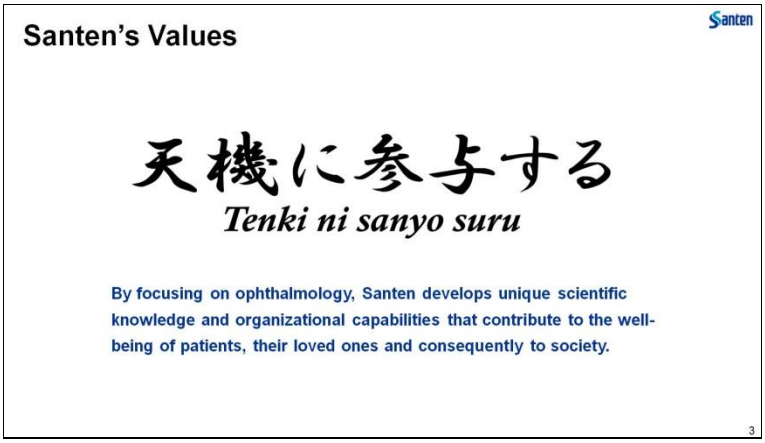
Speaker Remarks February 6, 2018 (summary)

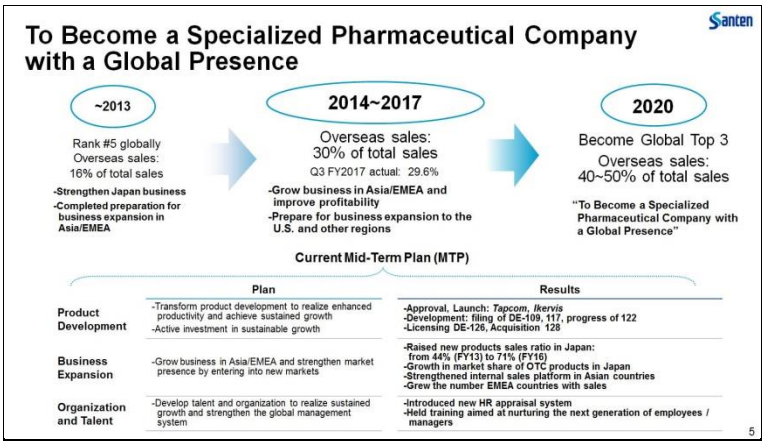
Santen's Financial Results and Status of R&D

Slide 3



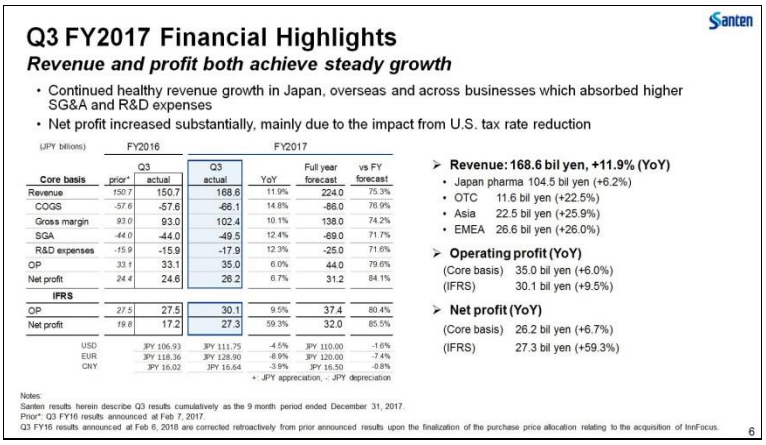
This is Koshiji speaking.
Here we show Santen's Values with an English explanation.

Slide 5



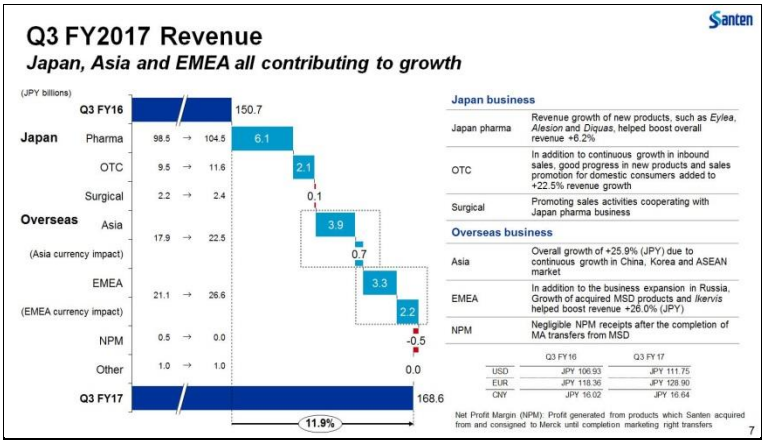
Based upon Santen's Vision to 2020, we are striving to become a specialized pharmaceutical company with a global presence. This is a long-term vision and as a step towards this, we have our mid-term plan from FY14-17 that we have been engaged in with the current year, FY17, as the last year of our mid-term plan – the content of which are described on the slide.

Slide 6



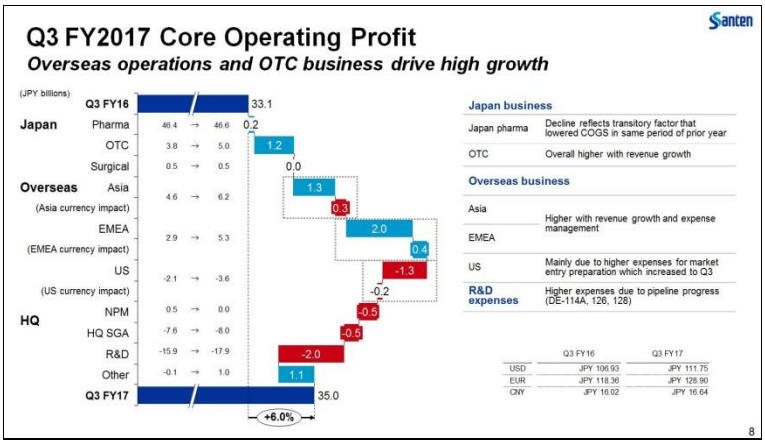
These are our Q3 financial highlights. On the left-hand side, we have provided revenue and profit. Compared to the previous year, revenue increased 11.9%, gross margin increased 10.1%, SG&A increased 12%, R&D increased 12% and OP increased 6%. Those were the core basis figures which shows our operational results. On IFRS full basis, OP increased 9.5% Y-o-Y and net profit increased 59.3%. This is due to the impact of the U.S. tax rate reduction and the tax was reduced on the accounting book and that is the reason behind the 59.3% increase of net profit.

Slide 7



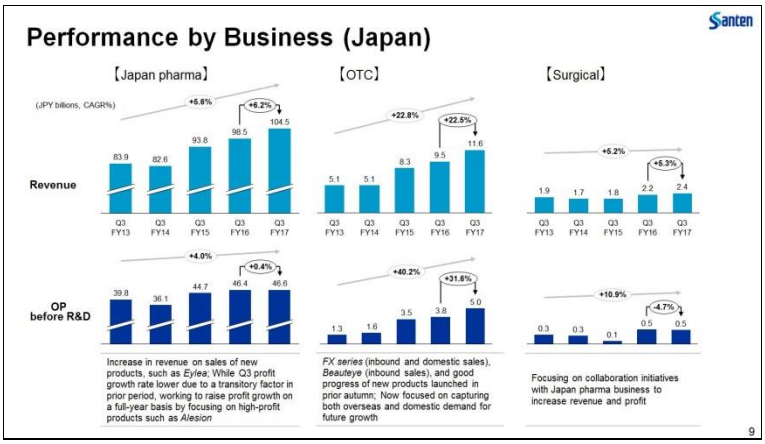
This slide shows the revenue increase of 11.9% and a breakdown of the factors including contributions from both Japan and outside Japan.

Slide 8



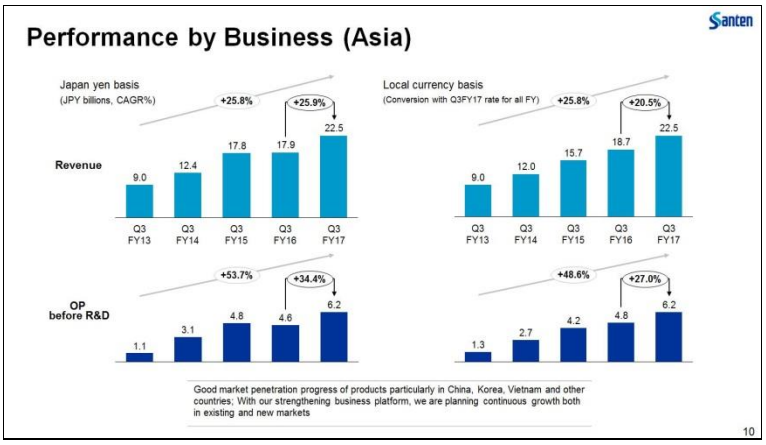
This is our core operating profit breakdown. And likewise, the growth has been very smooth both within Japan and outside Japan, especially in Europe, there was significant growth that also includes some benefit from foreign exchange rates.

Slide 9



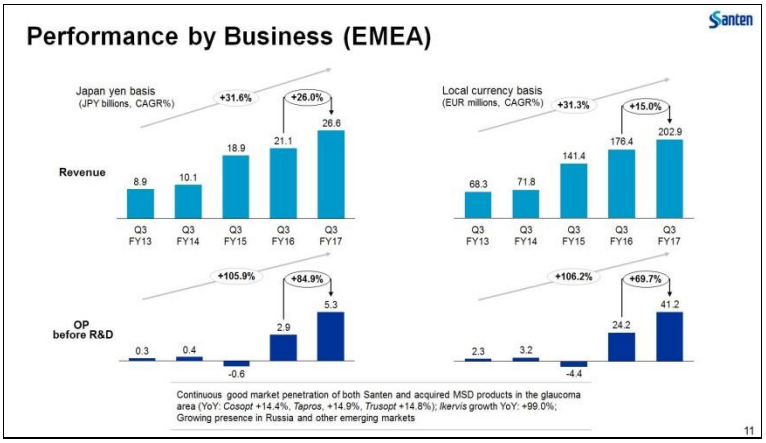
This is the performance by business in Japan. Including Japan Pharma, OTC and Surgical, these are the revenue and also the OP before R&D and you can see the trends of the results.

Slide 10



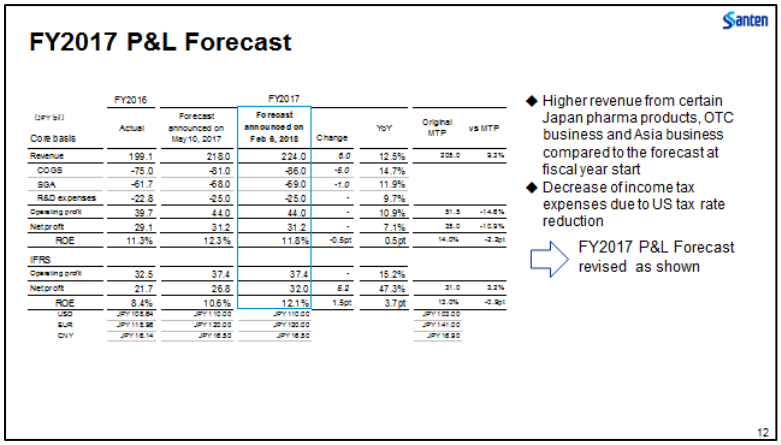
This is our business in Asia. On the left hand side are the Japan yen basis and on the right hand side are the local currency basis results.

Slide 11



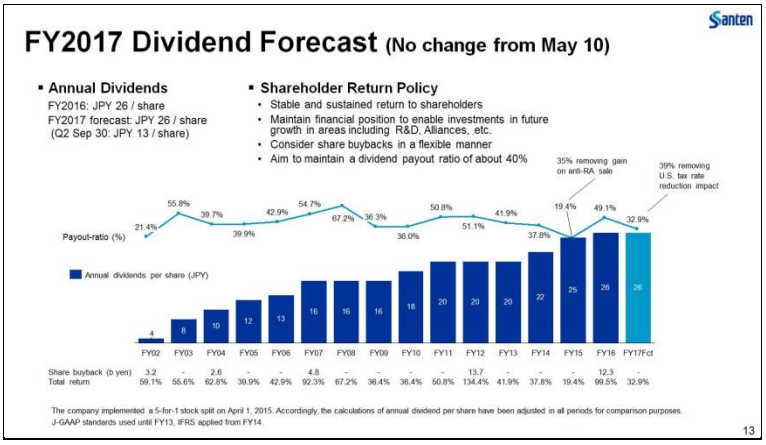
This this is our EMEA business. Shown are revenue and OP before R&D – again on yen basis and local currency basis.

Slide 12



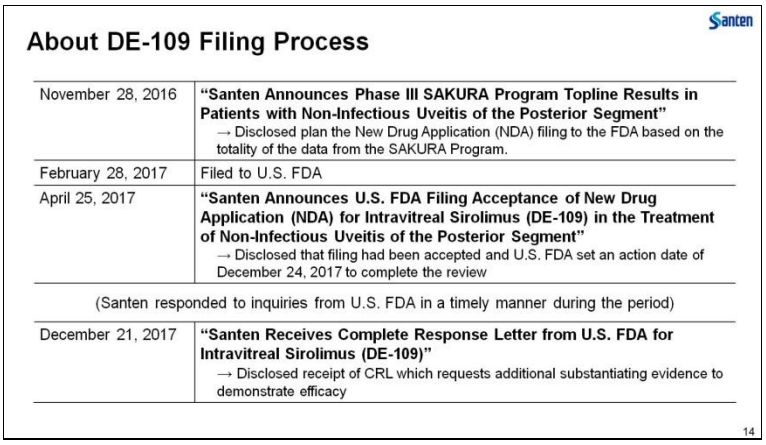
And with Q3, based upon the cumulative FY17 performance shown on slide 12, we forecast our P&L shown here. There have been some changes to revenue and IFRS-based net profit. With regard to our revenue forecast of May 10th last year, what we announced ¥218 billion, that has been changed to ¥224 billion, meaning a ¥6 billion increase. And in IFRS-basis, a net profit, initially was forecast as ¥26.8 billion but now increased to ¥32 billion, an increase by ¥5.2 billion. And the revenue increased due to positive business momentum. And with regard to the IFRS-basis net profit, there was a positive impact by the U.S. reduction of tax.

Slide 13



This is our dividend forecast. This Q3 dividend forecast has not been changed from the initial forecast. Using a simple calculation, our FY17 payout ratio forecast comes to 32.9%, which is below our initial forecast of 40%. However, because the increase in profit is only based on accounting and non-cash, we decided that our stable dividend policy should hold and we decided not to make changes to the dividend. That concludes my remarks about the third quarter results.

Slide 14



And next, I would like to talk briefly about an event during the quarter, which was our December 21st announcement of the receipt of a complete response letter from the FDA for intravitreal sirolimus, DE-109. Feedback from the market
including a drop in our stock price was significant.

In particular, there was a negative surprise based on the difference between our disclosure on April 25th when our filing was accepted and this disappointing result. I am afraid this may have caused uncertainty which may still exist.

Therefore, as we have said, we are reviewing the CRL and plan to work with the FDA to determine what steps including possible additional data needed to address the FDA's concerns. While we have no updates on this today, I
wanted to explain the background in more detail.

As a person in charge of IR, let me explain to you the process that we have experienced to this day. On page 14 of the handouts, press release and the process is cited. First of all, on November 28, 2016, we announced Phase 3 SAKURA program top-line results in patients with noninfectious uveitis of the posterior segment. Findings from SAKURA Study 1, the first Phase 3 trial, established the efficacy and safety of *Opsiria* as a potential treatment.

In SAKURA Study 2, the second Phase 3 trial, the difference in the effect between the low dose of sirolimus injection and *Opsiria* was not statistically significant, though clinical findings provided supportive evidence confirming the efficacy of the product. As a result, Santen planned the new drug application filing to the FDA and based on the totality of the data from the SAKURA program. In particular, Santen most emphasized that the Study 1 and Study 2 consistently showed statistical significance in the majority of subjects where

mild subjects are excluded based on the data from baseline visual acuity, retinal thickness and oral corticosteroid.

Later, we submitted our filing on February 28, 2017 and disclosed that our filing had been accepted by the FDA on April 25th of the same year. At that time, we recognized that the application was accepted, including integrated data of Studies 1 and 2. Since March 31, 2017, we have been supplying data and samples and answering questions as requested by the FDA in a timely manner. Over the period, normal communications, including meetings and e-mails took place.

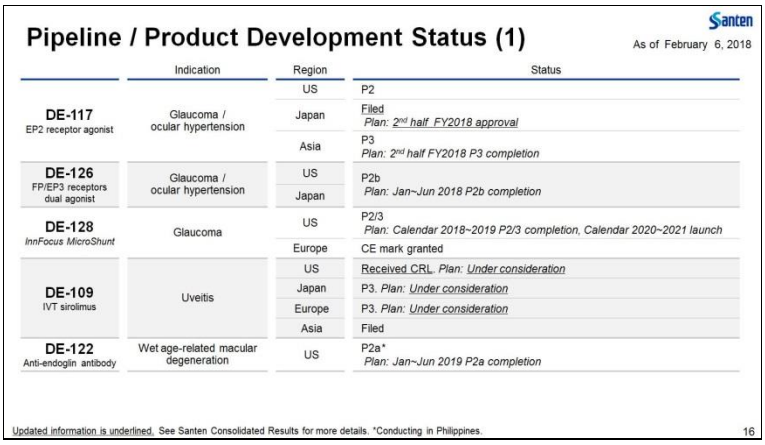
In the October-November months, Santen began to feel a slight discrepancy regarding the FDA's view on our emphasized visual acuity. But it was our view that the review was continuing as expected and based on a belief that efficacy and safety had been established, and therefore, we could only wait for approval and review completion. In the end, we received the CRL on December 21st, while it is not clearly known at the present time what additional information will be necessary to confirm efficacy, we will confirm in a planned future FDA meeting.

This was the DE-109 process from filing to CRL. As disclosed the CRL announced on December 21, is not expected to have a material impact on fiscal year 2017 earnings. Specifically, we planned to have about ¥3 billion in expenses this year versus prior year to prepare for the launch of the product. But a portion of this spending was frozen in the fourth quarter based on the CRL. Also, when ready, we expect to have a similar level of costs in the future related to the sales and marketing of this future product.

At the earnings announcement last May, we disclosed our plan for DE-109 that included reaching $30 million and breakeven profit in fiscal 2020. This impact on the consolidated results of Santen is not significant.

At the same time, from the strategic point of view of entering the U.S. market, the world's largest ophthalmic market, the impact is not small. So later, President Kurokawa and CEO Kurokawa, will discuss our future direction and growth. He will share with us what he can say as of today. That is all from myself.

Slide 16



Pipeline / Product Development Status (1)

Santen

As of February 6, 2018

	Indication	Region	Status
DE-117 EP2 receptor agonist	Glaucoma / ocular hypertension	US	P2
		Japan	Filed *Plan: 2nd half FY2018 approval*
		Asia	P3 *Plan: 2nd half FY2018 P3 completion*
DE-126 FP/EP3 receptors dual agonist	Glaucoma / ocular hypertension	US	P2b *Plan: Jan~Jun 2018 P2b completion*
		Japan	
DE-128 *InnFocus MicroShunt*	Glaucoma	US	P2/3 *Plan: Calendar 2018~2019 P2/3 completion, Calendar 2020~2021 launch*
		Europe	CE mark granted
DE-109 IVT sirolimus	Uveitis	US	Received CRL. *Plan: Under consideration*
		Japan	P3. *Plan: Under consideration*
		Europe	P3. *Plan: Under consideration*
		Asia	Filed
DE-122 Anti-endoglin antibody	Wet age-related macular degeneration	US	P2a* *Plan: Jan~Jun 2019 P2a completion*

Updated information is underlined. See Santen Consolidated Results for more details. *Conducting in Philippines.

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This is Naveed Shams, Head of R&D. I will start with giving you a quick update on first the three IOP lowering agents, then just a brief comment on DE-109 and an update on the rest.

So DE-117, as you know, is a EP2 receptor agonist to lower intraocular pressure, we filed in Japan at the end of last year and we expect approval in the second half of fiscal 2018, which is later in the calendar year.

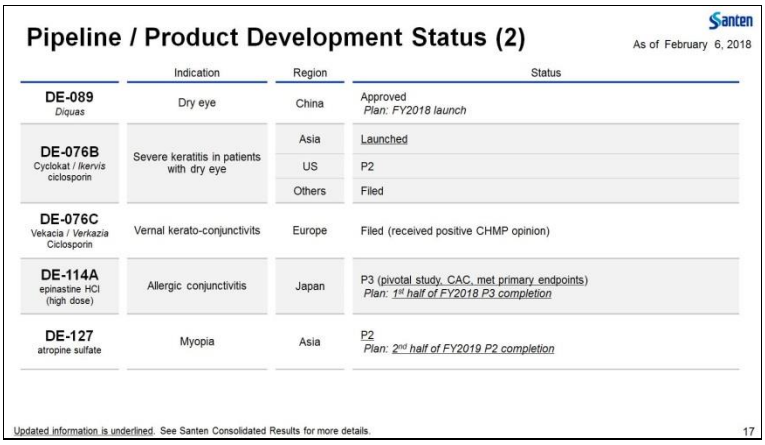
DE-126 is an FP / EP3 receptor agonist again to lower intraocular pressure and it is finishing Phase 2b. We expect a completion by June of 2018.

The market authorization trial for our DE-128 *MicroShunt* device for glaucoma, is running smoothly and we continue to forecast launch in the calendar years 2020-2021 as planned.

DE-109 as you've heard a detailed explanation, I won't go into the details of it, but except to say that we look forward to having a fruitful conversation with the FDA to determine next steps.

Our retina product DE-122 an anti-endoglin antibody is currently in Phase 2, and we hope to see results in sometimes in the middle of 2019.

Slide 17



Pipeline / Product Development Status (2)

Santen

As of February 6, 2018

	Indication	Region	Status
DE-089 *Diquas*	Dry eye	China	Approved *Plan: FY2018 launch*
DE-076B Cyclokat / *Ikervis* ciclosporin	Severe keratitis in patients with dry eye	Asia	Launched
		US	P2
		Others	Filed
DE-076C Vekacia / *Verkazia* Ciclosporin	Vernal kerato-conjunctivits	Europe	Filed (received positive CHMP opinion)
DE-114A epinastine HCl (high dose)	Allergic conjunctivitis	Japan	P3 (pivotal study, CAC, met primary endpoints) *Plan: 1st half of FY2018 P3 completion*
DE-127 atropine sulfate	Myopia	Asia	P2 *Plan: 2nd half of FY2019 P2 completion*

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

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We had mentioned this before the product DE-089 or *Diquas*, this is slide 17 and for dry eye in China was approved and we are planning a launch in fiscal 2018.

Ikervis or DE-076B product for severe keratitis in patients with dry eye, we continue to expand geographically the availability of the product. DE-076C, which is also referred to as *Verkazia*, received a positive opinion from CHMP and we are waiting for European Commission approval.

Epinastine, DE-114A is for allergies. It met its primary endpoint in the pivotal Phase 3 study and we look forward to completing everything by the first half of fiscal 2018 to complete the entire Phase 3 program.

DE-127, which is atropine sulfate for myopia, severe myopia, in Asia is running without a hitch currently, and we continue to forecast looking at the data in second half of fiscal 2019.

And that's all from my side. Thank you very much.

Slide 19

This is Kurokawa speaking. Today, we are explaining the Q3 fiscal year 2017 performance. And with regard to the performance, Mr. Koshiji has already given you an explanation and we have exceeded our plan. Q3 of fiscal year 2017 has had good momentum with good speed and we would like to achieve the objectives of fiscal year 2017 in order to meet your expectations.

At the same time, in the mid and long-term management strategy, there has been some issues causing impact. One is the changes to the Japan NHI price reform system. And secondly, but this is just a Santen issue, as discussed, we received a CRL from FDA related to DE-109.

With regard to the changes to the Japan NHI price reform system, the impact can be said to be significant magnitude, generally speaking. However, as far as Santen is concerned, I don't think there will be an exceptionally large impact. However, as the years go on in the long-term it could have more impact. What I want to say is that in 2018 and 2019 fiscal years, a big negative impact is not expected.

With regard to DE-109 in the United States, the fact that we have received CRL from FDA, was explained fully by Mr. Koshiji about the process and we would like to further discuss with FDA to confirm the content and intent behind the CRL. Based on this, we need to consider our future policy or how to best adapt our strategy. But with regard to our business strategy in the United States, there will be no changes as far as the company is concerned.

The United States is an attractive market for Santen. And with regard to DE-109 and other products like *MicroShunt* and DE-117, which is being developed in the United States right now for treatment of glaucoma, we can say that we can go into the U.S. market with great

differentiation and we have products that are highly competitive. Therefore, our policies for the U.S. market will not change.

With regard to DE-109, the result was disappointing, but the level of negative impact to our business will not be large in general. By responding to the issue in the right manner, we would like to consider how to deliver this good product to the patients in the United States. And as has been said, we want to become a specialty company, we want to leverage our strength as a specialty company and we want to establish our global presence - that is our ultimate objective. In Japan, Asia, and EMEA the growth and the profit abilities level is increasing.

So part of the profit in Japan and in Asia will be used for further R&D and business development. We want to accelerate such growth and also in the United States. With regard to the glaucoma pipeline, we would like to go into
the U.S. market. This is the policy that we will continue to have.

With regard to Vision 2020 and its implementation, that is our goal, of course. And with regard to this policy, we will fund R&D and also improve productivity. And furthermore, business development speed is important to increase our global presence. This will lead to new opportunities to create new businesses as well. And so, we would like to use such speed to further develop the company.

With regard to the strengthening of the personnel in the organization, this is a matter of great need and Santen has been dependent on the Japanese market, but we are developing ourselves globally and therefore global management and personnel development and also the strengthening of the organization is an urgent topic we will continue to improve.

So, we would like to consider the needs of the patients and we would like to compete strongly with our competitors, so that we can become a global company in the true sense. From myself, that is all.

Q/A session (summary) (February 6, 2018)

Q1-1
The forecast for this fiscal year, the change of the forecast, there was a change of ¥6 billion of the sales and *EYLEA* has changed a lot. And on the other hand the COGS of *EYLEA* has been very high and it's very high. So if you can explain how you changed, or the background of those changes?

A1-1
The increase is mainly due to *EYLEA*, our OTC business and Asian business. Some COGS increase was in our Asian business. Also, with the increase of *EYLEA* in our product mix, COGS increased. The COGS of OTC has been 30%. In EMEA, COGS grew slightly on inventory spoilage.

Q1-2
DE-109, well, let me confirm as you have explained, SAKURA 1 and SAKURA 2, the data of those two studies were different. So you combined those two and made it integrated SAKURA. And I understand that you got an agreement about this process by FDA and the situation remains the same or maybe there was no agreement between you and FDA on how to treat the data.

A1-2
Maybe I can try to answer the question. We presented the data to the agency with different analyses. And one of the analyses had to do with integration of the data. However, the decision, while I cannot say for sure because we have not had a conversation with the agency since we received the CRL, was based on the totality of the information presented to the agency, not just one way of analyzing the data. That's my best estimate at this point. But we are waiting to hear and discuss this with the FDA as soon as they can make themselves available to us.

Q1-3
In your presentation you talked about the visual acuity regarding the efficacy, so there may be a difference of understanding as to the visual acuity in terms of the efficacy of the product. About this point, FDA is not satisfied with the improvement of visual acuity is that the problem?

A1-3
This is Naveed. I just would second what Koshiji San just mentioned, it could be premature to say what the agency looked at and what the basis for the CRL was. I think, I would ask for some patience, as soon as we get into discussions with the FDA, we will have clarification. Like I said, as you know, SAKURA 1 and SAKURA 2 had slightly different primary outcomes, and so, we just have to wait for the agency to tell us how they looked at the data. We made our best case. And then, we'll get back to you as soon as we have some clarity on this from the agency, whenever they can make themselves available.

Q2-1
First, with regard to sirolimus. So you say that there was a difference in opinion with regard to visual equity between you and FDA. And what you're saying is in the SAKURA program, BCVA, I think it was about five letters with regard to the range and it's not very large. Is there a difference in that view?

A2-1
I would like to just go back to the point that we don't really know at this point, what exactly was the concern. We, as I mentioned, analyzed the data many different ways for our file to support the efficacy and safety of the product. And we are waiting to talk to the agency about what is the basis for their CRL and after that, I think we can make some next steps and let you know.

Q2-2
With regard to your commitment to the United States market, you said that your policy towards the United States is not changing. And on the 21st of December and after that, I think, there have been various discussions with investors. And as the investors evaluate your company's business in Asia and Europe very highly, I think if you're going to use resources for the United States, investors might want you to favor resource allocation to Asia and Europe - how would you respond?

A2-2
With regard to the future growth expectations, the global presence is what we want to establish to lead us to sustainable growth. That is our belief. The United States is a very attractive market which is growing. Therefore, I establishing a presence in the United States will lead us with a global presence.

Q2-3
And how are you going to implement this?

A2-3
Well, it should be product driven where competitiveness is most important. Marketing in the United States depends on the product. Our Santen R&D is less emphasized on basic drug discovery. Business development is a very important opportunity for us to achieve further growth. And when we consider that, a U.S. presence is very essential. Not to have a presence in the United States, will be problematic when we discuss matters with third parties and so forth.

And sometimes, the negotiation can be very complicated. So based upon this background, the development projects we have today, DE-109 is one of them, but *MicroShunt*, DE-117 and DE-126, these are glaucoma pipeline projects which would be competitive products. Such glaucoma products are critical to our business entry into the U.S. market.

Some people say that we should emphasize the three territories of Asia, EMEA, and Japan. However, when we look at the total Santen business, it can be unbalanced. So the U.S. business, I think, is very important and in fact, necessary.

Q2-4
With regards to the revision of the forecast. I understand about the revenue and the profitability, but in case of costs, you have increased by ¥1 billion and you said in the second half there's not increasing. Yet, in spite of that, you have increased ¥1 billion in terms of cost, why is that?

A2-4
There were sales promotion related costs that is mainly what increased. For the future, upfront investment is being made in a sense, especially in Asia in order to capture the growth opportunity. So, we feel these expenses are valuable to future growth.

With regard to 2017 forecasts, sales forecasts were raised. In Japan, we are expecting the approval of DE-117 and our *Diquas* launch in China is on the way. With revenue growing in Japan, Asia and Europe, our policy is to also implement cost control in order to maximize OP.

Q3-1
I have a question about DE-117. According to your materials, there was a good result from FUJI Study. So in response to these good results, how do you assess the potential of this product, the potential number of patients and the situation of the competitors? And in terms of the global development, including the U.S., I understand that you are starting with Japanese market, but how are you going to expand the geographical market of this product?

A3-1
As to DE-117, we filed this product and are now waiting for approval. As for glaucoma agents, prostaglandin is mainstream today. Among others, we have *Tapros* and, in the market, there are *Xalatan* generics already. DE-117 doesn’t seem to have the side effects that prostaglandins have. As to the potential of this product, we are looking at non-responders of prostaglandin and/or those patients who are having problems or concerns about side effects.

So, DE-117 seems to be a high potential product.

I think this is a very good option for such patients. What is encouraging is the fact that we are launching this product in Japan where we have a number one market share, we have had very good relationships with glaucoma doctors, and are always enhancing product service.

As to potential, it's about 20% of those patients who are having problems with the current products and as for the sales, as we are having the situation related to NHA price change, we cannot say any clear figure, but I think it can be close to *Tapros*.

Some of the products expire in 2022. So given that situation, we have a very high expectation for this product.

Q3-2
As to overseas market what's your plan?

A3-2
As I mentioned, has been successful in Japan and we have high expectations for the U.S. as well with the same concept and the same profile. I think we can satisfy American doctors and we've already gotten market survey results. In the U.S. as well, glaucoma market is a very attractive market and we do not need to change the profile of this product for the U.S. market. So, as to DE-117, we are now considering the global promotion.

Q3-3
About OTC. It's been very successful this year. What about the demand forecast and also the peak sales for the future? And as to OTC year end, what is the situation?

A3-3
As to OTC business, we are now having a big momentum particularly thanks to inbound sales. That's why we're seeing extra sales for this fiscal year. For the full year, our forecast is that ¥14 billion and 45% of that comes from inbound sales. As for the inbound sales, we're talking about tourists, overseas tourists to Japan and that tourists are increasing by 20% to 25% annually. So that ¥14 billion portion, I think, we're going to have double digit growth for foreseeable future.

And as to switch OTC, we are targeting launch in late fiscal year 2018, around October. With inbound, the increase of the existing products and switch OTC, the increase of the sales have come allow us to have a very good forecast. As to switch OTC, we do not believe there

will be cannibalization risk vs the prescription drug. We are expecting ¥1.5 billion and so that would be the increase.

Q4-1
I had two questions, one is with regard to the sales of our glaucoma in the Japanese market, your sales forecast of some products has been shifted downward. And the revenue is going upward but the OP's revision has not been revised so much. And from the first quarter, I believe that there was some slowdown. And how do you analyze this performance of the glaucoma market in Japan?

A4-1
As you have indicated, with regard to *Tapros* and *Timoptol*, we have made a revision. *Tapros* was revised from ¥10.4 billion to ¥9.7 billion. With regard to *Timoptol*, there has been a revision from ¥850 million to ¥790 million.

We have revised the numbers to be more conservative, but the sales figure itself is not facing a drastic headwind. This is mostly just due to a greater level of analysis on our part.

Q4-2
Epinastine is the high dose product, you have met the primary endpoint and what kind of results did you have? If my memory is correct, the administration frequency was reduced and you wanted to prove the non-inferiority to existing product, was that your intent of the study?

A4-2
Yes.

Q4-3
Were there any other positive matters that you were able to prove this time?

A4-3
I think this could be an attractive new product in the future with both differentiation and protection after launch.