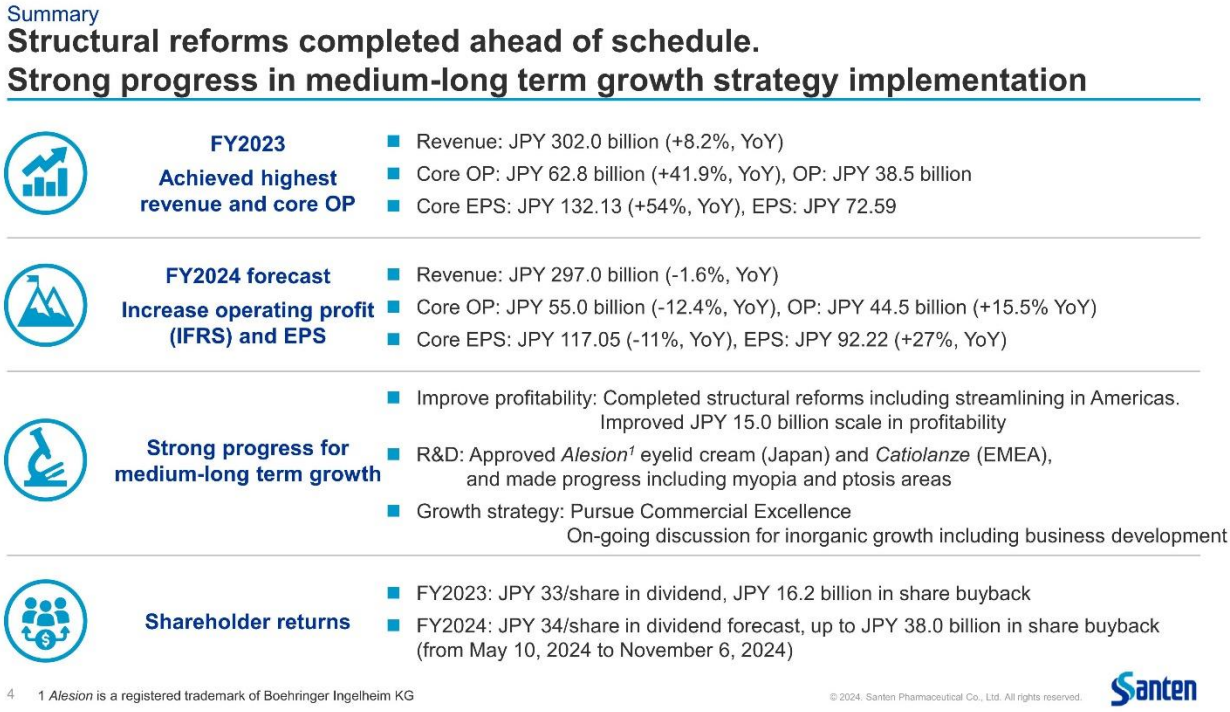
FY2023 Financial Results Transcript

Ito: I'm Ito, CEO of Santen. Thank you for taking time out of your very busy schedule today to attend our FY2023 financial results briefing.

First, I would like to explain the financial summary.



See page four.

At the beginning of the FY2023, we made a very conservative estimate of the impact of the launch of generic products in the Japanese business, the scale and speed of implementation of company-wide structural reforms, and other factors. However, the impact on the Japanese business was minimal due to the delayed launch of generic products, overseas business also grew stronger than expected, and structural reforms, including streamlining in the Americas, were completed ahead of schedule and on a larger-than-expected scale. As a result, revenue was JPY302.0 billion, and core operating profit was JPY62.8 billion, reaching a record high.

Operating profit on an IFRS basis was JPY38.5 billion mainly due to impairment losses on intangible assets and structural reforms costs. In FY2024, we expect certain impacts in Japan due to the impact of generics of mainstay products, NHI price revisions, and reasons for co-pay hikes for long-listed products that will start in H2, but we expect continued strong growth in overseas regions.

As for the impact of the Noto Peninsula earthquake that occurred on New Year's Day, most of the production has resumed since March although there is a single dose unit line that is still taking time to recover and we have factored that in. We are working to restore operations at the production site, but we see a certain amount of time required for recovery as a risk factor since it is not in operation at this time.

Based on the above, we forecast net sales of JPY297 billion and core operating profit of JPY55 billion, and we hope to achieve a core operating profit that is almost the same level as the target of the medium-term management plan. Operating profit on an IFRS basis is expected to increase by 15.5% to JPY44.5 billion due to the absence of structural reforms and impairment loss expenses incurred in FY2023, and EPS is also expected to increase significantly to JPY92.2.

We are also making steady progress in medium- to long-term growth measures in line with the medium-term management plan announced last fiscal year. As I mentioned earlier, the completion of structural reforms, including streamlining in the US, ahead of schedule, has created an improvement effect in profitability of JPY15.0 billion in FY2023.

There was also a lot of progress in R&D, including the approval of a pipeline that will support medium-term growth, including *Alesion* eyelid cream in Japan, a glaucoma treatment in EMEA, *Catiolanze*, as well as the completion of Phase III for 127 for myopia in Japan and 138 for ptosis, which is expected to make a significant contribution in FY2025 and beyond. We will discuss the topline results for ptosis later.

We will continue to pursue commercial excellence and aim for steady growth in our regional business, with an eye to inorganic growth through business development and other means.

We regard shareholder returns as an important management issue. First, based on the progressive dividend policy, we forecast an annual dividend of JPY34 per share, with a floor of JPY17 per half year for FY2024.

Next, with regard to share buybacks, we expect to begin share buyback tomorrow, up to JPY38.0 billion or 5.8% of outstanding shares in FY2024. We believe that the current share price level is still undervalued, and we intend to improve ROE and EPS through the acquisition. This brings the total to approximately 16% or JPY80 billion over the three-year period in addition to the 9.8% or JPY41.9 billion acquired in FY2022 and FY2023.

KPI progress for medium-term management plan

Next medium-term management plan to be formulated by end of FY2024

Basic policy until FY2025
- Profit maximization through structural reforms and sales maximization of each region
- Lay the organizational groundwork for FY2026

KPI	FY2020	FY2021	FY2022	FY2023	FY2024 FCST	MTP FY2025
Revenue	JPY 249.6bil.	JPY 266.3bil.	JPY 279.0bil.	JPY 302.0bil.	JPY 297.0bil.	JPY 280.0bil.
Core operating profit/margin	JPY 50.1bil / 20%	JPY 46.3bil / 17%	JPY 44.2bil / 16%	JPY 62.8bil / 21%	JPY 55.0bil / 19%	JPY 56.0bil / 20%
Revenue growth ratio per overseas employee	-1% (CAGR for FY19-22 FCST)[1]			33%(YoY)[2]	19% (FY22ACT-24FCST CAGR)[2]	Over 7% growth[3,4]
Core ROE	12.3%	10.9%	10.5%	16.2%	14%[5]	13%
Growth rate of core EPS	+5%(YoY) JPY 94.09	-6%(YoY) JPY 88.16	-3%(YoY) JPY 85.86	+54%(YoY) JPY 132.13	+17% (FY22ACT-24FCST CAGR)/ JPY117.05	Over 10%[4]
EPS (IFRS)	JPY 23.30	JPY 68.07	JPY -38.60	JPY 72.59	JPY 92.22	-

5 1 China, Asia, EMEA. Excluding FX impact, calculated based on FY2022 FX rate 2 China, Asia, EMEA. Excluding *Ikervis* one-time factor in FY2023
3 China, Asia, EMEA. Excluding FX impact, calculated based on MTP rate 4 CAGR for FY2022 forecast- FY2025 5 Including share buy-back

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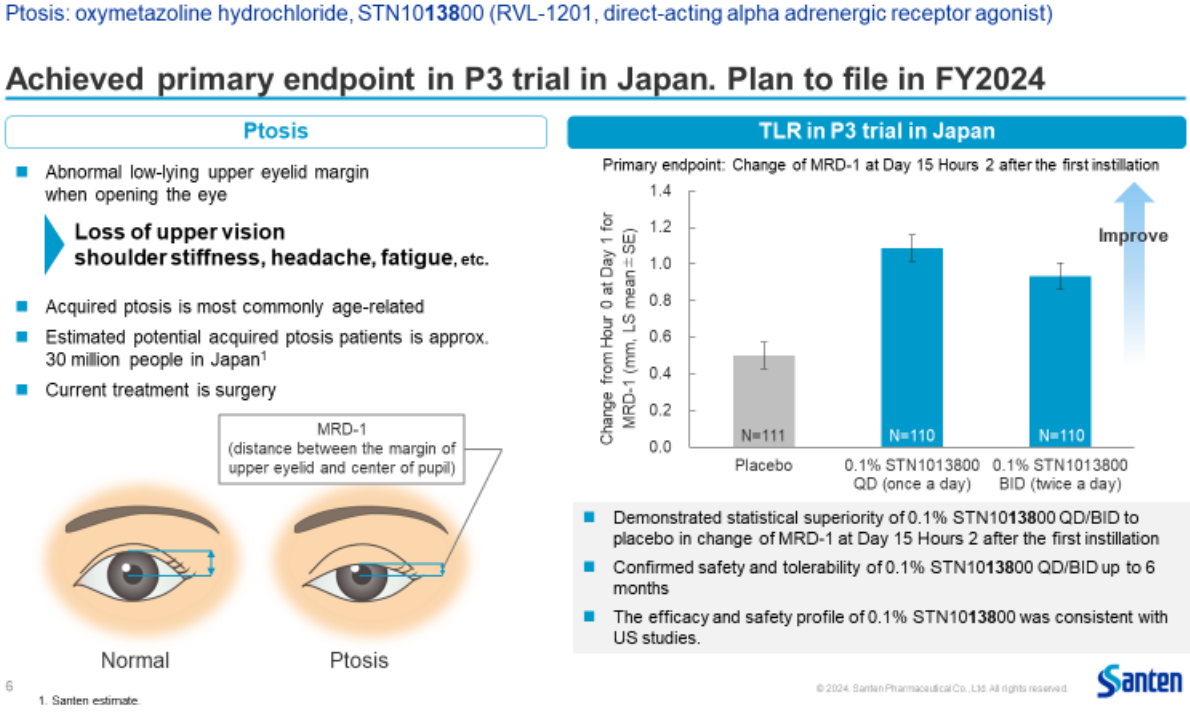
Next, please see page five.

In the medium-term management plan disclosed last year, we set targets for FY2025 in terms of revenue, core operating profit and profit margin, productivity improvement in overseas business, and core-based ROE and EPS growth rate as indicators.

As I mentioned earlier, we realized each of these indicators ahead of schedule due to the very strong performance in FY2023. Our basic direction remains unchanged: to maximize earnings through structural reforms and maximization of regional sales and to build an organizational foundation that will support significant growth in FY2026 and beyond. In terms of medium- to long-term growth, product development is progressing smoothly, and we will aim to maximize the value contribution from our scalable pipelines.

The forecast for FY2024 is also generally expected to exceed the target. However, due to changes in the business environment, including the impact of long-term listed products, a new medium-term management

plan starting in FY2025 is scheduled to be formulated during the current fiscal year, and the specific timing and period of disclosure will be announced as soon as they are determined.



Regarding the Phase III study in Japan for ptosis, we explained at the capital markets day on overseas business in March that the primary endpoint was achieved. Today, we will also discuss a few top-line results.

Please see page six. First, let me briefly review ptosis.

Acquired ptosis is thought to be caused primarily by aging, which weakens the muscles and the tendons that attach to the eyelids. It is one of the most common eyelid diseases in people over 50.

You may be under the impression that this is merely an aesthetic issue because of its effect on appearance, such as looking sleepy. However, drooping eyelids can affect vision by making it difficult to see information and can also cause stiff shoulders, headaches, fatigue, and other symptoms. Currently, the only treatment available in Japan is surgical eyelid lifting.

As you know, the drug has already been marketed in the US by RVL, the company that introduced the drug. Now, for the first time, its efficacy has been confirmed in Asian patients in a Phase III study in Japan. In the clinical study, the effect was measured by measuring the distance from the center of the pupil to the upper eyelid, which is referred to as MRD-1.

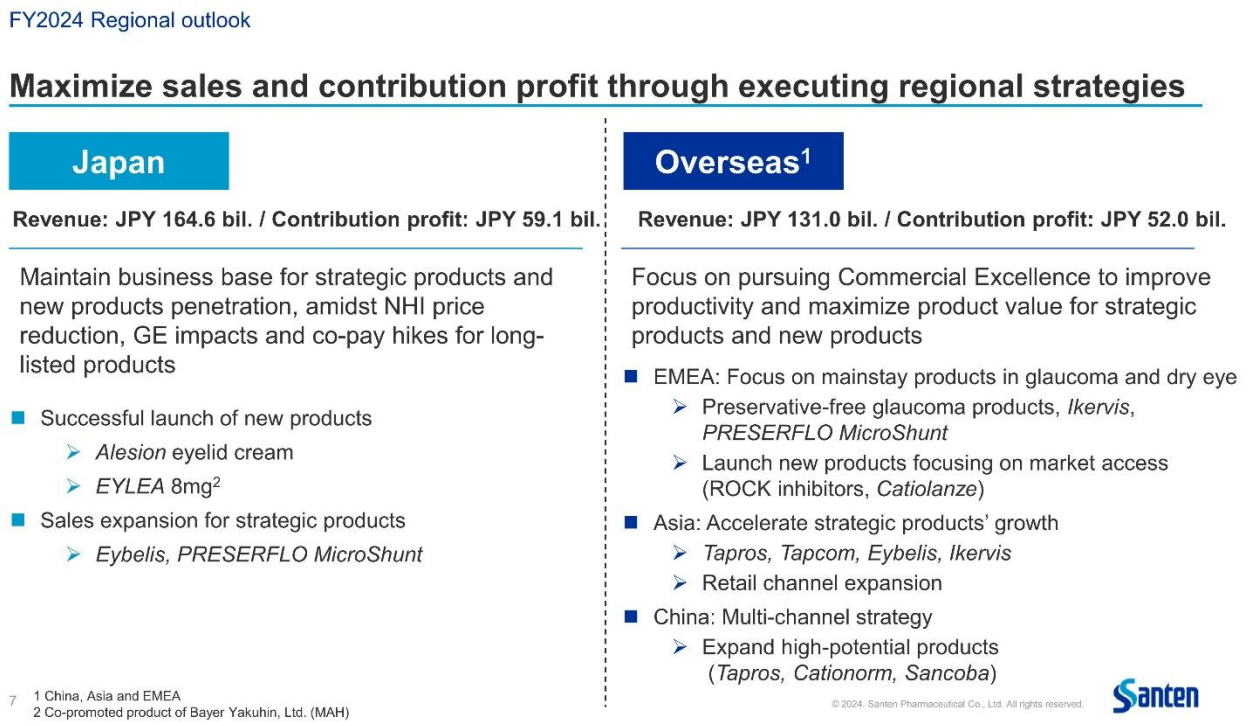
As shown in the graph on the right, both once-daily and twice-daily eye drops showed statistically significant improvement compared to the placebo group. We have also confirmed the safety and tolerability of the item for up to six months. The application will be submitted this fiscal year, with the aim of launching the item on the market in FY2026.

We believe that the launch of a treatment for ptosis may lead to the early detection of other ophthalmologic diseases that have few subjective symptoms by attracting new patients who were previously unfamiliar with ophthalmology to the clinic and having them undergo an examination.

As a company specialized in the ophthalmology, we aim to realize Happiness with Vision for people by providing valuable products and services to patients, consumers, and medical professionals around the world.

In addition to striving to expand contributions to patients in the areas of myopia for which we have already filed applications and ptosis, we will also work to make contributions in other ophthalmologic disease areas for which there are no therapeutic drugs available.

That's all from me for the presentation.



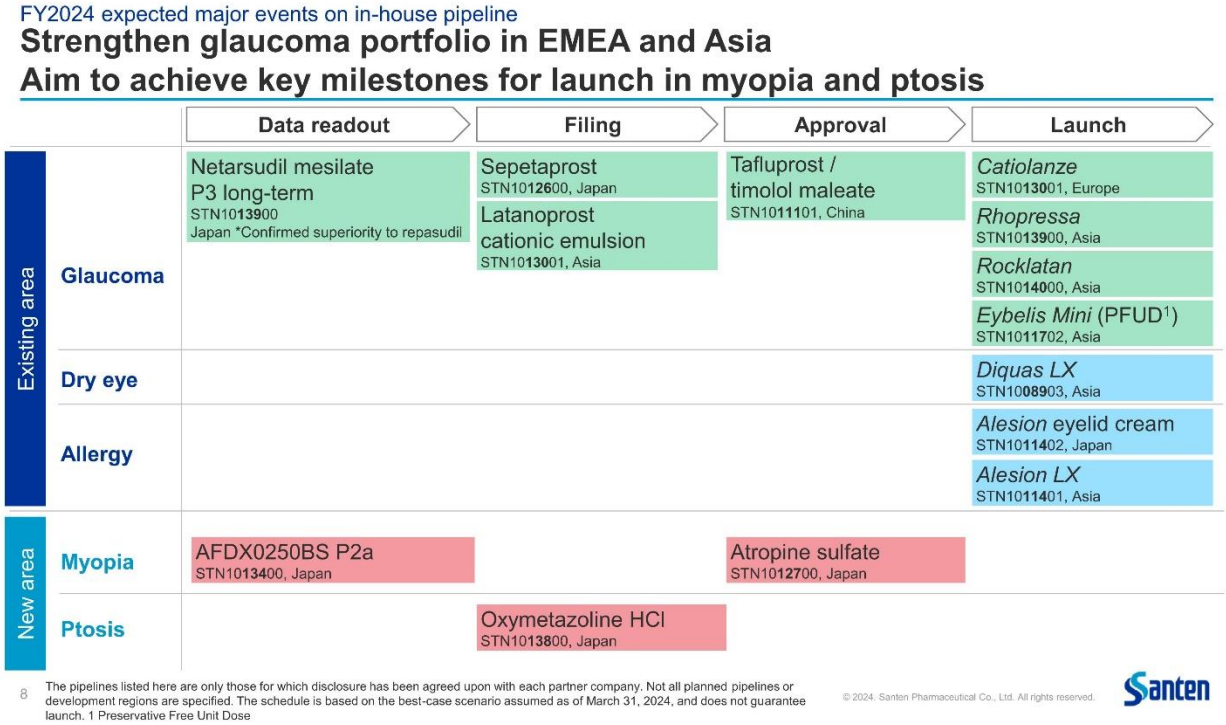
Nakajima: My name is Nakajima, COO. I would like to talk about the direction of each region's business for the current year.

See page seven.

In Japan, despite NHI price reductions, the impact of generics, and the shift to selective treatment of brand-name drugs, we will secure revenue of JPY164.6 billion and a contribution profit of JPY59.1 billion by expanding new products that offer new value to patients, such as *EYLEA* 8 mg, which was launched in April, and *Alesion* eyelid cream, which will be explained later.

In our overseas business, we will further improve productivity and maximize the value of strategic products by instilling commercial excellence in each region. Revenue is projected to increase 6% YoY to JPY131.0 billion and contribution profit to JPY52.0 billion. In the Americas, the loss will be eliminated from the current fiscal year due to the completion of streamlining. In addition to the growth in these products, we are also exploring inorganic growth opportunities.

While business development in the past has focused on expansion into the US, we are now considering business development from the perspective of how we can enhance business growth in line with our regional strategies in Japan, China, Asia, and EMEA. While adhering to financial discipline, we intend to invest aggressively in promising opportunities.

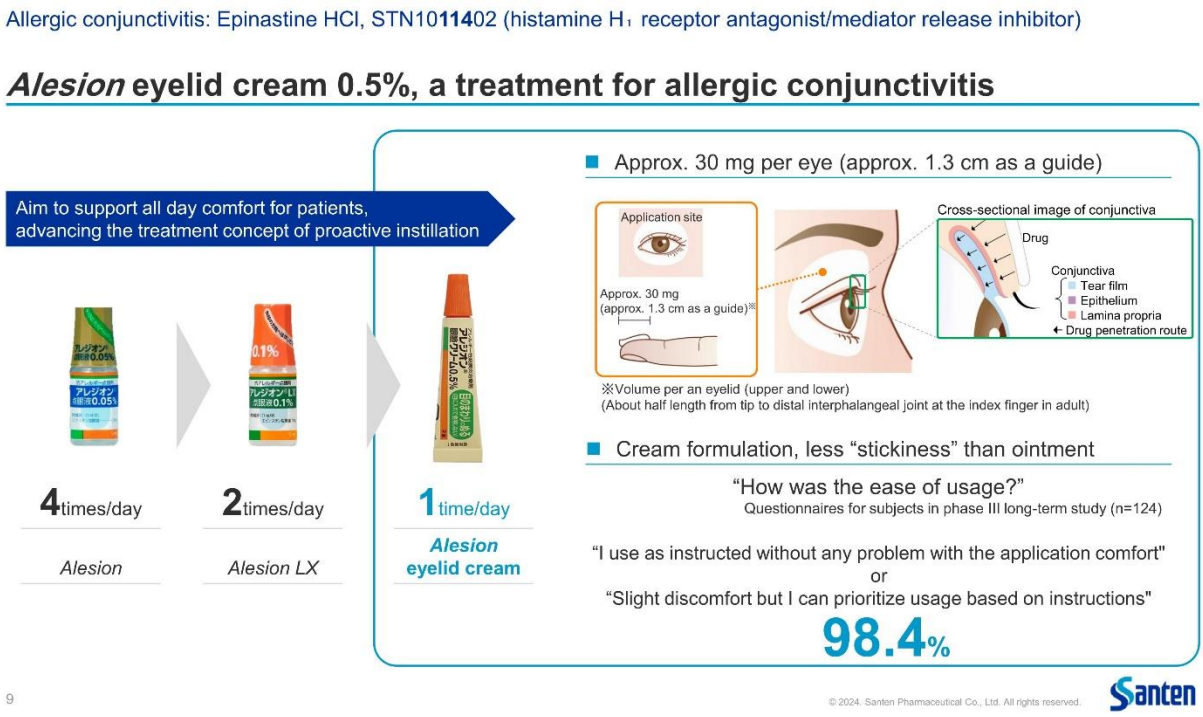


Next, from a pipeline perspective, here are some of the major events expected this year. Please see page eight.

In Europe and Asia, we plan to launch a number of items, including glaucoma and dry eye. In EMEA, these include *Catiolanze,* which can provide value to glaucoma patients with ocular surface disease, and ROCK inhibitors, a glaucoma treatment with a new mechanism of action in Asia. Since the product will be launched sequentially in each country, sales will start slowly, but we will strive for market penetration through commercial excellence and develop them into products that will support growth in the short to medium term.

As Ito mentioned earlier, development of products for myopia and ptosis, which are being developed as products that will drive growth in FY2026 and beyond, is also progressing steadily. This year, ahead of other regions, 127 for myopia and 138 for ptosis will move to the approval or application step in Japan. The product for myopia is expected to be launched in Japan in FY2025 and for ptosis in FY2026.

I will explain a little more about *Alesion* eyelid cream, which is expected to make the fastest profit contribution of all the products shown on this slide, on the next slide.



Please see page nine.

Since the launch in 2013 of *Alesion* eye drop, which is a four-times-a-day ophthalmic solution, we have made a number of improvements aimed at making patients comfortable throughout the day, such as improving the formulation to one that does not contain the benzalkonium chloride as preservative and reducing the number of times the drops are required. The drug has already been approved in Japan and is expected to be listed on the NHI drug price list soon, with a prompt launch planned after the listing.

This product is the world's first cream-type allergic conjunctivitis treatment applied around the eye. When applied around the eyes once a day with the fingers, it diffuses into the eyelid tissue and ocular surface to reach and treat the areas that cause allergic symptoms.

In addition to the fact that it is administered once a day, we believe that it is also convenient for patients because it is applied by direct touch, rather than by eye drops, which some people find difficult.

On the other hand, some may be concerned about the feel of the product, but since it is a cream formulation rather than an ointment, it is expected to be less sticky, and in a survey of those who participated in the clinical trial, approximately 80% said they had no problem with its feeling of application and could use it as directed. When those who responded that it leaves a slightly uncomfortable sensation but they can prioritize using it as instructed were combined, the percentage was 98.4%.

Since patients with allergic conjunctivitis such as hay fever often visit non-ophthalmology departments, we plan to co-promote with Mitsubishi Tanabe Pharma, with whom we have collaborated on *Alesion* and *Alesion LX*. Santen will be in charge of ophthalmology, and Mitsubishi Tanabe Pharma will be in charge of non-ophthalmology departments. By bringing this breakthrough formulation to the medical field as a new treatment option, we aim to contribute to the comfortable lives of as many patients as possible.

That is all from me.

FY2023 Consolidated results

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

	FY2022 ACT	FY2023 ACT
USD (JPY)	135.40	144.80
EUR (JPY)	140.97	156.88
CNY (JPY)	19.72	20.24

(JPY billions)	FY2022		FY2023				
	Actual	vs Revenue	Actual	vs Revenue	YoY	Forecast (Nov. 7)	vs forecast
Revenue	279.0	-	**302.0**	-	**+8.2%**	302.0	100%
Cost of sales	113.0	40%	123.1	41%	+9.0%	121.0	102%
Gross profit	166.1	60%	**178.9**	**59%**	**+7.7%**	181.0	99%
SG&A expenses	93.5	34%	90.8	30%	-2.9%	94.0	97%
R&D expenses	28.3	10%	25.3	8%	-10.7%	29.0	87%
Core operating profit	44.2	16%	**62.8**	**21%**	**+41.9%**	58.0	108%
Non-core expenses	2.7	1%	1.0	0%	-62.6%	1.1	92%
Amortization on intangible assets associated with products	9.5	3%	9.5	3%	-0.5%	9.4	101%
Other income	3.5	1%	1.5	1%	-56.1%	1.5	103%
Other expenses	38.6	14%	15.3	5%	-60.4%	8.0	191%
Operating profit	-3.1	-	**38.5**	**13%**	-	41.0	94%
Finance income	1.2	0%	1.6	1%	+36.4%	1.5	105%
Finance expenses	1.5	1%	2.7	1%	+77.7%	1.2	222%
Share of loss of investments accounted for using equity method	2.4	1%	7.6	3%	+220.7%	3.0	252%
Profit before tax	-5.8	-	29.9	10%	-	38.3	78%
Income tax expenses	9.2	3%	3.2	1%	-65.5%	8.8	36%
Actual tax ratio	-	-	*10.6%*	-	-	*23%*	-
Net profit	-15.0	-	**26.7**	**9%**	-	29.5	91%
Core net profit	33.2	12%	48.5	16%	+46.0%	43.5	112%

Revenue: +8.2%

- Overseas business+24% YoY*1

Gross profit: +7.7%

- COGS ratio increase versus forecast mainly resulting from region/product mix

Core OP: +41.9%

- Reduced SG&A from cost optimization and structural reforms

OP (IFRS)

- Structural reforms costs, Noto plant operating loss, impairment loss (intangible asset related to cell therapy products JPY 7.0 billion) and others

Net profit (IFRS)

- Share of loss of investments (including Twenty Twenty Therapeutics)
- Tax ratio excluding one-time factors : 23.8% (FY2023)

*1 China, Asia and EMEA (including one-time factors)

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Koshiji: I am CFO Koshiji. See page 10.

As explained earlier by our CEO, in FY2023, we achieved record revenues of JPY302.0 billion and core operating profit of JPY62.8 billion. In addition to overseas business being a growth driver, efforts to control expenses through structural reforms and cost optimization led to the results.

Under core operating profit, operating profit on an IFRS basis was JPY38.5 billion. Non-core expenses of JPY1 billion, and other expenses of JPY15.3 billion include structural reforms-related expenses including streamlining in the US and early retirement program in Japan, operating loss of the Noto Plant due to the earthquake on New Year's Day, and impairment of intangible assets. .

Net income was JPY26.7 billion due to impairment losses on equity method investments, including Twenty Twenty Therapeutics, a joint venture with Verily.

FY2024 Outlook

Decrease in revenue from GE impacts and other factors in Japan
Increase in profits and EPS in IFRS basis

	FY2023 ACT	FY2024 FCST
USD (JPY)	144.80	145.00
EUR (JPY)	156.88	155.00
CNY (JPY)	20.24	20.00

(JPY billions)	FY2023		FY2024		
	Actual	vs Revenue	Forecast	vs Revenue	YoY
Revenue	302.0	-	**297.0**	-	**-1.6%**
Cost of sales	123.1	41%	127.5	43%	+3.6%
Gross profit	178.9	59%	**169.5**	**57%**	**-5.2%**
SG&A expenses	90.8	30%	88.5	30%	-2.6%
R&D expenses	25.3	8%	26.0	9%	+2.9%
Core operating profit	62.8	21%	**55.0**	**19%**	**-12.4%**
Non-core expenses	1.0	0%	-	-	-100.0%
Amortization on intangible assets associated with products	9.5	3%	8.8	3%	-7.1%
Other income	1.5	1%	0.7	0%	-54.8%
Other expenses	15.3	5%	2.4	1%	-84.3%
Operating profit	38.5	13%	**44.5**	**15%**	**+15.5%**
Finance income	1.6	1%	2.0	1%	+27.2%
Finance expenses	2.7	1%	1.5	1%	-43.7%
Share of loss of investments accounted for using equity method	7.6	3%	-	-	-100.0%
Profit before tax	29.9	10%	45.0	15%	+50.6%
Income tax expenses	3.2	1%	11.5	4%	+262.6%
Actual tax ratio	*10.6%*	-	*26%*	-	-
Net profit	26.7	9%	**33.5**	**11%**	**+25.5%**
ROE	8.9%		11%		
Core ROE	16.2%		14%		
Core net profit	48.5	16%	41.3	14%	-15.0%

Revenue: -1.6%

- Impacted by GEs, NHI price reduction and co-pay hikes for long-listed products in Japan. Growth trajectory in overseas

Gross profit: -5.2%

- Increase COGS ratio due to product mix and cost increase

Core OP: -12.4%

- Maintain same SG&A ratio level as FY2023

OP (IFRS): +15.5%

- Decrease in other expenses resulting from completion of structural reforms, and others

Net profit (IFRS): +25.5%

- EPS：Increase JPY 73 to JPY 92

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Next, I would like to discuss the forecast for FY2024. See page 11.

For FY2024, we forecast revenue of JPY297.0 billion, core operating profit of JPY55.0 billion, and IFRS-based operating profit of JPY44.5 billion. As explained by the CEO and COO, the core base will see a decrease in profit due to factors such as the impact of the Japan business, an increase in the cost of sales ratio, and the Noto earthquake. SG&A expenses will be kept at the same level as the previous year by continuing to manage them appropriately.

On the other hand, on an IFRS basis, the income will increase by 15% YoY due to the lower expense incurrence of under core operating profits. As a result, net income and EPS are expected to be JPY92, an increase of JPY19 or 27% from the previous year.

Capital allocation

Balanced cash allocation to investments and shareholder returns as planned

Operating cash flow in FY2023: JPY 72.6 billion (historically highest). Maintain strong momentum
3-year operating cash flow excluding R&D expenses until FY2025 to be JPY 250.0 billion scale (+JPY 60.0 billion from MTP)

Outflow

Use[1]		Amount[1]	FY2023 actual / outlook
Growth investments	Capital Expenditures	JPY 26.0 bil.	• FY2023: JPY 10.2 billion (production related) • Expect some investment in Noto plant, but totally decrease in big scale investment after FY2024
	Research and development expenses	Over JPY100.0 bil. Including development milestones	• FY2023: JPY25.3 billion • Prioritize investment including early-stage pipelines
	Business development investment	JPY 80.0 bil. to JPY 90.0 bil.	• Investment opportunities to contribute to cash flow and align with regional needs, capture global medium-long term growth
Shareholder returns	Share buybacks		• FY2023: JPY 16.2 billion, FY2024: JPY 38.0 billion (maximum) • Implement opportunistic share buybacks, factoring in business development opportunities and share price
	Dividend	JPY 37.5 bil.	• FY2023: JPY 11.9 billion (33 yen per share / annual basis) • Continue progressive dividend policy in line with medium-long term profit growth

12 1. Accumulation in FY2023-FY2025

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Please move on to the next page. Based on the capital allocation in the medium-term management plan explained last April, we will balance investment in growth and shareholder returns. Operating cash flow in FY2023 was a record JPY72.6 billion, and the ability to generate cash conversion cycles and other inflows has improved due to the liquidation of receivables and other factors.

For outflows, the first priority is to invest in growth including R&D, and business development. Business development, in particular, was limited in FY2023, but we will strive for inorganic growth with discipline so as not to damage P/L and B/S.

In the event that investments in business development and other activities do not proceed and surplus funds accumulate, we plan to implement share buybacks as an investment that exceeds the cost of capital, subject to stock price and capital market conditions.

Capital expenditures are expected to decrease in total, as the construction of new plants in Japan and overseas will run their course.

With regard to dividends, as explained earlier by the CEO, we will continue to pay progressive dividends, increasing them in line with profit growth over the medium to long term.

Shareholder returns

Increased annual dividend forecast to JPY 34 on the back of completion of structural reforms and clarity on medium-long term sustainable profit levels

Medium-term management plan dividend policy:
Continue progressive dividend policy in line with medium-long term profit growth, notwithstanding volatility from business environment

(FY)	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024FCST
Total return ratio (IFRS)	38%	19%	106%	30%	76%	46%	120%	47%	-	106%	154%
Share buy-back (JPY billions)	-	-	12.3	-	13.9	-	-	-	25.7	16.2	38.0 (max.)
Treasury shares cancellation (share)	-	-	8.30 mil.	-	7.50 mil.	-	-	-	24.87 mil.	12.00 mil.	-
EPS (JPY)	58.18	128.99	52.96	86.73	78.67	59.16	23.30	68.07	-38.60	72.59	92.22

Finally, overlapping with the capital allocation mentioned earlier, I would like to discuss shareholder returns.

Based on the policy of progressive dividends, we forecast an annual dividend of JPY34 per share for FY2024. In addition, the Company plans to begin the buyback of its own shares tomorrow with a maximum amount of JPY38.0 billion or 5.8% of outstanding shares. As a result, the total return ratio for FY2024 is projected to be 154%.

By combining the pursuit of profitability improvement and recapitalization, we will drive the improvement of ROE and EPS.

That is all for the explanation from me.

Question & Answer

Yamaguchi [Q]: Thank you very much. I'm Yamaguchi from Citigroup Global Markets.

The first question I would like to ask is on the slide of ptosis. I was wondering why the data looks better for QD than BID, and also, I understand that the current treatment is surgery, but if you know how many surgeries are being performed, please let me know. This is the first question.

Sakuma [M]: Thank you for your question. Sallstig will answer the question.

Sallstig [A]*: Regarding the first question, additional analysis shows that baseline is a factor in the better results for QD compared to BID.

Regarding the second point, the number of surgeries is 100,000.

Yamaguchi [Q]: Thank you very much. As for my second question, you mentioned some of the risks incorporated in the earnings forecast. One is about selective treatment in Japan. I thought the other was regarding the unit dose line at the Noto Plant.

How much of these two, on a rough basis, are in now? Whether in some cases it may not be that much? Last year was quite conservative at first, but in the end, it swung up quite a bit, and I would like to know if there are any such factors this year as well. This is my second question.

Sakuma [M]: Thank you for your question. Nakajima will answer the question.

Nakajima [A]: Let me answer this question about selective treatment. With respect to 2024, we believe that the risk of selective treatment is a factor pushing down core OP by about JPY2.0 billion.

Since we know that 17 products with 11 ingredients will be subject to selective treatment, this is the result of factoring in a downside risk of 30% to 40% for each product.

Sakuma [M]: Thank you very much. Koshiji will answer the other question.

Koshiji [A]: As the CEO explained earlier, this is due to the delay in restoring the unit dose production line. Since the business is a unit dose, there will be some recovery from multiple dose products, etc., but we have roughly factored in JPY3.0 billion in sales and JPY2.0 billion in gross profit.

In theory, however, this is only the case when unit dose is factored, and in practice, we believe that other factors will also recover the impact. That's all.

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

Sakuma [M]: Thank you very much, Mr. Yamaguchi. Next up will be Mr. Muraoka from Morgan Stanley MUFG Securities. Please go ahead.

Muraoka [Q]: Hello, this is Muraoka from Morgan Stanley. Thank you.

As for the assumptions of each product in this fiscal year's plan. First, in terms of the impact of generics, how do you view *Alesion* and *Diquas*? More to the point, talking about *EYLEA.* I think it's 8 mg, but what assumptions are you factoring in the impact of the biosimilar launch and the AG launch? What is the background of your thinking on each of three products, *Alesion, Diquas*, and *EYLEA*?

Sakuma [M]: Thank you for your question. First of all, Nakajima will answer the question.

Nakajima [A]: I would like to start with *Alesion*. As for *Alesion*, generic approval for *Alesion LX* was not done in February, but we expect it to come next time, at the earliest. Next means in August for approval and in December for NHI price listing. Naturally, we have also taken into account the AG of *Alesion LX* in our sales forecast, so I hope you can consider that factored in.

On the other hand, the sales forecast for regular *Alesion* not *LX* from October will be affected by the change to selective treatment, so we have taken that into account as well as the replacement of *Alesion LX* with *Alesion* eyelid cream, which I mentioned earlier. This is a situation for *Alesion*.

Then, about *EYLEA,* this is based on the assumption that *EYLEA* biosimilars will enter the market. That has been factored in, and I hope you will see it that way.

Also, since a generic product has already entered the market for *Diquas* in April of this year, we have naturally factored this in. However, we will continue to actively promote the switch to *Diquas LX*, and although it will be a different battle from the past, we will continue to promote the switch to *Diquas LX* even as generic versions of *Diquas* are being launched in the market. This is the premise of our plan.

Muraoka [Q]: Thank you. Let me confirm. As for *EYLEA*, the assumption is that the competitor biosimilar is a July-to-September launch, which I think is probably true. What assumptions are you making about AG in this plan? Is the assumption that the unit price will go down as soon as it is released in June?

Nakajima [A]: I am very sorry, but we do not have anything to say on this matter due to our contract with Bayer, so I would like to refrain from answering at this time.

Muraoka [Q]: I see, but if we are talking about *EYLEA* as a whole, the premise is being made in a modest way, right?

Nakajima [A]: Yes. You can understand it that way.

Muraoka [Q]: Also, sorry, I am going back and forth. The drug price has not been given to *Alesion* eyelid cream yet, so outsiders cannot imagine how much it would be. Is my understanding correct that you are including the figures assuming a fair price?

Nakajima [A]: As you said, we cannot give you an answer on the NHI price since it has not yet been announced, but we assume that we will be able to obtain a NHI price that is appropriate for the product value.

Muraoka [Q]: Thank you. It was assumed that *PRESERFLO MicroShunt* would grow quite a bit in Japan, but I wonder if there is any real demand for these in Japan. Can you give us some background, or rather, the premise behind this growing, yet still small, product?

Sakuma [M]: Nakajima will answer this question as well.

Nakajima [A]: We believe there is plenty of room for growth for *PRESERFLO MicroShunt*. We are trying to penetrate the glaucoma surgery market with the strategy of targeting people with moderately or severely advanced glaucoma who have a high degree of progression with this device.

At this point, we are mainly training doctors who perform a large number of glaucoma surgeries to use the device, but there are still many doctors who are waiting for the training. Although the amount is not that large, we expect it to grow steadily in the future.

Muraoka [Q]: Thank you. The third and final question. I understand that you are going to actively promote BD from this fiscal year. I understand very well what you are talking about by region, but what areas do you have

in mind? It could be front of the eye or back of the eye. I don't think so, but it could be device, it could be OTC, I don't know, please let me know.

Sakuma [M]: Thank you for your question. First of all, Nakajima will answer the question.

Nakajima [A]: Since we specialize in ophthalmology, we don't have a specific focus on the front of the eye or the back of the eye, but we would like to explore opportunities in areas where Santen's strengths can be utilized. We do not think it is absolutely either back of the eye or front of the eye, as we mentioned earlier.

However, we think the devices are a bit more difficult to handle from the standpoint of our experience over the past few years, verification of whether our strengths can really be utilized, and compliance with financial discipline, so we think they are a bit lower on the priority list.

We also see considerable growth opportunities for OTC in each region, especially in Asia, so we have not specifically excluded these from the areas of opportunity that we are exploring.

Muraoka [M]: I understand. Thank you. That's all.

Sakuma [M]: Thank you very much, Mr. Muraoka. Next, Mr. Ueda from Goldman Sachs, could you please go ahead?

Ueda [Q]: This is Ueda from Goldman Sachs.

First from me, I would like to ask your company's assessment of the progress of the mid-term plan. Is it correct to say that core operating income of JPY55.0 billion for the current fiscal year is fairly certain to be achieved against the JPY56.0 billion plan, or is it correct to say that it is on an upward trend?

In addition, I think that R&D expenses are a little low in relation to the three-year total progress, even including the current year's plan. Could you give us an idea of how we should look at this?

Sakuma [M]: Thank you for your question. First of all, Ito will answer the question.

Ito [A]: I believe that we are now achieving better-than-expected results, especially in terms of progress toward core operating profit in the mid-term plan. As I mentioned at the beginning, we started the structural reforms with a certain amount of uncertainty in terms of scale and implementation, but we have achieved more than 100% results, and our overseas business is also growing steadily, so I think we are doing extremely well.

On the other hand, as I also mentioned at the beginning, there are many things to be determined, such as the introduction of a selective treatment system in Japan. In particular, we do not hold substance patents or usage patents for our mainstay products, which are followed by generic products in the future, but we do hold formulation patents for them. We would like doctors to select our products based on a clear understanding of the superiority of our formulations, and we would like to make this a reality. We would like to present our plans for FY2025 and beyond to you after we have a better understanding of what the results will be in this area.

Also, as for R&D, we are short of the plan to a certain extent, but I understand that this does not mean that there have been any major negative factors at all. For example, a product that we licensed out in the US business was originally subject to post-marketing clinical trials as a condition for approval, and we did not incur any budget for such trials, which the other party was willing to conduct after we licensed out the product. Many of these are factored in.

Therefore, I recognize that progress itself is rather steady, and by "rather steady," I mean that the product is progressing extremely well in terms of what we want it to do well and what we think it should do well. That is all.

Ueda [Q]: Thank you very much. Second, I would like to ask you about the *Alesion* eyelid cream preparation. I see from your recent release that you are going to focus on this cream with the co-promotion agreement with Mitsubishi Tanabe Pharma. I wonder how your company plans to proceed. Also, I wonder if the dosage form will be quite different from *Alesion LX* and others, so I wonder what kind of shift you expect, whether it will penetrate quickly like *LX* or whether it will only be used by some patients here. What is your view on this area?

Sakuma [M]: Thank you for your question. Nakajima will answer the question.

Nakajima [A]: We plan to develop *Alesion* eyelid cream, like *Alesion LX*, into a formulation that can be used by a fairly broad range of patients. We decide to co-promote with Mitsubishi Tanabe Pharma this time largely because we share the same goals, sense of purpose, and worldview that we are aiming for.

Naturally, Mitsubishi Tanabe Pharma is very strong in fields outside of ophthalmology, such as otolaryngology, pediatrics, and internal medicine. It has strong relationships with doctors and has many MRs there, so we would like to promote this formulation more widely through co-promotion with Mitsubishi Tanabe Pharma.

As you say, it is a cream, so we recognize that it is a big challenge to change from the conventional idea of suppressing allergies with eye drops, but we are sure that we can make a breakthrough in this area from the perspective of co-promotion between Santen and Mitsubishi Tanabe Pharma and from the perspective of commercial excellence we have cultivated.

Ueda [Q]: Thank you very much. Finally, third, I would like to know about the premise of your China business. Please let us know if there are any trends by area or if you have factored in any risks of centralized purchasing, etc.

Sakuma [M]: Thank you for your question. Nakajima will answer the question.

Nakajima [A]: Regarding the China business, our basic premise is that we will invest resources to properly expand our business in two areas with the highest sales, *Hyalein* and *Cravit*, of course. In addition to these products, we are also looking for opportunities in the Chinese market for products that we think have potential, such as *Sancoba*, *Flumetholon, Benoxil,* and *Tarivid*, which are not necessarily large products but are older products that can meet the needs of doctors and patients.

The biggest VBP (volume-based purchasing) risk was the VBP of *Diquas,* which became a target at the end of last year, so given the impact of VBP of *Diquas* has been factored in for 2024, so I do not think there is anything more significant for FY2024.

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

Sakuma [M]: Thank you very much, Mr. Ueda. Next, Mr. Sakai of UBS Securities Japan, please go ahead.

Sakai [Q]: Excuse me, this is Sakai from UBS.

One is for ptosis. You mentioned that there have been 100,000 surgeries in Japan, and it seems that these surgeries can be performed without cutting, so it is more like a procedure than a surgery, I heard.

In the overseas business briefing, you mentioned a peak of JPY45.0 billion for ptosis, but I suppose this means that the NHI price has not yet been determined or that it can be obtained through out of pocket treatment.

What kind of assumptions are you going to make about this market even though you have not yet applied for approval, and if you have any concrete figures to share with us.

Sakuma [A]: I'm sorry, correction, Mr. Sakai, it's not surgery, but I just want to confirm that our current product development for ptosis is eye drops, different from surgery.

Sakai [Q]: I know. I am told that the surgery is done quite simply. Medication, on the contrary. Is there a shift toward this direction, or is the idea to move toward drug therapy among these potential patients, even though it may be out of pocket treatment? I would like to know about that including the out of pocket treatment.

President Ito also mentioned that the number of medical examinations will increase as these procedures become more common and that other eye examinations will also be promoted. I would like to confirm whether that is really likely or not.

Sakuma [M]: Thank you very much. First of all, Ito will answer the question.

Ito [A]: I'm sorry I can't explain with specific numbers, because I didn't bring the specific numbers you just asked about. We have interviewed many people about this kind of products for ptosis.

Providing the information on various prices and the fact that this will be out of pocket treatment, we have repeatedly conducted surveys to see how people would react if a product with this kind of profile were to appear on the market.

I understand that, as you pointed out, there are now some procedures in the field of cosmetic surgery that are quite non-invasive, but there are still many patients who are resistant to such procedures, and there are also many people who would prefer to have their eyelids examined by an ophthalmologist if possible. We are now making forecasts for Japan based on the results that there are probably a considerable number of people who would like to receive such treatment if eyelids can be raised by such drugs.

Of course, JPY45.0 billion is our global sales, not JPY45.0 billion in Japan, but we would like to achieve appropriate results first in Japan, where we have the strongest foundation.

As for your second question, most of the patients seen for ptosis are middle-aged or older. Even if we take glaucoma as just one example, there are still many people who have undiagnosed glaucoma because of a lack of subjective symptoms. We think there is ample opportunity for such things to be unearthed through medical examinations.

We would like to inform ophthalmologists that by examining patients with ptosis, they have an important opportunity to identify patients whom they may consider as originally, I'm not sure if this word "originally" is right, potential candidates for treatment, and we would like to create an environment in which such patients are accepted.

As I mentioned glaucoma, dry eye can also be detected simply by performing a simple examination for the use of this kind of ptosis medication. As a company specialized in ophthalmology, we would like to link this to the results.

Sakai [Q]: I understand. I will ask for a breakdown of the JPY45.0 billion, again to IR separately.

There was just one more point. As BD's question was raised earlier, I think the word "inorganic" was mentioned about three times in your presentation. I should have asked this during the overseas business capital markets day, but what are your thoughts on future expansion in the US? I know it is not easy to talk about the next steps again since the withdrawal or deficit has just been eliminated, but how would you

position the US in this idea? I would like to know, no need to go into specifics, if this will be included in the next mid-term plan.

Sakuma [M]: Thank you for your question. Ito will answer the question.

Ito [A]: As I think Nakajima touched on earlier in her presentation, we are currently discussing several business development projects with a peak sales scale of JPY30.0 billion to JPY40.0 billion. We are still in the process of discussing this, so I will not be more specific than that.

To answer some of the questions that were raised earlier, I would say that most of the work we are doing is in areas where there are not necessarily sufficient therapeutic agents at the present time, or in areas where initial therapeutic agents are being produced. We are discussing the acquisition of rights in Europe, China, Asia, and Japan, which are the regions we are currently working on.

The US is not a target for such a BD-related matter. As I mentioned earlier, our stance on entering the US market has not changed, and we will continue to carefully consider how to enter the US market, including the case if something very competitive emerges.

Sakai [Q]: I understand. Thank you. One last thing. When I visited the Noto Plant earlier, I had the impression that it was a factory, but it would be interpreted as offending to say that it was a rather historical building. I believe that this factory is your company's main factory, so including the recent earthquake's impacts, it is currently a single-dose unit, but is there any possibility of drastic expansion, renovation, or even construction of a new factory even if it is in Japan?

Sakuma [M]: Thank you very much. Ito will answer the question.

Ito [A]: We have no plans to build a new factory in Japan at this time. Currently, Noto supplies products not only to Japan but also to China and the rest of Asia. With the completion of our new plant in Suzhou, China, we would like to reduce the burden on Noto by basically supplying products for the Chinese market in China.

In addition to that, a new building was completed last year at the Shiga Plant, and we are now considering ways to reduce the load on Noto. Did I answer your question?

Sakai [M]: I see. Thank you very much.

Sakuma [M]: Thank you very much, Mr. Sakai. There are still people waiting to ask questions, but as the closing time is approaching, we will let the next questioner be the last. Mr. Wakao from JPMorgan Securities, please go ahead.

Wakao [Q]: Thank you very much. This is Wakao from JPMorgan Securities. Sorry, I was listening to another company's briefing, so I may have missed a few things. Excuse me.

First of all, in the Q&A that was just mentioned, there was talk that the generics of *LX* formulation of *Alesion* may be approved in August. How should I consider the certainty of this? As I recall, there is a patent on the *LX* formulation, and it has been approved but not yet covered by insurance. How about it?

Sakuma [M]: Thank you very much. Nakajima will answer your question.

Nakajima [A]: This concerns another company, so please understand that we are only sharing a prediction. I naturally think that it will come with a fair degree of certainty. From the generics' point of view, it is a very attractive product, and I have heard that some other companies tried to have it approved as early as February. We think it will probably be approved in August and listed on the NHI drug price list in December.

Wakao [Q]: I understand. Secondly, I would like to know more about ptosis and how it compares to surgery. Regarding efficacy, I was wondering if the difference of about 1 mm in MRD this time is about the same or slightly lower than that of surgery. I wonder how its efficacy is compared to surgery.

Also, what should I consider as the duration of administration? I think for surgery, once is enough, but how long do you expect to administer this medicine? Also, please tell me what happens when you stop administering this.

Sakuma [M]: Thank you for your question. Ito will answer the question.

Ito [A]: In terms of comparison with surgery, it may be possible to control to some extent how much the surgery raises the MRD-1, but I don't mean to directly compare it with surgery, but the normal MRD-1 is usually in the range of 3 mm to 5 mm. For a healthy patient, raising it by a little more than 1 mm is a very big change, I understand that there are many patients who are satisfied with the results of using eye drops.

Of course, there are many ways to perform a surgical procedure, but it is possible to obtain a safe result without having the feeling that the result is not what you imagined. I believe it is the method like that.

Regarding the duration of administration, we are only looking at the duration of clinical trials. Are you asking about safety?

Wakao [Q]: I am wondering if progresses happen again when the patient finishes the administration.

Ito [A]: I don't think it will progress. However, if you don't administer it, it will lose its effectiveness, and I think you will be back to your original state.

I would like to add that during the administration period of the clinical trial, there were surprisingly no side effects. We were also concerned about the possibility that the repeated use of this type of product might gradually build up resistance, but the results show that there was no such problem.

Wakao [Q]: I'm sorry. Then, when patients stop, their eyelids become heavy again, is that what you are saying? Than compared to surgery.

Ito [A]: Of course it is. It is a drug and is used once or twice daily. However, the number of doses has not yet been determined, so if you stop using it and the drug is no longer effective, it will revert to its original state. That's right.

Wakao [Q]: I would think that would be more inconvenient than surgery, but what's your take?

Ito [A]: What's my take? There would be some people who have surgery and think that they want to have a permanent state, but the number of people who are aware of their droopy eyelids and had surgery is only about 100,000. In terms of age, most of the population, the majority of people in the target age group, have droopy eyelids to a greater or lesser degree or extent. Therefore, I believe that there are many people who would not choose surgery but instead use drugs if their condition is not that serious.

Wakao [Q]: I understand very well. Thank you. Finally, just a quick question, SYD-101, I think Phase III is ending this fiscal year, but it would be helpful if you could be a little more specific and let us know when the data readout will be. That's all.

Sakuma [M]: Thank you for your question. Sallstig will answer the question.

Sallstig [A]*: This trial is being conducted by our partner, Sydnexis, and is being tested in Europe and the US. Looking at ClinicalTrials.gov, the data completion is listed as Q1 of 2024. Given this, one could theoretically assume that the data would be shared within this fiscal year at the latest.

Wakao [M]: Thank you.

Sakuma [M]: Thank you very much, Mr. Wakao. This concludes the Q&A session for institutional investors and analysts.

[END]