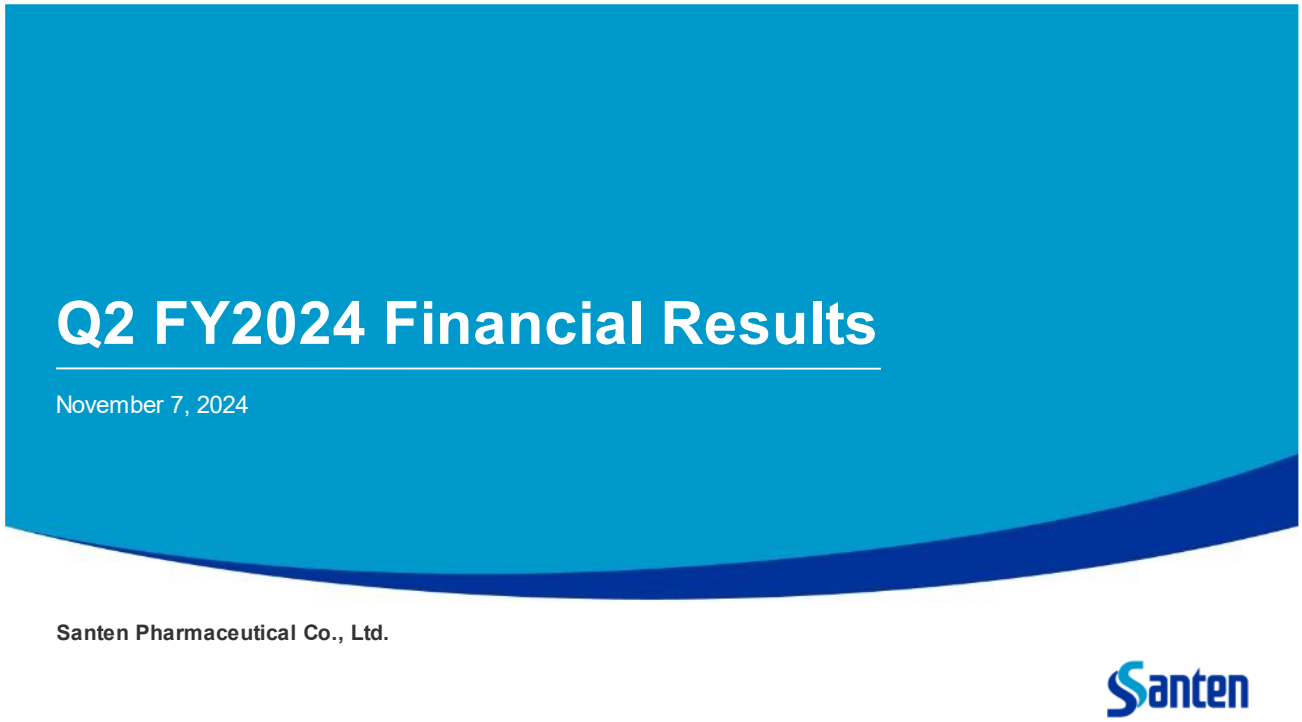
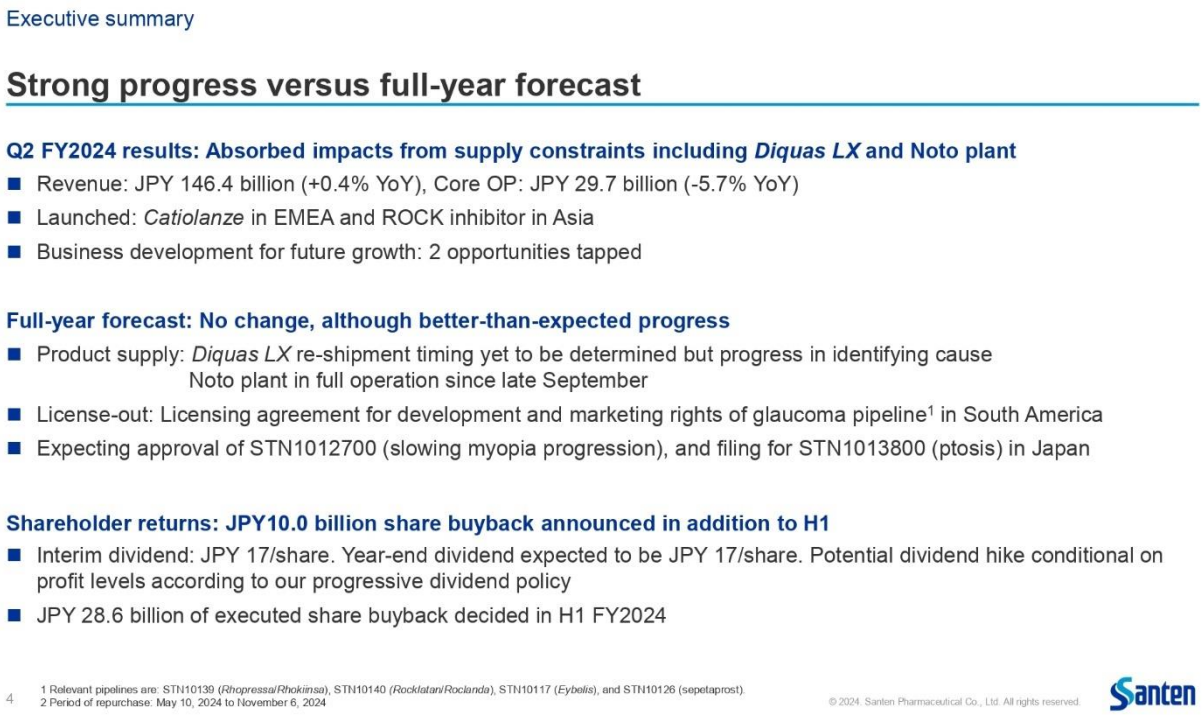
Q2 FY2024 Financial Transcript



Ito: My name is Ito, CEO of Santen Pharmaceutical. Thank you for joining us today for our financial results briefing for Q2 of FY2024.

First, I would like to explain the financial summary.



See page four.

In H1, there were delays in the restoration of the unit dose production line. This was due to the effects of the earthquake. There was also the suspension of shipments of *Diquas LX.* The factors including these two prevented the delivery of some products to medical facilities. Even with these headwinds, which we have worked to address, several factors contributed to a YoY increase in revenue to JPY146.4 billion. These factors include sales growth in the *Eylea* and *Alesion* families, which saw new product launches in the spring, and contributions from overseas businesses, including foreign exchange gains. Core operating profit was JPY29.7 billion, showing a YoY increase and good progress toward the full-year forecast for the current fiscal year, excluding one-time factors related to *Ikervis* last year.

With regard to activities for future growth, we launched *Catiolanze*, a glaucoma drug with data showing improvement in ocular surface disease, in the EMEA region. We are also making steady progress in the regional expansion of our existing pipeline, including the launch in Asia of a ROCK inhibitor. This is being expanded regionally in EMEA as a product that offers a new treatment option.

In addition, as we have reported in the past, business development is essential for future growth, and we are giving priority to this investment. Following the license-in of the pterygium treatment announced in August, we have obtained marketing rights in China for a development candidate for the treatment of macular edema associated with uveitis. We anticipate this project will contribute to our regional business in the short term. We will continue to examine ways to develop projects that contribute to local businesses.

We have conservatively estimated the full-year forecast based on variable factors in H2, and have not changed it from the forecast we announced in August. This means that our forecast revenue is JPY302.0 billion and forecast core operating profit is JPY55.0 billion. We are striving to exceed the profit plan we announced to you.

The co-pay hikes for long-listed products started in October is one of the factors causing fluctuations in H2. We see the effects of this as being within the expected range, and will continue to closely monitor the impact of this.

With respect to *Diquas LX*, the main cause of the decrease in silver content that occurred in some lots has almost certainly been identified. Several options exist for resolution, and we are in the process of moving forward with these. We have not yet reached the stage where we can say when shipments will resume, but we will continue to make every effort to resume shipments in the next fiscal year.

The Noto Plant was fully restored at the end of September. In the Q1 earnings announcement in August, we mentioned that we are taking into account inorganic upside factors that are expected to be substantial in the current fiscal year in our full-year forecast. In October, we concluded an agreement with Alcon to out-license the development and marketing rights for our glaucoma pipelines in South America.

One of the important issues is how to deliver our products to patients in regions where Santen does not operate, including North America. We will continue to consider the best way to commercialize the product, while assessing its potential.

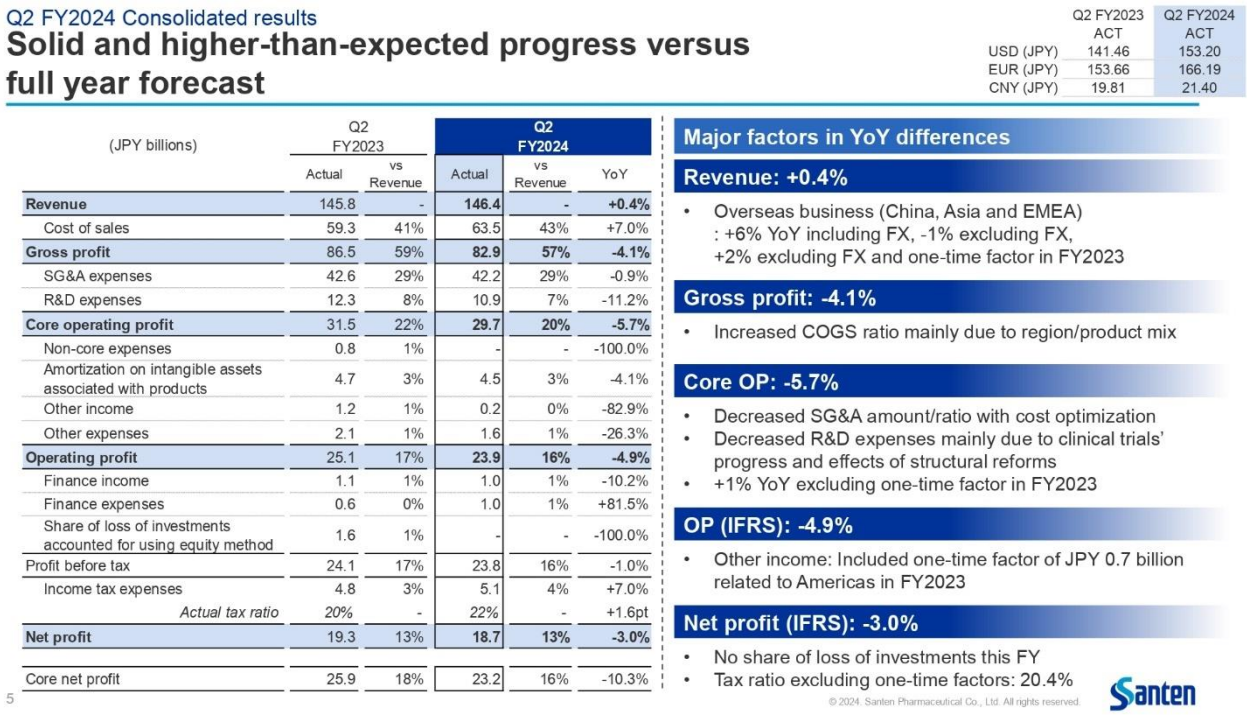
As for R&D, we expect to receive approval in Japan of 127, an inhibitor of myopia progression, and file for 138, a blepharoptosis in Japan in H2. We will also steadily pursue initiatives for future growth.

We continue to regard shareholder returns as an important management priority. In light of the current stock price level and our current cash position, we have resolved in H2 to repurchase up to JPY10.0 billion, equivalent to 1.4% of outstanding shares. This will start tomorrow and end on March 21 next year. As for dividends, we expect to pay a year-end dividend of JPY17, the same as the interim dividend of JPY17. We will also consider increasing dividends in accordance with the profit level based on our progressive dividend policy.

As I mentioned earlier, there will be certain variable factors in H2. However, as before, we will aim to exceed the disclosed forecast for the full year, even if only by a small margin.

We are currently in the process of formulating a new mid-term management plan, and we will make another announcement when the timing and other details are finalized.

That is all from me.



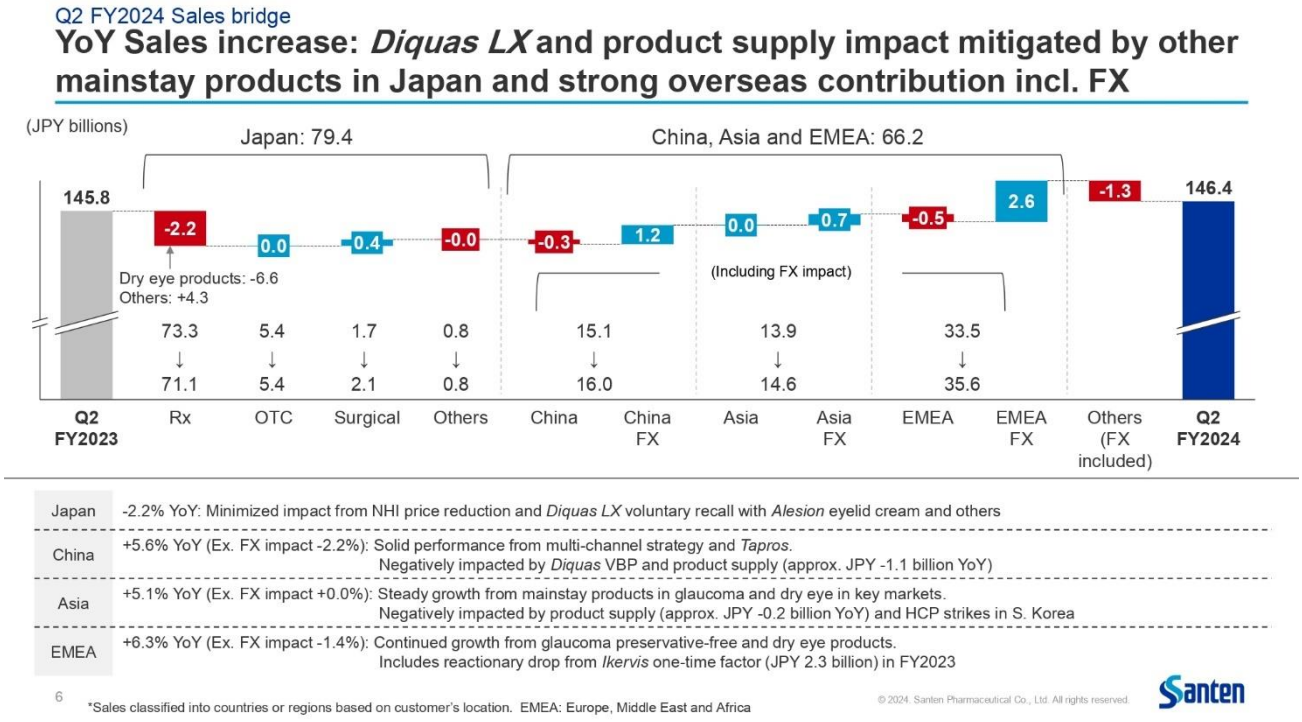
Koshiji: Koshiji here. Let's start on page five.

In H1 of FY2024, revenue increased 0.4% YoY to JPY146.4 billion, with the impact of *Diquas LX* offset by other products in Japan and overseas business, including foreign exchange gains.

Cost of sales, SG&A, and R&D expenses are generally as planned, although both absolute amounts and ratios have changed from the previous year. As a result, core operating profit decreased by 5.7% YoY to JPY29.7 billion. However, taking into account the one-time factors from the previous fiscal year and other factors, we recognize that, in real terms, both revenue and profit increased.

Under Core, operating profit on an IFRS basis declined 4.9% to JPY23.9 billion. This was due in part to the absence of one-time gains such as the transfer of business in the Americas in the previous fiscal year.

Overall, although the profits trend was lower than the previous year, the impact of the recall and suspension of shipments of *Diquas LX* was recovered in other areas in Japan and overseas. At present, we are on track to exceed the Company's full-year forecasts.



Japan	-2.2% YoY: Minimized impact from NHI price reduction and *Diquas LX* voluntary recall with *Alesion* eyelid cream and others
China	+5.6% YoY (Ex. FX impact -2.2%): Solid performance from multi-channel strategy and *Tapros*. Negatively impacted by *Diquas* VBP and product supply (approx. JPY -1.1 billion YoY)
Asia	+5.1% YoY (Ex. FX impact +0.0%): Steady growth from mainstay products in glaucoma and dry eye in key markets. Negatively impacted by product supply (approx. JPY -0.2 billion YoY) and HCP strikes in S. Korea
EMEA	+6.3% YoY (Ex. FX impact -1.4%): Continued growth from glaucoma preservative-free and dry eye products. Includes reactionary drop from *Ikervis* one-time factor (JPY 2.3 billion) in FY2023

*Sales classified into countries or regions based on customer's location. EMEA: Europe, Middle East and Africa
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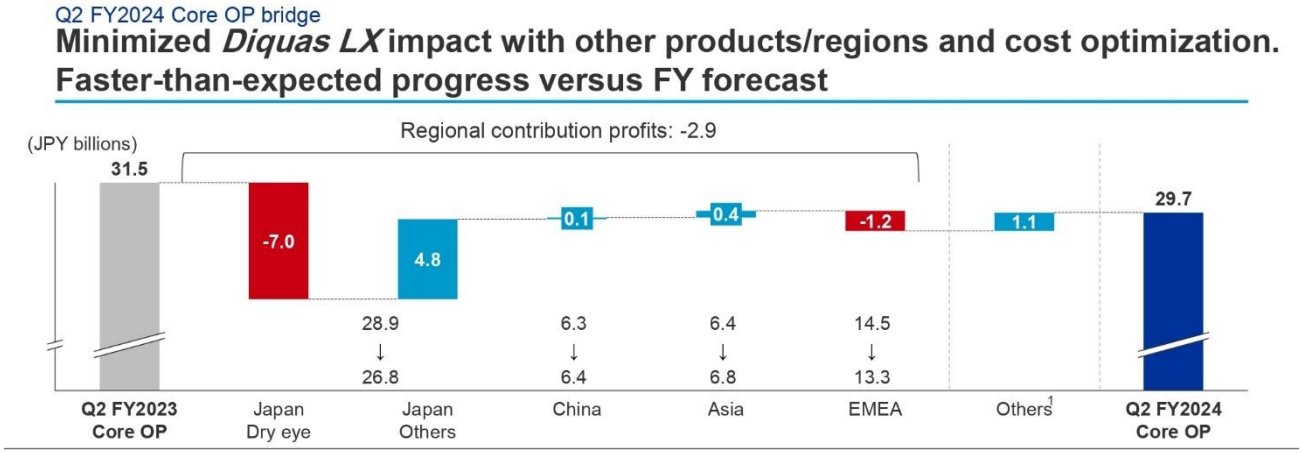
From page six, we will look at factors underlying changes in revenue.

The JPY146.4 billion is broken down into JPY79.4 billion in Japan and JPY66.2 billion overseas, in China, Asia, and EMEA. These three regions account for 45% of the total.



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 China: Increased profit despite impact from *Diquas* VBP and product supply Asia: Increased profit despite product supply and other factors EMEA: Mainly due to reactionary drop from *Ikervis* one-time factor in FY2023. Ex one-time factor, solid progress with increased profit.
Others	Completion of structural reforms including streamlining in Americas pharmaceutical commercial business and promotion of cost optimization

1 R&D and back-office expenses in region and global functions, and contribution profit not related to the regions above
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Page seven. This shows factors underlying changes in core operating profit.

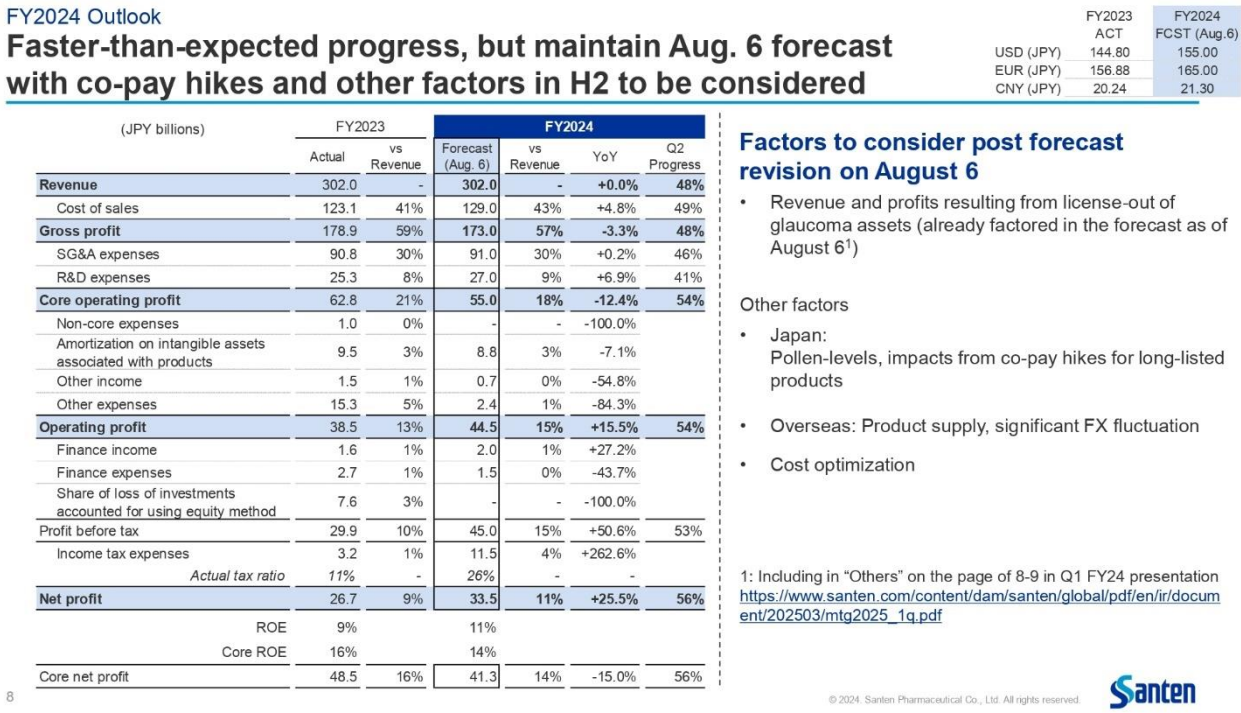
On a contribution profit basis for each regional business, the segment saw a decrease of JPY2.9 billion. In Japan, sales decreased by JPY2.2 billion for the region as a whole, including a JPY7.0 billion YoY decrease in

the dry eye field. The sales decrease in the dry eye field, which was shown on the previous page as JPY6.6 billion, appears large at JPY7.0 billion compared to the JPY6.6 billion shown on the previous page, but this is due to factors such as the recall costs of *Diquas LX*, and product mix changes. The impact of the significant reduction in the drug price of *Diquas* due to the return of the Price Maintenance Premium was also a factor.

On the other hand, products in other areas are performing well. The decrease in SG&A expenses and other factors have minimized the impact of *Diquas LX* on the Japanese business as a whole.

In China and other Asian countries, despite the impact of product supply and other factors, profit growth was secured. In EMEA, excluding the rebound from the one-time factor of *Ikervis* in the previous fiscal year, the trend of profit growth is continuing.

In addition, factors outside the regional level, such as the completion of structural reforms, including streamlining in the Americas, and Company-wide cost optimization, also contributed to earnings.



FY2024 Outlook

Faster-than-expected progress, but maintain Aug. 6 forecast with co-pay hikes and other factors in H2 to be considered

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

(JPY billions)	FY2023		FY2024			
	Actual	vs Revenue	Forecast (Aug. 6)	vs Revenue	YoY	Q2 Progress
Revenue	302.0	-	**302.0**	-	**+0.0%**	**48%**
Cost of sales	123.1	41%	129.0	43%	+4.8%	49%
Gross profit	178.9	59%	**173.0**	**57%**	**-3.3%**	**48%**
SG&A expenses	90.8	30%	91.0	30%	+0.2%	46%
R&D expenses	25.3	8%	27.0	9%	+6.9%	41%
Core operating profit	62.8	21%	**55.0**	**18%**	**-12.4%**	**54%**
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%**	**54%**
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%	53%
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%**	**56%**
ROE	9%		11%			
Core ROE	16%		14%			
Core net profit	48.5	16%	41.3	14%	-15.0%	56%

Factors to consider post forecast revision on August 6

- Revenue and profits resulting from license-out of glaucoma assets (already factored in the forecast as of August 6[1])

Other factors

- Japan:
  Pollen-levels, impacts from co-pay hikes for long-listed products
- Overseas: Product supply, significant FX fluctuation
- Cost optimization

1: Including in "Others" on the page of 8-9 in Q1 FY24 presentation https://www.santen.com/content/dam/santen/global/pdf/en/ir/document/202503/mtg2025_1q.pdf

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Next is page eight.

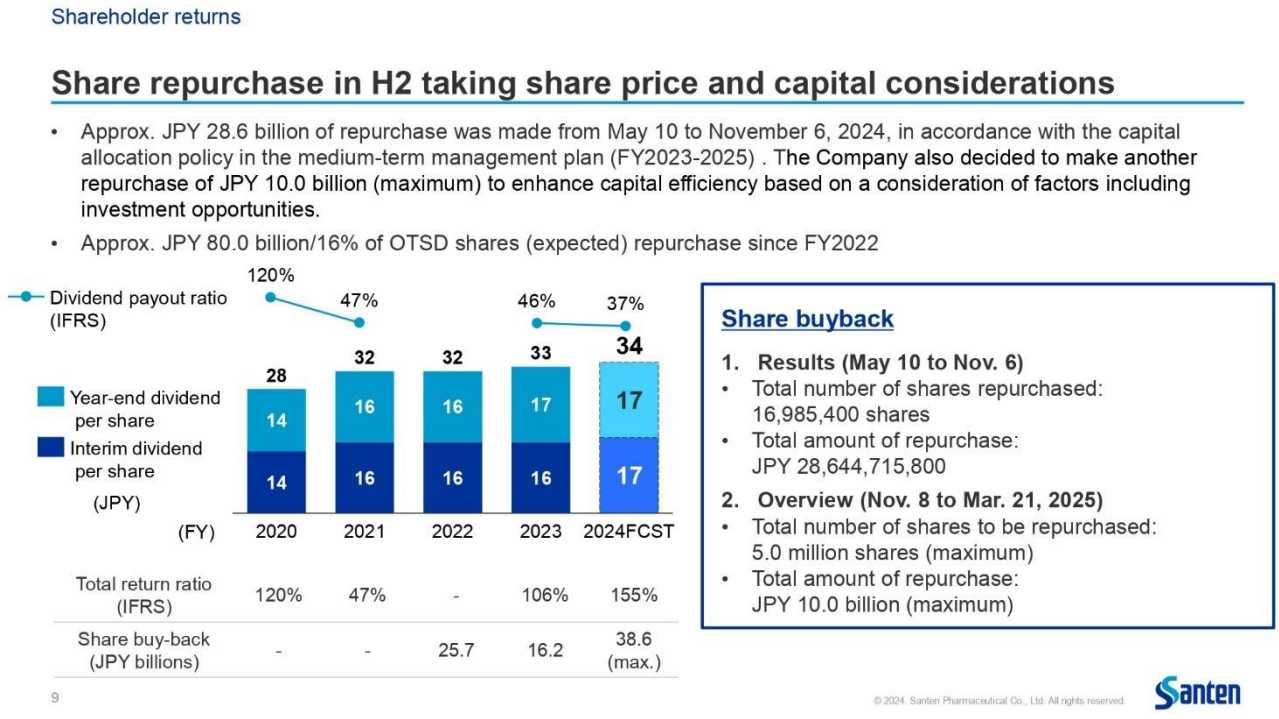
There is no change in the forecast for the full year from that disclosed in the Q1 financial results on August 6.

Immediately after the disclosure at 3:00 PM today, a Bloomberg news report reported that the full-year forecast had been revised downward, but this is not true. There is no change in the earnings forecast. Revenues are projected at JPY302.0 billion and core operating profit at JPY55.0 billion.

The revenue contribution element, which was explained as upside potential including inorganic factors in the Q1 results presentation, has now been licensed out for glaucoma assets, as explained by the CEO at the beginning of the presentation.

From the H1 results, the Company's overall performance seems to be on track to exceed the full-year forecast. On the other hand, as the CEO explained earlier, there are some uncertainties in H2. At this point,

we are still maintaining the momentum of H1, but it will take some time to determine the specific amount of overachievement, Therefore, we have decided to leave our previous forecast unchanged as of the current quarter.

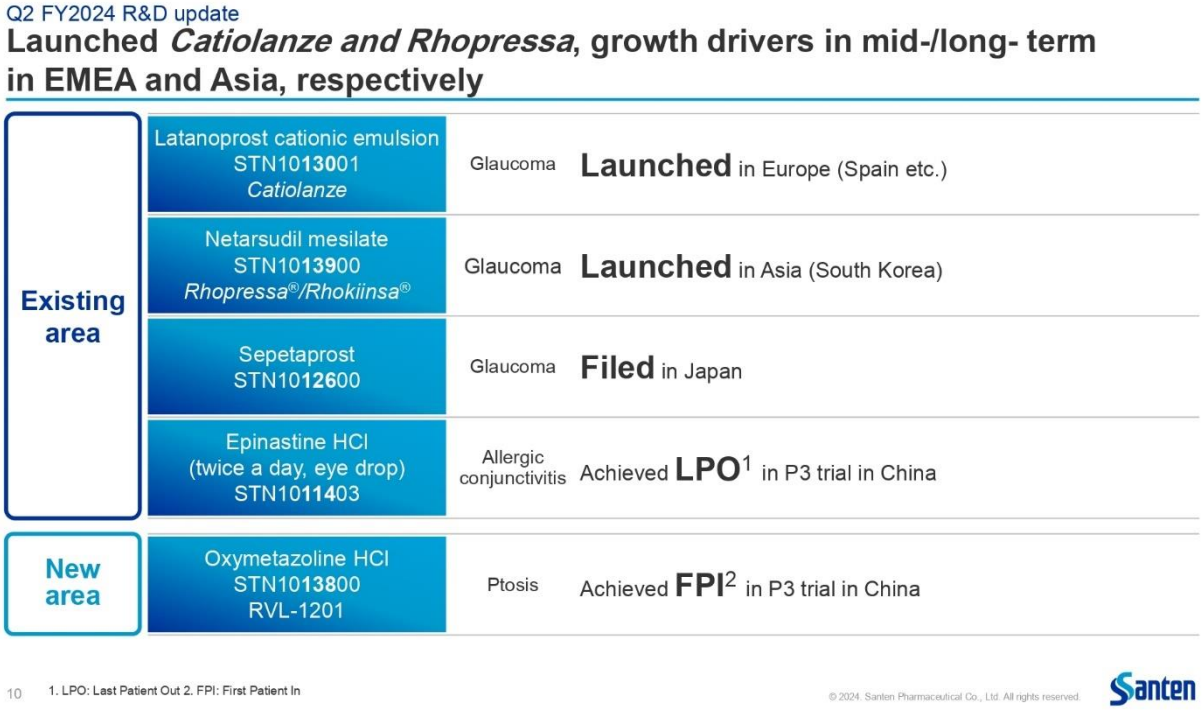


Next, page nine. Shareholder returns.

The Company has been repurchasing its own shares based on its medium-term capital allocation, with a deadline of yesterday. In light of the current share price level and the size of the capital needs associated with investment opportunities, we plan to repurchase up to 5.00 million shares or JPY10.0 billion of our own stock starting tomorrow, and will continue to do so until March 21.

Regarding dividends, the Company today resolved to pay an interim dividend of JPY17 per share. Combined with the end of the fiscal year, we forecast JPY34 per share for the year.

That is 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.

In one of our main historical areas, Glaucoma, we have seen good progress. We launched *Catiolanze* for glaucoma treatment in Europe with data to support use in glaucoma patients with ocular surface diseases. We plan to file in Asia this fiscal year.

Rhopressa, a ROCK inhibitor that we have marketed since 2023 in Europe, was launched in South Korea most recently. In the future, it will be marketed in other Asian countries, including combination drugs.

In Japan, we filed for sepetaprost, a dual-agonist of FP and EP3 receptors.

In other areas, in China, P3 study of epinastine hydrochloride with a twice-a-day posology, which is marketed as *Alesion LX*, has achieved LPO ahead of schedule. In addition, the P3 study of 138 for ptosis was initiated.

Uveitic macular edema (UME): ARVN001

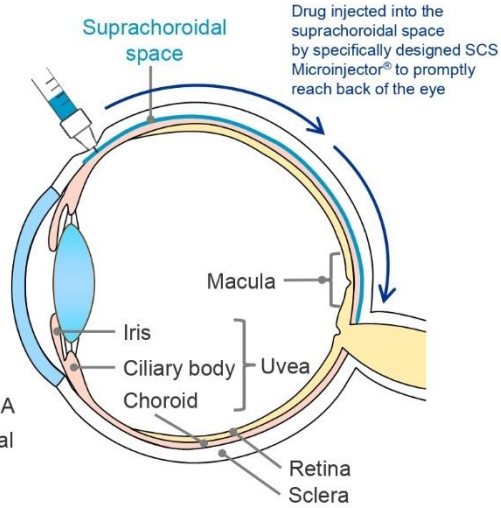
Obtained exclusive commercialization right of ARVN001 in China. Arctic Vision is developing it to be the first drug indicated for UME in China

Uveitic macular edema (UME)

- Uveitis is an intraocular inflammation that occurs in the uvea, and often chronic and relapsing. It can cause vision loss and blindness.
- UME is a type of uveitis characterized by the development of edema in the macula, which is the central part of the retina and critical for vision.
- Approximately 490,000 patients with UME in China.[1]
- Currently, approved drugs with other indications are used for UME treatment as off-label in China.

ARVN001

- Triamcinolone acetonide injectable suspension for suprachoroidal space (SCS®)
- Launched under the name of *XIPERE*® in US following approval by FDA
- Arctic Vision announced ARVN001 achieved primary endpoint in P3 trial for UME in China and plans to file NDA in FY2024



1 Santen estimated.
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Santen

Let's move to page 11 please.

Now let me explain to you about the recently in-licensed asset for treatment of uveitic macular edema, UME, which we just announced today at the same time as our earnings.

As shown in the right picture, the uvea is the tissue in the eye composed of the iris, ciliary body, and choroid. Uveitis is a disease in which inflammation occurs. It is often chronic and relapsing and can cause vision loss and blindness. It is also one of the main causes of visual impairment among the working-age population.

UME is a type of uveitis with oedema in the macula, which has a primordial function for vision. The number of patients in China is estimated to be approximately 490,000, which, although seems less than the glaucoma patient population, does not fairly represent the importance of this disease as there are no approved drugs with UME indication in China. ARVN001 will be the first drug indicated for unmet needs for UME.

ARVN001 consists of triamcinolone acetonide injected into suprachoroidal space between the choroid and the sclera by a specifically designed injector to reach the macula at the posterior segment of the eye. It is already marketed in the U.S. as *XIPERE*. In China, P3 study met primary endpoint and Arctic Vision, Santen's licensor, plans to file within this fiscal year.

This concludes my part. Thank you.

Question & Answer

Muraoka [Q]: Hello. Morgan Stanley, Muraoka. Thank you very much.

Regarding the issue of silver nitrate concentration in *Diquas LX*, now that you are coming to understand the issue better, is it safe to assume that after April, things will return to normal? I hope that my wording is not interpreted as being confrontational. It would be helpful if you give us a little more detail about the situation there.

Also, there was a little note in the pipeline section that you had obtained approval for *Diquas LX* in South Korea, but withdrew it, and I was wondering if this issue in Japan affected that decision, or if it is completely separate.

Sakuma [M]: Thank you for your question. Mr. Ito will take this question.

Ito [A]: Yes, I mentioned that we have found the cause of the problem related to the decrease in the concentration of silver-containing preservatives in *Diquas LX*.

As I mentioned in my opening explanation, we would like to refrain from talking specifically about a timeline at present. There are methods to prevent silver from deteriorating, such as storing it in a cool place, or changing the formulation. Unfortunately, if we take that approach, it would take a year or two.

We have been working to determine the cause of the problem in order to find a way to prevent it from happening, and we are almost certain we have identified the cause. There are approaches we can take to address that issue. We are in the process of confirming the outcome when we take these necessary steps.

As we do not yet know that outcome, it is too early to comment specifically. However, as we have identified the problem, I am not pessimistic about returning this product to the market in FY2025.

Muraoka [Q]: Okay. Are you able to comment on when it will be in the fiscal year?

Ito [A]: I don't think we are at that stage, but one thing we have to do is to solve the technical issues and then consult with the authorities. If we can solve the technical issues in the direction we thought, it is likely to be surprisingly fast. However, with ongoing discussions with the authorities, I think at this point it is difficult for me to comment too much on the timeframe.

Muraoka [Q]: Thank you very much. Also, could you comment on the application in South Korea?

Sakuma [M]: Indeed. I will pass this question to Peter Sallstig.

Sallstig [A]: Simply put, yes, it is related with this issue in Japan. Just as we were preparing for the launch of *Diquas LX* in South Korea, this Japanese issue came up. We discussed it with the authorities at that time, and they said that before the launch, before the market launch, we had to resolve this issue of silver content. In order to continue to deliver the original *Diquas* to Korean patients, it was necessary to withdraw the *LX* application, so we have taken that action. Thank you.

Muraoka [Q]: Thank you very much. Second question. Regarding *Alesion*, please let me know what is happening with the cream in Japan. Also, has anything changed with an *LX* generic?

Sakuma [M]: Thank you for your question. Mr. Ito will take this.

Ito [A]: Well, as mentioned at the beginning of this presentation, the fact that the shipment of *Alesion* cream was much higher than initially expected was one of the factors that covered the decrease in sales and profit due to the shipment halt of *Diquas LX*.

As for actual use, a great number of facilities adopted this product speedily at the very first stage. Medical institutions are now using it with their patients for them to see how well it works.

However, since the product was launched in May, and the sales since then are in the off-season for allergies, the actual shipments and sales trend of the product is not significantly large. However, we would like to prepare for next year's pollen season by making efforts to have medical professionals understand the value of these products by the beginning of the new year, after which the pollen season will be in full swing.

Regarding *LX*, I think you are talking about generic *Alesion LX* here, but our current assumption for the full year is that the generic product will be listed and launched when the NHI price is listed in November (Santen post amendment: December).

In contrast, our current outlook is based on the assumption that we have a decent supply of authorized generic products and that we will respond appropriately. In terms of the impact on that, I would say that there was no approval of a new generic product in August or September, although we had factored in the possibility of new generics being approved to some extent.

So, even if generics come out next year, the situation is that it will be limited to one. This is the situation for the time being.

That is all.

Muraoka [Q]: Thank you very much. Another question about *Alesion LX*: I don't think your company has been active in the allergy field in China. If this can be approved and launched, how much potential do you see there?

Is there a possibility that we will hear about such top products in your company becoming top products in China? Or should we consider that there are many other competitors already and it's not practical? Can you talk about this in terms of commercial potential?

Sakuma [M]: Thank you. Mr. Ito will answer this question as well.

Ito [A]: It's a little difficult to comment on a specific numerical outlook.

In China, a product called olopatadine, which is also available in Japan, is already on the market, I believe. Our product would compete against it. In China, olopatadine has the same twice daily administration as *Alesion LX*, so I don't think the degree of differentiation of *Alesion LX* is as great as it is in Japan. So basically, we do not anticipate that this will become a top product in China.

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

Sakuma [M]: Thank you very much, Mr. Muraoka. Next, Mr. Yamaguchi of Citigroup Securities.

Yamaguchi [Q]: Thank you. I am Yamaguchi from Citi.

The first question is about the results for H1. Although the Company forecast is not disclosed, I think you said that this JPY29.7 billion figure exceeded your company's expectations. I would like to know by how much the sales and expenses exceeded your expectations.

Sakuma [M]: Thank you. I will pass this question to Mr. Koshiji.

Koshiji [A]: The H1 results suggest that core operating profit for the full year will be JPY55.0 billion, and the progress rate for H1 and H2 is usually approximately 1:1 in our case, the figure is simply higher than JPY27.5 billion.

In this respect, sales and profits exceeded the budget, especially on a profit basis. The main drivers of this are cost containment, and gross profit was roughly in line with expectations.

Yamaguchi [Q]: Thank you. Also, in H2, about BD, I think it was written JPY2.5 billion to JPY3.5 billion in Q1 presentation, and it was actually done in October and will be recorded in Q3. In H2, I think you expected severe negative impact of co-pay hikes for long-listed products in the individual product category, but it sounds like there is room for improvement considering such factors.

My question is about co-pay hikes for long-listed products. I think you were baking in a harsh impact on sales. I wonder how it is in response to what we were seeing. Is it less, or not?

Sakuma [M]: Mr. Koshiji will also take this question.

Koshiji [A]: We had expected about JPY2.0 billion for the full year in terms of the impact of the co-pay hikes for long-listed products. The program started in October and while we have observed an impact, I am aware at this point that the JPY2.0 billion figure was a bit conservative. So that's the potential upside we're seeing.

There were other upside including business development projects, one-time revenues from out-licensing. And we have revised our full-year forecasts for individual products, respectively. In this context, we are aware that high-profit products such as *Alesion*, which we have also revised upward, will be a driver for profits in H2.

Yamaguchi [Q]: Thank you. Lastly, I would like to ask you about the ARVN001, which seems to have been licensed-in from a company called Clearside. I understand the plan is for sale in China, but I would like to ask you if there is any possibility of such a launch in other regions, including Japan, for example.

This time, the license-in is from Arctic Vision, but originally it seems to be related to a company called Clearside. As for your company, this is being licensed-in from Arctic, so this time it is only for China. Is the intention to stick to that country for this product?

Sakuma [M]: Thank you for your question. Peter Sallstig will take this question.

Sallstig [A]: That's right, I guess you could call it a three-way partnership. The agreement is between Arctic Vision, Clearside and Santen, and this license is only for China.

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

Sakuma [M]: Thank you very much, Mr. Yamaguchi.

Next, Mr. Sakai of UBS Securities.

Sakai [Q]: Sakai, UBS. First of all, I would like to ask Mr. Koshiji a question. You have always said that Santen's share price is undervalued, and this time the share buyback is a little smaller. You said that JPY10.0 billion will be allocated, but what is the reason for limiting the amount to JPY10.0 billion this time?

The previous share buyback, on the other hand, had a ceiling of JPY38.0 billion, of which only JPY28.0 billion was purchased, I believe. If I think about it simply, JPY10.0 billion is this difference. So, I wonder if you could comment on the logic in this increase in corporate value. Could you please explain a little about this?

Koshiji [A]: Well, first of all, the actual purchase amount in H1 was JPY28.6 billion, or 4.7%, against a figure of JPY38.0 billion, or 5.8%.

Out of the share purchase about to be executed, the leftover amount from the previous buyback is JPY9.4 billion. The amount of the share buyback this time is JPY10.0 billion, which is almost the same amount, so we will purchase treasury stock throughout the full year as we promised at the beginning of the fiscal year.

As to why the scale in H2 is smaller than H1, we took into consideration holistic factors such as our cash position, the future cash needs that could arise from potential business development projects, and other factors.

Sakai [Q]: Okay. Is it fair to assume you keep on considering these points in the future, is that correct?

Koshiji [A]: Yes, you are absolutely correct on that point, and we are of the view that the appropriate stock price level should still be higher than the current level. In addition, in terms of improving capital efficiency, we will take initiatives to improve ROE, EPS, and other such factors, in accordance with our cash position.

Sakai [Q]: Okay. Thank you very much. One more thing, I would like to know about the status of high-dose *Eylea*, and the level of sales in H1.

I know biosimilars are coming out in some areas, and I don't know if this is applicable to eye drops, but I think there was some talk of amending the rule so that a therapy could be applicable to all indications as long as there is one matching indication.

I don't think this applies to *Eylea* at this time, but we know that your company expects JPY2.0 billion impact of co-pay hikes for long-listed products in H2, for generics, so I would like to know what your thoughts are in this amending, or if you have any opinions.

These are my two questions about *Eylea*.

Sakuma [M]: Thank you. Mr. Koshiji will take the first question.

Koshiji [A]: Regarding the *Eylea* results, the interim result disclosed individually is JPY39.2 billion. Of that, the figure for 8 mg is JPY6.0 billion. The rest, for 2 mg, is JPY33.2 billion. That's the breakdown.

Sakai [Q]: It seems to me that the penetration of high concentrations is slower than expected. What do you say to that? I guess I am referring to the penetration or switch rate.

Sakuma [M]: Mr. Ito will take that question.

Ito [A]: Regarding the market penetration of the higher dose of *Eylea*, our first approach is to focus on new patients, and once the effectiveness of this product is fully recognized by doctors, we will work on switching the current lower dose of *Eylea*.

Also, regarding market capture, first of all, there is age-related macular degeneration, AMD. We have been addressing new patients here first, and we will then try address new patients with diabetic macular edema (DME).

I believe that we are making extremely good progress this way. I can't give you a figure on the percentage of new patients who are getting high-dose, but I understand that it is progressing well, in line with the strategy. First of all, that is basically my understanding.

Next, on biosimilars. I'll talk about the indications. One biosimilar has been approved, which has limited indications, and I understand that this is the situation for the time being. I regret to say I do not have enough information at this point to know if it will be launched or not, nor do I have enough information to answer how the situation will change in the future.

Sakai [Q]: Okay. Thank you very much. Lastly, I would like to briefly ask about ARVN001, which you introduced this time. Since the application is already scheduled to be filed in China, I think it will be launched in 2026 at the earliest. How much potential did you anticipate in this contract for your company?

I would like to ask in terms of either sales or profit. I was wondering if you could give me some indication as to what you are considering in that area.

Sakuma [M]: Thank you. Mr. Koshiji will take this question.

Koshiji [A]: Yes, there are some uncertainties and external factors that may affect our plans for the market. Then there is also the factor of the authorities on the other side, but we are looking at 2027.

In terms of scale, peak sales are approximately JPY5.0 billion. So expected sales volume would be slightly smaller than for our current mainstay products, such as *Hyalein* or *Cravit*.

Since there are still unmet medical needs in this area, I think there is a possibility that this contributes on a larger scale, but if I was to assign a number to the scale now I would it would be as I just did .

Sakai [M]: Okay. Thank you very much. That is all.

Sakuma [M]: Thank you very much, Mr. Sakai.

Next, Mr. Wakao of JPMorgan Securities, go ahead.

Wakao [M]: Wakao, JPMorgan. Thank you. First, I would like to ask for your company's assessment of your progress in Q2 outside of Japan.

As for Japan, my impression is that it was so-so, although from my perspective it was better than I had expected. On the other hand, I have the impression that performance in China, Asia, and EMEA are all a bit weak. Could you first tell us how Q2 is progressing in terms of sales against your company's internal plan in these regions?

Sakuma [M]: Thank you for your question. Mr. Koshiji will take this question.

Koshiji [A]: This is page 13 of the earnings presentation. As you are aware, all sales in yen basis have increased YoY, but in local currency terms, sales % progression rate v.s. full year forecast in China, Asia, and EMEA have been slightly less than 50% of the previous year's level. It was around 49%. Then there is the rate of progress. These rates of progress are local currency basis on the graph I am showing here for the full year.

Then there is contribution profit. As for H1, we are slightly behind in China and Asia, at approximately 46% to 47%. This is slightly less than 50%. This is where the product mix and other factors of the product have a slightly negative effect.

For EMEA, it is about 50%. Rounded off, the progress to the full-year forecast is something like 50%, such is the situation on a local currency basis. That is our evaluation.

Wakao [Q]: Okay. If so, is it correct to say that although there are some areas where progress is slightly behind, the situation is generally as planned, and there are no events occurring in the respective areas that should make me pessimistic about the trend I am seeing

Koshiji [A]: Yes, that is correct. In China and Asia, there were some downside factors compared to the previous year, such as product supply problems in Noto and Shiga. Overall, we are on track for a double-digit increase in profits and sales over the medium term, as I mentioned at the March meeting.

Sakuma [M]: Mr. Ito will say a few more words on this.

Ito [A]: As Mr. Koshiji just explained, China and Asia, in particular, have been affected by the Noto earthquake disrupting the unit dose line. This line has been restored already. The supply of products is progressing smoothly, and we expect sales to increase again, although it will take some time. In particular, unit dose products are quite differentiated in Asia and China. Our initial plan was to achieve significant growth in these products in the current fiscal year, but the earthquake has had a negative impact. I think we can get back on track in these areas from here.

In Asia, the South Korean doctor strike has been going on for quite a long time, and we have been affected by it, but I do not think that this situation will continue forever. I believe that once the environment becomes favorable again, the figures will continue to rise.

Wakao [Q]: Thank you very much. Second, R&D expenses have decreased compared to the previous fiscal year. While I think this is good from the perspective of eliminating waste, when R&D expenses decrease, I wonder if that means R&D is not going well.

I am also concerned about effects on future growth. Regarding the H1 figures, is it fair to say that this is just an elimination of waste? Also, with the current progress, I wonder if H2 will also be reasonably low. If so, will the results end up being at a level several billion yen below the full-year plan?

Sakuma [M]: Thank you. Mr. Koshiji will take this.

Koshiji [A]: First of all, regarding the decrease in H1, research and development is an essential upfront investment for the future, so we will continue to place the highest priority on this area.

So why has it decreased? For example, the withdrawal of the *Diquas* application in South Korea has reduced expenses by hundreds of millions of yen.

Also, for each of the themes under development, there was an unexpectedly large supply of active pharmaceutical ingredients. There was a small accumulation of such things, and as a result, the budget was not met. In addition, in comparison to the previous year, products that were developed in the previous year are not available in H1 of the current fiscal year, which shows the difference in pipeline development and clinical development in a half-yearly comparison.

The full-year forecast is JPY27.0 billion, but considering the current trend and the current slight trend of unfulfilled orders, or rather, saving potential, the final forecast may be JPY26.0 billion or JPY25.0 billion.

However, rather than leaving a surplus, we would like to give priority to putting it into other pipelines.

Wakao [M]: Okay. Thank you very much. That is all.

Sakuma [M]: Thank you very much. Next, Mr. Ueda of Goldman Sachs Securities, please go ahead.

Ueda [Q]: My name is Ueda from Goldman Sachs Securities.

First, I would like to ask you about the *Alesion* product line. I understand that you have raised your sales forecast of *Alesion* products. I would like to know about the thinking behind your increase in confidence, such as the replacement rate of *Alesion* cream formulation from *LX* or regular formulation ahead of the period during which demand tends to increase.

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

Ito [A]: As I explained earlier, the reason we are revising the figures upward is that the number of facilities adopted was considerably larger than initially expected. We are looking at the portion where products were distributed smoothly as an upward revision.

The adoption of the new dosage form was also favorable, although doctors at medical institutions had been cautious to some extent because they believed that allergies could only be cured with eye drops.

I don't have detailed information on the usage rate, but I don't think the usage rate is that high yet. Naturally, this type of dosage form makes the most sense, and I think the doctors are now looking at how it would work in pediatric patients.

That is all.

Ueda [Q]: Yes, I understand. Thank you very much.

Second, I would like to know about the myopia progression inhibitor. 127 is expected to be approved in FY2024, and I was wondering what preparations your company is currently making for its launch.

Also, can you tell us whether there is any change in your view that the main market here is for out-of-pocket medical care?

Ito [A]: To answer your question, there has been no change in the idea of selling this drug in the form of out-of-pocket medical treatment, in the form of a drug that is not subject to a NHI price. Although I can’t say detail, we are building sales strategy on that premise.

The approval of such products is also important, and I believe that the significance of this treatment for myopia is gradually deepening among ophthalmologists.

We are trying to create an environment in advance so that when the product is launched, it will be available to patients who need it. And doctors are also positive. That is all.

Ueda [M]: Yes, sir. Thank you very much. That is all from me.

Sakuma [M]: Thank you very much. There are still people waiting to ask questions, but we will close the floor for investors and analysts after the next question.

Mr. Hashiguchi of Daiwa Securities, please go ahead.

Hashiguchi [Q]: Daiwa Securities, Hashiguchi. Thank you very much. Thank you.

My first question is about the status of the *Alesion* cream formulation. You said that you don't have detailed information about the usage rate, but in terms of your company's shipment base, what was the situation in Q2 as a percentage of these sales? What is the percentage of your sales in Q2?

Sakuma [M]: Thank you. Mr. Koshiji will take this.

Koshiji [A]: As disclosed in the financial results and data book, the figure in H1 was JPY10.6 billion in Japan. Of this, JPY8.5 billion was *Alesion LX* and JPY1.7 billion was cream.

Hashiguchi [Q]: So, compared to Q1, the composition in terms of your company's shipment base is increasing.

Koshiji [A]: Yes, that's right. However, as mentioned earlier in the introduction, it is the off-season for pollen, and shipments did not grow that much in Q2, so the basic trend is not so different from before.

Hashiguchi [Q]: I'm sorry, I just misunderstood. Are those figures cumulative?

Koshiji [A]: Yes, cumulative. Excuse me. If we go by quarter, sales of the cream were only JPY200 million in Q2.

Hashiguchi [M]: I see. Thank you for clarifying.

Koshiji [A]: But that doesn't necessarily mean that the penetration rate is declining, just that it is off-season.

Hashiguchi [Q]: Yes, I understand. Thank you very much. Also, regarding the response to *Diquas LX*, I believe Mr. Ito mentioned in his presentation that you are considering various options.

Does that mean you have already narrowed down to the option you consider as first priority, and if that doesn’t work out then you will try option B, and then if that doesn’t work out you will move to option C? Does it mean that to some extent, you already have several countermeasures in front of you, including backup options?

Or, at this point, do you have a range of options with different advantages and disadvantages, and you're considering which to choose? Which of these is closer to the current situation?

Sakuma [M]: Mr. Ito will answer.

Ito [A]: There are several options that can solve the problem in the short term. Of course, first of all, we want try one of these options first to definitively confirm the cause of the problem. If this works, there will be no problem from a technical standpoint, so I think that we will give priority to that. I hope that answers your question.

Hashiguchi [Q]: It does, thank you. So you have narrowed it down to one option that you would be most happy to work on.

Ito [A]: Yes. We will try that first.

Hashiguchi [Q]: Can you give us an update in three months as to whether it worked or not?

Ito [A]: I hope so, but I think it is still difficult to specify timing here.

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