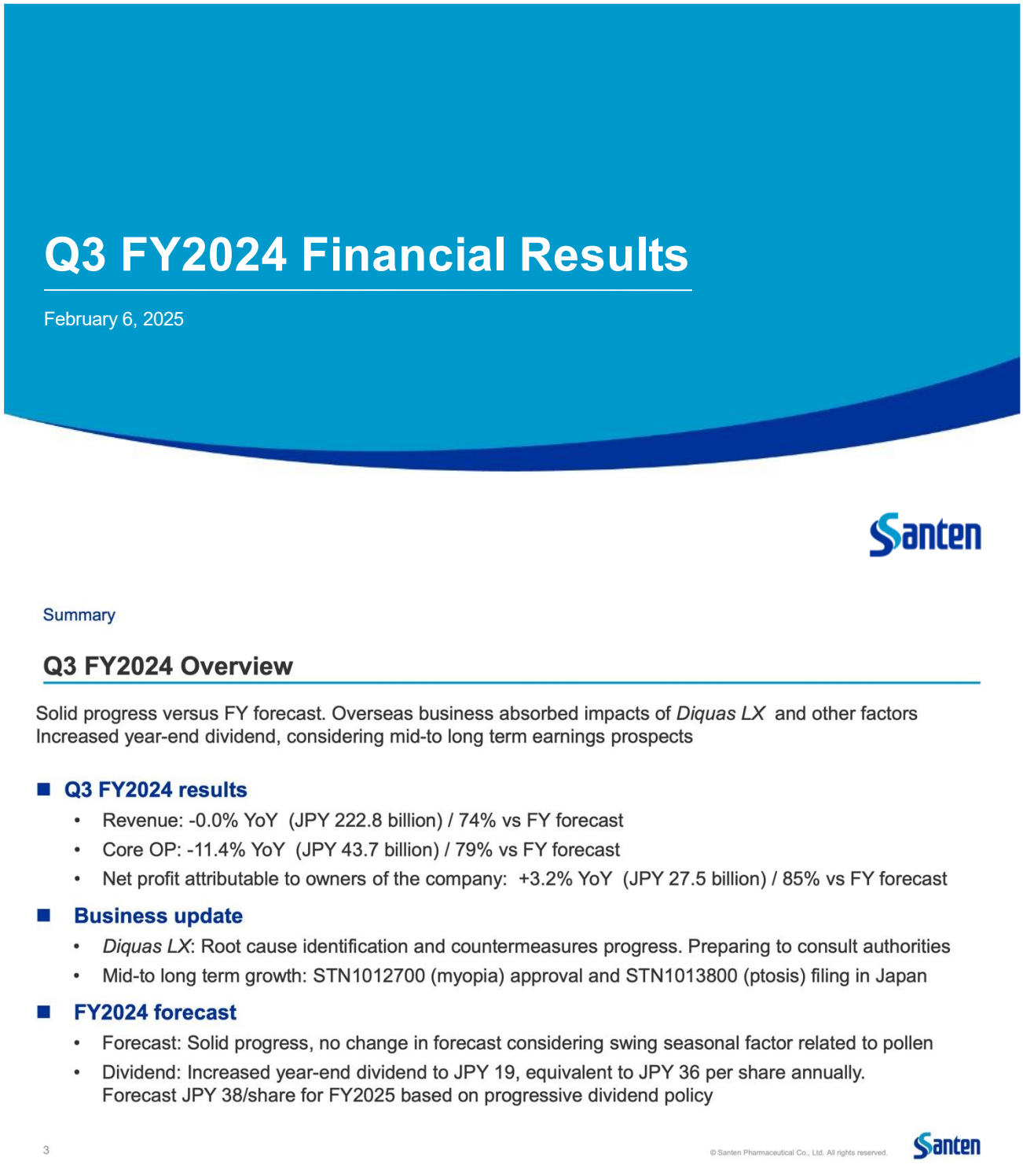
Q3 FY2024 Financial Results Transcript



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

In Q3 of FY2024, steady progress in overseas business, including foreign exchange, and other factors absorbed impacts of *Diquas LX,* product supply issue and other factors, resulting in steady progress against the full-year forecast.

Sales were almost flat YoY, and 74% of the full-year forecast of progress rate was achieved. Core operating profit was negative 11.4% YoY, but 79% of the full-year forecast. Net profit attributable to owners of the company increased by 3.2% YoY. The progress rate against the full-year forecast is 85%.

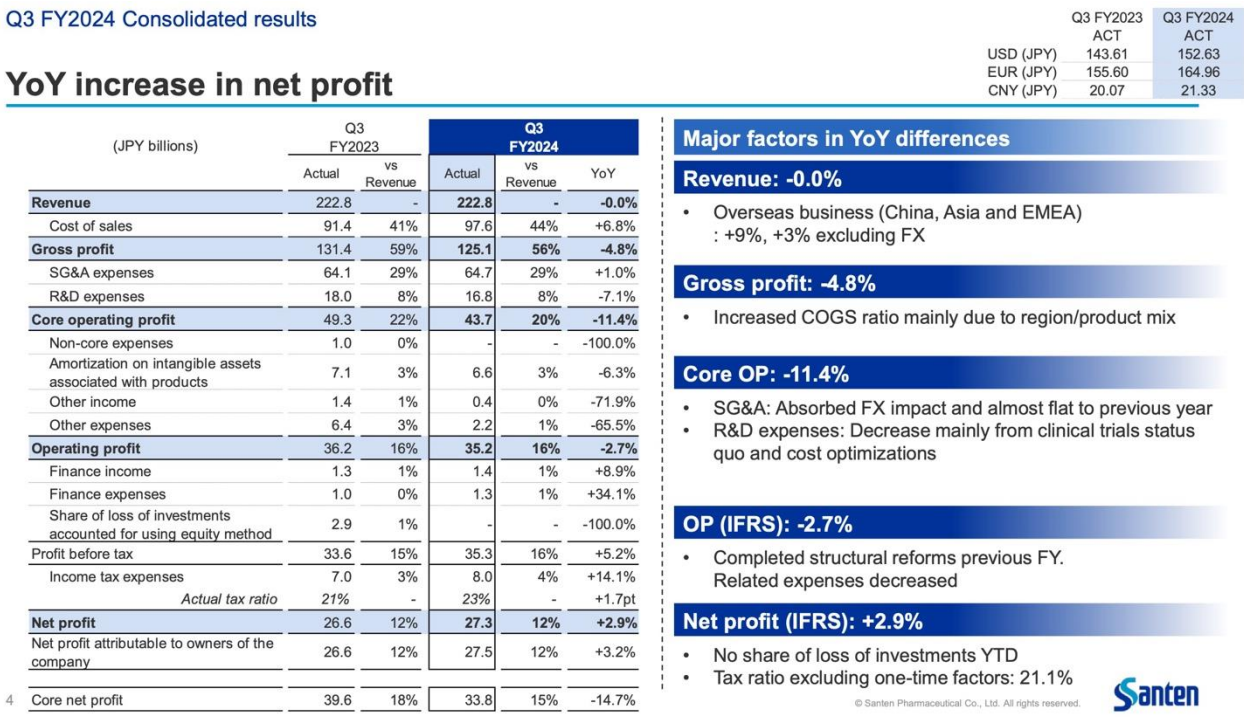
As for the other updates. First of all, regarding *Diquas LX*, I told you at the Q2 results briefing that we had identified the cause of the problem and that we would be discussing several options for how to respond to the problem. Subsequently, we were able to identify the measures to be taken, including their reproducibility tests. And now, we are aware that we are making steady progress toward reshipment.

We are planning to consult with the authorities and are taking steps to resume shipments as soon as possible. We intend to update our progress, including sales guidance for the relevant products for the next fiscal year, during the announcement of Q4 financial results in May.

As you can see, we also made progress in the pipeline for new areas that will support medium- to long-term growth. Sallstig will explain this later.

On the full-year forecast, both revenue and profits are progressing at a high rate compared to the full-year earnings forecast, but there are variable factors such as pollen dispersion, so we have decided not to change the full-year forecast.

Considering future earnings prospects, we have revised upward the year-end dividend to JPY19 per share, an increase of JPY2 per share, for an annual dividend of JPY36 per share. As a result, based on our progressive dividend policy, which implies no reductions in dividends, we expect JPY38 per share to be the baseline for the next fiscal year.



Q3 FY2024 Consolidated results

	Q3 FY2023 ACT	Q3 FY2024 ACT
USD (JPY)	143.61	152.63
EUR (JPY)	155.60	164.96
CNY (JPY)	20.07	21.33

YoY increase in net profit

(JPY billions)	Q3 FY2023 Actual	Q3 FY2023 vs Revenue	Q3 FY2024 Actual	Q3 FY2024 vs Revenue	Q3 FY2024 YoY
Revenue	222.8	-	**222.8**	-	**-0.0%**
Cost of sales	91.4	41%	97.6	44%	+6.8%
Gross profit	131.4	59%	**125.1**	**56%**	**-4.8%**
SG&A expenses	64.1	29%	64.7	29%	+1.0%
R&D expenses	18.0	8%	16.8	8%	-7.1%
Core operating profit	49.3	22%	**43.7**	**20%**	**-11.4%**
Non-core expenses	1.0	0%	-	-	-100.0%
Amortization on intangible assets associated with products	7.1	3%	6.6	3%	-6.3%
Other income	1.4	1%	0.4	0%	-71.9%
Other expenses	6.4	3%	2.2	1%	-65.5%
Operating profit	36.2	16%	**35.2**	**16%**	**-2.7%**
Finance income	1.3	1%	1.4	1%	+8.9%
Finance expenses	1.0	0%	1.3	1%	+34.1%
Share of loss of investments accounted for using equity method	2.9	1%	-	-	-100.0%
Profit before tax	33.6	15%	35.3	16%	+5.2%
Income tax expenses	7.0	3%	8.0	4%	+14.1%
Actual tax ratio	*21%*	-	*23%*	-	+1.7pt
Net profit	26.6	12%	**27.3**	**12%**	**+2.9%**
Net profit attributable to owners of the company	26.6	12%	27.5	12%	+3.2%
Core net profit	39.6	18%	33.8	15%	-14.7%

Major factors in YoY differences

Revenue: -0.0%

- Overseas business (China, Asia and EMEA) : +9%, +3% excluding FX

Gross profit: -4.8%

- Increased COGS ratio mainly due to region/product mix

Core OP: -11.4%

- SG&A: Absorbed FX impact and almost flat to previous year
- R&D expenses: Decrease mainly from clinical trials status quo and cost optimizations

OP (IFRS): -2.7%

- Completed structural reforms previous FY. Related expenses decreased

Net profit (IFRS): +2.9%

- No share of loss of investments YTD
- Tax ratio excluding one-time factors: 21.1%

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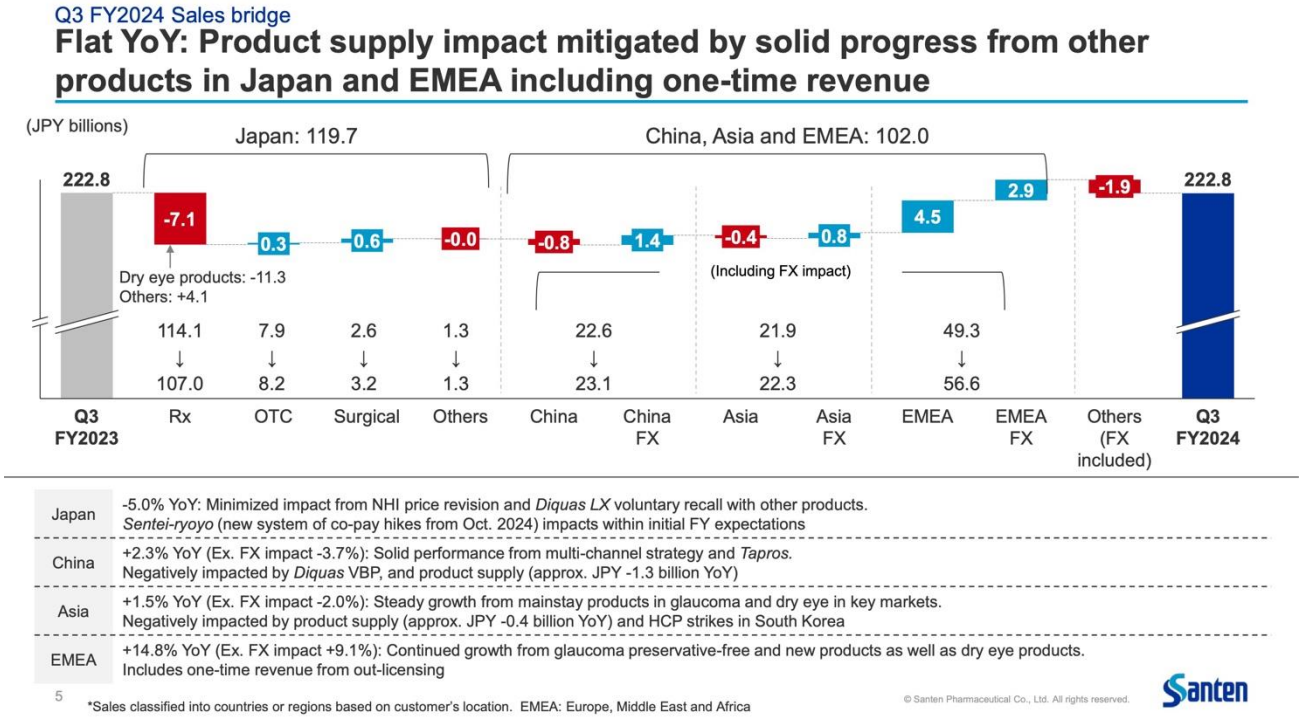
Please refer to page four. Here are the results for Q3.

As explained at the beginning of this report, the Q3 results show sales revenue of JPY222.8 billion. Core operating profit, which indicates the profitability of the business, was JPY43.7 billion.

Although overseas sales offset the impact in Japan, the increase in the cost of sales ratio due to the region/ product mix and other factors had a slight impact on core operating profit.

As for the items below core operating profit, the previous fiscal year, expenses for structural reforms had put pressure on items below operating profit, but these expenses were eliminated this fiscal year, resulting in JPY35.2 billion for operating profit and JPY27.3 billion for net profit, on an IFRS basis.



Japan	-5.0% YoY: Minimized impact from NHI price revision and *Diquas LX* voluntary recall with other products. *Sentei-ryoyo* (new system of co-pay hikes from Oct. 2024) impacts within initial FY expectations
China	+2.3% YoY (Ex. FX impact -3.7%): Solid performance from multi-channel strategy and *Tapros*. Negatively impacted by *Diquas* VBP, and product supply (approx. JPY -1.3 billion YoY)
Asia	+1.5% YoY (Ex. FX impact -2.0%): Steady growth from mainstay products in glaucoma and dry eye in key markets. Negatively impacted by product supply (approx. JPY -0.4 billion YoY) and HCP strikes in South Korea
EMEA	+14.8% YoY (Ex. FX impact +9.1%): 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

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Let's move on to the next, page five. The factors affecting the increase and decrease in revenue are as follows.

Revenue of JPY222.8 billion includes JPY119.7 billion in Japan and JPY102.0 billion in China, Asia, and EMEA. The ratio of these three regions to consolidated revenue is 46%.

In Japan, sales decreased by 5% YoY, but the impact of the NHI price revision and *Diquas LX* was minimized by other products. As for *Sentei-ryoyo*, a new system of co-pay hikes for long-term listed products that started in October, the results were within the scope of the forecast made at the beginning of the fiscal year.

Our overseas businesses, despite the impact of product supply, and the *Diquas*'s VBP in China and other factors, sales have been well, especially for mainstay products such as glaucoma and dry eye, including in EMEA. There is also a contribution from the one-time revenue related to the out-licensing that we discussed in the Q2 results, and this is included in EMEA sales.

Q3 FY2024 Core OP bridge

Minimized *Diquas LX* impact with cost optimization and one-time revenue

Regional contribution profits	Japan Dry eye products: Mainly due to decrease in revenue from *Diquas LX* voluntary recall and NHI price revision, coupled with *Diquas LX* recall related expenses (FY2024 NHI price revision *Diquas*: -32%, *Hyalein 0.1*: -10%) Others: Steady progress in other therapeutic areas, and decrease in SG&A Overseas (including FX) China: Maintained profit despite impact from *Diquas* VBP and product supply Asia: Increased profit despite product supply and other factors EMEA: Solid progress with increased profit coupled with one-time revenue from out-licensing
Others	Increased expenses with FX. Positive impact from completion of structural reforms including streamlining in Americas pharmaceutical commercial business

6 1 R&D and back-office expenses in region and global functions, and contribution profit not related to the regions above

Please see page six. This shows factors in change in core operating profit.

On a regional contribution profit basis, there was a decrease of JPY3.9 billion YoY.

First of all, in Japan, the dry eye field saw a decrease of JPY11.4 billion YoY due to the impact of the recall of *Diquas LX* and a significant reduction in NHI drug prices. On the other hand, products in other areas are performing well, and in addition, SG&A expenses are decreasing, reducing the overall impact from the JPY11.4 billion shortfall in profit.

Overseas, profit growth was secured in China and Asia, despite the impact of product supply and other factors. In EMEA, in addition to steady growth, the one-time revenues from out-licensing have also contributed to the increase in contribution profit.

FY2024 Outlook (maintain as of August 6)

	FY2023 ACT	FY2024 FCST (Aug.6)
USD (JPY)	144.80	155.00
EUR (JPY)	156.88	165.00
CNY (JPY)	20.24	21.30

Faster-than-expected progress

(JPY billions)	FY2023		FY2024			
	Actual	vs Revenue	Forecast (Aug. 6)	vs Revenue	YoY	Q3 Progress
Revenue	302.0	-	**302.0**	-	**+0.0%**	**74%**
Cost of sales	123.1	41%	129.0	43%	+4.8%	76%
Gross profit	178.9	59%	**173.0**	**57%**	**-3.3%**	**72%**
SG&A expenses	90.8	30%	91.0	30%	+0.2%	71%
R&D expenses	25.3	8%	27.0	9%	+6.9%	62%
Core operating profit	62.8	21%	**55.0**	**18%**	**-12.4%**	**79%**
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%**	**79%**
Finance income	1.6	1%	2.0	1%	+27.2%	
Finance expenses	2.7	1%	1.5	0%	-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%	78%
Income tax expenses	3.2	1%	11.5	4%	+262.6%	
Actual tax ratio	*11%*	-	*26%*	-	-	
Net profit	26.7	9%	**33.5**	**11%**	**+25.5%**	**82%**
Net profit attributable to owners of the company	26.6	9%	32.5	11%	+22.0%	85%
ROE	9%		11%			
Core ROE	16%		14%			
Core net profit	48.5	16%	41.3	14%	-15.0%	82%

Factors to consider for FY forecast

- Japan: Pollen-levels
- Overseas: Material FX fluctuations
- Cost optimization
- FYE fluctuations in sub-Core items

The next page, page seven, is the full-year outlook.

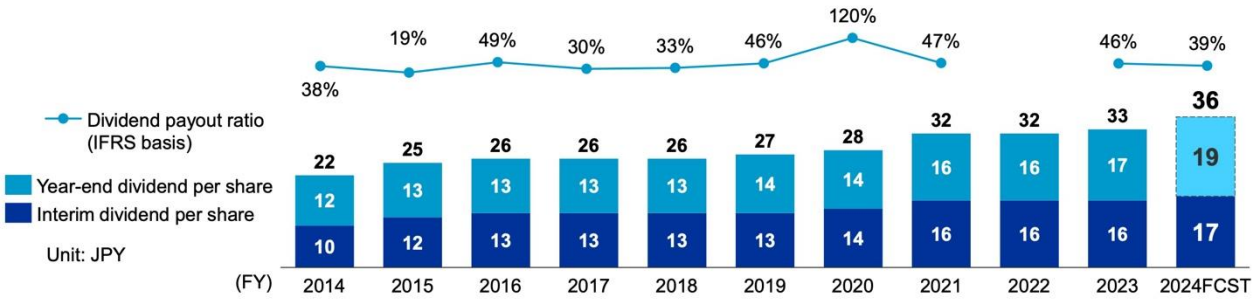
As I mentioned earlier, there is no change in the full-year forecast from what we disclosed in the Q1 financial results on August 6 of last year. Revenue was JPY302.0 billion and core operating profit was JPY55.0 billion. The figures below core operating profit are projected as shown.

As mentioned at the beginning of this call, we continue to exceed our full-year forecast, but in consideration of variable factors such as the amount of pollen dissemination in Q4, we have not made any changes to the previously disclosed figures.

Shareholder returns

Increased year-end dividend to JPY 19 based on progressive dividend policy

- Dividend raised considering mid-to long term prospects in earnings
- Approx.16% / JPY 79.0 billion of OTSD shares repurchase since FY2022

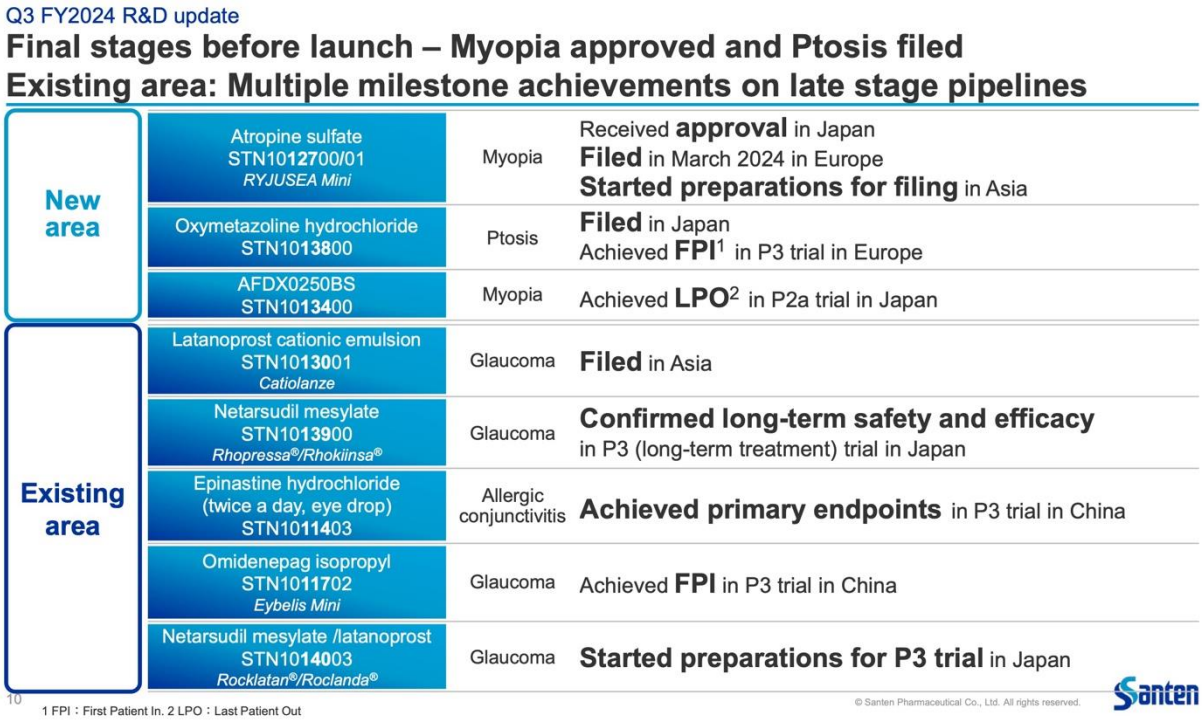


(FY)	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024FCST
Total return ratio (IFRS)	38%	19%	106%	30%	76%	46%	120%	47%	-	106%	152%
Share buy-back (JPY billions)	-	-	12.3	-	13.9	-	-	-	25.7	16.2	37.1 (completed)

Please see page eight. Shareholder returns.

As explained at the beginning of this section, the Board of Directors also resolved today to revise the year-end dividend forecast based on the progressive dividend policy and in consideration of the medium- to long-term earnings outlook. The dividend will be JPY19 per share, up JPY2 from the previous forecast of JPY17 per share, for an annual dividend of JPY36 per share.

The share buyback, which was announced in the Q2 financial results, was executed from November 8 to December 12, and a resolution was passed today for the cancellation of the shares acquired, scheduled to be effective at the end of this month, on February 28. The Company repurchased a total of JPY37.1 billion of its own shares in the current fiscal year, and that's included in the JPY79.0 billion cumulative amount acquired over three years. The ratio to the number of the outstanding shares is 6% and 16%, respectively. That's all from me.



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

Let's go to page 10.

There has been much progress in the areas of myopia and ptosis, which we expect to drive growth in the medium to long term.

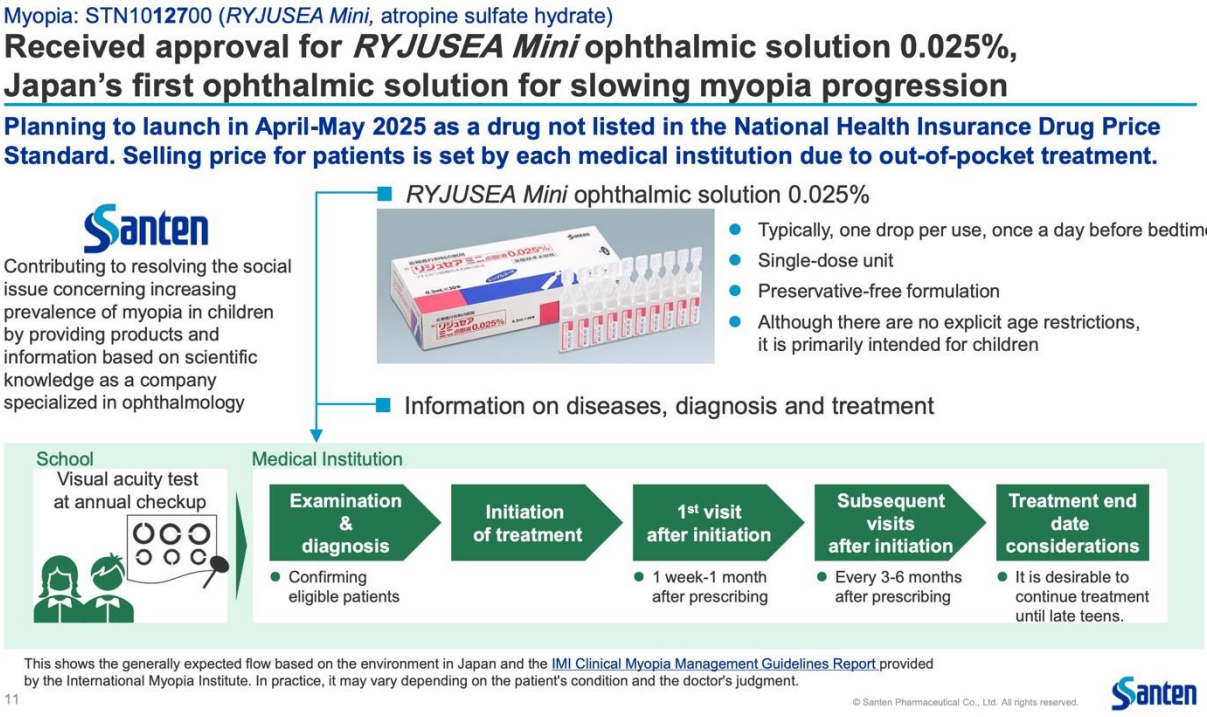
Santen obtained an approval of atropine, 127, for myopia in Japan in December. In response, we have started preparations for filing in Asia, aimed to take place next fiscal year. In addition, due to the ongoing development by Sydnexis in the US, we have not been able to inform you until now, but we have also filed in Europe in March 2024.

We filed for approval of oxymetazoline, 138 for ptosis in Japan in December. Following China, P3 was started in December in Europe as well. We expect to complete it in the next fiscal year.

In the existing area, there has been progress mainly in glaucoma.

We completed a long-term study of ROCK inhibitor, netarsudil mesylate, 139, in Japan. With this, we have all the data required for the filing, so we plan to file in the next fiscal year. We are also preparing P3 study for 140, a combination drug, and are planning to start this fiscal year.

In China, in a P3 study of epinastine hydrochloride administered twice daily, 11403, which is sold in Japan and South Korea as *Alesion LX*, the primary endpoints were achieved. We also started a P3 study of *Eybelis* as a new glaucoma product. It is scheduled to be completed in fiscal 2026.



Let's move to page 11 please.

From here, I will introduce about the individual pipeline.

As I mentioned earlier, in December in Japan, we received approval for *RYJUSEA Mini* as Japan's first ophthalmic solution for slowing myopia progression. We aim to launch between April to May as a drug not listed in the NHI drug price standard.

As myopia may progress even around the age of 18 years, the committee of the Ministry of Health, Labor and Welfare in Japan did not specify the restriction of the target age, and so while the package insert does not have an age restriction, it is basically for children. The product was developed as a single-use unit without preservatives in view of its safety because it is administered for a long period to children.

As an initiative that is unique to us, we will contribute to resolving the social issue of increasing myopia in children by providing not only products but also a wide range of information on disease, diagnostic, and treatment based on scientific knowledge.

Myopia: STN10127701 (atropine sulfate, SYD-101)

Filed in Europe in March 2024 with P3 data which met primary endpoint. Expecting to receive approval early in FY2025

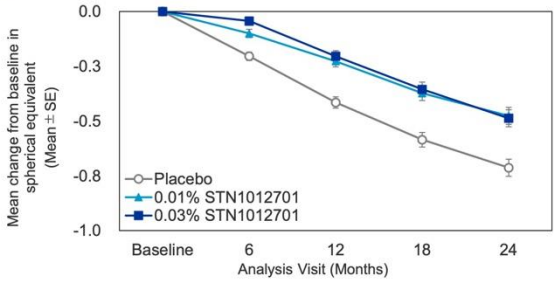
Confirmed statistically significant lower annual progression rate (primary endpoint) and change from baseline in spherical equivalent of 0.01% and 0.03% STN1012701 (SYD-101) compared to placebo at Month 24. Safety and tolerance confirmed for 0.01% and 0.03% STN1012701.

■ **Primary endpoint**

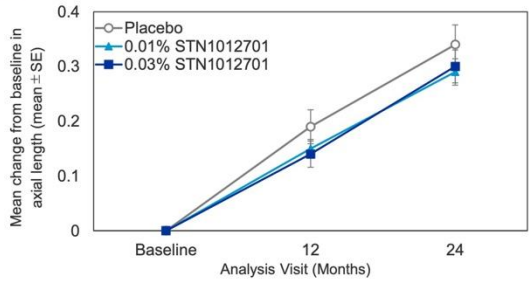
Annual progression rate of myopia at month 24 (diopter/year)

	Placebo	0.01% STN1012701	0.03% STN1012701
LS mean rate	-0.44	-0.31	-0.32
95% CI	-0.50, -0.38	-0.37, -0.25	-0.38, -0.26
P-value	NA	0.0003	0.0009

■ **Change from baseline in spherical equivalent (diopter)**



■ **Change from baseline in axial length (mm)** *<50% sites collected AL Data



- Showed numerically better effect of 0.01% and 0.03% STN10127701 compared to placebo on axial length change (not powered statistical significance).
- The most frequently reported treatment-emergent adverse event at 24 Months was photophobia (Placebo: 16.7%, 0.01% STN10127701: 24.1%, 0.03% STN10127701: 30.4%).
- This study (STAR study) was designed to continue for a total of 48 months and is estimated to be completed in the summer of 2025.

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Santen

Let's move to page 12 please.

Let me now take you through the filing data for atropine in Europe.

We filed our MAA in Europe, as planned, with 24-month data from the STAR Study clinical trial which Sydnexis is conducting as a multinational study in Europe and the US. This is the largest pediatric study for myopia and enrolled a broad range of patients between the ages of 3-14 years old.

In the Full Analysis Set, the primary endpoint of annual progression rate of spherical equivalent at 24 months was achieved for both the 0.01% and 0.03% concentrations with a statistically significant decrease in myopia progression compared with placebo. In addition, the change from baseline in spherical equivalent at 24 months for both the 0.01% and 0.03% concentrations showed statistically significant reductions in myopia progression when compared with placebo.

We also measured axial length in this study but due to the small number of clinical sites that were able to measure axial length, which was less than 50% of clinical sites, this secondary endpoint was not powered for efficacy. Pertaining to the right-hand graph, the axial length of the eye was also reduced compared to placebo with both concentrations tested.

We filed our MAA with EMA in March 2024 and we believe that CHMP opinion will be announced within this fiscal year.

These are exciting results for us to share with you today and we are looking forward to providing informative subgroup data at future congresses and similar events post approval.

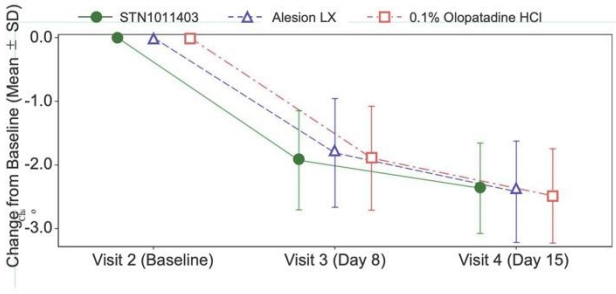
Allergic conjunctivitis: STN10**11**403 (epinastine hydrochloride, twice-daily eye drop)

Epinastine hydrochloride designed formulation for China, twice-daily eye drop, achieved primary endpoints on pivotal trial (P3)

Demonstrated non-inferiority of STN1011403 compared to *Alesion LX* and 0.1% olopatadine hydrochloride at Day 15 on both primary endpoints, ocular itching score and bulbar conjunctival hyperemia score change from baseline and confirmed safety and tolerance. STN1011403 for China market is a reformulated version of *Alesion LX*, a twice-daily eye drop sold in Japan and South Korea.

Ocular Itching Score

Change from baseline in the most severe ocular itching score within 24 hours



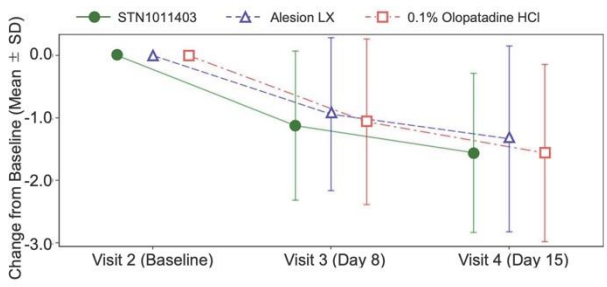
LS mean differences between groups at Day 15 (95% confidence interval)

	Alesion LX	0.1% Olopatadine HCl
STN10**11**403	0.05 (**-0.11, 0.21**)	0.05 (**-0.12, 0.21**)

Non-inferiority margin: **0.5**

Bulbar Conjunctival Hyperemia Score

Change from baseline in bulbar conjunctival hyperemia score



LS mean differences between groups at Day 15 (95% confidence interval)

	Alesion LX	0.1% Olopatadine HCl
STN10**11**403	-0.10 (**-0.24, 0.03**)	-0.03 (**-0.16, 0.10**)

Non-inferiority margin: **0.4**

Santen

Let's move to page 13 please.

This is the result of a pivotal trial of epinastine hydrochloride, 11403, administered twice daily, in China.

In order to meet local regulations, the 11403's formulation is slightly different from *Alesion LX*, which is sold in Japan/Korea and we therefore set *Alesion LX* group as the comparator. In all groups including olopatadine, which is an existing drug, the drug was administered twice a day.

On the change from baseline of ocular itching score and bulbar conjunctival hyperemia score at Day 15, 11403 was noninferior to *Alesion LX* and olopatadine and achieved the primary endpoint.

Based on this data, we plan to file in the next fiscal year.

This concludes my part. Thank you.

Question & Answer

Yamaguchi [Q]: This is Yamaguchi from Citi. Thank you. For the first question. You have updated the information on *Diquas LX*. I know it's difficult to talk about how the situation evolved between Q2 and Q3 results, and what else needs to happen inQ4, given the timeline it is not uniquely dependent on you, but I would appreciate it if you could explain a little more about the progress and what we should be looking for in terms of milestones in the future.

Koshiji [A]: I, Koshiji, will answer first. Peter can add something if necessary. First of all, as of Q2, I mentioned that as of November 7, we had identified the root cause. However, at that point, several countermeasures were being considered to prevent a recurrence, including reproducibility, as I mentioned earlier, and I explained that we were in the process of narrowing down those countermeasures. In Q3, after trying several approaches, we were able to identify a final approach that would work.

With this information, we are currently making the necessary preparations for consultations with the authorities, including the preparation of some data. Once those are in place, we will go up to the authorities for consultation. That is our situation.

At this point, however, there are some factors that are outside of our control, or that we cannot control. Based on several possible responses, we are currently trying to determine when we will be able to ship next fiscal year, and we are examining and estimating various things, such as next fiscal year's budget, etc., separately from the application to the authorities.

Yamaguchi [Q]: Thank you very much. Now, secondly, the European out-licensing is inserted in the European part, so the amount you mentioned before, I think it was JPY3.0 or 4.0 billion. I think it's a high-profit contribution because it’s out-licensing. Even including this, the gross margin for Q3 does not seem very high. You mentioned the mix in Q3, but is there any reason why the cost ratio does not seem very high even including this?

Koshiji [A]: In this regard, there are several factors that have caused a one-time increase in costs, such as the disposal of active pharmaceutical ingredient for a product. The other major factor is the deterioration of the product mix.

Yamaguchi [Q]: Thank you very much. Lastly, on atropine, since you said that it was also approved and filed overseas, not in Japan, does that mean that in the next fiscal year, both Japan and Europe will launch atropine in the market?

Koshiji [A]: Your understanding is right about that.

Sallstig [A]: I would like to add to Mr. Koshiji's explanation that the application is submitted in Europe this fiscal year and is scheduled to be launched next fiscal year.

Yamaguchi [Q]: Can you give us an idea of your peak annual sales in each region now?

Koshiji [A]: We are still evaluating this. As I mentioned last March, the peak figure on a consolidated basis is JPY60.0 billion, and we are currently calibrating the figures for each region, taking into account sales strategies and the advantage of this product.

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

Sakuma [M]: Thank you very much, Mr. Yamaguchi. Then, next is Mr. Hashiguchi of Daiwa Securities. Please go ahead.

Hashiguchi [Q]: I'm Hashiguchi. Thank you. First question, could you tell us about the situation of the *Alesion* eyelid cream? The season has started, but what is your view on the sales results so far? I would also like to ask for the contribution of the cream product and the amount of sales, if you are able to disclose it, as part of the results of *Alesion* for this Q3.

Koshiji [M]: The first question is the current status of *Alesion* cream, and the second is for Q3. Could you repeat the question again?

Hashiguchi [M]: It's about the contribution of creams to your company's sales.

Koshiji [A]: In that respect, as for *Alesion* cream, the pollen season has already started, but in terms of the results for Q3, the results of *Alesion* cream for Q2 and Q3 are not yet noticeable. In Q3, in that respect, *Alesion* cream is at the level of JPY1.9 billion on a YTD basis. Therefore, Q1 was JPY1.5 billion, but the total for Q2 and Q3 was roughly JPY0.4 billion, so if we look at Q3, QTD, we are at JPY0.24 billion. We are expecting this number to increase in the future.

Hashiguchi [Q]: Do you have any quantitative information on prescribing trends in the field that you can share with us?

Koshiji [A]: Regarding prescribing trends, we do not have any quantitative data on hand at this time that we can provide. Since pollen has not yet dispersed, although our first distribution to wholesalers amounted to JPY1.5 billion in Q1, we are yet to see a determining trend wherein doctors keep on prescribing eyedrops or promote the switch to the cream. I am sorry, but it is difficult for us to provide quantitative information at this time.

Hashiguchi [Q]: Thank you. The second question is about the factor you mentioned earlier that caused the disposal of APIs. Was it due to a change in the sales forecast for some product or was there some quality problem? If you don't mind, I would like to know what kind of product and how much impact it had.

Koshiji [A]: This is not an existing product, but a product that would be launched in the future. In that respect, there is absolutely no impact on our earnings forecast for the current fiscal year. However, in monetary terms, the loss of disposal is approximately hundreds of millions of yen range. Nevertheless this contributed to the rise in cost of goods sold.

Hashiguchi [Q]: Thank you. Lastly, in your explanation of the full-year forecast, you mention fluctuations in sub-Core items toward the end of the fiscal year as a factor in Q4. Is it correct to understand that you are just saying that Q4 is generally prone to such changes? Is it something that could be specific to this year that is being considered, or something that may occur irregularly, I am assuming impacting both positively or negative, that has made you mention this in the presentation?

Koshiji [A]: Both factors are in play. The first is part of the normal financial closing process, which includes an impairment test of intangible assets currently on the balance sheet. So, in that respect, the results of the impairment test in Q4 may be directly reflected in the P&L.

However, since we have already recorded various impairment losses until last year, even if such losses were to occur, they would no longer be large and would not affect profits in the billions of yen range. However, we cannot rule out the possibility that some of the early-stage assets could be subject to such evaluation. That is our situation. That's for the first factor.

The second factor is concerning Twenty Twenty Therapeutics, a joint venture with Verily, a subsidiary of Google (Santen post amendment: a subsidiary of Alphabet), which recorded a loss last fiscal year. We were supposed to undertake liquidation, but this has not been completed yet.

Originally, the liquidation was to be completed this fiscal year. In that respect, we liquidated last year with cash, so we had also factored in a liquidation dividend at that stage. If the remaining cash that funds the liquidation dividend decreases and cash burns, the resulting liquidation dividend may appear in the current period as a loss if it is less than originally planned. There are such uncertainties.

However, this too depends on whether or not the company in question will be dissolved, and this is also the case for the liquidation process for the Chinese joint venture company, for which, although we have decided on the direction of the liquidation, there is a possibility of losses occurring due to the evolution of procedures and negotiations with the other party as an external factor.

However, the impact of both of these items will not be in the billions of yen, but mostly in the hundreds of millions yen range, so the impact will be minor and will not have a significant impact on EPS; it's just that in theory we are aware that such things could occur. Apologies for my long explanation.

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

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

Ueda [Q]: This is Ueda from Goldman Sachs. First, I would like to ask about progress concerning costs vis a vis forecast. You mentioned earlier that there are temporary factors in the cost of sales, but even taking this into account, if sales proceed as planned, will the gross profit margin progress in line with the plan? Progress in SG&A and R&D expenses as well. In particular, it seems that progress in R&D expenses has been slow this fiscal year. Can you tell us what your outlook is for Q4?

Koshiji [A]: The cost to sales ratio has worsened through Q3 to 44%, a 3% deterioration from the previous year, but we have confirmed based on the sales plan that if Q4 goes according to plan, taking into account the pollen scattering and other factors, we should eventually land at 43%. As for uncertainties, I believe that the aforementioned disposal of APIs and other items that will have a negative impact on costs are currently anticipated and have already been accounted for.

And SG&A and R&D expenses. As for this, I think it is easy to understand if we take the R&D expenses as an example, so as for the rate of usage, it is 62% against JPY27.0 billion while we have already been through up to Q3 at the moment. In that regard, I am wondering if there is a possibility that this one could be slightly unfulfilled, JPY25.0 billion or some such level.

This was due to the progress of in-house cost optimization, and also to delays in the development of some LCM products due to the need to redesign formulations, etc. This is not fatal, but we recognize that there is a possibility, about JPY25.0 billion, that this area will go unachieved due to the combined effect of such factors.

The last part, SG&A expenses, are roughly JPY91.0 billion, as per our guidance. That's the kind of level we're looking for. Since we can control this item at our discretion, we believe we will be able to keep the ratio within 30% of net sales.

Ueda [Q]: Thank you very much. The second point is the overseas business, especially in China, where sales in this quarter seem to be a little weak, so I would like to know what the situation is like. In your explanation, you mentioned that the supply of products in China and the rest of Asia has had a slight negative impact, so I was wondering if you could tell us when you expect a recovery in this area and how you see sales recovering.

Koshiji [A]: As we have disclosed on page five and page six, sales in China were up 2.3%, but this was due to the yen weakening by around 6% compared to the previous year, so if we exclude the impact of foreign exchange, sales were down, with negative growth of 3.7%. The same situation applies to the contributed profit.

This is mainly due to two factors. One is the operation of the VBP. Since the VBP is being implemented much more strictly than we had expected, sales are concentrated in products that were not affected by the VBP, which is slightly different from our expectations.

Also, although the impact is not material, another is the anti-corruption movement. We have responded by changing our channels and distributing our products mainly through channels that would be less susceptible. However, there was also some negative impact felt in the out-of-pocket, private hospital channels. As a result, we are running at a shortfall of roughly a few percent, or a little over 5%, of our originally planned sales.

However, as shown on page 15 of today's materials, the final result, in yen terms, is JPY32.6 billion in sales and JPY12.3 billion in contribution profit. These sales may weaken slightly, but as for the contribution profit of JPY12.3 billion, it can be realized well. That is our estimation. Did that answer your question?

Ueda [Q]: How should we think about the issue of product supply?

Koshiji [A]: Although the product supply situation has been generally resolved, the sales of both Asia and China have been affected by approximately JPY3.0 billion (Santen post amendment: JPY1.7 billion) on sales basis by Q3 of this fiscal year. The impact is approximately JPY1.5 billion (Santen post amendment: JPY1.0 billion) in contribution profit basis.

In that respect, I believe that without it, we would have managed to achieve positive growth. However, the problem was generally resolved in Q3, and we expect to return to normal operations in Q4 and thereafter. Did that answer your question?

Ueda [Q]: Thank you very much. Finally, thirdly, I would like to know about your approach to increasing dividends. In your capital allocation policy, you explained that you are taking into account the medium- to long-term earnings outlook. While you haven't changed your plans, could you explain how your outlook has changed?

Koshiji [A]: There are two things. One is that at the end of last year, a drug for myopia, which Sallstig explained earlier, was approved in Japan. In addition, we have achieved data that enables us to differentiate and establish a competitive advantage in other new products, such as ptosis and other new products, and we are confident that we have overcome one hurdle in terms of future growth and profitability over a time horizon of three to five years. That is one perspective.

One more thing, you say that we did not revise the earnings forecast, but here, too, from a medium- to long-term perspective, *Diquas LX*, although it did not contribute to profits this fiscal year, will return at some point in the next fiscal year or later.

Considering this, we have not revised our forecast, but we believe that we can achieve a profit level of nearly JPY60.0 billion on a core basis even without *Diquas* this fiscal year, and if taking the return of *Diquas* into account, combined with the new products mentioned earlier, it will give us enough room to increase the dividend by JPY2.

Ueda [M]: I understand. Thank you. That’s all from me.

Sakuma [M]: Thank you very much, Mr. Ueda. Then, Mr. Wakao of JP Morgan Securities.

Wakao [Q]: I'm Wakao from JPMorgan. Thank you. Mr. Koshiji has mentioned JPY60.0 billion for core OP just now. Does that mean that with what you have now without new products and without *Diquas LX*, you can achieve JPY60.0 billion organically? Now, the core OP JPY60.0 billion came out of nowhere, so I wasn't sure. Please explain that part again.

Koshiji [A]: The figure of JPY60.0 billion is just an example, and it not a disclosed figure, but the current progress rate of core operating profit in Q3 is 79%. If we follow the trend, the core OP will probably reach JPY59.0 billion or even JPY60.0 billion; that's what we are expecting.

Wakao [Q]: That's the landing for this fiscal year.

Koshiji [A]: Yes. I am not talking about the next fiscal year.

Wakao [Q]: I understand. So, continuing with that, I would like to know the direction for the next term. You mentioned that you may be able to produce around JPY60.0 billion on a core basis this fiscal year, but when we look at the next fiscal year, there will be new growth drivers and other various factors, while there will also be the timing of the resumption of shipments of *Diquas LX* and the impact of generics, etc. At this point, what are your thoughts on the direction for the next fiscal year?

Koshiji [A]: We are in the process of discussing that, but there are some swing factors. However, in the larger picture, Japan is still likely to experience negative growth due to the relatively large downside, such as the penetration of generics. This will be recovered and offset in the medium term by new products, myopia and ptosis as mentioned earlier, but for the next fiscal year, it will not be there slightly, and Japan will see a decline in sales and profit. So we need to pare this decline with overseas sales. I think that is the situation.

The degree of the decrease in revenue and profit will depend on several swing factors and we are currently assessing these, after which we will disclose this in May as our earnings forecast for the next fiscal year. However, we are thinking of achieving at least a 10% ROE. We are currently examining what the figures should be like to achieve this goal.

Wakao [Q]: I understand. How should we think about the speed of market penetration of the product for myopia? I think it will be released in April or May, and the price will probably be around JPY3,500. Since there are no similar products, it is difficult to have a good idea on market penetration. Could you please tell us what your company is thinking now, to the extent possible?

Koshiji [A]: Let me say something first, and then Sallstig will add some. First of all, that JPY3,500 is not our official comment. This is currently under consideration. What we can say is that, although penetration will require a certain amount of time, we have been disclosing individual products with annual sales of more than JPY1.0 billion, and we think we can say with certainty that the myopia product will definitely be included.

As for profitability, we are still considering this, but for example, if you look at page 15, and you look at the contribution margin in Japan, you can deduce that this product will take a path that contributes to an improvement of the profitability. Did that answer your question?

Wakao [M]: Okay, thank you. I understand very well.

Sallstig [A]: I will add a few more. Since I presented the data from this ORANGE study at a conference last year, there has been quite a bit of interest from the academic community. In the past few months, we have been approaching doctors and preparing guidelines, and we have been talking to them about understanding the disease and the specifications of this drug. We are quite prepared in that sense and consider the situation good. We believe that the penetration will be quite advanced.

Wakao [M]: Thank you. I understand very well.

Sakuma [M]: Thank you very much, Mr. Wakao. Then next, Mr. Muraoka of Morgan Stanley MUFG Securities. Please go ahead.

Muraoka [Q]: Hello, this is Muraoka from Morgan Stanley. Thank you. I have a question based on Mr. Koshiji's earlier comment that the landing of core operating profit for this fiscal year is likely to be around JPY59.0 billion to JPY60.0 billion, exceeding JPY55.0 billion.

I believe the AG of *Alesion LX* and the generic from other company should have been released since this past January. I think it was January 20. I am nervous because the unit price is half of this, but I wonder if it is too much to worry about a sharp drop in profits after switching to this AG and if, in fact, it is totally safe.

Koshiji [A]: Koshiji will answer. In this respect, once the generic version of *Alesion* is released, we will also ship the authorized generic version of *Alesion LX*. Your understanding is right that this would automatically reduce the sales and selling price by half.

Generally, the price is half, and this will mean a reduction in the sales with a certain degree. We have factored in this discounted portion in our forecast, and I would like you to think that the JPY30.4 billion for the full year reflects the amount discounted for the authorized generics. Did that answer your question?

Muraoka [Q]: Thank you. AG has already launched, I think it was January 20 for both your company's and the generic company's. Is it right to understand that it is already in the market?

Koshiji [A]: You are correct. The products are already on sale in January.

Muraoka [Q]: That will not be a problem this season, but next season. When I hear about the slightly unsettling figures for the cream you mentioned earlier, I am a little concerned about the LX for eye drops, given the unit price is still down even if the volumes may increase. Is it correct to think that there is not much need to consider this as a negative factor for the next fiscal year, given the current state of your company's performance?

Koshiji [A]: Yes. Not there at all. As for the next fiscal year, and before talking about next fiscal year, you mention that you are concerned about the figures for this fiscal year, but since the pollen has not yet started until Q3, we think that sales of *Alesion* cream will increase from now on, so we think that we are still on track with our plans.

As for the next term, I think that there will be more pollen flying around again, and that the awareness of doctors and patients of the cream will be even greater next fiscal year, so in that respect, I think it is difficult to imagine that the situation will continue where the authorized generic is still over-weighted and the cream does not grow in the next term. In conclusion, I hope you will consider that we have a bullish view of the next fiscal year without concern that much.

Muraoka [Q]: Thank you. One more thing, about the pipeline 134. It's the next generation of myopia drugs, AFDX. This is in the phase IIa in Japan, the last patient out, and I think we will hear how this phase IIa is in the upcoming May Q4 earning release.

So, just to confirm in advance, can you tell us if we can hear that this is an improvement in safety, rather than efficacy, like glare-free, or something like that? Can we expect better points besides that? Please let me know as preparation.

Sallstig [A]: That is correct, and we plan to explain the data at the time of the earnings announcement in May. We are in the process of looking at all the data available for us, so I will refrain from further explanation as of today.

Muraoka [M]: Thank you, that's all.

Sakuma [M]: As the end time is approaching, the last one is Mr. Sakai from UBS Securities. Please go ahead.

Sakai [Q]: This is Sakai from UBS. Let me ask you two questions. One is share buybacks. Mr. Koshiji, you indicated JPY37.1 billion in your figures this time, but this is JPY37.1 billion out of a total of JPY72.5 billion, which means that only half of the total has been purchased. So, out of the final JPY30.0 billion, JPY10.0 billion was left over, and you were unable to buy most of the remaining amount.

This is what President Ito and then Mr. Koshiji have always said that Santen Pharmaceutical's corporate value is not fully appreciated. You do not directly mention stock prices. If so, would you be a little more aggressive about this share buyback? I know that once a brokerage firm places an order for a share buyback, the result depends largely on the skill of their traders. If you are not more flexible about that point, there is a high possibility that simply saying that you will buy back the Company's own shares will end up as an empty gesture. Please tell us about this point first.

Koshiji [A]: I'm afraid my explanations were inadequate. For JPY37.1 billion, it is the amount of share buybacks conducted twice this fiscal year. And for JPY73.0 billion (Santen post amendment: JPY79.0 billion), this is the amount of share buybacks done in the three-year period, FY2022 through FY2024. Therefore, it does not mean that only half of the shares have been purchased, but the total amount of share buybacks for the period from FY2022 to FY2024 was JPY73.1 billion (Santen post amendment: JPY79.0 billion). The ratio is 16% of outstanding shares., that should have been my explanation. Therefore, it does not mean that we are only buying half. Just the purchase rate in H1.

Sakai [Q]: Rather than whether you are buying or not, if your company's approach to enterprise value has not changed, I think you should either be a little more proactive or more flexible. What do you think about that?

Koshiji [A]: In this regard, we have not changed our stance in executing share buybacks as a function of our share price and cash position, as part of our considerations to maintain our share price level.

Sakai [Q]: If you are going to buy back your shares, buy more aggressively, although it may not be appropriate to say that you should do so with some level of impact , I think you should do so taking impact into consideration. And one last question. The myopia medication that has been discussed earlier is sold as out-of-the pocket, or out-of-the pocket medical treatment, but I would like to know what the advantages of selling it as out-of-pocket treatment are, and if there is anything that we do not understand well, such as the difficulties involved, please tell us. If there is nothing special to consider, or it's not different from a regular NHI listed product, then please say so.

Sallstig [A]: We have decided from the beginning that we will sell it at out-of-pocket treatment, and we do not anticipate any opposition to the decision. At this point, we believe this will work.

Sakai [Q]: I understand. So there is no particular order from the regulatory. For proceeding it with out-of-pocket treatment.

Sallstig [A]: That's correct.

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

Sakuma [M]: Thank you very much. With that, I would like to conclude today's briefing. Thank you very much.

[END]