative Director President and Chief Executive

Noboru Kotani **Outside Director** Independent Officer

Kanoko Oishi **Outside Director** Independent Officer

7 Tamie Minami **Outside Director** Independent Officer

4 Yutaro Shintaku Outside Director Independent Officer

B Hiroshi Isaka

Standing Corporate Auditor

10 Yumiko Ito Outside Corporate Auditor Independent Officer

Hirofumi Yasuhara **Outside Corporate Auditor** Independent Officer

Masahiko Ikaga Outside Corporate Auditor Independent Officer

#### 70 Corporate Executives

## Governance

# Directors and Corporate Auditors, Executive Officers (As of September 30, 2022)

#### Directors



Akira Kurokawa Representative Director

- 1977 Joined the Company
- 1997 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 Representative Director, President & COO 2008 Representative Director, President & CEO
- 2018 Representative Director, Chairman & CEO 2020 Representative Director, Chairman (incumbent)

#### Takeshi Ito Representative Director President and Chief Executive Officer

- 1982 Joined the Company
- 2012 Corporate Officer, Head of Prescription Pharmaceuticals Sales Department, Sales & Marketing Division, Prescription Pharmaceuticals
- 2014 Senior Corporate Officer, Head of Japan Sales & Marketing Division, Prescription Pharmaceuticals
- 2016 Executive Corporate Officer, Japan Business, Head of Japan Sales & Marketing Division, 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 & Marketing Division 2022 Representative Director, Executive Vice President, Head of Japan
- Business, Head of Japan Sales & Marketing Division Representative Director, President & CEO (incumbent)



#### Kunihito Minakawa **Outside Director** Independent Officer

- 2010 Corporate Vice President, and General Manager of Finance and Accounting Division, Ricoh Company, Ltd. Outside Audit & Supervisory Board Member, Ricoh Leasing Company, Ltd.
- 2012 Corporate Senior Vice President, and General Manager of Finance and Accounting Division, Ricoh Company, Ltd.
- Audit & Supervisory Board Member, Ricoh Company, Ltd.
- 2017 Outside Director of Sony Corporation 2018 Outside Director of the Company (incumbent)
- 2019 Commissioner of the Certified Public Accountants and Auditing
- Oversight Board, Financial Services Agency (incumbent)
- 2020 External Director of Nippon Sheet Glass Co., Ltd. (incumbent)



#### Noboru Kotani Outside Director Independent Officer

- 1991 Vice President of Boston Consulting Group 2000 Representative Director of Dream Incubator Inc.
- 2005 Representative Director of Vehicle Inc. (incumbent) Outside Director of the Company
- 2006 Outside Director of JINS HOLDINGS Inc. (incumbent)
- 2013 External Director of SanBio Company Limited (incumbent)
- 2018 External Director of Medley Inc. (incumbent) 2022 Outside Director of the Company (incumbent)



#### Hirofumi Yasuhara Outside Corporate Auditor Independent Officer

Corporate Auditors -

2010 Joined the Company

2015 Head of Surgical Division

Hiroshi Isaka

2012 Head of Corporate Development Division

2020 Standing Corporate Auditor (incumbent)

2019 General Manager, IOL Business Planning Group

Standing Corporate Auditor

2013 Deputy Head of Human Resources Development and CSR Division

- 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)
- 2020 Outside Audit & Supervisory Board Member, Sumitomo Rubber Industries, Ltd. (incumbent)
  - Outside Corporate Auditor, Hitachi Zosen Corporation (incumbent)



#### Yumiko Ito **Outside Corporate Auditor** Independent Officer

- 2007 Executive Officer, Legal & Corporate Affairs, Microsoft Co., Ltd.
- (currently Microsoft Japan Co., Ltd.) 2013 Director, Executive Officer and General Counsel, Sharp Corporation 2014 Director, Executive Managing Officer and General Counsel,
- Sharn Corporation 2019 Established Ito Law Office; Representative (incumbent)
- Independent Director, Kobe Steel, Ltd. (incumbent) Outside Corporate Auditor of the Company (incumbent)

# **Corporate Officers**

Nikolaos Tripodis

Shinichi Teramachi	Head of Sales Department, Japan Sales and Marketing Division
Frank Binder	Head of Supply Chain Division
Ken Araki	Global Head of Business Development, Strategy
Takahiro Morita	Global Head of Core Principle & People Centricity, HR, Sustainability & Administration

**Executive Management Team** 

Jozica Grenz

Luis Iglesias

Ippei Kurihara

Takayuki Yamada

Marianthi Psacha

Robert Wagner

Reza Hague

Peter Sallstia

Akio Kimura

Minori Hara

Nobuko Kato

Kazuo Koshiji

Mika Masunari

Chris Reindel

(Not including Directors who also serve as executives)

Head of Asia Business

Head of EMEA Business,

Head of China Business

Global Head, Cell & Gene

Global Head, Medical Tech

Head of Ophthalmology

Innovation Center

Chief Risk Officer

General Counsel &

Chief Business Officer

Chief Compliance Officer

Chief Strategy Officer, Chief HR.

Sustainability & Administration Officer

Chief Medical Officer

Solutions Business Segment

Chief Product Supply Officer

Chief Digital & Information Officer

Chief Communications Officer Chief Financial Officer &

Business Segment

Head of North America Business

Head of Japan Business, Head of

Head of Marketing Department

Japan Sales and Marketing Division,

For more about the corporate executives please see the Company's website.



#### Yutaro Shintaku Outside Director Independent Officer

Kanoko Oishi

**Outside Director** 

Representative Director (incumbent)

2015 Outside Director of the Company (incumbent

Outside Director of Suruga Bank Ltd. 2016 External Director of Shiseido Company, Limited (incumbent)

2010 Outside Director of Astellas Pharma Inc

1993 Partner, McKinsey & Company, Inc

Independent Officer

2000 Established Mediva, Inc. Representative Director (incumbent)

2004 Established Platanus Medical Corporation; COO (incumbent)

Established Seinan Mediva Co., Ltd. (currently Seeds 1 Co., Ltd.);

External Board Member of Ezaki Glico Co., Ltd. (incumbent)

- 2010 Representative Director, President and CEO of Terumo Corporation 2017 Corporate Advisor of Terumo Corporation
- External Director of J-Oil Mills Inc. (incumbent) Outside Director of the Company (incumbent)
- 2018 Outside Director of Kubota Corporation (incumbent) Visiting Professor, Business Administration, Hitotsubashi University Business School 2019 Project Professor, Business Administration, Hitotsubashi University
- Business School (incumbent) Outside Director of KOZO KEIKAKU ENGINEERING Inc. (incumbent)



#### Tamie Minami **Outside Director** Independent Officer

- 2008 Vice President and General Manager, Home Care Division, 3M Company 2013 Vice President, Southeast Asia Region, 3M Company
- 2015 Vice President, Latin America, 3M Company
- 2017 Vice President, Asia, 3M Company
- 2019 Senior Vice President, Safety & Industrial Business Group, Asia.
- 2022 Outside Director of the Company (incumbent)



#### Masahiko Ikaga **Outside Corporate Auditor** Independent Officer

- 2000 Representative Director and President of Tohmatsu Consulting Co., Ltd. (currently Deloitte Tohmatsu Consulting LLC)
- 2010 Director and Chairman of Deloitte Tohmatsu Consulting LLC 2016 Representative Accountant, Masahiko Ikaga Certified Public Accountant
- Representative Director of PrajnaLink Co., Ltd. (incumbent) External Audit & Supervisory Board Member of Morinaga Milk Industry Co., Ltd. (incumbent)
  2017 Outside Audit & Supervisory Board Member of Yamaha Motor Co., Ltd.
- Outside Director of RYOBI LIMITED (incumbent)
- 2022 Outside Corporate Auditor of the Company (incumbent)

72 Glossary

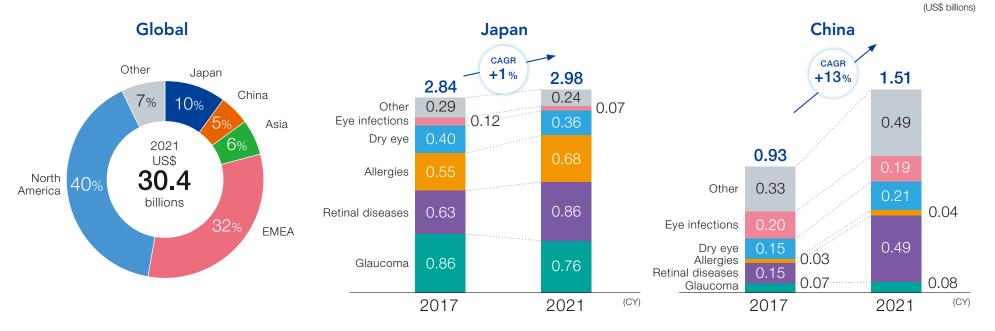


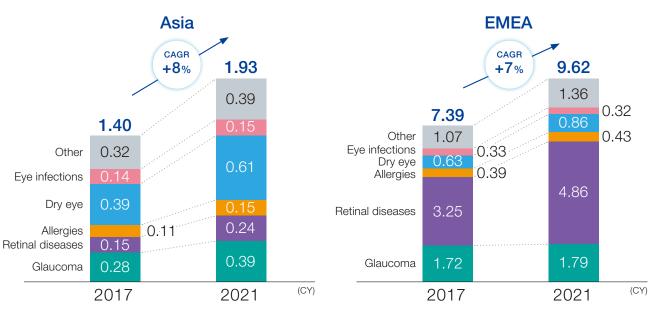
# Glossary

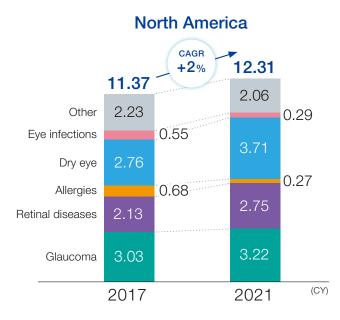
Category	Term	Definition	
Santen	Executive Management Team (EMT)	Management team consisting of executive officers reporting directly to the CEO	59, 63, other
	Key opinion leader (KOL)	A physician or other specialist with influence on treatment in practice and the industry.	28
	Life cycle management (LCM)	Increasing product value over the long term through the use of formulation or other technologies to adapt a single compound to therapeutic needs. This may involve changing the application, dosage or dosage form, combining the compound with other compounds or other methods.	34
	Quality of Life (QOL)	The degree to which an individual can healthily and comfortably participate in and enjoy life.	26, 35, other
Medical/ Pharmaceutical	Rx	Prescription pharmaceuticals	22, 30
	Translational research	Bridging research that links basic research, clinical research, and medical treatment to efficiently and effectively commercialize results that contribute to medical development	33
	Patient journey	A representation of the patient's Behavior, Thoughts, Feelings, and other processes from the patient's recognition of a disease or symptom to the patient's eventual treatment, including hospital visits and medication	33
	Holistic medicine	Medical care that not only treats diseases but also provides comprehensive disease prevention, diagnosis and treatment from all angles, including the psychological and social aspects of patients	42
	MR	Medical representative	13, 15, other
	Age-related macular degeneration	A disease in which the macula, which is a tissue that plays an important role in vision, is damaged as the patient ages, causing deterioration of eyesight.	2, 8
	Ptosis	Low-lying upper eyelids of one or both eyes, usually caused by partial or complete dysfunction of the muscles that lift the upper eyelid, resulting in possible narrowing of the patient's field of vision and reduced quality of life due to its effect on appearance.	8, 10, other
Ophthalmology	Retinitis pigmentosa	A disease in which a genetic mutation causes extensive degeneration of retinal photoreceptor cells and pigment epithelial cells. Characteristic symptoms are night blindness, loss of peripheral vision and decreased visual acuity. It typically develops in the second decade of life and often leads to blindness in middle or old age.	36
	Glaucoma	A disease in which the optic nerve, which transmits information coming from the eyes to the brain, is damaged and the visual field narrows.	2, 5, other
	Vernal keratoconjunctivitis (VKC)	A recurrent severe allergic ocular disease most commonly seen in children and young adults, it is characterized by severe inflammation of the ocular surface, including the cornea and conjunctiva, with severe itching, pain, and photophobia of the eyes. Severe cases may cause corneal ulceration and visual impairment.	16, 27, other
Business	Smart factory	A new way of manufacturing that introduces advanced technologies and improves productivity from multiple perspectives	9, 38

73 Ophthalmology Market Data

### **Ophthalmology Market Data**







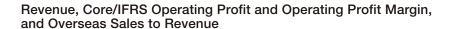
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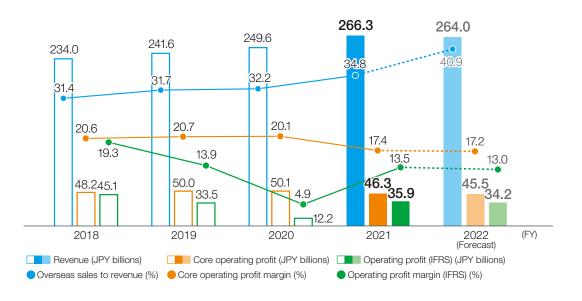
<sup>\*</sup> Copyright © 2022 IQVIA. Santen analysis based on IQVIA MIDAS 2017.1Q-2021.4Q. Reprinted with permission.

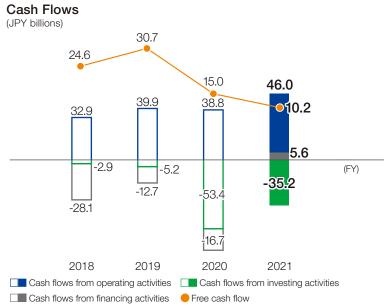
74 Financial and Non-Financial Highlights

### O Data

### Financial and Non-Financial Highlights (Financial)

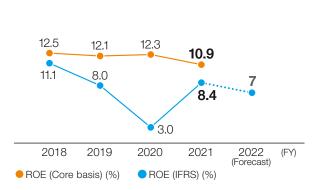




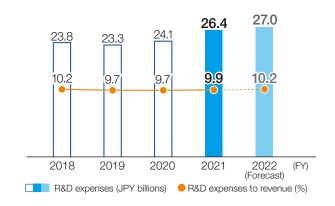


Free cash flow = Net cash flows from operating activities minus capital payments for acquisition of property, plant and equipment, and intangible assets

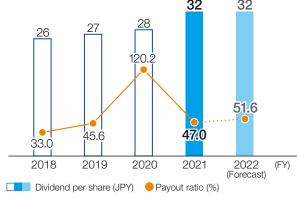
#### ROE



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



#### Dividend per Share and Payout Ratio



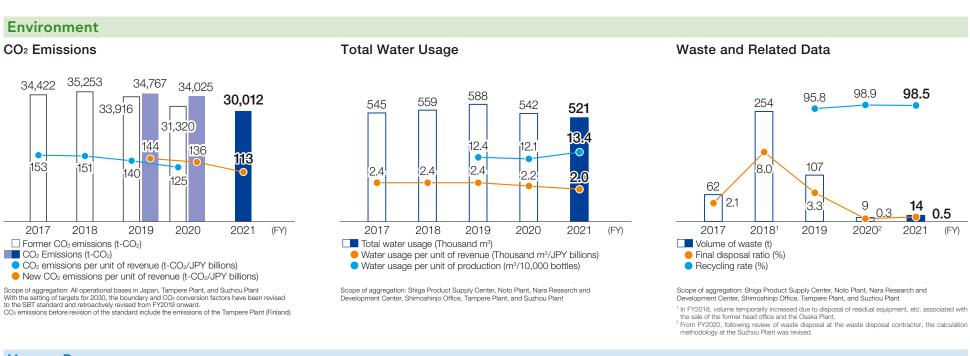
Dividend payout ratio for FY2020 was 120.2% mainly due to the effects of impairment losses on intangible assets, etc. relating to InnFocus, Inc. (U.S.)

<sup>\*</sup> As a result of the completion of the purchase price allocation of Eyevance Pharmaceuticals Holdings Inc. (U.S.) in the second quarter of FY2021, figures for FY2020 have been retroactively restated.

74 Financial and Non-Financial Highlights

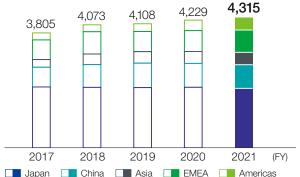
### O Data

### Financial and Non-Financial Highlights (Non-Financial)

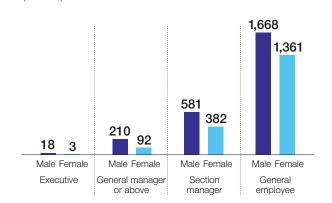


#### **Human Resources**

### Number of Employees

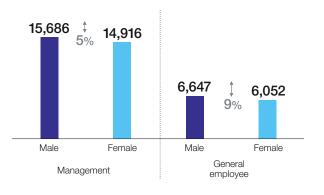


### Number of Employees by Gender and Rank (FY2021)



#### Average Annual Salary by Gender and Rank

(FY2021; JPY thousands)



For environmental and social data (including that for which third-party assurance has been obtained), please see the Company's website.

74 Financial and Non-Financial Highlights

### C Data

### Financial and Non-Financial Highlights (Non-Financial)

#### **Human Resources**

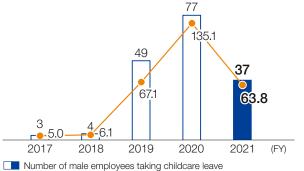
#### Female Employee Ratio and Manager Ratio



- Female employee ratio (non-consolidated) (%)
- Female manager ratio (consolidated) (%)
- Female manager ratio (non-consolidated) (%)

The method of calculating the consolidated female employee ratio and female manager ratio was changed in FY2020.

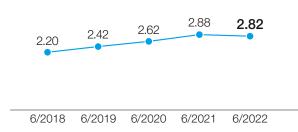
#### Male Employees Taking Childcare Leave



- (Santen Group in Japan)
- Percentage of eligible male employees taking childcare leave (Santen Group in Japan) (%)

The method of calculating the number and rate of male employees taking childcare leave was changed in fiscal 2021

#### Ratio of Employees with Disabilities (%)



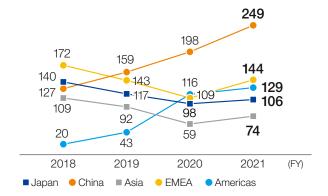
Santen Pharmaceutical Co., Ltd. and consolidated subsidiaries in Japan (as of June of each year)

#### Average Days of Annual Paid Leave and **Average Monthly Overtime**

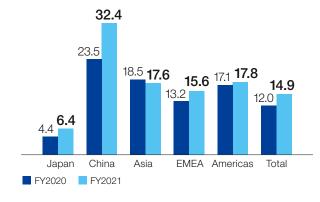


 Average monthly overtime hours (Santen Group in Japan) (Hours/employee/month)

#### **Number of Newly Hired Employees**



#### Employee Turnover (%)



For environmental and social data (including that for which third-party assurance has been obtained), please see the Company's website.

77 MD&A



### MD&A

### **Summary of Consolidated Results in FY2021**

#### Revenue, Operating Profit and Net Profit

Revenue in FY2021, the fiscal year ended March 31, 2022, increased 6.7% year-on-year to JPY 266.3 billion. In the mainstay prescription pharmaceuticals business, sales grew 6.3% year-on-year to JPY 249.6 billion. This is due to steady growth in mainstay products (despite the impact of NHI drug price revisions in Japan), minimization of the impact from volume-based purchasing in China, as well as stable growth in mainstay products in EMEA.

Gross profit increased 3.4% year-on-year to JPY 156.6 billion. SG&A expenses on a core basis increased 8.7% year-on-year to JPY 83.9 billion and R&D expenses increased 9.4% to JPY 26.4 billion. As a result, core operating profit decreased 7.5% to JPY 46.3 billion.

SG&A expenses on an IFRS basis increased 6.2% year-on-year to JPY 84.5 billion. In addition to SG&A expenses on a core basis of JPY 83.9 billion as described above, expenses of JPY 0.6 billion included one-time expenses in connection with the integration of Eyevance Pharmaceuticals Inc. (U.S.). There are no adjustments to R&D expenses related to IFRS. Amortization of intangible assets associated with products in the fiscal year ended March 31, 2022 decreased 8.6% year-on-year to JPY 9.7 billion. This was mainly due to the amortization of intangible assets associated with products acquired from Merck & Co., Inc. (U.S.) in 2014, *Ikervis* which was launched in Europe in 2015, STN2000100 (DE-128, *PRESERFLO MicroShunt*) acquired in connection with the acquisition of InnFocus, Inc. (U.S.) in 2016 (amortization began in April 2019), and ophthalmic products acquired in connection with the acquisition of Eyevance Pharmaceuticals Holdings Inc. (U.S.) in 2020.

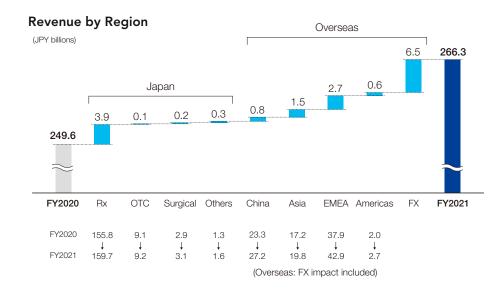
Provisional accounting for the September 2020 business combination related to Eyevance Pharmaceuticals Holdings Inc., which Santen acquired in the fiscal year ended March 31, 2021, was finalized in the fiscal year ended March 31, 2022, and the consolidated financial statements were retroactively adjusted for FY2020. Amortization of intangible assets associated with products was JPY 1.9 billion.

Other income amounted to JPY 1.0 billion, mainly due to the transfer of fixed assets owned by Santen. Other expenses amounted to JPY 1.1 billion. As a result, operating profit on an IFRS basis in the fiscal year ended March 31, 2022 increased 194.5% year-on-year to JPY 35.9 billion.

Finance income amounted to JPY 2.5 billion, mainly due to valuation gains on investment securities owned by the Santen Group. Finance expenses amounted to JPY 1.2 billion. Share of loss of investments accounted for using equity method amounted to JPY 1.6 billion, mainly due to losses incurred at Twenty Twenty Therapeutics LLC (U.S.), a joint venture with Verily Life Sciences LLC (U.S.).

Income tax expenses increased JPY 5.9 billion year-on-year to JPY 8.4 billion. This is mainly due to a change in the composition of corporate profits within the Group, which led to a reduction in corporate tax, offset by a decline in the reversal of deferred tax liabilities resulting from impairment losses on development, manufacturing and sales rights incurred in the fiscal year ended March 31, 2021. As a result, net profit on an IFRS basis for the fiscal year ended March 31, 2022 increased 197.9% year-on-year to JPY 27.2 billion.

Net profit attributable to owners of the company in the fiscal year ended March 31, 2022 increased 192.3% year-on-year to JPY 27.2 billion. The ratio to revenue was 10.2%.



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#### MD&A

In the fiscal year ended March 31, 2022, revenue from prescription pharmaceuticals in the Japan business increased 2.5% year-on-year to JPY 159.7 billion on steady growth in mainstay products despite the impact of NHI drug price revisions in Japan. Revenue from OTC pharmaceuticals increased 1.4% year-on-year to JPY 9.2 billion. Revenue from medical devices increased 7.3% year-on-year to JPY 3.1 billion. As a result, total revenue in the Japan business increased 2.7% year-on-year to JPY 173.6 billion.

In China, on a JPY basis revenue in the fiscal year ended March 31, 2022 increased 16.5% year-on-year (+3.6% excluding FX impact) to JPY 27.2 billion. The Company focused further on strengthening sales promotion of ophthalmic solutions *Diquas* and *Tapros*, which are new products in China, as well as expanding other market channels such as private hospitals and pharmacies, although revenues from mainstay ophthalmic solution products *Cravit* and *Hyalein* were impacted by volume-based purchasing.

In Asia, on a JPY basis revenue in the fiscal year ended March 31, 2022 increased 15.1% year-on-year (+8.7% excluding FX impact) to JPY 19.8 billion.

In EMEA, on a JPY basis revenue in the fiscal year ended March 31, 2022 increased 13.2% year-on-year (+7.1% excluding FX impact) to JPY 42.9 billion.

In the Americas, on a JPY basis revenue in the fiscal year ended March 31, 2022 increased 35.0% year-on-year (+27.4% excluding FX impact) to JPY 2.7 billion. Of this amount, revenue from Eyevance Pharmaceuticals Holdings Inc. (U.S.), which Santen acquired in the fiscal year ended March 31, 2021, was JPY 1.4 billion.

#### **Financial Position**

Total assets as of March 31, 2022 amounted to JPY 460.0 billion, up JPY 54.7 billion from the end of the previous fiscal year. This was mainly due to an increase in intangible assets associated with a license contract with Aerie Pharmaceuticals, Inc. (U.S.) as well as increases in property, plant and equipment related to the construction of the No. 3 Plant for the manufacture of prescription pharmaceutical eye drops at the Shiga Product Supply Center, cash and cash equivalents, and others.

Equity as of March 31, 2022 amounted to JPY 336.8 billion, up JPY 27.2 billion from the end of the previous fiscal year, due to increases in other components of equity, retained earnings and others.

Liabilities as of March 31, 2022 amounted to JPY 123.1 billion, up JPY 27.5 billion from the end of the previous fiscal year. This was due to increases in financial liabilities from long-term

loans and others, trade and other payables, financial liabilities from short-term loans, and others.

As a result, the ratio of equity attributable to owners of the company to total assets at

March 31, 2022 decreased 3.1 points from the end of the previous fiscal year to 73.4%.

#### Capital Expenditures and Cash Flows

Capital expenditures in the fiscal year ended March 31, 2022 amounted to JPY 22.2 billion. (JPY 11.3 billion in the fiscal year ended March 31, 2021.) With the aim of addressing expanding demand and reinforcing the production and supply structure, Santen has added a building for the manufacture of prescription ophthalmic solution on the site of its Shiga Product Supply Center. The Company also continued investment in a new factory for Santen Pharmaceutical (China) Co., Ltd. This timely move adds production capacity that will enable it to proactively meet anticipated market growth, thereby establishing Santen's competitive edge globally for even greater business growth. In addition, Santen will continue to invest in next-generation ERP, with the aim of enhancing administrative standardization and production efficiency to support global business expansion.

Cash flows from operating activities for the fiscal year ended March 31, 2022 amounted to an inflow of JPY 46.0 billion. (Inflow of JPY 38.8 billion in the fiscal year ended March 31, 2021.) This was mainly due to net profit of JPY 27.2 billion, depreciation and amortization of JPY 17.1 billion, income tax expenses of JPY 8.4 billion, and income taxes paid of JPY 10.2 billion.

Cash flows from investing activities in the fiscal year ended March 31, 2022, amounted to an outflow of JPY 35.2 billion. (Outflow of JPY 53.4 billion in the fiscal year ended March 31, 2021.) This was mainly due to payments for the acquisition of property, plant and equipment and payments for acquisition of intangible assets amounting to JPY 17.3 billion and JPY 18.5 billion, respectively. Reflecting the Company's accelerated review of strategic equity holdings, there was a cash inflow of JPY 3.9 billion owing to the sale of four equity holdings.

Cash flows from financing activities in the fiscal year ended March 31, 2022, amounted to an inflow of JPY 5.6 billion. (Outflow of JPY 16.7 billion in the fiscal year ended March 31, 2021.) This was mainly due to proceeds from short-term loans and proceeds from long-term loans of JPY 10.5 billion and JPY 10.0 billion, respectively, the total of which exceeded cash dividends paid of JPY 12.0 billion. As a result, cash and cash equivalents at the end of the fiscal year ended March 31, 2022 increased by JPY 20.1 billion from the end of the previous fiscal year to JPY 83.0 billion.

77 MD&A

### MD&A

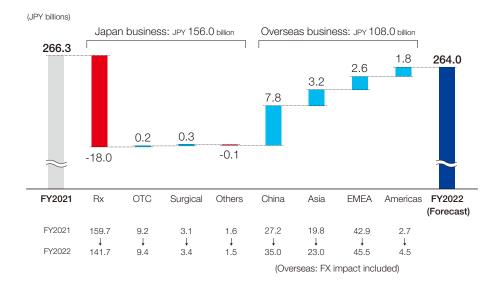
#### Outlook for FY2022

For the fiscal year ending March 31, 2023, revenue is forecast to be JPY 264.0 billion, essentially unchanged from the fiscal year ended March 31, 2022. SG&A expenses are forecast to be JPY 88.5 billion, up 5.5% from the fiscal year ended March 31, 2022, and R&D expenses are projected to be JPY 27.0 billion, up 2.4%. Core operating profit, which reflects the Company's recurring profitability, is forecast to be JPY 45.5 billion, essentially unchanged from the previous fiscal year's figure. The Company aims to secure continued profit growth by allocating resources for future growth while remaining disciplined in controlling expenses through a continued focus on stepping up measures to limit ordinary expenses.

Operating profit in the fiscal year ending March 31, 2023 on an IFRS basis is forecast to be JPY 34.2 billion, down 4.7% from the fiscal year ended March 31, 2022. Net profit is forecast to be JPY 24.4 billion, a decline of 10.3%.

These forecasts are based on foreign exchange rates of 1 USD = 125 JPY, 1 EUR = 135 JPY and 1 CNY = 19.0 JPY. Forecasts above are based on currently available information. Actual results may differ materially depending on a number of factors including adverse economic conditions.

#### FY2022 Revenue Forecast by Region



For financial related materials, please see the Company's website.



80 Eleven-Year Summary of Selected Financial Data



# **Eleven-Year Summary of Selected Financial Data**

JPY millions

_	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020 <sup>4</sup>	FY2021
	JGAAP	JGAAP	IFRS	IFRS							
For the year:											
Net sales/Revenue	114,416	119,066	146,260	161,831	195,291	199,096	224,942	234,026	241,555	249,605	266,257
Cost of sales	35,385	41,501	57,353	56,373	72,829	74,966	86,378	90,764	94,831	98,221	109,671
Selling, general and administrative expenses <sup>1</sup>	35,073	36,164	41,642	48,893	59,406	62,193	68,788	71,273	73,360	79,554	84,499
Research and development expenses	17,225	16,719	16,862	17,477	19,990	22,786	24,398	23,759	23,341	24,112	26,377
Operating profit	26,733	24,681	29,878	35,374	80,180	32,479	38,691	45,098	33,535	12,187	35,886
Core operating profit	_	_	30,403	39,088	43,067	39,687	45,378	48,230	50,023	50,101	46,348
Income taxes/Income tax expenses	10,630	9,070	10,643	11,831	26,097	8,331	4,000	11,174	10,377	2,562	8,427
Net income/Net profit for the year	17,160	16,520	19,718	24,032	53,373	21,724	35,261	31,943	21,714	9,126	27,189
Core net profit for the year	_	_	19,813	25,948	29,163	29,125	33,458	36,092	35,894	37,549	35,195
Capital expenditures/Payments for acquisition of property, plant and equipment, and intangible assets	3,281	3,609	5,879	66,440	9,092	9,500	9,937	8,332	9,228	23,804	35,841
Depreciation and amortization	2,949	3,291	2,841	6,958	9,338	9,882	10,896	10,969	16,573	17,498	17,055
At year-end:											
Total assets	198,801	199,640	237,640	304,200	355,399	358,906	388,463	391,186	408,768	405,285	459,976
Net assets/Total equity	164,861	165,132	187,210	211,779	260,009	255,929	287,557	292,572	302,560	309,646	336,844
Liabilities	33,940	34,507	50,430	92,421	95,391	102,977	100,905	98,614	106,208	95,639	123,133
Per share data <sup>2</sup> (JPY):	-										
EPS (Net income/Basic earnings)	196.96	195.81	47.78	58.18	128.99	52.96	86.73	78.67	59.16	23.30	68.07
Core EPS	_	_	48.01	62.82	70.48	70.99	82.29	88.89	90.00	94.09	88.16
Equity/Equity attributable to owners of the company <sup>3</sup>	1,887.81	1,998.44	452.43	511.14	627.78	628.09	702.54	728.97	758.50	776.16	843.60
Cash dividends, applicable to the period	20.00	20.00	20.00	22.00	25.00	26.00	26.00	26.00	27.00	28.00	32.00

Research and development expenses are excluded under JGAAP

<sup>&</sup>lt;sup>2</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>&</sup>lt;sup>3</sup> Equity is calculated by deducting stock subscription rights from net assets under JGAAP.

<sup>&</sup>lt;sup>4</sup> As a result of the completion of the purchase price allocation of Eyevance Pharmaceuticals Holdings Inc. (U.S.) in the second quarter of fiscal 2021, figures for fiscal 2020 have been retroactively restated.

80 Eleven-Year Summary of Selected Financial Data



### **Eleven-Year Summary of Selected Financial Data**

JPY millions

_	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020 <sup>4</sup>	FY2021
	JGAAP	JGAAP	IFRS	IFRS							
Cash flows:											
Net cash flows from (used in) operating activities	21,483	9,942	26,686	25,386	22,525	10,843	42,843	32,894	39,947	38,808	46,043
Net cash flows from (used in) investing activities	-10,272	-4,595	-7,847	-61,709	37,052	-28,201	-8,259	-2,935	-5,175	-53,355	-35,169
Net cash flows from (used in) financing activities	-8,559	-21,557	-7,954	28,960	-24,066	-28,657	-17,631	-28,107	-12,729	-16,685	5,557
Free cash flow <sup>1</sup>	18,203	6,334	20,807	-41,054	13,433	1,342	32,906	24,562	30,719	15,004	10,203
Interest coverage ratio (times)	1,285.0	3,037.8	2,855.4	309.8	230.9	206.6	1,573.6	4,330.0	210.1	244.6	191.6
Financial data:											
ROE (Return [Net income] on equity/Return [Net profit for the year] on equity attributable to owners of the company) (%) <sup>2</sup>	10.7	10.0	11.1	12.0	22.6	8.4	13.0	11.1	8.0	3.0	8.4
Core ROE (%)	_	_	11.2	13.0	12.4	11.3	12.4	12.5	12.1	12.3	10.9
ROA (Return [Net income/Net profit for the year] on total assets) (%)	8.9	8.3	8.9	8.9	16.2	6.1	9.4	8.2	5.4	2.2	6.3
Equity ratio/Equity attributable to owners of the company ratio $(\%)^2$	82.8	82.6	78.8	69.6	73.2	71.1	73.6	74.4	74.1	76.5	73.4
Debt equity ratio (Interest-bearing debt <sup>3</sup> to equity ratio/Interest-bearing debt to equity attributable to owners of the company ratio) (times) <sup>2</sup>	0.0	0.0	0.0	0.2	0.1	0.1	0.0	0.0	0.0	0.0	0.1
PER (Price earnings ratio) (times)	17.9	22.7	19.2	30.1	13.1	30.4	19.8	21.0	31.4	65.4	18.0
Dividend payout ratio (%)	50.8	51.1	41.9	37.8	19.4	49.1	30.0	33.0	45.6	120.2	47.0
Issued shares at fiscal year-end (thousands, including treasury shares)	87,147	82,469	82,583	82,653	414,192	406,173	406,848	399,782	400,028	400,369	400,695
Number of employees	3,053	3,050	3,072	3,230	3,463	3,667	3,805	4,073	4,108	4,229	4,315

<sup>1</sup> Free cash flow = Net cash flows from operating activities minus capital payments for acquisition of property, plant and equipment, and intangible assets

<sup>&</sup>lt;sup>2</sup> Equity is calculated by deducting stock subscription rights from net assets under JGAAP.

<sup>&</sup>lt;sup>3</sup> Excludes lease obligations

<sup>4</sup> As a result of the completion of the purchase price allocation of Eyevance Pharmaceuticals Holdings Inc. (U.S.) in the second quarter of FY2021, figures for FY2020 have been retroactively restated.

#### 82 Stock Information

### Data

### Stock Information (As of March 31, 2022)

#### Major Shareholders (Top 10)

Name / Company Name	Number of Shares Owned (1,000 shares)	Holding Ratio (%)
The Master Trust Bank of Japan, Ltd. (Trust account)	69,398	17.3
Custody Bank of Japan, Ltd. (Trust account)	34,282	8.6
STATE STREET BANK AND TRUST COMPANY 505223	28,509	7.1
Nippon Life Insurance Company	10,662	2.7
MUFG Bank, Ltd.	10,605	2.6
RBC IST 15 PCT LENDING ACCOUNT - CLIENT ACCOUNT	8,245	2.1
Ono Pharmaceutical Co., Ltd.	7,756	1.9
STATE STREET BANK WEST CLIENT - TREATY 505234	7,330	1.8
Custody Bank of Japan, Ltd. as trustee for Eisai Co., Ltd. Retirement Benefit Trust Account re-entrusted by Mizuho Trust & Banking Co., Ltd.	6,863	1.7
SSBTC CLIENT OMNIBUS ACCOUNT	5,412	1.4

#### Yearly High and Low Prices (JPY)

FY	2017	2018	2019	2020	2021
High	1,946	2,061	2,234	2,216	1,718
Low	1,463	1,450	1,408	1,370	1,210

#### Total Shareholder Return

FY	2017	2018	2019	2020	2021
Total shareholder return (%)	108.0	105.5	120.2	101.1	84.7
Comparative index: TOPIX including dividends (%)	115.9	110.0	99.6	141.5	144.3

#### Composition of Shareholders

#### By number of shares

#### - Financial institutions Treasury shares 0.2% 0.1% Treasury shares -- Securities firms 0.0% Individual investors -- Financial institutions 0.2% 8.9% 37.3% Other institutions 0.6% - Foreign investors 2.9% Number of Number of shareholders shares issued 400,694,754 23,901 Securities firms

2.0%

Other institutions 5.7%

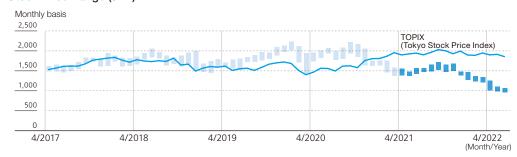
By number of shareholders

Individual investors -

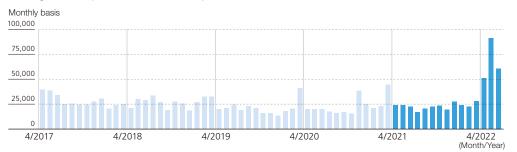
#### Stock Price Range (JPY)

Foreign investors -

46.1%



#### Trading Volume (Thousands of shares)



#### 83 Corporate Information

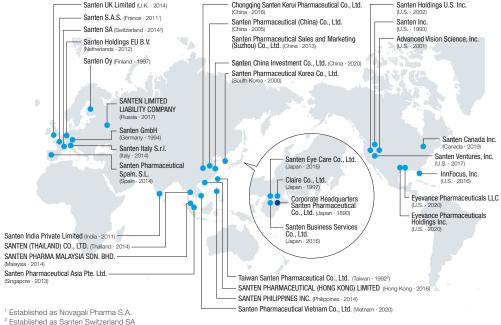
### Data

### Corporate Information (As of March 31, 2022)

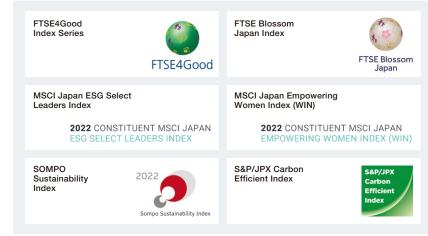
Corporate Headquarters	Santen Pharmaceutical Co., Ltd.					
	Grand Front Osaka Tower A, 4-20 Ofuka-cho, Kita-ku, Osaka 530-8552, Japan					
	TEL: +81-6-7664-8621					
Website	https://www.santen.com/en/					
Established	1890					
Paid-in Capital	JPY 8,672 million					
Number of Employees	4,315 (consolidated)					

Number of Shares Issued	400,694,754
Number of Shareholders	23,901
Stock Exchange Listing	Tokyo Stock Exchange
Ticker Code	4536
Shareholder Registry Administrator	Mitsubishi UFJ Trust and Banking Corporation
Transfer Agent	Osaka Stock Transfer Agent Division, Mitsubishi UFJ Trust and Banking Corporation 6-3, Fushimi-cho 3-chome, Chuo-ku, Osaka 541-8502, Japan

#### Group Companies (Country/Region and year of establishment indicated in parentheses)



#### Inclusion in ESG Indexes



FTSE Russell (the trading name of FTSE International Limited and Frank Russell Company) confirm that Santen Pharmaceutical has been independently assessed according to the FTSE4 Good criteria, and has satisfied the requirements to become a constituent of the FTSE4Good Index Series. Created by the global index provider FTSE Russell, the FTSE4Good Index Series is designed to measure the performance of companies demonstrating strong Environmental, Social and Governance (ESG) practices. The FTSE4Good indices are used by a wide variety of market participants to create and assess responsible investment funds and other products.

FTSE Russell (the trading name of FTSE International Limited and Frank Russell Company) confirm that Santen Pharmaceutical has been independently assessed according to the index criteria, and has satisfied the requirements to become a constituent of the FTSE Blossom Index Series. Created by the global index provider FTSE Russell, the FTSE Blossom Index Series is designed to measure the performance of companies demonstrating strong Environmental, Social and Governance (ESG) practices. The FTSE Blossom Index are used by a wide variety of market participants to create and assess responsible investment funds and other products.

The inclusion of Santen Pharmaceutical in any MSCI index, and the use of MSCI logos, trademarks, service marks or index names herein, do not constitute a sponsorship, endorsement or promotion of Santen Pharmaceutical by MSCI or any of its affiliates. The MSCI indexes are the exclusive property of MSCI. MSCI and the MSCI index names and logos are trademarks or service of MSCI or its affiliates.

<sup>3</sup> Established as TAHMIN SANTEN CO., LTD.

### **Editorial Note**

### **Editorial Note for Santen Report 2022**

Thank you for taking time to read Santen Report 2022.

We recognize that improving profitability in fiscal 2022 for medium- and long-term growth is a pressing issue for our company. Therefore, we structured this integrated report with a focus on our approach and efforts related to this issue. Of course, we also endeavored to incorporate external perspectives in communicating our ability to execute strategies toward greater corporate value over the long term, projected risks, and ESG initiatives.

Regarding strategy execution in particular, we have reconsidered and presented a number of topics, including:

- the business environment and our strengths in various regions
- the source of our strength in the Japan business and measures for future growth
- our pipeline supporting medium-to-long-term growth
- financial policies supporting improved capital efficiency and profitability

The non-financial information we present includes disclosures of KPIs for ESG materialities and related progress. Beyond providing more in-depth information on corporate governance, including specific initiatives to improve the effectiveness of the Board of Directors and descriptions of risks, *Santen Report 2022* includes information on environmental measures, including disclosures based on TCFD recommendations, which we endorsed in June 2022. We also provide information on improving access to healthcare and our human resource strategies.

In preparing this report, we have taken into consideration the opinions received through dialogues with investors and stakeholders. Project members and members of each area and function worked together to ensure that *Santen Report 2022* remains a report that shows the faces of the people behind Santen, a specialized company dedicated to ophthalmology.

The cover of our report includes photographs from Santen employees around the world.

I hereby declare that the process to prepare this integrated report has been appropriate and nat its contents are accurate. We hope this report provides a deeper understanding of Santen

that its contents are accurate. We hope this report provides a deeper understanding of Santen and serves as a way to further dialogue with us.

We continue to support the United Nations Global Compact, and we incorporate the Ten

We continue to support the United Nations Global Compact, and we incorporate the Ten Principles of the Compact in our daily business activities across the four areas of human rights, labour, environment, and anti-corruption. In this way, we endeavor for the development of sustainable societies.

We will continue to value opportunities for constructive dialogue with stakeholders and strive to contribute to society as we enhance corporate value through appropriate information disclosure.

We welcome your suggestions for improving future dialogues, including opinions related to this integrated report.

#### Takeshi Ito

President & CEO

#### Santen Report 2022 Production Members

Investor Relations / Sustainability (Impact & Reporting)
K.Itagaki, G.Sakuma, S.Akao, A.Tanaka,
M.Inoue, Y.Nagaosa, S.Kajiya, M.Hora

#### Inquiries:

Investor Relations (ir@santen.com)

#### Reference Guidelines

The International Integrated Reporting Framework (International Integrated Reporting Council), The GRI Sustainability Reporting Standards (Global Reporting Initiative), Environmental Reporting Guidelines (Japan's Ministry of the Environment) and Guidance for Integrated Corporate Disclosure and Company-Investor Dialogues for Collaborative Value Creation (Japan's Ministry of Economy, Trade and Industry)

# Environment Social Governance Guidance for Collaborative Value Creation

#### 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. Please refer to the link below for key differences between generally accepted accounting principles in Japan (Japanese GAAP) and IFRS, as well as core basis definitions.