

## Speaker Remarks November 2, 2017 (summary)

### Santen's Values, Long Term Strategic Vision and MTP

#### Slide1: Santen's Values



## 天機に参与する

*Tenki ni sanyo suru*

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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Thank you very much for joining us for Santen's Investor Meeting. Let me start my presentation. I will explain our performance up to the Second Quarter FY 2017. *Tenki ni sanyo suru*, that Santen's value, corporate value is shown here. We focus on ophthalmology to contribute to well-being of patients in this therapeutic area and we make contribution in medicine.

#### Slide 2: To Become a Specialized Pharmaceutical Company with a Global Presence



### To Become a Specialized Pharmaceutical Company with a Global Presence

~2013

Rank #5 globally  
Overseas sales:  
16% of total sales

- Strengthen Japan business
- Completed preparation for business expansion in Asia/EMEA

2014~2017

Overseas sales:  
30% of total sales  
Q2 FY2017 actual: 29.6%

- Grow business in Asia/EMEA and improve profitability
- Prepare for business expansion to the U.S. and other regions

2020

Become Global Top 3  
Overseas sales:  
40~50% of total sales

"To Become a Specialized Pharmaceutical Company with a Global Presence"

Current Mid-Term Plan (MTP)

	Plan	Results
<b>Product Development</b>	<ul style="list-style-type: none"> <li>-Transform product development to realize enhanced productivity and achieve sustained growth</li> <li>-Active investment in sustainable growth</li> </ul>	<ul style="list-style-type: none"> <li>-Approval, Launch: Tapcom, Ikervis</li> <li>-Development: progress of DE-109, 117, 122</li> <li>-Licensing, Acquisition: DE-126, 128</li> </ul>
<b>Business Expansion</b>	<ul style="list-style-type: none"> <li>-Grow business in Asia/EMEA and strengthen market presence by entering into new markets</li> </ul>	<ul style="list-style-type: none"> <li>-Raised new products sales ratio in Japan: from 44% (FY13) to 71% (FY18)</li> <li>-Growth in market share of OTC products in Japan</li> <li>-Strengthened internal sales platform in Asian countries</li> <li>-Grew the number EMEA countries with sales</li> </ul>
<b>Organization and Talent</b>	<ul style="list-style-type: none"> <li>-Develop talent and organization to realize sustained growth and strengthen the global management system</li> </ul>	<ul style="list-style-type: none"> <li>-Introduced new HR appraisal system</li> <li>-Held training aimed at nurturing the next generation of employees / managers</li> </ul>

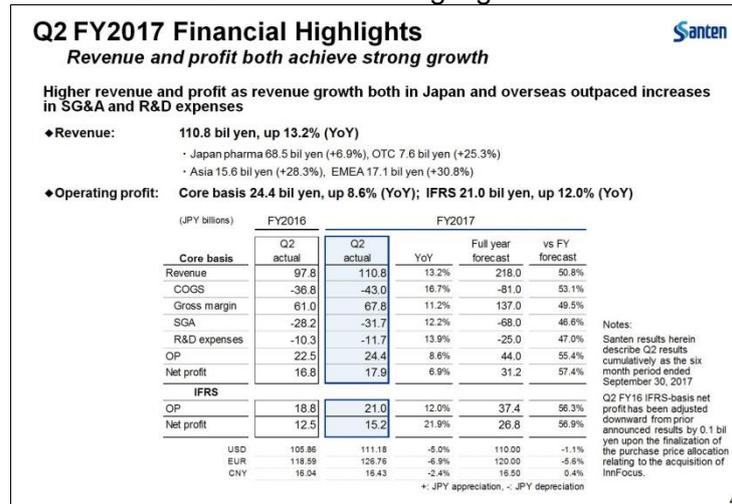
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FY 2014 to 2017, this is the important midterm to achieve our goal in 2020 and this year is the last year in this current midterm plan. As shown here, we want to achieve overseas sales 30% of the total and Asia/EMEA growth and profitability and prepare for business entry expansion into the US and other regions. Those are the goals and the pillars are product development, we need to develop new products and then business expansion and as I said not only in Japan, Asia, Europe and the US, those areas are in our perspective to strengthen our business.

Additionally, we need to strengthen organization and talent. As for overseas sales ratio, in the second quarter FY 2017, in this first half, we reached 29.6%. Therefore, our ultimate goal is 30% for FY 2017 and we are very close to achieving that. That may give you the overview of the financial results for the first half very briefly.

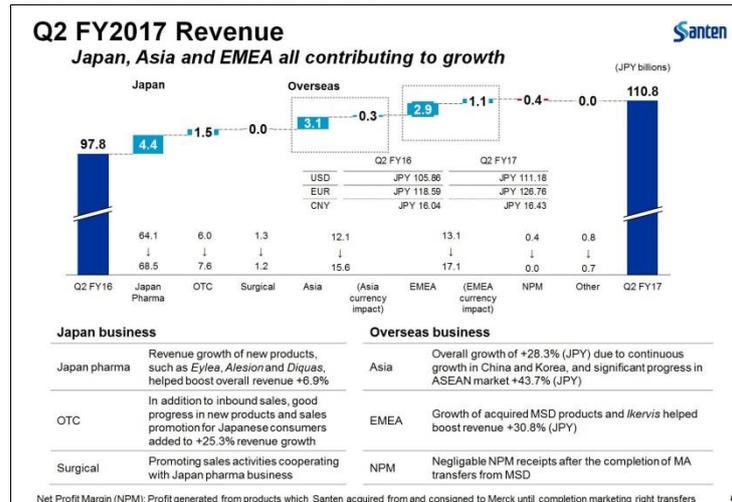
## Q2 FY2017 Financial Highlights

### Slide 4: Q2 FY2017 Financial Highlights



In the first half, in sales of Japan overseas, sales were very good and the revenue year on year was up 13.2% to 110.8 billion Yen. There were expenses necessary for acceleration of growth in existing markets and also for US market entry preparation and for further growth in future, we increased SG&A and the R&D cost also increased because we need to strengthen pipeline, therefore expenses were higher than last year, but in terms of profit, core base profit was up 8.6%, which shows our earning capability in core business and for the full base up 12.0% to ¥21.0 billion, this shows our factors impacting sales up to the second quarter by business.

### Slide 5: Q2 FY2017 Revenue



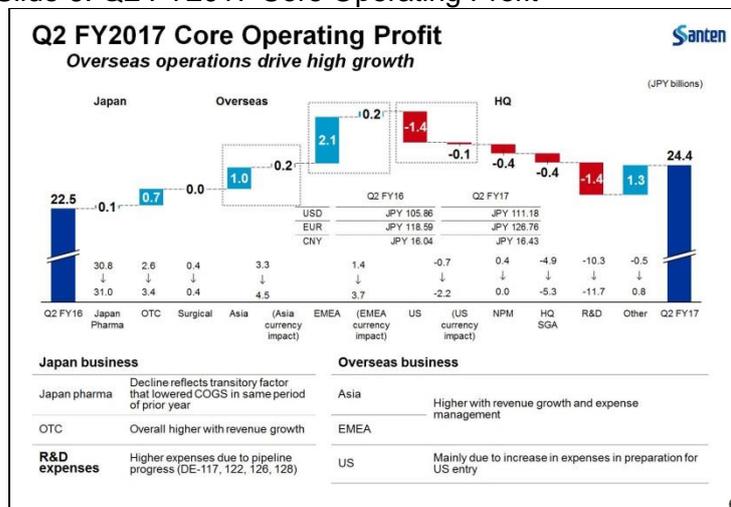
Domestically, we penetrated new products and we could capture demand in the overseas, we could penetrate existing products and we expand geographical areas and by region, by business, we are able to make steady growth. Overall, we had an increase of 13.2%. As the graph shows, domestic prescription business was well and also for OTC business we could capture in-bound demand and as for the in-bound business, it continues to grow, it is growing now, I don't know what happens after Tokyo Olympic Games, but until then we will continue to have more visitors. In terms of changing quality, so far, only some buyers tend to buy in large quantity, but nowadays, general tourists tend to buy more and as tourists at the drug stores, maybe you have a chance to look at the product displays and Santen's shelf space is much more than the competitors' shelf space. Sante FX products and the character

ONE PIECE, that's our character and Sante Beauteye, those were well received on the market, pushing up sales, 25.3% is the result. As shown here for Asia business, China, Korea and ASEAN countries included, we were able to have a good growth. Market growth is around 10% or higher.

We are outpacing the market growth, that's what we tried and as I have explained, many LCM products and new products were on market now and SG&A costs were a bit higher, but the sales coverage is better and market share is increasing, 28% is the growth rate.

The market share should further grow and we want to focus on Asia business and we hope to have further growth here. As for EMEA business, 30% growth was marked. IKERVIS may have been some disappointment to you, but actually glaucoma business is growing very well. In Europe, in glaucoma for 6 months, more than ¥10 billion can be achieved and for the year, more than ¥20 billion in sales and they are both double digit growths, Cosopt, Timoptol, those are existing products in Japan and the Timoptol, Timoptol XE, those existing products have high growth, so that's quite a strong and sustained growth, that's quite encouraging and overall 13.2% was the growth.

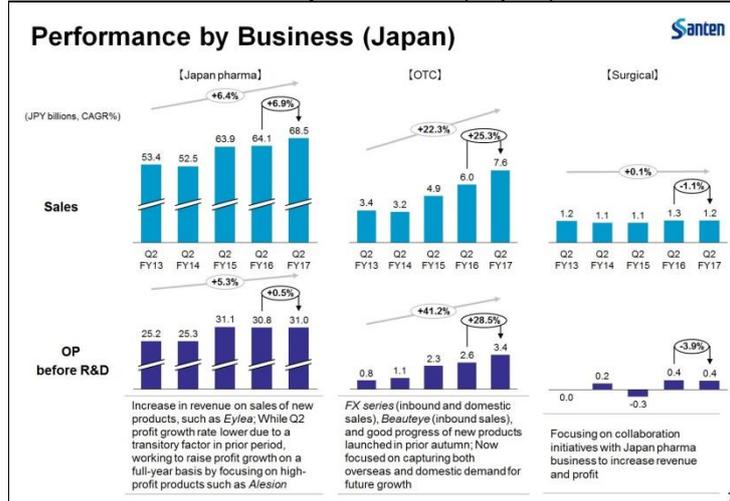
Slide 6: Q2 FY2017 Core Operating Profit



Next is the core operating profit. In each business, we needed investment for further acceleration of growth. The expenses overall increased, but we were able to spend in a balanced manner in line with the revenue growth. Our profit was up 8.6% to ¥24.4 billion. As for SG&A, some people say we are spending too much money and globally we are reviewing our costs in this domain. Our expenses include large symposiums and the promotion items such as ballpoint pens, we review all of those items and we want to reduce expense level by 3% to 5%.

As you can see in terms of profit, compared to a prescription OTC in Asia contributed very much. As I said for OTC business and also glaucoma products and the existing products, for example Cravit and Tarivid in Asia or Hyalein, Flumetholon, those products, although the prices are low, but they are quite profitable. There are many similar drugs on market, but winning competition and we have good margin products and that pushed up our sales and that is quite encouraging for us, overseas expansion with quality is going very well, that is my assessment.

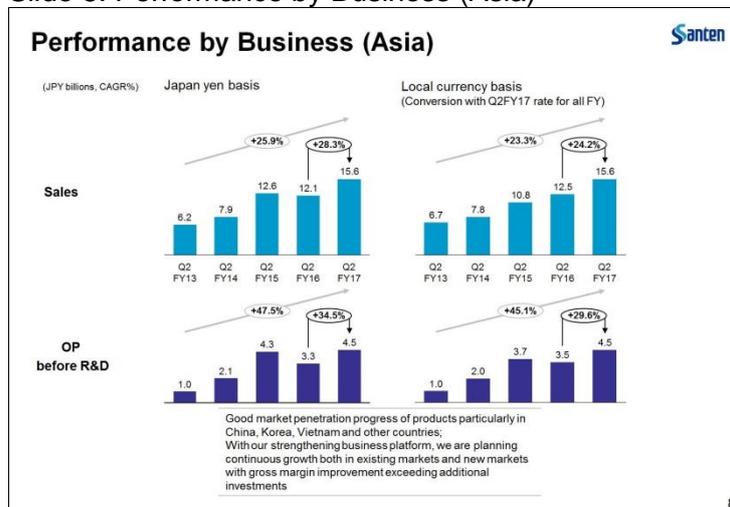
## Slide 7: Performance by Business (Japan)



The slide shows sales and operating profit before R&D deduction in the past 5 years by business. In prescription pharmaceuticals, in spite of NHI price revision every 2 years, we have a very stable growth led by new products such as Eylea, Alesion and Diquas. In key therapeutic areas, we maintained number 1 market share and I am sure you know the significance of number 1 market share. Business opportunities are much expanded because of this position. We take advantage of information and opportunities as much as possible, so that we can lead that to the next step growth.

For OTC business, as was mentioned before, significant growth was achieved by capturing in-bound demand in addition to promotional items. By doing so, we will be able to have sustainable growth. In surgical business, by working in collaboration with our pharma business, we are promoting this area and there will be new intraocular lens launched in 2018, until then we have viscoelastic gels for surgical purpose in Japan and surgical team and pharma team will work together and we are seeing good signs.

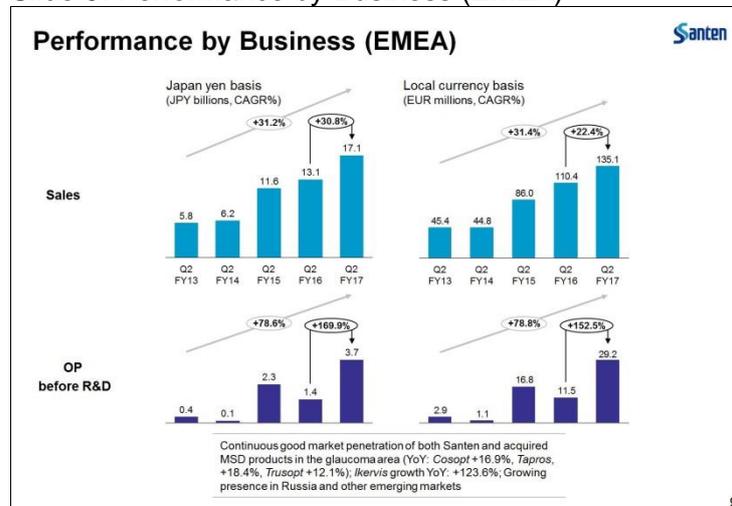
## Slide 8: Performance by Business (Asia)



Next is the performance by business in Asia. As I mentioned earlier, Cravit, Cosopt and Hyalein, those existing products are very profitable. As for Cravit, sales is decreasing here in Japan, however in China and the Asian markets, the demand is quite strong, 23% growth in those markets and as for Cosopt 22% growth and for Hyalein 22% growth as well, so with these products as the axis we are seeing growth in those markets and as for Diquas, we were able to have approval in China, as was announced before, and it will not make any contribution this fiscal year, but dry eye

has a very high potential in China, so we hope that we can expect a lot for growing Diquas market in China. In China, for Hyalein, it is sales of ¥5 billion and growth of 20%, so this market is growing very rapidly, so we hope to be able to put more new products into those markets and contribute to the business model as a whole.

Slide 9: Performance by Business (EMEA)



Next is the performance by business in EMEA. Of course, we have an operation that is focusing on glaucoma products, Cosopt and Timoptol XE, these are the products that we have acquired from Merck, all these have shown 17% growth and the demand is very solid for glaucoma products. Glaucoma patients are very sensitive to glaucoma new products and they are expecting and choosing new products that offer lowering of intraocular pressure, therefore we hope we will be able to answer to such needs.

IKERVIS is showing solid growth, but the size of the growth is less than what we had expected. It was 1 billion for the 6 months and 2 billion for the full year and we are developing this in Asia, especially in South Korea and also in Taiwan as well and we hope that IKERVIS will continue to grow and contribute to our business.

Slide 10: FY2017 P&L Forecast

**FY2017 P&L Forecast (No change from May 10)**

**Core basis** Revenue: Growth forecast in all businesses, particularly overseas  
**Operating profit:** Increased spending on future growth (listed below), while also strengthening cost control systems. OP is forecast to increase.  
 - Investments in pipeline progress and the maximization of product value  
 - Investments in US entry preparation

**IFRS** Amortization on intangible assets associated with products is not expected to change substantially and, excluding non-recurring items, core results to grow in proportion with revenue

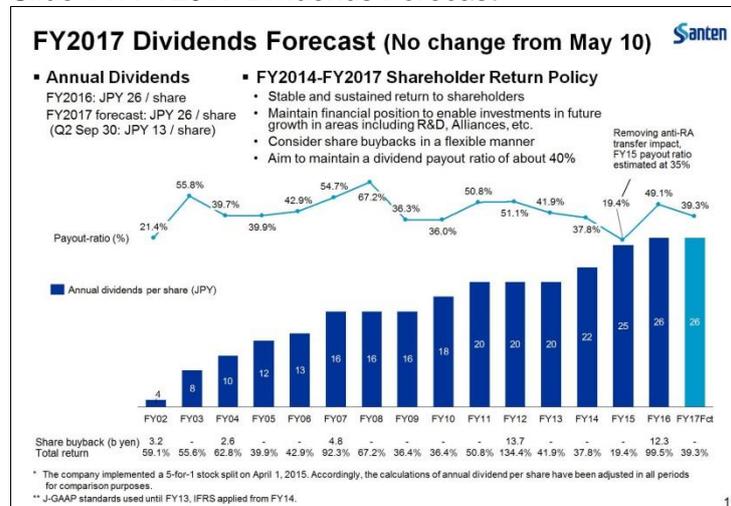
Notes:  
 There is no significant difference between Santen estimates at the start of FY17 and actual progress of earnings.  
 While the yen weakened more than expected at the start of FY17, the financial impact from this FX rate change is not material.  
 As a result, no change in FY17 P&L forecast from May 10

(JPY billions)	FY2016		FY2017		Original MTP	vs MTP
	Actual	Forecast	Forecast	YoY		
Revenue	199.1	218.0	218.0	9.5%	205.0	6.3%
COGS	-75.0	-81.0	-81.0	8.1%	-	-
SGA	-61.7	-66.0	-66.0	10.3%	-	-
R&D expenses	-22.8	-25.0	-25.0	9.7%	-	-
Operating profit	39.7	44.0	44.0	10.9%	51.5	-14.6%
Net profit	29.2	31.2	31.2	6.9%	35.0	-10.9%
ROE	11.3%	12.3%	1.0pt	14.0%	-1.7pt	-
IFRS						
Operating profit	32.5	37.4	37.4	15.2%	-	-
Net profit	21.7	26.8	26.8	23.4%	31.0	-13.5%
ROE	8.4%	10.6%	2.2pt	13.0%	-2.4pt	-
USD	198.64	110.00	110.00	-	101.00	-
EUR	118.96	120.00	120.00	-	141.00	-
CNY	16.14	16.50	16.50	-	16.90	-

Next is the P&L forecast for fiscal year 2017. There is no significant difference between Santen estimates at the start of fiscal year 2017 and the actual progress of earnings and the Yen is weakening, but at the start of fiscal year 2017 the financial impact from the FX rate change is not material and no change in fiscal year 2017 and

P&L forecast from May 10, revenue is expected to growth at 9.5% year on year to ¥218 billion and core operating profit is expected to grow at 10.9% to ¥44 billion. We will continue to put our efforts into achieving targets by continuing to work on growth and investment in a balanced manner in the second half.

### Slide 11: FY2017 Dividends Forecast



Lastly, this is the forecast of dividends. We aim to maintain stable dividend payout ratio of about 40%. As was announced yesterday, the interim dividend will be ¥13 per share with annual dividend of ¥26 per share, which will come to a payout ratio of 39.3% and there is no change from the announcement made on May 10<sup>th</sup>. Thank you very much for your attention.

### Status of Research & Development Q2 FY2017

#### Slide 20: Pipeline / Product Development Status (1)

**Pipeline / Product Development Status (1)** 

	Indication	Region	Status	As of November 1, 2017
<b>DE-117</b> EP2 receptor agonist	Glaucoma / ocular hypertension	US	P2	
		Japan	P2b/3 (AYAME pivotal study met primary endpoint) Plan: Q3 FY17 filing	
		Asia	P3 Plan: 2 <sup>nd</sup> half FY2018 P3 completion	
<b>DE-126</b> FP/EP3 dual receptor agonist	Glaucoma / ocular hypertension	US	P2b	
		Japan	Plan: Jan-Jun 2018 P2b completion	
<b>DE-128</b> InniFocus MicroShunt	Glaucoma	US	P2/3 Plan: Calendar 2018-2019 P2/3 completion, Calendar 2020-2021 launch	
		Europe	CE mark granted	
<b>DE-109</b> IVT sirolimus	Uveitis	US	Filed Plan: Dec 24, 2017 PDUFA date, Jan-Jun 2018 launch	
		Japan	P3	
		Europe	P3 Plan: 2nd half FY2017 re-filing	
		Asia	Filed	
<b>DE-122</b> Anti-endoglin antibody	Wet age-related macular degeneration	US	P2a* (Completed P1/2) Plan: Jan-Jun 2019 P2a completion	

Updated information is underlined. See Santen Consolidated Results for the 2<sup>nd</sup> Quarter Fiscal 2017 for more details. \*Conducting in Philippines.

Thank you very much for allowing me to speak in English. I'll give you a very quick update on our pipeline products as well as line extensions and geographic expansion of some of our products. So, the first one which we are very excited about is DE-117. DE-117, as you know, the AYAME Study met its primary endpoint and we are looking to filing in Japan any time as the filing is imminent, I guess. We had promised Q3 of FY 2017. Even more exciting is the fact that our DE-128, MicroShunt product is on schedule and we have completed enrollment in the pivotal study. DE-126, which is also a glaucoma product, an IOP lowering agent, FP/EP3, a dual receptor agonist, is

running just fine and we should be able to complete or have some information in the middle of 2018.

The next product, DE-109, as you know, is under review by the US FDA and there is nothing to report other than the PDUFA date is the third week in December. DE-122 is our anti-endoglin product, a combination used with anti-VEGFs and that's in phase IIa and hopefully, we will be complete investing somewhere in the first half of 2019.

## Slide 21: Pipeline / Product Development Status (2)

Pipeline / Product Development Status (2)			
			
<small>As of November 1, 2017</small>			
	Indication	Region	Status
<b>DE-089</b> <i>Diquas</i>	Dry eye	China	Approved <i>Plan: FY2018 launch</i>
<b>DE-114A</b> epinastine HCl (high dose)	Allergic conjunctivitis	Japan	P3
<b>Cyclokat</b> <i>Ikervis</i> ciclosporin	Severe keratitis in patients with dry eye	Asia	Approved
		US	P2
		Others	Filed
<b>Vekacia</b> <i>Verkazia</i> Ciclosporin	Vernal keratoconjunctivitis	Europe	Filed (received positive CHMP opinion)
<b>DE-127</b> <i>atropine sulfate</i>	Myopia	Asia	Preparing P2

Updated information is underlined. See Santen Consolidated Results for the 2<sup>nd</sup> Quarter Fiscal 2017 for more details.

Furthermore, we are absolutely also very, very excited to announce that Diquas was approved in China and looking forward to a launch in 2018. Epinastine 114A, we will be sharing the data from the pivotal study in the very near future. Verkazia, as you know, was approved by the CHMP, we are waiting for the final approval from the Commission and then marketing activities will start.

DE-127 is a new product in the pipeline. This is atropine for myopia and indicates our interest in the indication, myopia which is prevalent in Asia, so that is a very quick and brief update and I would be happy to answer any questions later on. Thank you very much.

## Q/A session (summary)

### Q1-1

My first question is focused for the full year. Last year, because of the pollen and Q4 was a bit weak, but for this year, progress is going very well. In Japan, for example, including idea, you are going beyond your expectation, you did not change your forecast, are you on track plus alpha or any specific risk in the second half, can you explain that first?

### A1-1

(CFO) For the full year, actually last year we did not achieve the full year guidance and for this year, we want to achieve the announced focused surely and we kept the guidance unchanged and for the first half whether the performance is on track or not, as you know, on core operating profit base, we are achieving 55% of the plan. Based on the internal expectation, we are a bit ahead of the plan, however, we had experienced last year in the fourth quarter February and March pollen situation and also the Asian market because of the operating days in the third and fourth quarters we have less working days and considering all those factors, for the full year guidance, rather than thinking of upside, we want to make sure that we achieve the

guidance, we provided to you already, that's why we have no change from our forecast originally. Thank you.

**Q1-2**

As for China, just a quick question, many companies are now refocusing on China, according to their comments, not only your company and in development and the review of filing acceptance process, procedures changed according to some other companies, I am sure you know that and going forward China's speed in review process are going to be changed and since business is going very well, generics are very, very cheap, but still you have good business, is that because of your marketing style, like Japanese-marketing style, is it working, so from those two points, can you answer to the question, please? Thank you.

**A1-2**

(CSO) So I can comment on the development part of the question. Yes, clearly, there are very good signs from China that they are trying to, at least from the outside they are trying to encourage new chemical entities and new products to come into China and they are trying very hard to reduce the review times, which was a real hurdle for everybody, so without a doubt, I think we will leverage our presence in China in our portfolio of products that you have seen today, some of them can be leveraged very quickly, so the R&D side is going to be looking into speeding up our efforts to support the China business, which we are doing quite well.

(CEO) As for marketing and sales, it may seem it is going well, however, compared to our competitors how are we doing, I am sure that is the intent of the question. I do not know how our competitors are doing, but with Santen, I think we are a specialized ophthalmological company and as I mentioned before, every year, we have come up with new measures and not only in the coastal areas, but we are working inland of China as well and as for overseas market, we are focusing on those areas and also we are focusing on JV areas as well, so providing information and service is something that we specialize in and, of course, scientifically and human resource-wise, we are working to higher the recognition of Santen among the medical doctors in China. Of course, in China, we haven't done a customer satisfaction survey, but the market share is about 14% at the moment and we have support of the doctors in China. I think that is our understanding. Whether we do everything Japan way in China, that is not so, but in the ophthalmological area as a domain, we are able to elevate the recognition of Santen and elevate the Santen loyalty among our customers in China is going to be very important going forward.

**Q1-3**

As for DE-127, this is for atropine sulfate and in Singapore, we are working in this product, whether we are going to only target Asia, but are we going to target Japan domestically as well?

**A1-3**

(CSO) So, we are starting just with Singapore and Asia and all I can probably say is that for the rest of the world and including actually as a second stage for Asia, Japan and the rest of the world, we are working on similar pathways and to have some innovative new products and so this is just the beginning, I hope, and it will prove the concept that atropine or the muscarinic pathway is valid and we can do that faster in Asia than we can do anywhere else because of the number of patients, but eventually we should be able to pursue new entities, this is not the end, just the beginning.

**Q2-1**

My question is about Europe, I want to know the situation. It seems you are having a good business in Europe. In the beginning, you have the products from Merck and those matured products and you are now moving on a very positive situation and this

growth going forward, would that be sustainable, what's your outlook for your European business? Thank you.

**A2-1**

(CEO) And how long this level of growth continues I can't say for sure, but for glaucoma area, we have strong basis and that will support our long-term growth. When you look at Europe, as you know the market itself is mature overall, but for glaucoma there is very strong, persistent demand. Glaucoma area, in ophthalmology, is our specific focus area. As Naveed Shams (CSO) explained, 117, 126, MicroShunt, those are candidates for the next products and we need good basis and that's why we are focusing in Europe and more than our expectation, the existing products are going very well. People received existing products very well. As you know, glaucoma is a chronic disease and to lower IOP and to have a good control of IOP is the basis for treatment guideline and the products that fit that guideline that is what we have, therefore they are strong and we can sustain the growth, I think. I can't say exactly until when this pace continues. Cosopt and the other products I mentioned are very competitive. There are similar drugs on the market, but still we are growing, that's because our MR's effort, human resource and medical affairs are supporting very well, so scientifically and human resource-wise, we are capturing customers and we have been very successful in that.

**Q2-2**

Next is about DE-117, I think you are doing the FUJI Study for Latanoprost non-responders, the study, I believe, is ongoing, so when will the data be disclosed and after the data becomes available, what will be the filing arrangements here in Japan and what are the possibilities in the US and what is that going to bring about an impact on the results here in Japan?

**A2-2**

(CSO) Yes, very briefly, the intention is to use the FUJI data for support of R&D filing in Japan. As you know, the goal is to show that we don't get not only better safety, but also if you are not responding very well to an FP agonist, that you can switch them to an EP2 agonist and get additional benefit, so I think it's going quite well and we would like to use all of that data to support our position in Japan. Similarly, we have the China, the Asia Program running and we are now planning our US strategy and so in the very near future, we should be able to tell you what the plan is for the US.

**Q2-3**

Last question is OTC drugs, switch OTC of Hyalein. In the previous conference call, you mentioned that you are preparing for that. If you are going to launch switch OTC of Hyalein, are you going to be the first comer in this OTC Hyalein and if that is launched, what about cannibalization again to ethical Hyalein product or is that going to be added on revenue source, what's the potential of that?

**A2-3**

(CEO) As I explained, as for switch OTC of Hyalein, we want to launch as soon as possible. As for the impact on ethical Hyalein, we don't know exactly, but when you look at other company's way and how it goes, it's not so much impact and we don't think OTC Hyalein will impact ethical Hyalein very much. However, we need to be creative on how we launch in the market that are you going to use the same name as Hyalein, how would that be successful, we need to consider the way of promotion for OTC drugs. Yes, we need to think about that.

**Q3-1**

First is about Asia, you talked about China earlier. Asian countries, other than China, you talked about Vietnam in the material provided, but can you give us more

granular information, like which area is growing and which areas are going to maintain growth going forward? Thank you.

**A3-1**

(CFO) First of all, let me talk about the details of the Asian business. If you look at the presentation material, if you go to page 8 of the presentation material, this year, if you look at Asia, 2017, first half, 15.6 billion, so 30 billion for the full year and if we look at specifically, China was 16 billion and South Korea 7 billion and Taiwan and other areas and other countries comprised the rest. And when we look at our products, as you can see in the material, Hyalein and Cravit are the core products and other products are also available in the Asian markets as well.

**Q3-1-2**

So, can you talk about the volume and the values, please?

**A3-1-2**

(CFO) Well, volume and value-wise, I understand your concern is that the volume may be increasing, that the value may not be, so I do understand your concern, however, in each of the countries, situation is different, but strategically, we are targeting the high-end market, so we are targeting areas where price competition is less likely to occur, that is our operation, so price pressure midterm is not going to be that strong. Having said that, there may be some country risks, so in the midterm with this pace of 20%-30%, growth can be maintained is a question, however, for up to 2020 on the midterm, I believe that we will be able to maintain the momentum going forward, that is our understanding. Thank you.

(CEO) I may add a comment. Maybe I showed you a slide or not, but for the midterm towards 2020 every year in ASEAN markets, every year we have new products of 40 items, that's the number of filing and so far 25 filings of LCM were introduced and Diquas was included in that and there are other Hyalein products and Tapros, depending on each local needs, we are introducing those items, so 40 items altogether and as new products in that country, they are accepted as new products, therefore we have premium price as a branded product, that's how it's launched. Thank you very much.

**Q3-2**

My second question may be repetitive, but this is DE-109. You mentioned that there is nothing new to be reported about DE-109, but a great cycle meeting has been completed, is that the correct understanding?

**A3-2**

(CSO) It's an internal FDA timeline that we are not exposed to, but, however, we get questions from the FDA, we respond to those questions, that's very routine, so that's what we have been doing and we know they'll make up their mind in the next couple of months.

**Q4-1**

For the second half, end year outlook for the cost and expenses, so far the first half has been very good, it looks like there is some upside, that's how we see it and in Asia, Europe, you have good business, I don't want to say the same pattern as last year, but you can afford to have more investment. Is that applicable for the second half including SG&A, do you have that option or not?

**A4-1**

(CEO) How to optimize SG&A expenses and that's a comment I mentioned before, so what's the optimal level because there are ways in SG&A, if you spend the same money, you sometimes waste money, I mentioned ONE PIECE and to have brand enhancement, we use three vendors to use this character that could be a possibility, I am not saying that is done, but the way how we spend money should be reviewed and we have profit and that should be spent sometimes to R&D or for business development, so you need to consider various allocations. For this year, we

achieved this year's focused surely and if we can afford, then we can have some extra investment, that is possible.

**Q4-1-2**

When you make that kind of a decision, is that going to be in a few months? Well, last year, up to February, you mentioned that you have may have some extra money or excess money, but that happened, so that was the price that does not happen this year, that's what I am asking.

**A4-1-2**

(CEO) Well, as was explained, as for the last year, we had a lesson learned. In the end, we did not achieve the goal and the profit was lower. This year, we want to make sure that doesn't happen. We ran PDCA very well, that's our commitment to you. Thank you very much. But, of course, there are areas in which we cannot really understand. Of course, there will be NHI price revision with the allergy products, so what kind of impact it will have, we are not quite sure, so if there are certain situations, we are sure to explain it to you.

**Q4-2**

In the US, I think the budget was 3 billion, but how much of it have you used up so far?

**A4-2**

(CFO) Well, in that sense, I think this is the end of first half, so I think we should have used 50% of that budget, but the budget was, I think it is 45 to 55 at the moment, so the weight is higher in the latter half of the year, however, the situation we have at the moment is that we are below the actual budget arrangement, but there are some expenses that is not bringing any sales and that may be necessary, so in the latter half, we believe that the expenses will increase to sales, but in the core operating profit, we hope we'll be able to achieve the target, so we would like to have a good control going forward. Thank you.

**Q4-3**

For the next midterm range, starting from 18 until 23, in the last year, you wanted to be the top three, how are you realizing that goal? That's the question I am asking. When you think about that, are you going to do something different from the past and it's not just M&A in your idea, Mr. Kurokawa, can you suggest something that may be quite different from the past?

**A4-3**

(CEO) So, in 2020, we want to be top three, that remains unchanged, however top three companies and us, we are number four now and in terms of market share, there is a gap, if you try to fill the gap, you mentioned M&A, M&A of significant size would be required to fill the gap. If that's the case, there is also a risk, so you need to make judgment for each possible deals and we are focusing in organic growth, that's our basis, so whether we are going to be a company like some players in the US, I don't think so, we are R&D based, we have good R&D and we have good results so far, we make steady progress in ophthalmology and we are raising our presence, we are trusted by others and I think that's the approach we should pursue furthermore, that's my current thinking.

**Q4-4**

My next question is about the number of employees here in Japan shown on page 9 of data book. I think it will be natural to decrease the number of head counts, but in Japan there are 2014 employees, so you are increasing the head count, so what is the number going to be going forward?

**A4-4**

(CFO) Well, as far as the number of head counts, it is increasing as you point out, but whether we are increasing the number of MRs dramatically, that is not so. For

globalization purposes, we need to strengthen the headquarter function and for that purpose we needed to increase the head count. I hope you understand.

(CEO) Globalization plus we have an increase of personnel in production, the volume is increasing and demand is hard to predict nowadays, for example, in-bound demand is hard to predict. There is much fluctuation and it's growing constantly. S&OP Meeting is regularly held, demand forecast and supply plan may have some gaps and because of that it can impact line volume in production. Well, nowadays the government is saying, you need to change your working style and there is some scrutiny regarding overwork and that may impact some of the arrangements, so the employees for healthy way of working, we need to increase the number of employees, for example, packaging lines may require more resources. In Japan, productivity efficiency is very important and the business is mature, NHI price is coming down, so better productivity is the key, so regarding increasing human resources we would do that if necessary, but basically we want to reduce the number of employees.

**Q5-1**

Regarding DE-117, I don't know whether somebody has asked in Japan pivotal results are out and I asked you before, your glaucoma portfolio is now enriched of those, you need to have priorities, otherwise differentiation would be difficult, 117 is probably the most differentiating product, I think, going forward, what do you think of this? In the US, phase II is more or less completed, I suppose, have you started consultation or discussion with FDA?

**A5-1**

(CSO) Last question first, we have definitely have had several discussions with the FDA on a development plan for DE-117 in the US and so it's, as I mentioned earlier, we are just in the process of finishing our planning and then we can talk about it more in the near future and I agree that 117, with its characteristics, is a very well-differentiated product, not only for Japan, but also for Asia and the US and worldwide, so I believe it will compete very effectively with some of the new products that are in line, whether in the US or outside the US, so it meets true unmet needs.