

## Investor Meeting on Q2 FY2019 Results

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Hello everyone. Thank you for visiting us today. I am Taniuchi, I would like to talk about our business performance overview. To begin with, I would like to talk a little bit about our basic philosophy and mission, as well as the field of "eyes" in which we conduct our business.

Santen's Values and Mission Statement 

Values

**天機に参与する**  
*Tenki ni sanyo suru*<sup>1</sup>

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

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

Mission Statement

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

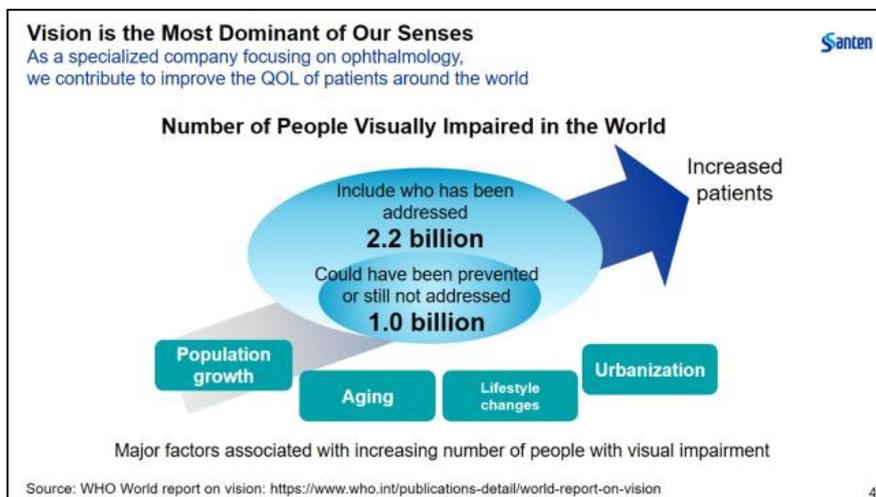
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This slide shows our basic philosophy and mission. We are conducting business based on this philosophy and toward the goal of "Tenki ni sanyo suru". Since it was founded in 1890, it is a very long-established company with a very long history, with next year celebrating its 130th anniversary. The word "Tenki ni sanyo suru" was created by Kenkichi Taguchi, Santen's founder, inspiration from a section of *Zhongyong* (The Doctrine of the Mean) by Confucius. Also, this is the origin of our company name, "Santen". That is to say, our company name is based on a very philosophy.

In the sense of this is to clarify the mysteries of nature and promote people's health. We set this goal as our philosophy in 1890, and have worked on the company's business till now.

Through the realization of this goal, we focused on ophthalmology and strategically focused our resources on this particular the "eye" area.

We have also strengthened our relationships with patients, doctors, and medical professionals while contributing to society by strengthening our expertise.



We always say that the eyes are the most important sensory organs.

Last month or so, the World Health Organization (WHO) issued a report on eyes, and the same thing was written in it. Eyes are the most important of the sensory organs, or the world is created on the assumption that people can see. It says that all means of communication such as road signs and economy is built on the assumption that we can. Therefore, it is written that the eye is the most important thing in sensory organs or in human socio-economic activities, and I am very encouraged that it is in a sense supported that what we have done so far is correct. Since this report has nothing to do with Santen, we hope that you will understand it and that this happened to be the case. We believe that this is in a sense a single "Tenki."

In fact, there are 2.2 billion people around the world with visual impairments. There are one billion people who can actually be treated, prevented, or not innate. On the other hand, vision impairment, of course blindness, is a very serious condition. If you are not blind, you have severe vision problems, or if you are correcting something, such as myopia, astigmatism, or far-sightedness, you can't work without proper correction, you can't see a blackboard, you can't drive a car. People with glaucoma have a high rate of traffic accidents.

In addition, these eye diseases are increasing around the world.

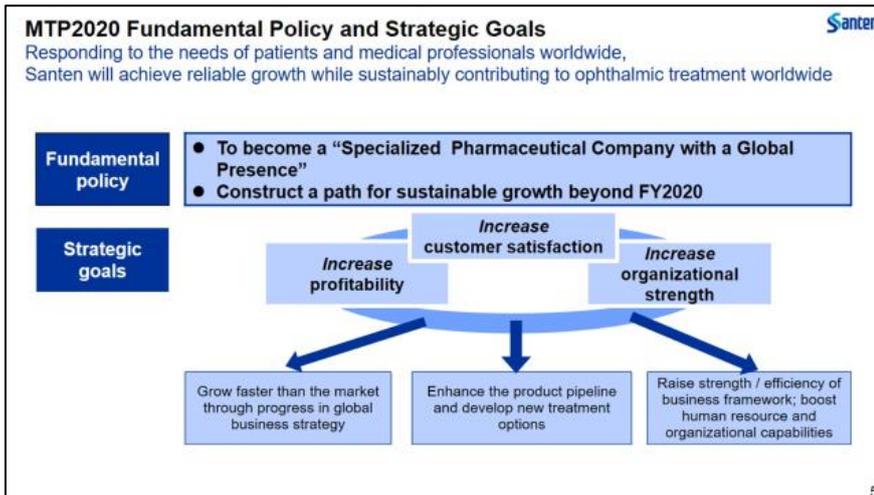
The background is, of course, an aging population in addition to population growth around the world.

In Asian countries as well, the aging of the population has rapidly progressed over the next ten or twenty years. In terms of changes in lifestyles, people are becoming forced to use their eyes more heavily cause of using smart devices or under more indoor work environments. We work in an environment that is not good for our eyes. Since then, in terms of urbanization, these people have begun to live in cities on one side. Alternatively, the expansion of cities will dramatically increase the number of patients attending. Together with this, the number of patients is rapidly increasing, and will continue to increase in the future.

Of course, this is a business opportunity for us, but if it doesn't stop, it will become a social problem.

For example, it is scheduled to be broadcast on TV today, myopia is becoming a social problem in Japan. Similarly, it is said that China have to adopt short-sightedness as a national policy. If Chinese government leave it, hundreds of millions of people in China will be short-sighted, and it will affect various areas, such as GDP growth. The Chinese government has begun to work on this issue and the number of Asian countries have begun such efforts is increasing. This is not just an increase in medical treatment opportunities. While feeling that we are faced with such social problems and social crises, all of our employees want to go back to our basic philosophy of contributing not only to business growth but also to society by making the most of our strengths in this business, a company that focuses on ophthalmology, and the fact that we are expanding

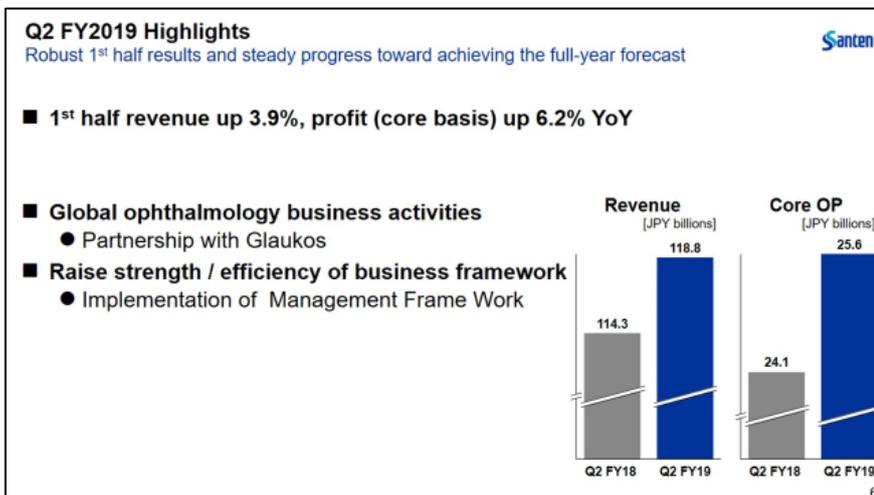
these strengths globally.



Now, let me talk about the "MTP2020" that we are currently working on at our feet. This is a three-year plan for 2018-2020. Originally, we created Vision 2020, a ten-year plan starting in 2011, with the aim of becoming a speciality company with a global presence.

The first point for MTP is how to realize a specialty company with a global presence in the last three years. In addition, we are working to clarify the growth path for how we will grow after 2020.

As for the contents, we have carried out the initiatives described here on a global scale to improve profitability, improve customer satisfaction, and improve organizational capacity.



This is a highlight of our achievements as of the end of the second quarter and first half of FY 2019. I recognize that the overall results have been very steady and smooth. I believe that we have made steady progress toward achieving our goals for the full term, as well as the realization and achievement of the MTP. Sales increased 3.9% YoY. Originally, MTP2020 was aiming for 6% growth, and this year's target is 6%. As a matter of fact, the Chinese business, the Asian business, and the European business are growing at a higher rate than planned. In terms of local currency, Sales was +24% YoY in China and +11.5% YoY in Europe, while the market growth was strong. However, due to the exchange rate problem in the first half of the fiscal year, the yen was growing stronger. Under the assumption of the exchange rate at the beginning of the fiscal year, sales was growing by 6% YoY, but at the end of the first half, sales was 3.9% YoY due to the effect of

the appreciation of the yen. I think nothing can be done about the exchange problem. We are now steadily growing in the local currency as planned or beyond our plans, and we are working toward the second half with great confidence. In terms of profits as well, we achieved a 6.2% YoY increase in core-based profits with the aim of growing sales and then promoting more efficient use of costs.

As for the details of the business, I talked a little bit about it when we announced FY18 results in May, but we announced at the end of April that we will be partnering with Glaukos in the U.S. We are continuing to steadily move forward with various exchanges with Glaukos in the first half of the fiscal year, as well as preparations for development within the company and the establishment of a sales system, and is working toward entering the US market, which is the last big piece of global expansion. In addition, in order to support the U.S. industry, Canada has just entered the market.

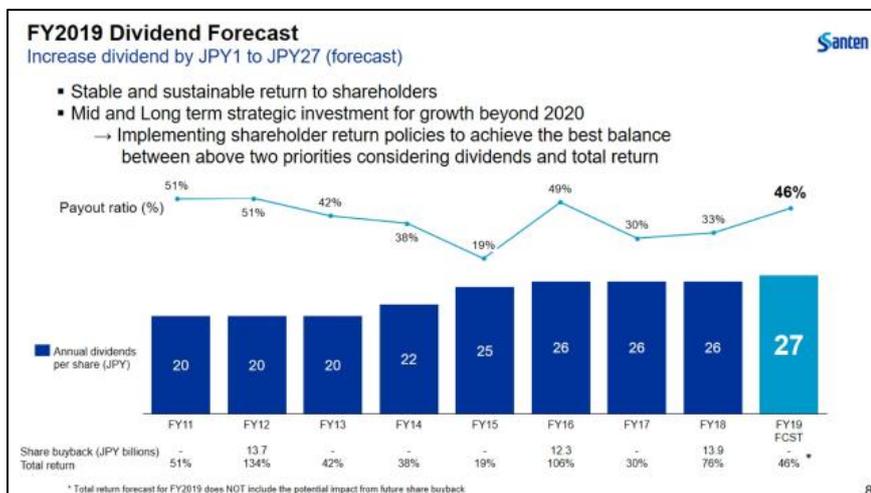
In terms of our business infrastructure, we have spent the past few years working on the foundations that support globalization, and this has made further progress. While Management Frame work may be a bit of an internal term, we have clearly defined the roles of each organization globally, the reporting lines of each organization, or the cooperative relationships of each organization, and are transforming each region's business, the corporate function, or the functions that support it, into a globalization-based organization. We have been doing this since April, and we are changing everything into a global organization. This has made it possible for us to advance our business infrastructure more efficiently.

**FY2019 Forecast (No Change from May 9)**  
Aiming for further growth and efficiency improvements 

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

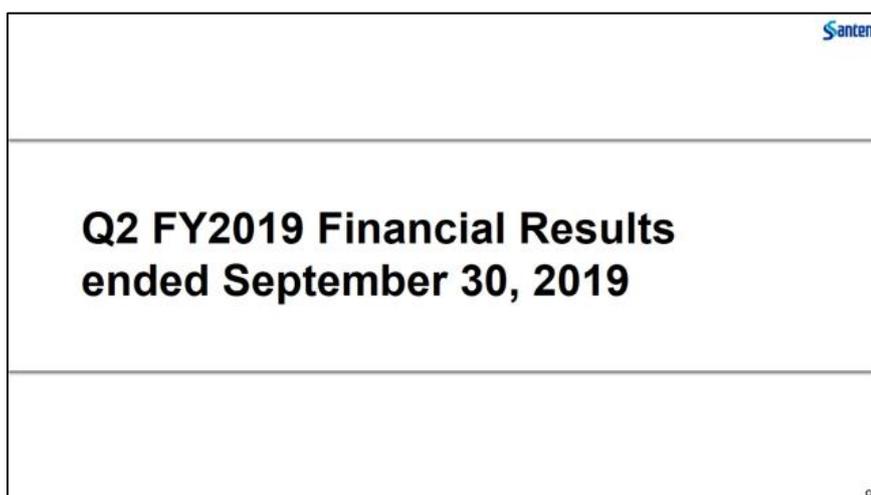
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And it's a full-year performance forecast. This has not been changed from the figures announced on May 9th. We would like to work on this in the second half, aiming for growth of 248 billion yen in sales and also aiming for a figure of 51 billion yen in operating profit.



Then, I have one more thing I would like to tell you. We decided to increase dividends. This is also the next issue to be approved at the shareholders' meeting, but we would like to increase the annual dividend by a yen to 27 yen. With regard to the concept of dividends, I have been telling you that we attach importance to stability and sustainability for a long time. With this stability and sustainability in mind, we intend to increase the dividend by a yen in view of the prospect of achieving this year-round performance.

In the future, we will continue to make strategic investments aimed at medium to long-term growth, invest in business development, pay dividends to shareholders, and buy-in-stock purchases that we have made in the past. In this way, we will continue to make strategic investments that meet our objectives. We look forward to your continued understanding and support in the years ahead, and look forward to working with you. So far, we have explained it to you from Taniuchi.



Here is Koshiji. I have just received some highlights from the president regarding important points regarding the achievements, so I will explain them in a little supplementary way.

**Q2 FY2019 Results**  
Strong overseas sales led revenue and profit growth (core basis)

(JPY billions)	FY2018		FY2019		YoY
	Q2 Actual	Q2 Actual	Q2 Actual	Q2 Actual	
<b>Core basis</b>					
Revenue	114.3	118.8			3.9%
COGS	45.8	48.3			5.5%
Gross margin	68.6	70.5			2.8%
SG&A	33.5	33.4			-0.2%
R&D expenses	11.0	11.4			4.1%
OP	24.1	25.6			6.2%
Net profit	17.8	18.8			5.6%
<b>IFRS</b>					
OP	20.8	19.0			-8.7%
Net profit	14.4	13.1			-8.7%
USD	110.21	108.82			
EUR	129.81	121.28			
CNY	18.70	15.77			

**Revenue**  
Japan: Steady growth of key products  
Overseas: Maintain strong growth, particularly in Asia and China  
⇒ Increase by JPY4.4 billion (+3.9%)

**Core operating profit**  
• Steady growth of overseas business  
• Increase profits by cost optimization  
⇒ Increase by JPY1.5 billion (+6.2%)

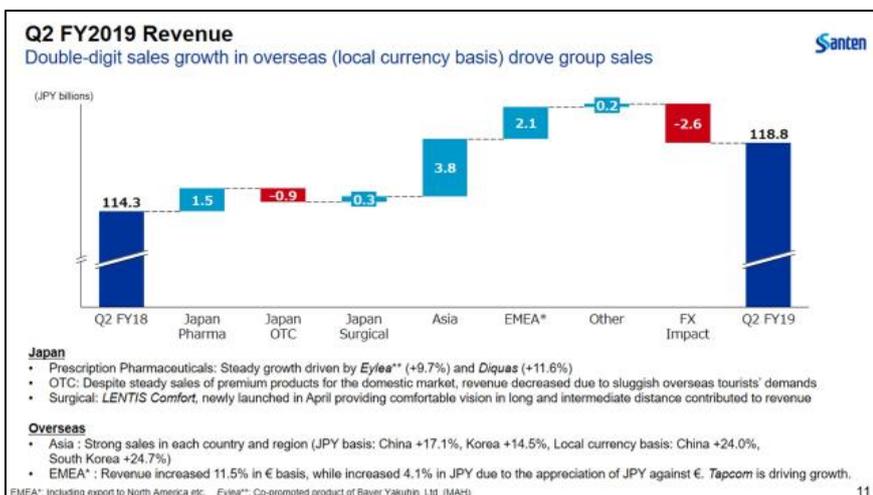
**IFRS operating profit and net profit**  
Temporary expenses increased due to the start of DE-128 amortization, and review of the timing and accuracy of milestone payments through development progress and business alliances.  
Operating profit ⇒ Decreased by JPY1.8 billion (-8.7%)  
Net profit ⇒ Decreased by JPY1.2 billion (-8.7%)

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First of all, about page 10, it is a profit and loss statement. As written here, up to this second quarter, we have achieved to realize an increase in revenue and profit on a core basis through our overseas business. As explained in the highlights earlier, the sales revenue is 3.9% YoY, but considering the impact of the exchange rate and other factors, there was an impact of approximately 2.3% on sales on a consolidation basis, so in reality sales is about 6.2% YoY. In terms of gross sales profit, the exchange rate had an impact of 2.8 %, SG&A 2.3 %, and R&D 1.8 %. It was roughly 3.7 % impact for core OP by the exchange rate. Apart from this impact, we are aware that about 10% could have achieved growth on a core basis OP.

On a full basis, we see a decline in profits. There are two major factors behind this. One, the biggest is the impact of InnFocus. This is a company that was acquired in 2016.

The increase in the reserve associated with the progress of *PRESERFLO MicroShunt* in InnFocus was a major impact, resulting in a decline in profit. The second is the effect that the depreciation cost for the purchased products has been starting this term. These two impacts have resulted in a decline in profits.



The next page, page 11, was also explained in the highlights just now, but it shows the growth in sales revenue. In overseas business, as you can see in the comments below, China is +17.1%YoY on a yen basis, but it is +24.4% YoY on a local currency basis. South Korea is +24.7% YoY on a local currency. Asia as a whole including Korea saw a +13% YoY. Regarding EMEA, the yen rate is +4.1% YoY, but it is +11% YoY on Euro and local currency basis. Overseas has been the driving force behind the growth in sales.

**Q2 FY2019 Income Statement**  
 Revenue and profits (core basis) increased, however profits (IFRS) declined mainly due to DE-128 amortization.

(JPY billions)	Q2 FY18		Q2 FY19		YoY
	Actual	vs Revenue	Actual	vs Revenue	
Revenue	114.3		118.8		3.9%
COGS	45.8	40.0%	48.3	40.7%	5.5%
Gross margin	68.6	60.0%	70.5	59.3%	2.8%
SG&A expenses	33.5	29.3%	33.4	28.1%	-0.2%
R&D expenses	11.0	9.6%	11.4	9.6%	4.1%
Core operating profit	24.1	21.1%	25.6	21.6%	6.2%
Amortization on intangible assets associated with products	3.5	3.0%	4.9	4.2%	42.1%
Other income	0.3	0.2%	0.2	0.1%	-38.1%
Other expenses	0.1	0.1%	1.9	1.6%	..
Operating profit (IFRS)	20.8	18.2%	19.0	16.0%	-8.7%
Finance income	0.5	0.5%	0.5	0.4%	-5.3%
Finance expenses	1.6	1.4%	1.1	0.9%	-29.1%
Profit before tax	19.8	17.3%	18.4	15.5%	-7.0%
Income tax expenses	5.4	4.7%	5.3	4.4%	-2.5%
Actual tax ratio	27.4%		28.7%		
Net profit (IFRS)	14.4	12.6%	13.1	11.1%	-8.7%
Core net profit	17.8	15.6%	18.8	15.8%	5.6%

Impact of starting amortization of DE-128: +1.4

Revaluation of InnFocus contingent payment: +1.2

Since tax effect cannot be recognized on the expense from the change in the fair value of contingent payment (described above), income tax expense would not be reduced, resulting in an increase in actual tax rate.

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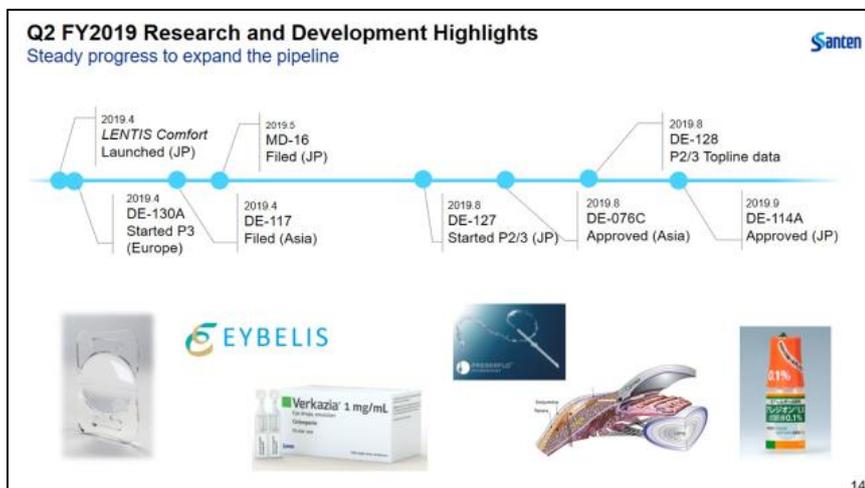
Page 12 slightly overlaps with the profit and loss statement mentioned earlier, but it shows the revenue ratio, etc., so I will explain it to you including my future thinking. The main reason for this is that the cost ratio was 40.7% compared to the initial forecast of 38.3% for the full year, which is due to the impact of the product composition. This is reason for the influence of a relatively high cost of products in Japan is increasing.

In addition, SG&A costs are negative compared to the previous year. This is partly due to the appreciation of the yen, but even if the impact of the appreciation of the yen is excluded, the increase has been kept at around 2% from the previous year, and it seems that a significant part of my activities are devoted to controlling costs. Especially as a company, in order to secure important KPIs such as ROE and core sales profit, we control PL based on the idea that SG&A control expenses should be kept within 30% of the sales ratio. In terms of core sales profits, we have control over securing at least 20% or 21% or more in that respect. By controlling SG&A expenses, we are able to secure R&D expenses for the future and secure a certain level of profit. In this way, we are controlling profits and losses. I intend to implement the full-term outlook based on the same concept.

As for the tax rate, it says it is 28.7% until the second quarter of this fiscal year, but as you can see in the note, the tax rate is rising because some of the costs related to the InnFocus are unable to recognize the tax effect. In fact, it is about 26.4% and we are thinking about controlling the tax rate here at about 25-26%. That is all for the explanation.

## Status of Research & Development

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First of all, it is the first slide. What you would like to see here is that the pipeline's products are progressing. We are making progress as planned. Moreover, it's smooth. As you can see, we were able to launch the *LENTIS Comfort* lens from April to September this year. Then, we started P3 trial of DE-130A in Europe. And the intraocular lens is in the process of being applied. Then, the DE-117 of EP2 receptor agonist is applying in various Asian countries. DE-127 is a short-sighted program which has begun its P2/3 trial in Japan. And as for DE-076C, it was approved in Asian countries. This is a cyclosporine formulation. And we are currently expanding our DE-076C in the Asian region. Then I can report with great pride, it's *PRESERFLO MicroShunt*, DE-128, but the top line data came out. And finally, DE-114 will launch as soon as the pricing negotiations are over.

### The Current Status of Research and Development

Pipeline/product Development (1)

As of October, 2019  
Updated information is underlined

	Indication	Region	Status
<b>DE-111</b> <i>TAPCOM / TAPTIQOM</i> Combination of latanoprost and timolol maleate	Glaucoma / ocular hypertension	China	P3 <u>Plan: FY2020 P3 completion</u>
<b>DE-117</b> <i>EYBELIS</i> EP2 receptor agonist	Glaucoma / ocular hypertension	US	P3 <u>Plan: FY2020 P3 completion</u>
		Japan	Launched
		Asia	Filed <u>Plan: FY2020 approval</u>
<b>DE-126</b> FP/EP3 receptors dual agonist	Glaucoma / ocular hypertension	US	
		Japan	P2b
<b>DE-128</b> <i>PRESERFLO MicroShunt</i>	Glaucoma	US	P2/3 <u>Plan: FY2019 PMA rolling submission completion, FY2020 launch</u>
		Europe	CE mark received
<b>DE-130A</b> Catioprost latanoprost	Glaucoma / ocular hypertension	Europe	P3
		Asia	<u>Plan: FY2021 P3 completion</u>

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And furthermore, DE-111 is a combination of *Tapcom/Taptiqom*. This is the P3 trial in China. This exam is scheduled to end in fiscal 2020. Then, DE-117 of EP2 receptor agonist, the product name in Japan is *Eybelis*, but the P3 trial of this is going on in the US. We are scheduled to finish this P3 trial shortly. Top line data is scheduled to appear in FY2020. DE-126 is the second ophthalmic lowering agent, FP/EP receptor dual agonist. And we are now doing exploratory research on these molecules. I talked about the *MicroShunt* (DE-128), but I announced the top line data. And we are currently applying for a phased application to the FDA, and we are planning to be able to launch it in FY 2020. In Europe, we have already obtained the CE mark. P3 trial of the latanoprost formulation DE-130A/Catioprost is scheduled to be completed in FY2021. This is primarily the case in Europe and Asia.

The Current Status of Research and Development			Santen
Pipeline/product Development (2)			As of October, 2019
Indication	Region	Status	
<b>DE-109</b> IVT sirolimus	US	P3 <i>Plan: FY2022 P3 completion</i>	
	Japan	P3	
	Europe	P3	
	Asia	Filed	
<b>DE-122</b> Anti-angiogenic antibody	Wet age-related macular degeneration	US	P2a <i>Plan: FY2019 P2a completion</i>
		Europe	Launched
<b>DE-076C</b> Vekacia / Verkazia cyclosporin	Vernal kerato-conjunctivitis	Asia	<u>Approved of expanded indication to Ikervis in Aug 2019 in Taiwan</u>
		Others	Approved, <i>Plan: FY2019 launch</i>
		Japan	Approved in Sep 2019 <i>Plan: Nov 2019 NHI price listing and launch soon after</i>
<b>DE-114A</b> epinastine HCl (high dose)	Allergic conjunctivitis	Japan	Approved in Sep 2019 <i>Plan: Nov 2019 NHI price listing and launch soon after</i>
		Japan	Started P2/3 in Aug 2019 <i>Plan: FY2023 P2/3 completion</i>
<b>DE-127</b> atropine sulfate	Myopia	Asia	P2 <i>Plan: FY2019 P2 completion</i>
		Japan	Filed <i>Plan: FY2019 approval</i>
<b>MD-16</b> Intraocular lens	Cataract	Japan	Filed <i>Plan: FY2019 approval</i>

I will go ahead and make a DE-109. What I reported last time was that the clinical trial site will be expanded to areas other than the U.S. By doing so, we would like to promote incorporation. Incorporation is moving forward quickly in this regard. And I'm still looking for a facility outside of the U.S. Then, DE-122 P2 trial for wet AMD will be finished by the end of FY 2019, so it's only two to three months left. As I mentioned earlier, cyclosporine products have already been approved in several regions. It will be launched in Europe and Asia and other regions in FY 2019. DE-114A is a high-dose product of *Alesion*. The approval has already been received in September. We have almost finished the price negotiation, so we plan to put it on the market as soon as that is finished. DE-127 is a short-sighted product, but as I mentioned earlier, we plan to finish P2/3 trial in FY 2023. And with regards to the new intraocular lens called MD-16, this has already been applied and will be approved by the end of this fiscal year.

## Question & Answer

### Q1-1

I would like to ask you about the progress of Asian business. I think it has been very favorable so far and continues to be in 1Q. I would like to know the background to this, and if there is anything you see as a risk factor in China in particular in the future, please let me know.

### A1-1

(Taniuchi): First of all, in terms of the fundamentals, there are a number of social factors such as the one I mentioned earlier, and the market itself continues to increase on a quantitative basis as the absolute number of patients and the absolute number of patients visiting the hospital continues to increase, or for example, the number of cases of cataracts, including aging, continues to increase, or the coverage of medical insurance is increasing. And with economic development, there is a growing need for better medical care, better drugs, and better treatment. There is a trend of this kind in general. In addition, in our case, for example in China, the market share has been continuously growing, so the combined effect is that we are achieving high growth that exceeds the market. I understand that the number of such short-term products is increasing due to a considerably sustained factor rather than to such short-term products.

Regarding the risk factor, the first risk is probably what to do with the supply. In a sense, it exists as a medium-term risk. The scale of the business in China has changed considerably compared with when I was doing

business in China ten years ago. If that is the case, where and how we will secure production for China. On the other hand, China is a country with strict regulations, so we need to prepare a production system very flexibly. If we do not prepare such a system of product supply in advance to a certain extent in a long term, we will not be able to meet the increase of demand in the local area. If you do too much, there is a risk of overinvestment. Alternatively, China's various legal systems and regulations, including supply, will become more stringent. It's a very good thing to be strict, but if we don't take measure through various procedures or make pharmaceutical applications in a timely manner, the factory will not be able to supply with anything easily. I believe that the biggest risk is how to firmly support such a stable supply with a long term, and I am trying to recognize the risk and take measures as soon as possible.

Q1-1-2

I think you mentioned that there was a large social factor, but I think that the situation is also getting very favorable when the Mid-Term Plan was formulated. Is there anything that seems to have changed in the past one or two year?

A1-1-2

(Taniuchi): Although this has not changed dramatically in the first year, the market is growing more stable than expected, and not only as an external factor but also as an internal factor, we are steadily increasing the number of MRs to gain market share, or to steadily increase the number of hospitals that use our products. As a result, I understand that the field is working hard to achieve better results than planned.

Q1-2

The second question is *Diquas* in China. How do you evaluate this rise now? Is it necessary to reimburse insurance in order to expand in earnest? For example, in China, *Hyalein* is becoming very large, so does *Diquas* has any such potential? Or is it difficult because the market is different due to dry eye and glaucoma in the first place? Could you please give us a comment around here, including a little medium-term potential?

A1-2

(Taniuchi): I recognize that the current *Diquas*'s figures are still small. This again takes time for China to reimburse its insurance. We have to clear the central insurance reimbursement and the reimbursement of insurance by the ministry one by one, so it will take some time for the market to penetrate. So, although it is within the assumption to some extent, naturally we recognize that *Diquas* is still small compared to the scale of the *Hyalein* business. I intend to firmly settle down and make it bigger in the future. *Hyalein* has been released for a long time, so we have established it not only as a reimbursement for insurance, but also as a brand, so we would like to continue to carefully nurture it so that it will become larger like that.

Q1-3

I would like to ask you about Japan in the last three points. In Japan, the numbers seem to be strong in 2Q, such as *Alesion*. Could you tell me, for example, if there are items that seem to be a hypothetical demand

prior to the revision of the drug price, if there is a temporary factor or if there is a favorable performance based on the actual situation?

A1-3

(Taniuchi): Domestically, for some items, there was a rush demand before the consumption tax hike, but rather than the overall movement, it is a movement by item and by individual facility. There were naturally things that happened. However, basically the assumption is that there is an increase in actual demand, or the overall trend is that there was a slight temporary demand in September.

Q2-1-1

Santen haven't written down forecast, so I think it's going well. In that context, regarding domestic issues, I have an impression that *Eybelis* sales appearance is not good. Is there any reason for this as well? It is strange that it is a cannibalism with other glaucoma, but do you think there are places where it can't be extended a little? First, please tell us about this point.

A2-1-1

(Taniuchi): As for *Eybelis*, it is never true that there is cannibalism. We are doing this because *Eybelis* should be used, and we want patients to use it in the first line. However, the start-up is slowing a little. It has still a new mechanism of action. So in our activities as a medical and pharmaceutical information officer, we are taking time to explain safety more thoroughly than explaining the characteristics of products.

Since its launch, the number of new hires has been increasing steadily, and in that sense, there has been an increase in the understanding of our products. After that, we are looking at the safety of patients and asking them what kind of patients should doctors actually use them. As a matter of course, there are restrictions on the prescription of new drugs, so we have been making a somewhat cautious start over the first half of the fiscal year due to these factors. However, the number of new prescriptions is increasing, so I understand that if doctors understand the safety profile of such products or if *Eybelis* are out of the prescription limit in the future, we will improve them.

Q2-1-2

I think the lifting of the ban on long-term prescriptions is still a little ahead of schedule, but do you mean that this plan should be implemented without that?

A2-1-2

(Taniuchi): We have not updated them individually, and as a whole, we are aiming our FY estimate 248 billion. However, I would like you to understand that there are some strong points and weak points in individual products.

Q2-2-1

I would like to ask you is about the pipeline and other competitors. The pipeline is going smoothly, so I have

not heard much about it, so I would like to ask you this. Novartis' brolocizumab has produced quite good data in non-inferiority clinical trial of with *Eylea*. In short, there is quite good data compared to one year, and the FDA has approved it. In Japan, I think Novartis will be applying for it soon. I don't know well because I can't get the information from Novartis.

If do so, I think that there is a possibility that *Eylea* will be pushed by competitors a little ahead of schedule, although it was said that *Eylea* would be stable until 2022 or 2023 when it entered the generic market. The potential of competitor product is highly regarded abroad, but what risks do you have when viewed from your company? Novartis in particular is trying to focus on ophthalmology, isn't it? Tell me a little about it.

A2-2-1

(Suzuki): First of all, we recognize that *Eylea* itself is a product that is beneficial to both our customers and patients, as well as our partner, Bayer, so we are continuing to discuss this issue with the mindset of continuing to do the same. That is the basis for all of our discussions.

Since the situation of RTH is similar to that of other companies, we also think that the risk there is not zero, but we are paying attention to how those who could not get on the prescription for rather economic reasons will move when the biosimilar comes out. In that sense, I believe that the market will expand with the use of patients such as RTH, *Eylea*, and *Lucentis*, but I think the impact is within the controllable range.

Q2-2-2

You're talking about the assumption that the BS won't come out until 2022 or 2023, aren't you? Am I correct in understanding that we will not compete against *Eylea* so much?

A2-2-2

(Suzuki): I can't say that it is not a competitor at all, but I believe that the impact of this is within a manageable range.

Q3-1-1

It may be a little bit detailed, but there are three things. The first is the evaluation replacement of conditional compensation accompanying the acquisition of InnFocus. I think that the results of the clinical trial have emerged since the time when it was planned at the beginning of the term. Am I correct in understanding that there was no change in the assumption due to that?

A3-1-1

(Koshiji): There are some changes in that respect. That's for the first half. We haven't disclosed our performance forecast for half a year, but on page 12, there are other costs of ¥1.9 billion, and this InnFocus conditional compensation replacement falls under that. The total is 1.1 billion yen, which is an additional 1.2 billion yen compared to the previous year. This is slightly different from the initial estimate. However, the total amount for the full year has not changed as it was at the beginning of the fiscal year.

Explaining this reason, as a result of reviewing the projection along with the conclusion of a sales contract with Glaukos, the possibility of the occurrence of conditional compensation increases, which mean is increase

cost. In addition, the payment of milestones associated with the progress of the development, this is the same as the initial application period and the application period that is in progress this year, but as a result of reflecting the slight lag in timing, the cost is down. The total cost remained unchanged in the final year, but the cost increased slightly in the first half of the fiscal year. I have explained above.

Q3-1-2

In the first half of the fiscal year, the cost has increased more than expected, and in the full year, it's no different from the expectation. That's fine, isn't it?

A3-1-2

(Koshiji): That's right.

Q3-2

Also, regarding the *Alesion*, you mentioned that you would co-promote a new formulation with Mitsubishi Tanabe. I did not hear much about this. What are your expectations? Also, regarding the impact on business performance, could you once share revenue a little and temporarily turn it into a negative? Or would it immediately benefit your company as long as you simply do it?

A3-2

(Taniuchi): We have signed a promotional agreement with Mitsubishi Tanabe for *Alesion LX* and *Alesion*. The market for allergic eye drops is both an ophthalmologist market and a non-ophthalmologist otologist or pediatrician physician. Our Santen MRs, as well as our ophthalmologists, including glaucoma drugs, are usually around, and our company covers this market. With regard to non-ophthalmology areas, we have been creating and covering such a special unit of our own company until now, but with regard to the arrangement, in the future, the market other than ophthalmology will be covered by over 1000 MRs from Mitsubishi Tanabe. Therefore, they have allergic agents in-house. They all have coverage of KOL in the allergy market, so we will borrow the capacity of their judgment. So, it is slightly similar to the shape of the Glaukos model, but instead of paying the cost for what we do by ourselves, we will have them borrow FTE to increase the sales for that, so economically speaking, we can expect a bigger sales. On the other hand, the cost may be more efficient than ourselves, so according to your question, the more it sells, the more it will be. We have contracts that are profitable for both companies.

Q3-3

Lastly, regarding the DE-127, I would like to remind you that the results of the doctors-led trial were announced at an academic conference about three to four years ago. The announcement at that time was effective as a whole. However, there are responders and non-responders. I think it was an announcement that there are still some places where we do not know well how and what to use it. It has been a while since then that Santen will be able to start a P2/3 trial in Japan as well. Could you tell us if a certain hypothesis has been constructed regarding this, and based on that hypothesis, the clinical trial has begun to be conducted this time? Or has the clinical trial been conducted in such a way that hypotheses will be created through this

trial in the future? Could you also tell us how much strategic development has been made at this point in time?

A3-3

(Shams): It's a wonderful memory. As you say, with regard to this trial that we are talking about, data for the entire trial is not yet available. I plan to come out in the first quarter of next year. However, it contains an interim analysis. This is an exploratory study of the Early Phase, so we have already had some data and had discussions with the PMDA based on that data. The trial design is based on that data and other already published data, which leads to P2/3. Before moving from P2/3 smoothly, we plan to decide the final amount. I would like to set the amount before entering the third phase and smoothly enter the third layer.

The reason for this is that the original data is data based on us before we entered the P2 where we were presented with effective amounts, but it became clear that new data may require high amounts or higher amounts may be more effective, and we decided to test this hypothesis by conducting P2/3 to see if it is correct.

The long-term objective is to slow the progress of short-sightedness. The burden of this disease must be reduced, particularly in Asia. This clinical trial has just begun. And as far as information is concerned, it will be clear on tonight's TV program, but this is a strategic and tactical development plan. The two are integrated. We will see what happens in P2 and modify Phase 3 as necessary. However, I want to save time. This will be a long trial, so I would like to make an effort to complete the trial in as short a period as possible. I would like to provide the medicine as soon as possible.

Q4-1-1

I would like to ask you a few questions because there have been a lot of near-sightedness stories coming up, but in the first place, I do not quite understand the concept of having to prevent short-sightedness that much. In particular, Japan and China have very different views on myopia. Looking at China, it seems that some sort of national effort to prevent myopia was announced in 2018, and that everything about children would be examined and something like a medical record would be created. To be sure, I think that people don't like glasses themselves in rural areas or they believe that glasses will make their eyes worse. But I don't think there's any problem in China's cities. Perhaps there is no nation-wide attempt to prevent short-sightedness in Japan, so why is China so different?

Of course there are two places that fall into your business, and first of all, it is DE-127, this is certainly not in clinical trials in China, and it is Atropin, it's probably all over there, so it won't be a bit of a business even if you start clinical trial from now on. How will this be leveraged into China's business? The other connection is, of course, orthopedic operation if it doesn't have glasses, but if you look at this, you will probably use a considerable amount of antimicrobial agents, and after that, something like *Hyalein*. Are there any developments in this market? If your company has any Chinese statistics or anything like that, I would like you to share those as well. This is the first point.

A4-1-1

(Taniuchi): As for myopia, it begins with how to understand myopia. If you watch today's television, you will be able to understand in more detail. For example, the Chinese government or the United Nations is the

reason why the number of short-sightedness is increasing dramatically a few years ago or a few decades ago. That is one of the reasons why the number of short-sightedness has increased dramatically. One reason is that the number of people who are short-sighted is increasing dramatically, especially in the Asian population, due to the fact that they basically do not engage in outdoor activities or changes in environmental factors.

So, I think patient should correct myopia, but when he makes progress, he gets intense myopia. When you are myopia, you don't have the level of being able to refract with your glasses. When you refract, you can't see far away, or when you get even more myopia, you can lead to retinal detachment and retinal disease, finally you lose sight. When it comes to the form of causing such a disease. In doing so, a market of serious near-sightedness that is totally different from the level of the market that is generally considered to be short-sightedness, contact lens, and LASIK is actually emerging. This has arisen from a variety of statistical and epidemiological facts.

If you do so, the number of blind people will increase if you leave this alone. If the number of visually impaired people just mentioned has increased dramatically. In the case of illness, the incidence is usually some percentage or other of zero points, but if near sightedness increases by 50% or 80%, it is suggested that the number of people with visual impairment who have to bear the economic burden as a nation is rising by billions in China. Under such circumstances, there has been a change in the recognition that this is an issue that must be addressed by the entire country or at the United Nations level. Therefore, I think we need to include the recognition that myopia correction methods are not simply glasses.

It is not surprisingly easy to correct eyeglasses. In Japan, we can get easily at a high level and at a low cost including the degree of short-sightedness and astigmatism of the person, or eye correction according to lifestyle, through eyeglasses shops, contact lens shops. However, many people in emerging countries do not correct eyeglasses in this way. In this way, for example, it is difficult to see a blackboard even in a class, or to hold a conscious symptom of near sightedness, so I believe that it is becoming quite underlying in that it leads to socio-economic problems, such as problems with grades and literacy rates, after many years of time before children notice near sightedness. This is the first point, isn't it?

On the business front, as for DE-127, we are prioritizing the clinical trial in Japan, but we are considering the development of Asian countries including China, including social requests and market opportunities. I would like to discuss the details with you when we can talk specifically.

In such a situation, of course there are opportunities for the market in the vicinity, such as LASIK and contact lenses, to grow, but I would like to face the issue of short-sightedness in a more fundamental way in the future. Thank you in advance.

Q4-1-2

Am I correct in understanding that your company's share of these antimicrobials and artificial tears is small in terms of refraction surgery?

A4-1-2

(Taniuchi): Yes. Although they vary slightly from country to country, they are basically small and have a relatively large share of cataracts. In developed countries, for example, a significant proportion of cases of

cataract operation are resulting in fewer opportunities to become infectious diseases, so in Japan and elsewhere, cataracts are more common than infectious diseases. On the other hand, since LASIK surgery is not widespread in Japan, what comes with refractive correction will be limited. In China and elsewhere, the number of infectious diseases is increasing, and even more people are suffering from cataracts. I think it is better for people to understand that the market is still limited for those related to LASIK.

Q4-2-1

Lastly, I would like to ask you about the second question. Are you currently building a factory? What's going on now and when will it start launching? Your company has olopatadine been approved for generics in China, and this is probably the previous slide and so on, but your company will certainly sell the 3rd tier or specialist, and the joint venture will attack the 1st tier or the clinic. This is certainly not yet available in *Patanol* in China, so this GE launch at first. Also, it seems that brimonidine has also been licensed from a Korean company. This was released only in Korean though. Could you please give us any suggestions on how the generic strategy will affect you?

A4-2-1

(Suzuki): The environment surrounding generics in China has changed sharply over the past year or two, and in that sense, it is related to the opening question, but we have come to the point where high quality products should be put on the market in a way that exactly matches the starting point. In that sense, Santen's formulation and manufacturing technology will be an advantage. On the other hand, the priority of the country over generics and innovation is changing steadily in test cases such as the 4+7 that you also know, so we are considering which direction we should take while looking at them.

In that sense, at present we have both the development and manufacturing capabilities of Santen China and the relatively reasonable products that Chongqing Santen had in mind that you asked us about, and we have a system that allows us to go anywhere. Regarding the progress of Chongqing that you asked about, it is still in the process of building the factory. In addition, we are proceeding with the project of product transfer in parallel.

Q4-2-2

Is it still undecided when the joint venture will begin operating?

A4-2-2

(Suzuki): The joint venture itself has been launched, and the next step is, of course, the transfer of products from now on, prototype production after the factory has been established, and approval will be obtained, so I think it will be a little further.

Q5-1

Just to confirm a little, the second table from the bottom of the finance on page 10 of the data book. The IPRD here is 12.2 billion, and it has fallen steadily since the end of March. Could you please explain a little bit about whether this is connected to the story of the InnFocus?

A5-1

(Koshiji): That's right. R&D costs associated with the DE-128 related to the InnFocus have been transferred from the R&D costs to intangible assets. In terms of the difference, *LENTIS Comfort* and intra-eye lenses had been in-work R&D expenditures until the first half of the fiscal year, but this is mainly due to the transfer of development, manufacturing, and sales rights to intangible assets from the current fiscal year.

Q5-2

Also, in your talk about *Eylea* future risk factor, Mr. Suzuki, he said "biosimilar" to the effect that if *Avastin's* biosimilar comes out, that off-label may increase quite a bit in Japan as well?

A5-2

(Suzuki): *Lucentis* biosimilars will be launched first, there will be more patients after launching BS. As a matter of course, there will be more patients who will not be able to access to *Lucentis* and *Eylea* cause of economic burden. However, I think there is another aspect of whether or not to move from the initial stage to the biosimilar.

Q5-3-1

Lastly, I would like to ask you a little bit of a favor. The figures for operating profits by region are missing from this document. Yesterday, I told the IR that I would like to ask you to do so. But I think the profit of the U.S. in particular will be an important indicator for us in the future. Can't we revive the disclosure of this number?

A5-3-1

(Suzuki): First of all, there are many sales partners and distributors in the situation where our growth drivers are still focused mainly on Asia. We are in a situation where volatility continue to occur due to the timing of exports, seasonal changes in the recipient's inventory requirements, or inventory sorting.

In recent years, in response to the ongoing question "How is it compared to the previous fiscal year?", The situation continues to answer "There was a temporary sale". The top-line trace is done exactly, but it is still difficult to disclose operating profit by region quarterly. I would like to think about the future direction depending on the situation.

Q5-3-2

I would appreciate your explanation, especially for the part of America.

A5-3-2

(Suzuki): Yes, I understand.