Investor Meeting on Q2 FY2020 Results

Q2 FY2020 Results

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Santen
Imagine Your Happiness

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- Information given in this presentation contains certain forward-looking statements concerning forecasts, projections and plans whose realization is subject to risk and uncertainty from a variety of sources. Actual results may differ significantly from forecasts.
- Business performance and financial condition are subject to the effects of medical regulatory changes made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.
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CORE PRINCIPLE and WORLD VISION

CORE PRINCIPLE

天機に参与する

Tenki ni sanyo suru

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

WORLD VISION

Happiness with Vision

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

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

Taniuchi:

This is our basic philosophy and World Vision. As explained in the Long-term Vision announced recently, we intend to realize the health and happiness of people through treatment of eye disease. This is based on our basic philosophy of "Exploring the secrets and mechanisms of nature in order to contribute to health" with the concept of "Happiness with Vision" in mind. In addition, we place prime importance on our social contributions, and integrate this approach on a daily basis.

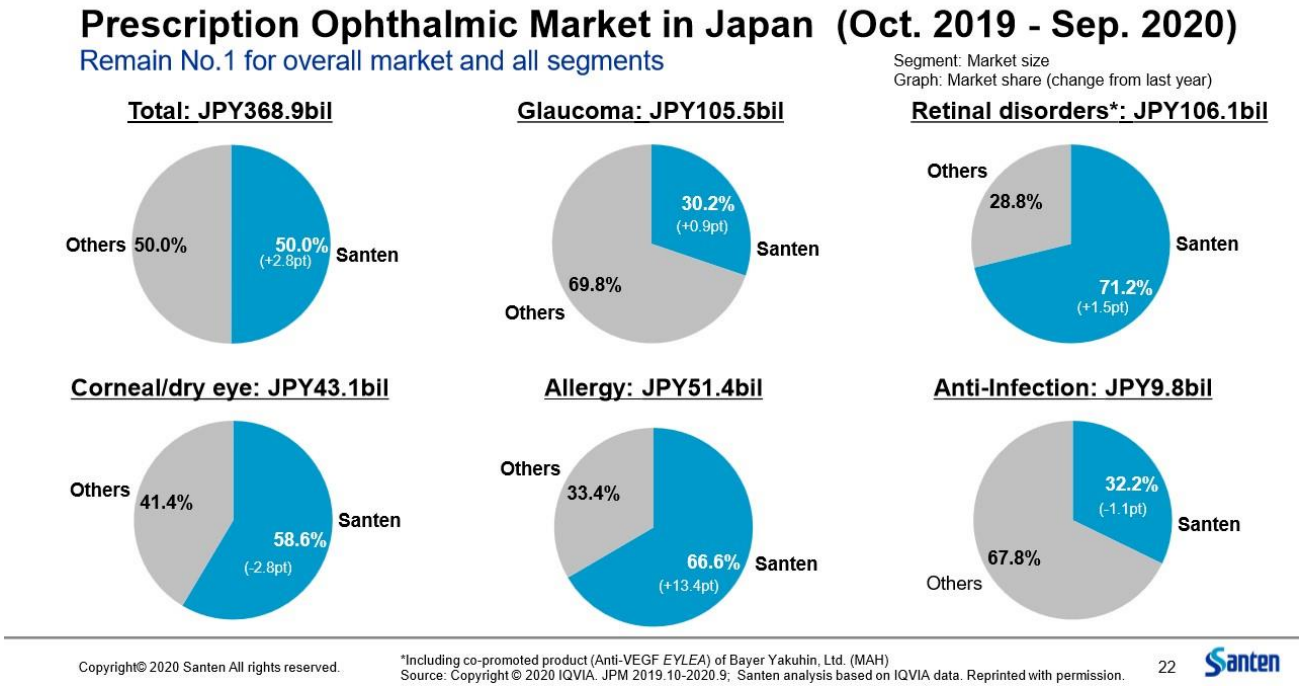
H1 FY2020 Highlights

- **Execute medium-to long-term measures to achieve Santen 2030**
  - Ophthalmology & Wellness: jCyte Alliance, Osmotica Alliance, Orbis International (NGO) Alliance and ***Hyalein S* Launch (1), In-licensing ROCK Inhibitors (2) , Eyevance Acquisition (3)**
  - Inclusion: Long-term partnership with JBFA and IBF Foundation
- **Progress in the final year of Vision 2020**
  - Strong revenue recovery from COVID-19 impact, but potential for uncertainty remains
  - **China continues to have high market potential, although there are short-term risk factors. Established a new holding company and proactively pursuing business (4)**
- **Revenue：JPY 118.9billions, Core OP：JPY 25.7billions**
  - Matched previous year's levels. No change to full-year forecast

This is for a summary of the first half of the year.

First of all, this year is the final year of the MTP and the final year of Vision 2020. We are very satisfied with the results so far since this year is the crucial turning point for us. We are very pleased with the content, achieved through our strong organic growth as well as our initiatives towards 2030.

As we approach the end of the medium-term management plan, I believe that we have achieved satisfactory results with respect to these financial figures, and we have maintained an upward trend in both sales and profits, matching previous year's levels. We are happy to see this steady growth regardless of factors including COVID-19 and its market impact.



Information about the Japanese Business is also detailed on page 22. We have hit a 50% market share, perhaps for the first time in our 130-year history. This has been achieved despite a very challenging market environment and we believe we are strongly expanding our business in Japan

Talking about outside of Japan, with the acquisition of Eyevance Pharmaceuticals, we also believe that we have marked a milestone in our goal of entering the US market, which has been a long-time challenge.

As for stepping stones to Santen 2030, we have been proceeding in line with the three strategic pillars of Ophthalmology, Wellness, and Inclusion that I had explained at the time of Vision. The progress includes partnerships such as jCyte Inc., Osmotica Pharmaceuticals, Orbis International, or the introduction of *Hyalein S* and ROCK inhibitors, the acquisition of Eyevance, and our various efforts to popularize blind football.

Today, I would like to explain about the introduction of *Hyalein S* and ROCK inhibitors, as well as information about Eyevance. I would also like to update you on our Chinese Business as there has been some changes in market situation.

1. Launched "*Hyalein S*" in OTC Segment in Japan

The only eye drops in Japan*1 containing the same concentration of sodium hyaluronate as the prescription drug

"For tiredness of eyes, drying of eyes, and blurring of eyes". Medicines requiring guidance. Please use this drug after receiving an explanation from a pharmacist and carefully reading the "Usage Notes."

*1: As of September 15, 2020

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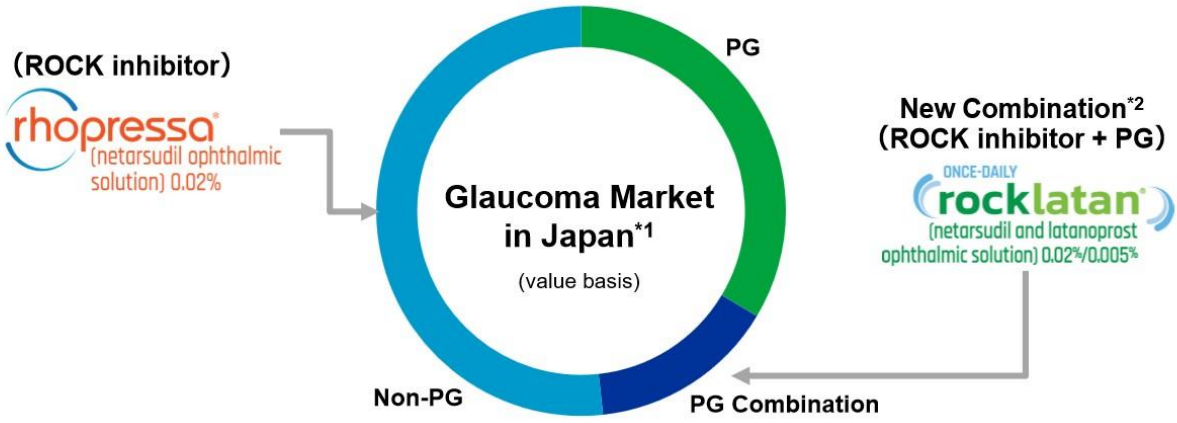
This is the switch OTC, *Hyalein S*, that we launched in Japan. This is actually Santen's first switch OTC product, and its launch has very important implications for us.

For many years in Japan, we have developed two businesses: the prescription pharmaceuticals, and the OTC Pharmaceuticals. Both businesses have built a strong presence, and this is the first product that combines the strengths of both.

Hyalein has been used as a first-choice drug for dry eye for over 20 years in Japan as well as in Asia. Taking advantage of the medical expertise and brand image of *Hyalein* for health professionals, we hope to deliver it directly to patients through an OTC sales channel. We are very pleased that this will enable us to offer patients new options for the treatment.

I think that the importance of self-medication is once again being recognized, particularly in the midst of the current COVID-19 pandemic. We are pleased being able to offer new treatment options for Japanese market and we hope it will help improve QOL of patients. Through our cross-functional collaboration including OTC pharmaceuticals and prescription pharmaceuticals, we are aiming to provide rich and complete information that is only possible by Santen. From this strong determination, with huge support from Ms. Ishihara Satomi, our brand ambassador of *Hyalein S,* we will be maximizing the value of product. In addition, from the perspective of our long-term vision, this is one of the initiatives in the area of Wellness, which is the second pillar of our strategy.

2. In-licensing ROCK Inhibitors for Japan and Asia to Maintain and Improve Our Presence in Glaucoma Treatment to Support Next Growth



*1 Source：Copyright © 2020 IQVIA. JPM 2019.10-2020.9; Santen analysis based on IQVIA data. Reprinted with permission.
*2: As of October, 2020

This is some more information about ROCK inhibitors.

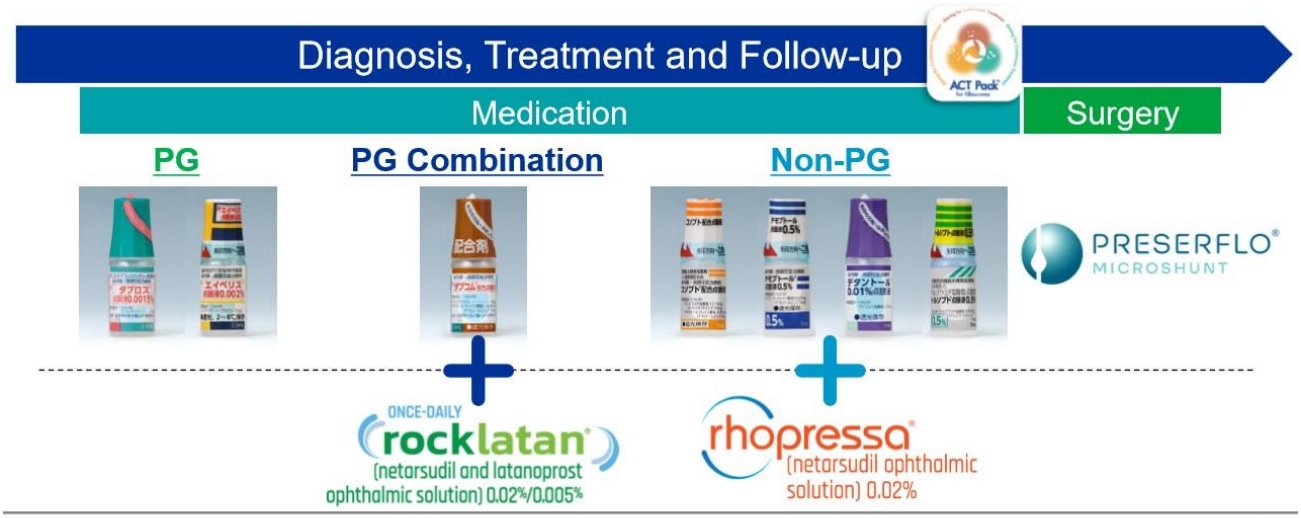
In terms of our long-term vision starting from next fiscal year, we believe that the continuing and sustainable growth of our existing businesses, namely the current prescription ophthalmic pharmaceuticals businesses, is an extremely important theme. I am very pleased that we were able to introduce ROCK inhibitors, which is an important step toward that goal.

As we have explained before, glaucoma is a major pillar of Santen's business. In addition to Japan, we are working to position glaucoma as a pillar of our business in Asia and Europe.

In addition, as you know, glaucoma requires a variety of treatments according to patients' condition. In line with the disease conditions and lifestyles of patients, we will successfully combine multiple types of drugs and methods of treatment. By doing so, we can provide the treatment necessary to control eye pressure over a lifetime.

Therefore, we are happy to be able to present *Rhopressa,* a drug with a novel mechanism of action, and *Rocklatan*, which is being developed as a latanoprost combination drug.

2. Further Enhancing Glaucoma Portfolio with the Licensing-in of ROCK Inhibitors



*Includes products sold only in some regions

This is the existing portfolio of Santen, which includes medications like *Tapros* or *Eybelis*. This slide gives some idea of the positioning of newly added *Rhopressa* and *Rocklatan*. This addition will further leverage our broad portfolio, under the umbrella of single-agent PG, PG combination and Non-PG which can be used in combination with PG or PG combination.

Also, we are currently developing *PRESERFLO MicroShunt, surgical device*.

3. Full-scale Entry into the U.S. Market with the Acquisition of Eyevance

*FOTE: Front Of The Eye

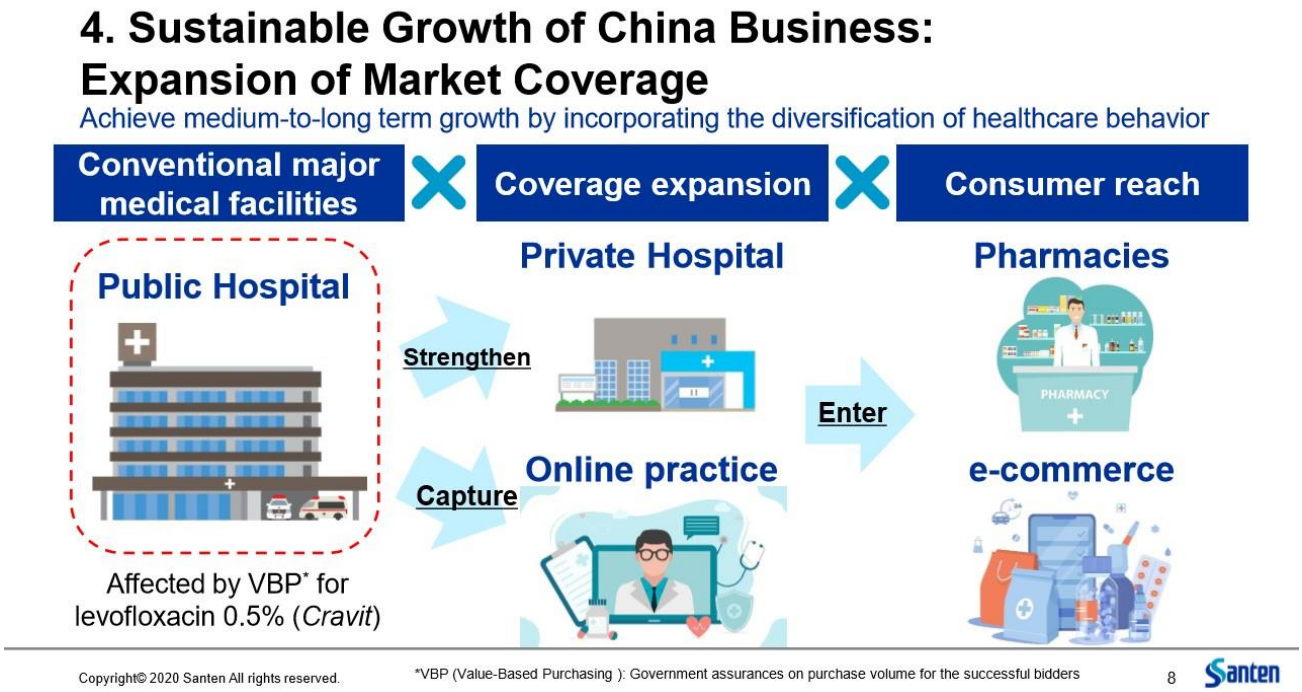
Thirdly, I would like to talk a little about the acquisition of Eyevance.

Eyevance is a new company that was created mainly by individuals who had worked at a specialist ophthalmology company in the US. Therefore, although the company itself is still a relatively young company, its employees have a deep experience of the ophthalmology business in the US. In addition, the company has a group of products that are already well known in the market with experienced specialists. Since its launch, Eyevance has continued to grow well.

While Santen also has multiple pipelines, what we should supplement in the future is experience in the US market, or marketing channels that will help us to cover such a large market. In this sense, I think that Eyevance is an ideal partner.

As a result of this acquisition, we will be able to minimize the risks, cost and time associated with the start-up of independent sales, for a smooth entry into US market.

In addition, we believe we were able to acquire a key platform for launching pipelines by tapping into the US market. The US market had been the last territory for us to enter, and it has been a key area in meeting our Vision 2020 goals to become a global company. Going forward, we intend to grow globally, including this foundation in the US, as well as the overseas foundations that we have already established in Japan, Asia and Europe.



I would now like to touch upon our Chinese Business.

This has already been announced by the authorities, but the Chinese government is moving forward with Value-Based Purchasing (VBP) at large public hospitals across the country. One medication targeted is levofloxacin, the main ingredient of *Cravit*. As a result, our products were removed from the scope of purchase because of the fact that domestic levofloxacin, which is extremely inexpensive, has become eligible for purchase.

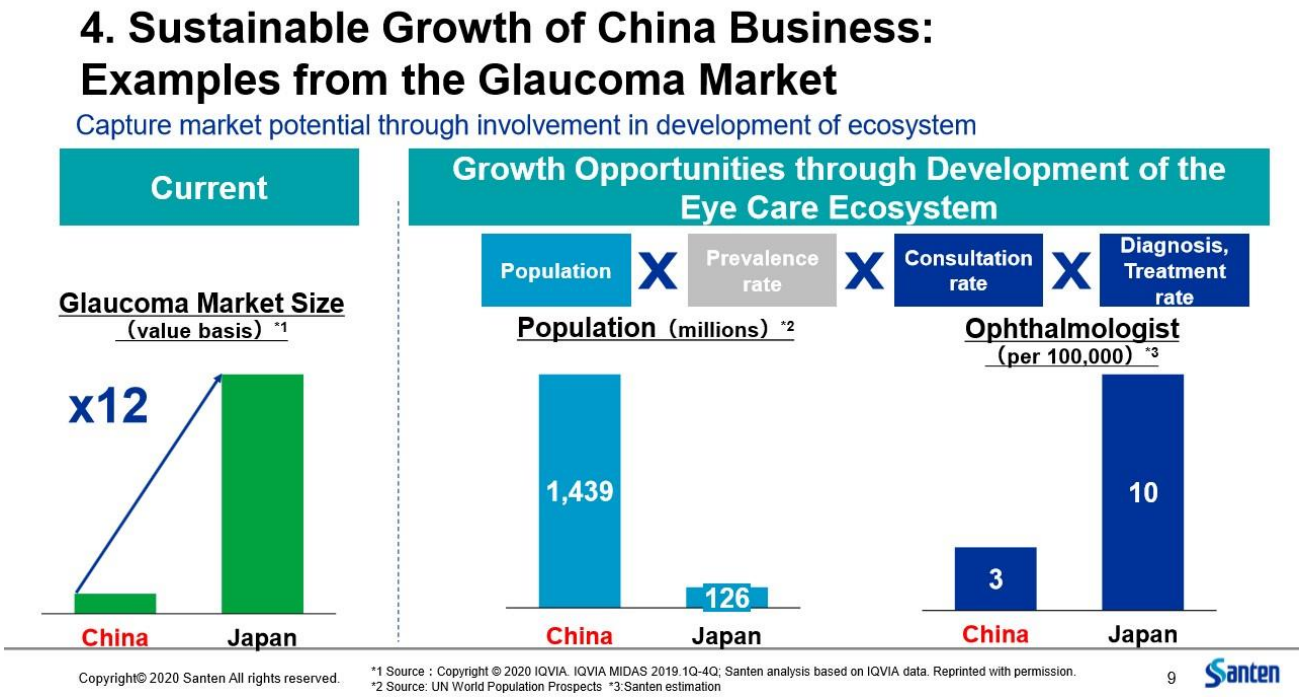
With that said, the impact of this still needs to be assessed. There are still many unknowns, including the extent to which companies that won bids in the first place can supply medications.

At the same time, we have been implementing some alternative measures in response. We are focusing on the change in medical trend due to the impact of COVID-19.

In the past, large-scale national hospitals, represented by so-called Tier 3 hospitals, were the dominant players, but with COVID-19 in particular, there is a growing diversity, with second-tier, first-tier, and private hospitals starting to play a larger role.

In addition, the flow of pharmaceuticals is rapidly growing through new channels such as on-line medicine and on-line pharmacies as a result of COVID-19.

Under these circumstances, although there will be an impact by VBP initiative at large public hospitals, there are also these dynamic changes in the overall market, which we see the opportunity to grow.



Next, let me explain about mid-long term growth potential of the Chinese market, taking the glaucoma market as an example. The size of the glaucoma market in China is one-twelfth that of Japan. Japan's market is 12 times that of China, while China's population is roughly 12 times that of Japan. In other words, in terms of population, the size of the market is only 1 in 144.

This is not to say that Chinese people do not suffer from glaucoma, but rather that they have not been diagnosed, or have been diagnosed but are not being treated.

For example, the number of ophthalmologists in China is thirty percent of that of Japan. Among those doctors, not all of them have trained expertise in glaucoma area, thus there still remains some challenges in terms of accurate diagnosis, timely treatment or access to treatment. The current market in China is only the tip of the iceberg, and we wish to do what we can to help develop this market and provide treatment for these patients.

Not surprisingly, for example, the number of ophthalmologists on a population basis is only about a third of that in Japan. In particular, fewer specialists have been trained in glaucoma, and there are a variety of bottlenecks, such as disease awareness, and the size of the market is extremely small.

To this end, as a social innovator, we will work with academic societies, governments, NGOs, and other stakeholders to address these social issues for potential territories including glaucoma. We will strive to realize this by offering more improved treatment environment and easy access to more patients. In that sense, the Chinese market will continue to be an important market for us as well.

Q2 FY2020 Results

Sales and net profit increased year-on-year despite impact of COVID-19

(JPY billions)	FY2019 Q2 Actual	vs Revenue	FY2020 Q2 Actual	vs Revenue	YoY
Revenue	**118.8**		**118.9**		**+0.1%**
Cost of sales	48.3	41%	49.7	42%	+2.9%
Gross margin	70.5	59%	69.2	58%	-1.8%
SG&A expenses	33.4	28%	32.4	27%	-3.1%
R&D expenses	11.4	10%	11.1	9%	-2.5%
Core operating profit	**25.6**	**22%**	**25.7**	**22%**	**+0.2%**
Non core SG&A expense	--	--	0.9	1%	--
Amortization on intangible assets associated with products	4.9	4%	4.9	4%	-1.2%
Other income	0.2	0%	0.3	0%	+118.1%
Other expenses	1.9	2%	1.6	1%	-12.5%
Operating profit (IFRS)	19.0	16%	18.7	16%	-1.7%
Finance income	0.5	0%	0.6	0%	+9.4%
Finance expenses	1.1	1%	0.9	1%	-21.2%
Profit before tax	18.4	15%	18.4	15%	-0.3%
Income tax expenses	5.3	4%	4.7	4%	-11.8%
Actual tax ratio	*28.7%*		*25.4%*		
Net profit (IFRS)	**13.1**	**11%**	**13.7**	**12%**	**+4.3%**
Core net profit	18.8	16%	19.7	17%	+4.7%
USD (JPY)	108.82		106.72		
EUR (JPY)	121.28		121.54		
CNY (JPY)	15.77		15.21		

Revenue and net profit

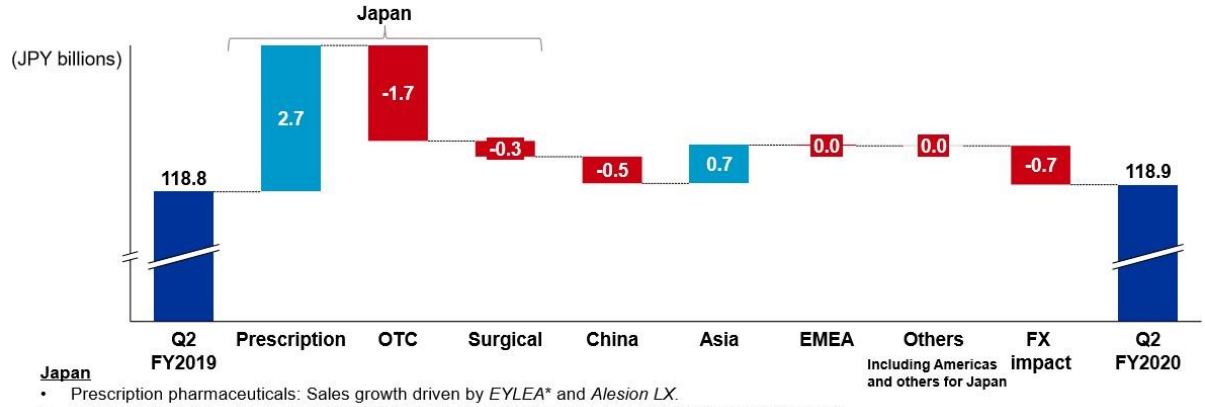
- **Revenue: Exceeded expectations**
- **Net profit (IFRS): Increased 4% year-on-year**

Koshiji: These are the results for the second quarter of FY2020.

As described in this message line, although there was an impact from COVID-19, both sales and profits increased compared with the previous fiscal year. As shown in the column to the right of the income statement, sales are up 0.1%, and core operating profit is up 0.2%. Further down the table, we can see that other income and expenses, and finance income and expenses are at about the same level as the previous fiscal year. Taxes were slightly lower than the previous fiscal year, so the figure for quarterly profit is up 4.3% compared to the previous fiscal year.

Q2 FY2020 Revenue (YoY)

Matched previous year's sales level despite the impact of COVID-19 and foreign exchange



Japan

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

Overseas

- China: Sales exceeded expectations, despite sales decline due to the negative impact of COVID-19 (-4% excluding FX impact).
- Asia: Steady growth despite COVID-19 impact (8% excluding FX impact).
- EMEA: Solid sales led by *Cosopt* and *Tapros*. (0% excluding FX impact).

Classified into countries or regions based on customer location.

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

This is a bridge chart for sales, and the trend is from the previous fiscal year figure of JPY118.8 billion. Each point is as written at the bottom of the page.

FY2020 Forecast (Unchanged from May 8th)

Aiming to achieve earnings forecast despite uncertain factors

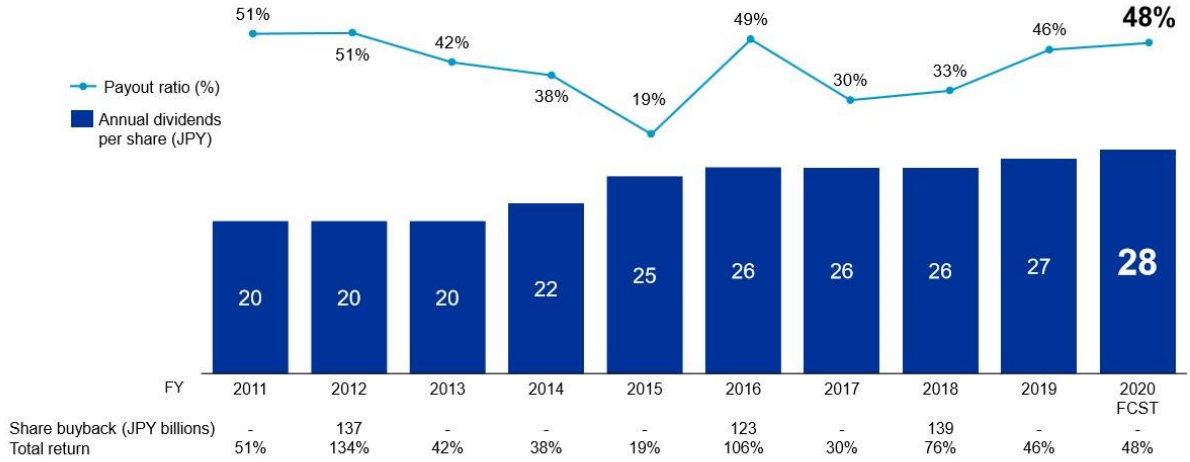
(JPY billions)	FY2019 Actual	FY2019 vs Revenue	FY2020 Forecast	FY2020 vs Revenue	YoY
Revenue	**241.6**		**235.0**		**-3%**
Cost of sales	94.8	39%	90.0	38%	-5%
Gross margin	146.7	61%	145.0	62%	-1%
SG&A expenses	73.4	30%	70.0	30%	-5%
R&D expenses	23.3	10%	23.0	10%	-1%
Core operating profit	**50.0**	**21%**	**52.0**	**22%**	**+4%**
Amortization on intangible assets associated with products	9.9	4%	9.7	4%	-2%
Other income	0.4	0%	0.9	0%	+131%
Other expenses	7.0	3%	8.2	3%	+17%
Operating profit (IFRS)	33.5	14%	35.0	15%	+4%
Finance income	1.0	0%	0.8	0%	-16%
Finance expenses	2.4	1%	1.0	0%	-58%
Investment loss by equity method	--	--	0.8	0%	--
Profit before tax	32.1	13%	34.0	14%	+6%
Income tax expenses	10.4	4%	11.0	5%	+6%
Actual tax ratio	*32.3%*		*32.4%*		
Net profit (IFRS)	**21.7**	**9%**	**23.0**	**10%**	**+6%**
Core net profit	35.9	15%	38.7	16%	+8%
Core ROE	12.1%	--	12.6%	--	--
ROE	8.0%	--	7.5%	--	--
USD (JPY)	108.81		110.00		
EUR (JPY)	120.80		120.00		
CNY (JPY)	15.64		15.00		

These are the earnings forecasts for the full fiscal year.

Regarding this matter, we are not considering any changes from the disclosure on May 8th at the moment. Although there are uncertainties, based on the conditions in the first half and the second quarter, we believe that the progress will be as predicted, and that the results will be in line with our initial performance forecasts.

Dividend

Unchanged annual dividend (forecast)



FY	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020 FCST
Share buyback (JPY billions)	-	137	-	-	-	123	-	139	-	-
Total return	51%	134%	42%	38%	19%	106%	30%	76%	46%	48%

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

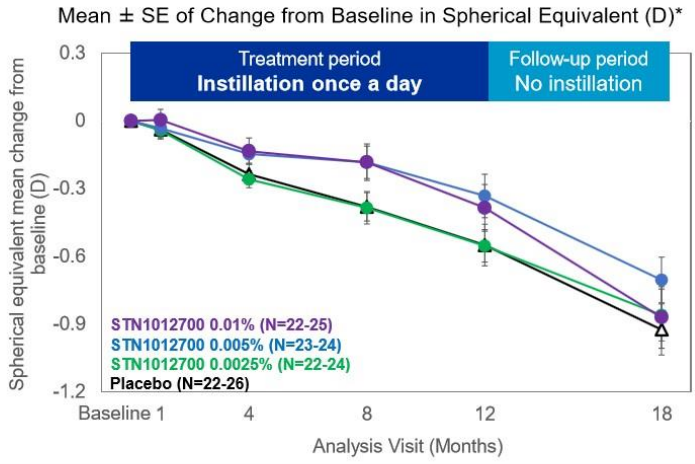
Shareholder returns and dividends.

We have not changed our stance toward returning profits to shareholders, as our earnings situation is in line with our initial expectations.

DE-127: APPLE study / P2 (NCT03329638)

Both high doses, 0.005% and 0.01%, demonstrated efficacy in controlling myopia progression

- **Achieved primary endpoint**
  Spherical equivalent at 12 months
- Demonstrated **similar axial length** to spherical equivalent
- **Safe and well tolerated**
- Plan to present detailed report at **Annual Meeting of Japan Myopia Society** (May 22-23, 2021, Tokyo)



*Indicator calculated by merging refraction and astigmatism components to evaluate refractive error.

Morishima:

First of all, I would like to briefly report on the APPLE study, the Phase 2 trial for DE-127 conducted in Asia. This is scheduled to be announced at the Japanese myopia academic conference in May, but as that is a long way off, we have decided to announce the results today.

In children with myopia, 0.005%, 0.01%, and once daily instillation of this drug showed that there were statistically significant reductions in objective equivalent spherical power and refractive power, which were the primary endpoints, compared with placebo at 12 months of administration. The change in the eye axis length, which is a secondary endpoint, also shows the same trend as equivalent spherical power. This is consistent with the LAMP study, an overseas myopia trial, which also found a dose-dependent effect. In addition, no serious issues were observed with regard to safety or tolerability.

As mentioned earlier, this study will be reported at the meeting of the Japanese Society of Myopia in Tokyo in May 2021. In addition, as will be discussed later, we are currently conducting Phase 2/3 trials for DE-127 in Japan. We have just completed the enrollment of patients.

Current Status of Research and Development

Pipeline / product development (1)

As of October, 2020
Updated information is underlined

	Indication	Region	Status
DE-111 STN10111 *TAPCOM / TAPTIQOM* Combination of tafluprost and timolol maleate	Glaucoma / ocular hypertension	China	P3 *Plan: FY2022 P3 completion*
DE-117 STN10117 *EYBELIS* EP2 receptor agonist	Glaucoma / ocular hypertension	US	P3 *Plan: FY2020 filing*
		Japan	Launched
		Asia	Approved *Plan: FY2020 launch*
DE-126 STN10126 FP / EP3 receptors dual agonist	Glaucoma / ocular hypertension	US	P2b (dose finding study completed) *Plan: FY2020 additional P2 start*
		Japan	
DE-128 STN20001 *PRESERFLO MicroShunt*	Glaucoma	US	Completed PMA rolling submission *Plan: FY2020 approval, FY2020 launch*
		Europe	Launched
		Asia	Filed *Plan: FY2020 approval*
		Others	*Plan: FY2020 filing in Canada*

The numbering method for development codes has changed. We show both existing development codes (DE-XXX) and new development codes (STNXXXXX).
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In addition, I would like to discuss the progress we have made.

For DE-117, we have been making steady progress in preparing for the US application. We are also in the process of filing applications in various countries in Asia, and have received approval in Thailand, Taiwan, and South Korea. In South Korea, we plan to launch this product within the current fiscal year.

For DE-128, we have also obtained the two-year data for the pivotal trial, and we have confirmed the same trends as the previously disclosed one-year data. I would like to present detailed data at the American Glaucoma Society in March next year. We are also in the process of communicating with the FDA, aiming for approval by the end of the year.

We submitted an application for DE-128 in Canada in October. We are currently waiting to hear from the authorities about its receipt. We are also planning development in Japan and China, and once the details of the clinical trials have been decided, we plan to post them on this list.

Current Status of Research and Development

Pipeline / product development (2)

As of October, 2020
Updated information is underlined

	Indication	Region	Status
DE-130A STN10130 Catioprost latanoprost	Glaucoma / ocular hypertension	Europe	P3 *Plan: FY2021 P3 completion*
		Asia	
DE-109 STN10109 IVT sirolimus	Uveitis	US	P3 *Plan: FY2022 P3 completion*
		Japan	P3
		Europe	P3
		Asia	Filed
DE-127 STN10127 atropine sulfate	Myopia	Japan	P2/3 *Plan: FY2023 P2/3 completion*
		Asia	P2 (met primary endpoint)
MD-16 Intraocular lens	Cataract	Japan	Approved *Plan: Launch in November 2020*

U.S. FDA accepted the NDA for DE-076C (STN10076, *Verkazia* / generic name: ciclosporin) for the treatment of vernal keratoconjuctivitis in October 2020.

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

Regarding DE-127, we are conducting a Phase 2/3 trial in Japan as I mentioned earlier, and we are now in the process of completing patient enrollment as planned.

In addition, although not included in this list, *Verkazia*, a treatment for the rare disease vernal keratoconjunctivitis that is already sold in markets such as Europe, Canada, and Asia, has also been accepted for approval in the US

In addition, we are currently confirming the requisite regulatory requirements in various regions for cell therapy introduced by jCyte Inc. and for a blepharoptosis drug introduced by Osmotica Co., Ltd. We would like to disclose the details of our clinical trial plans in this list once we have decided on the details.

We also plan to announce the results for DE-117 or DE-128 at the US Ophthalmic Society meeting that will be held online in November. After the announcement, we plan to inform you of the abstract as well.

This concludes my presentation.

Question & Answer

Q1-1-1
The first question relates to the impact of this VBP in China discussed on page eight. Could you please suggest anything about when this will start and how much impact it will have? Also, what should we think about the possibility that *Hyalein* may eventually be a target medication of this initiative?

A1-1-1
Taniuchi: Regarding VBP, the system started a few years ago. This is the first time that our Company has been affected by it. I don't know how long it will last because this is China's policy, but I think it is likely to stay in place long-term after it has been implemented.

It depends on the policy of the authorities as to what kind of products will be targeted in the future, so we cannot make any predictions. We believe that it is possible that widely used products could be targeted, and we intend to consider that as a precondition.

Q1-1-2
When does it start, and how much impact it will have? I think your Company said that this was certainly out of the scope. How should the impact on sales be considered?

A1-1-2
Taniuchi: The impact on sales is not known at this time, but the result will be that this product will not be purchased by Tier 3 facilities anymore.

Q1-1-3
How much of your company's current sales are made up of sales to Tier 3 hospitals?

A1-1-3
Taniuchi: It is a little difficult to give a precise figure, but for many of our products, Tier 3 hospitals make up a very large part of sales.

Q1-1-4
And when did you say that this would start?

A1-1-4
Taniuchi: It is just starting now.

Q1-1-5
I see. Is this included in the earnings forecast?

A1-1-5
Taniuchi: While incorporating this in the second half of the fiscal year, we believe that our earnings forecasts will be as planned. There will be somewhat of an impact in the second half of the fiscal year. There are other positive effects for the China Business, as well as various factors affecting other businesses. Therefore, the full-year results forecast is in line with expectations.

Q1-2-1
OK. Secondly, if you look at sales in Asia in the second quarter, they were very strong. Was there some factor that resulted in particularly strong sales of *Cravit* or *Hyalein*?

A1-2-1

Taniuchi: Regarding the Asian region, we have seen solid organic growth in the South Korean market. Like the Japanese market, the impact of COVID-19 has been relatively mild. That has been the major fundamental factor. There have also been transient changes in some countries, so there is some heterogeneity. However, the trend overall in Asian countries, including South Korea, is an upward one.

Q1-2-2
OK. This means that there were some temporary events.

A1-2-2
Taniuchi: That's right. It was in Vietnam and elsewhere, but the effect of these is not significant.

Q1-3
OK. Finally, regarding *Rhopressa*, I think your Company has quite a bit of a pipeline like this that is not made public in early stages. With regard to *Rhopressa,* Aerie has been saying that they were looking for partners in Japan for a long time, so I think that perhaps this was under discussion for some time.

It may not be possible to provide any detailed information about this type of development items, but without these, it is not possible to get a full appreciation of the development pipeline. Could you comment on this?

A1-3
Taniuchi: That is a tough question. Naturally, we have been introducing products at various business development opportunities or making acquisitions. We will continue to actively engage in such efforts, as I have mentioned before.

From a negotiation standpoint, it is a little difficult to provide specific information in some cases. I would like to consider enhancement of communication with the IR team.

Q2-1-1
My first question is about how to interpret the DE-127 data presented today.

For the purple 0.01% line, I believe there is something like this on the market already, so is it okay to consider this as an active comparator? Is the intention here to show the benefit of 0.005% and 0.0025%?

If that is the case, the results for 0.005% appear similar to those for 0.01%. Is there any other data available for these, such as differing side-effect profiles, or safety data?

A2-1-1
Taniuchi: Morishima will answer it due to scientific topic.

Morishima: We do not intend to make a final decision on this APPLE study alone. In the LAMP study from Hong Kong, it was shown that even a slightly higher dose is tolerable.

In that sense, we believe that we should aim for something that is somewhat more effective, and we would like to proceed with development, including for doses higher than 0.01%.

Regarding the tolerability, although there is a phenomenon of a slight dilation, this tends to resolve spontaneously by the morning while patients are asleep.

Q2-1-2

Would you be able to disclose the volumes used in the current Phase 2 trial?

A2-1-2
Morishima: I am afraid not.

Q2-2
Understood. Also, regarding the ROCK inhibiting agent that was introduced today, I thought it was true about the significance of your company's use. In this category, *Glanatec* is already on the market in Japan. However, at this point, it cannot be said that it is very widely used, and I think that its market share is not high. In response, how do you plan to differentiate yourself from competitors?

Could you tell us what will make the market bigger than that of *Glanatec* today?

A2-2
Taniuchi: First of all, I would like to refrain from commenting on the situation of *Glanatec*, as it is the product of another company.

In addition, I am not aware of clinical trials that directly compare *Glanatec* and *Rhopressa*, so in that sense, it would be difficult for me to comment. Our product portfolio contains products that can be used at various different points in the treatment pathway. As a company, we hope to build on our information provision services, so that we can help ensure that the right treatment is matched to the right patient. This is part of our strategy to position Santen as a leading company in the field of glaucoma.

Q2-3
Finally, with *Hyalein S*, with the launch on September 15, what contribution did it make to Q2 performance? Can you comment on the scale of sales that is currently forecast in the second half and beyond?

A2-3
Taniuchi: First of all, the product launched in September, and you may have seen the TV advertisements, but these promotions actually started in October. As a result, there was virtually no activity in the first half of the fiscal year. In fact, since October, we have been in the midst of conducting business negotiations, starting with these TV commercials and so on, so I think it will be contributing from the second half onwards.

However, in the second half of the fiscal year, we will naturally increase our coverage at stores and other locations, but the product will start as a guidance drug. Therefore, we recognize that there are still some difficulties in terms of access, such as whether sales will quickly start up. I would like to move forward while looking at those points. As such, I would not like to commit to any specific sales targets for the second half of the fiscal year at present.

Morishima: I would like to add a few words about *Rhopressa.* As a differentiating factor, *Rhopressa* is administered once daily, while *Glanatec* is a twice-daily medication.

Q3-1-1
I would like to first confirm the third-tier public hospital situation in China. I believe *Cravit* accounts for about 40% of sales in China. As you mentioned earlier, widely used drugs may become the target of this purchasing practice in the future.

So, if *Cravit* makes up 40% of sales in China, and 70% or 80% of those sales are to large public hospitals*, for example, does that mean that at some point, those sales will cease? (*Santen notes: Sales of *Cravit* for public hospitals accounts for approximately 60 % of its sales in China)

A3-1-1

Taniuchi: That's right. Whether it disappears suddenly or gradually depends on how the system operates and how purchases are actually carried out afterwards. Honestly speaking, we do not know how much the amount will be at this point, but from our understanding of how it operates, that interpretation is correct.

However, on the other hand, we are naturally increasing sales through other sales channels and expanding sales at municipal hospitals in particular, so we will naturally reduce some of the impact on our business performance, while at the same time naturally recouping other areas. Although there will be certain negative impacts, including those impacts, I hope you will understand that as a whole, we will do our best to absorb them as much as possible.

Q3-1-2
I think China have seen double-digit sales growth before. If this affects *Hyalein* or other products in the future, what would you predict the effect on sales to be? Will sales level off, or are they likely to fall?

A3-1-2
Taniuchi: I think such a scenario is sufficiently conceivable in the short term. However, over the medium to long term, we will naturally increase the number of new products, while products such as *Cravit* and *Hyalein* are, of course, our mainstay now. We have been mindful of the fact that something like this might happen. I think this will have a major impact on the Company's business results in the short term, because it is just about to come. This means that we are firmly accelerating the development of new products, and, as I have just mentioned, exploring the great potential that exists in channels other than large national hospitals. In the medium to long term, we intend to overcome these challenges by steadily expanding our operations.

In particular, we have relied heavily on *Cravit* and *Hyalein*, products with long histories. In recent years, we have strengthened our development system and increased the number of simultaneous pipelines. This timing is certainly an issue, but from a long-term perspective, we intend to steadily increase sales while contributing to new products and also looking at the potential of the market as I just mentioned.

Q3-2
My second question concerns OTC in Japan. Performance in the second quarter has recovered sharply when compared against the first quarter.

I thought that this may be due to the impact of *Hyalein* S, but you mentioned earlier that *Hyalein S* had hardly any sales. I would be grateful if you could explain to me the cause of this sharp recovery in the second quarter.

A3-2
Taniuchi: Indeed, *Hyalein S* has not had an effect on sales in the second quarter. I think that what you are describing is a result of the overall market environment resulting from lockdown due to the coronavirus pandemic in the first quarter, followed by somewhat of a recovery of demand in the second quarter. As I mentioned earlier, we expect that *Hyalein S* will contribute to sales in the third quarter and beyond.

Q4-1-1
I would also like to ask about VBP issue in China. Simply looking at *Cravit*'s sales, the cumulative total is 17% less. That's why second quarter alone is very strong, down 7%. Although this may not be a good reference, Eisai's *Aricept* dropped by 40% due to intensive purchase. Is that a factor as to why the second quarter result is better?

A4-1-1

Taniuchi: This is simply due to the impact of COVID-19 in the PRC, where outpatient clinics and surgery were affected. Cataract and glaucoma operations and surgical correction of refractive errors were not carried out starting in January, and the effect of sales from that point onwards was significant. Sales improved somewhat in the second quarter, although they are still down YoY. This is a completely separate issue from the VBP issue.

Q4-1-2
Does it mean that the impact will be fairly serious in the future?

A4-1-2
Taniuchi: Yes.

Q4-1-3
Regarding the figure on page eight just now, I have a question about the impact of the VBP of *Cravit*. Is this the rationale for developing sales of *Cravit* in Tier 2, Tier 1, and private hospitals, as well as moving online to expand the Chinese Business?

A4-1-3
Taniuchi: That's right. This is not to say that levofloxacin will not be prescribed, but large national hospitals will be buying a different brand of levofloxacin than the one our Company provides. *Levofloxacin* itself is becoming widely used as an indispensable drug in ophthalmology in China. As a result, there is scope for developing the market outside of large-scale national hospitals which to date were not a focus for us. Naturally, the biggest segment will disappear, so sales will decrease, but we will steadily recover elsewhere.

In addition, we will do our utmost to develop new areas of the market. We also intend to steadily grow our new products, such as *Diquas* and tafluprost, and we intend to absorb and overcome these short-term impacts in order to keep the Chinese Business steady.

Q4-1-4
On page nine, you talk about glaucoma. As for the Chinese strategy, as is the case with anti-infection agents, from what you have explained up to now, do you think that there will be no significant change?

A4-1-4
Taniuchi: That's right. In other words, in the past, the actual market for patients was rather concentrated in large-scale hospitals of this Tier 3 national level, so we have been putting together medical representatives and others in both of these markets.

In response to the diversification of this market, how can we efficiently cover other facilities, outside the conventional visits of MRs to large hospitals? Or how can we respond to the commercial distribution with online pharmacies or new channels?

For private hospitals, this will also be different, and this will require so-called key account management. In this way, we will continue to negotiate with and manage each account.

I think that our own commercial activity will become more diversified. That change has become more pronounced, particularly in COVID-19, so we are changing that.

Q4-1-5
The Chinese government is also talking about strengthening the infrastructure of Tier 1 and Tier 2 hospitals. For your Company, this will be your focus for development, I think?

A4-1-5
Taniuchi: In some regions, we already cover some Tier 2 and Tier 1 hospitals. We have already covered the areas where ophthalmology sales are significant, but the ratio of these areas will increase

steadily. Therefore, we are responding to the current situation by changing the way sales are conducted, shifting, and allocating, or by starting partnerships with local online pharmacies for commercial distribution to such new online pharmacies. In addition, we intend to continue to take such actions in the future.

Q5-1
The first question I would like to ask is about the plan for this term. I understand that there will not be a revision from the beginning of the term. Looking at the progress in the first half, I feel that it is very high in terms of the progress rate, either in the second half or in terms of seasonality. What are the reasons why you have left it unchanged this time?

Also, you have disclosed the items by item this time. Could you please tell us whether you have disclosed the revised items from May to this point, or if there has been no change?

A5-1
Taniuchi: Regarding the outlook for the full term, I recognize that there are the positive factors that you mentioned. On the other hand, we think it is necessary to take a close look at the anticipated downturn in sales in China, including the effect of VBP in China, particularly in the second half and the short term.

Or in the current European context, or even in the Japanese context, there is still plenty of risk that the negative impact of the COVID-19 pandemic will be apparent in the second half of the year. The negative impact of this external factor, again halting outpatient visits and reducing the number of procedures, will also need to be considered. Of course, some of the above-mentioned factors, including allergies, or *Eylea*, etc., may also have a negative effect.

In any case, there is some degree of volatility in the results for individual elements. There may be an upside, or a downside. Therefore, our reading of the situation is that it is neutral.

With this in mind, we intend to work on cutting costs in the second half of the fiscal year so as to reduce volatility as much as possible. However, the current situation remains unchanged.

Also, I would appreciate it if Mr. Suzuki could say a few words about the disclosure point.

Suzuki: Thank you. In particular, at the beginning of the period, for example, there were some aspects that could not be evaluated at that time, including the impact of COVID-19 in China and the impact of VBP, as well as the impact of what products might be affected. As a result, we decided to refrain from disclosing individual products.

As of the end of the first half of the fiscal year, we are now able to evaluate some products more clearly. Therefore, we have disclosed figures that reflect a certain degree of reading rather than adjusting, including products that were not disclosed previously.

Q5-2
The second question is about ROCK inhibitors. I would appreciate it if you could tell me about this development strategy. Certainly, I understand that *Rhopressa* is aiming for launch in 2024, and *Rocklatan* for launch in 2026.

On the other hand, looking at the 10-Q of the introduction company Aerie, two of the three trials are 28-day trials, and one is a 12-month safety trial. If a Phase 3 trial starts by the end of this year, why will the process take so long?

In the future, I think that there is a possibility that the indications for ROCK inhibitors will be expanded to include retinal diseases and similar conditions. Could you please tell me what you think about that possibility?

A5-2
Taniuchi: Currently, we recognize that we need to complete this in more detail, including consulting with the PMDA in the future. Naturally, Aerie has been working with the regulatory authorities on this development, but we have been working on it this time, so I hope that you will understand the timing of the development as it is being updated in the future.

I also think that there is a potential for various other indications in the future. This is still an early stage, and I intend to discuss this with the other party and consider the possibility in a positive manner.

Q5-3
OK. Thank you very much.

Finally, regarding the acquisition of Eyevance, how will this affect the thinking about DE-117 and DE-109 in the future, including whether to sell independently when selling in the US or whether to form an alliance.

Also, with regard to DE-117, in particular, how do you think about the concept of partnerships?

A5-3
Taniuchi: In the future, regarding the commercialization of products in the pipeline, as we have acquired Eyevance in the US, it is assumed that we will be able to work based on this platform. Therefore, first of all, we will consider selling independently.

However, we also have Eyevance's existing product portfolio. Besides Eyevance current products, there is also the coverage with the current employees, although limited. Naturally, how do you compensate for this shortfall, compatibility with the existing product, or, for example, the need for expert coverage, or the need to match the characteristics of each of these products with a single Eyevance platform. I think that we will consider whether we will reinforce that, or whether we will form a positive or different partnership.

Q6-1-1
Overall sales are the same, but I think sales by region are changing in China and Japan. As you explained earlier, I can imagine, but I would appreciate it if you could tell me if there have been any particular items where there was significant movement. I would appreciate it if you could let me know.

A6-1-1
Taniuchi: In the first half of the year, in Japan, COVID-19 had a mild impact, and in particular, there was some recovery in the second quarter, so as the number of operations increased, and our share increased, growth was relatively good.

In China, on the other hand, the country itself closed down considerably from January to March, and from April this year onward, the situation suddenly stopped, with outpatient visits and operations discontinued. However, the country has recovered since the second quarter. For that reason, I think that the overall figure looks relatively weak in July to September. Therefore, I hope that you understand that the whole movement is that April to June was very weak, and that the recovery was not completed in July to September.

Q6-1-2
That's why in the forecast, you are allowing the two to balance each other out. Overall, it is zero.

A6-1-2
Taniuchi: Yes.

Q7-1-1
I would like to ask about VBP in China.

I think it was mentioned that there was some uncertainty over whether sales of *Cravit* would reduce gradually, or suddenly decrease. My concern is the risk *Cravit* sales could almost disappear from January onwards.

I think that sales are currently JPY700 million. What do you think about this risk?

A7-1-1
Taniuchi: I will explain this first, and the details will also be supplemented by Suzuki.

First of all, I hope you understand that everything will not disappear. Hospitals that are subject to VBP will cease to buy our product, but we have sales outside that segment that will not be affected.

In addition, there is a market in China where products are purchased directly at pharmacies and sold to patients. This area will also remain unaffected. As a result, we will aim to increase this market. I think it would be better to think that although it will be greatly affected, a certain amount of sales will remain. I would appreciate it if Mr. Suzuki could say a few words on this also.

Suzuki: Thank you. As mentioned, we still have private hospitals and other sales channels. In addition, there remains a market where we can make direct sales to pharmacies. VBP is centered on bidding at national hospitals, but these hospitals do not make up all of our sales.

In addition, we have the choice to enter these auctions, and decide if the price is right. It may also be the case that other suppliers are not able to meet all of the supply initially, so we may be taking some orders in that way at first.

Taking these points into account, I understand that the scenario of gradually decreasing is higher, rather than decreasing at once, while looking at the impact.

In particular, with regard to aseptic formulations that are similar to these injections, there no makers that can produce them. We intend to make judgments by looking at the extent to which they will pass simultaneous evaluation tests.

Q7-1-2
Do you think that prices other than VBP will not be affected?

A7-1-2
Suzuki: That's right. Regarding VBP, this auction process applies to top national public hospitals, but outside that it will be a normal business negotiation, so I think it will not be affected.

Q8-1
Thank you. I would like to ask about your Company's growth strategy in China in the future.

This time, on pages eight and nine of the slides, there is a mention of some initiatives aimed at achieving sustainable growth. Currently, you are working on specific measures, such as on-line medical treatment or initiatives to increase the percentage of people receiving glaucoma treatment. Could you give us any more detail on such specific measures?

In addition, I would like to ask what kind of sales potential will be from your glaucoma products in China in the future, if there are any internal plans or those that can be announced externally.

A8-1

Taniuchi: Thank you. In China, including glaucoma, we refer to ophthalmic healthcare as an ecosystem, and we have for many years been working on how to enhance the environment surrounding these types of healthcare.

Recently, we renewed the contract locally, but more than a decade later, we conducted a scholarship program in collaboration with ophthalmologists' associations to train doctors. And, in reality, the number of ophthalmologists has been increasing, perhaps by about five thousand over the past decade. In addition, we are working to improve the quality and quantity of these professionals.

On-line initiatives include local companies, but we have formed an alliance with these companies to engage in activities with on-line pharmacies.

Also, regarding medical treatment, we have not signed a contract yet, so I cannot give you a name, but we have been discussing with various local partners and ophthalmology-related companies. We have already begun efforts to enhance access, such as better screening, or developing a flow from screening to treatment. We are also putting more effort into this project.

How much we will put into developing the glaucoma market is something we are discussing internally at present, and we are not in a situation where we can talk about it yet. As I mentioned earlier, the current level is only the tip of the iceberg, which is overwhelmingly small compared to Japan. While we cannot suddenly develop the market to the level of Japan, I am eager to move forward with this while focusing on areas of growth. I am afraid that is all I can say today.