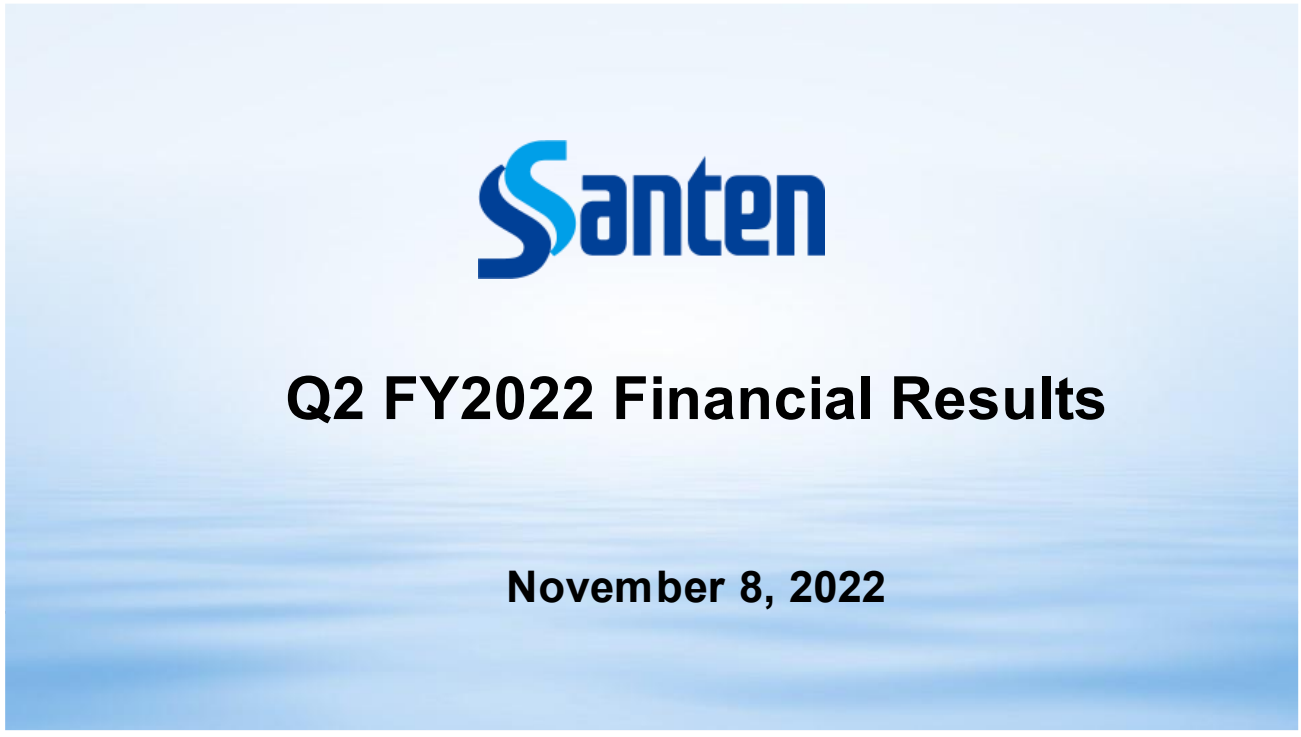
Q2 FY2022 Financial Results Transcript



Summary

Overview

Q2 FY2022 Consolidated results

- Revenue: +0.1% YoY（JPY128.9bil.）
- Core OP: -32.3% YoY（JPY16.5bil.）
- COGS increase from region & product mix and transient causes
- R&D expenses increased from pipeline progress

FY2022 Outlook

- Maintain core operating profit FY initial forecast
- Net profit: Revised downward to JPY-5.5bil. Eyevance impairment

FY2022 Shareholder returns

- JPY16 interim dividend unchanged. Additional JPY13.0bil. share purchase from November 9

Koshiji: Koshiji here. I would like to present our business performance in Q2.

In Q2 of FY2022, sales revenue, JPY128.9 billion, remaining at the same level as in the previous fiscal year. On an IFRS basis, operating profit and the items below it were in the red due to an impairment loss related to Eyevance in the US.

On a core basis, operating profit was JPY16.5 billion, down 32% YoY. The decrease in profit on a core basis was due to the impact of the coronavirus quarantine measures in China, deterioration in the cost-of-sales ratio, and an increase in R&D and other expenses. In light of these circumstances, we have revised downward our full-year forecasts for FY2022, except on a core basis.

On the other hand, with regard to shareholder returns, although profits have been revised downward, the dividend remains unchanged at JPY16 for the interim period and JPY32 for the full year.

Also, as in H1, the Company repurchases its own shares as a complementary shareholder return measure, effective tomorrow.

Q2 FY2022 Consolidated results

COGS ratio and FX impact core OP despite flat revenue
OP: Loss from Eyevance impairment

(JPY billions)	Q2 FY2021		Q2 FY2022		
	Actual	vs Revenue	Actual	vs Revenue	YoY
Revenue	128.8	-	**128.9**	-	**+0.1%**
Cost of sales	52.9	41%	55.9	43%	+5.7%
Gross margin	75.9	59%	**73.0**	**57%**	**-3.8%**
SG&A expenses	39.2	30%	42.3	33%	+7.8%
R&D expenses	12.3	10%	14.3	11%	+15.6%
Core operating profit	24.3	19%	**16.5**	**13%**	**-32.3%**
Non core SG&A expense	0.4	0%	-	-	-100.0%
Amortization on intangible assets associated with products	4.8	4%	5.2	4%	+7.9%
Other income	0.2	0%	0.3	0%	+28.5%
Other expenses	0.5	0%	30.6	24%	-
Operating profit	18.8	15%	**-19.0**	-	-
Finance income	0.7	1%	1.2	1%	+85.3%
Finance expenses	0.4	0%	0.3	0%	-40.5%
Share of loss of Investments accounted for using equity method	0.6	0%	1.1	1%	+65.4%
Profit before tax	18.4	14%	-19.1	-	-
Income tax expenses	4.1	3%	2.9	2%	-29.5%
Actual tax ratio	*22.5%*	-	-	-	-
Net profit	14.3	11%	**-22.0**	-	-
Core net profit	18.6	14%	12.5	10%	-32.8%

Gross Margin

-3.8% YoY

- Revenue: flat to FY2021 partially from positive FX impact.
- YoY higher COGS ratio from changes in product/region mix and one-time contractual-related costs

Operating Profit (Core basis)

-32.3% YoY

- Increase in R&D expenses as a result of pipeline progress
- Increase in SG&A/R&D expenses from FX impact (total of JPY3.9bil.)

Operating Profit (IFRS)

- JPY-19.0bil. (down JPY37.8bil. YoY) primarily from impairment loss of Eyevance (JPY 30.0bil.)

Net Profit (IFRS)

- Positive FX impact on finance income
- Equity-method investment loss

Page six.

Sales were JPY128.9 billion, remaining at the same level as in the previous fiscal year including the positive impact of foreign exchange rates, despite the NHI price revision in Japan and the difficult situation in China.

On the other hand, core operating profit decreased 32% YoY to JPY16.5 billion. This was due in part to a higher-than-expected cost ratio resulting from a changing regional and product mix and increased expenses related to outsourced manufacturing. On the expenses side, there were higher R&D expenses due to the progress of the pipeline, as well as an overall increase in expenses due to the weaker yen.

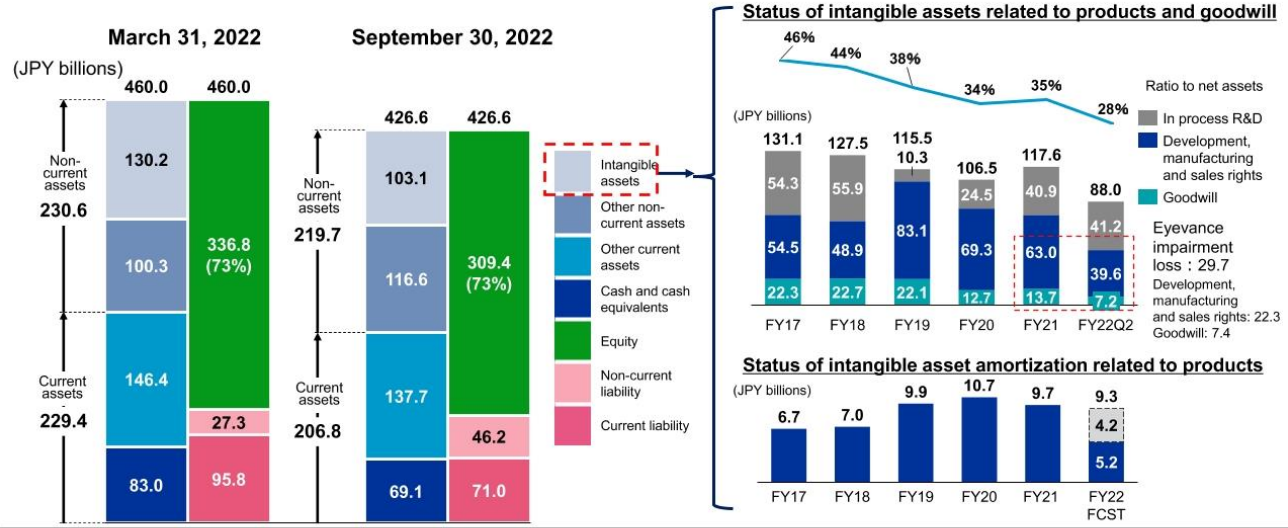
In addition, as disclosed today, an impairment loss was recorded as a result of a careful review of the expected recovery of the investment in Eyevance, the US company acquired in FY2020. The amount is 100%, totaling JPY30 billion.

Details are on page 26.

As a result, operating income on an IFRS basis was a negative JPY19 billion.

Q2 FY2022 financial position

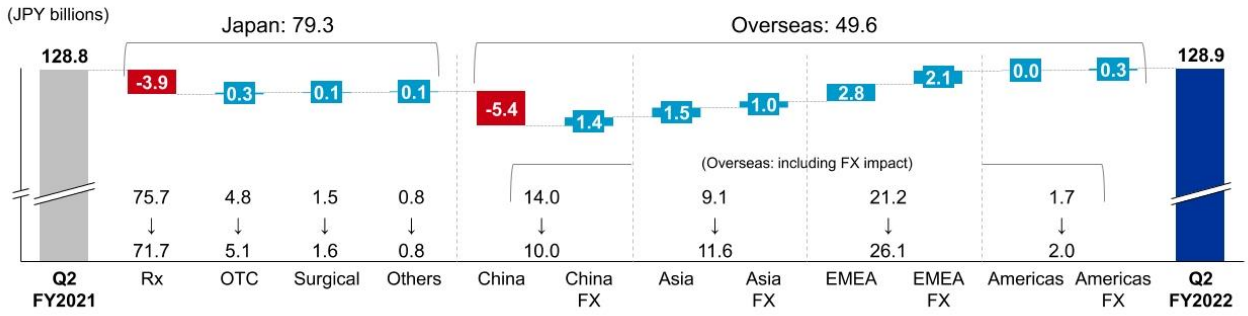
Appropriate balance between financial health & assets increase from investments. Aim for ROE improvement through capital turnover



Q2 FY2022 Sales bridge

Price cuts in Japan and China impact absorbed by other regions

	Q2FY2021 ACT	Q2FY2022 ACT
USD (JPY)	110.09	133.46
EUR (JPY)	131.14	138.61
CNY (JPY)	17.05	19.84



Japan	-4.2% YoY: Steady progress exceeding expectations. Impact from NHI price cuts offset by core products
China	-29.0% YoY (Ex. FX impact -38.9%): Recovery trend, but impact from strict COVID-19 measures expected to continue until Q4
Asia	+27.9% YoY (Ex. FX impact +16.8%): Growth trajectory exceeding expectations led by glaucoma and dry eye in key markets
EMEA	+22.9% YoY (Ex. FX impact +13.1%): Exceeding expectations, primarily driven by glaucoma core products
Americas	+19.4% YoY (Ex. FX impact +2.1%): On a recovery path vs Q1 with FX tailwind on sales

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

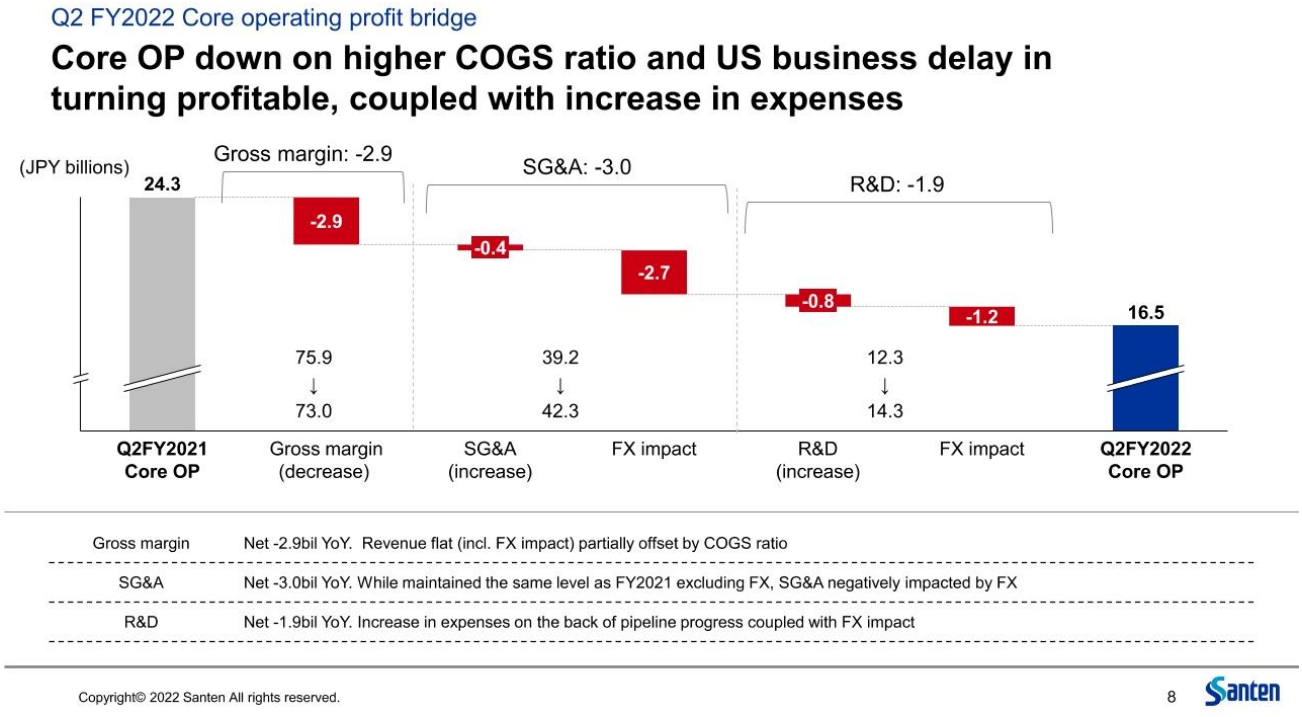
Page seven. Here are the sales revenues by region.

The breakdown is JPY79.3 billion in Japan and JPY49.6 billion overseas. Sales in Japan were down 4.2% YoY. Although there was an impact from the NHI price revision, this was offset by growth in mainstay products and was stronger than expected.

In China, although there has been a gradual recovery in Q2, we have not seen a return to the previous year's level. Sales were slightly lower than we had forecast in Q1.

Asia and EMEA posted double-digit growth on a currency-neutral basis due to growth in core products and in key countries.

Details are shown on pages 21 through 25 of this document and on page 18 of the financial statements.



Page eight shows factors behind the change in core operating profit.

There are three major reasons for the JPY7.9 billion YoY decrease. The main factors are negative JPY2.9 billion in gross margin, negative JPY3 billion due to increased SG&A expenses, and negative JPY1.9 billion due to increased R&D expenses.

First of all, regarding the cost ratio and gross profit factor, the COGS ratio increased from 41% to 43%. This had a significant impact, resulting in a negative of JPY2.9 billion. This is the result of an increase in the cost ratio due to changes in the product mix, such as the NHI price reduction in Japan and the situation in China, as well as one-time costs.

With regards to SG&A expenses factor, it was down JPY3.0 billion YoY including negative impact from yen depreciation of JPY2.7 billion. Excluding the factors due to the yen's depreciation, we believe that we have been able to generally control expenses. However, we recognize that the increase in SG&A expenses as a percentage of sales this quarter, which were below 30% of sales in Q1, is an issue that needs to be addressed.

Next is R&D expenses, which resulted in a negative of JPY1.9 billion. The increase in expenses due to the progress of the pipeline and development, combined with the impact of the yen's depreciation, resulted in a JPY1.9 billion YoY increase.

As a result of these factors, core operating profit was JPY16.5 billion.

FY2022 Outlook: Revised

Core OP: Aiming to achieve initial target

	FY2021ACT	FY2022FCST (Nov 8)	FY2022FCST (May 10)
USD (JPY)	112.57	140.00	125.00
EUR (JPY)	130.75	140.00	135.00
CNY (JPY)	17.55	20.00	19.00

(JPY billions)	FY2021		FY2022 (Nov. 8)							FY2022 (May 10)	
	Actual	vs Revenue	H1 Actual	vs Revenue	H2 Forecast	vs Revenue	FY Forecast	vs Revenue	YoY	FY Forecast	vs Revenue
Revenue	266.3	-	128.9	-	151.1	-	1 **280.0**	-	**+5.2%**	264.0	-
Cost of sales	109.7	41%	55.9	43%	56.1	37%	112.0	40%	+2.1%	103.0	39%
Gross margin	156.6	59%	73.0	57%	95.0	63%	2 **168.0**	**60%**	**+7.3%**	161.0	61%
SG&A expenses	83.9	31%	42.3	33%	49.2	33%	91.5	33%	+9.1%	88.5	34%
R&D expenses	26.4	10%	14.3	11%	16.7	11%	31.0	11%	+17.5%	27.0	10%
Core operating profit	46.3	17%	16.5	13%	29.0	19%	**45.5**	**16%**	**-1.8%**	45.5	17%
Non core SG&A expense	0.6	0%	-	-	1.5	1%	3 1.5	1%	+135.3%	-	-
Amortization on intangible assets associated with products	9.7	4%	5.2	4%	4.2	3%	4 9.3	3%	-4.1%	10.3	4%
Other income	1.0	0%	0.3	0%	0.4	0%	0.7	0%	-37.7%	0.5	0%
Other expenses	1.1	0%	30.6	24%	0.8	0%	5 31.3	11%	-	1.5	1%
Operating profit	35.9	13%	-19.0	-	23.0	15%	**4.0**	**1%**	**-88.9%**	34.2	13%
Finance income	2.5	1%	1.2	1%	0.5	0%	1.7	1%	-33.2%	0.9	0%
Finance expenses	1.2	0%	0.3	0%	0.4	0%	0.7	0%	-42.1%	0.6	0%
Share of loss of Investments accounted for using equity method	1.6	1%	1.1	1%	0.9	1%	2.0	1%	+24.7%	2.0	1%
Profit before tax	35.6	13%	-19.1	-	22.1	15%	3.0	1%	-91.6%	32.5	12%
Income tax expenses	8.4	3%	2.9	2%	5.6	4%	8.5	3%	+0.9%	8.1	3%
Actual tax ratio	*23.7%*	-	-	-	-	-	-	-	-	*25.0%*	-
Net profit	27.2	10%	-22.0	-	16.5	11%	**-5.5**	**-**	**-**	24.4	9%
ROE	8.4%						-			7%	
Core net profit	35.2	13%	12.5	10%	21.6	14%	34.1	12%	-3.1%	34.1	13%

1 Increase from progress over regions and positive FX impact

2 Reflecting COGS control effect in 2H

3 Structural reform costs and others

4 Decrease in depreciation/amortization associated with Eyevance impairment loss

5 Eyevance impairment loss of JPY30.0bil.

Next, page nine shows the full-year forecast for FY2022.

First, the stage profit under core will be in the red on a net income basis, reflecting the impairment of Eyevance.

On the other hand, we recognize that sales and core profitability will not decline significantly, although profits declined significantly in H1.

Core profit is expected to differ from H1 due to the launch of *Diquas LX* in Japan, recovery in China compared to H1, and the strengthening of the Company's new system, which was introduced effective September 12 under the new management structure. Specifically, we are assuming a 10% increase in sales and a 17% increase in gross profit over the previous year in H2, and a cost of sales ratio of 37%.

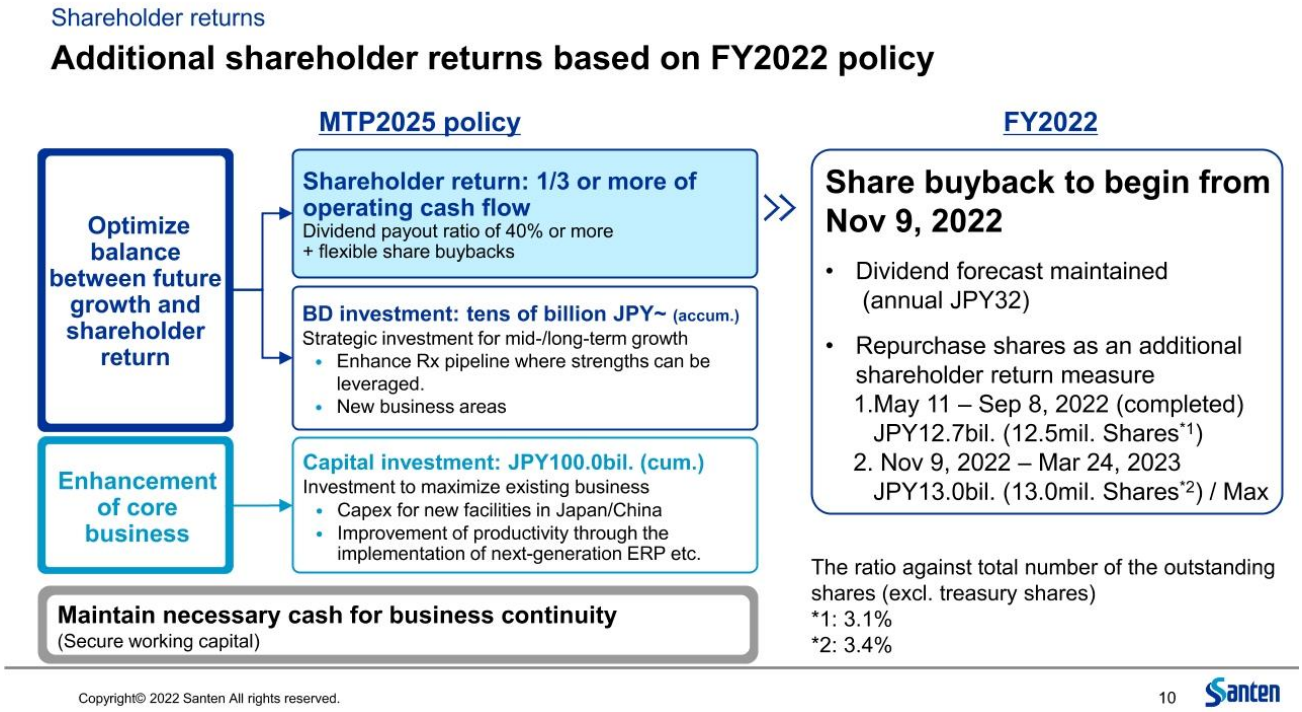
This will absorb increases in SG&A and R&D expenses. We plan to realize core operating profit of JPY29.0 billion in H2. The cost of sales ratio, which is a particularly important point, swung as high as 43% in H1 due to the regional mix and one-off factors such as outsourcing-related expenses. However in H2, we expect changes in the regional and product mix, with the ratio of sales of *Alesion* set to increase and the launch of *Diquas LX*. As a result, we expect the cost-to-sales ratio to fall to 37%, giving a full-year figure of 40%. In Q2, we updated our full-year forecasts by product to include these changes in H2. This is shown on page 18 of consolidated performance.

The main upward revisions are for *Alesion* in Japan, which is JPY4.8 billion, and *Diquas* in Japan, which is JPY2.9 billion. We believe that these high-profit products will deliver results in H2.

Nevertheless, there are still uncertainties, such as the business environment in China and the pollen count in Japan. We recognize that it will be quite challenging to recover from the decline in H1, but we plan to achieve the initial forecast figures in the remaining period by further increasing sales, optimizing costs, and other measures.

We will promptly disclose any discrepancies in our plans after reexamining the quick hits in the current period and re-examining the degree of recovery in China in light of the time line for structural reforms. This will be explained later by the CEO.

Other information under core operating profit is as shown.



Page 10. This covers shareholder returns.

As I mentioned at the beginning, we will repurchase 6.5% of our shares over the full year. This is the largest share buyback in our Company's history, and was set with the upside of the share price after the acquisition in mind.

This concludes my presentation. Thank you very much.

R&D update

Made steady progress in late phase pipelines
New disease and mode of action on keratoconjunctival disease

STN1011700 *EYBELIS / OMLONTI*	Glaucoma	**Approved** in US
STN1013001 Catioprost	Glaucoma	**Filed** in Europe
STN1012600 Sepetaprost	Glaucoma	Achieved **FPI**[*1] in P3 trial in Japan
STN1011402 Epinastine ophthalmic cream	Allergic conjunctivitis	Achieved **primary endpoints** in pivotal trial (P3) in Japan
STN1013800 Oxymetazoline hydrochloride	Ptosis	Achieved **FPI** in P3 trial in Japan
STN1012600 Sepetaprost	Glaucoma	Achieved **LPI**[*2] in P2 trial (exploratory study) in Europe
STN1010905 Sirolimus eye drop	Meibomian gland dysfunction	**Not meet primary/secondary endpoints** in P2a trial (exploratory study) in Japan. But **observed efficacy on some exploratory endpoints** and detailed analysis in progress
STN1014100 Olodaterol hydrochloride	Dry eye	**Started preparations for P1/2a trial** in Japan

*1 FPI; First Patient In. *2 LPI; Last Patient In.

Sallstig: I would like to update with regards to status of the pipeline.

First of all, we will introduce the development code with only three numbers indicating the active ingredients. In the document, the numbers are in bold.

See page 12. This quarter has seen a lot of progress, mainly in glaucoma. In September, 117, marketed as *Eybelis* in Japan and Asia, was approved in the United States.

In Europe, we filed for marketing approval of 130, which is a cationic emulsion of latanoprost. In addition, we initiated P3 of 126, sepetaprost for glaucoma in Japan. So good progress overall. Other than glaucoma, in 114, subjects with allergic conjunctivitis achieved the primary endpoint in our pivotal studies in Japan. I will explain about this later.

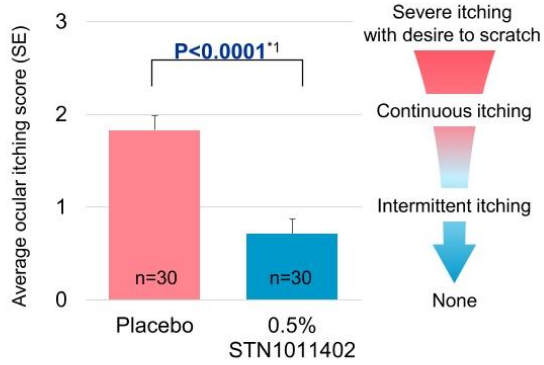
As for 109, sirolimus eye drop, for the treatment of meibomian gland dysfunction, the PoC study did not meet the primary and secondary endpoints. Having said that, there are however no established endpoints for this disease. Therefore, when looking at additional exploratory endpoints this study showed efficacy of meibomian gland function. The data is still subject to further analysis to help determine next steps.

We are also preparing to start 141/olodaterol clinical trials with the aim of providing new dry eye therapeutics.

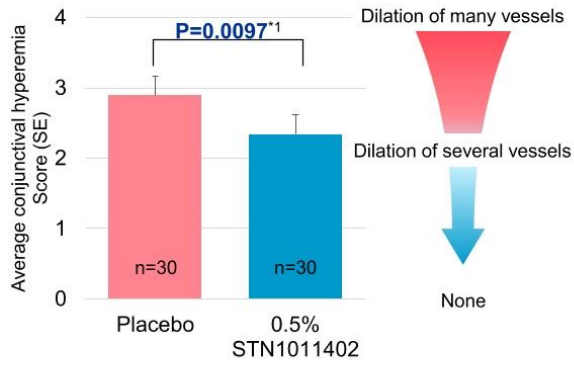
STN10**114**02: epinastine HCl (ophthalmic cream)

Achieved primary endpoints on pivotal trial (P3)
Confirmed safety and tolerability

Efficacy on ocular itching after 24 hours



Efficacy on conjunctival hyperemia after 24 hours



◆ **Demonstrated same changes level as 0.1% epinastine ophthalmic solution on long-term trial** (see Appendix)

*1 Wald test of linear mixed effects model

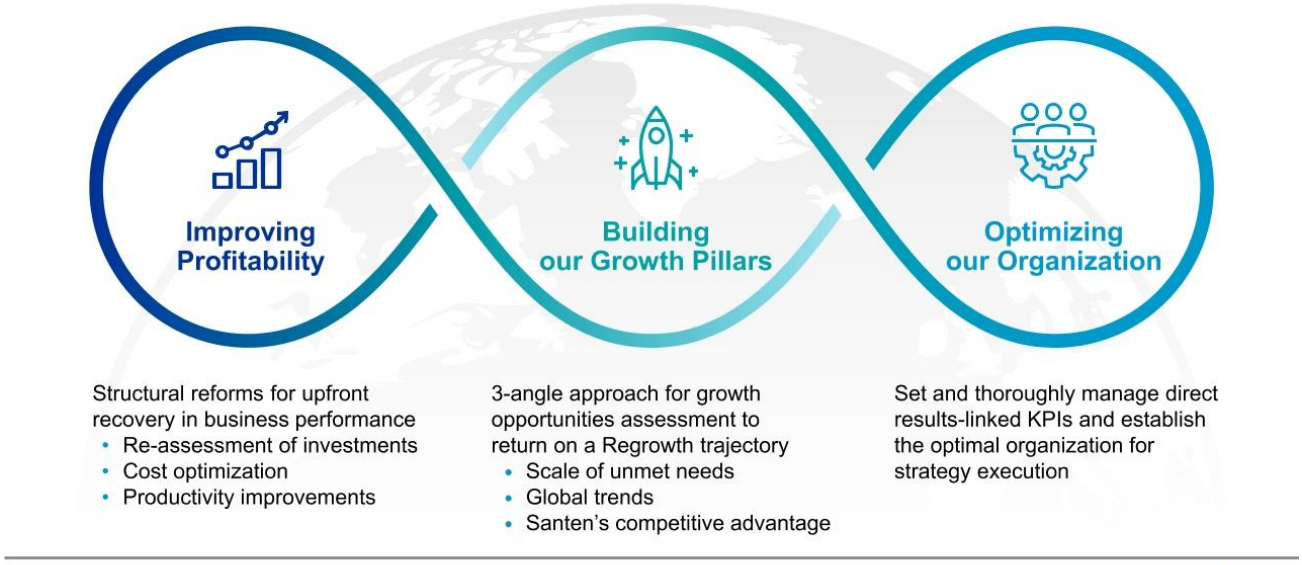
Next, I would like to explain the results of the pivotal study of 114, *Alesion* cream.Please move on to page 13.

We are developing cream formulation to further improve the convenience of *Alesion LX* applied twice a day, and to ensure all-day comfort for patients on the basis on once-a-day dosing.

In the pivotal study, both itching and conjunctival hyperemia showed statistically significant improvements compared with the placebo group, achieving the primary endpoint.

In a long-term study with *Alesion LX* as the reference group, similar changes were observed in both indices of itching and conjunctival hyperemia. We are preparing for submissions later in this fiscal year.

This concludes my part. Thank you.



Ito: Ito here. Thank you. I would like to explain the measures we are currently considering to return Santen to growth.

Looking back over the past few years, Santen has taken on a variety of challenges, but unfortunately, in terms of profits, we have not been able to meet the expectations of our investors. Therefore, since assuming the position of CEO in September of this year, I have been working to develop a concrete plan to create a path for Santen's growth. Today, I would like to share that plan with you.

First, please see page 15. We intend to promote the three measures shown on this slide for growth.

The first is to improve profitability. While we are making various new efforts, I personally believe that we are currently not sufficiently disciplined in various aspects, including costs. By steadily implementing structural reforms, we will strive to get back to where we should be in terms of business performance.

The second is to establish pillars for growth. While there are, of course, things that seem to be working and have shown potential in our various efforts to date, there are others where that cannot necessarily be said. We would like to take these circumstances into consideration as we move forward with the development of a renewed strategy for growth.

When we consider our growth strategy, the most important thing is how we can deliver unprecedented and important value to consumers and patients through our products and services.

Of course, there are still many individuals in the world who have great trouble with their eyes. I believe that it is the mission of Santen, and myself, to add significant value to the lives of those individuals. Basically, we would like to consider our future strategy based on a firm return to these starting points.

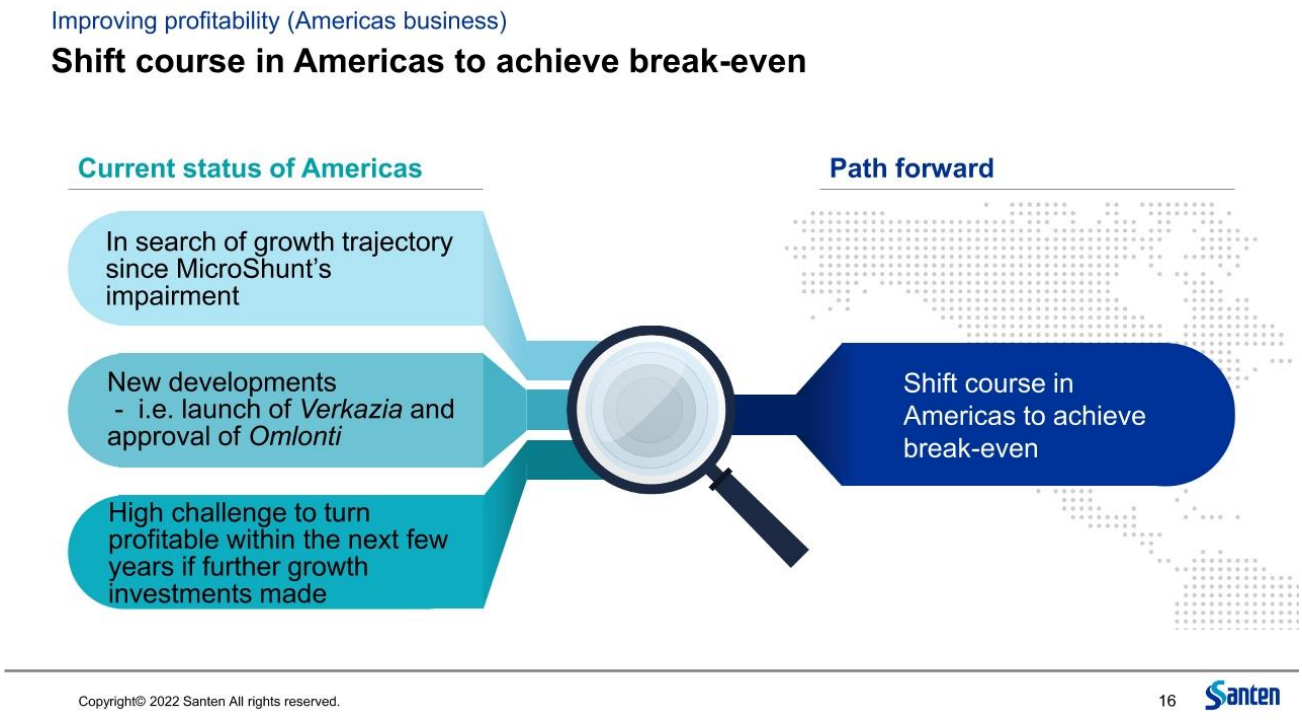
Of course, it is important to keep abreast of the world's technological trends. We will not just follow the trends, but we will also carefully reevaluate our efforts to ensure that they are connected to our original strengths, that they can be reliably delivered to patients and consumers, that they can solve unmet needs in the world, and what the time frame is for their delivery. I will reevaluate these issues myself and link them to our future growth. That is my personal plan.

The third is to build an optimal operational and organizational structure. We would like to establish KPIs that are directly linked to results and conduct thorough monitoring. We would also like to create an organizational structure that will enable us to do so and to link our strategies to results.

I am sure you will understand that I am stating the obvious, but I personally believe that we have not been able to fully accomplish what I have just mentioned as we have been expanding our new initiatives over the past several years. At the same time, we also feel a sense of responsibility. We would like to establish an organizational structure in which KPIs that lead to these results are firmly incorporated into the organization and monitored.

I will work out the details of the three measures I have mentioned above, and as CEO, I will implement them steadily and promptly.

Today, out of these three measures, I would like to focus on improving profitability.



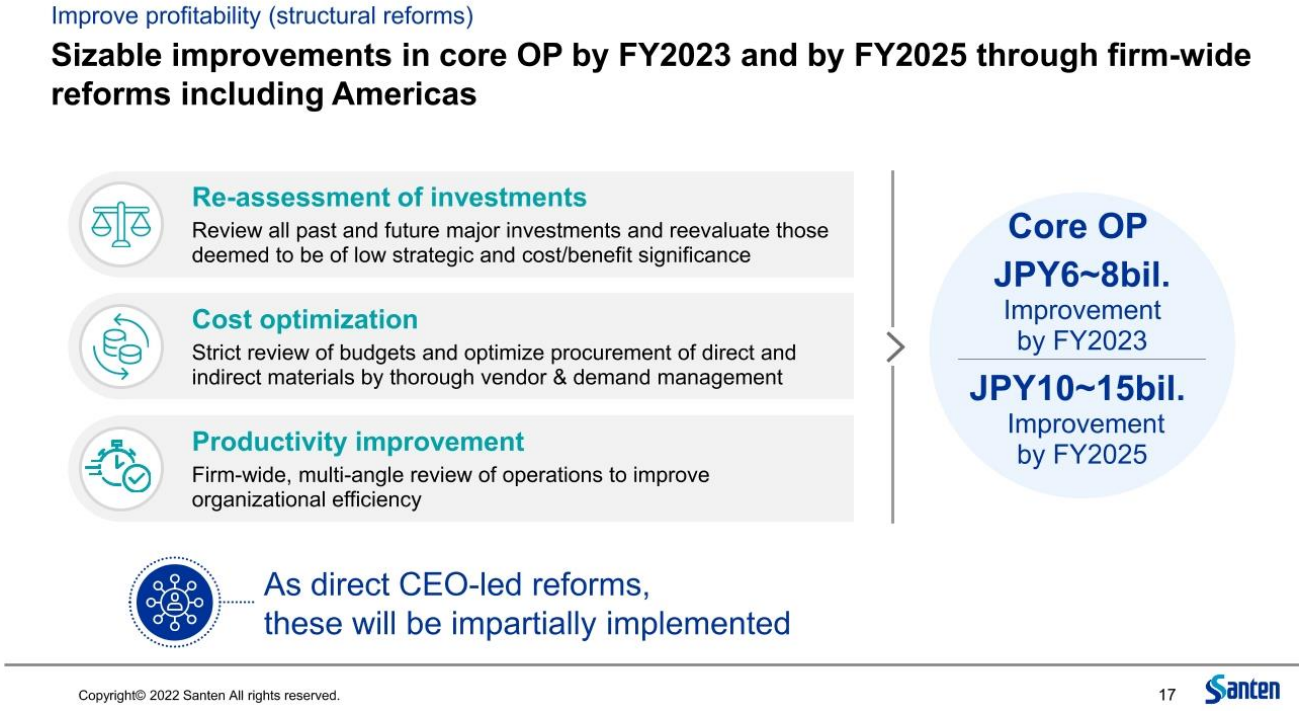
See page 16. First of all, I would like to talk about our recognition of the current status and direction of our business in the Americas.

As you are all aware, since the MicroShunt impairment in fiscal 2020, we have been planning to achieve significant growth in the Americas by putting our developed products on the Eyevance business platform, which we acquired before that. With this in mind, we have successfully launched or obtained approval for products such as *Verkazia* and *Omlonti*, for example.

However, in order to achieve significant growth in the Americas with these product lines, we have determined that it will be difficult to turn a profit even if we invest more aggressively in resources or expand our investments.

We have come to the conclusion that first of all, stopping the bleeding, or in other words, reducing the deficit, is probably the most important thing for Santen to return to a growth path in the medium

to long term. In our business in the Americas, we have changed direction, and we will work to reduce the deficit as the most important issue.



Next, page 17. This section describes the improvement in profitability of businesses other than the Americas business.

One is to review investments. We have made significant investments in the past. In fact, however, some of them are showing a slight gap when compared to the current business environment. We will thoroughly review past, ongoing, and future investments from a zero-base perspective, and review those that do not meet our strategic and cost-effectiveness criteria.

The second is cost optimization. As I mentioned at the beginning, I believe that this is an aspect of the lack of sufficient discipline. Basically, we would like to rigorously review the process from budget formulation to its management. And at the same time, we would like to optimize procurement of direct and indirect materials by stringently managing vendor orders and unit prices, as well as managing demand generated within the Company.

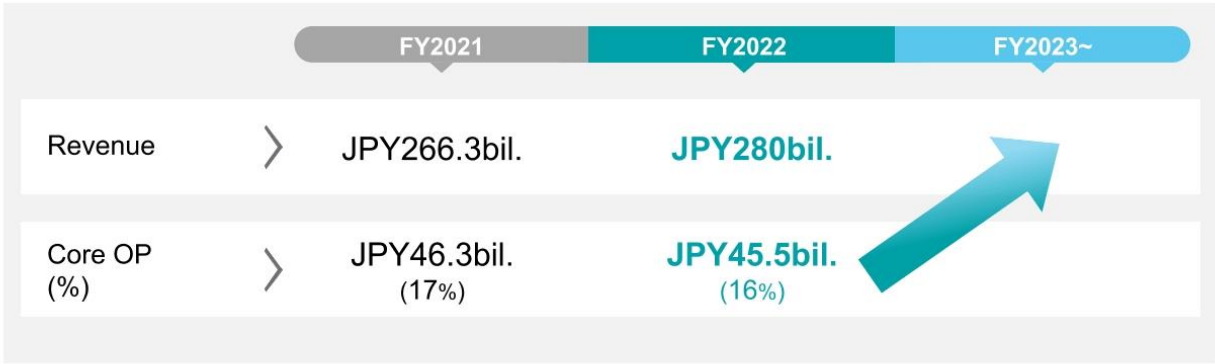
The third is to increase productivity. In the past, the Company's scope of business expanded rapidly, and it has continued to expand its scope of operations and the organizations that execute those operations, in the form of further up-front investment. We would like to improve the productivity of the entire organization by reviewing our operations from all perspectives throughout the Company at this time.

By combining the promotion of structural reforms described above with the review of the direction of our US business, as explained on the previous slide, we hope to improve core operating profit by JPY6 billion to JPY8 billion in FY2023.

In FY2025, we would like to improve our earnings so that these results will be on the scale of JPY10 billion to JPY15 billion.

Target KPI

Target core OP growth as focus on business profitability



Implement necessary reforms to allow for profit generation resilient to business environment conditions

I would like to touch a little on what numbers we should target in implementing these reforms and delivering new growth in the Company.

As we move forward with structural reforms, we expect to see some one-time gains and losses. For this reason, I would like to place the highest priority on core operating profit, which is a measure of the Company's ability to generate earnings. We are committed to promoting structural reforms and transforming our corporate structure into one that can generate earnings regardless of the business environment. As a result, we will place the highest priority on creating a form of continuous growth in core operating profit.

This is the last slide. Page 19. I would like to explain the future milestones of the measures that I mentioned at the beginning of this presentation.

Today, I have explained in some detail the direction we are taking with regard to improving profitability. Furthermore, we hope to be able to explain the progress of this element in more detail when we announce our Q3 financial results.

Regarding the second point, that of establishing pillars for growth, we hope to be able to introduce a specific direction at the time of the announcement of the Q3 financial results.

Finally, we would like to integrate everything, including the establishment of this optimal operational and organizational structure, and create a new mid-term plan by the end of March 2023. We would like to present this plan to you at an appropriate time.

By steadily achieving these mid-term plans, we will contribute to patients, consumers, and healthcare professionals. At the same time, we would like to improve our corporate value. As a result, we would like to create a structure that will enable us to firmly meet the expectations of our shareholders and investors.

On behalf of the Santen Group, I would like to ask for your continued support. Thank you very much for your kind attention.

Question & Answer

Q1-1:
On the first point, regarding structural reforms, today you have shown us the extent of improvement in earnings. I am well aware that the details are still to be worked out, but basically, it sounds like the idea is to raise the profit base by reviewing costs, not so much the top line, but rather costs and structural reforms, which will be implemented strongly this fiscal year and next fiscal year. I would like to know if this is correct and if you have any information about the main items. This is the first question.

A1-1:
Ito : Thank you. Of course, the main focus will be on improving the cost and expense aspects as you have just pointed out. However, if we also consider factors such as the reallocation of resources, I think it is possible that this is somewhat connected to the top line.

As I explained earlier, I would like to be more specific in Q3, and if possible, I would like to talk about the cost reductions that we plan to implement in this area. I would be happy to discuss with you in more detail at that time, if possible, how we plan to reduce costs.

However, I believe that the figures I have just mentioned have a good basis at this point. For example, regarding the Americas business, how many options are available, and what would be the form of each pattern? We have already finished looking at a certain range of investment reviews, cost optimization, and productivity improvement.

Of course, these are not all 100% achievable, so today's explanation is the sum of the figures that are expected to be achieved at least to this extent. We hope you understand it that way.

Q1-2:
Thank you very much. Secondly, I would like to make a simple point, and it is related to what you have just said, but I think that this time you have announced a shift in strategy in the US. Perhaps you would call it a shift, in a sense, an impairment loss, and the message has come out strongly that the deficit in the US must be reduced.

We have been talking about this for some time, but now that *Eybelis* has been approved, how do you plan to sell this product in the US? On the subject of sales in the US, it seems as if for the first time in about 20 years, lots has come in, and I think there was talk of pulling out once in the past. This time, basically, your company is reviewing its own full-fledged efforts, including *Eybelis*, and the strategy for the US will be revised quite a bit once you are in that area. Compared to other regions, I understood that the US is the only country where you have taken a step in that direction.

A1-2:
Ito : Ito here. Yes, I think that understanding is fine. Business will continue. Our current development pipeline is also very promising for the future. Basically, I believe that in order to break into the US market, we must enter with products that are highly differentiated and have decisive product appeal.

If you are asking me if there is anything like that in the pipeline right now, I would say that yes, I think there is. We have that kind of decisive product in the pipeline. Therefore, we are not in a hurry to withdraw from the market, but rather, first of all, we must firmly control the deficit. We believe that this does not take the approach of unnecessarily chasing the top line now. Thank you.

Q2-1-1:
I would like to ask a little more about the improvement of JPY6 billion to JPY8 billion, which you said you have a fairly certain outlook for. Productivity, and especially gross profit margin, may be related to the improvement of gross profit margin in H2, but when I look at your company's performance like

this, gross profit margin has been at a fairly low level since Q3 of last year. That has continued in H1 of this fiscal year.

This time, of course, in H2, the product mix will change, and I think that we will see a rebound in China, but is such cost improvement also included in H2 in terms of gross profit?

I believe there was some sort of penalty on the commissioning of this by a company called Next Pharma or something like that, but I think just getting rid of that would be an improvement to some extent. Can you tell us first of all how we should look at the connection between the improvement in H2 and this cost improvement, and what is the productivity aspect of this improvement?

A2-1-1:
Ito: Thank you. First, Mr. Koshiji will answer your question about H2, and if necessary, I would like to make some additional comments.

Koshiji: For H2, I mentioned earlier that the cost ratio for H2 alone will be 37%, which is a 6% improvement from 43% in H1.The main reason was, as I mentioned earlier, from change in product mix.

As I mentioned earlier, the relative increase in the ratio of *Alesion* sales, and *Diquas*, will contribute to our achievement of the initial earnings forecast.

In this respect, the contribution of these products compared to the previous year will also increase. In theory, the cost ratio, which has been slightly high since Q3 of last year, can be brought down.

One-time expenses, or CMO-related expenses, totaled approximately JPY1.2 billion over H1, but in theory this is a one-time expense and is not expected to continue in the next fiscal year or thereafter.

However, this is slightly tied to the CMO and its commitment to the volume of purchases, and to a certain number, so depending on the volume of purchases, it may continue into the next fiscal year. We are aware that this is an issue to be considered in the future, including the terms and conditions of the contract with the other party. Thank you.

Q2-1-2:
In short, H2 does not include any new initiatives, just the usual product mix, and next year, other productivity improvements will be added, is that correct?

A2-1-2:
Koshiji: Yes. However, although we are making self-initiated efforts on a daily basis within the Company, the effect on cost to sales ratio is 1%, which is equivalent to JPY2.8 billion, so we perceive only this would not meet the overall level of cost cut effect.

We are now considering how to make it a little larger and how to influence the percentages. Thank you.

Q2-2:
Regarding SG&A expenses, there are some low-hanging fruit, such as organization of staff in America. Also, I have always wondered about the JPY12 billion in professional fees and commissions for the fiscal year ended March 2022. I think that this could easily be cut by JPY2.0 billion to JPY3.0 billion.

A2-2:
Koshiji: In that respect, not all of the fees and commissions can be reduced, but we recognize that

there is much room for review. As a result, a certain percentage of the JPY6.0 billion to JPY8.0 billion that the CEO just explained will be accounted for by such fees and commissions.

Q2-3:
Okay. Lastly, I was wondering if you could give me just a hint about the growth pillars mentioned here. I think DE-127 will probably be included, but other than that, what else is your company currently focusing on?

I was thinking that Catioprost is the biggest one. Are there any others? Also, would *PRESERFLO MicroShunt* be another? Maybe you can give us some hints as to what kind of things would go into the growth pillars now. Thank you.

A2-3:
Ito: From the viewpoint of development products, I think there are two areas of particular promise: the atropine drug for myopia, which is currently under development, and new drugs for ptosis.

We believe that Catioprost has plenty of room for growth in Europe, and the *PRESERFLO MicroShunt,* which was launched in Japan a few months ago, has been very well received.

As for products, I think that the myopia program and the ptosis program, for which no drugs have been available so far, are very promising.

Q3-1-1:
The first question is about the profit improvement you indicated on page 17.

Do you expect the improvement effect to include a decrease in R&D expenses as a result of the reevaluation of investments? If possible, could you please provide us with the approximate level of improvement of cost of sales, R&D, and SG&A expenses that you expect to achieve?

A3-1-1
Ito: Thank you. I think your question was about the extent to which R&D expenses are included in the structural reforms, but of course this does not mean that there is no R&D component in the structural reforms.

On the other hand, when we talk about investment in development projects themselves, it has been difficult to make steady progress in all projects in the recent past, as we have not been able to generate a solid core operating profit.

We are hoping to allocate a portion of the expenses from the implementation of these profit improvements to investments to move forward with research and development projects. The amount of improvement in earnings shown here is based on the assumption that there will be a slight increase in investment in direct R&D projects. Thank you.

Q3-1-2:
In other words, you are projecting this improvement effect as a gross effect of structural reforms rather than an increase in core operating profit by this amount on a net basis.

A3-1-2:
Ito: Yes, that's right.

Q3-2-1:
I understand. Thank you very much. Second, could you tell us your thoughts at this point on how to monetize *Eybelis* in the US?

A3-2-1:
Ito: I will answer that as well. Preparations are now underway in the US for the launch of this product. On the other hand, I believe that the resulting label makes it difficult to differentiate between this and conventional prostaglandins.

Therefore, as I mentioned earlier about turning around the US business and reducing the deficit, we are currently in the process of considering which products, in which segment, in what way, and with what resources are best suited to be invested, while laying out a number of options.

I hope to be able to discuss some more specifics at the next briefing.

Q3-2-2:
At this point, I guess you can't tell us when the product will actually go on sale or what immediate sales are forecast.

A3-2-2:
Ito: Indeed. I would appreciate it if you could give me a little more time, as I believe that sales will depend on market segment and the degree of resources invested in the project.

Q4-1:
First of all, I would like to ask you about the impairment loss in the US. What is the background of the decision that led to the impairment loss this time? I would like to know how you arrived at this decision based on the assumptions you made regarding the future sales and profit forecast.

In addition, I would like to know if there has been any change in your viewpoint, as you said in Q1 that you would like to aim for core operating profit of about 50.0 billion next year, even in light of the impairment loss this time. Thank you.

A4-1:
Ito: Mr. Koshiji will take your question.

Koshiji: First of all, regarding the impairment of Eyevance, we acquired Eyevance in FY2020. When we announced it in our current mid-term management plan, we said that in FY2025, we expected JPY24.0 billion in US sales and JPY13.0 billion in contribution profit.

Considering the Eyevance contribution, we were looking at sales of about JPY12. 0 billion, profit of JPY7.0 billion. As you know, we were in the red last year, and we are still in the red this year, and there is no prospect of monetization at present. As such, after testing for impairment and re-projecting, we are unable to find a projection that will allow us to reach JPY10.0 billion in sales in the medium term, or to turn a profit in the long term in FY2025.

As a result of the impairment test based on the projection, we concluded that the fair value of the asset was significantly lower than the book value, and therefore, the asset had to be impaired. Does that answer your question?

The second point is that the above is related to impairment. We are aiming for JPY50.0 billion in core operating profit next year, which in percentage terms is roughly a double-digit increase from the current year's core operating profit forecast.

As the CEO explained earlier, based on the current JPY45.5 billion, we are looking at JPY6.0 billion to JPY8.0 billion improvement. Considering the effect of this profit improvement, even if we have to make a small change, we are aware that we are looking at a level of JPY50.0 billion. We are not yet

at this stage in the budget formulation and compilation process, but that is the way we see it. Thank you.

Q4-2:
Thank you very much. Second, I would like to know about the domestic business. When you raised the forecast for *Diquas*, I think you probably included the contribution of LX. I wonder what kind of market penetration you are assuming when the LX formulation is released. Also, I would like to ask for your comments on the next fiscal year and beyond. Can we expect sustainable growth with the emergence of this LX formulation, even though generic competition and the like are inherently conceivable? Thank you.

A4-2:
Ito: Thank you. As for *Diquas LX,* we believe that the results of the clinical trials and development were truly excellent. Naturally, there are risks involved, so we always consider a certain range, but I believe that we were able to complete the clinical trial with results that were almost at the highest level of achievement.

I believe that the value of this product to patients was fully reflected in the comments received during the approval review process. Some new mechanisms of action were described in the package insert.

The existing product *Diquas*, which has been on the market for some time now, has become so large that its sales have already exceeded JPY15.0 billion once and it has received a re-calculation of the NHI drug price. On the other hand, if we look at the percentage of patients with dry eye, less than 30% are receiving this treatment. The reason why only 30% of the patients use this product is because of the high frequency of eye drop administration, or because of the irritation. This LX formulation addresses both of those points.

Therefore, I don't want to sound biased, but I am quite confident. Originally, we had not factored that much into our annual sales plan, so we are expecting a considerable upward revision to our original plan. I hope this has answered your question.

Q5-1:
I have heard that you are reviewing this strategy, but in September, you announced the transition to a new system. At that time, I think you also publicly announced that you would review your growth strategy. I think the progress towards a new mid-term plan will probably come out at the end of January or beginning of February, since this is when the Q3 financial results are announced. However, it seems to me that the time frame is a little long. How will this time be used?

If you are talking about management restructuring, the sooner you let the outside world know about it, the better it will be, including for employee motivation. What do you think about the time frame and how you are planning this schedule? What are your thoughts during this time?

I think you already have a lot of the parts, so I'm wondering if you are just going to combine them or if there will be some internal adjustments.

A5-1:
Ito: Thank you. I would like to say that we are very sorry if we have created any misunderstanding that we would be announcing more specific growth strategies in today's session.

As I explained today, I believe that no matter what strategy is adopted, the first step must be to build a solid profit structure on a firm footing, and I have been working on this as my first priority since taking my current position in September.

However, on the other hand, we are not saying that we will start discussing growth strategies from here. Of course, we have been considering this process up to this point as well as during the process itself. We have come up with several options and are now discussing the necessary discussions internally.

As you have just pointed out, we believe that the best way to achieve this is to combine the various structural reforms and growth strategies into a neat set for discussion, but in the two months that we have been here, this is the where we have reached.

Q5-2-1:
Okay. This wasn't mentioned today, but I'd like to know how you view the competition with *Eylea* from *Vabysmo*.

Also, this is often talked about, but the Regeneron *Eylea* is at a high concentration. Considering the future of *Eylea*, I think this is probably the best way to cooperate with Santen, but can you say anything about the status of the Company's negotiations? Are they in progress?

A5-2-1:
Ito: Thank you. The name of another company's product, *Vabysmo*, has been mentioned. Naturally, we were well aware from the planning stage at the beginning of the year that competing products would enter the market in May of this year. How much erosion will occur at that stage? To be more specific, we have factored into our plan what share of the VEGF market our competitor's products will take. Our understanding is that the current situation is a little lower than we had expected, and that we have been able to produce the results of our thorough consideration. That is one thing.

As for the higher concentration of *Eylea*, the 8 mg formulation, Regeneron and others have already reported the results of global clinical trials, and we have naturally heard about them and believe that the results are excellent. I may have mentioned this before, but basically, we are the ones who will be selling these products. Thank you.

Q5-2-2:
Is that confirmed?

A5-2-2:
Ito: That's what the contract says.

Q5-2-3:
Is it correct to say that it is finalized, not AG?

A5-2-3:
Ito: Yes. AG too. This one will also be cooperated with Santen. Of course, not all the details of the contract are in place, but the main points of the contract are established.

Q6-1:
I would like to ask you to explain again what will change now that Mr. Ito has assumed the position of president.

I would like to ask how Mr. Ito is trying to change the Company now, considering two major impairments in a short period of time, and that he was involved in the decision-making process previously as a director. Please explain again what we, as investors and capital market people, should expect from your company now. Thank you.

A6-1:
Ito: Thank you. As to your question about what will change, you mentioned impairment. I would like to explain a little about what I think about this. As I reflect on this, I also regret that my judgment on various investment opportunities was a bit poor in terms of risk assessment.

I have to admit that I was a little lacking in rigor and didn't sufficiently scrutinize what kind of market size the deal really was, if it was a product introduction deal, for example, and what kind of figures we could really achieve. I regret that. We will do our best to avoid such a situation in the future.

I don't know if this will answer your question about what would change, but, for example, we have been asked earlier about our *Diquas LX* product. The patent for the formulation of *Diquas* itself will continue for the time being. Next year, the patent for its use will expire. Such a thing can be expected years in advance, unless, for example, the next level of improved products are developed at that time. The kinds of things to think about are what kind of products should be developed, what kind of things are necessary and at what time, in view of the reality of the current dry eye disease among today's patients and consumers.

In addition, we will be launching *Diquas LX* at the end of November, and we are also facing a major issue in dry eye treatment today: patients have difficulty in understanding the disease. Even though it is a chronic disease, it is treated only in the short term. We will also combine this with a completely different dry eye treatment support system, which is a simple digital technology that will support doctors in communicating this information during their daily treatment time.

As for the Japanese business, we have been trying to achieve solid growth in sales, rather than increasing costs and personnel, as has been the case in the past.

As I said at the beginning of this presentation, we have been working on various initiatives, and results have been mixed. I believe that we are good at making a clear distinction between these things, reassembling the various elements, and linking them to the results. We would like to continue conducting this form of analysis, making sure that the results obtained from past efforts will lead to the next concrete numerical results. I'm not sure if that answers your question, but in the context of your question, I think these are important points to address.

Q6-2:
Thank you very much. Corporate and shareholder value have been stagnant for quite some time. Although you have been buying back many of your own shares, I would like to know what you think about the current situation.

A6-2:
Ito: Thank you. One reason, as I mentioned earlier, is that we have not been able to achieve solid results in our business, as represented by our core operating profit. Recently, what we have worked on has not necessarily always resulted in success. I will take this seriously and work to achieve solid results that are more consistent than our recent results.

Q6-3:
Thank you very much. The value of what you are doing as a company is recognized by the capital markets as very valuable. You have a good business that solves social issues, so I hope that you will become a company that is well accepted in the capital markets. That's all from me. Thank you very much.

A6-3:
Ito: Thank you.

[END]