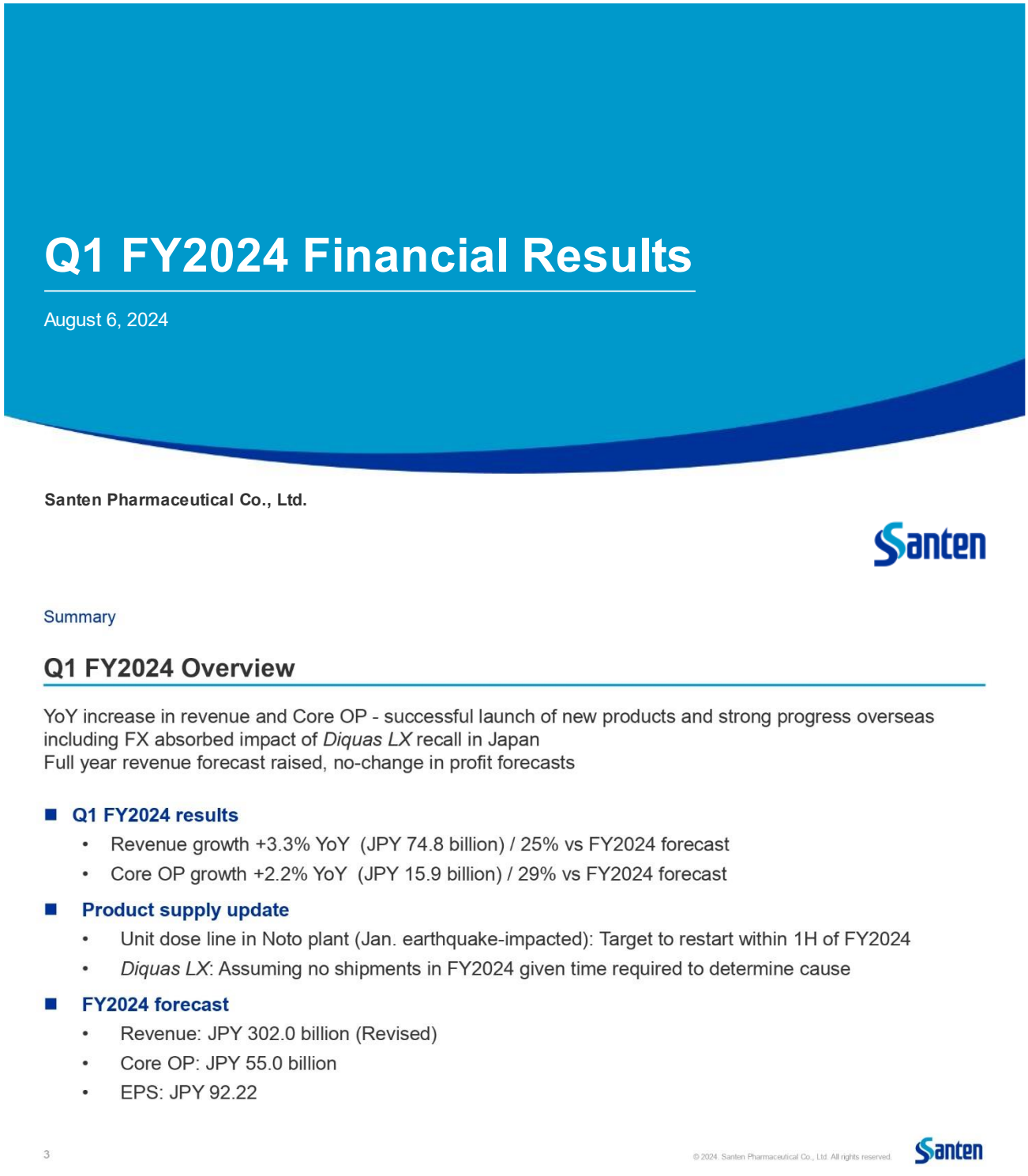
Q1 FY2024 Financial Transcript



Koshiji: My name is Koshiji. Please see page three.

This is a summary of financial results for Q1 of this fiscal year. In Q1 of FY2024, despite the impact of the voluntary recall of *Diquas LX*, both revenue and profit increased YoY due to the successful launch of new products in Japan and solid performance of overseas business, including the impact of foreign exchange rates.

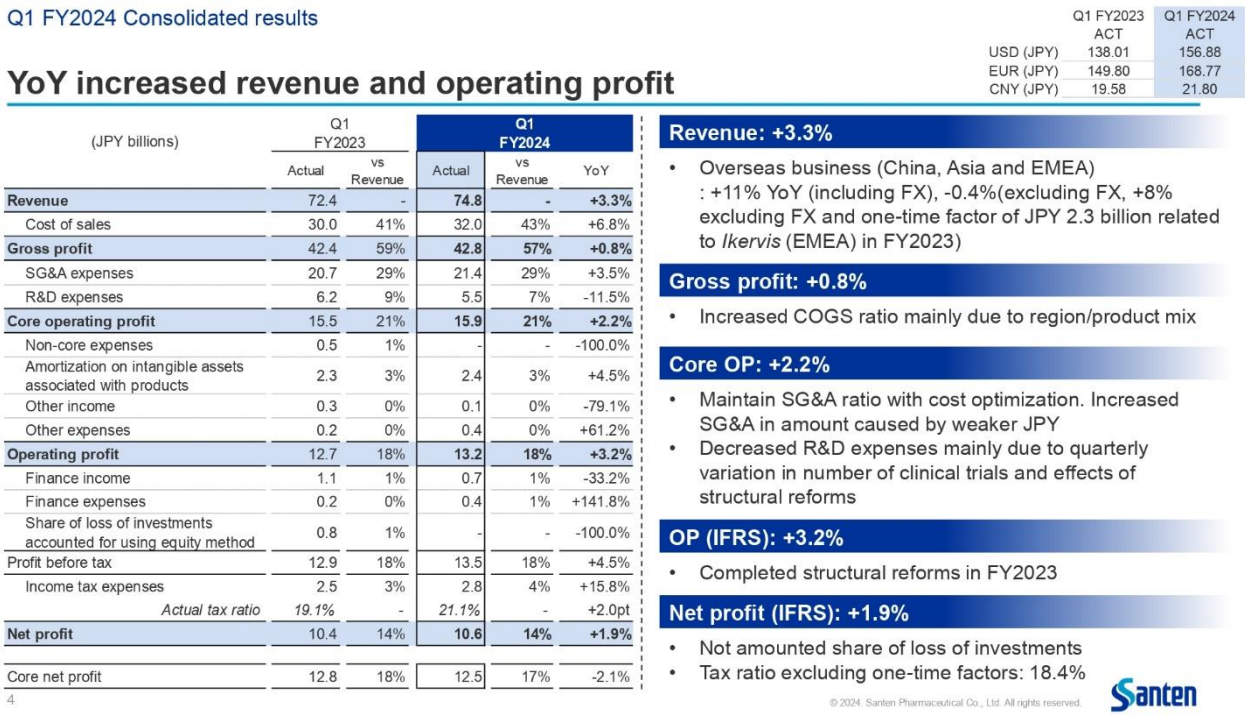
Revenue increased by 3.3% YoY to JPY74.8 billion and core operating profit increased by 2.2% YoY to JPY15.9 billion.

There are two other topics related to product supply in Q1. As explained in the May financial results, we are taking measures to restart one line at our Noto Plant, which has taken some time to restart, with the aim of restarting the line during H1.

One more point, we have been recalling *Diquas LX* since May 21. We have decided to temporarily remove this product from the budget for this fiscal year, as we expect it will take time to track down the cause of the decline in silver nitrate, which is added as a preservative, in some lots of this product.

Based on these Q1 conditions, we have revised our full-year earnings forecast to JPY302.0 billion in revenue. There is no change in all kinds of profits below core operating profit. As for a major change in assumptions, we will work to secure the EPS of JPY92 that we promised at the beginning of FY2024.

Due to the suspension of shipments of *Diquas LX*, limited shipments of dry eye products have continued, but a stable supply system has been in place since August and is currently being addressed (Santen post amendment: shipment of *Diquas* ophthalmic solution 3% was changed to “A. normal shipment volume (2. limited shipment due to the Company circumstances) from August shipment”). I would also like to add that we do not currently anticipate that the suspension of shipments of *Diquas LX* for the full year will affect our growth in the medium to long term.



Q1 FY2024 Consolidated results

	Q1 FY2023 ACT	Q1 FY2024 ACT
USD (JPY)	138.01	156.88
EUR (JPY)	149.80	168.77
CNY (JPY)	19.58	21.80

YoY increased revenue and operating profit

(JPY billions)	Q1 FY2023 Actual	Q1 FY2023 vs Revenue	Q1 FY2024 Actual	Q1 FY2024 vs Revenue	Q1 FY2024 YoY
Revenue	72.4	-	**74.8**	-	**+3.3%**
Cost of sales	30.0	41%	32.0	43%	+6.8%
Gross profit	42.4	59%	**42.8**	**57%**	**+0.8%**
SG&A expenses	20.7	29%	21.4	29%	+3.5%
R&D expenses	6.2	9%	5.5	7%	-11.5%
Core operating profit	15.5	21%	**15.9**	**21%**	**+2.2%**
Non-core expenses	0.5	1%	-	-	-100.0%
Amortization on intangible assets associated with products	2.3	3%	2.4	3%	+4.5%
Other income	0.3	0%	0.1	0%	-79.1%
Other expenses	0.2	0%	0.4	0%	+61.2%
Operating profit	12.7	18%	**13.2**	**18%**	**+3.2%**
Finance income	1.1	1%	0.7	1%	-33.2%
Finance expenses	0.2	0%	0.4	1%	+141.8%
Share of loss of investments accounted for using equity method	0.8	1%	-	-	-100.0%
Profit before tax	12.9	18%	13.5	18%	+4.5%
Income tax expenses	2.5	3%	2.8	4%	+15.8%
Actual tax ratio	*19.1%*	-	*21.1%*	-	+2.0pt
Net profit	10.4	14%	**10.6**	**14%**	**+1.9%**
Core net profit	12.8	18%	12.5	17%	-2.1%

Revenue: +3.3%

- Overseas business (China, Asia and EMEA) : +11% YoY (including FX), -0.4%(excluding FX, +8% excluding FX and one-time factor of JPY 2.3 billion related to *Ikervis* (EMEA) in FY2023)

Gross profit: +0.8%

- Increased COGS ratio mainly due to region/product mix

Core OP: +2.2%

- Maintain SG&A ratio with cost optimization. Increased SG&A in amount caused by weaker JPY
- Decreased R&D expenses mainly due to quarterly variation in number of clinical trials and effects of structural reforms

OP (IFRS): +3.2%

- Completed structural reforms in FY2023

Net profit (IFRS): +1.9%

- Not amounted share of loss of investments
- Tax ratio excluding one-time factors: 18.4%

The next page, page four. This is the profit/loss situation for Q1.

First, sales revenue grew mainly overseas, amounting to JPY74.8 billion. Excluding the one-time factor of *Ikervis* in EMEA in the previous year, the overseas business grew 8% even excluding currency effects.

Cost of sales was affected by the one-time accounting factors mentioned earlier in the same period of the previous year, but after taking these factors into account, cost of sales was almost the same level as the previous year.

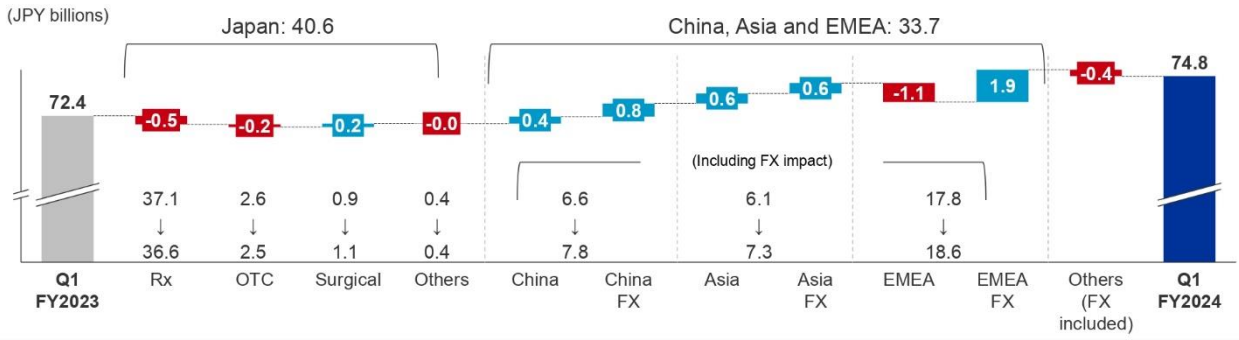
Core operating profit increased by 2.2% YoY to JPY15.9 billion. Although the absolute amount of SG&A expenses increased due to the impact of yen depreciation and inflation, the SG&A to sales ratio was maintained through ongoing cost optimization efforts.

R&D expenses decreased in monetary terms from the previous year due to the difference in the number of pipelines in the clinical trial stage and structural reforms, but there was no delay in the progress of pipelines.

In terms of IFRS based earnings, both operating profit and net profit increased due to the elimination of restructuring-related expenses and losses from equity-accounted subsidiaries in the same period of the previous fiscal year.

Q1 FY2024 Sales bridge

Solid performance overseas including FX pared decrease in Japan



Japan	-1.1% YoY: Minimize impact from *Diquas LX* voluntary recall with *Alesion eyelid cream* and others
China	+18.4% YoY (Ex. FX impact +6.4%): Solid performance from multi-channel strategy absorbed impact of *Diquas* VBP (volume-based purchasing)
Asia	+20.0% YoY (Ex. FX impact +9.9%): Steady growth from mainstay products in glaucoma and dry eye in key markets such as South Korea and Vietnam
EMEA	+4.5% YoY (Ex. FX impact -6.4%): Continued growth in glaucoma and dry eye products. Includes reactionary drop from *Ikervis* one-time factor (2.3 billion) in FY2023

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

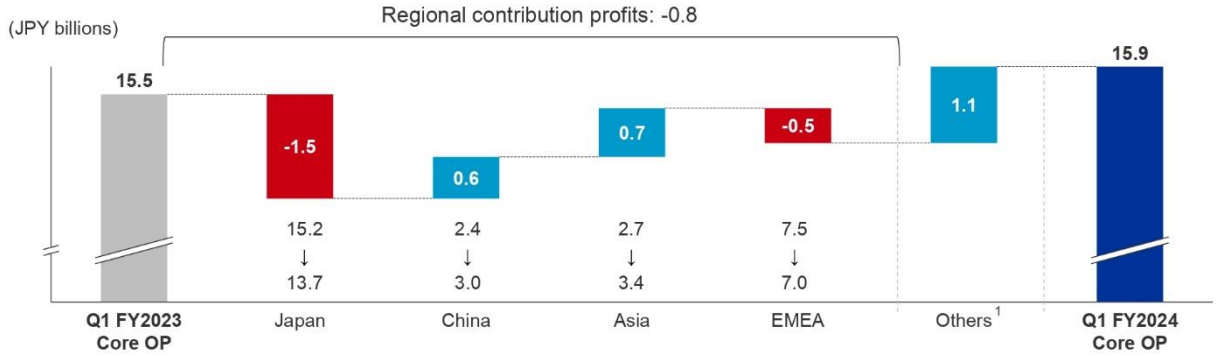
The next page, page five. Here are the factors for the increase/decrease in revenue.

Revenue of JPY74.8 billion consists of JPY40.6 billion from Japan and JPY33.7 billion from China, Asia, and EMEA, with overseas sales accounting for 45% of total sales. In Japan, sales were down 1% from the same period of the previous year. Although there was a NHI price revision in the high 6% range and the recall of *Diquas LX*, on the other hand, the impact was minimized by the steady launch of *Alesion* eyelid cream and other factors.

Overseas, three regions grew by 10% in yen terms on a gross basis and roughly 8% in local currency terms after adjustment for one-time factor. The situation in each region is as shown in the materials.

Q1 FY2024 Core OP bridge

Overseas business contributes to Core OP YoY increase



Regional contribution profits	Japan: Decrease in contribution profit, mainly due to product mix including decreased sales including *Diquas LX* voluntary recall and associated costs as well as NHI price revision Overseas: Increase in contribution profit in China and Asia resulting from revenue increase and cost optimization. In EMEA, decrease in contribution profit mainly from reactionary drop related to *Ikervis*'s one-time factor in FY2023
Others	Completion of structural reforms including streamlining in Americas pharmaceutical commercial business and promotion of cost optimization

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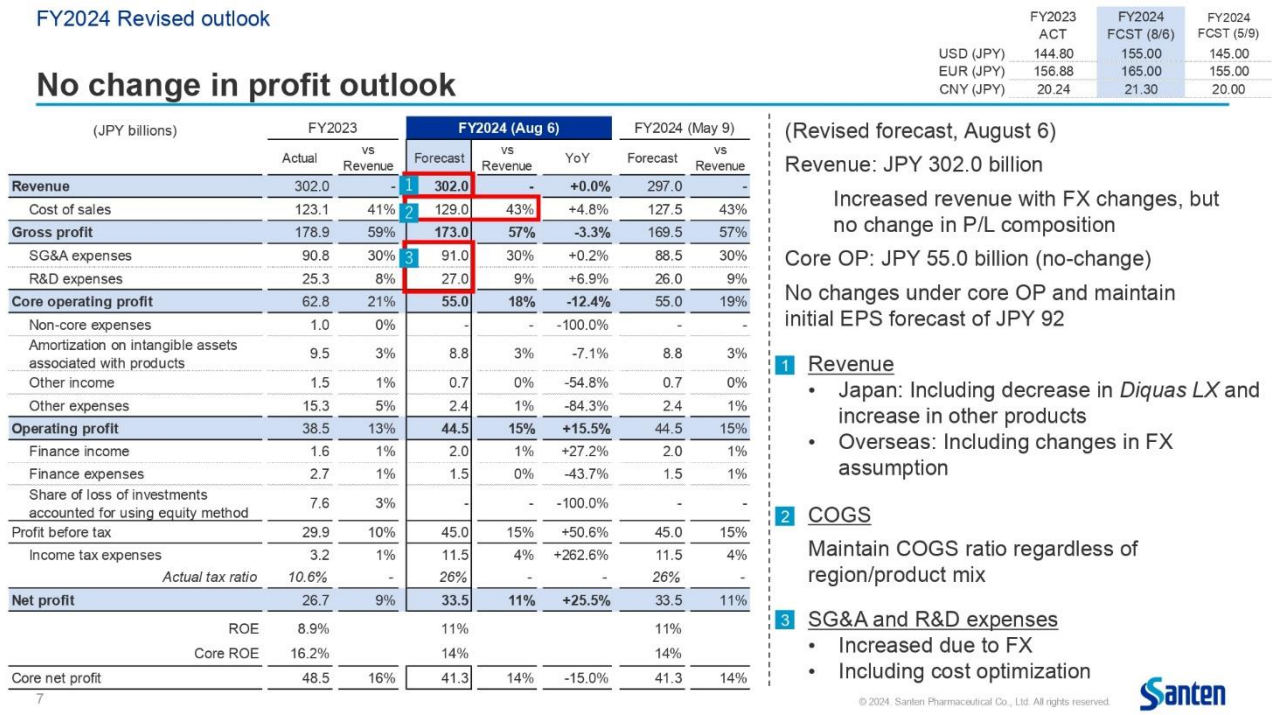
1 R&D and back-office expenses in region and global functions, and contribution profit not related to the regions above

The next page, page six, shows the factors for changes in core operating profit.

This figure increased to JPY15.9 billion, securing an increase over the same period last year. Total of regional contribution profit basis decreased by JPY0.8 billion. In Japan, sales decreased by JPY1.5 billion YoY due to a voluntary recall of *Diquas LX*, as well as the impact of recall costs.

In China and Asia, the contribution profit increased from the previous year due to higher revenue and cost optimization. In EMEA, there was a JPY2.2 billion gain on the reversal of the *Ikervis* provision in the previous fiscal year, and the decrease is a reactionary decline from that.



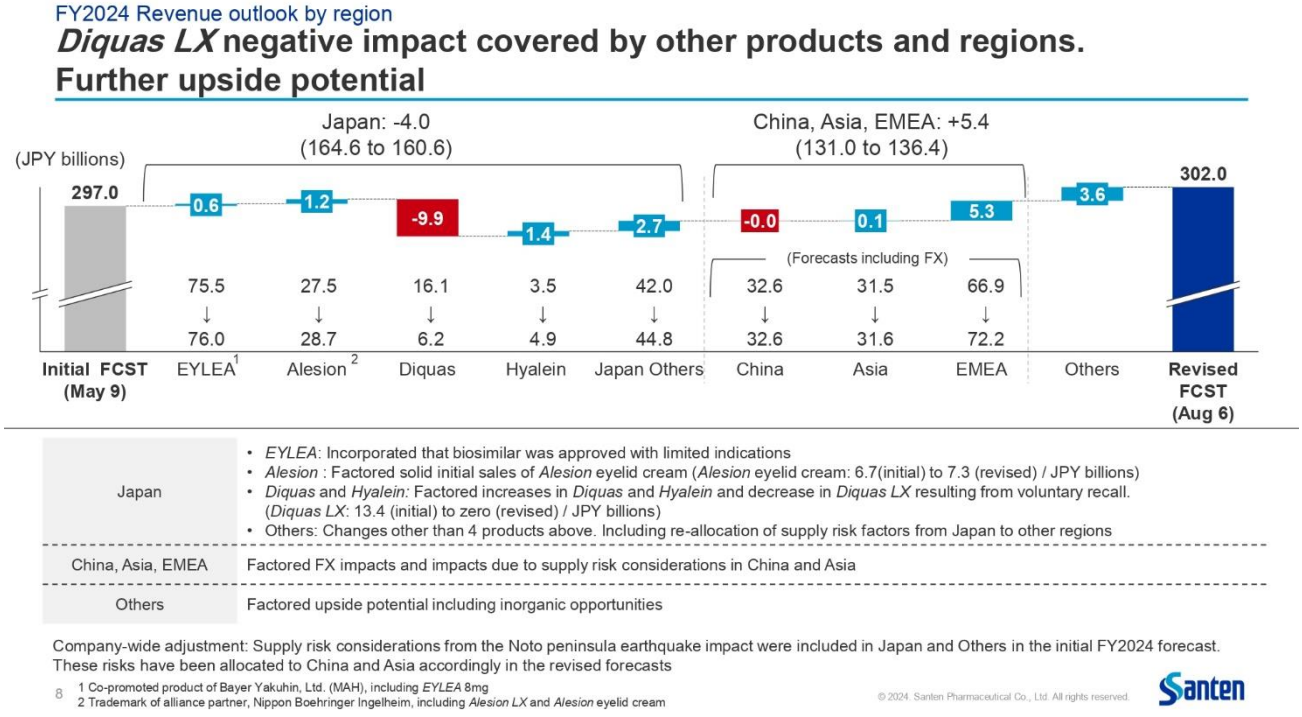
Next, page seven. I would now like to explain our full-year forecasts.

As I explained at the beginning of this presentation, there were major changes in assumptions after Q1, such as the *Diquas LX* issue, foreign exchange rates, new product prospects, and other potential upside factors. We have taken this opportunity to fundamentally revise our annual budgets and forecasts.

As a result, we have revised our full-year forecast from JPY297.0 billion which we announced on May 9, to JPY302.0 billion. On the other hand, there will be no change in core operating profit of JPY55.0 billion and the following phased profits.

Diquas LX is a core profitable product that accounts for a significant portion of our profits; however, we have not made any changes to the profit level announced at the beginning of the fiscal year, considering the substitution of other products in the dry eye, the maximization of products in other therapeutic areas, and the upside factors that are expected to have a high probability of success. We have not made any changes to the level of profit announced at the beginning of the fiscal year. We expect to secure an EPS of JPY92, which we promised at the beginning.

As for the composition of the P&L itself, the core-based portion has increased overall due to the change in the exchange rate, but the composition ratio, or so-called sales ratio, is almost the same level as the forecast at the beginning of the period, or so it seems.



Please see page eight. I would like to explain the components of sales revenue related to the full-year forecast.

By region, Japan was down JPY4.0 billion from the initial forecast of JPY164.6 billion to JPY160.6 billion. The total for the overseas business, including China, Asia, and EMEA, is JPY136.4 billion, an increase of JPY5.4 billion from the initial forecast of JPY131.0 billion.

Other factors are expected to increase by about JPY3.6 billion.

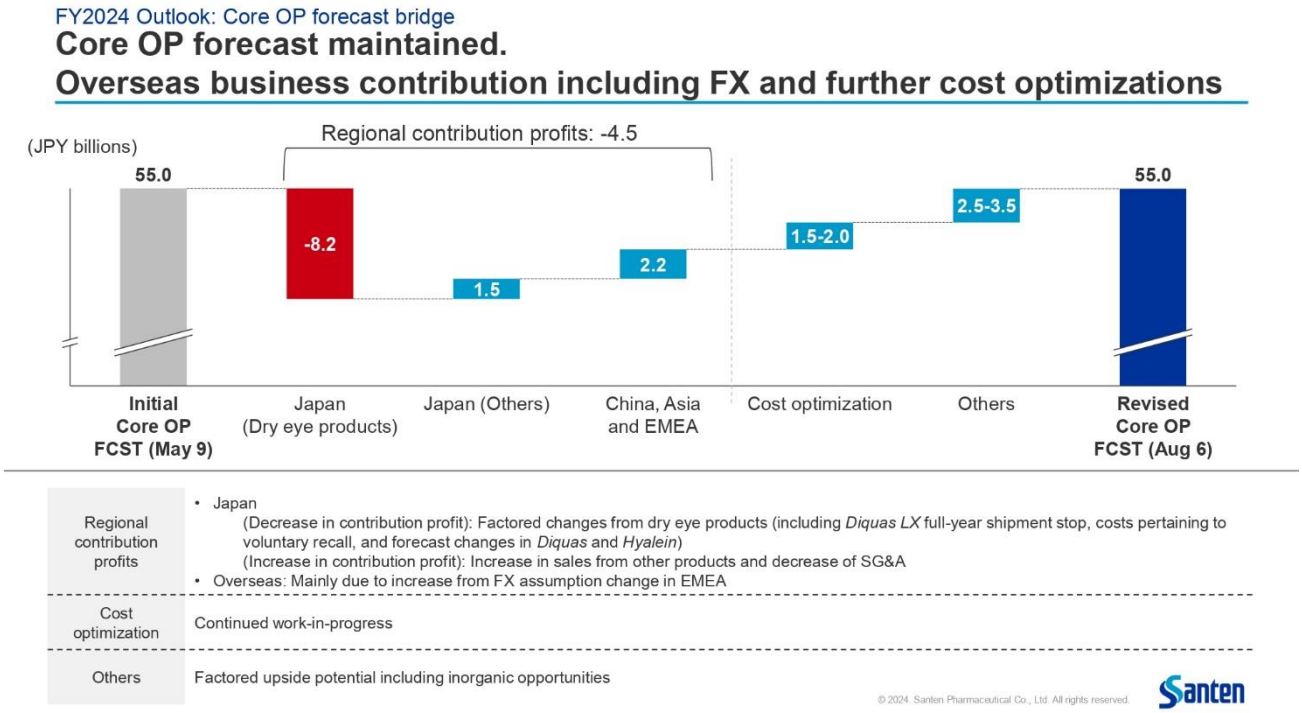
First of all, regarding the assumption for the entire consolidated performance, I spoke at the May financial results briefing that we expect a downside of JPY3.0 billion in revenue and JPY2.0 billion in gross profit as a result of the suspension of the Noto Plant. At the beginning of the fiscal year, this was accounted for by Japan and company-wide adjustments at other, as the prioritization of the entire supply, including unit doses and products outside of this line, was under scrutiny. Subsequently, since the Company-wide production adjustment has been closely scrutinized, we have now estimated the downside impact by region, and allocated it accordingly to China and Asia.

By region, Japan first reflects a review of major products. *EYLEA* and *Alesion* reflect the upside. For dry eyes, we have assumed zero in our forecast based on the assumption that shipments of *Diquas LX* will be suspended for the full year and have factored in the upside of *Diquas* and *Hyalein* as a substitute.

For other details, please refer to the sales by product in the financial results report and the data book.

As for overseas, although there is upside in China and Asia due to the impact of foreign exchange rates, the level is the same as at the beginning of the period, reflecting the supply risk I mentioned earlier. For EMEA, reflecting the impact of exchange rate, the upside is straightly accumulated from that impact.

The second column from the right of the graph shows the others, which includes the Company-wide adjustment included in the initial forecast, which was allocated to China and Asia, and then the inorganic factors, which were not expected at the time but can be expected with a high degree of certainty at this point, are counted as upside and listed here. That's the situation.



Let's move on to the next, page nine. This is about the components of core operating profit.

First, we will maintain the same overall level of JPY55.0 billion, from the left side to the far-right side. By region, the Japan business will see a decrease of about JPY4.5 billion from initial forecast due to the negative impact in Japan. This decrease was JPY8.2 billion related to dry eye products. Offsetting the other upside, it is negative JPY4.5 billion.

Since the launch of *Diquas LX* in November 2022, we have been promoting the switch from *Diquas*, the former *Diquas*, to *Diquas LX* as a way to reduce the burden on patients due to the reduced number of eye drops. As for *Diquas*, the safety data accumulated over many years remain strong, and we will continue to make efforts to recover the downside of LX as much as possible during the term.

The upside is JPY1.5 billion due to contributions from other products and a decrease in SG&A expenses.

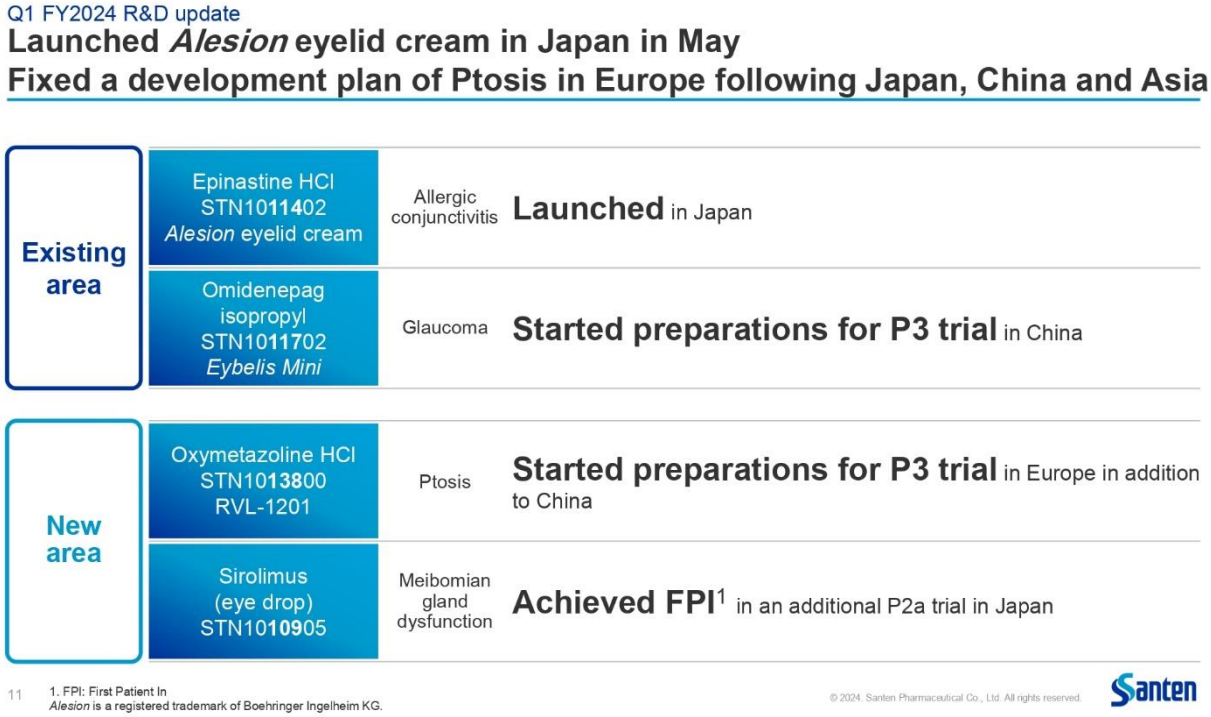
Overseas, on the other hand, we expect an increase of JPY2.2 billion in three regions, mainly due to the impact of foreign exchange rates in EMEA. The details by region are shown in the appendix on a core revenue and contribution profit, which you can find on page 15 of the appendix.

In the non-regional businesses, we expect an increase due to cost optimization and other cost containment measures, as well as the upside potential I mentioned earlier in the sales forecast section, which will offset the decrease in the regional businesses, resulting in JPY55.0 billion. This is how we see it.

We revised our full-year consolidated earnings forecast in Q1 of this fiscal year based on our existing disclosure policy of informing and communicating appropriately about the current situation.

Although there are still uncertainties such as the prolonged suspension of *Diquas LX* shipments and the co-pay hike for long-listed products that will begin in H2, we will pursue sustainable growth by maximizing cash flow, improving capital efficiency, and optimizing capital allocation, etc., through improving profitability, which we have been implementing since the new structure in H2 before last, and by digging deeper into these efforts.

That concludes my explanation.



Sallstig:

Good afternoon, I'm Peter Sallstig, Chief Medical Officer, allow me to provide you an update with regards to status of the pipeline.

Let's go to page 11.

As announced in May, we launched *Alesion* Eyelid Cream in Japan. This product can maintain its efficacy all day with once—a-day dosing. This type of drug applied to the eyelids for allergic conjunctivitis is the world's first formulation, and we expect it to be a more easily administered formulation than eye drops.

Eybelis marketed in Japan and Asia, is the world's first glaucoma drug that selectively acts on EP2 receptors. In China, we plan to begin P3 this fiscal year with the aim of providing a new treatment option there as well.

Pertaining to oxymetazoline, 138, for ptosis treatment which we expect to be a growth driver after fiscal year 2026, we plan to begin P3 in Europe in addition to China later this year.

As for sirolimus ophthalmic solution, 109, for meibomian gland dysfunction treatment, a post-hoc analysis of the first P2a study suggested an improvement over the placebo group in the number of obstructed meibomian gland orifices. Based on this findings, an additional P2a trial was initiated.

Pterygium: CBT-001

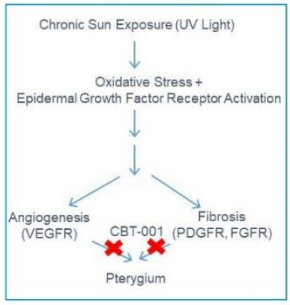
Aim to offer a new therapeutic option through an ophthalmic application of systemic drugs, for pterygium, currently mainly treated through surgery

Pterygium

- Triangular abnormal proliferative tissue originating conjunctiva with blood vessels, penetrating into the center of the cornea
- Often occurring from nasal limbus and not malicious
- Major risk factor is exposure to sunlight (ultraviolet)
- Most common in geographic latitude 40 degrees around the equator, where sun exposure is common
- Cause foreign body sensation, hyperemia and astigmatism
- Dry eye medications and corticosteroids may be prescribed for symptom relief, but radical treatment is currently only surgery
- Depending on the procedure, recurrence risk is considered an issue in pterygium surgery
- Prevalence: 4% in Japan aged 40 years or older.[1] 3.8% in S. Korea.[2] 10.1% in Vietnam, Malaysia, the Philippines, and Thailand in ages 40 years or older.[3]

CBT-001

- Eye drops containing nintedanib as the active ingredient
- Multikinase inhibitor that inhibits angiogenesis and fibrosis by acting on VEGF, PDGF and FGF receptors
- Completion of P2a in US (see next page)
  P3 is ongoing as a multinational study (excl. Japan)



P3 design (NCT05456425)	
Arms	• 0.1% CBT-001 • 0.2% CBT-001 • Vehicle
Dosing frequency	Twice a day
Duration	24 months
Enrollment	600 eyes
Primary endpoints	• Conjunctival hyperemia • Pterygium length • Eye symptom score
Final data collection date	December 31, 2025
Location	AU/CN/IN/NZ/US

12 1. Tano et al, *Acta Ophthalmol* 91(3):e232-6, 2013 2. Rim TH et al, *PLOS One* 12(3) e0171954, 2017
3. Ang M et al, *Ophthalmology* 119(8):1509e15, 2012

Santen

Please see page 12.

Now let me explain to you about the in-licensed asset for pterygium treatment which we just announced today at the same time as our earnings.

As shown in the picture, pterygium is the triangular proliferation tissue with blood vessels toward the center of the black eye. Exposure to ultraviolet radiation is a major risk factor and is known to be common in low-latitude areas. Although not malignant, it can cause vision foreign body sensation, hyperemia, and impairment, such as astigmatism.

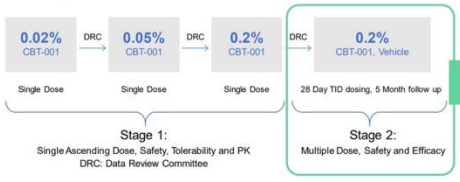
Dry eye medications and corticosteroid eye drops may be prescribed for symptom relief, but the only currently available therapy is surgery to remove the growing tissue. In addition, depending on the procedure, the high rate of recurrence after surgery is recognized as issue. For this reason, surgery is usually performed when subjective symptoms such as foreign body sensation or visual impairment occur.

CBT-001 in which we in-licensed, is an ophthalmic solution containing nintedanib as active ingredient. P2a trial in US have shown that eye drops of CBT-001 may inhibit growth or regress pterygium.

Pterygium: CBT-001

Obtained POC in P2a trial in US

Safety and Efficacy of CBT-001 Ophthalmic Solution in Patients With Pterygium (NCT03049852)



Stage 2 Results

- The most commonly reported adverse events associated with CBT-001 were ocular, mild in severity (Conjunctival Discoloration), resolved after therapy, and did not result in discontinuation
- Baseline demographic characteristics were similar between patients receiving CBT-001 (n=25) and vehicle (n=23).
- After 4 weeks of dosing, mean vascularity scores significantly decreased in patients receiving CBT-001 (-0.8) compared to vehicle (0.0) (p<0.001).
- Vascularity remained at significantly decrease levels at weeks 8 and 16, but not at week 24.
- CBT-001 group showed significantly greater mean reductions in lesion length at weeks 4 and 8 (p<0.05).

Figure 1. Pterygia vascularity mean grade change from baseline (Statistically significant drug vs vehicle p-values are shown)

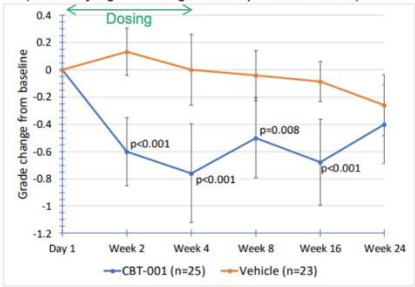
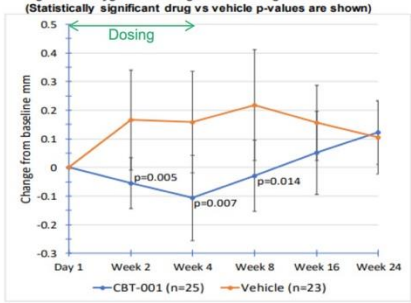


Figure 4. Pterygia lesion length mean change from baseline (Statistically significant drug vs vehicle p-values are shown)



13 A Phase 2 Multicenter, Randomized, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of CBT-001 for Pterygia
https://cloudbreakpharma.com/wp-content/uploads/2024/05/ARVO-2019-Poster_Scott.pdf

Santen

Let me move on page 13.

The P2a trial consisted of two stages. Stage 1 was to confirm safety and tolerability with a progressive increase in dosage and stage 2 was to compare safety and efficacy with placebo-treated patients.

In the stage 2, the administration was 3 times a day for 4 weeks, followed by a 5-month follow-up period.

The graph on the left shows the change in pterygium vascularity grade as a primary endpoint. The vascularity grade is a measure of the density of blood vessels in the pterygium. Orange is placebo. Blue is CBT-001. A statistically significant inhibitory effect compared to placebo was maintained at Weeks 2 and 4 in the treatment period.

The graph on the right shows the change in the length of the pterygium, which is one of the secondary endpoints. This also showed a statistically significant inhibitory effect compared to placebo at 2 and 4 weeks in the treatment period.

There were no events that were problematic in terms of safety and tolerability, including the follow-up period.

Based on these results, we are planning now the development schedule in Japan and Asia where Santen have acquired the rights and we aim to provide this new treatment options to our patients at the earliest possible time.

This concludes my part. Thank you.

Question & Answer

Yamaguchi [Q]: Thank you very much. Let me ask you three simple questions.

I think you explained this on page eight, but I was wondering if you could tell me if you envisioned this other inorganic item as a one-time, direct hit to profits, by sale of some business or threesome asset

Koshiji [A]: Regarding your question, I will answer. In this respect, we are considering temporary income in the form of technology licensing. It is not a sale of the business.

Yamaguchi [Q]: I see, I understand. I could not understand whether the negative JPY2.0 billion caused by the Noto issue was allocated somewhere or not, or whether it remains as it is. Could you please clarify?

Koshiji [A]: In that respect, pertaining to the Noto line, actually Noto and Shiga, the decrease in sales is JPY3.0 billion and JPY2.0 billion for gross profits due to the delay in restoring the line. That has not changed on a consolidated basis, but we are counting it as a downside to our full-year forecast for China and Asia.

Did I answer your question?

Yamaguchi [Q]: So, you are accounting for that outside of Japan.

Koshiji [A]: Yes, that's right.

Yamaguchi [Q]: I see. Thank you. Secondly, I think the plan is to cover the issues and negative points of *Diquas*, but the important thing is that *Diquas LX* will not have any sales this fiscal year, and it seems that it will take time.

What is the process for remanufacturing now? Please let me know if you've already had an idea.

Koshiji [A]: In that regard, first of all, this is a Class 2 recall. The situation is that silver nitrate, which is a preservative, is declining. As a result, deviation from the standard is the main reason for this recall.

In response, we must identify the root cause of the problem, and we know that the cause is in the drug substance, but we still need time to clarify the root cause is.

However, we are conducting several tests and are repeating trial and error, so at this point, we are aware that we hope to have a rough idea by the end of this fiscal year. At this stage, we cannot say exactly how far we are willing to go, but first, we have made a decision to reduce the sales count to zero in our earnings forecast.

Yamaguchi [Q]: I see. Finally, CBT-001. The existing technology is surgery, so it is probably indicated for severe condition. In the case of this drug, is it also indicated for severe condition or for a milder form of the disease?

I heard that pterygium surgery is quite popular in Japan, but if you know the number of surgeries performed, please let me know. That is all.

Sallstig [A]: Thank you for your question. Regarding your question about the target patients, the clinical trials Cloudbreak is conducting now are targeting a wide range of patients. It includes a wide variety of patients, from those who have recently been diagnosed with the disease to those who have undergone surgery and had a recurrence of the disease. At this time, we believe that the drug will cover mild to severely ill patients.

As for the number of surgeries, I have heard that there are about 22,000 in Japan. That's all from me.

Yamaguchi [M]: Thank you. That's all from me.

Sakuma [M]: Thank you very much. Now, we will move on to the next question.

Mr. Muraoka of Morgan Stanley Securities, please go ahead.

Muraoka [Q]: This is a bit of a repeat of the same question, but it's about *Diquas LX*. You mentioned earlier that you would like to somehow get to a point by the end of this fiscal year, but is it safe to say that it is extremely unlikely that sales will be registered again by the end of this fiscal year as a possibility?

And is it safe to assume that sales are likely to return throughout a relatively full year in the next fiscal year? Please tell us about this point. Please tell us a little bit about that, including whether it is a regulatory process that would allow you to resume sales as soon as the cause is identified in the first place, about *Diquas*.

Koshiji [A]: Koshiji will answer the question. As for the first point, the possibility of sales in the current fiscal year, we have made a judgment that there is almost no possibility of restarting sales at this point, and we have made a forecast of zero.

However, the possibility of generating sales is not zero if the root cause can be identified and the authorities give us permission. However, that is what we expect currently.

As for the situation in the next fiscal year, at this point, we can say that we hope to be able to record sales in the next fiscal year, but this will depend, in part, on whether we can identify the root cause.

However, our management's intention, or the Company's intention, is based on such a premise. Since shipments are currently suspended, whether sales will recover at once to the JPY13.0 billion level expected for this fiscal year is not clear because that will depend on how much market share is taken away by competitive products. We are also aware that the sales of *Diquas LX* on a stand-alone basis will depend on the recovery of sales in combination with the alternative products we are currently focusing on.

Muraoka [Q]: Thank you. I'm sorry, if the root cause can be identified, is it possible to resume shipments rather quickly, based on that regulatory mechanism?

Koshiji [A]: Yes, that’s my understanding. Given our obligations to supply the product, and also, from the standpoint of the needs of patients and other medical institutions, as well as from the regulatory perspective of the authorities, once the root cause is identified we should be able to react quickly.

Originally, as of May 9, we were expecting to be able to ship by late May. In fine, you can see that things have not evolved as we had expected.

Muraoka [Q]: I see. Thank you. I am surprised at how well *Alesion* cream is doing in its sales, that it will be a quarter of the JPY7.3 billion raised forecast for the year already. How should I interpret this in terms of what the May, June, 2 month sales represent vis a vis this figure.

Should I expect this to lead to an upward revision given the sales momentum?

Koshiji [A]: I will answer the question. We will keep an eye on the momentum and will see whether that translates into an upward revision. The data disclosed for *Alesion* as a whole is JPY6.3 billion, of which *Alesion* cream is JPY1.5 billion and *Alesion* LX is JPY4.5 billion, and that is the breakdown. Since this JPY1.5 billion portion was better than expected, we have revised our forecast for the full year.

Muraoka [Q]: Do you already have a firm grasp of repeat demand and such?

Koshiji [A]: I'm afraid we can't answer that question at this stage, or rather, we don't have that sufficient information to answer that question yet.

Muraoka [Q]: I see. Thank you. One last thing, this CBT-001 today, one of the problems with surgery is that there are many recurrences. I have a feeling that the conditions will get worse again if users stop administering this CBT-001, as far as the clinical data are concerned. How will this medicine be used?

Will the users have to keep using it for a long time, instead of just using it for four weeks and be done with it? Please tell me how to use that in the clinical setting, in the real world.

Sallstig [A]: In the P2a trial conducted, it was for four weeks, followed by an observation period. In the P3 Cloudbreak is conducting now, it is designed to be longer than that, with a 12-month administration. The timing of the dosing pace will be identified by future clinical trials.

I guess we will see how the authorities, and the patients, react to this, and whether it is a year or what kind of length of time it will be. All I can say at this point is that Cloudbreak and Santen will be looking at how to design future clinical trials as we think about them, so I can't say much more at this stage, but I hope you will understand.

Muraoka [M]: Thank you. That's all from me.

Sakuma [M]: Thank you very much. Now let's move on to the next question. Mr. Wakao of JPMorgan Securities, please go ahead.

Wakao [Q]: The first question is about the Noto Plant. First of all, regarding the Noto Plant issue, is it correct to say that this problem will have already been solved if the plant is restarted during H1?

Also, this issue of supply has been incorporated into the plan because of its impact on China and other Asian countries. Is this something that is already affecting their sales currently? Or is it something that will actually be reflected through sales after Q2?

Koshiji [A]: Koshiji will answer. First of all, regarding the status of the line at the Noto Plant, we believe that shipments will be possible as soon as the line is restored.

However, we initially said that we would be able to resume production in late August, but the media fill test, a test of the process to guarantee aseptic processes, is taking longer than expected. We expect that by the end of September, we will be able to get a handle on the situation, and we anticipate that operations will resume as usual in October.

On the other hand, what about the impact on business performance, as I mentioned earlier, in Asia and China, it is already becoming apparent in our business performance in that regard. Therefore, shortages, which mainly include products manufactured not only at the Noto Plant but also at the Shiga Plant, are already having a noticeable impact in China and Asia due to the inability to supply products.

So, if the restoration of Noto, for example, is delayed further to October or November, will this cause a further downside to our business performance, we have already factored in this to some extent, so there will be no further downside to the supply of Noto and Shiga-related products, we suppose.

Wakao [Q]: I'm sorry, how have you incorporated the fact that Noto will be restored and fine in October into your current revised plan?

Koshiji [A]: In this respect, the products produced and subject to this delay in Noto are not so profitable, so even if there is a slight delay, it can be absorbed to some extent by the budget buffer in the P&L budget. This is what we think.

Wakao [Q]: I understand very well. That way, even if there is a slight delay, it means a slight delay.

Koshiji [A]: Yes, that's right.

Wakao [Q]: Secondly, page nine, I think you have explained it very clearly. I could see that it was because of *Diquas*. And you mean offset by the exchange rate.

The yen has been rapidly appreciating, and the euro is particularly impacted. If the euro were to depreciate to JPY160 or JPY155, and the yen becomes stronger, I am not sure how you would be able to secure EPS of JPY92 at the beginning of the fiscal year. Of course, I am asking knowing that no one really knows how the exchange rate will evolve

The slide also mentions further upside, so could you please explain what will happen if the yen appreciates?

Koshiji [A]: In this respect, I believe there will be a downside impact if the yen appreciates. Since we are not professionals in the field of foreign exchange, we have calculated the year-to-go exchange rate to March based on the forecasts of financial institutions, and the rate has been automatically adjusted to accordingly.

Therefore, if the euro, for example, were to land at JPY155, which we assume at this time at JPY165, we would expect a negative impact of several hundred million yen. However, we do not anticipate that it will be at the billion-yen level, so we believe that we can absorb some of the potential upside in the budget, or rather, the buffer that we are currently assuming.

Also, regarding EPS, we are hedging foreign exchange rates in the financial income and financial expenses, so if the yen becomes stronger than expected, we will absorb it to some extent in the hedging section, and we do not expect a decline, at least on a core basis, even if there is a decline. We believe that there is room to make such efforts to secure the bottom-line net profit, and that there is room to make adjustments.

Wakao [Q]: I understand. By the way, in the title of this eighth slide, it says "Further upside potential," is it correct to understand that there are some upsides that are not incorporated this time?

Koshiji [A]: In terms of further upside potential, I think we can make a little more profit if we can make best efforts in, for example, purchasing and cost containment.

The current situation is roughly JPY55.0 billion, based on calculations of what we can expect with a certain degree of certainty.

Wakao [M]: I understand very well. Thank you. That's all from me.

Sakuma [M]: Thank you very much. Now let's move on to the next question. Mr. Hashiguchi of Daiwa Securities, please go ahead.

Hashiguchi [Q]: The first question is about your company's future development plans for CBT-001. Since the global Phase 3 trial has already started, is it correct to say that your company will conduct its own trial without participating in it?

If so, what is your schedule for development, and when do you hope to submit an application or receive approval? I would appreciate it if you could provide a specific timeline to show us what you are thinking at this time.

Sallstig [A]: As of today, Santen plans to develop its own. Clinical trials will be conducted in Japan.

The P3 trial being conducted by Cloudbreak is progressing well, and there is no possibility that Santen will participate in it, and there are also regulatory hurdles to overcome so we are planning to conduct Santen's own trials in Japan.

Our current assumption for approval is after 2030. Of course, this will change depending on the delay in the progress of clinical trials, and the P3 trial that Cloudbreak is conducting is itself 12 months long, so we are assuming approval in 2030 or later, including such factors.

Hashiguchi [Q]: Thank you. One other point is regarding your plans for research and development expenses.

You did not spend that much in Q1, but your forecast for the full year is slightly higher, and you expect a considerable increase from Q2 onward. I'd like to understand this background a little better.

In the previous fiscal year, there was quite a difference between the plan you presented in advance and the actual results, but is there anything like that in your forecast for this fiscal year? Has the accuracy or sophistication of forecasts improved? Or is there some kind of buffer there that Mr. Koshiji mentioned earlier? Could you comment a little on this point?

Koshiji [A]: In that respect, R&D expenses at the beginning of the period increased by JPY1.0 billion from JPY26.0 billion to JPY27.0 billion, but this is a direct reflection of the exchange rate, the depreciation of the yen. In fact, roughly 65% of R&D expenses are denominated in foreign currency, so the change in the exchange rate this time is roughly 7%, so if it were a 7% change, it should be a little more like JPY26.0 billion to JPY28.5 billion. But the baseline has been lowered to incorporate cost containment during the period, clinical trial cost containment, and other factors and forecast revised to JPY27.0 billion to reflect the weaker yen exchange rate.

Although Q1 is indeed a low rate of progress and expenses digestion, we are aware that from Q2 onward, the digestion rate will increase, and that is how we perceive it in terms of our internal forecasting.

However, in the case of the last fiscal year, the considerable unconsumed was the final landing against JPY29.0 billion. I am sorry, it ended up unconsumed, but for the full year, yes, it ended up at JPY25.3 billion. For this fiscal year, at this stage, we assume that JPY27.0 billion will be used up. I don't know if there is a possibility that the buffer could end up with about JPY500 million unconsumed to some extent, though.

I think there is a point where not everything goes in order. However, at this stage, we are aware that it is JPY27.0 billion. Did that answer your question?

Hashiguchi [M]: I understand. Thank you. That's all from me.

Sakuma [M]: Thank you very much. There are still people waiting to ask questions, but as the closing time is approaching, we will let the next questioner be the last.

Now, Mr. Ueda of Goldman Sachs, could you please go ahead?

Ueda [Q]: My first question, I would like to know your thoughts on the prospects once *Diquas LX* shipments normalized.

I have the impression that sales in dry eye were reduced by about JPY10.0 billion this time, and that the upside potential of inorganic products was raised by more than JPY3.0 billion, etc., but on a real basis, I wonder if the increase was due to favorable overseas sales and cost containment, etc.

Is this due to the fact that you have been applying a little bit of excessive cost containment in this fiscal year based on those situations? Can you tell us what you think about the prospects for normalization in the next fiscal year and beyond?

Koshiji [A]: In this respect, regarding the outlook after the normalization of *Diquas LX*, first of all, in this fiscal year, we are not forcibly restraining expenses in order to recover the downside of *Diquas LX*.

We do forecasting and budgeting on an annual basis, and we do cost optimization for upside cost constraint, but it is just a part of our normal day-to-day operations.

In this respect, once the situation normalizes from the next fiscal year onward, that is not assuming we stretch ourselves this year and recovery delays as a result, we believe that this product will make a positive contribution to earnings because the gross profit margin of *Diquas LX* is extremely high, which is about 20% higher than that of conventional products.

Also, in terms of production capacity, we believe that a virtuous cycle can be formed if production can be resumed as soon as possible, taking into consideration that the number of units to be produced can be smaller than that of the previous *Diquas* because of its high concentration (Santen post amendment: the concentration is the same. The administration frequency is half; *Diquas LX* is three time a day while *Diquas* is six time a day and).

Therefore, we recognize that the identification of the root cause is already a top priority. Did that answer your question?

Ueda [Q]: Thank you very much. One more thing, regarding the *Alesion* eyelid cream, I would like to know if there is any deviation from your company's initial assumption regarding this penetration after the product is launched. If so, what is the reason for this? Also, the revision seems to be a little small compared to the progress made in Q1, but I would like to know if there are any factors such as initial shipments that differ from the seasonality of previous years. Could you comment on that?

Koshiji [A]: In that respect, as reflected in the full-year forecast, we have revised the sales forecast for *Alesion* cream itself upward by about 10% and disclosed it as the overall *Alesion* figure, because the initial shipments are slightly strong as far as the initial shipments and the accompanying response are concerned. This is what we are doing.

At the beginning of the fiscal year, we initially assumed JPY6.7 billion for *Alesion* cream, and we raised that to JPY7.3 billion. Overall, from JPY27.5 billion to JPY28.7 billion. As I mentioned earlier, Q1 was JPY1.5 billion, so even considering the seasonality of Q1, the JPY1.5 billion in Q1, and the high season in Q3 and Q4, this quarter is somewhat stronger than expected.

However, since it is pollen, a drug for an extremely volatile field, we are not sure if it will grow more strongly, but at this point, we are making a rather cautious assumption.

Ueda [M]: I understand. Thank you. That is all.

Sakuma [M]: Thank you very much. This concludes the briefing for today.

[END]