Conference Call on Q1 FY2020 Results

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Santen
Imagine Your Happiness

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CORE PRINCIPLE and WORLD VISION

CORE PRINCIPLE

天機に参与する

Tenki ni sanyo suru

"Exploring the secrets and mechanisms of nature in order to contribute to people's health" *

WORLD VISION

Happiness with Vision

The Happiest Life for every individual, through the Best Vision Experience

* Santen's original interpretation of a passage from chapter 22 of Zhongyong (The Doctrine of the Mean) by Confucius.

Taniuchi: This is our core principle which we always mention, and world vision: Happiness with Vision. As I have been saying, I believe our world vision, which I announced last time, stems from our basic mission statement. I intend to continue to work toward the goal of Happiness with Vision in the future.

Q1 FY2020 Highlights

1. **Revenue: JPY 57.6bil, Core OP: JPY 11.7bil**
   Q1 results were in line with expectations

2. **Entering the US market: Steady progress**
   Completed FDA rolling submission for DE-128 to provide new value to patients

3. **New measures in line with our long-term vision**
   Addressing unmet needs through alliances with jCyte, Plano and Osmotica

Taniuchi: I would like to talk about the highlights of the first quarter.

We achieved net sales of JPY57.6 billion and core operating income of JPY11.7 billion. In this section, there are some factors between individual financial results, but as a whole, we believe that they are in line with our assumptions.

The second point is that we are making steady progress toward entering the US market. From the standpoint of our activities in the current fiscal year, our medium-term management plan and long-term vision, entry into the US market is a major challenge for us, and we believe this is a major opportunity. We have successfully completed our FDA filling for DE-128, *PRESERFLO MicroShunt*.

Even with the current COVID-19 situation, this completed application is the accumulated result of a significant effort. The team will continue to work together until the application is approved, the product is launched, and the product is delivered to patients.

Thirdly, I would like to mention the measures related to the long-term vision that I discussed recently, as well as the activities that I have been working on for some time. In recent years, we have been able to acquire opportunities in new fields, such as the partnership with jCyte, Inc. or Plano Pte. Ltd., which has already been announced, as well as a company called Osmotica Pharmaceuticals Plc., in the area of ptosis.

This is not just a treatment, but part of an interesting field that spans medical treatment and wellness. We will continue to work with great excitement on how to develop this field and how to put it into operation in the future.

Mr. Morishima will also explain this topic later.

Taniuchi: We are working on a variety of initiatives globally to respond to COVID-19. While we are working on both internal and external initiatives, I will first summarize what we are doing for external stakeholders.

We have thought about what support we are able to provide. The first is that we are distributing these slit lamp shields. While this will depend on various factors of timing and regulations by country, we intend to distribute it worldwide.

I am sure that some of you have experienced this before, but during an eye examination, the patient and the doctor have to come into close contact, so that the eye can be properly examined with a slit lamp. It is also impractical to use a face shield. Under these circumstances, we are engaged in a variety of initiatives, and we listen to the opinions of patients and their doctors about what kind of slit lamp shields might be good, and make sure that they are being prepared.

We are also working to provide information to the general public about eye conditions. We anticipate that there may be an increase in eye conditions associated with increased remote working, and people spending less time outside. As a leading ophthalmology company, we engage in a variety of activities, such as providing information to patients who are in trouble because of their inability to trust information. And we are also using webinars to provide ophthalmologists with COVID-19-related and general information.

Taniuchi: We have been working internally on this since May. We are developing a work style that is not restricted by time and place. We are reviewing the response to various human resources rules and the further utilization of technology at the global level. Basically, we are building an environment in which employees around the world can work without visiting a physical office. We are also ensuring that a variety of administrative procedures can be completed without going to the company.

As for the ideal office, the photograph shows our Tokyo office. It is not so much a place to commute to work, but rather, a place where people gather. It is a new vision of a workplace, and we will work to implement this.

In this new normal, I would like to incorporate new normal as an opportunity to increase productivity, and use those gains to improve our performance. We are moving forward with this, and we look forward to your continued support.

Q1 FY2020 Financial Results ended June 30, 2020

Q1 FY2020 Results

In line with expectations despite it was the impact of COVID-19

(JPY billions)	FY2019 Q1 Actual	vs Revenue	FY2020 Q1 Actual	vs Revenue	YoY
Revenue	**59.1**		**57.6**		**-3%**
Cost of sales	24.1	41%	24.7	43%	+3%
Gross margin	35.0	59%	32.8	57%	-6%
SG&A expenses	16.0	27%	15.6	27%	-3%
R&D expenses	6.2	10%	5.6	10%	-9%
Core operating profit	***12.8***	***22%***	***11.7***	***20%***	***-9%***
Amortization on intangible assets associated with products	2.5	4%	2.4	4%	-1%
Other income	0.1	0%	0.2	0%	+75%
Other expenses	1.2	2%	1.4	2%	+17%
Operating profit (IFRS)	9.2	16%	8.0	14%	-13%
Finance income	0.4	1%	0.5	1%	+20%
Finance expenses	0.7	1%	0.2	0%	-73%
Profit before tax	9.0	15%	8.4	15%	-7%
Income tax expenses	2.6	4%	2.2	4%	-14%
Actual tax ratio	*29.0%*		*26.7%*		
Net profit (IFRS)	6.4	11%	6.1	11%	-4%
Core net profit	9.7	16%	8.8	15%	-9%
USD (JPY)	109.86		107.46		
EUR (JPY)	123.06		118.69		
CNY (JPY)	16.14		15.13		

Core Basis

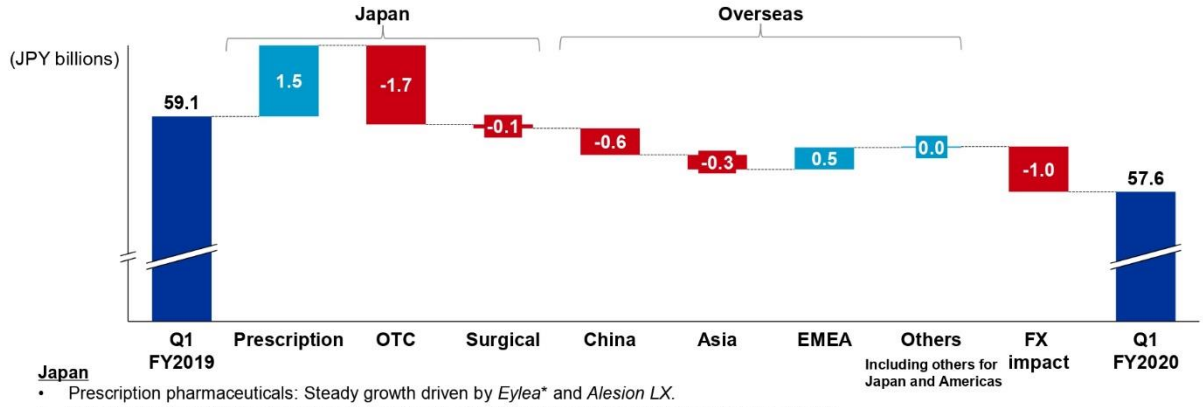
- **Revenue: In line with expectations**
- **Core Operating Profit: Maintained 20% profit rate by controlling activity cost**

Decrease in tax burden rate due to changes in the profit composition ratio of corporation in Santen Group

Koshiji: This is a slight overlap with the highlights of the previous section, but this is the situation in the first quarter profit and loss statement. Although sales, core operating income, and profits declined, we expected the largest negative impact of COVID-19 in the first quarter of the fiscal year under review. In this respect, we recognize that this is in line with our expectations.

Q1 FY2020 Revenue (YoY)

Each region was in line with expectation and trends to recovery.



Japan

- Prescription pharmaceuticals: Steady growth driven by *Eylea** and *Alesion LX*.
- OTC: Decreased due to the impact of COVID-19, including sluggish demand from overseas tourists.

Overseas

- China: Sales decreased due to the negative impact of COVID-19 (local currency basis -8%). The recovery is higher than expected.
- Asia: Same as above (-7% excluding FX impact). Currently, Korea, Taiwan, and Thailand are recovering to almost normal times.
- EMEA: Increased +5% without FX impact led by solid sales of *Cosopt* and *Tapros*.

 *Eylea**: Co-promoted product of Bayer Yakuhin, Ltd. (MAH) Classified into countries or regions based on customer location.

Koshiji: This is a waterfall chart showing sales in comparison with the results from the previous year.

Domestic sales remained almost unchanged, while overseas sales decreased by 6.5% YoY. However, the foreign exchange rate had a total effect of around 4.5% overseas, so overseas sales were negative YoY by approximately 2%. However, given the current situation, this was slightly less than we expected.

Individually, the Japanese, overseas, and other businesses are listed below the table at the center of this report. The negative impact excluding FX impacts are listed.

FY2020 Forecast (Unchanged from May 8th)

Aim to increase profits through efficient cost management

(JPY billions)	FY2019 Actual	vs Revenue	FY2020 Forecast	vs Revenue	YoY
Revenue	**241.6**		**235.0**		**-3%**
Cost of sales	94.8	39%	90.0	38%	-5%
Gross margin	146.7	61%	145.0	62%	-1%
SG&A expenses	73.4	30%	70.0	30%	-5%
R&D expenses	23.3	10%	23.0	10%	-1%
Core operating profit	***50.0***	***21%***	***52.0***	***22%***	***+4%***
Amortization on intangible assets associated with products	9.9	4%	9.7	4%	-2%
Other income	0.4	0%	0.9	0%	+131%
Other expenses	7.0	3%	8.2	3%	+17%
Operating profit (IFRS)	33.5	14%	35.0	15%	+4%
Finance income	1.0	0%	0.8	0%	-16%
Finance expenses	2.4	1%	1.0	0%	-58%
Investment loss by equity method	--	--	0.8	0%	--
Profit before tax	32.1	13%	34.0	14%	+6%
Income tax expenses	10.4	4%	11.0	5%	+6%
Actual tax ratio	*32.3%*		*32.4%*		
Net profit (IFRS)	21.7	9%	23.0	10%	+6%
Core net profit	35.9	15%	38.7	16%	+8%
USD (JPY)	108.81		110.00		
EUR (JPY)	120.80		120.00		
CNY (JPY)	15.64		15.00		

Core Basis

- Revenue: Expect COVID-19 impact
- Operating Profit: Expect growth due to lower activity levels resulting from COVID-19 restrictions, and cost optimization

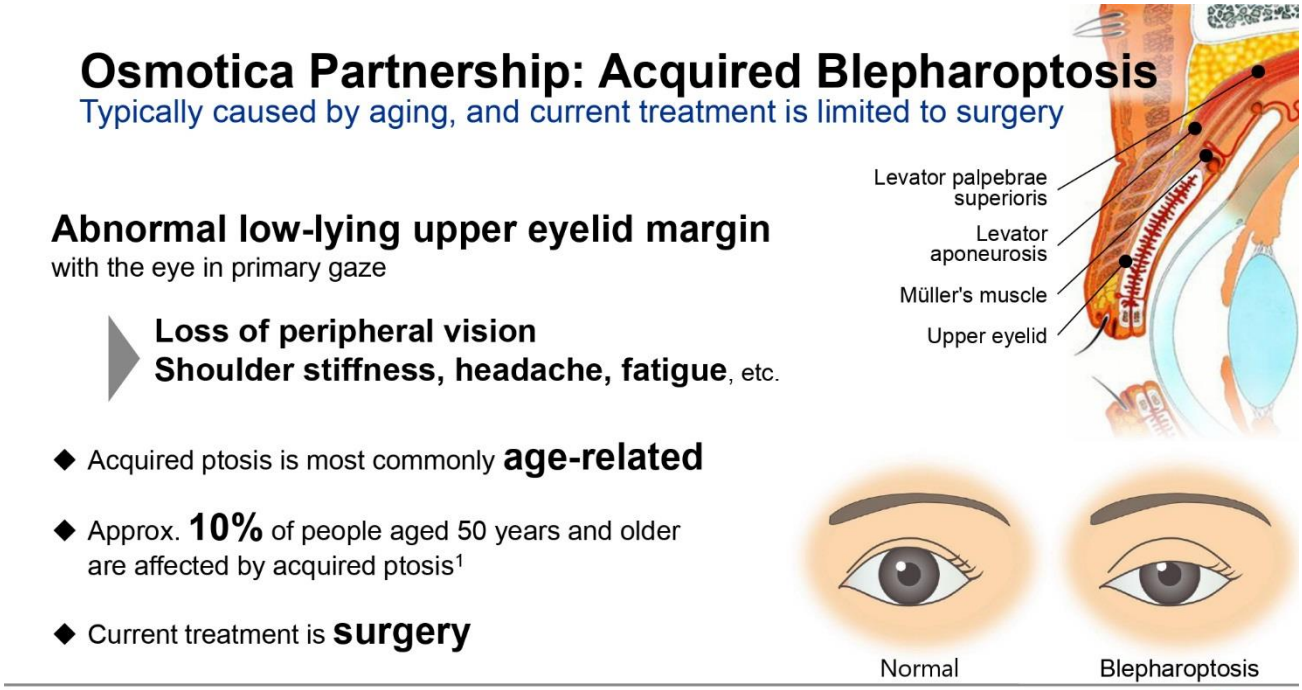
Koshiji: This is the forecast for the full fiscal year. There is no change here. Based on the results for the first quarter of the fiscal year under review, as I mentioned earlier, the trend is in line with expectations.

We expected the COVID-19 to have the largest effect in the first quarter of this fiscal year, and we anticipated progress towards the full year forecast of around 20% in sales and slightly below 20% in core operating profit. In this regard, we recognize that both sales and profits exceeded our initial plan.

Regarding our approach to PL in the future, we still recognize that there is uncertainty about the impact of COVID-19. Consequently, sales were in line with expectations in the first quarter, but there is uncertainty as to whether or not we will be able to get on a recovery trend from that point forward.

However, by flexibly controlling selling, general and administrative (SG&A) expenses, and by using R&D expenses as needed, we will secure core operating profit as initially forecast. As we adopt this approach, we do not plan to change our earnings forecasts for the current fiscal year. That is all.

Status of Research & Development



Morishima: In July, we announced an alliance with Osmotica in the US for the treatment of blepharoptosis. Let me explain about this.

Blepharoptosis is a disease in which the eyelid falls below its normal position when the eye is opened. It can be congenital or acquired, but the main cause is thought to be age-related weakening of the muscles that lift the eyelids.

It is one of the most common eyelid ailments for people over 50 years of age. Drooping eyelids can make it difficult to look up, and may also give ‘sleepy’ lookand other problems. Although there is an aesthetic element because it affects the appearance, it is a disease that affects the vision and causes shoulder issues, headaches, fatigue, and other symptoms. It is treated under insurance in Japan. In one study, about 10% of people over the age of 50 years were reported to have blepharoptosis.

The current treatment is surgery to lift the drooping eyelids.

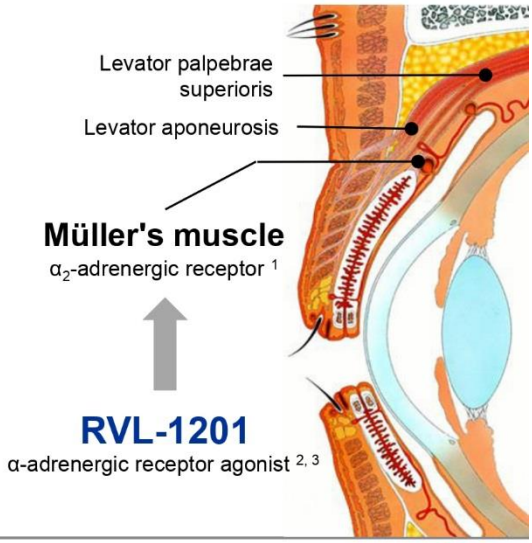
In July, Osmotica received approval in the United States for a treatment for blepharoptosis by eye drop.

Osmotica Partnership: RVL-1201

Planning to develop in Japan, China, Asia, and Europe

July 2020: Osmotica received approval from FDA as a treatment for acquired blepharoptosis in adults

- 0.1% oxymetazoline hydrochloride ophthalmic solution
- Instilled once a day
- Preservative-free eye drop
- Demonstrated improvement of superior visual field and MRD-1* in P3 in US



*MRD (Marginal Reflex Distance): distance between the margin of upper eyelid and center of pupil

1. *Ophthalmic Plast Reconstr Surg*. 1999 Mar;15(2):92-9.
2. *Fundam Clin Pharmacol*. 2010 Dec;24(6):729-39.
3. *Br J Pharmacol*. 1996 Jul;118(5):1246-52.

Morishima: Oxymetazoline hydrochloride 0.1% ophthalmic solution, or RVL-1201, has been approved in the United States. By instilling to work on Müller's muscle, which is one of the muscles that lifts the eyelids, it improves the condition. Santen has obtained development licenses in Japan, China, Asia and Europe, and will begin development in each region in the future.

We anticipate that offering a new treatment methodology, eye drops, will increase the number of options and lower the barriers for treating the disease that up to now has been treated only with surgical procedures.

Current Status of Research and Development

Pipeline / product development (1)

As of July, 2020
Updated information is underlined

	Indication	Region	Status
DE-111 STN10111 *TAPCOM / TAPTIQOM* Combination of tafluprost and timolol maleate	Glaucoma / ocular hypertension	China	P3 *Plan: FY2022 P3 completion*
DE-117 STN10117 *EYBELIS* EP2 receptor agonist	Glaucoma / ocular hypertension	US	P3 *Plan: FY2020 filing*
		Japan	Launched
		Asia	Approved *Plan: FY2020 launch*
DE-126 STN10126 FP / EP3 receptors dual agonist	Glaucoma / ocular hypertension	US	P2b (dose finding study completed) *Plan: FY2020 additional P2 start*
		Japan	
DE-128 *PRESERFLO MicroShunt*	Glaucoma	US	Completed PMA rolling submission in June 2020 *Plan: FY2020 approval, FY2020 launch*
		Europe	Launched
		Asia	Filed *Plan: FY2020 approval*

The numbering method for development codes has changed. We show both existing development codes (DE-XXX) and new development codes (STNXXXXX).

Morishima: In this section, I will present areas of the R&D pipeline where there have been major changes. Since the numbering rules for development codes have been changed, the old and new codes are listed here together.

The first compound is DE-111, which is undergoing Phase III trials in China. The Phase III trial for DE-111 is expected to be completed in FY2022, with some delay due to the impact of COVID-19.

We will submit an application for DE-117 in the US in the second half of this fiscal year. The application will be based on a total of 11 clinical trials, including four Phase III trials in Japan, Asia and the US. Of the two Phase III trials conducted in the US, one failed to achieve the primary end point. However, we completed a consultation with the FDA before the application, and we believe that the data for submission is complete.

Following on from Mr. Taniuchi's presentation, the submission for DE-128 was completed in June, and the submission was accepted in July. We expect approval and launch during this fiscal year, as we had planned.

Current Status of Research and Development

Pipeline / product development (2)

As of July, 2020
Updated information is underlined

	Indication	Region	Status
DE-130A STN10130 Catioprost latanoprost	Glaucoma / ocular hypertension	Europe	P3 *Plan: FY2021 P3 completion*
		Asia	
DE-109 STN10109 IVT sirolimus	Uveitis	US	P3 *Plan: FY2022 P3 completion*
		Japan	P3
		Europe	P3
		Asia	Filed
DE-127 STN10127 atropine sulfate	Myopia	Japan	P2/3 *Plan: FY2023 P2/3 completion*
		Asia	P2 (met primary endpoint)
MD-16 Intraocular lens	Cataract	Japan	Approved *Plan: FY2020 launch*

The numbering method for development codes has changed. We show both existing development codes (DE-XXX) and new development codes (STNXXXXX).

Morishima: The status of these development compounds is as described here, with no change from the previous disclosure. I will not provide any further information about these in this presentation.

The impact of COVID-19 could still affect clinical trials. It should be noted that there is a risk that the plans for any of these projects could be subject to delays.

This concludes my presentation.

Question & Answer

Q1-1

I would like to ask about the presentation from Mr. Koshiji regarding the business results. Regarding Q1, was it in line with expectations or slightly above expectations? I think it was recognized that the expected results would be weak for your Company this quarter, but I would like to confirm that.

A1-1

Koshiji: Sales and profits were slightly stronger than anticipated.

Q1-2-1

OK. The second question is about Osmotica. I believe the medication is used as an anti-allergic agent, and the effect of vasospasm, which is being used here. I haven't seen the data, but that is my understanding. In terms of efficacy, from view point of risk-benefit, it fall, however, is it something like the benefit is slightly inferior to that of surgery and the risk is relatively low?

A1-2-1

Taniuchi: In clinical trials, we look at data in terms of the extent of improvement in field of vision, and other clinical endpoints. In fact, I believe that we need to explore the doctor and patient's needs for this value.

Mr. Morishima explained the novel means by which this treatment works, specifically, its action on Müller's muscle. With this in mind, I think that the positioning of this product will be decided in the future, as we consider potential QOL benefits for patients.

Q1-2-2

However, I suppose that the contraction is not constant, so the medication will have to be used continuously. In the case of an operation, the shape is restored and fixed, but in this case, the eyelid's shape changes when it is administered, but when the medication wears off, the eyelid falls again. Is this correct?

A1-2-2

Taniuchi: Yes, treatment is once daily. Naturally, in severe cases, if the visual field is completely obstructed, it is probable that surgery will be the first choice, but not everyone will undergo surgery.

I think that in the future we will work with health professionals to look at how to use this product while reviewing its clinical evaluations.

Q1-3

OK. Thank you very much. Finally, regarding the *MicroShunt* device, has the FDA's review deadline, like PDUFA date, been disclosed?

The review deadline, the time by which an FDA judgment will be released. In the case of pharmaceuticals, they are disclosed on a date, but since this is PMA, it may be a bit different. Do you know when the FDA will finish the review? I wonder if it's likely to be in the region of six months.

A1-3

Taniuchi: Well, we are considering the timeline in terms of the information that we have released. We have not disclosed any specific dates. Currently, we are looking at something in the order of six months, and we are thinking that it will be approved and launched in FY2020.

Q2-1

Let me first ask you about the impact of COVID-19. In your Company's case, the individual forecasts were not disclosed at the outset, so I don't know very much about progress on a per-item basis.

I imagine that COVID-19 is having different effects in different regions, in areas such as treatment of glaucoma and dry eye. What are the impacts of these factors? Also, could you please let me know about whether a recovery is taking place, and the current state of affairs?

A2-1

Taniuchi: Thank you. Although the breakdown will vary depending on the country, the impact on chronic diseases will be less than that on other diseases. The impact of COVID-19 has been relatively weak. On the other hand, for areas other than chronic diseases, there is a larger impact on performance. In other words, the effects on glaucoma and AMD treatments are relatively weak, while dry eye and infectious disease treatments are more strongly affected.

Second, in terms of hospitals and private clinic, the impact on sales through private clinic is also relatively weak. While hospitals have strongly restricted patient visits, or stopping outpatient appointments altogether, there has been a change in demographics. In China, for example, with people moving to medical practitioners, or from a Tier 3 hospital to a Tier 2 hospital.

On the other hand, in terms of the current situation, it is not the case that curbing of clinic visits is directly linked to sales. Although the number of visits has fallen, more medication is prescribed at a time. Generally speaking, the change in the number of patients, which is commonly described, is not linearly linked to sales.

In the early spring in Japan, China, Asia, and Europe, performance was weak, but there has been a remarkable recovery towards the end of the first quarter. The number of patients seen and the number of surgical operations performed in China shows that operations are returning almost to normal.

There are still second-wave movements, including those in Japan, and we cannot predict the future situation. However, that has been the general situation in the first quarter.

Q2-2

Thank you very much. Secondly, I would like to ask about DE-117 in the US. I would like to ask you the strategy relating to the alliance. Given that the application is expected to be completed within the year, when would you anticipate forming such an alliance?

A2-2

Taniuchi: Regarding DE-117, the current situation is still completely open, and I hope that we will be able to make decisions and talk about it after considering the status of the application in the future. I would like to focus on the preparation for this application.

Generally speaking, DE-117 is a more standard glaucoma treatment than *MicroShunt*, which makes it easier to think in terms of commercialization. Therefore, I think that, unlike in the case of *MicroShunt*, we should simply look at this product in terms of profitability. I hope to be able to talk about this again in the future.

Q2-3

OK. Thank you very much. Finally, a question about the Osmotica partnership. What is the expected time from start of treatment to clinical effect? Is there an immediate change, or does it take months for an effect to appear?

A2-3

Taniuchi: We anticipate that we will have more data on this in the future. At the moment, I have heard that onset of clinical effect is very fast. It is not a product that will take months to have an effect. In the future, I hope to be able to speak specifically about this issue as development continues.

Q3-1-1

My first question relates to an earlier question for Mr. Koshiji. I think that Q1 sales were originally expected to be 10% of the Company's full-year forecast, with operating income at around 20%. Is that correct?

Then, although it was originally assumed there would be a core operating profit of about JPY10 billion based on a rough calculation of the first quarter, this time it was slightly higher than that.

However, in terms of sales, progress is 10% higher than anticipated. What do you think of this imbalance? Please tell us about whether the cost of the product will fluctuate or whether you anticipate this being an irregular problem?

A3-1-1

Koshiji: Initially we had assumed sales of more than 20%, and this to over 10%. The core operating profit was expected to be slightly less than 20%, so sales were stronger than expected at 20%, and core operating profit was somewhat weaker. Both of these results were over 20%.

Q3-1-2

The biggest reason for the good progress was that the situation overseas was not as bad as expected.

A3-1-2

Koshiji: Well, yes. Both in Japan and abroad. Japan pharmaceutical business did not fall as much as expected. Overseas, the impact of the appreciation of the yen was also felt, but it was not so seriously affected by COVID-19. These were the two main factors.

Q3-2-1

Next, regarding this blepharoptosis medication, I think there are roughly 15,000 operations in Japan per year. Because it requires a stay of about 3 days in hospital, I think this is quite a burden, so many people will switch to once-a-day eye drops if they are available. Will this roughly 15,000 cases be the initial target?

Of course, if the product comes on the market, I think there will be other people who will come forward and want to start taking it. What do you think about that?

A3-2-1

Taniuchi: As we continue to develop and conduct clinical trials, we will be able to give a more concrete answer to this question. As you said, we believe that there are considerable portion of the people who are currently undergoing an operation.

While we can consider this in terms of figures, I think there is a more complete picture that lies behind those figures.

Q3-2-2

Considering that complete picture, as it is covered by health insurance, the physicians can receive medical fees. As a result, I think that there will be an impact in setting the drug price. What would be the best way to think about that?

A3-2-2

Taniuchi: We see the severe form of this disease, where it is affecting field of vision, as our entry point. This may be covered under medical insurance, and coverage may differ by country. From there, I would envision the acceptance and clinical value of this product expanding a little further, and while there will be differences in in terms of expenditure by country such as out of pocket, I think there will be other factors at play in the future, and with that in mind I think we will be able to show the value of this product in the future.

Q4-1

First, I would like to ask about the influence of COVID-19. In the answer to previous question, it was mentioned that there is not a direct relationship between the changing number of patients and sales. Is there a delayed effect, where the current decrease in patients would have a negative impact on sales from July to September?

A4-1

Taniuchi:

For example, if the number of visits to a patient declines by 30%, the number of prescribed bottle does not decline by 30%. Despite the decreasing number of visiting patients, the number of prescriptions may be 2-3 bottles at one time visiting. So in that sense, for example, even if the number of patients drops by 30%, sales do not decrease 30%. We say that there is a case that stays at 10%.

Q4-2-1

Understood, many thanks. So considering the impact of COVID-19, Q1 has probably seen the most significant negative impact, both in Japan and elsewhere. From this point on, sales in China and elsewhere are recovering, so do you think it is very unlikely that sales will deteriorate from the second quarter onwards?

A4-2-1

Taniuchi: That's right. We have not changed our initial forecasts, as Mr. Koshiji explained. It is not possible to predict what will happen in the future, given the second wave and the situation in each country. Of course, there has been recovery as initially expected, and if things get back on course in a fairly conventional form from the second half of the fiscal year, the figures will improve, and there is a possibility of exceeding our forecasts. If things return to how they were in spring, then results will probably follow a similar path. As we look forward, the breadth of the range of forecasts increases.

Q4-2-2

I see, thank you very much. The negative impact of COVID-19 on sales was smaller than expected. As mentioned earlier, even if the number of medical examinations fell by 30%, the number of

prescriptions per visit increased, so I think it should be understood that the negative impact on sales was less than anticipated as a result of this offset.

A4-2-2

Taniuchi: That's right. Such factors are probably affecting ophthalmological examinations. In Japan, for example, sales were slightly stronger than we expected. This is probably because there were many patients visiting private clinics. It is not a case of simply not attending hospitals, but rather, patients are visiting private clinics instead of going to hospital outpatient appointments.

As a whole, of course, the pie is shrinking, but from a patients' point of view, there are some patients who will still need to see a doctor during COVID-19 pandemic.

Q5-1

My first question is about the gross profit margin. In your full-year forecast, I think you planned to improve the margin by 1 point. In this first quarter, it has worsened by 2 points. What factors do you think have contributed to this, and what effect will this have on the full-year outlook?

A5-1

Koshiji: Thank you. In the first quarter, the COGS was higher than we expected. There are two reasons for this: firstly, changes in the product mix of sales. There has been an increase in the proportion of products with high cost ratios.

The second reason is that if we look at OTC sales in Japan, sales have fallen as a result of COVID-19, but accordingly, the COGS per product has actually increased.

However, in terms of the full fiscal year, the high-margin products such as *Alesion* are likely to keep selling well, which should compensate. Therefore, in the current budget, we are still aiming to achieve the original target of 38%. Even if the sales composition differs from expectations, we would like to secure profits by controlling selling, general and administrative expenses.

Q5-2-1

Yes, Thank you. One more thing, please. In the US, Phase III study of *Eybelis*, I think there was a mention that the primary endpoint was not achieved in a study. I'm afraid I don't know the details about these studies, but could you kindly tell us which primary endpoint was not met?

Regarding the application, could you say any more about the response of the FDA?

A5-2-1

Taniuchi: This was the one of the SPECTRUM studies, SPECTRUM-3. In this study, the drug was compared with timolol, a standard β-blocker.

Regarding DE-117, *Eybelis*, the studies of “AYAME” and “PEONY” have been conducted in Japan and Asia for some time, and it is known that this will work. The result has been reconfirmed. However, this comparative study showed that timolol was extremely effective, so it was not possible to achieve the primary endpoint in this study. In this regard, we consulted with the FDA openly and presented our explanation of the overall data set.

Although we cannot disclose any specifics relating to those meetings, we presented the evidence that we had obtained from the SPECTRUM trials, as well as other trials, showing the efficacy and safety profile of the drug.

Mr. Morishima, do you have anything to add?

Morishima: So, with SPECTRUM-3 and -4, the protocol is basically the same, and timolol is the comparator drug. As Mr. Taniuchi mentioned, although the effects of *Eybelis* on eye pressure were very stable, there was a variation in how patients responded to timolol. We were not able to meet the comparison endpoint in trials where patients responded strongly to timolol. However, in our other trials, all the endpoints were met.

As a result of consulting with the FDA and presenting all data, including the studies in Asia and Japan, we were advised that we are at a level where we can submit an application.

Q5-2-2

In the SPECTRUM-3 study, was *Eybelis* unable to demonstrate non-inferiority in IOP-lowering effect compared to timolol?

A5-2-2

Morishima: The study in the US required measurement three times a day at three visits during the study (3 points a day x 3 days, total 9 points). We were not able to meet the endpoint because of the criterion that we have to show non-inferiority at all measurement points. The required criteria for the US and other countries are slightly different, so we consulted with the FDA.

In the case of *Eybelis*, rather than simply comparing the effects of inter ocular pressure, we intend to make the argument that it is of value in the market, including the benefit that it has a good side-effect profile.

Q5-2-3

In that case, what do you think will happen with regards to insurance reimbursement and how will this affect the sales potential?

Timolol and generics are also on the market and prices are falling. How do you appeal in terms of cost-effectiveness? What are your thoughts on how to persuade insurers in particular?

Morishima: Though prostaglandin were not target drug subject to clinical trials, basically, prescription ophthalmic drugs approved in the US targets timolol. We basically follow the same process as other companies' application process for prostaglandin. Therefore, I think there will be negotiations from now on, but there will be no major difference from the previous ones.

Taniuchi: This is true of payers in the US as well as payers elsewhere, but while clinical trials are an important source of data, actual real-world data also contributes to these decision-making processes. We have sufficient data to support the argument for overall cost effectiveness.

The issue here is that although we have this other data showing non-inferiority to latanoprost as a prostaglandin, in the case of this single trial, some slightly unusual data came out. In that context, we have enough data to have constructive talks with payers.

This new mechanism of action is also an important point in insurance reimbursement. Especially in the US, a new mechanism of action is a very large factor, so I feel that we are able to move forward with confidence.