Q2 FY2023 Financial Results Transcript

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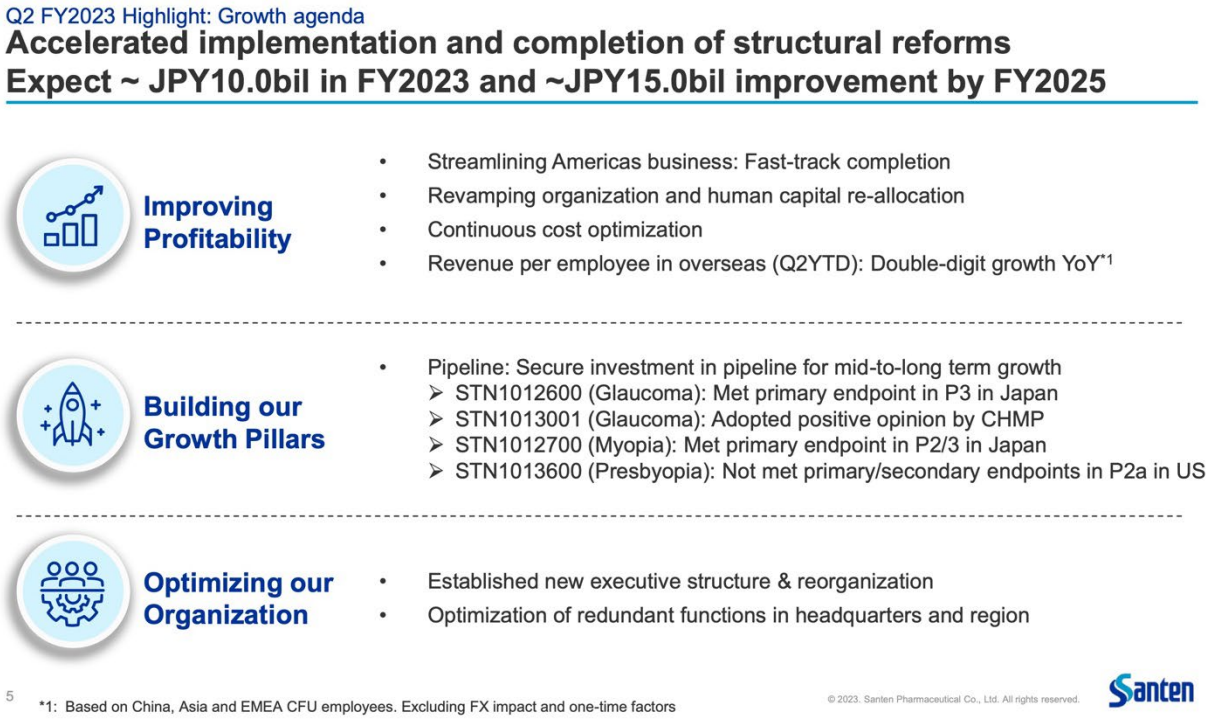
November 7, 2023

Santen Pharmaceutical Co., Ltd.

1

Executive Summary

Takeshi Ito
President & CEO



Ito: This is Ito, CEO of Santen Pharmaceutical. One year has passed since I assumed the position of CEO last year. During this period, we have been promoting a variety of initiatives centered on the three axes of improving profitability, building growth pillars, and establishing an optimal organizational structure, as well as engaging in numerous dialogues with our investors in an effort to restore market confidence.

As you are already aware, since the beginning of this fiscal year, we have also accelerated and proceeded with certain painful reforms, such as streamlining of Americas business and restructuring of organizational structure. As a result, we made steady progress in building a lean organizational structure for renewed growth. At the same time, we believe that we are now in a position to reflect the results of these efforts in our management figures. I would now like to take a brief look back over the past year along the three axes I just mentioned.

Regarding the first point of improving profitability, we are on track to complete the streamlining of Americas business ahead of schedule. In addition, we have been accelerating measures to optimize the company-wide organization and personnel structure, especially overseas, and to optimize costs, and we believe that structural reforms are largely complete. As a result, we are beginning to see the effect of improving profit by JPY10.0 billion in FY2023 and JPY15.0 billion by FY2025.

In the regional businesses, we are particularly focused on improving productivity, as the COO and each regional business are working together to improve the productivity of overseas operations, which has been an issue. Due in part to better-than-expected growth in European and other businesses during the period under review, sales per employee, an important KPI in the medium-term management plan, showed double-digit growth in Q2 as well, compared to the previous year.

As for the second pillar of growth, we will continue to place priority on investment in R&D activities, as results in R&D activities and business development are indispensable for future growth.

As for the progress of the pipeline under development, first of all, STN1012600 for glaucoma achieved its primary endpoint in Phase 3 in Japan. Preparations for the application will be made in the near future.

In addition, in Europe, we submitted an application last year for STN1013001 for glaucoma under the product name *Catiolanze*, which was recommended for approval by the Committee for Medicinal Products for Human Use (CHMP) in September. Together with the ROCK inhibitor launched at the end of last year, this is a very unique ophthalmic drug that is expected to grow significantly in the glaucoma field in the short to medium term and is based on latanoprost and utilizes technology used in dry eye treatments such as *Ikervis*.

There were also data readouts for STN1012700 for myopia and STN1013600 for presbyopia. With regard to STN1012700 for myopia, which, along with ptosis, is a pillar of growth for FY2025 and beyond, the Phase 2/3 study conducted in Japan achieved its primary endpoint. We believe that we have obtained very good results and plan to file the application in Japan within this fiscal year.

On the other hand, for STN1013600 for presbyopia, both the primary and secondary endpoints were not met in the P2a study in the US. We will continue to conduct detailed analysis and decide on a future course of action. Mr. Sallstig will explain the details of the pipeline later.

We are very excited about the upcoming data readout for STN1013800, which is a development for ptosis, or STN1014100, a next-generation dry eye treatment, and 1013400, a secondgeneration myopia drug. In addition to creating a positive trend toward medium- and long-term growth, we have already begun efforts to successfully commercialize new areas such as myopia.

Regarding the third point, the establishment of an optimal organizational structure, the transition to the new executive structure was completed by July. We believe we have established a foundation that will allow each region to grow while increasing productivity in response to uncertainties including Japan's NHI drug pricing system and overseas market conditions.

As for management, we are already moving toward growth. We will continue our efforts to improve profitability and accelerate our growth strategy.

Q2 FY2023 Highlight: Financial results and forecasts

Strong progress from overseas business
FY2023 forecasts raised

■ **Q2 FY2023:**

	Actual	YoY
Revenue	JPY 145.8 billion	+13.1%
Core operating profit	JPY 31.5 billion	+91.7%
Operating profit	JPY 25.1 billion	-
Net profit	JPY 19.3 billion	-

■ **FY2023 forecasts:**

	FY forecasts (Nov. 7)	YoY	Revised forecasts (Sep. 20)	Revised forecasts (May 11)
Revenue	JPY 302.0 billion	+8.2%	JPY 285.0 billion	JPY 273.0 billion
Core operating profit	JPY 58.0 billion	+31.1%	JPY 50.0 billion	JPY 46.0 billion
Operating profit	JPY 41.0 billion	-	JPY 35.0 billion	JPY 32.0 billion
Net profit	JPY 29.5 billion	-	JPY 25.0 billion	JPY 22.4 billion
EPS	JPY 80.64	-	JPY 68.34	JPY 61.24

6

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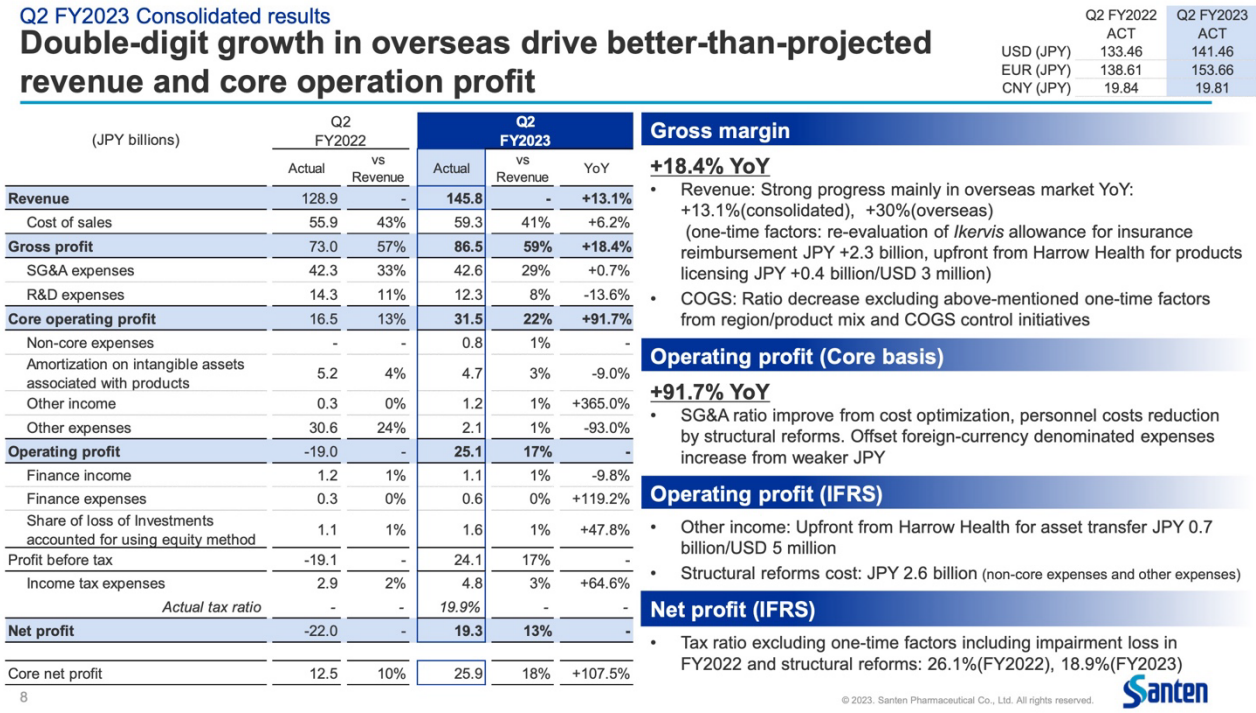
Next, on page six, we cover single-year results for FY2023. In H1, strong trends, especially in overseas operations, and cost optimization led to a higher-than-expected level of core operating profit, which, excluding one-time factors, was the highest ever recorded in H1 of a fiscal year.

Revenue was JPY145.8 billion and core operating profit was JPY31.5 billion, a significant increase over the previous year.

We revised our full-year forecasts upward on September 20, and we are revising again today in light of the current situation. We are aiming for a significant improvement in EPS through revenue of JPY302.0 billion, core operating profit of JPY58.0 billion, and corresponding upward revisions to operating profit and net profit.

Mr. Koshiji will give a detailed explanation of the actual results and the forecast for the current fiscal year. We will continue to work toward medium- to long-term growth, including preparation for commercialization of large pipeline products such as myopia and ptosis. That is all from me.



Q2 FY2023 Consolidated results

Double-digit growth in overseas drive better-than-projected revenue and core operation profit

	Q2 FY2022 ACT	Q2 FY2023 ACT
USD (JPY)	133.46	141.46
EUR (JPY)	138.61	153.66
CNY (JPY)	19.84	19.81

(JPY billions)	Q2 FY2022 Actual	Q2 FY2022 vs Revenue	Q2 FY2023 Actual	Q2 FY2023 vs Revenue	Q2 FY2023 YoY
Revenue	128.9	-	**145.8**	-	**+13.1%**
Cost of sales	55.9	43%	59.3	41%	+6.2%
Gross profit	73.0	57%	**86.5**	**59%**	**+18.4%**
SG&A expenses	42.3	33%	42.6	29%	+0.7%
R&D expenses	14.3	11%	12.3	8%	-13.6%
Core operating profit	16.5	13%	**31.5**	**22%**	**+91.7%**
Non-core expenses	-	-	0.8	1%	-
Amortization on intangible assets associated with products	5.2	4%	4.7	3%	-9.0%
Other income	0.3	0%	1.2	1%	+365.0%
Other expenses	30.6	24%	2.1	1%	-93.0%
Operating profit	-19.0	-	**25.1**	**17%**	-
Finance income	1.2	1%	1.1	1%	-9.8%
Finance expenses	0.3	0%	0.6	0%	+119.2%
Share of loss of Investments accounted for using equity method	1.1	1%	1.6	1%	+47.8%
Profit before tax	-19.1	-	24.1	17%	-
Income tax expenses	2.9	2%	4.8	3%	+64.6%
Actual tax ratio	-	-	*19.9%*	-	-
Net profit	-22.0	-	**19.3**	**13%**	-
Core net profit	12.5	10%	25.9	18%	+107.5%

Gross margin

+18.4% YoY

- Revenue: Strong progress mainly in overseas market YoY: +13.1%(consolidated), +30%(overseas) (one-time factors: re-evaluation of *Ikervis* allowance for insurance reimbursement JPY +2.3 billion, upfront from Harrow Health for products licensing JPY +0.4 billion/USD 3 million)
- COGS: Ratio decrease excluding above-mentioned one-time factors from region/product mix and COGS control initiatives

Operating profit (Core basis)

+91.7% YoY

- SG&A ratio improve from cost optimization, personnel costs reduction by structural reforms. Offset foreign-currency denominated expenses increase from weaker JPY

Operating profit (IFRS)

- Other income: Upfront from Harrow Health for asset transfer JPY 0.7 billion/USD 5 million
- Structural reforms cost: JPY 2.6 billion (non-core expenses and other expenses)

Net profit (IFRS)

- Tax ratio excluding one-time factors including impairment loss in FY2022 and structural reforms: 26.1%(FY2022), 18.9%(FY2023)

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8

Koshiji: I'm Koshiji. See page eight. Profit and loss situation in Q2.

In Q2 of FY2023, we were able to maintain the strong growth momentum in both sales and profits that we saw in Q1. Both sales and profit increased significantly from the same period of the previous year. Overseas operations and cost optimization are the drivers.

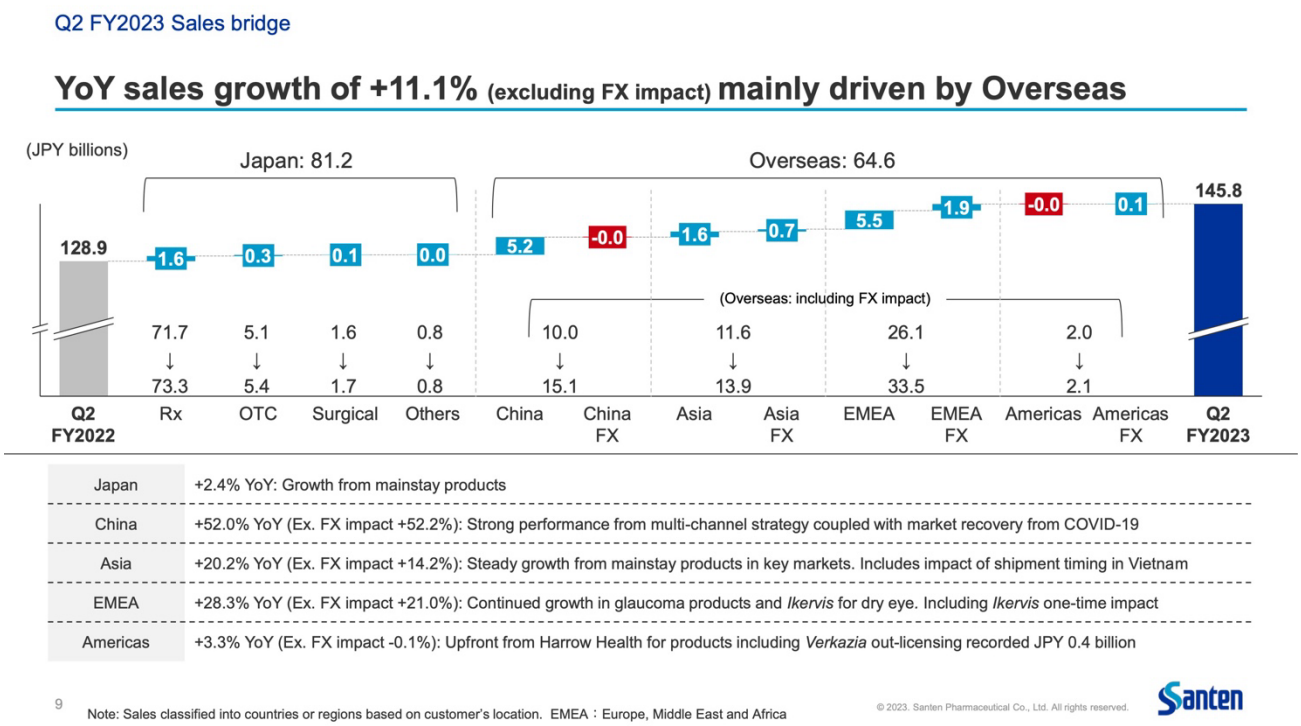
Revenues grew 13.1% to JPY145.8 billion, and for overseas operations, growth was 30%. Excluding the one-time factors including the reversal of the provision for *Ikervis* recorded in Q1 and the out-licensing of *Verkazia* and other products to Harrow Health in the Americas recorded in Q2, the overseas business grew about 25% and is a strong driver of overall growth.

Cost of sales, excluding one-time factors, is on an improving trend due to the strengthening of regional and product mix and cost control.

In addition, ongoing cost optimization efforts and lower labor costs due to structural reforms resulted in a 91.7% YoY increase in core operating profit to JPY31.5 billion.

Items under the core base include the transfer of the assets of the former Eyevance in the US to Harrow Health, the proceeds from the sale of those assets, in addition to some structural reforms-

related expenses. As a result, operating profit on an IFRS basis was JPY25.1 billion. Below that, the effective tax rate was 19.9%. Quarterly net profit was JPY19.3 billion, up from the previous year.



Japan	+2.4% YoY: Growth from mainstay products
China	+52.0% YoY (Ex. FX impact +52.2%): Strong performance from multi-channel strategy coupled with market recovery from COVID-19
Asia	+20.2% YoY (Ex. FX impact +14.2%): Steady growth from mainstay products in key markets. Includes impact of shipment timing in Vietnam
EMEA	+28.3% YoY (Ex. FX impact +21.0%): Continued growth in glaucoma products and *Ikervis* for dry eye. Including *Ikervis* one-time impact
Americas	+3.3% YoY (Ex. FX impact -0.1%): Upfront from Harrow Health for products including *Verkazia* out-licensing recorded JPY 0.4 billion

9

Note: Sales classified into countries or regions based on customer's location. EMEA：Europe, Middle East and Africa

Page nine. This shows the factors that contribute to the increase or decrease in sales revenue.

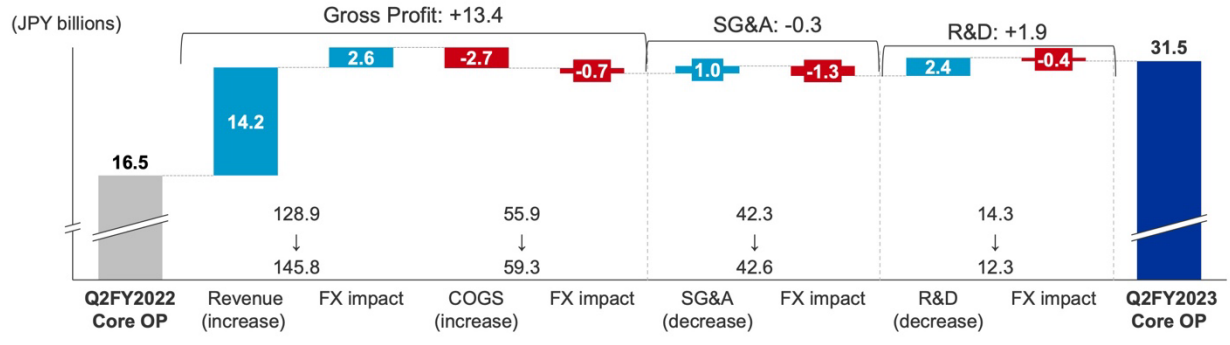
Revenue of JPY145.8 billion is broken down as follows: JPY81.2 billion in Japan and JPY64.6 billion overseas, with the overseas ratio at 44.3%. We remained focused on overseas markets, achieving double-digit growth of 11.1% YoY, excluding the impact of foreign exchange rates.

In Japan, although there were some reactive factors such as inventory adjustments of *Alesion* from strong pollen concentration season at the end of the previous period, growth of mainstay products drove overall growth, resulting in a 2.4% YoY increase.

Overseas, market recovery in China and strong sales in EMEA, even excluding transitory factors, are driving overall growth. In Asia, sales in South Korea, Thailand, and other major countries remained strong. Sales in the Americas remained almost unchanged from the previous year. As I explained earlier, the upfront payment of JPY400 million from the out-licensing of *Verkazia* and other products to Harrow Health is included here.

Q2 FY2023 Core OP bridge

Significant improvement in Core OP and ratio YoY from strong sales and cost optimization



Gross profit	Net JPY +13.4 billion YoY. Increased revenue (+13.1% YoY including FX, +11.1% YoY excluding FX) and decrease in COGS ratio (-2.7pt YoY) resulting from region/product mix and one-time factors
SG&A	Net JPY -0.3 billion YoY. SG&A ratio significantly decreased resulting from cost optimization and structural reforms including personnel expenses reduction (SG&A ratio: -3.6pt YoY). Foreign-currency based expenses increased from a weaker JPY
R&D	Net JPY +1.9 billion YoY. Mainly from development schedule change in certain projects (R&D expenses ratio: -2.6pt YoY). No change for FY plan and policy to prioritize investment to R&D

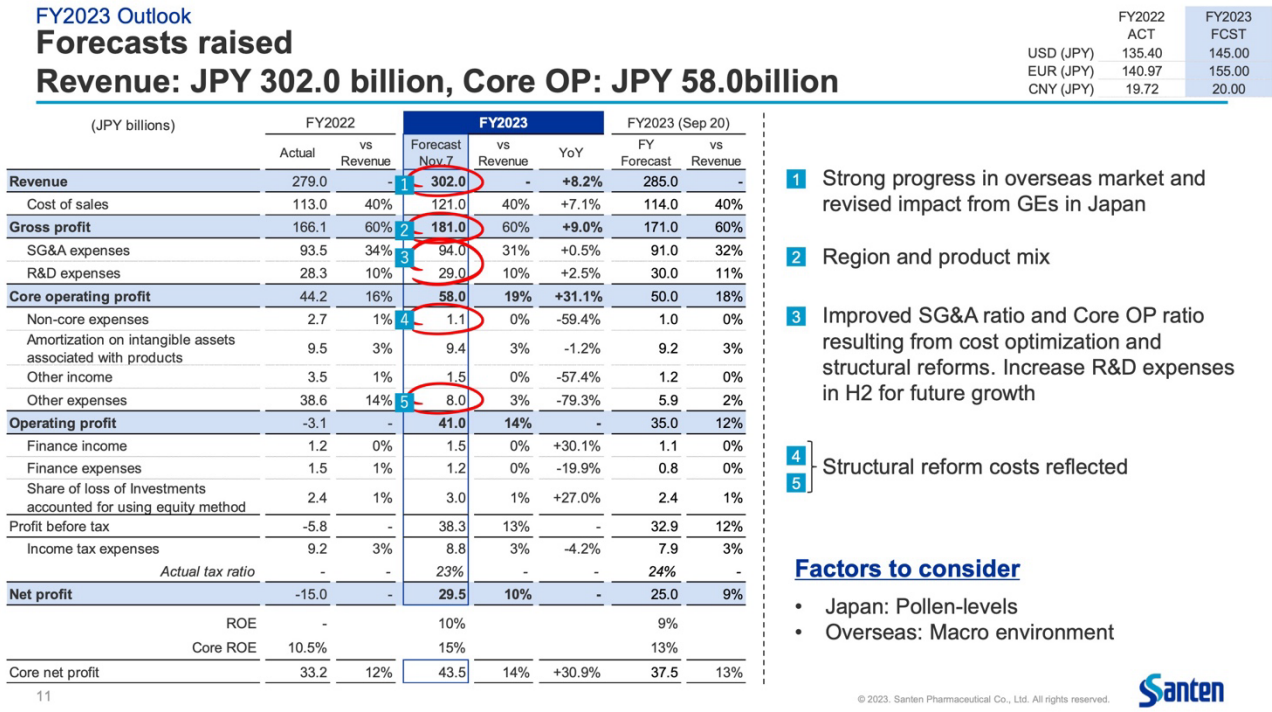
10

Page 10. This shows factors contributing to the increase or decrease in core operating profit.

First of all, the gross profit factor was the increase in sales itself due to strong overseas growth, as I mentioned earlier. Following this, due to changes in the region/product mix and one-time factors, cost reduction efforts came to fruition, resulting in a 2.7pt improvement in the cost of goods sold ratio compared to the same period last year. Gross profit was JPY13.4 billion, an increase from the previous year. These are gross profit factors.

As for SG&A factors, the SG&A-to-sales ratio declined 3.6pt YoY due to progress in structural reforms, including cost optimization and streamlining of Americas business. In absolute terms, foreign currency-denominated SG&A expenses increased due to the impact of the yen's depreciation, but since the foreign exchange impact was approximately JPY1.3 billion, the amount decreased at the local currency level, and we believe we are managing our expenses appropriately.

R&D expenses decreased by JPY1.9 billion from the previous year. As a result, core operating profit improved significantly from the same period last year to JPY31.5 billion. Core operating margin was 21.6%. These are the results.



Next, on page 11 is the forecast for the full year.

As Mr. Ito explained earlier, this is a further revision from the September 20 forecast. Revenue and core operating profit were revised to JPY302.0 billion and JPY58.0 billion, respectively.

The recent revision on September 20 was an upward revision due to the strong overseas business and the accelerated streamlining of Americas business, etc. This time, we have further reviewed the upside of the overseas situation and the impact of generics on individual products in Japan for this fiscal year, which has now been verified.

In accordance with the revision of revenue, cost of sales is disclosed in a separate document to reflect the product and region mix.

As for SG&A expenses, we are promoting up-front spending, cost optimization, and structural reforms for future growth, but we expect a significant improvement in the SG&A expense ratio.

With regard to R&D expenses, although there were some changes in the development schedule in H1 of this fiscal year and the posting of expenses was postponed, we intend to prioritize the investment of resources in H2 of the fiscal year for future growth.

As a result, R&D expenses in H2 are expected to total JPY29.0 billion, in line with the May forecast at the beginning of the fiscal year. As a result, we forecast core operating profit of JPY58.0 billion and core operating margin of 19%.

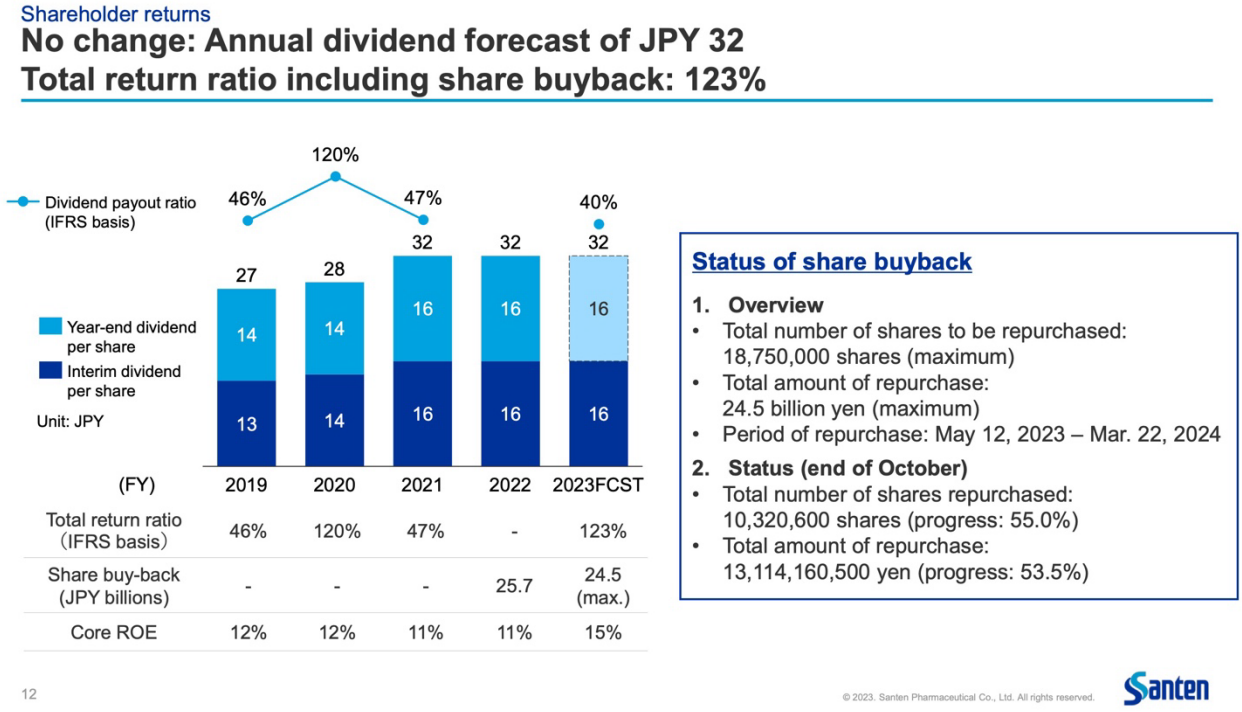
Below core levels, we expect an increase in structural reforms-related expenses. The absolute amount is included in the sum of JPY1.1 billion for non-core expenses and JPY8.0 billion for other expenses, or approximately JPY9.0 billion.

The reason for the increase from the initial projection is due to an increase in the number of retirees and the impact of the yen's depreciation on the overseas portion.

Operating profit and net profit on an IFRS basis are expected to be JPY41.0 billion and JPY29.5 billion, respectively.

EPS was expected to be JPY61 at the beginning of the period, and JPY68 at the time of the revision of the earnings forecast on September 20, but is now forecast to be JPY80. ROE is expected to be 15% on a core basis and 10% on an IFRS basis.

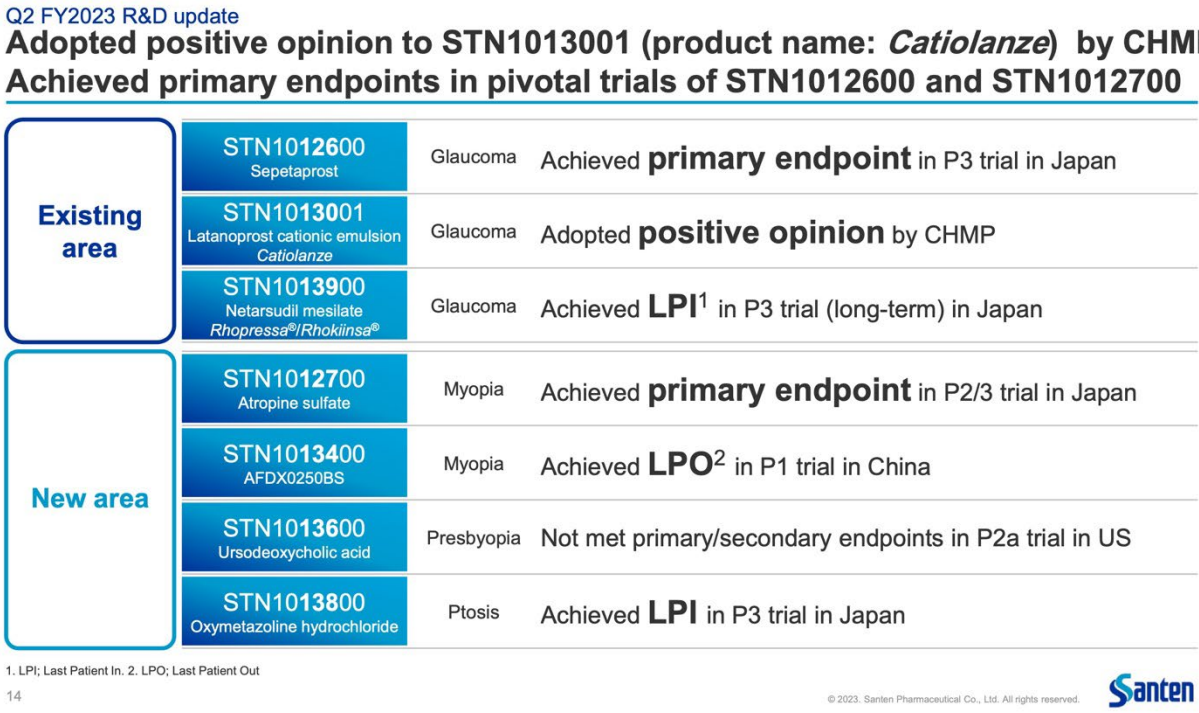
Please refer to the Appendix in this document and the Data Book for revenue/profit projections by region, as well as the profit contribution.



Page 12 shows shareholder returns. The annual dividend for this fiscal year is expected to be JPY32 per share. There is no change at this time from the beginning of the period. Assuming JPY29.5 billion mentioned earlier, or JPY80 in EPS, the dividend payout ratio would be 40%.

Currently, the Company is implementing a share buy-back program, with 5% of outstanding shares to be repurchased by the end of March next year, for a total of JPY24.5 billion. The total return ratio on net profit, including these share buy-backs and dividends, is expected to be 123%.

Since the Company acquired and cancelled 6.6% of its own shares in FY2022, it plans to acquire and cancel a little less than 12% of its own shares for two years, FY2022 and FY2023. That is all from me.



Sallstig: See page 14.

As introduced by our CEO, we have achieved many milestones including positive opinion from CHMP and success of our pivotal studies in this quarter. I will explain TLR of these later.

In the STN1013600 POC study for presbyopia, the primary and secondary endpoints were unfortunately not reached. We will continue to conduct detailed analyses to take further action.

In addition, STN1013400, which is being developed as a next-generation myopia treatment, began P1 in August in China and has already achieved LPO.

In STN1013800 for ptosis, we have achieved LPI by significantly accelerating the study enrollment and thus the readout.

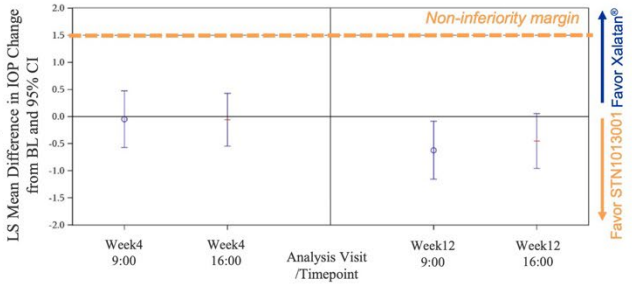
STN1013001: Top line results of P3 study in Europe and Asia

Reposted from presentation slides at FY2021 financial meeting

Achieved primary endpoint on IOP (non-inferiority vs *Xalatan*®) , Superiority vs *Xalatan*® on key secondary endpoint (CFS)

Primary endpoint

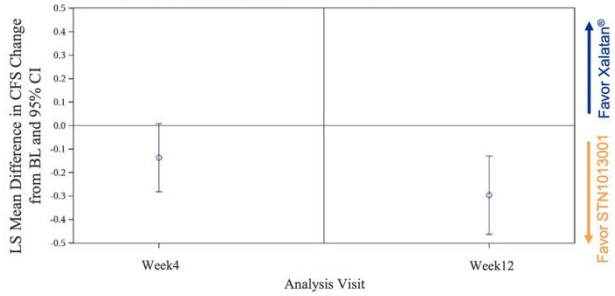
IOP LS mean treatment difference of STN1013001 vs *Xalatan*®



- **STN1013001 statistically non-inferior to *Xalatan*® at all time points**
- Superiority of STN1013001 showed at 9am (peak) at W12 vs *Xalatan*®

Key efficacy secondary endpoint

CFS (corneal fluorescein staining) LS Mean treatment difference of STN1013001 vs *Xalatan*®



- **Superiority of STN1013001 was demonstrated vs *Xalatan*® at W12 with a 0.3 CFS difference on modified Oxford Scale**

15

This is on page 15. This slide shows TLR of STN1013001 pivotal study, which we reported previously.

It has been reported that approximately 50-60% of glaucoma patients have ocular surface disease which manifest as signs and symptoms of dry eye in the treated eye.

STN1013001 showed the non-inferiority to Xalatan for the IOP-lowering effect and superiority for corneal fluorescein stain, which is an indicator for ocular surface diseases or discomfort in lay mans term, in a P3 study that we conducted in Europe and Asia.

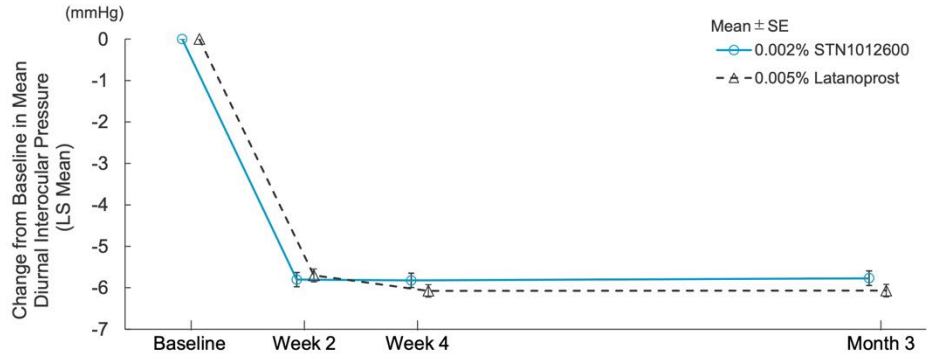
While there are other preservative free prostaglandin products, there are no other products specifically designed and properly studied in glaucoma patients having ocular surface disease, such as dry eye.

We therefore expect STN1013001 to offer a new treatment option.

Glaucoma: STN10**126**00 (FP/EP3 receptors dual agonist)

Met primary endpoint in pivotal trial (P3) in Japan. Confirmed safety and tolerance

■ **Change in mean diurnal interocular pressure**



- The non-inferiority of STN10**126**00 compared to 0.005% latanoprost in mean diurnal IOP was confirmed at Week 4. (Met primary endpoint)
- The non-inferiority of STN10**126**00 compared to 0.005% latanoprost in IOP was confirmed at all the nine time points after 3-month treatment.
- Safety and tolerance confirmed in Japanese patients.

16

Next, I will explain the P3 data of STN1012600 in Japan. This is on page 16.

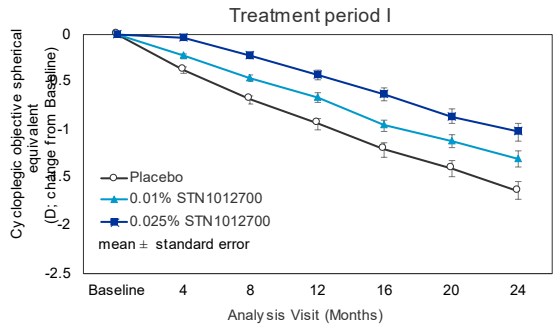
STN1012600 is a FP/EP3 receptor dual-agonist for glaucoma. Non-inferiority to latanoprost was confirmed in the primary endpoint of mean diurnal IOP at Week 4. Noninferiority was also confirmed at all 9-point time points for 3 months, which is the most stringent FDA criteria, when viewed globally.

We are preparing for submission in the next fiscal year.

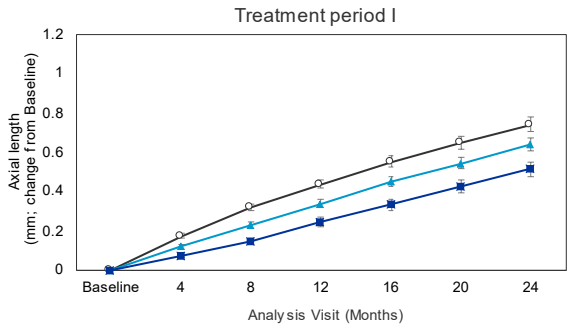
Myopia: STN10**127**00 (atropine sulfate)

Met primary endpoint in pivotal P2/3 trial in Japan. Observed similar results for axial length. No apparent rebounds (no worsening after cessation)

■ **Primary endpoint: Spherical equivalent**



■ **Secondary endpoint: Axial length**



- Confirmed statistically significant suppression effects of 0.01% and 0.025% STN10**127**00 compared to Placebo on spherical equivalent change at Month 24 from baseline, which is primary endpoint.
- Also showed suppression effects on axial length change (secondary endpoint).
- Rapid worsening after cessation of 0.01 or 0.025% STN10**127**00 administration (Treatment period Ⅱ, 24~36M) in both evaluations was not observed.
- Safety and tolerance confirmed for 0.01% and 0.025% STN10**127**00. The safety profile of STN10**127**00 was consistent with reported low dose atropines.
- The most frequently reported adverse drug reaction at 24 Months was photophobia (Placebo: 1.0%, 0.01%STN10**127**00: 4.0%, 0.025%STN10**127**00: 10.9%).

17

The next is STN1012700 Japan P2/3 study. This is on page 17. STN1012700 is an atropine preparation that aims to reduce the progression of myopia in children.

Myopia is presented as an elongation of the eyeball. The elongation or progression is defined by axial lengths, which is the length of the cornea at the surface of the eye to the retina at the back of the eye and its intensity is determined by equivalent spherical power.

The figure on the left shows the spherical equivalent change, and the lower the number, the stronger the myopia. The figure on the right shows the axial length change, so the larger the number, the longer the axial length of the eye. As you can see, both show the suppressive effect of STN1012700 on myopia progression and how it is dosage dependent. The primary endpoint, change in spherical equivalent at 24 months from baseline, was significantly more effective for both 0.01% and 0.025% than for placebo.

In addition, although not shown in these slides, there was no rapid worsening in both concentrations during the 24-to 36-month washout period after stopping study treatment.

Safety profile was consistent with what has already been reported concerning low-dose atropine. Based on this data, we expect to make a regulatory submission for approval within this fiscal year.

There is a high degree of comfort and ease for the medical practitioner and patient in using eyedrops for treatments, and it allows also for treatment to start at an early age. Pediatric myopia is reported to progress significantly in Japan at around the age of 8, and therefore starting treatment early is key. As of today, there are also no approved drugs or device to control myopia in Japan. We expect STN1012700 would be the first approved drug in Japan and would contribute to patients widely. This concludes my part. Thank you.

Question & Answer

Q1-1-1
I was a bit surprised that this was the second upward revision earlier than I expected. I thought that since you had not yet raised the Japanese portion at the time of the last revision, you would raise Japan's portion this time and Europe's a little more. I am not sure what the correct way to ask this is, but is further additional upside from this point on unlikely or not?

A1-1-1
Koshiji: First of all, regarding the drivers of the initial forecast and the upward revision on September 20, as you can see on page 20 and page 21 of the presentation material, the two major drivers were Japan and Europe. Japan was JPY6.6 billion and Europe was JPY6.4 billion, and these were the two main pillars of the project.

As for further upside for the full year, at this stage we have revised our forecast upward, taking into account various uncertainties. However, considering the fact that the previous forecast was not achieved, I think it can be said at this stage that we are disclosing the figures considering a certain degree of achievability.

Q1-1-2
I understand. You mentioned JPY8.0 billion for *Alesion* and JPY9.0 billion for *EYLEA*, so you are saying that you have put in what you could afford to put in this time?

A1-1-2
Ito : Let me also answer this. As Mr. Koshiji mentioned, we are basically committed to achieving the figures we announced to the public this fiscal year, and we are disclosing figures based on this perspective. Therefore, although we have revised the figure to JPY 58.0 billion, we would like to do our utmost to exceed them.

Q1-1-3
I understand. In the medium-term management plan, you expect JPY 56.0 billion in FY2025, so am I correct in assuming that will basically slide upward as well?

A1-1-3
Ito: In terms of the medium-term management plan, we must put aside the numerical aspect for the moment, but we must firmly improve profitability. Additionally, we will work hard to maximize each regional business from several perspectives, while also securing investments for growth in FY2025 and beyond, with the aim of achieving significant growth in FY2025 and beyond. We believe that nothing will change this basic concept, no matter what the numbers in front of us are. The idea is to proceed firmly based on that concept.

I am sure that there will be many changes in the future, so if I were to make a comment on the figures at this point, I would say that we will work to achieve and exceed the FY2025 figures that we have already set forth. I hope you will understand this.

Q1-2-1
Lastly, I am a little concerned about *Diquas* because its sales forecast in Japan has been lowered slightly. In Q2, Japanese sales of this were down in QoQ. The momentum of *Diquas LX* was good at first, but I guess the regular formulation was taken by generics more than you expected. Is my understanding correct?

And, if you don't mind me asking, do you have any figures on the ratio of *Diquas LX* to regular formulations and the percentage of regular formulations replaced by generics, such as this?

A1-2-1
Ito: I will answer this. I think the most recent situation is that the *Diquas LX* has just switched about 50% of its volume from the previous *Diquas*. On the other hand, the generic version of *Diquas* will be available soon, but it is not yet on the market. However, a generic product has been approved this time, and I believe it is about to be released shortly.

Regarding *Diquas family*, which we are now focusing very hard on sales-wise, the previous prescription was for six times daily eye drops, whereas for this *Diquas LX*, it is three times daily. There are places where patients are being instructed to use *Diquas* four times instead of the six times it was used in the past, and now we need to re-inform doctors who think four times and three times are not so different.

We are now focusing our efforts on convincing that the drug (*Diquas LX*) can have a higher effect than the clinical effect by using it three times. That is the current situation.

Q1-2-2
Thank you very much. Sorry, I know this is very detailed, but regarding the full year sales forecast for *Diquas* in Japan, what is the background behind the JPY21.8 billion being lowered to JPY20.8 billion?

A1-2-2
Koshiji: That's coming from the generic entry, as the President explained earlier. There are also other factors to consider, such as the prescription he mentioned earlier, so we have lowered our full-year forecast by JPY1.0 billion from the JPY21.8 billion to JPY20.8 billion mentioned earlier, to be slightly conservative. But this does not mean we are struggling. When we revised our earnings forecast this time, as I mentioned achievability earlier, there are areas where we are forecasting with normal caution, areas where we are forecasting with bullishness, and areas where we are forecasting with bearishness. We hope you understand that we have been somewhat conservative in our settings here.

Q2-1
First, I would like to ask you about trends in your business in China. Can you tell us about changes in the business environment?

I believe that there have been some measures to strengthen anti-corruption measures, and *Cravit* has continued to perform well in Q2. I would like to know about LASIK and cataract surgeries, including the number of surgeries.

A2-1
Ito: Regarding the China business, first of all, I think the market is recovering steadily. Although the market has not yet completely returned to its pre-pandemic state, our understanding is that the market is recovering better than we expected at the beginning of the period.

On the other hand, as you pointed out, the anti-corruption law has made it a little more difficult for MRs to meet with doctors, and as you already know, doctors are a little hesitant to use high-priced drugs such as orphan drugs. We have not yet seen a significant impact, but I believe that we are gradually being affected by the situation. However, we are not at all worried about achieving the final figures for the current fiscal year, and we believe that the China business will exceed the figures we assumed at the beginning of the term.

As for the various refractive surgeries and procedures that you pointed out, I understand that they have not yet returned to normal so vigorously, partly due to the anti-corruption laws and partly due to the economic stagnation in China.

Q2-2-1
The second point I would like to ask is about the trend of cost of goods sold ratio. Cost of goods sold ratio and gross profit margins improved from Q1 to Q2. There was also a revision of the provision estimate for *Ikervis* insurance reimbursement in Q1, among other things. Assuming that Q2 is probably only JPY400 million of one-time revenues from Harrow, could you please explain what factors are responsible for the further improvement here?

A2-2-1
Koshiji: In terms of accounting, as I mentioned earlier, there was a JPY2.3 billion gain on the reversal of the provision for *Ikervis* in Q1, which had the effect of lowering the cost of goods sold ratio by about 1%. Also, in Q2, we received the JPY400 million from the out-licensing to Harrow Health as mentioned earlier, and also, as you may remember, there was an increase in the penalty for CMOs in Europe last fiscal year, but that problem was resolved this fiscal year, so there was a reversal of the provision for the penalty from last fiscal year of about JPY600 million. In this Q2, there were also factors that reduced costs by about JPY1.0 billion.

Therefore, in the cumulative Q2, there were factors that reduced costs by a total of JPY2.0 billion from an accounting standpoint, resulting in an improvement of slightly less than 2% on a cost of goods sold ratio basis.

On the other hand, we are also working to reduce manufacturing costs, but we expect to see the results of our efforts to strengthen cost control H2 of this fiscal year and in the next fiscal year and beyond. We plan to reduce manufacturing costs by absorbing the depreciation burden of the new Shiga Plant and other factors.

Q2-2-2
Thank you very much. One point I would like to make sure is that if we compare Q1 and Q2, I think the one-time factors had a slightly larger negative impact, so am I right in understanding that the product mix is a major part of the improvement?

A2-2-2
Koshiji: You are correct. As explained in the section on sales bridges, in Q1, inventory adjustments of *Alesion*, our highly profitable product, caused a slight weakening compared to the previous year and to our initial forecast, so the cost of goods sold ratio itself had some upward pressure. However, we expect the product mix to improve toward H2 of the fiscal year, which is the premise for our full-year forecast.

Q3-1
I would like to ask you about STN1012700. The results seem very good, but I would like to know if there are any differences compared to the data of existing unapproved drugs. And I think you said that the unapproved drugs are currently used in about 30% of the facilities, and if the proper approved drugs are released, they will be used in about 50% of the facilities. Please tell us first if that view does not need to be changed.

A3-1
Sallstig: Thank you for your question. First of all, thank you for recognizing that we have very good data. I totally agree.

First of all, regarding your question about differences, this is the first therapeutic drug to be approved specifically for Japan. And the data that came out of the clinical trial was very strong and solid, so although the unapproved drug is now being used in institutions, once it is approved, I am confident that patients and physicians will be able to use it as a therapeutic agent that can be used to start treatment early.

To explain the difference from another perspective, patients with rapidly worsening myopia were enrolled, and we were able to confirm a solid improvement from the test results there, so I think we were able to demonstrate the benefit of this treatment drug. In addition, it has also been shown that the treatment not only suppresses the worsening of myopia, but also delays the elongation of the length of the axial length. It's also impressive in the sense that we have been able showcase there is no rapid worsening of the outcome when you stop the treatment.

We are hopeful that the very good results we have achieved will provide a very good option for patients and for physicians. Thank you very much.

Ito: I would like to add a little more. As Mr. Sallstig just explained, we have achieved very good results in terms of spherical equivalent, axial length, and rebound after discontinuation of use. We are very satisfied with the results. I don't think any other study has included only patients with myopia changes of 0.5D(diopters) or more in the past year. I myself believe that these results are highly commendable in that they were achieved by properly targeting patients who actually have advanced myopia and clean results were produced.

As to your other question, you mentioned that about 30% of ophthalmologists are already using unapproved drugs, such as imported drugs, at the request of their patients, and about 50% of doctors would be willing to use such drugs even if they are available under out-of-pocket treatment if approved drugs are officially available. That view has not changed at all. It is important for us to find a way to get 70% to 80% of doctors to use this type of treatment, even if it is out-of-pocket treatment. We are now solemnly working on a plan for that.

Q4-1
The first is the business potential of STN1012700 in Japan. If there is no approved drug, the drug price is based on the cost accounting method, and for atropine, the drug price is not likely to be very high. Then I think it is important for the business to be able to produce quantities, but as you explained earlier, the evidence showed efficacy in patients with rapidly worsening myopia.

If the inclusion criteria are strictly followed and reimbursement is limited, it may not be possible to use the product for a wide range of patients because only patients who have been seeing the doctors continuously can be diagnosed if they are eligible for the product. I was wondering if you could comment on your company's outlook with regard to price and volume.

A4-1
Ito: Since we are still in the process of considering Japan's strategy, goals, etc., I would like to refrain from commenting on the quantity or amount at this time. However, as a basic understanding, I do not believe that insurance reimbursement will be available. We are considering the business based on the assumption that myopia drugs will not be covered by insurance as a normal disease.

Q4-2
Secondly, regarding STN1012600, since we only have one slide of data that you presented today, I wonder if you could comment a little more on how much business potential we can expect from this trial.

I would like to ask because it is not clear from this alone what kind of patients this drug can be used for, how it fits, and what kind of positioning can be expected if the effect on IOP is only that it is non-inferior to latanoprost.

In Japan, of course, given your company's sales force and the way doctors think about treatment options, I think we can expect a certain level of sales, but I would appreciate your comments on the business potential in the western as well.

A4-2
Sallstig : Thank you. The program itself has been tested not only against latanoprost, but also against timolol, so we believe we have a pretty good profile when looking at the data as a whole. Of course, we are still considering which positioning to take, but looking at the data itself, we see that there is market potential to meet the unmet needs of patients. Our immediate priority is to achieve success in Japan, so other markets will be considered in the future.

Q5-1
Since we are short on time, let me just ask about STN1012700. I am sorry that there are several things regarding STN1012700, but am I correct in understanding that the application will be for a 0.025% dose based on this data? Also, in the case of 0.025%, the probability of photophobia or blinding of side effects seems a bit high at 10%, but is this within a manageable range? Are there any possible obstacles to continued administration?

If I may ask all my questions first, it seems to me that the difference between the placebo and 0.025% of spherical equivalent at this 24 month point is roughly 0.5D or more. I would like to know what this actually means clinically. I am not talking about a simple 0, 0.9, 0.5 or whatever for eye sight. This is spherical equivalent, so I am not quite sure what you mean by a difference of 0.5D or more.

I would like to ask one more question. You said you could not comment on the marketability of the product, but from the data obtained this time, I think it was very good data that would also support continued administration. Also, considering the number of nearsighted children in Japan today, I think the market size in Japan alone is around JPY100.0 billion. Could you tell us again about its marketability in Japan? I think there are many hurdles to overcome, but I also think that there is a certain amount of potential, and although you have been highlighting China quite a bit, I feel that Japan has a large market potential as well. I apologize for the length of the question but thank you in advance.

A5-1
Sallstig: The number of patients suffering from myopia has been growing in recent years, and it is predicted that about half of the population will be nearsighted by 2050, and in Asia, including Japan, it is expected to be even higher. Of course we cannot give a sales forecast at this time, but we believe that there is a very good opportunity with high potential.

Regarding your question about photophobia, there were no dropouts due to this, and the primary endpoint was 24 months plus follow-up, which was also achieved, indicating that photophobia is not a major problem and can be managed.

Regarding 0.5D difference, it is a little difficult to answer because there is no general consensus on the rules, but we believe that this will result in a benefit to the patients. The results were very good, even at 0.025%.

We are currently in discussions regarding the concentration to be applied for and are unable to disclose it. That is all.

Ito: I would like to add some additional information. The difference from placebo over this two year evaluation period was 0.5D, but that is not the issue, for example, that is just what the two year evaluation was. Myopia progresses rapidly, so what is important is that a person who would be about minus 7D myopia with no treatment would stop at about minus 4D, for example. I think it is about how much that means. The ability to keep patients who would have reached the level of high myopia from doing so is, I believe, a great thing considering the subsequent risk of retinal disease.

Conversely, I think it will be important to convey to people who would be minus 5D myopia if left unchecked, for example, exactly what kind of value stopping at about minus 3D will have in their lives.

As for the size of the Japanese market, if we assume that elementary and junior high school students are eligible for treatment, there are about 8 million or 9 million people in the Japanese population. In fact, many of them are nearsighted. If all of these people were to be treated with the medicine, as you mentioned, the amount of money involved would be outrageous. We would like to create a market that targets people who really need this drug treatment. [END]