

# **Become A Social Innovator**

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Participants



Shigeo Taniuchi President, Chief Executive Officer



Takeshi Ito Executive Vice President, Head of Japan Business, Head of Japan Sales and Marketing Division



Kazuo Koshiji Chief Financial Officer & Chief Risk Officer



Peter Sallstig Chief Medical Officer

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# **CORE PRINCIPLE and WORLD VISION**





### Tenki ni sanyo suru

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



# **Happiness with Vision**

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

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

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Taniuchi: Hello everyone. I am Taniuchi, CEO of Santen Pharmaceutical. Thank you very much for joining us today.

Please turn to page three of the handout.

As usual, I would like to introduce our core principle and world vision. Our core principle, which is also the origin of our company name, is "Tenki ni sanyo suru". We are working every day to realize "Happiness with Vision," the ideal that Santen is striving to achieve.



Next, please see page four.

This is Santen 2030, our long-term vision through to 2030. We announced this plan in 2020.

With the vision "Become A Social Innovator," we aim to reduce the social and economic opportunity loss for people around the world caused by eye diseases and conditions.



Evolution from Vision 2020 to Santen 2030

Next, please see page five.

This slide shows the first five years working toward the realization of Santen 2030: the MTP2025 mediumterm plan.

While maximizing the value of our core ophthalmology business, which we have cultivated over the years, we intend to enter new business areas and growth fields, leading to growth beyond 2026 and the realization of Santen 2030.

We also see the five years through to 2025 as a period of transformation into a truly global ophthalmic pharmaceutical company. We are working to enhance our competitiveness as a global company and strengthen our ability to execute our strategies.

#### **Executive Management Team**

#### EMT: Bolster organization and accelerate execution as a global company



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#### Next, please see page six.

As we have already announced, we reformed our executive structure as of April 1.

This team will work together to ensure the implementation of the medium-term plan through to 2025, and the execution of strategies to achieve the long-term vision, Santen 2030. The new team consists of highly experienced individuals of various nationalities and backgrounds.

Some of us are present today. In addition to myself, also present today are Mr. Ito, Mr. Koshiji, and Dr. Sallstig.

As mentioned earlier, Mr. Ito assumed the position of Representative Director of the Board and Executive Vice President in April. We will further accelerate the execution of our strategy for global expansion by leveraging our marketing planning capabilities. These skills have driven the growth of our Japanese business to date, and are based on our thorough knowledge of our customers and deep expertise in ophthalmology.

#### First year of MTP2025: FY21 highlights

### Increased revenues, decline in Core profits Paving the way for medium-term growth

Profit ratio improvement in core businesses	<ul> <li>Accelerating global profit growth</li> <li>➢ Revenue: JPY 266.3 bil. (+7%), Core OP : JPY 46.3 bil. (-7%)</li> <li>➢ Contribution profit ratio by region Japan: Overseas(excl. US) = 66 : 34 (excluding US)</li> <li>➢ Further focus on productivity and profitability enhancement (Consolidated OP CF +19% YoY)</li> </ul>
Expansion of new areas	<ul> <li>Achieved: Pipeline enhancement, Work in progress: U.S. profitability</li> <li>US: Slower growth momentum from new product launch delays and existing products sales Completed preparations as U.S. market-access platform</li> <li>Progress in mid-to-long term growth drivers: Ptosis/Myopia/Presbyopia/Cell therapies</li> </ul>
Strengthening of foundation as a global company	<ul> <li>Steady progress</li> <li>Product development: Strengthen function in US &amp; China, pipeline prioritization</li> <li>Production: Strengthen cost competitiveness from new plants (Shiga and Suzhou)</li> <li>Management: Revamping to reinforce execution in strategy &amp; governance</li> <li>ESG: ESG metrics-linked executive compensation</li> </ul>

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Page eight outlines the highlights of FY2021.

In the first year of the MTP2025 medium-term plan, the Company posted an increase in sales and decrease in core profits.

Revenues grew 7% YoY to JPY266.3 billion, while core operating profit declined 7% to JPY46.3 billion. As the person in charge, I take this decline in core operating profit very seriously.

Although sales and profitability of the overseas base business have been improving, we believe there are issues with productivity and profitability on a global basis. We are taking steps to improve these issues.

In terms of perspectives to support medium- to long-term growth, growth drivers have been enhanced. As I will discuss later in the R&D section, we have made progress in each of the new growth areas and new areas that we are working on, such as ptosis, myopia, presbyopia, and cell therapies.

How about if we consider the regional axis? The US must become a new growth pillar. We have temporarily lost some momentum there due to delays in new product development and other factors, as well as sluggish growth of Eyevance products acquired in the US.

We remain aware that the US is the world's largest and most important market. We have been working on the development of a market access platform to ensure steady growth in the future pipeline, and this has been completed as planned.

In terms of strengthening our global functions, we are working to enhance our development functions in the US and China. In addition, we are also working to reduce costs over the medium to long term through the construction of a new plant and other measures, and to expand our supply.

We intend to accelerate the building of our foundations as a global company under the new EMT leadership team I mentioned earlier.

As part of the pipeline consolidation, we have also decided to discontinue the development of STN1010900. I will discuss this later in the R&D part of the presentation.

In FY2021, we made changes to encourage companywide cooperation on ESG management, such as incorporating ESG indicators into executive compensation.

(JPY billions)	FY2020		FY2021								
	Actual vs Revenue		Actual	vs Revenue	YoY	Forecast	vs forecast	Gross Margin			
Revenue	249.6	-	266.3	-	+6.7%	260.0	102%	<sup>%</sup> +3% YoY			
Cost of sales	98.2	39%	109.7	41%	+11.7%	101.0	109%	YoY revenues increase from sales expansion in each region			
Gross margin	151.4	61%	156.6	59%	+3.4%	159.0	98%	<ul> <li>Gross margin ratio slightly impacted from product mix and on</li> </ul>			
SG&A expenses	77.2	31%	83.9	31%	+8.7%	81.0	104%	time contractual-related costs			
R&D expenses	24.1	10%	26.4	10%	+9.4%	26.0	101%	time contractual-related costs			
Core operating profit	50.1	20%	46.3	17%	-7.5%	52.0	89%	Operating Profit (Core basis)			
Non core SG&A expense	2.4	1%	0.6	0%	-73.2%	0.4	159%	operating Frenc (cere saere)			
Amortization on intangible assets associated with products	10.7	4%	9.7	4%	-8.6%	8.9	109%	-7% YoY			
Other income	16.0	6%	1.0	0%	-93.5%	0.5	209%	Increased from carried-over domestic sales promotion			
Other expenses	40.9	16%	1.1	0%	-97.2%	1.7	67%	expenses (JPY 0.9 bil), Eyevance consolidation, strategic			
Operating profit	12.2	5%	35.9	13%	+194.5%	41.5	86%	investments (cell therapies, etc.) and FX impact			
Finance income	1.3	1%	2.5	1%	+88.9%	0.9	283%				
Finance expenses	1.5	1%	1.2	0%	-18.8%	0.2	604%	Operating Profit (IEBS)			
Share of loss of Investments accounted for using equity method	0.4	0%	1.6	1%	+348.6%	1.2	134%	Operating Profit (IFRS)			
Profit before tax	11.7	5%	35.6	13%	+204.7%	41.0	87%	<u>+194% YoY</u>			
Income tax expenses	2.6	1%	8.4	3%	+228.9%	10.5	80%	<ul> <li>Other income and expenses: Reactionary drop of</li> </ul>			
Actual tax ratio	21.9%	-	23.7%		+1.7pt	25.6%	-1.9pt	impairment loss on STN2000100 from previous year			
Net profit	9.1	4%	27.2	10%	+197.9%	30.5	89%				
ROE	3.0%		8.4%			10%		Net Profit (IFRS)			
Core net profit	37.5	15%	35.2	13%	-6.3%	39.0	90%	<ul> <li>+198% YoY</li> <li>Increase in strategic invest. (equity-method investment loss)</li> </ul>			

#### FY2021 Consolidated results

# Core operating profit: Below forecast and YoY decline

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Page 10, please. This slide shows the results for FY2021.

Revenues increased YoY to JPY266.3 billion, but core-operating profit fell short of the forecast. As I explained earlier, operating profit on a core basis was JPY46.3 billion, a decrease of 7% from the previous year. Operating profit on a full IFRS basis was JPY35.9 billion.

Despite the increase in revenue, the cost of sales ratio worsened YoY due to changes in product mix and onetime expenses. Another factor was the increase rate in SG&A expenses exceeding that of sales, as I have mentioned in past financial briefings.

This increase in operating profit on an IFRS basis is due to the absence of impairment losses on STN2000100 or *PRESERFLO MicroShunt* last year.



I will now discuss the sales revenue results by region. Page 11, please.

Sales revenue was JPY266.3 billion, of which JPY173.6 billion came from domestic operations and JPY92.6 billion from overseas operations. Overseas sales accounted for 35% of total sales.

In Japan, the market for anti-allergic agents shrank significantly in February and March, partly because the amount of airborne pollen was much lower than usual. Although sales of *Alesion* were very severely impacted, falling JPY3.4 billion YoY, sales of other mainstay products grew, resulting in an overall sales increase of 2.7% for the Japan business.

In the overseas business, although there was naturally a tailwind from foreign exchange rates, sales in all regions increased even after excluding this foreign exchange factor.

In China, we are making progress with our shift to new channels, as well as with market penetration of new products. In Asia and EMEA, we are growing faster than the market, especially in our mainstay glaucoma and dry eye products.

As for Russia, which people have been asking about, it accounts for about 1% of our consolidated sales. Therefore, as of the end of FY2021, we hope that you understand that the impact of current events will be minimal. Here, we will continue to place the safety of our employees as our first priority. We will closely monitor developments in the region while providing a system to ensure a stable supply of products.

In the Americas, we have been affected by the removal from formularies of products acquired from Eyevance. Another issue has been shortages in the supply chain, which have been occurring for a certain period of time. Unfortunately, we have fallen short of our forecast.

### FY2021 Operating profit bridge Decline in Core operating profit



Next, please see page 12. Here is an analysis of changes in operating profit.

Gross profit increased due to higher sales revenue. However, core profit decreased due to factors such as a worsened cost of sales ratio caused by product mix changes and increased SG&A expenses, including corporate functions. Delays in increasing the profitability of Eyevance have been another factor.

Please refer to the appendix of this document and the databook for the actual profit contribution by region.

#### MTP2025: FY2022 positioning

### FY2022-23: Transition to a resilient structure



Next, please see page 14. I would now like to discuss our forecast for FY2022.

We are aware that this and the following fiscal year will be a difficult time due to the NHI price revision, and LOE in Japan, with the patent expiration of some of our major products.

As I mentioned in the section on results for FY2021, we believe it is imperative to improve profitability and build a resilient structure in order to ensure medium- to long-term growth.

We strongly recognize that we are at a critical point where we must continue to produce results every month and every quarter from this fiscal year to the next. First of all, we will place the improvement of profitability as our first priority. We will work on measures to maximize productivity in our core businesses.

Also, in addition to existing products, we will promote new products and products in the pipeline, building sales from these products, and increasing the ratio of overseas sales in order to achieve our goals.

#### MTP2025: FY2022 positioning

# Towards a global competitive company by building financial resilience

Short/	<ul> <li>Accelerate and strengthen strategy execution and governance through EMT</li> <li>Core business: increase profitability of China/Asia/EMEA</li> </ul>
Mid-tem	<ul> <li>Manufacturing: cost reduction through production efficiency and management</li> </ul>
impact	SG&A: optimization and Zero-based review of all costs
Actions	R&D expenses: prioritization and optimization of R&D pipeline
	New business: accelerating all measures deemed necessary to turn U.S. profitable
Long-term impact Actions	<ul> <li>New business: accelerating all measures deemed necessary to turn U.S. profitable</li> <li>Strengthening foundations as a global company</li> <li>Pipeline: building out by prioritizing projects and optimizing portfolio</li> </ul>

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Page 15, please.

As I have just explained, our priority in these two fiscal years is to continue our transformation into a globally competitive company by shifting to this resilient structure. We are working on specific measures to achieve this goal.

First, I will discuss measures that will have short- to medium-term effects. That is, measures directly related to the current P&L.

As a prerequisite, we will first accelerate strategy execution and then strengthen business execution governance by launching the new executive structure I mentioned earlier.

This is the first point. Maximize profit contribution from core businesses. Specifically, we will further improve profitability in China, Asia, and EMEA while maintaining Japan's profit contribution as much as possible. We will continue developing our activities in China, Asia, and EMEA, increasing profits as we work to achieve MTP2025. However, there is still plenty of room for us to improve the productivity of our Japanese operations.

Within this EMT organization, we will further promote and strengthen cooperation between Mr. Ito and the head of each region. We will work to improve operational excellence in our overseas operations as we have done in Japan, to increase sales productivity and profitability of our business.

This is the second point. Reduction of manufacturing costs. First, in the short term, we will thoroughly implement cost reduction measures by reviewing manufacturing processes, manufacturing process management, and purchasing management.

In addition, there is a new building at the Shiga Plant. The new building, which has been under construction since last year, will be completed this summer. In the medium term, a new plant in Suzhou will be up and running.

In these new factories and new production lines, we will achieve sustainable reductions in manufacturing costs through the introduction of high-speed lines and automation. This will allow us to improve production efficiency. We will also be able to review the supply chain as a whole, optimizing our production sites.

Third point, SG&A expenses. We will continue to invest in future growth, focusing on what is necessary for our current activities. In this context, we will thoroughly examine and reallocate our current activities from a zero base to determine whether they are truly necessary and whether they will lead to the Company's growth. These activities are focused on improving the efficiency of the Company as a whole.

Fourth, R&D expenses. We will maintain the figure at about 10% of sales, but we will evaluate the business potential of each project, prioritize investments, and make strict "go" and "no go" decisions.

On top of that, with regard to new businesses, for example, we will work to pave the way for the US business to become profitable, and then work to increase sales revenue. In addition, we will work to tighten SG&A expenses and review duplicated functions.

We recognize that this year is a critical time for us. We hope to update you in the future on the initiatives I have just mentioned, using the quarterly financial briefings and other occasions as appropriate.

Continuing on, here are some long-term measures. This is related to strengthening our foundation as a global company, as stated in MTP2025.

First, as I mentioned earlier, we will focus on the development of products that will realize growth in 2025 onward. We will do this by promoting projects in line with these priorities and by organizing and optimizing our portfolio.

In addition, we are currently in the process of introducing next-generation ERP. The system is already in operation in some regions and for some functions. This is another measure that will lead to improved operational efficiency and optimization of SG&A expenses. We will proceed with company-wide rollout without delay.

#### FY2022 Outlook

#### -1% YoY revenue from price revisions in Japan. OP margins YoY flat. Transforming to deliver second-half of MTP2025

(JPY billions)	FY2	2021		FY2022		
	Actual	vs Revenue	Forecast	vs Revenue	YoY	Gross margin
Revenue	266.3	-	264.0		-0.8%	
Cost of sales	109.7	41%	103.0	39%	-6.1%	<u>+3% YoY</u>
Gross margin	156.6	59%	161.0	61%	+2.8%	<ul> <li>Impact by change in product mix and measures to reduce</li> </ul>
SG&A expenses	83.9	31%	88.5	34%	+5.5%	manufacturing costs
R&D expenses	26.4	10%	27.0	10%	+2.4%	
Core operating profit	46.3	17%	45.5	17%	-1.8%	
Non core SG&A expense	0.6	0%	-	· ·	-	Operating profit (core basis)
Amortization on intangible assets associated with products	9.7	4%	10.3	4%	+5.8%	<u>-2% YoY</u>
Other income	1.0	0%	0.5	0%	-52.0%	<ul> <li>Increase allocation to R&amp;D from FY2021</li> </ul>
Other expenses	1.1	0%	1.5	1%	+32.4%	<ul> <li>Reducing SG&amp;A</li> </ul>
Operating profit	35.9	13%	34.2	13%	-4.7%	
Finance income	2.5	1%	0.9	0%	-64.6%	
Finance expenses	1.2	0%	0.6	0%	-50.4%	Operating profit (IFRS)
Share of loss of Investments accounted for using equity method	1.6	1%	2.0	1%	+24.7%	-5% YoY
Profit before tax	35.6	13%	32.5	12%	-8.7%	
Income tax expenses	8.4	3%	8.1	3%	-3.6%	
Actual tax ratio	23.7%	-	25.0%		+1.3pt	Net profit (IFRS)
Net profit	27.2	10%	24.4	9%	-10.3%	
ROE	8.4%		7%			<ul> <li>-10% YoY</li> <li>Increase in strategic investments</li> </ul>
Core net profit	35.2	13%	34.1	13%	-3.1%	(equity-method investment loss)
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Page 16, please. Here is the consolidated forecast for FY2022.

In fiscal 2022, we expect net sales of JPY264 billion, down 1% from the previous year. This is due in part to the difficult external environment, such as the NHI price revision in Japan.

Operating profit is projected to be JPY45.5 billion on a core basis and JPY34.2 billion on an IFRS basis, with similar profit margins as in FY2021.

We recognize that FY2022 is a turning point. We recognize that we need to transform ourselves into a resilient organization for future growth. In FY2022, we will proceed with a focus on profitability.

#### FY2022 Outlook

Accelerating global dissemination of Japan's "Commercial excellence" Improving productivity and profitability coupled with growth overseas

	<u>Revenue outlook</u>	Action items
Japan	JPY156.0 bil. (YoY -10%)	<ul> <li>Maximize value of existing products</li> <li>Launch of new products/LCM products</li> <li>Improve diagnosis/adherence through digital tool</li> </ul>
Overseas	JPY108.0 bil. (YoY +17%) *Overseas sales ratio: 41%	<ul> <li>China/Asia/EMEA: Core countries &amp; Core products-centered growth with productivity increase through cost controls</li> <li>US: accelerate trajectory to turn profitable</li> </ul>

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Page 17, please. I would like to begin by briefly discussing our efforts by region with regard to sales revenue for FY2022.

The breakdown of the revenue forecast for FY2022 is JPY156 billion for the Japan business, down 10% from the previous year, and JPY108 billion for the overseas business, up 17% from the previous year. We forecast an overseas sales ratio of 41%.

First, Japan. Japan is Santen's original market, where we hold a 55% share. We recognize that this area continues to be a major contributor to cash generation.

We will endeavor to minimize the impact of drug price reductions, including the market expansion repricing of *Alesion*, and work to recover from the effects of LOE.

Specifically, we will be working on the growth potential of *Alesion* products in departments other than ophthalmology, such as internal medicine and otolaryngology, for example.

We will also seek to further penetrate the market with new mainstay products such as *Eybelis*.

In FY2022, we will roll out a new formulation of *Diquas*, as well as the PFUD for *Eybelis*, a single-dose disposable ophthalmic solution, in order to rebuild market share. On top of that, we are planning a soft launch of the *PRESERFLO MicroShunt*, which was approved in February.

In addition to the glaucoma treatment continuity ACT Pack, which has already been introduced, we will actively utilize digital tools, such as a dry eye treatment support system and an itch duster application in the allergy field, which we plan to launch this fiscal year. These initiatives are being launched in order to improve diagnosis rates and support patients in continuing treatment. We will continue to support patients to continue their treatment.

Next, overseas. In China, Asia, and EMEA, which are our core regions, we will invest resources in priority products and countries to further improve business growth and profitability.

In the US, we will first focus on obtaining approval for STN1011700 and achieving profitability as soon as possible. For STN1011700, the application was resubmitted to the FDA on May 6.

In addition, Verkazia, a treatment for vernal keratoconjunctivitis, was also launched recently.

As you can see, the lineup is in place, although later than planned. First, we would like to promote the launch of *Verkazia*. Then, we aim to resolve the supply problem of Eyevance products to quickly develop a recovery trend and pave the way for the business to become profitable.



Next, page 18. Here are the details by region.

The exchange rate assumptions are JPY125 for the US dollar, JPY135 for the euro, and JPY19 for the yuan.

In China, we are forecasting a 29% YoY increase, due in part to the impact of foreign exchange rates, as we continue to promote growth centered on existing initiatives such as market penetration of new products and channel shift.

However, we are naturally aware of the current restrictions in Shanghai and other major cities due to the coronavirus pandemic. We are also aware of the significant impact this has on socioeconomic activities. Therefore, we will naturally keep a close eye on the impact on our business performance. We will continue to adapt our response to these restrictions as the situation develops.



### Cash flow Stable cash-generating ability

Please see page 19.

In recent years, we have also been improving the efficiency of our management and financial activities from a global perspective.

As part of these efforts, we are working to maximize cash flow. As you can see, we have achieved sustainable and stable cash generation by shortening our cash conversion ratio, or cash conversion cycle.

The graph on the left-hand side shows EBITDA, operating cash flow, and cash conversion ratio.

While core operating profit has been fluctuating up and down, cash flow has been improving steadily YoY, as you can see. Currently, the conversion ratio is at 87%.

In addition, the graph on the right, which shows the working capital and cash conversion cycle, also contributes to improved cash generation as we continue to reduce working capital as we improve overall efficiency.

#### Cash allocation

#### Proactive allocation to strategic investments and shareholder returns



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#### This is page 20.

Based on this ability to generate stable cash flow, there is no change in our policy of aggressively implementing strategic investments and shareholder returns.

Here on the left is the policy we discussed in MTP2025. The right-hand side shows the direction for the current fiscal year.

As indicated, we had made the assumption in the MTP that a certain amount would be invested as business development investment. As we will discuss later in the pipeline, we have been able to acquire many promising assets over the past few years.

While we will maintain a certain investment for future opportunities based on cash allocation, for FY2022 we will not invest in new projects. Instead, we will focus on maximizing the assets we have acquired to date and on developing and promoting the projects we have in the pipeline.

For this reason, we are already working on capital investment. We will first focus on making sure that the new factory production line or ERP system is well advanced.

On top of that, we plan to pay a total return ratio of approximately 150% this fiscal year by conducting flexible share buybacks in addition to dividends.

#### Shareholder returns

# Annual dividend of JPY32 (JPY16 for interim/year-end) Total payout ratio of approx. 150% expected for FY2022



FY2022 return ratio forecast includes the share buy-back announced on May 10. Calculations are based on J-GAAP until FY2013 and IFRS from FY2014 onwards. Dividend payout ratio and total return ratio in FY2020 are adjusted due to the completion of the allocation of consideration for acquisition of Eyevance. Share buy-back : Representing 2.0% of the total number of shares outstanding (excluding treasury shares) in FY2016 and FY2018

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120%

Page 21 details shareholder returns.

In FY2021, the annual dividend was JPY32 per share, for a payout ratio of 47%. The dividend forecast and policy for FY2022 are as I have just discussed.

We take the current level of our stock price very seriously and consider it to be an evaluation of our management by our investors.

On the other hand, we believe that the current share price is undervalued, and as we disclosed yesterday, we have resolved to repurchase JPY15 billion of our own shares.



# FY2021 R&D update

Now, let me conclude with a few words on R&D. Please turn to page 23.

This is a list of products under development that we aim to bring to market by 2025. We introduced these at the product development meeting in October last year.

As I mentioned earlier in the cash allocation section, we are working on how to accelerate development and maximize value by advancing existing assets that are here now.

In FY2021, 12 out of 24 projects advanced the development phase or acquired pivotal study data.

In addition, although not shown here, we are also making steady progress in our pipeline, mainly for compounds treating new disease areas. We are aiming for launch of these compounds in 2026 and beyond.

#### Q4 FY2021 R&D update

	STN1011702 EYBELIS PFUD	Approved as EYBELIS Mini ophthalmic solution 0.002% in Japan
	STN10 <b>126</b> 00 Sepetaprost	Started preparations for P3 trial in Japan
Glaucoma	STN2000100 PRESERFLO MicroShunt	Approved in Japan
	STN10 <b>139</b> 00 Rhopressa®/Rhokiinsa®	Filed in Asia
	STN10 <b>130</b> 01 Catioprost	Met primary endpoint in P3 trial in Europe and Asia
Myopia	STN10 <b>127</b> 00 Atropine sulfate	Confirmed safety and tolerability in P1 trial in China Started preparations for P3 trial in China
Presbyopia	STN10 <b>136</b> 00 Ursodeoxycholic acid	Confirmed safety and tolerability in P1 trial in Japan Started preparations for P2a trial in US
Ptosis	STN10 <b>138</b> 00 Oxymetazoline hydrochloride	Started preparations for P3 trial in Japan Expanded licensed territories including additional EMEA countries and Canada
Allergic conjunctivitis	STN1011402 Epinastine ophthalmic cream	Achieved <b>FPI</b> <sup>*1</sup> in P3 trial in Japan
VKC*2	STN10 <b>076</b> 03 Verkazia	Launched in US. Approved in China
Uveitis	STN10 <b>109</b> 00 Sirolimus ivtravitreal injection	Discontinued development upon reassessment of business feasibility
Copyright© 202	22 Santen All rights reserved.	*1 FPI; First Patient In. *2 VKC; Vernal keratoconjunctivitis.

#### Pipeline progress in core-business & new areas

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Next, I would like to report on the progress made in this quarter. Page 24, please.

In the glaucoma field, our core business, there have been many late-stage developments, such as the approval of STN2000100, PRESERFLO MicroShunt in Japan.

We have obtained the top-line results for STN1013001, an intraocular pressure-lowering agent that was in Phase III clinical trials in Europe and Asia. We have confirmed that the primary endpoint was achieved in this trial. I would like to discuss this in more detail on a later slide.

We have also started a Phase III study in Japan for STN1011402, an ophthalmic cream, which is one of the Alesion products.

We have also recently launched STN1007603, Verkazia, for a rare disease, vernal conjunctivitis in the US. In addition, we have recently received approval in China. We look forward to this product being a driver of growth in these two important countries, the US and China.

Then there are the new areas of myopia, presbyopia, and ptosis. Here too, we are passing safety and tolerability study, and making steady progress toward global development.

On the other hand, as already reported here, an interim analysis of STN1010900, which has been under development for several years for the treatment of uveitis, was conducted by the Data Monitoring Committee, DMC, at the end of last year.

The recommendation from the DMC was to continue the study with a large increase in the number of subjects. In response to this, we have once again examined the project closely, taking into consideration the increase in the number of subjects, the additional development time required, and the costs involved. We also took into consideration the future competitive environment.

As a result, I would like to report here that we have come to the conclusion that we have decided to terminate the development of this project, mainly from the standpoint of business feasibility. We are currently working with the authorities, as appropriate, and then with each of the study sites to bring this to a conclusion.

This compound, Sirolimus, on the other hand, continues to be developed for meibomian gland dysfunction, MGD, and Fuchs' corneal endothelial dystrophy. We are developing this in collaboration with ActualEyes.

Then there is STN1011700 in the US. As you know, we received a CRL in November last year, mainly due to GMP problems at our contract manufacturing facility in the US. As I mentioned earlier, we resubmitted the application on May 6. The application is currently awaiting acceptance by the FDA.

We would be pleased to provide further notice of the target date for completion of the review under PDUFA at the time this application becomes accepted.

#### STN1013001 (Catioprost)

#### Aim to provide new treatment option for glaucoma in Europe / Asia

ltem	Notes
Product	Latanoprost 50µg/mL eye drops emulsion in single-dose container (cationic emulsion)
	<ul> <li>The vehicle of STN1013001 is <u>similar to Cationorm®</u>, which is a product approved as artificial tears in many countries</li> </ul>
Background	Ocular Surface Disease (OSD) is an emerging problem in the management of glaucoma
	Glaucoma is a leading common cause of blindness worldwide
	<ul> <li>It is reported that up to 60% of glaucoma patients have ocular surface disease (OSD)*1 which manifest as signs and symptoms of dry eye disease</li> </ul>
	<ul> <li>OSD negatively influences QoL, compromises compliance and can jeopardize the efficacy of anti-glaucoma therapy<sup>*2</sup></li> </ul>
	<ul> <li>Santen developed STN1013001 as a glaucoma treatment that <u>reduces intraocular</u> <u>pressure</u> and also improves OSD</li> </ul>
Plan	Market Authorization Application (MAA) in FY2022 in Europe
	Clin Exp Ophthalmol 2008;246:1593–160; Fechtner, et al. Cornea 2010;29:618–621; Leung et al. J Glaucoma 2008;17:350–355; Pai et al. Asian J Ophthalmol 2018;16:101-109 halmol 2009;9:572-9; Zhang et al. Eve Contact Lens 2019;45(1):11–18.

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#### Next, page 25.

This product is a single-use emulsified ophthalmic suspension containing latanoprost as the active ingredient. The solvent in these emulsified eye drops is similar to *Cationorm*, which is already available in many countries as an artificial tear solution.

This ocular surface disease is a new problem that is becoming a hot topic among patients who are undergoing long-term treatment for glaucoma and need daily eye drops.

Ocular surface disease, which has been reported in many glaucoma patients and presents with signs and symptoms of dry eye, reduces the patient's quality of life and jeopardizes the continuation of appropriate treatment.

Santen has applied the formulation technology of emulsified eye drops used in *Cationorm, Ikervis,* and *Verkazia* products to develop this product, STN1013001, with the goal of reducing intraocular pressure and improving ocular surface disease.

#### STN1013001: Top line results of P3 study in Europe and Asia

# Achieved primary endpoint on IOP (non-inferiority vs *Xalatan*<sup>®</sup>), Superiority vs *Xalatan*<sup>®</sup> on key secondary endpoint (CFS)



Some more detail is given on page 26. Here are the results of the Phase III trial.

Please refer to the primary endpoint on the left. In terms of intraocular pressure, the compound has been proven to be statistically non-inferior to the control drug *Xalatan* at all time points.

At the 9:00 point in week 12, it also showed superiority over Xalatan.

On the other hand, the key secondary endpoint of corneal fluorescein staining showed superiority over the control drug *Xalatan* at the 12-week point. This reflects one of the useful characteristics of this drug.

Corneal fluorescein staining is used to stain the cornea to determine the degree of damage, and is also used in dry eye testing to determine the degree of damage to the epithelium of the cornea.

These results are in line with Santen's expectations. We will proceed with the European application for STN1013001 this year.

This concludes my presentation. Thank you very much for your time.

# **Question & Answer**

#### Q-1-1:

First, could you tell us how you assess the progress against the mid-term plan? I think that following the announcement of the mid-term plan, we have seen issues about *Alesion* pricing, competition with generics, and also, I think that the situation in China is changing a little bit. With that in mind, please tell us how you evaluate progress against the mid-term plan at present.

#### A-1-1

#### Taniuchi :

As for the progress toward the mid-term plan, I believe that there are areas where things are going well, areas where overall changes have been made, and areas where things are not going well.

First of all, we are making progress as expected in areas such as the pipeline, strengthening our global infrastructure for medium- and long-term growth, and capital investment. We are making progress in our transformation into a global company.

On the other hand, it is true that the situation has changed compared to what we anticipated when we put together the medium-term management plan.

For example, the situation in the US. We are aware that there are some deviations from the medium-term plan because Eyevance is still behind schedule. New products are also behind schedule compared to the assumptions of the medium-term plan.

In China, the COVID situation is ongoing, and the market both there and in Asia in general has been a little soft.

In terms of the direction of the strategy of the medium-term plan, I do not think that there will be any major changes during the year. We will review our progress and consider the extent to which our assumptions still hold, as well as considering the effects delays or development in new products.

We have nothing more specific to share at this time regarding the mid-term plan. We would like to update you on our review of the figures, our approach to achievement, our priorities, and so on, if any changes occur during this fiscal year or beyond.

#### Q-1-2:

The second question is about development compounds. I would like to know more about control of myopia progression.

First, regarding STN1012700, I think there are other companies that are currently ahead in terms of development. How will your company catch up and differentiate yourselves from them? In relation to STN1013400, could you also tell us at what point in the future you will update your development strategy? Could you give us an outlook for the future? Thank you.

#### A-1-2

#### Sallstig:

Thank you for your question. Regarding STN1012700, we have very robust strategy in place, we are well progressing with regard to program in Japan, and we are about to embark also in China. So I think, on that circumstance, the program is doing quite well. The program itself, I believe, is progressing very well, as it is quite advanced in Japan and is about to enter China as well.

Regarding STN1013400, I think that this drug is differentiated from others because it is a selective M2 receptor agonist and is less likely to cause mydriasis compared to atropine products.

Overall, we can say that STN1012700 is moving forward nicely, and considering previous programs, the ATOM study and the LAMP study, we think that our program is differentiated itself, we are trying to make sure that we find the fine line where you actually don't see any type of rebound effects, so from that perspective, I think our program is very robust.

#### Q-1-3:

Regarding STN1013400, do you have any kind of timeline or anything that you can show us in the current term or in the future, for example, what you are going to do after Phase I?

#### A-1-3

#### Sallstig:

Thank you, absolutely, there is the timeline, as of right now, we want to make sure that it is to have a robust plan in place as soon as we can, we will share that with everyone. However, as of right now, we focus on we are making sure that we are successfully prepared for that.

#### Q-2:

My question is about STN1012600, Sepetaprost. It was announced that preparations for the Phase III trial have started in Japan.

I believe that you have not explained the overall picture of Phase II in detail, but what kind of positioning are you aiming to establish for the Phase III trial? What kind of design have you decided on, and can you confirm if you have begun preparations?

#### A-2

#### Sallstig:

Thank you. First of all, we have shared the previous results that was conducted as the phase 2 vs timolol in the US, which actually showed that the study met the primary endpoint with some positive outcomes for certain endpoints.

We are looking at this from multiple facets, we also have exploratory study currently on-going, which is trying to get a better picture of how we can differentiate ourselves.

This is FP3 (correctly, FP/EP3) agonist which to be expected to have a great efficacy.

For Japan, the program is most advanced. I think we have a clear picture what we are trying to achieve. Then, we are moving forward, as making this a global program, will have other regions coming on board as well. One of the attributes taking into consideration is that regions have different requirements, particularly with regard to competitors, so we are really trying to make sure that we have a study well differentiated for the region and that really I can showcase the true potential which is believed to have.

#### Q-3-1

I'm not trying to ask for too much detail here, but I think there are probably a lot of investors who are a little concerned about China. How much of a temporary impact is the lockdown having? What kind of area does it cover? I know that Shanghai is affected, but can you say any more about the area affected?

And is it still possible to for people to visit medical institutions, attend appointments, and so on? I would appreciate it if you could tell us anything more about the timing and the level of effect.



#### A-3-1

#### Koshiji:

Regarding China, as shown on page 31 of the presentation, we expect sales of JPY35 billion for the current fiscal year, which is over 25% of the previous fiscal year's sales (Santen postscript: 29% including the impact of FOREX), or roughly 18% growth in local currency terms.

The impact of the lockdown, which just started in April, has been quite significant. There is a considerable impact in terms of the monthly forecast achievement rate.

However, as in the severe lockdown in FY2020, we do see some balancing of decreased sales with a decrease in educational activities, so in this respect, SG&A expenses will also fall.

Therefore, at this point in time, as far as the April results are concerned, there are considerable uncertainties as to whether the JPY35 billion sales forecast will be achieved. However, we are confident that we will at least be able to secure the bottom line, our planned earnings.

I cannot say at this stage the degree of downside risk to sales in quantitative terms, but I would like to emphasize the importance of securing profits.

#### Taniuchi:

The quantitative aspect of the situation is still changing on a daily basis. There are many towns where there is almost no retail market right now for products such as *Cravit, Hyalein*, and *Diquas*, which are currently the biggest sellers in the retail sector.

Treatments like *Diquas* or *Tapros* are prescribed in hospitals or clinics, but there are some towns where the hospitals are closed, and there are even some where you can't walk around outside. In that sense, the situation in April varied from region to region, with some towns almost completely losing their markets, and others where the market remained to some extent.

Basically, we do not know how far this will go. As Mr. Koshiji mentioned earlier, we are aware that there is a downside, and we are keeping our goal in mind, but we are also aware of what will happen if the downside is prolonged. We are now thinking about cost management.

We will keep a close eye on the market situation and, depending on market trends, we will step on the accelerator when the time is right to do so. Until then, we will turn off the engine. We will think back to what we did in FY2020 during the lockdown then, and think seriously about personnel costs and head count. All we can do here is look at costs.

Also, I would be happy to discuss the quantitative details in more detail at the next financial results briefing.

#### Q-3-2:

Secondly, and this may be a simple question, but I believe that along with China, you are also anticipating a significant increase in revenue in the US, even putting aside the exchange rate.

In terms of individual products, of course, if you look at *Verkazia*, you can see the rate of increase in sales. Overall sales are quite strong. Is your forecast based on the assumption that the insurance and manufacturing issues at Eyevance that you mentioned will recover in general, and that Eyevance's sales will return to normal?

# 4. Consolidated Reference (1) Revenue of Major Products

(JPY millions)

			Year ended N	larch 31, 2022	Year ending M	Year ending March 31, 2023		
Brand name	Thorsportio		Year ended	Changes	Year ended	Changes		
Generic name/formulation	Therapeutic category	Region	March 31,	from	March 31,	from		
			2022 Actual	previous year	2023 Forecasts	previous year		
		Total	11,712	(7.4%)	11,852	1.2%		
Cravit	Bacterial	Japan	1,754	(11.0%)	1,489	(15.1%)		
levofloxacin/ ophthalmic solution	conjunctivitis	China	6,966	(12.1%)	7,195	3.3%		
		Asia EMEA	1,866 1,126	8.3% 9.4%	2,056 1,112	10.2% (1.2%)		
		Total	1,120	11.9%	1,491	(6.6%)		
Tarivid	Bacterial	Japan	323	(4.4%)	315	(2.2%)		
ofloxacin/ ophthalmic solution	conjunctivitis	China	910	33.2%	942	3.5%		
		Asia	364	(10.5%)	233	(35.8%)		
Tapcom		Total	6,971 2,738	15.5% 5.1%	7,577	8.7%		
tafluprost-timolol maleate/	Glaucoma	Japan Asia	2,730	49.3%	2,028	18.3%		
combination ophthalmic solution		EMEA	3,417	18.4%	3,985	16.6%		
		Total	18,423	2.8%	19,705	7.0%		
Tapros	~	Japan	8,409	(3.4%)	7,847	(6.7%)		
tafluprost/ ophthalmic solution	Glaucoma	China Asia	1,170 2,077	94.3% 8.9%	2,740 2.051	134.1% (1.2%)		
		EMEA	6,767	1.1%	7.067	4.4%		
Cosopt		Total	21,752	4.2%	21,523	(1.1%)		
dorzolamide hydrochloride-timolol	Glaucoma	Japan	5,650	(18.6%)	4,898	(13.3%)		
maleate/ combination ophthalmic	Claucona	Asia	5,157	15.6%	5,630	9.2%		
solution		EMEA	10,945	15.5%	10,995	0.5%		
Timoptol		Total Japan	2,098	(4.4%) (12.2%)	1,894 785	(9.7%) (21.4%)		
timolol maleate/ ophthalmic solution	Glaucoma	Asia	302	14.4%	332	9.8%		
(* Including Timoptol XE)		EMEA	797	0.4%	777	(2.5%)		
Trusopt		Total	4,374	0.2%	4,224	(3.4%)		
dorzolamide hydrochloride/	Glaucoma	Japan	1,108	(9.7%)	965	(13.0%)		
ophthalmic solution		Asia EMEA	382 2.883	10.9% 3.2%	413 2.847	8.0%		
Evbelis		Total	3.420	34.8%	4.030	17.9%		
omidenepag isopropyl/ ophthalmic	Glaucoma	Japan	3,304	31.3%	3,648	10.4%		
solution		Asia	116	475.4%	332	187.4%		
Alesion		Total	29,392	(10.3%)	24,074	(18.1%)		
epinastine hydrochloride/ ophthalmic	Allergy	Japan	29,286	(10.5%)	23.821	(18,7%)		
solution (* Including Alesion LX)		Asia	106	465.8%	253	138.1%		
	Vernal	Total	633	255.2%	1,588	150.7%		
Verkazia	keratoconjuncti	EMEA	585	260.6%	743	27.1%		
cyclosporin/ ophthalmic emulsion		Americas	49	201.0%	792	-		
	vitis							
Flumetholon		Total	3,354	19.3%	3,224	(3.9%)		
fluorometholone/ ophthalmic	Inflammation	Japan China	911 2.023	(13.4%) 45.4%	827 1.996	(9.3%) (1.3%)		
solution		Asia	420	13.9%	401	(4.4%)		
Piropovino Ophthalmia Curananian		Total	4,215	5.5%	4,181	(0.8%)		
Pirenoxine Ophthalmic Suspension (Former sales name : Kary Uni)	Senile	Japan	2,326	(2.7%)	2,276	(2.1%)		
pirenoxine/ ophthalmic solution	cataract	China	894	15.9%	861	(3.8%)		
Oftan Catachrom		Asia Total	995	(5.3%)	1,044	(23.9%)		
cytochrome C, adenosine,	Senile							
nicotinamide/ ophthalmic solution	cataract	EMEA	1,733	(5.3%)	1,319	(23.9%)		
Sodium Hyaluronate Ophthalmic		Total	2,129	(2.8%)	1,963	(7.8%)		
Viscoelastic Preparation	Adjuvant for							
(Former sales name : Opegan Hi)	ophthalmic operations	Japan	2,129	(2.8%)	1,963	(7.8%)		
sodium hyaluronate/ adjuvant for ophthalmic operations	operations							
EYLEA	lates devel	Total	72,484	12.5%	61,896	(14.6%)		
aflibercept/ solution for intravitreal	Intravitreal VEGF inhibitor	Japan	72,484	12.5%	61,896	(14.6%)		
injection					-			
Hyalein		Total	17,779	(3.5%)	17,235	(3.1%)		
sodium hyaluronate/ ophthalmic	Dry eye	Japan China	0,400 8,943	(7.2%)	5,115 9,344	(20.9%) 4.5%		
solution		Asia	2,370	8.0%	2,776	17.1%		
Diquas		Total	18,835	30.8%	24,422	29.7%		
diguafosol sodium/ ophthalmic	Dry eye	Japan	13.342	8.6%	15,157	13.6%		
solution		China	4,074 1,419	468.5%	6,964 2,301	70.9%		
		Asia	1,419	1.1%	2,301	62.1%		

		Total	3,230	5.5%	3,785	17.2%
Cationom	Decore	Asia	467	82.5%	406	(13.0%)
Cabonomi	Dry eye	EMEA	2,078	5.6%	2,458	18.3%
		Americas	685	(18.3%)	920	34.4%
	Intraocular lens	Total	1,422	18.9%	1,742	22.5%
LENTIS Comfort	for cataract treatment	Japan	1,422	18.9%	1,742	22.5%
PRESERFLO MicroShunt	Glaucoma	Total	1,612	80.9%	2,398	48.7%
PRESERVEO Microsituit	implant device	EMEA	1,612	80.9%	2,364	46.6%
		Total	9,780	3.9%	10,650	8.9%
OTC pharmaceuticals		Japan	9,185	1.4%	9,400	2.3%
		China	7	-	650	-
		Asia	588	67.1%	600	2.1%

\* Forecasts in this reports are based on the currently available information. Actual results may differ materially depending on a number of factors including changes to the business environment and others. Our full-year forecasts are based on our foreign exchange assumptions. Revenue by region shows that of major countries or regions

#### A-3-2:

#### Koshiji:

As you can see on page 23 of the financial report, the disclosed figures for the US business are approximately JPY800 million for *Verkazia* on a yen basis.

For *Cationorm*, the figure is JPY900 million. Together, these total JPY1.7 billion. The remainder consists mostly of Eyevance.

In this respect, Eyevance had supply problems last year, as well as several other unforeseen circumstances. Since we are making progress in resolving the supply problems and other uncertainties, we have conservatively set the figures I just mentioned, and I believe they will be realized.

Also, there are uncertainties here, but we are aware at this point that we will at least secure the bottom line by controlling expenses. Thank you.

#### Q-4-1:

My first question is about the sales plan for *Eylea* for this fiscal year. I would appreciate a little explanation on the impact of the Lucentis biosimilar and the impact of the faricimab competitor.

#### A-4-1

Ito:

First, with regard to the impact of the Lucentis biosimilar, we have not seen a significantly effect as yet. We will work to ensure that this continues to be the case.

On the other hand, regarding faricimab, of course there will be a certain amount of impact as new products are introduced into a market.

Quantitatively speaking, however, I think that the first use will probably be for patients who are not getting satisfactory results with *Eylea*, and who are switching to other formulations among the options available now.

On the other hand, since the product was launched in the US and is now available in Japan, Japanese doctors are, of course, highly motivated to conduct various studies and write papers. I am sure that the product will be used to a certain extent.

However, we do not foresee that the position that *Eylea* has built up over the past 10 years will change so easily. That is all from me.

#### Q-4-2:

I have a question about domestic sales of *Eybelis*.

I get the impression that it has had a slow start. I wonder if the peak forecast at the time of approval was a little high. Can you tell us how it differs from your original expectation? That is all from me.

#### A-4-2:

#### Ito:

As for *Eybelis*, a few things were a little different from our initial assumption, such as that its use would be contraindicated in patients who had had cataract surgery, or the side effect profile in some retinal diseases.

In the first year since it was released, we became aware of the issues and provided information on it, and in the following two years or so after that, it has been a bit more of a struggle than we anticipated.

However, in the three years since it was released, a variety of evidence has emerged. We now have information on things like the cosmetic side effects, the kind of patients in which it can be used safely, and data on effectiveness.

My most recent impression is that the momentum has picked up, especially in new prescriptions. Although we had some difficulties during the first three years, I feel that there is still much more to come.

#### Q-5-1:

I would like to know more about the cost control part.

I see that you are working hard to control costs at your facilities, but I wonder if more could be done. For the current fiscal year, I'm not clear on what sort of changes would result in sufficient cost control. Could you tell us a bit more about what you have changed to control costs? I'd be grateful if you could give us a little more detail.

#### A-5-1

#### Koshiji:

First of all, regarding the previous fiscal year, I am very sorry for giving the impression that we have not been able to control costs as a whole.

On page 10, for example, you can see the SG&A expenses. The full-year forecast was JPY81 billion, but the actual figure was JPY83.9 billion, compared with the previous year's JPY77.2 billion. The major factor was the

impact of foreign exchange rates, which had an approximately JPY3 billion impact compared to the previous year.

In addition, there are some effects from the gap in domestic sales promotion expenses and the new consolidation of Eyevance, but excluding these, we believe that we are controlling expenses.

The reason for the JPY4.6 billion increase from JPY83.9 billion to JPY88.5 billion shown on page 16 is due in part to the impact of the exchange rate, which I mentioned earlier. This contributes approximately 4%. That is quite a big factor as we pay some US costs. That is the reason.

As described on page 15, the first step is to improve the structure of the Company as a whole on a zero base.

Specifically, with regard to SG&A expenses, we will first strengthen our purchasing function and, as the President explained earlier, eliminate any expenses that do not contribute to sales and growth. The cost to sales ratio was 41% in the previous fiscal year, and we are aiming for a target of 39% this fiscal year. We have set specific targets for manufacturing cost reductions in all manufacturing divisions, and are working to improve efficiency to meet these targets. We would like to ensure that this will be achieved. That is all from me.

#### Ito :

I would like to make a few additional comments on this topic.

From a slightly different perspective, I have been involved to some extent in the overseas sales business since this spring. My basic understanding is that we have been expanding sales by making considerable investments in sales and marketing in each region. I personally believe that it is time to enter the next phase.

For example, in the Japan business in 2012, ophthalmology sales at that time were about JPY90 billion. During the past 10 years, we have increased sales to about JPY160 billion without increasing the number of MRs. I think that it would be possible to introduce this approach to each region.

In particular, I believe that in China and the rest of Asia, efforts such as those in Japan will have a fairly straightforward effect.

One approach is to increase sales and marketing investments, and another is focusing on increasing productivity. Sorry, I just wanted to add that.

#### Q-5-2:

I would like to ask Mr. Taniuchi to make one last comment. The slump in corporate value has continued for some time, and you have made some very fervent comments today about your resolve in this matter. Is it correct to say that you believe, as a matter of course, that you will be able to achieve the results for the current fiscal year?

And what do you see as the reason for the slump in corporate value to this point? I would like to ask you, Mr. Taniuchi, as the person who has been COO and CEO for four years now. That is all from me.

#### A-5-2

Taniuchi:

Thank you. Once again, I would like to reiterate that we, both myself personally and the management team in general, take this current difficult situation very seriously.

There are, of course, several reasons for the slump. I think there are many external and internal factors, but overall, I believe that there have been problems delivering on what we've set out to do.

This is because we have not been able to achieve what we have planned and talked about, whether it be financial results or the progress of individual projects.

I believe that this is the situation that we are in, and that we are sincerely looking back, reflecting on our actions, and making corrections.

So, we will make sure to say and do what we mean, and achieve the results. As I mentioned earlier, I understand that our greatest mission is to regain trust by implementing the PDCA cycle every month and every quarter, talking to everyone, and making improvements.

Of course, we have made progress in some areas. We have communicated that in these briefings. However, I know many feel there are still far more areas that have not been completed yet. This is a critical time for us, and we will continue focusing on these issues during this fiscal year. Thank you very much.

#### Q-6-1-1

I have one question about *Eylea*. I was wondering if Bayer might expand the AG globally.

In Japan, it seems that the strategy is to establish a separate corporate entity, obtain approval, and sell the products there. This is a basic question, but can a brand and an AG coexist?

From your company's standpoint, I think it would be difficult to reconcile this with Bayer's policy. I would like to confirm whether or not there are any negative surprise elements in the recalculation of *Alesion*'s market expansion.

#### A-6-1-1

Ito:

You are correct that this AG has been approved by a subsidiary of Bayer Yakuhin, and when it is marketed, it will be marketed by Santen.

The final decision as to when and whether to actually play that card is ultimately up to Bayer, but we would like to make appropriate decisions in a way that maximizes sales of both drugs at all times.

#### Q-6-1-2

Is it correct to say that the approval will be taken by a Bayer subsidiary and the sales will continue to be handled by your company, and that this structure will not change?

#### A-6-1-2

Ito: Yes.

[END]