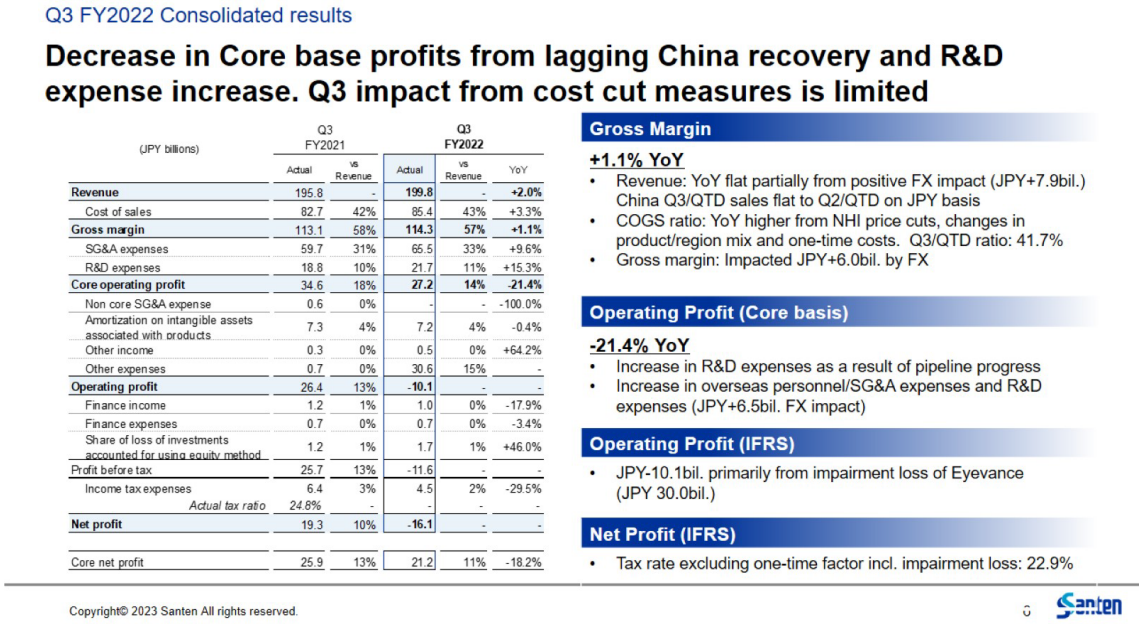
Q3 FY2022 Financial Results Transcript

Koshiji: I will take you through our Q3YTD business performance.

Sales revenue increased by 2.0% YoY to JPY199.8 billion while on a core basis, operating profit (OP) was down 21.4% YoY to JPY 27.2 billion for Q3 FY2022. On an IFRS basis, OP and profits below it were in the red due to an impairment loss in Q2 FY2022 on Eyevance in the US.

The decrease in profit on a core basis was due to the impact of the continued lag in China market, the deterioration in the cost-of-sales ratio, and an increase in R&D expenses. Our initiatives towards improving profitability that we had mentioned in Q2 results presentation have been progressing, however, the impact from such initiatives has been limited at Q3.

We have revised downward our full-year forecasts for FY2022, both on a core and an IFRS basis. The core basis revision has mainly been due to low performance Q3 and Q4 outlook in China and the IFRS basis revision due to a decrease in core OP mainly coupled with additionally incurred structural reform costs.



Koshiji: Page six.

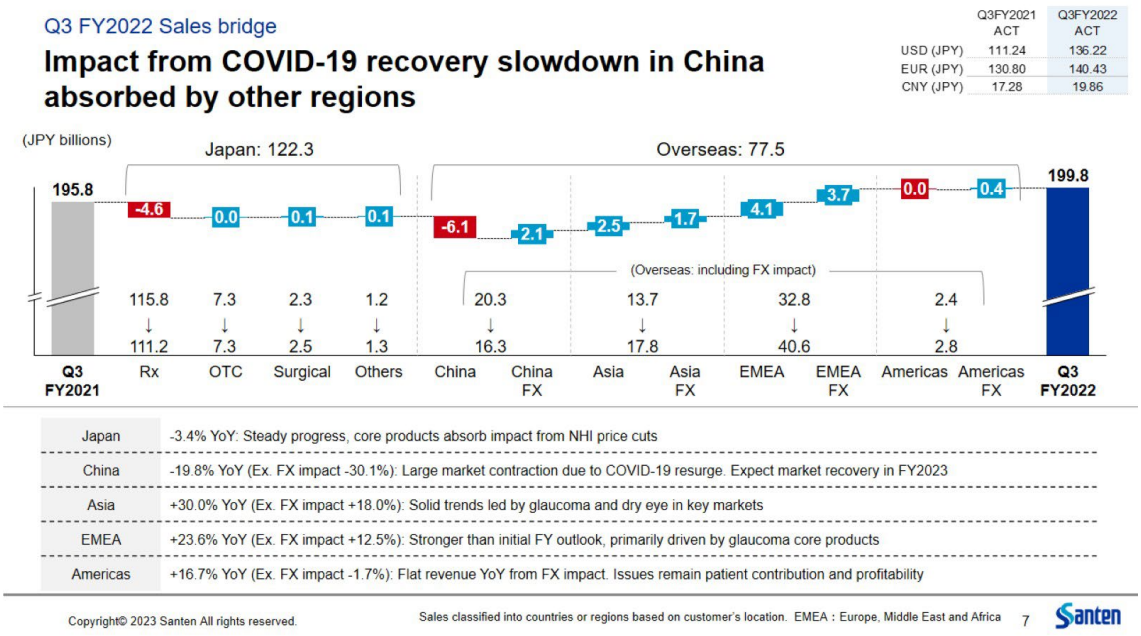
Sales were JPY199.8 billion, 2% up YoY on consolidated basis, despite NHI price revisions of mid 4% in Japan which constitutes an important market. The sales were down 2% YoY, excluding the positive impact of yen depreciation. This is mainly due to the slow recovery in China.

COGS ratio was higher than expected on YTD basis by 0.6pt YoY to 42.8%. The ratio slightly improved on QTD basis to 41.7% due to the absence of one-time expenses in 1H, together with improvements in product mix. With that said, the decrease in proportion of China sales which COGS ratio is relatively lower, weighed negatively on COGS ratios tightening, resulting into the current ratio on a consolidated basis.

SG&A expenses increased by 9.6% YoY to JPY65.5 billion (up 2.0% YoY considering FX impact). Although the improvement from Q2 YTD is limited, we have been able to flexibly reduce variable costs which constitute approx. 40% of SG&A, to levels lower than the previous fiscal year, excluding FX impact.

On the other hand, the R&D expenses increased by 15.3% YoY, 5.1% even excluding the FX impact. This is due to the progress in the pipeline, coupled with FX impact from high composition of foreign currency denominated portion of R&D expenses.

As a result, core OP decreased by 21.4% YoY to JPY27.2 billion. The FX impact on the profit is negligible due to neutral impact on sales/gross profit and expenses.
For the items below core, the net profit was negative JPY16.1billion, due to the impact from the impairment loss at Q2.

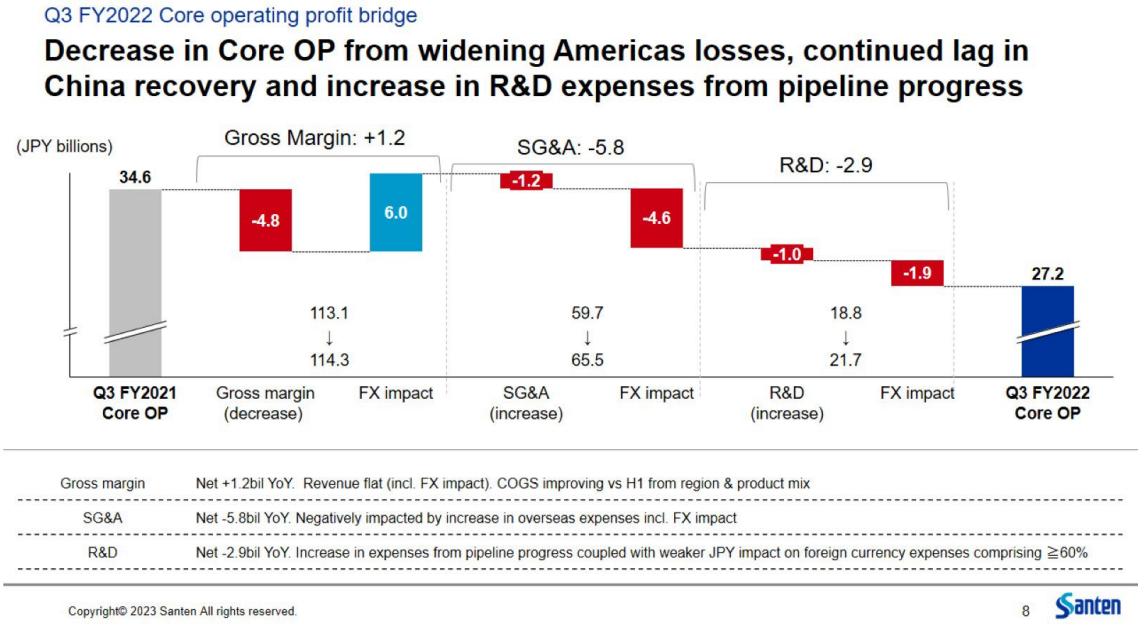


Koshiji: Page seven. Here are the sales revenues by region.

The breakdown of JPY199.8 billion is JPY122.3 billion in Japan and JPY77.5 billion overseas. Overseas ratio is 39%. Sales in Japan were down 3.4% YoY. Although there was an impact from the NHI price revision of mid 4%, this was offset by growth in core products and progressed upward above expectation.

In China, the lag in market recovery has been persisting longer than we had expected at Q2, which impacted our sales, down 20% and 30% YoY on JPN and CNY basis respectively. We have not seen a return to the previous year's level. Sales were lower than we had forecasted in Q2.

Asia and EMEA posted double-digit growth on a currency-adjusted basis due to growth in core products in glaucoma and dry eye in key countries.



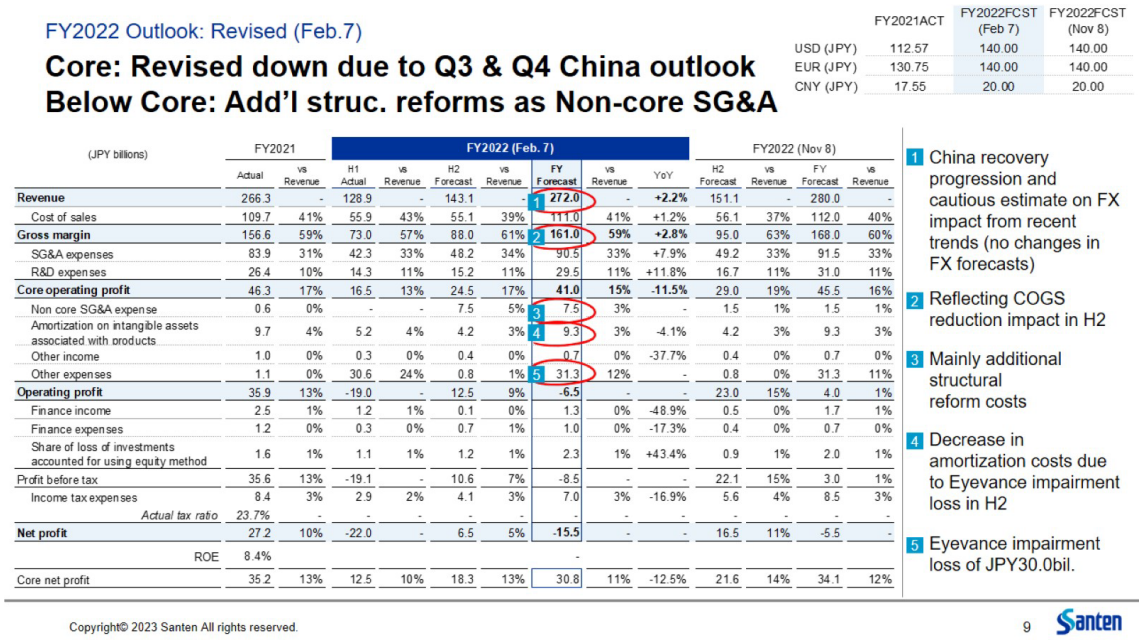
Koshiji: Page eight shows factors behind the change in core OP.

The main factor for the JPY7.4 billion YoY decrease is mainly an increase in JPY5.8 billion SG&A and JPY2.9 billion R&D expenses, totaling JPY8.6 billion in spite of gross margin increase by JPY1.2 billion. Among these the COGS and R&D expenses impact is larger than our expectation.

COGS ratio increased due to transient costs incurred in 1H and a lower proportion of China on consolidated sales, diluting the positive effect mainly from new product launch in Japan with lower COGS ratio.

With regards to SG&A expenses factors, the impact on core OP is negative JPY5.8 billion. This includes negative JPY4.6billion of yen weakening and net increase of negative JPY 1.2billion. The impact we have been able to reap from our profitability improvement efforts remain limited at this stage.

Finally on R&D expenses we have seen a negative JPY2.9 billion impact. This increase is due to the progress in our pipeline, combined with the impact of the yen's weakening from foreign currency expenses comprising a high proportion of R&D expenses, resulting in their overall increase.



FY2022 Outlook: Revised (Feb.7)

Core: Revised down due to Q3 & Q4 China outlook
Below Core: Add'l struc. reforms as Non-core SG&A

	FY2021ACT	FY2022FCST (Feb 7)	FY2022FCST (Nov 8)
USD (JPY)	112.57	140.00	140.00
EUR (JPY)	130.75	140.00	140.00
CNY (JPY)	17.55	20.00	20.00

(JPY billions)	FY2021		FY2022 (Feb. 7)							FY2022 (Nov 8)			
	Actual	vs Revenue	H1 Actual	vs Revenue	H2 Forecast	vs Revenue	FY Forecast	vs Revenue	YoY	H2 Forecast	vs Revenue	FY Forecast	vs Revenue
Revenue	266.3	-	128.9	-	143.1	-	1 **272.0**	-	**+2.2%**	151.1	-	280.0	-
Cost of sales	109.7	41%	55.9	43%	55.1	39%	111.0	41%	+1.2%	56.1	37%	112.0	40%
Gross margin	156.6	59%	73.0	57%	88.0	61%	2 **161.0**	**59%**	**+2.8%**	95.0	63%	168.0	60%
SG&A expenses	83.9	31%	42.3	33%	48.2	34%	90.5	33%	+7.9%	49.2	33%	91.5	33%
R&D expenses	26.4	10%	14.3	11%	15.2	11%	29.5	11%	+11.8%	16.7	11%	31.0	11%
Core operating profit	46.3	17%	16.5	13%	24.5	17%	**41.0**	**15%**	**-11.5%**	29.0	19%	45.5	16%
Non core SG&A expense	0.6	0%	-	-	7.5	5%	3 7.5	3%	-	1.5	1%	1.5	1%
Amortization on intangible assets associated with products	9.7	4%	5.2	4%	4.2	3%	4 9.3	3%	-4.1%	4.2	3%	9.3	3%
Other income	1.0	0%	0.3	0%	0.4	0%	0.7	0%	-37.7%	0.4	0%	0.7	0%
Other expenses	1.1	0%	30.6	24%	0.8	1%	5 31.3	12%	-	0.8	0%	31.3	11%
Operating profit	35.9	13%	-19.0	-	12.5	9%	**-6.5**	-	-	23.0	15%	4.0	1%
Finance income	2.5	1%	1.2	1%	0.1	0%	1.3	0%	-48.9%	0.5	0%	1.7	1%
Finance expenses	1.2	0%	0.3	0%	0.7	1%	1.0	0%	-17.3%	0.4	0%	0.7	0%
Share of loss of investments accounted for using equity method	1.6	1%	1.1	1%	1.2	1%	2.3	1%	+43.4%	0.9	1%	2.0	1%
Profit before tax	35.6	13%	-19.1	-	10.6	7%	-8.5	-	-	22.1	15%	3.0	1%
Income tax expenses	8.4	3%	2.9	2%	4.1	3%	7.0	3%	-16.9%	5.6	4%	8.5	3%
Actual tax ratio	*23.7%*	-	-	-	-	-	-	-	-	-	-	-	-
Net profit	27.2	10%	-22.0	-	6.5	5%	**-15.5**	-	-	16.5	11%	-5.5	-
ROE	8.4%						-						
Core net profit	35.2	13%	12.5	10%	18.3	13%	30.8	11%	-12.5%	21.6	14%	34.1	12%

1 China recovery progression and cautious estimate on FX impact from recent trends (no changes in FX forecasts)

2 Reflecting COGS reduction impact in H2

3 Mainly additional structural reform costs

4 Decrease in amortization costs due to Eyevance impairment loss in H2

5 Eyevance impairment loss of JPY30.0bil.

Koshiji: Next, page nine shows the full-year forecast for FY2022.
We have revised downward the outlook both on a core and an IFRS basis.

First of all, let me go over the core-base revision.
We mentioned earlier that we would be aiming to achieve a different P&L structure from 1H, through *Diquas LX* launch in Japan, a recovery trend in China vs 1H, and cost controls. The China situation evolving differently from our initial forecast, coupled with the continued high COGS ratio, have led us to the decision to revise our forecast downward from Q2.

Concretely, we have revised China revenue outlook to JPY22billion from JPY27 billion, which impacted the profit by around negative JPY3.5 billion. In addition, although some of it overlaps with the JPY3.5 billion pertaining to China, we have revised our outlook of consolidated COGS ratio to 40.8% from 40.0%. Core OP is downwards revised by JPY4.5 billion.

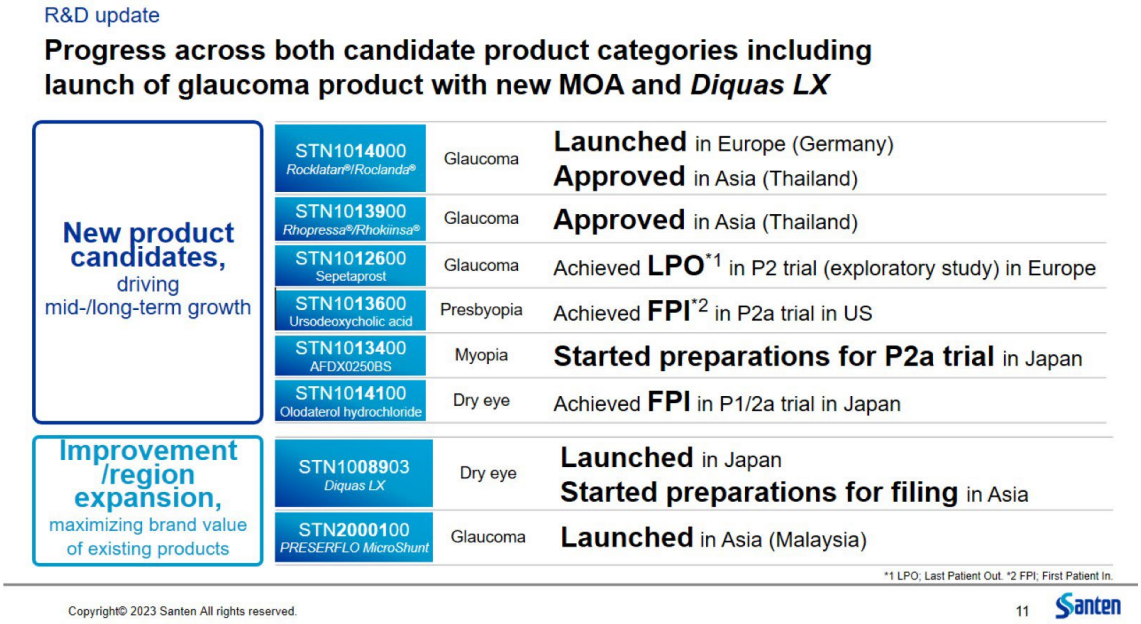
As a result, for Q4 QTD, although there are still uncertainties, such as the business environment in China and the airborne pollen volume in Japan, we expect record high revenue and core OP of JPY72.2billion, up 2.5% YoY and JPY 13.8 billion, up 17.4% YoY respectively.

Next, for the revision for items below core. In addition to the core OP downward revision impact, the major factor that has led us to the revision comes from non-core SG&A expenses mainly related to structural reform costs, that have been increased to JPY7.5 billion from JPY1.5 billion, our Q2 estimate, as stated in our timely disclosure and subsequent events in the Summary of Consolidated Financial Results, disclosed separately today. This reflects the one-time expenses that we are able to estimate at this timing. There is a possibility that these expenses will increase in the future, and these will be reflected additionally as a function of our accounting procedures pertaining to the precision of the estimated amounts and their final respective treatments.
As a result, net profit is expected to be negative JPY15.5 billion from negative JPY5.5 billion forecasted at Q2.

(Reference)

FY2022 revised outlook (Q3YTD actual and Q4/QTD forecast)

(JPY billions)	FY2021		FY2022 (Feb. 7)						
	Actual	vs Revenue	Q3YTD Actual	vs Revenue	Q4/QTD Forecast	vs Revenue	FY Forecast	vs Revenue	YoY
Revenue	266.3	-	199.8	-	72.2	-	**272.0**	-	**+2.2%**
Cost of sales	109.7	41%	85.4	43%	25.6	35%	111.0	41%	+1.2%
Gross margin	156.6	59%	114.3	57%	46.7	65%	**161.0**	**59%**	**+2.8%**
SG&A expenses	83.9	31%	65.5	33%	25.0	35%	90.5	33%	+7.9%
R&D expenses	26.4	10%	21.7	11%	7.8	11%	29.5	11%	+11.8%
Core operating profit	46.3	17%	27.2	14%	13.8	19%	**41.0**	**15%**	**-11.5%**
Non core SG&A expense	0.6	0%	-	-	7.5	10%	7.5	3%	-
Amortization on intangible assets associated with products	9.7	4%	7.2	4%	2.1	3%	9.3	3%	-4.1%
Other income	1.0	0%	0.5	0%	0.1	0%	0.7	0%	-37.7%
Other expenses	1.1	0%	30.6	15%	0.7	1%	31.3	12%	-
Operating profit	35.9	13%	-10.1	-	3.6	5%	**-6.5**	**-**	**-**
Finance income	2.5	1%	1.0	0%	0.3	0%	1.3	0%	-48.9%
Finance expenses	1.2	0%	0.7	0%	0.3	0%	1.0	0%	-17.3%
Share of loss of investments accounted for using equity method	1.6	1%	1.7	1%	0.6	1%	2.3	1%	+43.4%
Profit before tax	35.6	13%	-11.6	-	3.1	4%	-8.5	-	-
Income tax expenses	8.4	3%	4.5	2%	2.5	3%	7.0	3%	-16.9%
Actual tax ratio	*23.7%*	-	-	-	-	-	-	-	-
Net profit	27.2	10%	-16.1	-	0.6	1%	**-15.5**	**-**	**-**
ROE	8.4%						-		
Core net profit	35.2	13%	21.2	11%	9.6	13%	30.8	11%	-12.5%



Sallstig: Good afternoon, I'm Peter Sallstig, Chief Medical Officer. I would like to update you with regards to status of the pipeline.

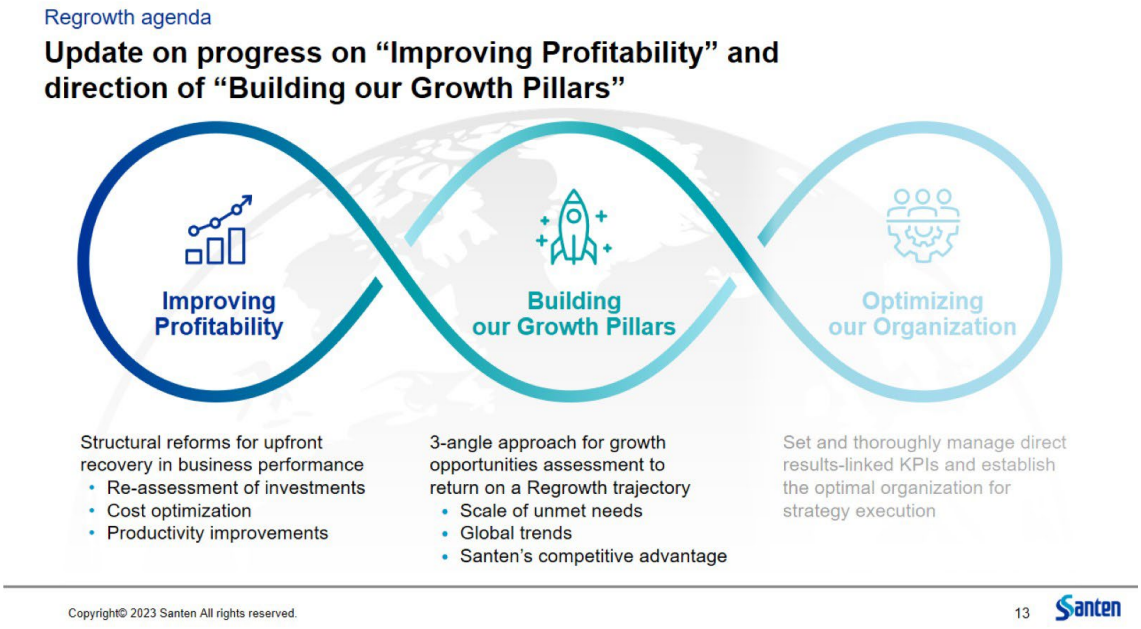
First of all, we will introduce the development code with only three numbers indicating the active ingredients. In the document, the numbers are in bold.

See page 11.
In the last quarter, R&D has had numerous developments, including new launches and approvals. STN 140 for glaucoma, was launched as the first combination drug containing a ROCK inhibitor in Europe. In addition, 140 and 139, a single agent ROCK inhibitor, were approved in Asia.

We are also progressing to obtain POC on new diseases and related mechanisms of action. 136 for presbyopia began P2a in the U.S. while 134, a next generation of myopia therapy, began preparing for P2a in Japan.141, aimed for the treatment of dry eye with a novel mechanism of action also began P1/2a in Japan. We estimate the timing at which we can share the results of these trials would be between late end FY2023 and 1H of FY2024.

Another focus area remains our work on product improvements and regional expansion to maximize the brand value of existing products. *Diquas LX* was launched in November in Japan, where the number of doses was reduced from six to three times a day. In Asia,

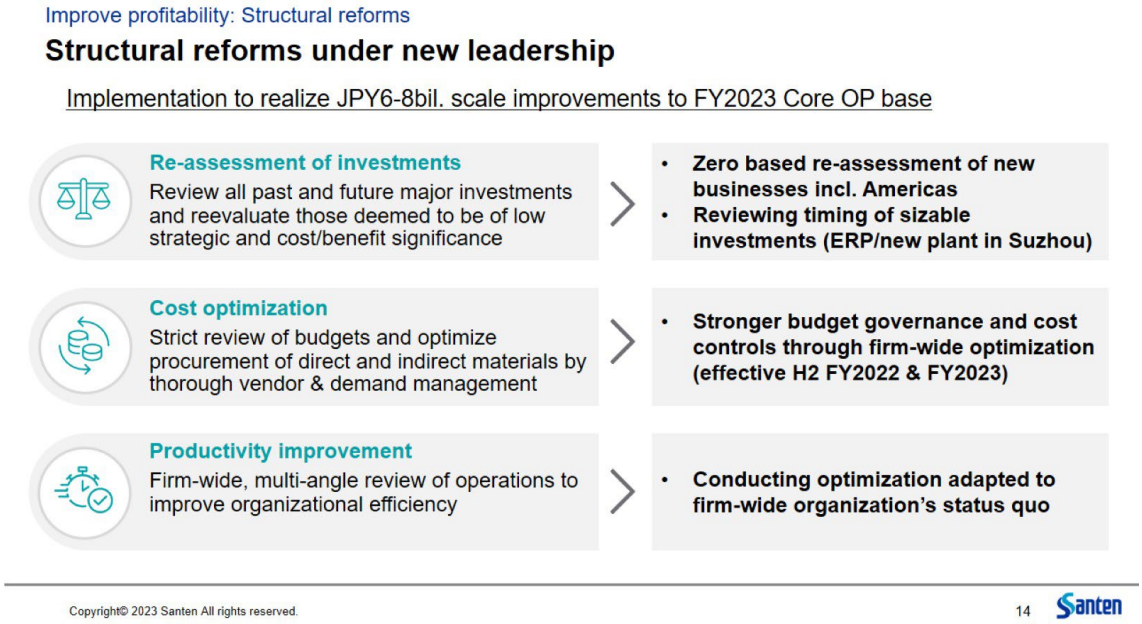
we also started preparing to file for *Diquas LX* while we achieved the launch of *PRESERFLO MicroShunt*. This concludes my part. Thank you.



Ito: Hi, this is Santen Pharmaceutical's CEO, Ito.

I would like to take this occasion to provide you an update on how we are progressing on our Regrowth agenda presented during our last 2Q earnings.

Please take a look at page 13. As you know, the current measures are undertaken in light of three objectives. I will provide an update today on progress concerning ”improving profitability” and the direction of “building our growth pillars”.



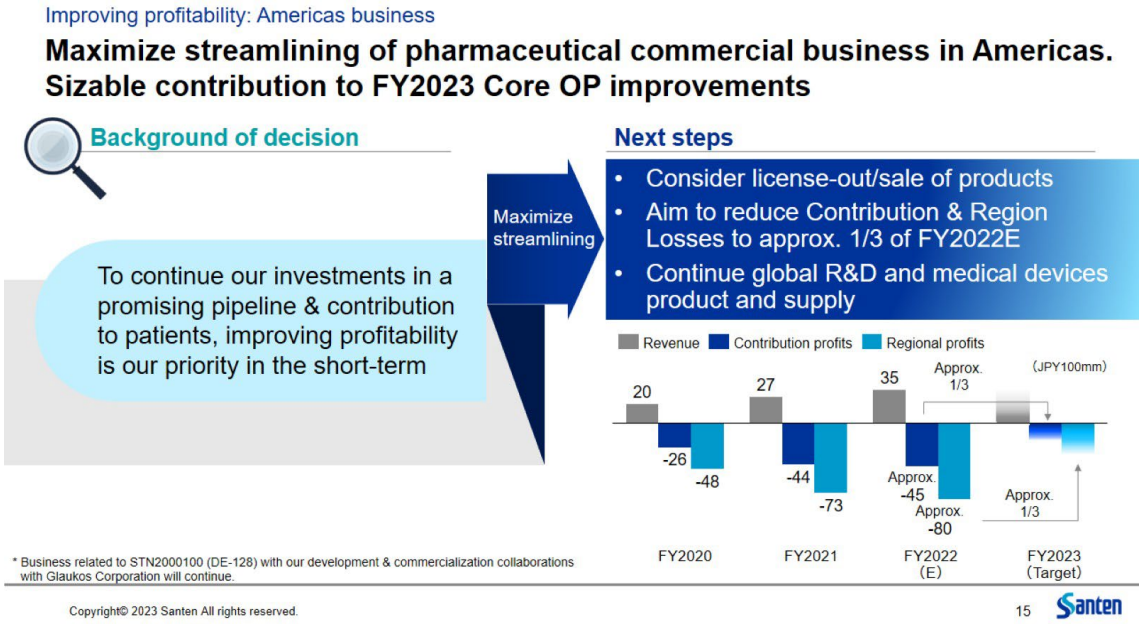
Ito: Please take a look at page 14.

First of all, concerning improving profitability: in order to deliver, with a high degree of certainty, JPY6 to JPY8billion scale improvements to FY2023 core OP base, improvement in profitability has been addressed by focusing on these 3 points, alongside structural reforms underway.

First point: Re-assessment of investments. Large scale investments are all being itemized and reassessed. Regions and our business portfolio are subject to zero-based re-evaluations, and we have first reached a conclusion pertaining to our Americas business which I will touch upon in the following page. We will also prioritize short term improvements in profitability improvements concerning our fixed investments, which translates into a re-evaluation of the rolling out timing of our ERP in China and Asia, as well as the investment timing related to our Suzhou factory.

Second point: cost optimization. Starting with the 3Q, we have hardened cost management measures, and implemented a more rigorous budget process for next fiscal year. Up until now, it is my understanding that the budget drafting process had been driven by each region's or business function's own optimization, placing less priority on firm-wide optimization, resulting into profit targets not being reached. As a result of reviewing the status quo, strengthening our budget governance, and thorough cost controls, we will realize cost optimization.

Third point: Productivity improvement. Since FY2019, we had divided our organization's functions into corporate functions, healthcare functions and customer-facing-unit functions based on a management framework concept. This was done with the intention to strengthen our organization but the by-product of this was redundancies in functions which we have identified and plan on optimizing based on the current business situation to promote firm-wide productivity improvements.



Ito: Please move to page 15.

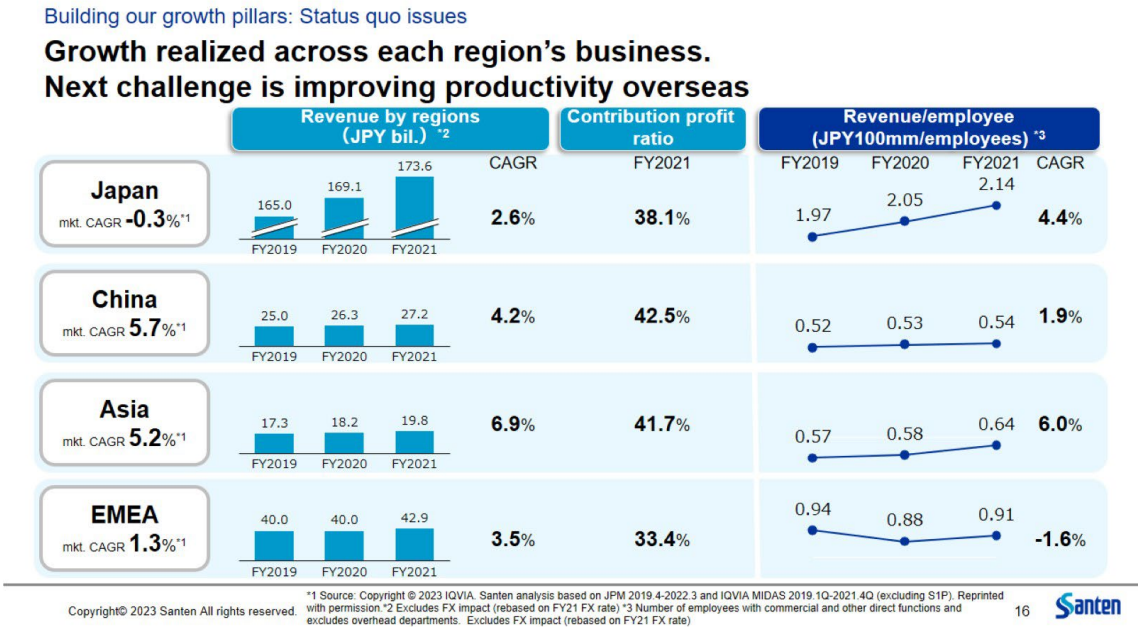
Let me elaborate now on the Americas business as a last point to improve profitability. You will recall my explanation during the 2Q earnings announcement on how we would not be able to breakeven by continuing our investments in the region in question, and how we had decided to consider as an utmost priority to shift course and reduce losses. We considered various options for our Americas business since then and we reached the conclusion that the appropriate choice would be maximizing the streamlining of the business.

Our development pipeline consists of opportunities that could lead the short-term to medium term growth in Japan, China, Asia and EMEA, and furthermore long-term growth if we include the US. In order to secure and capture investment opportunities that would allow such development pipeline to definitely contribute to patients globally, we decided to maximize the streamlining of the pharmaceutical commercial business in Americas.
The FY2021 Americas business contribution profit amount is negative JPY4.4 billion of losses and if you add the relevant overhead costs, you are looking at circa negative JPY7 billion of losses, expected to reach negative JPY8 billion in FY2022. We have deemed it necessary to eliminate these losses with the utmost urgency.

First, concerning already U.S. approved drugs, we have been exploring the licensing-out or sale options and will provide you a concrete update as soon as a decision is made pertaining to this.

Through the optimization of our Americas business platform, we are expecting contribution and regional losses to get reduced to one-third of FY2022E levels. As a result, we expect realizing a great portion of the JPY6-8 billion core OP base improvements we previously mentioned to you.
Global R&D activities including those conducted in the U.S. and medical devices product & supply activities will continue but we will further examine room for efficiencies in R&D activities.

Given we had seen a gradual improvement in our range of products being sold in the region, the optimization of the pharmaceutical commercial business in the Americas, is a big decision for our Company. Having said that, we hope these changes will prepare us better for the future when we will be able to increase our contribution to patients by making available products with stronger competitiveness in the U.S. market.

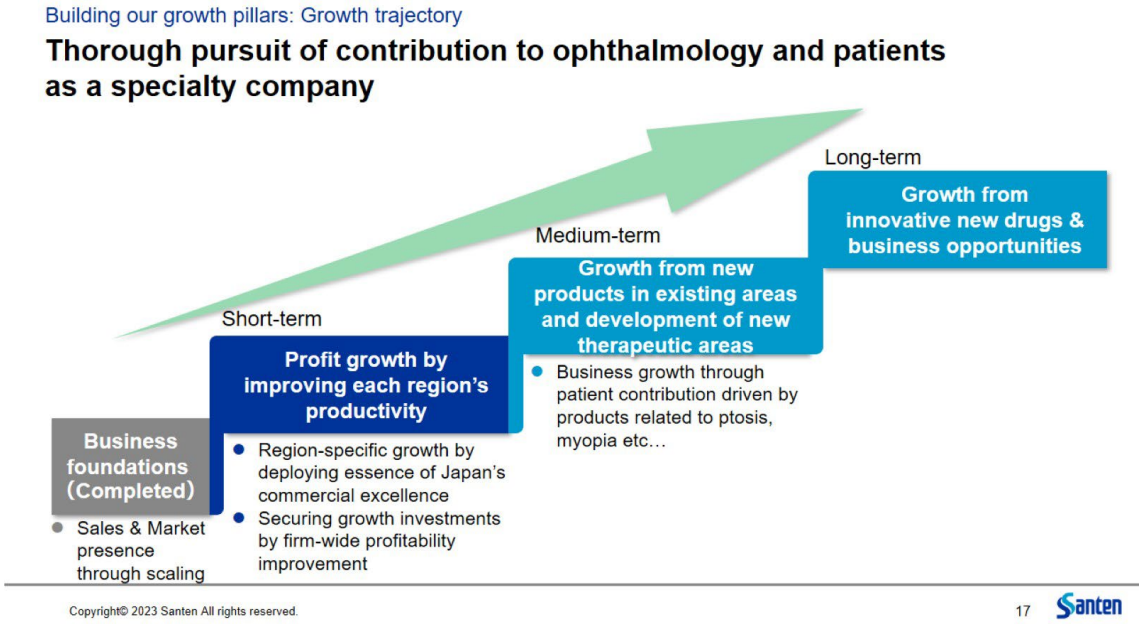


Ito: Please move to page 16.

As we are still in the process of drafting our new medium-term plan, we would like to provide you our basic way of thinking on “building our growth pillars”.

Let me first of all touch upon the status quo for each region’s business.

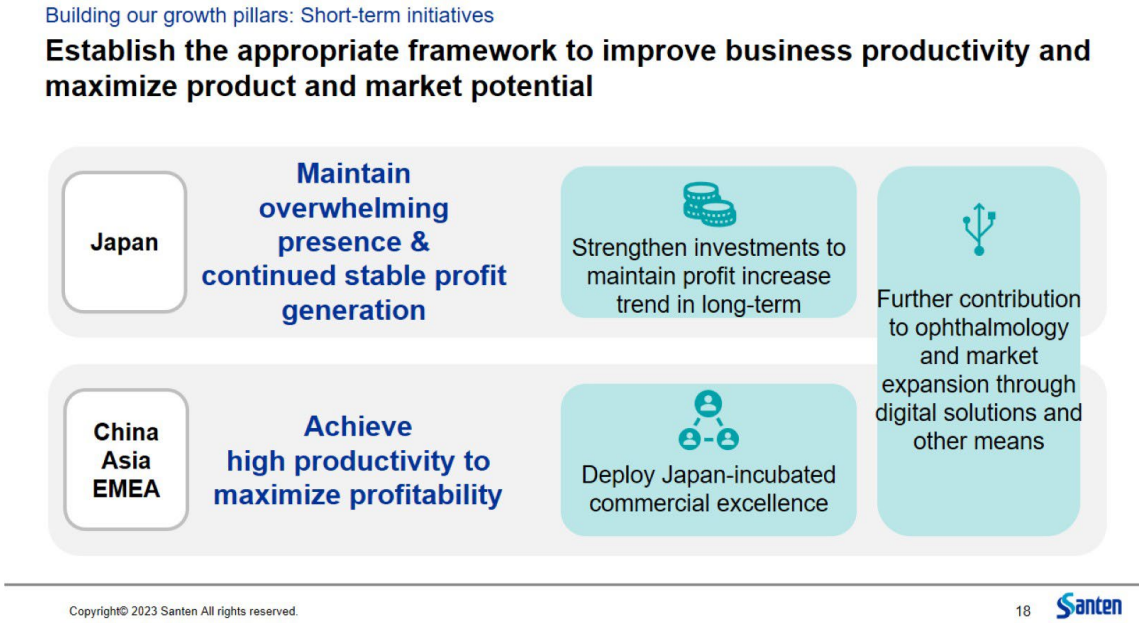
We have, over the past years, realized sales growth surpassing market growth across a number of regions, also securing a high contribution profit ratio.
Having said that, when we examine the overview from a productivity perspective as in the case of revenue/employee, we can point out that improvement outside of Japan has not been sufficient, or that productivity levels remain low. We think there is room for improvement in productivities for those regions concerned.



Ito: Please move to page 17.

In the short-run, as I explained earlier, we aim to achieve profit growth through improving each region's productivity by deploying the essence of Japan's commercial excellence to our overseas businesses and securing investments for our future growth by improving firm-wide profitability.

In the medium to long term, we expect realizing growth from new products in existing areas and also the launch of products in new therapeutic areas such as myopia and ptosis as examples, followed by growth from innovative drugs and the development of new business opportunities.



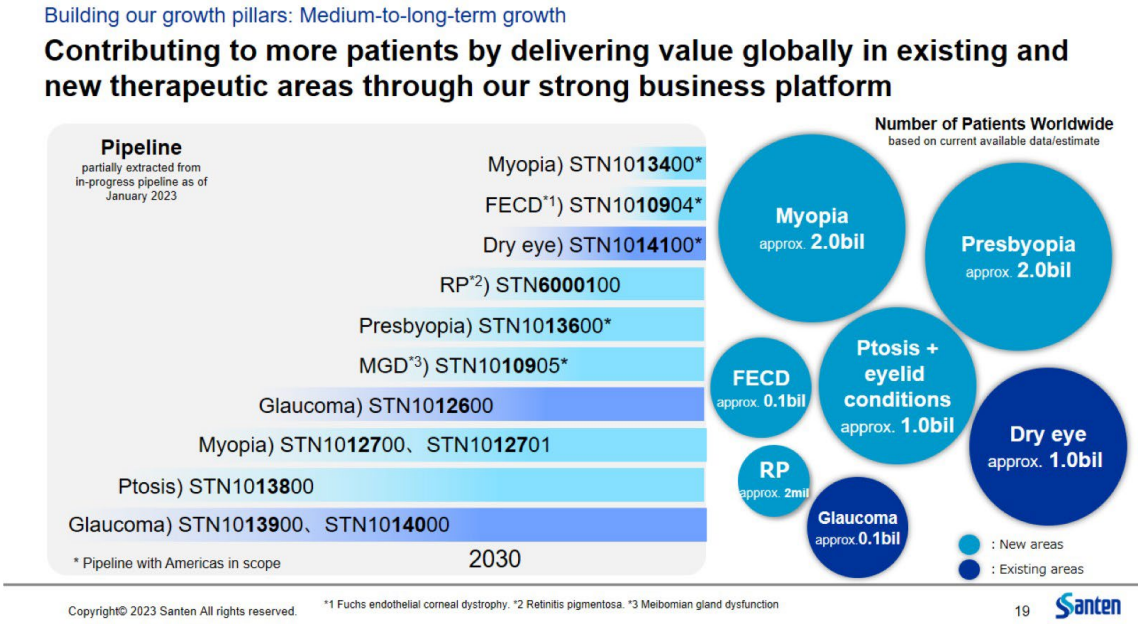
Ito: Please move to page 18.

Let me elaborate more on short-term measures.

We will aim at reinforcing investments that will enable us to secure long-term profit growth and maintain an overwhelming market presence and continue stable profit generation for our Japan business which has the largest scale.

We will deploy Japan-incubated commercial excellence across China, Asia and EMEA to maximize profits in those respective regions through productivity improvements.

Irrespective of the regions, we also intend to leverage digital solutions and other means to address untreated patients, realize optimal treatment, and lead to further patient contribution and market expansion.



Ito: Please move to page 19. This highlights our medium to long term perspective.

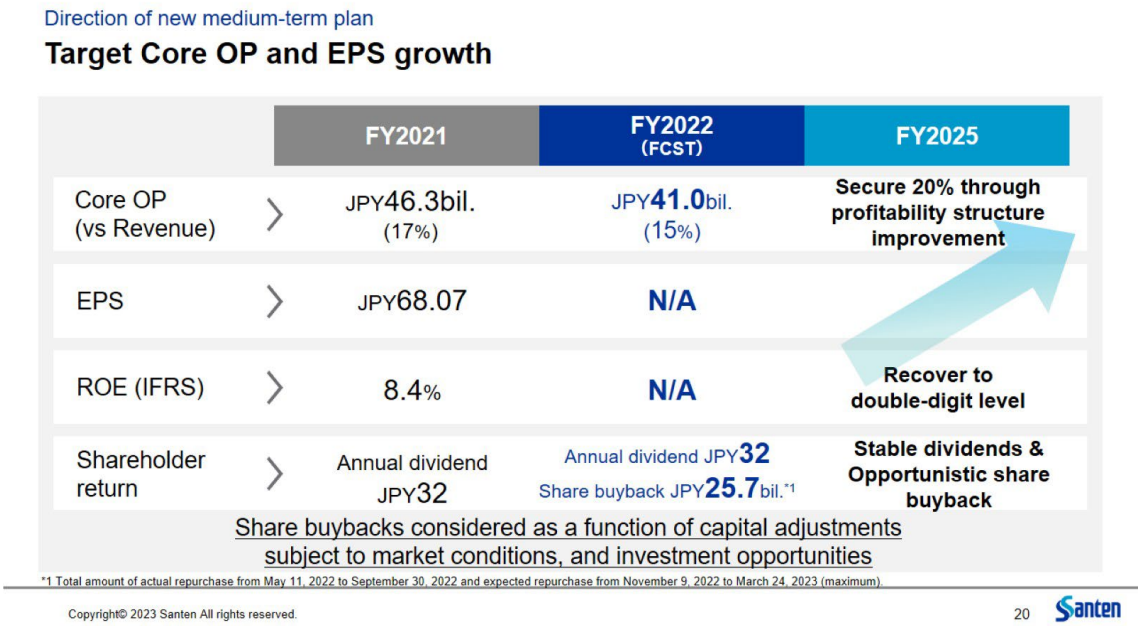
Our drug developments currently consist of pipelines in late phase clinical trials with good progress being such as in the cases of myopia or ptosis, or in POC trial stage such as in the case of presbyopia. These represent entry into new markets with huge potential.

Furthermore, our drug developments also consist of pipelines addressing high unmet needs such as in the case of FECD or RP and also pipelines consisting of innovative new drugs in existing markets such as in the case of dry eye.

We hope to develop new markets and contribute to patients in each region's business once these are bolstered by our short-term initiatives.

Pertaining to patient contribution in the U.S. market, we will consider this in light of our progress made in the development of competitive products.

This concludes what I can share at this stage on the direction of our growth.



Ito: Please move to page 20.

Let me briefly touch upon the direction of the new medium-term plan.
While we are still in the process of drafting the new plan, given the final year of our last medium-term plan was FY2025, let me use that FY as a point of reference.

At our 2Q earnings, I communicated to you that core OP growth is what we would be aiming at, given that represents our real profitability. While we expect our core OP ratio to be 15% this FY, as a result of our downwards revisions, amongst other things, we aim to bring this to a level of 20% by improving productivity in each region and improving quickly our profitability by optimizing our firm-wide organization as earlier mentioned.

As we proceed with structural reforms, we are expecting transient P/L impact. Having said that, we will also, on a best-efforts basis aim for EPS growth and ROE levels recovering to double-digit levels and improve shareholder value as a result.
Pertaining to shareholder returns, we will continue delivering stable dividends with share buybacks to be executed opportunistically subject to market conditions and capital allocation amounts for investment opportunities.

I explained today our progress on profitability improvements and on the direction of our growth pillars. We are currently drafting our medium-term plan with end of March as a target date for completion, and April-May for external disclosure. We will provide you an update as soon as we decide on the date of announcement.

By proceeding with structural reforms and eventually achieving our medium-term objectives to be outlined in our new medium-term plan, we think that this should contribute to patients and the medical community, improve enterprise value, and meet shareholders' and investors' expectations. On behalf of Santen Group, I thank you in advance for all your support.

Question & Answer (summary)

Q1-1
First of all, regarding the structural reforms of JPY6-8 billion, you mentioned today that the impact of the efforts on Q3 has been limited. What have you done and what challenges still remain? Also, you previously explained at Q2 presentation that you intended to be more specific about the reforms at Q3 briefing. I think these include the reform for the Americas, could you give us the specific items under this reform?

A1-1
Ito: As we explained earlier, we plan to streamline the US business in FY23, totaling to a nearly JPY5 billion improvement. Amongst JPY6-8 billion, this JPY5 billion comes from the streamlining of the Americas business. In addition, we are investigating various cost cuts measures, productivity improvement for regions other than Americas. We will refrain from going into details today, but we are beginning to have good prospects on the impact from improvements in FY23. We have set a core OP target of JPY41 billion, given we think cost improvements, which in the past had been difficult to realize, are becoming more achievable from more strict measures controlling expenses and demand management.

Q1-2
Secondly, I am aware of the difficult situation in China at this moment from the COVID-19 rapid spread. But I also believe it will get back to normal once the situation has subsided. I perceive you have been tackling volume base purchasing mainly by shifting strategy to private hospitals. Would you please comment on the outlook for recovery timing and FY23 onward?

A1-2
Ito: In Q2, we did not revise core OP guidance because the business was on a recovery trend then. However, since December the COVID-19 was rapidly spreading, and I understand the market as a whole, had been facing a difficult situation as 70% of our employees in China had been infected by the virus. As a result, we are unlikely to achieve JPY45.0 billion core OP.

With that said, as a general view, the situation seems to have bottomed out and it is said it will likely take three to four months to normalize. At the end of last year, when the infection spread, the ophthalmology market had stagnated because ophthalmologists were expedited to help treat COVID-19 patients. However, I perceive that some refractive and cataract surgeries are recovering as leading indicators. Although it is difficult to say exactly when we will obtain full recovery in the market, the first hand reporting we are receiving from our team in China, suggests we are finally entering a stage of recovery after a number of years of turmoil.

Q2-1-1
First question is regarding the product situation such as *Cravit, Hyalein* and *Diquas QoQ. Cravit* incrementally increasing YoY, *Diquas* struggling, *Hyalein* on progress. Since your products are related to refractive and cataract surgeries, I think the sales during Oct-Nov, especially Dec-Jan were sluggish because the patients were not able to come to hospitals, while *Cravit* sales increased. What is the background behind the figures?

A2-1-1
Ito: We have focused on refractive surgery territory with *Diquas* by positioning it as a strategically differentiated product without the scope of reimbursement. The number of refractive surgeries was the first to decline due to COVID-19 spread, despite what was an initially favorable trend.

Concerning *Tapros*, its share in the prostaglandin (PG) market grew rapidly, but the therapeutic areas that require patients to move across different regions took a significant hit. These two focal products have been largely impacted by COVID-19, but at the same time we are aware some surgeries are coming back, so we are seeing good prospect moving forward.

Regarding *Cravit* and *Hyalein* we are partially outsourcing the promotion utilizing contract resource. It has been delivering results matching our expectations.

As a whole, if we exclude the market contraction factors, we are progressing in line with our strategy and I believe the numbers will pick up as the market recovers.

Q2-1-2
When did you revise the outlook in China? I have a feeling that your guidance seems conservative considering more people are expected to move in February compared with before COVID-19, if the outlook reflects the move of the population and the number of outpatient surgeries.

A2-1-2
Ito: We might be conservative given the most recent situation however, as it is hard to gauge how it will recover, we have set this target as stated.

Koshiji: The outlook is based on the assumption as of last December. We are looking at the figures on a monthly basis and we take into account of Chinese New Year timing for Jan-Feb. Our assumption for market recovery is somewhat conservative.

Q2-2-1
Secondly, when you look at the revenue per employee on page 16, the figures on China and EMEA catch my attention. If you think about the OP per employee considering wage per employee, the overseas regions are much more behind Japan. Would it be correct to say EMEA's ratio would be especially the lowest amongst other regions?

A2-2-1
Ito: Yes, I think that understanding is fine.

Q2-2-2
If that is the case, I can imagine what the necessary actions will be. Are you planning to touch upon the details on this in May?

A2-2-2

Ito: I think we will discuss specifically at a separate timing. In the past, China and EMEA business have tended to be highly reliant on resources being invested into each of these regions to seek sales. From my perspective, as someone who has been overseeing the Japan business for a long time, I think there is still room for productivity improvement by pursuing commercial excellence. We will not comment specifically today, but we will build the appropriate organization structure moving forward.

Q3-1

First question is pertaining to the structural reform. You mentioned JPY5 billion comes from the streamlining of the Americas business amongst JPY6-8 billion. Are other measures for cost optimization and impact from productivity improvement limited? Or are you estimating additional impact from these on top of JPY6-8 billion?

A3-1

Ito: We do not think they are limited. We will refrain from commenting specifically today, but it is not as though we are pessimistic about figures. On the other hand, we expect to make large improvements. The Improvement amount we mentioned is the range of impact we expect to see in FY23, but we expect to see a slightly more impact in FY24.

Q3-2

Second question is regarding STN1013400. You have started preparations for P2a trial in Japan. Could you tell us if you have finalized the trial design? I wonder if it is difficult to set an appropriate dose which works for myopia but does not cause excessive mydriasis. Can I assume there is not much of a concern because the compound is highly M2-selective?

A3-2

Sallstig: We are currently creating the trial design. We would appreciate if you could understand we are not able to disclose the details at this timing since it is under progress. Once it is ready, we will publish the design through CRT (Japan Registry of Clinical Trials). We understand the mydriasis is extremely limited based on initial data, from which we view it as an enhanced differentiator.

Q4-1

First of all, concerning the increase in structural reforms expenses, can you tell us what has changed for the past three months with regards to your perspective on this, alongside the projection for future expenses? You mentioned earlier that you will finalize once ready. Could you tell us whether you expect further increase or impact on FY23 onward?

A4-1

Ito: There has been no major changes in our view for the past three months. We believe we will be able to step up the various structural reforms as initially planned, with full effect expected for FY23. We are currently discussing on how these structural reforms will be implemented with each function and who will be responsible to oversee these structural reforms including the current undergoing one. We expect limited impact in FY22, subsequently full roll-out in FY23. We will have to carefully examine the timeline of each of reforms according to characters, in order not to jeopardize the fundamentals of our business as pharmaceutical company. Given the timeline of each reform will be different, the impact felt and realized from these will also be different.

Koshiji: There are two factors for the reforms. The additional expenses we expect to incur in FY22 below core are one-time costs. At Q2, we only touched upon the direction of the US business. Now that we are able to estimate concretely each cost item, we have been able to reflect in our forecast. If we can obtain a reasonable estimate for expenses expected to be incurred in FY23, we will consider recording a provision in FY22. As we are able to have more concrete plans concerning reforms in regions other than Americas, there is also a possibility that we will incur additional provisions, which we will finalize while formulating the budget for FY23 and our medium-term plan.
Another factor is cost control. I mentioned earlier that the impact felt is limited at this moment. Let me clarify that it is not that our reform has been behind schedule, but that quick hit items are limited. For FY23, we expect to obtain a favorable impact from suppressing baseline costs, in addition to the impact from the US.

Q4-2

One more question. When you look at 3Q sales of *Diquas* in Japan, it seems the launch of *Diquas LX* has contributed to the sales. I would like to know your view whether you can manage the life cycle management as in the case of *Alesion LX*, including post-launch market penetration and evaluation from the medical community.

A4-2

Ito: Since its launch in last November, *Diquas LX* has enjoyed a satisfactory selection by medical institutions. Partially due to the pre-promotion impact prior to obtaining approval, the shipment to the wholesales and medical institutions have been progressing well, which had positive impact on sales. On the frontline, we are focusing on a switch from *Diquas* to *Diquas LX*, which enables to reduce the number of application from six times to the three times a day. Drastic transition might be difficult, but we are enhancing the promotion to allow for a smooth switch. For the previous *Diquas*, we had a number of voices pointing out to its irritating impact, but for new *Diquas LX*, we have received feedback pointing to its usability from patients evaluating their impression when applied, in line with the result of the clinical study.

Q5-1

I would like to know your views about the re-assessment of investment and its effectiveness. I am aware you have mentioned re-assessment of investment and cost cuts even under the previous CEO management. What has changed under the new management? Additionally, you previously mentioned how a core OP of around JPY50 billion for FY23 would be in sight before you revised the forecast. Is there still a possibility of reaching that level and its coherence to your downward revision?

A5-1

Ito: In the past, we viewed China as a huge potential market, and therefore tried to secure production capacity accordingly, resulting in focusing too much on getting close to the ideal first. This can also be said regarding investments in production facilities and ERP.

Under my leadership, we first evaluate and decide based on a realistic assessment. It follows that, taking the factory investment in China as an example, we are modifying the investment plan based on what the optimal investment size would be based on our current estimates – putting aside what the final investment size would be – and also pertaining to ERP as a I earlier explained, we are revising the plan as we think there is room for revision when we evaluate the impact and overall balance of deploying this in Asia and China.

Koshiji: We are currently discussing the budget for next fiscal year internally, and the profit level for FY23 is being discussed in a range. However, we have not changed our view on what could be achievable.