Q4 FY2022 Financial Results Transcript

Ito: This is Ito, CEO of Santen Pharmaceutical. Thank you for attending the FY2022 financial results briefing despite your busy schedule. Let me provide you a summary of the earnings.

After becoming CEO last September, I have focused on reinforcing initiatives to improve profitability, building our growth pillars and an organizational structure to promote these initiatives, with the aim of recovering our current business performance and achieving medium-to long-term growth. We announced in April a new medium-term management plan that reflects these measures. We will all work hard according to this plan to steadily deliver results. We strongly believe that this will enable us to meet the expectations of our shareholders and investors. We look forward to your continued support.

Summary

Profitability improvements and mid-to-long term growth initiatives in play
FY2023 focus: solid recovery in profitability

FY2022 Consolidated results

Revenue: JPY 279.0 billion (+5% YoY)

Core OP: JPY 44.2 billion (-5% YoY), Core OP ratio: 16%

Initiatives for mid -to-long term regrowth

- Profitability improvement: Plan to complete streamlining of Americas in H1 FY2023
  Contribution profit: FY2023 FCST JPY -1.1 billion, improved 3.4 billion YoY (FY2022: -4.5 billion)
  Regional profit: FY2023 FCST JPY -3.1 billion, improved 4.8 billion YoY (FY2022: -7.9 billion)
- Growth pillars: Promote initiatives to expand commercial excellence to overseas
  Solid investment on R&D for future growth

FY2023 Consolidated forecasts

Revenue: JPY 273.0 billion (-2% YoY)

Core OP: JPY 46.0 billion (+4% YoY), Core OP ratio: 17%

Shareholder returns

FY2022: Annual dividend of JPY 32, JPY 25.7 billion of share buyback

FY2023: Annual dividend forecast of JPY 32, resolved JPY 24.5 billion (maximum) of share buyback (from May 12, 2023 to March 22, 2024)

 5 Santen

Please refer to page 5. First of all, let me discuss the FY2022 results.

Revenue was JPY 279.0 billion, core operating profit was JPY 44.2 billion, and core operating profit ratio was 16%. In addition to the steady progress made in cost optimization initiatives that had been factored in our forecasts disclosed in Q3, mainstay products in Japan, such as *Alesion products*, performed better than expected in Q4. As a result, our performance exceeded our forecasts, but we recognize that improvement in profitability yet remains an issue to be treated with a sense of urgency.

Next, I would like to cover our initiatives for mid-to long-term growth.

For the Americas, one of the contributors to improve profitability, we are currently in the process of various negotiations and arrangements to complete its streamlining during the first half of this fiscal year. As a result, we expect contribution profit to improve by about JPY 3.4 billion and regional profit by slightly less than JPY 5.0 billion compared with FY2022.

In addition, under the leadership of Nakajima COO, we will develop measures to deploy Commercial Excellence to other regions aiming for the mid-to-long term growth of regional business. We also plan to invest more in research and development.

Next, our FY2023 forecasts.

We forecast a revenue of JPY 273.0 billion, core operating profit of JPY 46.0 billion, which translates into a decrease in revenue and an increase in profit from the previous fiscal year. Core operating profit ratio is forecasted at 17%.

Although certain improvements from structural reforms are factored in - including the streamlining of Americas business - we have taken into account transient factors in

FY2022 such as increased sales from the massive dispersion of pollen in Japan and also the impact of patents expiring on mainstay products in Japan, increases in R&D costs for future growth and increases in procurement costs for raw materials.

As a result, core operating profit is expected to increase incrementally compared with the previous fiscal year, but this is in line with our target for core operating profit of JPY 56.0 billion for FY2025, disclosed in our new medium-term management plan. We will continue to focus on improving profitability.

Finally, let me discuss shareholder returns. We plan to pay an annual dividend of JPY 32 in FY2023. Since my tenure as CEO, we have been promoting measures to improve profitability and achieve medium-to long-term growth, but we recognize that our share price remains undervalued. In light of these conditions, the Company resolved today a share buyback of JPY 24.5 billion at maximum.

This concludes my presentation. Our CFO, Koshiji will explain the details of business performance and shareholder returns.

FY2022 Consolidated results

Strong sales in fourth quarter mainly from Japan mainstay products absorbed impact from China

	FY2021 ACT	FY2022 ACT
USD (JPY)	112.57	135.40
EUR (JPY)	130.75	140.97
CNY (JPY)	17.55	19.72

(JPY billions)	FY2021		FY2022				
	Actual	vs Revenue	Actual	vs Revenue	YoY	Forecast (Feb.7)	vs forecast
Revenue	266.3	-	**279.0**	-	**+4.8%**	272.0	103%
Cost of sales	109.7	41%	113.0	40%	+3.0%	111.0	102%
Gross Profit	156.6	59%	**166.1**	60%	**+6.1%**	161.0	103%
SG&A expenses	83.9	31%	93.5	34%	+11.6%	90.5	103%
R&D expenses	26.4	10%	28.3	10%	+7.3%	29.5	96%
Core operating profit	46.3	17%	**44.2**	**16%**	**-4.5%**	41.0	108%
Non core SG&A expense	0.6	0%	2.7	1%	+324.9%	7.5	36%
Amortization on intangible assets associated with products	9.7	4%	9.5	3%	-2.2%	9.3	102%
Other income	1.0	0%	3.5	1%	+238.0%	0.7	542%
Other expenses	1.1	0%	38.6	14%	--	31.3	123%
Operating profit	35.9	13%	**-3.1**	-	-	-6.5	48%
Finance income	2.5	1%	1.2	0%	-54.7%	1.3	89%
Finance expenses	1.2	0%	1.5	1%	+24.0%	1.0	150%
Share of loss of investments accounted for using equity method	1.6	1%	2.4	1%	+47.2%	2.3	103%
Profit before tax	35.6	13%	-5.8	-	-	-8.5	68%
Income tax expenses	8.4	3%	9.2	3%	+9.0%	7.0	131%
Actual tax ratio	23.7%	-	-	-	-	-	-
Net profit	27.2	10%	**-15.0**	-	-	-15.5	97%
ROE	8.4%		-				
Core ROE	10.9%		10.5%				
Core net profit	35.2	13%	33.2	12%	-5.6%	30.8	108%

Gross Profit

+4.8% YoY

- Revenue: Increased mainly from stronger sales of mainstay products including *Alesion* products coupled with positive FX impact (JPY+9.4bil)
- COGS ratio: Decreased to 40% resulting from product mix, despite of one-time costs.
- Gross profit: Impacted JPY+7.0bil by FX

Operating Profit (Core basis)

-4.5% YoY

- Exceeded forecast on Feb 7, 2023 (Q3), from strong revenue, COGS ratio improvement and cost optimization, despite increase in R&D, personnel costs and other expenses including FX negative impacts

Operating Profit (IFRS)

- Mainly due to the impairment loss (Eyevance: JPY 30.1bil, STN10109: JPY 3.1bil) and expenses related to regrowth including Americas streamlining (total: JPY 4.8bil)

Net Profit (IFRS)

- Increased income tax expenses. Tax rate excluding one-time factor : 24.9%

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Koshiji: Please turn to page 7 for the consolidated financial results for FY2022.

As Ito explained earlier, mainly due to the strong performance of mainstay products such as *Alesion products* in Japan in Q4, revenue increased 4.8% year-on-year, to JPY 279.0 billion.

The COGS ratio was 40% due to changes in product mix in Q4.

Core operating profit was JPY 44.2 billion. As the forecast has been revised on April 27, this was due to the increase in sales and the effects of cost optimization.

Operating profit on an IFRS basis was JPY -3.1 billion due to impairments of Eyevance and STN10109 and provision for streamlining the Americas business.

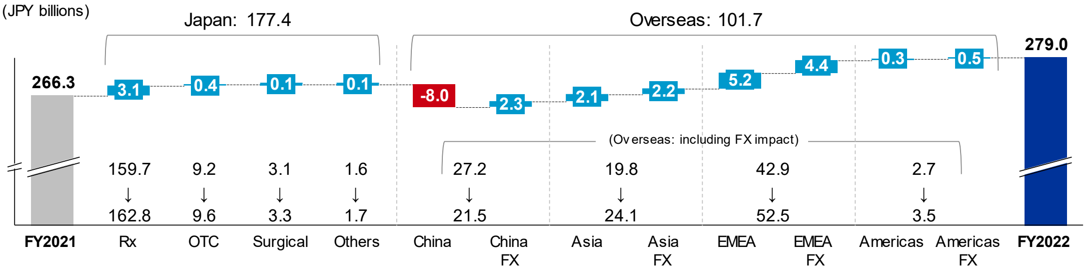
Costs under the core base, such as streamlining efforts in the Americas, totaled JPY 4.8 billion, adjusting non-core SG&A expense and other expenses. This is less than our expectation at Q3 of FY2022.

With regards to corporate income tax, the tax rate excluding one-time factor was 24.9%, increased by 1.2% YoY. (Santen postscript: +1.2pt YoY)

As a result, net profit for FY2022 was JPY -15.0 billion.

FY2022 Sales bridge

Japan, Asia and EMEA outperform expectations and contribute to revenue growth



Japan	+2.2% YoY: Stronger-than-expected sales of *Alesion* products and others, absorbed impact from NHI price cuts
China	-20.8% YoY (Ex. FX impact -29.4%): Revenue decreased from COVID-19 resurge. Confirmed market recovery trajectory
Asia	+21.7% YoY (Ex. FX impact +10.8%): Double-digit growth from glaucoma and dry eye products in key markets such as South Korea and Thailand
EMEA	+22.4% YoY (Ex. FX impact +12.1%): Double-digit growth from glaucoma and dry eye products in major countries such as Italy and Germany
Americas	+28.5% YoY (Ex. FX impact +9.5%): Increased revenue including FX impact, but profitability remains an issue. Maximized streamlining decided

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

Koshiji: See page eight for the factors behind changes in revenue by region.

Revenue increased to JPY 279.0 billion, JPY 12.8 billion up from the previous fiscal year. The breakdown is Japan business of JPY 177.4 billion and overseas business of JPY 101.7 billion.

First, as for Japan, as Ito mentioned earlier on page 5, it grew +2.2% year-on-year.

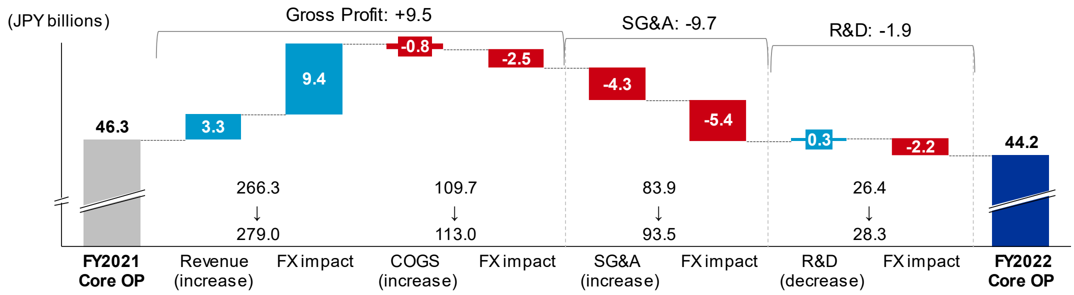
In China, sales decreased due to the impact of COVID-19. Although slightly impacted by the yen appreciation compared with the forecast at Q3, it was generally in line with expectations, hence we confirm that the market is on a recovery track.

In Asia and EMEA, sales of mainstay products were strong, mainly in primary markets. As a result, sales grew at a double-digit level even excluding the impact of foreign exchange rates, driving sales growth.

For the Americas, as we had reported in the previous two financial meetings, we have not focused on activities to expand sales since deciding to pursue maximizing streamlining the business.

FY2022 Core operating profit bridge

Gross profit improved from sales growth. Core OP impacted from expenses including FX. Cost optimization progresses as expected



Gross profit	Net +9.5bil YoY. Increased revenue (incl. FX impact) and decreased COGS ratio (-0.7pt YoY) from region/product mix
SG&A	Net -9.7bil YoY. Negatively impacted by increase in sales-linked costs and overseas expenses including FX impact (SG&A ratio: +2.0pt YoY)
R&D	Net -1.9bil YoY. Impacted from weaker JPY. Foreign currency comprises 60% (R&D expenses ratio: +0.2pt YoY)

Koshiji: Page nine shows factors behind changes in core operating profit, which decreased by JPY 2.1 billion YoY from JPY 46.3 to 44.2 billion.

Gross profit improved by JPY 9.5 billion YoY. Revenue increased by JPY 12.8 billion from previous fiscal year due in part to the impact of foreign exchange rates. In addition, the COGS ratio improved, even including one-time factors recorded in the first half of FY2022, resulting from the impact of product mix as explained earlier.

On the other hand, SG&A expenses increased by JPY 9.7 billion, compared with the previous fiscal year. This is due to an increase in expenses including sales-linked expenses mainly associated with co-promotion fees related to increase in sales of *Alesion products*, royalties and foreign exchange. The depreciation of the yen is included as factor in the amount of JPY 5.4 billion. It was JPY 4.3 billion as net amount. Although this is a net increase, considering factors such as sales-related expenses amounting to JPY 3.0 billion, we are aware we could properly control expenses.

R&D expenses increased by JPY 1.9 billion from the previous fiscal year because overseas expenses, which account for 60% of the total, were affected by the weaker yen.

As a result, core operating profit was JPY 44.2 billion.

FY2023 Outlook

Decrease in revenue from GE impact in Japan
Core OP increase from profitability improvement initiatives

	FY2022 ACT	FY2023 FCST
USD (JPY)	135.40	130.00
EUR (JPY)	140.97	140.00
CNY (JPY)	19.72	19.00

(JPY billions)	FY2022		FY2023		
	Actual	vs Revenue	Forecast	vs Revenue	YoY
Revenue	279.0	-	273.0	-	-2.2%
Cost of sales	113.0	40%	111.0	41%	-1.7%
Gross profit	166.1	60%	162.0	59%	-2.5%
SG&A expenses	93.5	34%	87.0	32%	-7.0%
R&D expenses	28.3	10%	29.0	11%	+2.5%
Core operating profit	44.2	16%	46.0	17%	+4.0%
Non core SG&A expense	2.7	1%	0.8	0%	-70.5%
Amortization on intangible assets associated with products	9.5	3%	9.4	3%	-1.2%
Other income	3.5	1%	0.6	0%	-83.0%
Other expenses	38.6	14%	4.4	2%	-88.6%
Operating profit	-3.1	-	32.0	12%	-
Finance income	1.2	0%	1.0	0%	-13.2%
Finance expenses	1.5	1%	0.8	0%	-46.6%
Share of loss of Investments accounted for using equity method	2.4	1%	2.4	1%	+1.6%
Profit before tax	-5.8	-	29.8	11%	-
Income tax expenses	9.2	3%	7.4	3%	-19.4%
Actual tax ratio	-	-	25%	-	-
Net profit	-15.0	-	22.4	8%	-
ROE	-		8%		
Core ROE	10.5%		12%		
Core net profit	33.2	12%	34.5	13%	+3.8%

Gross Profit

-2% YoY

- Revenue: Impactfrom GE erosion of mainstay products in Japan
- COGS ratio: Inflationimpact but maintain same level as FY2022 (FY2022: 40.5%, FY2023: 40.7%)

Operating Profit (Core basis)

+4% YoY

- Increase allocation to R&D expenses from FY2022
- Decrease in SG&Aexpenses ratio from progress in profitability improvement initiatives(SG&Aratio: -2pt vs FY2022)

Operating Profit (IFRS)

- JPY32.0 billion, reflecting structural reform costs

Net Profit (IFRS)

- Tax ratio: 25%. Decrease income tax expenses from FY2022. Expect net profit of JPY 22.4 billion

Koshiji: See Page 11 for FY2023 outlook.

As stated in the financial results meeting for Q3 FY2022 and in the new medium-term management plan announced on April 13, we will further work on improving profitability and strengthening R&D activities for future growth.

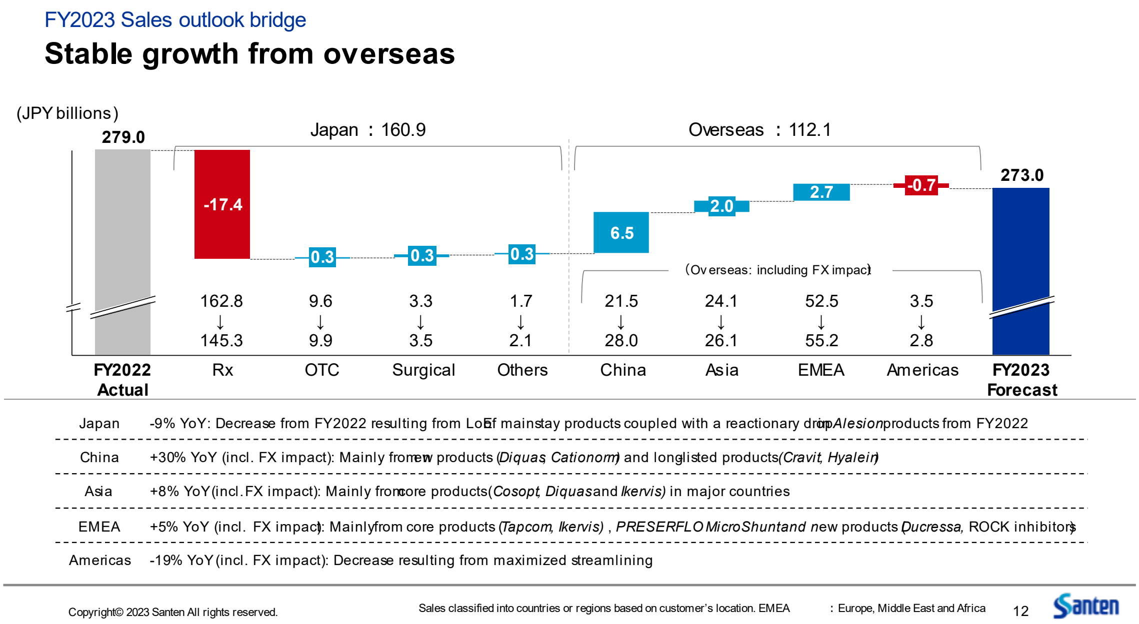
In the medium-term management plan, we set targets for FY2025; core operating profit of JPY 56.0 billion, core ROE ratio of 13%, and core EPS growth rate of over 10%. We position FY2023 as the first step to kick off, especially for core EPS, we will achieve over 10% growth rate (Santen postscript: 10%) after share buyback. For the rest, please kindly see page 5.

First, please refer to PL statement for revenue forecast. We expect a year-on-year decrease as we incorporate factors such as the impact of generic erosion for mainstay products in Japan. As you can see, we expect the yen to return slightly to a stronger level. The COGS ratio is expected to remain the same level as FY2022, as we will continue our efforts to reduce COGS despite the impact of NHI price cuts. However, due to the decrease in sales, in terms of gross profit in absolute term, it is expected to be down by 2.5% compared to the previous fiscal year.

R&D expenses are expected to increase by 2.5% year-on-year for investments for medium-to long-term growth. As I mentioned earlier, the decrease in gross profit and increase in R&D expenses are factors contributing to the decline in profit. In response to these factors, we are aiming to increase profits by reducing SG&A expenses by 7% year-on-year, down 2pt against sales.

Controlling SG&A expenses to be lower than the previous fiscal year is something that has not been achieved since FY2003 (Santen postscript: FY2008) in our company’s history. However, we will achieve a core operating profit ratio of 20% in FY2025 by optimizing expenses including streamlining Americas business and reducing SG&A expenses by 7% to around 30% vs revenue in FY2025.

With regards to operating profit on an IFRS basis, in FY2022, the Company experienced deficit primarily due to the impact of impairment and other factors. However, for FY2023, it is expected to be JPY 32.0 billion, incorporating structural reforms cost for the Americas and others that will remain at under core. Net profit for the period is expected to be JPY 22.4 billion.



Koshiji: Page 12. This slide shows the factors contributing to increase or decrease in revenue outlook by region.

For Japan, revenue is projected to decrease by 9% compared to the previous fiscal year. As I mentioned earlier, this is from the anticipated impact of generic erosion for mainstay products and the reactionary drop from the extremely strong sales performance of *Alesion* in FY2022.

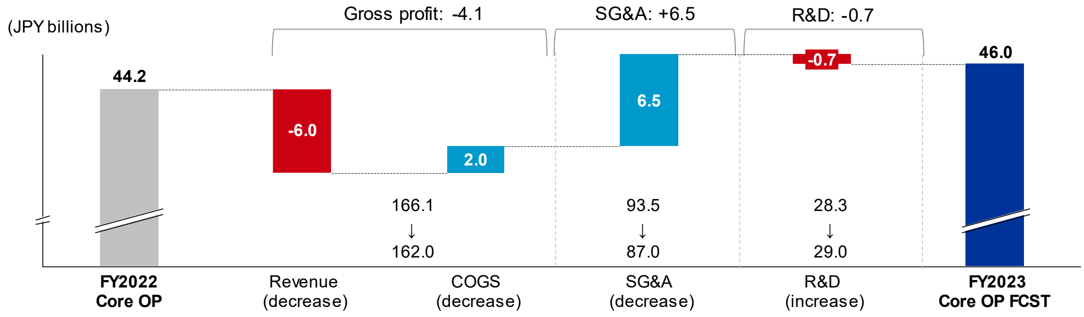
Next, let me move on to overseas business. The total revenue is expected to be JPY 112.1 billion, 10% up year-on-year or approximately 13% considering the stronger yen.

The overseas sales ratio against total consolidated sales is expected to be 41%.

First of all, regarding China which is expected to grow, the sales are forecasted to be JPY 28.0 billion, JPY 6.5 billion up YoY, as we expect the market to recover from COVID-19. For Asia and EMEA, despite various factors both positive and negative, we will continue to keep the growth trend. In the Americas, sales are expected to decline due to maximizing streamlining.

FY2023 Core OP outlook bridge

Allocation to R&D expenses for mid-to-long term growth
Core OP increase from profitability improvement initiatives progress



Gross profit	Net - 4.1bil YoY. Mainly due to decrease of revenue (COGS ratio: +0.2pt YoY)
SG&A	Net +6.5bil YoY. Companywide promotion of cost optimization initiatives (SG&A ratio: -1.7pt YoY)
R&D	Net -0.7bil YoY. Allocate sufficient R&D expenses for future growth (R&D expenses ratio: +0.5pt YoY)

Koshiji: Page 13. Factors behind changes in core operating profit outlook.

It is expected to increase by 4% or JPY 1.8 billion YoY, which we expressed as “marginal increase” earlier in page 5.

Gross profit is forecasted to decrease by JPY 4.1 billion mainly due to a decline in revenue.

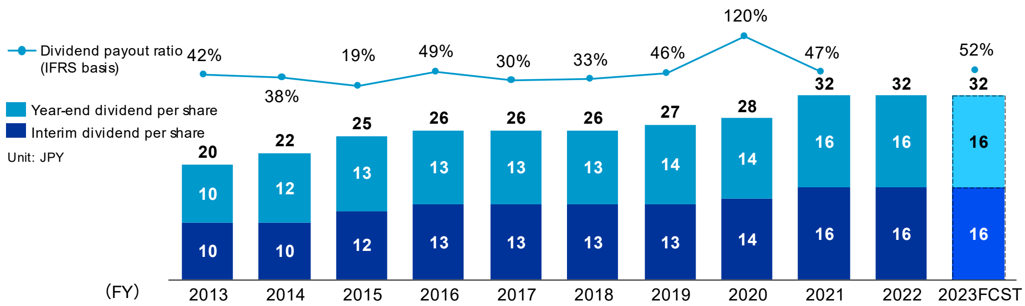
SG&A expenses are expected to decrease by JPY 6.5 billion year-on-year due to structural reforms and cost-optimization initiatives.

On the other hand, R&D expenses are projected to increase by JPY 700 million from the previous fiscal year to JPY 29.0 billion while it may contribute to a decrease in profit. We intend to secure investment necessary for future growth.

As a result, the core operating profit is projected to be JPY 46.0 billion. This is what we see for profit trend on a core basis.

Shareholder returns

Annual dividend forecast of JPY 32 (JPY 16 interim & year-end)
JPY 24.5 billion (maximum) share buyback



(FY)	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023FCST
Total return ratio (IFRS basis)	42%	38%	19%	106%	30%	76%	46%	120%	47%	-	162%
Share buyback (JPY billions)	-	-	-	12.3	-	13.9	-	-	-	25.7	24.5 (max.)
Core ROE	11%	13%	12%	11%	12%	13%	12%	12%	11%	11%	12%

Koshiji: Finally, please turn to page 14, let me discuss shareholder returns.

As we explained in the new medium-term management plan, we will continue to pay an annual dividend of JPY 32 per share for FY2023 based on our progressive dividend policy. Regarding the subsequent periods, we are considering increasing dividends in line with profit growth. That is the current plan.

In addition, as disclosed today, the Company will repurchase our own shares in light of the current share price level and other factors.

The total amount of repurchase is JPY 24.5 billion, representing 5% of the total number of shares outstanding. The period of repurchase will be for around one year starting from tomorrow.

Since we acquired 6.6% or JPY 25.7 billion of shares in FY2022, we will acquire and cancel 10.6% worth of shares (Santen postscript: 11.6%) over the course of two years.

Considering the projected capital level for FY2023 and the current share price, we thought it was appropriate to improve ROE and EPS for shareholders through share repurchases.

That concludes my part.

Q4 FY2022 R&D update

Progress across both Existing area contributing to growth and New area with scalability expected after FY2026

Area	Product	Indication	Progress
Existing area	STN1013900 *Rhopressa®/Rhokiinsa®*	Glaucoma	**Launched** in Europe (Sweden)
	STN1011101 *TAPCOM / TAPTIQOM*	Glaucoma	**Filed** in China
	STN1012600 Sepetaprost	Glaucoma	Achieved **LPO**[1] in P3 trial in Japan
	STN1008903 *Diquas LX*	Dry eye	**Filed** in Asia (South Korea)
	STN1011402 Epinastine HCl (ophthalmic cream)	Allergic conjunctivitis	**Filed** in Japan
New area	STN1012700 Atropine sulfate	Myopia	Achieved **LPI**[2] in P2/3 trial in China
	STN1013600 Ursodeoxycholic acid	Presbyopia	Achieved **LPI** in P2a trial in US

1. LPO; Last Patient Out. 2. LPI; Last Patient In.

Sallstig: I would like to update you with regards to status of the pipeline. See page 16.

As we outlined in the new medium-term management plan announced in April, existing therapeutic areas continue to contribute to FY2025, while from FY2026 onwards, products for which we expect scalability in new areas such as myopia and ptosis would take over our growth. In Q4, there has been a good progress toward achieving the plan.

In the existing area we launched ROCK inhibitor, STN1013900 for glaucoma in Europe. We filed for marketing approval of STN1011101 in China, STN1008903 in South Korea and STN1011402 in Japan. STN1011101 is marketed as *Tapcom* in Japan. STN1008903 is marketed as *Diquas LX* in Japan. STN1011402 is a cream formulation of *Alesion*. In addition to these, in STN1012600 for glaucoma, P3 study in Japan has achieved last patient out.

In new therapeutic area, P2/3 study of STN1012700 in China, atropine for myopia has achieved last patient in. POC study of STN1013600 for presbyopia also achieved last patient in and we plan to complete the study in this fiscal year.

6 out of the 7 R&D updates in Q4 will lead to FY2023 R&D "events" and there is a "good momentum" picking up.

FY2023 main events

Enhanced product lineup in China/Asia
PJ data readouts including pivotal study for myopia treatment

Area		Data readout	Approval	Launch
Existing area	**Glaucoma**	STN10**126**00 P3 (Japan) P2exploratory study (Europe)	STN10**130**01 (Europe)	STN10**139**00 (*Rhopressa*, Asia) STN10**140**00 (*Rocklatan*, Asia)
	Dry eye	STN10**141**00 P1/2a (Japan)	STN10**089**03 (Asia)	STN10**005**01 (*Cationorm*, China)
	Allergy		STN10**114**02 (Japan)	STN10**076**03 (*Verkazia*, China)
	Infectious diseases			STN10**001**01 (*Ducressa*, Asia)
New area	**Myopia**	STN10**127**00 P2/3 (Japan)		
	Presbyopia	STN10**136**00 P2a (US)		

Sallstig: Next, I will introduce the main pipeline-related events that I expect this fiscal year. This is page 17.

In the current fiscal year, we plan to launch new products, particularly in China and Asia, where market growth is expected to continue. One key driver will be to obtain approval for the cream formulation of *Alesion* in Japan.

As previously mentioned, data readouts of a pivotal study in Japan of atropine formulation, STN1012700 for myopia, and STN1013600 for presbyopia and STN1014100 for dry eye, which are undergoing topline result data readouts, are scheduled as well. We will share the results through the financial meetings, etc., as appropriate.

We have earlier mentioned an impairment loss for STN10109 (Santen postscript: STN1010904 and STN1010905) but we will continue its development.

Regarding STN1011101 development in China mentioned on the previous page, we had originally planned to file for the approval with results of P3 trial with completion expected later this fiscal year. However, as local regulation changed as a result, we could utilize data used from outside of China and were able to accelerate filing ahead of time upon consultation with the authorities. As in this case, we will continue to make all necessary efforts across all projects that allows for the earliest possible contribution to patients.

This concludes my part. Thank you.

Question & Answer (summary)

Q1-1
My first question is concerning the cost. You mentioned SG&A expenses are projected to decrease by JPY 6.5 billion YoY for FY2023. In Q2, you had mentioned JPY 6.0-8.0 billion of cost cuts for the upcoming period. I would have thought a similar range applies this time. There was also a mention of approximately JPY 3.0-4.0 billion related to the performance recovery in Americas. Considering the figures related to these costs, could you please provide a brief summary of the current situation, including how it has changed both from the initial plan and the current situation, as well as the progress of cost reduction in Americas?

A1-1
Koshiji: Regarding JPY 6.0-8.0 billion, we intend to improve profitability of this range on a core basis in FY2023, rather than a decrease in expenses. We recognize that progress has been made largely in line with our initial assessment. Earlier, we mentioned a projected reduction of JPY 6.5 billion in SG&A expenses and this is in line with the range of JPY 6.0-8.0 billion. We are expecting these improvements in profitability and amongst those, the profitability improvement in Americas is also proceeding as planned. I can explain from several angles. As you can refer on page 11, the reduction of JPY 6.5 billion in SG&A expenses includes approximately JPY 5.0 billion related to the United States. For contribution profit in the US, you could refer to page 20 on appendix and page 11 on data book. We are expecting the profitability improvement of JPY 3.4 billion in total on contribution profit basis. The reduction in expenses is significantly attributed to the portion related to the US. We will continue to implement cost reduction measures in other areas as well.

Q1-1-2
With regards to the improvement of core operating profit by JPY 6.0-8.0 billion, my understanding is you outperformed your initial expectations and therefore your base is JPY 41.0 billion but even so that translates into a JPY 5.0 billion so should I see this as a shortfall?

A1-1-2
Koshiji: That is one way to look at it.

Q1-1-3
Well, considering various factors including the situation in Japan, it seems that for this fiscal year, JPY 5.0 billion would be the more appropriate level of economies instead of JPY 6.0-8.0 billion. Is it fair to say so?

A1-1-3
Koshiji: We had initially tried to identify in the JPY 6.0 to 8.0 billion range what would directly result in an increase in profit but we also have to recognize increase in the cost

of production and COGS ratio have negatively impacted this.

Ito: I would like to add one comment. From my understanding, the profitability improvement of approximately JPY 6.0-8.0 billion that we have discussed so far is being pursued in a range very close to the JPY 8.0 billion. On the other hand, as Koshiji mentioned, taking into account factors such as cost increases due to inflation and the anticipated impact on earnings from the generics launch, we see the level of core operating profit would be around JPY 46.0 billion. I just wanted to clarify.

Q1-2
Regarding the data readouts for STN1012700, am I right in understanding that the data can be directly submitted for application once the readout is completed in Japan?

A1-2
Sallstig: If the data readouts from Phase 3 trial in Japan is available, we will proceed with the filing. Of course, this will depend on discussions with the PMDA, but we are confident to move forward.

Q2-1-1
Regarding the outlook for FY2023, you previously mentioned incorporating structural reform expenses as items under Core OP. Under which line item does this fall? Is this a one-off item for FY2023? Could you specify?

A2-1-1
Koshiji: It is included in the "other expenses" category on page 11 of PL statement. Amongst JPY 4.4 billion of other expenses, approximately JPY 3.5 billion is considered as structural reform expenses. The amount is expected to decrease further in the following fiscal years. For FY2024 and 2025, we anticipate achieving a balance where other income and other expenses cancel out their impact.

Q2-1-2
By the way, what do these structural reform expenses consist of?

A2-1-2
Koshiji: They consist mainly of two things. First, there are one-time costs associated with optimizing organizational functions. Additionally, we include one-time costs related to operational downsizing, such as office re-evaluation and contract termination. We estimate these expenses to be slightly more than JPY 3.5 billion, categorized as other expenses under Core OP.

Q2-2
Regarding FY2023 forecast for Japan, you mentioned it is projected to drop by 10% YoY due to a reactionary drop from the more-than-anticipated strong sales performance of *Alesion products* in FY2022. How conservative are your assumptions on the impact of generic drugs? In the medium-term management plan, you expect the forecast for Japan in FY2025 to be JPY 150.0 billion, so I would like to know how the impact from generic drugs will be reflected in that time frame.

A2-2
Ito: I may have answered this question before in a similar manner, but due to patent-related reasons, the launch of generics is a theoretical possibility. For example, although a formulation patent may still be effective, generics could be launched, circumventing such patents. However, in such cases, whether generics will truly emerge considering the drug price granted to generics and the expected cost is a different question.

With that said, for the outlook this fiscal year, we have taken into account everything conservatively, assuming that generics will be released if they theoretically can. In response, we have formulation patents in place as defense against such situations. If things work out well, one could assume we can achieve higher results. Regarding the situation with generics, we have already introduced new formulations for *Diquas* last year and have submitted applications for new formulation for *Alesion* this year. We have full confidence in generating solid sales from these products and achieving the targets in the mid-term plan.

Q3-1-1
I would like to ask about Japan concerning *Alesion, Tapros and Eylea.* It's surprising to see that *Diquas LX* has been performing very well and generating strong numbers. I wonder whether your estimates are the maximum achievable targets. Considering the possibility of generic for *Alesion* and biosimilar for *Eylea* - although it seems odd to me that the biosimilar has not yet been raised on the agenda for the First Committee on drugs- it seems like you have incorporated these factors into your outlook quite conservatively, is that correct?

A3-1-1
Ito: As you pointed out, our estimates are based on theoretical possibilities. Whether it will actually happen or not is uncertain, but we have taken a conservative approach in our projections.

Q3-1-2
Looking at *Tapros*, for example, sales are expected to decrease compared to the previous fiscal year, but the margin is relatively small. Considering that there are only two companies on master files for Tafluprost as mentioned earlier, it can be assumed this is because the cost is high. Also given that it is not easy to manufacture, is it safe to say that it is challenging to launch generics?

A3-1-2
Ito: Regarding *Tapros*, a generic product was recently approved, so we have assumed that it will be launched once listed on the drug price list. The penetration of generics drugs varies depending on the therapeutic area. In the case of conditions like glaucoma, generics tend to penetrate from new patients, but it takes a bit longer for generics to penetrate among existing patients who have continued treatment. Taking such past experiences into account, we have made our projections for FY2023.

Q3-2
The second question is about cost reduction. The majority of JPY 6.5 billion yen of reduction in SG&A expenses is attributed to the US. To achieve the target of JPY 10.0 - 15.0 billion moving forward, I think structural reform will be essential. I was surprised that around JPY 3.0 billion out of JPY 4.4 billion in other expenses is allocated for structural reform. Will there be no further expenses related to structural reform? Are you expecting to achieve the improvement of PY 10.0 -15.0 billion by deploying the approach used in Japan across other regions and ensuring you curb the headcount?

A3-2
Koshiji: Regarding one-time expenses, we understand that the scale of structural reform is relatively small. Currently, based on our calculations, we have set this amount for this fiscal year budget. In recent years, there was a trend where personnel costs increased associated with the increase in employees, resulting in expansion of SG&A expenses. From this experience, instead of significantly reducing the number of employees, for example, we can achieve significant cost reduction by implementing measures such as freezing new hiring. Based on what we have implemented over the past six months, we expect this level of cost reduction, taking into account the reduction from the existing baseline. We are planning to complete structural reforms within FY2023.

Nakajima: From the perspective of commercial excellence, we believe that achieving and surpassing the sales targets for FY2023 and FY2024 is one approach to confirm the effects of commercial excellence. Another approach is to achieve the same level of growth with fewer personnel, which involves suppressing the increase in headcount through commercial excellence.

Ito: Regarding the structural reform of the U.S. business, as we have mentioned before, we are currently exploring various alternatives consisting of finding partners. There are scenarios wherein we find a partner and also wherein we don’t find one. In either case, we will proceed with the reduction of personnel. In fact, we have already implemented structural reform for a determined scope in FY2022, so it is not just the structural reform expenses for FY2023 that we have accounted for.

Q3-3-1
Lastly, let me ask about China. I also believe that China will recover significantly, but with that said, it seems your outlook is quite strong; *Cravit* and *Hyalein* will perform quite favorably, while *Tapros* will decrease for some reason and *Diquas* will grow. I am assuming a resurgence of refractive correction surgeries and cataract surgeries is

necessary to achieve these targets. Can I assume that the current situation is as such that you have set these goals with high feasibility? Are you assuming that *Diquas* will be listed for VBP candidates since you already have its generics?

A3-3-1
Koshiji: As you mentioned, we anticipate growth in China as a whole, but we have incorporated both bullish and cautious aspects. In particular, we set a conservative target for *Tapros* which has strong market development elements. As for *Cravit* and *Hyalein, these* are already existing products, but as we explained in the previous earnings briefing, we see some room for expansion through distribution strategies and channel expansion for these products. That is the premise we are setting.

Q3-3-2
Are you incorporating risks in *Diquas*?

A3-3-2
Koshiji: Yes.

Q4-1:
I would like to ask about the gap between the guidance for FY2023 and your previous comments. As “soft guidance”, you previously mentioned you would be aiming for a core operating profit of JPY 50.0 billion for FY2023. Is the gap due to factors such as inflation? Even if we take into account this gap, can we assume that this does not impact your JPY 56.0 billion target in the medium-term management plan?

A4-1:
Koshiji: Yes. We were aspirationally aiming to achieve a core operating profit of JPY 50.0 billion, but it has been affected by inflation, especially COGS. Regarding the trajectory towards JPY 56.0 billion in the medium term, there are currently no significant changes.

Ito: When we set the target of JPY 56.0 billion in the medium-term management plan, we already considered the impact of inflation. Therefore, I understand that there are no issues to achieve this target

Q4-2:
Secondly, how can we confirm the progress of the structural reforms? While we can see some aspects through the reduction in SG&A expenses in the current fiscal year, if we are looking for a contribution of around JPY 15.0 billion in the future, how can we verify whether your company's initiatives are progressing smoothly or lagging behind? Could

you provide an explanation?

A4-2:
Koshiji: The progress of structural reforms involves core-based factors and extraordinary expenses in other expenses. As for what we can check on a regular basis, it may sound obvious, but we can consider the ratio of SG&A expenses and the core operating profit ratio. In the medium term, our goal is to bring SG&A expenses ratio and the core operating profit ratio to the circa 30% and 20% respectively - i.e. a return to previous levels. Even if there are slight fluctuations in sales and other factors this fiscal year, we will firmly maintain the SG&A expenses ratio and the core operating profit ratio. If you can use these indicators as a guide, it would be much appreciated.

Q5-1-1
Based on the previous soft guidance, I thought that the target would be JPY 47.0-49.0 billion by 2022 (Santen postscript: FY2023) and JPY 51.0-56.0 billion by FY2025. From what I interpret, although the profit level for this fiscal year will be affected by inflation resulting in increased costs, one could take a favorable view that your confidence has increased in the past one to two months to achieve the target of JPY 56.0 billion by absorbing those factors. Is this a fair interpretation?

A5-1-1
Koshiji: As you mentioned, the time frame is slightly different between the recent cost optimization progress and the confidence to achieve JPY 56.0 billion three years later. However, in order to achieve JPY 56.0 billion and to raise the core operating profit ratio to 20% from 16% in previous FY, it is essential not only to focus on top-line growth but also to optimize costs and control SG&A expenses. Therefore, we believe that we have been able to halt the increasing cost trend that had been expanding until the first half of FY2022. As disclosed in the latest data book, we have reduced the number of employees by 170 from 4,315 to 4,144 compared to the previous fiscal year, and we believe that we have properly controlled the cost increase factor in that regard.

Q5-2-1
Regarding the current fiscal year's budget, will the gains from the sale of *Eybelis* in the US be included somewhere? Or will it be added as an additional bonus if it occurs?

A5-2-1
Koshiji: Those types of expenses are not included. We do not include anything that is contingent on external parties.

Q5-2-2
If it goes well, it means it will be a positive for you, right?

A5-2-2
Koshiji: Yes, that's correct.

Q5-2-3
Does that mean we shouldn't have high expectations?

A5-2-3
Ito: We are currently in discussions, so I cannot provide specific numbers at this time. As Koshiji mentioned, we have not included any sale proceeds in the current plan.

Q6-1-1
Two points to address from my side as well. Many questions have been raised from various perspectives, but I would like to inquire about the visibility of this fiscal year's guidance. Last year, you provided guidance for operating profit at a similar level, and after one downward revision, you ended up finishing the year coming close to the initial guidance that had been provided. The level of core operating profit for this fiscal year is set at almost the same level as the target provided at the beginning of FY2022. How do you, as CEO plan achieving this target and the significance of this target in terms of the level at which it has been set. It is different from the "soft guidance" target and it wouldn't be surprising if you could achieve the latter earlier due to the undergoing structural reforms while, on the other hand, I also have the impression that you have factored in risks such as drug price revisions and generics competition. So, I would like to know what factors led you to set this target. That is my first point. The other point is concerning what you have mentioned in the appendix, but I would like an explanation of how the company utilizes ROIC and how your management plans to improve it.

A6-1-1
Ito: Regarding the first point, as I mentioned earlier, I am not the type of person that optimistically reflects factors with a high degree of uncertainty in how these would change in our projections. This applies to assumptions regarding generics and other factors which outcome are outside of our efforts. Therefore, I have set a sufficiently conservative target, and what I should do is to surpass this target in terms of both sales and profitability. While various things may happen, it doesn't mean I lack confidence. I want to deliver results in a steady way. I hope you understand my answer.

Koshiji: Regarding the second point, we have been tracking ROIC as an important indicator along with ROE on a consolidated basis. We have two concrete initiatives. The first one is the acquisition of new fixed assets. When making investments, we set a hurdle rate that is much higher than our company's weighted average cost of capital (WACC) to evaluate the investments. As our latest impairments suggest, we may have had too loose a standard and we plan to further tighten the processes related to making investment decisions in the future. We also disclose the allocation of existing assets and balance sheet by region in our financial statements, such as in P18 of our Consolidated Performance. While this does not directly become the denominator of ROIC, by analyzing the business from various perspectives, we assess whether appropriate profits are being generated in relation to the capital invested. We rigorously examine each segment from these two aspects. I would like to reiterate that our focus is on monitoring new investments and the profitability of existing operations.

Q6-1-2

Thank you for your thorough explanation. Regarding Ito-san's comment on the first question, it is true that your company's performance has been missing targets in recent years due to external factors such as the quantity of pollen dispersion or the operating environment in China. I hope you will continue to address and be conscious of the importance of bottom-line numbers. I also clearly understand the explanations by Koshiji-san. I hope you will continue on a best effort basis to keep us updated and carry on with what you can do. Thank you very much.