Investor meeting on Q3 FY2020 Results

Q3 FY2020 Results

Presentation / Q&A

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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: Hello everyone. Thank you**.**

This slide shows our basic philosophy, WORLD VISION. We have set "Happiness with Vision" as our corporate philosophy, displaying the kind of world we want to realize in the future.

Santen 2030 Toward 2030 and beyond

Santen's VISION

Become A Social Innovator

Orchestrate and mobilize key technologies and players around the world, to deliver happiness through vision.

GOAL

Aim to reduce the loss of social and economic opportunities for people around the world due to eye conditions.

STRATEGY

A **Ophthalmology**
Innovation in Ophthalmology and Acceleration of Ecosystem Development

B **Wellness**
Awareness and Proactive Care toward Better Eye Condition

C **Inclusion**
Building Society that is Inclusive regardless of Visual Impairment

This slide shows our long-term vision, Santen 2030. We are making steady progress with initiatives aimed at achieving medium- to long-term growth in these areas.

I will talk more about this later.

Q3 FY2020 Progress

Steady progress in each region despite the impact of COVID-19 and the Japan NHI drug price revision, and increased net profit for the period.

- Strong performance in Japan's Rx and Asia
- Smooth launch of Eyevance products as a first step to enter the U.S.
- China in line with expectations; long-term growth potential remains unchanged, we maintain to develop business actively

(JPY billions)	Q3 FY2019	Q3 FY2020	YoY
Revenue	182.3	181.8	-0%
Core OP	38.0	36.4	-4%
Net profit for the period	20.3	20.9	+3%

This is a summary of the progress made in Q3.

In Q3, there were a number of negative impacts worldwide, including the COVID-19 pandemic. Against this backdrop, our business is doing very well. In Japan, as well as in other parts of Asia, China, and Europe, we are striving to grow our business while forging significant partnerships with a variety of stakeholders.

Figures for Japan and Asia have moved very steadily. Similarly, we are seeing steady performance in Europe and China, despite the impact of the coronavirus pandemic.

In the US, the PMI following our purchase of Eyevance Pharmaceuticals, LLC. is making steady progress. Naturally, the coronavirus pandemic is an issue in the US too, so there are travel and other restrictions, but we are progressing with PMI remotely. We are not yet disclosing our business results as we are still in the process of launching, but we are starting up as planned, so we believe that our business will grow steadily here.

Regarding China, as I will explain on the next page, the impact on our current business performance is virtually in line with expectations, so we are working to achieve our medium- to long-term growth potential without any discrepancies.

As you can see, the figures have been realized in the form of sales and profits almost the same as those of the previous year. We intend to maintain this momentum in Q4 and into the next year.

China Short-term Business Impact and Direction

Despite a short-term impact from VBP*, we continue to aggressively expand our business to steadily adapt to the changing market environment, and to achieve medium- to long-term growth.

1. Cravit VBP* short-term impact

- Focus on retail and private hospital market; achieved healthy growth
- In Q3 (3 months) , maintain about 70% (value) of the Q3 FY2019 level

2. Hyalein 0.1 and Hyalein Mini 0.3 targeted for VBP*

- Bidding was held on February 3rd; local manufacturers won
- Limited impact expected on financial results in FY2021 and beyond

3. Steady progress for the mid-to-long term growth

- Development of measures exploiting growth opportunity

*VBP: Value-Based Purchasing

At 16:00 (JST) on February 5, we will present details of mid-long term China business strategy in the teleconference

Here, I would like to explain the status of the Chinese business, which was the topic recivinga lot of questions from all of you last time.

As is written here, I would like to talk about the details separately tomorrow evening, in a presentation including myself and members of the Chinese team. We will talk about what kind of strategy we are drawing up, and what kind of growth potential we are thinking about in the future. I will just say a few words about this today.

Firstly, as we saw last time, we have achieved almost the same results as expected for *Cravit*. In other words, we are in a situation where sales are declining in third-tier hospitals, but are solidly increasing in other areas. We are changing the allocation of sales, increasing the numbers in the areas of regional hospitals and retail, with a decrease of 30%.

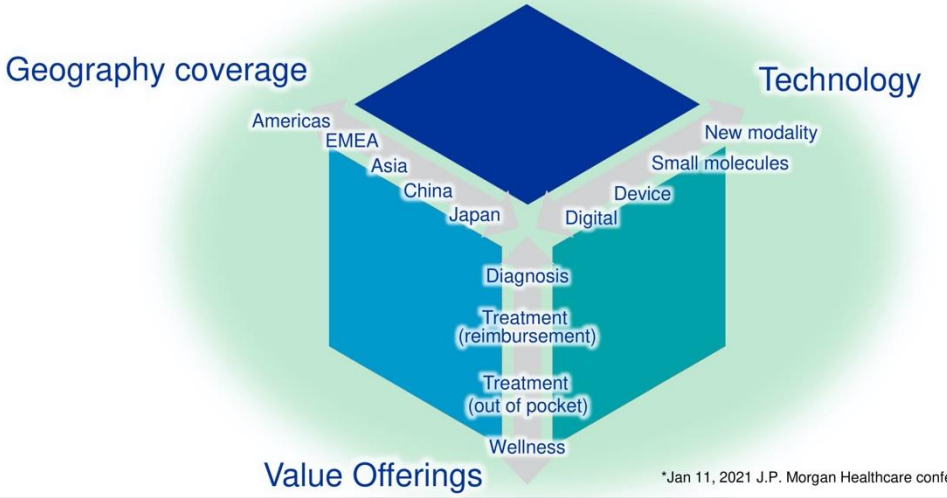
Yesterday, the tender was held for *Hyalein*. There are three *Hyalein* formulations. The largest, the multidose formulation, was not included. Included were products such as the 0.1 dose, or *Hyalein* Mini, which accounts for about 30% of total sales. The impact of this is very limited. This is because the composition ratio was small in the first place, and because *Hyalein* is a product that is less dependent on large hospitals than *Cravit*. This made up only a minor part of our business results.

I would like to explain in further detail tomorrow. We will continue to spend as much time sharing important events including figures of the results as possible, as we recognize there is limited time available for the announcement of financial results.

Regarding the strategic context in business areas such as China, I would like to cover this properly in a format where we can present the issues in detail.

Challenge of Diversification in Ophthalmology

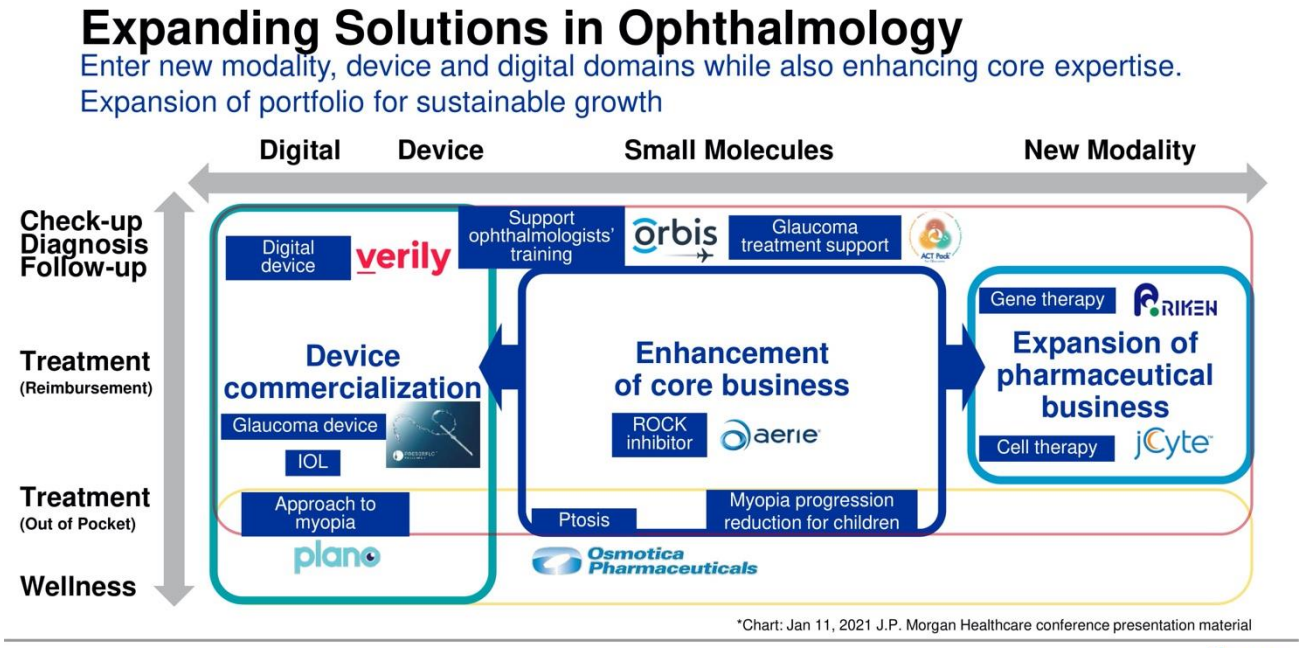
Expanding business scope for further growth as a specialized company



*Jan 11, 2021 J.P. Morgan Healthcare conference presentation material

This was a topic at JP Morgan in January, but I'd like to talk about it again here. Let me briefly discuss how we are aiming to grow over the medium-to-long-term and how it relates to the current situation.

This slide shows three axes: regional, technical, and service. Over the past decade, Santen has grown by focusing on small-molecule ophthalmic pharmaceuticals, while expanding into new regions. Following this trend, we are currently entering the United States market. Going forward, we will take steps to expand along the technology axis, as well as the "added value" or service axis.



In this slide, the part in the middle shows the insurance market for small molecular entities. The prescription medication business is our foundational business, and we are realizing steady growth here. For example, we are in-licensing the goods of Aerie. While doing this, we are using the money earned there to grow, and we are currently investing in the development of new modalities for genetic and cell therapy. This is shown on the right. We are working to make this a major business over the medium- to long-term.

On the left, we have the digital space and devices. We are currently undertaking MicroShunt and joint venture with verily.

Regarding the vertical axis, services, we will extend not only to medical treatment covered by insurance, but also to areas related to self-treatment or wellness, such as blepharoptosis.

We have made various preparations for the next medium-term management plan, and we are conducting management with the aim of realizing growth over the medium to long-term while acquiring new technologies.

As we work on that, these are the current points.

The first is to firmly engage growth drivers that will drive global growth. The first of these is to expand our pipeline. This has been ongoing, and we will continue to incorporate internal projects and external projects.

Next is regional development. We intend to expand not just into China, but also to the United States. I will talk about this again when discussing the next medium-term management plan, but I think the US will be a key point.

The US market accounts for more than half of the world market, but up to now, Santen has not been able make major inroads there. In this context, Eyevance is still a small step, but we will continue to introduce products and aim to realize new organic growth. First of all, in the next three to five years, we will take full advantage of the US as a growth driver.

In addition, the growth driver axis will be to launch new businesses that will drive future growth. We are making steady progress in each of these areas.

We will also strengthen and expand the foundations that support these efforts. Today, we announced a plan to steadily advance management toward a global management system. In particular, we will strengthen our implementation foundation and organizational capabilities in China and the United States, and then strengthen our supply bases to support such growth. In this way, we will make capital investments in Shiga, Suzhou, and other areas, and we will implement these strategies with a strong posture.

We will continue to pursue medium-to-long-term growth in this way. Naturally, we are keeping in mind the current coronavirus situation, but we intend to grow steadily while generating solid figures as we have in Q3.

That's all from me.

Q3 FY2020 Results

Sales and net profit for the period maintained year-on-year despite impact of COVID-19

(JPY billions)	FY2019 Q3 Actual	vs Revenue	FY2020 Q3 Actual	vs Revenue	YoY
Revenue	**182.3**		**181.8**		**-0.3%**
Cost of sales	74.4	41%	75.9	42%	+2.1%
Gross margin	108.0	59%	105.9	58%	-1.9%
SG&A expenses	52.8	29%	51.8	28%	-1.9%
R&D expenses	17.2	9%	17.7	10%	+2.9%
Core operating profit	**38.0**	**21%**	**36.4**	**20%**	**-4.1%**
Non core SG&A expense	--	--	1.0	1%	--
Amortization on intangible assets associated with products	7.4	4%	7.4	4%	-0.4%
Other income	0.3	0%	0.5	0%	+81.1%
Other expenses	1.9	1%	1.3	1%	-32.7%
Operating profit (IFRS)	28.9	16%	27.3	15%	-5.8%
Finance income	0.9	0%	1.0	1%	+16.3%
Finance expenses	0.9	0%	1.1	1%	+34.5%
Share of loss of Investments accounted for using equity method	--	--	0.2	0%	--
Profit before tax	29.0	16%	27.0	15%	-6.9%
Income tax expenses	8.7	5%	6.0	3%	-30.7%
Actual tax ratio	*30.0%*		*22.3%*		
Net profit for the period (IFRS)	**20.3**	**11%**	**20.9**	**12%**	**+3.3%**
Core net profit	27.2	15%	28.3	16%	+4.2%
USD (JPY)	108.87		105.96		
EUR (JPY)	121.06		122.34		
CNY (JPY)	15.66		15.38		

- **Revenue:** Maintain flat year-on-year level in spite of the COVID-19 impact and the Japan NHI drug price revision
- **Core OP** Decreased year-on-year due to COGS increase (product mix changes)
- **Net profit for the period (IFRS):** Increased profit due to the decrease of other expenses and tax burden rate

Koshiji: This slide shows the cumulative results for the third quarter of this fiscal year.

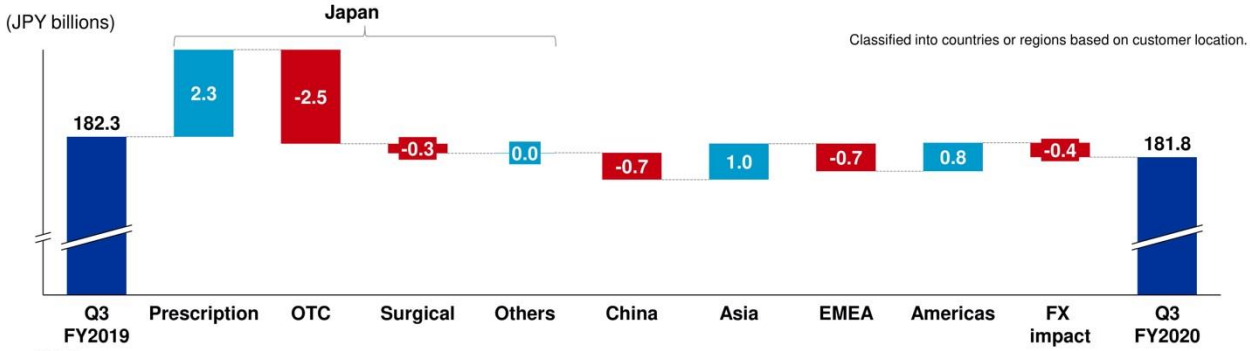
As explained earlier by the CEO, although there is an impact from the coronavirus pandemic, sales have been steady. Both sales and profits have been maintained at almost the same level as the previous fiscal year.

As you know, for the full fiscal year under review, we forecast a 1.7% decline in sales, a 4% increase in core operating income. However, sales are expected to remain almost unchanged and core operating income is expected to decrease slightly. With regard to internal budgets and the progress of plans, both sales and profits are moving at a faster pace than anticipated.

With regard to the items at the bottom, the quarterly profit basis section, here we see an increase of 3.3%. This was due to other expenses or financing costs, which were lower than in the previous year, and a reduction in tax rates. This was due in part to one-time tax effects, but the combination of these effects resulted in the results shown below.

Q3 FY2020 Revenue (YoY)

Japan Rx led the sales increase despite the impact of COVID-19



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 Cravit VBP and COVID-19 (-4% excluding FX impact)
- Asia: Korea and Taiwan, which are recovering from the COVID-19 outbreak, led the increase in sales (+8% excluding FX impact)
- EMEA: Solid sales led by glaucoma products despite the negative impact of COVID-19. (-3% excluding FX impact)
- Americas: Increase sales on contribution from Eyevance products (+126% excluding FX impact)

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

This slide shows a breakdown of sales. The left-hand side shows the cumulative sales for Q3 of the previous fiscal year, from which the respective breakdown is shown on the right-hand side.

As described in the second column from the right, there was no significant impact of foreign exchange rates for the current fiscal year. For details, please see the breakdown below.

FY2020 Forecast (Unchanged from May 8th)

Aim to achieve earnings forecast by expense control despite some factors for uncertainty

(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		

The full-year earnings forecasts for FY2020 are unchanged from the May 8 announcement.

However, with regard to changes in assumptions, Eyevance, which was acquired in Q2, has been included in the scope of consolidation in Q3 and Q4 of the fiscal year under review. Although there will be a sales contribution in the current fiscal year, it is negative on a profit basis. Even if it recovers within this fiscal year, we still aim to realize the results and core operating profit forecast at the beginning of the fiscal year.

The coronavirus pandemic has continued for longer than we anticipated in some regions. While such unforeseen factors may occur, including the annual pollen counts in Japan, which also have an effect on sales, we aim to respond to these uncertainties by controlling costs and securing our core operating income.

That is all for my explanation.

STN1011700 / DE-117: Acceptance of NDA Submission in US

Aim to provide a new option for glaucoma patients in US

- Submitted NDA with the data of a total of 12 clinical studies including four P3 studies (3 being US pivotal)
- One US and one Asian pivotal study met their primary endpoints, while one additional US study did not.
- P3 study data in US and Asia planned to be disclosed in H1 FY2021
- PDUFA date: November 19, 2021

List of STN1011700 clinical studies for NDA submission in US

	Region		Purpose
Spectrum-4	US	P3	**Pivotal** (non-inferiority v.s. timolol maleate)
Spectrum-3	US	P3	**Pivotal** (non-inferiority v.s. timolol maleate) & Long-term safety
PEONY	Asia	P3	**Pivotal** (non-inferiority v.s. latanoprost)
AYAME	Japan	P2	Dose finding
		P3	Pivotal for Japan (non-inferiority v.s. latanoprost)

	Region		Purpose
PK	Japan	P1	Human pharmacokinetics
	US	P1/2	Dose finding
	US	P2	Dose finding
	US	P2b	Dose finding
Spectrum-6	US	P2	Dose frequency finding
RENGE	Japan	P3	Long-term Safety
FUJI	Japan	P3b	Study in latanoprost low/non-responder patients
Spectrum-5	US	P3b	Study in latanoprost low/non-responder patients

Morishima: Thank you.

First, before looking at the table showing the development pipeline, I will say a few words about the development status of *Eybelis* eye drops in the US and the status of clinical development in China.

In November 2020, we filed the NDA with the US FDA for approval of STN1011700, which is marketed as *Eybelis* eye drops in Japan. The application has been accepted, and is currently under review based on the PDUFA process. We are anticipating completion for November 19, 2021.

In the review, we submitted data from a total of 12 clinical trials, including 4 Phase III trials. Two of the three trials that count as pivotal trials in the US have achieved their primary endpoints. Data on these pivotal trials conducted in the US and Asia will be disclosed in the first half of next fiscal year.

Topics in China Clinical Development

Promote the clinical development of STN2000100 and STN1007603

STN2000100 / DE-128 — Glaucoma implant device *PRESERFLO MicroShunt*

- Initiate unapproved medical device use program at Boao Super Hospital in the Hainan Boao Lecheng International Medical Toursim Pilot Zone
- **Successful first surgeries** operated on January 9, 2021

STN1007603 / DE-076C — Vernal keratoconjunctivitis *Verkazia*

- **Listed** in the third batch of **urgent unmet clinical needs list**
- Confirmed **clinical trial waiver** in China (post-marketing clinical study required)

In this slide, we introduce the clinical development topics in China.

Regarding *PRESERFLO* MicroShunt, two MicroShunt operations were performed as part of a program for the use of unapproved medical devices. They took place on Haina Island, which is designated as a special medical area in China. Although this does not automatically lead to MicroShunt approval, we expect this to support development in the PRC in the future.

The other topic is *Verkazia.* *Verkazia* has already been marketed in Europe and Asia as a treatment for vernal keratoconjunctivitis, a serious allergic disease often found in children and young people. It has the development number STN1007603.

This was added to China's list of new overseas drugs urgently needed for clinical purposes. The selection for the list was made by the National Bureau of Pharmaceutical Control and the National Health Commission. Drugs selected see expedited approval and launch.

In fact, with regard to Verkazia, although we are required to conduct post-market clinical study, we have confirmed the clinical study waiver before filing in China. With this drug as with others, we will continue to vigorously promote development in China.

Current Status of Research and Development

Pipeline / product development (1)

As of January, 2021
Updated information is underlined

	Dev. code	Indication	Region	Status
Omidenepag isopropyl *EYBELIS*	**STN1011700** DE-117	Glaucoma / ocular hypertension	US	Filed in November 2020 *Plan: FY2021 approval*
			Japan	Launched
			Asia	Approved *Plan: launch in February 2021 in Korea*
Sepetaprost	**STN1012600** DE-126	Glaucoma / ocular hypertension	US	Started additional P2 in December 2020 *Plan: FY2022 additional P2 completion*
			Japan	P2b (dose finding study completed)
Glaucoma implant device *PRESERFLO MicroShunt*	**STN2000100** DE-128	Glaucoma	US	Completed PMA rolling submission *Plan: ~H1 FY2021 approval*
			Europe	Launched
			Asia	Filed *Plan: FY2020 approval*
			Others	Filed in October 2020 in Canada *Plan: FY2021 approval*
Netarsudil dimesylate *Rhopressa*	**STN1013900** AR-13324	Glaucoma / ocular hypertension	Japan	Started P3 in November 2020 *Plan: FY2023 P3 completion*

I will now move on to the current development pipeline.

First, as I mentioned earlier, the NDA was filed for STN1011700 in the US in November. We anticipate that it will be approved by November 19, 2021. In addition, we are proceeding with submissions in Asian countries. In South Korea, we launched the product on February 1.

Next, STN1012600 has been in-licensed from Ono Pharmaceutical and is being developed as a glaucoma treatment. An additional Phase II trial was commenced in the US in December. The details of the plan are not yet ready for announcement, but we are continuing to consider clinical trials in Japan.

The next item is the *PRESERFLO* MicroShunt, STN2000100. We have completed the pre-marketing approval application in the US, and are in the process of negotiating with the FDA. We anticipate that it will be approved by the first half of FY2021. We also filed an application in Canada in October, and expect approval within the fiscal year.

A Phase III trial for STN1013900, or *Rhopressa*, was started in Japan in November, following agreement of a licensing contract in October. The trial is scheduled to be completed in FY2023.

Current Status of Research and Development

Pipeline / product development (2)

As of January, 2021
Updated information is underlined

	Dev. code	Indication	Region	Status
Atropine sulfate	**STN1012700** DE-127	Myopia	Japan	P2/3 *Plan: FY2023 P2/3 completion*
			China	*Plan: FY2021 P1 start*
			Asia	P2 (met primary endpoint)
Diquafosol sodium (long-lasting) *Diquas*	**STN1008903** DE-089C	Dry eye	Japan	P3 *Plan: FY2021 P3 completion*
Sirolimus (intravitreous injection)	**STN1010900** DE-109	Uveitis	US	P3 *Plan: FY2022 P3 completion*
			Japan	P3
			Europe	P3
			Asia	Filed

We begin to commence Phase I trials in China for STN1012700 in FY2021. This is a medication with the possibility to curb the progress of short-sightedness in children.

STN1008903, which is sold as *Diquas* in Japan and Asian countries, is undergoing Phase III trials with a new formulation in Japan. We expect to be able to reduce the number of eye drops per day, which will greatly reduce the burden on patients. The trial is scheduled to be completed in the next fiscal year.

Current Status of Research and Development

Pipeline / product development (3)

As of January, 2021
Updated information is underlined

	Dev. code	Indication	Region	Status
Tafluprost / timolol maleate (combination) *TAPCOM / TAPTIQOM*	**STN1011101** DE-111A	Glaucoma / ocular hypertension	China	P3 *Plan: FY2023 P3 completion*
Latanoprost	**STN1013001** DE-130A Catioprost	Glaucoma / ocular hypertension	Europe	P3 *Plan: FY2021 P3 completion*
			Asia	
Intraocular lens *Lentis Comfort*	**MD-16**	Cataract	Japan	Launched in November 2020

- STN1013800 (RVL-1201); The company is planning to start clinical trials for blepharoptosis in FY2021 in Japan and also considering the filing in Asia with data used for US approval.
  Licensing region / Japan, China, Asia and Europe
- STN6000100 (jCell); The company is planning to start clinical trials for retinitis pigmentosa in FY2021.
  Licensing region / Japan, China, Asia and Europe

Patient enrollment has been delayed for the China trial of STN1011101, which we sell as *TAPTIQOM* in Japan, Asia, and Europe. Completion of Phase III trials is expected to be delayed from FY2022 to FY2023.

MD-16, the *Lentis Comfort* lens for astigmatism, was launched to market in November.

We previously announced the launch of STN1013800 eye drops for blepharoptosis, as well as STN6000100, the cell therapy for retinitis pigmentosa. We are currently formulating a plan to commence clinical trials within the next fiscal year. We will inform you as soon as the clinical trial plan is finalized.

That concludes my presentation of the development pipeline. Please be aware of the fact that there is an ongoing possibility of delays to clinical trials and other research activities due to the coronavirus pandemic.

Question & Answer

Q1-1

In the fifth slide, regarding *Hyalein* in China, it is stated that there will be a limited impact on performance from the next period. Does this mean that the Company's sales of *Hyalein* will not drop so much?

A1-1

Taniuchi: There are three drugs: a *Hyalein 0.3% multi-dose, Hyalein 0.1%* and *0.3% mini*, , and the current bid is for the *Hyalein 0.1%* and *0.3% mini*. The *multi-dose 0.3%*, which accounts for the majority of sales, is outside the scope of the V.

Hyalein 0.1% and *0.3% mini* are more centralized purchases, but the associated sales to large hospitals are, in the first place, a small proportion of sales. The majority is sold to pharmacies, private hospitals, and retail. Sales in these areas will be completely unaffected, so the overall impact is very minor. It will be something in the region of 10%.

Q1-2

Understood. Thank you very much.

Secondly, regarding *Eybelis* in the US, what is your sales strategy for this product? Are you planning a partnership, or selling exclusively though Eyevance?

A1-2

Taniuchi: We will decide on exactly how to sell at a later date. As you know, there is of course the Eyevance platform, so the strategy for the future will be how best to use this platform for glaucoma medications. Rather than partnering, we plan to first use Eyevance and expand it in this way.

Q2-1

Thank you.

Could you give us some idea of how to consider the impact of the mid-year revision of drug prices in Japan?

I think it was mentioned before that the difference between the drug price and the actual price difference for a lot of your eye drop products was small, so I took that to mean that price revisions would have little impact. Since target medications have included those where the difference is 5% or more, it seems that there are some medications of your Company included as well. There seems many of your product borderline.

I have heard there has already been an unofficial announcement. Could you please comment on this?

A2-1

Taniuchi: Regarding drug prices, we cannot provide details yet, and there are no indications in particular about this, but essentially, our understanding is that there is no change in the trend for ophthalmology treatments.

In the future, as the details of drug prices are coming out, I think we can communicate a little more, but I think that you will understand that there is no significant change.

Q3-1-1

Thank you. I am partly asking to confirm, but regarding MicroShunt in the US, would the approval be in the first half of FY2021? Would it be correct to say that this is fairly certain? Previously, I think there were some observations that it would be by around March.

A3-1-1

Morishima: I cannot comment on the status of the review by the authorities. However, due to the impact of the coronavirus pandemic, the response by the authorities has been delayed, so we have reported that it will be delayed a little.

We have not had any information suggesting any issues with the data themselves.

Taniuchi: We do not have an exact timeline for the inspection at present.

Q3-1-2

For the GMP(Good Manufacturing Practices)?.

A3-1-2

Taniuchi: Yes, for inspection. The site inspection, moving is reltricted. The other party is in the same situation. It is not just our Company, but operations as a whole have stopped, and if everything starts up again, (the approval in) the first half of the year could be a possibility.

Q3-2

Understood. Regarding the earnings forecast, neither the core nor the full has been changed.

I think it was a $225 million acquisition when Eyevance was acquired, but I think it was mentioned that there was a negative impact on core operating profits after consolidation in the second half of the fiscal year was roughly JPY500 million. Looking at the so-called "full," the hit seems to be that the amortization of goodwill will now come to around JPY20 billion.

I was not able to sort out how long this was coming in because I didn't have enough time to look at the results in detail, so I would be very grateful if you could tell me.

A3-2

Koshiji: Okay. First of all, on the core side, the initial negative figure of JPY500 million as a hit in core operating income cannot be ruled out from the possibility that the negative figure will swell somewhat beyond this figure. This is a result of the prolonged coronavirus pandemic, as well as other factors.

For amortization of goodwill and core products, however, there is a possibility that the amount of amortization of intangible assets related to products, which are disclosed here, will increase further. However, regarding the PPA relating to goodwill and intangible asset amortization, this will be done in Q4. In the case of goodwill, there is no amortization burden, but there is a possibility that the amortization of intangible assets amount will increase.

However, as I mentioned earlier in the R&D pipeline, the timing of MicroShunt approval is also reflected in other expenses or part of finance costs, and this is due to changes in the likelihood of provisions for future contingency payments. In this respect, we believe that we can sufficiently secure the bottom. That's it.

Q4-1

Thank you very much. Regarding the progress up to Q3, sales are steady, but profit is somewhat weak, and various factors in Q4 were mentioned.

Is it a bit behind in the sense of profit when it comes to the internal assumptions up to Q3?

On the other hand, in Q4 there were several risk factors mentioned, such as pollen count or Eyevance, but the top line seemed to have a slightly less positive factor, so would it seem that the basic idea would be to cut costs to meet the profit forecast?

A4-1

Koshiji: Thank you.

In the first three quarters, the speed of progress towards our budget targets was fast. Relative to that, Q4 is fairly weighty. We anticipate that joint sales with Mitsubishi Tanabe Pharma, for example, or the pollen counts, will have a similar impact as last year.

In that respect, regarding the question of whether sales were weak, I mentioned some factors of uncertainty, but in fact, sales were JPY181.8 billion through to Q3 of the current fiscal year. For the full fiscal year, the Company's forecasts are JPY235.0 billion, which means that QTD is only JPY53.2 billion in Q4. I think that the figure may be a little stronger, exceeding JPY235 billion by perhaps JPY1 billion.

Later, I mentioned that the cost of sales ratio was rising slightly on page 10. The cost-of-sales ratio has been slightly higher in the past few years. I think it will be close to 38%, so sales will increase and equal gross profit will increase compared to the results forecast. We have fully anticipated the situation here. By saving SG&A expenses, the Company believes it can firmly secure the forecast on a core operating profit basis.

So I've mentioned the uncertainties, but we may actually go beyond the top line that’s written here.

Q4-2

Okay, thank you.

One more thing, a simple answer is fine, but I believe Dr. Shams is leaving the Company. Do you expect this to have any effect on your Company? Can you comment on the reason at all? Will this have any influence on your positioning as a global development leader?.

A4-2

Taniuchi: That was a little while ago. He had joined the Company about 10 years before, and he worked for about 10 years to contribute to the globalization of our R&D.

There are no major effects on our thoughts regarding R&D. This is an usual generational change, with the next leader of Reza and Peter. This is a planned process in the next stage of global organization and no more than that, just an ordinary part of human resources.

Q5-1

Thank you.

Firstly, I would like to ask about DE-117. I appreciate that the data will be released in the future, but given one study did not meet the primary endpoint this time, how is it that there is sufficient data for application this time? I would be grateful if you could comment on that.

In addition, if you have any information related to the expected scale of sales, could you comment on that?

A5-1

Morishima: Thank you.

We met with the FDA in advance, and received comments regarding consideration of the total risk and benefit in a comprehensive manner. On top of this, the FDA also responded that for this pivotal trial, although one study fell short of the endpoint, there was enough there to justify an application.

We believe that this drug is extremely valuable, and the FDA has accepted the information.

Regarding diseases, I think that we will proceed in the future, but as we have been advised, FDA is to think comprehensively about risks and benefits in this area.

Taniuchi: Later, in terms of sales, although we are still not in the stage of talking about sales planning, we think we can anticipate strong sales.

Q5-2

Ueda: Thank you very much. The second question is about the impact of COVID-19. In particular, what kinds of items in Asia and China have been irregular in the current fiscal year? Could you please comment on this point, such as the question of what sorts of areas will recover when the coronavirus pandemic settles down?

A5-2

Morishima: We will talk about this in more detail tomorrow.

This is not limited to China, but at the outset, surgery stopped worldwide. This is recovering now, including in China, but there was a time when operations stopped worldwide for more than three months. The use of related drugs for *Eyela* in Japan stopped, as it did in China.

In general, the situation is stabilizing and returning to normal, but in China, the market is shifting more and more toward online pharmacies and private-sector insurance as the trend toward digitization progresses. The market is shifting more and more toward online pharmacies and private-sector insurance. Drugs used in outpatient visits have been relatively robust, and I hope that they continue to perform well. Rather, I think they are moving with the feeling that paradigm shifts have already occurred, regardless of the coronavirus pandemic.

So the number of the operation declined for a while, but it has returned, but it is now more outside.

Since glaucoma is a global, chronic condition, changes to the market here are relatively independent of changes in outpatient appointments. This situation is similar in China, and as with *Tapros* and other products, there is steady growth.

Q6-1

Muraoka: Hello. I would like to confirm about *Hyalein* in China.

In the opening presentation, it was mentioned that *Hyalein 0.3%* was 70% of the sales, which means that the mini is 30% of the total.

However, in the explanation given just now in the Q&A, you said that the effect on sales would be about 10%, and I cannot reconcile those figures. Could you please tell me more about the relationship between the numbers?

A6-1

Taniuchi: First of all, these two sales account for 30%, but I would say, about 30% of sales are in the VBP centralized purchasing market. So, 30% of 30% gives us about 10%.

The remaining sales are, for example, sales of *Hyalein 0.1% mini* in pharmacies or private hospitals. Although it accounts for 30% of sales, only about 30% of those sales are affected, which is about 10% of the total.

Q7-1-1

Thanks. Regarding the US FDA MicroShunt site inspection, where is the site for which inspection is delayed? What relaxation in movement restrictions would result in access to the site being improved?

A7-1-1

Taniuchi: It is at Santen's InnFocus Inc. facility in Florida.

Q7-1-2

So, this isn’t a cross-border traffic issue.

A7-1-2

Taniuchi: Yes, that's right.

Q8-1

Thank you very much. I would like to ask one question regarding China.

This is regarding the *Hyalein* products, of which 70% do not lie in the scope of centralized purchasing. Why are they outside the scope of centralized purchasing?

A8-1

Taniuchi: This is something that the authorities have decided on, so it is not something that we are able to comment on. As for what will happen in the future, the authorities will make a decision on that, so I we are not able to comment.

However, in general, both *Cravit* and *Hyalein* have been products that have supported growth up to now. In the future, we are working on how to shift growth to the next new product or market growth, such as glaucoma, while continuing to protect the value of its components. We hope to see continued growth of *Cravit*, *Hyalein* in the future.

Q8-2

The second question is about DE-127 for myopia, the Phase I trial for which commenced in China. Could you tell us about the development plan, future prospects, anticipated completion of the Phase I study, and when the next study phase is expected? Could you give your opinions about the timeline here, and also about expectations for the Chinese market?

A8-2

Morishima: The developmental status will be disclosed at a later date. We are currently in negotiations with the government, so we will make an announcement when possible.

Taniuchi: We are closely watching what will happen in the future, as the market is still virtually unchanged. Conversely, we are considering how to create a market in this area. In short, it is not about building products in markets where we have something to do and taking a share, but rather about how we can work together with policymakers to create these markets in response to the myopia problem that the country is currently trying to tackle, or how we can contribute to prevention of myopia for people in China. We are hopeful about this in the future. I will discuss this in more detail tomorrow.