Become A Social Innovator

Q1 FY2021 Financial Results
Santen Pharmaceutical Co., Ltd.

Presentation: August 6, 2021

Santen
Imagine Your Happiness

Speakers

Presentation/Q&A

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Q&A

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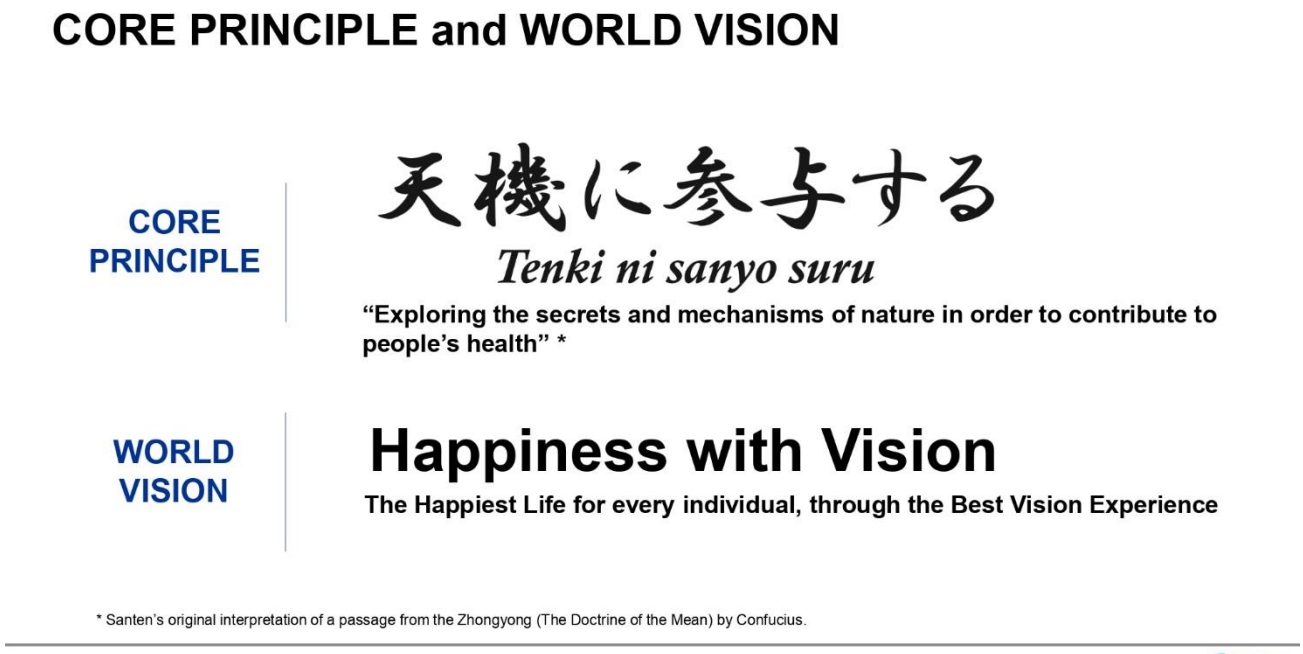
Taniuchi: Hello, everyone. I'm Taniuchi, CEO of Santen Pharmaceutical Co., Ltd.

Thank you very much for taking time out of your busy schedule today.

I would like to quickly explain based on the materials disclosed today for the financial results briefing for the first quarter of FY2021.



Please turn to page 3.

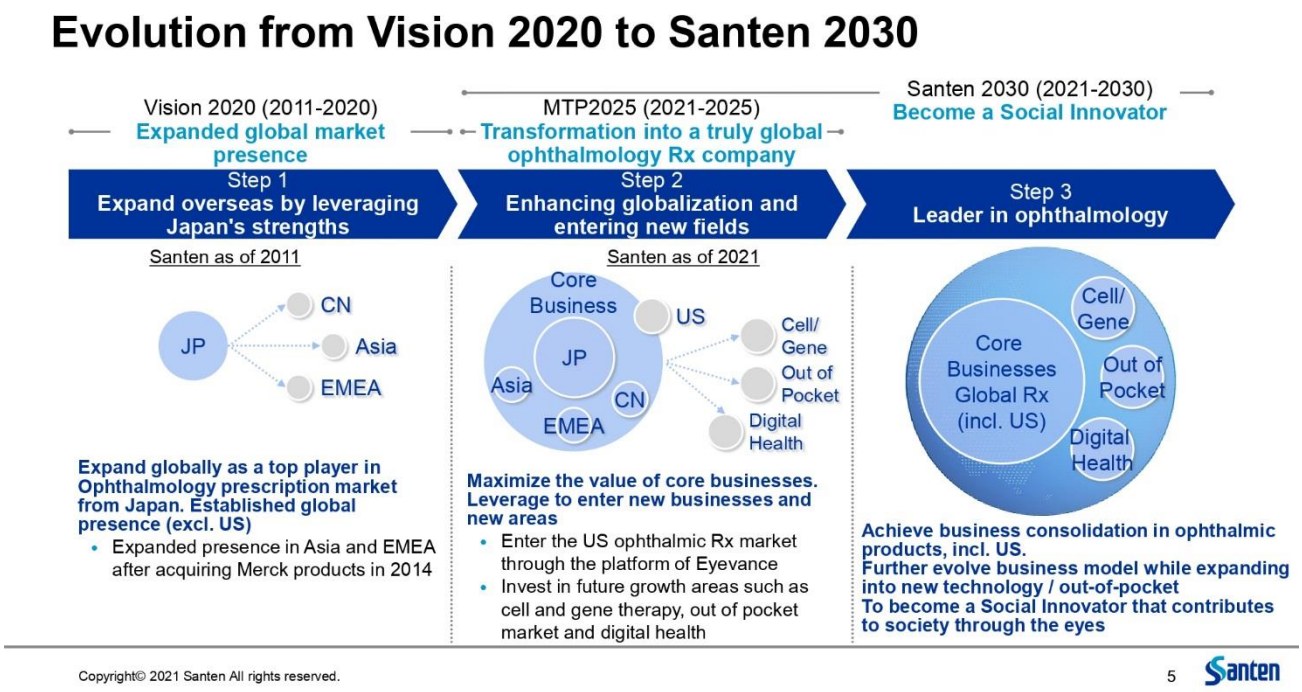
First of all, as usual, on the third page is the basic philosophy from which our company name is derived: Exploring the secrets and mechanisms of nature in order to contribute to people's health. This is as shown here.

The ideal that Santen is aiming for is WORLD VISION, Happiness with Vision, and in order to realize it, we are operating based on this philosophy.

Page 4, please.

Last year, in 2020, we announced our long-term vision, Santen 2030, with the aim of solving social issues related to the eyes. Our vision, Become a Social Innovator, is to reduce the social and economic opportunity loss of people around the world due to eye diseases and defects.

In order to realize this vision, we have 3 themes: Ophthalmology, Wellness, and Inclusion, and we are implementing measures to realize our mid- to long-term strategies based on these 3 themes.



Next, page 5.

Page 5 is the slide that I showed you in our Medium-Term plan, MTP2025, which was announced in May. It is a diagram of the past 10 years, and the 10 years to come.

We aim to further mature our global operations in the US and other countries in the next 10 years. This will be based on the strengths we have cultivated in the past 10 years; the strengths we have developed in our overseas operations mainly from Japan.

Next, new growth opportunities in ophthalmology. Cell and gene therapy, out-of-pocket treatments, and digital health. By expanding into these business areas where growth is expected, we will evolve our business model, aiming to become an organization that can realize people's happiness through sight.

The first 5 years of the plan is the Medium-Term Plan MTP2025. As I mentioned earlier, we will maximize the value of our core businesses and steadily move forward with activities to enter new business domains. We anticipate that this will lead to growth in the latter 5 years. That makes this 5-year span an extremely important time for us.

Agenda

1. Steady Progress Toward MTP2025

(1) Consolidated: Great Start

(2) Core Businesses: Progress in China

(3) New Areas, Progress in Americas

(4) Initiatives to Accelerate Medium-Term Plan

(5) Global Business Platform Enhancement

2. Q1 FY2021 Financial Results

3. R&D Update

Appendix

Please see page 6. Here is today's content.

Since this is the first quarter of the MTP2025, I would like to talk about the implications from the perspective of the mid-term plan as shown here.

1. (1) Consolidated: Great Start

MTP2025 Initiated: Implementation of Key Strategic Measures Driving Continued Growth Trend

Profit ratio improvement in core businesses

- Japan: **Steady revenue progress**, advancing product LCM
- China: **Strong growth trend in new channels and new products**
- EMEA, Asia: Progressing as planned despite the impact of COVID-19

Expansion of new areas

- Americas: **Eyevance continued to grow, *Verkazia* approved,** steady progress toward achieving profitability
- R&D：Progressing as scheduled

Strengthening of foundation as a global company

- Commenced construction of new factory in China
- CO_2 emission reduction targets endorsed by the **SBT**[*1] initiative

*1：Science Based Targets

Now, please take a look at page 7.

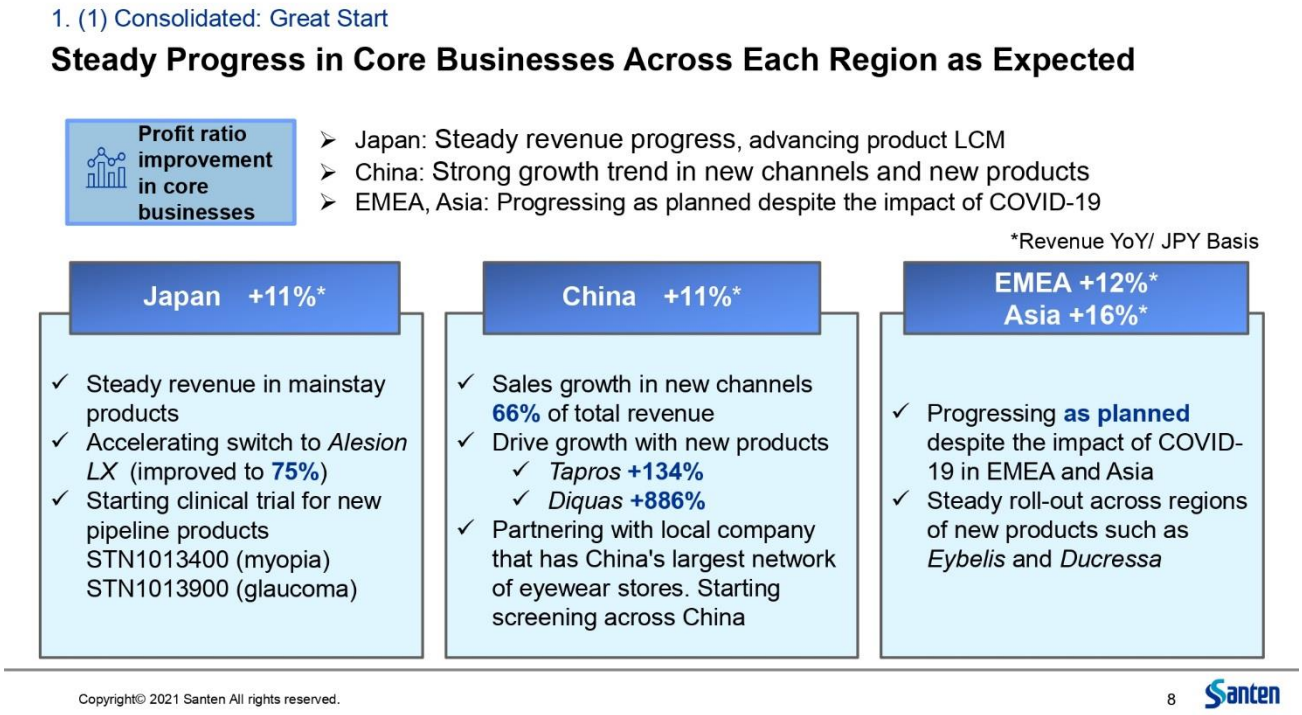
First, let's look at the first quarter. I believe that we have made a very good start, both in terms of performance and in terms of the content and progress of our strategy.

The changes in volume based purchasing in China last fall caused a lot of concern for some people. We have been working on the turnaround of our business in China in the form of transformation.

To be a bit more specific, we are working on the expansion of sales through new and more varied channels, as well as the growth of new products. Our efforts so far have been successful. We have recovered to a growth trajectory, so I think you can rest assured that we are on the right track.

In the US, which we expect to be the next pillar of growth, Eyevance's products are growing steadily. As we reported in June, we have also received approval for *Verkazia*. We recognize that this is a major step forward in our efforts to return to profitability.

As you can see, we have made progress in each of the activities and effective strategies detailed in this mid-term plan. In today's session, I would like to explain in more detail about the situation in China and the United States.

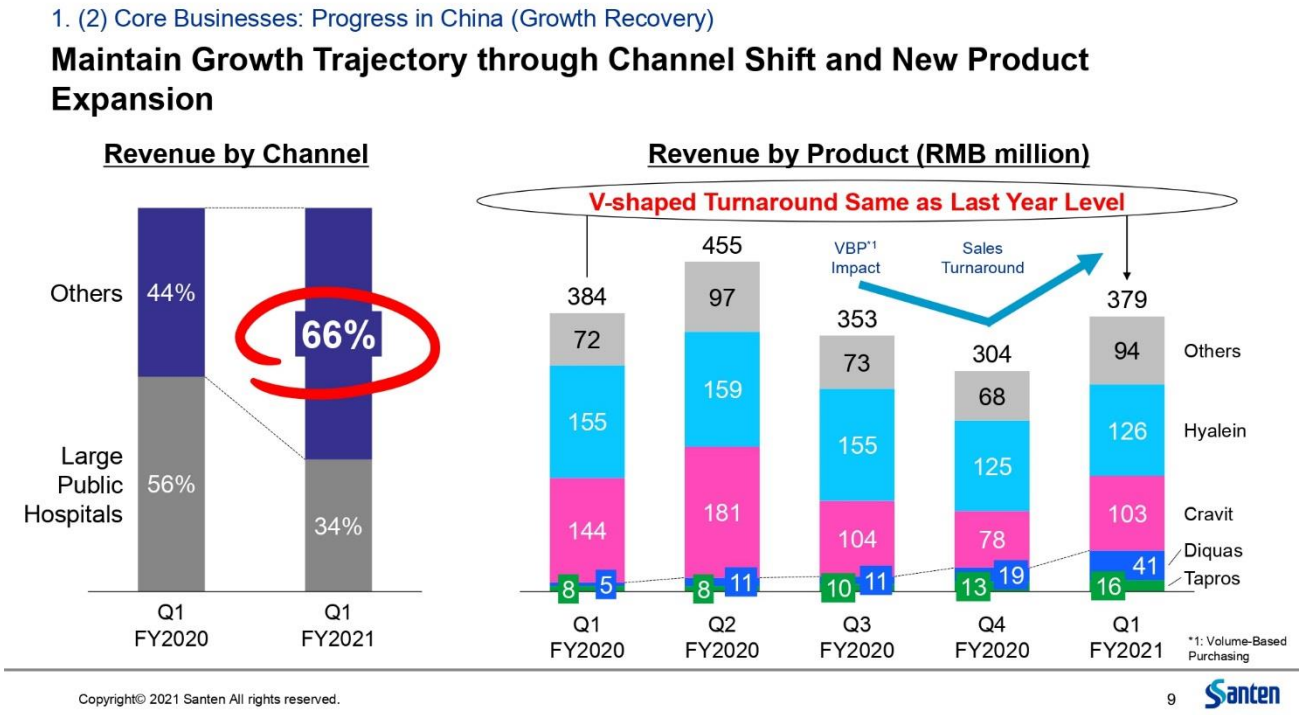


Page 8.

This shows the improvement of the profit margin in the core businesses; the status of the core businesses in Q1.

As you can see in this page, the core business projects, which are also divided by region, are performing well. In JPY terms, the growth rates were all double digits.

Here is a list of points and highlights for each region. As you can see, the profit margin for Japan is steadily increasing. I will talk about China later. EMEA and Asia are also growing steadily, despite the impact of exchange rates and other factors. In particular, new products are growing steadily, and the overall trend is generally positive.



Please turn to page 9.

Let me dig a little deeper into the status of our China business in the next few slides.

In the China business, as you know, the market environment has changed. Volume based purchasing has been introduced at national university hospitals. On the other hand, in response to the changes in the behavior of patients and consumers due to the coronavirus pandemic, we are actively promoting a shift to multiple sales channels. We are also engaging in an expansion of sales of new products that we had not previously been able to achieve.

Next, regarding *Hyalein*, and *Cravit*, which is now subject to volume based purchasing. As a result of our efforts to expand sales of these long-listed products, we have shifted our resources from the conventional market target of third-tier hospitals (so-called large national hospitals) to new channels such as private hospitals, pharmacies, clinics, and small hospitals, which are expected to grow in the future. As a result, we are currently undergoing a major turnaround in our sales activities.

Channels other than the national university hospitals have expanded to 2/3 of the total. This also means that the composition is becoming more balanced.

The graph on the right shows the quarterly trend in local currency and RMB.

In the first quarter of FY2021, due to the impact of foreign exchange rates, I mentioned earlier that net sales increased by 11% on a JPY basis.

On a RMB basis, as you can see here, we have almost recovered to the same level as last year, before the impact of volume based purchasing.

Last year, I remember that China's shipments were quite low in the January-March period, but I have the impression that shipments were high in the April-June period. The level of shipments appear to have recovered to about the same level as before.

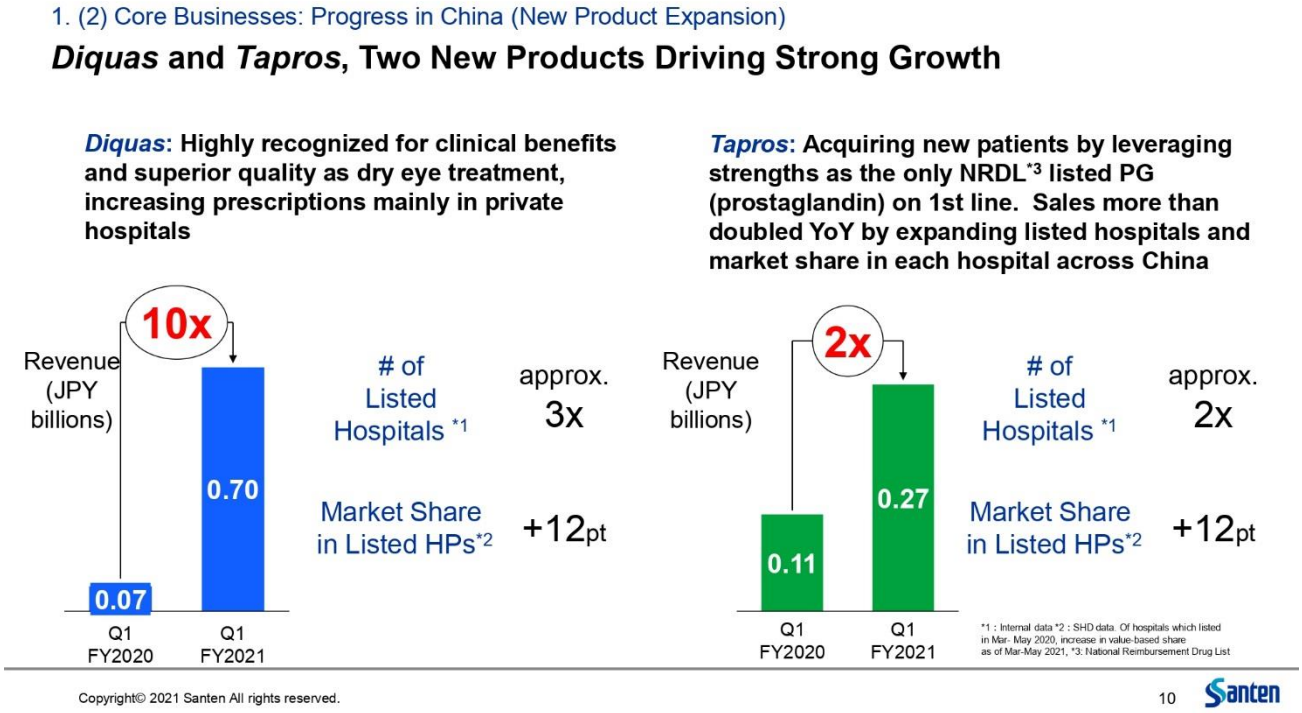
Although some felt that it would take several years to recover to the previous sales level after the impact of volume based purchasing, especially on *Hyalein* and *Cravit*, we were able to successfully complete the turnaround in almost 6 months.

We will continue to promote our China business as a medium- to long-term growth driver, as we have in the past, by taking advantage of our new multi-channel sales structure and the fact that new products, in addition to long-listed products, have become growth drivers.

As an additional note, we have heard that the Chinese government has been encouraging volume based purchasing for private hospitals, and we have received some inquiries about this. We are not in a position to comment on the policy of the administration.

Currently, our company is growing in a well-balanced manner, not only in private hospitals but in multiple other channels.

Also, in private hospitals, there is a clear need for branded products such as *Hyalein* and *Cravit,* which are selling well there. Even if volume based purchasing expands in the future, there will still be a need for our brands. We will continue to provide our products to patients and doctors who want to use Santen's *Cravit* and Santen's *Hyalein.* Even if volume based purchasing spreads, the need for our brand will remain. At present, we have not seen any impact at all, and we are not aware of any impact in the future, so we hope that you can rest assured.



Next, on page 10, I would like to talk about the status in China of our new products, *Diquas* and *Tapros*.

As you can see in the graph on the previous page, these 2 new products are strongly driving our growth.

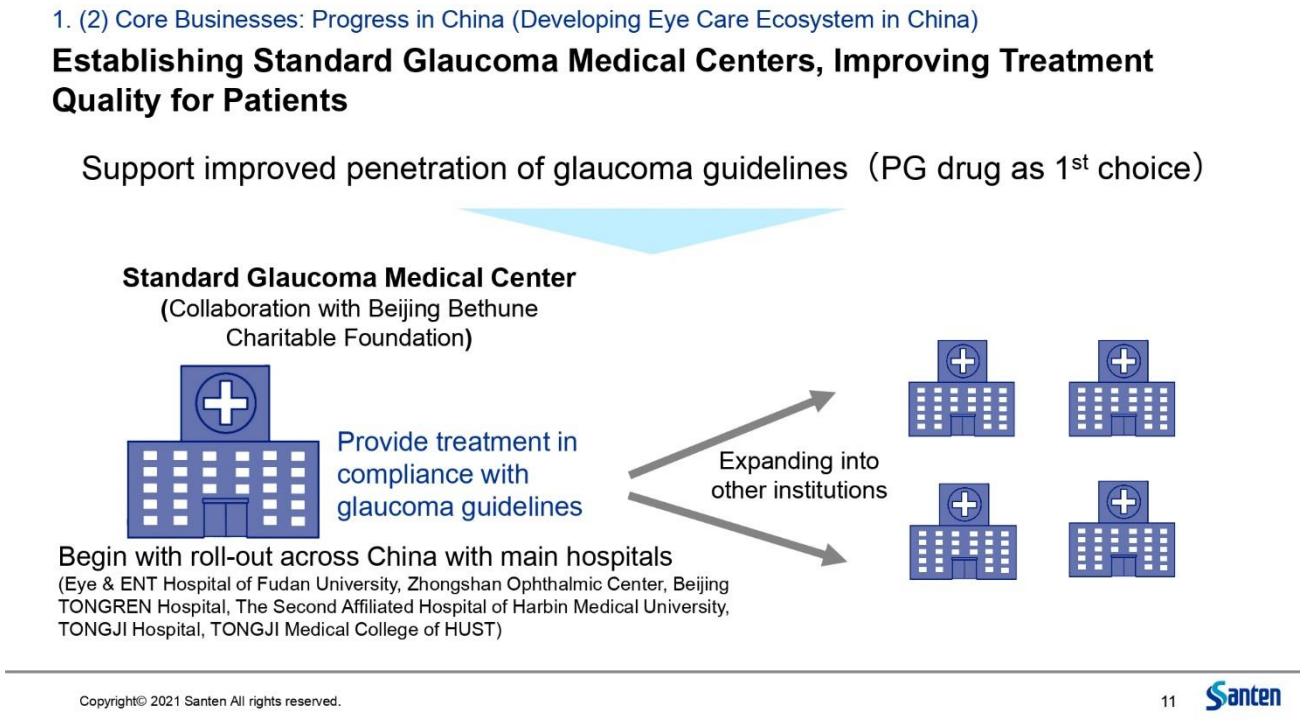
By leveraging the strengths of both products, we will be able to increase the number of facilities using them, as well as increase our in-store and intra-facility market shares. We have made great progress in this area.

In particular, although *Diquas* is not listed on the NRDL (National Reimbursement Drug List), it is recognized for its efficacy as a dry eye treatment, and its quality. This has been accepted by the market, and the use of

the product, especially in the perioperative period, has increased. Its use is growing in various channels, especially in private hospitals.

Although we would like to see *Tapros* do a little better than planned for the year, it has been performing very well. We are steadily increasing the number of facilities using our products and our in-store market share.

Glaucoma is a chronic disease, so we are making special efforts to acquire new patients. We expect this to lead to accelerated growth in the future. Also, as I will discuss later, we are working to build an ecosystem around glaucoma treatment. Based on the prescribing activities associated with this ecosystem development, we will continue promotional activities in this area with the expectation that growth will be further accelerated in the future.



On pages 11 and 12, I would like to talk a little bit about this ecosystem-related activity.

This was originally a major issue in ophthalmology treatment in China, where there was a lack of awareness of the disease and a lack of screening. As a result, I have often mentioned that there is a bottleneck in the upstream side of treatment, where diagnosis is not performed.

Therefore, we believe that it is important to not only boost instore share in downstream hospitals, but also to build up the upstream areas, especially in China and Asia.

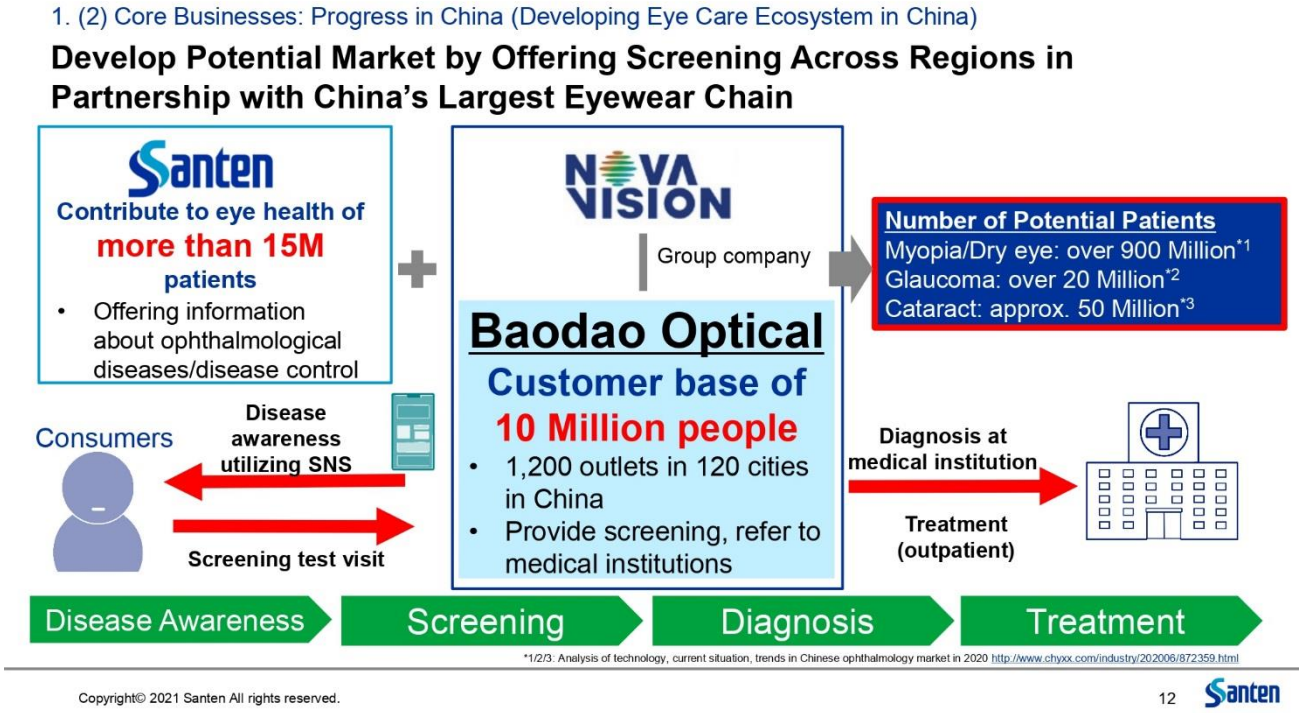
We have talked about this in our long-term vision, and I would like to talk about some specific examples of how we are making steady progress in this area.

The first step, on page 11, is to promote the spread of treatment guidelines.

This is mainly to free up the bottleneck at the diagnosis level. This is an initiative related to the elimination of that bottleneck.

In Beijing, we collaborated with public institutions to establish the Standard Glaucoma Medical Center, and from there we started this academic exchange project relating to treatment.

By doing so, we will promote the spread of guidelines recommending PG drugs as the first choice of treatment, as recommended by academic societies. With the involvement of hospitals, we will work to raise the level of treatment after diagnosis.



Next, on page 12 is another part of this effort, a partnership that started in June. We have partnered with 1 of the largest chains of opticians in China.

Baodao Optical is 1 of the largest eyeglass chains in China, and I'm sure those who have been to China have seen it on the street or at the airport. The parent company is NovaVision, and we have formed a partnership with them.

This is an attempt to eliminate bottlenecks in the area of upstream screening and diagnosis. In the future, while looking at diseases such as glaucoma and myopia, we will use our vast network to uncover patients and connect them to the market. We will start with glaucoma, and that is what this project is about.

The number of potential patients is increasing, but in light of the current situation in China, where access to medical care is restricted, we will make these sorts of attempts to expand the access points. We hope that this will lead to the emergence of new patients, growth of the market, and of course, growth of Santen.

1. (3) New Areas, Progress in Americas

New Business Pipeline in Myopia/Ptosis Showing Steady Growth
Significant Growth in Americas, a New Region for Santen

Expansion of new areas

- Americas: Eyevance continues to grow, *Verkazia* approved, steady progress toward achieving profitability
- R&D: Progress as scheduled

*Revenue YoY/JPY Basis

New Diseases

- ✓ Pipeline in new domains including myopia: **On track**
- ✓ Business roll-out preparation for new areas such as ptosis: Progressing
- ✓ Started preparation for study on meibomian gland malfunction (STN1010905/sirolimus)

Americas +306%*

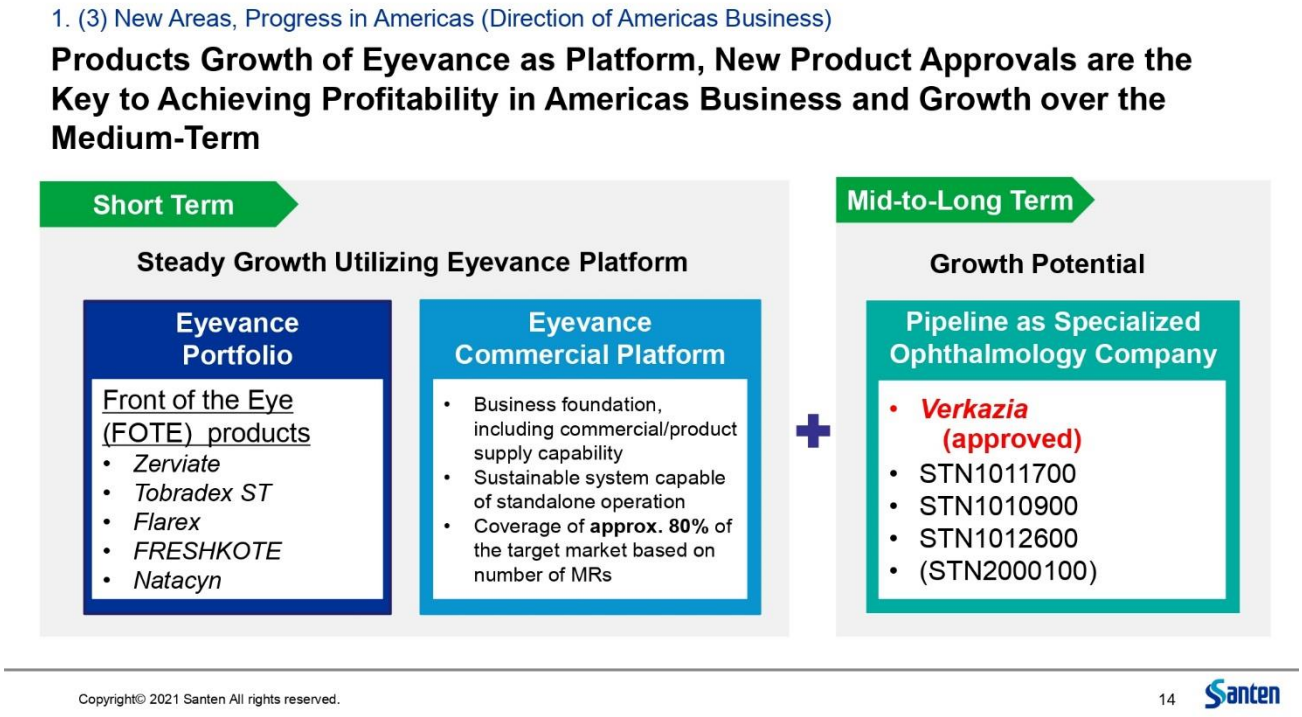
- ✓ Eyevance overall: **Approx. 2 times**[*1] compared to the same period in the previous fiscal year, **approx. 4 times** for Americas as a whole
- ✓ Steady increase in prescriptions for new product ***Zerviate***
- ✓ Major progress toward achieving profitability with ***Verkazia* approval**

*1 : Preliminary comparison with actual results (unaudited basis) when acquired

Next is the second pillar of the Medium-Term plan, which is new growth areas.

There are 2 main areas: pipeline-related updates and the US business.

Mr. Morishima will talk about the pipeline in more detail, but to sum it up, it is proceeding as planned. In the US, Eyevance is doing well. I would like to talk about this in some detail later.



Page 14, please.

This is the strategic direction of our business in the Americas. In the short term, we will use the Eyevance platform to launch this pharmaceutical business.

We plan to use Eyevance's MR network, which covers almost 80% of their target doctors, to sell the Eyevance anterior segment products listed here.

First of all, we have *Zerviate*, a new product that uses cetirizine, a well-known anti-allergic agent. Then we have *Tobradex* and *Flarex*, which are very familiar to ophthalmologists. By combining these products, we have created a portfolio of drugs mainly for the anterior segment of the eye, and are actively promoting them.

I've mentioned before that not only new products but also old products can benefit from solid promotion, and we are steadily growing by doing this. In other words, we are steadily developing a business model that takes advantage of existing scale of the United States.

In addition, the first item on the right side is focused on medium- and long-term growth. *Verkazia* has been approved without issue. I will talk about the details later.

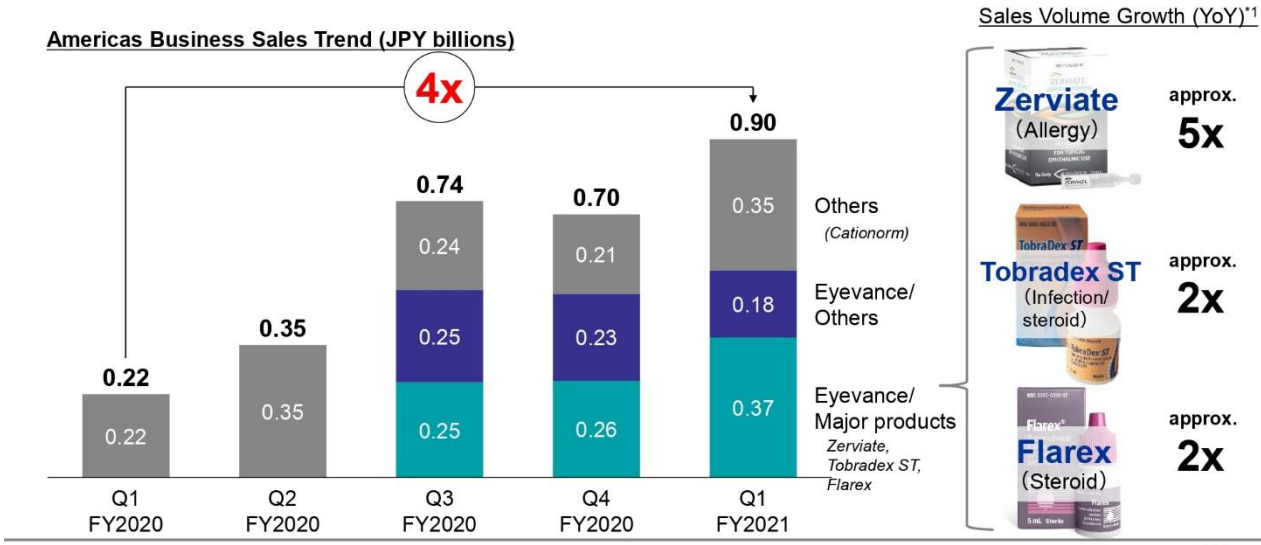
In addition to that, we will aim for further upside growth by launching other pipelines shown here, such as 117.

In any case, we would like to return Eyevance to profitability on a stand-alone basis, and by adding the growth of Santen to that, we would like to return the Americas business as a whole to profitability and contribute to profits, while expanding our business domain from anterior segment to glaucoma in the pharmaceutical field.

More details about the product can be found in the Appendix, so please review it at your leisure.

1. (3) New Areas, Progress in Americas (Americas Sales Trend)

Americas Business: Steady Growth Trajectory on Firm Growth of Eyevance Products

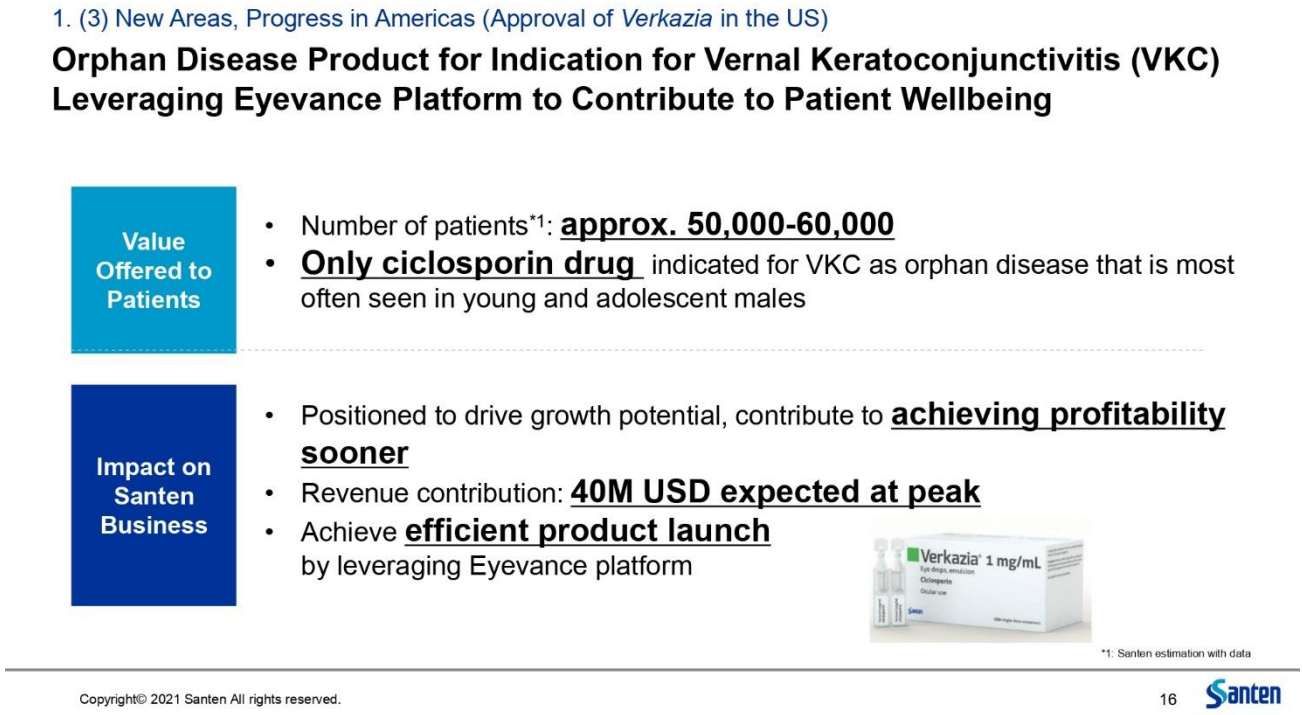


*1: Shipment data. Comparison of March-June period to eliminate the impact of products launched in April 2020

Page 15, please.

This is the quarterly sales trend of the Americas business. Since the inclusion of Eyevance, sales have quadrupled compared to the same period last year, but Eyevance's main products have also increased between 2-fold and 5-fold compared to the same period last year. In the US, there are many areas where the influence of the coronavirus pandemic is still relatively strong, but we have achieved this growth.

By maintaining this trend, we will be able to grow our US business and develop new products.



Please see page 16.

As you can see, *Verkazia* received approval at the end of June.

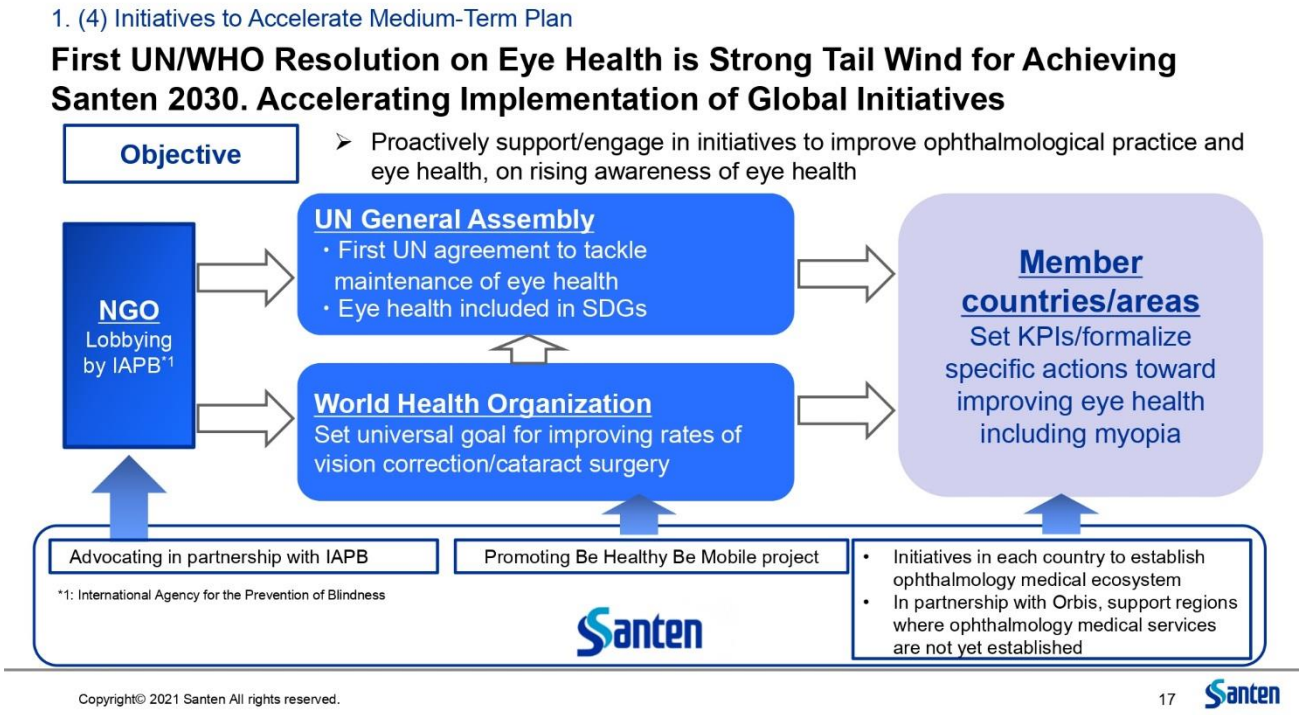
The indication is a rare disease called spring catarrh, and there are approximately 50,000 to 60,000 patients in the United States. It is a severe allergy that affects patients every spring, mainly affecting adolescent boys.

This is the only ciclosporin product available for VKC, and we hope to provide value to patients and medical professionals.

As you already know, we are selling this product in Europe and Asian countries. It is a global product, with a high drug price and very good reimbursement status in many countries. Based on this, we would like to do something like that in the US as well.

Also, VKC is usually already apparent in patients, as it recurs every spring. In addition, people who have been identified overlap with those who are currently covered by Eyevance.

We think it is possible to develop sales activities for a limited number of people in a specialty group without a large additional investment in sales. Peak sales are expected to be around USD40 million. While this figure itself may not be large, in terms of the top profit it is a very large product, and I believe that the approval of this product is a big step forward in the swift return to profitability of the Americas business.



On page 17, I would like to introduce a topic in medium- to long-term growth, which is very important.

This is a tailwind for our Santen 2030 initiative.

In May, the World Health Organization (WHO) adopted global goals for refractive errors such as myopia, hyperopia and astigmatism, as well as cataract surgery.

Following this trend, in July, the United Nations General Assembly adopted a resolution on eye health, making eye health part of the SDGs. Or rather, it was clearly defined as an important KPI to achieve the SDGs.

This is probably the first time in history that an issue related to ophthalmology or vision has been properly recognized at the UN level. The fact that the United Nations has decided on goals and actions to be taken at the national level is, in our view, a very significant milestone.

In the past, ophthalmology has often been pushed to the side in discussions like this, but this time, goals relating to eye disease have been decided, and are being tackled head on.

Also, although it is very presumptuous of me to say so, it feels as if that the goal of social contribution through eye health that we have aimed for in Santen 2030 has been endorsed by the United Nations and the WHO.

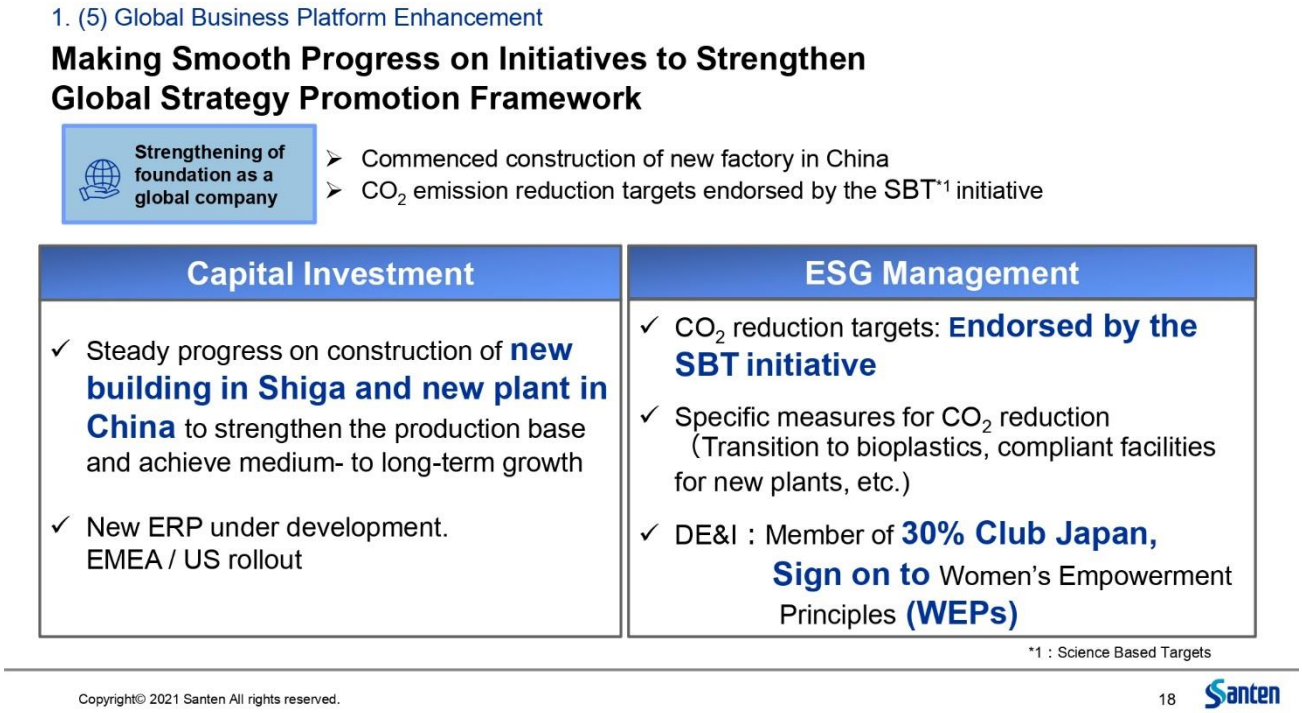
In the future, as a result of these movements at the United Nations level, it is expected that efforts will continue to be made in each country of the world to solve eye problems and improve the health of people with diseases like myopia and glaucoma. In the same way as with climate change, I believe that this will lead to national actions from the top. Santen would like to actively participate in this area as well.

Santen has also been supporting the Be Healthy Be Mobile project in collaboration with the ITU and the WHO, both of which are part of the United Nations.

We have also worked with IAPB, the International Association for the Prevention of Blindness. We have formed a long-term partnership with this organization to support global efforts to improve access to ophthalmology.

Refractive anomalies also appear here, as you can see. In particular, we have positioned myopia as a key area of focus for the future, and are developing several drugs such as DE-127 and 134 on a global basis.

With this movement as a tailwind, we will continue to actively participate in efforts to improve eye care and eye health in each country.



This is page 18.

This is to strengthen our foundation as a global Company, which is the third point mentioned in the Medium-Term plan.

To put it simply, we are making good progress, with the construction of the new plant underway, and SBT endorsement obtained for CO2 reduction targets. As you may have noticed, we are working on these initiatives.

We will let you know when we have decided on specific targets, especially in relation to DE&I.

Discussion of the Medium-Term plan has taken a little time, but I will now give you an overview of our business performance.

2. Q1 FY2021 Financial Results

Great Start Toward Achieving MTP2025 Objectives

(JPY billions)	Q1 FY2020 Actual	vs Revenue	Q1 FY2021 Actual	vs Revenue	YoY
Revenue	**57.6**		**65.0**		**+12.9%**
Cost of sales	24.7	43%	26.9	41%	+8.8%
Gross margin	32.8	57%	38.1	59%	+16.0%
SG&A expenses	15.6	27%	20.4	31%	+31.5%
R&D expenses	5.6	10%	6.1	9%	+9.0%
Amortization on intangible assets associated with products	2.4	4%	2.0	3%	-16.7%
Other income	0.2	0%	0.1	0%	--
Other expenses	1.4	2%	0.0	0%	--
Operating profit	**8.0**	**14%**	**9.5**	**15%**	**+19.0%**
Finance income	0.5	1%	0.6	1%	+11.3%
Finance expenses	0.2	0%	0.3	0%	+48.2%
Share of loss of Investments accounted for using equity method	--	--	0.3	0%	--
Profit before tax	8.4	15%	9.6	15%	+14.3%
Income tax expenses	2.2	4%	2.2	3%	-2.3%
Actual tax ratio	*26.7%*		*22.9%*		
Net profit	**6.1**	**11%**	**7.4**	**11%**	**+20.3%**
Core basis					
Revenue	57.6		65.0		+12.9%
Operating profit	11.7	20%	11.7	18%	+0.5%
Net profit	8.8	15%	9.0	14%	+2.5%
USD (JPY)	107.46		109.81		
EUR (JPY)	118.69		132.05		
CNY (JPY)	15.13		17.03		

Revenue

- Double-digit year-on-year increase in sales driven by domestic and overseas growth

JPY65.0 billion (YoY +12.9%)

Operating Profit

- Double-digit growth due to a decrease of other expenses (change in fair value of the InnFocus, Inc. (U.S.) contingent consideration) from the previous fiscal year

JPY9.5 billion (YoY +19.0%)

Core Operating Profit

- Profit growth on higher sales and changes in product mix, despite increase in SG&A expenses on higher co-promotion fees resulting from higher *Alesion* sales and new consolidation of Eyevance

JPY11.7 billion (YoY +0.5%)

Page 20, please.

These are the results for the first quarter. As I said at the beginning, we are off to a good start.

Sales revenue increased by 13% to JPY65 billion, and operating income on an IFRS basis increased by 19% to JPY9.5 billion. In addition to the growth of mainstay products in the Japan business, the overseas business also made a steady contribution, resulting in an increase in sales here.

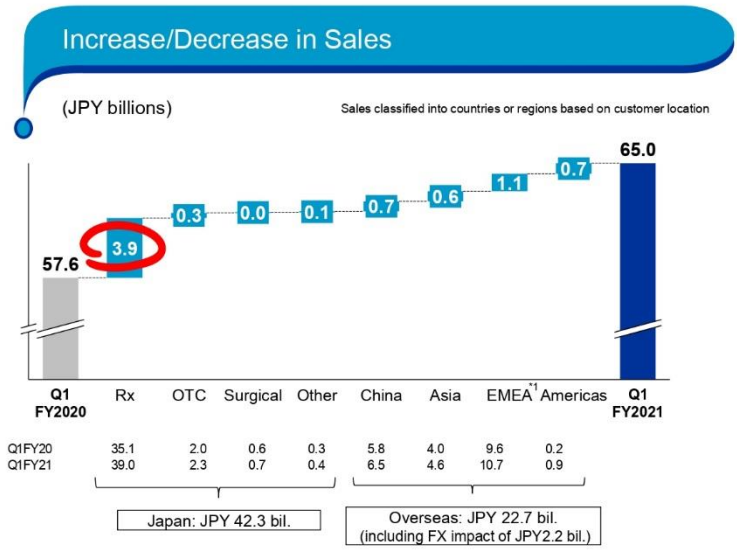
The increase in operating income is due to the effect of increased revenue and a decrease in other expenses. In terms of expenses, there has been a decrease related to the absence of previous InnFocus-related expenses.

SG&A expenses appear to have increased slightly, but this is due to the consolidation of Eyevance, which was not included last year, and also due to the significant increase in sales of *Alesion*, which is included in the area of co-production with Mitsubishi Tanabe Pharma. As a result, the increase in coprocessing costs is a little more noticeable.

The rest is due to the impact of foreign exchange rates, and as far as I am concerned, the contents are in line with our plan. We will continue to monitor our expenses closely and aim to achieve profits.

2. Q1 FY2021 Financial Results

Q1 FY2021: Growth Across All Businesses, Led by Solid Japan



Main Factors of Change

Japan
- Strong Rx business revenue
  Major products such as *Alesion LX* driving revenue growth (*Alesion*:LX=1:3)
- OTC revenue increased as impact of drop in inbound demand annualized

China
- Revenue growth in private hospital/retail channels and from new products *(Tapros/Diquas)* despite the impact of VBP*2

Asia
- Steady growth in Korea and Thailand, etc.
- Major products and new products to support continued growth

EMEA
- Revenue growth despite impact of COVID-19
- Contributions from product roll-outs, including preservative-free products which respond to local needs

Americas
- Revenue increased on contribution from Eyevance

*1: EMEA; Europe, Middle East and Africa, *2:Value Based Purchasing

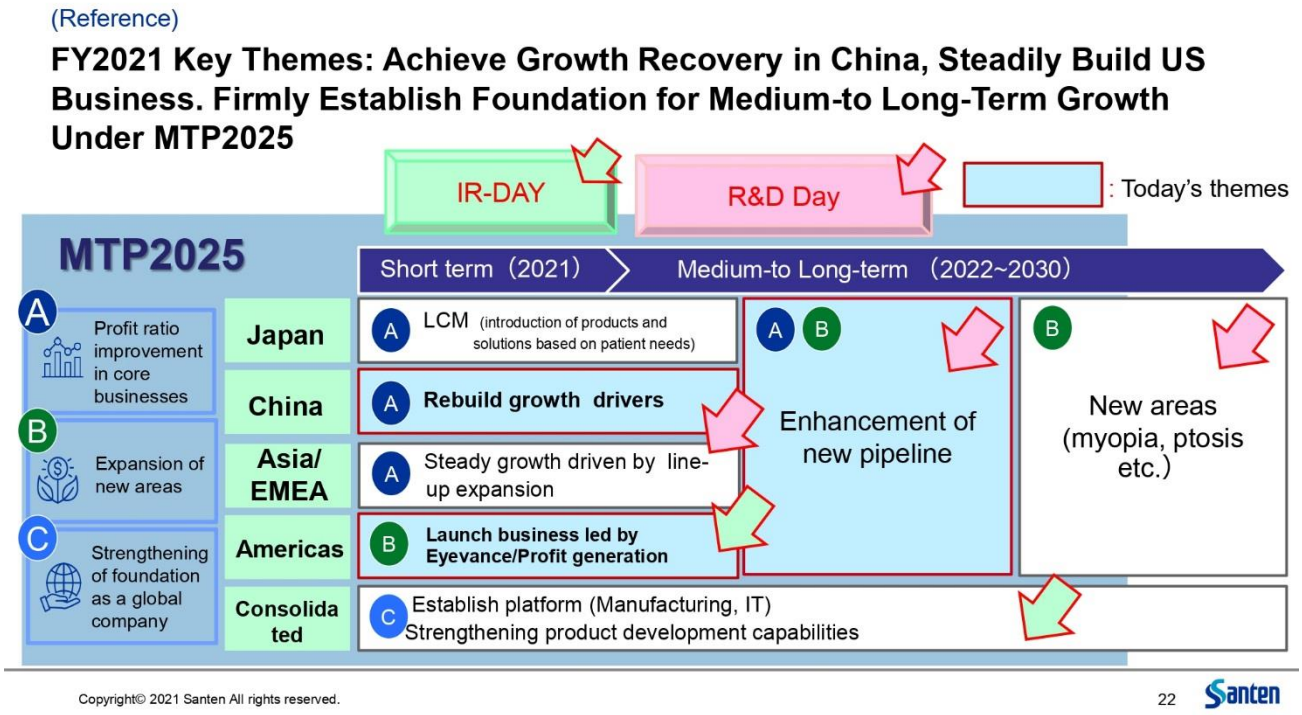
Page 21, please.

This shows the factors affecting sales by area. As mentioned earlier, the Japan business was strong. Regarding *Alesion*, a generic version was released in Japan in June, but the ratio of *Alesion LX* is already high. We have increased the percentage to 75%, so the impact is within our expectations.

As for OTC drugs, inbound sales have also decreased since last year, and the negative impact of inbound sales has run its course, so sales are on a growth trajectory again from here.

As mentioned earlier, our overseas businesses in China, Asia, EMEA, and the Americas each posted higher sales.

(Reference)



Page 22, the last page, shows the start of our Medium-Term Plan, MTP2025, which we talked about in May. Today's presentation was particularly focused on the theme of this mid-term plan.

The areas highlighted in red are what we talked about in particular today.

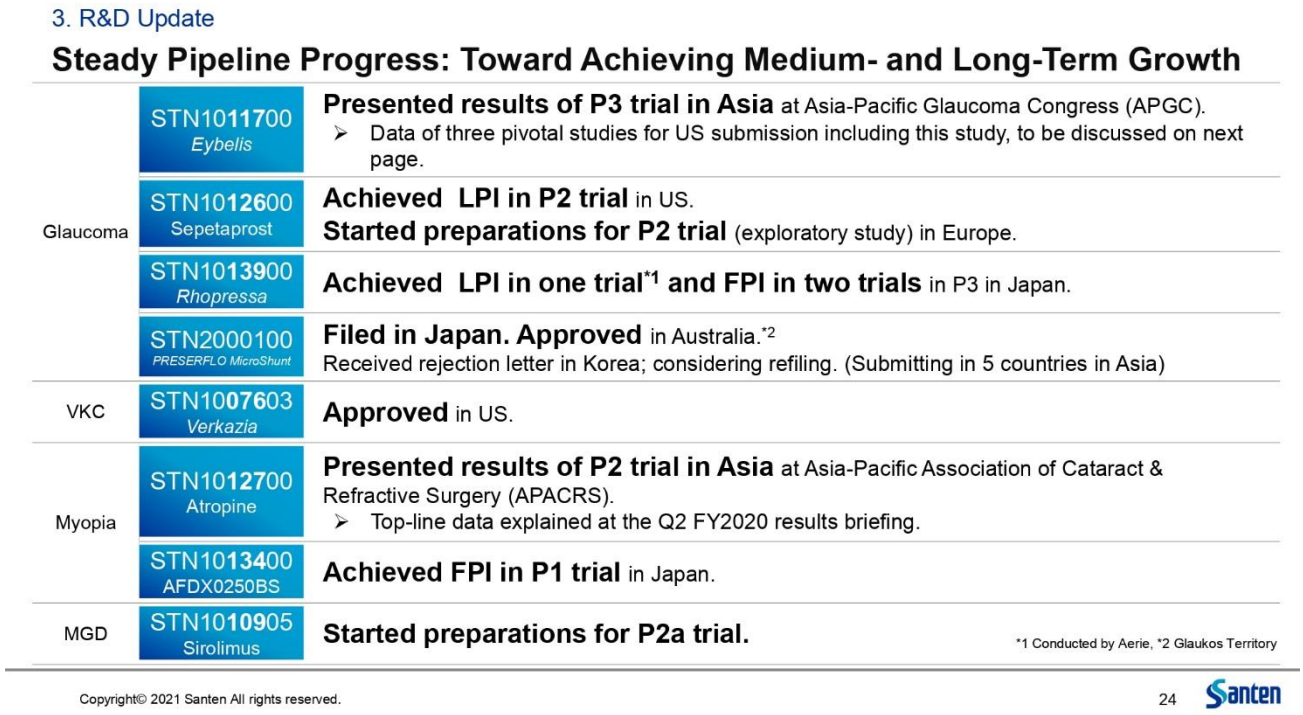
Mr. Morishima will explain about the pipeline in a few minutes.

In addition, in this fiscal year, the pink areas in the figure are the ones that are the most important. I would like to talk about these at the R&D Day, and I would like to talk about the strategy briefing, the green part, at the IR Day.

Today, I was not able to talk about the details, but I would like to take this opportunity to talk about new areas such as myopia and how we will consider them in the future, the specifics of the strategy for the US business, and ESG initiatives.

We are already a third of the way through FY2021. We have conducted vaccinations within our company. I had mine the day before yesterday. While taking every measure against COVID-19, we are firmly committed to growth, with an awareness of business activities and business continuity.

I would like to ask for your continued support as we continue to work toward achieving our goals in the Medium-Term Plan. That's all from me.



Itagaki: Next, Mr. Morishima will discuss the status of research and development.

Morishima: I'm Morishima from the Product Development Division. I would now like to give an update on R&D.

Slide 24, please.

First, I would like to report on the highlights of our R&D activities for the first quarter of FY2021.

STN1011700, or *Eybelis*, is currently under regulatory review in the US. The results of the PEONY study, 1 of the Phase III clinical trials in the application materials, were presented at the Asia Pacific Glaucoma Society meeting in June.

In the next slide, I will explain the data from the 3 Phase III clinical trials that we have submitted, including the PEONY trial.

Next, STN1012600, or sepetaprost, has achieved last patient-in in Phase II clinical trials in the US.

In Europe, we have started preparations for Phase II clinical trials. This trial in Europe is positioned as an exploratory trial to clarify the product profile and strengths.

As for STN1013900, or *Rhopressa*, 1 of the 3 Phase III clinical trials in Japan achieved last patient-in in June this year.

For the other 2 trials, the first patient enrollment was completed in May of this year, and we are now in the process of enrolling subjects. I will explain more about this later.

We filed an application for STN2000100, the *PRESERFLO MicroShunt*, in Japan in May this year. In Australia, which is the territory of Glaukos, approval was obtained in May.

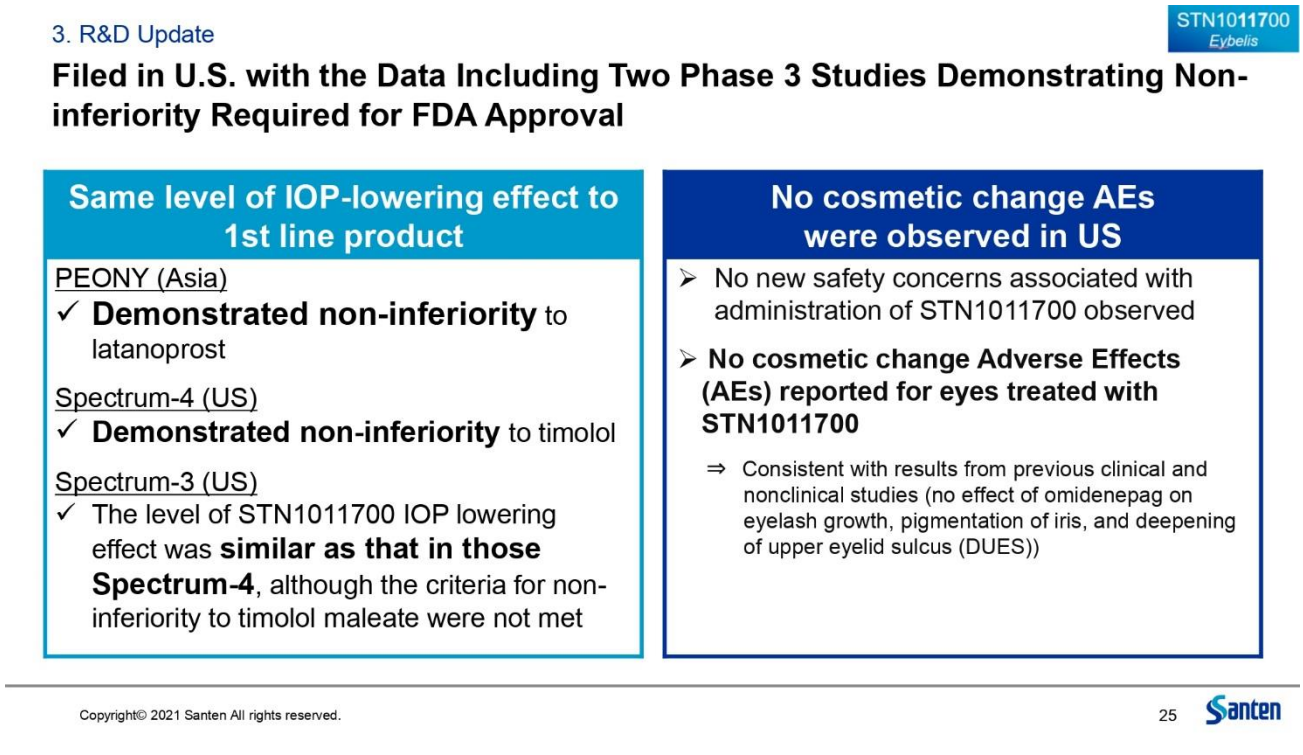
In Korea, where we applied last year, we received a rejection letter, and we are now preparing to reapply. In addition, applications are currently pending in 5 other Asian countries.

Finally, as reported in the press release of June 24, STN1007603, or *Verkazia*, has been approved in the United States. I will explain a little more about this later.

Regarding STN1012700, or atropine, for myopia, we reported the results of the Phase II clinical trial at the Asia Pacific Cataract and Refractive Society meeting in July. We reported on this top line in our financial results briefing for the second quarter of FY2020.

For myopia, we expect STN1013400 to be part of the next generation of drugs to inhibit the progression of myopia in children. We started Phase I clinical trial in Japan in July.

We are also preparing for a Phase II clinical trial of STN1010905 for meibomian gland dysfunction (MGD) as a new project this fiscal year.



Next, please turn to slide 25.

The results of 3 Phase III clinical trials of STN1011700, which were submitted to the FDA last year, and for which PDUFA is set for November 19, are summarized here.

In the next slide, I will present the data.

First of all, as for the results, in the US application, 3 studies were submitted as Phase III clinical trial data. Basically, the FDA requires 2 phase III clinical trials to be non-inferior to a comparator drug to ensure reproducibility.

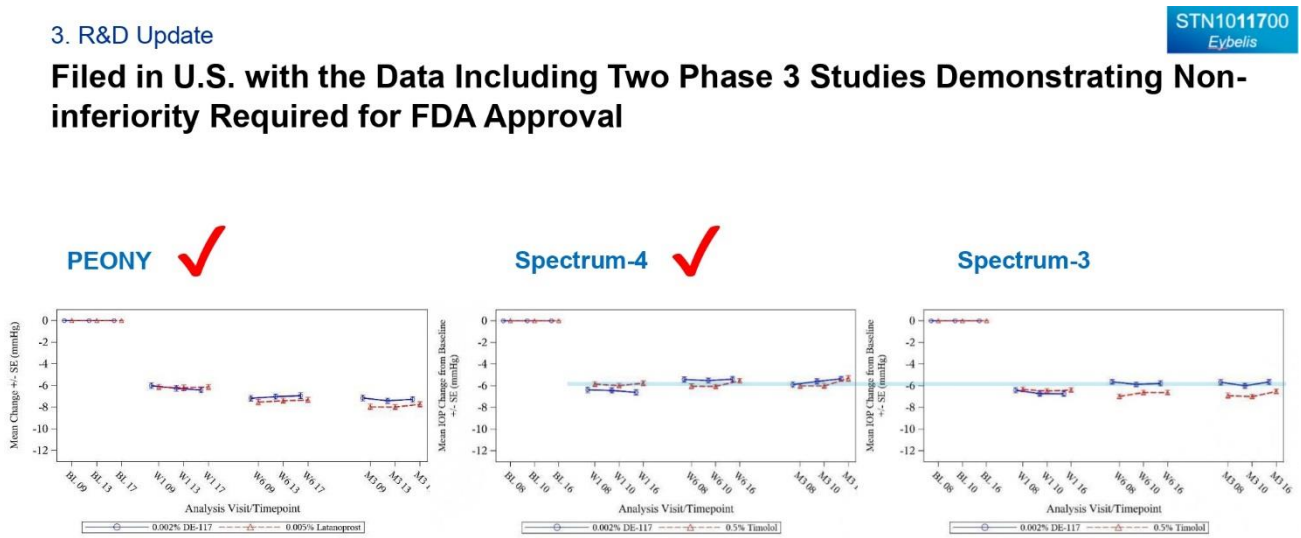
For STN1011700, this product has proven non-inferiority in 2 studies, the PEONY study and the Spectrum-4 study.

The PEONY study conducted in Asia demonstrated non-inferiority to latanoprost as a comparator, and the Spectrum-4 study conducted in the US demonstrated non-inferiority against timolol as a comparator, confirming reproducibility.

On the other hand, the Spectrum-3 study, which was also conducted in the US, did not prove non-inferiority to timolol as required by the FDA, but the reduction in intraocular pressure (IOP), 117, was almost the same as that of Spectrum-4, indicating a consistent IOP effect.

On the other hand, with regard to safety, the safety profile of this drug, which is already approved and marketed in Japan and Asia, has been confirmed through clinical trials. No new safety concerns have been identified in these 3 Phase III clinical trials. Once again, the safety and tolerability of this drug have been confirmed.

Side effects such as changes in the appearance of the eye's periphery are seen with existing first-line prostaglandin glaucoma drugs. Specifically, eyelash abnormalities and iris pigmentation. For 117 administrated subjects, we have not seen any cosmetic changes in Phase III clinical trials in the US.



Next, slide 26, please.

This is the data showing the degree of IOP reduction in the 3 trials. The vertical axis shows the degree of IOP reduction from baseline, and the horizontal axis shows the IOP measured at 8:00, 10:00, and 16:00 after 1 week, 6 weeks, and 3 months of treatment beginning.

As you can see, PEONY and Spectrum-4 showed the similar reduction in IOP as the control drugs, latanoprost and timolol, proving their non-inferiority.

On the other hand, in Spectrum-3, although there was a slight deviation in the degree of IOP reduction from that of timolol, the degree of IOP reduction of 117 itself was confirmed to be almost the same as that shown in Spectrum-4.

3. R&D Update

STN1007603 *Verkazia*

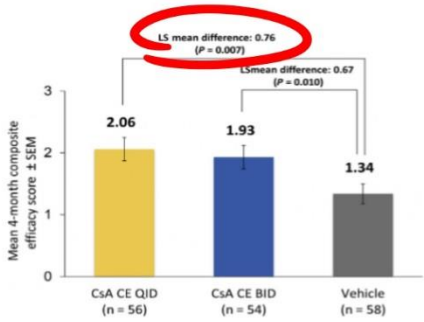
Received Approval in U.S. Following Europe and Asia Based on Vektis Trial

Vektis Study

Vektis was a prospective, multicenter, randomized, double-masked, vehicle-controlled phase 3 pivotal study assessing efficacy and safety of *Verkazia* in vernal keratoconjunctivitis (VKC)

Provide new treatments for children in the United States suffering from VKC, a rare disease that significantly affects quality of life

Mean composite efficacy score over the 4-month treatment period



Already launched in EMEA and Asia. NDA filed in China

This is slide 27.

As reported in the press release of June 24, *Verkazia* has been approved in Europe, Asia, Canada, and the United States.

This is the Vektis study, a phase III clinical trial. This result is shown on the right, and it shows a clear effect in comparison with the vehicle.

Basically, the FDA is looking for the results of 2 pivotal studies, but this drug has been approved from a single study.

As you can see from the p-value, the data shows a clear effect, with a p-value of 0.007.

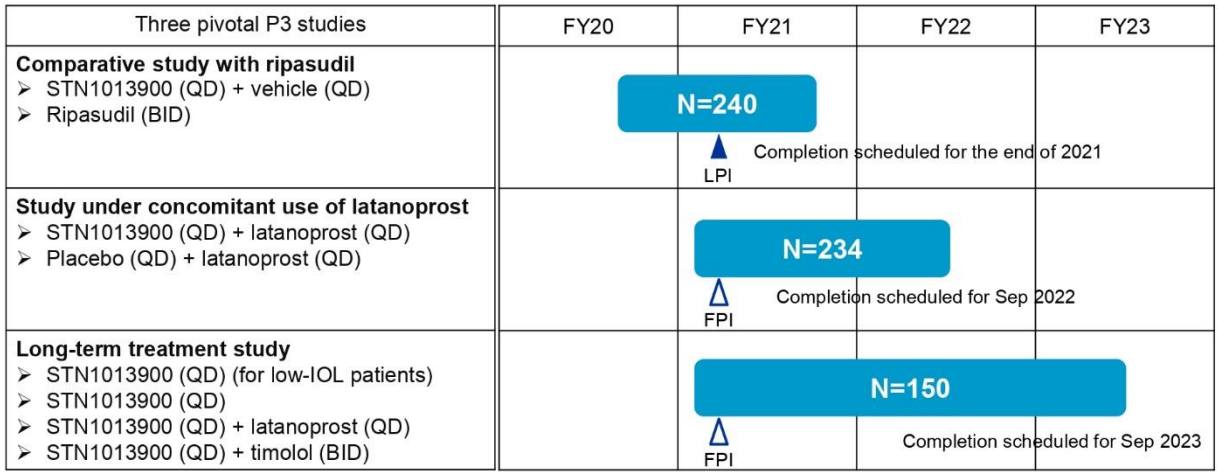
We believe that we will be able to provide a new treatment for children with spring catarrh, a rare disease, in the United States.

In China, the drug has been included in the list of overseas new drugs urgently required by the government for clinical use, and we filed for marketing approval in April.

3. R&D Update

STN1013900 *Rhopressa*

Three Pivotal Phase 3 Studies Are Ongoing in Japan
Expect to Obtain the Results of Comparative Study with Ripasudil in H2 FY2021



- **Filing in Asian countries** by using US Certificate of Pharmaceutical Product (CPP) is under preparation.

Next, please. This is slide 28.

This is a progress report on STN1013900, *Rhopressa*.

In a press release issued by Aerie on June 17, it was reported that last patient-in had been completed in the ongoing Phase III clinical trial in Japan. The trial is scheduled to be completed by the end of 2021, and the data will be disclosed after that.

Including this study, 3 Phase III clinical trials are being conducted in Japan for this drug. As for the other 2 Phase III clinical trials, the latanoprost combination trial and the long-term trial achieved first patient-in in May of this year, and enrolment is currently underway.

The 3 trials are scheduled to end in 2023, as shown here.

That's it for the R&D update.

Question & Answer

Q-1-1

I would like to start by asking about the situation in China. You mentioned that China's recovery was very smooth, but how did it compare to the plan? This time, in the first quarter, results have recovered to the same level as the same period of the previous year, but I am not sure if this is in line with the initial plan.

Also, if there are any items that are doing well or not doing as well as expected, could you please tell us about them?

A-1-1

Taniuchi:

The result is slightly higher than we had forecast. We are almost precisely on schedule.

In terms of what is working well and what is not, as I mentioned earlier, *Tapros* is a little bit weaker and *Diquas* is stronger than anticipated. The results for *Hyalein* and *Cravit* are almost as forecast.

However, in general, the figures are within the anticipated bounds.

Q-1-2

The second question is about DE-127, which I think was presented at APACRS recently, and I was wondering if you could introduce any new findings from the top-line data that you disclosed last year.

If there are any secondary endpoints or safety data that you can tell us about, please do so.

A-1-2

Morishima:

I'm Morishima. We are in the middle of the clinical trials, and there is no information that can be disclosed in either Japan or China. I hope to report more information as soon as it becomes available.

Q-1-3

You just made a presentation at an academic conference.

A-1-3

Morishima: This was a reiteration of what we have already reported.

Q-1-4

Last year, I believe, you presented the top line data. Are there any additional secondary endpoints, safety data, or any other information that you are able to share with us? I'm asking because I think you may have presented in more detail at the meeting.

A-1-4

Morishima: In the case of atropine, the side effect of mydriasis was the biggest concern, but in this study, there was no major concern at low concentrations, up to 0.01%.

Q-2-1

I would also like to ask about China.

What is your company's sales guidance for China for this fiscal year, and is it expected to grow YoY? When this was announced in May, many people, including myself, thought it was too high a target.

From your point of view, in the course of meetings with investors, what were their expectations for sales in China, and did the results in the first quarter exceed their expectations?

Also, why is *Diquas* doing so well in China? Is it through growth in private hospitals? Or is there a large increase in the number of replacements from *Hyalein*? I'd like to hear about that.

A-2-1

We have been told that our forecasts are bullish, and we are intentionally setting aggressive targets, but of course this is a growing market, and we are a top manufacturer. We have set a bullish target, and we will steadily work to achieve it.

I am sure that everyone has their own ideas about this, but I think that many investors and shareholders, in particular, would like to see the Company achieve solid growth over the medium to long term.

Aside from the current short-term impact of VBP, I would like to see the growth of new products and the enhancement of the pipeline in the future. I think there were a lot of people who are hoping that we can achieve in this area.

Of course, the current figures are important, but what is even more important is the ability to realize future potential in the China's growing market. This includes steps such as nurturing the ecosystem that I mentioned earlier.

By doing each of these things 1 by 1, we hope to achieve the expected medium- to long-term growth potential.

In terms of the current performance, I believe that it is almost in line with our expectations. This is 1 of several reasons why *Diquas* is doing so well.

1 of the factors is, of course, the switch from *Hyalein*, as you mentioned. After all, *Hyalein* has become very popular, and is highly regarded. On the other hand, given the backdrop of hospitals, in particular, having to use domestic products due to volume based purchasing, I think there was a natural shift to the use of *Diquas*.

Also, in private hospitals, some people who have been using *Hyalein* decide that they want to use a better drug, so they want to pay for *Diquas* themselves, even though it is not covered by insurance.

I think another cause is internal factors. We have been selling *Cravit* and *Hyalein* to anterior ophthalmologists and cataract and LASIK doctors, and our sales and marketing organization has a lot of experience in this area. If anything, they have an easier time selling *Diquas*.

On the other hand, I mentioned earlier that I would like to see *Tapros* do a little better. This is the first glaucoma product that we have developed in China, and it was developed by people who have worked in the anterior segment and dry eye area. I think that the MRs and marketing medical affairs staff is still not as familiar with glaucoma as it is in other areas.

This is the reason why there are elements that inevitably flow to *Diquas* in the field, and this is the result. Of course, we have been taking steps in the areas of employee training, resource allocation, and incentives, and we hope to strengthen our abilities in the area of glaucoma. That's all.

Q-2-2

As a supplementary question on China, can I conclude that the sales in China have already entered the positive growth trend after the negative growth in the short term since November last year?

Of course, there is the risk of volume based purchasing for *Hyalein*, but since the ratio of sales to large hospitals has been decreasing, is it safe to assume that we will enter a growth trend from here?

A-2-2

Taniuchi: Indeed. Basically, the market is growing, and this includes a shift of patients from large hospitals to private hospitals, clinics, and pharmacies. There are fundamentals for growth in this multi-channel market, especially in channels other than large national hospitals. We believe that we can achieve a growth trend by capturing a solid share of this market and expanding our business.

Of course, this is a long-listed product, so it may not be a high-growth market, but we can expect a certain level of growth while using the current scale as a source of revenue.

On top of that, we plan to try to increase overall sales by achieving high growth in *Diquas, Tapros,* and future new products.

Q-3-1

Regarding *MicroShunt*, I wonder if the reason it wasn't approved in Korea is something we should be concerned about. Please tell us about it.

A-3-1

Morishima: Thank you very much. The reason the Korean application was not approved this time was due to a lack of clinical data. This is basically the same as the communication we received in the US, and we received a rejection.

For Korea, we believe that we can take the same measures that we are discussing with the US, so we are thinking of making another application to Korea, reflecting the measures taken in the US.

Q-3-2

So what is the current situation in the US?

A-3-2

Morishima: In the US, we are currently communicating with the FDA, and the FDA is communicating with experts and medical professionals.

The FDA has responded to our request for a better understanding of the benefits in the field, rather than just comments from reviewers, and is meeting with experts.

Q-3-3

I understand. My next question is a bit backward looking.

Senju Pharmaceutical is launching its Lucentis biosimilar. I am not asking about what effect this will have, but rather, it seems that there are 2 indications: age-related macular degeneration and choroidal neovascularization. If you can tell me how much of *Eylea*'s sales would be accounted for if these 2 indications were applied to *Eylea*'s biosimilar, I would appreciate it.

A-3-3

Suzuki: Thank you. The first target of Lucentis biosimilars will naturally be the patients who are currently using Lucentis, and then new prescriptions will be made.

Q-3-4

The question is, if the indications that Lucentis BS has taken now fall into Eylea's territory, what percentage of *Eylea*'s sales would it account for?

A-3-4

Suzuki: We do not disclose *Eylea*'s sales by indication, but AMD accounts for about half of the total sales. Other than that, the figures vary by indication.

Q-4-1

I found the explanation about the *Eybelis* US trial very helpful. 2 of the 3 have already been released, and 1 is still in the works.

If you have 2 of these 3, do you think that you have basically fulfilled the application requirements? Somehow 1 of the 3 didn't work, so I had the impression that maybe I was missing something.

A-4-1

Morishima: Morishima here.

The main reason why the FDA is asking for 2 trials is that they don't want the application to be based on champion data from 1 trial, and based on this major premise, they are basically asking for us to repeat the clinical trial.

In that sense, I believe that we can sufficiently demonstrate that our test reproducibly lowers intraocular pressure, and in the third test, the intraocular pressure of *Eybelis* itself showed a very stable intraocular pressure effect. This is of course dependent on communication with the FDA, but we believe that we have met the requirements for approval and have submitted our application.

Q-4-2

And the second one, *Verkazia*? Regarding the peak sales in the US I think the figure mentioned was USD40 million.

I think it's a medium-sized market, but I think it's a bit high for an unmet medical need in this area. What do you envision as the time frame for reaching the peak?

A-4-2

Taniuchi: I'll answer this question. This is a confirmation of the timeline.

However, as you said, this is more about reaching out to specialists and existing patients, rather than reaching out to a wider audience. So, please understand that it will not take that long.

Q-5-1

I have a question about SG&A expenses. The figure for first quarter of the previous year was JPY15.6 billion, and the current quarter is JPY20.4 billion. This is quite an increase. You explained that the breakdown of this increase is the increase in expenses due to the acquisition of Eyevance and the impact of foreign exchange rates.

If the business continues to grow as usual, I feel there is a risk that it will exceed the budget set at the beginning of the fiscal year. How do you go about controlling this? Please tell me about this. That's all.

A-5-1

Koshiji: I will answer from Koshiji.

First of all, in the area of controlling expenses for the full year, it is true that there was a large increase compared to the same period last year, but there are some 1-time factors and foreign exchange factors. In that sense, the actual YoY increase is about JPY2 billion within our company. This is an increase compared to the previous year, so we plan to control the increase for the full year.

As for how to control the growth rate of gross profit and SG&A expenses, we are constantly controlling the balance between the 2. In the first quarter, gross profit actually increased due to the impact of foreign exchange, but excluding such factors, gross profit increased by about 12%.

On the other hand, in the area of SG&A expenses, there was an impact of about JPY900 million due to foreign exchange rates. As a 1-time factor, there were no items for Eyevance in SG&A expenses in the first quarter of last year, so this will add JPY900 million to the current year's SG&A expenses, making a total of JPY1.8 billion.

In addition, in the fourth quarter of last fiscal year, sales of *Alesion* increased significantly, and copromotion fees increased accordingly, some of what should be recorded in the fourth quarter will be recorded in the first quarter later. That is JPY900 million.

So, in that sense, out of the JPY4.8 billion, if you include the impact of foreign exchange rates, about JPY2.7 billion is considered to be related to 1-time factors. In constant terms, the increase is about 12%, which is roughly the same as the increase in gross profit as mentioned earlier. That is my understanding of the situation.

FY2021 IR Event

In Addition to Financial Results Meetings, Planning to Hold R&D Day and US Strategy/ESG Meeting

Date	Event	Main Contents (Planned)
E/Sep– B/Oct (Tentative plan)	R&D Day	Development-related session centered on new areas
B/Nov	Q2 FY2021 financial results meeting	Business update Q2 FY2021 results
B/Feb	Q3 FY2021 financial results meeting	Business update Q3 FY2021 results
February-March (Tentative plan)	IR-Day	US business strategy ESG initiatives
B/May	FY2021 financial results meeting	FY2021 results FY2022 forecast

IR) Finally, as you can see on the back page of this document, we are planning to hold several events this term. Our IR team will let you know when the dates are set. We hope you will be able to join us.

[END]