Q3 FY2019 Results

Conference Call on Q3 FY2019 Results

Santen
A Clear Vision For Life

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Santen's Values and Mission Statement

Santen

Values

天機に参与する

Tenki ni sanyo suru [1]

[1] **"Exploring the secrets and mechanisms of nature in order to contribute to people's health"**
Santen's original interpretation of a passage from chapter 22 of *Zhongyong (The Doctrine of the Mean)* by Confucius.

We think carefully about what is essential, decide clearly what we should do, and act quickly.

Mission Statement

By focusing on ophthalmology, Santen develops unique scientific knowledge and organizational capabilities that contribute to the well-being of patients, their loved ones and consequently to society.

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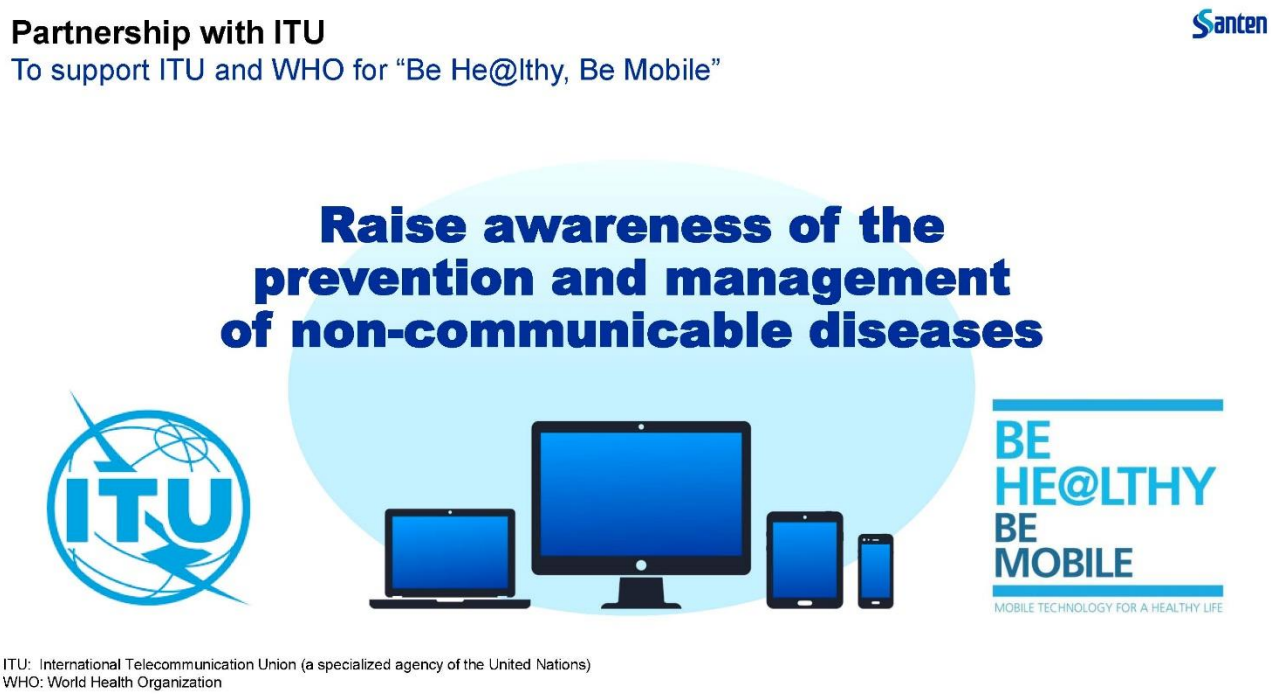
Taniuchi: Thanks. I will now start my presentation.

First of all, this is our value and mission statement. We aim to explore the secrets and mechanisms of nature in order to contribute to improving health. This is how we contribute to society. In particular, we have made efforts to contribute to society in a wide range of fields by focusing on ophthalmology. This year marks the

130th anniversary of the Company's founding, and we aim to continue developing our businesses based on this fundamental philosophy.

I would like to focus on three points relating to our business activities in this quarter, and then Mr. Koshiji will discuss the financial results.



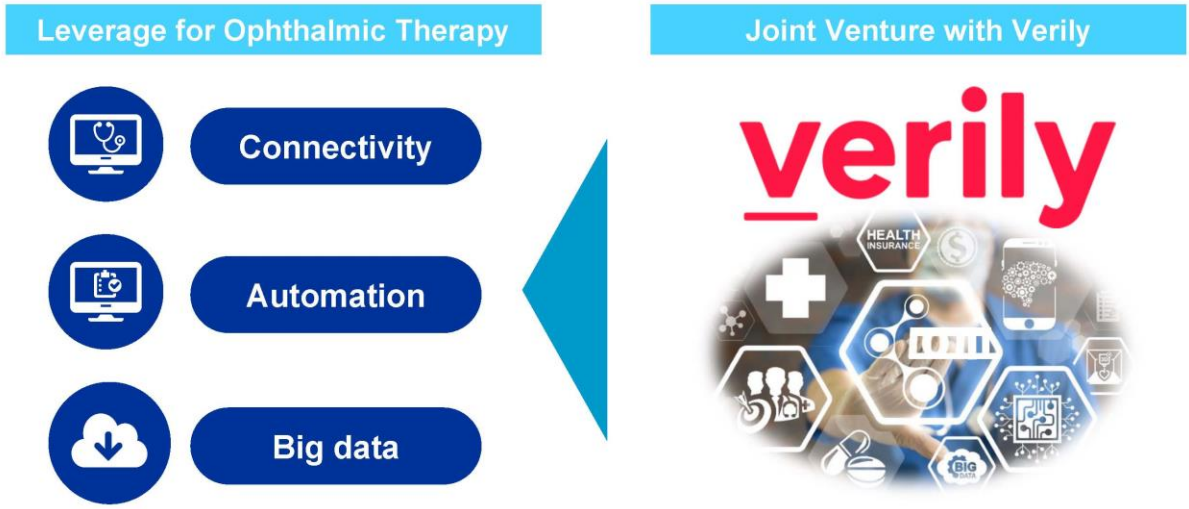
Taniuchi: First of all, our partnership with ITU. We released this in January, and there are projects in the mobile health field that ITU and WHO are moving forward with. As a partner in ophthalmology, we have concluded that we will be a global partner.

Based on SDGs (Sustainable Development Goals), the United Nations is working on a range of activities, including related to non-communicable diseases, as well as a variety of ophthalmologic diseases. This may include, for example, glaucoma or diabetes-related diseases. We would also like to cooperate with the ITU, and the WHO to provide information and solutions to people who are suffering with eye diseases around the world.

New Contributions to Ophthalmic Therapy through Advanced Digital Technology

Santen

Establish joint venture with Verily; aim to develop and commercialize UNIQUE devices for ophthalmic therapy



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Taniuchi: The second point is the use of digital technologies. We have established a joint venture with a company called Verily to develop ophthalmological products and solutions through the use of digital and microelectronic technology. Verily is an organization that conducts healthcare activities as part of Alphabet Group, which is the parent company of Google. We are pleased to make this announcement today.

This partnership capitalizes on our strengths: Alphabet Group's various digital assets and platforms, including Google, and our expertise in the ophthalmology field, as well as our networks of doctors and patients. In this way, we intend to develop unique and original solutions.

We have been developing products like *MicroShunt*, which transcend the traditional boundaries of pharmaceuticals and ophthalmic solutions. By our continued work in this area, we hope to improve quality of life for sufferers of ophthalmic diseases all over the world.

Q3 FY2019 Highlights

- **Q1-Q3 revenue up 5%, profit (core basis) up 8% YoY**
  - Steady growth mainly from growth in China
  - Sales in overseas business increase despite negative FX impact
- **Continue to contribute to improving the quality of life of patients with retinal diseases**
  - Extend co-promotion agreement with Bayer Yakuhin for *Eylea**

EYLEA® (aflibercept) Injection

- **Launch new product to provide further value for the patients**
  - Launch "*Alesion LX*" with longer-lasting efficacy: twice daily applications

*Eylea**: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

Taniuchi: This slide summarizes other highlights for the third quarter. As an overview of the third quarter, sales rose 5% YoY and profit rose 8% on a core basis, with steady growth overseas in particular.

As in the first half of this fiscal year, the overseas business was impacted by changing exchange rates. However, sales have grown on a local currency or budget basis as a result of steady progress.

We also have announced an extension of the co-promotion agreement with Bayer Yakuhin, Ltd. In this way, we will continue to contribute to improving the quality of life of patients in the area of retinal diseases.

Last November, we launched *Alesion LX*, a twice-daily allergy eye drop, in Japan. This is a product that is more convenient for patients than the previous four times-daily eye drops.

With a view to steadily expanding sales of such products in Japan, Santen is also utilizing *Eylea* and *Alesion*. We are also committed to our goal of continued overseas growth.

FY2019 Forecast (No Change from May 9)

Aiming for further growth and efficiency improvements

(JPY billions) Core basis	FY2018 Actual	FY2019 Forecast	FY2019 YoY
Revenue	**234.0**	**248.0**	**+6.0%**
COGS	90.8	95.0	+4.7%
Gross margin	143.3	153.0	+6.8%
SG&A	71.3	74.0	+3.8%
R&D expenses	23.8	28.0	+17.9%
OP	**48.2**	**51.0**	**+5.7%**
Net profit	**36.1**	**37.7**	**+4.5%**
Actual tax ratio	25.2%	26.1%	
ROE	12.5%	12.8%	+0.3pt

Taniuchi: We have made no changes to the full-year earnings forecasts.

Regarding the impact of the new coronavirus in China, there has been an extended New Year break, and we are not in a position to give any specific figures at this time. What we have been able to confirm is that all of our employees are safe. Also, we have confirmed that there are no major problems with the supply of products following the end of the New Year break, because we have certain amount of local inventory for the time being.

While we are expecting the short-term impact to continue, the current news from the authorities is that the plant will not be operating this week. We will be monitoring the situation as to whether the plant will return to normal operations after next week.

Q1-Q3 FY2019 Results

Strong overseas sales led revenue and profit growth (core basis)

(JPY billions)	FY2018	FY2019	
Core basis	Q3 Actual	Q3 Actual	YoY
Revenue	173.2	182.3	+5.3%
COGS	69.8	74.4	+6.5%
Gross margin	103.4	108.0	+4.4%
SG&A	51.2	52.8	+3.1%
R&D expenses	17.1	17.2	+0.4%
OP	35.1	38.0	+8.3%
Net profit	25.7	27.2	+6.0%
IFRS			
OP	33.7	28.9	-14.0%
Net profit	23.4	20.3	-13.2%
USD	111.2	108.9	
EUR	129.5	121.1	
CNY	16.6	15.7	

Revenue

- *Japan*: Steady growth of key products
- *Overseas*: Despite FX impact, China and Asia continue strong growth

⇒Increase by JPY9.1 billion (+5.3%)

Core operating profit

- Steady growth of overseas business
- Cost optimization

⇒Increase by JPY2.9 billion (+8.3%)

IFRS operating profit and net profit

- DE−128 amortization
- Profit decline in the absence of the sale of former head office and Osaka factory recorded in the previous fiscal year

Operating profit ⇒ Decreased by JPY4.7 billion (-14.0%)

Net profit ⇒ Decreased by JPY3.1 billion (-13.2%)

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Koshiji: Please refer to page nine.

Regarding the cumulative results for the third quarter, as the President explained earlier, there is no change to the full-year forecast. We are making steady progress toward the achievement of our full-year targets.

Revenue has increased 5.3% YoY. Growth was 7.5% excluding FX impacts, with exchange rate losses responsible for the 2.2% difference. Operating profit increased YoY by 8.3%, with exchange rates having an effect of negative 3.1%. Without the impact of exchange rates, the figure would be 11.4%.

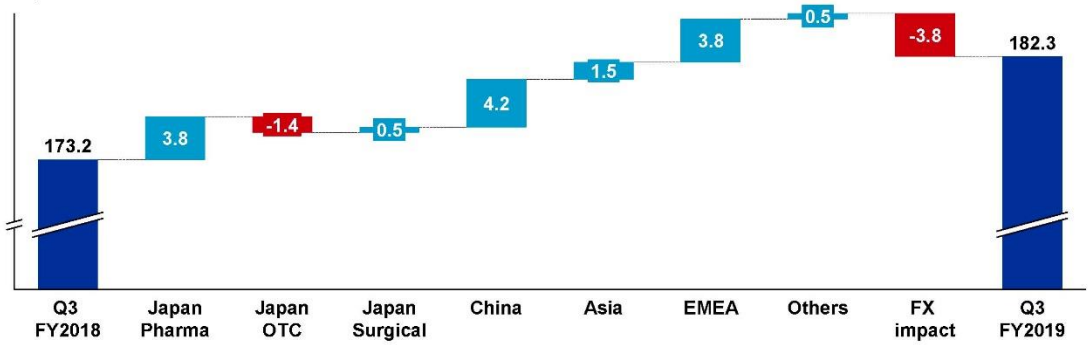
Operating profit and net profit declined by 14.0% and 13.2%, respectively. This was mainly attributable to higher costs due to the inception of DE-128 amortization, and the revaluation of InnFocus contingent payment. In the same period of the previous fiscal year, the sale of the former head office and Osaka plant contributed approximately JPY3.6 billion. There was no such contribution this year. As a result, profits have declined, as you can see.

However, on page 12 of the consolidated performance report is the cash flow statement. On an operating cash flow basis we are seeing an increase of 20.7%, or approximately 21%. Although accounting expenses increased, we recognize that we are maintaining strong momentum on a cash basis.

Q1-Q3 FY2019 Revenue

Steady growth in overseas drove group sales

(JPY billions)



Japan

- Prescription Pharmaceuticals: Steady growth driven by *Eylea** and *Alesion*. The prescription limits of *Eybelis* was lifted on December 1st.
- OTC: Despite steady sales of premium products for the Japanese market, revenue decreased due to sluggish overseas tourists' demands
- Surgical: Steady growth driven by new product *LENTIS Comfort*.

Overseas

- China: Local currency sales increased 26% YoY led by *Cravit* and *Hyalein*, which recorded double-digit growth. (JPY basis +19%)
- Asia: Strong growth in each country/region. (JPY basis +7%) (Korea: JPY basis +10%, Local currency basis +20%)
- EMEA: Revenue increased +14% in € basis, but rose +7% in JPY due to the appreciation of JPY against €. Major countries such as Italy and Germany drove sales growth. One-time UK sales is included.

*Eylea**: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

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Koshiji: Page 10 shows a waterfall chart from the previous year to this year.

In Japan, NHIP revisions started to take effect in October, but overall sales increased. Overseas, sales increased on a local currency basis by 26% in China and by 13% in Asia. This is described below the chart. On JPY basis, sales in Asia increased by 7%. Sales in South Korea increased significantly, by 20% on a local currency basis. In EMEA, we achieved double-digit growth in each of our overseas business segments, with sales increasing by 14% on a euro basis. The impact of foreign exchange rates on sales was negative 2.2%, but we have been able to absorb this and still achieve increased revenues.

Q1-Q3 FY2019 Operating Profit (Core Basis)

Sales growth and SG&A control led profit growth

Change factors

- Gross profit: Increased due to sales growth
- SG&A: Controlled SGA growth, particularly reducing advertising expenses
- R&D expenses: Largely unchanged year-on-year owing to development schedule delays and cost optimization
- FX impact: Negative 1.1billion JPY impact on core operating profit as a result of yen appreciation

Koshiji: Next, page 11 is a waterfall chart showing core operating profit.

There was gross profit growth of 4.4%. SG&A expenses have not increased by the same degree as gross profit. R&D expenses have remained flat. As a result, core operating income has grown by 8.3%. On the other hand, the negative impact of the exchange rate was about JPY1.1 billion on a profit basis, and excluding this would give a figure of 11.4%, as I mentioned earlier.

Q1-Q3 FY2019 Income Statement

Revenue and profits (core basis) increased, however profits (IFRS) declined mainly due to DE-128 amortization.

(JPY billions)	Q3 FY18 Actual	Q3 FY18 vs Revenue	Q3 FY19 Actual	Q3 FY19 vs Revenue	YoY
Revenue	173.2		182.3		+5.3%
COGS	69.8	40.3%	74.4	40.8%	+6.5%
Gross margin	103.4	59.7%	108.0	59.2%	+4.4%
SG&A expenses	51.2	29.6%	52.8	29.0%	+3.1%
R&D expenses	17.1	9.9%	17.2	9.4%	+0.4%
Core operating profit	*35.1*	*20.3%*	*38.0*	*20.8%*	*+8.3%*
Amortization on intangible assets associated with products	5.2	3.0%	7.4	4.1%	+41.7%
Other income	3.9	2.3%	0.3	0.2%	-92.6%
Other expenses	0.1	0.1%	1.9	1.1%	--
Operating profit (IFRS)	33.7	19.4%	28.9	15.9%	-14.0%
Finance income	0.9	0.5%	0.9	0.5%	+1.3%
Finance expenses	2.1	1.2%	0.9	0.5%	-59.7%
Profit before tax	32.4	18.7%	29.0	15.9%	-10.6%
Income tax expenses	9.0	5.2%	8.7	4.8%	-3.9%
Actual tax ratio	*27.9%*		*30.0%*		
Net profit (IFRS)	23.4	13.5%	20.3	11.1%	-13.2%
Core net profit	25.7	14.8%	27.2	14.9%	+6.0%

Sale of the former head office and Osaka factory

Impact of the start of amortization for DE-128

Revaluation of InnFocus contingent payment

The tax effect from the change in the fair value of the InnFocus contingent payment (described above) on expenses was not recognized, hence income tax expense was not reduced, resulting in an increase in actual tax rate.

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Koshiji: Some more detail is provided on page 12.

In terms of P/L control, the right-hand column shows the percent change compared to the previous fiscal year. In particular, we have aimed to keep the rate of SG&A expense increase below that of gross profit. YoY gross profit increase was 4.4%, while SG&A expenses increased by 3.1%, suggesting we have been able to achieve this goal.

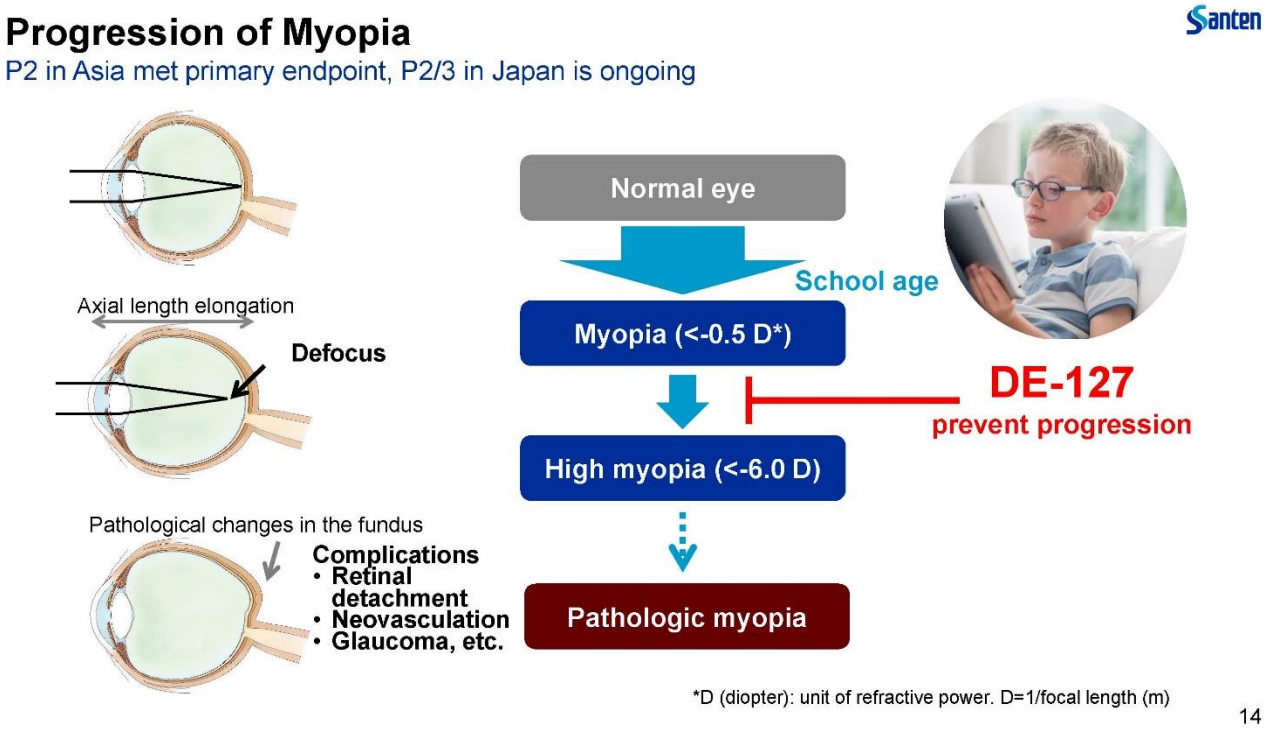
At the same time, in terms of improving profitability, we believe that SG&A expenses and the ratio of SG&A expenses to revenues will improve from the previous fiscal year. In this third quarter, the ratio improved by 0.6%, changing from 29.6% to 29.0%. As a result, on a core operating income basis, the ratio of operating income to revenues increased by about 0.5%.

Other income and expenses are as shown in the table.

The tax ratio in this third quarter was 30.0%. This may appear higher than before, but this is because the tax effect on DE-128 contingent payment is an accounting expense and, therefore, no tax effect can be recognized. As a result, the tax rate has gone up, and there are other changes related to the effects of the tax rate. If we exclude these one-time factors, we can still consider the tax rate for the third quarter to be 27%.

In the same period of the previous fiscal year, the ratio was 27.9% in nominal terms and 26.5% excluding special factors, so there was an increase of about 0.5%. This is attributable to a slight decrease in the amount of tax credits for research and development and the utilization of preferential taxation systems in Japan. Nevertheless, we recognize that we are making steady progress on a cash basis with regard to reducing this ratio to 26% during the medium term plan period.

This concludes the overview for the third quarter.



Morishima: Before discussing the current status of the development pipeline, I would like to talk about a pathology progress in the area of myopia, which has attracted attention in recent years.

As was previously released, our P2 trial of DE-127 in the Asian region achieved the primary endpoints for myopia. In other words, we confirmed the therapeutic window, where there is effectiveness and minimal side effects.

Myopia is not only a problem with focus adjustment. It has become clear that the eyeballs extend backwards and forwards, making it impossible to focus. For patients with myopia of more than minus six diopters, there is said to be a high risk of progression to pathological myopia.

The retina, choroid, sclera, and other parts of the eye are stretched, causing pathological changes in the fundus. There is occurrence of pathologic deformities known as posterior staphyloma. This puts stress on the back of the eye, which is important for vision, and can lead to vision loss. Our DE-127, is a treatment that we expect will prevent the eye from growing horizontally as the eye develops during childhood.

The number of patients with myopia is expected to increase rapidly in coming years, and some reports estimate that about 3.4 billion people will have myopia in 2030 in the world. Myopia-related economic losses were estimated at USD244 billion in 2015. There is a particularly large number of patients in Asia, with an estimated 76 million affected children in China.

P2/3 trials are currently being conducted in Japan, and enrollment is proceeding smoothly. Based on the results of the evidence we collected in Japan, we would like to expand into the rest of Asia.

The Current Status of Research and Development

Pipeline/product development (1)

Santen

As of January, 2020

Updated information is underlined

	Indication	Region	Status
DE-111 *TAPCOM / TAPTIQOM* Combination of tafluprost and timolol maleate	Glaucoma / ocular hypertension	China	P3 *Plan: FY2020 P3 completion*
DE-117 *EYBELIS* EP2 receptor agonist	Glaucoma / ocular hypertension	US	P3 *Plan: FY2020 P3 completion*
		Japan	Launched
		Asia	Approved in Dec 2019 (Korea) *Plan: FY2020 launch*
DE-126 FP/EP3 receptors dual agonist	Glaucoma / ocular hypertension	US	P2b (dose finding study completed) *Plan: FY2020 P2 start (exploratory study)*
		Japan	
DE-128 *PRESERFLO MicroShunt*	Glaucoma	US	P2/3 *Plan: FY2019 PMA rolling submission completion, FY2020 launch*
		Europe	CE mark received
DE-130A Catioprost latanoprost	Glaucoma / ocular hypertension	Europe	P3 *Plan: FY2021 P3 completion*
		Asia	

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Morishima: Pages 15 and 16 provide information on the status of our development pipeline.

DE-111, known also as *TAPCOM* or *TAPTIQOM*, is a combination of tafluprost and timolol maleate. A P3 trial is currently conducted in China.

DE-117, we are conducting P3 in the United States and are scheduled to complete this fiscal year. DE-117 was also approved in South Korea in December, marking the first approval outside Japan. We aim to launch this product in FY2020.

DE-126 is a dual FP and EP3 agonist. We have completed a P2b dose-finding trial. We believe it is very important to differentiate ourselves from our competitors, because this is a treatment for glaucoma, a disease for which there are already a lot of products on the market. We plan to conduct an exploratory trial to clarify the point of differentiation.

Regarding DE-128, or *PRESERFLO MicroShunt*, preparations for the application are going smoothly, and we are aiming to complete the application by March. Once the application is completed, we will make an announcement.

We are conducting P3 trials for DE-130A, latanoprost, in European and Asian countries.

The Current Status of Research and Development

Pipeline/product development (2)

Santen

As of January, 2020
Updated information is underlined

	Indication	Region	Status
DE-109 IVT sirolimus	Uveitis	US	P3 *Plan: FY2022 P3 completion*
		Japan	P3
		Europe	P3
		Asia	Filed
DE-122 Anti-endoglin antibody	Wet age-related macular degeneration	US	P2a *Plan: FY2019 P2a completion*
DE-076C Vekacia / *Verkazia* ciclosporin	Vernal kerato-conjunctivits	Europe	Launched
		Asia	Approved of expanded indication to *Ikervis*
		Others	Launched in Nov 2019 (Canada)
DE-114A epinastine HCl (high dose)	Allergic conjunctivitis	Japan	Launched in Nov 2019
DE-127 atropine sulfate	Myopia	Japan	P2/3 *Plan: FY2023 P2/3 completion*
		Asia	P2 (met primary endpoint) *Plan: FY2019 P2 completion*
MD-16 Intraocular lens	Cataract	Japan	Approved in Nov 2019 *Plan: FY2020 launch*

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Morishima: DE-109 is undergoing P3 trials, mainly in the United States.

For DE-122, anti-endoglin antibody, we have just begun analyzing data.

DE-114A, or epinastine hydrochloride, as the Company President stated, we have launched in Japan in November.

DE-127, as I explained earlier, has achieved its primary endpoints in P2 in Asia, and are currently conducting P2/3 trials in Japan.

MD-16, which is the *LENTIS Comfort* lens for astigmatism, was approved in November and is scheduled to be launched in FY2020.

This concludes the presentation on the current status of R&D.

Question & Answer

Q1-1-1
Firstly, about the partnership with Verily. I appreciate this is at an early stage, but could you tell us a little more about what kind of products you want to make?

A1-1-1
Taniuchi: Thanks for your question.
The details of the product have not yet been disclosed but, basically, we are already working on a number of projects related to treatment, diagnosis, and testing for ophthalmological conditions. This will be a form of joint development in the future.

Q1-1-2
So, the focus is on devices? Would it be fair to say the Company is developing medical devices?

A1-1-2
Taniuchi: Yes. We aim to develop medical devices that combine the technological capabilities of Verily with our know-how. We are considering devices either for treatment purposes or for diagnostic purposes, or for future consideration of a variety of other items.

Q1-2
I understand. I would like to ask you about Eybelis and Alesion separately.
First of all, although the prescription limits on Eybelis have been lifted and the monthly rate has risen slightly, I feel a little cautious, and I think there are questions about the results of this product on a full-year basis. What is the status quo?
Also regarding Alesion, I have heard that pollen dispersal has already been started this year, although I understand that initial shipments are progressing well. Could you give any further comment on this?

A1-2
Taniuchi: As you have indicated, the prescription limits for *Eybelis* has been removed and sales have been increasing. There may be a view that it has not yet reached our expectations, but we are currently working toward expansion.
Hospital listing process are in good progress, and we are explaining about the prescription restrictions. Glaucoma patients do not often have hospital appointments. Some of them go to the hospital once every few months. Because of this, I think the increase in prescriptions will come in stages. I think it will take some time for the number to increase.

Regarding *Alesion*, we have heard about the pollen counts and, even in autumn and winter, there is a certain degree of seasonality and indoor allergies. As a result, there is a great deal of interest surrounding this highly convenient medication. We hope to capitalize on this and achieve good market penetration into the full-fledged season.

Q1-3
Thanks. As for China, if there are a large number of patients who suffer from the coronavirus, will this prevent other patients from making outpatient appointments? Do you anticipate a temporary reduction in patients attending ophthalmology clinics as a result?

A1-3
Taniuchi: Honestly, as the hospitals are not yet open, it is difficult to imagine how the situation will evolve at this time. Looking at the previous SARS or MARS epidemics, it certainly seems possible that attendance at hospital appointments will decrease.

On the other hand, there are a certain number of patients who are undergoing surgery, or those with chronic illness who require refills, so they may get drugs at the doctor's office. Because of that, I anticipate prescriptions will continue at some level.
However, as you have indicated, there is a possibility of reduced demand, totally. This is probably the case with other companies as well.

Q2-1
I would like to ask about China as well.
It was mentioned that operation of the plant was halted for a while but, basically, what I understand is that there will be some risks to the Chinese business, as you mentioned. Also, I understand that your factory in China is basically manufacturing products for the Chinese market. Do you anticipate effects on the business in any other regions, or is the impact likely to be restricted to China?

A2-1
Taniuchi: Our products for the Chinese market are supplied by our Suzhou Plant and by export from Japan. There is no export from Suzhou to other regions. Therefore, I believe the impact would be limited to China.

Q2-2
Thanks. Second, I would like to ask about China's reimbursement drug list for national medical insurance.
As for the revision in November, it seems that *Tapros* was included, but that *Diquas* was not. How do you think this will affect the sales potential of *Tapros*?
Why do you think *Diquas* was not added to the list? Can you tell us anything about the price negotiations involved?
Has the process of price negotiations changed your outlook for the Chinese business and, if so, how?

A2-2
Suzuki: As you said, this time, two products were added: *Tapros* and *Benoxil*. *Tapros* is expected to expand following listing. Actually, the market had been responding very well until the current coronavirus situation developed. We are considering expanding the program once it becomes possible to resume operations in the future.
The NRDL listing in the China is somewhat complex. Between the time of approval and reimbursement, the performance of the dissemination activities determines some aspects of whether or not it will be included in the reimbursement. Therefore, rather than simply negotiating prices, there are factors of how much market feedback and data can be gathered after we start negotiating the NRDL listing.
This time, although we missed the timing, I think there are still more opportunities. In the same way, I believe that we will be able to try again after the current coronavirus epidemic has settled down.

Q2-3
Thanks. Finally, I would like to talk about over-the-counter drugs in Japan. I think performance is not as strong as last year, and I think there are some areas where inbound markets are likely to be slightly lower this time as well.
Could you give us your comments on the sustainability of sales, and on what points do you think the actual value will be a driving force in the future?

A2-3
Taniuchi: This is a somewhat difficult question but, as for inbound market, their numbers have fallen since the revision of the e-commerce law about a year ago. In particular, the market for medications has begun to cool. This has become more evident in 2019 and, given this backdrop, the number of inbound markets has fallen compared to the previous year.

In general, if you look at the situation in the last year or the year before, you can see that the number of inbound demand was about 30% or 40% higher than it is now.
While accepting that, we are also creating new products and new campaigns to stimulate demand in Japan. Although the inbound market has declined slightly, we are working to expand the market and increase market share by firmly tapping into demand in Japan.

Q3-1-1
I have three questions. The first is about the atropine for myopia that was mentioned. I understand that P2 trials are conducted in Singapore. Is it correct to understand that, as this was completed, Phase 2/3 trials is conducted in Japan?
ClinicalTrials.gov has not been updated yet, so I would just like to confirm this point.
In addition, there was a large-scale clinical trials in Singapore, and I think the dose was mentioned. I understand there are three doses. Has the dose for Japan already been decided? In particular, it may be pointed out that rebound is a problem. Is it appropriate to consider that as these issues have been cleared in the Asian trial, it is move on to a trial in Japan? This is the first question.

A3-1-1
Morishima: First of all, this Asia study focused on Singapore, but now administration has been completed, and we are currently in the process of follow-up for the observation period after the discontinuation of administration. Therefore, I think that the rebound will be clarified by analyzing future data. Basically, I think the treatment band is broader than we expected, and we have decided that Phase 2/3 can be implemented.
As it is Phase 2/3 in Japan, we cannot disclose the dose, but we are in the stage of confirming the effects of several doses. We recognize that the status of one country has already been disclosed in Japan, so we would invite you to confirm that. Essentially, we are aiming to conduct a clinical trial in Japan and then launch in other Asian markets thereafter.

Q3-1-2
Could you tell us what treatment period you are anticipating for the trial in Japan?

A3-1-2
Morishima: It is necessary to confirm the extent to which the period of clinical trials is disclosed. For general clinical trial information in the US, clinical trials are conducted in the form of a two-year clinical trial period and a one-year follow-up.

Q3-1-3
So, three years. A two-year administration period with a one-year observation period with.

A3-1-3
Morishima: Yes.

Q3-2-1
Thank you. In addition, I appreciate that as this question is about a product from another company, you may not be able to comment, but I would like to ask about *Beovu* from Novartis. It's an anti-VEGF drug for AMD, the same as *Eylea*. How do you view this drug from a competitive standpoint? I would like to ask you about the ongoing sales of *Eylea* from the next fiscal year onward in terms of the alliance with Bayer.

A3-2-1
Suzuki: Of course, the entry of new products will have a certain impact. This time, the contract with Bayer has been extended, so we would like to continue working with Bayer to maintain growth.
There have been academic conferences where the three-month administration data for *Eylea* has been presented. With this in mind, it seems we have a clear detail approach.

Q3-2-2
And *Beovu* is once every four weeks?

A3-2-2
Suzuki: *Beovu* is once every three months.

Q3-2-3
And *Eylea* is once every three weeks, is that right?

A3-2-3
Suzuki: *Eylea* is once every two months.

Q3-3-1
Understood. Regarding *LENTIS Comfort*, it seems there is a slight sense of delay, but could you update us about the status, including insurance coverage?

A3-3-1
Suzuki: The activities to emphasize the product characteristics of *LENTIS* have been carried out as explained before, but it still takes time to penetrate. I think the full-year outlook is somewhat harsh.
We have received very good feedback from people who use our products, but we may not have been able to fully convey this message yet. For example, we would like to communicate the value of this product, including procedure of post-surgery examination.

Q3-3-2
Do you feel that the full-year forecast is a little tough?

A3-3-2
Suzuki: I think so.

Q4-1-1
Thanks. I would like to ask about Verily. You have pointed out, for example, the issue of adherence in glaucoma. Is there a possibility that this new partnership could solve the issue of adherence?

A4-1-1
Taniuchi: Although we are not yet at the stage of disclosing specific projects, we naturally have therapeutic drugs that we are working on. We recognize glaucoma adherence issues as an unmet need in Japan.
Taking this into account, I would like to look at the current medicine and look at the various unmet needs in ophthalmology, including not only treatments, but also testing and follow-up, in order to find out where digital technology or electronics fits in. I hope that answers your question.

Q4-2
Thanks. Also, in Morishima's explanation of myopia in children, it was mentioned that there are 76 million myopia patients in China. Of those, how many are actually eligible for atropine treatment?
Also, please forgive my ignorance, but could you tell me how many such patients there are in Japan?

A4-2
Morishima: Basically, the number is based on the number of children in their school years and, in China in particular, many children wear eyeglasses. In addition, we will continue to narrow down the range of patients using atropine eye drops, including those with side effects. Today, I do not think we are at the stage of presenting specific figures.

The ratio of patients wearing eyeglasses is about the same as in other parts of Asia, so there is certainly a lot of potential in Japan.

Q4-3
Thank you. Finally, the application for P3 in the US for *MicroShunt* is completed by the end of March. Regarding the 24-month data that was discussed earlier, could you tell us when this will be disclosed?

A4-3
Morishima: For data for 24 months, since the data is organized by the time of application, it is assumed that all data will be collected by the end of March. There is a possibility that additional submissions may have to be made for some follow-up patients but, as of March, I think the data will be collected.
We would like to make a further announcement about disclosure of this information in the future.

Q5-1
First, regarding R&D expenses, I feel that the progress of the three quarter period is fairly low compared to the full-year forecast. What do you think about the current full-year forecast?

A5-1
Koshiji: The full-year forecast is JPY28.0 billion but, as of the end of the third quarter, the figure is JPY17.2 billion, so it is assumed that JPY10.8 billion will be spent in the fourth quarter on a QTD basis.
Historically, although R&D expenses tend to increase in the fourth quarter, we have never used QTD in units of JPY10 billion. On this point, there is a possibility that it will be slightly less than the JPY28 billion forecast for the full fiscal year.
Nevertheless, the Company has not changed its profit forecasts for the current year because of the sales progress of *LENTIS Comfort* aforementioned, domestic over-the-counter drugs, or slightly downside products and businesses. Therefore we have not changed our bottom profit forecasts.

Q5-2-1
Thanks. The second question is about atropine, DE-127. In the P2 study in Asia, where and how do you plan to publish specific data in detail?

A5-2-1
Morishima: Currently, we are collecting data in the follow-up period, and we would like to disclose the data in the future.

Q5-2-2
Could you tell us when approximately that will be?

A5-2-2
Morishima: We would like to disclose as soon as possible, but we are planning to analyze the data and consider adding patients, and conduct a deep analysis to obtain information that can be used in the next stage. Since we are in the follow-up period, as of today, it is impossible to be sure.

Q5-2-3
What was the planned duration of the follow-up period?

A5-2-3
Morishima: I do not think this has been disclosed, but I can say that it was a set period of time.

Q5-3
Thanks. Lastly, I would like to talk about DE-126. After dose-finding study have been completed, there are further exploratory study. Why can't you move on verification studies? What are you planning to explore in the next study?

A5-3
Morishima: The information we are working to obtain in P2b is the treatment range. We are confirming the treatment window, and the data we can obtain are limited as this is P2b, but the effects on intraocular pressure appear to be close to that of other therapies.
We are currently conducting animal trials to see what the effects of FP and EP3 are likely to be. We are also conducting clinical trials to verify what characteristics can be achieved compared with other existing glaucoma drugs. We are currently looking forward to verifying that we can expect more stable intraocular pressure effects over a longer period of time than currently available.

Q6-1-1
The first question is about DE-127. I believe that the P2 trial in Singapore has been completed. This drug is atropine, the mydriatic drug, which is already a well-established drug. What form will it be marketed in on this occasion?
Also, it is already on the market in Singapore, too, in drugs like *Myopin*. Even if we look at China, there are already talks about using atropine eyedrops for myopia. This leads me to wonder how strong this IP is. There is an image that for sale under the current conditions, something cannot be sold unless its patents are quite robust. Is this correct? Are there any issues in protecting patents?
Is this part of a broader plan in the area of myopia?

A6-1-1
Suzuki: First, the sales scheme varies from country to country and region to region. Currently, the mainstay products are dispensed mainly at hospitals. Considering the process and side effects associated with this, we believe that the low-dose atropine we are currently developing has sufficient value. We are aiming to obtain approval and sell the medication accordingly.
Of course, pricing in terms of whether this is a preventative medication or a treatment will be another major issue.
In terms of patent potential, of course, there are some areas that are protected by the fact that there are different formulations or data has been obtained. In terms of patents, as you mentioned, the drug product itself is already well known. In this respect, we believe that a certain degree of exclusivity can be ensured by the data exclusivity of the product or by drug formulation.

Q6-1-2
If the marketplace is somewhere where patent laws are not strongly protected, is there a risk of copycat products? Or will these issues not occur in markets such as China?

A6-1-2
Suzuki: Perhaps in a country such as China, the protection of school-age children may be considered an area of national policy. If the market were to be turbulent and, if copies were sold, I believe the regulatory policy would start to make an appearance.
In some countries, there is a risk that a similar product will emerge. Therefore, we would like to take steps to raise brand loyalty through a variety of comprehensive approaches.

Q6-2
The second question is about *Beovu*. In their conference call, Novartis said that Beovu is in about 90 percent of the hospitals. Also, about retinal fluid, it has been seen positively by doctors that the amount of liquid in the retina is decreasing. Of course, patients aren't aware of that.

Even considering the mechanism of AMD, intraretinal fluid causes damage, and the disappearance of this fluid is perhaps a great source of reassurance for doctors.
But, on the other hand, there are HARRIER and HAWK, which are trials to approve *Beovu*. It seems from HARRIER that *Eylea* is better in terms of improving visual acuity. Moreover, only 50% of patients have maintained 12-weekly administration for one year, and so on.
Is this way of thinking correct? It should reduce the amount of intraretinal fluids and, in effect, reduce the damage. But, if that's the case, why isn't visual acuity improving? So, how similar is *Beovu* to *Eylea*?

A6-2
Taniuchi: We do not analyze the detailed data of *Beovu*, and we are not in a position to talk about it. Therefore, we cannot answer your questions.
Basically, as mentioned earlier by Suzuki, I believe that the value of *Eylea* is in the accumulation of actual experience in the market, data and experience in the real world. The experience that patients and professors gain through this is the point of differentiation.
We will continue to emphasize this point, and we will look at our competitors' products in the real world rather than in specific clinical trials, and we will continue to look at them.

Q6-3-1
The last question is about DE-122. You have only just begun to analyze the data around this quarter. I wanted to confirm that this understanding is correct.
Many of these drugs have sought to further strengthen VEGF, either by VEGF antibodies or by other drugs that have been developed. I understand that this DE-122 provides a new mechanism by which reduces scarring, fibrous tissue formation. Is this correct?

A6-3-1
Morishima: Basically, this is a new mechanism, but it is assumed that this will complement anti-VEGF medications.

Q-6-3-2
Is the mechanism almost the same?

A6-3-2
Morishima: The mechanism is different, but it is unlikely to completely tackle AMD on its own. We expect this drug to be effective in complementarily increasing the duration of treatment and curbing the reduction in the effectiveness of treatment.

Q6-3-3
So, the expectations around fibrous tissue formation are not so high.

A6-3-3
Morishima: P2 trials have just been completed, and the number of cases is small. Rather than fibrous tissue formation, the important factor may be in preventing neovascularization.

Q6-3-4
The results of a study, which was conducted together with the University of Sydney, emphasize fibrous tissue formation considerably, but this is an experiment in mice, so it might merit review, but it has not yet been established as a mechanism.

A6-3-4

Morishima: Yes. Since this is basically an effect that suppresses endoglin, we have conducted a number of multifaceted evaluations and we think it will have some effects. We are currently analyzing the clinical data and considering what we can expect.

Q7-1

I have a question about R&D expenses for the next fiscal year.

The figure for this term is JPY28 billion, which is high in the first place. The answer to the previous question was that there was a possibility that not all of the money would be used in this period.

I think the explanation was that in this fiscal year, there will be a rolling application for MicroShunt in the US, so the costs and expenses will increase. When considering R&D expenses for the next fiscal year, this portion will be completed during this fiscal year, so on a YoY basis it will be less than JPY28 billion. If we looked at a level of around JPY26 billion, do you think there is a major difference?

A7-1

Koshiji: The difference between JPY26 billion and JPY28 billion is still being discussed, and I think it is still at the stage of budget formulation. Basically, we are considering a starting point at roughly the same level as this fiscal year's budget of JPY28 billion.

Regarding DE-128, since it is impossible to discuss whether or not it will emerge from the current fiscal year on a single-item basis alone, we are developing new products and managing the lifecycle in each region. At this stage, I would like to report that the level is roughly the same.