Speaker Remarks June 5, 2018 (summary)

Medium-term Management Plan (MTP2020)

I would like to provide the explanation to you. I introduced myself already in May but, let me start with a short self-introduction. I joined Santen in 1996, and have been working for the company ever since. For the first three years I worked in sales, mainly in Osaka, Japan, and then I moved to corporate planning and I’ve been involved in business planning, mid-term planning and other planning. For the domestic business, I worked in sales business strategy and a reform in the Japanese business for which I was project leader.

Also, as Santen became more global, I worked overseas in various functions and roles. In the beginning, after 2000, I was in the US for market entry and also partnership and withdrawal and so forth and I was working for partnership with local companies and I was involved in the negotiations.

In China, from 2008 I was in the Beijing office for three years to lead the business initiation there. More recently I was in Europe, working on the business expansion including the products from Merck and so forth, I was in Geneva, Switzerland. From April this year, I began the function of President and COO and have been back in Japan. During these first two months, April and May, I have been quite busy.

Today I will explain the “MTP2020” mid-term plan. I will cover these three topics.

1. Santen’s Vision
2. Review of MTP fiscal 2014-2017
3. MTP2020
The first is Santen’s vision. You know our vision but let me explain once again. *Tenki ni sanyo suru* is the basic philosophy of Santen. As you know, this is from a Chinese classic Zhongyong or the Doctrine of the Mean. The phrase is taken from that exploring secrets and mechanisms of nature in order to contribute to people’s health. That’s the Value that we have appreciated since our foundation in 1890. In ophthalmology, in this specialty area, we contribute to patients and their loved ones and we make contributions to society.

Through the ophthalmology area, we make social contribution. This is our value and that’s the basis of our company now and also for the future, we will try to evolve our business based on this philosophy.

This is Vision 2020. In 2010, we created Vision 2020, a 10-year plan. Around 2010, while Santen had begun overseas sales, such sales only made up 14% of the total sales. Domestic business was very strong in terms of sales and profit. On the other hand, around that time already, NHI pricing reform momentum was being built, and also the overseas’ high growth issues were being incorporated into our growth strategy. We want to have very active business development so that we can have sustained growth. That is why we have the Vision 2020 and we have been working to achieve those goals.
Towards the realization of 2020, we had five policies to achieve. For the actual, I will explain later, but we try to have product development so that we can provide products that truly meet customer needs and should be rolled out globally. Also, we need to build and maintain supply chain and quality assurance organizational platforms to continue to support our contribution to the ophthalmology field and that's what we have been doing.

Now, let me look back at the 2014 to 2017 mid-term plan. In this plan, we were able to have very good business expansion. MSD products were acquired, and we had an active implementation of new product launches. In Asia and EMEA, we were able to have good growth and profit contribution. On the other hand, in the US and other markets where we have not entered, we were able to prepare ourselves for business development in new market including product development.

For actual results, we were able to achieve more than 200 billion yen in sales. Our original idea was for this to be achieved in 2020. We were able to achieve the goal three years ahead of the plan. Our geographical footprint also expanded. We are now covering 64 regions / countries, and overseas sales achieved about 30% and we were able to achieve good result in globalization. Also, to support that, we were able to develop and enrich our pipeline – also an important achievement.
This is looking at the financials. This is for domestic business here in Japan. As for domestic business in the Japanese pharmaceutical business, we had Eylea, Alesion, Diquas; new products that were introduced into the market and they saw significant growth and exceeding our plans. As for the Japanese OTC business, we saw growth far exceeding our plan and this is because of contributions from inbound sales and we saw unit price growth as well.

As for Asia and EMEA, we saw sales far exceeding our plan. As I mentioned earlier, we achieved overseas sales ratio of 30%.

We were able to see strong revenue in fiscal year 2017 reaching 224.9 billion yen.

This is looking at the profit. As for the profit, we saw RA-exit in the middle of this period and it was adjusted for in MTP2017 and we were able to see that the profit was in line with our plan. Further, we were able to see expansion of our business to more than 60 regions / countries.

We were able to enhance our organization globally, and we were able to advance our product supply structure as well. We were able to strengthen the organizational structure here in Japan and overseas as well. We have about 4,000 employees at the moment and half of them are overseas employees. We can say that we advanced towards becoming a global company during the past four years.
Now, I’d like to talk about MTP2020 which will cover the period from 2018 to 2020; the last three years of Vision 2020. I would like to explain the measures we need to take and what we want to achieve.

First of all, I want to talk about Santen’s external environment. We focus on ophthalmology. The eye is a sensory organ which is very important to us as human beings. 80% of information comes through the eye; reading, recognizing images is done by eyes. Eyes are very important when we express our nonverbal communication as well, therefore vision plays a very important role – even thought to influence taste as well.

For example, I once participated in an experiment while overseas in which he had dinner in a nearly completely dark room. Without vision, even experts were not able to distinguish between red and white wine. This example reminds us of the importance of information we gain through our eyes.

Therefore, eye diseases can have a serious impact QOL. In the world, one out of every 30 people has impaired vision, and this brings hardships socially and economically as well. Especially in developing nations, this is a very serious social issue.
As the information society advances, the burden on our eyes is increasing and so are the needs to treat eye diseases, even in advanced nations. Santen understands deeply the needs of eyes, and by providing appropriate treatments and solutions with new technologies, we can further grow our company.

This is the MTP2020 fundamental policy and three key strategies. As I mentioned earlier, this is the last three year of Vision 2020, the fundamental policy is to become a specialized pharmaceutical company with a global presence and to construct a path for sustainable growth beyond fiscal year 2020.

To realize this, we must achieve three strategic goals: increase customer satisfaction that is very important KPI's for Santen, increased profitability, and increase organizational strength.

In order to realize these strategies, we have three key strategies. First, to grow faster than the market through progress in global business strategy; two, enhance the product pipeline and develop new treatment options; and three raise strength/efficiency of business framework and boost human resource and organizational capabilities. We hope we will be able to continuing to contribute to treatments worldwide by pursuing those strategies.
Next, I’d like to speak about the global business strategy for MTP2020. This can be divided into two areas. First, in the existing regions where we have entered up to 2017, they are Japan, Asia and EMEA. Of course, we will work on individual markets and furthermore, we can achieve highest growth in Asia. To realize this, we will use the strengths that we have gathered through the Japan and EMEA business, so that we will be able to put all these know-hows and skills into the Asian market. The other category is US and we will prepare for entry into the US going forward.

Santen has overwhelming strength in Japan. Of course, this is seen in sales and marketing as well. We have around 130 years of experience here in Japan. In addition, we are raising our presence in Europe. Europe has influence in global academia, global standards and also on regulatory authorities and policies in the world. Therefore, those presence and organizational abilities will be transferred to the Asian regions where high growth can be expected so that we will be able to capture the growth opportunities in these areas.

To give you an example, Ikervis eye drops which are on sale in Europe are now being developed in Asian countries with sales and marketing activities already begun in some countries. As a result of the work we have done in registering the products, gaining reimbursement and collaborating with European members and KOLs, I think we’ll be able to develop this product in Asia in a very efficient and expedited manner.

Of course, with the global supply chain building, we will have rich experiences from global business personnel who will play a central role in our business development in Asia. Of course, we have detailed know-how of sales activities here in Japan, and we have plants in Noto and Shiga. Production and quality assurance abilities are established in these areas which can be transferred to Asia. For example, our expertise from Japan is being leveraged in gaining GMP at our plant in Suzhou, China as well as work on our joint venture project in Chongqing. Experts with such backgrounds play an important role in these and other areas as well.

We identify and enhance the skills of our group in order to boost our activities going forward so that we’ll be able to realize growth which that exceeds the market.

Next, I will explain each individual market. First of all, I would like to cover our Japan business. We have the strategy and direction so far and that will be further evolved going forward.
We want to be a total solution provider in ophthalmology. Of course, NHI pricing will be impacting our sales and profit. However, at Santen, Japan is a big market and Santen’s strengths are very advanced and can be further enhanced here in our home ground. Utilizing these strengths, it's not only selling individual products, but we can provide good product information or therapy area information. We can provide valuable information that covers not only Rx, but also OTC, supplements and even plus surgical tools/devices as total solutions.

We can provide a more direct approach and including information provision to patients. We are the leader here and we can create and lead the Japanese market.

Also, in parallel, unique to Santen, we have strengths and activities that also include product container development / improvement. We can also provide information via web channels, not only via medical representatives. We can incorporate detailed needs in the ophthalmic area, that will enhance our sales and profit platform.

This is just one example, our glaucoma treatment continuation program that started full scale last year. As you know, glaucoma starts around in the 40s or 50s in one’s life, and once the disease develops, then you'll need to continue therapy, you'll need to control IOP (intraocular pressure), and you'll need to maintain a good level. At worst, you could go blind. However, nowadays because of advancement of diagnostics and therapy, if you take very good care, you can maintain your vision. Therefore, continuation of therapy is very important.
However, many patients do not perceive their symptoms because their damage to vision starts from peripheral areas. They have no pain or itchiness, and if that patient is in the working population, they sometimes forget to apply their eye drops. This is an important issue, not only in Japan, but globally. The red line shows the example in Japan. You visit the clinic once a month but after one year, adherence drops to 50% and the other 50% don’t even go to doctors any longer. Even though Japanese are thought to be very diligent with compliance and adherence, we still lose many patients.

Santen tries to address this issue together with ophthalmologists. We have our treatment continuation program package. We already cover 1,500 medical institutions. This pilot study demonstrated, after one year, 90% of the patients continued with therapy. If this continues 10 years, 20 years, that can make a huge difference in QOL. In addition to product groups, we can provide such solutions to patients unique to Santen. We want to evolve these kinds of programs further.

![Global Business Strategy: Overseas 1](image)

The next topic is our overseas business. China is our biggest overseas market now. Santen has has been building nationwide coverage in China, and we provide products, and our supply chain is being built from China and Japan. Naturally, we want to participate in the growth of China. Tapros and Diquas, those new products are also being approved and are penetrating in to the market. For each province, we expect to go through various procedures for reimbursement and tendering process for further penetration.

As for growth going forward, we need to increase our market coverage and also improve customer satisfaction – this is key.

Since 2008, we have had a direct sales system. We started from coastal areas in major cities and we built a sales network. Now, we are expanding our coverage by moving inland. As for hospital sizes, we first started with large hospitals - the so called level three hospitals. But now we are expanding to secondary and primary hospitals where there are more hospitals nationwide. We want to go deeper and broader as we have the Chongqing joined venture. Through this joint venture, we will be able to provide products so that we can cover more areas in the market. We want to realize high growth in this huge market with a population of 1.3 billion.
In Asian countries outside China, we also expect high growth. Southeast Asia has a very large population and high potential, so it is also very important for us as a mid to long-term growth driver. We will build our platform further and new launches should be aggressively pursued.

The Indian market also has high potential with a large population. Though we haven’t yet, we are now preparing ourselves for market entry. During this mid-term period, we hope to move to the next stage with a specific plan.

For the EMEA market, although the market growth maybe a bit lower than Asia, it’s higher than the Japanese market. In terms of the size of the market, it’s the second largest market in the world after the US. Beyond Western Europe, EMEA includes Russia, Turkey, and also the Middle East. It’s a very attractive market where we can expect good growth. We already have an existing business base with which we can gain good penetration of new products. We should increase market share while at the same time improve sales and profits. And as I mentioned in the beginning, EMEA’s strengths should be also rolled out to other regions in the world.

Next is the US. We need to prepare ourselves for the next stage after MTP2020. We are fully aware that this is a very competitive market, but also a huge market comprising about 50% of the global market. In terms of the life-sciences sector, innovation is led by the US. So, we want
to build our presence in this market for the long term. On the other hand, we need to have a good profit base; that is our first priority.

As you know, our DE-109 uveitis treatment, received a CRL at the end of last year. We are negotiating with regulators and we are preparing ourselves for an additional clinical trial. Launch timing could be a bit far from now, but today only steroids are available for uveitis, and patients suffer from adverse side effects and we believe 109 will fill an unmet medical need. Therefore, we want to make sure that we can bring this treatment to the market to contribute to the patients.

I will later explain more details about DE-117 and DE-128 MicroShunt for glaucoma. Those two products should be further developed as differentiated products in glaucoma area, and in the U.S. in particular. We want to launch and we want to achieve profitability in the shortest time possible.

Now, I would like to cover two new treatment options under development. The first is DE-117, a first-in-class glaucoma treatment. In Japan, we plan to launch this product later this year. We are now preparing for a P3 clinical trial in the US. In other Asian countries, we will prepare after the launch in Japan.
This EP2 receptor agonist acts through two outflow pathways: the uveoscleral and trabecular outflow pathways. Through these two pathways, you can expect a good IOP lowering effect. Prostaglandin analogues act as an FP receptor agonist but have some side effects. That can include abnormal eyelash changes, eyelid pigmentation or iris discoloration. But with DE-117, those side effects are not observed. This is going to be a big differentiating point.

The other pipeline I want to discuss is the DE-128 MicroShunt. This is made with a material called SIBS, which is already used in cardiac stents. It is well established as a great material that is stable and bioinert. The device is 8.5 millimeters in length and it’s a small tube. This is inserted into the eye from outside. Directly through the tube, aqueous fluid will outflow and you can lower IOP directly for longer time. Trabeculectomy itself is the way to deal with this disease after medicines, but DE-128 can be a replacement to the trabeculectomy procedure. The study we are conducting includes a comparison with trabeculectomy. We have already obtained the CE mark in Europe. We have launched this product in some limited hospitals as a controlled launch – an example is the very famous hospital in the UK, Moorfield Hospital. We have had good results already.

We are preparing development plans in Japan and Asia.

We will further advance development of such value-added products with differentiating points. Through providing products globally, we will grow our business and we will make further contribution in the ophthalmic area.

Along with the development of new products, there are other unique Santen activities as a company specialized in ophthalmology.

First is the development and improvement of product containers / bottles. Eye drops are used every day, sometimes once a day or sometimes four times a day. Therefore, convenience of use including ease of cap removal and ease of applying eye drops are very important, and can have an impact on compliance. Some patients use several medicines. In particular, many glaucoma patients use two or three agents, and therefore identification of each product is very important. Santen continues to improve ease of use, labeling and bottles so that we can best answer the needs of patients.

Eye drops are used repeatedly. Preservatives are used to prevent secondary containment. Sometimes there is contact with the eyelash and then bacteria can grow. Therefore, there are
preservatives to prevent that. However, some patients suffer from irritation, especially patients with dry eye who do not have sufficient tear production making them more sensitive to agents. On the other hand, single-use containers without preservatives are sometimes not easy to open and/or get proper installation, especially for elderly patients. We have PFMD, Preservative Free Multiple Dose. With PFMD, we are able to have this special container to address those needs of the patients.

Our third strategy is to make reinforcements and efficiency improvements to our business foundation for global sustainable growth. Of course, in the area of costs, we are implementing thorough efforts to optimize costs globally. We will not only reduce cost, but for globalization, we need to create an efficient organization and do business in an efficient way. We are working to achieve wide-ranging efficiencies.

As for global product supply, we are strengthening our structure. Manufacturing technology of products made in Europe or made externally is being transferred to our existing plants in Japan and China. We will be able to reduce cost and also strengthen our supply chain system. Of course, we are transforming our global supply chain so that we'll be able to accelerate business expansion. As for human resources, we need to advance our global skills so we will work on personnel who will play a role for growth in the next 10 years.
As I mentioned earlier, we have our Santen’s Values and Mission Statement. We are making a social contribution through our efforts in the ophthalmology area. We need to really understand the needs of society to produce goods which will best contribute to society. We believe this is the core of our CSR activities which will lead to improved QOL worldwide by providing products and services. Regarding the eye, we will contribute to the QOL of the patients directly and also we will be able to improve medical standards all over the world through collaborations with doctor groups and academia.

For example, we have provided educational sessions to young doctors in China, to improve the medical care. Glaucoma and AMD awareness activities et cetera are part of the CSR activities that we provide. And as a member of the global society, we will conduct responsible business expansion from the perspective of ESG.

Of course we are considering and you must be interested in our growth beyond fiscal 2020. We will build a long term vision and strategy for next stage in the current medium-term management plan. We have just started discussing what kind of strategies we need to take in order to realize the next phase of long-term growth.

We can say that we will always focus on ophthalmology and that this will not change. We would like to achieve growth as an ophthalmology company. However, having said that, in the next 10 years we can expect many changes to happen in society. Technological innovation will take place and we will see a number of disruptive innovations going forward. Even in the life science area, we will see many changes and transformation. Market wise, of course, growth in Asia is going to continue and it could even be perceived as economic center of the world in the future.

Social, technical, and economical changes need to be accurately grasped so that we can achieve transformation and innovation as an ophthalmology company. We will discuss this further, and with excitement, come up with a detailed strategy going forward.
Next, I'd like to talk about healthy growth and financial performance; the financial targets for MTP2020. We would like to continue to see growth in each region which exceeds the market.

We believe Asia and EMEA will pull those growths and we are looking at overall revenue growth of more than 6%. Of course, in order to realize that, we will continue with investments in our business and R&D.

Profit wise, core operating ratio will be maintained at more than 21%. ROE will be 11% or more. For Vision 2020, and for sustainable growth, we will actively work on investments into growth and to realize profit.

Next, I'd like to talk about capital policy. Of course, we will be proactive in making investments in growth. We will enhance our pipeline and accelerate the development of our business globally as foundations for future growth. Also, we need to make investments so that we can become a more globalized company and capital investments will be made to support future growth.

Investments will be made into plants, facilities, etc., so that we'll be able to raise capacity and enhance our foundation for growth. That will be conducted over the next few years. As for the strengthening of our global management framework, we will look at global revisions and enhancements so that will be able to improve capital efficiency and to enhance our cash
generation ability as well. We will continue to conduct stable and sustainable dividends going forward.

![Toward Realization of Vision 2020](image)

I have been talking about MTP2020. This slide lists some of the numeric targets to achieve by 2020. In 2010, we were active in only 35 regions and countries, but for 2020 we'll be active in more than 70 regions and countries. We'll accelerate global development and overseas sales ratio will increase to 36% in 2020, and the production number of bottles will increase to 460 million.

MTP2020 will let us realize Vision 2020 to become specialized pharmaceutical company with a global presence. All nearly 4,000 employees of Santen must work together to propel our business development and contribute to ophthalmology globally. That concludes my presentation. Thank you very much for your attention.

Q&A session (summary)

<Q1-1>: For domestic sales targets, assumptions and your outlook going forward is 2.5% or higher growth. What are your assumptions? And beyond NHI price cut, are you able to grow prescription business or OTC supplement business? What would be the growth driver going forward? And beyond 2020 you will have plans, but in terms of sustainable growth in Japan, what is your stance or policy, and what's your outlook?

<A1-1> COO Taniuchi: For the domestic business, as you mentioned in our prescription business, the NHI price cut is already incorporated in the plan, but we have new products and share will grow and that is also incorporated in the plan. OTC and supplements; we are looking at Hyalein as an OTC switch product in the future, for example. So, as a total, we expect growth in Japan. The sustainable growth beyond 2020; of course, the NHI price cut and Japanese economic situation will impact our business, but Japan's market is very important for us. Even when the market is not growing, we will continue to explore needs, and having a
population of 130 million, there are patients suffering from eye disease and we want to support them.

<Q1-2> Beyond 2020 the domestic business, you expect, will also grow or some room for growth. Is that what you’re saying?

<A1-2> COO Taniuchi: Yes. Although the growth rate would be a bit lower, which can’t be helped, we want to pursue growth.

<Q1-3> You mentioned European growth of 10% or higher. By product some are mature, but in that background, how do you achieve 10% or higher growth? Is share expansion your strategy, or you want to cover more markets or new products? What would be the driver for growth in Europe?

<A1-3> COO Taniuchi: Basically, we want to expand share and we want to increase the markets we cover and, of course, new products, so all that you mentioned. Our share is relatively low in some countries and there is opportunity to grow. Our share in Japan is 47%, so there’s not much room to grow here, but in Europe, we have many countries where we can grow share substantially. Our glaucoma products are the biggest sales. Of course, there will continue to be some pricing pressure, but we want to offset that with new products. For Ikervis, for example, we have covered the major countries, but we will be able to launch in other countries and so we will further increase the number of the markets where it is available.

<Q1-4> About the ROE 11% or higher; how do you realize that? ROE 11%, when you look at revenue and operating profit in the last year of the mid-term plan you will be able to achieve 11%, but for this year the plan is 10%. So, 11% on average sounds very high for you to achieve. What are strategies to achieve that?

<A1-4> CFO Koshiji: 11% or higher, when you look recent results, it’s not so high. Perhaps it seems high to you when you think about the operating environment. Our operating profit includes some financial expenses such as tax for which we assume a rate of 26%, that’s a rather conservative consolidated tax assumption, and considering all the factors, this is the number we came up with. But, ROE as you know, is a hybrid indicator, it also fluctuates on securities owned and assets in foreign currencies. There could be some fluctuations, but our assumption is flat for those factors. As for shareholder return and dividends, our assumptions in calculating an ROE of 11% includes payment of dividends of 26 yen per share.

Based on those assumptions, we came up with 11%, but in terms of that profitability, payout ratio, current mid 30% to 40%, could be lower to mid-20%. For example, if the dividend was increased to 30 yen from 26 yen, then theoretically ROE will improve 0.5%. Again, hypothetically, an increase in the dividend to 34 yen, would improve ROE by 1%. So, in our ROE calculation, we are conservative about the both the tax rate in R and the level of equity E.

<Q2-1> About shareholder return; the payout ratio had been given as a numerical target, but this time it was not mentioned; can you tell the reason why? With the explanation, you said that you’re looking at a flat return, but if cases permit you may increase it. What are the situations for you to increase returns to shareholders? Can you share your perspective, please?
<A2-1> CFO Koshiji: Yes, on page 27 you can see that these are the levels of growth that we are forecasting to 2020. We continue to prioritize investment for future growth. From this perspective, a specific numerical target of 40% has been removed. It is not as if we’re pessimistic, we are still looking for stable and sustainable shareholders return going forward as well.

<A2-1> COO Taniuchi: Looking at results in the past and expectations going forward, there have been and will continue to be business development deals that have different impacts on our short-run vs long-run profit. If we stick to a specific payout ratio, our dividend level would be volatile and seem unstable. So, rather than focus on a specific percentage of payout, we are focused on providing stable and sustainable dividends.

<Q2-2> About the US strategy - on page 20, you said that a flexible strategy will be taken in the scenario that you have drawn up. What are the options that you are looking at for business development? What are the ideas that you may have? You talked about flexible and agile strategy, what are the reasons you need to take such a strategy going forward?

<A2-2> COO Taniuchi: In the USA, we don’t have a foundation for sales or marketing. DE-128 MicroShunt and DE-117 are products we will be using to enter the USA market. DE-128 will target glaucoma surgeons which is a very small, targeted group of physicians who we can strategically approach. DE-117 is a glaucoma area with a wider targeted group of physicians, including optometrists. We need to strategize what will be our approach there. We’ll be entering the market with DE-117 and DE-128. We will take an agile strategy with priority given to profit contribution in the US market. In order to realize this, we need to consider carefully from several options. We will compare opportunities, so we’ll be able to realize the best commercialization strategy. That is why we call this an agile, flexible strategy.

<Q2-3> You’re still pre-approval, but are you considering a commercialization strategy using licensing-out?

<A2-3> COO Taniuchi: Well, of course we’re now just trying to increase the number of options available to us, but we are considering licensing as you mentioned - we’re focusing on achieving profitability. We want to enter the US market based on concrete path going forward. What nature of the resources we’ll use in the US will be considered so that we’ll can have a clear path to profit.

<Q2-4> You talked about DE-117 and DE-128 as new treatment options and you’ll be focusing on them in the next three years. Such products, I understand, but what about new pipeline beyond these? In the presentation you didn’t talk much about future products or pipeline. Can you talk about the pipeline going forward? Will you be creating a foundation for further development so that you’d be able to come up with successful products going forward, and how much of a focus or effort would you be making in these projects going forward?

<A2-4> COO Taniuchi: As for the pipeline going forward, I think it is the same with other companies, but we must continue to enhance our pipeline with a hungry spirit to further strengthen our pipeline going forward. We will collaborate with other companies so that we will be able to achieve this going forward.
DE-127, for myopia, is one example. Here, we are working with the Singapore Eye Research Institute. We'll be using such networks from academia and other networks overseas so that we'd be able to propel our development going forward. Of course, we also have other projects here in Japan as well, working with Japanese academia so that we hope that we'll be able to boost our successes.

Basically, eye drops are made from the dilution of systemic medicine compounds into a solution, we will also focus on that and we will work with other pharmaceutical companies as well. In addition, we want to increase the type of approach we are taking with DE-127 elsewhere going forward. As I mentioned during the presentation, we will not just work on compounds, but we need to develop products which will meet the needs of each region, that is very important. As for PFMD, I think there is a huge need in Europe, so I think changes in formulation, changes in bottles, will help generate more growth. Investing in these areas and enhancing our business foundation – this is what we want to continue to do going forward.

<Q3-1> Probably I'm repeating other questions, but Japanese sales growth of 2.5% sales - I wanted to ask more about this. It seems you have made assumptions regarding Eylea and DE-117. Can you tell us how you see potential competition for a Lucentis biosimilar, or is this not much of a concern? Lucentis is produced in E. coli and it's very profitable, so many players are interested to enter this business, so Eylea could see pressure. RTH258 may not be so much pressured, but they're quite similar. Modeling will give lower sales in Eylea. DE-117 is still a very modest impact, it's not available yet, but probably you have numbers, but do you have probability of success and outlook incorporated for DE-117?

<A3-1> COO Taniuchi: For Eylea to 2020, the current trend will continue, that is our assumption. As you mentioned, going forward, biosimilars or new products may come, but up to 2020 the current trend will continue. 55 billion yen in sales that would be more or less maintained, and of course additional indication and also with coverage of new markets that trend will continue, that is our assumption.

For DE-117, you may think this is conservative, we need to work on and assess market acceptance of such glaucoma products. Once it's in our market, we will see how it's assessed on the market as we talk with doctors - whether it's easier to use comparisons with other products and so forth. We hope to grow our sales further. You may think this is a conservative estimate, but we want to make sure that the drug is used for the long-term so we want to have a careful launch with very good data. We will work together with specialists in glaucoma, so that this product can be best used in creating maximum value.

<Q3-1-2> What would be the trigger to switch from conservative to less conservative?

<A3-1-2> COO Taniuchi: Safety and IOP lowering. For clinical studies, it is done in restricted conditions and with a number of selected patients. From clinical trials, we can say FP non-responders may benefit from DE-117, and that is a unique aspect, it's real-world evidence that will show how much this product supports non-responders and how effective it is. Also, for safety you need to see how it actual performs in the Japanese market. Clinical trial data alone is not enough, post marketing surveillance or data generation in post-marketing will give us the assessment we need to either stay conservative or become less conservative.
<Q3-2> Page 28, production number 310 million units or bottles. I think you are now producing Merck products for the Japanese market internally, and for the EU market, are you going to switch? And in that case, you have better profitability and what would be the improvement?

<A3-2> COO Taniuchi: Legacy MSD products are mainly made in a plant in France and some from the US CMO. They are for Europe and Asia. For the Japanese products, we produce in Japan. The products made in the French plant may be changed to the Japan plant and when that is realized, the cost will be lower and also better container can be provided. It’s our assumption that the products made in the US will continued to be made there.

<Q3-2-2> That is incorporated into this plan - a manufacturing shift from the French plant to the Japan plant?

<A3-2-2>Taniuchi: Yes, that is incorporated.

<Q3-3> Regarding the direction of development, I have a question. MicroShunt is not available in the mid-term plan, but beyond 2020 it will come; then not only prescriptions but also you are going to have more revenue from devices. Stent related devices can be your option, but what is your thinking? Maybe you focus more on prescription or maybe you focus more on devices because there will be no generics. What is your feeling about this either from COO of CEO?

<A3-3> COO Taniuchi: First, MicroShunt should be launched and that is our first focus. In Europe there have been a very limited, controlled launch, but Santen is a pharmaceutical manufacturer and within Santen, we need more capacity regarding product supply, regulations and so forth about devices. There are challenges. We sell some intraocular lenses, but that's not a global business yet and we are aware of the challenges that would be faced. If we are going to develop globally, we need to strengthen our organizational capability to address that, but of course, we need to build infrastructure and options. We hope to have very positive developments on that, but first, we want to focus on MicroShunt.

<Q4-1> Looking at your balance sheet, you have a large total of financial assets. For the medium-term management plan, how will you use cash? You talked about investments into growth areas, and in the past Santen Oy, InnFocus and Novagali investments were made. Can you explain your strategy for investments in the future, please?

<A4-1> COO Taniuchi: Yes, of course, we have financial assets including cash as well as future cash flow. I think we will be able to make investments into growth areas going forward. In the past, we acquired MicroShunt and as it continues toward successes, we will need to make milestone payments, so this is one area for which we need to secure cash. Investments into plants and there are other plans for investment as well. The remaining cash, as you mentioned, we will invest in our product pipeline and also acquisitions. That is a proactive plan that we expect, going forward.

<A4-1-2> CFO Koshiji: From the perspective of investments, commitment line is not that big, but 30 billion was the line that was set for short-term efficient investments. It was written in the shareholders meeting invitation. We will be agile so that we'll be able to respond to business opportunities and development. We will have backup cash for those purposes, but as has been indicated, intangible assets are one-third of the balance sheet. For real assets and intangible assets, what is the right balance is something we need to think about. We have 60 billion of
MSD 2014 legacy product sitting. This is also bringing us cash inflow. I think we need to secure that cash-flow going forward. For depreciation and amortization going forward, I think intangible assets for those purposes; I think that it's very, very limited. I think we’re in a very healthy stage for such impairments. That is an additional comment that I wanted to make.

<Q4-2> The Governance Code in Japan has been enhanced recently. Will it change the securities and equities you hold?

<A4-2> CFO Koshiji: Basically, our principle is that we only hold stocks that are an essential part of our business activities. We have holdings in companies with which we have technology collaborations and others with logistics collaborations - we limit holdings to such companies. Depending on the situation of these companies, the prices and values fluctuate. At the end of March 2018 compared to the previous year, the balance of stock holdings was down.

<Q4-3> Page 18; you talked about entry into the market in India. When are you looking at entering the Indian market, and what is going to be the scale of your entry there?

<A4-3> COO Taniuchi: We have a small team in India already. They’re registering our products in India. These are existing Santen products. It is a small-scale sales or agency type of business that we are going to start in a very short time period of time, probably this year or next year. We hope that it’s going to be a starting point for a large-scale entry into India.

What kind of partnership we’re going to have with Indian companies, local companies, is something that we are planning at the moment. I hope you will give us a little more time for us to disclose this.

<Q4-3-2> I would like to know what is going to happen. Are you talking about OTC products?

<A4-3-2> COO Taniuchi: No, this is for prescription pharmaceutical products. This could include MicroShunt and other new products, but we’re still in the planning stage.

<Q4-4> About R&D investments - what is the level of R&D investments that you are planning at the moment? You are looking at 25 billion at the moment, will this be maintained or will this increase as sales increases?

<A4-4> COO Taniuchi: The basic idea is that we would like to remain or maintain the ratio of R&D investments at present. Depending on the timing and scale of programs, of course, it may fluctuate. For example, when DE-117 clinical studies begin, of course, there will be more investment. For DE-122, this is a retinal product, so this needs more investment. There may be fluctuations, but we’d like to maintain the level that we have at the moment.

<Q5-1> How will the FY2020 P&L look? In my mind, the ratio of R&D would not change very much. But with some improvement in operating margins, does that mean lower SG&A versus sales? Will you contain costs or do you think it’s going to grow against the sales? What's your forecast on that?
COO Taniuchi: In the 2014 to 2017 MTP, SG&A increased, that is true. There are several factors to explain that. Overseas product and business roll-outs increased. Expenses have been necessary especially in Europe and Asia. Then including the headquarters, we have been transforming ourselves into a global organization. We needed new organizations and systems to replace prior ones. This transformation is still going on, how will we be towards 2020? The overseas business is boosting business growth and the SG&A ratio will come down. I was in Europe before, the SG&A ratio is much lower than in the past. In the beginning, you need to build the platform including organization and people. You need to make initial investments to achieve sales revenue. The relative portion of costs was also lowered similarly in Asia. In Asia, compared to Europe, higher growth is possible. So, although there are some initial investments, the overall SG&A ratio goes down. The headquarters and corporate bases, are in the midst of transformation to optimize costs in a lean structure appropriate to a global organization, and we want to lower the ratio. While the value amount might gradually increase, the ratio would be improve going forward.

On page 26 margin improvement is expected from 20% to 21%, or 1 percentage point higher, while R&D does not change very much. So, does that mean lower SG&A expenses will contribute to operating margin improvement?

COO Taniuchi: Cost saving are expected in COGS upon the internalization of manufacturing after the product manufacturing tech transfer.

About capex, in the three years of MTP, how much are you going to increase capex? I think it's about 7 billion yen now, over this three year period, should we expect capex to reach 30 billion?

CFO Koshiji: The current annual level is 7 billion yen, and capex is expected be flat for the next three years. As the COO mentioned, the production of MSD products is being internalized but this number will be lower in future. Also, capex investments in IT / ERP renewal could be a one-time event. In terms of projections of our capex levels on a recurring basis, our expectation is that the level will be almost flat or slightly lower.

Global glaucoma market share, you gave around 7% in the past. Now, I think it is about 8%, when we do a back calculation. By 2020, will you increase from 8% or decrease from 8%. The US glaucoma market is about 20% of the global market, will the market share increase or the profit increase because I don't think it will increase much? Can I have your perspective?

COO Taniuchi: Before 2020, as you said, we don't plan a product launch in the US market. MicroShunt is a device, not a medicine, so it's a bit different. As for DE-117, we expect contributions from Japan, Asia and Europe. On the other hand, Cosopt may face a price reduction, so growth seems challenging. I think that is a trend that we can expect going forward. We understand market share to be around 6.7% now. So, there is a possible reduction in Cosopt and glaucoma markets are very hard to foresee. Also, we are seeing expansion of generic products. So, with such uncertainty about both the numerator and denominator, market share is hard to estimate. While we monitor and have goals for market share, we need to focus most on our products which will then lead to increases in share.
You have Eylea in Japan and anti-VEGF DE-122 in the pipeline. I'd like to ask a question about your view on these, especially after 2020. Will DE-122 be sold in the USA and what are the opportunities for growth after 2020? What you are going to do the next three year MTP202 for future growth?

COO Taniuchi: The VEGF market is growing strongly and the largest market with many companies focused on it. But there are different issues that must be considered for the future. Of course, we are working on DE-122 at the moment. Today, we didn't mention DE-122 simply because there is no updated information to offer. In this area, we will look at trends as well as the progress in clinical studies so that we can make a careful, well-considered plan.

For beyond 2020, of course, there will be major events that will take place. What will happen with MicroShunt as well as the development progress of products related to the back of eye, like DE-122 and DE-109. I think that is something that we need to think about. With those products, we want to enter the U.S. and a detailed strategy needs to be drawn out. Trends in emerging markets will also be important beyond 2020. So, within MTP2020 longer term numerical impacts and targets are not ready to be disclosed to you today, but we will work diligently towards that goal. As our plans come together, we'll make sure that we will share that information, including our goals and vision going forward. Such communications will come later.

DE-128. The trial of one year data will soon be completed. According to the guidance, you need to have the two years of data - and what's your assessment as to whether the data will come this year or the next year. What's the situation?

COO Taniuchi: Well, our scientific officer Dr Shams is not here today, so I can't give you details, but in the end, both one-year and two-year data will be shown – it’s a matter of time. We are just discussing the plan. As of now, we can't tell you which. Of course, we hoping that data can be shown sooner rather than later and we're discussing the best approach.

On page 22, you show preservative-free multi-dose (PFMD) in the EU as part of market share expansion. This kind of improvement can be very effective. Are you going to use the Japanese bottle in Europe or are you going to develop anything new? How will you go about this?

COO Taniuchi: Regarding preservatives, regulations are different in the US, Europe and Japan. For Europe, we have a dedicated container available for the region. We have preservative-free containers that are dedicated to Europe and to Asia. Our dimple bottle, which is a very good container, can't be used as a preservative free bottle. For Japan, we use dimple bottles, but for Europe, we have a dedicated PFMD bottle – it is a different container.