

Investor Meeting on Q2 FY2018 Results – Summary Transcript

Investor Meeting on Q2 FY2018 Results



Shigeo Taniuchi
President & COO

November 7, 2018

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[Speaker: Shigeo Taniuchi] We would like to start the earnings report meeting for the first half results, FY2018. First, Taniuchi will give you an update.

Santen's Values and Mission Statement



Values

天機に参与する

*Tenki ni sanyo suru*¹

¹ “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.

2

I will explain Santen's consolidated first-half results for FY2018, which were announced yesterday, November 7th. First is our values and mission. As we always explain, Santen's Values are described in 'Tenki ni sanyo suru'. By focusing on ophthalmology, we contribute to the well-being of patients, their loved ones and consequently to society. That is our mission, and Santen continues to do business under this philosophy and mission.

MTP2020 Fundamental Policy and Strategic Goals



This shows our MTP2020, our midterm plan from 2018 to 2020. The fundamental policy is to realize our long-term vision of becoming a specialty company with a global presence and to construct a path for sustainable growth beyond 2020. We aim to do the following, as shown on the slide. We aim to increase customer satisfaction, profitability, and organizational capability by (1) making progress in our global business strategy; (2) enhancing our product pipeline and developing new treatment options; and (3) raising the strength, speed and efficiency of our organization. Since our announcement in June, I visited many sites in Asia, EMEA, US, in the various business units and at headquarters. I directly explained this plan. We have been rolling out activities to share and cascade this MTP2020 message in the organization. In order to deliver this plan, we had very active discussions and by realizing this plan, we hope to continue to contribute in global ophthalmology, in a sustainable manner.

We work as one team. All the members in the organization, 4,000 colleagues, are working all together. And in Japan and Asia and EMEA, we have been able to outperform the market growth, as will be explained in detail later. DE-117, *EYBELIS*, ophthalmic solution was approved in Japan in the first half for launch in the second half. In the US, clinical trials of DE-109 and DE-117 are starting and we are preparing for that. And so, we are making good progress in pipeline enhancement. So far, we had very good start for MTP2020.

Q2 FY2018 Financial Results ended September 30, 2018

Now, I will explain a summary of consolidated business results, up to the cumulative second quarter, FY2018.

Q2* FY2018 Financial Overview (year-on-year comparisons)

Higher consolidated revenue as strong growth from overseas business more than offset certain negative factors in Japan

OP made steady progress toward annual forecast, while the amount was relatively unchanged YoY

| | | |
|------------------------------|--|--|
| Revenue | In Japan, revenue growth of key products was achieved, though nearly flat overall due to transitory factors. Continued strong growth was generated from overseas businesses, particularly Asia, leading to overall consolidated revenue growth. | |
| | 114.3 bil yen | YoY: +3.2% |
| Operating Profit (OP) | Strong growth from overseas business offset by Japan transitory positive factors in prior period and negative impacts in current period, resulting in relatively flat OP YoY. Steady progress toward annual forecast both in core basis and IFRS OP supported by cost control efforts. | |
| | Core basis 24.1 bil yen | IFRS basis 20.8 bil yen |
| | YoY: -1.0% | YoY: -1.0% |
| | SGA 33.5 bil yen YoY: +5.7% | R&D 11.0 bil yen YoY: -6.6% |

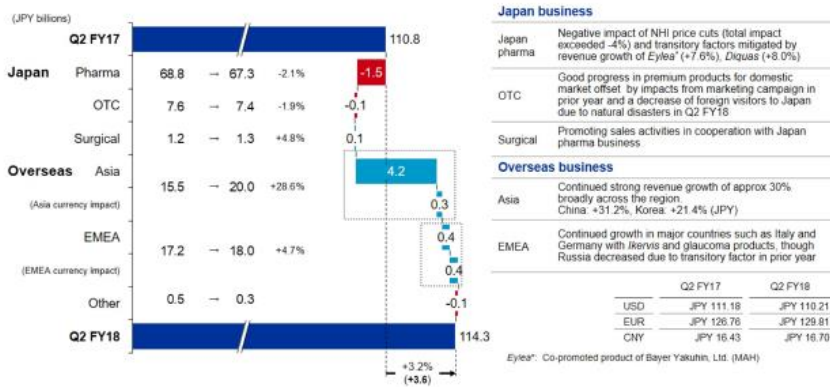
Notes: *Santen results herein describe Q2 results cumulatively as the six month period ended September 30, 2018. A summary profit and loss statement can be found in the Appendix.

First, revenue. Domestic sales were flat from the same period last year. *Eylea* and *Diquas* sales continued to grow but there were some impacts including a one-off channel inventory adjustment. And as you know, there was NHI price revision in April. So, for domestic sales, we had almost flat results. On the other hand, growth in overseas businesses in Asia and EMEA could offset this negative impact. As a result, overall sales went up 3.2% or about 3.6 billion yen from last year.

For operating profit, there were one-time factors in Japan and also the COGS ratio increased, due to NHI price revision and product mix. But they were offset by overseas business growth and cost control in various businesses and functions. As a result, core operating profit, showing the operating profit from our core business, as well as the IFRS base full base operating profit, were both more or less flat from last year. Core OP was 24.1 billion yen and for IFRS base OP was 20.8 billion yen. Although the comparison to the same period last year shows flat growth, against the full-year target, we have made good progress as planned, both on the core basis and full basis.

Q2 FY2018 Revenue

Japan business generally in-line with projection; Overseas business above Q2 FY17 and projection

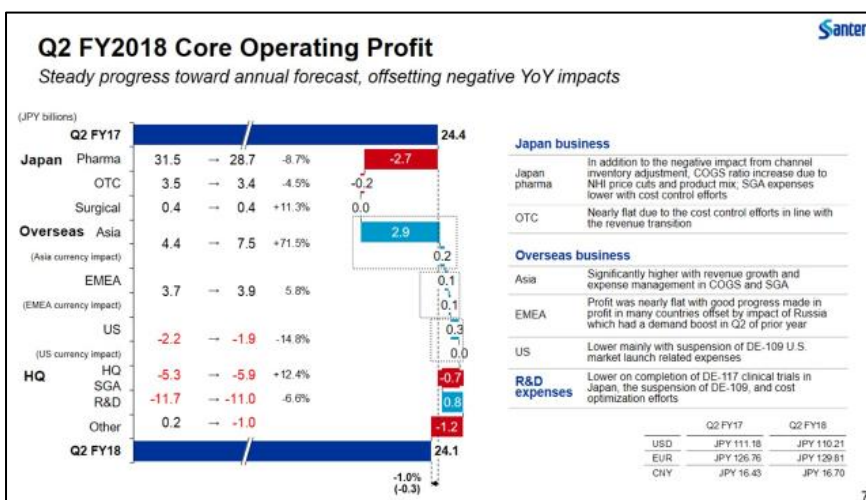


You can see more detail of the factors impacting sales after the second quarter by business segment in comparison to last year. Japan Pharma business sales, as I mentioned before, slightly decreased from last year because of the one-time factor of channel inventory adjustment and NHI price revision. But, some key products, such as *Eylea* and *Diquas* continued to grow. Excluding one-time factors, such as NHI price

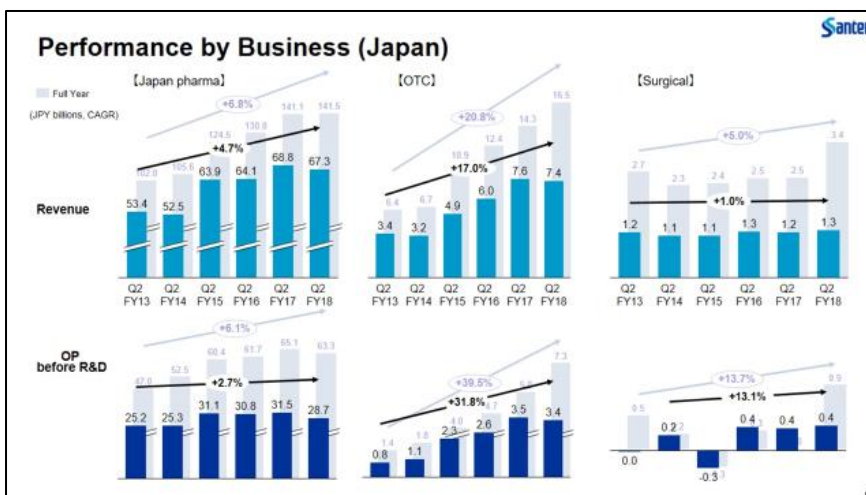
revision, underlying sales went up by about 5%.

For OTC business, there was a negative impact from marketing campaign last year. And as you know, there was a transient decrease of inbound demand due to natural disasters. But they were offset by good growth of domestic premium products and we had some earlier launching of products. So, the results were more or less flat.

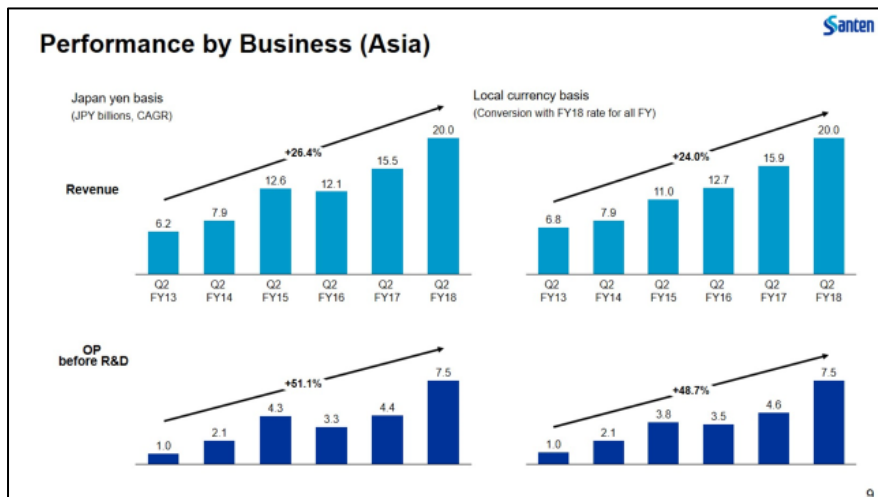
Overseas, first of all, Santen continued to expand its presence in Asia. On a yen basis, sales in China grew 31.2% and Korea grew 21.4% from last year. In EMEA (Europe, Middle East, and Africa), by focusing on glaucoma and dry eye products, we continued to grow in key markets although some countries were impacted by one-off factors from last year, including some discontinuation of low-margin products. But, in many countries, we had very good underlying growth. As a result, sales were up 3.2%, or 3.6 billion yen, from last year, to mark overall sales of 114.3 billion yen.



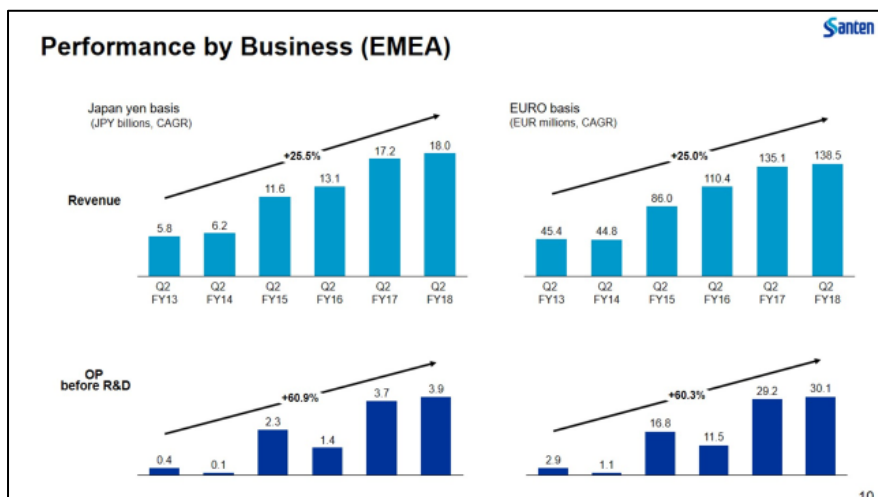
This shows core operating profit. For the domestic business, of course, we worked very hard at controlling SG&A costs. But, because of the decrease in sales, as was explained, operating profit went down slightly. Asia enjoyed more than 70% growth in profit, thanks to increased sales and a lower COGS ratio. EMEA business continued to enhance presence, but the profit was more or less flat, due to the one-off impact of Russia's strong demand from last year. In the first half, domestic business had some significant negative factors, but they were offset by overseas businesses. Overall results were 24.1 billion yen, almost flat from last year. And this is in line with our full-year target announced in May.



This slide compares the first half results from FY2013 to FY2018, both in domestic sales and operating profit before R&D. The FY2018 first half results showed some decline because of impact from negative factors. But we are actually making good progress to achieve the target for the year. We will continue to focus on realizing market potential and capturing strong demand to achieve sustainable growth.



Next is the business performance in Asia. As before, Santen products continue to penetrate Asia, outperforming the market growth. In China and other countries in Asia, we continue to expand geographical coverage. Through registration and launching of more than 30 products every year, we have tried to address local medical needs. And we deliver our products to the patient's in these areas. Last year, *Diquas* for dry eye was approved in China, and shipments started in China in September. We are making further efforts and contribution from these activities. We will make stepwise growth for further mid to long-term growth.

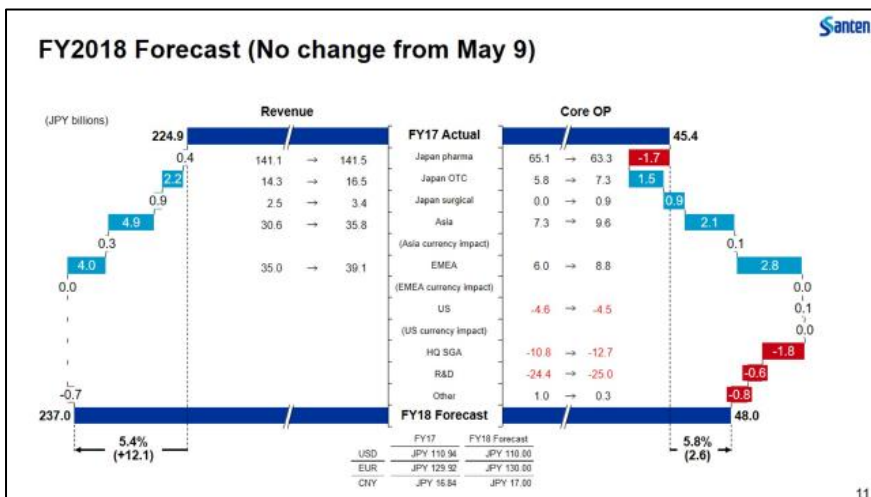


This is EMEA business performance. Growth continues, driven by strong market demands for glaucoma products and so on. And the soft launch of the DE-128 (*MicroShunt*) has been initiated and is making progress.

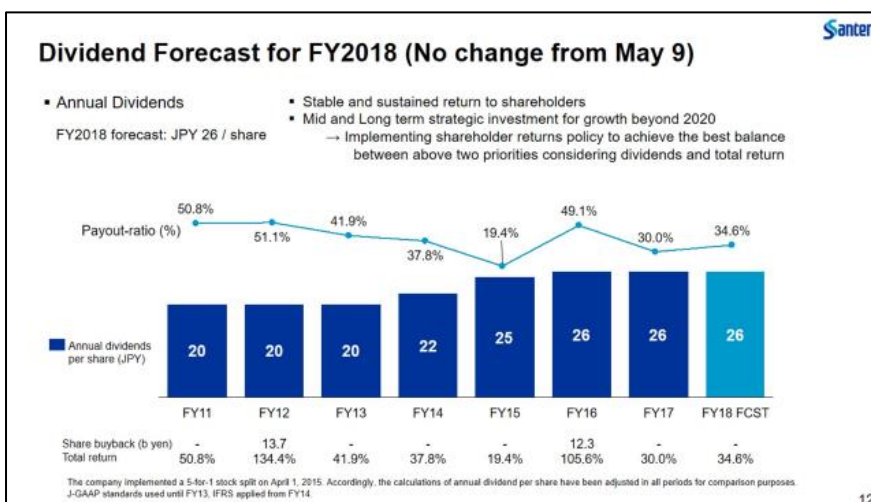
In July, DE-076C has obtained manufacturing and marketing approval in Europe as an ophthalmic solution for symptomatic alleviation of vernal keratoconjunctivitis. Vernal keratoconjunctivitis is an orphan disease

and this is a mainly pediatric refractory severe allergic conjunctival disease, or keratoconjunctivitis disease. Being a rare disease, with small patient population, no therapeutics have been ever developed for this disease in Europe before, and this agent was launched in late October in the UK, after getting approval. And, we have brought new therapeutics to those rare diseases, especially children and family members suffering from such diseases. We believe this is a quite unique achievement for the Santen Group, developing drugs to respond to clinical needs as a company specialized in ophthalmologic.

And *Ikervis* sales are growing too. We execute our strategic marketing programs with customer satisfaction as a core value to further penetrate these products, to expand our presence in EMEA.



And this is the fiscal year 2018 forecast. And 237 billion yen of revenue and 48 billion yen of core operating profit remain unchanged since our May 9th announcement. And year-to-date results show smooth progress versus the forecast.



And lastly, this is the dividend forecast for FY2018. The annual forecast is 26 yen per share, remaining unchanged since our May 9th announcement. That's it for the outline of the second quarter of FY2018 business results.

EYBELIS Ophthalmic Solution 0.002% Approval in Japan, World's First Selective EP2 Receptor Agonist for Glaucoma

Increasing number of new patients suffering visual impairment from glaucoma in Japan¹⁾ → Demand for new treatment options

→ **EYBELIS** : **New MOA in glaucoma treatment**
→ **First new mechanism of action for 1st-line medicine approved in Japan in nearly 20 years***

- **Significant IOP lowering effect²⁾**
Demonstrated non-inferiority to latanoprost in a clinical trial where primary endpoint was IOP lowering
- **Stable maintenance of IOP lowering for 52 weeks³⁾**
Demonstrated that *EYBELIS* stably maintains efficacy and the combination therapy with timolol enhances efficacy for 52 weeks in a clinical trial
- **IOP lowering for non/low-responders to other mechanism of action⁴⁾**
Demonstrated significant effect in non-/low-responders to other mechanism of action after switching to *EYBELIS*

*Since latanoprost launch in 1999. In Japan, prostaglandin analogues and β -blockers are used 1st-line drugs in glaucoma treatment. Latanoprost and timolol are respectively classified prostaglandin analogue and β -blocker.⁵⁾

1) Morizane Y, et al. Jpn J Ophthalmol. 2018 Sep;25.
2) A Phase III/III Study of EYBELIS Ophthalmic Solution in Subjects With Primary Open Angle Glaucoma or Ocular Hypertension. Santen Pharmaceutical Co., Ltd. Internal document (that assessed for approval in Japan).
3) A Long-term Open-label Phase III Study of EYBELIS Ophthalmic Solution Monotherapy and Concomitant Use of EYBELIS Ophthalmic Solution With Timolol Ophthalmic Solution in Patients With Open-angle Glaucoma or Ocular Hypertension. Santen Pharmaceutical Co., Ltd. Internal document (that assessed for approval in Japan).
4) A Phase III Study of DE-117 Ophthalmic Solution in Subjects With Primary Open-angle Glaucoma or Ocular Hypertension Who Are Non-Low-responders to Latanoprost Ophthalmic Solution. Santen Pharmaceutical Co., Ltd. Internal document (that assessed for approval in Japan).
5) The Japan Glaucoma Society Guidelines for Glaucoma (4th Edition) / Nippon Ganka Gakkai Zasshi. 122(1): 5-53, 2018.

And now, I would like to briefly explain about *EYBELIS* ophthalmic solution for glaucoma and ocular hypertension treatment, approved in Japan in September. In Japan, the number is rising of those newly recognized officially as visually impaired due to glaucoma. Thus, even though we already have products in the market, a new treatment option is always in demand. And, *EYBELIS*, newly approved for manufacturing and marketing in Japan, is an ophthalmic solution with a selective EP2 receptor agonistic effect, which is the world's first EP2 targeted MOA (mechanism of action) for glaucoma and ocular hypertension treatment. The approval was the first new MOA therapy option in Japan for about 20 years since the launch of latanoprost in 1999. In the clinical trial, non-inferiority of *EYBELIS* ophthalmic solution of 0.002% has been validated versus latanoprost solution, 0.005%. And IOP (intraocular pressure) has been confirmed to stay stabilized for as long as 52 weeks. And, IOP lowering effect has been demonstrated to non- or low-responders of other agents. And there are so-called non- or low-responders to such agents and glaucoma treatment, is always a problem. And we believe it makes a significant contribution to glaucoma patient offering a new treatment option.

And of course, having launched such an agent that has a new mechanism of action, we will proactively collect and disclose information on safety, making every effort to promote proper usage and grow this agent as the world's first glaucoma and ocular hypertension therapeutic born in Japan, also developing elsewhere. This concludes my presentation.

Pipeline / Product Development Status (1)

As of November 7, 2018

| | Indication | Region | Status |
|---|---|--------|---|
| DE-117 <i>EYBELIS</i> EP2 receptor agonist | Glaucoma / ocular hypertension | US | Started P3 in Sep 2018 <i>Plan: Jan-Jun 2020 P3 completion</i> |
| | | Japan | Approved in Sep 2018 <i>Plan: Nov 2018 NHI price listing and launch soon after</i> |
| | | Asia | P3 <i>Plan: 2nd half FY2018 P3 completion</i> |
| DE-126 FP/EP3 receptors dual agonist | Glaucoma / ocular hypertension | US | P2/3 |
| | | Japan | P2b |
| DE-128 <i>MicroShunt</i> | Glaucoma | US | P2/3 <i>Plan: Calendar 2018~2019 P2/3 completion, Calendar 2020~2021 launch</i> |
| | | Europe | CE mark granted |
| DE-109 IVT sirolimus | Uveitis | US | P3 <i>Plan: Nov 2018 additional clinical trial start</i> |
| | | Japan | P3 |
| | | Europe | P3 |
| | | Asia | Filed |
| DE-122 Anti-endothelin antibody | Wet age-related macular degeneration | US | P2a <i>Plan: Jan-Jun 2019 P2a completion</i> |

[Speaker: Naveed Shams] Good afternoon. Please allow me to speak in English. I will give you an update on our pipeline of products. There is much to talk about, some of which you've just heard from Taniuchi-san. So, we'll start with DE-117. DE-117 in Japan is referred to as *EYBELIS*. It was approved in September and we are currently in price negotiations before we launch this product. In addition to the approval and launch of this product in Japan, we have started three clinical trials in the United States. DE-117 is a selective EP2 receptor agonist with two large pivotal trials, and another pivotal trial to look at the response of non-responders. Those trials are currently ongoing.

Next, I think, in the same space, is DE-126, which is in Phase 2b at this time. DE-128, which is our flagship device for glaucoma patients is moving according to plan and we will stick to our commitment of launching in calendar somewhere 2020 ~ 2021.

DE-109, sirolimus for noninfectious uveitis of the posterior segment is going to start the third trial this month. It is ready and posted on relevant websites. We are looking forward to completion of this third trial as soon as possible and this continues to show our commit to the uveitis space, as well as to sirolimus and the mTOR target. DE-122, the endoglin receptor antagonist, is in Phase 2, and we look for data some time in the January-June timeframe of 2019.

| Pipeline / Product Development Status (2) | | | Santen As of November 7, 2018 |
|--|---|------------|--|
| | Indication | Region | Status |
| DE-089 <i>Diquas</i> | Dry eye | China | <u>Launched in Sep 2018</u> |
| DE-076B Cyclokat / <i>Ikervis</i> ciclosporin | Severe keratitis in patients with dry eye | Asia US | Launched P2 |
| DE-076C <i>Verkazia</i> ciclosporin | Vernal kerato-conjunctivitis | Europe | <u>Launched in Oct 2018</u> |
| DE-114A epinastine HCl (high dose) | Allergic conjunctivitis | Japan | <u>Filed in Sep 2018</u> <i>Plan: Jul-Dec 2019 approval</i> |
| DE-127 atropine sulfate | Myopia | Asia | P2 <i>Plan: 2nd half of FY2019 P2 completion</i> |

Updated information is underlined. See Santen Consolidated Results for more details.

Next, *Diquas*, which was approved earlier in China was recently launched. And as of September 2018, this also is going to, I hope, play a major role in support of the Santen business in China. The cyclokat *Ikervis* program, as you heard, is doing well, making good progress. And a variation of that product profile is now launched, as *Verkazia* in Europe. Epinastine (DE-114A), which is, again, a key product that the R&D team has reformulated, tested and seeks approval. It was filed in September this year and we are looking for approval somewhere in the middle to end of 2019. DE-127 is our myopia program. Myopia is a big problem in many parts of the world, especially Asia. And so, we are expecting results from this Phase 2 trial that we started in the second half of fiscal 2019.

I look forward to addressing any questions you might have. Thank you very much.

Question & Answer Session

Q-1-1

First question is for Asia business. And the reason why you had very good business in Asia. This year, there was a review of reimbursement in China that may be impacting. And is this really from the core business growth? And against the midterm plan, it seems there is some upside growth as I see it so far. And, what are the reasons for this upside?

A-1-1

Taniuchi COO: Thank you very much for the question. The reason for the good business in Asia, China is the biggest factor. As mentioned, *Hyalein* - this product is enjoying good growth. As was mentioned, there was a review of reimbursement in China and the competitor's product went off the list. And that increased our share. So, that's one of the reasons for the growth. It is exceeding our plan. But underlying growth has been already strong, and we are accelerating the growth against the medium-term plan. And we expected good results and so far, we even have very good growth. But I think going forward, it might sort of settle down. But, still, we would enjoy good growth going forward and *Diquas* is another driver. It's in the dry eye category and we want to capture this important opportunity in the dry eye area.

Q-1-1-2

Thank you very much. Regarding the review of reimbursement list, before it was five years and seven years cycle, but this year it's going to be reviewed in a few years and this competitive advantage will continue for the next few years is in your expectation?

A-1-1-2

Taniuchi COO: Well, the central government's review will come a bit later. So, I think, for the time being, this situation will continue. But for the province-level, there would be some changes, updates and reviews. We will watch the situation carefully, and for *Diquas* we will continue our sales promotion. And we hope to enjoy good, steady growth for the time being.

Q-1-2

Please explain about DE-109 study design and what about it gives you confidence.

A-1-2

Shams CSO: Although we did not apply for protocol assistance from the FDA, we had very good conversations with the agency before finalizing the study design. We believe the placebo arm is going to be helpful to clearly identify the effect from the active compound.

We believe that this drug should get to the market as soon as possible because the unmet need is significant, that's why we have a shorter duration (3 months). The FDA agreed that one injection at baseline and one two months later would be sufficient to determine the efficacy of the product. As for safety, we have a lot of data that has been accumulated over the program.

The study will be six months in duration but the primary endpoint is at 3 months. Our goal is, of course, for

this study to be successful and we believe this design will be helpful to this.

Q-1-3

Thank you very much. My last question is R&D expenses for the next year. What is your idea regarding this point? Phase 3 for DE-117 and DE-109, you have more trials in the US and you have 25 billion for R&D expenses. Do you think you can manage? Or do you think there will be an increase in R&D spending?

A-1-3

Koshiji CFO: As of now, our outlook for this year is unchanged. It is possible that some factors could increase expenses by about 1 billion yen, that would be the range of increase. Big differences vs plan in R&D expenses versus sales or absolute amount are not anticipated for FY2019 and FY2020.

Q-2-1

My first question is about OTC inbound in Japan. In Osaka, there are many Chinese visitors coming back. But in Hokkaido, they are having a difficulty to get more Chinese tourists and, what is the status right now? In coming January next year, there will be more restriction for the purchasing for somebody else. And so, please discuss your expectation for that too.

A-2-1

Taniuchi COO: As to the inbound, the purchasing, currently, and centering in Osaka area, we have been impacted by the order of a hundred million yen. And I don't know how long it will continue. It's difficult to forecast. But it seems like inbound sales might stay rather low compared to before. But overall, we are launching new products with higher or premium priced products aimed at the domestic market. And therefore, we do not think we will have a large impact overall. Further, the changes to rules in China about purchasing activities relating to ophthalmic solutions are unclear so difficult for me to comment.

Q-2-2

DE-109, the primary completion if February 2021. Will it take so long to recruit patients? And has the inclusion criteria about severity level changed? And is this a special protocol assessment (SPA) or not?

A-2-2

Shams CSO: We will have a reading center involved in order to make sure that we get the right patients into the study. This is critical to our success. However, unfortunately, it may slow down some of the recruitment as we get very good patients into the trial. That is the driver of the timeline. The inclusion criteria have not changed and yes, this was agreed to with the FDA. The only difference is that we have added the reading center assessment which removes any bias in patient recruitment. This is not an SPA. But as I mentioned, we have had deep discussions with the FDA before finalizing the protocol.

Q-2-3

In the third trial of DE-117 (Spectrum 5) for non-refractory patients, it seems it will not be included in the submission package – why not?

A-2-3

Shams CSO: Our first objective is to provide the medicine to patients as soon as possible. The idea was not to exclude the third study but to register quickly with the data we have. If data becomes available, we will consider a complete package. If it's not available, it should not slow down the approval process.

Q-3-1

What about China development? Your pipeline chart says "Asia" – but does this include China or not? I ask this because I would like to know, for example what is your development plan for example, regarding DE-117 in China or elsewhere in Asia?

A-3-1

Shams CSO: At this moment, development of DE-117 for China is not underway. However, unlike in the past when the IND approval process was very long, that is changing and so our working assumptions have changed as well. That means that now when develop a product, we consider China as a major potential market for Santen. We will develop products to meet the business needs in China. We will have to do a program in China for China, but we will have a lot of data to support it.

Q-3-1-2

So, now that *Diquas* has been launched in China - you do not have any ongoing projects there now?

A-3-1-2

Shams CSO: We have plans going on in China such as the *Tapticom* study. But for the new products we have been talking about China is included in the planning but we simply have not started the activities of any new China projects. But don't misunderstand that China is excluded from our plans – it's just a matter of priorities and goal setting.

Q-3-1-3

My third question is about budget control. I understand you're very strict in budget control and to bring the products fast, in the best, fastest way in China may be difficult. And if you continue, should I expect any changes in corporate culture? Or do you think it's possible to accept some exceptions because China is a growing market?

A-3-1-3

Taniuchi COO: Basically, as Naveed Shams mentioned, going forward in the new Chinese regulatory environment, we want to accelerate our plan in China, may be standalone or as a part of global. That means

we tried to have earlier development, not necessarily always wait until the development is completed in the developed countries. So, we want to accelerate the process in China as well.

Q-4-1

You haven't announced how these results compare to your mid-term financial results. But, *Hyalein* in China and also others are growing, and you're having some problems with OTC, maybe. But I think you are in line as you scheduled. But if you have any ups and downs, please tell me.

A-4-1

Koshiji CFO: We haven't disclosed the mid-term number and compared to the budget, are there any ups or downs, as you have just pointed out, in Asia there is much better result for both revenue and operating profit in the second quarter. And as to the major downside is, as has been pointed out, and the OTC business, and due to the natural disaster and also, due to the slowing down of the inbound sales. These are giving negative impact to the progress. And, as to other factors, in the domestic business and European business, both of them are progressing as to the plan.

Then what happens in the whole year base, and when we look into the balance between the first and second half, and in the latter half, there is overweight for all the spending and the revenue. Therefore, the profitability gets slightly smaller. However, as far as this fiscal year is concerned, compared to the regular year, we are going to suppress more of the spending. Therefore, in the second quarter, on a core operating profit basis, we have reached 50% of the progress. And towards the second half, we think we can make a good start. And we believe that we can also grow very smoothly in the latter half of the year too.

Also, net income is progressing ahead of plan due to tax levels.

Q-4-2

My second question is about *EYBELIS*. In Japan, you said this could be the first-line treatment. Of course, the price assumption will be determined after the price negotiation is over. But, including in Japan and also elsewhere, if there is any, and if you have any image of the peak sales, please tell me.

A-4-2

Taniuchi COO: At this moment, in the United States and in Asia, we are considering how to carry out business there, depending upon the result of the clinical trial and therefore we do not have any specific numbers to tell you at this moment. It's too premature to say that. But, for Santen, we have many products, MSD products and others for glaucoma and those are the very important pillars for our business. And we have *Taptiqom*, or Tafluprost. Naturally, glaucoma is a very important and central pillar for us. Therefore, in Asia, and also, in the United States, we would like to make glaucoma pillars of the business in those areas too.

Q-4-3

For DE-109, is the 2021 completion estimate conservative or aggressive?

A-4-3

Shams CSO: 2021 is a reasonable expectation for completion.

Q-5-1

I'm not going to pick up on your wording. But, my question, Mr. Taniuchi, you mentioned soft launch in the EU, controlled launch was the used words and it was provided free, and it means, soft launch means some revenues. And when is the timing for the hard launching?

A-5-1

Taniuchi COO: Thank you very much for remembering my words from last time. A controlled launch is not free of charge, given we actually sell to the clinical trial sites as a continuation of supply. Now, this time the soft launch expands provision toward the hard launch – creating a base for such a launch. We identify more than 100 sites and the provision of the products is expanded. In September this year, there was an academic meeting of ophthalmologic operations and as we introduced this product for more broad-based ophthalmologists. And we will promote our sales and marketing and training of doctors. And we also expanded infrastructure for that. Hard launching timing would be, of course, we need to look at the situation in market and we are looking at 2020 or 2021 launching, in line with the US launching.

Q-5-1-2

What will the FDA require for the follow-up period for DE-128 as a device?

A-5-1-2

Shams CSO: Currently, the agreement with the FDA for the follow-up period is two years. And our time schedule we have given is based on that agreement.

Q-5-2

Thank you. My last question. Page 9 and 10, you show the graph there. That is here. So, Asia is good. You are enjoying good growth and this slide shows it very well. Profit margin in EMEA is much lower than the growth in Asia. OTC and of course, domestic R&D needs to be covered. And so, it may look very high, or big. But you are thinking, or reviewing, more profitability, to boost profitability in Europe. In order to have investment in US, you need good source for investment. Is there any room for improvement or profitability in Europe? And this is, if it's core base, then intangible amortization is not included. So, whether this slide includes that or not.

A-5-2

Taniuchi COO: Regarding the last question, in Europe, the slide does not include amortization – it's not broken down that way. For the Asia business, first of all, recent profit before R&D was 7.5 billion yen. And

there are some one-time factors here. *Hyalein* which has very low COGS exceeded our expectation. That pushed profitability and for Asia, as Koshiji mentioned. In the second half, the expenses would be more shifted in the second half. So, in the first half, you have big numbers for various reasons.

As you mentioned, for the European business had profitability challenges, we think there is room for improvement. First, regarding manufacturing cost for the past few years, with tech transfer to sites in Japan or China, we have been doing that. And so far, we are seeing some of the procedures completed. And while there will be some delay, the profit contribution will happen. During the medium-term plan, we will start seeing some good contribution. So, COGS improvement first. That's the first step and that's what is being done. And organizational optimization and cost efficiency have also begun. We invested for the startup of those initiatives. SG&A ratio should be well controlled with good targets. That's what we are doing locally. Also, from headquarters, we are watching this very carefully. In Asia, there is also room for efficiency improvement and we want to further improve profitability there. So, for overseas business, we are aware of areas to improve.

Q-6-1

I have a question. I have heard the overall financial results and also, there is growth in Asia, as you have pointed out. And, profit before R&D is 7.5 billion in Asia. And as you have explained, and if we look into the main products, that would include *Hyalein* growth of 60%, *Cravit* 22% growth. So, excluding Asian, declines were all offset by the Asian growth and after the depreciation and you're still growing. What I want to say is that the Asian profit margin is 37.5% and increased by 10 points. And it revenue is growing very nicely. And *Hyalein* is growing by 60%. So, will future growth be somewhat diluted? Am I correct to interpret in such a way?

A-6-1

Taniuchi COO: As to the supply capacity, China is growing as we have expected. And we are making capital investment in China, as well as in Japan, to increase capacity. The production in China will shift to a high-speed line and we are now making the necessary investments. But this will not increase the production cost. And production cost stays flat. We would like to switch to the high-speed line so that we can secure the capacity. And that is how we cope with the increasing demand in China.

Q-6-1-2

Thank you. And *Hyalein*, 60% growth in Q2 is due to the drop out of the competition. And so, the whole year growth will be more like 24% to 25%?

A-6-1-2

Taniuchi COO: Yes. That would in the right range.

Q-7-1

I would like to ask about MDPF, multidose preservative free product. In Europe, you were saying that some

containers will be brought to the market. And when would that be? And would that be something in the pipeline? Is it possible to see this development in one way or another?

A-7-1

Taniuchi COO: From our sales, multidose MDPF containers, are currently being used for *Cosopt* and *Tafuprost*. Depending on the country we either got approval or we just started launching. And in Asia, we are preparing for that and we need to go through regulatory steps. We don't have the timeline yet. But, in the mid-term we want to introduce those products in Asia. It is true that it's not mentioned in our pipeline. So, we should improve on that. Thank you for your opinion.

Q-7-1-2

For multidose products, you have various containers and they are not really prevalent. It's not user-friendly. That's my perception. But your product has improved on that?

A-7-1-2

Taniuchi COO: Well, as of now, in Europe, we start having products using this type of container. But it's only to a certain portion of all products. The reason is, for unit dose is dominant and, in that case, regarding the switch acceptability in the market is not so strong. And there are various filters in the container and unique sterilization method. So, it's not for all the multidose products. For the switch, we need various tests or sometimes because of adhesion issue, you can't do that. So, there are technical limitations. The third point is that the container is more expensive because the structure is more complex. So we need to look at economic value of that and compare to the value to patients. We are assessing that. We are not switching all the products to this type of container. As for convenience, compared to regular multidose containers, it may be a bit hard or you may have a few drops instead of one drop. So, we need to make improvements, in consultation with the container manufacturers. We are making efforts to improve this further.

Q-7-2

Allergan released data about bimatoprost sustained release that suggests sustained IOP lowering, with, I think one patient experiencing lower IOP for even a year after one injection. I think they said they would submit this in the second half of 2019. This could be a competitor for DE-117. I think a partner of yours has disclosed work on a sustained release project. How will you position your future products in this competitive landscape?

A-7-2

Shams CSO: We are aware of this. I believe they will need one more study before filing. I don't see this data as very intimidating. More work is needed in this area. We are continuing to look at the work coming from this project as well as that of other companies in this area. It is in our interest to compete in the space of drug delivery. We will continue to work on different options. The goal is to make this efficacious, safe and patient friendly. Our approach is to test many different ways of delivering the product and then choose the best way

forward. But up to this point, we haven't yet seen anything that is impressive or productive enough in the long run.