Q3 FY2021 Financial Results

Become A Social Innovator

Q3 FY2021 Financial Results
Santen Pharmaceutical Co., Ltd.

Presentation: February 10, 2022

Santen
Imagine Your Happiness

Speakers

Presentation/Q&A

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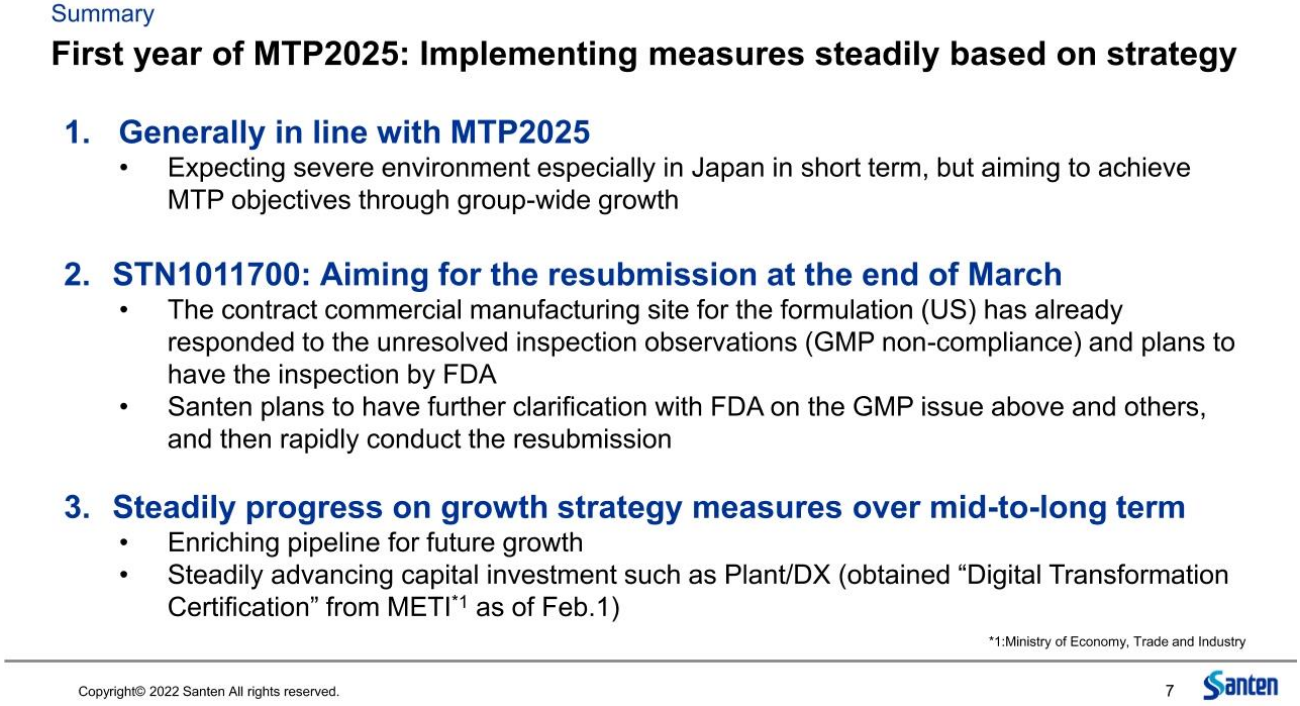


Taniuchi: Hello, everyone. I am Shigeo Taniuchi, CEO of Santen Pharmaceutical.

Please take a look at page seven. We are in the first year of our MTP2025 plan, and in this section, I would like to explain our current status with respect to our long-term vision.

Looking at the first year and up to the third quarter, the business environment has both tailwinds and headwinds. We are steadily implementing the measures set forth in the MTP, and are moving forward to ensure the realization of medium- to long-term growth.

In terms of business performance, we are generally doing well but, of course, we are aware that the business environment will be difficult in the short term. We are taking steps to deal with this.

First of all, as will be covered in more detail later, the US business is currently lagging behind the plan. In addition, as you all understand, the Japanese business is preparing for LOE (Loss Of Exclusivity) of main products in 2022 and 2023. With this backdrop, we are now working on both short-term and long-term issues.

In addition, as recently announced by the Ministry of Health, Labor and Welfare, as of April 1, the market expansion recalculation has been applied to *Alesion* due to the addition of new dosage forms. We are currently waiting for the NHI price announcement, so I will refrain from giving specific figures, but we need to expect a certain level of impact.

However, as I mentioned at the MTP briefing, from a medium- to long-term perspective, we will have to anticipate the impact of LOE in Japan, anticipating changes in price and considering how we can compensate for this with new products, growing through global expansion and entering new business areas.

We understand that these are key issues for management. We must steadily expand the pipeline. We must also take up growth opportunities. We will also further develop our strong presence in China and other Asian markets, which we recognize as growth drivers. The Company will also invest in a new plant with a view to reducing costs over the medium to long term. We are now steadily implementing measures and strategies to achieve this kind of medium- to long-term profit growth.

Even if there are short-term or local headwinds, I believe that we have a direction to achieve medium- to long-term growth through strategic investment, leveraging our solid cash flow and financial base.

We will aim to realize our long-term vision by overcoming such a transitional period through growth on a global scale.

Next, the second point. Here is an update on STN1011700 in the US, which we presented last time.

As we reported in November, we received a CRL (Complete Response Letter) for STN1011700 as a result of a GMP (Good Manufacturing Practice) non-compliance at a contract commercial manufacturing site in the US. This was in relation to production that is different from our ophthalmic drugs. I am pleased to report that we have made progress toward resubmission.

First of all, the US contract commercial manufacturing site has already taken measures to address the issues raised. We have confirmed that the FDA is planning to conduct another inspection, and our QA (Quality Assurance) department has also conducted a mock inspection and completed preparations for other alternative measures to minimize the risk.

In parallel, we have been having positive discussions with the FDA on a regular basis to confirm the requirements for resubmission. We are currently working as a team to prepare for the resubmission at the end of March.

Third, as a whole, I feel that we are responding to each of the measures we are taking based on our medium- to long-term growth strategy.

First, we are making progress in expanding and advancing our pipeline for future growth. There have been important developments in each of the growth areas of glaucoma, myopia, presbyopia, and allergies. Mr. Morishima will explain more about the status of each pipeline later.

In terms of reinforcing our management base, plant and DX investments are progressing steadily. As planned, the construction of the new building at the Shiga Plant is almost complete. We will proceed with internal work. Construction of the new plant in Suzhou is also progressing well.

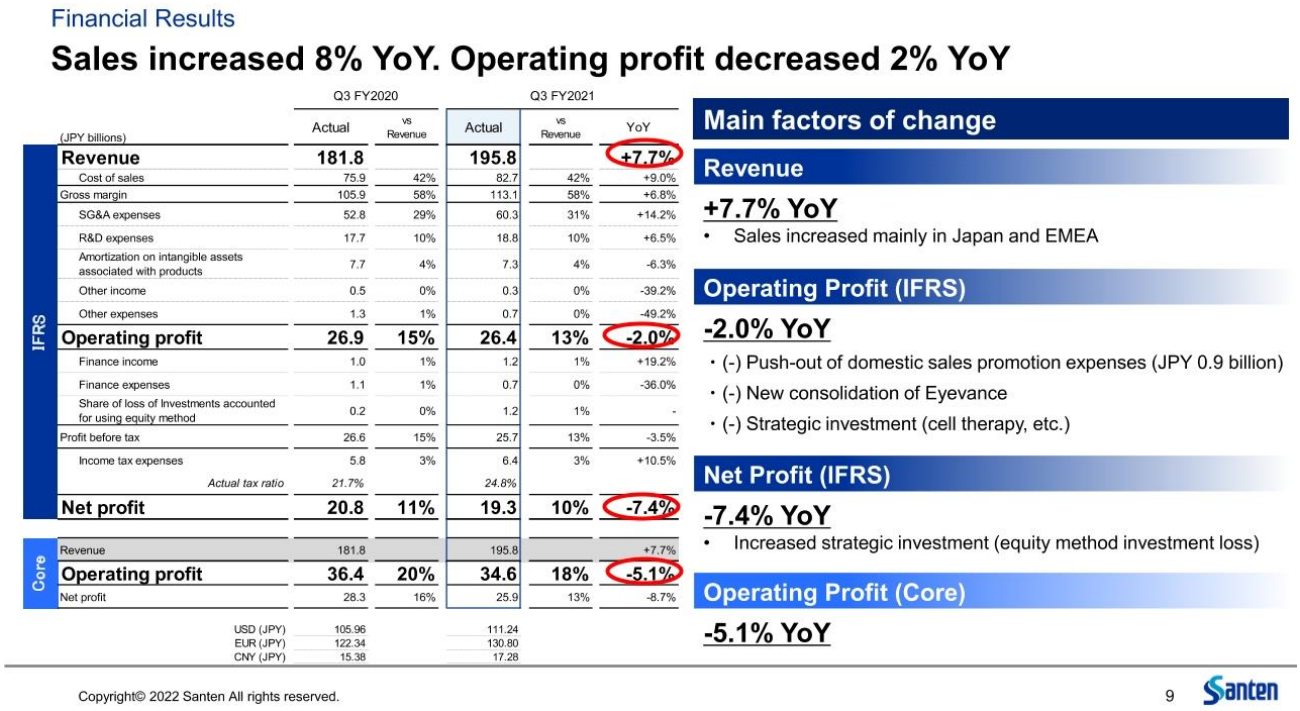
In addition to adding capacity, these plants will be environmentally friendly and digitally integrated. In this way, we aim to contribute to a stable global supply and cost reduction.

As of February 1, we also obtained "Digital Transformation Certification" from the Ministry of Economy, Trade and Industry. We will continue to work on improving our business efficiency and production efficiency by utilizing digital technology.

With regard to DX, we are also working to reform the way we work by utilizing this technology, "Work from Anywhere". The ways of working that do not require time or location restrictions are taking root around the world. In order to reduce costs and fixed assets, we are downsizing the Umeda office and selling the Shimoshinjo office at the same time.

On the other hand, we are aware that the social issues surrounding eyes and ophthalmology continue to be significant while the market environment is still hard across the globe under the impact of COVID-19. In order to capture such growth opportunities in the future, we will steadily implement what we need to do now and continue to work toward growth.

That's all from me. Mr. Koshiji will now present the business results for the third quarter.



Financial Results

Sales increased 8% YoY. Operating profit decreased 2% YoY

	(JPY billions)	Q3 FY2020 Actual	vs Revenue	Q3 FY2021 Actual	vs Revenue	YoY
IFRS	**Revenue**	**181.8**		**195.8**		**+7.7%**
	Cost of sales	75.9	42%	82.7	42%	+9.0%
	Gross margin	105.9	58%	113.1	58%	+6.8%
	SG&A expenses	52.8	29%	60.3	31%	+14.2%
	R&D expenses	17.7	10%	18.8	10%	+6.5%
	Amortization on intangible assets associated with products	7.7	4%	7.3	4%	-6.3%
	Other income	0.5	0%	0.3	0%	-39.2%
	Other expenses	1.3	1%	0.7	0%	-49.2%
	Operating profit	**26.9**	**15%**	**26.4**	**13%**	**-2.0%**
	Finance income	1.0	1%	1.2	1%	+19.2%
	Finance expenses	1.1	1%	0.7	0%	-36.0%
	Share of loss of Investments accounted for using equity method	0.2	0%	1.2	1%	-
	Profit before tax	26.6	15%	25.7	13%	-3.5%
	Income tax expenses	5.8	3%	6.4	3%	+10.5%
	Actual tax ratio	*21.7%*		*24.8%*		
	Net profit	**20.8**	**11%**	**19.3**	**10%**	**-7.4%**
Core	Revenue	181.8		195.8		+7.7%
	Operating profit	**36.4**	**20%**	**34.6**	**18%**	**-5.1%**
	Net profit	28.3	16%	25.9	13%	-8.7%
	USD (JPY)	105.96		111.24		
	EUR (JPY)	122.34		130.80		
	CNY (JPY)	15.38		17.28		

Main factors of change

Revenue

+7.7% YoY

- Sales increased mainly in Japan and EMEA

Operating Profit (IFRS)

-2.0% YoY

- (-) Push-out of domestic sales promotion expenses (JPY 0.9 billion)
- (-) New consolidation of Eyevance
- (-) Strategic investment (cell therapy, etc.)

Net Profit (IFRS)

-7.4% YoY

- Increased strategic investment (equity method investment loss)

Operating Profit (Core)

-5.1% YoY

Koshiji: This is page nine. This is the cumulative income statement for the third quarter.

Exchange rates by currency are shown at the bottom of the income statement. The US dollar increased by 5%, the euro by 7%, and the Chinese yuan by about 12% compared to the previous year, which has impacted the revenue, cost and profit on PL sheet.

Sales grew by 7.7%, but the foreign exchange factor was 3%. Profit items were affected by the depreciation of the yen to the tune of approximately 4%. In particular, sales and gross margin grew by 7.7% and 6.8%, respectively, but SG&A expenses increased by 14.2%, and R&D expenses by 6.5% compared to the previous year. This resulted in a decrease in operating profit.

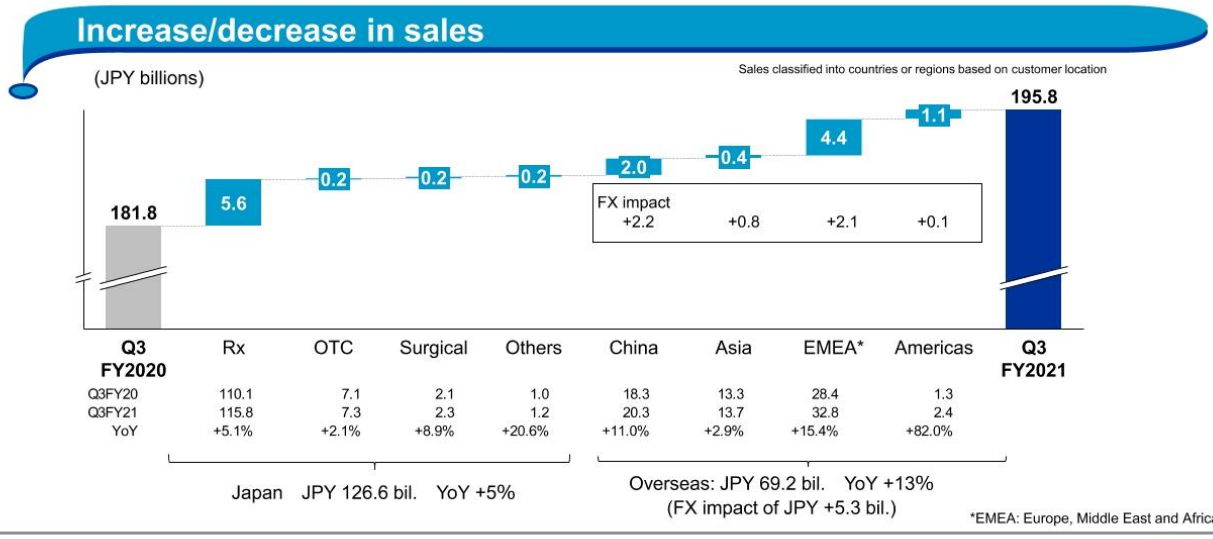
However, the reason for this increase in expenses is, as mentioned in the second quarter, the push-out of domestic sales promotion expenses and accounting treatment. In addition, it has taken some time for Eyevance, which we acquired in the US two years ago, to become profitable. This was expected to contribute to an increase in profit compared to the previous year, but as of the cumulative Q3 result, this has not been the case.

I'll say a little more about research and development expenses. In the past, there were many cases where R&D expenses went unaccounted for due to cancellations during the fiscal year, but this fiscal year, development is progressing smoothly and expenses are making the same progress. This is the situation.

This concludes the summary of the income statement.

Financial Results

Sales grew 8% YoY, main increases in Japan and EMEA



Page 10 provides details of changes in sales figures.

The factors on the left are for Japan, and those on the right are for overseas. These show the change from the previous year's figures for each factor. The impact of exchange rates is also shown.

FY2021 Forecasts

Unchanged from May 11th. Focusing on maximizing 4th quarterly profit

	(JPY billions)	FY2020 Actual after retroactive correction	FY2020 vs Revenue	FY2021 Forecast	FY2021 vs Revenue	FY2021 YoY
IFRS	**Revenue**	**249.6**		**260.0**		**+4.2%**
	Cost of sales	98.2	39%	101.0	39%	+2.8%
	Gross margin	151.4	61%	159.0	61%	+5.0%
	SG&A expenses	79.6	32%	81.4	31%	+2.3%
	R&D expenses	24.1	10%	26.0	10%	+7.8%
	Amortization on intangible assets associated with products	10.7	4%	8.9	3%	-16.4%
	Other income	16.0	6%	0.5	0%	-96.9%
	Other expenses	40.9	16%	1.7	1%	-95.8%
	Operating profit	**12.2**	**5%**	**41.5**	**16%**	**+240.5%**
	Finance income	1.3	1%	0.9	0%	-33.2%
	Finance expenses	1.5	1%	0.2	0%	-86.6%
	Investment loss by equity method	0.4	0%	1.2	0%	+235.5%
	Profit before tax	11.7	5%	41.0	16%	+250.8%
	Income tax expenses	2.6	1%	10.5	4%	+309.8%
	Actual tax ratio	*21.9%*		*25.6%*		
	Net profit	**9.1**	**4%**	**30.5**	**12%**	**+234.2%**
	ROE	3.0%		10%		--
Core	Revenue	249.6		260.0		+4.2%
	Operating profit	**50.1**	**20%**	**52.0**	**20%**	**+3.8%**
	Net profit	37.5	15%	39.0	15%	+4.0%
	USD (JPY)	105.95		105.00		
	EUR (JPY)	123.73		125.00		
	CNY (JPY)	15.61		16.50		

Revenue

+4% YoY

- Sales expected to increase YoY on sales growth in each region
- High likelihood of upside given foreign exchange rate levels

Operating Profit (IFRS)

+241% YoY

- Strengthen cost control in 4th quarter
- Absence of FY2020 impairment loss
- Also, increase in profit as a result of a decline in amortization of intangible assets related to products

ROE (IFRS)

- Improving capital efficiency (e.g. intangible asset management, reduction of investment securities)
- Aim ROE at 10%

Operating Profit (Core)

+4% YoY

- Aiming for well-balanced profit growth by maximizing sales
- SG&A expenses: control as a percentage of sales
- R&D expenses: within JPY 26.0 billion including strategic investment

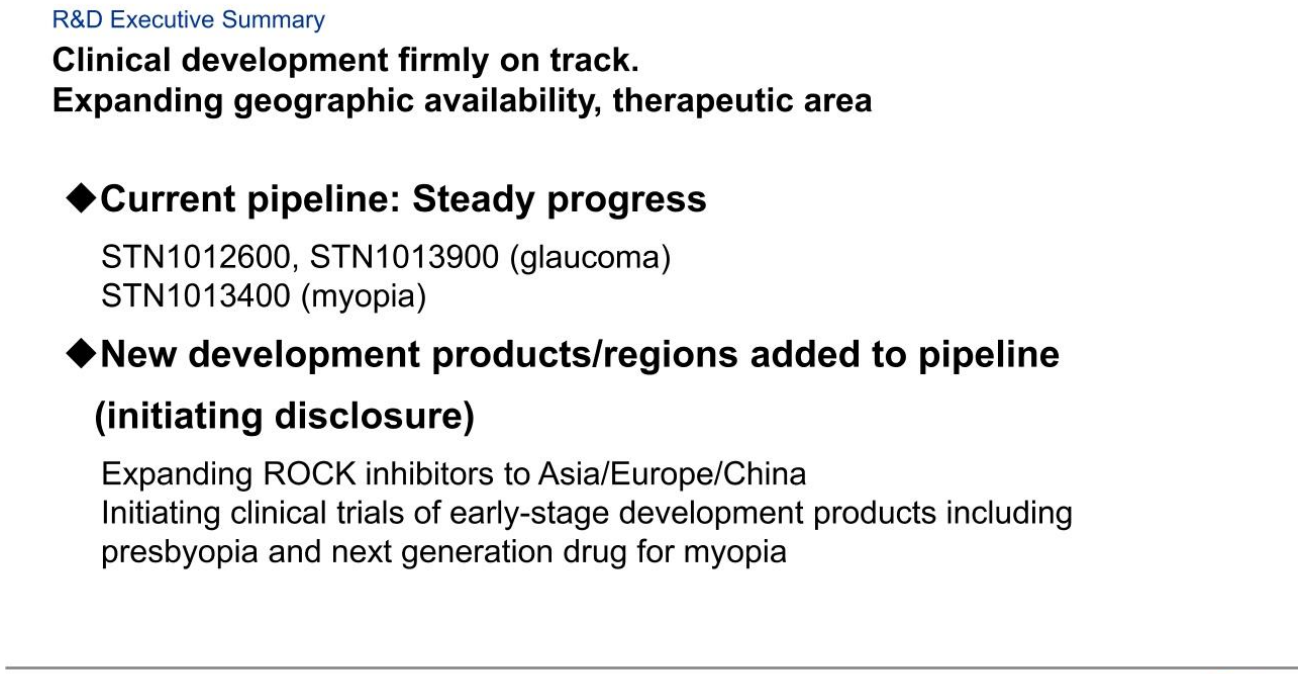
This is page 11. This is the full-year earnings forecast for the current fiscal year. This is unchanged from the disclosure at the beginning of the fiscal year.

Looking at the progress to the full-year forecast in Q3, we see progress in the neighborhood of 65%. In the fourth quarter QTD, we will maximize sales and profits in order to achieve the full-year forecast. That is how we see this.

As mentioned in the appendix, the quarterly weighting of our sales, expenses, and profits tends to vary relatively. In the past, our tendency has been to overweight expenses in the fourth quarter.

For the current fiscal year, we intend to control the factors affecting the figures in Q4. Another factor affecting this year's budget is the delay in the launch of STN1011700 in the US, as mentioned earlier. We had factored in a considerable amount of costs in Q4 for promotion and preparation for the launch, but we have been able to reduce these costs. Including these factors, we believe that we will achieve our full-year forecast by optimizing all of our efforts to control expenses and maximize sales in Q4.

That's all from me.

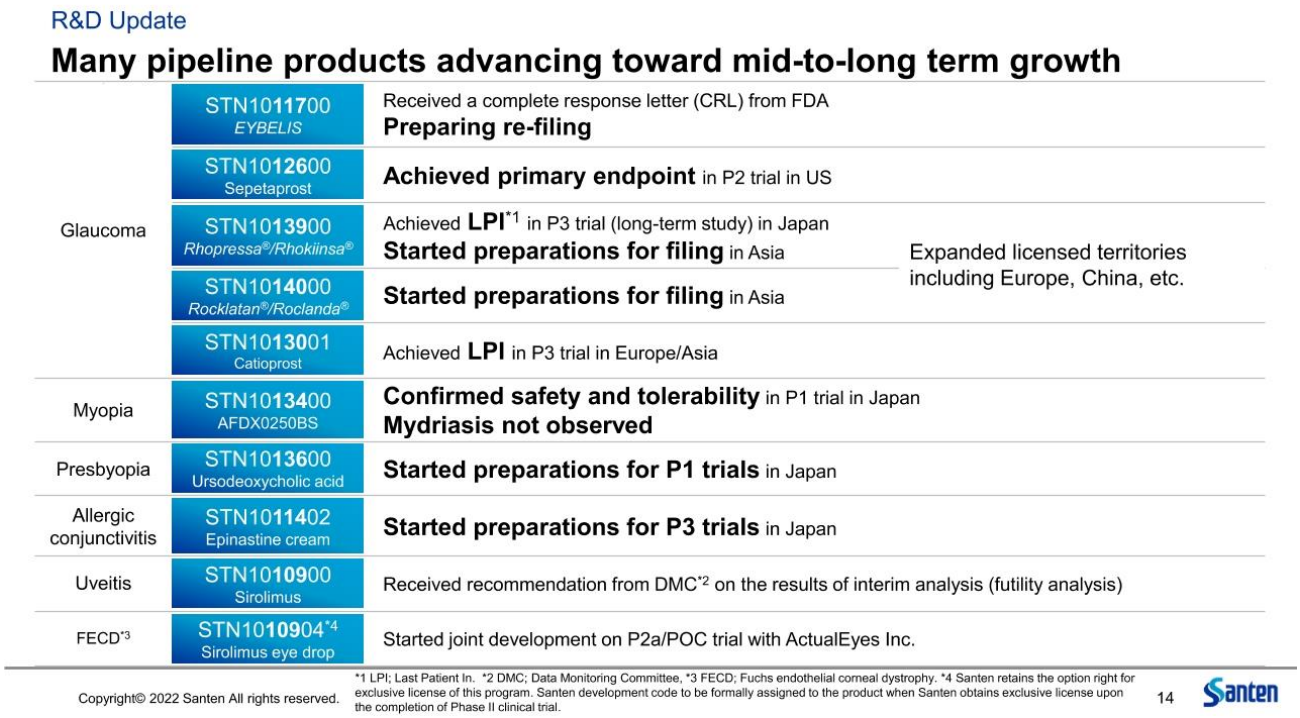


Morishima: Thank you.

Please see page 13.

First, we have STN1011700, as mentioned earlier by Mr. Taniuchi. We are seeing a clear path ahead for this therapy after swiftly addressing the CMO (Contract Manufacturing Organization) issue, and moving forward with reapplication in the US. We have five glaucoma medications in development, including STN1012600 and STN1013900. Also, there is STN1013400. STN1012700 is being developed in Japan and China, and late-stage development is progressing well for compounds such as STN1012701 in the US for prevention of myopia progression.

In addition, we have expanded the territory of ROCK inhibitors and started clinical trials for early-stage development of treatments for conditions such as next-generation myopia and presbyopia. These trials are progressing well, and demonstrate the breadth of our portfolio.



Next, please. From page 14, I will explain the progress of each item in Q3.

As for STN1011700, as we have already reported, we are preparing to reapply in March.

The US Phase II study of STN1012600 was completed six months ahead of schedule and met its primary endpoint. We will provide more detailed data later.

As for the ROCK inhibitor STN1013900 and its combination drug STN1014000, patient enrolment has been completed in Phase III trials for STN1013900 in Japan. We have also started to prepare for applications in Asia. In December last year, we expanded the licensed territory to Europe and China. In Europe, where Aerie has already obtained marketing approval, we have completed the regulatory transfer.

STN1013400, which is expected to be the next generation myopia treatment following the next atropine product, has been confirmed to be safe and well tolerated in Phase I trials. In this study, mydriasis was not observed, and I feel that the results were positive, at least in terms of safety, regarding the concept of separation between drug efficacy and mydriasis by increasing the receptor selectivity of muscarinic antagonists. We will confirm the efficacy of the drug in the next stage, but we believe this is a big first step that will create a clear differentiator from atropine.

The concept for STN1013600, a compound for presbyopia, was introduced at the product development meeting. This compound is scheduled to start Phase I trials this fiscal year. The mechanism of action is completely different to that of pilocarpine, which uses the pinhole effect to improve nearsightedness for a short period of time. We believe that this re-positioning approach of taking a new perspective to existing compounds typifies Santen's development style. We are considering developing it worldwide.

In addition, we will start Phase III trials of STN1011402, the next new formulation to follow *Alesion LX*, by the end of this fiscal year. We have already obtained the POC (Proof of Concept) data, which we will introduce later.

Finally, STN1010900 targets a rare disease, posterior uveitis. We have received a recommendation for interim analysis from the Independent Data Monitoring Committee, which is composed of third parties. Based on that result, we are now moving ahead with the trial. We are considering accelerating the operational timeline of the trial, such as the enrollment of patients.

+

STN1011402: Initiation of P3 Study Preparation of Epinastine HCl New Formulation

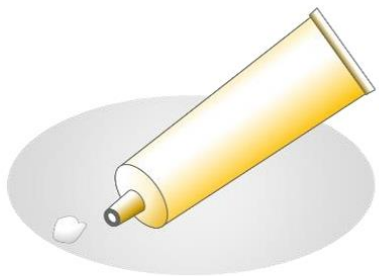
Ensure all-day comfort for patients,
advancing the concept of proactive treatment

Target product profile

- Application: **Allergic conjunctivitis**
- Formulation: **Ophthalmic cream**
- Administration frequency:

  Once a day; same efficacy level

  as ophthalmic solution maintained for one day



The next slide is slide 15.

This slide shows the product concept for the new *Alesion* formulation, STN1011402.

As we introduced at our Medium-term Plan briefing last year, we have been developing this product as a new concept product that will bring significant QOL improvements to patients. We aim to promote proactive treatment to prevent symptoms of itchiness caused by allergies.

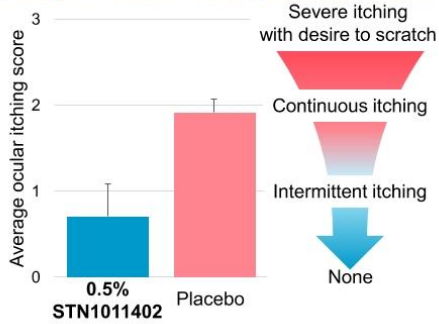
The main feature of this product is that it is a cream formulation. With this, we aim to create a new, sustained effect product that can be administered just once a day. This has not been realized with eyedrops.

We believe that this will relieve symptoms of itchiness for patients throughout the day, even during the allergy season. In particular, we have heard that there is an unmet medical need for allergy eyedrops, where people are unable to sleep due to itching. This product is expected to deal with this type of unmet medical needs.

STN1011402: Initiation of P3 Study Preparation of Epinastine HCl New Formulation

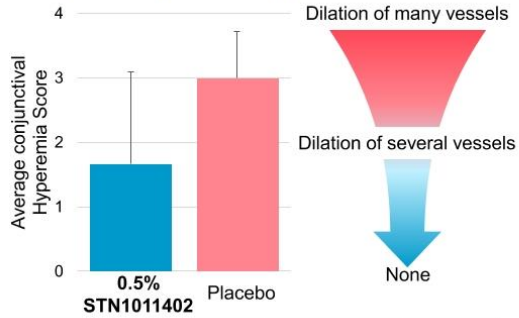
POC*1 study showed statistically significant difference between once a day STN1011402 and placebo

Efficacy on ocular itching after 25 hours



Treatment group (n)	Mean (SD)	Diff (STN1011402 VS placebo)	P value*2
0.5% STN1011402 (n=8)	0.71 (0.375)	-1.21 (0.396)	P=0.0001
Placebo (n=8)	1.92 (0.154)		

Efficacy on conjunctival hyperemia after 25 hours



Treatment group (n)	Mean (SD)	Diff (STN1011402 VS placebo)	P value*2
0.5% STN1011402 (n=8)	1.67 (1.425)	-1.33 (1.234)	P=0.0185
Placebo (n=8)	3.00 (0.713)		

*1 POC (Proof of Concept): to demonstrate the development concept. In development of a new drug, it means the efficacy/safety of the candidate is confirmed in humans. *2 Corresponding t-test
16

The next slide of slide 16 shows the results of the POC study, which will be the basis for the Phase III study to be conducted.

The details of the study design are described in the Appendix. The same subject received the study drug to one eye and placebo to the other, and 25 hours after administration, an antigen was administered to induce allergy. We compare and observe the inhibitory effects in both eyes.

This slide shows graph and table on the important endpoints of itching and conjunctival hyperemia.

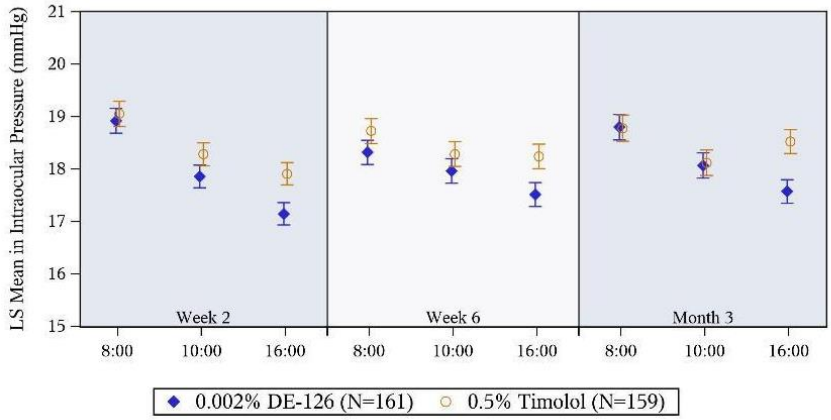
As you can see, there was a statistically significant reduction in itching and conjunctival hyperemia compared to placebo. The improvement in this score is from itchy to not itchy, and the degree of hyperemia has improved from many blood vessels being hyperemic to few or none.

In a different study, compared to previous data, we expect it to be as effective as the existing *Alesion* ophthalmic solution even after 24 hours of administration.

STN1012600: Result of Additional P2 Study in US

Achieved primary endpoint in the timolol-controlled study

Intraocular Pressure: Least Square Mean (+/- Standard Error) by Analysis Visit and Timepoint (Study Eye)



- Statistical non-inferiority of STN1012600 to timolol was confirmed at all points observed
- Intraocular pressure with STN1012600 at 16:00 of each observed day was statistically lower than that with timolol

This is page 17. This slide shows the results of the US Phase II study for STN1012600, which is being developed as an intraocular pressure lowering agent.

The primary endpoint of the study was non-inferiority of STN1012600 once-daily ophthalmic solution to timolol twice-daily ophthalmic solution, and the primary endpoint was met at all time points.

Especially at the 16:00 point on the measurement day, there was a statistically significant difference, with the value lower than that of timolol. This indicates the stable IOP effect of the drug over a long period of time.

Based on the results, we will consider the plan for Phase III trials.

That is all.

Question & Answer

Q-1-1

The first question is about cost/gross profit margin. As you can see on page 20 and page 21, the quarterly trend has worsened in Q3 compared to the first half. Are there any causative factors other than the product mix? Regarding the anticipated improvement in Q4, is it mainly SG&A expenses or can we expect an improvement in the gross profit margin as well?

Financial Results (IFRS)

Quarterly consolidated statements of income

(JPY millions)	FY2020 Q1	Q2	Q3	Q4	Full	FY2021 Q1	Q2	Q3	Q4	Full	FY2021 Full-year Forecast
Revenue	57,563	61,342	62,881	67,819	249,605	64,986	63,773	67,042			260,000
YoY	-2.7%	2.9%	-1.1%	14.5%	3.3%	12.9%	4.0%	6.6%			4.2%
Cost of sales	-24,741	-24,964	-26,192	-22,324	-98,221	-26,924	-25,943	-29,837			-101,000
YoY	2.6%	3.2%	0.5%	9.0%	3.6%	8.8%	3.9%	13.9%			2.8%
(Percent of revenue)	43.0%	40.7%	41.7%	32.9%	39.4%	41.4%	40.7%	44.5%			38.8%
Gross profit	32,822	36,377	36,690	45,495	151,384	38,062	37,829	37,205			159,000
YoY	-6.3%	2.6%	-2.1%	17.4%	3.2%	16.0%	4.0%	1.4%			5.0%
(Percent of revenue)	57.0%	59.3%	58.3%	67.1%	60.6%	58.6%	59.3%	55.5%			61.2%
SG&A expenses	-15,551	-17,691	-19,579	-26,732	-79,554	-20,447	-19,205	-20,671			-81,400
YoY	-3.1%	1.8%	0.9%	30.2%	8.4%	31.5%	8.6%	5.6%			2.3%
(Percent of revenue)	27.0%	28.8%	31.1%	39.4%	31.9%	31.5%	30.1%	30.8%			31.3%
R&D expenses	-5,616	-5,507	-6,530	-6,459	-24,112	-6,121	-6,218	-6,464			-26,000
YoY	-9.0%	5.1%	13.8%	4.4%	3.3%	9.0%	12.9%	-1.0%			7.8%
(Percent of revenue)	9.8%	9.0%	10.4%	9.5%	9.7%	9.4%	9.7%	9.6%			10.0%
Amortization on intangible assets associated with products	-2,448	-2,430	-2,866	-2,907	-10,650	-2,421	-2,366	-2,468			-8,900
YoY	-1.2%	-1.2%	15.7%	16.7%	7.6%	-1.1%	-2.6%	-13.9%			-16.4%
(Percent of revenue)	4.3%	4.0%	4.6%	4.3%	4.3%	3.7%	3.7%	3.7%			3.4%
Other income	176	174	174	15,483	16,007	120	82	116			500
Other expenses	-1,367	-253	330	-39,599	-40,889	-39	-473	-143			-1,700
Operating profit	8,016	10,670	8,219	-14,718	12,187	9,156	9,650	7,575			41,500
YoY	-13.3%	9.3%	-17.2%	—	-63.7%	14.2%	-9.6%	-7.8%			240.5%
(Percent of revenue)	13.9%	17.4%	13.1%	—	4.9%	14.1%	15.1%	11.3%			16.0%

Reprinted from Q3 FY21 Data Book

Financial Results (Core Basis)

Quarterly consolidated statements of income

(JPY millions)	FY2020 Q1	Q2	Q3	Q4	Full	FY2021 Q1	Q2	Q3	Q4	Full	FY2021 Full-year Forecast
Revenue	57,563	61,342	62,881	67,819	249,605	64,986	63,773	67,042			260,000
YoY	-2.7%	2.9%	-1.1%	14.5%	3.3%	12.9%	4.0%	6.6%			4.2%
Cost of sales	-24,741	-24,964	-26,192	-22,324	-98,221	-26,924	-25,943	-29,837			-101,000
YoY	2.6%	3.2%	0.5%	9.0%	3.6%	8.8%	3.9%	13.9%			2.8%
(Percent of revenue)	43.0%	40.7%	41.7%	32.9%	39.4%	41.4%	40.7%	44.5%			38.8%
Gross profit	32,822	36,377	36,690	45,495	151,384	38,062	37,829	37,205			159,000
YoY	-6.3%	2.6%	-2.1%	17.4%	3.2%	16.0%	4.0%	1.4%			5.0%
(Percent of revenue)	57.0%	59.3%	58.3%	67.1%	60.6%	58.6%	59.3%	55.5%			61.2%
Operating profit	11,655	14,035	10,738	13,673	50,101	11,713	12,593	10,247			52,000
YoY	-8.9%	9.3%	-13.0%	13.5%	0.2%	0.5%	-10.3%	-4.6%			3.8%
(Percent of revenue)	20.2%	22.9%	17.1%	20.2%	20.1%	18.0%	19.7%	15.3%			20.0%

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A-1-1

Koshiji : The fall in the gross profit margin in Q3 compared to the first half of this cumulative period is mostly due to the product mix. As for the manufacturing cost, we have achieved cost reduction below the standard cost that we set at the beginning of the fiscal year, but that is due to the product mix. This is especially true in relation to *Eylea* in Japan, which is higher than expected if you look at the sales details.

As for the cost-to-sales ratio for the full year, we expect it to decline in Q4. This is the annual trend: in Q4 of the preceding fiscal year, for example, the QTD was just under 33%, which is 8% to 9% lower than the cumulative total for the previous three quarters.

If you look at the details of individual items in the Summary of Financial Results for the current fiscal year on page 18, you will see that the sales forecast for *Alesion* for the fourth quarter of the current fiscal year is approximately JPY18.0 billion. We believe that the cost ratio will be reduced by factoring in these effects. Thank you.

Q-1-2-1

The second question is about STN1012600, on page 17. Do you think that the intraocular pressure-lowering effect you mentioned here is enough to differentiate this product? Or, if there are other expected points of differentiation? What kind of profile do you think you can develop in the future, including those points?

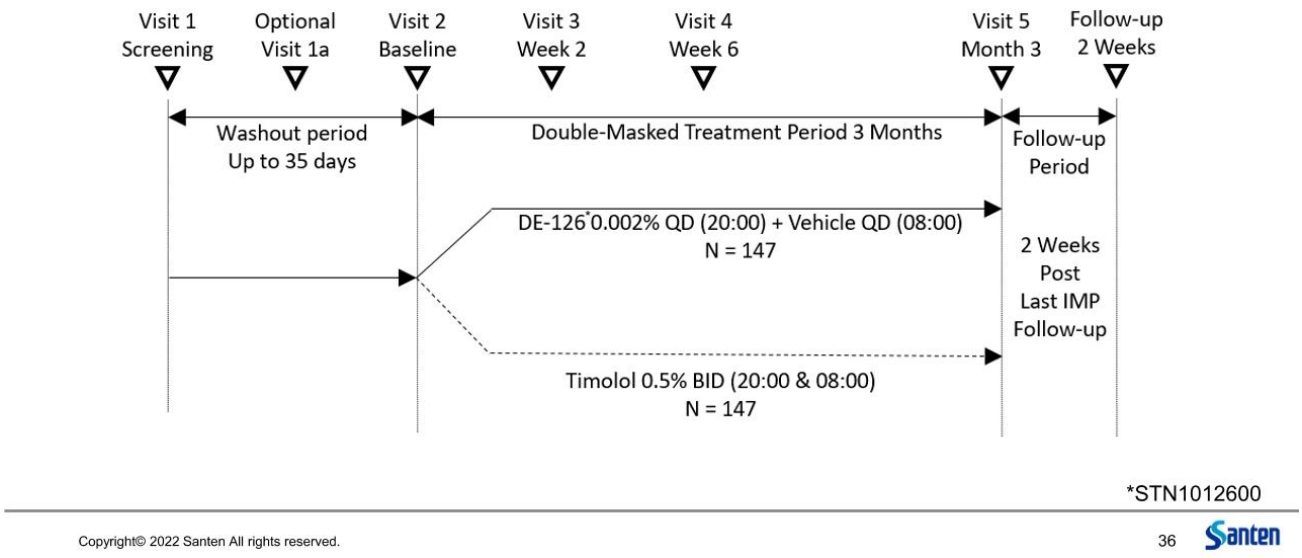
A-1-2-1

Morishima :

I think the first and most important point is that this drug has sufficient efficacy as an intraocular pressure lowering agent. Since the market is highly competitive, we are currently conducting exploratory trial in Europe to see if we can make a difference, especially in terms of sustained efficacy. At the very least, we believe that it can be one of the most potent intraocular pressure lowering agents.

Q-1-2-2

The dosing method described on the supplementary page is once a day, and I think there are a number of other existing once-a-day drugs. Are you trying to explore the possibility of extending the interval further?



A-1-2-2

Morishima:

Even with once-daily medication, there is a slight tendency for the intraocular pressure to return during the day. This is also the case with prostaglandins. Even with twice-daily timolol, there are cases where IOP is not sufficiently lowered during the dosing interval. This is a characteristic of current therapeutic drugs. We are aiming for a profile that reduces the weakening of efficacy within a day after the administration.

Q-2-1-1

Firstly, about the change in the sales channel mix in China. Can you give us a recent figure of the percentage of large national hospitals? That's the first question.

A-2-1-1

Suzuki:

In the first half of the current fiscal year, about 40% to 80% of our core products, depending on the product, were sold through so-called retail and private hospital channels rather than large national hospitals.

Therefore, the shift to non-public is continuing.

Q-2-1-2

Do you have any data from the third quarter?

A-2-1-2

Suzuki: Not at present.

Q-2-2-1

Understood. The other question is about STN1011700. How should we consider the timing of the FDA's re-inspection, and how long should we expect the review process to take after re-submission?

A-2-2-1

Morishima:

While we are not a direct party to discussions on the site inspection, we have heard that the inspection by the FDA will take place soon. It is up to the FDA to decide whether there will be an inspection of our product at the time of application. At present, it is not a certainty that there will be a product inspection.

Regarding the lead time from the re-submission to the approval, I have heard that it basically takes about six months in this kind of case.

Q-2-2-2

Just to confirm, if that's the case, can we assume that whether or not a re-inspection will be conducted is independent of re-submission?

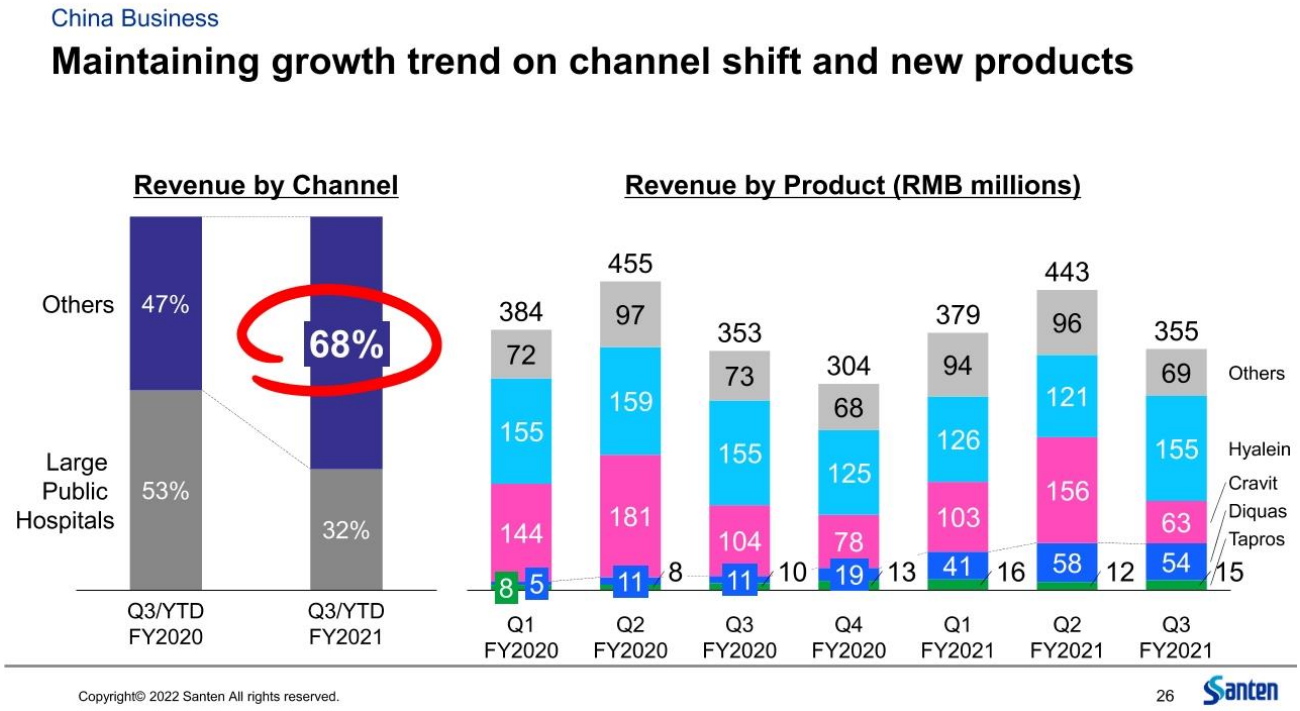
A-2-2-2

Morishima:

I heard that the basic lead time is about six months, even if there is a re-inspection.

Q-3-1-1

I am looking at slide 26, concerning sales in China. I see sales of *Cravit* in China from Q2 to Q3. Looking at Q2, it seems the YoY decline was getting smaller. However, when I look at YoY for Q3, I see a rather large decrease. Is there any specific cause for the decrease here?



A-3-1-1

Suzuki:

Usually, there is a slight fluctuation over National Day, which is in October. However, in this case, the main factor relates to the coronavirus. In Japan, for example, the symptoms of coronavirus infection include conjunctivitis in about 30% of patients. If the symptoms subside, the diagnosis of coronavirus can be adversely affected. So, guidelines have been issued to curb use of this medication in pharmacies.

Therefore, going back to the answer to the aforementioned question, as use of the drug is increasing in pharmacies, this policy has had an impact on sales. That's the main factor.

Another is that in the run-up to the Olympics, there have been lockdowns and restrictions on movement, and this has also led to restrictions on prescriptions.

However, in spite of these two points of seasonality and coronavirus-related issues, if you look at private and public hospitals, the trend in prescription numbers is solid there. I hope you can understand that this is a special situation affecting pharmacies in particular.

Q-3-1-2

So this is a transitory factor. Basically, sales to the national and public sectors have become quite small, so except for this transitory factor, *Cravit*'s sales have almost bottomed out, and the point where we can return to the revenue growth trend from here has not changed.

A-3-1-2

Suzuki: Yes. I think that's accurate.

Q-4-1-1

The first thing I would like to know is how you intend to achieve the plan. As mentioned earlier, sales have been steady, but gross profit has been a little low. How will you cover gross profit in order to achieve operating income? Also, can the reduction in gross profit be covered by reduced SG&A and R&D expenses? I have a feeling that it will be difficult to achieve a significant amount of gross profit as expected for the plan, so could you give us some more details?

A-4-1-1

Koshiji:

First of all, on page 11, our forecast for full-year sales is JPY260 billion. As noted on the right side of the page, considering the depreciation of the yen, although we set this figure at JPY260 billion at the beginning of the fiscal year, we believe that it is highly likely that it will increase to around JPY270 billion.

On the other hand, while we expect gross profit to rise, there is also the point of SG&A expenses and R&D expenses. R&D expenses will remain the same as these figures, but we believe that SG&A expenses may be higher than this JPY81.4 billion figure.

However, based on sales, the ratio of profit to sales, will be controlled to the level of the second column from the right in the total amount, so that even if expenses increase, the core operating profit will be close to JPY52 billion. We are considering such PL control.

Because of this situation, we have not made any changes to our earnings forecast on a profit basis, but you can expect sales to be slightly higher than these figures.

Q-4-1-2

In that case, even if the gross profit margin goes down, the amount will go up due to the increase in sales, which will result in achieving profit overcoming the increase in SG&A expenses. Is that correct?

A-4-1-2

Koshiji:

Yes, that is what we are thinking. However, as is the case every year, sales will depend considerably on the pollen season and sales of *Alesion* in the Japan business. Based on our conservative forecast, we believe that sales will be in the neighborhood of JPY270 billion.

Q-4-2

Secondly, I would like to know about the safety profile of the development item STN1013400. I think one of the points of STN1012700 is that it may be able to relatively suppress mydriasis compared to other atropine preparations. Could you please comment on whether this compound has a good profile, even compared to STN1012700?

A-4-2

Morishima:

The main reason why we cannot expect great efficacy from STN1012700 atropine is that mydriasis begins to occur, and the balance gap between efficacy and safety is very narrow. Although numerous data have shown that the efficacy of atropine can be increased by increasing the concentration, I think that STN1012700, or the profile of any atropine formulation, is limited by the presence of mydriasis.

On the other hand, our new next-generation inhibitor does not cause mydriasis. Although there may be other adverse events, we believe that we can increase the dose to achieve greater efficacy. We are developing the drug based on the idea that the efficacy profile is expected to be higher than that of atropine.

Q-5-1-1

I'd also like to ask about the gross profit margin. I saw that sales of *Eylea* didn't change that much between Q1 and Q2, and sales of *Alesion* decreased a little bit. If you look at the other products, they didn't change that much.

So, I can't understand why there is suddenly a 4% fall here. Is it possible that *Eylea*'s gross profit margin was good at the beginning of the fiscal year and gradually deteriorated, or is it possible that the gross profit margin will drop further as sales become very large? I don't understand the cause of this change.

A-5-1-1

Koshiji:

In that respect, the cost ratio of *Eylea* has not changed during the fiscal year. The ratio of *Eylea* to overall sales is increasing. That is the main reason.

In addition, we have not observed an increase in the cost ratio of our in-house products relating to manufacturing costs. Although *Eylea* is not the whole story, we are aware that the situation is the result of a change in product mix between purchased products and our in-house products.

Q-5-1-2

That would mean that the number of products from other companies besides *Eylea* has increased. Which product or products have increased?

A-5-1-2

Koshiji:

Although the majority is from *Eylea*, we have a number of products with different cost ratios, and I hope you understand that this change in product mix is the cause.

Q-5-1-3

Eylea is not affected by the depreciation of the yen or anything like that, is it? I think the gross profit margin is fixed at 20%.(Post-script by Santen: this is the view of analyst)

A-5-1-3

Koshiji:

That is correct. I would like to make a supplementary explanation about the cost ratio that was mentioned earlier.

This is regarding the purchase products other than *Eylea*. For example, for the European market, we used to manufacture products at our plant in Finland, but since we sold the plant to an external company, Next Pharma, we purchase from their CMO. From there, the timing of recording the cost

of purchasing products came out in a slightly irregular way in the third quarter. There are a few things that need to be taken into account.

I would like to add that there is a slight accounting bias in the product mix, and this is also associated with the product mix.

Q-6-1-1

I would like to ask you one question regarding the reapplication for STN1011700 in the US at the end of March.

As may have been explained, I understand that it is only possible to apply if the contract manufacturer has been inspected and approved. In other words, these two are sequential, is that correct?

A-6-1-1

Kimura:

As I mentioned in my previous report, the CRL indicated that there was a GMP compliance issue with another company's product, so this re-inspection is not of our company, but rather a re-inspection to confirm the correction of the issues raised with the other company's product. As you say, it is indeed sequential.

Q-6-1-2

They are connected, aren't they? So if there is a delay, for example, it will affect your company. If it gets the OK, then your company can apply as is, right?

A-6-1-2

Kimura:

That's right. At this point in time, we are in close communication with the CMO, but our understanding is that the FDA needs to re-inspect. In addition, the timing of the re-inspection has been announced.

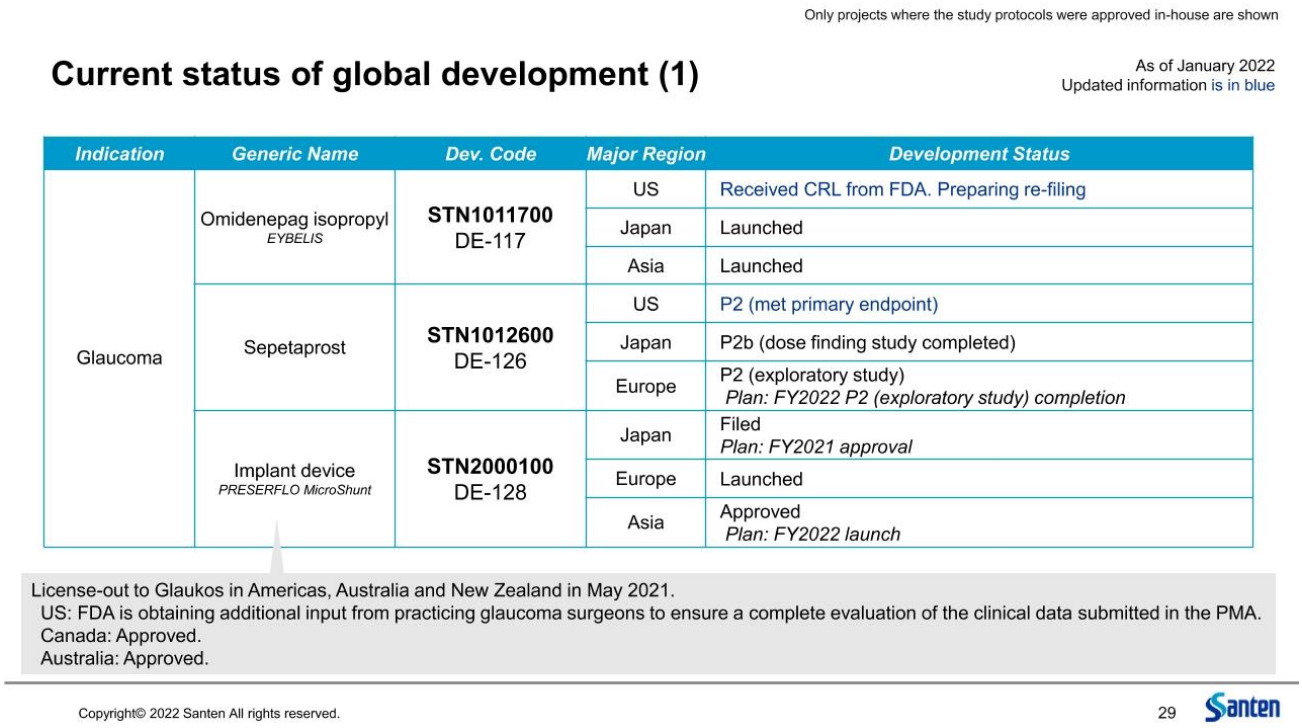
So, we are aiming to apply in March.

Q-7-1-1

At the bottom of page 29, the balloon below the *MicroShunt* section says that the FDA is collecting additional information from practicing glaucoma surgeons.

When I asked about the topic in November, I understood this was done by the FDA at an expert meeting. This is currently pending, but is it correct to say that this is now a step forward?

Collection of input is in progress, so if you have a timeline of when this will be completed, please let us know.



A-7-1-1

Morishima:

Since then, we have received information that the FDA is interviewing experts to gather expert opinion.

We are expecting them to start communication with us after the information gathering is complete. The exact timeline has not yet been communicated, but we expect to have some kind of response soon.

Q-7-1-2

What kind of additional information is being requested?

A-7-1-2

Morishima:

Basically, we have already disclosed the data itself, and we have provided information that the effect was slightly weaker than that seen with a trabeculectomy.

We believe that the effectiveness of the device itself should not be evaluated on the basis of effectiveness alone, but relative to a trabeculectomy, which is quite an involved procedure. The effectiveness should be evaluated also on its totality of benefit/risk, including its simple procedure and follow up.

The FDA has taken our suggestion seriously and is collecting information from experts in this area.

[END]