Q4 FY2019 Results

Santen Pharmaceutical Co., Ltd.
Financial Disclosure Meeting
FY2019 Business Highlights
FY2020 Forecast

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May 11, 2020

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- Information given in this presentation contains certain forward-looking statements concerning forecasts, projections and plans whose realization is subject to risk and uncertainty from a variety of sources. Actual results may differ significantly from forecasts.
- Business performance and financial condition are subject to the effects of medical regulatory changes made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.
- The process of drug research and development from discovery to final approval and sales is long, complex and uncertain. Individual compounds are subject to a multitude of uncertainties, including the termination of clinical development at various stages and the non-approval of products after a regulatory filing has been submitted. Forecasts and projections concerning new products take into account assumptions concerning the development pipelines of other companies and any co-promotion agreements, existing or planned. The success or failure of such agreements could affect business performance and financial condition significantly.
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- Santen Pharmaceutical is reliant on specific companies for supplies of certain raw materials used in production. Business performance could be affected significantly by the suspension or termination of supplies of such raw materials if such an event were to adversely affect supply capabilities for related final products.

Taniuchi: Hello everyone. I would like to thank you for your participation in the results briefing today. I am Taniuchi, President and CEO. I would like to express my gratitude to you for your understanding and support for holding this meeting remotely in response to the government's request to refrain from going outside in response to COVID-19.

I would like to commence my explanation.

Santen's Values and Mission Statement

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: As you know, the basic philosophy of Santen Pharmaceutical is "*Tenki ni sanyo suru*" ("Exploring the secrets and mechanisms of nature in order to contribute to people's health"). This year marks the 130th anniversary of our founding in 1890.

Santen Group Measures to Combat the Impact of the COVID-19 Outbreak

Our first priority is to deliver ophthalmologic drugs to patients around the world

Respond swiftly to maintain stable business operations in state of emergency

<Major actions taken globally by the Santen Group>

1. Measures to secure a stable supply of our products
2. Measures to prevent the spread of the virus
3. Initiatives for the achievement of innovations in ophthalmology

*Please visit our website for more details: https://www.santen.com/en/about/Infection19/

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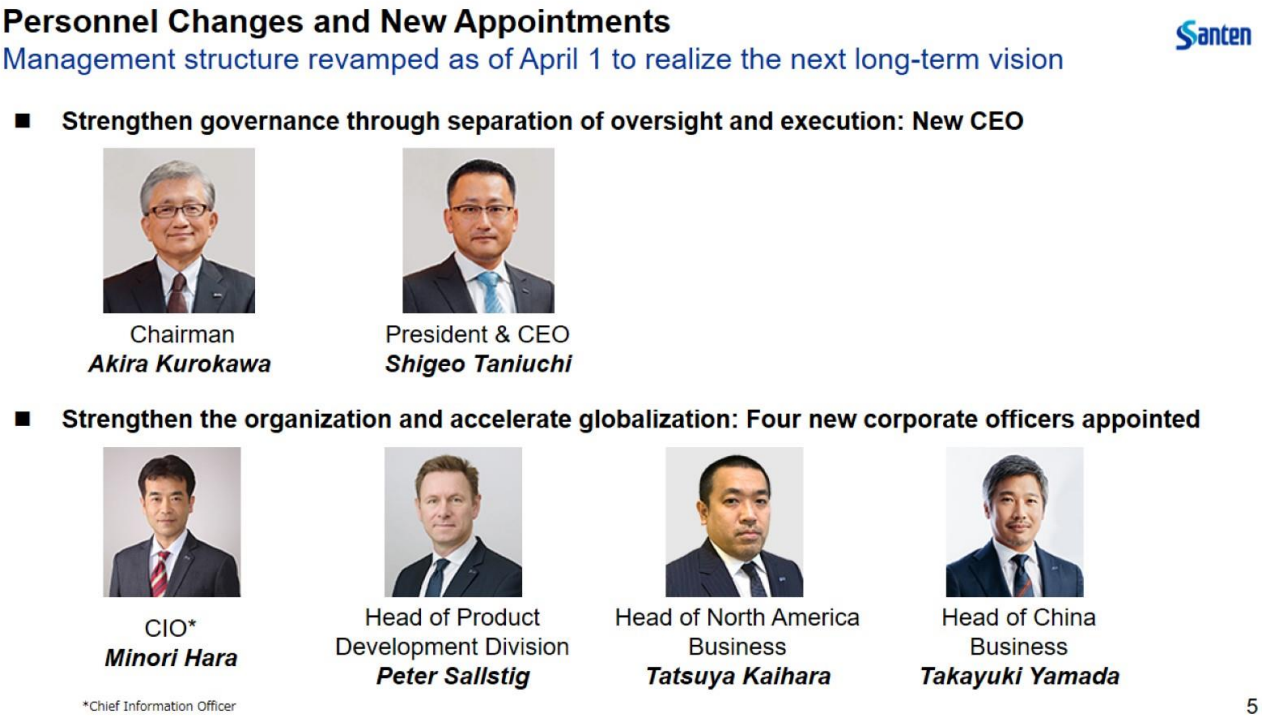
Taniuchi: First of all, I would like to explain Santen Group's approach to COVID-19. We have a majority of all Group employees overseas. We conduct business globally in about 70 countries.

Approximately 20% of our employees are working in China, where we supply and sell products to China. For this reason, at a relatively early stage in January, under the basic philosophy of "*Tenki ni sanyo suru*," we have clearly defined the following three policies as top priorities in response to the spread of the infectious disease: stable supply, prevention of the spread of viruses, and continuation of innovation. We have created a team under the direct control of the president and have been swiftly taking measures globally since the end of January, in order to ensure business continuity.

Specifically, we have implemented thorough safety measures at plants and laboratories in China, Japan, and the US; secured raw materials and testing chemicals; promoted the transition to telework worldwide and prohibited business trips; and shifted to holding lectures on the web, while ensuring business continuity.

I myself have already been working at home for almost three months, as is the case today. We will continue to focus on ensuring safety and business continuity.



Taniuchi: On April 1, we revamped our management system. As the president and CEO, I was responsible for the entire execution of the business. On the other hand, as the chairman, Kurokawa, who has been the CEO, will be responsible for management oversight and governance.

With the globalization of our operations and the acceleration of our business development, we have appointed four new corporate officers in order to enhance our ability to implement strategies. Yamada, who manages the Chinese business, has been leading the COVID response team locally since February.

I would like to talk about the current situation later.

Taniuchi: As we provided information at the previous briefing, we plan to announce in July this year our new long-term vision strategy, which will take over Vision 2020, our long-term vision that will be completed this year.

This is a summary of how Santen will grow toward 2030, based on the organizational capabilities it has cultivated over the past 130 years. I would like to discuss more details from July, but basically, the Vision includes how we will innovate technologies in ophthalmology as a whole beyond the traditional framework of pharmaceuticals, and how we will contribute to patients and society as a whole through eyes.

We have already commenced activities aimed at long-term growth, such as genetic therapy, cell therapy, and digital health. I would like to talk about the Vision as a new growth strategy that encompasses these initiatives.

FY2020 Approach (COVID-19 Impact)

Aim to increase profits by controlling activities and costs

Taniuchi: Finally, I would like to talk about our performance in FY2020.

Santen aims to raise profitability and increase profits, although the situation is still difficult worldwide. Of course, the impact of COVID-19 on sales varies by disease and country. However, I think it will be affected. On the other hand, we intend to secure profitability and increase profits by thoroughly managing expenses and carefully selecting activities.

At the same time, we will continue to invest in research and development, business development, and capital expenditure, which will lead to long-term growth, as we have done in the past. We will go through this FY2020 with an upward trend in profits and spur growth in 2021 and beyond.

Topics：China
Current Business Conditions Resulting from the COVID-19 Outbreak

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Yamada: Now, I, who oversee the China business, will explain the current status of the business associated with COVID-19 infection in China.

Current Business Conditions in China Resulting from COVID-19

Healthcare and economic activities suspended in February and March
Current conditions gradually recovering. Santen progressively resuming activities

Healthcare Activities	• Medical system: Ability to perform outpatient and surgical operations at about 70% of facilities • Outpatient: Recovery to around 50% of normal level • Ophthalmic surgery: Cataract surgery has also recovered to about 20-50% of normal levels
Our Response	• Production: Restarted operations on February 10. Now operating normally. No impact on supply • Sales activities: Resumed MR visits from April 1, as appropriate for conditions at each facility • Employees: Choice of telework or working in the office as appropriate

(Information based on an internal survey as of the end of April)

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Yamada: At present, economic and medical activities in China are recovering steadily. Accordingly, Santen has been properly resuming local activities and preparing for further growth in the future. As for medical activities, the number of hospital visits and patients undergoing surgery decreased significantly in February and March. Though the impact continues at present, it is gradually recovering.

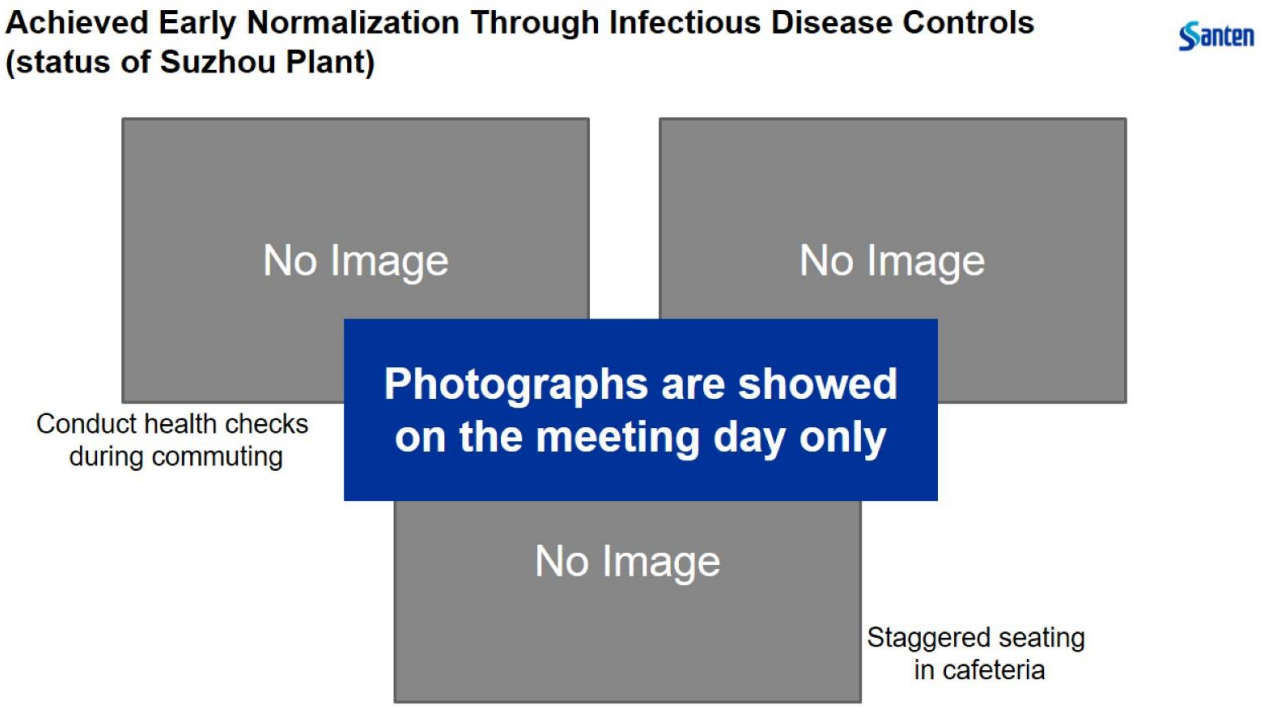
Regarding the operation, we have received a report that the number of LASIK, which is carried out in private hospitals and mainly for young people, is recovering quickly. We look forward to a bright future.

Regarding the situation of Santen, as Taniuchi mentioned earlier, we have given top priority to the supply of products, and since we resumed operations of the plants on February 10, the end of the Lunar New Year, there is no risk of supply.

Regarding our sales activities, since April 1, we have resumed our visits depending on circumstances of each facility. Before that, in February and March, we held 80 web seminars and other activities to continue our ongoing information activities. In doing so, we have been conducting sales activities appropriately.

Regarding our local sales situation, there was a major impact in the Q4. As I mentioned earlier, this is probably caused by the decrease in the number of outpatients or patients undergoing surgery.

We believe that this impact will continue for a while, but it will recover during the first half of the fiscal year. Based on this, in addition to the priority items, we are working to achieve further growth based on *Tapros*, which was newly listed in NRDL.



Yamada: This is an example of our countermeasures against the infection: our daily scene at the Suzhou Plant. We take all possible measures, such as checking the health of employees when they come to work, checking the body temperature, or holding seats at dining halls at intervals during meals. That's all.

FY2019 Financial Results
Ended March 31, 2020

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FY2019 Results

Higher sales and profits (core basis) due to growth in Japan and overseas businesses

(JPY billions)	FY2018 Actual	FY2018 vs Revenue	FY2019 Actual	FY2019 vs Revenue	YoY
Revenue	**234.0**		**241.6**		**+3%**
COGS	90.8	39%	94.8	39%	+4%
Gross margin	143.3	61%	146.7	61%	+2%
SG&A expenses	71.3	30%	73.4	30%	+3%
R&D expenses	23.8	10%	23.3	10%	-2%
Core operating profit	***48.2***	***21%***	***50.0***	***21%***	***+4%***
Amortization on intangible assets associated with products	7.0	3%	9.9	4%	+42%
Other income	4.0	2%	0.4	0%	-90%
Other expenses	0.2	0%	7.0	3%	--
Operating profit (IFRS)	45.1	19%	33.5	14%	-26%
Finance income	0.9	0%	1.0	0%	+6%
Finance expenses	2.9	1%	2.4	1%	-17%
Profit before tax	43.1	18%	32.1	13%	-26%
Income tax expenses	11.2	5%	10.4	4%	-7%
Actual tax ratio	25.9%		32.3%		
Net profit (IFRS)	31.9	14%	21.7	9%	-32%
Core net profit	36.1	15%	35.9	15%	-1%
USD (JPY)	110.82		108.81		
EUR (JPY)	128.38		120.80		
CNY (JPY)	16.52		15.64		

Core Basis

- Revenue increased in all geographic areas
- Core operating profit up on expense controls, other measures

DE-128 amortization

The absence of revenue from the sale of the former head office and Osaka Plant in the previous fiscal year

Impairment charges related to the discontinuation of DE-122 and impairment losses on joint venture in China

Tax rate rose due to the impact of unrecognized tax consequences on InnFocus contingent consideration and impairment losses on joint venture in China

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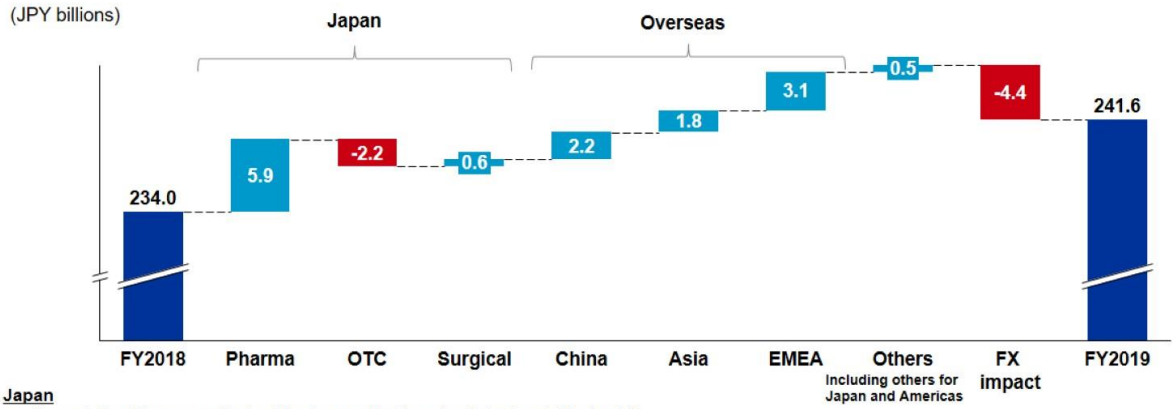
Koshiji: The full-year results for the fiscal year ended March 31, 2020 (FY2019) were strong. Despite the impact of COVID-19 infection in the Q4, overall revenue was favorable both in Japan and overseas. Operating profit on a core basis increased, due to a review of expenses and other factors.

FY2019 Revenue

Group sales up on steady growth in Japan pharma and overseas business



Japan

- Prescription Pharmaceuticals: Steady growth driven by *Eylea** and *Alesion LX*
- OTC: Decreased due to sluggish overseas tourists' demand
- Surgical: Steady growth driven by new product *LENTIS Comfort*

Overseas

- China: Local currency sales increased 10% YoY despite the negative impact of COVID-19 in the fourth quarter. (JPY basis +4%)
- Asia: Increased 6% in JPY basis (+12% excluding FX impact) (Korea: JPY basis +4%, local currency basis +12%)
- EMEA: Increased +8% in € basis (+ 2% in JPY basis)

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

Classified into countries or regions based on customer location. China is not included in Asia.

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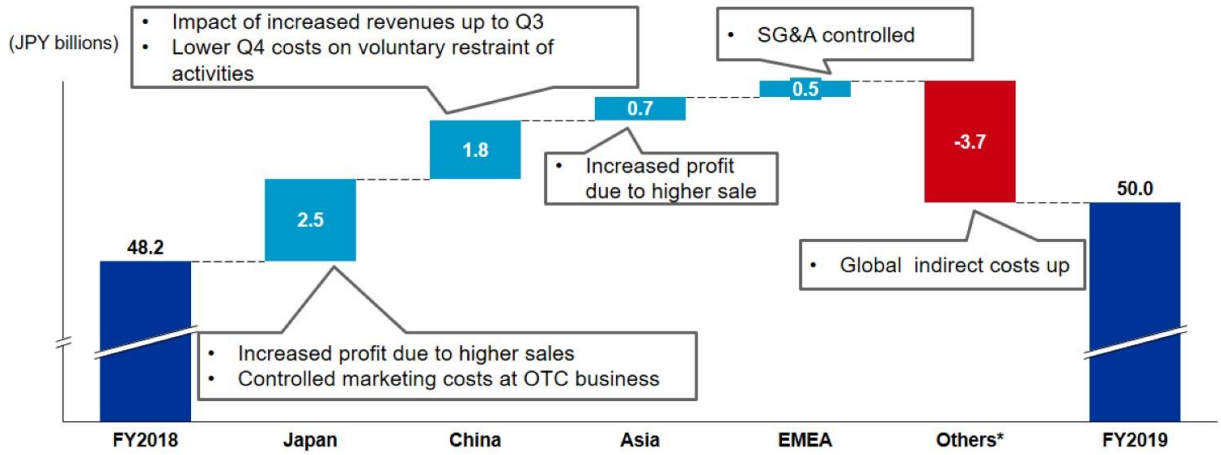
Koshiji: This is a detailed explanation of revenue. In Japan, the impact of the price revision has been seen since October, and there was an impact of strong yen in foreign countries, but despite those, we have realized an increase in revenue. Overseas, on a local currency basis, revenue increased by double digits in China and Asia, and 8% in Europe.

FY2019 Operating Profit (Core Basis)

Profits up on higher sales and control of SG&A due to COVID-19 related voluntary restraint of activities



	Japan	China	Asia	EMEA
FX impact		**-0.6**	**-0.4**	**-0.6**
Actual				
FY2018	67.6	8.3	5.0	9.5
FY2019	70.1	10.2	5.7	9.9

* Includes global R&D expenses and expenses for indirect departments (human resources, planning, manufacturing, etc.)

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Koshiji: These are the details of the core operating profit. The factors behind the increase in profits from FY2018 have been broken down by region. Profits have increased in each region including Japan, China, Asia, and EMEA.

FY2020 Forecast
Ending March 31, 2021

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FY2020 Forecast Assumptions

Aim to increase profits through efficient cost management
despite the negative impact of COVID-19

- **Revenue forecast: Timing of normalization varies by region**
  - Japan: Factor in impact in first half
  - China: Expect generally recovering
  - Asia: Conditions vary by country, but a moderate recovery
  - EMEA: Factor in impact around third quarter
- **Core operating profit forecast: In addition to the above, incorporate the following factors**
  - SG&A : Cost optimization, hiring restraint and investments on IT infrastructure for the new normal
  - R&D expense: Expect delays in some clinical trials

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Koshiji: The following pages, explain our forecasts for the full fiscal year ending March 2021. As the President explained earlier, revenue will be affected, but we are aiming to increase profits by controlling expenses accordingly.

FY2020 Forecast

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%**
COGS	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
- Core operating profit: Expect growth due to reduced activity and cost optimization

Revaluation of InnFocus contingent payment

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Koshiji: Page 16 shows details of the full-year forecast. Although revenue will decline, we will aim to increase core operating profit by optimizing selling, general and administrative expenses, and R&D expenses.

Dividend

Forecast dividend of JPY28 per share

- Total return forecast for FY2020 does NOT include the potential impact from future share buybacks
- J-GAAP standards used until FY2013, IFRS applied from FY2014

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Koshiji: Page 17 explains shareholder returns. We plan to increase the dividend from JPY27 in the previous fiscal year to JPY28 per share. That is all for my explanation.

Status of Research & Development

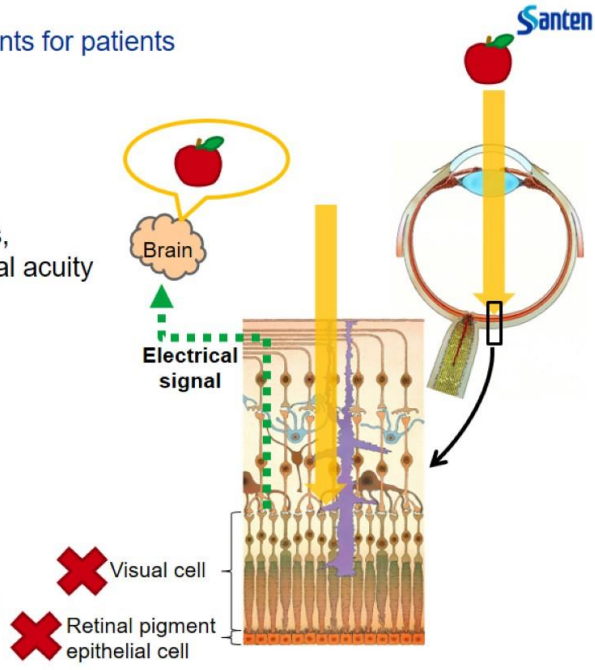
Morishima: I will explain the current status of research and development.

jCyte Partnership: Retinitis Pigmentosa

Inherited disease with no approved or effective treatments for patients

- **Inherited retinal disease**
  - ✓ Visual cells and retinal pigment epithelial cells become disorganized
  - ✓ Characteristic symptoms include night blindness, narrowing of the visual field and decreased visual acuity

- **No established treatment**
- **1 of 4,000** people[1)]
  (The leading cause for congenital blindness[2)] and the second leading cause for visual impairment[3)] in Japan)



1) *Lancet* 368:1795-1809, 2006, 2) *Nippon Ganka Gakkai Zasshi* 121:846-861, 2016, 3) *Jpn J Ophthalmol.* 63:26-33, 2019

Morishima: Santen Pharmaceutical Co., Ltd. entered into a licensing agreement with jCyte for the cell therapy program jCell for retinitis pigmentosa. I begin with a brief explanation of retinitis pigmentosa prior to jCell.

Retinitis pigmentosa is an inherited retinal disease caused by degeneration of visual cells and retinal pigment epithelial cells. More than 60 types of genes related to this disease have been reported.

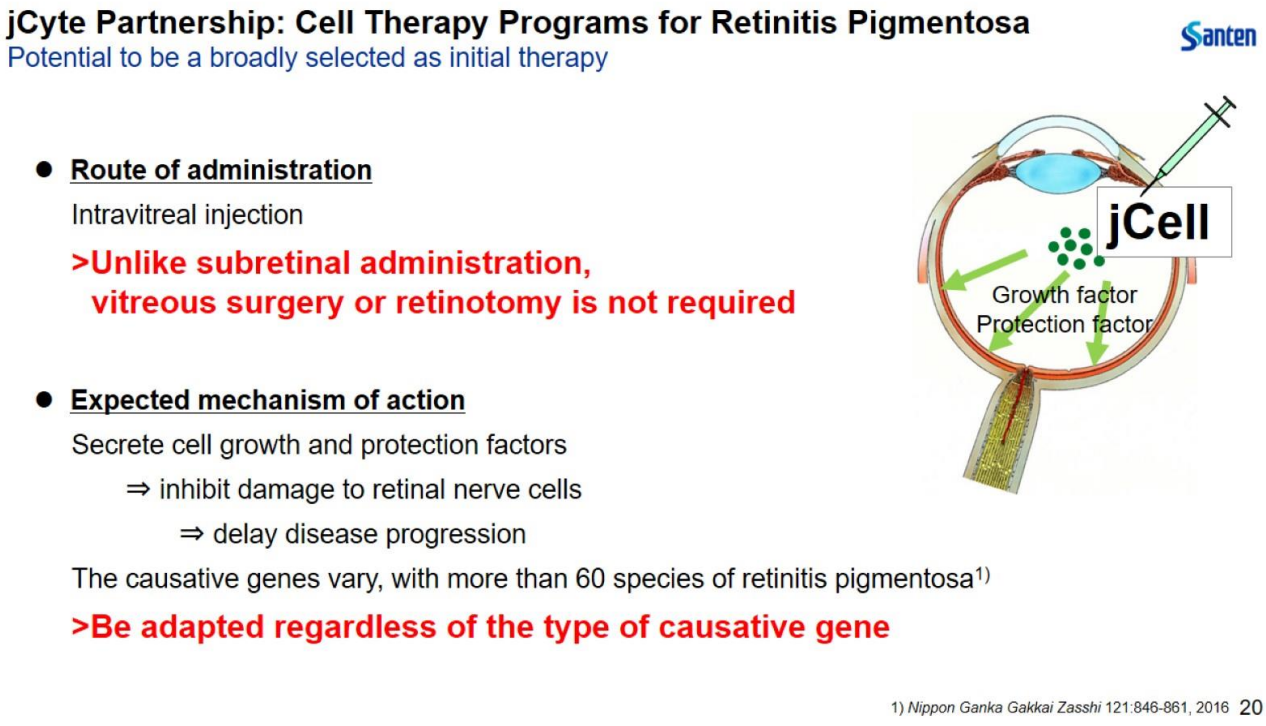
Visual cells represent the film of a camera and are responsible for converting light into an electrical signal. By communicating this electrical signal to the brain, we will recognize the image.

The retinal pigment epithelial cells behind the retina play an essential role in the maintenance of the visual cells, providing nutrients to them and eliminating the waste that has accumulated.

Retinitis pigmentosa is a disease that varies widely among individuals in its rate of progression. However, it generally appears in teenagers and gradually progresses to night blindness, narrowing of the visual field, and decreased visual function, often leading to blindness in middle-aged and older people.

In Japan, one in 4,000 to 8,000 and in the US, one in 4,000 are said to be suffering from retinitis pigmentosa, and it is estimated that there are 1.9 million patients worldwide.

In Japan, the disease is the leading cause for congenital blindness, the second-leading cause for visual impairment, and is one of the designated intractable diseases. It is a disease for which there are no established treatments at present, and development of treatments is strongly desired.

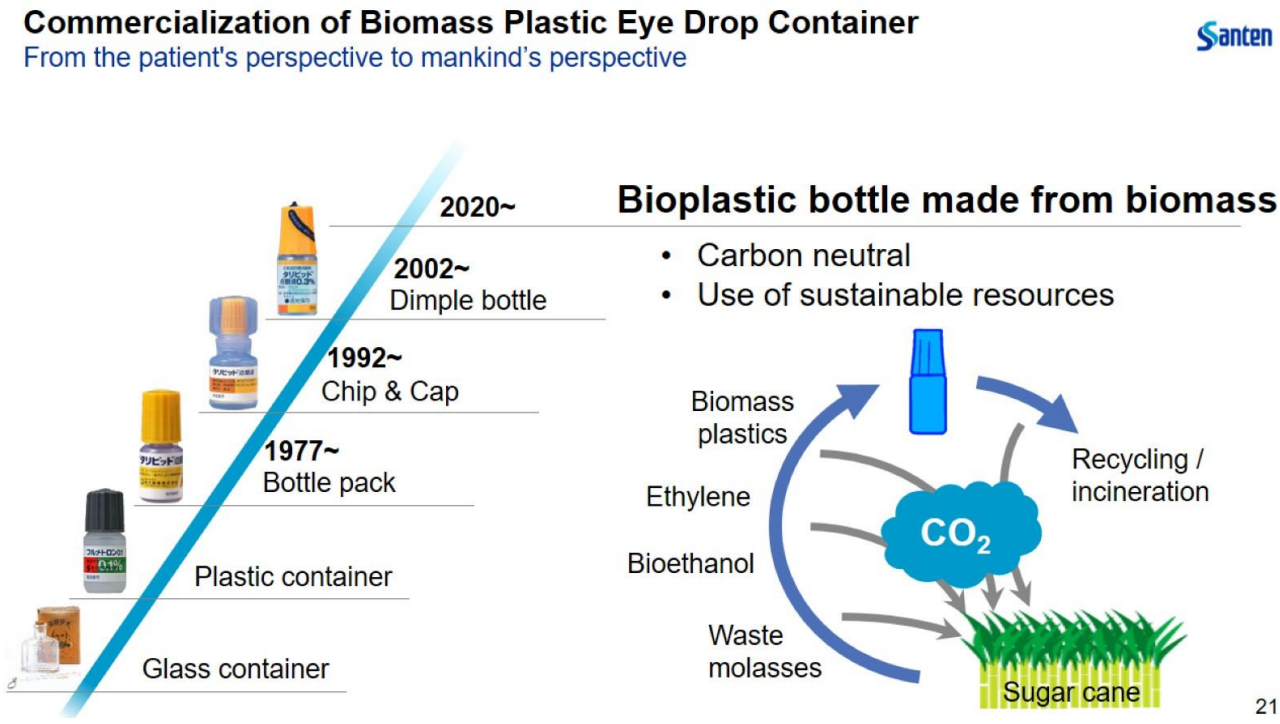


Morishima: jCell, for which we concluded the contract, is a product for a human retinal progenitor cell that is being developed by jCyte, Inc. in California, US. Phase 2b has been completed in the US and preliminary clinical evidence is provided.

Various approaches are in progress for retinitis pigmentosa, such as gene therapy and cell transplantation. jCell is administered by intravitreal injection and delays the progression of the disease by secreting neurotrophic factors and growth factors from the cells administered and inhibiting damage to the cells received light.

It does not restore the genetic variant that caused the disease. Therefore, we expect it to be used by a wide range of patients as an initial treatment, rather than limited to use in patients with specific genetic variants.

Another characteristic is that it is effective through intravitreal injection, which is familiar to doctors. Unlike direct subretinal injection, it does not require vitreous surgery or retinal incision, and offers simple, low-risk treatments.



Morishima: Santen Pharmaceutical succeeded in commercializing an eye-drop container with biomass plastic. Santen Pharmaceutical began with a glass container in the first place. As a result of pursuing user-friendliness, Santen has developed Japan's first plastic container, followed by bottle pack, chip & cap, and a dimple bottle that is easy to use for patients.

This time, we will start supplying products from biomass plastics made from sugar cane, which is friendly not only to patients but also to the global environment. First of all, we will switch the container of *Timoptol* this biomass plastic container as the first product for the Japanese market.

The expansion to other products and products for overseas markets will be accomplished while confirming its compatibility with drugs and the stable supply of biomass plastics. If we proceed smoothly with the expansion, we expect that around 2030 we will be able to use several thousand tons of biomass plastics for eye-drop containers.

Because an eye-drop container is small, this does not make a significant contribution, but we intend to address environmental issues together with our corporate activities.

Current Status of Research and Development

Pipeline/product development (1)

Santen

As of April, 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 *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: FY2020 PMA rolling submission completion, FY2020 launch*
		Europe	Launched
		Asia	Filed in Mar 2020 (Korea) *Plan: FY2020 approval*
DE-130A Catioprost latanoprost	Glaucoma / ocular hypertension	Europe	P3 *Plan: FY2021 P3 completion*
		Asia	

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Morishima: In this section, we report on the current state of research and development, mainly on the pipeline that had changes. However, as COVID-19 will have an impact on clinical trials in particular, please note in advance that the plan may be delayed.

First, DE-128 is slightly behind schedule due to the impact of COVID-19, but the Company is ready to complete the application in this quarter. Although there are uncertainties about the extent to which the screening will be affected by COVID-19, we expect to bring the product to market by the end of the year (FY2020).

This DE-128 has also been filed in Asia. It was filed in South Korea in March and is scheduled to be filed in other countries in the future.

Next, DE-126 is scheduled to begin an exploratory P2 study around this summer. There is also a risk of delay due to the impact of COVID-19.

Current Status of Research and Development

Pipeline/product development (2)

Santen

As of April, 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-076C *Verkazia* ciclosporin	Vernal kerato-conjunctivitis (VKC)	Europe	Launched
		Asia	Approved of VKC indication extension to *Ikervis*
		Others	Launched (Canada)
DE-114A epinastine HCl (high dose)	Allergic conjunctivitis	Japan	Launched
DE-127 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*

DE-122: Expected efficacy was not demonstrated in P2a; development discontinued in March 2020

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Morishima: Regarding DE-127, low-dose atropine, the last patient out was done in April in Asia and the results were scheduled to be announced at a conference in July. As this conference has been postponed, we are looking for opportunities to provide information at other conferences. P2/3 trials, which are carried out in Japan, are currently progressing as planned.

As already announced, as DE-122 did not show the expected efficacy in P2a, we have decided to discontinue development. That is all.

Question & Answer

Q1-1-1
First, regarding your thinking about the forecast for the current fiscal year, I think there will be a negative impact of coronavirus on revenue. While revenue declined by 40% in January to March in China, and although it is now recovering, the Company's positive forecast of a 16% increase for the current fiscal year appears somewhat optimistic. Please explain under what assumptions of recovery you made this forecast of a 16% increase.

A1-1-1
Taniuchi: I will answer it. Excuse me, but are you talking about the performance of China with a 16% increase?

Q1-1-2
That's right. I think that the revenue in China is forecast to increase 16% this year.

A1-1-2
Taniuchi: Yes, I will answer that. As Yamada explained earlier, the current situation has been recovering significantly since April, and in terms of medical examination behavior, we basically believe that it has been recovering at a rapid pace in April and May.

The slowdown was seen in the latter half of the previous fiscal year, and this has been recovering rapidly since April, which suggests that the market has been expanding. Furthermore, we did not think that this is transitory, but is a fundamental increase due to an increase in the number of patients undergoing medical examinations or surgical operations. Therefore, in China, we believe that we can expect solid growth, including the penetration of new products.

Q1-1-3
Thank you very much. I would like to ask about China a little more. Probably the first quarter will still be negatively affected by the coronavirus slightly. In that sense, would it seem that a YoY revenue increase in the first half will be slightly lower than 16%, and will it quickly recover in the second half?

A1-1-3
Taniuchi: Yes, please think so basically. Although there are some signs of weakness in the first quarter of the fiscal year under review, hospital visits are not necessarily linked to our shipments or actual digestion.

As you know, in China it relatively easy to purchase drugs, including getting a drug with a prescription at a hospital or by purchasing it at a pharmacy. Even if the number or frequency of hospital visits suddenly drops, drugs are sold relatively.

In addition, since drugs for chronic diseases or dry eye are constantly sold, and although we are seeing a slow start in the Q1, our business has been recovering rapidly since May. So, I currently think that it will grow strongly from the summer onward again.

Q1-2
Thank you very much. The second point concerns Europe. In the Company Guidance for this fiscal year, the revenue forecast is roughly flat. However, in the presentation material, it is written that the negative impact of the coronavirus is incorporated up to the Q3. With this negative impact for nine months in mind, the figure appears somewhat aggressive. I hope that you will give a more detailed explanation about this.

A1-2
Taniuchi: This is basically the same as in China. We carefully monitored actual shipments in February, March, and April this year. Obviously, there are declines in various activities in economy, but in fact, hospital visits and the prescriptions for products are continuing to a certain extent.

In Europe, the percentage of glaucoma is extremely high, particularly compared to China. Of course, glaucoma must be treated continuously since it is a chronic disease. Therefore, even if the frequency of treatment drops slightly, the prescription of the product is steady, and the impact on revenue is much lower than in other regions.

Taking account of that, the impact of coronavirus on actual product prescriptions, actual digestion, and shipments is milder. Therefore, we are confident that we will be able to achieve solid revenue accordingly.

Q1-3-1
Thank you very much. Lastly, regarding the SG&A expenses, other than the R&D expenses, in the current fiscal year, are the Milestone payments payments related to *MicroShunt* included? If they are included, you forecast the expenses to decrease by JPY3.3 billion compared to FY2019. Please explain in more detail how you plan to reduce the costs.

A1-3-1
Koshiji: Milestone payments payments for *PRESERFLO MicroShunt* filings and approvals are not included in the P&L statement. It will be recognized as a capital expenditure.

However, in terms of impact on the P&L statement, other expenses of JPY8.2 billion, on page 16, is recorded as a reserve (of changes) for future payments, including this milestone payment.

Q1-3-2
Thank you very much. The *MicroShunt* costs are not included, so do you plan to lower the expenses for this fiscal year to JPY3.3 billion by cutting costs naturally?

A1-3-2
Koshiji: Yes, that's right.

Q2-1-1
The deadline of the application for *MicroShunt*, which was originally until March, was extended to April to June. You mentioned that there is an impact of COVID, but please tell us what specifically is happening. I think there are both the application and the subsequent reception, but neither of them has been done. Could you first confirm whether the application will be made between April and June, and then wait for the reception?

A2-1-1
Taniuchi: I will reply to your question. One reason for the delay in *MicroShunt* is the impact of COVID. Specifically, we have been working on a variety of tasks to collect various application data, but there are outgoing restrictions on the factory of Miami and the shutdown of the factory, etc. The production did not stop but slowed down slightly.

In addition, there is a sterilization process in the process of preparing batches of products for submission, but the sterilization vendors are all directed toward COVID, and our sterilization work has to take a backseat. We can't help it as we are in an emergency situation, but the data for applications are being delayed a little bit at a time. That is the situation. However, it is not that there is a technical problem. Even though it is delayed, we expect that we will be able to apply during this first quarter, or within this month, if possible.

Q2-1-2
Understood. As for the sterilization, it was very easy to understand. I would like to ask you whether the local situation is that vendors of sterilization are already doing business with your company?

A2-1-2
Taniuchi: Well, I don't mean that our company was excluded, but it was only slowed down a little, so it took some time. The operation of the plant in Miami was suspended for a certain period of time as the patients of COVID-19 increased rapidly in Florida. However, it is calming down and the operation has resumed. Therefore, during this first quarter, in May if possible, we will file an application in order to move forward with releasing the product by the end of the year.

Q2-2-1
Understood. The second question. You talked about the top-down approach abroad. As for Japan, you have published the overall figure of negative 7%. I think there will be various factors such as an impact of drug-price revisions, particularly on the OTC market. Could you give me a brief explanation of the factors behind the 7% decline?

A2-2-1
Taniuchi: I will answer it. Suzuki will give a supplemental comment. In Japan, basically, RX has maintained the same trend, but of course there will be a negative effect of curbing medical treatment. However, we are also promoting the use of *Alesion LX*, and we believe that *EYLEA* will continue to grow steadily.

Another negative point is, as you said, OTC. This is where the direct impact is now coming out and, of course, the inbound portion cannot be seen. I think that its YoY decline from FY2019 to FY2020 is relatively large. Mr. Suzuki, if there are any more supplements, please.

A2-2-2
Suzuki: It is not a supplementary point. Looking at products or contents, factors such as the situation in products for chronic diseases and the decline in OTC inbound tourists are complicated. How to look at these points is very difficult, but under the current assumptions, we are seeing that the situation will trend almost at this level.

Q2-3
The new dosage of *Alesion*, for which you cooperate with Mitsubishi Tanabe, is selling very well. On the other hand, in the market, pollen is not spreading so much, and performances of other eye-drop manufacturers are quite declining. Please tell us if you received orders until March, or if you have a risk of becoming negative in April, as you have experienced in the past.

A2-3
Taniuchi: Regarding *Alesion LX*, with Mitsubishi Tanabe's strengths of course, we are seeing that it permeated extremely well beyond expectations, and because it is a high drug price, we believe that it contributed greatly to the results in Japan in the Q4.

As you pointed out, the pollen dispersal began early, and ended early in the fiscal year under review. However, this did not result in an accumulation of inventory, but the inventories were shipped out smoothly. Therefore, we are making steady progress in the current fiscal year without leaving an unwanted inventory. In addition, we are making steady progress in switching *LX* to high-concentration formulations, and we will continue to focus on these products.

Q2-4
Understood. Finally, you have explained the cell therapy. In the world, I think that there is a process of making the RPA cell itself from iPS. I would only like to ask you if you think that the cell therapy has an advantage in comparison with that.

A2-4
Taniuchi: I think naturally there is an approach to regenerate epithelial cells by regenerative medicine or other means. The jCell is the injection of nutrient-producing cells into these cells. We believe that it is better to understand that it is complementary rather than competing with new technologies or genetic therapy. Therefore, if such an approach comes out, it will produce more synergistic effects.

Q3-1-1
Regarding *EYLEA*, I don't ask about individual sales, but I think you received an approval of the indication for Neovascular Glaucoma (NVG), in March, and this may be the fifth indication. The reexamination period is 10 years, but I think you mentioned that the generics will appear around 2022. Although this will be included in the new vision, please tell us how you see this environment, including the indication for the remaining two years.

A3-1-1
Taniuchi: I would like to answer it first, and Suzuki will give a supplementary comment. Regarding the *EYLEA*, although we will continuously add the adaptation. We have been making efforts to improve the value of the whole franchise, although we do not know whether the additional adaptations contribute to a significant growth. Even though competing products are emerging, our strengths lie in our proven track record in various indications, as well as in the fact that doctors have experiences of how to use them according to their efficacy, safety, and patient status.

With this as a weapon, and with an abundance of data, we are working to maximize the value of this product and maintain a growth trend. We also do not know how generics will be launched, including biosimilars in the future, but our basic approach is to pursue value centered on them. Mr. Suzuki, will you add anything?

A3-1-2
Suzuki: As Taniuchi has just mentioned, we are working together with Bayer to maximize the value of the product. One thing that we want to do is to maximize the potential of this product so that we can contribute to our patients. I believe that some patients were unable to start treatment because of the drug price. This will probably be covered by a biosimilar that begins with *Lucentis* in the future. In any event, I think that the potential of this product will continue to be demonstrated for a while.

Q3-1-2
I understand. Another thing: I'm sorry for asking about the individual product, but I'd like to ask you about the current situation of *EYBELIS*. I understand that the ban on long-term prescriptions has been lifted in Japan. Could you tell us whether the trend has changed a little or not?

A3-2-1
Taniuchi: Regarding the lifting of the prescription restriction, we have been able to confirm that the trends have begun to change slightly. We are now in a situation in which large sales activities cannot be carried out due to the COVID-19, but we are disseminating information. We will continue to work through FY2020 to ensure that the value of this product is fully disseminated and that it can be used by more patients without prescription restrictions. We are also progressively expanding the sales in Asia, and we will make efforts to make it a growth pillar of glaucoma.

Q3-2-2
The US may be influenced by COVID, but do you mean that the schedule remains unchanged?

A3-2-2
Taniuchi: Well, at the moment, yes, you can think that way.

Q3-3-1
Yes, I understand. I'm sorry, but one more thing, please. I think this was the question from questioner at the beginning. Mr. Koshiji, I think it is on page 16 of the material.

For other expenses of JPY8.2 billion, there is a note "InnFocus contingent payment." This means, I think, that the raise of development stage results in a recognition of the payment to a vested interest under IFRS, and this was posted as an expense.

On the other hand, you mentioned about capital expenditure at the beginning of the meeting. Can I understand that this is the compensation that comes out after the products are launched on the market?

A3-3-1
Koshiji: Yes, that's right. Other expenses, in other words, are reserves for future payments and hence no cash outflows. As for the milestone, cash outflows will occur in the current fiscal year if the application and approval is made, but will not be recorded on P&L statement.

Q3-3-2
Do you mean that the total amount will be included in JPY8.2 billion?

A3-3-2
Koshiji: Yes, based on the method of IFRS that the present value of all future payments will be the amount in a certain valuation model.

Q3-3-3
Yes, I understand. Thank you very much.

Q4-1-1
Thank you very much. I would like to confirm your approach to expenses. Mr. Taniuchi and Mr. Koshiji also said several times that you plan to secure profitability and increase profits. Rather than a plan that simply reflects the portion that you can't use even if you want to use it due to activity restrictions, can I understand that you made the plan considering that if revenue is this amount, expenses must be about this amount?

Then, depending on the state of COVID-19, there is a possibility that revenue will fluctuate, and in the unlikely event that revenue is even lower, what scope do you have for further cost reductions to achieve the earnings forecasts? I think it's another problem whether you can or not and whether you do or not, but please tell us if revenue is even lower, and how much you are thinking about reducing expenses.

A4-1-1
Taniuchi: I will reply to it. First of all, with regard to the concept of cost, as you mentioned, we are thinking from both perspectives. One is to change the way we conduct our activities under the activity restriction or with a new model.

On this basis, we provide this figure by looking at the amount of expenses we will be able to do with, the actual sales outlook, from the standpoint of securing profit margins. Therefore, as you asked with the second question, if revenue is further reduced, we will further control costs accordingly. Basically, rather than revenue, we would like to focus on this JPY52 billion bottom line this year in particular.

The current expenditure is not limited to the minimum expenditure, but is based on certain assumptions, for example, on securing marketing and increasing market activities as the economy recovers. Naturally, if the infectious disease persists for a long time, marketing activities will be reduced accordingly. Through these efforts, we intend to protect this amount of profit of JPY52 billion.

Although we have not decided what to do at this point in time, we are viewing all options, the use of costs, revenue in each country and the expansion of infections every month, to maintain profits according to revenue.

Q4-1-2
I understand. Thank you very much. That is all.

Q5-1-1
I have one question. I apologize for the persistence, but I would like to ask Mr. Koshiji what and how much expenditure you will cut, as it is extremely important in order to achieve the target this time.

For the reason, your company's breakdown in FY2019 shows that there is considerable fluctuation in the cost category. In particular, the expert fees and commissions, perhaps a consulting fee, decreased by JPY2 billion in FY2019. I don't know what happened in March 2020, but as the application of *MicroShunt* has begun, I would like to know whether the portion includes the cost of such consultations that naturally decreases, and how much self-help is incorporated. Or is another planned factor incorporated? I wanted to confirm that.

I just want to confirm one more thing. Regarding the APPLE Study of DE-127, which has already been completed, I believe that the primary end point was changes in D (diopter). Did the axial length change? Was it restrained? Please give us a summary of these two points.

A5-1-1-1
Koshiji: Regarding expenses, Taniuchi, the President, explained the thinking behind how to realize them. First of all, under the activity restriction, for example, travel expenses can be reduced in a straightforward manner. For example, it cost approximately JPY3.5 billion in FY2019, so if you think about it on a quarterly basis, you can imagine roughly what impact it will have. We believe that we still need to cut other commissions by reviewing the way of utilizing these fees, and we believe there is considerable room for adjustments where we do in-house or not.

A5-1-1-2
Morishima: Regarding the results of the APPLE study, the official information will be presented at the next academic conference, but the expected results were obtained, including axial length.

Q5-1-2
I think that it would be meaningless if we did not curb the axis length of the eyes, even if we restricted short-sightedness. Is that the correct way of thinking?

A5-1-2
Morishima: Basically, the axial lengths and myopia progression move in parallel. The concept is to move both for our data, but also for data from Singapore. If we start with the atropine mechanism, I feel that both of them will move.

Q5-1-3
OK. Thank you very much.

Q6-1-1
Then just one point. On page nine, it is written that cataract operations recovered from 20% to 50% in China. I think it probably has stopped, also in Japan. This has recovered quite rapidly in China from the second half of the first quarter, and although we have received the figure for Japan, are you expecting a fairly rapid recovery from the second quarter onwards, or rather seeing a return action?

A6-1-1-1
Taniuchi: First of all, I would like to talk about the situation in China and the situation in Japan separately. Regarding the situation in China, as you mentioned, if the situation is recovering rapidly. I do not know, however, if we see a return action. As Yamada mentioned earlier, there has been an increase in the number of LASIK. As for cataracts, China is a country where the capacity for cataracts is insufficient, and patients are awaiting it. The hospital visits are increasing in April, especially from May, and as such, it is expected to recover rapidly. Mr. Yamada, can you make a quick supplement to the current situation?

A6-1-1-2
Yamada: Yes. As Taniuchi has just said, there are signs of a rapid recovery. Regarding the return action you mentioned, since there are restrictions on ophthalmologists and surgical instruments, etc., in the first place, and compared to the period prior to COVID, sterilization will be performed after each operation, procedure is increased, so it is expected that it will not increase immediately as a return action. That is all.

Q6-1-2
This 20 and 50 has an extremely wide range, but that means that there are considerable regional differences, such as Wuhan and Shanghai, isn't it?

A6-1-2-1
Yamada: Yes, you are right. There are restrictions on mobility, etc., depending on the metropolis and the provincial cities, so it would be fine if you could understand that there are variations depending on the city or province.

A6-1-2-2
Taniuchi: As for Japan, there is no major phenomenon so far. In particular, in Japan, cataract surgery is not necessarily performed only in large hospitals but is also performed by medical practitioners. This is true in Japan, as is the case with the US. If that happens, for example, even if the so-called large-scale core hospital is devoted to emergency response to the COVID and is unable to use an operating room, ophthalmologists will be able to receive adequate numbers of cataract patients.

As there is that capacity, I think we will probably see a recovery in the total volume within the capacity in Japan, but it is not as dramatically affected as in China, and there is a market centered on practitioners. On the other hand, as China is a large hospital-centered market, there has been an extreme change, such as a sudden halt due to the COVID. But I hope you will understand that Japan is milder than that.

Q6-1-3
In Japan, there are specialized hospitals where many operations are carried out in Osaka and Tokyo. Such hospitals are continuing the operations, aren't they?

A6-1-3
Taniuchi: Of course, taking all possible measures to avoid infections in the hospital, practitioners are carrying out the operations as usual.