CEO’s Message

From the start of my tenure as Santen President and CEO last September, we have endeavored to improve profitability and return to growth, pursuing a mission to make a positive contribution to patients, medical professionals, and society at large.

Our mission is to contribute to the greater health of patients and others under a CORE PRINCIPLE of *Tenki ni sanyo suru*, or exploring the secrets and mechanisms of nature in order to contribute to people’s health. As a company specialized in ophthalmology, we will contribute to Happiness with Vision through valuable products and services for consumers, patients, and medical professionals worldwide.

Takeshi Ito
President & CEO

We will refocus on growth by leveraging our strengths, particularly in the prescription pharmaceuticals business.

I want to share some of my thoughts that went into the creation of our new medium-term management plan (→Page 11) for fiscal years 2023 through 2025, announced in April this year.

We are a unique company in the world with a history of more than 130 years specialized in ophthalmology. We have grown on the strength of our ability to contribute to patients through the stable production of high-quality pharmaceutical products (→Page 30). Almost no one goes through life without experiencing an eye disease or issue. We have leveraged our R&D and technological capabilities (→Page 26) to provide value to patients through antibacterial agents in the past, and glaucoma, dry eye, and allergies in recent years. In addition to new drug development, **we also focus on latent needs identified through communications with patients and medical professionals for products already on the market.** Examples of this would include improvements for single-dose formulations or reduced-frequency eye drops. **This focus is the source of our strengths today and an asset that we must leverage (→Page 17).**

While we have never wavered in our path to serve patients, we dispersed resources across a wide range of investments over the past several years, including re-entry into the U.S. market and activities to build regional ecosystems. In addition, we proactively expanded our corporate functional reach outside of Japan ahead of earnings growth. Given this had not been yielding results, including profit generation, we had a strong sense of urgency to change our course of direction.

Reassessing the Company's resources, organizational capabilities, and assets, we formulated a new medium-term management plan that calls for improved profitability, including maximized streamlining of our business in the Americas. **The key of this strategy is to maximize our contribution to patients by concentrating heretofore dispersed resources on the prescription pharmaceuticals business and activities directly related to this business.** In addition, we will focus on strengthening the operational structure and framework of the organizations that support this growth, maintaining profit momentum, and solidifying a foothold for the next stage of growth.

New Medium-Term Management Plan Objective

Focus on our strength: Maximizing "Prescription Pharmaceuticals Business"

1. Steadily implement profitability improvement measures

2. Maximize people & patient value contribution in Rx business
   - i. Assess key values not yet provided to people and patients
   - ii. Realize value contribution through existing/new products and services
   - iii. Promote new businesses with knock-on effect on Rx business

3. Strengthen operational framework to ensure medium-term management plan (MTP) execution

The new medium-term management plan is designed to solidify our foothold by fiscal 2025 to make a long-term leap forward toward fiscal 2026 and beyond.

Currently, we are seeing differences in business productivity across regions. While our Japan business maintains a high level of productivity, there is room for improvement overseas. **Therefore, we have decided to implement the model of commercial excellence[1] in Japan to other countries to deliver more value to patients and medical facilities, which in turn will lead to improved productivity for the Company.**

In 2012, I became responsible for our Japan business, a responsibility I held for almost 10 years. During that time, we improved productivity per person without increasing the number of medical representatives (MRs) significantly. At first, a few outstanding individuals led our businesses, but sales methods and activities had not necessarily taken root throughout the organization. I felt strongly that we must contribute to patients by creating a standard model for our organization to communicate in a unique Santen way that identified and solved issues for patients and ophthalmic care. We created this model under which all Japanese operations worked together as one, focusing on our contribution to patients. We transformed our Japan business into a highly productive organization that now provides value unique among Japanese pharmaceutical companies.

The Santen model of commercial excellence became a model of understanding the value of our products, considering the world view of how to provide the best value to patients, ensuring a deep, shared understanding of this world view, setting goals and strategies, and implementing strategies through consistent implementation of the PDCA (plan-do-check-action) cycle.

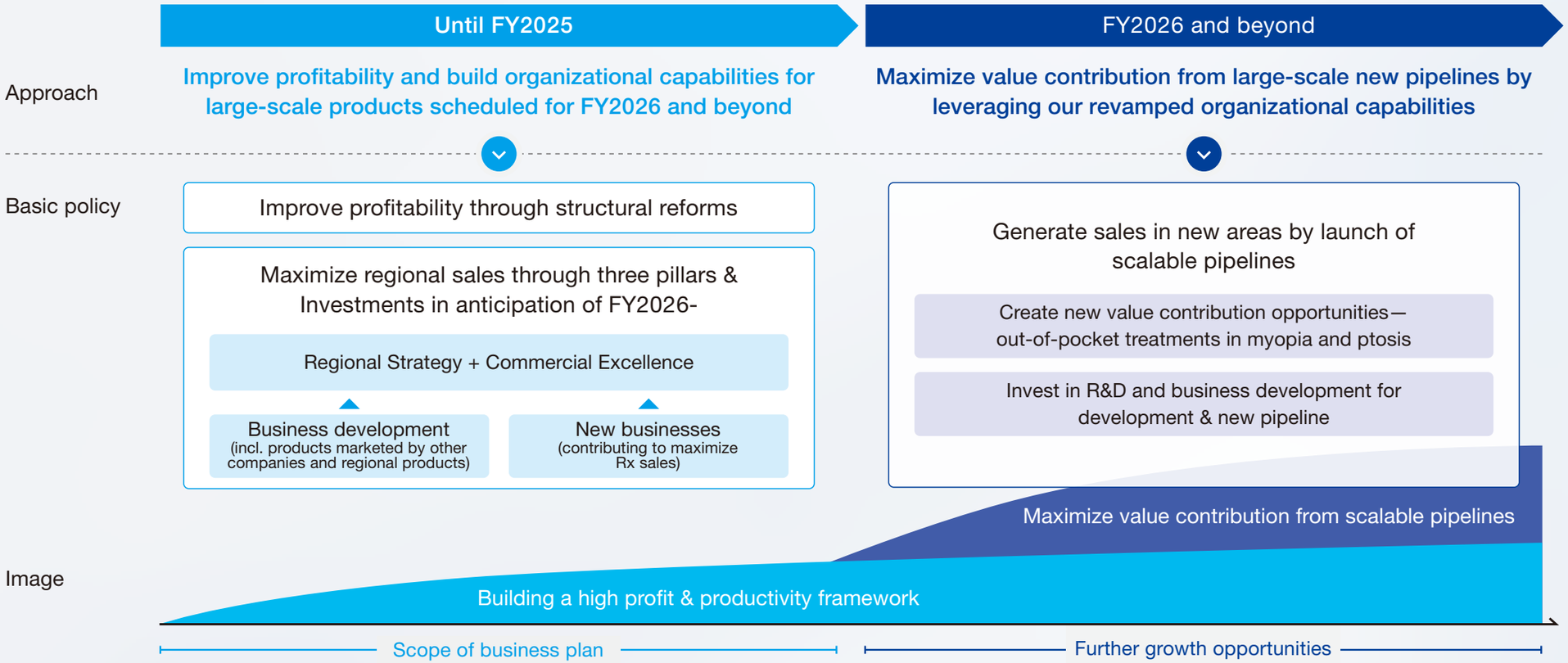
I became convinced that we could apply this model in our global expansion in the same manner, even accepting differences across countries and regions. Over the past two years, an internal project (→Page 24) to implement elements of Japanese commercial excellence has been underway in China and progressing better than expected. Seeing the results achieved to date, we reaffirmed the need to improve the productivity of regional operations through a model suited to each region, using this approach as the centerpiece of our strategy under the new medium-term management plan.

Further growth of regional businesses will require alignment with company-wide strategies and appropriate investments tailored to the needs of each region. Our corporate headquarters will work together on activities previously left largely to the discretion of each region. Alternatively, we will integrate business development and new business initiatives previously left to the corporate headquarters into regional operations. **In addition, examining the profit contribution to invested capital in detail, we will target investments leading to greater value by addressing the needs of patients and healthcare professionals while emphasizing relevance to future regional business strategies. We will also look at investments that will lead to better patient treatments and associated market development.** These are initiatives we must undertake simply because we are Santen, and we will work as one to strengthen the foundation for further growth in fiscal 2026 and beyond.

[1] Commercial excellence at Santen is our conviction to achieve the ideal state of ophthalmology care for patients. From product development to patient outcomes, continuous improvement of our corporate-wide capabilities will allow us to bring maximized value to patients through our products. Developing a consistent cross-functional strategic framework with tight alignment between strategy, planning and execution, underpinned by rigorous KPI monitoring and PDCA cycle management, will help us realize this ideal state.

We have several promising candidates in the pipeline leading to fiscal 2026 and beyond, including products for myopia and ptosis, and we intend to contribute to patients globally through the steady market penetration of these pipeline candidates.

Myopia and ptosis are new areas of out-of-pocket medical treatments that differ from conventional insured treatments. The key here will be to establish a system that helps patients to recognize the disease, understand treatment needs, and encourages patients to see a doctor for ongoing treatment. **There are several bottlenecks between seeing a doctor for the first time and treatment continuation. Solving these bottlenecks will maximize the value of these pipeline candidates.** This will be a substantial challenge, but we are preparing to deliver our pipeline candidates to as many patients as possible by taking advantage of our strengths, which include the ophthalmology networks and collaborations we have established with academic societies and other organizations in various regions around the world. Using operating centers and implementing activities in each region based on the wider adoption of commercial excellence through fiscal 2025 will provide more excellent value to patients and medium- to long-term growth for the Company.



We will assess risks properly, meeting and exceeding our targets for growth.

As we formulated our new medium-term management plan and numerical targets for fiscal 2023, the first year of the plan, we were particularly conscious of the need to understand and assess management and business risks properly. We were also conscious of discussing plans from the perspective of aligning our corporate headquarters, regional operations, and functions. During the corporate planning process, I fostered understanding by communicating my ideas and thoughts personally to each region and functional manager.

As we move our businesses forward, we will encounter risks (→Page 53) that include NHI price revisions, erosion caused by generics, product supply, and product development. We assessed these risks and factored them into our planning process. Of course, aspirational goals are necessary to maximize product value. **At the same time, we do not formulate overly optimistic plans that do not reflect risks properly.** It is also true that risks and changes in the environment are difficult to predict, such as the re-emergence of COVID-19 and related restrictions in China last year. We strive to strengthen systems that ensure an appropriate response when situations differ from expectations. Under these systems, each region and our corporate headquarters will discuss events from a shared perspective, keeping each other informed of new developments.

We also introduced a process for cost optimization to determine the necessity and appropriateness of expenses from a cross-organizational perspective. We appointed a person responsible for optimizing expenses in each category of high-impact spending, such as IT-related investments**. In addition, we are more sensitive than ever to profitability relative to invested capital, reviewing hurdle rates and strengthening financial discipline.**

By establishing and adhering to these mechanisms, we are building a solid business foundation to meet and exceed single-year goals and the overall goals of our new medium-term management plan.

Seeking greater contributions to patients and society through our businesses.

We pursue sustainability activities through our businesses. These activities include diversity, equity, and inclusion initiatives focused on the visually impaired (→Page 38) and the use of biomass plastics for eye drop bottles.

In formulating a new strategy, we revisited the 13 materialities (→Page 16) defined in fiscal 2020. Although we did not make any major changes, we identified two materialities as our most important priorities: (1) market penetration of products with social significance leading to the achievement of our medium-term management plan and (2) human resource development and promotion to support and drive business growth. **Our business itself is a response to social issues. We provide appropriate ophthalmic care to patients around the world through the wider market adoption of our products. And our global employees are the ones who ensure our return to growth. Developing and rewarding the efforts of human resources (→Page 36) who understand our CORE PRINCIPLE correctly and who can maintain a focus on and implement our strategy steadily is the most important thing we can do now for the sustainable growth of the Company in the future.** Clearly, management also discusses and strives to resolve issues not limited to these two materialities.

Maximizing shareholder value by enhancing our ability to generate cash.

We enhance our ability to generate cash by implementing the strategies I have discussed. We prioritize investments using the cash we generate in R&D and business development for future growth.

In particular, we prioritize funding for R&D at even greater levels than before, and we intend to step up investment in early-stage pipelines, such as the search for seeds, as well as in large-scale pipeline and life cycle management (LCM)[1] product development. I will assess the potential of each pipeline candidate and pursue R&D investments that, based on my past experience in R&D, I believe will lead to profitability by contributing to general patients and patients with more advanced needs.

In terms of shareholder returns, we mentioned in our new medium-term management plan that **we would eventually consider increasing dividends in line with profit growth. We established a floor of JPY 32 per share**, even in the face of various volatilities in the business environment, based on the policy of progressive dividends we have followed for some time. **We also intend to return profits to shareholders by conducting share buybacks flexibly in light of investment opportunities and capital needs (→Page 23).**

In the wake of the recent decline in profitability and stagnant stock price performance, the Board of Directors is acting with a sense of urgency to improve execution and organizational capabilities to ensure the achievement of our business goals. The diverse members of our Board are engaged in in-depth discussions to improve enterprise value. As CEO, I report to the Board of Directors in a timelier manner than ever before, including information on management-related risks and business progress. At the same time, we continue to strive for higher levels of corporate governance (→Page 46).

We believe the eye health needs of people around the world will continue to increase as the global population ages and new advances are made in diagnostic and treatment technologies. Through our products and services in the prevention, diagnosis, and treatment of eye diseases, we continue to provide important value beyond what has been available in the past. We strive to regain the trust of our stakeholders by returning to a growth trajectory in the short term. To this end, we restructured our organization, clarifying the roles and responsibilities of Corporate Officers and reorganizing reporting lines. We based these changes on the need to raise the quality of management further, while making maximum use of the strengths we have cultivated over our history.

I will do my utmost to face the challenges ahead while respecting our organizational culture, and I intend to stand with our employees in greater solidarity to implement the changes forthcoming. I ask for your continued support as Santen pursues these ambitious goals.

Takeshi Ito
President & CEO

CEO Career Highlights

Joined Santen Pharmaceutical Co., Ltd. in 1982

Experienced roles as a medical representative (MR) in the Japanese pharmaceutical business, as well as positions in business development, R&D, surgical business, etc.

Served as Corporate Officer, Senior Corporate Officer, and Director

Named Representative Director, Executive Vice President, Head of Japan Business, Head of Japan Sales & Marketing Division, in April 2022

Named Representative Director, President & CEO in September 2022

Research and Development	Involved in decision-making for the selection and concentration of development projects, pursuing the optimization of management resources by leveraging the Company's strengths in the most effective way to contribute to patients
Japan Business	Focused on developing and marketing new products and services that offer new value, including products that reduce the burden of treatment on patients and offer solutions to issues in the medical field Pursued life cycle management across core products, improving strategic execution, and expanding our organizational capabilities Contributed to sales and profit growth by planning and executing business strategies that integrate the perspectives of patients and the medical field while strengthening the foundations of the Santen business

[1] 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

FY2023–2025 New Medium-Term Management Plan

For more about the new medium-term management plan, please see the Company's website.
https://www.santen.com/content/dam/santen/global/pdf/en/ir/document/202403/mtg_FY2023-2025_en.pdf

Santen will renew its focus on maximizing the prescription pharmaceuticals business, which is its strength. We will improve profitability, maximize our contribution to people and patients by concentrating our resources on the prescription pharmaceuticals business and directly related initiatives, and strengthen the operational structure and framework that support these endeavors. During the period of the new medium-term management plan for fiscal 2023 through fiscal 2025, we will recover to our previous profit level and prepare for maximizing the value contribution from pipeline candidates with large-scale potential in fiscal 2026 and beyond.

Basic Policy to Achieve Growth

In the period through fiscal 2025, we will work to maximize earnings from two perspectives: improving profitability through structural reforms and the maximization of regional sales, and investing with a view to fiscal 2026 and beyond. In addition, we will build an organization that can maximize the value contribution of pipeline candidates with the potential to generate large-scale sales in fiscal 2026 and beyond. In the following period from fiscal 2026, we will generate new value in the myopia and ptosis therapeutic areas, and return to significant growth.

Of the funds generated by improving profitability through structural reforms, we intend to invest a portion in early-stage research and development, which will drive long-term growth. For our operations in each region, we will consider business development and new businesses that can support the growth of those operations. To that end, rather than major investment targets with inherent major risks, we expect to take on projects that will lead to improved regional productivity, maximize regional sales, and contribute to patients.

Until FY2025

Improve profitability through structural reforms

Maximize regional sales through three pillars & Investments in anticipation of FY2026-

Regional Strategy + Commercial Excellence

- Business development (incl. products marketed by other companies and regional products)
- New businesses (contributing to maximize Rx sales)

FY2026 and beyond

Generate sales in new areas by launch of scalable pipelines

- Create new value contribution opportunities—out-of-pocket treatments in myopia and ptosis
- Invest in R&D and business development for development & new pipeline

Until FY2025	FY2026 and beyond
Improve profitability through structural reforms	Generate sales in new areas by launch of scalable pipelines
Maximize regional sales through three pillars & Investments in anticipation of FY2026-	

Structural Reforms

Recognizing the urgent need for a recovery in core operating profit, which has been on a downward trend since peaking at JPY 50.1 billion in fiscal 2020, we are implementing four structural reforms under the new medium-term management plan, placing top priority on improving profitability.

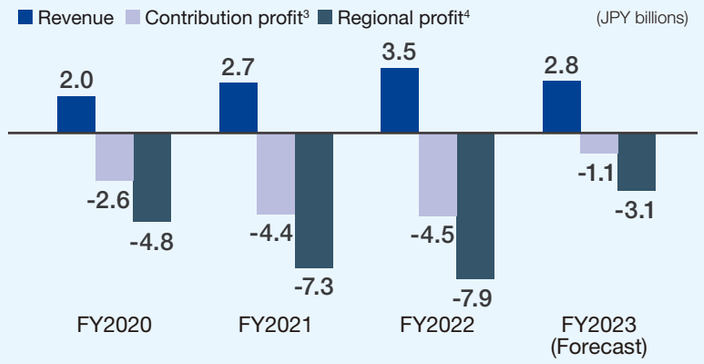
The first is to maximize streamlining of the Americas business. We acquired Eyevance Pharmaceuticals Holdings Inc. in fiscal 2020 as part of our re-entry to the U.S. market. However, due to product supply and other issues, we were significantly delayed in achieving profitability. As a result, we recorded an impairment loss in fiscal 2022. The launch of new products has also not proceeded according to plan, partly due to delays, which has made it difficult to achieve profitability in the short term. We therefore decided to streamline operations based on the belief that it was necessary to quickly eliminate losses in the Americas and improve profitability. The second reform is re-assessment of investments. After thoroughly examining the strategic significance, cost-effectiveness, and impact on the current business plan of large-scale investment projects we have previously committed to, we decided to postpone the introduction of the next-generation enterprise resource planning (ERP) system[1] in the China and Asia regions, as well as second-phase construction at the new Suzhou Plant. Future investments will also be scrutinized according to the same criteria. Reforms in the third area (cost optimization) and the fourth area (productivity improvement) will include tightening cost operating rules and eliminating redundant functions through cross-departmental reviews. We expect these four structural reforms to improve profitability by JPY 15.0 billion in fiscal 2025.

Four Structural Reforms

	Expected timeline			Expected effect
	FY2022	FY2023	FY2024 onward	(FY2025/year)
Maximize streamlining of Americas	Prep.	Execution	Generate impact & contribute to profits	Up to JPY **8.0** bil.
Re-assessment of investments	Prep.	Execution	Generate impact & contribute to profits	
Cost optimization	Prep.	Execution Generate impact & contribute to profits		Up to JPY **7.0** bil.
Productivity improvement	Prep.	Execution	Generate impact & contribute to profits	

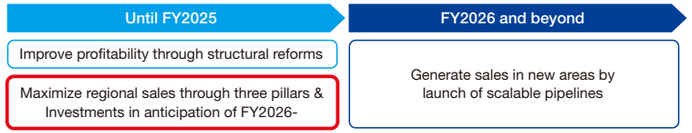
Maximize Streamlining of Americas

- Out-license or sale of products[2]
- Continue global R&D and medical device manufacture



[1] A system for centralized management of corporate resources and quick management decision-making [2] Santen announced licensing agreements and an asset transfer agreement for its pharmaceutical products in North America in July 2023 (https://www.santen.com/en/news/2023/2023_1/20230719)
[3] Amount calculated by deducting cost of sales and expenses related to revenue generation from revenue in each region [4] Amount calculated by deducting indirect expenses including human resource, financing, supply chain and other expenses from contribution profit in each region

Many Growth Opportunities Exist in Each Region



In each region, we identify countries, market segments and therapeutic areas where there are growth opportunities and the scope to expand our contribution to patients. In addressing each growth opportunity through activities centered on commercial excellence (→Page 24) that integrate corporate headquarters functions and operations in each region, we will achieve growth that exceeds the market average and expand our contribution to patients. We will also consider business development and new businesses that meet the needs of patients and healthcare professionals in line with the business strategies of each region.

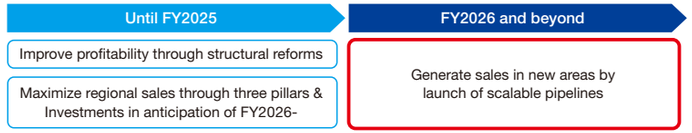
In Japan, although patent expirations of major products will have a significant impact, we will continue to provide products and solutions to address unmet needs, particularly by offering improved formulations. Through these efforts, we will grow the market as a market leader and maintain and strengthen our presence. Among our overseas businesses, which are key to sustainable growth, we believe that there is ample room for productivity improvement and sales growth. By optimizing and utilizing models of commercial excellence that we have cultivated in Japan, we will improve revenue per employee at customer facing units (CFUs),[1] which is an indicator of productivity, and strengthen our organizational capability. Our organizational strength, which continues to enhance our commercial excellence, will lead to growth in new therapeutic areas from fiscal 2026 onward. Overview by Region (→Page 65)

Santen's Main Growth Opportunities

	Basic policy	Key growth opportunities					Potential patient pool
		Target disease				Summary	(Millions of people)[2]
Japan	Maintain and further strengthen as a base market	Glaucoma	Dry eye	Allergy	Other[3]	Address unmet needs related to QOL[4] (instillation burden, etc.)	Approx. 20
		Glaucoma				Market development by improving rate of continued consultations	Approx. 0.6
			Dry eye			Improve treatment continuation rate by improving patient satisfaction	Approx. 5
China	Focus with long-term perspective on market expansion		Dry eye			Channel expansion into out-of-pocket medical treatment	Approx. 200[5]
			Dry eye		Other[3]	Channel expansion beyond large hospitals	Approx. 10[6]
		Glaucoma	Dry eye	Allergy	Other[3]	Early detection of undiagnosed patients and guidance for appropriate medical care	Approx. 200[7]
Asia	Build on further the strong South Korean market, and nurture the 2nd largest market in the region	Glaucoma				Market development through a higher rate of continued consultations	Approx. 0.2
			Dry eye			Market development for potential patients who have yet to undergo treatment	Approx. 30[7]
			Dry eye			Expand prescription of ciclosporine for patients with inflammation	Approx. 3
			Dry eye			Capture the self-medication market	Approx. 40[8]
EMEA[9]	Build on market presence by strategic prioritizations and productivity improvements	Glaucoma				Maintain and expand prescription opportunities in Rx area	Approx. 3
		Glaucoma				Capture untreated patients in the surgical field	Approx. 0.2
			Dry eye			Maximizing prescription opportunities of cyclosporin	Approx. 2
			Dry eye			Expansion in eye care segment utilizing digital tools	Approx. 60[8]

[1] Departments that interact directly with customers in each country and region [2] Estimated by Santen; rounded to one significant figure [3] Retinal diseases, infectious diseases, etc. [4] Quality of life
[5] Includes OTC users in optometry/pharmacy. OTC users calculated as the sum of potential patients (population × total prevalence, excluding patients receiving prescription pharmaceutical treatment) and patients who discontinued treatment.
[6] Includes patients of hospitals other than Tier 3 (the highest Chinese hospital classification) in the relevant area. [7] Includes potential patients [8] Target OTC users [9] Europe, the Middle East and Africa

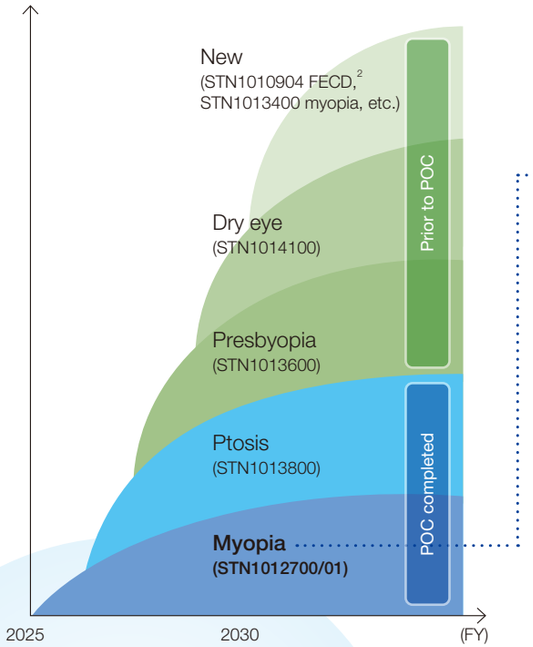
Toward Dramatic Growth in Fiscal 2026 Onwards



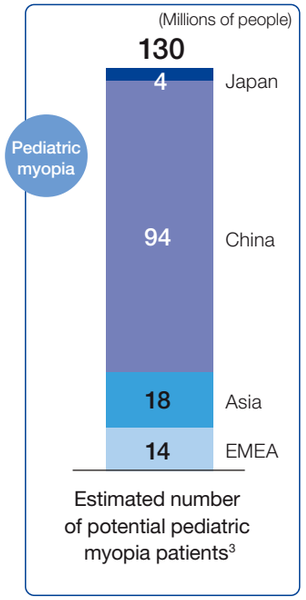
In the period through fiscal 2025, performance enhancement will be primarily supported by improved formulations and new products with new added value for patients in the therapeutic areas we currently serve, such as glaucoma, dry eye and allergies. During this period, we will also work to develop products in new areas with the potential to generate large-scale sales in fiscal 2026 and beyond.

We are also developing drugs for the treatment of diseases (such as myopia, ptosis, and presbyopia) for which there are no common medicine-based preventive or treatment options. We anticipate sales in emerging areas including out-of-pocket treatment for myopia and ptosis, areas where we have pipeline candidates for which we have already shown proof of concept (POC), and we have begun considering how to build acceptance of new treatment concepts among healthcare providers and patients. For each disease, there are many bottlenecks in the provision of diagnosis and treatment. The organizational strength with which we have firmly established our commercial excellence, will enable us to effectively implement initiatives to eliminate these bottlenecks, turn them into leverage points,[1] and pursue the maximization of product value. Moreover, we are taking on the challenge of developing a pipeline of highly competitive candidates that we also seek to launch in the U.S. These include drugs for presbyopia, new dry eye treatments, and next-generation myopia drugs, which although in the early clinical trial or pre-POC stages, have the potential to contribute to patients in the future. Steady progress in the development of these candidates will lead to dramatic growth in fiscal 2026 onwards.

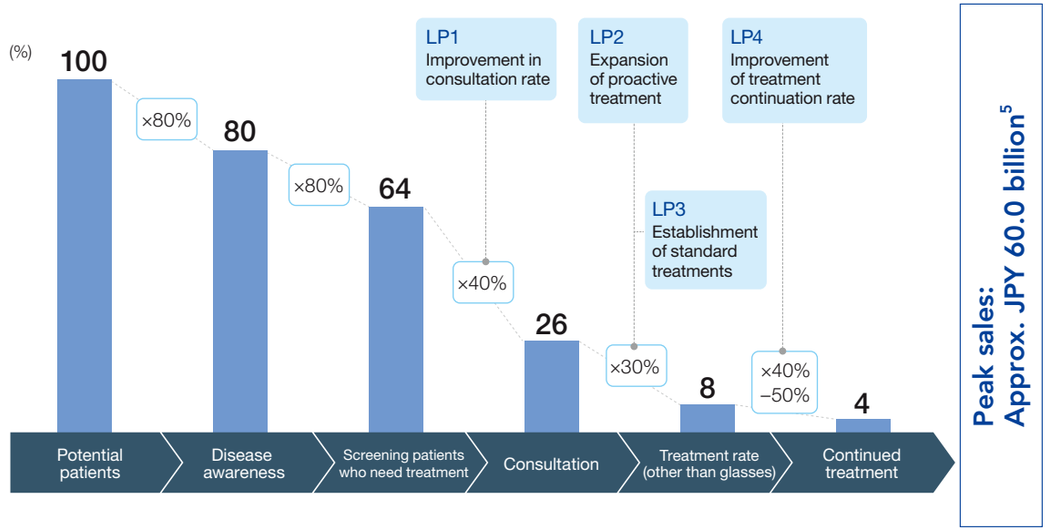
Major Pipeline Candidates



Market Potential of Pediatric Myopia and Leverage Points (LP)



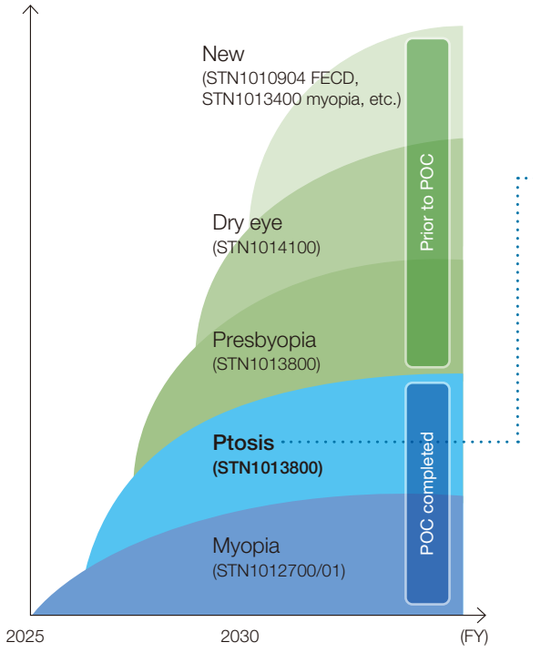
Opportunities to maximize product contribution value by fixing bottlenecks from consultation to continued treatment[4]



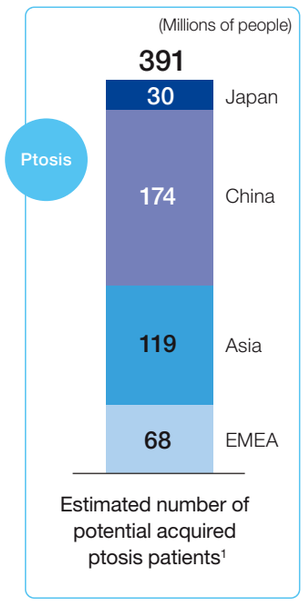
[1] Leverage point refers to the elements to be considered in order to maximize the product value in relation to the gap between the ideal form of medical care and the current situation. [2] Fuchs endothelial cornea dystrophy
[3] Santen estimate. Asia: South Korea, Taiwan, Singapore, Thailand, Philippines, Hong Kong, Indonesia, Vietnam, Malaysia. EMEA: U.K., France, Germany, Spain, Italy, Switzerland, Austria, Netherlands, Denmark, Norway, Sweden, Finland, Ireland, Portugal.
[4] Figures are based on survey results from Japan and China. [5] Upside forecast

Until FY2025	FY2026 and beyond
Improve profitability through structural reforms	Generate sales in new areas by launch of scalable pipelines
Maximize regional sales through three pillars & Investments in anticipation of FY2026-	

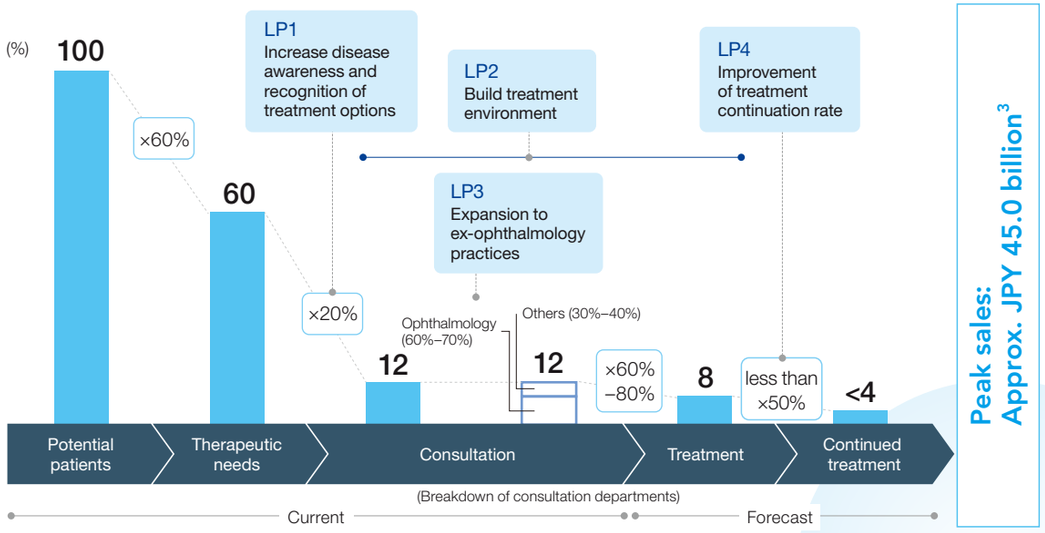
Major Pipeline Candidates



Market Potential of Ptosis and Leverage Points (LP)



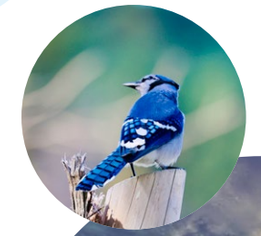
Underdeveloped market due to lack of promising products; opportunity to create a market with new product launch[2]

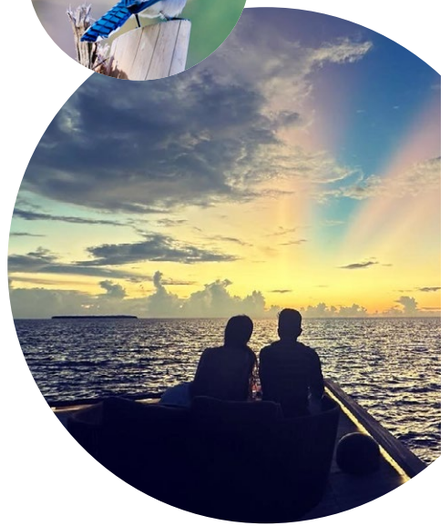


[1] Santen estimate. Asia: South Korea, Taiwan, Singapore, Thailand, Philippines, Hong Kong, Indonesia, Vietnam, Malaysia. EMEA: U.K., France, Germany, Spain, Italy, Switzerland, Austria, Netherlands, Denmark, Norway, Sweden, Finland, Ireland, Portugal.
[2] Figures are based on survey results from Japan, China, South Korea, Singapore, Taiwan, and EU5 [3] Upside forecast

Overview of Eye Diseases (Page 67)

Sustainability at Santen



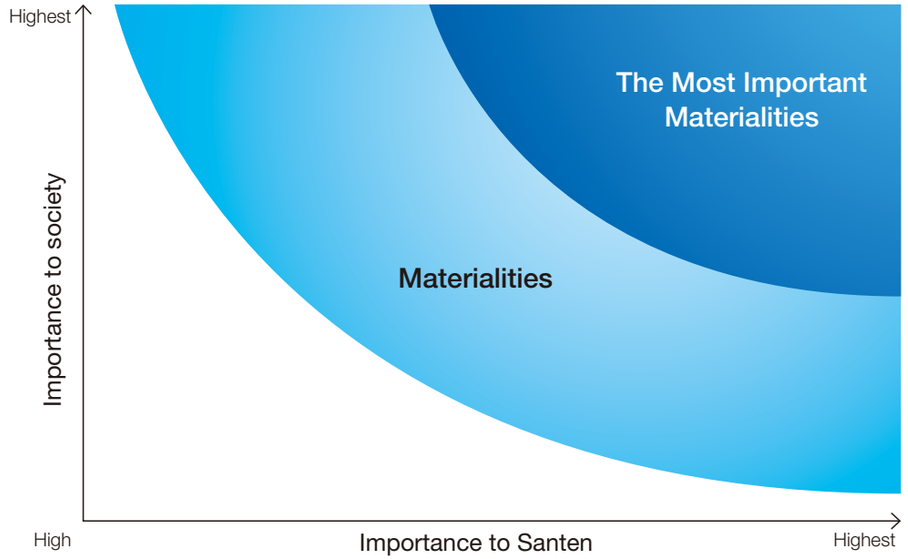


Contributing to Society through Our Business

In addition to contributions to society through our business, we have promoted sustainability activities such as inclusion with a focus on the visually impaired and the use of biomass plastic for eye-drop bottles and others. We will continue contributing to society through our business activities as a company specialized in ophthalmology.

Review and Revise Materialities

We assessed the challenges we face currently based on the assumptions of our new medium-term management plan. We identified *market penetration of products with social significance* and *human resource development and promotion* as the most important issues in continuing to contribute to society over the medium to long term.



Our 13 Materialities

Development and stable supply of socially significant products and services	**1. Market penetration of products with social significance** 2. Evaluation and management of the supply chain 3. Assurance of quality and safety, and establishment of an appropriate supply system 4. Providing appropriate information on products and services
Encouragement of an organizational culture that promotes value creation	5. Promoting diversity, equity, and inclusion 6. Building a high-value-added and highly productive work environment **7. Human resource development and promotion**
Strengthening governance, contributing to the realization of fair and equal society	8. Corporate governance 9. Compliance 10. Risk management 11. Respect for human rights
Conservation of the global environment	12. Measures against climate change 13. Environmental load reduction

For more about Sustainability at Santen, please see the Company's website.

https://www.santen.com/en/sustainability/policy

Value Creation Process

External Environment

Shrinking market due to changes in healthcare financing	Entry of new competitors into the ophthalmology field / Diversification of drug discovery modalities	Market disruption due to pandemics or regional conflicts	Need to address environmental issues (Increased risks including climate change)	Lifestyle changes (e.g., increased use of digital devices)	Increase in number of patients with glaucoma and other eye diseases due to aging population

INPUTS

Social Capital
- Strong worldwide ophthalmologist network
- Wide-ranging partnerships from ophthalmology research institutes to IT companies
- Business foundation in more than 60 countries/regions

Human Capital
- Approximately 4,000 diverse employees worldwide with expertise in ophthalmology
- Medical representatives (MRs) for steady product adoption
- High customer satisfaction (No.1 in Japan)[1]

Intellectual Capital
- Patents protecting formulations and manufacturing methods, in addition to substance, product application, and other types of patents
- In-depth ophthalmology expertise (familiarity with patients and medical professionals)
- Eye drop formulation development technologies and expertise based on a history of more than 130 years

Manufactured Capital, Natural Capital
- Production system specialized in ophthalmology that manufactures high-quality products (Noto, Shiga and Suzhou plants: Over 400 million units/year)
- Production capacity expansion through construction of new plants and conversion of plants to smart factories; installation of environmentally friendly equipment
- Efficient utilization of water resources and switch to eye drop containers made of biomass plastic

Financial Capital
- Robust balance sheet
- Disciplined capital expenditure investment approach

Business Model

(→Page 18)

Our Unwavering Strengths

Commercial Excellence

as a company specialized in ophthalmology

Bring maximized value to patients through our products

Foundation of our strengths

Research & Development | Production/Quality Compliance

Governance

(→Page 46)

OUTPUTS

Social Capital
- Expansion of an ophthalmologist network
- Mutual development of social capital through partnerships in various fields
- Further expansion of global business

Human Capital
- Diverse and open-minded organization; active human resources (increased productivity per capita)
- Maintenance of high customer satisfaction, diverse base of MRs for steady product adoption

Intellectual Capital
- Increase in the number of patents, patent quality improvements
- Enhancement of our expertise in ophthalmology
- Advancement in eye drop formulation development technologies and passing down expertise

Manufactured Capital, Natural Capital
- Achievement of sustainable and stable supply of high-quality products
- Strengthening of production capacity to contribute to more patients
- Reduction in the environmental load (net-zero, decrease in consumption per unit of revenue, etc.)

Financial Capital
- Increase in capital efficiency
- Improvement in profitability

[1] Percentage of ophthalmologists rating Santen the first among companies providing ophthalmic prescription pharmaceuticals. Santen calculations based on external data.

Value Creation Process (Business Model)

CORE PRINCIPLE

天機に参与する
Tenki ni sanyo suru

RISKS AND OPPORTUNITIES
(→ Page 53)

STRATEGY AND RESOURCE ALLOCATION
(→ Page 11) (→ Page 20)

Globalization
(→ Page 24)

The Santen Business Model

As a company specialized in ophthalmology, properly understand the needs of patients and doctors, and apply this understanding to product development, sales, and expansion into new businesses. Continue to provide patients with Happiness with Vision through the stable supply of high-quality products.

Our Unwavering Strengths

Commercial Excellence

as a company specialized in ophthalmology

Aiming to achieve the ideal state of ophthalmology care for patients

- Development of a consistent cross-functional strategic framework
- Tight alignment between strategy, planning and execution, underpinned by rigorous KPI monitoring and PDCA cycle management
- Continuous improvement of our corporate-wide capabilities

INPUTS ▶ Ophthalmic drugs, eye care services ▶ **OUTPUTS** ▶ **OUTCOMES**

OUTCOMES
Happiness with Vision

Bring maximized value to patients through our products

Foundation of our strengths

Research & Development
- Deploying existing API into ophthalmology
- R&D and business development specialized in ophthalmology
- Improvements based on the patient perspective

Production/Quality Compliance
- Large-scale manufacturing facilities and expertise
- Achieving both high-value-added and mass production
- Stable supply of high-quality products

PERFORMANCE
(→ Page 73)

Governance
(→ Page 46)

OUTLOOK
(→ Page 14)

Initiatives for Medium- to Long-Term Value Creation

Enhance Corporate Value

FY2023–2025	FY2026 and beyond

Basic Policy

- Improve profitability through structural reforms
- Maximize regional sales through three pillars & Investments in anticipation of FY2026-
- Generate sales in new areas by launch of scalable pipelines

Financial KPIs

Revenue	Core operating profit/margin
JPY **280.0** bil.	JPY **56.0** bil. / **20**%

Revenue growth ratio per overseas employee[1]	Core ROE	Growth rate of core EPS
Over **7** %[2]	**13**%	Over **10**%[2]

Cash Allocation

Growth investments

Actively invest in growth opportunities by profitability improvement & cash generation

Shareholder returns

Goal to increase annual dividend with current JPY 32 as the floor + Opportunistic share buybacks as capital adjust.

(JPY billions)

Sales Targets by Region	Japan	China	Asia	EMEA
Revenue[3]	150.0	36.0	32.0	61.0

- Create new value contribution opportunities– out-of-pocket treatments in myopia and ptosis
- Invest in R&D and business development for development & new pipeline

Santen 2030

Sustainability

Market Penetration of Products with Social Significance (→ Page 34)

Contribute to more than **50** million patients[4]

Human Resource Development and Promotion (→ Page 35)

- Restructure and implement human resource development program
- Evaluate and coach all managers in key positions[5]
- Clarify successor candidates for key positions and implement specific measures to systematically secure, train, and assign successor candidates
- Raise the ratio of female managers in Japan to at least 20%

Measures Against Climate Change (→ Page 42)

Environmental Load Reduction (→ Page 42)

Other

[1] China, Asia and EMEA. Excluding foreign exchange (FX) impact. [2] CAGR for FY2022 Forecast (announced February 7, 2023) - FY2025 [3] Other sales include royalty income and others of JPY 1.0 bil.
[4] Estimated total no. of patients to which Santen has 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. We revised the previously announced target when the new medium-term management plan was formulated.
[5] Major roles in the formulation and execution of business strategy and major roles in each function and region.

CFO's Message Financial Strategies to Improve Profitability and Support Sustainable Growth

FY2022 Results and FY2023 Outlook

We view FY2022 as a year of major milestones, including a change in top management in September. In the second half, in particular, we endeavored to restore profitability and clean up a negative legacy as part of our agenda for re-growth.

On a core basis, which indicates recurring profitability, we recorded higher revenue and profits year on year in overseas regions except China, which was affected by a resurgence of the COVID-19 pandemic. We also made progress in containing costs in our administrative departments. On a consolidated basis, however, we could not make up for the decline in our business in China. While revenue rose 5% year on year to JPY 279.0 billion, core operating profit declined 5% year on year to JPY 44.2 billion.

We recorded an operating loss of JPY 3.1 billion in part due to disappointing performance at Eyevance in the U.S., which we acquired in FY2020. We also recorded an impairment loss related to the STN10109 pipeline under development and a one-time charge associated with the streamlining of operations in the U.S.

In FY2023, the first year of the new medium-term management plan announced in April 2023, we intend to continue to improve profitability, including structural reforms. While we expect revenue to decrease 2% year on year to JPY 273.0 billion, we expect core operating profit to increase 4% year on year to JPY 46.0 billion. Although we have conservatively factored in the impact of generics in Japan, our core business, we aim to optimize our overall profit structure through structural reforms.

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

Financial Direction of the New Medium-Term Management Plan

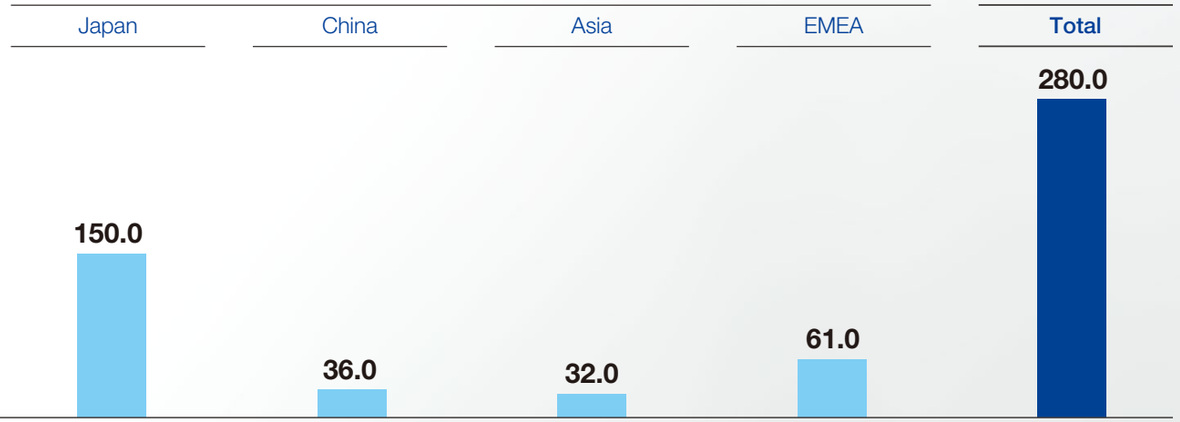
Our basic direction under the new medium-term management plan remains the same as before: we aim to increase profitability by specializing in ophthalmology, maximize our ability to generate cash, improve capital efficiency (ROE and ROIC), and ultimately maximize shareholder value. However, in light of our stagnant stock price performance in recent years and deterioration in ROE and other capital efficiency indicators, we are working towards a recovery with a sense of urgency. As announced, the minimum target thresholds in FY2025 consist of a 13% ROE and a 10% EPS average annual growth rate during the period of the new medium-term management plan.

1 Improving Profitability

Our first and most fundamental task is to improve profitability. We target a recovery in core operating profit margin from 16% in FY2022 to 20% in FY2025. While certain factors may put pressure on profits, including patent expirations in mainstay products, NHI drug price reductions, and inflation, we plan to reduce our SG&A ratio from 34% in FY2022 to 30% by FY2025. We intend to accomplish this through cost optimization and structural reforms, including structural reforms in our Americas business. We also plan to improve profitability on a core operating profit basis, while maintaining R&D expenses at current levels to secure future growth. While we expect revenue to remain effectively unchanged from FY2022, we target an increase in core operating profit from JPY 44.2 billion to JPY 56.0 billion, or an average of 8% annual growth over the period. We aim to grow Core EPS by an average of 10% or more over the period.

Sales Targets by Region

Business growth in each region that outperforms local market growth



	Japan	China	Asia	EMEA	Total
CAGR[2] (FY2022–2025)	-5%	18%	12%	6%	**1%**
Contribution profit ratio (FY2025)	43%	40%	40%	33%	—
Market CAGR[3] (FY2022–2025)	-5%	2%	2%	2%	**0%**

Core operating profit
JPY **56.0** billion

Core operating profit margin
20%

vs. FY2022 (forecast)
+ **5** pt

[1] Other revenue includes JPY 1.0 billion in royalty income and others. [2] Based on forecast for FY2022 as of February 7, 2023. Calculated based on exchange rates for each fiscal year.
[3] Based on Santen estimate using FY2022 forecast. Calculations for China, Asia, and EMEA exclude the retinal disease area. Calculations for Asia and EMEA are based on main sales countries.

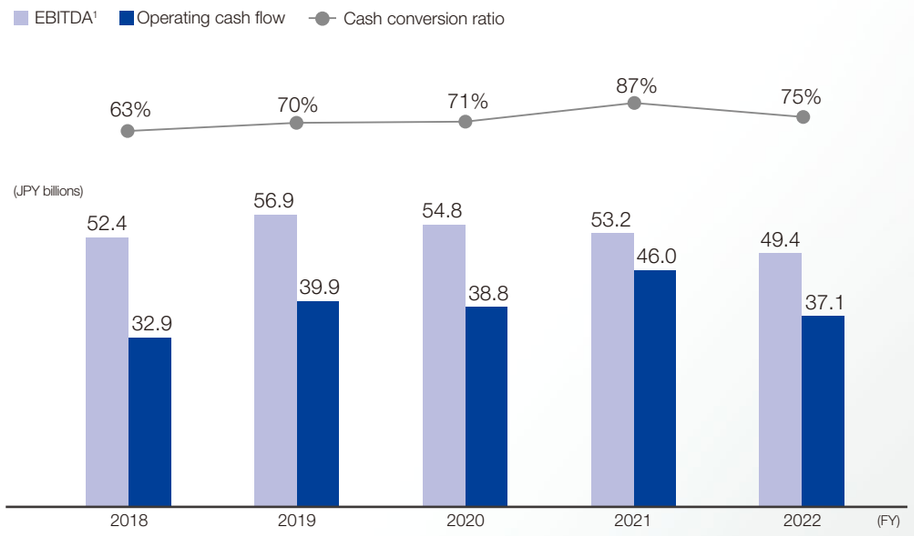
2 Strengthening Cash Generating Capacity and Reducing the Cost of Capital

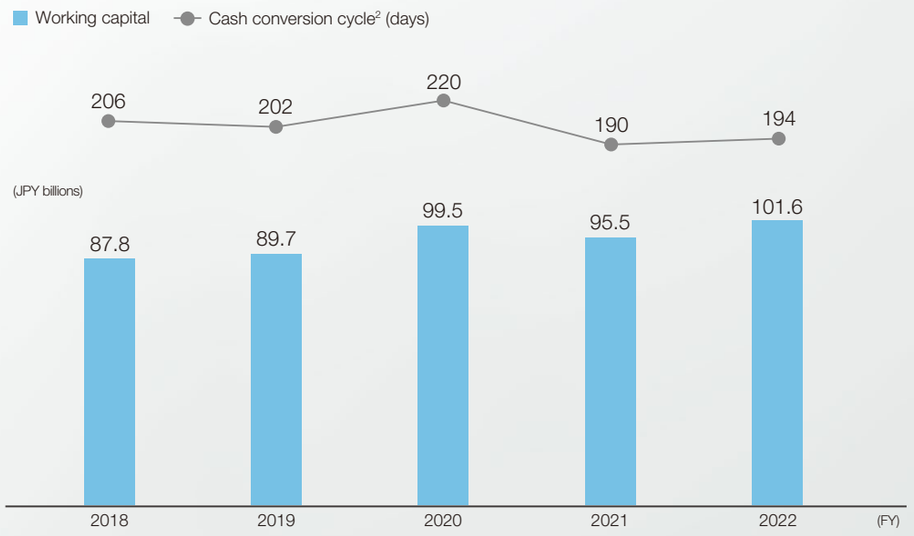
Recognizing that the capacity to generate cash is the source of corporate value enhancement, we have maintained operating cash flow on a growth trajectory, even during periods of earnings volatility. To maximize our investment capacity for future growth, we intend to strengthen our ability to create and manage our assets more efficiently.

We plan to manage the cash generated centrally under the International Financial Headquarters (IFHQ) in Switzerland, including management over currency structure and interest rates. Through a cash management system meeting the cash needs of each region, we will work to improve capital efficiency and reduce the cost of capital.

The cash conversion cycle (CCC), in particular, is an area in which we have room for improvement. Given the nature of pharmaceuticals, we must avoid any situation in which reduced inventory prevents us from fulfilling our responsibilities to supply products. However, we aim to reduce invested capital, mainly through increasing the liquidity of accounts receivable, and thereby improve return on invested capital (ROIC).

Stable Cash Generation





[1] EBITDA = (Operating profit) – (Other income) + (Other expenses) + (Depreciation) [2] Cash conversion cycle: Based on turnover period of trade and other receivables, inventories, and business operation related expenses.

3 Capital Allocation for Sustainable Growth

To achieve these aforementioned improvements in our stock price and capital efficiency as rapidly as possible, we intend to mobilize our balance sheet and cash flows driven by a recovery in profitability, conducting upfront investments for future growth while returning profits to shareholders at the same time.

Following FY2019 and FY2020, we recorded impairment losses on assets acquired from previous investments in FY2022. We also believe expectations of shareholders, and the capital markets more broadly, are for value creation through investments in business opportunities upon which only Santen can capitalize. Investments remain our top priority in capital allocation.

In particular, we will prioritize R&D investments for future growth, and we intend to allocate more than JPY 100.0 billion over three years. At the same time, we have kept capital investment at high levels over the past several years as part of an investment cycle that occurs once every 20 years. These investments include expanding production capacity in Japan and China, as well as upgrading to a next-generation ERP system. The peak of the investment cycle is behind us, and we expect capital expenditures during the medium-term management plan to be JPY 26.0 billion, less than half of the JPY 54.7 billion in accumulated capital expenditures from FY2020 through FY2022.

In accordance with our policy of progressive dividends, we have not reduced dividends, while increasing dividends in conjunction with profit growth. We will maintain this policy throughout our medium-term management plan period, keeping current JPY 32 dividends per share as the floor, considering a potential increase in the future as a function of profit growth.

In addition, we have been returning profits to shareholders through share buybacks of JPY 25.7 billion (representing 6.6% of outstanding shares) in FY2022 and scheduled buybacks of JPY 24.5 billion (5.0% of outstanding shares expected) in FY2023. Over the two years, we expect to have retired shares representing a total of 11.3% of outstanding shares (FY2023 figures are tentative). In the absence of investment opportunities in the future, we will prioritize share buybacks over retained earnings, subject to equity market conditions.

To increase shareholder value, we strive to meet the expectations of shareholders, investors, and securities analysts who have an interest in Santen. To this end, we are committed to listening to feedback from the capital markets and engaging in appropriate information disclosures and dialogue to ensure Santen shareholder value is evaluated in the most appropriate manner.

Inflow[1]		Outflow[1]	
		Use	Amount
Debt			
Operating cash flow (excluding R&D expenses) Approx. JPY 190.0 billion	Growth investments	Capital expenditures	JPY 26.0 billion
		Research and development expenses	Over JPY 100.0 billion (Including development milestones)
		Business development investments	Over JPY 40.0 billion (No additional financing) Over JPY 90.0 billion (With financing)
Surplus Approx. JPY 20.0 billion	Shareholder returns	Share buybacks	
		Dividends	JPY 37.5 billion

[1] Cumulative total for FY2023–2025

Establishing Commercial Excellence in All Regions

Under the new medium-term management plan, we are working to establish "Optimized Commercial Excellence" in each region, while leveraging the expertise we have accumulated in Japan in order to realize further growth in each region. The forerunner of this approach was a project to establish Santen's commercial excellence in China centered on the implementation of a business model that had been successful in Japan. This project focused in particular on commercial excellence activities for strengthening the PDCA (plan-do-check-action) cycle.

The project was evaluated as a successful cross-regional project that directly connects to the provision of value to patients, consumers, and healthcare professionals, as outlined in our CORE PRINCIPLE, and was selected for the *Tenki ni sanyo suru* Grand Prize in the Santen Value Award 2022 (our annual company-wide President's award program).

Expanding our contribution to patients through the market penetration of *Tapros* by applying Japan business best practices in China

Santen's Japan business has been able to achieve sustainable growth and high performance through a variety of efforts and initiatives while also maintaining a constant number of medical representatives (MRs). A project was launched to adapt the business model used by the Japan business to commercial activities in China, integrating it with activities to expand contribution to glaucoma patients through the market penetration of *Tapros*.

The Japan business has thoroughly implemented a system for the detailed monitoring of the progress and outcomes of sales activities and for strengthening the PDCA cycle. Applying these best practices to commercial activities in China, project members as a first step sought to approach 300 doctors with the aim of providing *Tapros* to a greater number of patients.

New initiatives succeed when goals and perceptions are carefully aligned

Even prior to the launch of this project, the information to be emphasized for each product was clearly defined in the China business; nevertheless, the procedures used in Japan were more meticulous in detail as was the organization for its implementation. Studying the successes in the Japan business, the project team carefully devised a system of procedures that would enable MRs in China to make proposals tailored to the needs of doctors, while taking into account the market environment and the situation of their MR colleagues.

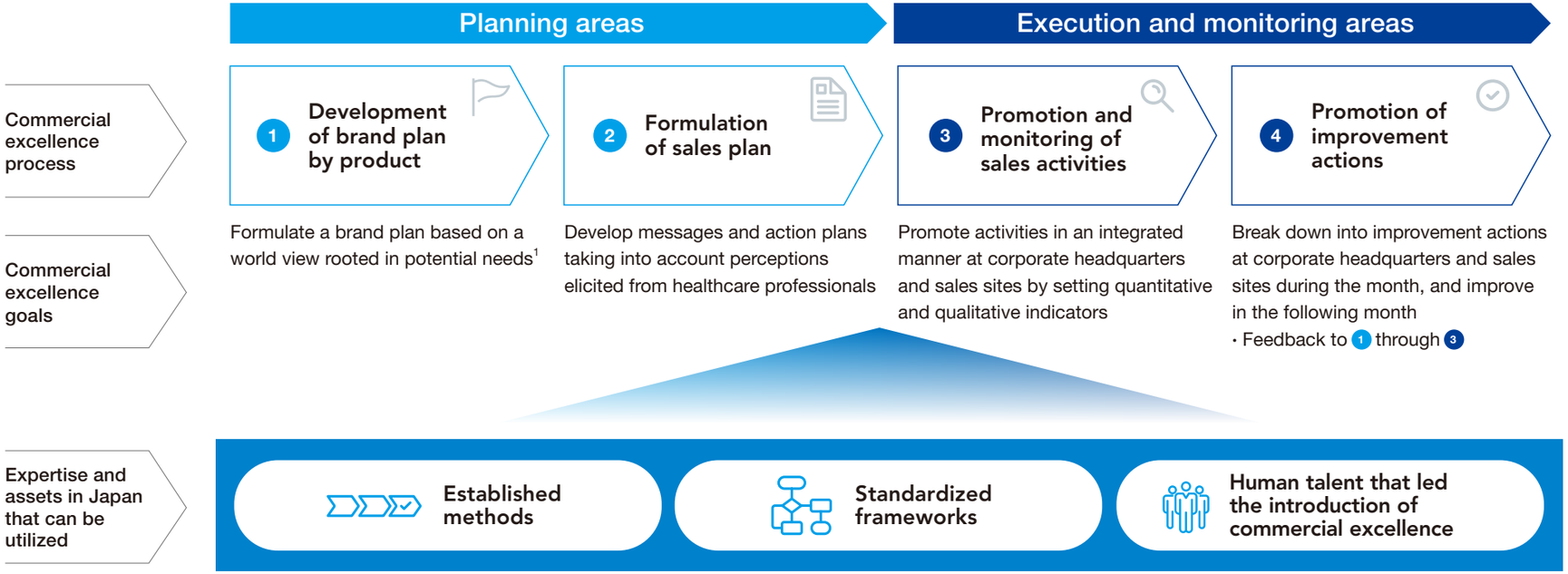
In addition to ensuring that each MR could fully understand the content of the sales procedures and execute them precisely, the project team also sought to strengthen the mechanism for monitoring the status of sales activities and outcomes, and then utilizing that information to accurately determine optimal actions to take or improvements to make. To this end, the project team reviewed key goal indicators (KGIs) and key performance indicators (KPIs) for sales activities, developed training programs for MRs, formulated a management plan that clearly indicates who does what and when, and set up meetings at key milestones throughout the sales journey to ensure that the entire organization including MRs could implement an effective PDCA cycle. A dashboard to visually represent data was also developed so that KGIs and KPIs were shared among the members. Previous MR training programs had been conducted separately by each department, but the new developed program was designed cross-functionally so as to enhance interdepartmental collaboration.

Positive outcomes strengthen our sense of purpose and collaborative spirit

Through this project, the team was able to improve the quality of communication between MRs and doctors, and to build a foundation for effective management of the PDCA cycle. As a result, sales of *Tapros* outperformed the market by achieving growth.[1] The project also resulted in additional positive impacts, such as raising awareness of good PDCA management, which in turn is fostering a mindset of cross-functional collaboration—not just for sales processes, but across the China business.

[1] Copyright © 2023 IQVIA. IQVIA MIDAS 2020-2022, Santen analysis based on IQVIA data. Reprinted with permission.

Santen's Commercial Excellence



Messages from Project Members

Xiaoyan Zou

Senior Director
Santen Pharmaceutical (China) Co., Ltd.

The China business operates in a complex market environment, and in the process of learning new methods and putting them into practice, we encountered challenges as a result of COVID-19 and national policy reforms. Nevertheless, our colleagues in Japan have been providing insights and suggestions, and we have been able to overcome many obstacles.

We will continue to drive this project to achieve higher business goals, as we aim to build an organization as efficient as that in Japan.

Kazumasa Fujio

Team Manager,
Sales Promotion Team
Japan Sales and Marketing Division

Helping to establish commercial excellence in China gave me a valuable opportunity to reflect on the activities of the Japan Sales & Marketing Division, and our discussions with members from the China business provided insights for continuous improvement.

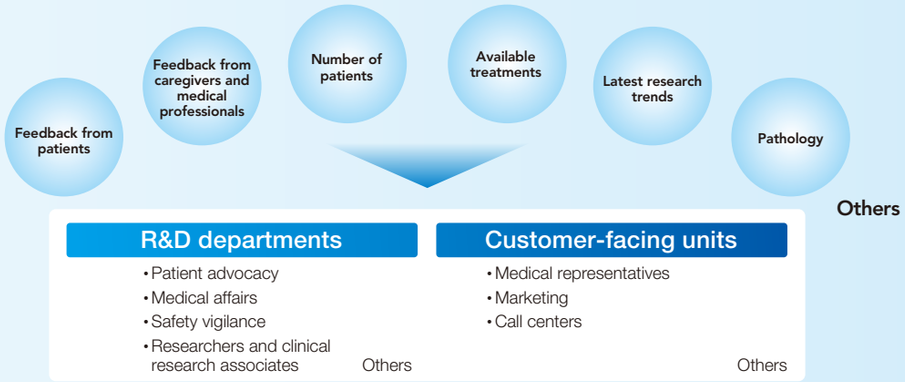
We will continue to strive for commercial excellence not only in Japan but in all of Santen's operations.

[1] The gap between the ideal treatment and the status quo based on Santen products

Product Development Aimed at Providing Value to Patients

For each disease and in each region, there are various unmet medical needs related to the maintenance and promotion of eye health. Among these are many latent needs that can be discovered by listening to patients, caregivers, and medical professionals. As a company specialized in ophthalmology, we are striving to increase our contribution to patients worldwide by identifying these needs as the basis for providing new therapeutic options.

Santen's Product Development



1 Understanding unmet medical needs → 2 Considering solutions → 3 Verifying hypotheses in clinical trials

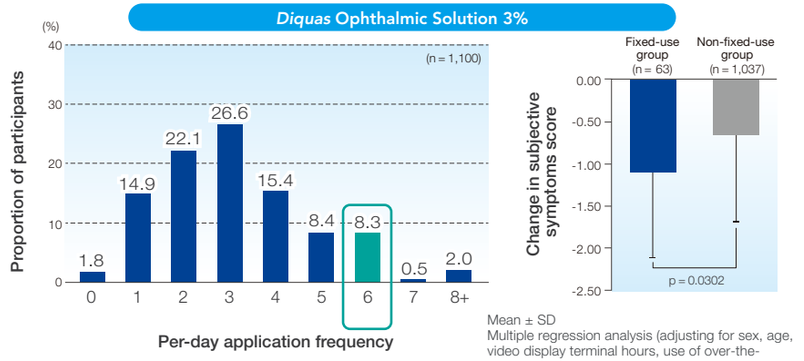
Our product development begins by understanding unmet medical needs. The R&D departments review literature as well as presentations at academic meetings, conduct research on disease pathology and patient numbers, and hold direct patient interviews. In addition, we aggregate data on needs seen by the medical affairs department and medical representatives in their day-to-day operations, from telephone and online feedback from patients, caregivers, and medical professionals, and from information gathered through post-marketing safety monitoring and pharmacovigilance (safety vigilance activities). Based on this data, we comprehensively evaluate needs in terms of magnitude, feasibility of solutions, and degree of contribution to patients when addressed, and select priority themes.

Product Case Study: *Diquas LX* Ophthalmic Solution 3%

1 Understanding unmet medical needs

It has been reported that 59.8% of patients prescribed with dry eye medications do not instill with the frequency specified on the label.[1] An analysis of a survey[2] of patients with dry eye showed that 8.3% of those that were prescribed *Diquas* adhered to the application frequency (six times a day) specified on the label. In addition, there was a significant difference in the change in subjective symptom score between patients who adhered to the application frequency specified on the label and who regularly instilled the eye drops regardless of the presence or absence of subjective symptoms (fixed-use group) and patients not included in the fixed-use group (non-fixed-use group). These results suggest the possibility that patients who do not instill *Diquas* according to the specified dosage regimen do not demonstrate the therapeutic effect.

In order for patients to obtain the therapeutic effect through instillation as specified on the label, we considered reducing the application frequency to be an important approach.



Mean ± SD
Multiple regression analysis (adjusting for sex, age, video display terminal hours, use of over-the-counter eye drops, application frequency of eye drops for dry eye during the study and subjective symptoms score before treatment)

Source: Uchino M, et al.: *J Clin Med* 11: 367, 2022

[1] K. Inagaki et al.: *Medical Journal of Nantan General Hospital* 17(1): 31-36, 2015
[2] Limitations of this research: The survey was administered via an online questionnaire and its subjects were limited to online users, and so results should not form the basis for broader generalizations.

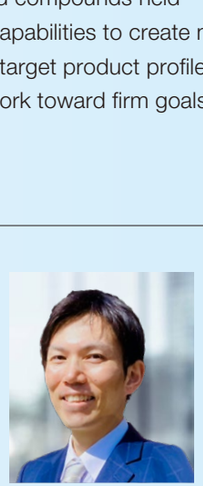
1 Understanding unmet medical needs | 2 Considering solutions | 3 Verifying hypotheses in clinical trials

We examine specific solutions for each theme across a broad range of options that include searching for new compounds, improving on existing formulations, and developing container designs. Furthermore, based on the knowledge we have cultivated as a company specialized in ophthalmology, we identify essential technologies and compounds held outside the Company and use them in combination with our R&D capabilities to create new therapeutic options. At the early stages of development, we define target product profiles of the products we want to deliver to patients, and as a team we work toward firm goals over the long course of development.

Close-up

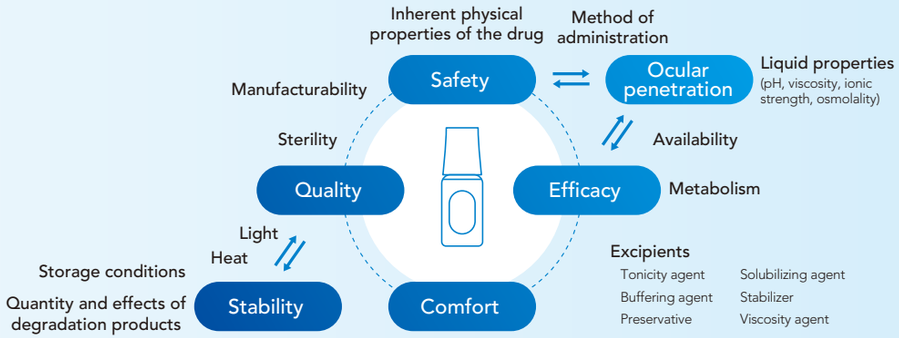
Formulation Design for Ophthalmic Solutions

In formulation design for ophthalmic solutions, in addition to efficacy and safety, we examine the quality and application comfort of ophthalmic solutions, which is important for supporting proper treatment adherence. Furthermore, the development of global products requires that a single formulation must meet the differing quality standards of various countries and regions. We aim to develop optimal formulations that meet the above requirements, leveraging the know-how we have cultivated over many years while also utilizing new technologies. For example, we consider how to achieve a balanced combination of buffering, tonicity, and viscosity agents that improves patient comfort after instillation.



Naoki Matsumoto

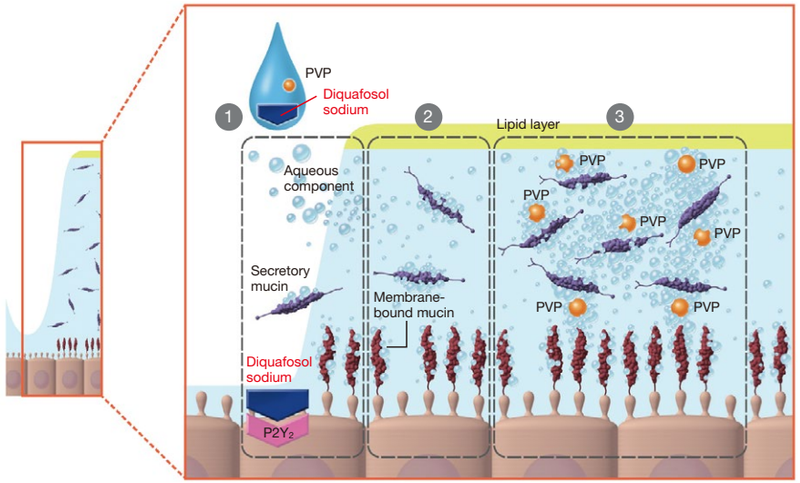
Head of Pharmaceutical Development, Pharmaceutics and Pharmacology Department, Product Development Division



2 Considering solutions

The new formulation, *Diquas LX* reduced the application frequency from six to three times a day through the addition of polyvinylpyrrolidone (PVP; also known as povidone) as an excipient. Tear fluid is composed of aqueous tears and mucins. The active ingredient of *Diquas* (diquafosol sodium) acts on corneal and conjunctival tissues to stimulate the secretion and production of aqueous tears and mucins. The combination of secreted aqueous tears and mucins, and PVP, may form a complex, which stimulates the retention of tear fluid on the ocular surface.

In the past, we have attempted to reduce the application frequency through technologies that increase drug exposure in target tissues, such as increasing the concentration of the active ingredient or increasing the retention of the drug by compounding a polymer that gels the drug on the ocular surface. ***Diquas LX* achieves a reduction in the per-day application frequency without increasing drug exposure through a novel approach and technological development.**



I. **Active ingredient acts on the corneal and conjunctival tissues to stimulate the secretion and production of aqueous tears and mucins.**
II. **Secreted aqueous tears and mucins form a complex and stay on ocular surface.**
III. **Furthermore, the combination of secreted aqueous tears and mucins, and PVP, form a complex and promotes the production of tear fluid that stays on the ocular surface.**

Takaoka-Shichijo Y, et al.: *Journal of the Eye* 28 (7): 1029-1033, 2011
Takaoka-Shichijo Y, et al.: *Journal of the Eye* 28 (4): 543-548, 2011
Fujihara T, et al.: *J Ocul Pharmacol Ther.* 18 (4): 363-370, 2002
Takaoka-Shichijo Y, et al.: *Journal of the Eye* 28 (3): 425-429, 2011
Sakamoto A, et al.: *Extra Number BIO Clinica.* 4 (3): 114-117, 2015
Efficacy of 3% DE-089C ophthalmic solution on lipids in tear fluid, in-house data of Santen Pharmaceutical Co., Ltd.
Website of Japan Dry Eye Society (https://dryeye.ne.jp/en/tfot-en/)
Suknuntha K, et al.: *Drug Dev Ind Pharm.* 37 (4): 408-418, 2011
Baszkin A, et al.: *Biomaterials.* 5 (3): 175-179, 1984

Supervised by Dr. Norihiko Yokoi, Kyoto Prefectural University of Medicine

1 Understanding unmet medical needs → 2 Considering solutions → 3 Verifying hypotheses in clinical trials

Clinical trials are conducted to assess efficacy and safety in humans. Going beyond the minimum requirements for regulatory approval, we also verify the product's potential to adequately meet unmet medical needs and achieve high competitiveness. When conducting clinical trials, we take advantage of Santen's global R&D system to select the most suitable region and study design, so that we can provide value to patients as quickly as possible. In developing new drugs, we conduct proof of concept (POC) trials at an early stage, as well as translational research[1] to improve the probability of success of POC trials and larger clinical trials in later stages.

[1] Bridging research that links basic research, clinical research, and medical treatment to efficiently and effectively commercialize results that contribute to medical development

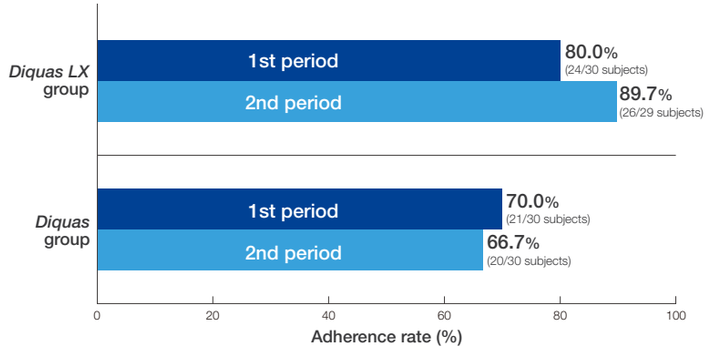
3 Verifying hypotheses in clinical trials

In a verification trial in dry eye patients, we confirmed the efficacy and safety of a new formulation, *Diquas LX*, which is instilled three times per day, and obtained approval. In addition to this trial, we also assessed the degree to which the formulation offered substantial added value to patients. Dry eye patients self-administered *Diquas* six times a day or *Diquas LX* three times a day for two weeks, respectively, and the adherence rate was compared. The results are shown in the graph below.

Since its launch in November 2022, ***Diquas LX* has widened our contribution to patients as a product with the lowest per-day application frequency among eye drops approved in Japan for dry eye, and can be expected to make it easier to adhere to eye drop regimens.**

Open-Label Cross-Over Comparative Study in Dry Eye Patients: Phase IIIb, Exploratory Study[2]

Adherence rate to the ophthalmic solution in each drug group from the day after the start of application to the day before the next visit in each period



Participants: 60 dry eye patients aged 20 years or older with a history of topical dry eye medication

Design: In the 1st period, group A used *Diquas LX* ophthalmic solution 3% (one drop at a time, three times per day) and group B used *Diquas* ophthalmic solution 3% (one drop at a time, six times per day) for two weeks. In the 2nd period, each group used the other ophthalmic solution for two weeks.

Main project members

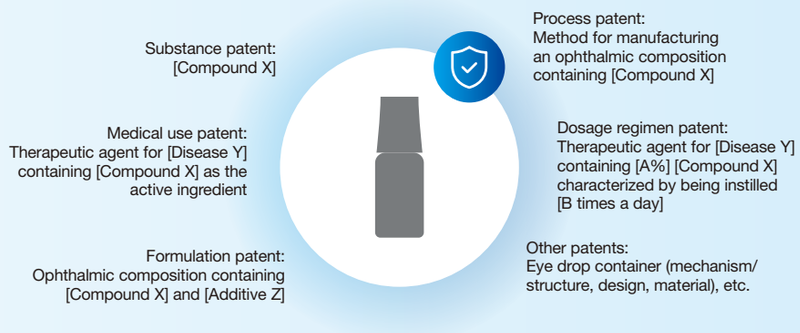
[2] Open-label crossover comparative study of 3% DE-089C ophthalmic solution and *Diquas* ophthalmic solution 3% in dry eye. In-house data of Santen Pharmaceutical Co., Ltd. (Data for reference at the time of approval)

Close-up

Patents in Ophthalmology

Masakazu Hatano
Global Head of Intellectual Property

The business, R&D and intellectual property departments work together to add new intellectual property to Santen's portfolio, particularly that relate to ophthalmology. At the same time, we strategically utilize intellectual property to maximize the value of Santen products from a global perspective. In addition to substance patents protecting active ingredients, we also strategically apply for patents protecting ophthalmic use of such active ingredients, as well as formulations, manufacturing methods, optimal dosage regimens, eye drop containers and other discoveries made during the development process. **These patents enable us sustain product value after the substance patent has expired.**



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

https://www.santen.com/content/dam/santen/global/pdf/en/business/pipeline.pdf

Development Status (Clinical Stages)

We aim to launch improved products with new added value and new products in our existing disease areas such as glaucoma, dry eye, and allergies in the period through fiscal 2025, and new products in new disease areas in fiscal 2026 and beyond, such as myopia, ptosis, and presbyopia.

In new disease areas, we will provide new therapeutic options for diseases for which drug treatments have not been widely available. This also means taking on the challenge of addressing areas without globally established assessment methods or where knowledge is scarce. Therefore, we will start by establishing non-clinical evaluation systems in-house and conduct a wide range of compound screenings, and in clinical trials, hold discussions with ophthalmologists on implementing evaluation indicators that can be considered to be the most appropriate at that time. When necessary, we introduce new measurement technologies and instruments, which includes verifying the suitability of methods used.

(As of April 2023)

		Development code	Generic name	Indication	Region	Clinical trial			Filed	Approval	Launch
						Phase 1	Phase 2	Phase 3			
Existing disease area	Glaucoma area	STN1011101 /DE-111A	Tafluprost/ timolol maleate	Glaucoma Ocular hypertension	China				Dec. 2022		
		STN1011700 /DE-117	Omidenepag isopropyl	Glaucoma Ocular hypertension	U.S.					Sep. 2022	
					Japan						Nov. 2018
					Asia						Feb. 2021
		STN1012600 /DE-126	Sepetaprost	Glaucoma Ocular hypertension	U.S.						
					Japan						
					Europe		(Exploratory study)				
		STN2000100 /DE-128	Glaucoma implant device	Glaucoma	Japan						Jul. 2022
					Europe						Apr. 2019
					Asia						Oct. 2022
		STN1013001 /DE-130A (Catioprost)	Latanoprost	Glaucoma Ocular hypertension	Europe				Sep. 2022		
					Asia						
		STN1013900 /AR-13324	Netarsudil mesylate	Glaucoma Ocular hypertension	Japan						
					Europe						Feb. 2023
					Asia					Jan. 2023	
		STN1014000 /PG-324	Netarsudil mesylate/latanoprost	Glaucoma Ocular hypertension	Europe						Jan. 2023
					Asia					Jan. 2023	
	Keratoconjunctival disease area	STN1007603 /DE-076C	Ciclosporin	Vernal keratoconjunctivitis	U.S.						May 2022
					China					Apr. 2022	
		STN1008903 /DE-089C	Diquafosol sodium	Dry eye	Japan						Nov. 2022
					Asia				Mar. 2023		
		STN1014100	Olodaterol hydrochloride	Dry eye	Japan		Phase 1/2a				
		STN1011402	Epinastine hydrochloride	Allergic conjunctivitis	Japan				Mar. 2023		
New disease area		STN1010904[1]	Sirolimus	Fuchs endothelial corneal dystrophy	U.S. France India		Phase 2a				
		STN1010905	Sirolimus	Meibomian gland dysfunction	Japan		Phase 2a				
	Refractive error area	STN1012700 /DE-127	Atropine sulfate	Myopia	Japan			Phase 2/3			
					China			Phase 2/3			
					Asia						
		STN1012701 /SYD-101	Atropine sulfate	Myopia	Europe						
		STN1013400	AFDX0250BS	Myopia	Japan						
		STN1013600	Ursodeoxycholic acid	Presbyopia	U.S.		Phase 2a				
					Japan						
	Other	STN1013800	Oxymetazoline hydrochloride	Ptosis	Japan						

[1] The development code (STN1010904) is due to be assigned to the product when Santen obtains an exclusive license upon completion of Phase 2 clinical trial.

Product Manufacturing Ensuring High Quality and Stable Supply

Mark Dawson
Chief Product Supply Officer

Maximizing the Value of the Product Supply Foundation

In order to contribute to society through our business as a company specialized in ophthalmology, it is imperative that we consistently provide a stable supply of high-quality products. Since fiscal 2021, we have continuously strengthened our production capacity to meet increasing global demand and diversifying needs. **We will strive to maximize the value of our assets and pursue a supply system that achieves high productivity, aligning with the realization of our new medium-term management plan.**

First, we will accelerate the transformation to a more efficient supply chain based on in-house manufacturing. Santen possesses unique manufacturing sites specializing in ophthalmology: the Shiga Product Supply Center, excelling in establishing production systems for new products; the Noto Plant, specializing in high volume, cost-effective continuous mass production; and the Suzhou Plant, providing production capacity for the important Chinese market. Our strength lies in the ability to optimize these manufacturing sites according to the product lifecycle. Currently, **we are proceeding with the reorganization of our supply chain, placing emphasis on maximizing the utilization of these in-house production sites.** Furthermore, by strengthening our strategic partnerships with contract manufacturers, we aim to complement our internal manufacturing capability with high-quality, cost-effective, and sufficient capacity for ongoing stable supply.

Moreover, to swiftly respond to changes in the internal and external environments, including the new medium-term management plan, greater collaboration with R&D departments and business divisions will become increasingly important. By integrating previously separate systems and **introducing a mechanism that facilitates real-time data sharing between organizations, we are establishing a structure to efficiently support our business strategies.** We have already restructured the processes, KPI management, and performance management system for the entire global supply chain, and we are starting to perceive cost-based benefits. Additionally, we will foster closer collaboration with the business development department to further incorporate evaluations from a product supply strategy perspective when introducing new business and products. In doing so, we will contribute as a product supply department to solidifying the pillars of growth for the entire Company.

The impact of recent changes in the social landscape, including the spread of COVID-19, has been substantial. However, this has also presented us with an opportunity to reaffirm our strength in global product supply, primarily through our extensive production facilities and experienced workforce in Japan. Building upon this foundation of stable and reliable supply, we will strive to further improve productivity and evolve our product supply system to be more sustainable.

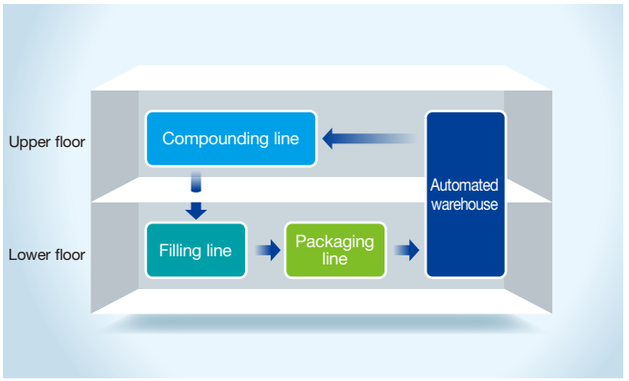
Building a Stronger Global Product Supply Base

In anticipation of the continuing expansion of ophthalmology demand worldwide and the further diversification of product markets, we completed the construction of a new building on the premises of the Shiga Product Supply Center in October 2022. The building will approximately double the annual production capacity for ophthalmic solutions at the plant to 170 million units (5mL unit equivalent) at initial operation. It is also expected to improve energy efficiency through an optimized piping system in which compounding lines are located on the upper floor and filling lines on the lower floor. Additionally, by unifying the filling and packaging processes on the same floor as a single line, we have streamlined the workflow for operators. We aim to improve productivity by more than 30% over the current manufacturing process, through automation of material handling, which leverages automated warehouse technologies and transport vehicles as core improvements. We believe proactively taking on the challenge of introducing new technologies and systems, ensuring high quality standards, reducing unit cost, and reforming business processes will increase production efficiency and profitability, and thereby contribute to achieving the goals of the new medium-term management plan.

We are promoting transformation not only in terms of facilities, but also in terms of human resources and operations. For the new building, rather than having separate teams managing each manufacturing process, we have established an operational system in which a single team manages the whole process. This measure will enable us to gain new insights by taking a bird's-eye view of the entire manufacturing process as we pursue performance improvements to achieve even higher efficiency.

Santen will achieve outstanding competitiveness (in terms of quality, cost, capacity and delivery) in the product supply process by incorporating systems that deploy operational excellence at every manufacturing step, as well as by strengthening production capacity for the growth of the Company into the future.

Shiga Product Supply Center (new building shown in the center)



Concept diagram of the new building

Interior of the new building

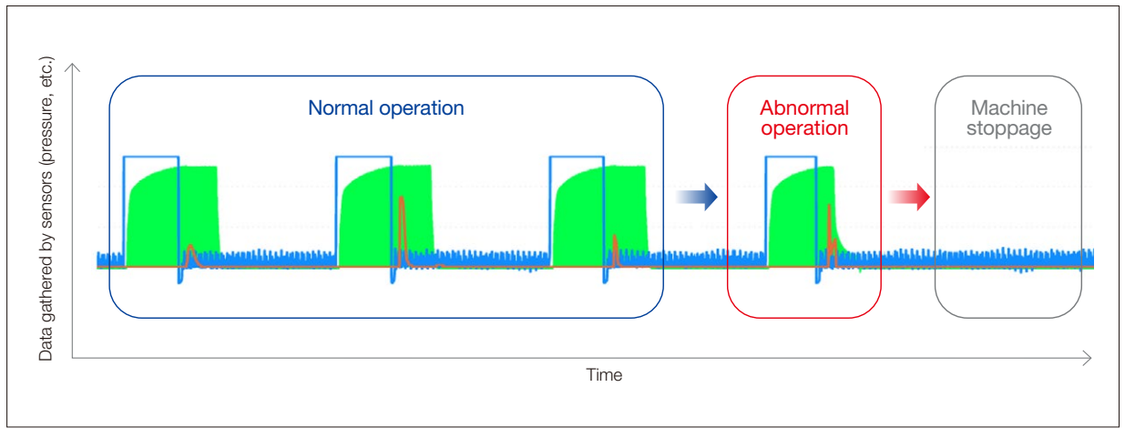
Data-based KAIZEN Project

Minimizing the frequency of and downtime from manufacturing issues at production sites is crucial to ensuring stable product supply. To that end, we are developing systems for digitalizing the experience and expertise of individuals who have long supported the maintenance of stable operations at our plants, and using digital technologies to reflect that knowledge in production processes. This is the starting point for promptly identifying the cause of errors and determining countermeasures, significantly contributing to enhanced productivity and stable supply.

For the packaging line at the Noto Plant, we developed a system that analyzes data collected by sensors, visualizes mechanisms behind the occurrence of production errors, and enables the easy detection of situations in which an error is about to occur. Furthermore, by improving the equipment for automatically adjusting parameters such as packaging speed based on feedback from the system, we have been able to preempt many incidents. As a result, for the line utilizing the new system, we achieved an 8% improvement in production capacity compared with the previous fiscal year. The successful implementation was driven by close collaboration between manufacturing, supply chain, and IT departments, each of whom leveraged their respective expertise. Overcoming several challenges, such as how to remove noise data, we worked as a team to devise a solution under the firm belief that we know about our plant better than anyone and implemented the system in just two and a half months. We expect that by applying this system to the whole production process we will achieve further enhancements to productivity.

Moreover, we have started deploying this approach at other plants as well. In the new building at the Shiga Product Supply Center (see previous page), we have introduced digital tools such as dashboards for real-time visualization of manufacturing status, manufacturing costs, and their constituent elements, as well as schedulers to streamline production and supply planning. By actively promoting digital transformation and transforming manufacturing sites into smart factories, we will create new value through the power of digital technologies.

Employees reviewing manufacturing data on site



Visualized process of an error occurrence (example)