



Q1 FY2022 Financial Results  
Presentation: August 4, 2022

# Become A Social Innovator



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## Featuring



**Kazuo Koshiji**  
Chief Financial Officer &  
Chief Risk Officer



**Peter Sallstig**  
Chief Medical Officer

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## CORE PRINCIPLE and WORLD VISION

### CORE PRINCIPLE

天機に参与する

*Tenki ni sanyo suru*

“Exploring the secrets and mechanisms of nature in order to contribute to people’s health” \*

### WORLD VISION

## 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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**Koshiji:** Hello, Koshiji here. I will now present a summary of the financial results.

We always start with our core principle and world vision, and it is presented here on page three. Our core principle is exploring the secrets and mechanisms of nature in order to contribute to people’s health. This is also the origin of our company name. Santen Pharmaceutical is working daily to realize “Happiness with Vision”, the ideal world that we aim for.

## Santen 2030 **Toward 2030 and beyond**

### Santen’s VISION

## Become A Social Innovator

Orchestrate and mobilize key technologies and players around the world, to deliver happiness through vision.

### GOAL

**Aim to reduce the loss of social and economic opportunities for people around the world due to eye conditions.**

### STRATEGY

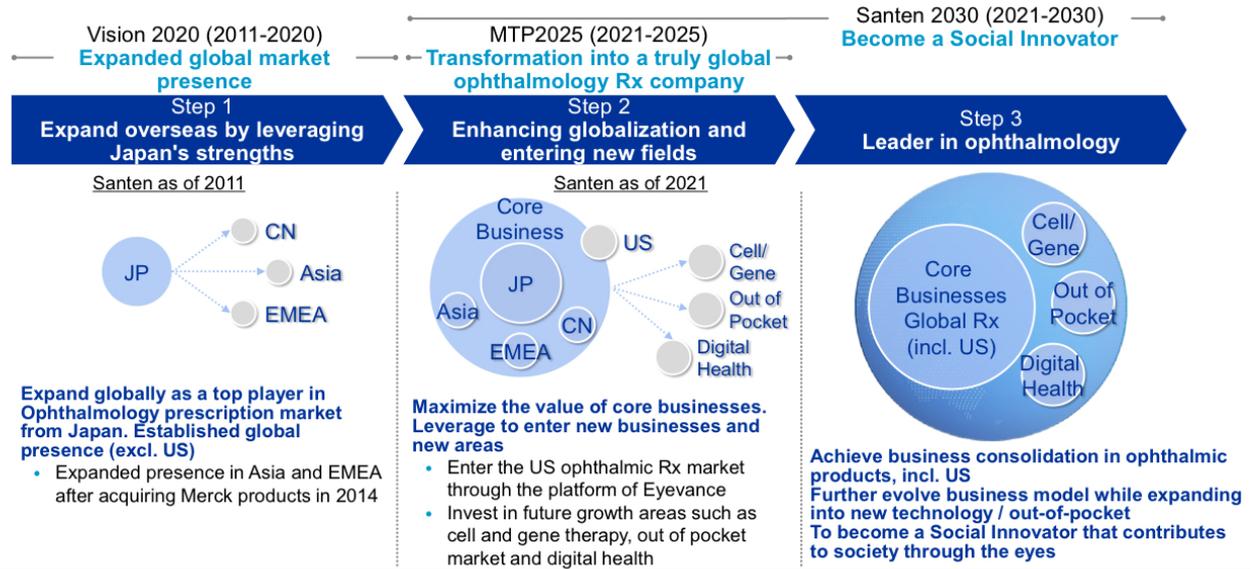
- A Ophthalmology**  
Innovation in Ophthalmology and Acceleration of Ecosystem Development
- B Wellness**  
Awareness and Proactive Care toward Better Eye Condition
- C Inclusion**  
Building Society that is Inclusive regardless of Visual Impairment

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Next is page four. This page presents Santen 2030, our long-term vision.

# Evolution from Vision 2020 to Santen 2030

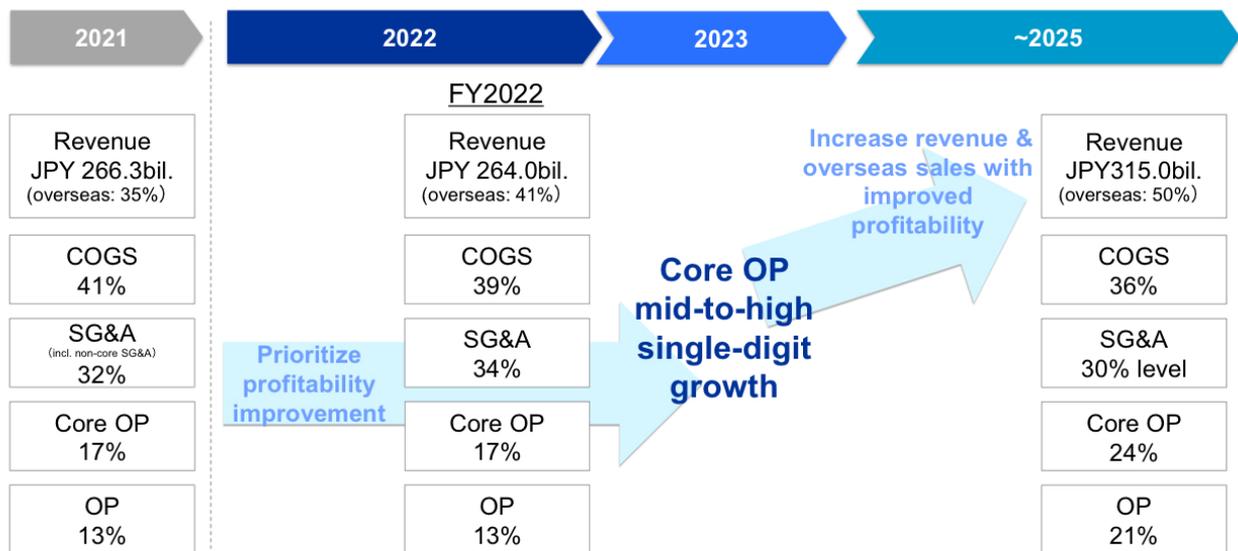


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Next, page five. This is an explanation of the Medium-Term Plan MTP2025.

## MTP2025: FY2022 positioning

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



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Next, page six. As I explained in the May financial results, we believe it is imperative to improve profitability and build a resilient structure to ensure medium-term growth.

First is ROE, which must be restored to 10% or more. To this end, we aim to return the core operating margin, which has fallen to 17%, back to the 20% range. R&D expenses for future growth will be secured, and taking into consideration the possibility of reducing the cost of sales ratio, SG&A expenses as a percentage of sales should be reduced to the 30% level. We are working to shift to this kind of P&L structure.

Although the forecast for the current fiscal year shows a decrease in core operating profit, we believe that for FY2023, we recognize the importance of returning to the levels of FY2019 and FY2020. We recognize that such a level, roughly JPY50 billion in core operating profit, is the minimum target, considering the stock price situation and other factors. We are working to improve profitability as an utmost priority issue.

## Q1 FY2022 Consolidated results

### Revenue: Overall performance offsets significant shortfall in China OP: Profits declined but rigorous cost controls in place

(JPY billions)	Q1 FY2021		Q1 FY2022		FY2022	
	Actual	vs Revenue	Actual	vs Revenue	YoY	Forecast
<b>Revenue</b>	65.0	-	<b>65.5</b>	-	<b>+0.8%</b>	264.0
Cost of sales	26.9	41%	28.4	43%	+5.5%	103.0
<b>Gross margin</b>	38.1	59%	<b>37.1</b>	57%	<b>-2.5%</b>	161.0
SG&A expenses	20.2	31%	19.4	30%	-4.0%	88.5
R&D expenses	6.1	9%	7.1	11%	+16.0%	27.0
<b>Core operating profit</b>	11.7	18%	<b>10.6</b>	16%	<b>-9.5%</b>	45.5
Non core SG&A expense	0.2	0%	-	-	-100.0%	-
Amortization on intangible assets associated with products	2.4	4%	2.6	4%	+5.5%	10.3
Other income	0.1	0%	0.3	1%	+176.3%	0.5
Other expenses	0.0	0%	0.0	0%	+17.5%	1.5
<b>Operating profit</b>	9.2	14%	<b>8.3</b>	13%	<b>-9.0%</b>	34.2
Finance income	0.6	1%	1.4	2%	+134.7%	0.9
Finance expenses	0.3	0%	0.1	0%	-55.8%	0.6
Share of loss of Investments accounted for using equity method	0.3	0%	0.5	1%	+75.4%	2.0
Profit before tax	9.2	14%	9.1	14%	-1.1%	32.5
Income tax expenses	1.8	3%	2.4	4%	+29.0%	8.1
<i>Actual tax ratio</i>	20.1%	-	26.2%	-	+6.1pt	25.0%
<b>Net profit</b>	7.3	11%	<b>6.7</b>	10%	<b>-8.6%</b>	24.4
Core net profit	9.0	14%	7.7	12%	-14.2%	34.1

#### Gross margin

##### -2% YoY

- Revenue increase offset by YoY increase in COGS ratio from changes in regional / product mix.

#### Operating profit (Core basis)

##### -10% YoY

- Increase in R&D expenses as a result of pipeline progress, but rigorous cost controls in place.

#### Operating profit (IFRS)

##### -9% YoY

#### Net profit (IFRS)

##### -9% YoY

- Positive FX impact on finance income
- Increase in strategic invest. (equity-method investment loss)

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The provisional figures used previously have been retroactively restated for Q1 FY2021.

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Page eight shows the results for Q1.

Revenues increased and earnings declined, but progress toward the full-year forecast is essentially as planned, with revenue of JPY65.5 billion and core operating income of JPY10.6 billion. In particular, in terms of cost containment, we are able to absorb the cost-increasing factors caused by the yen's depreciation, and we evaluate ourselves as being able to manage the entire P&L appropriately.

As for revenue and earnings, as I will explain in more detail later, although there was a significant decline in the China segment due to COVID-19-related market contraction, the overall decline was compensated for in other regions, and there was little change YoY.

On the other hand, the cost of sales ratio increased from the previous year due to the sales composition by region and product mix, resulting in a decrease in gross profit of 2%, or JPY37.1 billion, from the previous year.

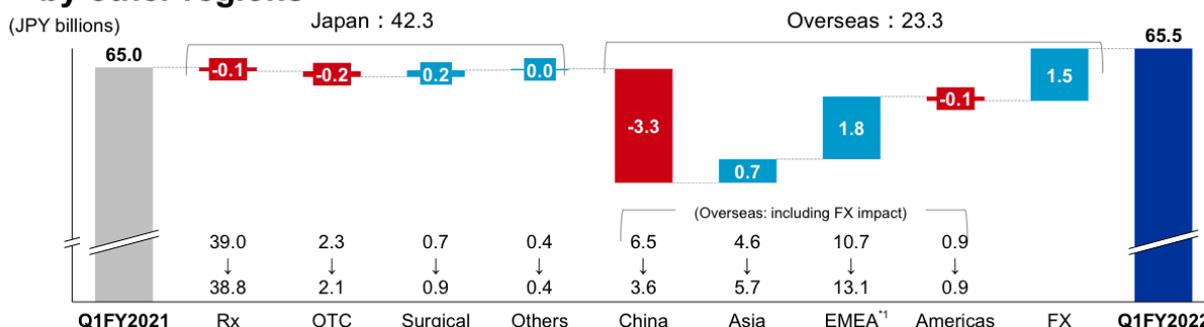
In terms of expenses, as I mentioned earlier, the depreciation of the yen has had a negative impact. Although R&D expenses have increased due to progress in development that will lead to future growth, we have implemented cost controls to improve profitability, including personnel management related to recruitment and strengthening of centralized purchasing. As you can see, the results are negative YoY in absolute terms, but improved as a percentage of sales.

However, core operating profit basis was JPY10.6 billion, down 9.5% YoY. On an IFRS basis, it was down 9%, at JPY8.3 billion. Quarterly profit was JPY6.7 billion. Regarding the tax rate, the rate increased YoY from 20.1% to 26%. This was mainly due to one-time factors such as adjustments to deferred tax assets in the previous year. Excluding these effects, we recognize that the tax rate on a net basis was 26.7% in the previous year, and roughly 24.9% or approximately 25% in the current year.

Q1 FY2022 Sales bridge

Impact from China market contraction absorbed by other regions

	FY2021 Q1 ACT	FY2022 Q1 ACT	FY2022 FCST
USD (JPY)	109.81	129.16	125.00
EUR (JPY)	132.05	137.80	135.00
CNY (JPY)	17.03	19.58	19.00



Japan	-0.1% YoY: Exceeded expectations. NHI price impact offset by market penetration in core products.
China	-43.8% YoY (Ex. FX impact -51.1%): Sales materially impacted by macro environment.
Asia	+23.5% YoY (Ex. FX impact +14.9%): Exceeded expectations. Growth led by glaucoma and dry eye in key markets.
EMEA	+22.0% YoY (Ex. FX impact +16.9%): Steady, above-market growth trajectory confirmed, primarily driven by glaucoma products.
Americas	-2.1% YoY (Ex. FX impact -13.9%): Eyevance sales declined from prolonged supply issues

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Sales classified into countries or regions based on customer's location \*1: EMEA : Europe, Middle East and Africa

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Page nine. Here are the sales by region.

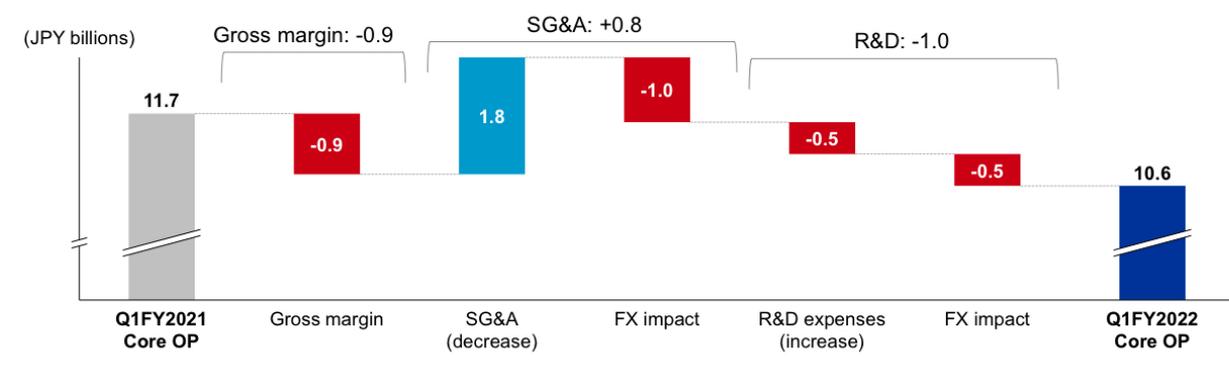
As explained earlier, sales revenue was JPY65.5 billion, of which JPY42.3 billion was domestic and JPY23.3 billion was overseas. This result has arisen after covering for reduced sales in China resulting from the market contraction.

Revenue in Japan was down 0.1% YoY, almost totally recovering from the impact of the NHI drug price revision. We recognize our extremely high market share of 52.9% as being an important factor here.

Revenue in China has fallen as a result of the macro environment. Asia and EMEA achieved double-digit growth as a result of efforts to expand sales. In the US, continuing supply problems relating to Eyevance, which we acquired, resulted in a decrease in sales.

Q1 FY2022 Core operating profit bridge

**Despite SG&A controls, Core OP down on lower gross margin and FX**



Gross margin	Net -0.9bil YoY. Revenue increase (incl. FX) partially offset by region / product mix and FX impact on COGS ratio.
SG&A	Net +0.8bil YoY. Despite cost controls, SG&A negatively impacted by FX.
R&D expenses	Net -1.0bil YoY. Increase in expenses on the back of pipeline progress coupled with FX impact.

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Page ten. This is the change in core operating profit.

The first factor is the gross profit. As I explained earlier, the cost ratio increased as a result of the NHI price revision, product mix, and also the composition by region. The figure has increased from 41% to 43%.

One thing we were not able to anticipate was the shrinkage of the Chinese market. This market is composed of a very low cost ratio and high gross margin. Contribution to consolidated results decreased, resulting in an overall increase in the cost ratio.

However, there is no change in the forecast full-year figure of 39%, or in our medium-term goal to achieve a figure of 36%. We are identifying drivers and other factors in our efforts to achieve this. Also, we are working on our own product manufacturing cost initiatives.

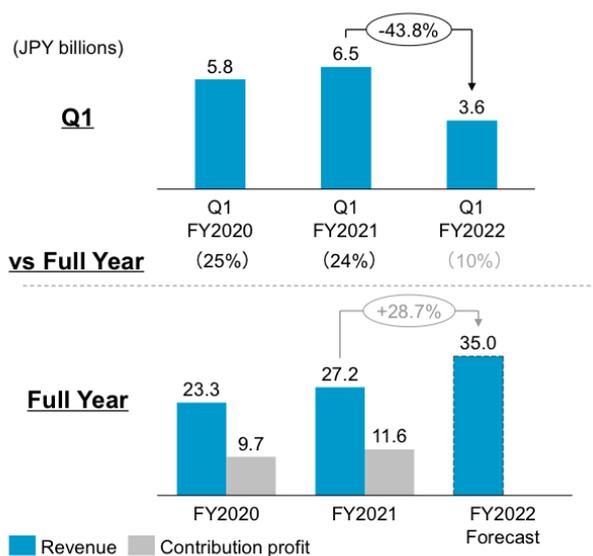
Next, we have achieved controls of SG&A expenses. Roughly 55% are denominated in foreign currencies. Therefore, although our results were affected by the exchange rate, the final result was negative JPY800 million from the previous year. The sales ratio also improved. This is the overall picture.

While R&D expenses increased, this increase was due to progress in development. 75% of R&D is denominated in foreign currencies, which was affected by the depreciation of the yen.

As you can finally see, core operating profit was JPY10.6 billion, down JPY1.1 billion from the previous year.

Q1 FY2022: Region review (China)

**Sales materially impacted by macro environment**



**Highlights**

- Significant impact from macro conditions as a result of high proportion of sales in dry eye and infection
- Continued focus on SG&A cost control but unable to fully mitigate impact of revenue decline.

**FY2022 Outlook**

- Macro environment impact including COVID-19 policy may exceed expectations in magnitude and duration for FY2022

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As for page eleven and beyond, I will break down the situation by region.

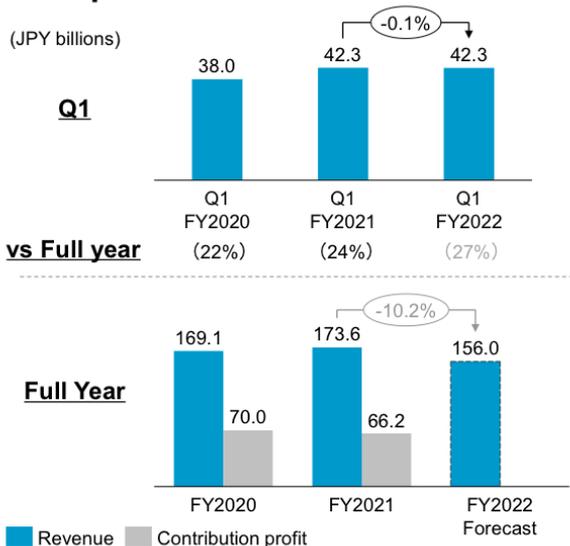
First is China. As you know, strict measures are being implemented in China to prevent the spread of COVID-19. The market has shrunk as a result, especially since the majority of our portfolio in China consists of products for dry eye and infectious diseases, which are also used in the perioperative period for many operations. The number of operations has decreased, and this is having a strong impact on the market.

In order to secure profits, expenses are being controlled in accordance with the sales situation. At present these measures have not been sufficient to absorb the decline in sales. That is the situation.

We will continue to absorb the volatility in China by standing our ground, and we have confirmed that we are on track to do so in Q1.

Q1 FY2022: Region review (Japan)

**Exceeded expectations. NHI price impact offset by market penetration of core products**



**Highlights**

- Market penetration of core products mitigates NHI price reduction (mid -4% o/w -20% for *Alesion*). *Eybelis* +0.27bil, *Diquas* +0.47bil YoY.
- Absence of *Alesion LX* GE (not launched in June); Santen's competitiveness maintained in core product segment.
- Received approval for *Diquas LX*. Preparation for launch ongoing.

**FY2022 Outlook**

- Current trend and momentum expected to continue Q2 onward.
- Taking countermeasures to maintain competitiveness.

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Page twelve shows the situation in Japan.

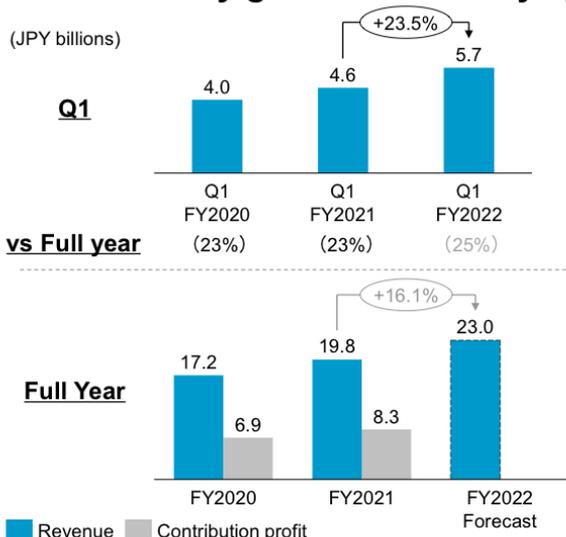
Here, sales were higher than expected. Although the NHI drug price revision reduced the cost of *Eybelis*, *Diquas*, and other products, sales by volume are growing steadily.

We received approval in June for our new formulation of *Diquas LX*. We are currently preparing for launch after the NHI drug price listing.

No launch took place in June for a generic version of *Alesion LX*. We had a very cautious outlook for the current fiscal year, assuming the penetration of generics in the *Alesion LX* and *Eylea* markets. However, we are now aware that the momentum is strong on a full-year basis, and that the materials to support this are now in place.

Q1 FY2022: Region review (Asia)

**Exceeded expectations**  
**Growth led by glaucoma and dry eye in key markets**



**Highlights**

- Korea: JPY +0.58billion (+23% YoY)  
Core products in glaucoma and dry eye led sales despite Omicron variant spread impact
- Double-digit growth in key markets (Taiwan: +0.14bil, Philippines:+0.11bil, Thailand: +0.11bil, Vietnam: +0.11bil.)

**FY2022 Outlook**

- Growth trend expected to continue subject to evolution of competitive landscape with GEs in key markets. Need to monitor changes in external environment.

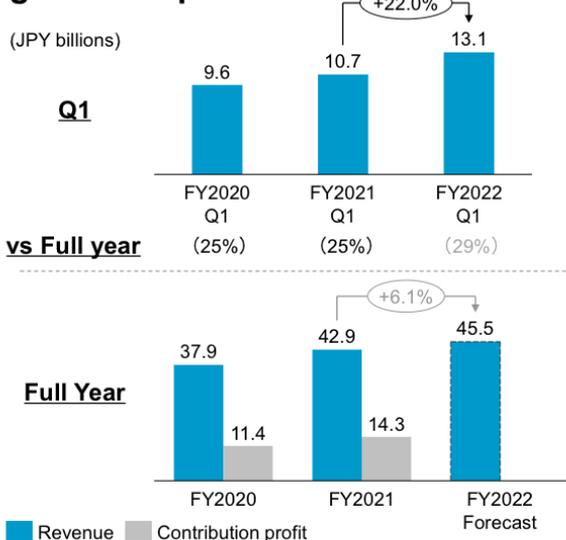
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In Asia, sales were also higher than expected, with strong growth in South Korea, which accounts for half of sales in the region. We also saw double-digit growth in other countries.

Q1 FY2022: Region review (EMEA)

**Steady, above-market growth trajectory confirmed, primarily driven by glaucoma products**



**Highlights**

- Steady growth in market penetration of glaucoma products. (*Cosopt* +0.52bil, *Tapros* +0.33bil, *Tapcom* +0.28bil and *PRESERFLO MicroShunt* +0.28bil YoY)
- New product growth: *Ducressa* +0.11bil YoY

**FY2022 Outlook**

- Stable growth trajectory with necessary measures to be taken for *Tapros* LoE

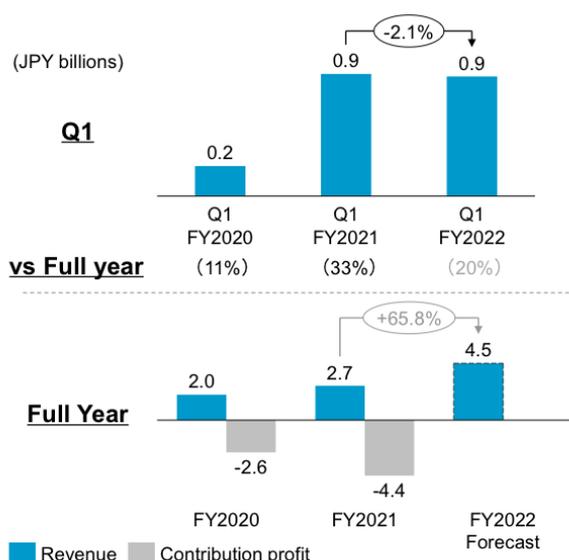
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Page fourteen shows the situation in EMEA. Glaucoma products, which make up a large portion of our portfolio, are growing steadily.

In addition to geopolitical instability in Russia and other countries, we are facing the LoE of *Tapros* and other factors in second half of the year. However, we are confident that we can absorb these factors and realize stable sales and profits.

## Eyevance sales decline from prolonged supply issues



### Highlights

- Expect recovery from back-orders impact on products Q2 onwards.
- Improved sales momentum in *Tobradex ST* and *Flarex* from commercial efforts.
- Positive impact from initial HCP feedback on *Verkazia* mitigated by launch post peak allergy season and Medicaid reimbursement procedure delay. Sales momentum expected post Q4 given seasonal trend.

### FY2022 Outlook

- Aim to minimize loss. Revamping of U.S. strategy post STN1011700 PDUFA

Next, page fifteen. This shows the situation in the Americas.

Although we are on track to resolve the supply problem of Eyevance products that has been occurring since last fiscal year, we expect a full recovery to begin Q2 onward of this fiscal year. With regard to *Verkazia*, which was launched in May, the response from the medical community has been positive, as the drug is indicated for the rare disease vernal keratoconjunctivitis.

However, the market started slowly due to delays in Medicaid reimbursement procedures and the fact that the market launch was after the allergy season, which was in May. We believe that a full-scale launch will take place in Q4 or later, taking into account the allergy season.

Apart from those individual situations, we recognize that improving profitability is an urgent issue for the Americas as a whole. For the current fiscal year, our first priority is to reduce the deficit. We will continue to implement measures to address this urgent issue. We are planning a PDUFA for STN1011700 in the second half of FY22, and plan to revise our strategy in response to that.

FY2022 Outlook: Maintain outlook

**Expect revenue -1% YoY on price revisions in Japan and flat OP margins**  
**Firm-wide mitigation of region-specific volatilities in performance**

(JPY billions)	FY2021		FY2022		
	Actual	vs Revenue	Forecast	vs Revenue	YoY
<b>Revenue</b>	266.3	-	<b>264.0</b>	-	<b>-0.8%</b>
Cost of sales	109.7	41%	103.0	39%	-6.1%
<b>Gross margin</b>	156.6	59%	<b>161.0</b>	61%	<b>+2.8%</b>
SG&A expenses	83.9	31%	88.5	34%	+5.5%
R&D expenses	26.4	10%	27.0	10%	+2.4%
<b>Core operating profit</b>	46.3	17%	<b>45.5</b>	17%	<b>-1.8%</b>
Non core SG&A expense	0.6	0%	-	-	-
Amortization on intangible assets associated with products	9.7	4%	10.3	4%	+5.8%
Other income	1.0	0%	0.5	0%	-52.0%
Other expenses	1.1	0%	1.5	1%	+32.4%
<b>Operating profit</b>	35.9	13%	<b>34.2</b>	13%	<b>-4.7%</b>
Finance income	2.5	1%	0.9	0%	-64.6%
Finance expenses	1.2	0%	0.6	0%	-50.4%
Share of loss of Investments accounted for using equity method	1.6	1%	2.0	1%	+24.7%
Profit before tax	35.6	13%	32.5	12%	-8.7%
Income tax expenses	8.4	3%	8.1	3%	-3.6%
<i>Actual tax ratio</i>	23.7%	-	25.0%	-	+1.3pt
<b>Net profit</b>	27.2	10%	<b>24.4</b>	9%	<b>-10.3%</b>
ROE	8.4%		7%		
<b>Core net profit</b>	35.2	13%	<b>34.1</b>	13%	<b>-3.1%</b>

**Gross margin**

**+3% YoY**

- Expect impact from change in product mix and measures to reduce manufacturing costs

**Operating profit (Core basis)**

**-2% YoY**

- Increasing allocation to R&D versus FY2021
- Reducing SG&A

**Operating profit (IFRS)**

**-5% YoY**

**Net profit (IFRS)**

**-10% YoY**

- Increase in strategic investments (equity-method investment loss)

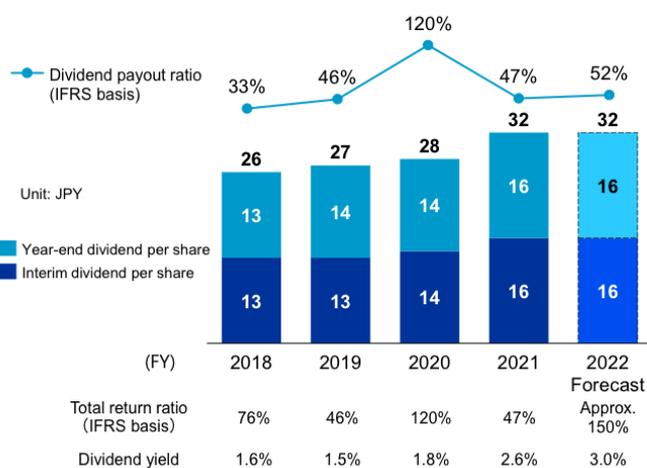
Page sixteen is the earnings forecast.

There are no changes at this time. Although the Q1 results showed a 9.5% decrease in profit on a core basis, we have not changed our full-year forecast at this time. The forecast figures are almost the same level, with a 2% decrease in core profit. In fact, given the current upside in the Japanese business, we are aware that the elements may be coming together to allow us to revise our forecasts upward.

However, given the downside, such as the uncertainty of the business environment in China, we will continue to monitor the situation closely and have reached the decision not to make any changes at present. That is the situation.

## Shareholder returns

**Annual dividend of JPY32. FY2022 total payout ratio of approx. 150%**  
**Current share buyback program until end of Q2**



### Current share buyback

#### 1. Overview

- Total number of shares to be repurchased: 12.5M shares (maximum)
- Total amount of repurchase: 15.0 billion yen (maximum)
- Period of repurchase: May.11,2022 - Sep.30,2022

#### 2. Status (end July)

- Total number of shares repurchased: 7,652,800 shares (progress: 61.22%)
- Total amount of repurchase: 7,793,548,859 yen (progress: 51.96%)

FY2022 return ratio forecast includes the share buy-back announced on May 10. Dividend payout ratio and total return ratio in FY2020 are adjusted due to the completion of the allocation of consideration for acquisition of Eyevence. Share buy-back: Representing 2.0% of the total number of shares outstanding (excluding treasury shares) in FY2018. Dividend yield calculated based on fiscal year-end share price (End-June share price for FY2022)

Page seventeen summarizes shareholder returns.

As announced in May, the dividend forecast is JPY32, and the total return ratio is expected to be 150%. Considering the status of our investments and business performance over the past three to four years, our first priority for the current fiscal year is to return profits to shareholders. As a part of this, we are conducting a share buyback until September, and the status is as shown.

CAPEX: Shiga Product Supply Center

## Completion of 3<sup>rd</sup> building in July On schedule for FY2023 start of operations



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### Higher productivity

- Automation and digitalization
- Labor-saving

### Environmental-friendly

- Energy saving equipment
- Equipment layout

### Capacity for global demand

Page eighteen.

Regarding capital investment, the third building of the Shiga Plant, which had been under construction, was completed at the end of July. Although there were concerns, such as the expansion of COVID-19 and the global shortage of semiconductors, the entire company, led by the production department, worked together to promote the project and reached a major milestone: the completion of construction.

This new Shiga building, the third building, is designed to achieve high productivity through automation and digitalization, as well as to be environmentally friendly. The plant is scheduled to start operation in FY23 as planned. It is expected to reduce depreciation burden and manufacturing costs, contributing to improved profitability.

This concludes my presentation.

R&D update

**Q1 progress in 12 pipeline products (9 in late phase)**

	STN1011700 <i>EYBELIS</i>	<b>Re-submission</b> in US. PDUFA date; November 6, 2022
Glaucoma	STN2000100 <i>PRESERFLO MicroShunt</i>	<b>Launched</b> (soft launch) in Japan
	STN1013900 <i>Rhopressa®/Rhoklinsa®</i>	<b>Met primary endpoint</b> in P3 trial under concomitant use of latanoprost in Japan
	STN1014000 <i>Rocklatan®/Roclanda®</i>	<b>Filed</b> in Asia
Dry eye	STN1008903 <i>Diquas LX</i>	Received <b>approval</b> in Japan
Allergic conjunctivitis	STN1011402 <i>Epinastine ophthalmic cream</i>	Achieved <b>LPI</b> <sup>*1</sup> in P3 trials in Japan
VKC <sup>**2</sup>	STN1007603 <i>Verkazia</i>	<b>Launched</b> in US. <b>Approved</b> in China
Myopia	STN1012700 <i>Atropine sulfate</i>	Achieved <b>FPI</b> <sup>**3</sup> in P2/3 trial in China
	STN1013400 <i>AFDX0250BS</i>	<b>Started preparations for P1 trial</b> in China
Ptosis	STN1013800 <i>Oxymetazoline hydrochloride</i>	<b>Started preparations for P3 trial</b> in China
MGD <sup>**4</sup>	STN1010905 <i>Sirolimus eye drop</i>	Achieved <b>LPO</b> <sup>**5</sup> in P2a
FECD <sup>**6</sup>	STN1010904 <sup>**7</sup> <i>Sirolimus eye drop</i>	Achieved <b>FPI</b> in P2a

\*1 LPI; Last Patient In. \*\*2 VKC; Vernal keratoconjunctivitis \*\*3 FPI; First Patient In. \*\*4 MGD; Meibomian gland dysfunction. \*\*5 LPO; Last Patient Out. \*\*6 FECD; Fuchs endothelial corneal dystrophy. \*\*7 Santen retains the option right for exclusive license of this program. Santen development code to be formally assigned to the product when Santen obtains exclusive license upon the completion of Phase II clinical trial.

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**Sallstig:** Thank you. See page twenty.

Solid progress continued in Q1. While there has been progress in nine projects in the later phases, there has also been some progress with new results, including in the areas of myopia, ptosis, MGD, and FECD.

As we announced in June, STN1011700 has been re-filed in the US and a target date of November 6 has been set for completion of the review.

In Japan, the soft launch of the *PRESERFLO MicroShunt* began late last month. The Company has also received approval for *Diquas LX*, which cuts the number of eye drops in half compared to the conventional prescription. We are aiming to have the drug listed on the NHI drug price list in November.

*Verkazia* is a treatment for the rare disease, vernal keratoconjunctivitis. This is a recurrent severe allergic disease that occurs mainly in children and young adults. *Verkazia* was launched in the US and received approval in China.

In China, we also initiated a Phase II/III study of STN1012700, an atropine formulation for myopia. Preparations have begun for a Phase III study of STN1013800 for ptosis.

For MGD, we plan to obtain PoC data during Q2.

STN1013900 (*Rhopressa*<sup>®</sup>, *Rhokiinsa*<sup>®</sup>)

## ROCK inhibitors for glaucoma – a global development

	STN1013900	STN1014000
	Netarsudil mesylate	Netarsudil mesylate / latanoprost (combination)
Contractual territory	Japan, Asia, Europe, China	
Development Status <small>*Only projects where the study protocols were approved in-house are shown.</small>	<p><b>Japan</b> P3 <i>Plan: FY2023 P3 completion</i></p> <p><b>Europe</b> Approved <i>Plan: FY2022 launch</i></p> <p><b>Asia</b> Filed <i>Plan: FY2023 approval</i></p>	<p><b>Europe</b> Approved <i>Plan: FY2022 launch</i></p> <p><b>Asia</b> Filed <i>Plan: FY2023 approval</i></p>

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Page twenty one, please.

This ROCK inhibitor for glaucoma has been in-licensed from Aerie and is under development in Japan, China, Asia, and Europe.

For both STN1013900, a single agent, and STN1014000, a combination drug, applications have already been filed in Asia. These are planned to be launched in Europe this fiscal year.

We are pleased to report that progress has been made in the Phase III study of STN1013900 in Japan.

## Status on three Pivotal Phase 3 trials for Japan filing

### Comparative study with ripasudil

- STN1013900 (QD) + vehicle (QD)
- Ripasudil (BID)

### Demonstrated superiority to ripasudil

Reported at Q2 FY2021 Financial Results Meeting  
[https://www.santen.com/en/assets/pdf/ir/document/202203/mtg2022\\_2q.pdf](https://www.santen.com/en/assets/pdf/ir/document/202203/mtg2022_2q.pdf)

### Study of adjunctive use of STN1013900 with latanoprost

- STN1013900 (QD) + latanoprost (QD)
- Placebo (QD) + latanoprost (QD)

### Demonstrated adjunctive effect of STN1013900

Report on next page ▶▶▶

### Long-term treatment study

- STN1013900 (QD) (for low-IOL patients)
- STN1013900 (QD)
- STN1013900 (QD) + latanoprost (QD)
- STN1013900 (QD) + timolol (BID)

On-going

QD (quaque die); once a day. BID (bis in die); twice a day.

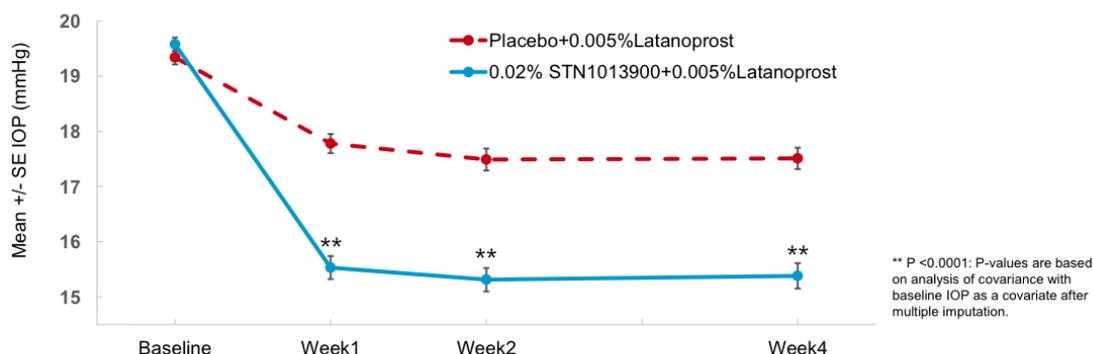
Page twenty two.

Three Phase III studies are required for application in Japan. As we have already reported, the first study showed superiority over ripasudil and met its primary endpoint. We are pleased to report top-line data from the second study, on the effect of the combination with latanoprost.

STN1013900 (*Rhopressa*<sup>®</sup>, *Rhokiinsa*<sup>®</sup>)

## STN1013900 showed a significant adjunctive effect of lowering intraocular pressure in the latanoprost ophthalmic solution combination study

▶▶▶ Mean +/- SE Study Eye Mean Diurnal Intraocular Pressure (mmHg) by Treatment Group and Visit



- STN1013900 met the study objective by demonstrating superiority to Placebo in Mean Diurnal IOP at Week 4 under concomitant use of latanoprost in Japanese subjects with POAG or OHT ( $\Delta$ -2.36mmHg)
- The most frequent AE was conjunctival hyperaemia by 53.3% in STN1013900 group and 6.5% in Placebo group

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The graph shows the decrease in IOP from baseline over time. Light blue is the group with STN1013900 and latanoprost, and red is the group with placebo and latanoprost. Please see the appendix for details on the protocol.

As you can see, the light blue STN1013900 combination group achieved the primary endpoint with a statistically significant advantage over the red latanoprost-only group from one to four weeks post-dose.

Since this is a combination study with latanoprost, as expected, more adverse events occurred. Conjunctival hyperemia was the most frequent adverse event.

We will continue to proceed with the third long-term study. This concludes my presentation.

## Question & Answer

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### Q-1-1

In the materials, you mentioned China, which has been a topic of discussion for the past several years. This time the factors are a little different from the past. I have the impression that there is a wider range of influences this time.

I think that these influences can't be helped, and it's just a question of responding appropriately to them. I have a feeling that it is difficult to take countermeasures when the market is weak. However, would you please comment on how you see the situation in China in the future, including your outlook for Q2, Q3, and Q4?

### A-1-1

**Koshiji** : The future outlook for China. I will take this question.

First of all, Q1 had an unexpected impact on our business. We are aware that we cannot be overly optimistic about Q2 and beyond. However, in this respect, we believe that Q2 will be slightly better than Q1, and we expect improvement over time in Q3 and Q4.

However, based on that assumption, our original forecast for the full year of JPY35 billion, which is on page eleven, seems quite implausible. That begs the question, what is a reasonable estimate? We are currently in the process of examining this question, whether it will be JPY35 billion, JPY30 billion, or JPY25 billion. After looking at the situation in Q2, I think we will be in a better position to determine a specific amount.

However, our current forecast is that sales, which in Q1 were JPY3.6 billion, will be much higher in Q2. We expect sales to almost double.

### Q-1-2-1

Another point is that you mentioned that SG&A expenses have decreased, so it seems you overcame the impact of the foreign exchange rate headwinds. Could you tell us which specific areas saw a decrease?

### A-1-2-1

**Koshiji** : Total SG&A expenses for Q1 were JPY20.2 billion in the previous fiscal year and JPY19.4 billion in this fiscal year, so there was a 4% decrease. As a percentage of the composition, that's a decrease from 31.1% to 29.6%. Although the YoY decrease was 4%, we recognize that there was about a 5% appreciation factor due to the exchange rate, so in real terms the decrease was 9%.

The majority of these expenses are direct adjustment expenses, which are things like variable expenses and personnel expenses. These are mostly denominated in foreign currencies. Variable expenses are down 20% YoY.

### Q-1-2-2

Does that include promotional costs and things like that?

### **A-1-2-2**

**Koshiji** : Yes, a lot of it is promotional costs associated with sales activities. Naturally, the COVID-19 measures have led to a decline in activities in China and other countries, so I believe that these factors are having an effect. We are also reviewing our marketing activities globally on a zero-based, new-normal basis. I am aware that such effects are emerging. Thank you.

### **Q-2-1-1**

First of all, I would like to ask you about the medium-term outlook, which you explained on page six today. How do you plan to restore core operating profit to the JPY50 billion level from the next fiscal year onward? Also, I am wondering if you could give us an update on the mid-term forecast at some point.

### **A-2-1-1**

**Koshiji** : In that respect, the overall PL control is as I just mentioned. In this context, we have identified drivers for reductions, particularly in expenses, and are working hard to address them.

SG&A, promotional expenses are two components. One is the variable cost portion, as I mentioned just now. At the same time, as covered on page fifteen, in the case of the US, the deficit has been on a persistent downward trend, so we need to curb this deficit. I believe those areas will be the major drivers of improvement in the ratio of SG&A expenses.

We will work on these two improvements. The situation will become clearer when the US business strategy is clarified and finalized.

In that respect, I am aware that the STN1011700 approval I mentioned earlier will be around the same time. Thank you.

### **Q-2-1-2**

Thank you very much.

If so, would it be correct to say that the first message is to raise the profit level by optimizing costs rather than by increasing sales?

### **A-2-1-2**

**Koshiji** : In terms of net sales, the assumptions used in this Medium-Term Plan differ from those in the previous plan. Delays in the launch of STN1011700 in the US mean that the assumption of sales of JPY315 billion is difficult to attain. However, profits will be secured with a resilient PL structure. We would like to manage our business based on such a concept.

### **Q-2-2**

Secondly, in the area of development, I would like to know about STN1013400 for myopia. We have heard that the safety and tolerability of the drug was confirmed in Phase I in Japan. If you have any comments on the development strategy, schedule, and so on, please let us know.

## **A-2-2**

**Sallstig** : Thank you for your question.

All I can say at this stage is that we are looking at those options and trying to move forward as quickly as possible. We are currently preparing to conduct Phase I trials in China as well as Japan, so I cannot give you a specific timeline, but I can tell you that we are in the process of moving forward with the project as quickly as possible.

## **Q-3-1-1**

First of all, you mentioned reviewing the US strategy after the PDUFA for STN1011700. Could you be more specific about this?

## **A-3-1-1**

**Koshiji** : We are considering whether to sell the product directly in-house or to out-license it. We are reviewing this and other issues. Does that answer your question?

## **Q-3-1-2**

Do you have any plans which entity to bring the product to?

## **A-3-1-2**

**Koshiji** : I can only say at this stage that we are pursuing various possibilities.

## **Q-3-2**

One more thing. Since the reason for the previous Complete Response Letter (CRL) relating to STN1011700 was due to a manufacturing problem at the contractor, is it correct to assume that the primary efficacy and safety issues are not a problem, and that STN1011700 will be approved without any problems by the PDUFA date?

## **A-3-2**

**Sallstig** : The CRL clearly specifies GMP-related issues at the contractor, so the agency and the contractor are discussing this point and taking measures to meet the requirements. We refiled on May 6 and are now waiting for the November 6 PDUFA date.

## **Q-4-1-1**

I think I know the sales for *Eylea* decreased YoY, and that the budget for FY22 incorporates the risk of biosimilars, but is the sales of *Vabysmo* having an impact on the sales of *Eylea*? If it is having an impact, what is the level of the impact?

#### **A-4-1-1**

**Koshiji** : In terms of Q1, we are not aware of any significant impact. We assume that it is mainly used in cases where existing products are not effective. However, *Eylea* has a long clinical track record, so it is not likely to be affected by a sudden and sharp decline in sales. We are aware that the current results are negative YoY as you have pointed out, but we are aware that this is not a factor of other products. Does that answer your question?

#### **Q-4-1-2**

And was there a negative impact from NHI price revision?

#### **A-4-1-2**

**Koshiji** : There was not.

#### **Q-4-2-1**

One more thing, I think it was after the Q4 announcement, there was a change in the division of management roles, and Mr. Kurokawa has come back to represent the Company. Could you please explain again the background and meaning of this change?

#### **A-4-2-1**

**Koshiji** : To the extent that I can speak here, I would like to say that we take very seriously the evaluation of our stock price and views of the market. There is a recognition that the management team must work together to do its best in order to maximize shareholder value. Although Chairman Kurokawa temporarily stepped down from his representative position, he will return and become more deeply involved in the Company's management.

#### **Q-4-2-2**

In other words, how have the responsibilities or actual management decisions changed since mid-May?

#### **A-4-2-2**

**Koshiji** : In that respect, there has been no change, since Chairman Kurokawa was the representative director until the end of March. In that respect, the method and manner of involvement has not particularly changed between the period up to March and from May onward.

To put it in chronological order, from April to June 24, he did not hold the representative director position. Since he was not in the office, his involvement was not as a representative director, but there was a bit of a gap, so we are now back to the situation we were in until March.

#### **Q-5-1**

First, I would like to understand a little more about China. Mr. Koshiji talked earlier about the impact of COVID-19. However, the COVID-19 pandemic has been going on for about two and a half years now. The fall in sales in this Q1 period has been quite dramatic. I'm wondering about the extent to which this is due to macroeconomic factors, and not COVID-19.

You also mentioned that you are holding down SG&A expenses and promotional activities, but I would like to ask you to also comment on whether you are maintaining a system that will enable a solid recovery in sales when the environment improves in the future.

#### **A-5-1**

**Koshiji** : I think it is possible that there are other factors behind the sharp decline in sales in China besides COVID-19. Certainly, COVID-19 has been ongoing for two years now, but we recognize that the situation this time is stricter than ever before. In that sense, we believe that most, if not almost all, of the impact on this occasion was due to the Chinese government's very strict COVID-19 measures.

We are not losing market share to other companies, so the other possible element is the macroeconomic factor.

We are aware of the fact that after the recovery, we don't want to be slow out of the gate, and so we are trying to control the situation appropriately in terms of cost reduction, especially in personnel expenses.

In China, the personnel retention rate has always been low. The turnover rate for the entire company is approximately 13% to 15%. In China, the figure is approximately 25%. We believe that we are managing labor costs in a way that allows a flexible approach, and variability in costs, in accordance with the environment. Thank you.

#### **Q-5-2-1**

Secondly, regarding Asia, I am not sure what you mean on page thirteen by changes in the external environment for the current fiscal year. Could you explain this in more detail?

#### **A-5-2-1**

**Koshiji** : This refers largely to COVID-19. Asia has shown steady growth over the past few years, but if we look at the quarterly results, we see that Vietnam and Thailand, which follow after South Korea in market size, tend to employ very strict COVID-19 measures. The resulting variability in sales is quite large. These and other changes in the external environment are under consideration in the full-year forecast.

#### **Q-5-2-2**

You mention here the impact of changes in the competitive relationship with generics. Are there any new developments in this area?

#### **A-5-2-2**

**Koshiji** : No, there are no new developments here. There is competition between generics and our *Diquas* and *Tapros* products. The competition is intensifying, but in fact, there is also greater competition between generics.

[END]