

## FY2018 Financial Results

### Business Highlights

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May 10, 2019

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President & Chief Operating Officer

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Thank you very much for joining us today. I'd like to give you our FY2018 business highlights.

## Santen's Values and Mission Statement



Values

**天機に参与する**  
*Tenki ni sanyo suru*<sup>1</sup>

<sup>1</sup> "Exploring the secrets and mechanisms of nature in order to contribute to people's health"  
Santen's original interpretation of a passage from chapter 22 of *Zhongyong (The Doctrine of the Mean)* by Confucius.

**We think carefully about what is essential, decide clearly what we should do, and act quickly.**

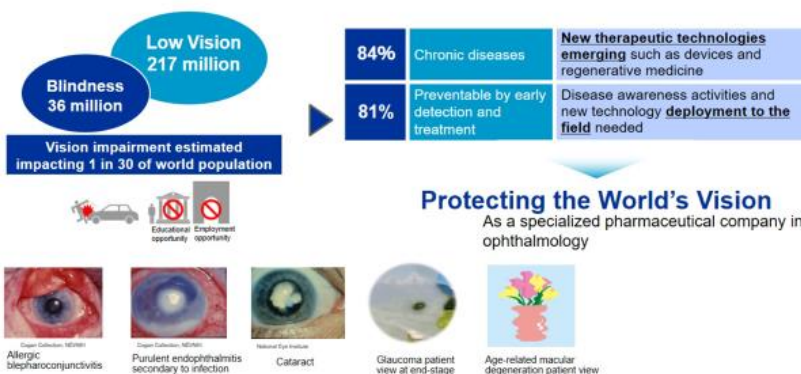
Mission Statement

**By focusing on ophthalmology, Santen develops unique scientific knowledge and organizational capabilities that contribute to the well-being of patients, their loved ones and consequently to society.**

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As you know, this is our values and mission statement: "Tenki ni sanyo suru." Based on our values, we explore the secret mechanisms of nature in order to contribute to people's health. And we are focusing on ophthalmology, we want to contribute to people, including patients, their loved ones and to society.

## Ophthalmology is our singular focus

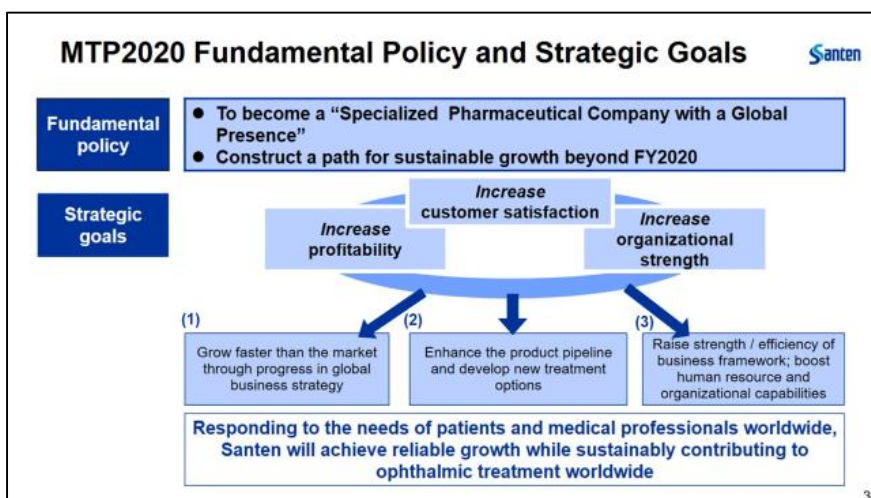


(Source: WHO World Sight Day poster, 2017) \*Santen estimates

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This organ, the eye, is only the size of a coin. It's spherical and essential for human activities. You see, you read, and in addition, it helps us balance, taste, and exercise. In every aspect of activities, eye function is involved and 80% of input into the brain. However, 1 in 30 suffers from eye disease, low vision or blindness and their various diseases. It's not just a disease affecting the eyes. It's impacting employment and how we live. It has social significance and economic significance.

We, Santen, focus on the eye, ophthalmology, and we focus on diseases in this area. And we want to provide solutions, including devices, information, and medicines. Through that, we hope that people in the world will be able to have a brighter future and live happily. And that is what we always keep in our mind in our day-to-day activities.



Last year, we announced MTP2020 and fundamental policy as shown here. We want to become a specialized pharma company with a global presence. And, for midterm, we want to construct a path for sustainable growth focused on three improvements, including customer satisfaction, profitability, and organizational strength. Details will be explained later. For FY2018, we were able to achieve our plans in many aspects. And financially, we have had very good results. I'll explain one by one later.



The first area is our global business and we want to outperform the market. Santen has our Vision 2020. And

based on that, in Asia and in Europe, we were able to significantly expand our business and business platform in a growing number of countries and products. And the next big challenge is US market entry. We have explained to you before our plan to launch in 2020. That's the goal. Once PRESERFLO MicroShunt is approved, we want to go into the US market with this product. And for Canada, this year Verkazia is our first product, and that's how we enter the market. Those are both differentiated products.

And at the end of April, we announced a partnership in the US in order to better start-up the business with a high probability of success. We entered a U.S. distribution agreement with a company called Glaukos. And this slide touches on how we want to go into the US market and the significance of this partnership. This is a distribution agreement. This is not a license-out. I want to be clear about that. Santen has its R&D activities and that will continue. And the registration will be done by us. And we, Santen brands, will be introduced to the market. And for this product, Santen will be responsible for activities including product supply, marketing, medical affairs activities, and medical congresses.

What does Glaukos do? Glaukos is approaching physicians who do surgeries and in the operating room, we may provide education, training, and explain the product. The training for surgeons about the product requires expertise. And, time is required to penetrate very well. In the US, Glaukos has the presence and know-how. This is a leading company in glaucoma. And by having the partnership with this company, this important start-up period can leverage their distribution channels thereby ensuring our success in the US market. This partnership, in terms of cost-effectiveness and speed, offers advantages compared to trying to hire and deploy surgical sales reps in the U.S. on our own.

I myself had experience in Europe and China. And I have started new businesses and launched new products. What I can say is, the key to success is, of course, differentiated products. You need that definitely. In addition, in each country, an actual marketing capability and trust relationship with the customer and operational capability is very important, including supply of product, finance, and human affairs. All those need to be well built up.

In the US, we have the Glaukos partnership. Santen will have MicroShunt and DE-117, as well as other pipeline assets. We can maximize the value of those products and pipeline with our marketing and operational capabilities. We can really focus on what we need to do. Through marketing activities, medical affairs and Congress activities, we can build trust relationships with experts in the US. Through this partnership in the US market, we want to ensure our strong presence. MicroShunt is a door opener for us in the US market and we have other products that should follow. And we are able to establish the foundation for those coming products to be successful. In the next three years, we want to build strong relationships and we want to be a company that can market products differentiated from other companies.



The next topic is Asia, where growth is quite significant. Four billion people live in Asia, and there is high economic growth and rapid development. But the healthcare infrastructure requires further development. On the top of that, beyond 2020, aging will be accelerating in these countries. And of course, we have good growth, but we are aiming at even higher growth with very high growth potential in Asia. Santen, with the activities so far, we have established ourselves as number one in China and Korea in terms of share. And in other major Asian countries we are among the top three. And we achieve both high customer satisfaction and good trust relationships with customers. There are some countries such as India where we have not yet entered, but we are preparing for that possibility. We have new products from Japan, US, and Europe to bring to those Asian markets in the future. Not only Asian members, but global team members, like our global medical affairs team which can support our Asian countries. Santen's global power should collectively support our business success in Asia. We should expand our share and scale of the business platform. We have already done so to some extent, but we want to continue that so that we can be number one in Asia. And we want to enjoy good profitability in a sustainable manner.



The second aspect is enriching our product pipeline and developing new treatment options. First, in glaucoma treatment, we believe PRESERFLO MicroShunt represents a new breakthrough. This is being developed in the U.S. Within 2019, the filing should be done, and in 2020 we should launch in the U.S. We are now preparing for that.

And from last year in Europe, our “soft launch” phase for MicroShunt has started and some important centers are receiving the product. Dozens of doctors have received training for the surgical procedure. Actually, procedures are now being implemented in clinical settings. Our experience of approval and marketing in Europe can be leveraged in US and then onward to Asia and Japan. And we are preparing our activities for that. That includes congresses and various society meetings and providing information to doctors and detailing. Various activities that are ongoing to support our global success.



Next, in September 2018 we had EYBELIS approved in Japan. EYBELIS is now being used and we are penetrating the market. Furthermore, Phase 3 in the US is ongoing. And in Asia, we are preparing for filing. In April, we completed filings in Korea and Taiwan. So, Japan-originated global products are growing, and we hope this is one of them. This medicine has a new mechanism of action and Japan was the first to launch. Since this is quite new in actual clinical settings, safety and efficacy must be monitored and examined very closely.

There is a lot of interest and inquiries about this product and information about actual patient use should be accumulated as data which is requiring more time than we anticipated. But we are steadily penetrating into the market and revenue is increasing. So, accumulating learnings from Japan is very important. We can utilize learnings for the US and also for Europe and Asia. We have cross-border activity so that this product will be a global product.



Another new product came this spring in Japan – the LENTIS Comfort intraocular lens. Compared to the traditional monofocal design, this has not only far, but also intermediate depth of vision. So, it has broader distance coverage for visual acuity. While there are multifocal lenses in the world, their optical characteristics can cause glare leading to discomfort for the user. With LENTIS Comfort, less optical discomfort is observed. And this can be covered by national insurance in Japan. For multifocal lenses, patients must pay the entire amount out-of-pocket. This is quite a merit for the patient.

In fact, my mother recently had cataract surgery and this product, LENTIS Comfort, was used. She tells us it's very good. My mother suffered with far-sightedness and bad presbyopia. She needed many kinds of glasses for each activity. But, after this new lens she doesn't need to use glasses so often for both short and far distances. And it was covered by insurance, so it was only 72,000 yen. That's my mother's comment as part of my own family experience.

Going forward, a dedicated injector will be used so that the insertion procedure will be easier. When that is approved, we can also promote more and leverage further strong growth.



We are working on, not only the projects I mentioned, but also mid- to long-term innovation. UCL and Singapore (SERI) are examples of partnerships we have established for co-development and co-research. From our collaboration with SERI, for example, came DE-127, for myopia which will start clinical studies this year in Japan.

Last year, we announced gene therapy joint projects with RIKEN and PeptiDream. We have such partnerships to generate new compounds. They are not here yet, but there are various unmet needs and we hope that these partnerships will bring about innovative therapies to address such needs in the future.



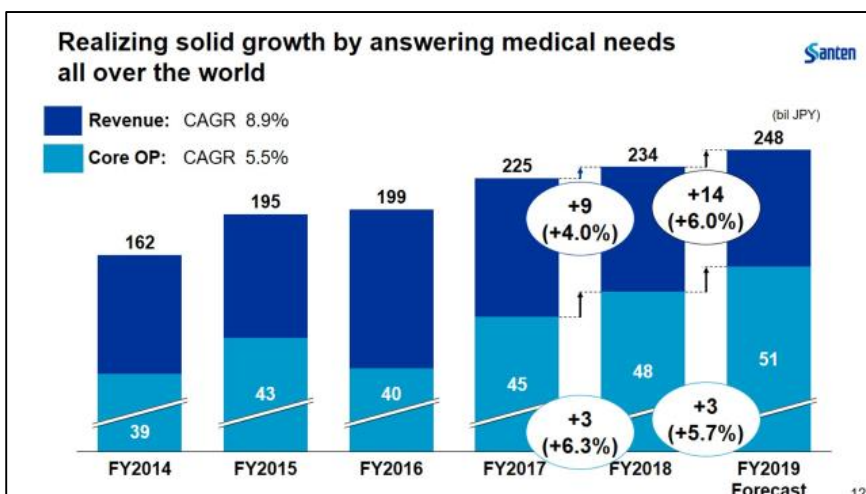
The third area is our business platform. In the past, we have globalized significantly. And in terms of business platform / framework, we learned a lot. We have many years of development experience in Japan. But, for global development, we have more channels and countries to cover. Therefore, we need to improve our business platform / framework. FY18, cost reduction and BPR initiatives were implemented.

And at a global level, we need to standardize and we have streamlined businesses so that we can have more efficient business operations and business framework. We have already achieved billions of yen in cost reductions. We have a new management framework and a global organizational structure has been created. This business organization was established for global strategy creation and operational improvement.

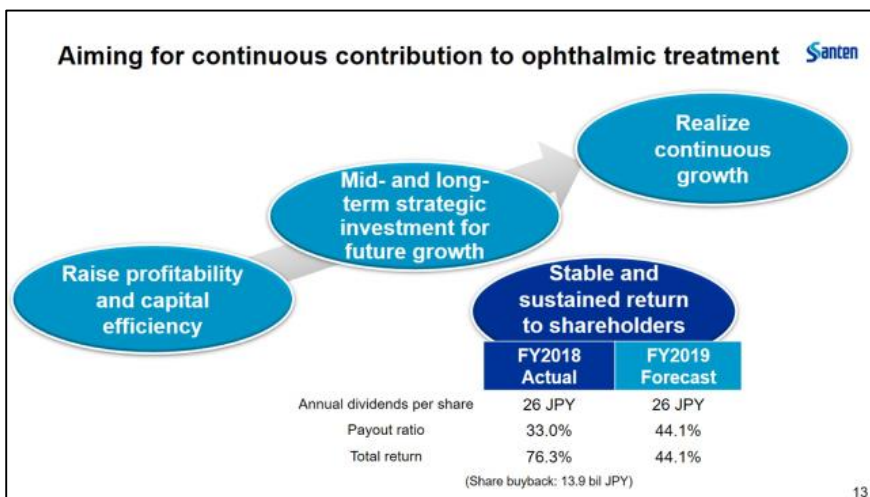
Going forward we want to make our business more efficient and a new ERP will be introduced. There are many more activities we are planning as well.



Supporting the growth of our treatments and promotion of our corporate message, we have various activities for patients suffering from diseases. For example, we collect donations from doctors for patients with eye disease. Another activity we do is the hosting of seminars aimed to help glaucoma patients seeking cosmetic ways to minimize the appearance of eye region discoloration resulting from the use of certain medications. And we don't simply provide sponsorships. For children with visual impairment, we arrange inclusive soccer events. And we have World Glaucoma Week activities. Of course, our main business is drugs and devices in ophthalmology. And through that, we will make a contribution. But we also want to provide activities for patients from social aspects as well.

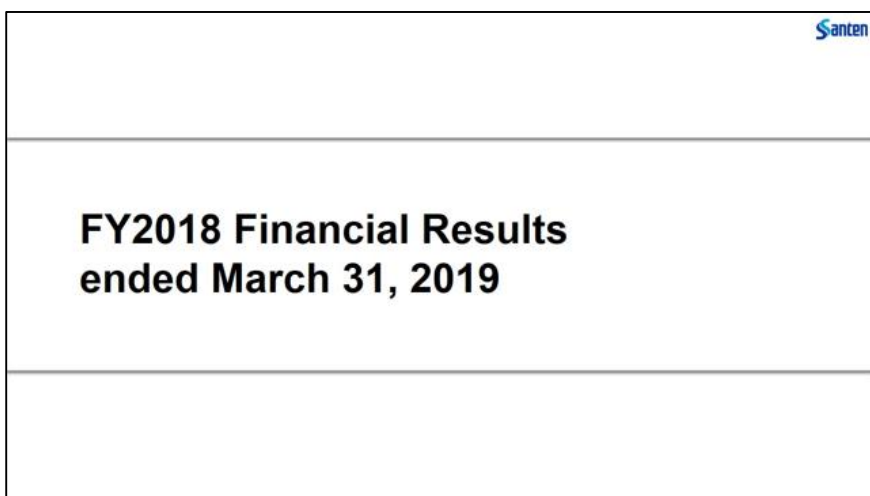


Last year was the first year of MTP2020. We were able to achieve a lot. And for the mid- to long-term, we have already begun various initiatives. Included in the revenue and profit announced yesterday, we had NHI price cut and there are various negative factors. But, in spite of those, we were able to grow in Japan, Asia, and in Europe. And company-wide cost reductions were conducted thoroughly. We were able to record revenue of 234 billion and core operating profit of 48.2 billion. For FY2019, we want to continue similar growth trends.



The purpose of our business, as I said in the beginning, is that we will focus in ophthalmology to try to meet the increasingly diversified needs of patients. We want to generate sustainable growth for the mid- to long-term range. For that, we will make investments, including in R&D, in a proactive manner. In order to support that, we also have capex including investment in production capabilities and a new ERP – which we will continue. We want the world to be brighter and happier. We are unified at Santen to achieve these goals of growth together. Thank you very much.

**FY2018 Results and FY2019 Forecasts**



This presentation has been already published yesterday. Therefore, I would just like to focus on the major points.



## FY2018 Financial Highlights

Achieved higher revenue with steady growth overseas and key products in Japan more than offsetting negative impact from NHI price cuts in Japan; Strong OP growth on higher revenue and cost optimization

	FY2017		FY2018		vs FY forecast
	Full Year actual	Full Year actual	YoY	Full year forecast	
<b>Core basis</b>					
<b>Revenue</b>	224.9	234.0	4.0%	237.0	99.7%
COGS	-86.4	-90.8	5.1%	-91.0	99.7%
<b>Gross profit</b>	138.6	143.3	3.4%	146.0	99.1%
SGA	-68.8	-71.3	3.6%	-73.0	97.6%
R&D expenses	-24.4	-23.8	-2.6%	-25.0	95.0%
<b>OP</b>	45.4	48.2	6.3%	48.0	100.5%
<b>Net profit</b>	33.5	36.1	7.9%	35.3	102.2%
<b>IFRS</b>					
<b>OP</b>	38.7	45.1	16.6%	40.7	110.8%
<b>Net profit</b>	35.3	31.9	-9.4%	30.4	105.1%
Actual tax ratio	10.2%	25.9%			
ROE	13.0%	11.1%	-1.9pt		
USD	JPY 110.94	JPY 110.82	+0.1%	JPY 110.00	-0.7%
EUR	JPY 129.92	JPY 128.38	+1.2%	JPY 130.00	+1.2%
CNY	JPY 16.84	JPY 16.52	+1.9%	JPY 17.00	+2.9%
			+ JPY appreciation, - JPY depreciation		

### Revenue

Japan: Growth of key products absorbed the negative impact from NHI price cuts  
Overseas: Continued strong growth, particularly in Asia  
**Consolidated total growth: 9.1 bil JPY (+4.0%)**

### Operating profit

#### Core basis

Increased 2.9 bil JPY (+6.3%) with continued overseas growth and group-wide cost optimization offsetting negative impact from NHI price cuts

#### IFRS

Business growth on core basis and gain on sale of former HQ/Osaka plant site, **increased by 6.4 bil JPY (+16.6%)**

### IFRS Net profit

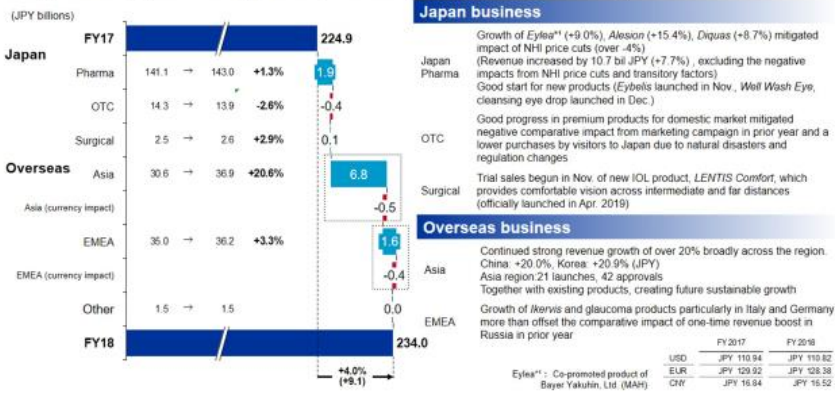
With one-time benefit of reduced corporate tax rate in U.S. in prior year and impact of accounting treatment of InnFocus acquisition costs, **decreased by 3.3 bil JPY (-9.4%)**

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Let me now begin by explaining the financial results of FY18. The results were very close to our guidance. On a core basis, revenue grew by 4%. And there were price revisions in Japan and this impact is also included. Minus this factor, we would have seen growth of 7%. For the core and IFRS, operating profit levels are shown here, as is net profit. In FY17, we had a tax rate reduction and the impact benefit of 5.1 billion yen. Including that gain, the comparison shows a decline of 9.4%, year-on-year.

## FY2018 Revenue

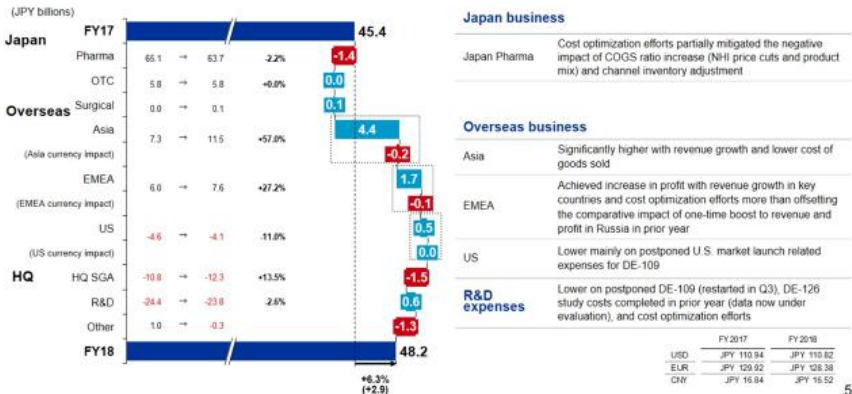
Japan: steady growth of key products; Overseas: strong growth, particularly in Asia



Let's move on to the next page. This shows the breakdown of revenue and this was quite as we had expected. There was only minimum currency impact. Especially in Asia, we had major growth. And, as mentioned in the materials, new and key products were contributors in Asia where we launched 21 products and received 42 approvals.

## FY2018 Core Operating Profit

Strong growth in overseas business and group-wide cost optimization to offset NHI price cut impact



Let's move on to the next page. This shows the bridging from the previous fiscal year, in terms of the core operating profit. In Japan, it stayed rather flat, due to the government mandated price revision. However, in overseas, mostly in Asian countries, we achieved strong growth.

## FY2019 Forecast ended March 31, 2020

## FY2019 Forecast Overview

As middle year of MTP2020, targeting to raise both revenue growth and operating efficiency

(JPY billions)	FY2018	FY2019	
	Actual	Forecast	YoY
<b>Core basis</b>			
<b>Revenue</b>	234.0	248.0	6.0%
COGS	-90.8	-95.0	-4.7%
<b>Gross profit</b>	143.3	153.0	6.8%
SGA	-71.3	-74.0	-3.8%
R&D expenses	-23.8	-28.0	-17.9%
<b>Operating profit</b>	48.2	51.0	5.7%
<b>Net profit</b>	36.1	37.7	4.5%
Actual tax ratio	25.2%	26.1%	
ROE	12.5%	12.8%	0.3pt
<b>IFRS</b>			
<b>Operating profit</b>	45.1	34.5	-23.5%
<b>Net profit</b>	31.9	23.2	-27.4%
Actual tax ratio	25.9%	32.4%	
ROE	11.1%	7.9%	-3.2pt
USD	110.82	110.00	+0.7%
EUR	128.38	130.00	-1.2%
CNY	16.52	16.00	+3.3%

### Revenue

**Japan:**  
To grow with increased revenue from key products (including Eybelis, High-dose Alesion and LENTIS Comfort) covering the negative impact from NHI price cuts

**Overseas:**  
Maximize revenue both in Asia and EMEA  
**Consolidated total revenue 248 bil JPY (+6.0%)**

### Core basis

**Continuous profit improvement from core business**

- SGA: 74 bil JPY (+3.8%)
- Accelerate cost optimization under new management framework
- R&D expenses: 28 bil JPY (+17.9%)
- Continue strategic investment to lead growth to 2020 and beyond
- Operating profit: 51 bil JPY (+5.7%)**

### IFRS

Other expenses increase mainly from raised assumptions regarding DE-128 milestone payment probability based on development progress; Operating profit and net profit lower YoY

So now, let's move to the FY19 forecast. For the year, we forecast 248 billion for revenue and 51 billion yen for core operating profit and 7.7 billion yen for net profit. And for IFRS, operating profit will be 34.5 billion yen

(down 23.5% year-on-year) and net profit is 23.2 billion yen (down 27.4%). We are going to maintain the momentum of the revenue which has been continuing through the past few years. Another item is SG&A, where 3.8% growth is expected.

This has already been explained by Mr. Taniuchi, since last year, we've been carrying out significant cost reduction activities. Cost should be suppressed under the growth of the gross profit. SG&A can be classified into four different types, variable costs, labor costs, royalty, and cost amortization. Royalty will increase in terms of sales growth, however, variable costs should be flat or 1% growth at the most. For labor cost, there should be about 3 to 4% growth. This must be strongly controlled so that we can secure profit.

And then, R&D expenses-- this will be 28 billion yen, which is higher from the previous fiscal year. This R&D spending is necessary for future growth as it says in the materials. But last year, there were some underspend in R&D. However, we expect this year's R&D will be 28 billion yen and fully used. Core operating profit will be 51 billion yen, or 5.7% higher year-on-year.

As to the IFRS figures, DE-128 milestone payment is expected. In FY16 when we purchased InnFocus we paid up-front purchase price and contracted to make "milestone" contingent payments. The achievement of milestones in the future, such as regulatory approval, etc., will trigger the need to make such payments. They were all regarded as the noncurrent liabilities. And when the event happens, then the payment will occur. In FY19, we expect to book the contingent liability expenses related to DE-128's filing and approval based on an increased assessment of the probability of the milestone payment will occur.

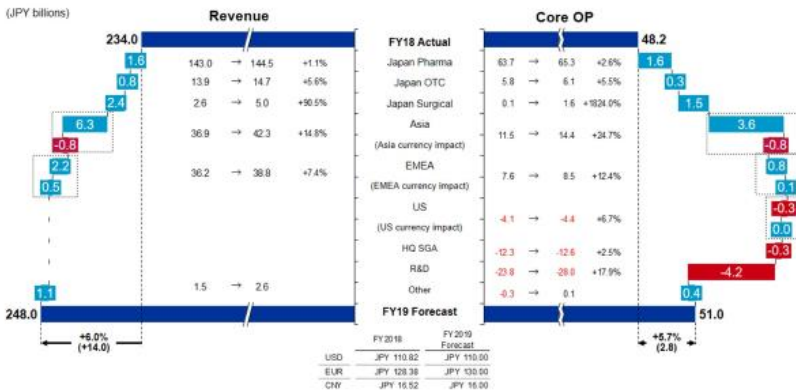
These are booked as costs under IFRS in the amount of 8 billion yen. And this is a one-time cost for accounting purposes. If the contingent payment happens, then of course, there is a payment occurring. But this will not impact the P&L.

Therefore, we expect large declines in IFRS profit year-on-year, but this will not recur next year at the level of 9 billion yen. The development-related (filing and approval) milestone payments are already included this fiscal year. But, once we start the production and marketing, then there could be other future milestones such as the achievement of certain sales targets. If those milestones have a high probability, we might need to review the contingent payment again next fiscal year. However, the potential size of such an impact size would not be as large as what happened this year. While it really depends on certain factors, the range could be around 2 billion yen.

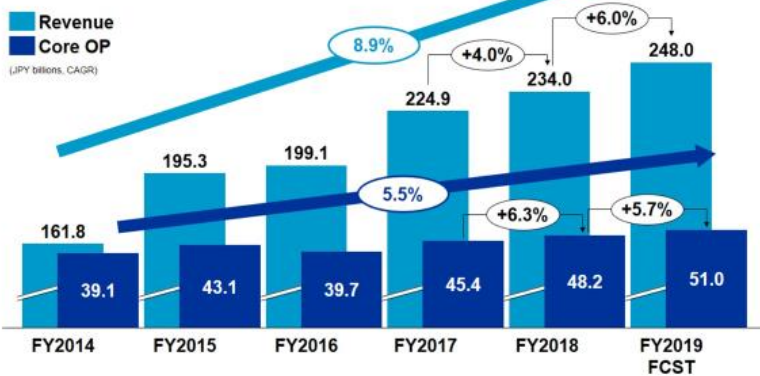
In terms of the amortization, with the soft launch started in Europe, we expect amortization of 2.8 billion yen this year. And this year the sales of MicroShunt will be slightly more than 400 million yen. Therefore, in the IFRS base, the amortization is slightly higher. But we believe that this can be offset by increased revenue.

### FY2019 Forecast

Growth in Japan and overseas businesses and further optimization of costs in order to realize strategic investment and higher profit

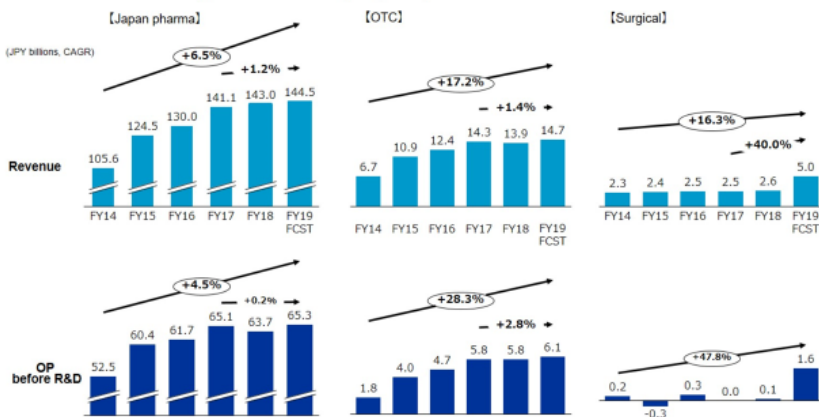


### Consolidated Performance

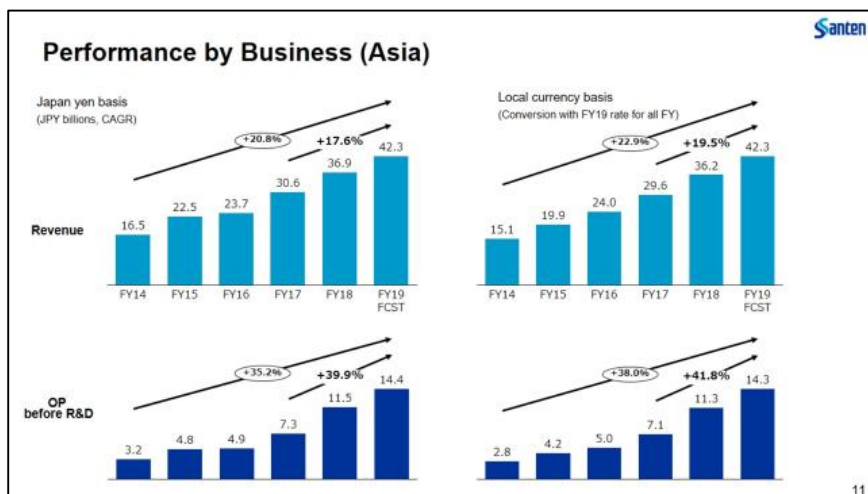


Now this shows consolidated performance from FY14, meaning the last MTP period. We had some negative growth in the profit in FY16. But in principle we maintain sustainable growth. That's always our goal. So, with the increase of R&D cost or price revision, we would not expect major negative impact from those, and we will continue to make efforts to cut costs, and streamlining spending, so that we can maintain the positive growth in revenue and operating profit.

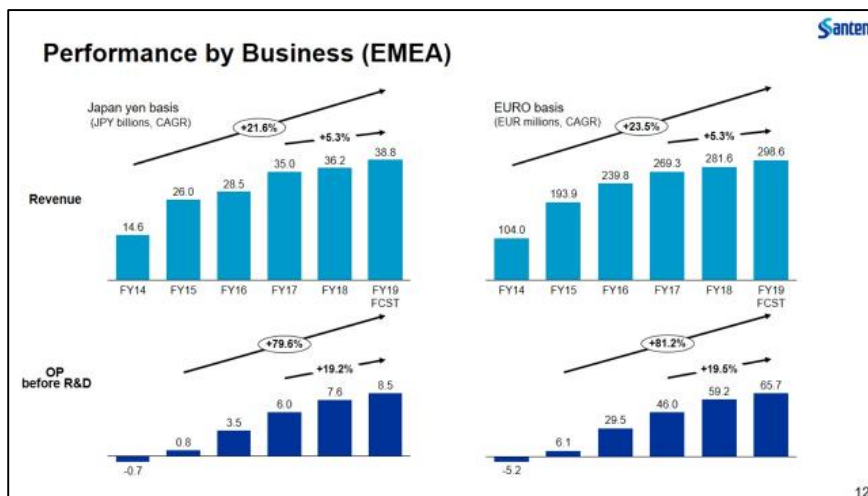
### Performance by Business (Japan)



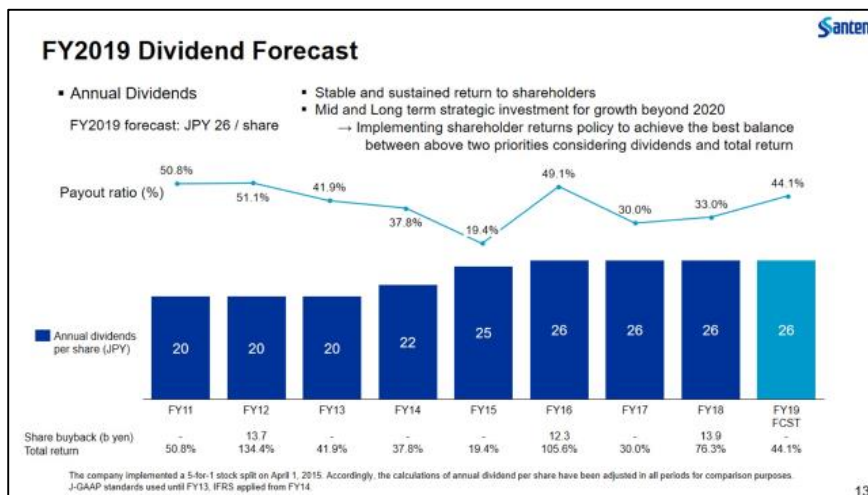
Here is the performance by business in Japan. Of course, we have to expect drug price revisions in Japan pharma. Last year, sales of long-term listed products were relatively small in terms of revenue, so we didn't see any major negative impact. And from this fiscal year, we will strengthen the surgical business also.



Here, we have the Asia business performance. This business generates about a 30% contribution margin ratio which is expected to continue.



Revenue and profit growth are expected to continue and this is also expected for the EMEA region as well.



Here is our dividend forecast for FY19. As has been discussed by Mr. Taniuchi, this year we are planning to pay 26 yen per share which is maintaining the same level as last year.

And on page 15, the Data Book says that as of the end of March, the shareholder mix shows institutional investors make up 75.6%. So, we have a high ratio of institutional investors, both in Japan and elsewhere. And of course, the return to investors is one of the major focuses.

While we did not disclose the specific amount of the dividends for the entire MTP2020, we consider very carefully. We would like to maintain the dividends payment with consideration of total return. Thank you very much for your attention.

Pipeline / Product Development Status (1)			
Indication	Region	Status	
<b>DE-111</b> <small>TAPCOM / TAPTIQOM</small> Combination of latanoprost and timolol maleate	China	P3	<u>Plan: 1<sup>st</sup> half FY2020 P3 completion</u>
	US	P3	<u>Plan: Jan-Jun 2020 P3 completion</u>
<b>DE-117</b> <small>EYBELIS</small> EP2 receptor agonist	Japan	Launched	
	Asia	<u>Filed (Apr 2019, including Korea)</u> <u>Plan: 1<sup>st</sup> half of FY2020 approval</u>	
	US	P2b	
<b>DE-126</b> <small>FP/EP3 receptors dual agonist</small>	US	P2/3	<u>Plan: calendar 2019 PMA rolling submission completion, calendar 2020 launch</u>
	Japan	CE mark received	
<b>DE-128</b> <small>PRESERFLO MicroShunt</small>	Europe	P3 started (Apr 2019)	<u>Plan: calendar 2021 P3 completion</u>
	Asia		
<b>DE-130A</b> <small>Catioprost latanoprost</small>	Europe		
	Asia		

I will give you a quick update on projects in our pipeline. So, let's start with DE-111. This is for glaucoma and ocular hypertension and is mainly for the China market. The plan is that in 2020 we will complete the Phase 3 studies and we are on track. I want to say that DE-117, that Taniuchi-san mentioned, is currently in Phase 3 in the US. We are on track with our enrollment in the pivotal study and expect to meet the plan for first half of 2020 approval.

DE-126, as you know, is an FP/EP3 agonist, and we've had the Phase 2 data for a while. We are trying to properly position the product and looking for differentiation of the product before we move forward.

DE-128, there's been a lot of discussion. We are committed to completing our PMA filing by the end of this year in calendar 2019, and then getting approval in 2020.

Catioprost, which is a formulation of latanoprost in a proprietary formulation, is in Phase 3 and we are expecting completion in calendar year 2021.

## Pipeline / Product Development Status (2)

As of May 9, 2019

Updated information is underlined

	Indication	Region	Status	
<b>DE-109</b> IVT sirolimus	Uveitis	US	P3	
		Japan	P3	<i>Plan: Jan~Jun 2021 P3 completion</i>
		Europe	P3	
		Asia	Filed	
<b>DE-122</b> Anti-angiogenic antibody	Wet age-related macular degeneration	US	P2a	<i>Plan: 2nd half of FY2019 P2a completion</i>
<b>DE-089</b> Diquas	Dry eye	China	Launched	
<b>DE-076C</b> Vekacia / Verkazia oxyclosporin	Vernal kerato-conjunctivitis	Europe	Launched	
		Asia*	Filed, <i>Plan: Jul-Dec 2019 approval</i>	*Product name <i>IKERVIS</i>
		Others	Approved, <i>Plan: calendar 2019 launch</i>	
<b>DE-114A</b> epinastine HCl (high dose)	Allergic conjunctivitis	Japan	Filed	<i>Plan: Jul-Dec 2019 approval</i>
<b>DE-127</b> atropine sulfate	Myopia	Japan	<i>Plan: 1st half of FY2019 P2/3 start</i>	
		Asia	P2	<i>Plan: 2nd half of FY2019 P2 completion</i>
<b>MD-16</b> Intraocular lens	Cataract	Japan	<i>P3 completion (Mar 2019)</i>	<i>Plan: 1st half of FY2019 submission</i>

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On the next slide, DE-109, as you know, is our posterior noninfectious uveitis product. It is in Phase 3. The recruitment is challenging, but we are continuing to move forward as best as we can currently. We are still looking to January-June as our 2021 Phase 3 completion timing.

DE-122 is an anti-angiogenic product which is for wet AMD. We will have data from the Phase 2 study in the second half of this calendar or fiscal year.

Vekazia in Canada, we have just gotten approval in December, and it's going to be launched in this year, 2019.

DE-127 also was mentioned by Taniuchi-san. We are looking to start a Phase 2 and 3 program in the second half of fiscal 2019. On the lens side, there is the MD-16 in our pipeline, which is a toric lens-- we have completed Phase 3 and are looking to submit later this year, the first half of 2019.

That's the end of my portion of it. I'll be happy to discuss in detail in the question and answer session. Thank you very much.

## Question & Answer

### Q1-1-1

My first question. Maybe I did not quite understand. But, Glaukos, you mentioned this is a distributor arrangement. As you work together with Glaukos, up to launch, there will be training, and you also do sales separately. So, the sales part of that would be done by Glaukos. That's how it sounded to me. So, there are various payments. In the future, will you take over all the sales? As sales go up, costs also go up. What are the merits / demerits for Glaukos? Can you explain this from the P&L point of view?

### A1-1-1

**Taniuchi COO:** Let me explain that. This is a distributor agreement. It's not that you give everything to the distributor. In terms of P&L, Santen will have SG&A and marketing costs. But, we do not hire sales reps, this is done by Glaukos. Therefore, in terms of P&L for Santen, there are no sales costs. And that is the structure. Therefore, this is a multi-year distribution agreement. We do not disclose details. But during that agreement

period, medical affairs and marketing expenses are conducted by Santen. And through Glaukos, they have margin and they will bear the sales cost. That's the design.

Q1-1-2

Sales will be recognized through Glaukos. So, the sales price may be a bit lower?

A1-1-2

**Taniuchi COO:** The sales will come through Glaukos, through distribution.

Q1-1-3

When sales scale up, will you then take back all the sales activities?

A1-1-3

**Taniuchi COO:** As for what happens after the agreement period is over, we will see how it goes. But one thing that we want to tell you is - sales activities related to the operating room (MicroShunt) are not so relevant for our other pipeline projects, DE-117,126 or 109. So, going forward, when the device increases in volume we may need to consider how to best support. But, as I said, for our other pipeline, this is not so relevant and our marketing focused role for MicroShunt is sufficient. And separately from the MicroShunt agreement with Glaukos, we will be able to sell our other pipeline projects once approvals are given.

Q1-2

EYBELIS domestic is my next question. Timing wise, it's not really a time for push. But the 400 million yen seems a bit soft. I thought it could have been a bit stronger. But the side effect on PI was mentioned. Can you explain the balance between efficacy and side effects? But there's high expectation. But maybe there was some feedback that was not anticipated beforehand and what are your actions?

A1-2

**Taniuchi COO:** For FY18, it is true, the number was a bit slow or soft, as you said. And the reason for that this is an entirely new product. Of course, side effect profiles are shown from clinical studies. But what about the actual experience in real world? Well, this requires a lot of careful communication. For example, after the first patients use this product, we carefully collect feedback. We also use significant resources in monitoring related to edema. Because of the activities, the initial pickup was a bit slow. But it has settled, more or less. And the physicians know how to use this product versus latanoprost and FP analog, including differences in the side effect profile - no discoloration or pigmentation. So, they understand more, and we have better penetration recently. So, compared to our initial idea, FY18 was a bit slow. But pickup is steady and growing. And we want to continue that in FY19.

Q1-3

Regarding the surgical business, in the past, intraocular lens was introduced and there was a high



expectation. But in the end, because of the competitive environment, results were not that great. But this time around, you seem to be very confident about this product. Can you explain more about that in comparison to the past approaches?

A1-3-1

**Taniuchi COO:** Let me start with our expectations. In clinics we have had very positive actual physician feedback. At the end of April, there was the Japan Ophthalmology Society event in Japan, and we had two large meetings that were completely full with doctors. We shared data and actual use experience. And people are very interested in this, particularly because of its unique qualities including insurance coverage. From April, our surgical and Rx business are integrated as one team. And MR activities and surgical team members are working together for promotion. So far, we have very good feedback. After the new injector arrives, we will further promote. Again, feedback has been very positive.

A1-3-2

**Kurokawa CEO:** Well, compared to the past, well, I don't know what to say. Our offering in the past and continuing today, the AVS lens, did not quite meet up to our expectations. Perhaps it's to do with lens flexibility and/or the inserter. The insertion process is not perfect and required longer than expected procedures. These factors may have led to customer dissatisfaction. And now, this LENTIS Comfort product, after the physicians use we hear their very positive feedback. Patient comfort is high - especially glare is reduced or eliminated with this lens. That is one of the reasons for the positive feedback. We have high expectations for this product. Thank you.

Q2-1

The first question is about the trend in the Asian business. In the past fiscal year, Hyalein saw very high growth. And this year, you may not have the same benefit in the marketplace you had last year. So, you can't expect such rapid growth. In the midterm, is 15% growth sustainable? As for Diquas, if it is reimbursed in China, what will be the potential? For example, can Diquas be as big as Hyalein is today?

A2-1

**Taniuchi COO:** In terms of the Asian business, in FY19, we do not expect any major changes. And centering around China and Korea and Southeast Asian countries, our business is growing and will continue to grow. Also, Tafluprost, TAPCOM, Diquas and Ikervis are new products in Asia, and they are showing a very rapid ramp-up. And we believe that these products will greatly contribute. As for Diquas, reimbursement will take more time to complete. But we are now working, one province at a time. And we would like to make it another Hyalein. However, it really depends upon the progress of our negotiations regarding reimbursement. But in principle, we would like to make it as big as possible.

Q2-2-1

The next question is about Alesion assumptions in Japan. This year, you have a very aggressive plan and

you expect some market share growth. Also, the high-dose product will be launched. Then, what will be the impact of these activities? And if possible, please tell your idea for the pricing and volume.

A2-2-1

**Taniuchi COO:** The FY18 allergy season started early. Therefore, Alesion has been somewhat helped by that. But the allergy period ended earlier this year. Last year, allergy season is ended after spring, however this year, it seems the allergy season ended earlier than the prior season. And for the upcoming high dose medicine, we hope to get approval in the latter half of the year. Also, we are still negotiating with the authorities for the drug price. One large difference is the dosing per day. The new high-dose is just twice per day. And for allergic patients, they may have a difficulty using eye drops throughout the day. So, by having administration just twice a day, they can use before going to school or the office, and then after they come home. So, that is an important advantage. Therefore, we would like to promote this so that we can differentiate these two products. And also, we would like to make every effort to launch and grow the high-dose product revenue.

Q2-2-2

And then, you expect the growth in the high-dose product, right?

A2-2-2

**Taniuchi COO:** Yes. That's right.

Q2-3

That's about the intraocular lens. And it's about the profit ratio. In domestic surgical business, sales are also growing. But you are expecting the increase of the profit. The growth was 1.5 billion yen in profitability. Do you think that this is really such a profitable business?

A2-3

**Taniuchi COO:** Well, we are going to make a midterm projection in the future. But as far as FY18 is concerned, that was the timing for the breakeven. So, of course, we are spending more to expand the market channel. But as I said, we have our ophthalmology division and we can use the existing salesforce. And therefore, the SG&A, especially headcount growth, should be suppressed. And we are going to increase the gross profit. That's what we expect in FY19. So, that contributes to a major improvement in profitability. And in Japan, the marketing cost is not that high compared to Asia or America. Therefore, we will use our normal market channel with the most appropriate costs considering profitability. Thank you.

Q3-1-1

First, I don't have knowledge about intraocular lenses. What's the domestic market situation? And, there are various types of IOLs, including multifocal and toric lenses. Can you explain how they are segmented and what's the market size for each? That's the first question.

A3-1-1

**Taniuchi COO:** I don't have the amount or detailed number regarding the market with me now. But much of the market is monofocal, and foldable lens is widespread. AVS products fall into this category. And there are various manufacturers' products, including major players. They have high share. Our share is not so high in this segment. As for multifocals – the product costs are out-of-pocket. Share is still very small. It depends on the hospital, but the patient needs to pay half a million yen or a million yen. So, not many patients go to use those IOLs. But the number is steadily increasing. There are monofocal and multifocal. And toric, this is for astigmatism. Whether it's mono or multifocal, you need to make adjustment. But if you have astigmatism, then focus is not clear. So, you need to add astigmatism and SKU increases significantly because we need to change the angle. It's like glasses. And so, it's a value-added type IOL. Toric, it should be included in product portfolio, we don't have toric at this moment, because our market share with AVS lenses has not been very high.

Q3-1-2

So, LENTIS Comfort is for multifocal and you're not aiming at monofocal?

A3-1-2

**Taniuchi COO:** We are, of course, aiming at monofocal with insurance coverage. This is monofocal with greater visual depth. So, depth and breadth of focus are strong characteristics that are differentiating points. So, we want to aim at the main market, which is monofocal.

Q3-2

The last question is about the MicroShunt. I think at the ASCRS meeting that was held on May 6, the MicroShunt European data, two-year data, has been disclosed. And I think this is 124 patients. This is probably the largest data set we've seen so far. And it looks like the IOP does go from 22.5 mean, to 13.9 post-operation. I think this is probably acceptable. The only problem I see is that there is a little bit of-- about 13 patients out of 124 had undergone glaucoma reoperation. And obviously, there was no detail disclosed here. Is this a pretty significant reoperation, as in, a full on trabeculectomy, or is this just basically something to do with blebs, or a very small procedure?

A3-2

**Shams CSO:** So, let me just be generic in one way, which is that reoperations to treat rising IOP or progression of disease is not unusual at all. I would also say that we should take that data with a bit of a grain of salt, because these are open label studies conducted in two very different centers, with two very different surgeons, their own techniques, etc. So, I think we should probably wait for the control study data to draw some conclusions.

But that rate is probably, if I'm guessing at this point, I don't have the exact numbers, is lower than what you

might expect from leaking blebs after trabeculectomy. So, I don't think that's unusual. But, let's wait for the good data to come out later in this year.

Q4-1-1

The first question is about R&D spending. In your FY19 plan, you said that you always have a cap. But this year you would not give any cap and I think Mr. Koshiji said that in his presentation. And when you make a budget, you make a different budgeting this year. What is the reason? And what is the possibility for the forecast versus actuals?

A4-1-1

**Koshiji CFO:** Let me answer your question. In the budgeting process and the procedure, the overall concept hasn't changed. It's just a slight adjustment. This year, we have some improvement with bottom up calculations. And then, that was reflected directly into the budgeting amount. And as to the forecast versus actuals, therefore we see in the previous year, in FY18, against 25 billion yen, then actual was 23.8. But this year, we also have to look into the trend in the term. In principle, at this moment we believe that we will reach the budget amount. But of course, we have included the bottom up input a little bit more than usual. That's what we have done.

Q4-1-2

Then, why have you changed that?

A4-1-2

**Koshiji CFO:** To give you more background, this is not really a single year number adjustment. But, in order to enhance the pipeline, then in R&D, there are some challenges. But among them, we would like to prioritize those challenges. And therefore, this was more from the viewpoint of a strategic consideration.

Q4-2-1

Thank you. My second question is in the progress status, the current year against the midterm plan and next year you will expect a drug price revision. Therefore, up to FY19, you have to have lots of sales growth to cope with the price cut. And would you say your overseas sales were in-line, or slightly weaker than previously projected?

A4-2-1

**Taniuchi COO:** In principle, we perceive it is in line. Of course, we have individual plus and minuses. But overall, I think we are in line. Naturally, the 6% growth is the target for FY19. Of course, we expect a price revision in Japan. But we have intraocular lens. And also, we have other growth potentials. Also, we have growth in Asia and Europe – therefore, I think that we are in line.

Q4-2-2

Your MTP2020 called for Asia +16%, EMEA +10% or more. But that may be a little bit challenging?

A4-2-2

**Taniuchi COO:** Well, EMEA 10% for FY18 and FY19 may be somewhat difficult to achieve.

And there are some differences in assumptions. We stopped the selling certain less profitable products. So actually, some top line has been sacrificed by this. Also, for product supply we had some quality issues from outsourced product. Therefore, we had some special factors. But including them all, then we are still growing steadily.

Q4-3

Lastly, from a long-term point of view, I would like to ask for your view for China. And the Chinese government is now evaluating and accepting of innovation. And many companies are enriching their pipeline in China. On the other hand, there is a very strong price cut for the non-innovative products. I also would like to know how much risk you expect. And if there is such a risk, is your development pipeline organized so that you can still grow in such a situation?

A4-3

**Taniuchi COO:** In a long-term, trend wise, yes. You are right. We need appropriate development of innovative medicine and those should be priced appropriately. But also, the price cuts expected are other products or non-innovative products. And what we can do on a long-term basis is prepare for our expectation of the market growth in China. In China, the market size is still very limited compared to the total population size. And, the number of ophthalmologists is maybe 20% compared to Japan, in terms of the per capita basis. And, for example, the number of the cataract surgeries is limited because the number of specialists is limited.

So, there are many bottlenecks existing. And of course, we like to launch any new product as quickly as possible and we are carrying out clinical development locally. We would like to strengthen such capabilities in China. Of course, the market has a huge potential. It will grow many times what it is today. I really have my mind of future capacity. If our sales triple or more, what happens? We must avoid the situation that we cannot meet the opportunity due to a lack of sales capacity. Therefore, we have to make a capex and other investments, so that we have sufficient capability to cover Chinese market growth.

Q5-1-1

Regarding China, you make investment in China and have profit. I understand the scheme may develop furthermore, but how to recover the profit from China is an issue. Western pharma companies are reinvesting profit in China because you can't really absorb the profit from China to outside China. Including capital flow, we don't know how the money moves. But the profit in China, how is it utilized at present? Can you explain that?

A5-1-1

**Koshiji CFO:** Regarding the money flow, I will explain. As for China, we have two flows. One is reinvestment in—mostly the joint venture in Chongqing. So, we make investment there, and that is done through our subsidiary in China. We have this joint venture. So, investment in a second plant in China, and the building is being constructed now, and that's the investment.

Another is of the cash position we have from our China business. We have conducted an upstream loan. That's the scheme. It's not a dividend. But it was loaned to the Japanese organization for use here in Japan. That's how we absorbed the money from China, and we have reached cash position in Japan. So, in the US, in R&D, there is demand for R&D financing. And that money goes to the US. Going forward, when there's excess cash in China, and in Chongqing, reinvestment that may not be enough to absorb. Therefore, excess cash would be directed to ASEAN countries or to the US, where there is a demand for cash. And, we will consider our best options at that time.

Q5-1-2

That is through the scheme of loan.

A5-1-2

**Koshiji CFO:** Yes. So, in the end, it will go back to China. But it is a long-term loan. For example, three year or five year, those schemes. Within the group companies, the group as a whole, cash flow status does not change and of course, we will make judgments as needed.

A5-1-3

**Taniuchi COO:** Regarding reinvestment, as mentioned, capex in Chongqing, we have a building being constructed. In Suzhou and we have a plant, and there are three shifts already. And we have a high-speed line being introduced. When we get permission from the authorities, this will be launched. 80 million or 90 million bottles is the amount in China. And in Japan, we have three shifts. In China, we also have three shifts. Therefore, we would need further capex.

Rather than the current plant, maybe we need extra plants. And that's one possibility. In Suzhou, it was a 2-billion-yen plant 10 years ago. And the ophthalmology plant does not require so much money. But several billions of yen would be required. And for R&D, in China so far, we have done clinical studies, but not large scale. It is more or less procedural steps. But going forward, we may need to conduct more activities such as possible clinical studies.

Q5-2

Dr. Shams, when you explained 109, you said the word "challenging". That's the word you used. And, we don't like to hear the word challenging. So, can you give us an update on that?

A5-2

**Shams CSO:** We don't like it, either. However, if you recall that we had hit a road bump a year or two ago, and the goal of this program is to be successful. That's number one. And so, we identified at that time about

eight potential corrective actions that we should take to maximize the probability of technical success. And those eight different initiatives are slowing down the recruitment of subjects. However, we are looking at options to deal with the situation. And therefore, the current timeline has not changed, at least not today. So, the goal for us is that we would like to maintain the timeline and recruit the best patients, the appropriate patients, so we can succeed. That's why I used the words challenging. But we can manage this with tuning. But we don't want to do too much tweaking that it compromises the probability of success. Approval is very, very important. The drug is very, very important to patients. So, that's why I used the word cautiously. But we have ideas and we will implement those as soon as possible.

Q6-1

I have two questions, just briefly. And this is the request for clarification for MicroShunt. MicroShunt positioning in the US market entry, you said that you are going to use it as a door opener. With MicroShunt, you are going to maximize sales. And in addition, you will conduct marketing and regulatory affairs. Are you going to review how you do business in future? What is the priority right now?

A6-1

**Taniuchi COO:** Actually, MicroShunt is a very important asset for us. Therefore, we have to maximize it. For the US business, this is the first product to enter the market and we will maximize it. But that is not really the end. We maximize it, but also Santen will establish a strong presence there. And therefore, we would like to establish a platform so that we can do business properly in the US. So, that's why we say it is a door opener. Given these goals, we view Glaukos as having great expertise and sales infrastructure.

Q6-2

Therefore, the MicroShunt alone and in 2022, then the competition will be very severe. Then, in terms of development of the other follow-on products and quite naturally, in non-US market is now growing very rapidly. Therefore, for the MIGS business in Europe, you have made a soft launch. When will that be a significant amount?

A6-2

**Taniuchi COO:** About Glaukos' current products – these are mainly for cataract surgery doctors with intraocular lens insertion. Also, the surgical approach for such products is made from ab-interno (from the inside out). On the other hand, MicroShunt is ab-external. Offering more options is an advantage. And when I spoke with them at a recent academic conference and they said they will happy to have an enhanced portfolio. Therefore, rather than being competitors, we would like to cooperate and grow together. And in terms of the European market, in FY19 we would like to make a phased approach to expand. We have a soft launch already made in UK, France and Germany. Our surgical reps are working there now. Doctors are now being trained to earn certificates of qualification. And in the latter half of FY19, we'd like to complete the establishment of the sales force in those countries.