

Speaker Remarks May 11, 2017 (summary)

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

I'm Akira Kurokawa of Santen. I'd like to start with FY2016 results overview and forecast for FY2017.

Slide1: Santen's Values

**Santen**

## 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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You may know our values already. By focusing on the field of ophthalmology, we continue to contribute to patients through advanced therapies.

Slide2: To Become a Specialized Pharmaceutical Company with a Global Presence

**Santen**

### 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

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

Current Mid-Term Plan (MTP)

2020

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

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

	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% (FY16)</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 sales countries</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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And we are striving to become a specialty pharma company with a global presence. Toward this, we created our "Vision 2020" as well as the 2014-2017 mid-term management plan in which we are now in the final year.

As you can see, the mid-term plan calls for us to achieve 30% of our revenue from overseas sales, profitable growth in Asia / EMEA, and preparation for market entry into US and other markets. This is what we are focusing on now, in particular product development, business expansion and the strengthening of our organization and talent.

Regarding product development, as you know, Tapcom and Ikervis were launched. Furthermore, important glaucoma and retina area development has been making progress including DE-109, 117 and 122. Of course, we want to further strengthen our new products and pipeline. We have strengthened our pipeline with DE-126, a glaucoma pipeline licensed from Ono, and MicroShunt (DE-128), a device in development we acquired last year.

Regarding business expansion, we strengthened our Japan business. The Japanese market experienced NHI revisions and generic promotion, so the environment is rather challenging. However, based on our strengths, we worked very hard and increased our market share in line with our plan. Currently, our market share is 45.5%, which I'll come back later. It is true that our market share as well as customer satisfaction have been increasing among ophthalmology specialists.

In the OTC business, our market share is also expanding and now stands at 25.6%. We are second in share in OTC, but catching up swiftly with number one player. In Asia, our presence has been strengthened and we are confident to have the number one share in Asia in 2020. In EMEA, the number of countries where our products are sold is increasing steadily.

And in order to achieve true globalization, we need to strengthen our organization and talent. We are working very hard to strengthen our management structure necessary to develop the next generation of talent. We have already made solid progress in this respect.

## FY2016 Financial Results

### Slide4: FY2016 Financial Highlights

FY2015			FY2016		
	Full Year Actual	Full Year Actual	YoY	Previous FCST	vs FCST
<b>Core basis</b>					
Revenue	195.3	199.1	1.9%	200.0	99.5%
COGS	-72.8	-75.0	2.9%	-76.5	98.0%
Gross margin	122.5	124.1	1.4%	123.5	100.5%
SGA	-59.4	-61.7	3.8%	-59.0	104.5%
R&D expense	-20.0	-22.8	13.9%	-20.4	111.7%
OP	43.1	39.7	-7.8%	44.1	90.0%
Net profit	29.2	28.7	-1.6%	30.2	95.0%
ROE	12.4%	11.2%	-1.2pt	9.5%	
<b>IFRS</b>					
OP	80.2	32.5	-59.5%	36.3	89.5%
Net profit	53.4	23.1	-56.8%	25.3	91.2%
ROE	22.6%	9.0%	-13.6pt	11.4%	
USD	120.45	108.64	8.8%		JPY appreciation
EUR	122.46	118.96	12.2%		JPY appreciation
CNY	19.05	16.14	15.3%		JPY appreciation

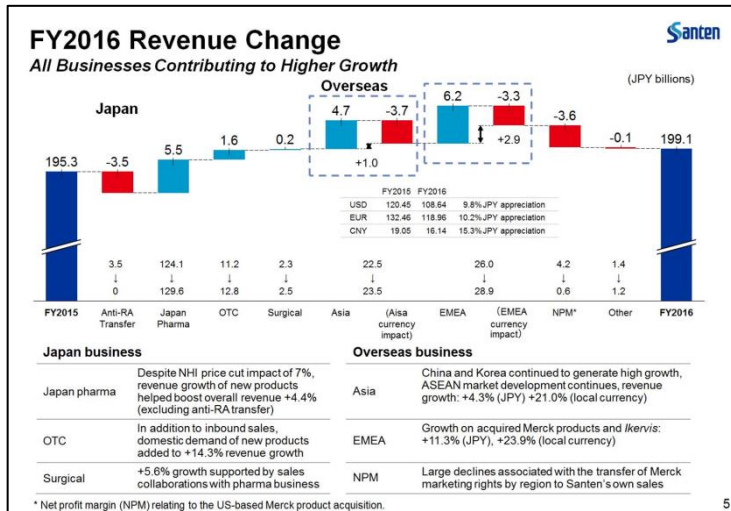
This gives an overview of 2016 fiscal year, we achieved revenue of 199.1 billion, an increase of 1.9%, slightly below our plan.

The year included negative factors such as the NHI revision, the stronger yen and the lack of the anti-rheumatoid business due to the sale of the business. Still, we were able to overcome these factors and achieve a 1.9% increase in revenue. Removing these negative factors, the increase in revenue would have been 12%.

Core operating profit shows earnings power. And through the third quarter, we made solid progress, but in the fourth quarter, in order to strengthen our platform in Asia, we needed additional spending in sales and

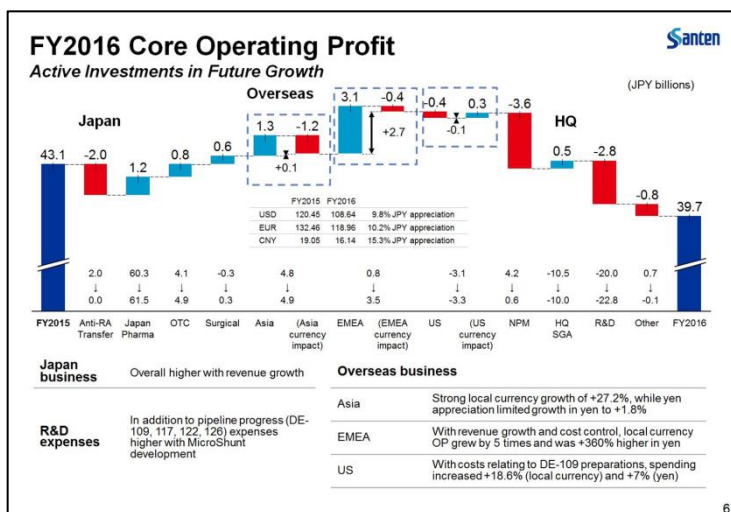
promotion. Also, in order to strengthen our marketing capability in Europe, we had more spending including expenses to promote Ikervis and thus higher SG&A costs as we strengthened our business platform in each region. Finally, our pipeline progress led to R&D spending above our forecast. This resulted in core operating profit that was down year-on-year by 7.8% to JPY39.7 billion. IFRS results included a special JPY44.5 billion gain on the anti-RA business sale, caused a decrease in operating and net profit. ROE was 11.2% on a core base while IFRS ROE was 9.0.

Slide 5: FY2016 Revenue Change; All Businesses Contributing to Higher Growth



This slide shows factors impacting revenues in FY2016 by business. In all segments we were able to achieve higher revenue. While we exited the anti-RA business, we were still able to overcome and grow our Japan business during the year. As for our overseas business, we were negatively impacted by FX, but as you can see, we increased sales in all areas.

Slide 6: FY2016 Core Operating Profit; Active Investments in Future Growth



This shows core operating profit. We increased spending for future growth, and as I have explained, for each business, there has been an increase in profit; however there were also negative impacts such as the R&D cost increase and FX.

Slide 7: FY2016 Profit / Loss Change

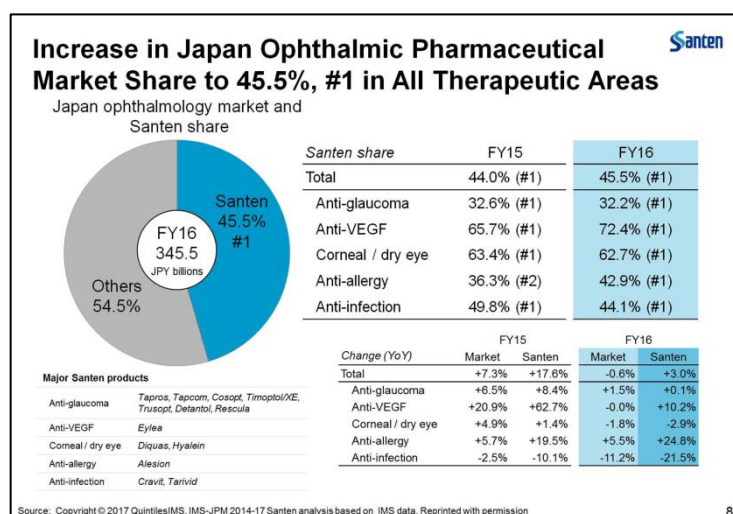
(JPY billions)	FY2015		FY2016		YoY
	Actual	vs Revenue	Actual	vs Revenue	
Revenue	195.3		199.1		1.9%
COGS	-72.8	-37.3%	-75.0	-37.6%	3.0%
SGA	-59.4	-30.4%	-61.7	-31.0%	3.8%
R&D expense	-20.0	-10.2%	-22.8	-11.4%	13.9%
Amortization on intangible assets associated with products	-6.2	-3.2%	-6.4	-3.2%	3.4%
Other income	45.0	23.0%	0.5	0.2%	-99.0%
Other expense	-1.7	-0.9%	-0.7	-0.4%	-57.2%
Operating profit (IFRS)	80.2	41.1%	32.5	16.3%	-59.5%
Finance income	0.8	0.4%	0.9	0.5%	13.6%
Finance expense	-1.5	-0.8%	-1.6	-0.8%	4.4%
Profit before tax	79.5	40.7%	31.8	16.0%	-60.0%
Income tax expense	-26.1	-13.4%	8.8	4.4%	-133.6%
Effective Tax burden ratio	-32.8%		27.6%		60.4pt
Net profit (IFRS)	53.4	27.3%	23.1	11.6%	-56.8%
ROE	22.6%		9.0%		-13.6pt
Core operating profit	43.1	22.1%	39.7	19.9%	-7.9%
Core net profit	29.2	15.0%	28.7	14.4%	-1.8%
Core ROE	12.4%		11.2%		-1.2pt

Annotations:

- Progress in pipeline projects (points to R&D expense)
- Recognition of gain from anti-RA transfer in FY2015 (points to Other income)
- Recognition of gain from anti-RA transfer in FY2015 (points to Other expense)
- Recognition of gain from anti-RA transfer in FY2015 (points to Profit before tax)
- Decrease in tax amount and tax burden ratio due to the tax incentive on R&D in FY2016 (points to Effective Tax burden ratio)

This shows P&L for FY2016. This has been explained already, so I skip this.

Slide 8: Increase in Japan Ophthalmic Pharmaceutical Market Share to 45.5%, #1 in All Therapeutic Areas



Our biggest strength is in the domestic ophthalmic pharmaceutical market. As you can see, our share is now 45.5%. In the allergy area, we had traditionally been ranked second place, but have increased our promotions beyond ophthalmologists to otolaryngologists (ear, nose and throat doctors) since, as you know, allergy from pollen is not limited to ophthalmologists, sometimes patients go to otolaryngology specialists so we have newly focused on those. And we had good promotion that now includes ophthalmologists, we have gained the number one market share at 42.9%. That means in all major segments, we have number one market share.

## FY2017 Forecast

### Slide10: FY2017: Vital Step in Santen Group's Journey

### FY2017: Vital Step in Santen Group's Journey Santen

To Become a Specialized Pharmaceutical Company with a Global Presence

As a leading ophthalmology company with close proximity to patients,  
answer unmet patient needs through our commitment to treatments

- Current Strengths
  - Strong presence in Japan and Asia  
 Particularly strong contributions to glaucoma treatment with products and pipeline

- Actions for FY17
  - Further strengthen the presence and productivity of the Japan operations as a business pillar
  - Capture growth in Asia and build EMEA market presence
  - New growth opportunities
    - Contribute with current products and well differentiated future products (DE-109, DE-117, DE-128, etc.)

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Next is our forecast for FY2017. In FY2017, as a leading company in ophthalmology, we will continue our contributions to therapies in this area. Santen has a strong presence in Japan and Asia in ophthalmology and in glaucoma, specifically, where incidents and risks of becoming blind are rather high and we have a rich pipeline of products. We want to make further contributions to ophthalmologic therapies while leveraging and boosting our strengths. Our top priority is further raising our presence and productivity in Japan, while also capturing growth in Asia and raising our presence in EMEA.

Through R&D and M&A in the past few years, we now have a pipeline that includes DE-109, 117 and 128. Our pipeline products are differentiated and many are late-stage and first-in-class products. We must make the successful development of these products as our top priority, preparing ourselves so that we can contribute to more patients.

### Slide 11: FY2017 P&L Forecast Overview

### FY2017 P&L Forecast Overview Santen

**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 will change substantially; non-recurring items; revenue and core operating profit to grow in proportion

	FY2016		FY2017		
	Actual	Forecast	YoY	Original MTP	
<b>Core</b>					
Revenue	1,991	2,180	9.5%	2,050	6.3%
COGS	-750	-810	8.1%		
SGA	-617	-680	10.3%		
RD expense	-228	-250	9.7%		
Operating profit	397	440	10.9%	515	-14.6%
Net profit	287	312	8.8%	350	-10.9%
ROE	11.2%	12.3%	1.1pt	14.0%	-1.7pt
<b>IFRS</b>					
Operating profit	325	374	15.2%		
Net profit	231	268	16.2%	310	-13.5%
ROE	9.0%	10.6%	1.6pt	13.0%	-2.4pt
USD	108.64	110.00		103.00	
EUR	118.96	120.00		141.00	
CNY	16.14	16.50		16.90	

**Major variances between MTP and FY17 FCT**

**Progress above plan**

- Japan pharmaceutical growth (overcame NHII price revision and GE promotion plan by the government)
- OTC growth (driven by in-bound demand)
- Asia growth (mainly China)
- EMEA

**Newly added**

- Discontinuation of anti-RA business
- LTD administration: Increase of expenses to enhance business platform
- US market entry preparation
- R&D: Increase of spending on late-phase pipeline projects including medical affairs activities
- Inn-Focus

Moving to concrete activities to attain long term strategic vision to 2020

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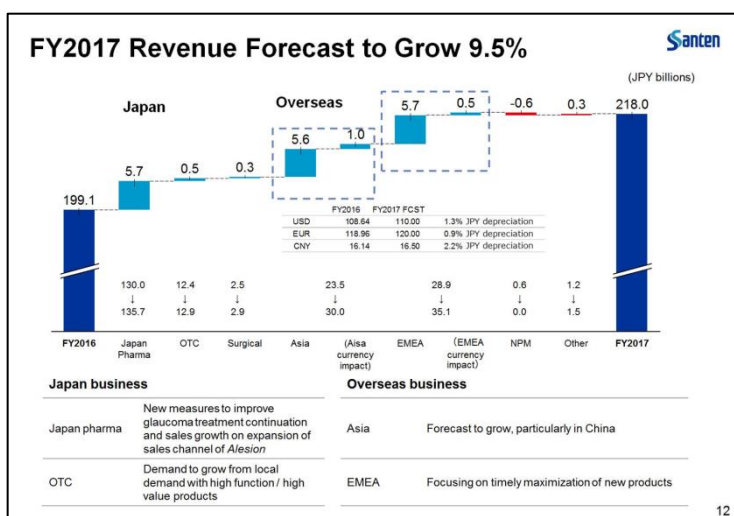
In our FY2017 P&L forecast overview, revenue is expected to increase on a year-on-year basis by 9.5% to JPY218 billion. Core operating profit is forecast to increase by 10.9% to JPY44 billion. In FY2017, the final year of the current MTP, compared to our assumptions in 2014, there are three points I would like to



make. First, the Japanese ophthalmic pharmaceutical industry has been able to grow, overcoming price revisions and generic promotion plans by the government. Next, our OTC business has grown to become an over JPY10 billion business, and our overseas business growth has grown well. As a result, our revenue is expected to be about 6% higher compared to our MTP.

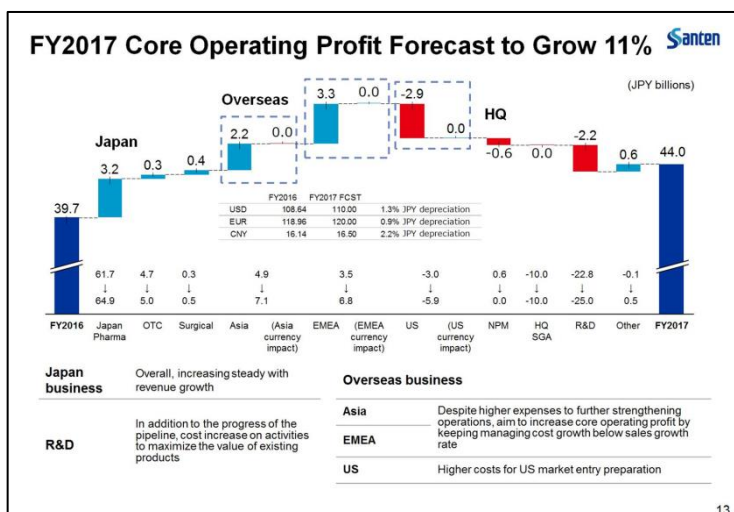
Also, as I explained in the previous slide, we will enhance our presence. As part of this, we've been preparing for U.S. market entry as a new growth opportunity. R&D and other preparation activities to secure the realization of our long-term vision require investment. As a result, our core operating profit is expected to be 14% below our original MTP. But we would like you to look at these actions from a long-term growth perspective.

Slide 12: FY2017 Revenue Forecast to Grow 9.5%



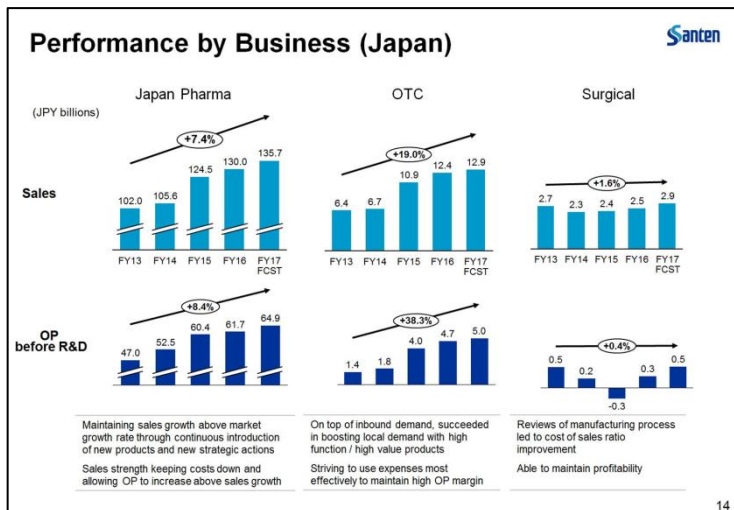
This shows revenue growth by business. From FY2016, each business showed growth and overall we aim at 9.5% growth.

Slide 13: FY2017 Core Operating Profit Forecast to Grow 11%



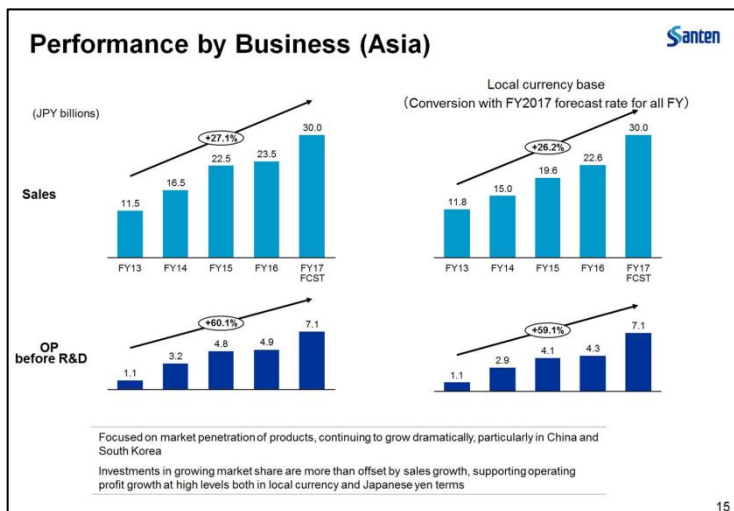
Regarding core operating profit: while R&D and US market entry preparation expenditures will increase, we will control other expenditures and aim at 10.9% profit growth.

Slide 14: Performance by Business (Japan)



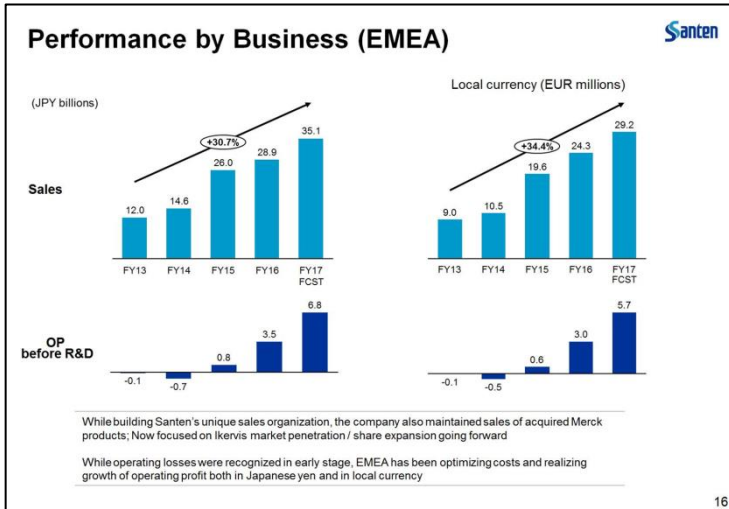
This is our performance by business in Japan. As you can see, in all businesses we will achieve the increase.

Slide 15: Performance by Business (Asia)



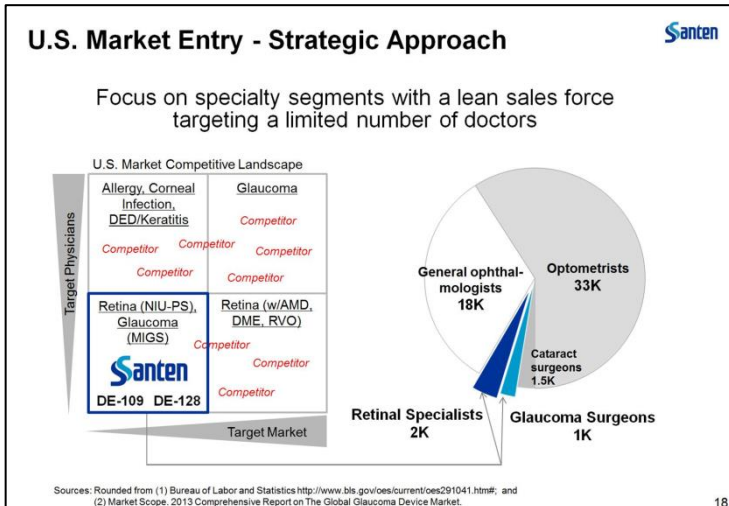
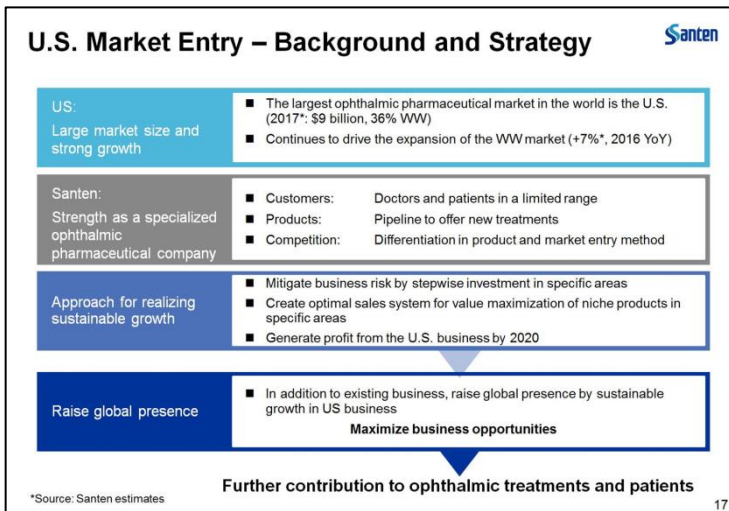
This shows growth in our Asia business. We see steady high growth rates achieved both in yen and local currency basis.

Slide 16: Performance by Business (EMEA)



This shows our EMEA business growth. We acquired ophthalmology products from Merck. Takeover of the products required costs at the initial stage that resulted in an operating loss. However, we have been steadily penetrating the markets and we now have a good base and are realizing high growth.

Slides 17/18: U.S. Market Entry – Background and Strategy, Strategic Approach





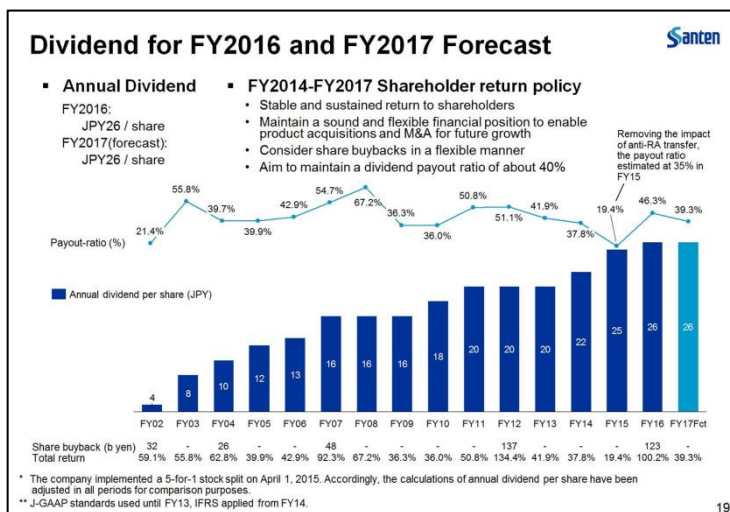
Now I'd like to explain about our US market entry background and strategy. As we have repeated many times, the US ophthalmology market is the largest market in the world, accounting for 36% of the total global market. Further, growing at 7%, the US is an attractive growth engine and the biggest driver of world market growth.

The establishment of the presence of Santen in the US market is very important from the viewpoint of how to commercialize products such as DE-109 and MicroShunt. How we can we build this presence is very critical. While we felt it would be difficult to enter into the US market with only a single product, having these two highly differentiated products, I believe that it is possible to establish a certain presence by offering unprecedented treatment methods.

Making use of these two business opportunities retina, specifically non-infectious uveitis, and glaucoma surgery, both areas where the target doctors are relatively limited, we believe that we'll be able to provide therapies which are not available elsewhere. And we have explored how to market our products in this market and we decided to use our own sales organization for these products.

Having said that, the US market is highly competitive. The next slide shows the competitive status in the US. The chart on the left shows the target market on the horizontal axis against the target physicians on the vertical axis in allergy, glaucoma, retina and uveitis therapy areas. As you can see, the uveitis market is a niche market segment having less competition. There are about 57,000 patients with uveitis. In terms of non-infectious uveitis treatment, there are about 33,000 patients we have determined as our primary target patients. In this target area, we believe that rather than an alliance or partnership, promoting on our own allows us to maximize profit soonest. This is why we decided to market using our own organization. DE-109 will be launched in the beginning of 2018 and it will be followed by MicroShunt. Both will compete in limited market segments where we'll be able to grow by offering important novel therapies. We have conducted various market surveys and price sensitivity analysis. With this most appropriate approach, we believe that we will be able to successfully enter into the US market. In 2020, we plan to achieve profitability from our US business.

Slide19: Dividend for FY2016 and FY2017 Forecast



Here is our FY2016 dividend and 2017 forecasted dividend. Also, we maintain our shareholder return


policy in which we maintain a dividend payout ratio of about 40%.

That concludes my remarks.

Thank you very much.

## Status of Research & Development FY2016

### Slide 27: Future Development and Regulatory Milestones

Future Development and Regulatory Milestones 			
As of May 10, 2017			
	Development status*	Indication	Development region: milestone
<b>DE-117</b>	P2b/3	Glaucoma/ ocular hypertension	Japan: Q2/Q3 FY17 filing
<b>DE-126</b>	P2a	Glaucoma/ ocular hypertension	US/Japan: Q1/Q2 FY17 P2b start
<b>DE-128</b> <i>(MicroShunt)</i>	P2/3	Glaucoma/ ocular hypertension	US: calendar 2018~2019 P2/3 completion, calendar 2020~2021 launch
<b>DE-109</b> <i>(IVT sirolimus)</i>	<u>Filing</u> <u>Accepted</u>	Uveitis	US: Dec 24, 2017 PDUFA date, Jan~Jun 2018 launch
	P3		EU: 2 <sup>nd</sup> half FY17 re-filing
<b>DE-122</b>	P1/2	WetAMD	US: Q1 FY17 P2a start**, FY17 P1/2 completion

\*Updated information is underlined  
\*\*Conducting in Philippines

I'll give you in the next five minutes a very quick update on our innovative pipeline products and their progress.

If you see on the slide, there are two major buckets of products, one in the glaucoma space and the other in the retina space. Let's start with DE-117. DE-117, as you know, is an EP2 receptor agonist. It's a new chemical entity and we believe that it will be very helpful to patients who are not getting full response with the regular FP agonist as well as give an IOP lowering effect that's as good as the standard of care. We also believe that this product will not have issues with pigmentation or hair growth cosmetic effects. We are, as planned and as indicated in the past, on track to make a filing in Japan in Q2 / Q3 timeframe which should be the case unless something very unexpected takes place. The Asia studies for DE-117 are running and we are looking forward to data from those studies as well this next year.

DE-126, as planned, we look forward to starting the Phase II study this year fiscal '17 and DE-128, described by Kurokawa, the MicroShunt is in a pivotal study in the US and in Europe, though mostly in the US. The recruitment for this trial is going really well at this point and we look forward to completing the study in the 2018-2019 timeframe and then launch around 2020 or so timeline. This, as you know, is a very well differentiated product to be used in lieu of the trabeculectomy surgery, which is used to treat glaucoma. Key differentiation points are the material that is used to make this product and the surgical procedure.

DE-122 is another retina product designed to enhance the effect of anti-VEGFs in patients with wet AMD. The Phase I/II study is finishing in the US and we plan to start the Phase II study in Asia in the summer of this year. So we look forward to data from this study. The target for inhibition is quite novel.

So that is a very brief summary and I'll be happy to answer any questions during the Q&A session. Thank you.