Q3 FY2023 Transcript

Q3 FY2023 Financial Results

February 8, 2024

Santen Pharmaceutical Co., Ltd.

Financial Results

Kazuo Koshiji
Chief Financial Officer &
Chief Risk Officer

Q3 FY2023 Consolidated results

Strong progress in revenue and core operating profit. Overseas business driving growth

	Q3 FY2022 ACT	Q3 FY2023 ACT
USD (JPY)	136.22	143.61
EUR (JPY)	140.43	155.60
CNY (JPY)	19.86	20.07

(JPY billions)	Q3 FY2022		Q3 FY2023			FY2023	
	Actual	vs Revenue	Actual	vs Revenue	YoY	Forecast Nov. 7	vs Revenue
Revenue	199.8	-	**222.8**	-	**+11.5%**	302.0	-
Cost of sales	85.4	43%	91.4	41%	+7.0%	121.0	40%
Gross profit	114.3	57%	**131.4**	**59%**	**+14.9%**	181.0	60%
SG&A expenses	65.5	33%	64.1	29%	-2.2%	94.0	31%
R&D expenses	21.7	11%	18.0	8%	-16.7%	29.0	10%
Core operating profit	27.2	14%	**49.3**	**22%**	**+81.5%**	58.0	19%
Non-core expenses	-	-	1.0	0%	-	1.1	0%
Amortization on intangible assets associated with products	7.2	4%	7.1	3%	-2.0%	9.4	3%
Other income	0.5	0%	1.4	1%	+161.3%	1.5	0%
Other expenses	30.6	15%	6.4	3%	-79.1%	8.0	3%
Operating profit	-10.1	-	**36.2**	**16%**	-	41.0	14%
Finance income	1.0	0%	1.3	1%	+32.0%	1.5	0%
Finance expenses	0.7	0%	1.0	0%	+38.4%	1.2	0%
Share of loss of investments accounted for using equity method	1.7	1%	2.9	1%	+69.2%	3.0	1%
Profit before tax	-11.6	-	33.6	15%	-	38.3	13%
Income tax expenses	4.5	2%	7.0	3%	+55.3%	8.8	3%
Actual tax ratio	-	-	*20.8%*	-	-	*23%*	-
Net profit	-16.1	-	**26.6**	**12%**	-	29.5	10%
Core net profit	21.2	11%	39.6	18%	+87.2%	43.5	14%

Gross margin

+14.9% YoY

- Revenue: Strong progress mainly from overseas YoY: +11.5% (consolidated), +25% (overseas) (Including one-time factors in H1*1)
- COGS: Ratio decrease excluding above-mentioned one-time factors from region/product mix

Operating profit (Core basis)

+81.5% YoY

- Improved Core OP ratio. Reduced SG&A from cost optimization, personnel costs reduction by structural reforms and offset foreign-currency denominated expenses increase from weaker JPY

Operating profit (IFRS)

- Other income: Upfront related to Americas of JPY 0.7 billion*2
- Structural reforms cost: JPY 6.8 billion (non-core expenses and other expenses)

Net profit (IFRS)

- Tax ratio excluding one-time factors including impairment loss in FY2022 and structural reforms: 24.1% (FY2022), 20.6% (FY2023)

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*1:Re-evaluation of *Ikervis* allowance for insurance reimbursement JPY +2.3 billion, upfront from Harrow Health for products licensing JPY +0.4 billion/USD 3 million *2: Asset transfer to Harrow Health (USD 5 million), H1

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Koshiji: This is Koshiji. Now, please see page three of the document. In Q3 of FY2023, we continue to see strong growth momentum in both revenue and profits, maintaining the strong performance of H1. Overseas sales per capita, a key KPI in the medium-term management plan, also achieved double-digit YoY growth, excluding foreign exchange effects and transitory factors.

Specifically, revenue increased by 11.5% YoY to JPY222.8 billion, and overseas business grew 25%. Growth remained strong in Q2 and beyond H1.

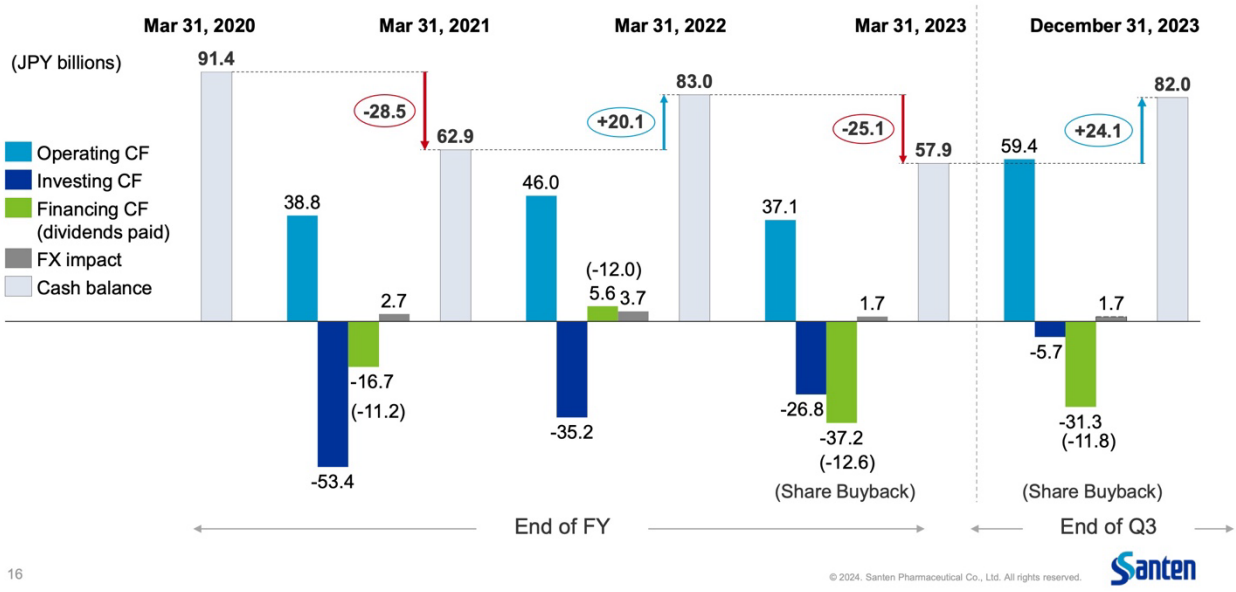
As for cost of sales, the cost of sales ratio is improving, even excluding transitory factors, depending on the region and product mix. In addition, ongoing cost optimization efforts and a decrease in labor costs due to structural reforms resulted in an absolute decrease in SG&A expenses, offsetting the impact of the yen's depreciation. As a result, core operating income increased by 81.5% YoY to JPY49.3 billion.

Next, under the core. In addition to one-time gains related to the Americas, structural reforms expenses are included in non-core expenses and other expenses.

Operating profit on an IFRS basis is JPY36.2 billion, and the tax rate excluding one-time factors is 20.6%. Quarterly net profit was JPY26.6 billion, a significant increase from the previous year.

Financial supplement

Cash flow

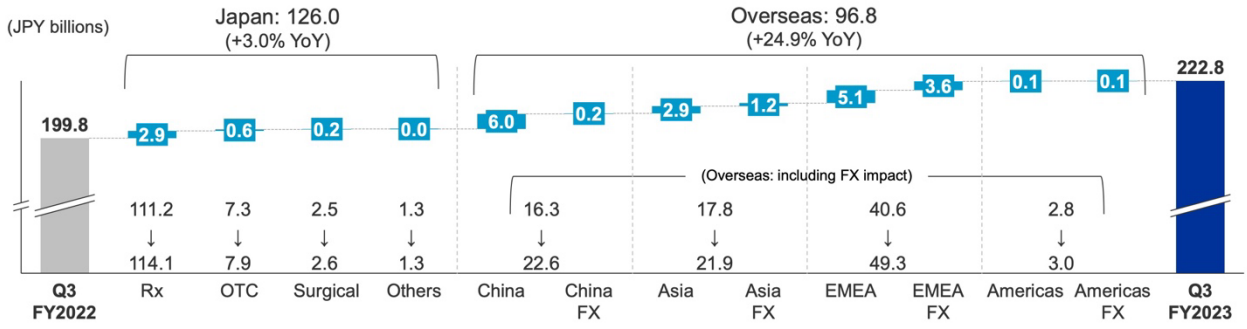


In addition, the Company began liquidation of trade receivables in Q3 of this fiscal year. In this document, as you can see on slide 16 and the statement of cash flows in the financial statements, operating cash flow has improved significantly.

We intend to continue to improve capital efficiency in terms of ROIC, return on invested capital, by reducing working capital and other measures.

Q3 FY2023 Sales bridge

YoY sales growth of +9.0% (excluding FX impact) mainly driven by Overseas



Japan	+3.0% YoY: Growth from mainstay products
China	+38.3% YoY (Ex. FX impact +36.9%): Strong performance from multi-channel strategy coupled with market recovery from COVID-19
Asia	+23.2% YoY (Ex. FX impact +16.4%): Steady growth from mainstay products in key markets. Including impact of shipment timing and high-demand related to infection products in Vietnam
EMEA	+21.5% YoY (Ex. FX impact +12.7%): Continued growth in glaucoma products and *Ikervis* for dry eye in EU5 and Nordic. Including *Ikervis* one-time impact
Americas	+7.2% YoY (Ex. FX impact +3.6%): Upfront from Harrow Health for products including *Verkazia* out-licensing recorded JPY 0.4 billion

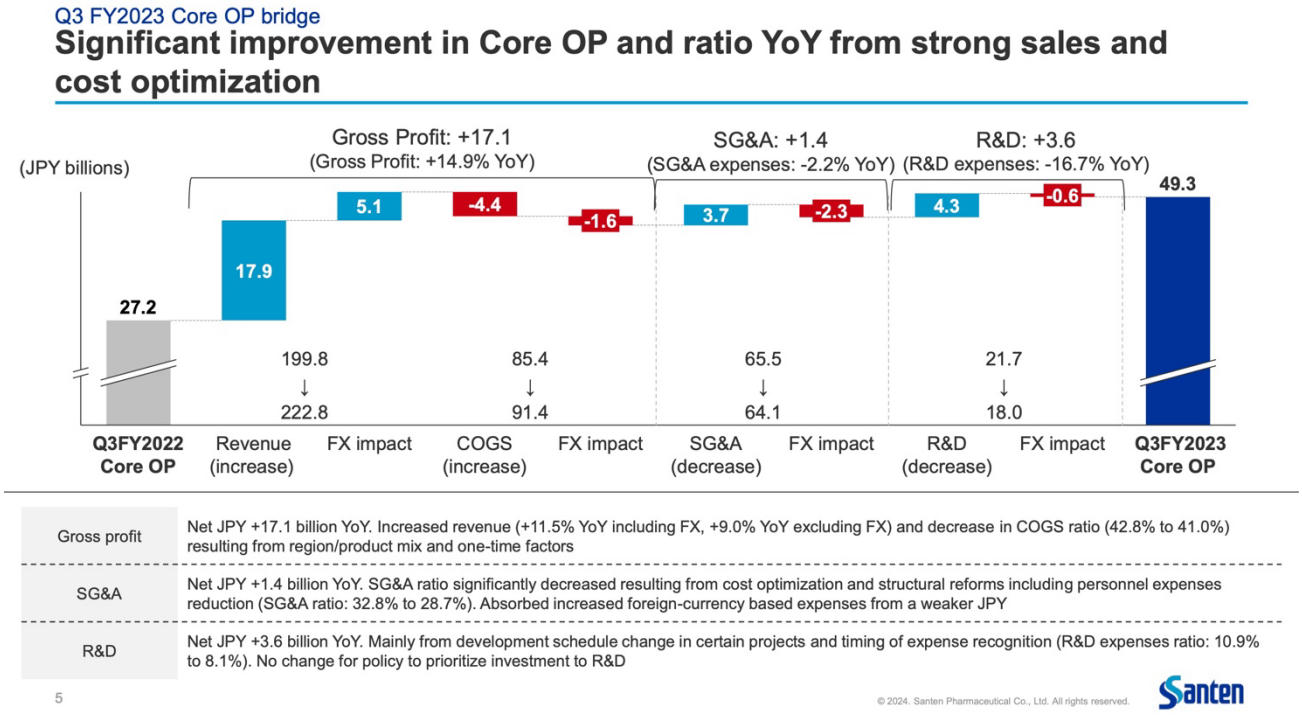
Note: Sales classified into countries or regions based on customer's location. EMEA：Europe, Middle East and Africa

Please turn to the next, page four. Next is the factors for the increase or decrease in overall revenue.

Revenue of JPY222.8 billion consists of JPY126.0 billion in Japan and JPY96.8 billion overseas. The overseas ratio is 43.4%. Sales continued to be strong, especially overseas, and even excluding the effect of foreign exchange rates, sales grew 9% YoY.

In Japan, overall growth was driven by mainstay products. As a result, growth was 3.0% YoY.

Overseas, especially in Asia, EMEA, and China, where there is a return from COVID-19 compared to the previous year, there was double-digit growth even excluding the effect of exchange rates. The most significant drivers of YoY market recovery are China, as I mentioned earlier, and EMEA, which has a high market share in glaucoma and dry eye.



Let's move on to the next, page five. Here are the factors for the increase and decrease in core operating profit.

First, from left, the gross profit factor. As I mentioned earlier, revenue increased by JPY23.0 billion YoY, including the effect of foreign exchange, due to growth mainly in overseas markets. The cost of sales ratio improved from the same period last year due to changes in the regional and product mix, as well as some one-time factors, resulting in a JPY17.1 billion increase in total gross profit.

SG&A expenses as a percentage of SG&A expenses improved YoY due to cost optimization and progress in structural reforms, including streamlining of the Americas. As I mentioned earlier, SG&A expenses denominated in foreign currencies increase when the yen is depreciated, but they were absorbed and decreased in absolute terms.

R&D expenses decreased by JPY3.6 billion YoY due to changes in the development schedule of some projects and changes in the timing of recording. This will not have a serious impact on the future clinical development and, consequently, the timing of future new product launches. We intend to continue to invest funds aggressively in R&D from FY2023 to FY2025 based on the capital allocation in the current mid-term management plan.

As a result, core operating profit improved significantly from the same period last year to JPY49.3 billion. Core operating profit ratio was 22.1%.

FY2023 Outlook

No change from November 7
Revenue: JPY 302.0 billion, Core OP: JPY 58.0billion

	FY2022 ACT	FY2023 FCST
USD (JPY)	135.40	145.00
EUR (JPY)	140.97	155.00
CNY (JPY)	19.72	20.00

(JPY billions)	FY2022		FY2023		
	Actual	vs Revenue	Forecast Nov.7	vs Revenue	YoY
Revenue	279.0	-	**302.0**	-	**+8.2%**
Cost of sales	113.0	40%	121.0	40%	+7.1%
Gross profit	166.1	60%	**181.0**	**60%**	**+9.0%**
SG&A expenses	93.5	34%	94.0	31%	+0.5%
R&D expenses	28.3	10%	29.0	10%	+2.5%
Core operating profit	44.2	16%	**58.0**	**19%**	**+31.1%**
Non-core expenses	2.7	1%	1.1	0%	-59.4%
Amortization on intangible assets associated with products	9.5	3%	9.4	3%	-1.2%
Other income	3.5	1%	1.5	0%	-57.4%
Other expenses	38.6	14%	8.0	3%	-79.3%
Operating profit	-3.1	-	**41.0**	**14%**	-
Finance income	1.2	0%	1.5	0%	+30.1%
Finance expenses	1.5	1%	1.2	0%	-19.9%
Share of loss of investments accounted for using equity method	2.4	1%	3.0	1%	+27.0%
Profit before tax	-5.8	-	38.3	13%	-
Income tax expenses	9.2	3%	8.8	3%	-4.2%
Actual tax ratio	-	-	23%	-	-
Net profit	-15.0	-	**29.5**	**10%**	-
ROE	-		10%		
Core ROE	10.5%		15%		
Core net profit	33.2	12%	43.5	14%	+30.9%

Factors to consider

- Japan: Pollen-levels
- Overseas: Macro environment

- 2024 Noto Peninsula Earthquake
  No material business impact expected

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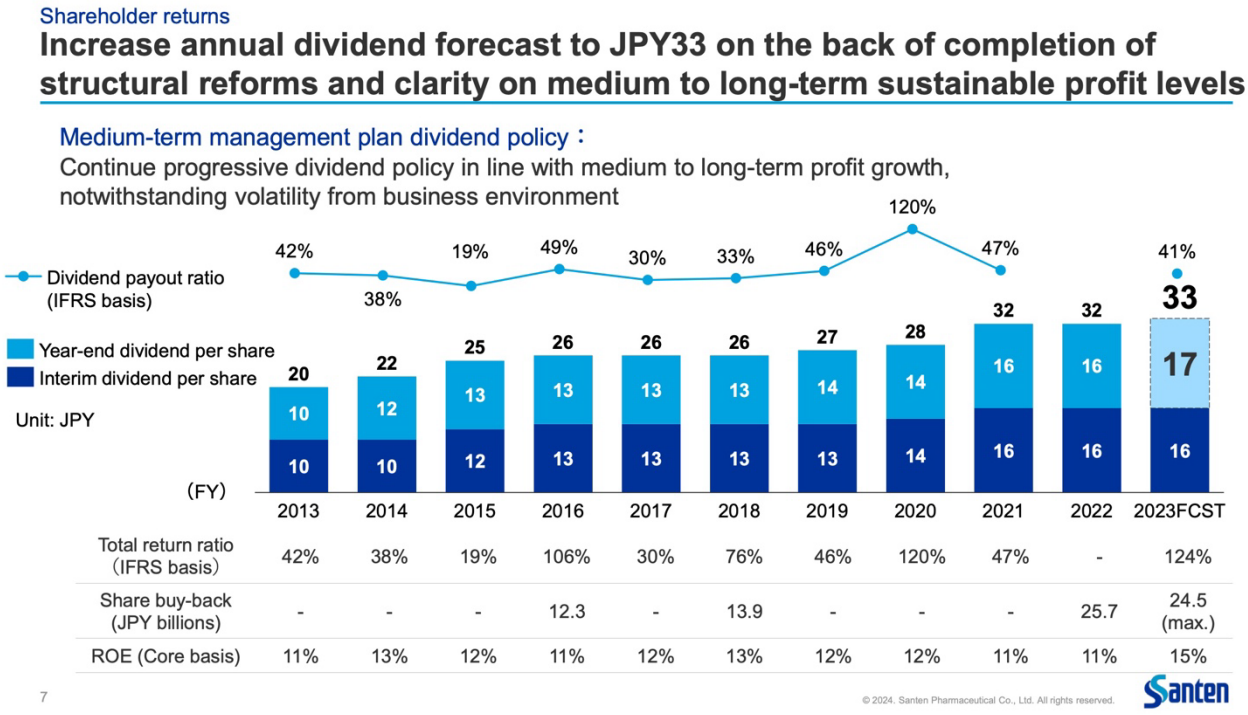
The next page shows the full-year forecast.

As for the landing in the current fiscal year, there is no change from the revised forecast at Q2 of JPY302.0 billion in revenue and JPY58.0 billion in core operating income.

Although both revenue and core operating profit have made high progress in Q3, we have decided not to revise them at this time because there are many variable factors in Q4, such as pollen dispersal trends.

The impact of the Noto Peninsula Earthquake that occurred on New Year's Day is expected to have no material effect on this fiscal year's forecast. In terms of whether there is an impact or not, we expect a slight increase in other expenses under the core, but this does not go so far as to require a significant change in what we have revised in Q2 of this fiscal year. We have made that determination.

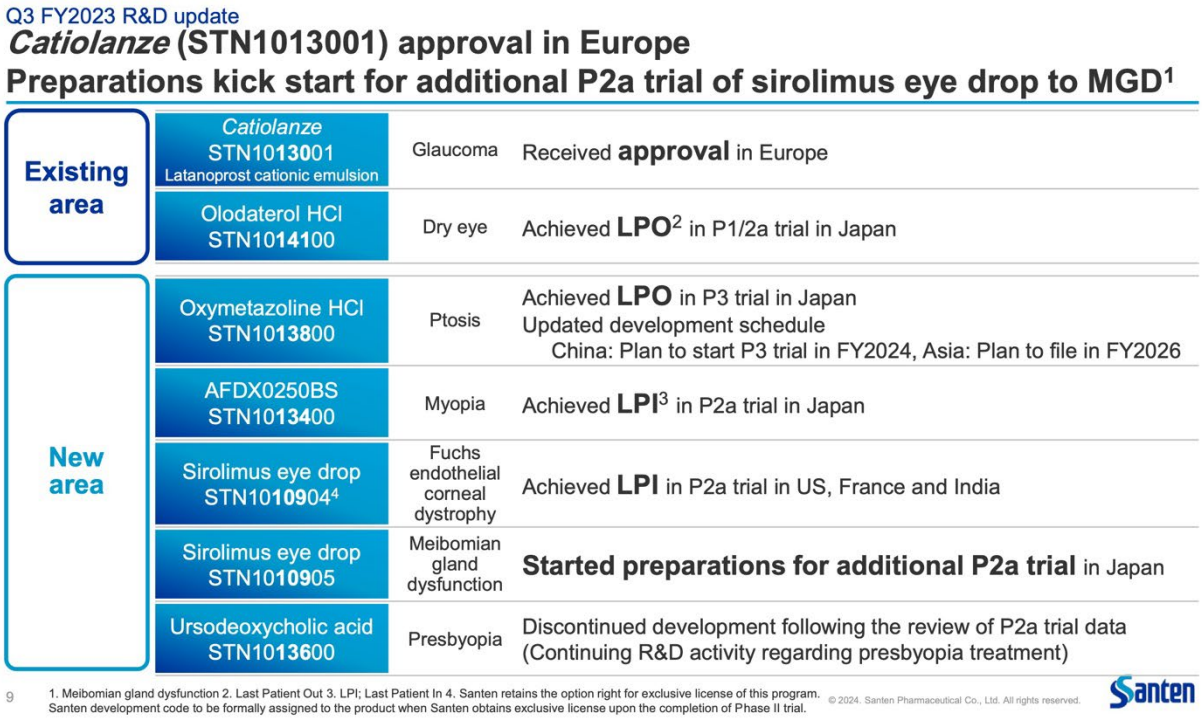


I would like to talk about shareholder returns on page seven.

The policy in the medium-term management plan is to increase dividends in line with medium- and long-term profits as progressive dividends, and with the completion of structural reforms in Q3, the foundation is now in place for stable profit generation over the medium to long term. This is how we see it.

Based on this, the year-end dividend forecast for FY2023 is increased from JPY16 to JPY17 per share. This is how we see it. As a result, the annual dividend will be JPY33, and based on the progressive dividend policy, we believe that the lower limit for the next fiscal year 2024 will be JPY17 for the half year and JPY34 for the full year. We will continue to consider increasing dividends in line with profit levels.

That’s all from me for the presentation.



Sallstig: Good afternoon, I'm Peter Sallstig, Chief Medical Officer, allow me a quick update with regards to status of the pipeline.

Let's go to page 9. We have achieved many milestones in this quarter, including the approval of *Catiolanze*, a treatment for glaucoma patients with concomitant ocular surface disease in Europe. We also plan to file *Catiolanze* in Asia.

Olodaterol, STN1014100, developed for dry eye treatment with a new mode of action (MOA) achieved LPO in P1/2a study in Japan. We expect to disclose the results in the first half of next fiscal year.

Regarding oxymetazoline, STN1013800 for ptosis, we also achieved LPO on a pivotal study in Japan and we plan to report TLR (Top line results) in the first half of next fiscal year as well.

Regarding China and Asia, we changed development plan because the CMO received warning letter from FDA. There is no impact on development schedule in Japan.

We have decided to conduct an additional POC/P2a study of sirolimus eye drop, STN1010905 for meibomian gland dysfunction in Japan. I will explain this in more detail later.

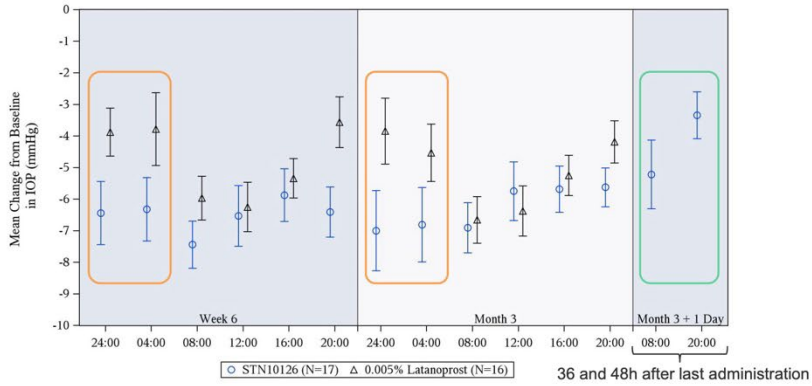
On the other hand, we decided to discontinue the development of ursodeoxycholic acid, STN1013600 for presbyopia, for which the primary and secondary endpoints have not been achieved. We believe unmet needs still remain in presbyopia area and we will continue our research and development activities for this indication.

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

Investigated IOP for/over 24h in P2 (exploratory study) in Europe

*This study was not adequately powered, and statistical sample size wasn't designed.
*This was conducted in preservative-free formulation (STN1012601).

■ **Intraocular pressure change (IOP, mmHg)**



- A numerically higher lowering effect than latanoprost was observed in nocturnal IOP at week 6 and month 3.
- At 36 and 48 hours after administration, the IOP decreased by 3 to 5 mmHg compared with time-matched baseline.
- Plan to submit in Japan in FY2024 with a pivotal study data that achieved the primary endpoint (disclosed at Q2 FY2023 briefing meeting).

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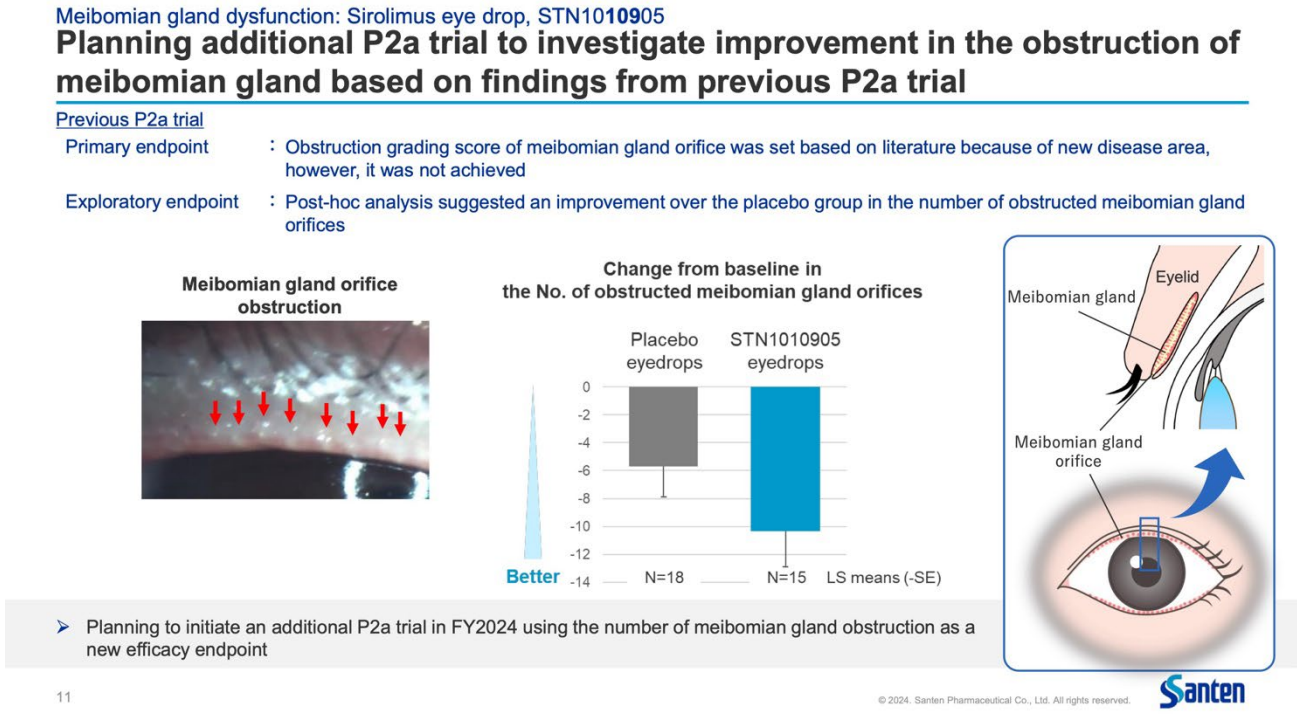
Page 10 please. Previously, we reported the achievement of the primary endpoint in pivotal study of sepetaprost, STN1012600 for glaucoma in Japan. I will explain the results of the exploratory study conducted in Europe today.

It has been reported that intraocular pressure circadian variation varies among individuals, and a certain number of glaucoma patients have an intraocular pressure peak at night. In terms of prevention of progression, a strong reduction in nocturnal IOP is also important in clinical practice. In addition, in real clinical practice, it may be impossible to continue the administration of the drug once a day at 24-hour intervals.

In this study, sepetaprost had a numerically greater lowering effect on nocturnal intraocular pressure than latanoprost. In addition, the IOP lowering efficacy was maintained at 36 and 48 hours after the last administration although showing waning effect after 24 hours.

Although it is an exploratory trial, we believe that such a product profile may have benefits for patients. Again, the pivotal study in Japan has achieved the primary endpoint, and we plan to file in fiscal 2024 based on the data.



Let's move to page 11. As I said earlier, we have decided to re-conduct POC study of sirolimus eye drop for meibomian gland dysfunction, MGD. Let me explain a little about the background.

The meibomian gland is a sebaceous gland in the eyelid that opens along the eyelash line. Lipid is secreted from the orifices to prevent evaporation of tears. MGD is a condition in which the function of the meibomian glands is diffusely abnormal due to various causes and involves chronic ocular discomfort. It's an eye disease in which many patients are often considered to be dry eye patients. In Japan however, the first clinical practice guideline was developed last year, and it has been pointed out that "MGD is a clinically important disease that reduces QOL of many people."

We are aiming to develop sirolimus eye drop as the first approved drug for MGD. In the last POC study, we set a score based on the obstructive grading of the meibomian gland orifice as the exploratory primary endpoint with reference to published articles, etc., but this was not achieved.

Now, on the other hand, a post hoc analysis of the number of obstructed meibomian gland orifices suggested higher effectiveness than the placebo group. This led us to decide on an additional POC study with the number of obstructions as the indicator. It is scheduled to start in fiscal 2024.

This concludes my part. Thank you.

Question & Answer

Q-1-1
The first question is about progress up to Q3 and how you see the current fiscal year. As you mentioned, there are still several factors to be considered, but as a background, the pollen was quite severe in Q4 of last year so that the performance was good. I think you forecast the standard level of pollen for Q4 of this fiscal year.

Conversely, there are news reports that the pollen this fiscal year will be relatively severe, and if it is actually severe, as is the case every year, you may be able to exceed the Company's forecast. Is this assumed level correct? This is my first question.

A-1-1
Koshiji : In Q4 of this fiscal year, the assumption related to pollen dispersal forecast is intermediate level, or rather, less than last year. This is our recognition.

However, does this mean it will be overwhelmingly decreasing rapidly? We don't think so. In this respect, we believe that there is a possibility of a slight increase in the core earnings forecast for the full year described on page six. Did I answer your question?

Q1-1-2
It depends on the situation, but if the pollen is severe as much as it was last year, of course the forecast will be exceeded, am I correct in understanding?

A1-1-2
Koshiji : I would say about last year, or even if it is not severe as much as last year, all of our products are not for pollen only. Considering the momentum overseas and on an overall consolidated basis, we believe that there is room to exceed this JPY302.0 billion or 58.0 billion level on a core basis.

Q1-2
I would like to ask one more question on R&D. Thank you very much for your explanation about STN1010905. I would like to ask you two questions about STN1010905.

The first question is, I assume this is an immunosuppressive agent, what is the mode of action to reduce the number of obstructed meibomian gland orifices? You also showed us the amount of change in the number of obstructed meibomian gland orifices, what percentage of improvement is there, not in absolute but in relative terms?

In short, how many obstructions are there, how many meibomian gland orifices are there, if any?

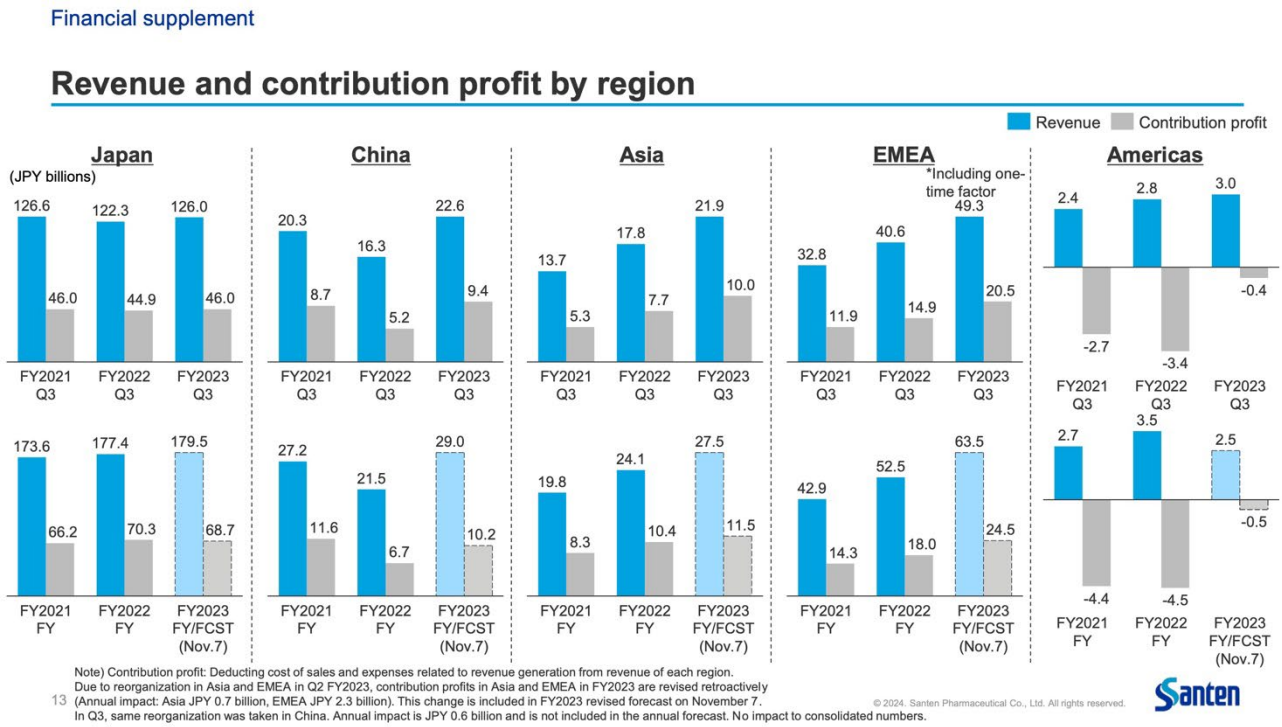
A1-2
Sallstig : First, let me talk about MOA (mode of action). This is a sirolimus drug, mTOR inhibitor and we expect this to control hyperkeratosis-related protein. This would restore the function of the meibomian glands.

This is our hypothesis. How much will the number of obstructed meibomian gland orifices actually improve with the additional studies we will be conducting? We expect to see 30% to 40% improvement, but the specific number will be determined by actual data from future trials and will be communicated as soon as we know.

Q2-1-1
I know this is a bit detailed, but I think there was data in the document showing quarterly sales figures for individual products, and here we see that *Diquas* in China, which had been doing well up to this point, suddenly saw a sharp QoQ drop in sales. I wonder what's happened here.

And also, regarding *Diquas* in Japan, as well. For the older formulation that is not *Diquas LX*, I believe it is about time for a generic to be released or not. Is there a generic already available or not, and if so, how is it working now? Please give us your explanation about it.

A2-1-1
Koshiji : The reason for the sharp slowdown in sales of *Diquas* in China in Q3 is that *Diquas* sales up to Q3 were JPY1.0 billion (Santen post amendment: JPY1.1 billion) in Q1, JPY1.3 billion in Q2, and JPY0.4 billion in Q3. This is due to the fact that *Diquas* was listed in the target for the VBP in China in November. In light of this, the impact of the buying freeze has been seen in Q3. That is how we interpret it.



However, although the reluctance to buy there is slightly stronger than we had expected, we do not expect the overall revenue and profits of the China business to be affected by the above, as shown on page 13 of the materials disclosed today, to reach JPY29.0 billion in revenue and JPY10.2 billion in contribution profit on a full-year basis.

The second question about the generic of *Diquas*. We recognize it has not yet been launched into the market. As for the timing of the market launch, we do not expect the product to be launched this fiscal year. This is not something we can be happy or sad about based on information from other companies, but at least we do not see any negative factors for the sales and earnings of our Japanese business this fiscal year.

Q2-1-2
You said *Diquas* in China became a target of VBP. Does that mean that we should be a bit cautious about *Diquas* outlook in the future in China from Q4 onward, including the next quarter?

A2-1-2
Koshiji: I think the major trend will not change that much. Basically, we believe that the growth trend will continue, but we think we will have to be a little cautious from the next fiscal year onward.

Q2-2
I wonder if it passed the subcommittee the other day or will pass it now. I think the *Alesion* cream is at such a review stage in Japan right now, maybe scheduled to be released around May, what can we expect from this? I think it was something like, just applying it once a day on your eyelids. Can you discuss what kind of time frame and what kind of scale we should look at, including education for dissemination.

Likewise, the NHI price has not yet been determined, but can we look at the NHI price with confidence? Is there a risk if the price would become surprisingly high or low? Please explain about it.

A2-2
Sallstig : Our assumption is that the market launch will be later this spring. As we have already reported, we have high expectation for this new product in that the dose is once-daily cream formulation compared to the current *Alesion* formulation. (Santen post amendment: With once-daily application, the same level efficacy can be expected as the current *Alesion* with twice-a-day application)

We are still negotiating on the price at this time, so I will refrain from commenting, but we are aiming to get the best price possible.

Koshiji : As for the price, we will do our best as it is mentioned just now, the premise of our mid-term management plan is the mid-term plan will be affected to some extent by generics and other factors given the actual results were around JPY30.0 billion for the last and current fiscal year. While considering that, many parts can be replaced and recovered with *Alesion* cream to some extent. I would like to add that we have such a prospect in the medium term.

Q3-1
I would like to know about the first question, the progress of R&D expenses.

I think Q3 was well controlled and settled at a relatively low level. If you continue at this rate, you will not meet your full-year plan, or rather, you are likely to land at a low level. Is my understanding right?

Also, in the mid-term plan, there was talk of JPY100.0 billion over three years, but if you continue to be at this level the next fiscal year and beyond, the level below JPY100.0 billion would be enough, I suppose. How do you think about this point?

A3-1
Koshiji : First of all, as for the landing of the R&D expenses for this fiscal year, as stated on page six, we might be slightly below JPY29.0 billion. This is what we think about it.

As I explained earlier, this is not about a serious delay in clinical development, but a component of R&D that includes activities related to clinical development, early-stage development, pre-clinical development, and medical affairs for products that have already been launched on the market. We have these activities, so what we are particularly restraining and controlling right now is medical affair matters. Due to the optimization of these and the delay in some clinical development phases, we are now expecting slightly below JPY29.0 billion.

The JPY100.0 billion in the mid-term management plan is not based on OPEX, but includes, for example, CAPEX, capital expenditures, and milestone payments related to ongoing research and development. So, this fiscal year, so if you multiply JPY30.0 billion by three, it would be JPY90.0 billion, but for now it will also remain at about JPY30.0 billion for the next fiscal year and beyond.

Considering that milestone will be added to that, we are looking at a base of about JPY100.0 billion. As such, there is no change in our basic policy at this time.

Q3-2-1
I think that the impact of generics will ease considerably from the next fiscal year onward with the release of the *Alesion* cream formulation. I would like to confirm whether your company's thinking is more relaxed than in the past on some points that we had to look at with caution.

Since you told us earlier about the *Alesion* cream, I was wondering even if we assume that generics will be available for *Alesion*, will that be a reasonable figure in terms of the initial plan for the period than in the past? Also, since *EYLEA* is also coming out with an 8 mg formulation, is it correct to assume that even if biosimilars were to come out, the guidance would still factor in the positive aspects and would not be that much more conservative than in the past?

Also, the treatment for patients' choice system has been specified, but I don't think it will have such a broad impact, so I don't think we need to look at this as much of a risk. Please check about this.

A3-2-1
Koshiji : I think one of the first points in your explanation is how to think about the system. In this respect, the possibility of losing market share to generics is slightly milder than when we formulated our mid-term management plan, as seen in the revision of our earnings forecast for the current fiscal year. Our perception is that business performance is moving in a positive direction.

However, this does not rule out the possibility that generics will be launched in H2 of the next fiscal year and beyond, so this will have a certain impact. Our basic idea is to manage the life cycle of the product and recover it as I mentioned earlier. That is our thinking regarding *Alesion* and high dose of *EYLEA* you mentioned.

However, the impact of the treatment for patients' choice system, for example, on the next fiscal year and the year after that, is still a swing factor for us, and we are currently assessing its impact. This depends on the definition of generics, but for example, for *Alesion*, assuming we are talking about next year or the year after next, there are three types of products: the old *Alesion*, *Alesion* LX, and high-dose *Alesion* cream. Do you equate the presence or absence of generic products, the high dose and the conventional ones?

At this stage, we are still looking at whether they will be treated the same way or not, and the impact will depend on that. This is what we think about it.

Overall, however, the impact in FY2024 is limited considering the time frame and other factors. However, we are still considering internally how it will be affected for FY2025 and the medium-term impact.

Q3-2-2
Could you give me a comment on the 8 mg formulation of *EYLEA*?

A3-3-2
Koshiji : We consider it positive about this, but since we have a partner, we also have to depend on our partners' ideas. I would like to refrain from commenting that it is positive or that we should be conservative at this stage.

Q3-3
I understand. Lastly, I believe that you are planning to present detailed data on STN1012700, the myopia drug for which you recently announced success at another academic conference. If the timing of its release at a conference has already been determined, please let me know. That's all from me.

A3-3
Sallstig: I think it will be next term, but we are still discussing which conference to present at, so I will let you know as soon as I know.

Q4-1
I would first like to ask you to tell us about the progress of structural reforms and the outlook for costs in the next fiscal year and beyond.

In your explanation earlier, you mentioned that structural reforms have been completed. I would like to confirm that the structural reforms are progressing as planned. I believe that the mid-term management plan calls for JPY15.0 billion in structural reform benefits, but could you please explain how much of this will be realized this fiscal year and how much will be added next fiscal year and thereafter? What basis we should consider next fiscal year and beyond in response to the landing of costs in the current fiscal year?

A4-1
Koshiji : In that regard, on page three, we have almost completed all of the progress in structural reform that is now being contemplated: the thorough streamlining of the sales business division, particularly in the United States, and the introduction of an early retirement program in other regions, particularly in Japan. In Japan, as of December, all applicants for the early retirement program have left the Company. Therefore, in terms of the structural reforms I mentioned earlier and the extent to which they have progressed, we have almost completed what we initially envisioned at this point.

From a medium-term perspective, we do not expect to achieve a JPY15.0 billion increase in profits by reducing expenses. In terms of raising the profit base, this will be a combination with sales, but we recognize that in this fiscal year, we have achieved almost all of the JPY15.0 billion effect compared to FY2022, including improvements in expenses and gross profit.

As I mentioned in Q2 financial results, we are looking at core operating income of JPY56.0 billion for FY2025, and we believe that we are in a position to achieve this level of stable income, regardless of any revisions to the NHI drug price system, etc. In this regard, we believe that we are in a position to achieve the effects of structural reforms and a JPY15.0 billion improvement in profits on a sustained basis. That is what we are recognizing now.

As for what will happen in the next fiscal year, we expect SG&A expenses to remain flat to slightly decrease in the next fiscal year, based on the structural reforms mentioned earlier, especially the optimization of personnel and other factors. Although there is an upward trend due to the impact of the foreign exchange, the weaker yen, and other factors, the budget is being prepared with the goal of a flat to slight decrease in absolute amounts. Did it answer to your question?

Q4-2
The second point I would like to ask is about the situation of the business in China. I was wondering if there has been any particular impact from the tightening of anti-corruption measures that have been in place since last year. Also, as you mentioned earlier about volumed based purchasing (VBP), could you please explain your thinking on how *Diquas* can expect future growth, including whether there are any risk factors in these areas?

A4-2
Koshiji : In this respect, the anti-corruption movement has had an impact. Having this impact in particular, we are actually facing some restrictions on sales promotion of our new products, such as *Diquas*, that I mentioned just right now, and *Tapros* for glaucoma.

Although we were affected by VBP as it included it, we are recovering from the downside more than initially expected by using existing products such as *Cravit* and *Hyalein*, which are conventional products.

However, due to the impact of the macroeconomic downturn in China, for example, the number of ophthalmology-related surgeries itself is declining, and although there is a strong correlation between the number of surgeries and these old products, our mainstay products of the past, we will recover and maintain overall growth by expanding retail channels that are not affected by VBP. This is how we see it.

The same is true for *Diquas*, which we hope to eventually put on a growth trajectory by developing routes that are not affected by VBP, etc.

Q5-1
I would like to start with the first question, which is: it seems that the business in Europe is performing well, including temporary factors, but what is the outlook for the European business and how much do you expect peak sales of *Catiolanze* or latanoprost which have just received approval. If possible, please let me know. That is the first question.

A5-1
Koshiji : In this respect, we have reported 22% growth in revenue and 38% growth in contribution profit in yen terms for Europe this time, but this was affected by the exchange rate by about 11%, so we recognize that revenue grew by 10% and contribution profit by about 15%, which is roughly the actual growth rate, since there are some transitory factors. We believe that the same momentum can be maintained in the next fiscal year.

In particular, double-digit growth has been achieved in major countries such as Germany, Italy, and the UK, which are large markets, and we expect this momentum to continue into the next fiscal year.

In particular, ROCK inhibitors, DE-139 and 140 (Santen post amendment: STN1013900、STN1014000）, will be added into the market for the new products. *Catiolanze*, which was mentioned in the previous question, will also be added.

As for peak sales, as CEO Ito mentioned in the past, we believe that the potential is more than JPY10.0 billion, and we expect such potential in comparison with other competing drugs. We are currently discussing how to incorporate this into next year's budget.

Q5-2
My second question is on page three of the slide, under operating profit, share of loss of investments accounted for using equity method. The figure is JPY2.9 billion on an actual basis and JPY3.0 billion on a planned basis, but is this JPY3.0 billion estimate correct? I wish you could tell us about what is happening here and now.

A5-2
Koshiji : Regarding the share of loss of investments accounted for using equity method, which you pointed out on page three, whether JPY2.9 billion is JPY3.0 billion for the full year or only JPY100 million for Q4, one of the uncertain factors is here, as we said earlier that we would not revise the earnings forecast. As a conclusion, we expect the amount here to be slightly above JPY3.0 billion to about JPY3.5 billion.

As for the background and what is happening, this is mostly share of losses of Twenty Twenty Therapeutics, a joint venture with Verily, a subsidiary of Alphabet, Google's holding company, but the product under development has been launched in the US. The associated milestone payments caused expenses to arise earlier than expected. The amount was approximately JPY500 million in a yen base or USD3.5 million.

Therefore, our initial projection for Q3 was approximately JPY2.4 billion, but this figure has now increased to JPY2.9 billion. For the full year, that is where the upward swing will be.

There are other factors such as damage from the Noto peninsula disaster; however, we believe we can absorb overall by boosting core operating profit I mentioned earlier.

Q6-1-1
On page four, in the section on Asia, it is mentioned that the demand caused by infectious diseases and timing of shipments in Vietnam partially affected. Please tell us about it more in detail and which product was affected.

A6-1-1
Koshiji : This is about an infectious disease, so the product is *Cravit*. The disease is called pink eye, which is a type of conjunctivitis. We are in a situation where sales of *Cravit* are increasing rapidly due to the pandemic of this disease.

As you know, *Cravit* is a highly profitable product, even though in-licensed product, and we believe that it is contributing to the increase in contribution profit in the Asian business mentioned earlier.

Q6-1-2
What is about the shipment timing?

A6-1-2
Koshiji : In that respect, we export products to Vietnam, so it was largely significant in Q3, but the rebound will not be extreme in Q4. It does not result in a sharp decline in revenue and profits. Therefore, among the JPY11.5 billion in profit for the full year, which we have just shown in the profit contribution of each region for the full year on page 13, we have reached JPY10.4 billion (Santen post amendment: JPY10.0 billion) by Q3, so we believe that we are at a level where we can certainly realize and exceed it. Did I answer your question?

Q6-2
In brief, the Noto Plant will have only a negligible impact on the business performance, but some expenses will be incurred partly. Could you please explain a little bit about the situation regarding the damage here and the full reopening at the end of March?

A6-2
Koshiji : In that respect, as I mentioned earlier, in terms of the impact on P&L, I think there will be some impact on other costs.

We are currently projecting JPY8.0 billion of other expenses for the full year, and we currently expect an increase in these expenses of about 10% or more to this amount. This depends on the timing of the recovery. I think it depends on whether it is the middle or the end of March. Specifically, this is the loss of operation, which means that the labor, maintenance, and utility costs related mainly to the Noto Plant will be reduced once the plant starts operation. We believe that this will be reflected in the cost price.

As for the restoration status, the warehouse and some factory functions have already been in operation since the end of January. However, for processes that require compliance with GMP, manufacturing control and quality control regulations, we expect to gradually and progressively restart production lines from March onward, as sterilization, cleaning, and subsequent validation will require more time. We are expecting full reopening by the end of March. [END]