Q2 FY2021 Financial Results

Become A Social Innovator

Q2 FY2021 Financial Results
Santen Pharmaceutical Co., Ltd.

Presentation: November 9, 2021

Santen
Imagine Your Happiness

Speakers

Presentation/Q&A

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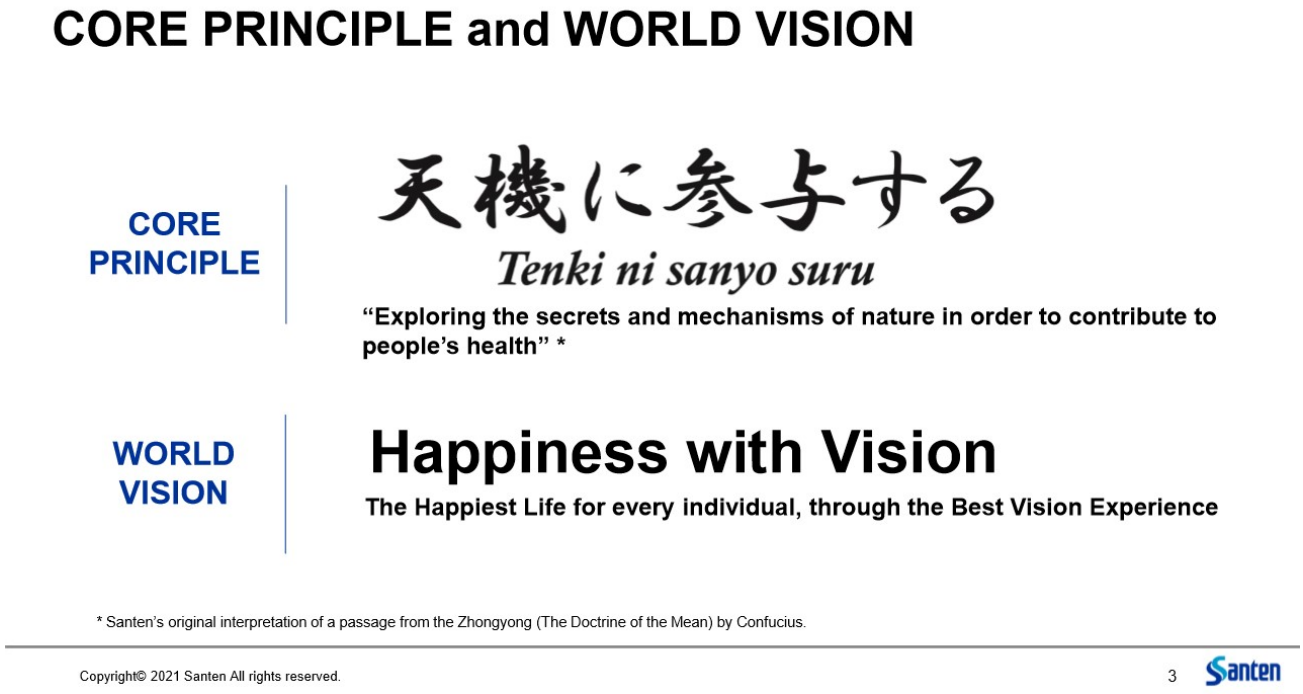


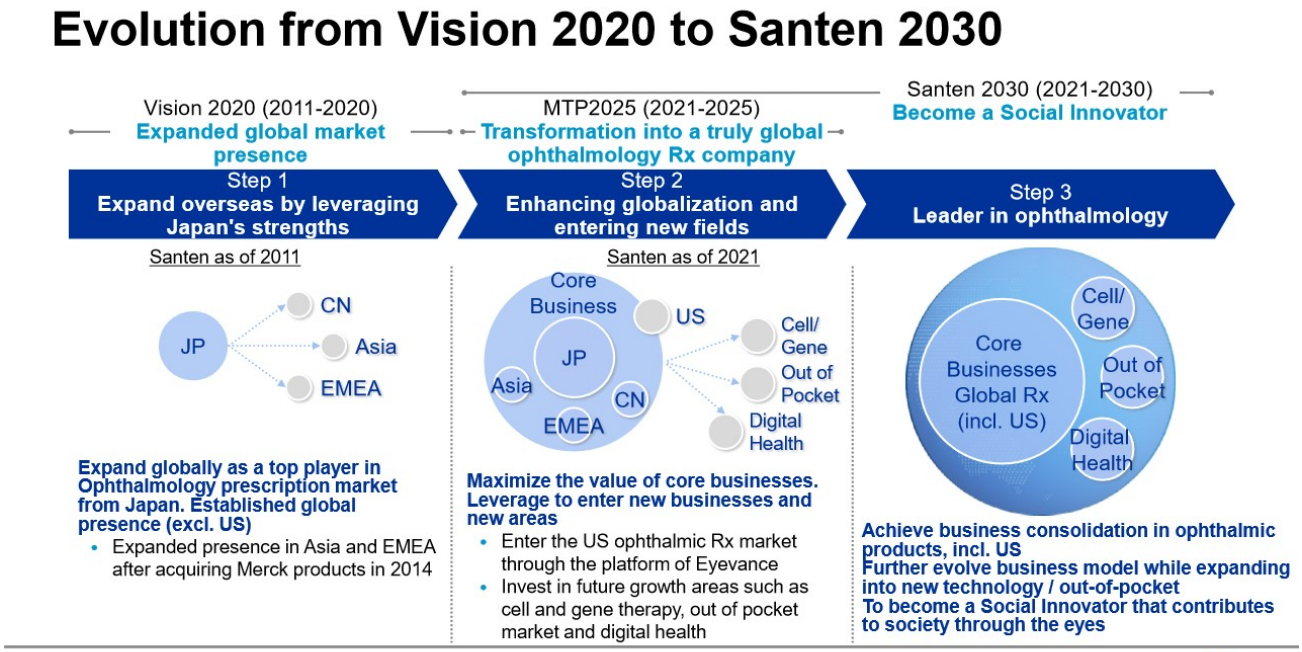
Taniuchi: Hello, everyone. I'm Taniuchi, CEO of Santen Pharmaceutical. Thank you very much for taking time out of your busy schedule to join us today.

First of all, on the third page, you will find the basic philosophy from which our company name is derived, "Exploring the secrets and mechanisms of nature in order to contribute to people's health."

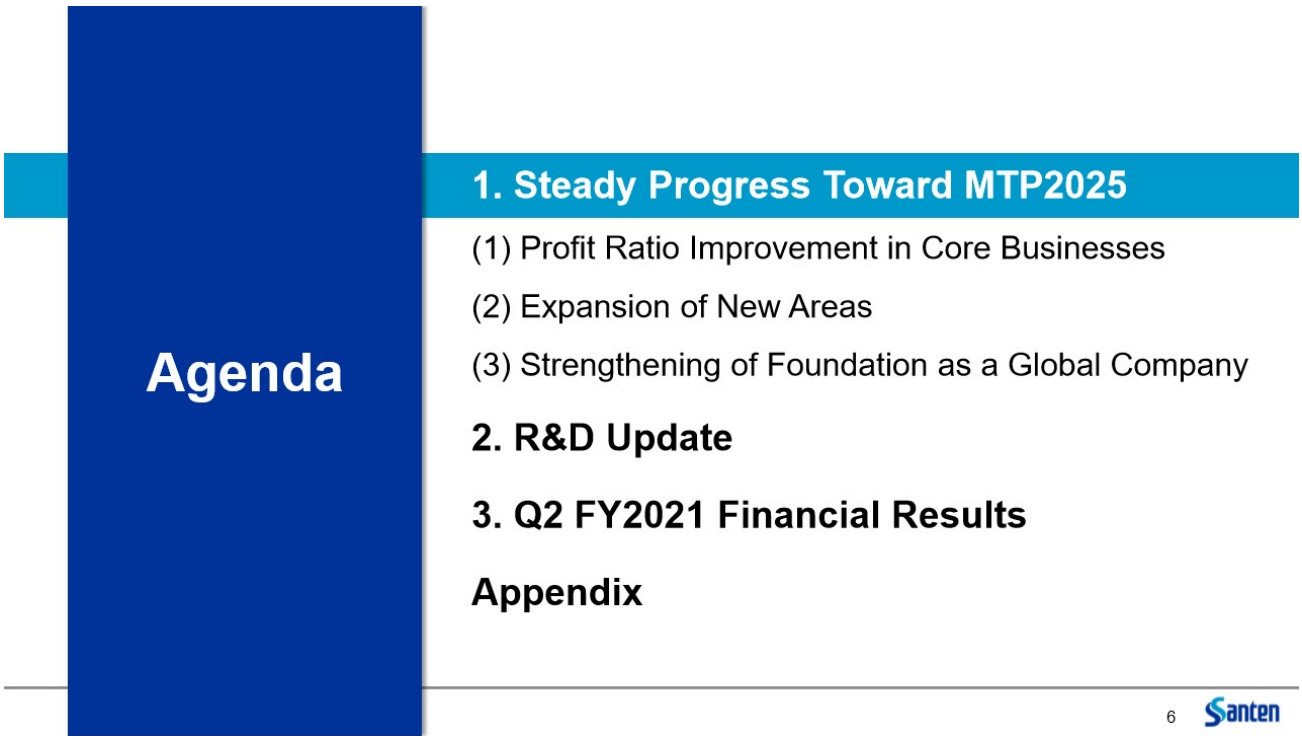
We, Santen, aim to create a better world through our WORLD VISION, "Happiness with Vision." We strive to achieve this every day in our business.

Please go to page 4.

Last year, we announced our long-term vision, “Santen 2030” which aims to address social issues related to eye disease. Our vision is to become a social innovator, and our goal is to reduce the social and economic opportunity loss of people around the world caused by eye disease.



Page 5. This is the slide that I showed you in the Medium-Term Plan. The first half of this plan, MTP2025, will take us to 2025. This is shown here in the middle. We will focus on maximizing the value of our core businesses, while entering new business fields. We have positioned the next five years as a very important period for us to achieve growth in 2026 and beyond.



Now look at page 6. This is an introduction to today's content. I would like to talk about today's results through the prism of the 3 strategies set forth in the Medium-Term Plan.

Financial Summary

MTP2025: Steady Growth in First Half of the First Year as Planned. Focus on Achieving Full-year Targets Emphasizing Appropriate Balance of Mid-to-Long Term Growth Investments and Profitability

- **Q2 FY2021 Results:**
  - Revenue: JPY128.8 billion (+8.3%)
  - OP: JPY18.8 billion (+0.6%), Core OP: JPY24.3 billion (-5.4%)

- **FY2021 Forecast: Unchanged**
  - Revenue: JPY260.0 billion (+4.2%)
  - OP: JPY41.5 billion (+240.5%), Core OP: JPY52.0 billion (+3.8%)

- **FY2021 Dividend Forecast: Unchanged +JPY4 YoY**
  - Annual dividend forecast JPY32 per share (Interim dividend JPY16 per share)

On page 7, you will find a summary of our business results for the second quarter.

The fiscal year to date constitutes the first 6 months of the Medium-Term Plan. The plan is progressing smoothly.

In terms of sales, performance was good across all regions and products.

As for expenses, we are making strategic investments for growth in the US and China. Our investment is ahead of schedule, but overall, from the perspective of the Medium-Term Plan, expenses are generally as expected.

Regarding forecasts, there is no change from the initial forecast.

As announced in the financial results in May, we have raised our annual dividend forecast by JPY4 from the previous year to JPY32. The interim dividend is JPY16. Mr. Koshiji will discuss our performance in detail in his presentation.

Page 8, please. I would like to talk about the progress we have made based on the 3 strategies of MTP2025.

First, the Core business. This is the status of existing projects in each region. As described here, the Core business is performing according to our plan in each region. Although foreign exchange rates are having an impact, we continue to be on a growth trend.

In Asia, there was a slightly larger volume of bulk shipments in the previous fiscal year, the absence of which has had a negative influence in this quarter. In effect, there was positive growth. We are also promoting product development to improve future profitability, and creating an ophthalmic ecosystem with a focus on Asia.

The Americas are an important aspect of the Medium-Term Plan. There are several important points of note here, and I will come back to this later.

Progress was also made in new areas. First, STN2000100, the *PRESERFLO MicroShunt*. This product has been approved in Singapore. This is the first approval in Asia. As previously announced, in the myopia field, we have introduced SYD-101 in Europe. We are preparing for global expansion with our in-house pipelines, STN1012700 and STN1013400.

With regard to the third strategy, strengthening our foundation as a global company, we are transforming our global structure by strengthening the foundation for R&D, production, and product supply. We are also bolstering ESG initiatives.

(1) Profit Ratio Improvement in Core Businesses: Japan Business

Japan Business

Solid Business Base by Deploying Products and Solutions Driven by Patients' Needs

Patient-centric Product Development

Product Life Cycle Management

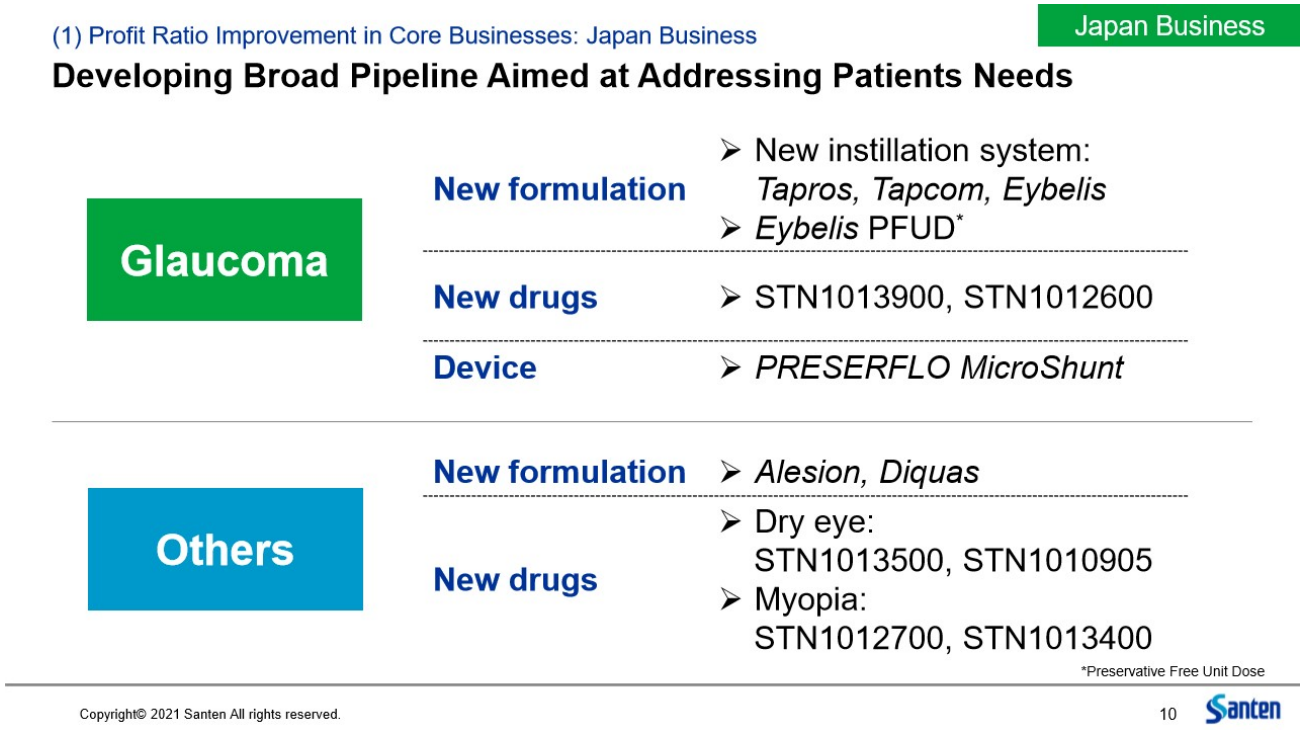
Strong Customer Relationships

Let's move on to page 9, the Japan business. The Japan business is the first of the existing regions that I would like to talk about.

In the Japanese market, we have more than 50% market share. It could be seen as our home ground, where we have the greatest strength.

We are constantly developing and improving our products, with the patient's perspective at the forefront. We have built up a strong market presence by developing a wide range of products, including product formulations and highly identifiable containers. As already mentioned, we are also working to strengthen our product lifecycle management with an eye on LOE. 1 example of this is *Alesion LX.*

In addition, the Japanese business has very strong customer service capability. During the coronavirus pandemic, we have improved our competitive productivity by meticulously developing sales activities that respond to customer needs. We will delve a little deeper into these 3 points on the next page.



Please turn to page 10.

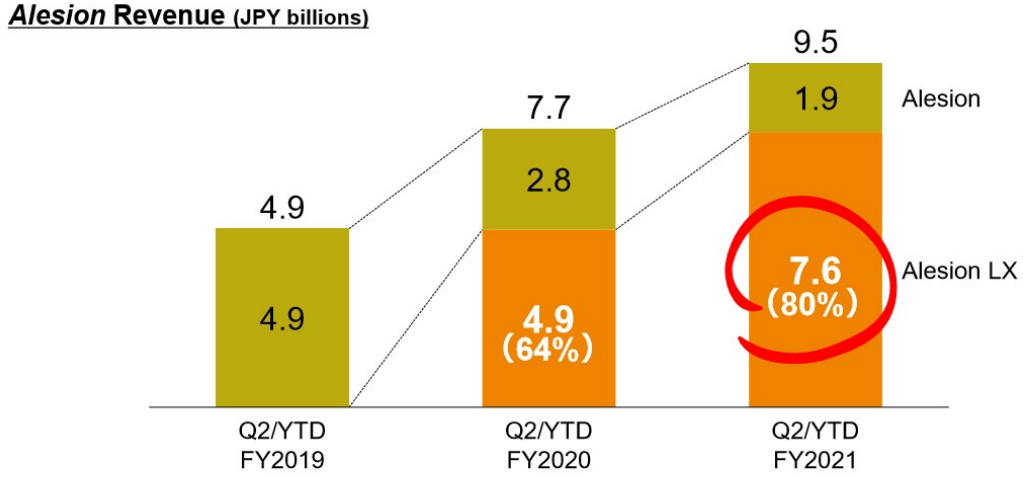
First, developing new products from the patient's perspective. As you can see, we have a lot of new product projects running right now. For example, a new ophthalmic formulation of a major product in the field of glaucoma. We are also developing products in areas such as myopia, where growth is expected in the future.

We will maintain and improve our presence by understanding and meeting the wide range of needs of patients over the medium and long term.

(1) Profit Ratio Improvement in Core Businesses: Japan Business

Japan Business

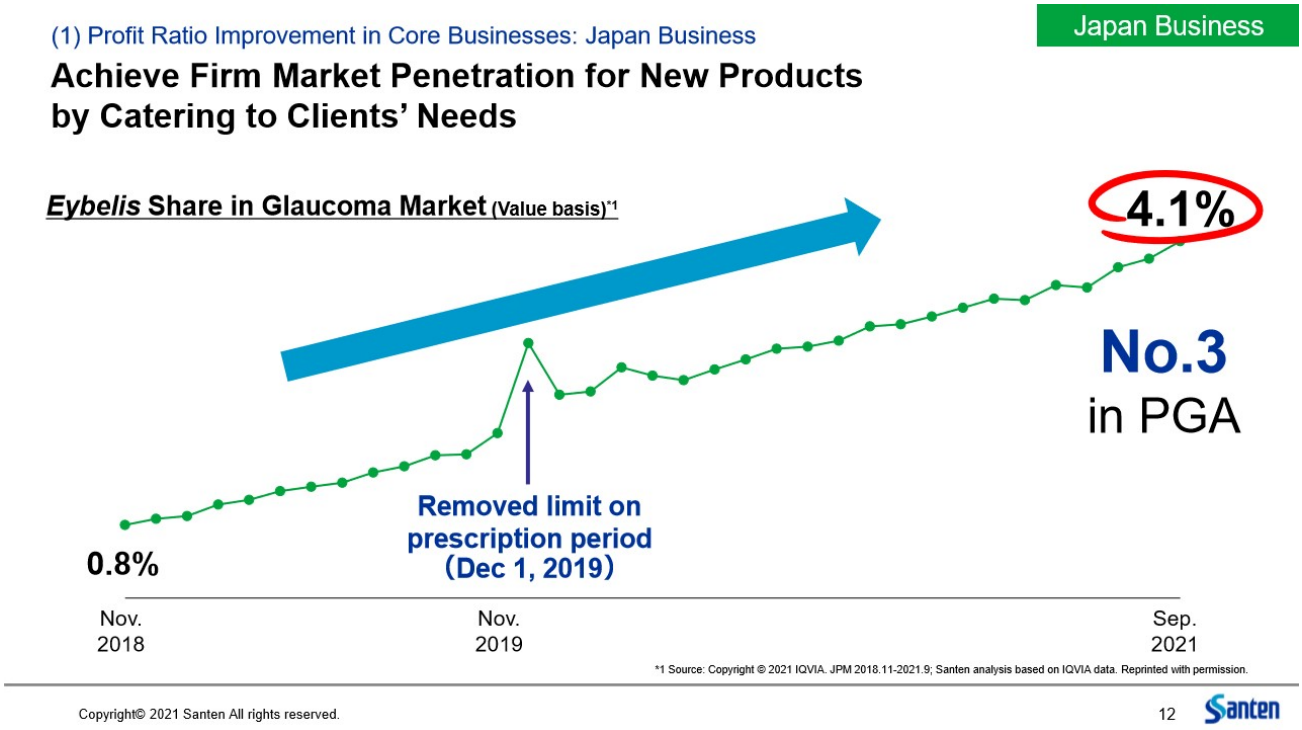
Proactively Switching to *Alesion LX* as Life Cycle Management Product



Next is page 11. I would like to talk a little about the second point, product lifecycle management, using the example of *Alesion*.

Alesion LX was launched in November 2019. This is a highly concentrated version of the existing *Alesion*, and we have been moving forward with the changeover at a very fast pace. The convenience of *LX* twice-daily eye drops has been well received by the market. Co-promotion with Mitsubishi Tanabe Pharma Corporation has also been successful, resulting in steady penetration of the product into the market.

In the last 6 months, sales of the new *LX* have accounted for about 80% of total *Alesion* sales. We will continue to work on the market penetration of *Alesion LX*, and link it to the new formulation of *Alesion*, which is currently under development and whose launch is scheduled.



On page 12, I would like to talk about the third item, high customer service, using *Eybelis* as an example.

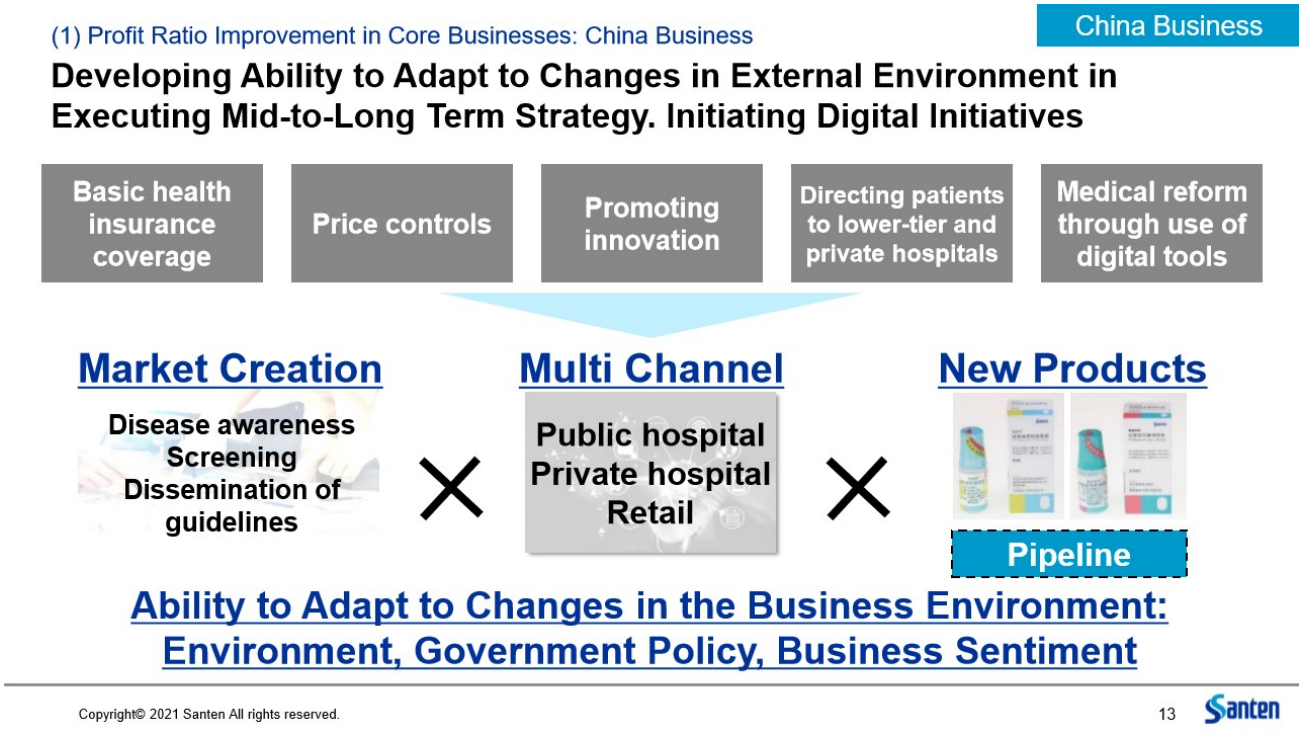
Eybelis is a glaucoma eye drop that has been on the market for 3 years now. Initial sales were a little slow immediately after the launch of the product, but since then we have been steadily promoting the dissemination of information on its efficacy and safety. As you can see, sales and market share have been steadily increasing.

As a glaucoma drug, *Eybelis* has the effect of lowering intraocular pressure. It differs from other drugs in not causing cosmetic side effects. Through our efforts in this area, understanding of these characteristics has spread.

According to the most recent data, we have moved up to third place in terms of prostaglandin product sales on value basis. I think this demonstrates the ability of the Japan business to steadily launch products, penetrate the market, and maximize the value of its products.

I have talked about our Japan business with respect to these 3 areas, and of course we will have LOEs for some of our main products in the coming years. Therefore, we will make sure to implement the strategies that we are currently working on.

By building on our strengths, we will be able to introduce new products to the market. Although there will be headwinds, we are confident we will be able to overcome them as we move forward.



Next, I would like to talk about our China business, which is our growth driver. Page 13, please.

As I have already mentioned, the Chinese business is growing while the market itself is undergoing major changes. This is due, for example, to the shift from tertiary hospitals to private hospitals, as well as the spread of private insurance. In response to these changes, our current fundamental strategy is to focus on multi-channel marketing and a shift to new products.

In the field of glaucoma, we are steadily promoting disease screening, dissemination of glaucoma treatment guidelines, and, of course, patient outreach. We are undertaking these activities in cooperation with local partners and academic societies, as well as working to incorporate new initiatives.

We believe that this is a very important and attractive market. In myopia, we are developing a very solid pipeline of new products. Construction of the new plant in Suzhou is progressing well. We anticipate that the plant will function as a base to support long-term growth.

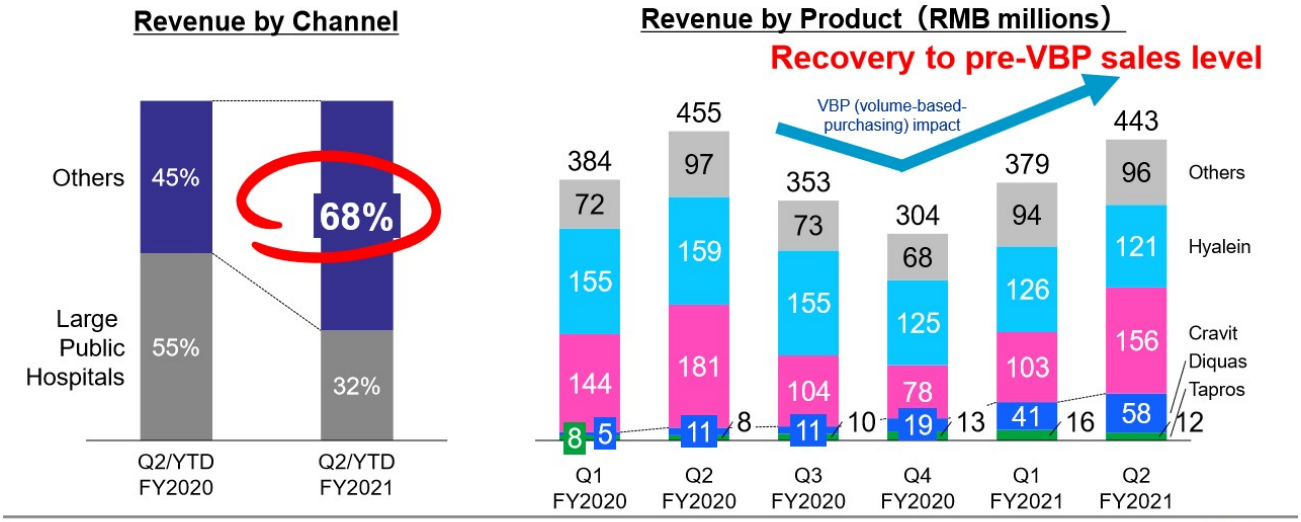
China is a very volatile market, with many regulatory changes occurring all the time. On the other hand, from a medium- to long-term perspective, the ophthalmology field is a market with enormous potential. This remains the case.

Our goal is to achieve solid profits in this area, while at the same time nurturing medium- to long-term growth to support this as an important business area in the future.

(1) Profit Ratio Improvement in Core Businesses: China Business

China Business

Maintaining Growth Trend on Channel Shift and New Products



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I will now give a little more detail on the China business. This is an update of sales by channel and by item.

As you can see in the graph on the left, the channel shift is progressing steadily, following the same trend as the previous time point. Thanks to this shift to multiple channels and the market penetration of new products, we are continuing our growth trajectory. In RMB terms, we have already recovered to the level we were at prior to the impact from volume-based-purchasing. I'm aware that this was a concern for some people.

Diquas has been performing very well. In addition, *Tapros* already has a 40% share of the prostaglandin market. We would like to continue to grow our sales by increasing the size of the glaucoma market as a whole. We intend to do this by continued screening activities, as well as through the dissemination of guidelines.

On page 15, I would also like to talk about Asia and EMEA.

One of the challenges of health care in Asia, including ophthalmology, is that the health care infrastructure and ecosystem is still inadequate. The problem of capacity is very pronounced, especially in Southeast Asia, where the per-capita number of ophthalmologists is low. This has become a bottleneck.

As we announced recently, in order to recognize and address this issue, we have partnered with Singapore National Eye Centre. We have decided to jointly conduct activities to support medical professionals involved in eye care, such as examination staff.

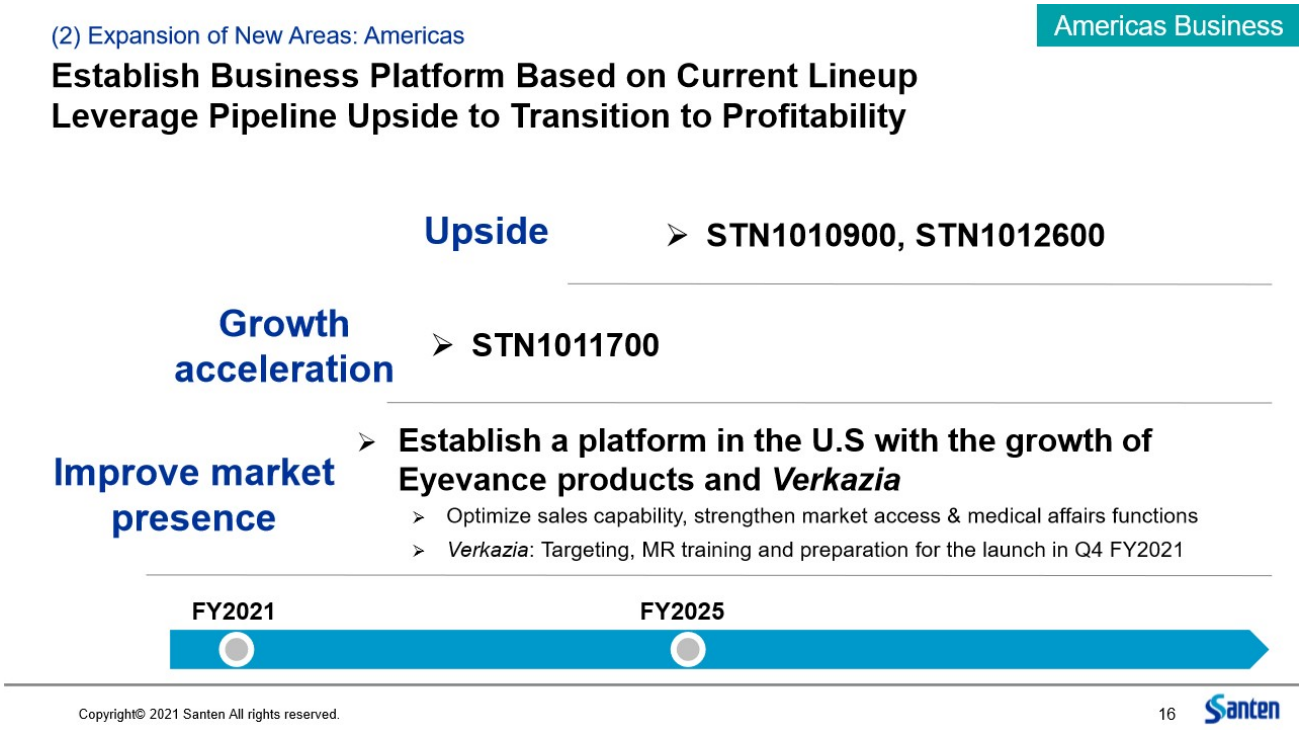
This is a medium- to long-term project to increase the number of staff who can perform this kind of inspection in Asian countries by roughly 1,000s. Through these efforts, we will expand the capacity of ophthalmology treatment. This can also be seen as an effort to increase throughput.

In addition, we are already making full use of digital technology in Asia. We have already developed an app that provides the latest ophthalmic information, such as webinars, educational videos, KOL columns, and conference information. This app is widely used in Asia. Even during the coronavirus pandemic, we have fortunately been able to continue carrying out these information dissemination activities.

Today, more than 6,000 medical professionals, or roughly 60% of the population of this area, use our services on a daily basis. Perhaps the word 'platform' would be an exaggeration, but this is our unique tool for providing information.

In this way, in the Asian region, we would like to continue contributing to patient care by raising disease awareness, improving test diagnosis rates, and improving the expertise of physicians. We aim to cement a leadership position for Santen in this area.

As you can see below, the EMEA region is also performing as planned. *PRESERFLO MicroShunt* is 1 example of a new product that is driving growth.



Next, let's look at page 16.

This is the second strategy of the MTP. In terms of expanding into new business areas, I would like to talk about the situation in the US here.

In the Americas business, as you can see here, our strategy is to build on the foundation of Eyevance. Additionally, we aim to turn a profit with *Verkazia*, which was approved in June, and build a presence in the market.

We acquired Eyevance last year because they have several ophthalmic products and have daily contact with ophthalmologists. As a newcomer to the market, we thought they would be a good base for our commercial activities in the future.

Put simply, products on the market, contact with ophthalmologists, and an existing sales organization were the strong points. By utilizing these strengths, when we enter the US market and launch new products in the future, we will not have to start from scratch or make upfront investments. By utilizing existing products and the sales organization of Eyevance, we will be able to absorb such upfront investments. The company was acquired with this intention.

The coronavirus pandemic has affected our schedule somewhat, but we are steadily moving forward with post-merger integration. We plan to complete the integration within this fiscal year.

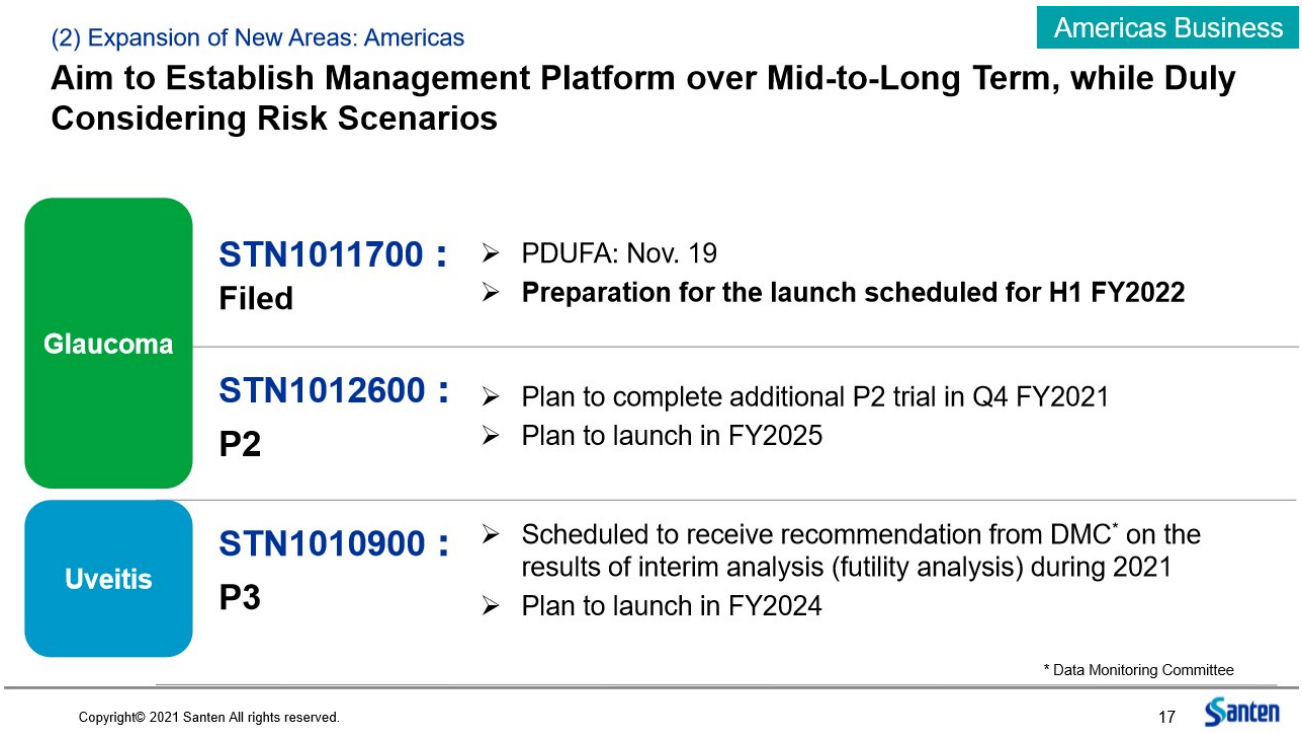
On the other hand, the current sales are a bit volatile due to the impact of the coronavirus pandemic and other factors. This may have a temporary impact, but in any case, we would like to build a foundation for commercial activities in the US by firmly promoting integration and enhancing organizational strength. We are working on this in order to solidify our foothold.

We are also preparing for the launch of the new product *Verkazia*, which was approved in June. The target disease, Vernal Keratoconjunctivitis, is a severe allergic disease, and is also quite rare. Therefore, it is a very concentrated market, with approximately 5% of the total number of ophthalmologists covering 60% of the patients. Of course, it is a business area where high drug prices can be expected.

We are planning to launch this product in the fourth quarter, in the period from January to March. By using the Eyevance platform as mentioned earlier, we are aiming to quickly penetrate the market while keeping upfront investment low.

On top of that, STN1011700, the application for which has been filed, is expected to add to growth. This is the current plan for the MTP. Of course, we will also be using Eyevance's infrastructure to sell STN1011700.

On top of that, we would like to further increase our upside by developing products that are in the pipeline, such as STN1012600, STN1010900, and so on.



Page 17 shows the status of the US pipeline.

First, we have STN1011700, that is, 117, which are scheduled for PDUFA this month. As for the status of this project, it is still in progress, but I think it is of great interest to all of you, so I would like to talk about the situation as of today.

First of all, we are currently in discussions with the FDA, and we have already reached an agreement on a candidate product name, including backup. So far, we have not received any critical comments regarding the efficacy, safety on clinical trials of this product or the content of the application. We believe that it is likely that the FDA will consider the product to be worthy of approval, given the previous experiences.

On the other hand, we have received comments about GMP in production, and we are currently working on a response. This product, STN1011700, is manufactured mainly in the US by a contract manufacturer. In this context, in our recent communication with the FDA, we were informed that among the contract manufacturers, there is a company with which the FDA is currently communicating on GMP issues. We are currently working with the companies involved to determine the facts and how to respond.

This is still in progress, so we can't make any definitive statements yet, but it has been suggested that there may be some impact on the approval process for this product. Therefore, we are openly discussing with the authorities about the future schedule and next steps.

The future outlook will depend on future communications with the FDA, but unfortunately there is a possibility that there will be a slight delay due to GMP issues at the supplier.

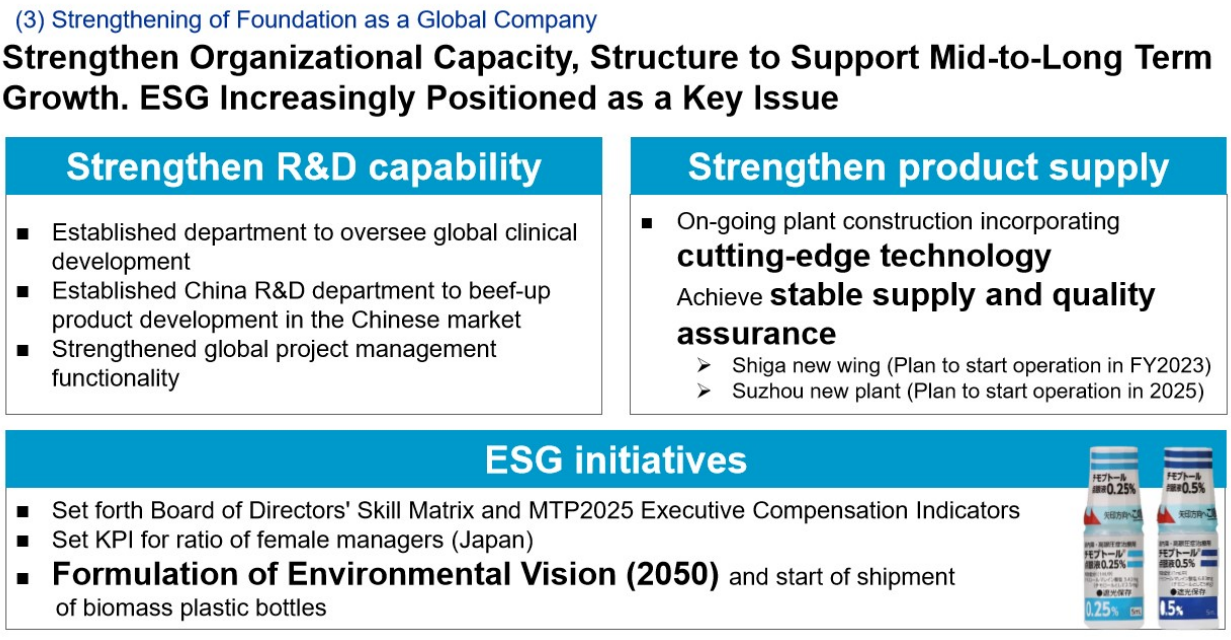
For example, considering case studies of other companies, there are cases where the review was completed by the PDUFA deadline, the letter was issued, and then the GMP issues were cleared and the approval was delayed for several months. We will continue to monitor this.

In any case, we will continue to work closely with the relevant authorities and our partner companies to obtain approval and supply products as soon as possible. I can't say much more at this point, but in any case, the date for the PDUFA is approaching. It is on November 19. Towards that timing, we expect to have more detailed information, including information relating to the technical and regulatory issues that I just mentioned, so I will report to you as soon as I learn more.

I would also like to reiterate that this is an issue specific to the STN1011700 application, and does not in any way affect the supply of products in our existing business.

Second, we are planning to complete additional Phase II trials on STN1012600 by the end of this fiscal year. We are planning to launch this product in FY2025.

We are also planning to conduct an interim analysis of STN1010900 for uveitis in the near future. We are expecting to receive a recommendation from the third-party committee by the end of this year to either continue or suspend the study. In the case of continuing the trial, Phase III will be completed by the end of FY2022, and we will aim for product launch in FY2024. We hope to have a discussion about the future direction of this project around the beginning of the next year.



Next, page 18. This is the third strategy of the Medium-Term Plan, which is to strengthen our foundation as a global company.

As for research and development, as I mentioned at the recent Product Development Meeting, we are currently working on strengthening our functionality.

In terms of our production system, we are constructing plants in Shiga and Suzhou that incorporate advanced technologies, including comprehensive consideration of environmental issues.

With regard to ESG, we have established the disclosure of the skills matrix of the Board of Directors and the indicators for executive compensation in line with the Medium-Term Plan.

From the perspective of diversity, equity, and inclusion (DE&I), we have also disclosed in the integrated report the issues we are facing, including the goal of increasing the ratio of women in management positions in Japan from 13% to 25% by FY2025.

In May this year, we set our environmental vision for 2050 and our environmental goals for 2030. We are also currently preparing for TCFD.

Last year, we announced the use of biomass plastic for eye-drop containers. Production has started for *Timoptol* and shipments have started from November in a phased manner.

Next, page 19.

DE&I has long been important for Santen, and we have endeavored to create a flexible work environment. In May of this year, we established guidelines for flexible work styles, a new way of working throughout the Company.

Remote work became the norm in the coronavirus pandemic, and we are continuing with remote work globally. We aim to define the office as a place to connect with people rather than a place to commute. Therefore, coming to work is not mandatory, and we have a so-called 'work-from-anywhere' setup. By promoting the appointment of human resources regardless of where they live, we hope to acquire excellent human resources in a more flexible manner.

On the other hand, we are also working on the development of a digital virtual community and other platforms so that our employees can actively communicate with each other in this environment and globally. We will continue to build a vibrant work environment while promoting diverse human resources and creating an environment where they can play an active role.

Next is research and development.

Mr. Morishima is joining us by telephone today, as he is in China to accelerate local development. I will therefore provide an update on this section.

Please turn to page 21. There have been many developments in the pipeline over the past 3 months.

First of all, for glaucoma, as for STN1013900, or *Rhopressa*, in-lisensed from Aerie in the development of this product in Japan, we have confirmed its superiority to Ripasudil. We are also continuing with the remaining two Phase III trials.

PRESERFLO MicroShunt, as I mentioned earlier, has been approved in Singapore. In Asia, we have also submitted applications in Thailand and Vietnam, so we expect to be able to market the product widely in Asia in the next fiscal year and beyond.

In the area of dry eye, we filed an application in Japan in August for a long-lasting *Diquas* that reduces the number of administration from 6 to 3 per day. We are hopeful that we will get approval next fiscal year.

As for new areas, we have started clinical trials for new diseases such as Meibomian gland dysfunction and ptosis.

For myopia, as announced in August, we introduced SYD-101, an atropine formulation, in Europe. We will accelerate our global strategy for myopia with atropine STN1012700, STN1013400, and other such products.

This concludes my presentation.

Financial Results

Sales Increased 8% YoY. Core Profits Down on One-off Factors but True Profit-generating Capability Improving

(JPY billions)	Q2 FY2019 Actual	vs Revenue	Q2 FY2020 Actual	vs Revenue	Q2 FY2021 Actual	vs Revenue	YoY
Revenue	**118.8**		**118.9**		**128.8**		**+8.3%**
Cost of sales	48.3	41%	49.7	42%	52.9	41%	+6.4%
Gross margin	70.5	59%	69.2	58%	75.9	59%	+9.7%
SG&A expenses	33.4	28%	33.2	28%	39.7	31%	+19.3%
R&D expenses	11.4	10%	11.1	9%	12.3	10%	+10.9%
Amortization on intangible assets associated with products	4.9	4%	4.9	4%	4.8	4%	-1.9%
Other income	0.2	0%	0.3	0%	0.2	0%	-42.1%
Other expenses	1.9	2%	1.6	1%	0.5	0%	-68.4%
Operating profit	**19.0**	**16%**	**18.7**	**16%**	**18.8**	**15%**	**+0.6%**
Finance income	0.5	0%	0.6	0%	0.7	1%	+18.6%
Finance expenses	1.1	1%	0.9	1%	0.4	0%	-50.1%
Share of loss of Investments accounted for using equity method	--	--	0.0	0%	0.6	0%	--
Profit before tax	18.4	15%	18.4	15%	18.4	14%	+0.2%
Income tax expenses	5.3	4%	4.7	4%	4.1	3%	-11.1%
Actual tax ratio	*28.7%*		*25.4%*		*22.5%*		
Net profit	**13.1**	**11%**	**13.7**	**12%**	**14.3**	**11%**	**+4.1%**
Core basis							
Revenue	118.8		118.9		128.8		+8.3%
Operating profit	**25.6**	**22%**	**25.7**	**22%**	**24.3**	**19%**	**-5.4%**
Net profit	18.8	16%	19.7	17%	18.6	14%	-5.7%
USD (JPY)	108.82		106.72		110.09		
EUR (JPY)	121.28		121.54		131.14		
CNY (JPY)	15.77		15.21		17.05		

Main factors of change

Revenue

+8.3% YoY

- Steady growth in each region

Operating Profit

+0.6% YoY

- (-) Impact of one-off negatives factors specific to H1. Push-out of domestic sales promotion expenses (JPY 0.9 billion) and new consolidation of Eyevance (JPY 1.7 billion), etc.
- (-) Amortization of intangible assets associated with products: retroactive revision of Eyevance
- (+) Valuation expense related to contingent consideration for InnFocus, Inc. acquisition in FY2020

Core Operating Profit

-5.4% YoY

- Up approximately 3% after adjusting for the above one-off factors (approx. JPY 2.0 billion)

Koshiji: We'll start from page 23. These are the results for the second quarter. The left side shows the income statement and the right side shows a brief summary.

From this year, we are making full-basis results the main KPI, and as you can see, both sales and profits increased on a full basis. On a core basis, operating profit decreased by 5.4% compared to the previous year.

I will now explain the main factors behind the change in operating profit. First, let's look at SG&A expenses. Here we see a 19% increase over the previous year. One way of considering this is in terms of cost control. On the other hand, as you can see here, there were one-off factors in the second quarter of this fiscal year.

One is the time shift in domestic SG&A expenses. There was a 32% increase in sales of *Alesion.* As for its expenses, compared to the previous year, as explained earlier by Mr. Taniuchi, this is part of the accounting process, but some of the previous year's costs were to the current fiscal year. The figure is JPY900 million.

This is the liquidation of coproduction fees. The payment method with partner company and the accounting treatment are strictly slightly different, with some being paid based on actual results and others being charged to expenses in the form of valuation allowances, or allowances for expected sales in the relevant period.

In the case of a 32% increase over the previous year, as was the case in the previous fiscal year, the expenses recorded in the previous fiscal year, which were underestimated, were postponed to the first quarter of the current fiscal year.

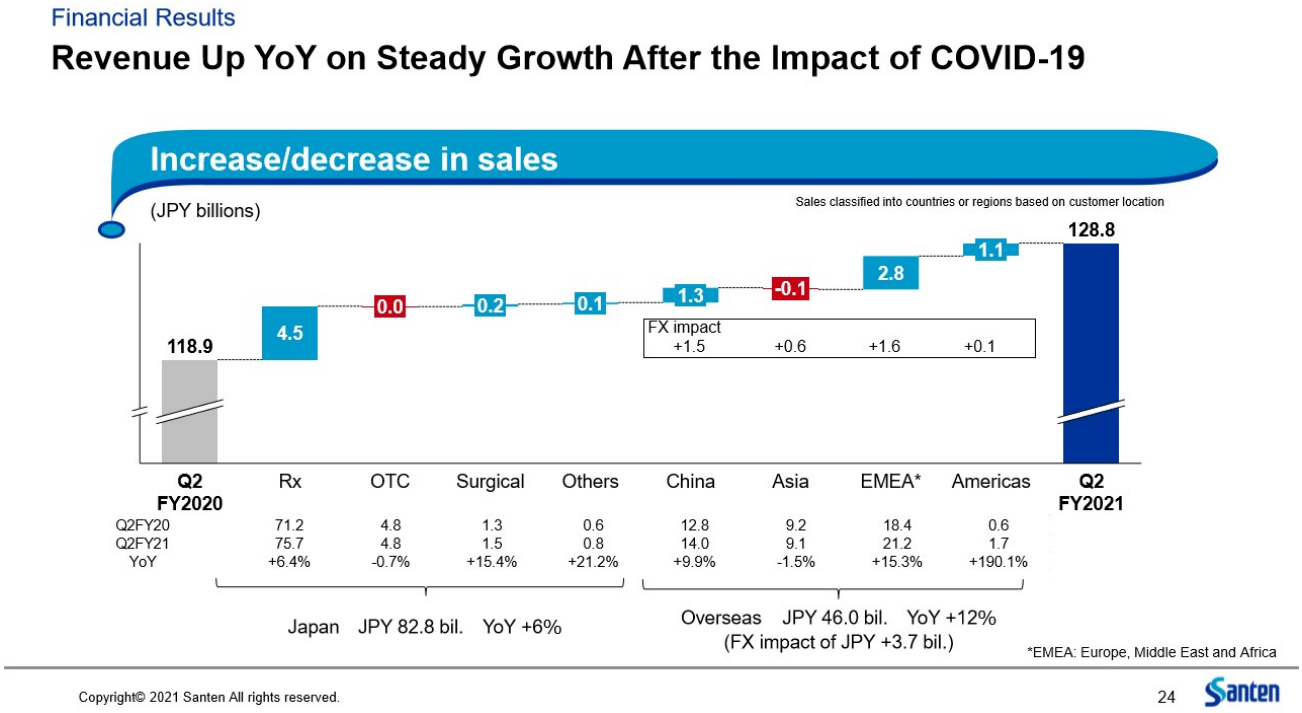
Another source of costs was the consolidation of Eyevance. As you can see in the operating profit section, we added about JPY1.7 billion in new SG&A expenses. Since we acquired Eyevance at the end of the second quarter of FY 2020, we did not consolidate Eyevance's expenses, sales expenses or profits in the first half of the previous year. Therefore, the total cost here is JPY1.7 billion.

Of the JPY39.7 billion in SG&A expenses in the income statement, JPY2.6 billion is made up of 1-time expenses. If you factor that in, the YoY increase is 12%. The ratio to sales is 31%, but in actual terms it is 29%.

However, the increase of 12% in cost compared to the growth rate of gross profit might seem too high,but we have been managing it well internally. Of the SG&A expenses, 85% are those we can manage, and this controllable part consist of about over 40% from variable costs and about 40% from personnel expenses.

In particular, personnel expenses will not decrease without painful restructuring, but we have been actively controlling variable costs. Compared to the previous fiscal year, when we were in a state of lockdown due to the coronavirus pandemic, compared to FY2019, we were able to control the cost to the lower level than the growth rate of gross profit.

This concludes my explanation of the status in Q2.



Below that, on page 24, there is a breakdown of sales.

The increase of 8% compared to the previous year was mainly due to foreign exchange factors, and was supported in part by this. As the CEO explained earlier, the reason why Asia looks a little worse is due to the 1-time shipment factor in the previous year. This is described on page 4 of the data book.

FY2021 Forecasts

FY2021 Forecast Unchanged from May 11th. Retroactive Restatement of FY2020 Results due to Completion of Eyevance PPA*

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

Main factors of change

Revenue

+4% YoY
- Sales expected to increase YoY on sales growth in each region
- High likelihood of upside given foreign exchange rate levels

Operating Profit

+241% YoY
- Absence of FY2020 impairment loss
- Decline in amortization of intangible assets related to products to contribute to increase in profit

Core Operating Profit

+4% YoY
- Aiming for well-balanced profit growth by maximizing sales
- One-off factors from H2 FY2020 to H1 FY2021 drop out

Note on retroactive restatement:
FY2020 profit increased JPY 2.5 billion due to retroactive adjustments associated with the allocation of Eyevance's acquisition price to assets and liabilities.

*Purchase Price Allocation

Next, page 25. This is the forecast for the full year. There is no change from the disclosure on May 11.

Profit is down on a core basis in the first half compared to the previous year. In terms of the rate of progress for the full fiscal year, sales are almost 50%, but profits are around 47% in terms of core operating profit, operating profit, and net income. Comparing the historical profits level, you might think we are little behind rather than the first half dash type, however, we believe that we will be able to achieve our full-year forecast for the current fiscal year.

Our basic approach is that, based on the situation with coronavirus, the top line grew by 8% in the first half, but we continue to recognize that we are in an environment of uncertainty. In this context, we will aim to secure profits. In order to achieve this, we will flexibly and resiliently control SG&A expenses.

Specifically, as I'm sure you all know, we are thinking of controlling gross profit and SG&A expenses. As you know, we have established figures that show that the gross profit margin tends to improve significantly in the second half of the year. We can say this based on past experience. For this fiscal year, the gross profit margin was 59% in the first half and is expected to improve to 62% in the second half, resulting in 61% for the full year.

On the other hand, the ratio of SG&A expenses to sales were 31% in the first half. Based on these figures, the SG&A ratio for the second half of the fiscal year will be approximately 33%, and although the ratio of SG&A to net sales is forecast to increase slightly, we believe that we can still keep the ratio to 31%.

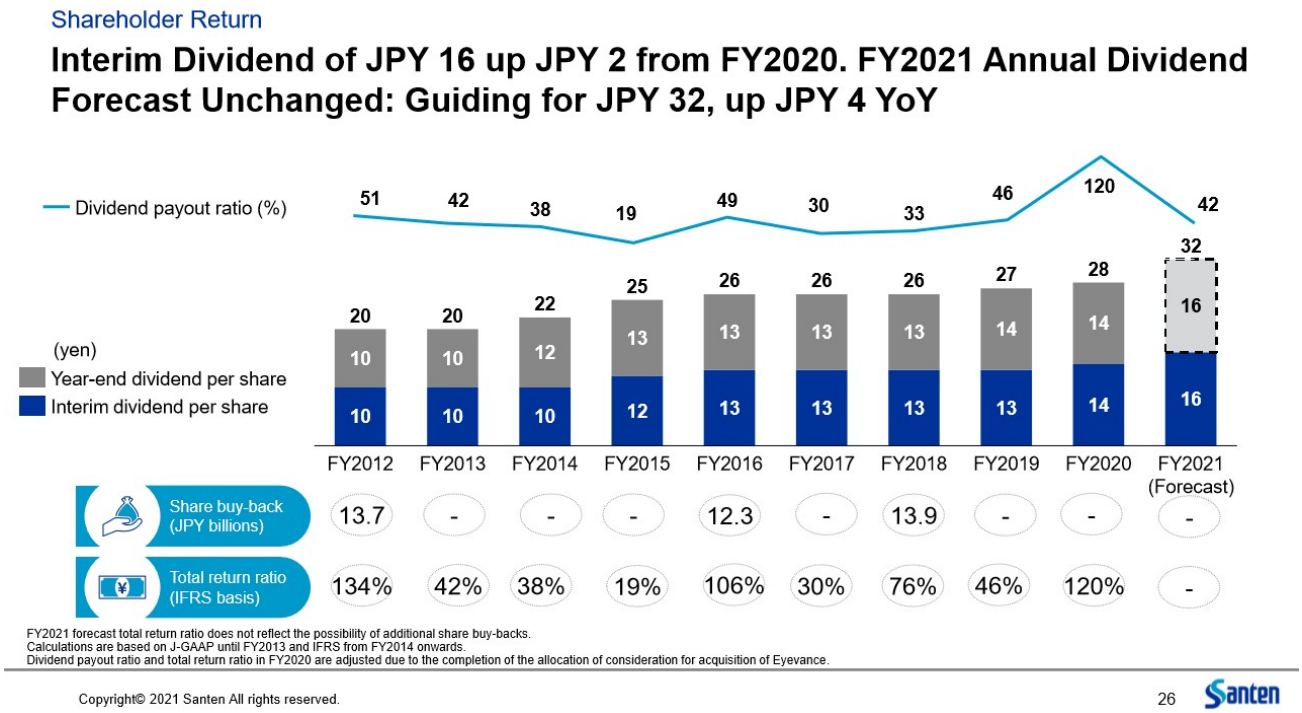
Under such circumstances, we will control the JPY52 billion core operating profit. As for research and development expenses, we will keep expenses within this JPY26 billion figure. On the other hand, we will prioritize spending for future growth without extreme cuts or savings.

Below that, until the previous fiscal year, there was a slight increase in other expenses and financial expenses, such as provisions for future contingent payments related to *MicroShunt*, which caused fluctuations in operating profit and net profit. However, this year, these factors have been eliminated, so it is relatively easy to estimate net profit.

The tax rate is 22.5% for the first half of the year, but as you can see here, it is likely to be within 25% to 26%. We believe that we will be able to secure JPY30.5 billion in net profit in the end, and as a company, we are committed to focusing on net profit EPS.

As you know, you can see the FOREX on the bottom. Currently we see JPY105 for 1USD, JPY125 for 1EUR. The depreciation of the yen has a slight negative impact on our profit and loss, approximately JPY3.7 billion on sales. If the exchange rate were to fluctuate in the same direction, the figure would be JPY3.5 billion to JPY4 billion, and on a profit basis, it would be negatively JPY500 million to JPY700 million. However we believe we could absorb this impact and achieve our annual target.

In particular, as of September 30, 47% of our shares are held by overseas institutional investors and 27% by domestic institutional investors. A total of 74% of our shares are held by institutional investors. In the Perception Study, we are aware that people place a lot of importance on EPS and ROE, so we will make sure to focus on these areas.



Next, page 26 shows shareholder returns.

There is no change to the dividend forecast from the beginning of the fiscal year. The interim dividend will be JPY16, an increase of JPY2 from the previous fiscal year.

As you can see from the graph, in the past, dividends were increased in increments of JPY1 per half year, but from this fiscal year, dividends will be increased by JPY2. This equates to JPY4 per year. We have increased dividends for 3 consecutive terms.

On the other hand, if you look at our balance sheet, we have a cash position of JPY76 billion. Some people may think that this is too much, but for us, it is a temporary increase. We believe that it is an appropriate level considering the capital investment for this fiscal year.

Specifically, as mentioned in the financial summary, we invested JPY3.9 billion in capital expenditures in the first half of the previous fiscal year, and we have already invested JPY13.7 billion in the first half of this fiscal year. We plan to achieve JPY30 billion for the full year.

In this regard, as the CEO explained earlier, we are considering investing funds in domestic production facilities in Japan and China, as well as in DX-related investments such as ERP and productivity improvement.

This concludes my presentation.

Question & Answer

Q-1-1

Regarding STN1011700, I think you mentioned a problem with 1 of the contractors. However, when you say that the process could not be covered by other contractors, does that mean that you were planning to entrust the process to that contractor alone? Couldn't your company have identified the GMP issue earlier and taken measures beforehand to avoid delays?

A-1-1

Taniuchi: I will answer your question. First of all, there are a number of contractors, each of which has its own key processes. We were not told which company is responsible for each of them. The FDA told us that 1 of the companies in the list with which we filed for the application has this issue. The company is not directly related to us, but is interacting with another company and is involved in something like product inspection.

It is not that there was a problem in our manufacturing process or in our selection of contractors, but we have been informed that such problems have recently come up.

We are still in the process of exchanging information, so there is not much we can say about the specific situation. I hope you can appreciate that we are sharing what information we can.

Q-1-2-1

Thank you very much. 1 more point, on page 35, you show the quarterly trend of sales at Eyevance. In the second quarter, sales were down compared to the first quarter, and even if you look at half-yearly sales, that is, the sum of sales for Q1 and Q2, they are almost flat compared to Q3 and Q4 of the previous fiscal year.

I think you mentioned earlier that there were a lot of things that happened due to the coronavirus pandemic, but I would like to ask how we should interpret this situation, and what the outlook is for the future.

A-1-2-1

Suzuki: I am Suzuki, General Manager of Planning, and I would like to answer.

First of all, as you mentioned, with COVID-19, formularies have been narrowing down or shifting products in a sort of 'coronavirus shift.' This is not limited to ophthalmic medications, but in some cases, our products were taken out by PBMs. This became apparent in the second quarter.

This is, of course, due to the transient factor of the coronavirus pandemic, which means that we will be negotiating with the PBMs to reel them in. Internally, we were also working to further strengthen the Eyevance team by making personnel changes between differently performing teams in the course of PMI. This became apparent in Q2.

In any case, since we are a company of this scale, we are affected by the turbulence in the market, but we will work to get back on a recovery track.

Q-1-2-2

Did you mean to say that you narrowed down the scope of the project because the financial situation of insurance companies was worsened by the coronavirus pandemic?

A-1-2-2

Suzuki: Yes, that's what I've heard.

Q-2-1-1

First of all, on page 14, there is a figure of sales channel makeup in the Chinese market. Sales in major national hospitals are decreasing and others are increasing. If you look at this and, for example, sales of *Hyalein* and *Cravit, Hyalein* has fallen because of volume-based-purchasing and seems to be struggling, while *Cravit* fell and is recovering quite rapidly. This may not be relevant for something like *Diquas*, because it is growing in a stable and strategic way, but what is the relationship between changes in channels and changes in products?

A-2-1-1

Suzuki: I would like to respond.

First of all, in terms of products, *Hyalein* and *Diquas* were originally intended to be used in private hospitals to shift the focus of sales.

For *Cravit*, while public hospitals are switching away from *Cravit* due to volume-based-purchasing, we are also shifting to private hospitals that perform, for example, LASIK and cataract surgeries. Campaigns conducted with these facilities as the coronavirus situation settled in China. As a result, sales of *Cravit* jumped a little in Q2.

As for *Hyalein* and *Diquas*, they are shifting as before. On the other hand, *Cravit s*eems to have made a particularly big impact, partly because of the campaign.

Q-2-1-2

Can we expect to see the same trend in the future for *Cravit,* focusing on pharmacies and private hospitals?

A-2-1-2

Suzuki: Private hospitals in particular perform corneal and cataract surgery, LASIK, and so on, and the therapy is used preventatively. This trend is continuing as the number of these surgical cases is increasing rapidly.

The retail channel is also a growing market for patients who have limited access to drugs, so we expect this trend to continue for some time.

Q-2-2

My last question relates to page 21. Xi Jinping seems to be quite concerned about myopia, and there has been a focus in the Chinese market for some time. SYD-101 was launched in Europe, but will it be possible to launch it in China too?

A-2-2

Taniuchi: I will answer your question. Basically, SYD-101 and STN1012700 are very similar. The question then becomes why we introduced SYD-101. We introduced SYD-101 because we thought it would give us an advantage over other competing products in terms of time rather than introducing STN1012700, so this is basically a product for Europe.

For China, on the other hand, we will develop STN1012700. For Japan and China, we will first release STN1012700. We will use different products for different regions.

Q-2-3

I understand. This is a very hot topic in China, but should we expect that the market for myopia control in Europe will also be quite large?

A-2-3

Taniuchi: Of course, in China, as you pointed out, myopia has been adopted as a national policy, so it is treated as an important issue. China and Asia are naturally the hottest markets in terms of numbers.

On the other hand, what about Europe? With SYD-101, development for myopia is progressing in Europe. There is another leading product in the United States, and the number of people with myopia is increasing in Europe as well. We will have to wait and see what will happen in terms of the scale, but at the moment, through discussions with various authorities and payers, I think that we can expect a certain level of response.

Q-3-1

This is a follow-up from the previous question on STN1011700. You mentioned about GMP in contract manufacturing, but even though we don't know what will happen in the future, if this is the cause of a CRL or something like that, could it mean that approval cannot be obtained until the problem at the contract manufacturer is resolved?

In that case, how long it will take is a little difficult for your company to control, but will it be resolved in 6 months or something like that? Could you give us a sense of the time frame involved here?

A-3-1

Taniuchi: Thank you very much. As you pointed out, we don't know how long it will take, but we do know that it may take a certain amount of time. We don't yet have all the details available, but we see there is a possibility of taking a certain amount of time.

I cannot say at this time whether this will be resolved in a few months, as in the case of other companies, or whether it will take longer. We will continue discussions with all parties, and work to resolve the issues as quickly as possible. I am sorry that I cannot be more specific about the time frame today.

Q-3-2

In the part of your presentation on 117, the launch is planned for the first half of FY2022, and the PDUFA was originally on the November 19. It seems like you have some time to sort things out between those 2, right?

If it is approved on November 19, under the main scenario there is still half a year of preparation time until the launch. Or are you targeting this launch timing with this possible risk scenario coming up here in mind?

A-3-2

Taniuchi: This was originally a PDUFA due date, with the launch timing aimed at the early part of the first half of the next fiscal year. We are now preparing the system, including the sales system towards it. We were planning to launch *Verkazia* in February, with STN1011700 launched in the next quarter after that. Regarding which timing of the first half of FY 22 the launch will be, I think we will know more about the timing next week or the week after that.

Q-4-1-1

Just 1 question. The application in Asia for ptosis is scheduled to be filed in FY 2022, I believe. In the past, I think the topic came up of whether you could apply with the US data or not. Is it the case that you have already agreed with the authorities that you can apply only with the US data, and that is why you are able to file the application in FY 2022? Thank you.

A-4-1-1

Morishima: Thank you. Morishima here.

Basically, we are following the guidelines for this application. Since there are no special circumstances where we have a specific relationship with the authorities. It seems that it is possible to apply basically as before, following the guidelines.

However, in some areas, special safety data will be required, so we will have to work out the details with the authorities, but basically, we plan to apply using a very standard process.

Q-4-1-2

Thank you very much. In that case, if your company can file the application in FY 2022, can we expect the product to be released in around FY 2023?

A-4-1-2

Morishima: The lead time from application to approval differs greatly from country to country in Asia, so it isn't possible to give a blanket answer, but basically we are thinking of applying and getting approval as per this plan. (Santen postscript: Treatment of acquired ptosis are planned to be launched in FY 2024)

Q-5-1-1

On page 11, you talked about LCM for *Alesion*, and the switch to a new product. I wonder if you could tell us what kind of changes you are expecting in the future when the long-lasting formulation of *Diquas* is released in the next fiscal year.

In particular, I would like to know if there are any differences between antiallergic drugs and dry-eye drugs that I need to think about. That's all.

A-5-1-1

Suzuki: I would like to answer.

As you know, first of all, a new formulation of *Diquas* is planned to be released in FY2022, and then a new formulation of *Alesion* will be released in FY2024. As you may remember, Mr. Ito explained about both of these when he explained the Japan project. Through the new *Alesion* formulation, we are aiming for greater ease of use for patients, as it further raises the itch threshold. The formulation would become more user-friendly.

For dry eye, too, the development of formulations reflects the opinions of people in the field on how to use these products. We believe that the value of these 2 products will be further enhanced by the release of formulations that are more in line with the concerns of people in the field.

Q-5-1-2

If that is the case, is it correct to say that you are expecting a rapid penetration of the product, as is expected for *Alesion LX*?

A-5-1-2

Suzuki: Yes. It is as you say.

Q-6-1-1

I would like to ask about page 31, the part about retrospective adjustment of allocation of the acquisition consideration for Eyevance. What I would like you to explain a little more about is whether goodwill and development, manufacturing and sales rights are equivalent to intangible assets or not. We know that the PPA is fluid, but why did the difference arise before and after retroactive restatement? I guess you could call it the value of the Eyevance acquisition.

I understand that, at least for this fiscal year, there will be no hit to the P&L, although I think goodwill will not be amortized because the forecast has not been changed this time. What will the effect be in the future?

A-6-1-1

Koshiji: I will answer your question. On page 31, the previous year was JPY4.1 billion for development, manufacturing and sales rights, and this has increased to JPY20.6 billion. Goodwill has decreased significantly. This is certainly a major change, but since this is a PPA, we believe that it should reflect some arbitrariness or thinking on the part of the company, even though it is a certain fair value assessment.

Considering the impairment of *PRESERFLO MicroShunt* in the fourth quarter of last fiscal year, it was thought that in terms of balance sheet soundness, it would be healthier for the balance sheet to overweight development, manufacturing and sales rights and amortizable intangible assets, gradually amortizing them on an annual basis rather than increasing goodwill. Based on this philosophy, we have arrived at this result. That's a quick summary.

What will the annual depreciation burden be? We expect the total JPY20.6 billion amortization figure to be JPY1.9 billion per year. The rate for this fiscal year is JPY1.9 billion. This will occur in the future.

As for the impact on the current fiscal year, in the budget at the beginning of the fiscal year, we had expected JPY1.3 billion. At the stage of the earnings forecast, we had factored in JPY1.3 billion as being between the 2 figures, but the final figure is just under JPY1.9 billion. As a result, there will be a slight impact of about JPY500 million for this fiscal year.

However, that and other factors will be absorbed and we will achieve what we forecasted earlier, at the beginning of the fiscal year.

Q-6-1-2

Yes, I understand. In relation to this, the term ‘development, manufacturing and sales rights’ refers to the annual amortization of JPY1.9 billion for existing products that have already been sold, not the development and amortization of the Eyevance pipeline; is that correct?

A-6-1-2

Koshiji: Yes, that is correct.

Q-6-1-3

Understood, thank you. Could I clarify the time period?

A-6-1-3

Koshiji: It's about 10 years and plus. It depends on the product, but it is roughly JPY20.6 billion, and with JPY1.9 billion, it is a little over 10 years.

Q-6-1-4

You mean 10 years of non-cash?

A-6-1-4

Koshiji: That's right.

[END]