Speaker Remarks February 26, 2018 (summary)

Japan and Asia Business Update

I’m Kurokawa from Santen Pharmaceuticals. Thank you very much for joining us for this Japan and Asia Business Update.

Santen’s Values

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.

These are Santen’s values. I am sure you know this already very well. Based on Santen’s values shown here, we create business strategies and make progress toward our goals. We focus on ophthalmology. We contribute to diagnosis and treatment in ophthalmology. We are absolutely always patient-oriented.

Progress of Santen under Vision 2020

Under Vision 2020, we have our mid-term plan, which ends in March 2018. So, FY17 is the last year in the mid-term plan and we have been making steady progress towards our goals including steady growth. As you can see, in terms of revenue, we grew 11.2% annually, and in terms of profit as shown here, growth of nearly 10% has been achieved. I’m sure you know this already, but this process, has included epoch making development of our business including M&A.

First, we acquired the ophthalmology products of MSD. For Santen’s global business development, this was a significant development. Then, the transfer of anti-rheumatic business outside Santen allowed us to have a complete focus on ophthalmology. Going forward, we want to ensure our competitive strength as a global
player in ophthalmology. That became very clear after our quite effective transfer of our anti-RA business. Then last year, we acquired InnFocus. Ophthalmology is not just eye drops. We cover also devices and that was clear with this project. We are a company that provides solutions.

Going forward, it is essential that Santen achieves sustainable growth, especially in terms of contribution in ophthalmology. We need to achieve our vision and we need to make sure we execute our plan leading to sustainable growth across ophthalmology. There is so much potential in our field. With societies aging globally, the number of people with ophthalmic problems is increasing, so demand is strong. However, by each geographical and therapeutic area, there are special situations that need to be considered such as pricing in Japan, for example.

In Japan, as you know, a new round of NHI pricing reform becomes effective on April 1st. Further, we see the market as relatively mature. We look at the business with an understanding of these conditions. Going forward, we should not depend only on the domestic business. We need to accelerate sales and profit growth in overseas business. That is imperative for us. So, we want to be number 1 in Japan and Asia and we want to have a higher sales ratio coming from overseas. Through those activities, we want to make further contribution in ophthalmology. So, this has been my introduction – now I’d like to turn to the Japan business specifically, with an update from Ito.

I am Ito, in charge of the Japan business.
Now, you are looking at the revenue size and breakdown by category in FY2016. This is the Japan business. And as you know, the prescription pharmaceuticals actually make up nearly 90% of revenue in Japan. And quite naturally, you are very interested in the fact that, as mentioned by Kurokawa, there will be a revision of the NHI pricing system. That is a very challenging situation for us and you and I’m sure you want to know how we are going to cope with it. I would like to now explain to you what we are actually doing - focusing on the activities in each business unit.

1. Our Direction Forward in the Prescription Pharmaceutical Business

Let me begin with the prescription pharmaceutical business. The challenging situation caused by the latest NHI price revision had been expected already for a couple of years. With that understanding, we have conducted several initiatives in recent years. And, as shown on the left on the slide, if the market will not grow, then we still have actions to take to expand market share further. In the middle chart, while there are strong headwinds to further growth, we are working on ways to expand the market itself. Thirdly, we can also exploit our significant strengths. Compared to competitors, we have very strong relationships with almost all ophthalmologists in Japan. This gives us the opportunity to expand and develop new markets such as non-prescription markets.

Now, let me begin with market share. I think you are very familiar with these numbers. The left side chart shows the revenue transition in prescription pharmaceuticals and on the right you will find our market share.
trend in the prescription ophthalmic market. Revenue as well as the composition ratio of our main products has grown rapidly. And, we believe in FY17, we will exceed 46% in terms of market share.

1. Our Direction Forward in the Prescription Pharmaceutical Business

1) Raise market share

Eylea Revenue & Market share (Anti-VEGF market)

Alesion Revenue & Market share (Anti-Allergy market)

The left-side graph shows Eylea launched in 2012, and on the right there is Alesion, an anti-allergy treatment launched in 2013. These charts show the revenue and the market share for both products. And at a glance, you understand that, of course, each individual product has its own potential. We create strategies to make the products most usable and helpful to patients. Over the past few years we have rapidly strengthened the collective power of our organization. Our R&D is now developing new products. And, we are now capable of reaching the full product potential increasingly quickly after launch. Apart from this, even though that’s not included in this slide, two years ago we established Santen Eye Care Company, a company for generics. So, we will be ready to launch generic product when the timing is right.

Secondly, I would like to talk about market expansion. Obviously, we would like to provide appropriate treatments to the patients who need such treatment. However, there is a problem that many patients drop out before their treatment course is complete. As shown in the chart, we would like to provide benefits to patients. By doing so, we would like to help the medical personnel. And ultimately, this would be a “win” for Santen as well. We would like to show you some good examples of this.
This graph shows the treatment continuation retention of glaucoma patients. Horizontally, we put the times of medical examination and vertically plotted retention percentage. It is well known that about one half year after the diagnosis, about 50% of patients drop out. The red curve shows the experiences in the past. After the sixth or seventh visit to the clinical hospital, about 50% of patients drop out of their treatment regimen. This is also related to the properties of the disease. The patients do not have lots of subjective symptoms and the disease progress is very slow.

We thought about a method to improve the retention ratio. Communication between the medical providers or ophthalmologists, and the patients can be improved through a system and associated tools. We developed such a program beginning with a pilot program at about 20 institutions in Japan. The red curve shows the situation before the introduction of the program and the blue curve shows the situation after. More than 90% of the patients continue to be treated. This is only an example. By expanding this kind of program widely to institutions, we believe the market is expanding appropriately. We have launched ACT Pack, meaning “aiming for continuous treatment package” last year and currently about 1500 institutions are using the package.

We can also generate new markets in areas in our specialty area. On the left slide, you see the photo of a supplement Sante Lutax that was launched nine years ago. This product is a nutritional therapy for those patients who are diagnosed with age related macular degeneration by their ophthalmologist. Last year we
launched a new supplement. This is the supplement supporting nutritional management for glaucoma patients. Currently, we have two supplements available. But in addition to these, we are developing the supplement to be recommended by ophthalmologists. Since they are supplements, anybody could be able to imitate it. But, we always develop a product based on evidence. Also, we would like to defend ourselves with patent filings on such products. Through such a scheme we would like to launch more products. But, of course, in addition to these, we are also involved in many other projects, which I do not mention today.

2. Over-the-Counter Business (OTC)

And next, let us move on to the OTC business. Now you are looking at the revenue trend of the last seven years. Since FY15, there was a sharp revenue growth as you know. Some of our products are growing quite rapidly due to the inbound demand. The trend will continue for the coming few years. We would like to continue to capture such demand and expand further growth in FY18 and 19 in a continued manner.

In addition, in the past couple of years, we launched Sante Medical Series, which are premium priced with high added value. Judging from the environment, we would like to expand the knowledge, technology, know-how and assets built up in our prescription pharmaceutical business to benefit our OTC area. We have also mentioned our intention to begin so-called “switch OTC” activities, that is, bringing pharma products to OTC. In addition to that, we would like to further expand our activities in OTC area by leveraging upon our past experiences, knowledge and technologies, in order to grow our business.

3. Surgical Business
Lastly, I would like to touch on the surgical business. Currently, we are almost exclusively focused on the intraocular lens business under the brand name of *Eternity*. This product is very good with its very high quality acrylic material but this material is rather hard and rigid. Recently, however, the trend is a very small incision to insert the flexible lens. Therefore, we are having some challenges with this product. Of course, this lens is also very good to the segment of the patient who can enjoy the benefit of the material. However, in terms of the total market size, our competitive segment is quite small. We are now developing the lens with a new material and a very competitive optical design. In November of last year, we already filed the product with the authorities for approval in Japan. We believe that we can launch this product sometime in 2019. This enjoys a very unique optical design, which can become a game changer in the current intraocular lens market. It has great potential. As you can see in this graph, we would like to make the very rapid growth of the revenue through this. The surgical business unit is rather small in scale. We have a limited number of the sales resources. We have a very small coverage of the market. You might think like that we also have to expand the sales force and this might increase costs significantly once we launch such a new product. However, we will be supported strongly by the prescription pharmaceutical business unit including on the human resources side, so that we can expand the sales activities without increasing the cost.

In Conclusion

Santen will provide solutions that meet ophthalmology needs and will always continue to be a company that contributes to people's quality of vision.

So, we have the prescription pharmaceutical business, the OTC business and the surgical business. In the past, they have been discrete units with each one taking their own approaches to their customer segment. But from now on, we would like to cooperate with each other to generate new value and new markets. Therefore, we would like to focus on this cooperation to best respond to the expectations from society, including patients. With this, I would like to conclude my presentation of Japan Business. Thank you very much for your attention.

I, Kurokawa, will explain the Asia Business.
Our Vision 2020 is to be number one in prescription ophthalmic share in Japan and Asia, which are very important business areas for us. Asia is very critical for us to achieve our overseas sales ratio target of 40% to 50% of total sales.

5 Steps Toward the Achievement of Long-term Strategic Vision

1. Develop products that meet true customer needs swiftly
2. Transform domestic business for further growth
3. Accelerate business expansion in Asia and promote market entry in Western Europe/U.S.
4. Establish competitive global product supply and quality assurance systems
5. Strengthen talent and organizational capabilities to promote “Creation and Innovation”

There are five steps to realize Vision 2020 as shown here. Of these, accelerating our business expansion in Asia is very important. Asia’s population is big and growing, so the potential is so great. This is why we have been working hard in Asia for some time now.
We have the mid-term plan from FY2014 to FY2017. So, let’s look back at the Asia business from this point. Regarding sales growth, we were able to increase sales much higher than the market growth, as we had promised. Asian pharmaceutical business growth is about 10%, or a bit higher. In the case of Santen, we achieved 28% average growth. So, we were able to deliver very good growth.

The second point is our distributor model to be shifted to direct Santen sales. Especially since we acquired the MSD products, we have shifted more to Santen’s own sales across south-east Asia. Currently, we sell directly in about 10 countries including China, Korea and ASEAN with our own sales infrastructure. In that way, we are able to observe customer needs that could be reflected in services and in development. That was what we intended. Also, approach allows us faster management decision-making. Meanwhile, this approach allows us to learn directly what is happening in the field. This field knowledge improves our governance and strategy execution. So we believe Santen’s own sales structure is more preferable. Of course, there are risks associated with that but we believe the risks are manageable and outweighed by the benefits.

Enter BOP Market is the third point. BOP stands for the base of the economic pyramid. We want to reach this broad patient segment that is not only the hospital market but also the general physician market. As a measure to gain more broad coverage, we established a new company, a joint venture in Chongqing, China. We also want to cover essential drugs broadly and strengthen patient and physician mindshare. As you know, we’re providing over 50 ophthalmic products to doctors in Japan and we enjoy very high mind-share among doctors. Doctors always use a wide variety of Santen’s products including mydriatics, miotics and anesthetics. Santen’s brand equity is very strong. We have acquired strong trust and that is positive leverage to the next business opportunity. We want to duplicate this positive cycle in Asia.

Next, we are expanding our product portfolio. We were able to expand our glaucoma portfolio by acquiring the MSD products. As you know, those products including Cosopt and Trusopt are now promoted and sold by us. Those MSD products, in addition to Tafluprost developed in-house, are contributing to our expanding portfolio. When you think of the Asia business, then you might think of existing products like Cravit, Hyalein and so forth. In China, doctors need Flumetholon which has been on the market for 40 years. Those existing products are accepted still by ophthalmologists and that is contributing to higher profit. Having said that, going forward, we need to promote new products like Diquas and Ikervis. Those dry eye products should be further promoted so that patients can have more treatment options. The Singapore Eye Research Institute is our partner and we have a collaboration with them that is going very well. Candidates for myopia treatment and glaucoma DDS are being developed there. Those are not the type of products for only Asian markets,
but we can have a very strong collaboration with this partner physically close to us. That can also help us to expand our portfolio, an advantage from the management of this project.

We are also focused on entrance into new markets. We are considering market entry in India, Pakistan, Sri Lanka and Myanmar. Of these, India is a bit ahead in our plans. We want to further enter such markets with large populations and future growth.

Then, the strengthening of our business capability is the last point. We are upgrading the capabilities of our Suzhou Plant in China in order to improve manufacturing and product supply. There are many kinds of Santen products in Asia. And, we need produce in large quantities for China, Korea and elsewhere in Asia, but we need to make many items and variations for ASEAN countries. So, supply chain and manufacturing capabilities are very important. We have entered the OTC market in Singapore which has also developed into our regional HQ for Asia. In addition, we are enhancing the local understanding of Santen’s Values as well as promoting education including management training.

Aggressively Expanding Business
Subsidiaries or Representative Offices in 10 Countries / Areas

You can see subsidiaries or representative offices in Asia. Our development in the region has been very aggressive. Those in red are newly established: Shanghai, Singapore, Thai, Malaysia, Hong Kong, India and Vietnam, within the mid-term plan. In those countries and economies, we want to have good bases and offices from which to expand our business.

Started Santen Own Sales Model and Entered New Countries / Areas Partnering with Distributors
In various markets, we are selling products on our own. Also, we are expanding very strongly into new markets through distributor relationships. On the top of this chart, you find areas in which we sell our own products by Santen. Over the period, we have expanded our own sales from three countries/areas in FY14 to nine countries/areas in FY17. Some distributor relationships are still in place in FY17, but we may switch some of those to our direct sales model when the economics and governance have progressed to the necessary levels. So, in terms of business models, we are aiming to respond in customized ways based on the need and make quick decisions while having a high level of governance. Along with Asian business expansion, there are important governance considerations including pricing issues and regulatory change in each market. We need to get information more efficiently and faster, so that each office functions well including a solid direct sales infrastructure that can deal with changes quickly.

It’s not mentioned here but we have valuable relationships with academic societies and their ophthalmologist members in each country based on our marketing strategies. They are very much interested in education and training of the younger generation and we are also involved in that. And, we have supported the creation of guidelines for diagnosis and treatment in the areas of infection, glaucoma, and dry eye. For example, in terms of infection, we have Cravit and Tarivid. We provide those products and supported guideline creation for the early treatment of infection with US and Japanese physicians.

This shows the list of countries, therapeutic areas and the products we offer in which market. In each region, we cover glaucoma, dry eye, infection, and others.

As you know, our key products are listed here. China has Cravit and Hyalein. Korea has Cosopt, Diquas and Tapros. Revenue from Cravit (in China) is more than ¥7 billion and grows by double-digits. Hyalein (in China) is about ¥5 billion and also enjoys double-digit growth. Cosopt, Diquas and Tapros are growing very significantly, and they are ¥1 or ¥2 billion products. Focusing on those main products, we want to further advance our strategy in each market.
We describe Asia in one word, we continue our aggressive investment as we try to stabilize the business platform so that sales can be expanded. We have been able to outgrow market growth through the years including FY17. We were able to achieve average annual growth of 28% in sales and 60% in profit.

So, sales contribution of our Asian business is increasing. Santen as a whole is enjoying 11.3% but Asia growth is 28%, as I said. So, in Santen group’s entire sales in FY17 of about ¥224 billion, ¥30 billion comes from Asia. And the sales proportion of the Asia business has increased from 8% in FY13 to comprising 14% of our sales in FY17.
Let me now discuss our Asia business strategy going forward. Asia, as you know, enjoys good population growth. Additionally, the population over 40 years old is significant and increasing. On the left, you can see the proportion in Asia. The gray colored area shows how the over 40 year old population is growing. On the right, you can see populations and the over 40 year old ratios in some Asian regions. In particular, the populations of China and India are large and ratio of over 40 is increasing. In fact, 70% of the total patient using prescription ophthalmics is over 40 years old. Incidences of glaucoma, dry eye, AMD increase as people get older. And those over 40 are the majority of patients visiting clinics. The younger people, although they may have a disease, they don’t find time to go to a clinic. So, prescription demand from those over 40 is very high. This situation in Asia, including the demographic to population distribution, is very important for us.

So, we expect Asian ophthalmology market will continue its high growth. This is our forecast of the market including infection, glaucoma, dry eye, retina and others until 2020. We expect average growth of 8.2%. You may think this is a bit conservative, but we have a conservative approach for China. Annually, overall China growth is slowing down somewhat. It’s about 10% now, but going forward, we think we should look at the market with some conservative perception. Overall, 8.2% is our forecast of growth.
This shows our strategy in Asia. This schematic shows our product offering, geography and the patient segments where we seeking to expand and raise customer satisfaction. We are a bit different from other pharma companies. We don’t start with drug discovery. Rather, we focus on strengthen our development capabilities to launch faster and grow through our commercial activities. How to improve customer satisfaction from doctors and patients is very important. And services are very important. As explained, in our domestic business, we try to capture information and respond quickly to the needs in the market. Of course regulations must be fully met, but we try to respond to markets as much as possible.

This shows strategy by country and by therapeutic area. Our number one share in the infection segment should be maintained. Then we will achieve number one share in the dry eye segment. DE-117 and DE-128 MicroShunt should be added to enrich our product offerings in glaucoma. That strategy remains unchanged. We are pursuing strategies by region in Singapore, Taiwan, Philippines, Vietnam, Hong Kong, Malaysia, Thailand, Korea and China – while also the new market of India. So, while we drive local strategies, we also constantly review our strategy for Asia as a whole to maximize further growth.
This is my last slide. Going forward, we want to outgrow the market. So, growth going forward should be annually more than 15%. When you think of business in Asia, maybe you think of risk factors. Pricing is one possible risk factor. Prices may decline and therefore growth may be challenging. We strengthen market access and regulatory affairs, so that we capture information as soon as possible. And, we must be ready to take actions including pricing strategies according to the changes in the market.

The next is regulation changes which are also challenging. There are always changes in regulations. And, how we assess the impact of such changes on our business is very important. While very challenging, we have experienced such regulation changes in the past. It is important that we try to get the fullest information at the earliest timing so that we best react accordingly when the actual changes happen. So, we need to improve our flexibility and ability to respond as we strengthen Asian business.

And, how do we compete against generics? Well, we have overcome and we are actually growing in spite of the fact that there are many generic products in Asia.

Those three points are some of the risks we always consider. We will strengthen our business and we should be very aware of risk factors as we proceed. We must ensure proper governance and strengthen management capability. This includes our employee surveys in which we gain information about employee satisfaction as well as try to identify and assess risks.

The next topic is the Santen Business in China and Liu is going to explain.

I give my slides the title of “Challenge, Opportunity and Strategy.” Basically, it consists of these three parts.
At the beginning, I would like to explain our Vision 2020 for Santen China. In 2014, Santen China made its mid-term plan as well as long-term plan. So, 2014 was the starting point. At that time, Santen China’s business model was basically sales-oriented, which was quite similar to the local companies. That means at that time, our business was based solely on the product promotion through MR activity. For the mid-term plan to be completed this year, we worked toward and were successful in upgrading our promotion model to be market-oriented, which is similar to most mega pharma in China. But for our long-term view for 2020, we would like to make Santen China a solution provider to Chinese patients as well as the Chinese ophthalmology society. That means regardless of what kind of needs from patients and doctors, we will always be able to provide solution to help the patients. So, based on this, we would like to establish our promotion model as E-promotion. E-promotion itself is quite high tech. In China now a limited number of companies already started trying but we would like to be a pioneer in this area. If we realize this, we will be able to establish an IT platform with a human touch. We will be able to be a solution provider to Chinese society covering all the disease categories with an extended product plan. Of course, during this period, we would like complete geographic coverage that means covering the whole and very large country of China.

External Environment of Pharmaceutical Market in China is Not as Strong as Before

- Growth of pharmaceutical market is slowing down
- Multinational corporations are losing their advantage in bidding and pricing

So, at the beginning, I would like to give a basic general explanation about the overall market environment in China. Frankly speaking, now the China market is getting tougher. Looking at this diagram, in 2013, the Chinese pharmaceutical market growth rate, I mean in general, was about 13%. But in 2017, only 4 years later, we can see the growth rate dropped to only 5%. According to IMS, for the coming years, for the China pharmaceutical market itself generally will grow only 6% to 7%. At the same time, most of MNCs including Santen China are experiencing the regulatory price reductions. This chart shows price cuts in sample provinces in 2016 for various companies including Santen China. We can see from A company to H company, the price cut is something about 4% to 6.3%. In Santen China, the price cut in the sample provinces last year was about 4.3%, which is the number three smallest among other MNCs and the number one smallest among ophthalmology companies. Even so, 4.3% is still a lot.
Moreover, government regulations in the Chinese pharmaceutical industry are becoming more and more strict. This photo was taken from a hospital. We can clearly see the sign “no MR.” And, the government also is introducing IT systems to secure their regulations are followed. They have even introduced facial recognition systems in certain hospitals. That means once the MR enters hospital, their face will be immediately capture by this system and upload to the central system. If all MR visits a lot, the hospital authority will give a call to the company and ask you “why has your MR visited our hospital so frequently?” So, it’s very challenging. That means the tradition of one-on-one MR visits with doctors is not very sustainable in China.

I’m going to introduce something about the China ophthalmology market. During the past four years, the growth rate of the China ophthalmology market has been about 10% which is higher than the pharmaceutical market in general. So, this suggests that the ophthalmology market in China is still a promising market for the future. Since the last quarter of 2014, Santen China’s market share is growing dramatically. With the rise during the last quarter we went beyond over main competitor in China and became the number one eye drop company in China with 17.3% market share.
And, this gives some details about IMS data as well as Santen sales growth. According to IMS, from 2013 to 2017 the China ophthalmology market grew about 46%. Our main competitor grew also quite similar to the market average. But Santen China grew 74% which is much higher than market average as well as our main competitor. In terms of sales growth during the past four years, we doubled our sales. And, in 2017 our growth rate above 25%. Although we have one month left, we estimate our growth will be above 25% in China, so much higher than the market itself.

Now I am going to introduce something about our Santen China Strategy to realize our Vision 2020. First of all, we would like to expand our hospital coverage through our sales activity. Here are some figures to see that from 2013 to 2017, our hospital coverage extended from 38% to 70%. So basically, we cover most of the Chinese hospital. In China, there are over 6,000 big hospitals. We call them level three and level two hospitals. At the same time, we would like to strengthen Santen’s brand in this market through our marketing activity. Basically, there are two big organizations in China, the COS (China Ophthalmological Society) as well as COA (Chinese Ophthalmologist Association). We collaborate with these two organizations very well. Shown is an example of the COS annual conference. This is the guideline of this meeting. At the beginning they list out all the partners in their coverage. You can see that Santen is here as the number one partner to this society followed by other companies on the list. This shows that we are the main partner to the China Ophthalmology Society. For this reason Suzuki from Santen group (Head of Asian Division at the time, Head of Corporate Development Division as of February 26, 2018) made a speech as a representative of the
I would like to take this chance to introduce something about the Disease Oriented Promotion. Here is an example of pterygium treatment. We collaborated with China Ophthalmological Society to standardize the diagnosis as well as the treatment of this disease. By such kind of standardization, we propose and build consensus for treatment and product package to Chinese doctors and patients. Such a process starts from pre-operative 3 days with anti-infection, anti-inflammation, anti-dry eye to post-operative with anti-infection, anti-inflammation, and wound healing as well as following up treatment. So, rather than the typical promotion of only one or two products, such a disease oriented promotion, allows us to work with Chinese doctors to help Chinese patients with standardized treatment.

And also, we are building our e-platform. This platform will integrate KOLs as well as doctors with their Santen China contacts. Santen China Headquarters is supporting a system using a single platform. Once we finish this platform, any question, support or need requested by Chinese doctors can be immediately managed by this system. In this case, we will play our role as a solution provider for services to the ophthalmology society in China. Shown, is one of the example of a program on this platform - sorry it's in Chinese.
As a pharmaceutical company we do believe it is our mission to provide new products to Chinese patients continuously. But as you know in China, the regulations are getting tougher and tougher. For example, in China, there are over 4,000 local companies and 200 MNCs, but from September 2015 to October 2017, during these 2 years, only 27 new molecules have been approved by China regulatory authority, which we call the CFDA. Among these 27 new molecules, only two of them are eye drops, but both of them are from Santen China. They are Tapros and Diquas. This suggests that China Authority really recognizes Santen’s efforts to help Chinese patients.

With continuous new product supply, we are able to continue to help Chinese patients and have a sustainable business. Here I list out the launch plan of Santen China from 2016 to 2020. In 2016 we launched Tapros, in 2017 we launched Azep, in 2018 we are going to launch Diquas, and in 2019 we are hoping to have approval of Tapros-S as well as Sancoba OTC. In 2020 could also get the two additional products Cationorm and Hypromellose. In this case our portfolio of products and pipeline are richer and richer to help more and more patients.
As you know, China is a very heterogeneous country. That means patients are quite different in different areas. In China, we have about 8,000 hospitals in the cities. Rather wealthy patients are served in such hospitals. But actually, the majority of patients who is not as rich, are treated in almost 1 million small community hospital or clinics. Currently, Santen China is covering the hospitals mainly. But in the future, we would like to cover more hospitals or smaller hospitals into this country to help more patients. This is the reason why we created the joint venture we call Santen Kerui. The mission of this joint venture is to provide Chinese patients with high quality and reasonable priced product. In March 2016, we signed our agreement with Kerui which is owned by China government for the joint venture. And, in June 2017 we started construction of its factory. This picture shows the starting point. This is half year ago, the construction yard and this is last month. We can see that basically the whole project goes very well.

Last, if somebody asks me what is the most important factor to make business sustainable in China, I answer compliance. This is the reason why Santen China pays huge attention on compliance. Compliance applies not only product development, but also sales and marketing activity and manufacturing as well. This gives an example showing Santen’s China Compliance Guideline for Promotion Activity. And you can see my signature at last. That means I, myself, take whole responsibility of compliance management in China. Also take the final responsibility of compliance management in China. With strict compliance management, we are able to get customer trust and we are able to work with Chinese doctors to have Chinese patients and, as a result, we are able to have sustainable growth. Thanks everybody.
1-1

Q

Japan business support package to improve compliance looked like very effective. But in future is that limited to Santen’s products? Or is it for industry? And, in your case if it’s good for the industry, 50% of the industry’s benefit will be yours. But how extensive is this program and how does this lead to your business profit and sales expansion? So, how much of this problem is relevant to Santen products?

A

Today we showed you an example in glaucoma, but by each therapeutic area, our market share differs. For dry eye our share is more than 60%. In that therapeutic area, if we do the same thing, then we can enjoy 60% of the merit. In glaucoma our share is about 32% to 33%. The way it is, two-thirds will go to our competitors. This program is not limited to our products. Applying the program to only our products, would not be well received by the community including physicians. What we can do with depending on patients as a contribution will be the driver for this kind of program. On the other hand, an ophthalmologist told of us their patient who cried with happiness after using this program. The patient said he is so happy and came to this clinic to show his appreciation. The doctor could really remember the reasons why he became ophthalmologist in the first place. And also, a strong reputation is building online and word-of-mouth. Clinics using the program are being rated highly – such as five out of five in rankings. Of course, physicians use the same medicines for some time and they won’t switch easily to a new ones. Physicians like Santen through our solution providing activities - they are impressed and some newly saying “I will start using Tapros”.

1-2

Q

I have a few questions regarding e-promotion in China. Is a platform provided by Santen? And e-promotion is done by many companies. How competitive is your platform, is the competition very fierce?

A

Actually this platform is provided by third party in terms of technical support. Of course, this platform is owned by us. Now just like you mentioned, so many companies are trying e-promotion, but how to be successful? I think the most important thing is your brand in the field. For example, if you are not the number one brand, you will not be able to attract doctors to the platform. This is the most important thing. This is the reason why we believe we will be successful since we are the number one brand in this field. And, our brand is getting stronger and stronger.

1-3

Q

CFDA, China FDA recently changed the review process. That may not be relevant to you directly, but please comment on the recently changing China regulations.

A

Actually you are right. China CFDA has changed – in fact, dramatically. I just chatted with my colleagues. During the past year I think I saw almost over 200 different new regulations. I would like to see, in general, this change benefit the pharmaceutical industry, especially for the companies with innovation. So, CFDA
becomes very strong in their support of innovative drugs. Recently, we see the approval period significantly shortened compared to before, but this is only for innovative drugs.

2-1
Q
The first question is in terms of the Japan business. You strengthened your franchise and if you have anything about digital health, please tell me. I think ophthalmology is really a good area to use such a technology.
A
For example, in the field of diabetes overseas, WebDoc is a supporting program for patient treatment and is digitized and will be reimbursed by insurance in the future. We don't have anything specific right now. However, the ACTPack is the treatment program package for glaucoma while it is not digitized right now, we are considering how to do this now.

2-2
Q
When you discussed the Asian business in the past meeting, you said that China became breakeven at that time. Currently, in Asia and China you are enjoying high margins. Will margins further increase or stay flat in the future?
A
In principle, if we limit to China alone, then profitability is improving and the Asia market per se is growing 10% per annum. Therefore, we have to invest money in R&D and SG&A. However, we have also started cost reduction activities. We differentiate the necessary versus unnecessary investments. Therefore, we are now reviewing and revising our activities. And the cost ratio is not really high in the case of Santen Asia. In Japan, we especially have Eylea and other licensed products and that tend to have a higher cost. However, in Asia, we are mostly selling our own products. Therefore, the cost is not very high as a percentage. But we have to control SG&A. And as you have pointed out, the profitability is now improving. I cannot promise any specific percentage in 2020 yet. However, we think that it’s possible to expect further improvement.

3-1
Q
In the Japan prescription business, what is your view going forward regarding product portfolio and strategy of product lineup? NHI pricing scheme is changing and MHLW has a new definition of innovative drugs. They include requirements for new MOAs or you have to show superiority in an objective manner in clinical trials, etc. Those are important in terms of price setting. Are there any changes in your efforts in this respect?
A
Regarding the portfolio, we now face the recent NHI pricing changes and there is a focus on innovation. For example, long listed products and innovative premiums could change. So, we need to consider that. Now more than ever, we need innovation incorporated into our development plan - that does not change. But, we need to enhance our activity in that respect. The development capability needs to be strengthened to live up to your expectations. Going forward as we have global activities, we need to review and strengthen development capabilities including clinical studies, non-clinical, regulatory affairs and market access capabilities. Regarding our future portfolio, at a later date when we announce our midterm plan, we will explain more.
3-2
Q
Regarding a huge vision of Asia business, in future, do you want to duplicate the situation in Japan or do you have a different business model in Asia? What’s your vision in 10 years or 20 years and beyond?
A
The Japanese style business model can be applicable in Asia. I think that probability is high. Unlike the US, the payers are different. The mentality in prescription patterns in Asia is rather close or similar to those in Japan. We explained the creation of guidelines in the Asia business session earlier. Japanese and Asian physicians historically have strong relationships. So the Japanese style may be quite applicable in Asia. It can be a part of our goals but the stages of development are somewhat different across the various countries. So, we can’t duplicate everything in Asia. But, if product development, marketing activities and business activities go as we plan, then our business model will be able to gain deep roots and be very firmly established.

4-1
Q
In terms of the Japan’s business you expect a series of the patent expirations in Japan including Alesion and Diquas over the next few years. And, of course, it’s important to launch new products. But other than that, what kind of measures are you planning to put into practice to cope with the patent expirations?
A
Launching new products to replace is important. But in terms of the new drug development there is no guarantee that they will succeed as is planned. I touched upon in my presentation that we have a generic subsidiary. The authorized generics holder will be this generic company owned by us. And also there are a variety of measures we can take on a product-by-product basis such as Alesion. We are now proceeding with clinical development activities aimed at effective life cycle management of our major products. We are considering new formulations or the launching of authorized generics. And, we will make appropriate decisions based on the specific circumstances and best timeline.

4-2
Q
Well, I do not desire this but reducing the number of the sales force like MR is often times done by other companies. And, I don’t know whether it is really the appropriate thing to do in the ophthalmology or not. But, do you plan to reduce the number of the MR?
A
Recently digital promotion is being done and this includes use of M3. And, we have Santen Medical Channel for which many Japanese ophthalmologists have registered. So, we have platforms and we have web MRs. Whether or in person or digital, it is our most important strength that we cover almost all ophthalmologists in Japan. Such relationships are also supported by the program mentioned today for the retention of patients being treated for glaucoma. That’s been done in many hospitals and clinics. Of course, we cannot promise that we will never reduce the number in the future, but at this point we need to further by enhance our efforts to boost the productivity of our existing MR force.

5-1
Q
You mentioned a possible game changer. An intraocular lens is in your pipeline and there are many cataract patients overseas. What is your plan in Asia, especially in China, you don’t need phase III studies. That means you can be shorter to the market.

A
A material and optical designs of the lens were licensed from a company in Europe. As of now, we have the rights only in the Japanese market. But whether we can have an option in China or not that is a huge point to discuss. In China, possibly, we can expand from prescription drugs to medical devices. If that is the idea, it could be an option. Of course, this would depend on the partner. This is all that I can mention today.

5-2
Q
In Asian countries, you have a business shifting from distributor-based to direct sales. Do you have any specific criteria when considering to make this shift? Or, maybe when you have a conflict of interest with distributors then you shift to your own sales platform model?

A
Regarding direct sales, I have explained this to some extent in my presentation. Ideally only the direct sales can achieve that customer satisfaction at the highest level and profit can be sustained in the long-term. In ophthalmology, there are not that many physicians in each market. So, through our Santen products, we want to meet the needs of physicians including prescription patterns and behaviors – this is very important. On the other hand, you don’t want the direct sales that generates losses, you need profit. So, you will need to evaluate the decision as an investment. That will determine whether we use distributors or we use our own sales infrastructure. For example, the India market is very attractive. But, there are low priced, mass market segments and there are some segments that have high value and prices. But you need to be very careful in your assessment of the market. And as of now we use distributors and marketing decisions are based on this. So, we have a long term assessment of profit analysis and planning. That will determine the best option between use of distributors or own sales. Over time, it is also possible to switch from distributors. So, we can be quite flexible.

5-3
Q
About people. You have subsidiaries and you have to consider staffing in a changing environment. In order to support overseas business, do you need a different type of personnel than you did before?

A
As you mentioned, particularly, with our headquarters in Japan, we need to strengthen management and staffing to support good operations. In terms of retention, it’s not so much different from other pharma companies. But in China, for example, our retention policies are working well. Low retention is, of course, good. As a pharma company, we need people with experience who understand Santen’s values and Santen’s ideal behaviors. And so for retention we distinguish high performers and low performers. Of course, for high performers we try to have good retention in terms of incentives. Also, in terms of work environment, we try to give good measures and actions. How to build up global career experience? So not only people in
Japan, but overseas people should also have some training in Japan. And, we also develop our domestic staff. So, exchange of personnel should be further accelerated as we think it’s necessary.

6-1
Q
In terms of the China market, you touched upon the compliance at the end of your presentation. From my viewpoint, maintaining relations with the distributors is really something like a black box. I think Santen is really successful in terms of management to relation to the wholesalers or distributors. And, how have you developed these relations? And, how many distributors do you have business with? And, some of them are listed in stock market. And, I think you are mostly doing business with those large companies. So including that and in terms of risk management, I would like to know how you manage your relationships with distributors.

A
Thanks a lot for your question. I think you are right. The compliance risk in China for dealing with distributors is quite high. The most important thing is choosing reliable distributors. So, most of our distributors are government-owned. Government owned distributors are bigger and they are managed by government. So, in this case, they are much more reliable compared to private distributors. Another important thing is your brand. If your brand is strong enough in China, quality distributors will support you more. But, if your brand is weak and your promotional activity insufficient or lacking in compliance areas, it will be very hard for you to manage your distributors.

6-2
Q
With how many primary distributors do you have business?

A
We have about 120 distributors in China. So, technically, we have many different distributors. But many of them have are actually subsidies of the same group. Such as groups have many subsidiaries in different provinces.

A
Not limited to China, but also the larger Asia region, the relations with distributors and also the distribution channel really gave us some hard lessons in the past. Then, we had to switch from existing distributors to other ones in China, Korea and other Asian countries. And, we have seen rebate practices and also the lack of transparency in the distribution channel. Therefore, we really fully understand the importance and that’s why I said that it is so important for us to try to market and distribute on our own. And, to every extent possible we would like to eliminate interdependencies or relationships that lack transparency.