August 2, 2018 Conference Call – Summary Transcript

Q1 FY2018 Earnings Conference Call



August 2, 2018 Santen Pharmaceutical Co., Ltd

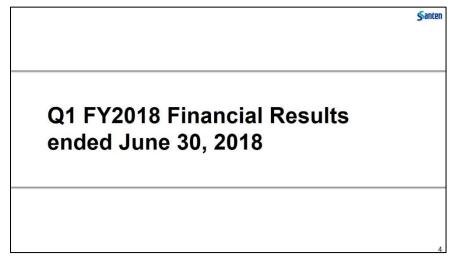
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I begin with an explanation of the earning conference call materials. As you know, "Tenki ni sanyo suru," which means "exploring the secrets and mechanisms of nature in order to contribute to people's health" expresses Santen Pharmaceutical's Values. Our Mission Statement is "by focusing on ophthalmology, we develop unique knowledge and organizational capabilities that contribute to the well-being of patients, their loved ones, and consequently the society." We move our business forward based on these Values and Mission.



This is MTP2020, outlining our medium-term management plan from FY2018 to FY2020. The fundamental policy is to achieve our long-term vision of becoming a specialized pharmaceutical company with a global presence and establish a path for sustainable growth after FY2020. In order to achieve this, we seek to increase customer satisfaction, profitability, and organizational strength by promoting global business strategies, enhancing the product pipeline and developing new treatment options, and strengthening and streamlining our business framework.

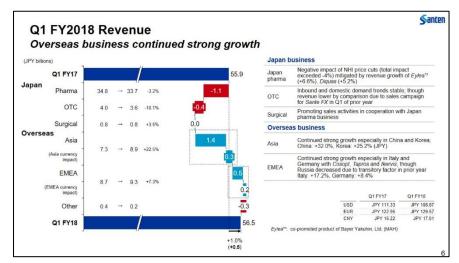


Now I will move on to the summary of the consolidated results for the first quarter of FY2018.



In terms of revenue, the domestic pharmaceutical business was affected by the timing of inventory channel adjustments and a revision of drug prices from April. The overseas businesses in Asia and EMEA, which continue to grow, were able to absorb the negative impact and revenue grew year-on-year by 1.0%, or approximately 600 million yen.

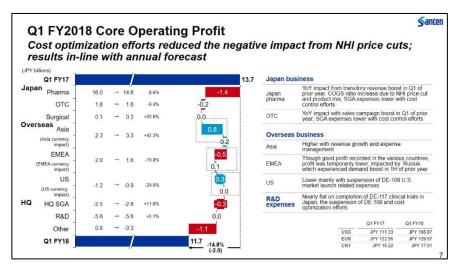
With regards to operating profits, each business sector is controlling SG&A expenses, and the research and development expenses remain flat nearly compared to the last year. However, there was impact from transitory factors in the Japan business in comparison with the previous year. There was a rise in cost ratio due to the drug price revisions and the product mix this term affected the core operating profit, which showed core operating profit decreasing by approximately 15% to 11.7 billion yen. IFRS operating profit decreased by approximately 17% to 10 billion yen. However, this decline was largely influenced by transitory factors compared to the previous term. We are making progress in line with annual forecasts and still expect a 6% increase in core operating profit for FY2018. There are no major transitory factors in the other comprehensive income included in full base operating profits.



This shows the factors that led to fluctuations in revenue by business segment for the first quarter of this fiscal year. In Japan, the pharmaceutical business was impacted by transitory inventory adjustments in the distribution channel, drug price revisions, and campaign activities from the previous fiscal year in the OTC business, but growth trends for our focus products did not see any big changes. Overseas, we continue to

grow steadily in each region as a result of our continued focus on introducing new products, and penetration and expansion of existing products.

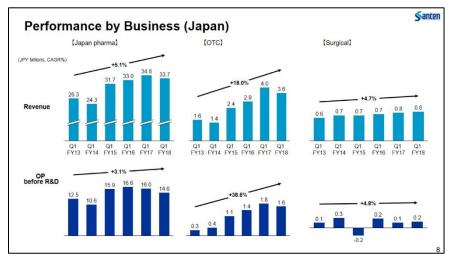
These factors enabled us to absorb the negative impact as a whole, resulting in an increase in revenue of 1.0%.



These are the core operating profit trends. For the Japan business, we are striving to control SG&A expenses and there was a year-on-year decrease, but due to a decrease in revenue from the factors I explained earlier, profits decreased as well. Our Asia business continues to grow profit steadily with an increase of over 40% on a Japanese yen basis.

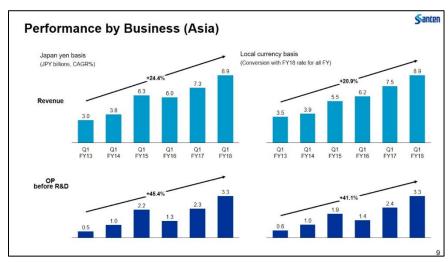
In our EMEA business, there were unused expenses in the same quarter of last year along with unusually strong demand in Russia also in the prior year, resulting in decreased profits in the first quarter year-on-year. In EMEA there was no change in the growth trends and we are steadily increasing our presence.

With no corresponding special factors boosting this Q1 performance, group profits decreased by approximately 15%. At the same time, we are working to maintain and improve the overall profit growth trend. We are on track to achieve our target for this fiscal year.



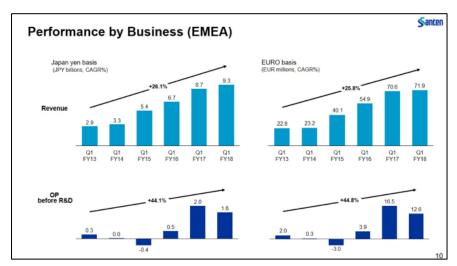
This shows the performance of first quarter revenue for the Japan business from FY2013 to FY2018 as well

as operating profits before R&D expenses. During the short three month period, there are effects of systemic changes as well as transitory factors which standout noticeably, but we are aiming to continue growth through catching stable demand and potential new markets.

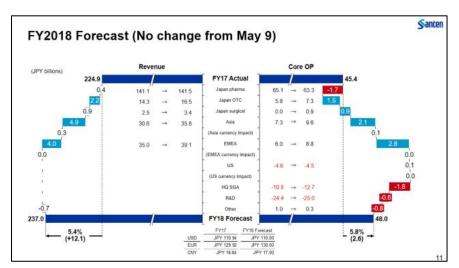


Next is our Asia business performance.

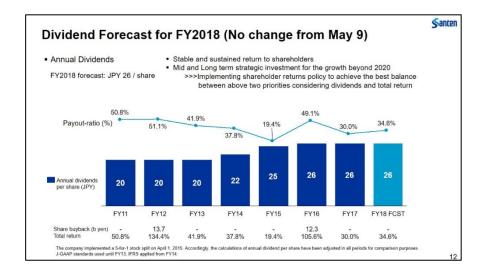
As in the past, we continue to grow steadily as Santen products permeate the market beyond growth levels of the overall market. In China and other Asian countries, in order to continue to expand in area as well as meet healthcare needs, we are registering and launching more than 30 products annually. These products are starting to contribute to our business. We will continue our efforts to achieve further growth in the medium and long term.



Here we have the EMEA business performance. We are continuing to grow with strong demand from markets centered on glaucoma products. The revenue from Ikervis which treats dry eye is also growing, and we will continue to penetrate these products further and increase our presence.



This is the FY2018 forecast, which we announced on the 9th of May as projected to be 237 billion yen in revenue and 48 billion yen in core operating profit. No changes have been made to these figures.



Lastly, here is our dividend forecast for FY2018. The annual dividend is projected to be 26 yen, which remains unchanged from the announcement on the 9th of May. This concludes the summary of the consolidated results from the first quarter of FY2018. Next, Dr. Shams will explain the current status of research and development.

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	Indication	Region	Status
DE-117 EP2 receptor agonist	Glaucoma / ocular hypertension	US	P2 Plan: 2 nd half FY2018 P3 start
		Japan	Filed Plan: 2 nd half FY2018 approval
		Asia	P3 Plan: 2 nd half FY2018 P3 completion
DE-126 FP/EP3 receptors dual agonist	Glaucoma / ocular hypertension	US	P2b
		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	P3 Plan: 2 nd half FY2018 an additional clinical trial start
		Japan	P3
		Europe	P3
		Asia	Filed
DE-122 Anti-endoglin antibody	Wet age-related macular degeneration	US	P2a Plan: Jan~Jun 2019 P2a completion

Let's start with DE-117, this is an EP2 receptor agonist. The indication is going to be glaucoma and ocular hypertension. Currently, we are planning to start a Phase 3 study in the US. We are on track to start a Phase 3 program in the US in the second half of FY2018. As you know, we have already filed in Japan and are expecting approval on time in the second half of FY2018. The Asia study will complete in the second half of FY2018.

DE-126, this is an EP3 receptor dual agonist also indicated for glaucoma and ocular hypertension. It continues to be in Phase 2b and we are analyzing the data.

Next is DE-128. This is the InnFocus MicroShunt device for glaucoma. We continue to forecast to complete the study in the 2018 - 2019 timeframe and launch between 2020 and 2021 calendar year.

DE-109, this is the intravitreal sirolimus for uveitis. We plan to start an additional pivotal study in the second half of FY2018.

DE-122, this is for wet age-related macular degeneration. It's currently in Phase 2a. We plan to complete this study in the first quarter of 2019 calendar year.

DE-089 Diques	Dry eye	China	Approved	
			Plan: FY2018 launch	
DE-076B Se	Severe keratitis in patients with dry eye	Asia	Launched	
Cyclokat / Ikervis ciclosporin		US	P2	
DE-076C Vekacia / Verkazia ciclosporin	mal kerato-conjunctivits	Europe	Approved	
DE-114A epinastine HCI (high dose)	Allergic conjunctivitis	Japan	P3 completion Plan: 2 rd half of FY2018 filling	
DE-127 atropine sulfate	Myopia	Asia	P2 Plan: 2 nd half of FY2019 P2 completion	

We plan to launch DE-089, or Diquas as it is commonly known, in FY2018 in China. We think this will be a very important product for the Chinese market.

For our ciclosporin product DE-076C, vernal kerato-conjunctivitis or severe allergy of the eye, was approved in Europe and will be launched very soon.

Similarly, DE-114A, this is epinastine for allergic conjunctivitis. In Japan, we intend to file for approval in the second half of FY2018.

DE-127, which is atropine for myopia is in Phase 2 and we intend to complete the study next year in the second half of FY2019. That's all from R&D.

Question & Answer Session

<Q1-1>: My first question has to do with what Mr. Sakurai spoke about in the beginning regarding the transitory inventory of pharmaceuticals domestically and other factors. This was after the price revision in Japan so I would expect this to be a factor in inventory increasing. Can you please explain what the impact of the factors were if you are aware of that?

<A1-1>: (Sakurai) What you mentioned would be the expected trend having the revision in drug prices, but as the amount of pollen was higher this year and it was expected to have a prolonged presence, we shipped in March to ensure distributors had the necessary stock for hay fever symptoms. Therefore, the amount we shipped in March was very large. So we felt this impact when Q1 began and shipments decreased compared to a year ago when our shipments we less concentrated in March. When comparing the first quarter of this year to the first quarter of last year, where no special circumstances occurred, revenue appears to have decreased. The impact was approximately 1 billion yen.

<Q1-1-2>: Is that a result of unusual circumstances that occurred this time and the pollen stopped earlier than expected so the shipped inventory was not used up? It was somewhat unpredictable, and the circumstances arose due to the shipping situation?

<A1-1-2>: (Sakurai) If you are referring to forecasting, yes there was probably some discrepancy, but looking

at the actual inventory consumption it is steadily being consumed.

<Q1-1-3>: Does that mean this 1 billion yen will be gradually covered over the course of the fiscal year?

<a1-1-3>: (Sakurai) It's only been three months, so it has had an impact, but as the fiscal year progresses it will balance out.

<Q1-2>: I have another question regarding R&D. You said that 109 was in Phase 3 additional testing. When I took a look at ClinicalTrials.gov, there was still no information about study design. Can you please tell us anything you can about the design and timeline?

<A1-2>: (Shams) We are currently in discussions with the FDA and will very soon be able to finalize the protocol so that we can start on time in the second half of this year. There are no red flags, but we wish to make sure that we are in complete alignment with the agency on this pivotal study. We are taking extra effort to align with the agency on every major element of the study such as inclusion criteria and statistical plan, et cetera. I can't give you any more details but the goal here is to succeed. The goal here is not to fail. We are working very closely with the agency. Thank you.

<Q2-1>: My first question is about cost. Last year there were some initiatives to cut expenses and yesterday I heard the same thing from Mr. Sakurai. What is the margin you are looking at for this fiscal year? I am aware cost control is an issue you are tackling, but did you realize benefits in the term from April to June? Can you tell me what the status is?

<A2-1>: (Sakurai) As you mentioned, optimizing costs is currently a major goal for us. It is still early days so there has not been any effect that is worth announcing or mentioning here at this moment. However, when we compare each of our businesses year-on-year, there are not simply unused expenses; they are most certainly taking actions to decrease them. When we proceed a little further into the fiscal year I think there will be an opportunity to speak about this in more detail in the future, but we are seeing effects.

<Q2-2>: My second question is for Mr. Naveed. Regarding the MicroShunt, testing is expected to finish between 2018 and 2019, but were you able to have the FDA to agree to a 12-month follow up period? Or will it be 24-months?

<A2-2>: (Shams) We are in discussions with the FDA about the 12-month data, and we will provide information as it becomes available in the near future, but we are currently sticking to our original plan unless something changes.

<Q2-2-2>: This discussion has been going on for some time now to my understanding. Can you tell me what the issues are?

<A2-2-2>: (Shams) You are right in that. There is no guarantee how long this will take, but the issue at hand is the duration. How long is sufficient, actually to see safety and efficacy for this type of device. According to the guidance for MIGS devices, two-year data is required and is set as precedence. Therefore, you can imagine that we would like to convince the agency, if possible, to reconsider that guidance.

<Q2-3>: Shire is talking about a delay in Europe for the dry eye medication, Xiidra. How do you think this delay will affect your European business for Ikervis?

<A2-3>: (Sakurai) Ikervis is growing well and regarding this fiscal year in particular, it has shown better than expected growth since the year started. This is all I can say about that at this point.

<Q3-1>: I would like you to explain about the effect of the transitory factors on OTC. I think there was an impact from last fiscal year's Sante FX campaign, but I would like to know how big the impact was in terms of a monetary amount, and I would like to know how much the OTC business has grown in actual terms. Can you comment on that please?

<A3-1>: (Sakurai) Regarding the effect of transitory factors on our OTC business, as you mentioned, the biggest factor was the collaborative campaign with the Sante FX based on a popular "anime" series we held in June 2017. The effect of this campaign was between 600 to 700 million yen. We did not hold any special campaigns between April and June in 2018 so there were no special elements and it appears as a decrease in revenue. However, there was no particular change in the trend aside from the temporary demand due to the campaign. The understanding is that the inbound business continues unchanged from before.

Although the inbound business has elements which includes the tourist business, which is an accumulation of small demands, and there is also the broker business element. The business involving tourists is moving forward without much change, but regarding brokers, we cannot forecast the timing. Unfortunately, there were no major changes between April and June, but we do foresee that there will be some throughout the fiscal year.

<Q3-1-2>: In that case, last year the OTC revenue was about 3.9 to 4 billion yen and this term OTC is at 3.4 to 3.5 billion yen so if we adjust 600 to 700 million yen, it is still growing. Is that the correct way of looking at this?

<a>3-1-2>: (Sakurai) Yes, that understanding is correct.

<Q3-2>: My second question is about the Asia business. Looking at the numbers for China, Korea, and Asia overall, there seems to be nearly 20% growth. When referring to the mid-term strategy, it seems that the current situation is very good. Can you give us some background on what the factors are in this growth, including any transitory factors that may be playing a role?

<a>A3-2>: (Sakurai) There were no special transitory factors contributing to the growth of the Asia business in this first quarter. My understanding is that our activities of continued area expansion and providing products in response to local needs have been successful and this has led to steady growth.

<Q3-3>: I would like to ask about DE-117. Development in the US has been decided officially. Looking back, initially it was going to be launched in the US. Then, the launch was changed to Japan, and the result is that it was deemed to have enough competitiveness in the US. I believe AYAME and FUJI were showing very good results recently. Can you please explain what made you confident on the competitiveness in the US? Also, my understanding is that your policy with development of products is that it's going to be concluded independently, though I believe sales will be in cooperation with other companies to a certain degree. Can you please talk about that?

<a><A3-3>: (Shams) I'll briefly answer the last part of the question. No decision has been made on how the product will be commercialized in the US at this point, but all of the options are probably on the table. As far as 117, why we are confident that this will be a solid product for the US has to do with what we have seen in the Asia and Japanese development programs.

Most importantly, there are two elements that make us very comfortable. One is the long-term 12-month data in Japanese subjects showing very robust lowering of IOP for at least 12 months. The second is as you mentioned, or somebody mentioned is to do with non-responders to latanoprost and the effect of 117 on the subjects where additional lowering of IOP was seen.

<Q3-3-2>: I'd like to ask another question. With regards to development, are you going to proceed independently or are you thinking about developing cooperatively - has that been decided?

<a>3-3-2>: (Shams) Currently, we'll develop this product on our own.

<Q4-1>: I'm sorry to bring this up again, but with regards to domestic revenue, drug prices fell 4.5% and the revenue according to these materials is minus 3.2%, which means the volume only grew 1.3%, but earlier you said there was a negative impact of about 1 billion yen. I believe it was mainly Alesion, but were there any other domestic factors that held back growth? For example, generally speaking, ophthalmic solutions are not too affected by generic products, but did generic products have an influence? If there were any other negative factors, please tell us about them. That's the first question.

<A4-1>: (Sakurai) For the pharmaceutical business, other than the drug prices, we did not have any specific products subjected to any specific events worth mentioning this fiscal year. In comparison to last year, it is less from that perspective, but there is no specific reason aside from drug prices or specific product that has been holding us back.

<Q4-2>: I see. Regarding overseas, *Hyalein* in Asia is growing very well. The year-on-year is 50%, and on

page 9 of the consolidated performance material, it is already at 2.6 billion yen. The annual plan is 9.1 billion yen and it seems to be expanding at a much higher pace than expected. Is that correct? It is performing beyond expectations? Or was there a specific factor in the first quarter that caused this? Please confirm that for me.

<A4-2>: (Sakurai) The growth of *Hyalein* in China was the largest contributing factor to the growth of *Hyalein* in Asia. This can be attributed to the continuous measures taken for area expansion in China that have been successful. There were no transitory or special factors, rather it is a case of our continuous activities bearing fruit. The year-on-year 50% growth in China is a result of those efforts.

<Q4-3>: I want to confirm a point regarding R&D. In the explanation about DE-126, Mr. Shams explained it is in Phase 2b data analysis. What is the timing on the data read out?

<A4-3>: (Shams) We have had data read out already. We are trying to fully understand the outcome of the study. As soon as we complete all of the reviews including our business assessment and everything else, then we will discuss that in the near future. That should not indicate any problems or red flags.

<Q4-3-2>: I don't think I will be able to get an answer to this, but if for example, when the stage moves up, will a milestone payment be incurred at the introduction source?

<A4-3-2>: (Shams) That is probably correct, but I'll have to confirm that later.

<Q5-1>: My first question is regarding cost of sales. I think it is probably due to the decline in drug prices and that could explain almost all of it, but in the consolidated performance materials it says 40.8% and it has risen 200 basis points. I think the annual forecast is 38.3%. So this is going to decrease from the second quarter. Can you explain about the factors that pushed this up in the first quarter and then what would make this decrease going forward?

<a>A5-1>: (Sakurai) Yes, as you mentioned the cost ratio rose to 40.8% in the first quarter. The main reason for that is, as you have mentioned, the fall in drug prices. In addition to that, *Eylea*'s sales are growing. *Eylea* is one of our products that has a high cost ratio.

On the other hand, as I explained earlier, *Alesion*'s sales dropped from April to June as a result of the distribution inventory adjustment, and therefore our sales composition ratio of *Alesion* dropped. *Alesion* and Eylea are at the opposite ends of the spectrum. *Alesion* is one of the products with extremely low cost ratios in our product line, and this contrast has become quite prominent over the last three months. This has been raising cost of sales. As the year progresses, *Alesion's* sales will become higher in our sales composition. Especially the latter half of the fiscal year, as it will be hay fever season, and the cost rate of this product is low, we will get closer to our target of 38.3%.

<Q5-1-2>: I assume there won't be much change in *Eylea's* growth, and *Alesion's* contribution to profits is generally in hay fever season so it will be from the third quarter and later, is this correct? In that case, costs of sales will be fairly high until the second quarter or mid-way through the third quarter? Is that the image?

<a><A5-1-2>: (Sakurai) Regarding these two products, yes that is correct. But the company is moving forward as a whole so the situation will gradually be alleviated. That is the understanding we want you to take away.

<Q5-2>: I have one more question. Regarding 109, I'm sorry to ask this to Dr. Shams over and over. I think once you review with the FDA and the protocol is determined we will know the answer, but it is something I'm concerned about. The clinical trial period can change quite a bit depending on whether or not visual strength is measured. Can you comment on that at all?

<A5-2>: (Shams) That and similar points are under discussion exactly as you say.

<Q6-1>: I mainly want to ask questions to Dr. Shams. My first question is, in the Roche presentation the results of the Phase 2 ladder test came out. This is the port delivery system; *Lucentis'* delivery system is implanting rice grain sized objects into the eye. Looking at it, the median value is generally one refill in 15 months, but in actuality 80% of patients refill after a period of about six months.

In other words, administration frequency is much lower than that of *Eylea*. This is now entering Phase 3 which is supposed to start in 2018. In my opinion, I think many Japanese people will be reluctant to choose implants. Will this product be a threat to *Eylea*? Can you please comment on that? That is my first question.

<A6-1>: (Shams) It's kind of difficult to comment on a competitor's product but I feel, from basically as a clinician, that there is a room and there is place for a lot of these products and it should not have a dramatic effect on either *Lucentis* or *Eylea*. That's probably my best guess.

<Q6-2>: Thank you for your well thought-out comment despite the difficult question. My next question is about *MicroShunt*. I may be mistaken about this, but on ClinicalTrials.gov testing will finish in November 2018 and study completion is set for November 2019.

In November 2018, the first year results will come in and of course, according to the guidance, two years is required so we must wait. What I wanted to ask is if this first year data is extremely good, can it be disclosed? Or will disclosure result in bias towards the test and therefore it cannot be disclosed? Can you please comment on how the test results will be disclosed?

<A6-2>: (Shams) That is exactly what we are discussing with the agency, and it's taking time because we have to make the case to do exactly what you are saying. I am sure you would agree that without the agreement of the FDA, we will not be able to release any data before the study is completed in two years.

<Q6-2-2>: What I don't really understand is how disclosure will affect bias. The first year data will be finished

and everyone will already have their implants so I can't understand how this will bias the second year data. Can you comment on that please?

<A6-2-2>: (Shams) That is our argument as well that there may not be any bias, but there is precedence as I mentioned in the guidance. As you know, regulators are conservative people. They like to stick to the guidance.

<Q6-3>: This question is about the MicroShunt INN-007 test. After the earnings announcement, there were test results listed in the earnings announcement materials. Last time I asked a bit of a misleading question, so I would like to correct that. According to this, after 12 months intraocular pressure only drops to 15mmHg and that didn't seem to be enough as I saw it at that time.

However, Glaukos and other products result to 15mmHg after a cataract surgery and in your case cataract surgery is not conducted. Obviously if the crystalline lens is removed the intraocular pressure will drop. So having said that you have been able to lower the IOP to 15 without IOL, this means that it is very competitive. I think it was written in some guidance somewhere that dropping IOP lower than 10 is too low. Can you please comment on that? This is my last question.

<A6-3>: (Shams) Yes. Briefly, somewhere, the gold standard would be 15 millimeters of mercury or less, and above 6 millimeters of mercury. Somewhere between 6 and 15 is the sweet spot.

<Q6-3-2>: I'm just guessing it got lost in translation. Let me try this in English. DE-128 does not require an insertion or interocular lens. Obviously, all of the other competitors with the exception possibly of XEN require IOL. And so if you insert an IOL, just by the fact of doing so, it will lower the IOP. And in your case, you didn't do that and still got 15 mmHg, is that correct?

<A6-3-2>: (Shams) That's correct.

<Q7-1>: I'd like to ask a question related to the implantables just mentioned. This is about competition. The other day Allergan had a successful Phase 3 for a glaucoma PD type pharmaceutical implant that is implanted once every four months. Can you please comment on the impact this will have on your midterm glaucoma strategy?

One more question is as these implantables become more successful, what kind of sustained release technology does Santen have or are you thinking you need to acquire some?

<A7-1>: (Shams) We don't consider, at least in its current configuration, a threat to our glaucoma franchise from this product. It will take some time to develop. All I can say is that we have our own effort in this area and we will disclose that whenever it's ready to be disclosed.

<Q7-1-2>: I'd like to ask a little further. What can you tell me about when and what kind of pharmaceutical

we can see coming from Santen?

<A7-1-2>: (Shams) In this business, it's very difficult to forecast how long it will take, but we are trying our best to expedite and clearly communicate when it is ready. I'm sorry I don't have an exact date for you. I can only say that we have a team working on drug delivery systems.

-END-