

February 5, 2019 Conference Call

Conference Call on Q3 FY2018 Results



Shigeo Taniuchi

President and Chief Operating Officer

February 5, 2019

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Thank you very much. I would like to present the results of Q3 FY2018 (nine months ended December 31) of Santen Pharmaceutical Company, Ltd., which was announced at 3:00 PM today.

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.

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Page 2. As you know, *Tenki ni sanyo suru* is our values of Santen. Our mission statement is that by focusing on ophthalmology, we want to contribute to the well-being of patients, their loved ones, and consequently, to the society. Based upon these values and mission statement, we are developing our business globally.

MTP2020 Fundamental Policy and Strategic Goals



Page 3. This is the outline of the MTP2020, which is a mid-term plan from 2018 to 2020. To become a specialized pharmaceutical company with a global presence, and to construct a path for sustainable growth beyond FY2020 we have our fundamental policies. Profitability, customer satisfaction and organizational strength are to be increased. And based upon that, we want to make progress in our global business strategy, enhance the product pipeline, develop new treatment options, and raise the strength and efficiency of our business framework. We presented this MTP2020 in June and after that, I visited Asia, EMEA, US, and of course, the headquarters in Japan and various other sites in Japan to explain about MTP2020. And we have united as a team to execute this.

As I will be explaining later in detail, from 2018, in Japan, Asia and EMEA, we have been outperforming the market growth. DE-117 (*EYBELIS*) has been approved in Japan. And from the second half, in the United States, DE-109 and DE-117 started their clinical studies. In terms of our pipeline, we have intensified our projects and we have been able to make a good start of MTP2020.

**Q3 FY2018 Financial Results
ended December 31, 2018**

From page 5, this is the Q3 FY2018 financial overview. First, with regard to revenue, in the Japanese market, *Eylea* and *Diquas*, which are our key products, are growing continuously. At the beginning of fiscal year 2018, there was a one-time inventory adjustment and there was impact from the NHI price cut. But these have been absorbed by the growth of our key products.

In Asia and Europe, we are enjoying continuously strong growth. And the consolidated total growth was 4.6 billion Japanese yen, or 2.7% year-on-year. With regard to the operating profit, we have been growing overseas. Also, we have been able to raise cost optimization group-wide. With regard to the core basis operating profit, we were able to earn 35.1 billion yen.

Also, we have been making asset reduction and business reorganization. In the third quarter, the former headquarters and Osaka plant sites have been sold. Due to this sale, we have been able to make a special

Q3* FY2018 Financial Overview (year-on-year comparisons) Santen

Achieved higher revenue with strong overseas growth more than offsetting negative impact from NHI price cut in Japan

(JPY billions)	FY2017		FY2018	
	Q3 actual	Q3 actual	Q3 actual	YoY
Core basis				
Revenue	168.6	173.2	173.2	2.7%
COGS	-66.1	-69.8	-69.8	5.5%
Gross margin	102.4	103.4	103.4	0.9%
SGA	-49.5	-51.2	-51.2	3.5%
R&D expenses	-17.9	-17.1	-17.1	-4.5%
OP	35.0	35.1	35.1	0.1%
IFRS				
OP	30.1	33.7	33.7	11.9%
Net profit	27.3	23.4	23.4	-14.6%

USD	JPY 111.75	JPY 111.15
EUR	JPY 128.90	JPY 129.51
CNY	JPY 16.64	JPY 16.57

Notes: *Santen results herein describe Q3 results cumulatively as the nine month period ended December 31, 2018.

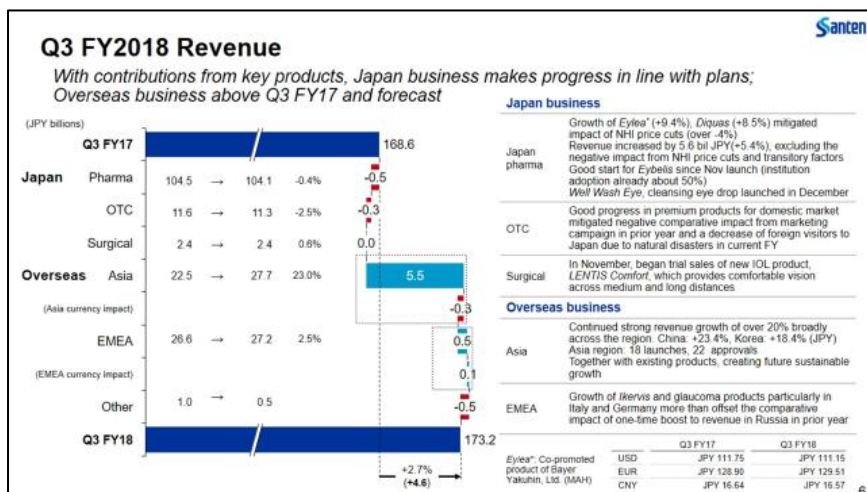
• Revenue
 Japan: Growth of key products absorbed the negative impact from NHI price cut
 Overseas: Continued strong growth, particularly Asia
Consolidated total growth: 4.6 bil JPY (+2.7%)

• Operating profit (Core basis)
Maintained prior year level with continued overseas growth and group-wide cost optimization offsetting negative impact from NHI price cut

(IFRS basis)
 With achievement of asset reduction / business reorganization including gain on sale of former HQ / Osaka plant site, **Increased by 3.6 bil JPY (+11.9%)**
 (Agreed sale of plant and its operations in Finland in Q4 to be accounted for in FY2019)

• Net profit
 Mainly due to one-time benefit of reduced corporate tax rate in U.S. in prior year, **decreased by 4.0 bil JPY (14.6%)**

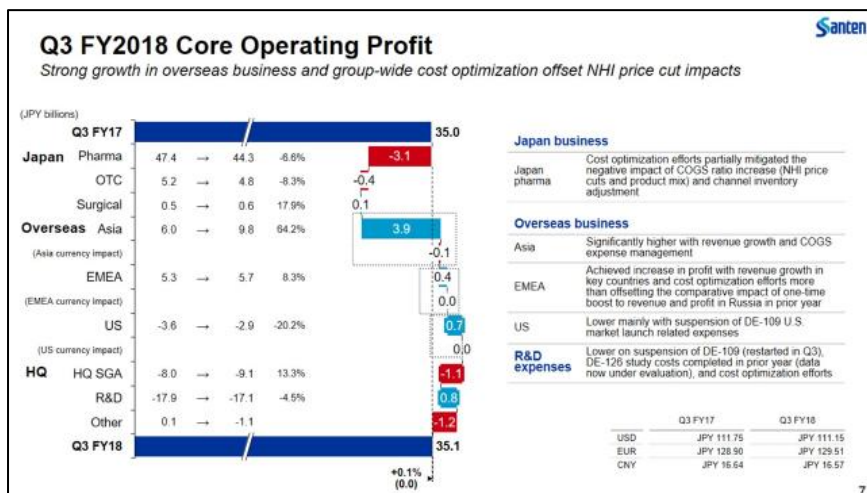
gain and in the IFRS basis, we have incurred 33.7 billion yen of operating profit, which was a 12% increase year-on-year. Also, we have agreed on the sale of our plant and its operations in Finland, namely Tampere Plant, to NextPharma. With regard to the net profit, there has been a decrease by 4 billion yen. But this was due to one-time benefit of the reduced corporate tax rate in the United States in the previous year. Toward the annual forecast, both revenue and operating profit are making good progress.



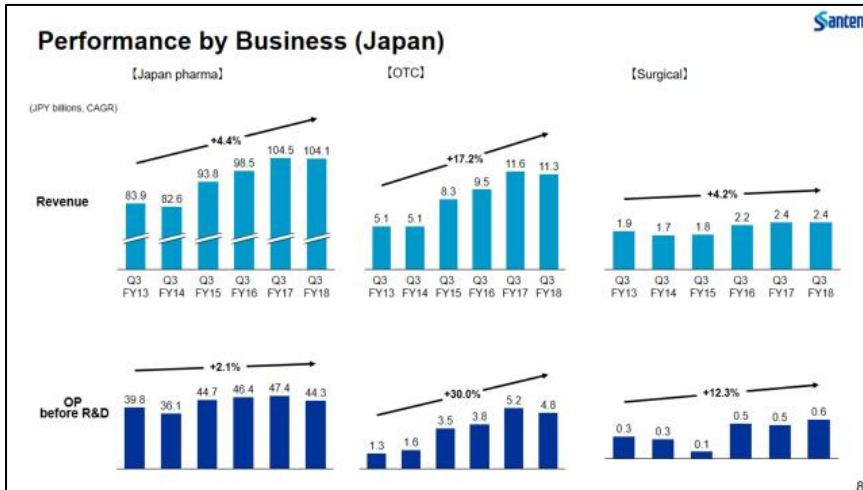
Next, page 6. These are the factors behind Q3 FY2018 revenue fluctuation, in comparison with Q3 FY2017. In the Japanese business, *Eylea* and *Diquas* are growing very well. And excluding the negative impact from NHI price cuts, the revenue increased by 5.6 billion yen, or 5.4%. With this, our market share is 46.9% and is still growing. *EYBELIS*, which was launched in November, has experienced two months on the market after the launch and we have been able to record 50% of the institutions adopting this new product. Also, *Well Wash Eye*, a new type of cleansing eye drop, has been launched in December.

With regard to OTC, there has been a negative comparative impact from our marketing campaign in the prior year and also, a decrease of foreign visitors due to the natural disasters, also impact from new China's e-commerce law. However, there has been good progress in premium products for the domestic market, which has mitigated these negative impacts. And year-on-year performance has been flat. With regard to surgical, in November we began trial sales of our new IOL product, *LENTIS Comfort*. This is to provide comfortable vision across medium and long distances. It is a differentiated product that has been accepted in the market. With regard to this product, we will further focus in order to expand our sales.

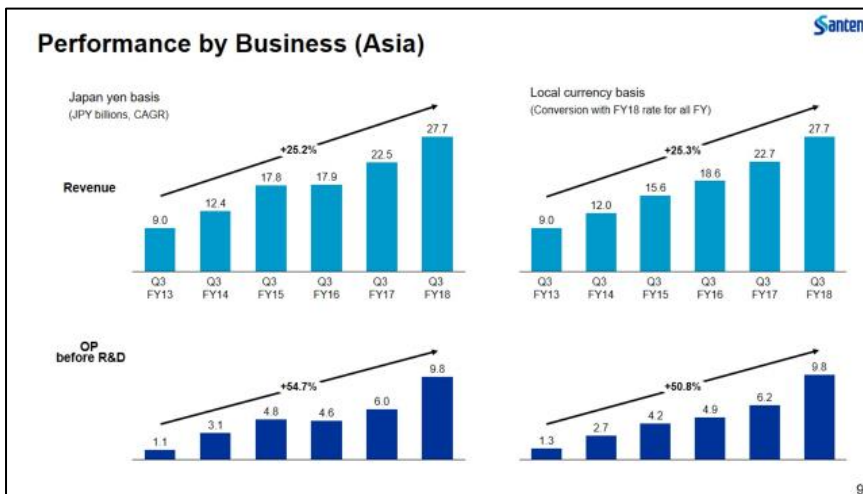
With regard to overseas business - though somewhat less in three-month Q3 - we have been enjoying very strong revenue growth in Asia in the cumulative Q3. In China, plus 23.4%. In Korea, plus 18.4%. Not only the revenue growth, but in the Asian region over the period we launched 18 products and received 22 approvals. And, due to these efforts, we have been enjoying this growth. In EMEA, (Europe, the Middle East, and Africa), *Ikervis* and glaucoma products are growing. The glaucoma products will be further focused for greater penetration, especially in main countries like Italy and Germany. Through such performance, in total in Q3 FY2018, we have been able to enjoy 173.2 billion yen revenue, plus 2.7% year-on-year.



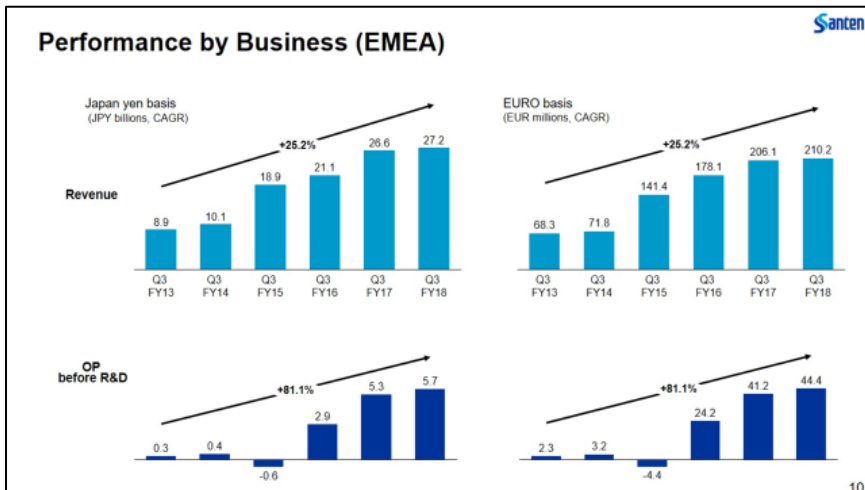
This is the core operating profit. With cost optimization, we have been able to mitigate the negative impact of COGS in the Japan pharma business. In Asia we have been growing the revenue and COGS expense management. And we have enjoyed more than 60% YoY core operating profit. In EMEA, we have achieved 8% increased profit through cost optimization efforts. Strong growth in overseas business and group-wide cost optimization has offset NHI price cut impacts. In total, in Q3 FY2018, 35.1 billion yen of OP has been recorded. This is progressing smoothly with annual forecasts announced in May.



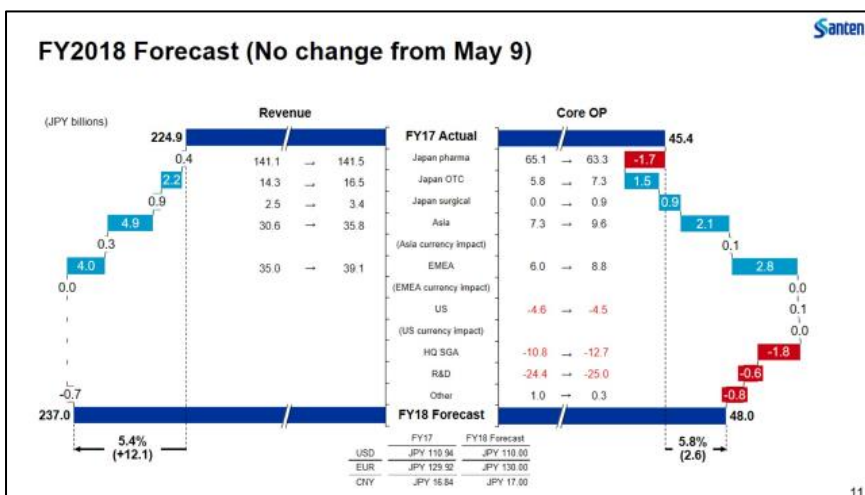
Page 8. This is the business trend in the domestic market between 2013 and 2018. It shows sales revenue and operating profit before R&D. We are on track to achieve our full-year target in the Japanese market. We launched *EYBELIS* in November. Also, we will focus on the new IOL, *LENTIS Comfort*. We would like to try to expand the value of our products to grow further.



Page 9 is for Asian market. As before, our products are outperforming the market growth. We are growing very steadily in these markets. COGS and coverage have been improved in the past, and going forward in addition to these, we would like to introduce new products in these markets, so that we can expand our business in the Asia market and also in China.



Page 10 is about EMEA business. As I mentioned before, we are increasing our share in the glaucoma markets and *Ikervis* is growing fast. Thanks to this, both revenue and OP are increasing. *PreserFlo MicroShunt*, which used to be known as *InnFocus MicroShunt*. Our new name is *PreserFlo*. And we've completed our soft launch in Europe. In 2019, we would like to expand this product further. We would like to improve our presence in the European market. And we would like to have a strategic marketing plan in the European market and that will also contribute to other markets, including Asia.



Page 11, this is the forecast for 2018 full year. The revenue is 237 billion. Core operating profit is 48 billion. There has been no change from the announcement made in May. We are on track to achieve our full-year target.

Dividend Forecast for FY2018 (No change from May 9)

- Annual Dividends
- Stable and sustained return to shareholders
- Mid and Long term strategic investment for growth beyond 2020
- FY2018 forecast: JPY 26 / share
- Implementing shareholder returns policy to achieve the best balance between above two priorities considering dividends and total return



This is the forecast for dividend for 2018. Our plan is 26 yen and there's been no change from the announcement made in May. That's all for the summary explanation of the third quarter fiscal 2018.

Pipeline / Product Development Status (1)

As of February 5, 2019
Updated information is underlined

	Indication	Region	Status
DE-111 <i>TAPCOM / TAPTIQOM</i> Combination of tafiprost and timolol maleate	Glaucoma / ocular hypertension	China	<u>Started P3 in Jan 2019</u> Plan: <u>1st half FY2020 P3 completion</u>
		US	P3 Plan: <u>Jan~Jun 2020 P3 completion</u>
DE-117 <i>EYBELIS</i> EP2 receptor agonist	Glaucoma / ocular hypertension	Japan	<u>Launched in Nov 2018</u>
		Asia	P3 Plan: <u>2nd half FY2018 P3 completion</u>
DE-126 FP/EP3 receptors dual agonist	Glaucoma / ocular hypertension	US	P2b
		Japan	P2/3
DE-128 <i>PreserFlo</i> ¹	Glaucoma	US	Plan: <u>calendar 2019 PMA rolling submission completion, calendar 2020 launch</u>
		Europe	CE mark granted

¹PreserFlo is the new name of the pipeline project which has been known by the development code DE-128 and/or trade name *InnFocus MicroShunt* in Europe.

Thank you very much. I'm going to be a little slow speaking just to make sure that the translation can keep up. So, I apologize in advance. Thank you. So, I'll start with DE-111, the *TAPCOM/TAPTIQOM* product. We have just started a Phase 3 in China. The first patient was randomized into the trial in January of this month. We plan to complete this study in the first half of fiscal 2020. The next project is DE-117, *EYBELIS* (in Japan). We have launched the product in Japan as Taniuchi-san mentioned. We have a Phase 3 study running in Asia, which will complete in the second half of fiscal 2018. We then plan to use this data and data from the Japanese study to seek approval of this product in various Asian countries.

DE-126, we are still evaluating the positioning of this product. DE-128, which is our *PreserFlo MicroShunt*, we plan to file a PMA this year, calendar year 2019. And we expect approval for the MicroShunt in 2020.

Pipeline / Product Development Status (2)

As of February 5, 2019
Updated information is underlined

	Indication	Region	Status
DE-109 IVT sirolimus	Uveitis	US	P3 (LUMINA trial started in Dec 2018) <i>Plan: Jan-Jun 2021 P3 completion</i>
		Japan	P3
		Europe	P3
		Asia	Filed
DE-122 Anti-endoglin antibody	Wet age-related macular degeneration	US	P2a <i>Plan: 2nd half of FY2019 P2a completion</i>
DE-089 Diquas	Dry eye	China	Launched
DE-076B Cyclokat / Ikervis ciclosporin	Severe keratitis in patients with dry eye	Asia	Launched
		US	P2
DE-076C Velacia / Verkazia ciclosporin	Vernal kerato-conjunctivitis	Europe	Launched
		Asia*	Filed in Nov 2018. <i>Plan: Jul-Dec 2019 approval</i> *Product name is Ikervis.
		Others	Approved in Dec 2018 in Canada. <i>Plan: calendar 2019 launch</i>
DE-114A epinastine HCl (high dose)	Allergic conjunctivitis	Japan	Filed <i>Plan: Jul-Dec 2019 approval</i>
DE-127 atropine sulfate	Myopia	Asia	P2 <i>Plan: 2nd half of FY2019 P2 completion</i>

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Our DE-109 noninfectious uveitis program-- the LUMINA trials, these are the Phase 3 studies, were started in December of last year. And we plan to complete the studies in the January-June timeframe in 2021.

DE-122, the study is running. We are looking to completing this Phase 2 trial in the second half of fiscal 2019. I will skip the next two items because they have been launched, and rather focus on DE-076C. This product was recently approved in Canada. And we plan to launch the product in 2019 in Canada. Regarding DE-114a, epinastine, we are looking for approval in the July-December timeframe in 2019.

And finally, DE-127, the atropine for myopia-- we plan to complete the study in the second half of fiscal 2019. Thank you very much. I'll be happy to answer any questions.

Question & Answer Session

Q1-1-1

With regard to progress up to Q3 is my question. The revenue, looking at Q3, it seems to be a little slowing down. But in total, the progress is good. And especially in terms of cost, you have mitigated the cost. But throughout the term, I think there may be some upward fluctuations. Can you explain more?

A1-1-1

Taniuchi COO: Let me respond to your question. With regard to the Q4 forecast, I think it will be following the annual forecast. And with regard to the fluctuations, one factory regards the allergy market in Japan. From which timing, how much of our products will be demanded and how long the allergy season will last, those are factors of uncertainty - and there may be some fluctuations based upon this factor.

Q1-1-2

How about costs -- R&D, or SG&A?

A1-1-2

Koshiji CFO: With regard to R&D, our forecast for the full year is 25 billion, and the progress is less than

70%. As of today, with the clinical study plan considered in the fourth quarter, I think we will be spending the total amount.

With regard to SG&A, likewise, about 70% has been spent. And throughout the company, we are working on the reduction of expenses. However, having said so, for example in Asia, and also some regions overseas, in Q4 bonuses, or incentives to be paid to the MRs, will be necessary. This will be a seasonal factor. And together growth of revenue with the pollen amount, there is a seasonal factor behind SG&A as well. And therefore, we don't change the full-year forecast.

Q1-2

I have a question about *EYBELIS*. It looks like the number of accounts is increasing. But there's been no announcement as to the sales. But I think it's less than 100 million for a month. So, it looks like 200 million or 300 million for two months. And going forward, I think it's going to be penetrating farther.

A1-2

Taniuchi COO: Yes. The number of accounts is as you mentioned. As to market share, this is a new mode of action and a new compound. Therefore, we'll be very careful and we'll have a lot of scientific discussions with the doctors so that we can be sure that this can be delivered to appropriate patients. As the study is in a very limited condition, we have to be very careful. That's why we've been very conservative, because we are focusing on the appropriate use of this product. The market demand is very big. However, we've been controlling it and we've been making sure how appropriately this drug should be delivered to our patients. That's the initial situation, in terms of the sales. But I think we want to be patient.

Q1-2-2

So, in terms of this product, this is intentional, you're not pushing too hard?

A1-2-2

Taniuchi COO: Yes. We've been very careful and conservative so that we can be sure that this drug is delivered to the appropriate patients.

Q1-3

Ok. Thank you very much. The last question. I have a question to Naveed-san, as to DE-126. You said that you are now evaluating the positioning and you said that you are going to elaborate on this.

A1-3

Shams CSO: Thank you very much for the question. The DE-126 product-- as you know, we have a very robust glaucoma portfolio. So, we would like to make sure that the positioning of the product, vis-à-vis the rest of our portfolio, as well as the pacing between product launches, is maximized. So, we continue to work on it.

Q2-1

My first question is with regard to DE-128. In 2019, you will complete the submission in the United States. And you are planning to launch in 2020. I think it's proceeding faster than you had expected. Could you explain the reason why it has been accelerated and what kind of discussions have you had with FDA? And what are the timing of disclosing your data?

A2-1

Shams CSO: We always have had a range that we were comfortable with, in terms of filing and launching the product. The second is that our submission is in a modular form, which means we are submitting as we complete the various sections of the file. Finally, we understand that the agency can make a decision on all of the data collected up to a certain point this year. Which means that most of the data used for approval is going to be month-12 data. That is why the package will include more than 12-month data of course. But the bulk of the data will be month-12. Therefore, we can now file faster than we thought.

Q2-1-2

With regard to Phase 2/3 data announcement, do you have any plans for the announcement of such data?

A2-1-2

Shams CSO: We have not made any decision.

Q2-2

Thank you very much. Another question is also related to DE-128. You're planning to launch it in 2020. So, as to the preparation of American business, the cost is going to increase from the next year for this? Or if you have any plan.

A2-2

Taniuchi COO: Yes. Toward the launch in 2020, we will have to make preparation starting in 2019. But how we are going to market it is still under discussion. So, when the time comes, we will make an announcement. In any case, of course prior costs will be incurred. And already now in March, there will be a glaucoma world conference in Australia. In that conference, we are planning some activities for *PreserFlo*. Starting from 2019, we will have to spend to prepare for the launch of this product. As to the US market, we will explain the details of how we are going to enter the market in the US market when the time comes.

Q2-3

The last question, it's about OTC. For the first quarter and second quarter, there are many special occasions. But for now it's increasing by 12% to 13% YoY. Is it now back on track? If you can elaborate on the current situation of OTC.

A2-3

Taniuchi COO: As to OTC, the new product for Japanese market, *Beautéye* or *Medical* series, those are progressing very well. Those products are on track. But what is difficult to forecast is inbound needs because it's fluctuating a lot. If you only look at the numbers alone, it may be difficult for us to make any specific comments. But as far as our products are going, they are progressing very well and they are on track.

Q3-1

With regard to Asian business, in the three months from October to December, the revenue growth is in the single digits. Was it because of high inventory levels? Or was there any special factor behind this?

A3-1

Taniuchi COO: This is due to China. Especially in December, the wholesalers in China at the end of the year, they were trying to reduce their inventory. Therefore, in terms of shipments, from October to December compared to last year, there was some inventory adjustment included.

Q3-1-2

Thank you. As a follow-up question, there was a greater reduction of inventory compared to the other years?

A3-1-2

Taniuchi COO: Yes. That is correct.

Q3-2

Thank you. My second question, this is to Dr. Shams, as a follow-up question. With regard to DE-128, data for the filing is already acquired? Is my understanding correct?

A3-2

Shams CSO: The data for the filing is almost collected. We are going to now prepare the data for a database lock and filing. That would happen in the coming months, approximately, if everything goes okay. Then we'd follow that with the filing.

Q3-3

Thank you very much. My third question, looking at the balance sheet, the cash is accumulated more compared to the past. With regard to the stock level right now, share buyback, is this share buyback expected?

A3-3

Koshiji CFO: With regard to this question, I cannot answer by yes or no. But in the mid-term policy, first of all, investment for growth will be prioritized. That is all I can say at this point of time. Thank you.

Q4-1

I have two questions. The first question, it's about *EYBELIS*. You said that you'll have to be very careful in marketing this product. And you have other products for glaucoma, mainly *Tafluprost* and *Cosopt*. What's the difference in terms of the marketing of those products? Or what's the positioning of those products? The initial sales have been slow and you said that this is because you've been very careful. But six months or one year ahead. As a product, how much do you think it will grow?

A4-1

Taniuchi COO: In order to explore that, we've been talking and communicating with doctors. Glaucoma is, as you know, a lifetime disease. Patients have to try to maintain their vision for a long time. Therefore, they have to use a lot of products-- sometimes single agent products, sometimes combined-agent products, several medicines, they try changing the application order-- there are so many approaches. FP prostaglandin analogs including *Tafluprost*, and *Latanoprost* are now first-line drugs and they are very powerful products in terms of the efficacy. But at the same time, there is FP-specific non-responder problem. Also, there are some side effect issues, like eyelash growth. *EYBELIS* has a new mechanism of action and efficacy is the same. However, the safety profile is different.

So, what is the patient profile? Who's appropriate for this product? Do we use this for new patients? If patients want to switch, when or how they should switch? There are a lot of options or combinations. Now we are exploring the best way to use this product. It's not that we are worried about cannibalization. We just want to be careful in defining the positioning of this product. There are also cautious issues, because for those patients who are worried about the side effects of other products, maybe we can use this product as first-line. Those are the situations now. We'd like to carefully watch the situation of the patients and the treatment and EP2 receptor. This is a new mechanism of action and that's how we want to position these products.

Q4-2

The second question is about EMEA market. From the first to the third quarter, if I look at those figures on page 11, the core operating profit, the growth of core operating profit. There is an absolute number and there is a progress up to the third quarter. I think it's relatively slow. Is this due to former Merck products? There may be some saturation, and because of the saturation, this is slow? Or are there any other factors which is dragging the sales? My question is, do we have to worry, especially about the European market?

A4-2

Taniuchi COO: As to the European market, of course those former Merck products are mature products. So, we are suffering from price pressure. However, in response to these we've been developing preservative-free products, and unit / single-dose single-use products. It's not been very profitable. We've been changing it to multi-dose preservative-free products. And that way we've been trying to secure profits. Those are the measures we've been taking in European markets. Even if the sales are going down, we are increasing our profit. The profits have been better than expected. Now it's a better structure. As to 2018, there was another factor in Russia. In Russia there was an old product which is an OTC product and it declined a lot because of the competition. This is a very highly volatile OTC product that was not doing very well. That's the one

reason. And it accounts for 40% of the sales in Russia. And that's a relatively big product for the entire European market. That's why you may think that the sales have been slow. However, in many other products we've been enjoying double-digit growth, for example, in Italy, Germany, and the UK, thanks to *Ikervis*. That's the situation.

Q4-3

Thank you very much. With regard to *MicroShunt*, this time you have a new name, *PreserFlo*. And in Europe, you say it's still a soft launch. But with regard to the hard launch or full launch, will it be in 2019?

A4-3

Taniuchi COO: Now it's in a soft launch. In six or seven institutions, we are selling *PreserFlo* and the revenue is small. But in 2019 fiscal year, we would like to increase step by step. It's not as advanced as a hard launch, but it's kind of a prelaunch. In Switzerland and Australia, salespeople will start their marketing and they will cover these regions. That will be for FY2019. The hard launch or full launch will be in 2020. In FY2019, we want to increase the number of countries. And we want to work on the infrastructure of the market.

Q5-1

Thank you. The first question is with regard to China. You said that the wholesalers adjusted inventory at the end of the year. And could you tell me the background behind this? Because of the changes in the environment, or is it because of a specific wholesale individual situation? And with regard to preparation for the future, do you have any ideas? If the inventory is going to increase and if there is going to be any rebound, we want to prepare ourselves.

A5-1

Suzuki DM: With regard to the inventory reduction at the end of the year, we don't know the specific individual wholesaler situation. But from April of last year, there has been a revision in the system and they are controlling in a more restrictive regulatory manner. Looking at the numbers from January, however, they seem to be coming back. So, I think this is a healthy situation for us.

We have seen changes including to equivalence testing and insurance consolidation. We believe the policy changes benefit our branded, high-quality products and weed out competing products which have quality issues. So, we believe that revenue from our high quality products will be supported by the de-listing of certain local products.

Q5-2

Thank you. The second question is about *Hyalein* in China. In the second quarter the sales increased. But as compared to the second quarter, in the third quarter, it's declining. In the second quarter the list has been changed and as compared to competitors, the indication was different for *Hyalein*. And that's why there was a lot of demand. But for the third quarter, do you think this level will continue going forward? Or because of the list change, do you think that this figure will decline further? What's the trend?

A5-2

Suzuki DM: *Hyalein* grew dramatically at one time because certain tear substitutes were delisted. On the other hand, for dry eye, these products increased in demand. That situation has subsided. So, there was one-off condition back then.

Q6-1-1

The first question, DE-117. I think you said it before, of course, this is a new mechanism of action. So, I don't think the initial sales would be very big. But as to this product, my biggest concern is macular edema described in packaging inserts. Of course, this is a problem for IOL patients. But what's the situation now? Are we seeing the macular edema patients? If you have any safety information, is there any difference in terms of the data between the real clinical situation and the study? And I think, because of the side effects, you've been very careful. But at what timing or when do you think you can be very aggressive in marketing this product?

A6-1-1

Taniuchi COO: As to macular edema, this can happen for patients who no longer have their natural lenses and use FP drugs. It seems that doctors are not overly sensitive to the side effect of macular edema as this is well understood. As to the situation since launch, we are not in a position to disclose the numbers in terms of safety now. But in a clinical setting, a slit lamp is used to examine for anterior inflammation. If there is inflammation, we ask doctors to stop the medication. We are asking doctors to be very careful, especially about the inflammation of the eye. The mechanism of action is different from FP. Inflammatory macular edema has been observed. On the other hand, this medicine seems to avoid many of the other side effects which are common with FP. Now we are carefully explaining those characteristics to doctors. That's the situation now.

Q6-1-2

I think the issue pigmentation change is one difference between FP and this product. And the conjunctiva problem. What do you think? Is there any feedback?

A6-1-2

Taniuchi COO: These are the comments we've received from doctors but these are not quantitative. So, this is just for your reference. As to conjunctiva, this is always going to be observed to some extent, so doctors do not seem overly worried. Of course, there are side effects common with other medicines including pigmentation and eyelash problems, or the recess of the area around the eyes. And these are problems for both men and women including working age populations. But DE-117 doesn't seem to cause such side effects. This could be an important benefit for those patients who are very worried about those side effects. Some are saying that this could in future be used as first-line adding to the number of options for doctors. Going forward we would like to explore how better we can serve doctors and patients with this product.

Q6-2-1

The second question is about *PreserFlo*. Maybe I didn't hear but, I think FDA only accepted two-year data, but now they say that one-year data is sufficient. And I would like to ask you the background behind this.

A6-2-1

Shams CSO: Thank you for the question. Honestly, we can't comment on what the FDA is thinking. But I can tell you that our device, based on a lot of different characteristics, is different than the run-of-the-mill MIGS devices currently on the market. So, the 24-month guidance probably does not apply to *PreserFlo*. By the way, as I mentioned, bulk of the data or all of the 12-month data will be the basis for the file. But we will have significant amounts of 24-month data as well.

Q6-2-2

When you compare your device to other MIGS devices, I think you don't need to receive a new training with the *PreserFlo* and the operation is easier than trabeculectomy. Is that the reason why maybe 12-month data is sufficient, rather than 24 months?

A6-2-2

Shams CSO: Thank you for the question. The major difference is that, first of all, we are going head-to-head against trabeculectomy, which is the standard of care. So, we have a well-controlled study. And to the best of my knowledge, all of the currently available MIGS devices are used in combination or secondary to cataract surgery. It's difficult for anybody-- because of cataract surgery has an IOP lowering effect on its own, it becomes difficult to assess the effect of the device. Hence, a longer study is required. Thank you.

Q6-3

Thank you. And my last question. So, 2020 is the time we have to think about the launch. We were interested in cost. Those doctors who are doing these kinds of surgery, I think they are very familiar and comfortable with these surgeries. And the number of institutions is not that big. I don't think that the number of doctors who can do this is limited. And I don't think it will incur a lot of cost.

A6-3

Taniuchi COO: As Naveed mentioned, existing MIGS often used with cataract surgery. So companies need big sales forces to cover those institutions who are doing cataract surgeries – the same for the US, Japan and Europe. However as to *PreserFlo*, this is only for glaucoma surgery doctors. As compared to existing MIGS and other medications, the number of institutions should be limited. In the US, it's about several thousand institutions, but not like hundreds of thousands of institutions. We will have to create a model on how to go reach the appropriate institutions. And that will be reflected in the numbers in the future.

Q7-1

My first question, we've been talking about European and Asian markets and it's been slow. In order to achieve this year's target, we don't have to worry too much about the slow progress in Asia and Europe?

A7-1

Taniuchi COO: You're correct. Of course, it is a business with various volatility, there may be some unevenness, but thinking about growth trends continuing since April - Asia will continue smoothly in the fourth quarter as well. We are doing well, and latest figures in January have been progressing as such. Europe also doesn't show a big change in trend and the cost will be well controlled toward achievement of the profit targets to be steadily carried out in the fourth quarter as planned. We are on target.

Q7-2

There was a share buyback question and Mr. Koshiji said the company wants to prioritize investment. How about your 150 billion strategic investment capacity? Is this the level unchanged?

A7-2

Koshiji CFO: First of all, we haven't said that we plan 150 billion yen of investment. That level was mentioned as a theoretical capacity that would be possible without affecting the financial foundation of our company. There was a question about share repurchase. For this, we want to prioritize investment for now. As I mentioned at the medium-term plan announcement, we would like to maximize shareholders' value and share price. We are always considering our shareholder return policy carefully. We, of course, comprehensively consider potential investment projects in our judgments about the possibility of increasing the dividend or the repurchase of shares.