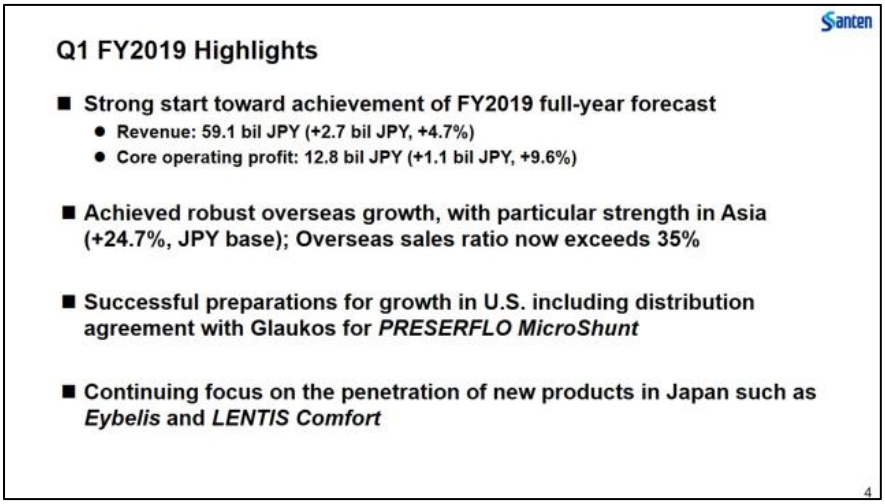
Conference Call on Q1 FY2019 Results

(Taniuchi COO) My name is Taniuchi, President and COO. I would like to give you the highlights.
Please turn to page two and three. This gives you Santen's values and mission statement and also MTP2020 fundamental policy and strategic goals. As we have finalized the first quarter of 2019, this is the second year or the middle year of MTP2020. And from 2011, we have been based on the 10-year long term plan VISION 2020 and MTP2020 is the final midterm plan in VISION 2020. This year is the middle year of MTP2020. In this first quarter, we have been able to progress greatly.

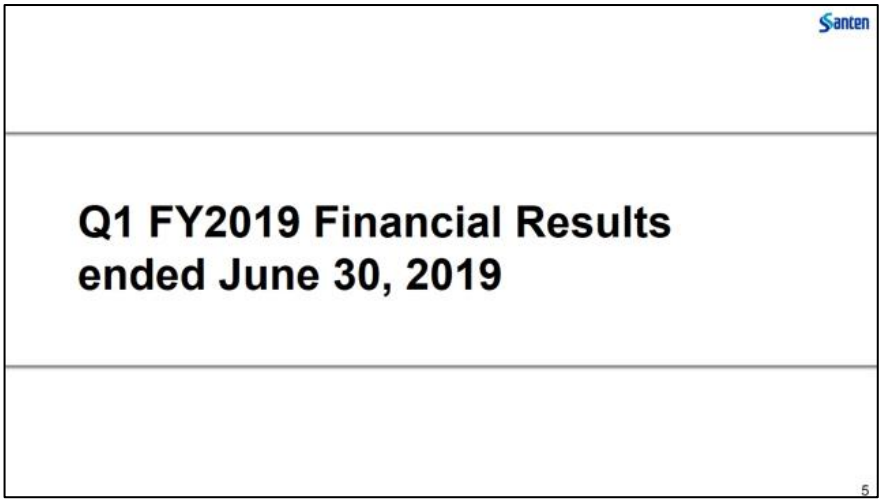


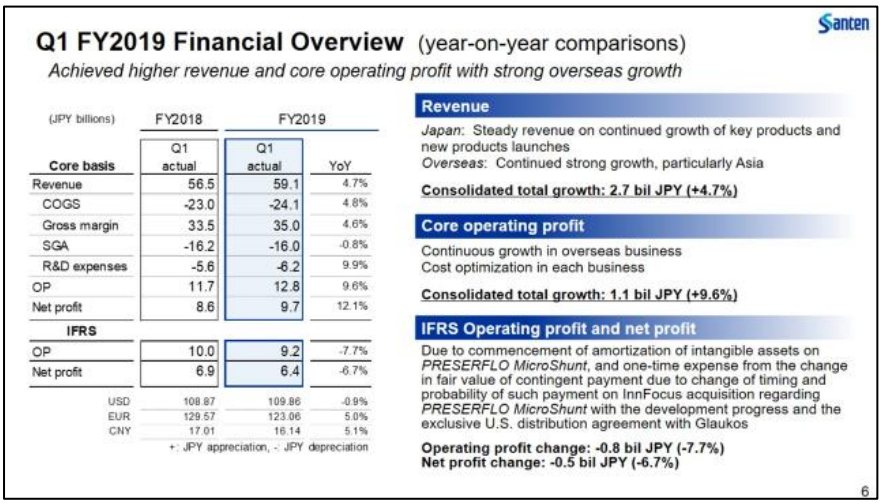
As stated on page four, these are the highlights of Q1 FY2019. We have made a strong start toward achievement of FY2019 full-year forecast. Revenue of 59.1 billion yen was an increase of 4.7%. And core operating profit of 12.8 billion yen was an increase of 9.6%.

With respect to the contents in MTP and going forward, the overseas business is very important, especially Asia. We have achieved robust overseas growth with particular strength in Asia. I think this was very great progress that we have been able to make. Also, in Europe, as well, we have made great progress in growth and the overseas sales ratio now exceeds 35%. So, based upon VISION 2020, in order to become a global company, I think we have been able to make great progress.

And, with respect to PRESERFLO MicroShunt, as of the end of April, we have signed a distribution agreement with Glaukos. And in the following three months, we have been discussing with them, with respect to sales activity and product supply and the negotiation is going on. And for the launch of the product, we are making great progress in our preparation.

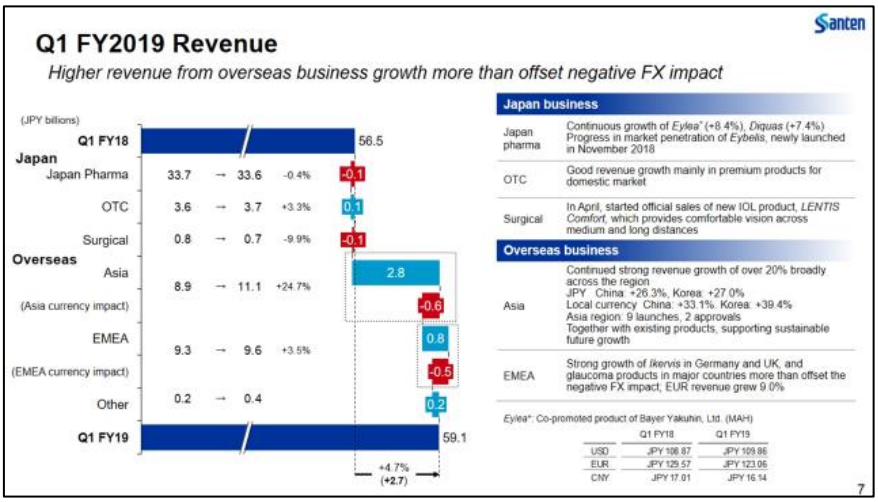
With respect to the Japanese market, the pollen distribution occurred earlier than expected. And in the fourth quarter of last fiscal year, Alesion sold well. So, as a reflection of that, in the first quarter of this fiscal year, there was some decline with respect to this product. But, with respect to new products such as Eybelis and LENTIS Comfort, we are making a penetration. And so, 47% is the market share that Santen has at present and we are continuously very strong and it's doing very well. So, at the end of the first quarter, I think we can say that we have made a good start for fiscal 2019 and we plan to continue this great progress starting in the second quarter as well. Now I would like to introduce Mr. Suzuki.





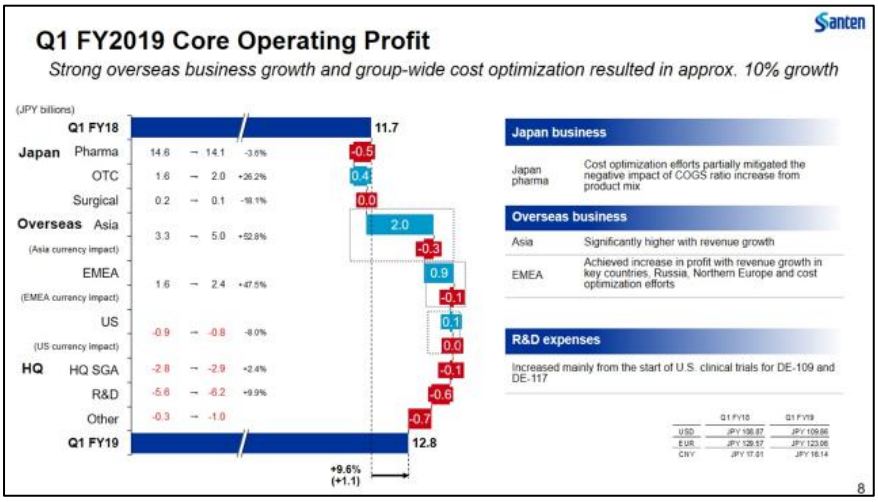
(Suzuki SCO) Some of the parts may overlap what Taniuchi already mentioned.

This shows the results for this year. The revenue was 59.1 billion yen. And, as Taniuchi mentioned, there was big growth especially in Asia. The revenue was up 4.7% from the previous year. That's an equivalent of 2.7 billion yen. If you look at the Japanese market, it's progressing well with major products such as Tapros, Tapcom, Diquas, Eylea, and new products Eybelis and LENTIS Comfort. As to core base operating profit, in addition to overseas growth, because of the optimization of the cost, it's up 9.6% from the previous year and that's 1.1 billion yen up from the previous year. As the IFRS base, it was 9.2 billion yen of operation profit and 6.4 billion yen of net profit. This is caused by the progress of PRESEFFLO MicroShunt DE-128 and the cost was increased because of accounting items.

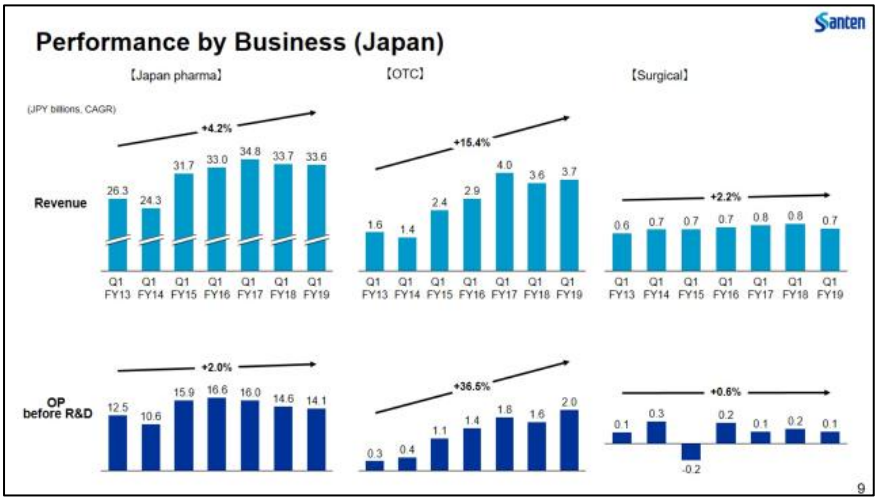


Page seven. This is about the causes of the ups and downs of the revenue. The upper part is 2018. That's 56.5 billion yen. 2019 was 59.1 billion. As to the Japanese market, Eylea and Diquas are progressing well. So, it's positive from the previous year. With regard to our new products, Eybelis, there is still prescription limitation, and we are waiting for the launch of kit components for LENTIS comfort. However, we are increasing the number of accounts.

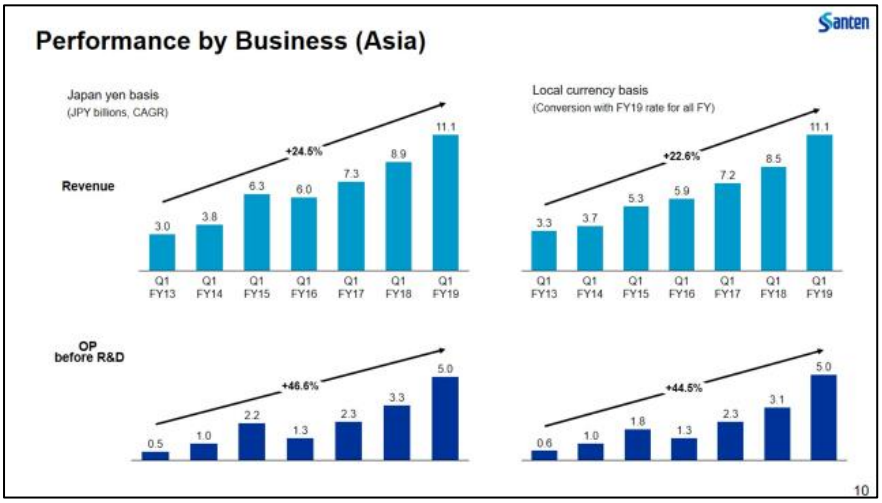
As to the overseas market, both Asia and EMEA are growing. Especially in Asia, in major markets, we are seeing growth of more than 20%. In China and Korea, which account for 80% of the Asian market, on a local currency basis, the growth rate was more than 30%. As a result, in total, in the overseas market, the revenue was up by 2.5 billion yen, with exchange rate. But, without that, the increase was a 3.6-billion-yen increase.



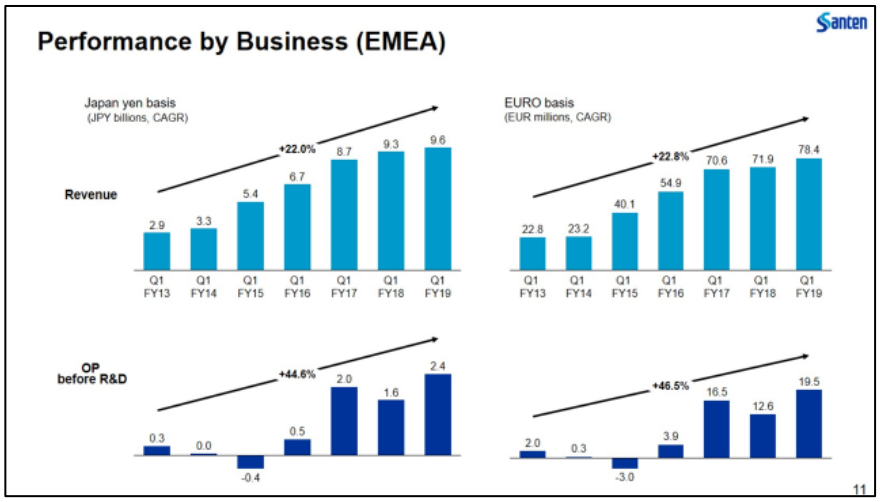
Page number eight. Likewise to the previous page, this is about the causes of the ups and downs of the core operating profit. FY2018 was 11.7 billion yen and it has grown to 12.8 billion yen in FY2019 first quarter.
With regard to Japanese market, there was a COGS ratio increase. However, by applying cost optimization policy, we have been able to mitigate this increase. And with regard to overseas, there has been increasing revenue. And therefore, the core operating profit has also increased. In addition to this, we enhance the investment efficiency and achieve to offset FX impact. This leads to further growth in our operating profit.



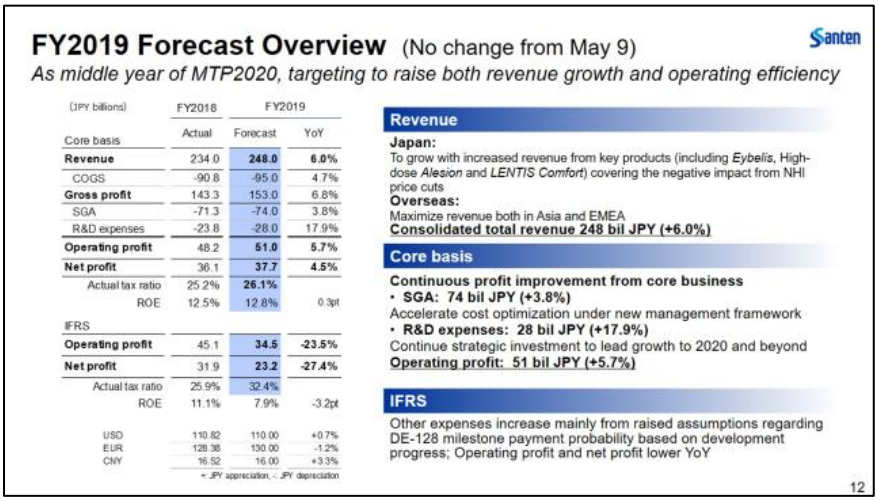
With respect to the following three pages, this is the first quarter performance by business, starting from FY2013 to FY2019.
With regard to page nine, this is Japanese market. Though there is some fluctuation, in total, there has been increase in revenue and operating profit.



On page 10, this is Asia business. As you can see, the CAGR is a two-digit growth rate and this fiscal year has also incurred the same growth. Also, as Asia region including China, the latest market growth is 12% and our sales achieved much higher, 2-times growth and our market share is also increasing.



This is EMEA. The business environment such as approval and pricing is tough. However, this market is very important and attractive as a Pharma cluster with respect to clinical study, healthcare infrastructure and data generation. Santen makes profit and is building our presence in this market as well.

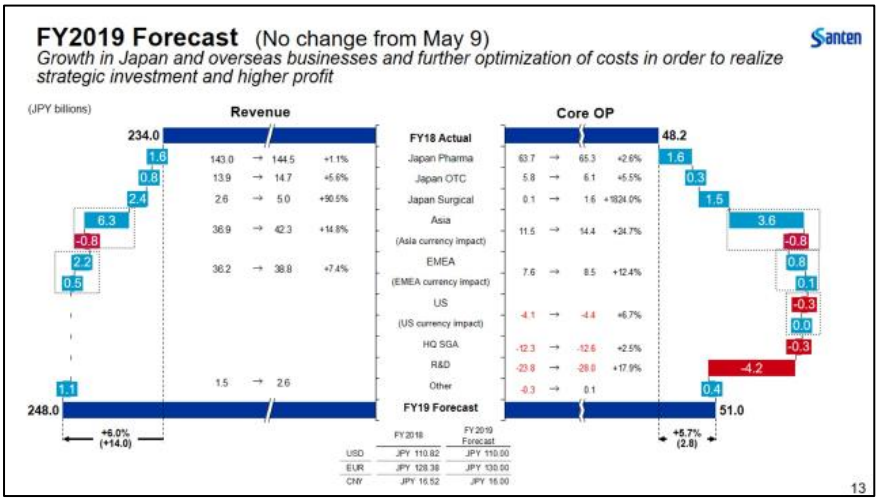


On page 12 is the forecast overview of FY2019. There is no change from the announcement in May. 248 billion yen of revenue, 6% increase year-on-year and operating profit of 51 billion yen, 5.7% increase. And operating profit on IFRS base, 34.5 billion yen, which is minus 10.6 billion yen, year-on-year.

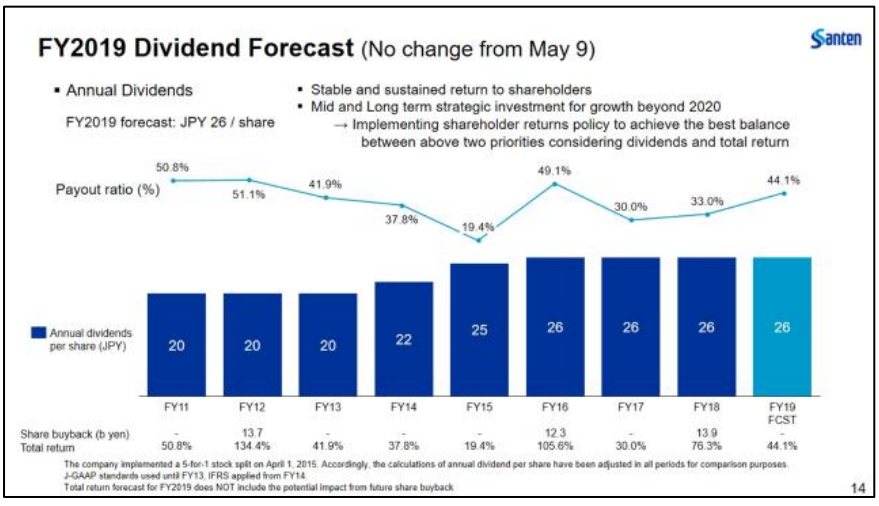
With regard to Japanese market, we will increase our penetration for new products and also grow our focused products.

In Asia, we are increasing by double digits. We would like to continue this trend, and also, we would like to grow in the EMEA market as well.

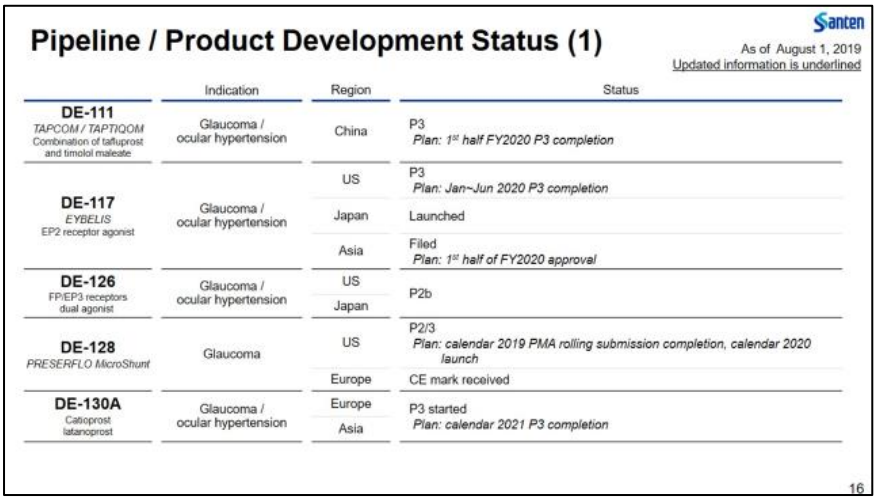
In terms of cost, SG&A, we have been accelerating our cost optimization. With respect to R&D expenses, as we are expecting the progress in each project and the amount will increase compare to the previous fiscal year. Naveed will make an explanation with regard to R&D.



This is just a graphic view of what I have just explained. So, I would like to skip the explanation.



On page 14, this is the dividend forecast and there is no change from the announcement in May, 26 yen per share. Stable and sustained return to shareholders and mid- and long-term strategic investment for growth beyond 2020, the balance between the two is being considered in order to return to our shareholders of our profit. That is all from myself. Now, Naveed, please.



(Shams CSO) Thank you very much. My name is Naveed Shams. I'm going to give you an update on our pipeline.

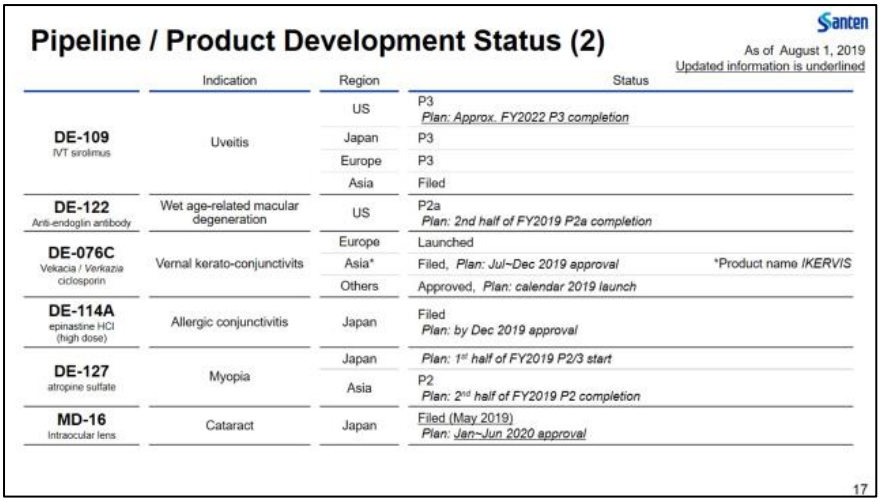
I will start with DE-111. As you heard, the China business is very important to Santen and we continue to develop products for this market. This Phase 3 trial is going well and will complete in the first half of fiscal 2020.

DE-117, also called Eybelis, is in Phase 3 development in the US and will complete Phase 3 in fiscal 2020. We have also started the geographic expansion of DE-117, mainly in the Asia region.

DE-126. This is a Phase 2 asset. We are hoping to start exploring some differentiation for this product in the very near future.

PRESERFLO MicroShunt, DE-128. As we have planned, we are trying very hard to complete the rolling submission by the end of this year, November/December timeframe.

DE-130A. This is Catioprost, a new formulation of a prostaglandin analog for the European and Asian market. And we hope to complete Phase 3 in 2021.



Pipeline / Product Development Status (2)

Santen

As of August 1, 2019
Updated information is underlined

	Indication	Region	Status	
DE-109 IVT sirolimus	Uveitis	US	P3 *Plan: Approx. FY2022 P3 completion*	
		Japan	P3	
		Europe	P3	
		Asia	Filed	
DE-122 Anti-endoglin antibody	Wet age-related macular degeneration	US	P2a *Plan: 2nd half of FY2019 P2a completion*	
DE-076C Vekacia / Verkazia ciclosporin	Vernal kerato-conjunctivits	Europe	Launched	
		Asia*	Filed, *Plan: Jul~Dec 2019 approval*	*Product name *IKERVIS*
		Others	Approved, *Plan: calendar 2019 launch*	
DE-114A epinastine HCl (high dose)	Allergic conjunctivitis	Japan	Filed *Plan: by Dec 2019 approval*	
DE-127 atropine sulfate	Myopia	Japan	*Plan: 1st half of FY2019 P2/3 start*	
		Asia	P2 *Plan: 2nd half of FY2019 P2 completion*	
MD-16 Intraocular lens	Cataract	Japan	Filed (May 2019) *Plan: Jan~Jun 2020 approval*	

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DE-109 is the intravitreal sirolimus product. A third Phase 3 study is currently running in the United States. We plan to open sites outside the US, for example, in the UK, to expedite enrollment.

DE-122, the endoglin antibody for wet AMD, will complete Phase 2a study in fiscal 2019 second half.

DE-076C, which is also called the Vekacia / Verkazia, has already launched in some countries, and we plan to get approval in the Asia region in this calendar year.

For epinastine, DE-114A, for allergic conjunctivitis, we are looking for approval by the end of this year in Japan.

DE-127, atropine for myopia, we were planning to start Phase 2/3 in the first half of fiscal 2019 and I'm delighted to tell you that we already have enrolled our first patient in the study today. A Phase 2 study is also running in Singapore, which will complete at the end of this fiscal year.

MD-16, intraocular lens for cataract, we are looking for approval by the end of 2020 and it's on track.

Thank you very much.

Question & Answer

Q1-1:

In the presentation from the President, I understand that the discussion with Glaukos is proceeding and I would like to ask you, in your discussion, how are you going to sell the product and the potential, and also, the commitment of Glaukos toward this discussion. Is there any update information that you can give us?

A1-1:

(Taniuchi COO): Yes. Let me respond to your question. As of today, I cannot say that there is positive nor a negative discussion yet. In reaching our agreement, we discussed about the market scale and our sales forecast. And we have agreed upon this kind of information. What we are discussing right now is the working level discussion, for example, how are we going to do the training and what are we going to do with the training materials. These matters are being discussed as of today. That is how our discussion is proceeding.

Q1-2:
With regard to Eybelis in Japan, I know that you are conducting your sales activity carefully. I saw in one of the sites, with regard to cataract in the hospitals there have been some mistakes with regard to administration of the drug. I understand that you have sent a letter in, correcting the way of administration. Could you give us some update on that?

A1-2:
(Taniuchi COO) Yes. With regard to cataract patients, this is a contraindication to the patients who have gone through a cataract surgery. However, due to the decision made by the doctors, the drug is sometimes used or is continuously used in these kinds of patients. If there are any side effects because of this action, we are informed and we also have to provide reports to agent. Through discussions with an agent, we have issued a white letter. However, this is not different from the kind of information provision that we have made in the past. And it is not an issue on our side but rather on the prescriber side. In fact, our views and policies, have not changed.

Q1-3:
It's like 100 million yen of sales per month according to the information that I am looking at. And if this is the pace, I don't know. I wonder whether you will be able to achieve the full year goal. And from April to June, in terms of sales, maybe you are having some difficulties. Or is it not true or so, what do you have to say with regard to the sales trend?

A1-3:
(Suzuki SCO) Right now, there is a prescription limitation that will expire in December. So, the prescription is only up to two weeks, as of today. Therefore, the volume of prescription to be increased is one matter. But, rather than that, we want to increase the number of accounts or patients. And we have achieved 70% of our goal objective, with respect to the number of patients. Also, as I said, there is still prescription, two-week limitation. And sometimes, as has been said, there are some doctors who kind of use it in a different way. But we will continue to provide a careful detailing to our customers.

Q1-4:
Last year's Q1, the actual business was okay but there were some difficulties in terms of its looks or appearance. But with regard to Alesion, I understand that there was some shift in the seasonal environment. So, there was a shift than you had expected. It is that understanding correct?

A1-4:
(Taniuchi COO) Yes. That is correct. The pollen peak was earlier than we had expected. Also, cypress pollen was not very much or greater this year. So, that is one of the other reasons.

Q2-1:
First, I want to ask about Asia. The numbers in Asia are very strong, especially Cravit in China, and also Diquas in Asia. They are growing very fast. Is there any special situation in this quarter, or is it actually growing? If we look at the budget, Alesion sales is a bit lower than the budget, but what is the situation in Asia.

A2-1:
(Suzuki SCO) As to Cravit, I think this is a growing actually, especially in China and other Asian nations. LASIK and cataract surgeries are increasing, and at the perioperative time, this product is being used. And this is growing faster than our expectation. So, that's why we are seeing a very good growth.

Q2-1-2:
So, Diquas in Asia, what's the situation?

A2-1-2:
(Suzuki SCO) Likewise, for dry eye, the awareness is higher. Hyalein/Hialid and Diquas, there are two lines in Santen. As to Asia, Diquas is growing fast and is penetrating well. Diquas has just launched in China and it has not been listed yet. So, the expansion in China will be in the future.

Q2-2:
My second question is the progress of the sales and also profit in the first quarter. Lower sales of Alesion seem to have negative contribution to the profit. But, on the other hand, it's going very well in Asia. So, in total, against the full year, what's the progress?

A2-2:
(Suzuki SCO) As to the budget, as to the balance between the overseas and domestic market, overseas, including Asia, is stronger. In Japan, we manage including SGA control to get close to the original budget. So, if you look at the balance, Asia is taking the lead with strong growth.

Q2-3:
I have a question about DE-109. The completion, expected completion is delayed from 2021 to around fiscal 2022. I want to ask why it's been delayed in the US. And also, as to this product, it will be protected by data protection period. So, even if it's delayed, it won't affect the value of the product. It is this understanding correct?

A2-3:
(Shams CSO) This is Naveed. I'll try to answer your question. Yes, your understanding is correct. Because of the orphan indication, the data protection will start after we get approval. And so, that will not change

because of this delay. It will have no effect on that.
We have taken several steps to increase the probability of technical success. One such step is the use of a reading center to make sure that the correct patients enter the study. This is causing an impact on the recruitment of patients, as the screen failure rate is becoming high. However, it is very important not to lower the chances of success. So, at this point, we do not wish to amend the protocol. Instead, we will open sites outside the US. For example, in the United Kingdom. So, success is very important. Thank you.

Q3-1:
In general, your business is doing well. And I would like to ask you with respect to some specific product. According to the plan that you have, by product, in Japan, Tapros, Cosopt are glaucoma related products. You said that you are expanding Eybelis. Therefore, the other products will be shrunk. And so Eybelis will be focused. And the plan says that Eybelis will be growing. However, you were talking about the white letter but, add it seems that the first-quarter startup of Eybelis is not so magnificent. On the other hand, in Cosopt and Tapros, Cosopt seems to be declining a little bit. I wonder what will happen in the second quarter and beyond. Are you going to recover in the second quarter and beyond? Would you give us your forecast?
And another product that I would like to ask you about is Timoptol. The plan in EMEA, I think, was a very big. And to that, the first-quarter results was smaller. And I would like to ask you the reason why you have a gap between the actual and the plan.

A3-1:
(Suzuki SCO) With respect to your first question, let me respond. With respect to Eybelis and other glaucoma products relations, what Eybelis is focusing on is PG products, aside from Tapros. That's the positioning. So, there are no relations between the good progress of existing products including Tapros and the progress of Eybelis. With regard to Tapros, the sales is higher compare to our detailing focuses and generic impact is less than our expectation for other products. With regard to Eybelis, the number of accounts is growing, as expected. So, after the limitation of two-week is lifted, beyond the fourth quarter, I think it will be growing. Therefore, in glaucoma business in total, there may be some fluctuations. But in total, I think we are progressing as planned.

Q3-1-2:
With regard to Eybelis, in the first quarter trend, will that continue in the second and third quarter? And in the fourth quarter, you will be accelerating. Is that correct?

A3-1-2:
(Suzuki SCO) The number of accounts is increasing. So, I think the number will be growing in spite of the fact that there is a limitation of two weeks. And after the limitation is lifted, we will be accelerating.

A3-1-3:
(Taniuchi COO) Let me discuss about the Timoptol. And there are two items Timoptol and Timoptol EX. And the formulations are different between the two. But if you add the two, this is as planned. And depending on the countries, there may be some gaps and it might look irregular. But if you add the two columns together,

we are proceeding as scheduled or planned.

Q3-1-3:
So, this is a situation specific to EU, depending on the different countries. Is that correct?

A3-1-3:
(Taniuchi COO) Yes. there are two formulations with respect to Timoptol in Japan, as well. And so, if you could add the two columns, you will be able to get the correct figure.

Q3-2:
With regard to DE-127. In Japan, Phase 3 has started, you said. And the results of the clinical study in Asia was the basis I think you said in the past. I think this means you can get some progress for Asian clinical studies. Did you move up the clinical schedule? And also, Singapore, you have said that you have completed the clinical study in Singapore. But was it a shift of the site from the Philippines to Singapore?

A3-2:
(Shams CSO) This is about DE-127 in myopia product. I think a few reminders. We started a Phase 2a study in Singapore, a small study. As you know, the treatment involves a lot of children. As you may also know, that there is substantial amount of data available in, regarding atropine and myopia. So, taken together, we did analysis for safety concerns. As we were comfortable, we decided to proceed in Japan. The study was very small and short duration. So, the trends were similar to published atropine data. But the study is still running. It has not ended yet. It will end later in the year. I hope that answers your question.

Q3-2-2:
So, you were talking about the Asian study?

A3-2-2:
(Shams CSO) Yes.

Q4-1:
About LENTIS Comfort, as compared to full-year plan, the progress seems to be delayed. From the second quarter and beyond, how do you see the progress of this product? Are there any factors which may enhance the growth?

A4-1:
(Suzuki SCO) As to LENTIS Comfort, the number of accounts, it’s on track or even faster than original plan. As compared to the past IOL product, the speed of the adoption, the number of adoptions is progressing faster. So, I think the progress is well. But on the other hand, as we mentioned, the inserter kit hasn’t been supplied yet. So, after the start of the kit, I think the growth will be accelerated.

Q4-1-2:
I understand it was approved in May. When do you plan to launch this? I don't think the kit will make much difference, but what do you think?

A4-1-2:
(Suzuki SCO) As to the inserter, we haven't launched it yet. We are thinking that it will be launched in this summer or beyond. Some doctors are saying that they would like to have an inserter to increase the number of operations. So, that number of adoptions is progressing very well and I think, by introduction of inserter, we can, we'll be able to see even better figure.

Q5:
There is one question with regard to MicroShunt, DE-128. November to December will be the timing of filing, when is the data announcement? I think before, you said that you will do the filing and then announced the data after that. Has your plan not been changed?

A5:
(Shams CSO) The data has to be made available before we can complete the filing, which is the last module, as we call it, the last component of the PMA.

Q6-1:
I have a question about Eybelis. In case full-fledged sales will start from December and beyond, several billions of sales will be necessary for Eybelis in the fourth quarter to achieve full year target. Is this understanding correct?

A6-1:
(Suzuki SCO) There is a prescription limitation now. But this situation is different, depending on prefecture. The number of account is increasing and this made change, depending on the judgment of the doctor. So, it will not be that 100 million yen sales continue until December and then it will explore right after that. It will grow gradually, we think. The specific numbers, we do not know yet because it just launched recently. So, we would like to continue to make efforts.

Q6-2:
As to overseas market, Asia has been strong and that range. As to Europe, you said that there are many factors and I believe that you have two grow by 7% for this year on JPY basis. Are you thinking that if Asia is good, that will offset slow progress of Europe?

A6-2-1:
(Suzuki SCO) We are not thinking that Asian growth will offset the slow progress of Europe, because we would like to see growth in Europe as well. However, it's more challenging in Europe. So, we would like to

see the balance between the investment and the benefit. As to Asia, the top line is very high. We are seeing strong growth. So, that will have a very big contribution to the profit and would also like to see even bigger profit, by cost optimization.

A6-2-2:
(Taniuchi COO) As to EMEA, new products like Ikervis are penetrating well and they are enjoying double-digit growth. On the other hand, glaucoma portfolio, there are some factors such as pricing or generic products. But in total, we are expecting healthy growth. As to the market situation, as compared to Asia, it’s more conservative. However, the price is higher than Japan and we want to be optimistic about the sales and the growth of EMEA.