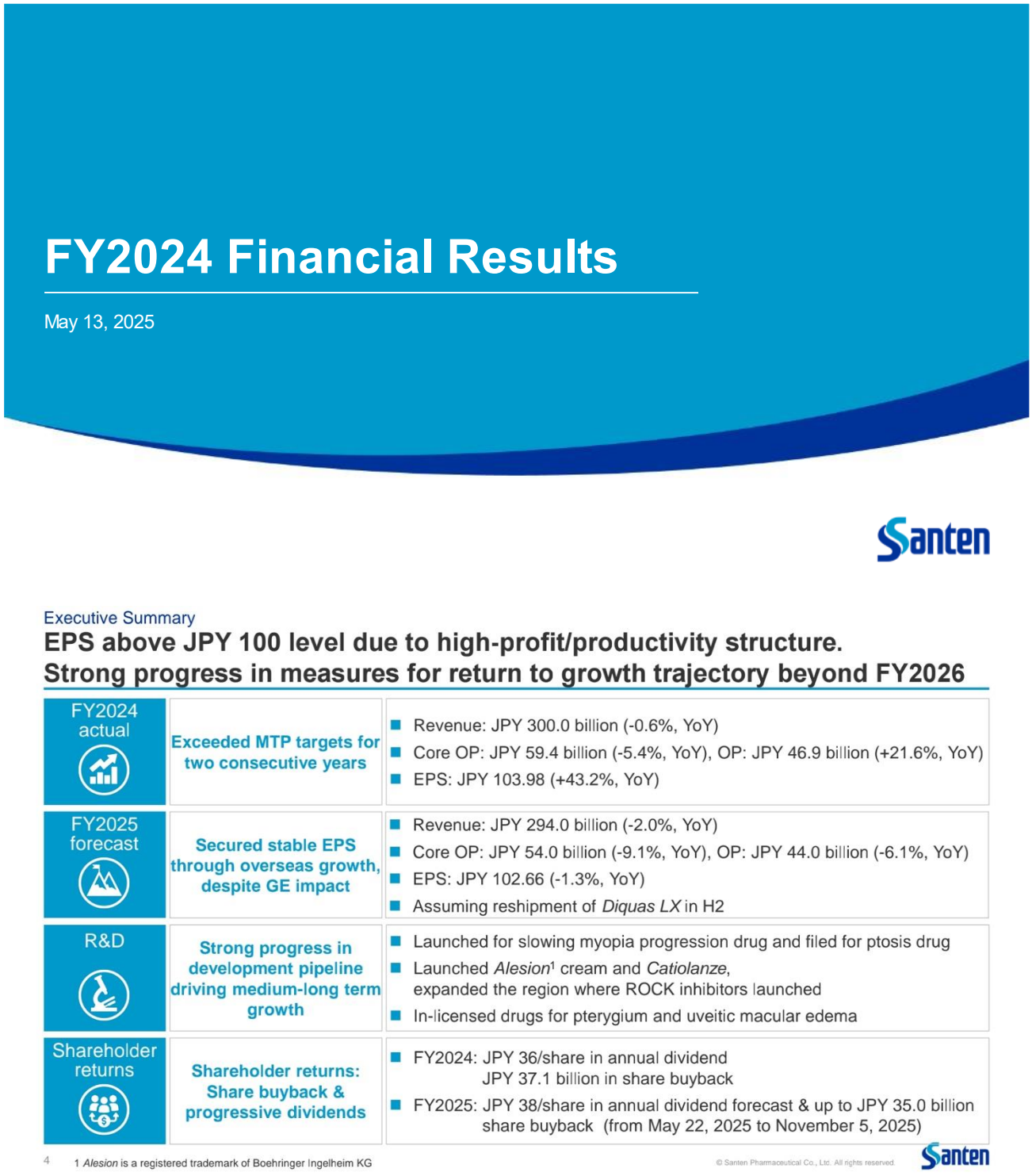
FY2024 Financial Results Transcript



Ito: My name is Ito, CEO of Santen Pharmaceutical. Thank you very much for taking time out of your very busy schedule today to attend our FY2024 financial results briefing.

First, I would like to explain the financial summary. Please see page four.

In FY2024, although we were unable to deliver some products to medical facilities due to factors such as the restoration delay of the unit dose manufacturing line following the earthquake at the beginning of the year and the suspension of shipments of *Diquas LX,* we achieved our sales target in Japan thanks to the growth of

the *Eylea* and *Alesion* products, as well as the fact that the original formulation of *Diquas*, which replaced *Diquas LX*, exceeded the initial plan while minimizing the impact of generics.

Furthermore, contributions from Asia and EMEA resulted in revenue of JPY300.0 billion, core operating profit of JPY59.4 billion, and EPS of JPY104. For the second consecutive fiscal year, we achieved a higher level of profit than before the completion of structural reforms, and EPS exceeded JPY100 for the first time since the fiscal year ended March 31, 2016. Although there were some one-time revenue associated with the out-licensing of products, we believe that these were the result of the establishment of a foundation for a highly profitable and productive structure built through structural reforms and regional business growth as outlined in the medium-term management plan announced for FY2023.

For FY2025, we expect revenue of JPY294.0 billion and core operating profit of JPY54.0 billion, as this fiscal year is expected to be most affected by the launch of generic versions of our main products in Japan. However, due to structural reforms that have reduced variable factors below the core operating profit on P&L, we expect EPS to remain at almost the same level as FY2024 at JPY103.

As for *Diquas LX*, we are consulting with the authorities with a view to resuming shipments. The full-year forecast is based on the assumption that shipments will resume during H2 of the fiscal year. We feel that expectations for *Diquas* products, especially *LX*, remain high and will continue to make every effort to deliver them to the medical setting as soon as possible.

Although we expect a decrease in revenue and profit in the current fiscal year, we believe that the Company will return to a growth trend in the next fiscal year and beyond. The driving force will be the launch of new products, the addition of new formulations of existing products, regional expansion in existing disease areas, and the creation of new disease markets through such products as drugs for slowing progression of myopia, and ptosis, which are expected to grow in size in the medium term.

I will explain in more detail later about R&D that will drive medium- to long-term growth. To enhance our pipeline, we also in-licensed a therapeutic drug for pterygium, announced in August last year, and a drug for uveitic macular edema, announced in November. We will continue to promote this type of business development and link it to growth.

We regard shareholder returns as an important management issue. First, based on the progressive dividend policy, we forecast an annual dividend of JPY38 per share, with a lower limit of JPY19 per half year for FY2025.

Next, the Company resolved today to buy back its own shares up to JPY35.0 billion, or 5.8% of outstanding shares, and plans to begin the buyback on May 22, the day after the announcement of the new medium-term management plan. We believe that the current share price level is still undervalued, and we intend to improve ROE and EPS through the buyback. This will result in the acquisition of 23%, or JPY114.0 billion, of the Company's own shares over a cumulative 5-year period.

KPI progress for FY2023 -2025 medium -term management plan

Achieved medium -term management plan KPIs for two consecutive years ahead of schedule

KPI	FY2022	FY2023 -2025 MTP	FY2023	FY2024
Revenue	JPY 279.0bil	JPY 280.0bil	JPY 302.0bil	JPY 300.0bil
Core OP / margin	JPY 44.2bil / 16%	JPY 56.0bil / 20%	JPY 62.8bil / 21%	JPY 59.4bil / 20%
Revenue growth ratio per overseas employee[1]	-1% (CAGR for FY19-22 FCST)[2]	Over 7% growth (CAGR for FY22FCST-FY25)[3]	33% (YoY)[4]	19% (CAGR for FY22-24ACT)[5]
Core ROE	11%	13%	16 %	15%
ROE (IFRS)[6]	-5%	-	9%	12%
Growth rate of core EPS	-2% (CAGR for FY19-22 FCST)[2]	Over 10% (CAGR for FY22FCST-FY25)[3]	+54% (YoY)	+23% (CAGR for FY22-24ACT)[5]
EPS (IFRS)	JPY -38.60	-	JPY 72.59	JPY 103.98
Shareholder returns	Dividend: JPY32/share Share buyback: JPY 25.7bil	Increase dividend with JPY 32/share as the floor + Opportunistic share buybacks as capital adjust.	Dividend: JPY33/share Share buyback: JPY 16.2bil Total return ratio: 106%	Dividend: JPY36/share Share buyback: JPY 37.1bil Total return ratio: 137%

5 1 Total for China, Asia and EMEA. 2 Calculated based on FY2022 forecast FX rate 3 Calculated based on MTP rate
4 Excluding *Ikervis* one-time factor in FY2023 5 Excluding license-in one-time factor in FY2024 6 Reference value

Next, I will review the medium-term management plan announced for FY2023 in terms of business performance. Please turn to page five.

Despite changes in the business environment that were not anticipated when the mid-term management plan was announced, such as the shift to the *Sentei-ryoho* Scheme for long-listed products (new system of co-pay hikes), all KPIs exceeded their targets for FY2023 and FY2024 as well.

FY2024 R&D update

Successfully achieved milestones to create myopia/ptosis markets. Added new formulation/Expanded regional to increase sales in existing area

	Clinical trial	Filing	Approval	Launch
New area Myopia Ptosis MGD[1] etc.	Oxymetazoline HCl P3 start STN10138**00**, Europe/China	*Ryjunea* Positive CHMP opinion STN10127**01**, Europe		*Ryjusea Mini* (April 21st, 2025) STN10127**00**, Japan
	Sirolimus Additional P2a start STN10109**05**, Japan	Oxymetazoline HCl STN10138**00**, Japan		
	AFDX0250BS, P2a completion Development discontinued STN10134**00**, Japan			*Catiolanze* STN10130**01**, Europe
Existing area Glaucoma Allergic conjunctivitis etc.	Omidenepag isopropyl P3 start STN10117**02**, China	Sepetaprost STN10126**00**, Japan	*Tapcom* STN10111**01**, China	*Rhopressa* STN10139**00**, Asia
	Netarsudil mesylate P3 long-term trial completion STN10139**00**, Japan *Confirmed superiority to repasudil	Latanoprost cationic emulsion STN10130**01**, Asia		*Rocklatan* STN10140**00**, Asia
		Epinastine HCl (twice a day, eye drop) STN10140**03**, China		*Eybelis Mini* STN10117**02**, Asia
	Netarsudil mesylate / latanoprost P3 start STN10140**03**, Japan			*Alesion*[2] eyelid cream STN10114**02**, Japan
				Alesion LX STN10140**01**, Asia

6 1 MGD: Meibomian Gland Dysfunction 2 *Alesion* is a registered trademark of Boehringer Ingelheim KG

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Please see page six. The following is a list of the major development in progress for FY2024.

In the new diseases area, we launched *Ryjusea Mini*, Japan's first slowing myopia progression ophthalmic solution, on April 21. Although we are not yet at the stage of being able to report quantitative information such as sales, the initial response has been favorable as expected. In Europe, *Ryjunea* received a positive recommendation from the CHMP in March.

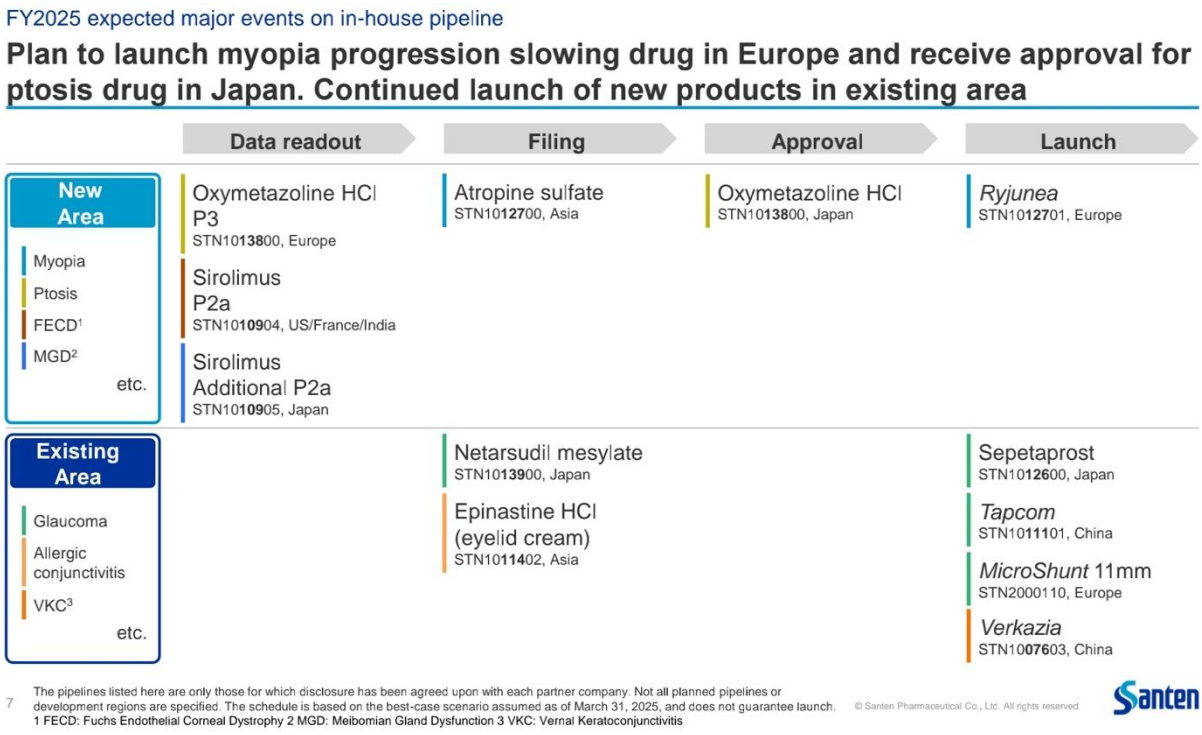
We also filed an application for ptosis in Japan last December and have started Phase3 trials in Europe and China.

In both areas, development is progressing as planned for myopia and ptosis, for which we expect to achieve larger scale sales.

In the existing disease area, new glaucoma products such as *Catiolanze* and ROCK inhibitors were launched in Europe and Asia. With regard to *Alesion*, the cream formulation was launched in Japan and *LX* , the ophthalmic solution, was launched in Asia, and we are working to expand the contribution of *Alesion* by adding new formulation forms and expanding the geographic scope of its use.

The development of STN1013400, which had been developed as a next-generation myopia drug, was discontinued as a result of P2a study data analysis. We will continue our research and development for the myopia by utilizing the findings from this trial.

We will continue to LCM for the preceding atropine ophthalmic solutions as we have done for the existing products.



Here are the main events for this fiscal year regarding the pipeline. Please refer to page seven.

As we reported earlier, we assume that *Ryjunea* will soon be approved in Europe as an eye drop to slow myopia progression, and we plan to launch the product sequentially from Germany this fiscal year. As in Japan, this is the first approved drug for slowing myopia progression in Europe. Because of the need for careful marketing, such as expanding awareness of the fact that the progression of myopia can be slowed by eye drops and instilling the proper treatment flow at medical institutions, sales growth in the current fiscal year

is not a rapid start, but we will first create new markets from Japan and Europe and expand the scope of our contribution regarding eye care.

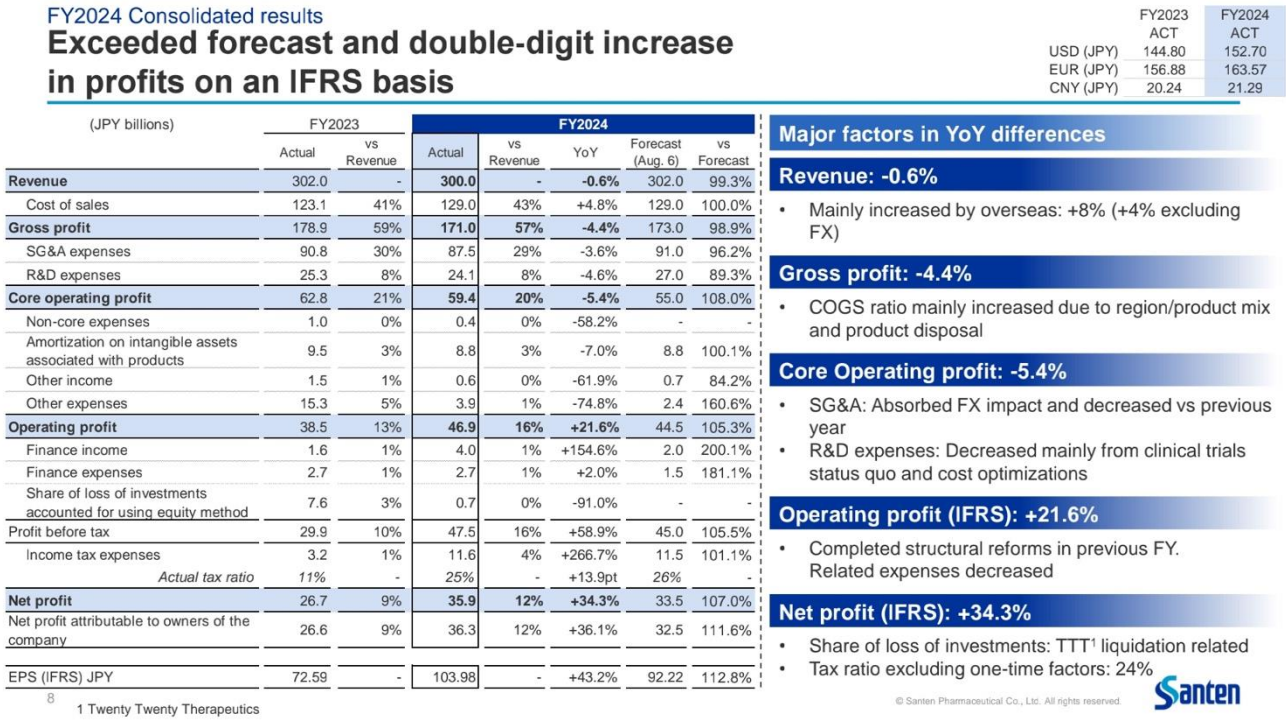
Although the launch will be next fiscal year, we also expect to obtain approval in Japan for a drug for ptosis.

In the existing areas, the portfolio of new products in China will be expanded with the planned launch of *Tapcom*, a glaucoma treatment, and *Verkazia*, a treatment for vernal keratoconjunctivitis, a rare disease.

In Japan, we plan to launch sepetaprost ophthalmic solution, a glaucoma treatment with a new mechanism of action, to provide a new treatment option for glaucoma patients who require treatment over a period of decades. In addition, *MicroShunt*, a glaucoma surgery device with global sales growing to JPY6.0 billion, plans to launch a product with a length of 11 mm, longer than the current 8.5 mm, to meet the needs in Europe.

Today, I have explained our performance for FY2024 and our forecast for FY2025. In our new medium-term management plan, which we plan to announce on May 21, I will explain Santen Pharmaceutical's vision and the path for growth over the next five years, from 2025 to 2029.

That concludes my presentation.



FY2024 Consolidated results

Exceeded forecast and double-digit increase in profits on an IFRS basis

	FY2023 ACT	FY2024 ACT
USD (JPY)	144.80	152.70
EUR (JPY)	156.88	163.57
CNY (JPY)	20.24	21.29

(JPY billions)	FY2023		FY2024				
	Actual	vs Revenue	Actual	vs Revenue	YoY	Forecast (Aug. 6)	vs Forecast
Revenue	302.0	-	**300.0**	-	**-0.6%**	302.0	99.3%
Cost of sales	123.1	41%	129.0	43%	+4.8%	129.0	100.0%
Gross profit	178.9	59%	**171.0**	**57%**	**-4.4%**	173.0	98.9%
SG&A expenses	90.8	30%	87.5	29%	-3.6%	91.0	96.2%
R&D expenses	25.3	8%	24.1	8%	-4.6%	27.0	89.3%
Core operating profit	62.8	21%	**59.4**	**20%**	**-5.4%**	55.0	108.0%
Non-core expenses	1.0	0%	0.4	0%	-58.2%	-	-
Amortization on intangible assets associated with products	9.5	3%	8.8	3%	-7.0%	8.8	100.1%
Other income	1.5	1%	0.6	0%	-61.9%	0.7	84.2%
Other expenses	15.3	5%	3.9	1%	-74.8%	2.4	160.6%
Operating profit	38.5	13%	**46.9**	**16%**	**+21.6%**	44.5	105.3%
Finance income	1.6	1%	4.0	1%	+154.6%	2.0	200.1%
Finance expenses	2.7	1%	2.7	1%	+2.0%	1.5	181.1%
Share of loss of investments accounted for using equity method	7.6	3%	0.7	0%	-91.0%	-	-
Profit before tax	29.9	10%	47.5	16%	+58.9%	45.0	105.5%
Income tax expenses	3.2	1%	11.6	4%	+266.7%	11.5	101.1%
Actual tax ratio	*11%*	-	*25%*	-	+13.9pt	*26%*	-
Net profit	26.7	9%	**35.9**	**12%**	**+34.3%**	33.5	107.0%
Net profit attributable to owners of the company	26.6	9%	36.3	12%	+36.1%	32.5	111.6%
EPS (IFRS) JPY	72.59	-	103.98	-	+43.2%	92.22	112.8%

Major factors in YoY differences

Revenue: -0.6%

- Mainly increased by overseas: +8% (+4% excluding FX)

Gross profit: -4.4%

- COGS ratio mainly increased due to region/product mix and product disposal

Core Operating profit: -5.4%

- SG&A: Absorbed FX impact and decreased vs previous year
- R&D expenses: Decreased mainly from clinical trials status quo and cost optimizations

Operating profit (IFRS): +21.6%

- Completed structural reforms in previous FY. Related expenses decreased

Net profit (IFRS): +34.3%

- Share of loss of investments: TTT[1] liquidation related
- Tax ratio excluding one-time factors: 24%

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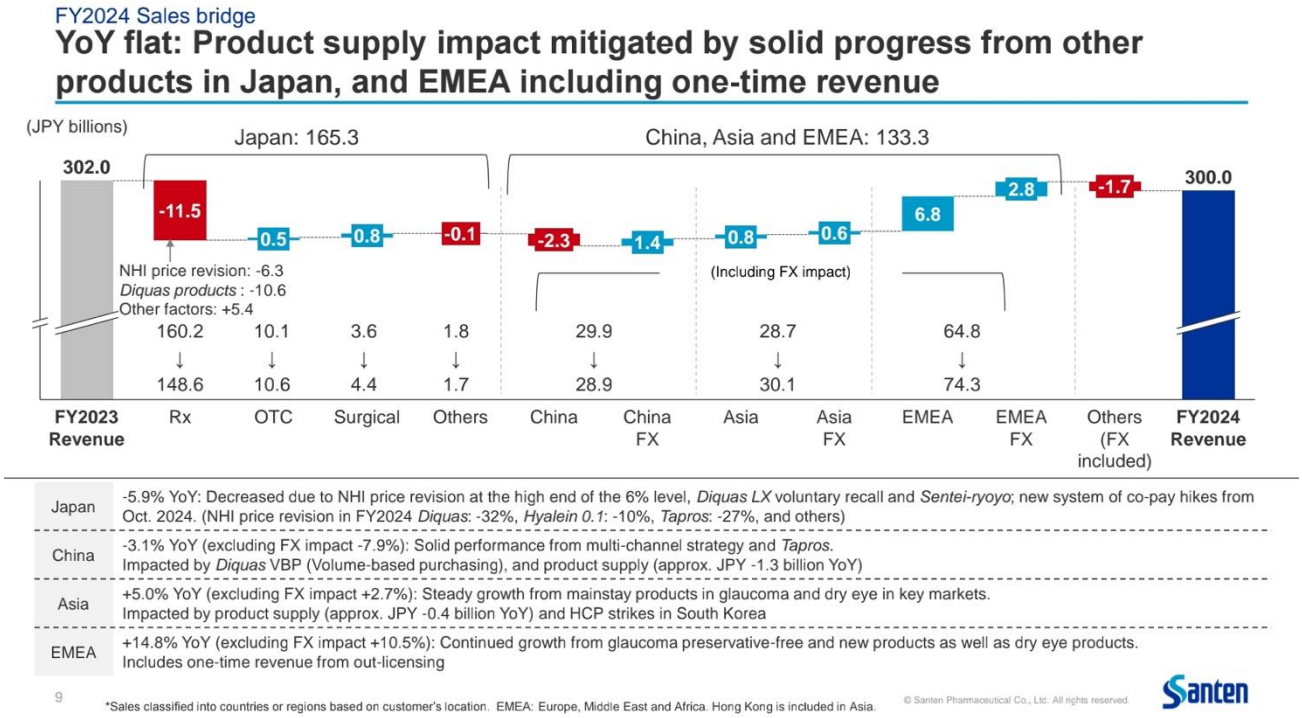
1 Twenty Twenty Therapeutics

Koshiji: My name is Koshiji.

Please see page eight. This is the results for FY2024.

As explained by the CEO earlier, profits exceeded the full-year forecast.



Japan	-5.9% YoY: Decreased due to NHI price revision at the high end of the 6% level, *Diquas LX* voluntary recall and *Sentei-ryoyo*; new system of co-pay hikes from Oct. 2024. (NHI price revision in FY2024 *Diquas*: -32%, *Hyalein 0.1*: -10%, *Tapros*: -27%, and others)
China	-3.1% YoY (excluding FX impact -7.9%): Solid performance from multi-channel strategy and *Tapros*. Impacted by *Diquas* VBP (Volume-based purchasing), and product supply (approx. JPY -1.3 billion YoY)
Asia	+5.0% YoY (excluding FX impact +2.7%): Steady growth from mainstay products in glaucoma and dry eye in key markets. Impacted by product supply (approx. JPY -0.4 billion YoY) and HCP strikes in South Korea
EMEA	+14.8% YoY (excluding FX impact +10.5%): Continued growth from glaucoma preservative-free and new products as well as dry eye products. Includes one-time revenue from out-licensing

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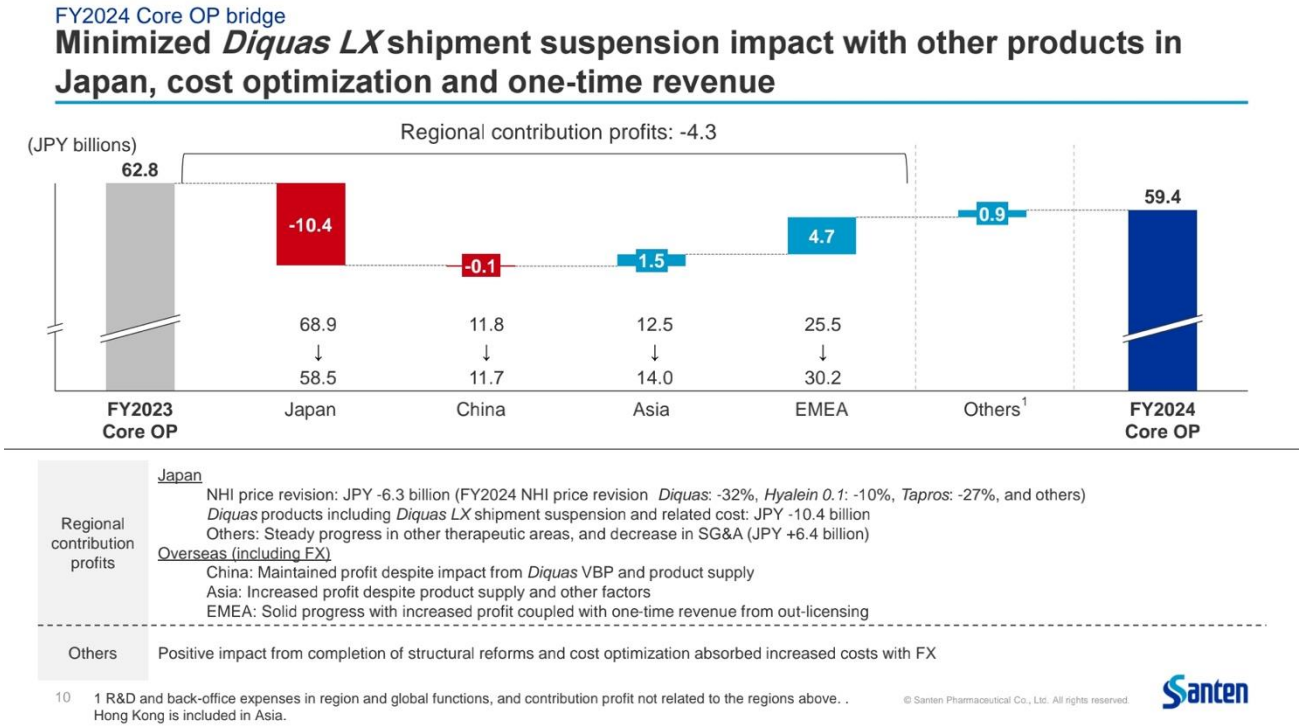
*Sales classified into countries or regions based on customer's location. EMEA: Europe, Middle East and Africa. Hong Kong is included in Asia.

Page nine shows the factors behind the increase/decrease in revenue.

Revenue of JPY300.0 billion includes JPY165.3 billion in Japan and JPY133.3 billion overseas (Santen post amendment: China, Asia and EMEA). The ratio of overseas (Santen post amendment: ratio of the three areas) was 44%, up from 41% in FY2023.

As for Japan, revenue was down 6% from the previous year due to the NHI price revision, suspension of shipments of *Diquas LX*, and the *Sentei-ryoyo* Scheme for long-listed products. However, the impacts from *Sentei-ryoyo* Scheme for long-listed products, which started in October, was within the scope of the assumptions made at the beginning of the fiscal year, and the market share of *Alesion* products remained strong, despite the launch of LX generics. Therefore, mainstay products have performed steadily.

As for Overseas, China was negatively affected by some product supply issues and *Diquas* VBP, resulting in a negative YoY growth. On the other hand, in Asia, the impact of the supply of some products was offset by glaucoma and dry eye products in key markets, resulting in growth even excluding the impact of foreign exchange rates. In EMEA, the Company has also shown stable growth, even excluding the contribution of one-time revenues.



Page 10 shows the factors of change in core operating profit.

Overall, regional contribution profit decreased by JPY4.3 billion, but cost optimization and other factors resulted in a JPY0.9 billion decrease, for a net decrease of JPY3.4. The result was a JPY59.4 billion, or 5%, decrease in profit.

However, when we look at the factors contributing to each of these declines, we do not perceive a decline in profitability in the core business or on a core basis.

First, in Japan, the NHI price revisions for major products such as *Diquas*, *Hyalein*, and *Tapros* had an impact of about JPY6.0 billion. In addition, the impact of the recall of *Diquas LX*, including the suspension of shipments and recall costs, was approximately JPY10.0 billion, which was covered by other areas of the Company's business. That's the situation.

Sales in China decreased by JPY1.0 billion from the previous year. However, on a contribution profit basis, they remained at the same level as the previous year.

In Asia, despite the impact of supply disruptions for certain products, we achieved double-digit profit growth. In EMEA, we have established a business structure that can generate stable profits even excluding one-time revenue in both FY2023 and FY2024.

FY2025 Outlook

Stable EPS from growth in overseas business

	FY2024 ACT	FY2025 FCST
USD (JPY)	152.70	145.00
EUR (JPY)	163.57	160.00
CNY (JPY)	21.29	20.50

(JPY billions)	FY2024 Actual	FY2024 vs Revenue	FY2025 Forecast	FY2025 vs Revenue	FY2025 YoY
Revenue	300.0	-	**294.0**	-	**-2.0%**
Cost of sales	129.0	43%	123.0	42%	-4.6%
Gross profit	171.0	57%	**171.0**	**58%**	**-0.0%**
SG&A expenses	87.5	29%	92.0	31%	+5.1%
R&D expenses	24.1	8%	25.0	9%	+3.7%
Core operating profit	59.4	20%	**54.0**	**18%**	**-9.1%**
Non-core expenses	0.4	0%	-	-	-100.0%
Amortization on intangible assets associated with products	8.8	3%	8.7	3%	-1.3%
Other income	0.6	0%	0.7	0%	+18.8%
Other expenses	3.9	1%	2.0	1%	-48.1%
Operating profit	46.9	16%	**44.0**	**15%**	**-6.1%**
Finance income	4.0	1%	1.3	0%	-67.5%
Finance expenses	2.7	1%	1.4	0%	-48.5%
Share of loss of investments accounted for using equity method	0.7	0%	-	-	-100.0%
Profit before tax	47.5	16%	43.9	15%	-7.5%
Income tax expenses	11.6	4%	10.4	4%	-10.6%
Actual tax ratio	*25%*	-	*24%*	-	-
Net profit	35.9	12%	**33.5**	**11%**	**-6.6%**
Net profit attributable to owners of the company	36.3	12%	34.0	12%	-6.2%
ROE	12%		12%		
EPS (IFRS) JPY	104	-	103	-	-1.3%

Major factors in YoY differences

Revenue: -2.0%

- Overseas business: +4% YoY
  (including negative FX and one-time revenue in FY2024.
  YoY excluding FX: China +17%, Asia +13%, EMEA +2%)
- Japan: Anticipate largest impact from generics for major products in FY2025. Resume growth trajectory with new products in the medium-term perspective

Gross profit: -0.0%

- Decreased COGS ratio mainly due to region/product mix

Core OP: -9.1%

- SG&A: Control under 30% level in medium-term
- R&D expenses: Same range as FY2024

OP (IFRS): -6.1%

- Including steady income and expenses factors

Net profit (IFRS): -6.6%

- Steady EPS (JPY 103)

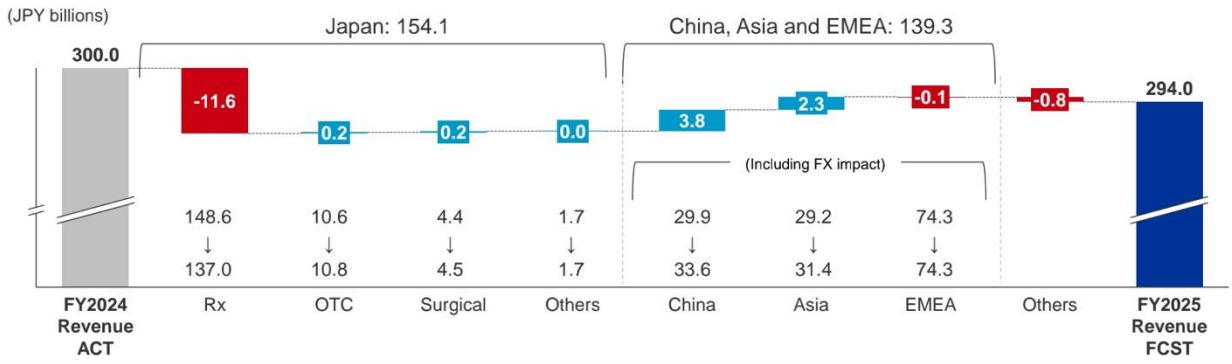
Page 11 shows the full-year outlook for FY2025.

Revenue was JPY294.0 billion. Core operating profit was JPY54.0 billion. Both are based on the assumption that the yen will be affected by the appreciation of the yen compared to the previous year. Operating profit on an IFRS basis is projected at JPY44.0 billion. As a whole, we will build a P&L structure that is resilient to inflation and other cost-increasing factors and that will realize this structure to generate stable profits.

For EPS, we forecast JPY103, the same level as in FY2024. We also aim to achieve ROE of 12%, the same level as in FY2024, which we regard as equally important as EPS.

FY2025 Forecast sales bridge

Japan: YoY decrease. Focus on market creation by *Ryjusea* for future growth
Overseas: Accelerate growth trajectory



Japan	-6.8% YoY: Launched *Ryjusea* and anticipate *Diquas LX* shipment resumption, while including impacts from generics and full-year basis *Sentei-ryoyo*
China	+12.6% YoY (excluding FX impact +17%): Contribute the market with *Benoxil*, while anticipating impacts from VBP and product supply
Asia	+7.8% YoY (excluding FX impact +13%): Steady growth from mainstay products in glaucoma and dry eye in key markets. Anticipate impacts from product supply and HCP strikes in South Korea
EMEA	-0.1% YoY (excluding FX impact +2%): Continued growth from glaucoma preservative-free and new products as well as dry eye products. Maintain growth trajectory excluding one-time revenue in FY2024

*Sales classified into countries or regions based on customer's location. EMEA: Europe, Middle East and Africa. Hong Kong is included in China for both in FY2024 and FY2025 and excluded from Asia.

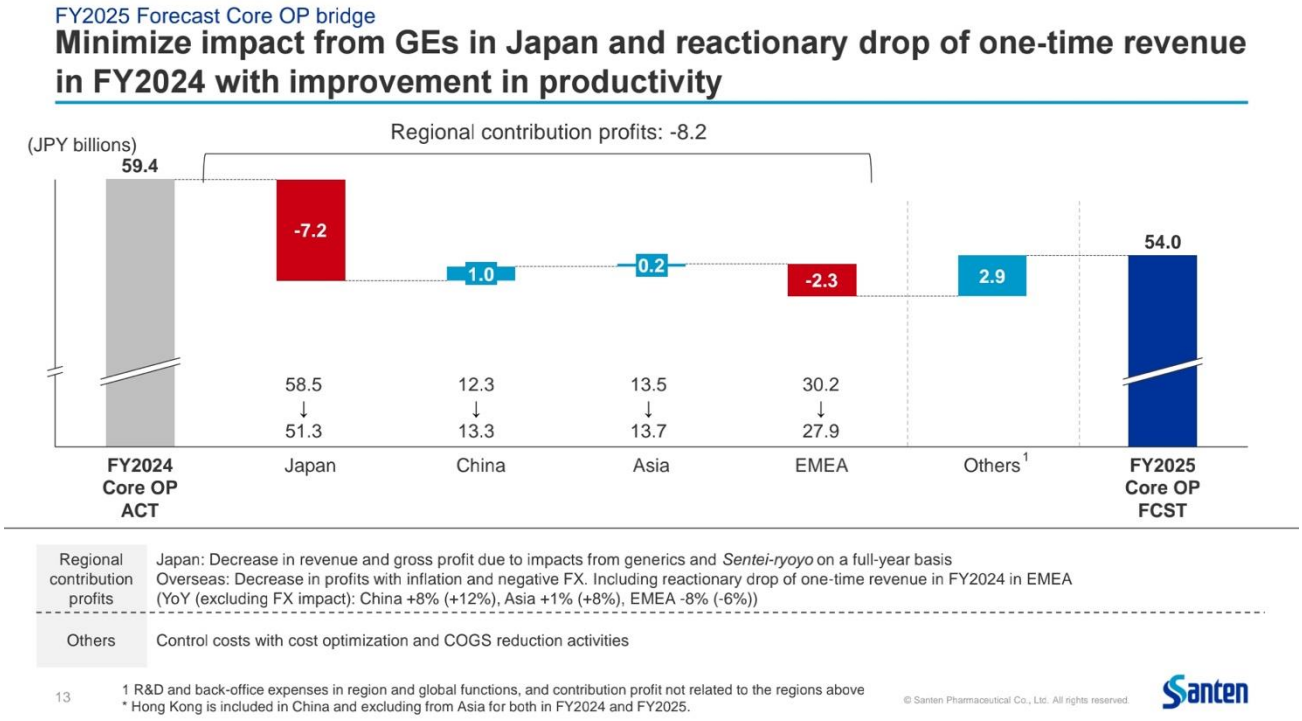
Page 12 shows factors for changes in forecasted sales profit.

Revenue of JPY294.0 billion includes JPY154.1 billion in Japan and JPY139.3 billion overseas (Santen post amendment: China, Asia and EMEA). The overseas ratio (Santen post amendment: ratio of the three areas) is 47%.

For Japan, FY2025 is the year that will be most affected by generics of major products in the medium term. In addition, the impact of the *Sentei-ryoyo* Scheme on long-listed products lasts throughout the year. Therefore, we expect a 7% decrease in sales from the previous year.

On the other hand, positive factors include the launch of the myopia drug, *Ryjusea* and the glaucoma drug, sepetaprost. Although shipments of *Diquas LX* will resume in H2 of the fiscal year, etc., the contribution will be limited for the current fiscal year, and priority will be given to preparation for growth in FY2026 and beyond. This is how we see it.

Overseas, sales in China and Asia will continue to be affected by the supply issue of some products partly, but overall revenue will increase. Excluding foreign exchange impact, we expect double-digit growth. In EMEA, the growth trend remains the same, although there is a reactionary decline from the previous year's one-time revenue.

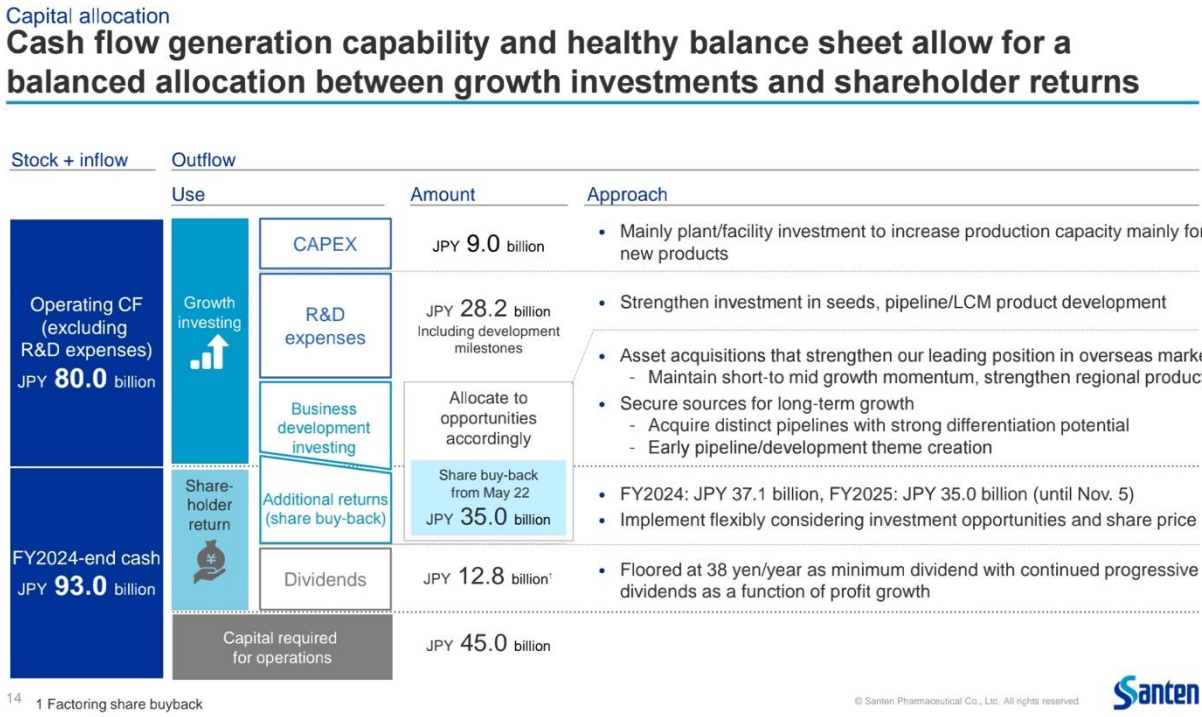


Page 13, factors for change in forecast core operating profit.

The decrease in contribution profit in each business is JPY8.2 billion versus the previous year, while the increase in income due to cost containment and other factors was JPY2.9 billion. These were offset and resulted in a JPY4.4 billion decrease in profit. As a result, we assume a JPY54 billion, or 9%, decrease in profit.

First, with respect to Japan,. We also expect a double-digit decline in profit because of limited recovery from new products and *Diquas LX* against the decline in sales due to the impact of generics, mainly including the replacement of *Alesion LX* with AG, the *Sentei-ryoyo* Scheme for long-listed products and other factors. Overseas, although there is an increase in expenses due to inflation and other factors, the Company secured an increase in profit. High growth rate excluding exchange rate effects.

We will continue to optimize costs, etc. at the company-wide level, and at the same time, strengthen cost reduction efforts on a global basis to secure a foundation for stable profit generation.



On page 14, I will explain capital allocation.

In addition to JPY93.0 billion in cash on hand at the end of FY2024, we expect to generate JPY80.0 billion in R&D-adjusted operating cash flow in FY2025, and we will use these funds to both invest in growth and return profits to shareholders.

We will first secure JPY45.0 billion in working capital requirements, which we will then allocate preferentially to investments that will lead to medium- to long-term growth. As for capital expenditures, we will invest approximately JPY9.0 billion in production-related investments to expand production capacity, mainly for new products, and JPY28.2 billion for R&D, including milestone payments. In business development, as has been our policy, we will aim to acquire candidates that will strengthen our presence in overseas markets and pipelines that will lead to medium- to long-term growth. We will invest our resources with a certain financial discipline, including the management of side effects, especially dilution of ROIC investment profitability.

Regarding shareholder returns, based on the progressive dividend policy, the annual dividend will be JPY38 per share, which is the lower limit for this fiscal year, resulting in a total dividend of JPY12.8 billion. In addition, we believe that the current share price level is extremely undervalued. Therefore, as the CEO mentioned at the beginning of this presentation, we will implement a share buyback of JPY35.0 billion.

Shareholder returns

Dividend raised to JPY 38 considering mid-to-long term prospects. JPY 35.0 billion (maximum) of share buy-back from May 22

(FY)	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025 FCST
Total return ratio (IFRS)	19%	106%	30%	76%	46%	120%	47%	-	106%	137%	141%
Share buy-back (JPY billions)	-	12.3	-	13.9	-	-	-	25.7	16.2	37.1	35.0 (Max.)

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Page 15, shareholder returns. This chart shows the return of profits to shareholders through stable dividends and shares buybacks over the past 10 years.

This concludes my explanation.

Question & Answer

Sakuma [M]: Mr. Yamaguchi of Citigroup Global Markets, could you please go ahead?

Yamaguchi [Q]: Thank you very much. I'm Yamaguchi from Citigroup Global Markets Japan. First of all, regarding *Diquas LX*, I believe the updated forecast includes JPY4.1 billion, and I understand that it is highly certain, but I would appreciate it if you could provide more details about the current situation. Is there much risk in assuming a resumption of shipments in H2, or would it be a bit sooner? This is my first question.

Ito [A]: Thank you for your question. Regarding *Diquas LX*, as I explained earlier, we have already started discussions with the authorities. At this point, we are not at all pessimistic about the situation.

I believe I mentioned this during the Q2 financial results briefing, but we understand the causes of the problem and have several ideas on how to address them without resorting to drastic measures such as application for partial changes to the product. Since then, we have repeatedly examined various measures at the actual production level and have concluded that we are confident that we can deliver products of stable and consistent quality, and that we are confident of shipping such products.

However, I would like to refrain for a moment from discussing the content of our discussions with the authorities here. I am not pessimistic at all anymore.

I would say that the timing of the return is H2, but I would like to resume shipments as early in H2 as possible. That is all.

Yamaguchi [Q]: Thank you very much. One more point, you explained a little about the *Ryjusea Mini*. I think it was JPY1.6 billion globally. I think there were a little less in Japan, but I guess all I can ask is, how do you think about it now?

There is also an existing product like *Myopine* coming in from Singapore. Are you switching from those, or is this a completely for new patients? I understand that you already have some existing data, including your strategy and on-site reactions. Could you please provide us with some figures to show the current situation?

Nakajima [A]: Nakajima will answer the question. *Ryjunea* was launched in Japan on April 21, and we believe it is off to a very good start. The product has already been adopted by more than 1,000 facilities nationwide. Of course, we believe that the product will be actually prescribed to patients and begin to circulate from now on, but we have received many inquiries from doctors, and we have also heard from the field that some patients are even buying it.

There are a good number of facilities in Japan where Myopine was originally used, and it is of course possible to switch completely from Myopine. Patients who have been using Myopine to control myopia are naturally eligible for treatment with *Ryjusea*, so I suppose that the doctor would be willing to make the switch at his/her discretion.

What we would like to focus on even more is to take this opportunity to raise awareness of the significance of myopia treatment and the benefits to patients and their parents by using the properly approved *Rujusea*. We will continue to work to create a market in which people can receive prescriptions at ophthalmology clinics and continue their treatment. We would like to create a market where we can not only switch from *Myopine* necessarily, but also properly penetrate this *Ryjusea* into the market and make it useful for patients properly. That is all from me.

Ito [A]: I would like to add some information. As Nakajima just explained, we launched the product on April 21, and most of the medical institutions were closed due to the Golden Week holidays, although it was a long period, but the product has already adopted by about 1,000 medical institution. In Japan, this product will probably be used mainly in the market of general practitioners, so the total number is about 8,000, but we already have about 1,000 adoptions. We are aware that many of these medical institutions have a rather active attitude toward treatment.

However, as we have said in the past, we will never create a market in such a way that things would fall off the calendar, a case in which the patients who are prescribed our products simply use them for a month or so and then stop. I would like to add that rather than placing the priority in accelerating sales buildup this fiscal year, we are focused on establishing the right way to use our products.

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

Sakuma [M]: Mr. Hashiguchi of Daiwa Securities, please go ahead.

Hashiguchi [M]: I'm Hashiguchi. Thank you.

Sakuma [M]: Thank you.

Hashiguchi [Q]: Thank you. First, I think you said that from the next fiscal year onward, you will recover to a satisfactory growth trend, but just to make sure, can we have a basic image on how profits will increase next fiscal year, the year after that, and the year after that as well? Even if it is unclear whether growth will recover next fiscal year, the fiscal year after that, or the fiscal year after that, I think that the expression would be "growth will recover in the next fiscal year and beyond" in Japanese. Is it correct to say that you are forecasting a decrease in profit for this fiscal year, but that next fiscal year there will be a recovery of *Diquas LX* and the startup of *Ryjusea*, and that basically you are forecasting an increase in revenue and profit for the next fiscal year at this stage?

Ito [A]: Thank you for your question. As I mentioned at the beginning of this briefing, FY2025 is the year in which we saw a decrease in revenue and profit. So, you mean the next year, right? I am confident that we will return to a steady growth trend. In terms of the actual results for FY2024, we are looking at a big picture where we are sure to exceed the results for FY2024 in terms of profit and EPS indicators. That is our big picture of forecast.

As you have commented, there is the factor that sales of myopia drugs and the like will gradually take off in FY2026, and on the other hand, you might assume that Santen Pharmaceutical will be affected by the launch of generic versions of *Alesion*.

In fact, for example, with regard to *Alesion*, we have launched AG, which is licensed under the formulation patent of the original product, and in three months since its launch in January, AG has captured 97% of the market share. Also, the volume share of Santen Pharmaceutical's *Alesion* products increased considerably from January to March, and we expect sales of allergy products to expand in FY2025, and probably more in FY2026 than in FY2025. That is my understanding, including the cream.

Therefore, we believe that we will be able to achieve such results firmly, although we expect tail heavy profits in QTD, as allergy drugs will continue to make a large contribution.

Hashiguchi [Q]: So, you mean, in terms of *Alesion* products as a whole, the decline in sales this fiscal year was mostly due to the drop in the unit prices, but the increase in cream sales will outpace this decline, so we can expect an increase in revenue next fiscal year. That's what you mean.

Ito [A]: Yes. Although sales of the cream were a little sluggish until the allergy season got into full swing, most of the important medical institutions used the cream during the season, and we have a good reaction, so we expect sales of the cream to continue to be favorable.

To repeat what I said earlier, the market share of our *Alesion*, epinastine in terms of volume has been in the range of 35% to 40% per quarter, but in Q4 of the last fiscal year, the market share has suddenly swelled to about 45%. In short, there were quite a few customers who were reluctant to use *Alesion LX* because the drug price was a little too high, but since AG and GE were launched, the drug price has dropped, and the volume base of AG has expanded beyond our expectations. We would like to make sure this trend continues in the future.

Hashiguchi [Q]: I understand very well. Thank you very much. The second question is your plan for SG&A expenses, which are expected to increase by JPY4.5 billion in FY2025 compared to FY2024. The exchange rate has shifted toward a stronger yen, and sales of *Alesion* are also declining, so I think co-promotion fee will decrease as well. So, what is the main factor behind this increase? Is this only for this fiscal year, or should we expect a continuous increase in the next fiscal year and beyond? Please tell me your thoughts.

Koshiji [A]: Yes. SG&A expenses will indeed increase, but the main reason for the increase is personnel expenses. This is the so-called variable cost portion. Promotional expenses remain flat, and as you pointed out, royalties and sales rights fees decrease YoY, but personnel expenses increase by approximately 5%. So that is the increase for this fiscal year. There is also an increase in amortization costs associated with the introduction of ERP, but the majority of the increase is personnel costs.

As for future trends, personnel expenses will naturally increase slightly, but we will keep SG&A below 30% of sales as a P&L structure by controlling costs, so that they do not put pressure on earnings. We believe so.

Hashiguchi [Q]: It is 31% this fiscal year, but if you say below 30%, does this mean that you can return to that level as soon as possible in the next fiscal year?

Koshiji [A]: This fiscal year, it is 31%, but in the medium term, 30%, and in the next fiscal year, 30%. In the next fiscal year, or rather in the medium term, we expect to curb the ratio to less than 30%.

Hashiguchi [M]: Yes, I understand. Thank you very much. That is all.

Sakuma [M]: Mr. Wakao of JPMorgan Securities, please go ahead.

Wakao [Q]: I'm Wakao from JPMorgan. Thank you very much. Can you tell me a little bit about overseas? I would like to ask you about each area. First of all, regarding China, first the term already ended, I think that Q4 was a little weak due to the VBP, but I would like to know if that is correct. Regarding this fiscal year, although there is a certain degree of impact of VBP, we expect growth to continue due to the focus on the new value provided by *Benoxil*. I would like to hear more about the details here.

Also, I think that Asia and EMEA are performing rather firmly, but could you tell me if my understanding is correct?

Nakajima [A]: Yes. Nakajima will answer the question. Regarding China, rather than Q4, let me first talk about what was weak throughout the year, and then I will answer how that may or may not resonate in 2025.

In China, there were actually three main reasons for the decline in revenue and profit. One is that it was a year in which the supply problem was quite pronounced. The first and most significant reason is that the supply of *Benoxil*, *Flumetholon*, and *Hyalein Mini*, some of which are related to the Noto Earthquake, could not meet market demand.

The second is, as you say, the impact of VBP, especially *Diquas*. The second major factor was that *Diquas* was unable to maintain sales at public hospitals as expected after designated appointed to VBP this year and was unable to launch enough retail business to cover the loss of that.

Third, it is about CSO. We have been selling products such as *Cravit* and *Hyalein* in China through a distributor, but there was a slight surplus of these products in the market, so we adjusted the supply, particularly in Q4, by holding back on sales. As a result, sales in China as a whole for 2024 are as shown in the chart.

As for 2025, the supply issues I mentioned earlier will be almost completely resolved. We have secured a certain amount of supply necessary to generate sales in China, so we will accelerate to generate the sales of products such as *Benoxil* and *Flumetholon*. As for the CSO inventory issue, we plan to resolve it in Q1, so we expect to see figures for *Hyalein* and *Cravit* rise in Q2 and beyond.

Finally, regarding the impact of VBP, since the sales of *Diquas* will be affected throughout this year, we plan to launch a retail business and maintain the sales of *Diquas* at roughly the same level with a slight decrease from 2024 in China.

Now, does this answer your question regarding China at least?

Wakao [M]: I understand very well.

Nakajima [A]: Asia and EMEA are in a growth trend, as you can see here. We do not have any particular bombshells.

If I may make a few comments, I believe that we will continue to grow in Asia, with South Korea, Thailand, and Vietnam as our core markets, and we will continue to grow our overall portfolio of dry eye and glaucoma products in each of these three countries. Here, we do not have any bombshells in the Asian market, such as generics, so I think we can expect steady and solid growth in Asia.

In Europe, new glaucoma products, such as ROCK inhibitors and *Catiolanze*, have been launched steadily since last year, so we will drive these new products firmly. On the other hand, there are several old products whose prices are expected to be reduced. The decline in these areas will be partially offset by new products, but overall, we expect to see solid growth in EMEA. This is what we think about it. That is all.

Wakao [Q]: I understand very well. By the way, how should I look at this EMEA myopia suppressant? I understand that China and Japan are large markets and EMEA is next in line, with relatively small potential, but with JPY200 million sales planned for this fiscal year, what kind of potential should we expect? Also, it would be helpful if you could comment on market growth and so on.

Nakajima [A]: Nakajima will answer this one, too. It is true that the market does not look that big when looking at revenue, but in terms of the number of potential patients, Europe is actually a market with a potential of about 14 million patients. In addition, unlike Japan, the majority of countries are planning to provide insurance treatment, so the start-up is a little slower. As Ito mentioned earlier, it is a bit of a gradual start, including the fact that we have to do some careful marketing to a certain extent, just like in Japan.

Furthermore, rather than entering all countries at once, we will proceed in stages, starting with Germany, followed by Northern Europe and Italy, so there will be no sudden vertical growth. However, this is a region with significant potential, and there are advantages to entering through insurance-based medical care, so we hope you will look forward to this as well.

Wakao [Q]: As for atropine, isn't there any existing drug?

Nakajima [A]: That's right. There is no existing drug here. However, as a market, there is already a market for clinic-compounded atropine, so although this is the first approved drug, it is not a market that has never used atropine before.

Wakao [Q]: By the way, how is the price? Will the drug be priced accordingly or is it rather inexpensive?

Nakajima [A]: We are currently discussing this matter with authorities in various countries, so I will refrain from commenting on drug prices at this time. However, from a medical economics perspective, we believe that the drug prices will be reasonably set.

Wakao [Q]: I understand very well. Lastly, the acquisition assets by your company. Can you tell me about business development investment? You have been saying this for quite some time, and there has been no particular movement, but is there no urgency regarding this business development investment? For example, in the medium-term plan to be announced next time, will the assets obtained from this business development investment play an important role? Or is the medium-term plan basically created without assets acquired business development investment, and if business development investment is made, will it be positioned as a plus?

Ito [A]: I will talk about that in next week's medium-term plan, but the figures in the medium-term plan itself do not specifically incorporate the sales contribution from business development. I will be happy to explain again next week what we have created plan that can be achieved on a basically organic basis.

On the other hand, we will continue to actively invest in business development, regardless of the basis for the figures. However, we will emphasize the profitability of investments, so we will not consider investments that will require immediate impairment loss later on, but we would like to be more aggressive.

In FY2024, we obtained two projects by business development, but they were not on such a large scale, but our basic idea is to be more proactive and aggressive in the future.

Wakao [M]: I understand very well. That is all.

Sakuma [M]: Now, Mr. Ueda of Goldman Sachs, could you please go ahead?

Ueda [Q]: This is Ueda from Goldman Sachs. First, I would like you to follow up your explanation regarding the outlook for the *Alesion* franchise. During the Q&A earlier, you mentioned that growth is expected to resume again in the next fiscal year and beyond. Could you please explain your thinking behind this?

Once the switch to AG is complete, will growth continue to increase gradually with a shift to cream formulations, or do you anticipate a further increase in market share? Could you please explain this point?

Ito [A]: As I mentioned earlier, I think the reaction to *Alesion* cream in this allergy season, from January to March, was very good, so I expect it to produce reasonable results next season, or rather, next spring again. I believe that it will continue to grow steadily, and considering the nature of disease as allergies, I think that this cream, which is applied to the eyelids and then active pharmaceutical ingredient is released slowly, is the optimal design. I believe that this has been well understood by the doctors at the medical institutions this season, and I believe it will continue to grow.

Another point is that, as I mentioned earlier, the share of Santen Pharmaceutical 's epinastine eye drops in terms of volume grew significantly this spring, exceeding our initial expectations. This is an opportunity for us to continue to grow more, and I believe we must pursue such results, so I am looking forward to the contribution in this area.

Nakajima [A]: Just a few additions from Nakajima. I have received comments that the switch to AG has been completed this fiscal year, but the percentage of AG in our sales base has already reached nearly 70% of *Alesion LX* (Santen post amendment: Q4 FY2024 QTD actual). I am not saying that there will be no further growth, but since we have switched to AG to some extent, as Ito just mentioned, I think that from now on we will really step on the accelerator for cream and maximize the cream growth, and that is how we will compete.

Ueda [Q]: Thank you very much. Second, I would like to ask you about the impact of the *Sentei-ryoyo* Scheme. You mentioned that the impact was not as significant as expected, but could you tell us how much of an impact it had on the results of the previous term in the amount of sum or scale, and how you have factored this into your plans? I would like to know if there is any need for us not to be concerned about this impact, including what items are actually affected.

Koshiji [A]: I will answer first. In that respect, the fiscal year that ended, FY2024, was roughly less than JPY2.0 billion. Since there are multiple factors such as a decrease in sales due to the NHI drug price revision, it is difficult to say the impact of the *Sentei-ryoyo* alone, but it is approximately less than JPY2.0 billion. The budget for the current fiscal year includes a total of approximately less than JPY4.0 billion, which will be multiplied by two for the full year.

It is quite difficult to specify which products are affected by the S*entei-ryoyo* Scheme. As noted on page 19 of the presentation materials distributed today. I will not go into detail in the explanation. That is all.

Financial supplement

Sentei-ryoyo **(new system of co-pay hike from Oct. 2024) impact:**

Revenue and FY2025 forecast

Listed 17 products[1] (including different concentration products, as of April 2025)
Anticipate future listings including *Diquas*, *Tapros*, *Tapcom* and *Alesion LX* for which GEs have been launched

(JPY millions)

Product	Therapeutic area	FY2021	FY2022	FY2023	FY2024	FY2024 FCST	vs FY2024 FCST	FY2025 FCST
Cosopt [2]	Glaucoma	5,047	4,039	3,347	2,395	2,111	113%	1,073
Alesion (4 times/day)	Allergy	4,440	2,987	1,807	889	786	113%	532
Hyalein 0.1/0.3 [2]	Dry eye	5,800	4,949	4,268	3,848	3,590	107%	2,565
Cravit 0.5/1.5	Bacterial conjunctivitis	1,754	1,285	1,126	679	674	101%	420
Timoptol XE 0.25/0.5	Glaucoma	3,092	2,807	2,445	1,516	1,550	98%	1,328
Timoptol 0.25/0.5	Glaucoma							
Alegysal	Allergy							
Livostin	Allergy							
Flumetholon 0.1	Others							
Santeson 0.02/0.1	Others							
Sancoba	Others							
Mydrin-M	Others							
Total		20,134	16,067	12,994	9,327	8,710	107%	5,918
Japan business total		173,633	177,373	175,608	165,310	160,649	103%	154,109
Ratio vs Japan business total		11.6%	9.1%	7.4%	5.6%	5.4%	-	3.8%

19 1 Only eye drops 2 Unit-dose products excluded

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

Sakuma [M]: Mr. Muraoka of Morgan Stanley Securities, please go ahead.

Muraoka [Q]: Thank you. This is Muraoka from Morgan Stanley. I would like to ask about *Alesion*, the cream. I was happy with the sales from January to March, but since patients only use one tube a month, it's hard to know, but I wonder if the repeat rate after the second use of this product is also as expected. I wonder if there

were actually a lot of people who returned to using eye drops after one use, it's fine just with a feeling-base, but could you tell me what kind of result you got?

Ito [A]: I'm sorry, I don't have the repeat rate data at hand, so I can't give you the answer, but I am sure that the reputation from the patients is very good. I don't think there have been any cases where patients tried the cream but then returned to eye drops at their own request, as you mentioned earlier. That is our understanding.

Muraoka [Q]: I see. Thank you very much. One more thing, many people had high expectations for myopia treatment, so there were voices among investors wondering if it would take off more quickly. After completing the Q1, is it better not to consider the possibility that it will suddenly take off? I understand that you need to proceed cautiously while educating people, but is it okay not to consider the possibility of a sudden vertical takeoff?

Nakajima [A]: Nakajima will answer the question. I will give a somewhat ambiguous answer but looking at the patients and the noise on social media, I cannot say for sure that it is impossible for this to suddenly take off, with sales exploding, and be patient-driven.

However, our activities themselves are quite solid, and we are conducting marketing activities with a clear vision of ensuring that clinics that recognize the significance of this treatment properly understand the merits and profile of this product, prescribe it appropriately, and ensure that patients continue to take the medication as directed. We are aware that it will take some time before each clinic is able to use *Ryjusea* as a out-of-pocket treatment, so we are proceeding with that understanding. While we do not deny the possibility of a sudden surge in prescriptions driven by patient demand, we believe it is more realistic to expect a steady, gradual increase.

Muraoka [Q]: I see. One more thing, in the course of conversation about *Ryjusea*, you mentioned that AFDX failed, and lifecycle management was also mentioned. Does lifecycle refer to high dosage in the case of *Ryjusea*, which is a single-dose unit formulation? Or I know it might be difficult, but is it something like once a week? What kind of image should we have?

Ito [M]: I'm sorry, but I can't give you any specifics about this idea, but drugs for myopia and ptosis as well are very different from the conventional eye drops. The conventional eye drops are administered into the eye, and the focus is on how much of the active pharmaceutical ingredient can be passed through the cornea and we can make it reach the tissue s at front of the eye. In that sense, conventional eye drops are considered the optimal formulation.

In case of myopia and ptosis treatment, where the drugs reach and work in places are completely different from what I just mentioned. The question of how to efficiently deliver the drugs to those places is an area that we are particularly skilled in, so to speak. With that in mind, we actually have various ideas for improvements.

Muraoka [Q]: Thank you. So, are you saying that the myopia life-cycle strategy could possibly be applied to ptosis in a similar way?

Ito [A]: Yes, that's right. Our primary mission and responsibility is to strive to achieve higher levels of efficacy for patients. We will not talk about the specifics today, but we are thinking about it carefully, as was the case with *Diquas* and *Alesion*, and we will think about it in the same way.

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

Sakuma [M]: Thank you very much.

[END]