

## The 38th Annual J.P. Morgan Healthcare Conference



### Focus on the Eye: Toward the Next Growth Phase

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Good morning, everyone. Thank you for joining us. I am Shigeo Taniuchi. I'm President and COO of Santen. I'm glad to be here, come back again to make a presentation at J.P. Morgan Healthcare Conference 2020. Today, in next 20, 25 minutes, I'd like to explain about Santen and its project, how we are going to contribute to patients suffering from eye conditions, eye diseases by focusing on innovation in ophthalmology field, and explain how we continue our growth.

### Specialized Ophthalmology Company with a History of 130 Years

- Established in 1890
- Headquarters in Osaka, Japan
- Total sales \$2.1 billion in FY2018\*



**> 60** Distribution Region    **3** Plants    **4,000** Employees    **30%** Overseas Sales

\*US\$1=JPY110.99

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First of all, I'd like to start from who we are, because as a specialty company in ophthalmology, Santen is not necessarily well-known to everyone here, although Santen has very strong presence and brand in ophthalmology field. Santen has a long history and heritage in ophthalmology.

Since its foundation in 1890, Santen has been continuously growing by focusing purely on ophthalmology and by enhancing our knowledge, our network, and the competitiveness. This year, 2020, is our 130th anniversary. Sometimes old means not necessarily good thing. But In our case, long history means trust, commitment, and promise for delivering high-quality products and services.

At present, as one of leading global ophthalmology companies in the world, Santen is operating in more than 60 countries with 4,000 employees worldwide, and offering not only prescription pharmaceutical products, which is the biggest segment, but also medical devices, as well consumer health products.

Our global headquarters is located in Osaka, Japan, where many R&D activities are carried out in our global team here in Bay Area.

## Santen's Values

# 天機に参与する

## *Tenki ni sanyo suru*<sup>1</sup>

<sup>1</sup> “ Exploring the secrets and mechanisms of nature in order to contribute to people's health”

Santen's original interpretation of a passage from chapter 22 of *Zhongyong (The Doctrine of the Mean)* by Confucius.

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

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3

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In 1890s, our founder first set core value, which is "*Tenki ni sanyo suru*" in Japanese, which was based on ancient Chinese text written by Confucius, and also where our company name, Santen, was invented.

It basically means exploring the secrets and the mechanism of nature in order to contribute to people's health. Based on this core value, Santen's way of doing business is that always first understand unmet medical needs in society and in ophthalmology, and then find out solution to address needs so that we can contribute to the society.

In other word, every strategy in Santen starts and ends at the patient's side. Under this unique business model, we are applying a hybrid model to develop solution. We do have our internal capability to polish our expertise and also seeds technology.

At the same time, we are also maximizing our partnership and network to bring best of solutions from all around the world. In fact, most of our success are coming through partnership. We are proud of bringing innovation to patient as an orchestrator.

## Focus on the Eye: Toward the Next Growth Phase

**1 Eyes are an important organ**

**2 Growth in our business**

**3 New business domains**



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4

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Today, I'd like to highlight three area in order to explain how Santen is going to grow further based on this unique core value. Why eye is critical to us, human, and then how Santen intends to grow in next years, and how Santen can consider longer-term growth toward the next decade.

## Eyes: An Important Organ Vital to Everyday Life

### Expression

#### Daily life



#### Sports



“Vision plays a critical role in every facet and stage of life”

#### Education



#### Work

Source: WHO World report on vision

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5

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For more than 100 years, Santen has believed that eye and the visual function plays most critical role in the human body. Hence, we believe that dealing with eye condition could best contribute to the society. In fact, last year, the World Health Organization published probably the very first report about the vision.

It basically mentioned the same message that Santen has believed for more than 100 years. It said, "Vision plays a critical role in every facet and stages of life." Indeed, according to the report, the world is built on the ability to see. Therefore, visual function plays very critical role in every human activities, such as communication, study, or employment.

That exactly means that having eye problem, or even visual impairment, would directly affect quality of life. Eye disease may not directly kill us. However, eye disease may destroy one's life. This is why Santen believes eye disease is life-threatening disease.

## Globally, the Number of People with Vision Impairments is Increasing

### Visually Impaired People



**2.2 billion**



**Global population growth**



**Aging**



**Lifestyle change**



**Environmental issues**

Source: WHO World report on vision

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6

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Social and economic impact and the cost are also enormous. In fact, at least 2.2 billion people around the world should have some sort of eye disease. Unfortunately, the number is continuously growing because of population increase, aging societies, lifestyle change, and environmental change.

Therefore, Santen is determined to tackle on these kinds of issues in order to contribute to the society by not only leading innovation, but also bringing and orchestrating innovation in the ophthalmology field. At the same time, we also believe this will give us a tremendous opportunity for growth.

## Focus on the Eye: Toward the Next Growth Phase

1

Eyes are an important organ

2

Growth in our business

3

New business domains



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7

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I'd like to talk how we are going to grow further by answering unmet needs in ophthalmology. Let me first talk about near-term opportunities.

## US: Aiming for Growth with Differentiated Products



- Differentiated pipeline / products
- Tailored strategy for entering the US
- Realizing profitability and growth

GLAUKOS®



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8

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This year, 2020, Santen is entering into US market with DE-128, *PRESERFLO MicroShunt*, which is an innovative surgical medical device for glaucoma.

Glaucoma is one of the leading causes for blindness in many developed countries, of course, including the United States. We can only slow down its progression by decreasing intraocular pressure by using eye drops for basically until the end of life. While various types of eye drops were developed, number of patients who have progressing glaucoma is increasing. However, besides eye drop, there's only one golden standard of surgery called trabeculectomy, which is quite invasive, bloody, time-consuming, and risky surgery. Hence, there is clearly an unmet medical need to deal with such as severe glaucoma condition and to save also from blindness.

DE-128, *PRESERFLO MicroShunt*, could have a potential to become a medical device that has minimally invasive and promised efficacy, so offering much safer option compared to trabeculectomy. Indeed, Santen has already marketed this product in European countries and has obtained very strong and good feedback from top glaucoma doctors, surgeons in European countries.

In the United States, Santen has developed a partnership with Glaukos, a leading player in MIGS products, in order to penetrate efficiently into the market so that we can contribute to glaucoma society in the United States as quickly as possible. Once we developed our commercial foothold in the United States together with *PRESERFLO MicroShunt*, we are planning to launch other products which are currently in the pipeline for us to establish strong commercial presence in the United States and also sustain our growth momentum in the biggest market in the world.



## Building on Strengths in Japan and EMEA\*

- High market share and know-how
- Manufacturing, quality assurance capability

**Sustainable growth**

- Global Influencer
  - Academia and KOLs
  - Regulatory expertise
- Market presence

Japan EMEA

\* Europe, the Middle East and Africa

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Next, let me talk about our core business in Japan and EMEA. As a matter of fact, Japan and EMEA are very important business bases for us and have performed very nicely in terms of both top line and bottom line. Japan is our origin, where market share is close to 50 percent, five-zero percent.

We're leveraging Japan as not only commercial opportunity, but also a key country for manufacturing, as well as R&D operations. In Europe, we have headquarters in Switzerland and have deployed our business in about 50 countries across EMEA region.

Having EMEA business also is very important for us not only because of its second biggest market size, but also its importance as a global influencer, especially for Asian markets. By leveraging our strong presence in Japan and EMEA, Santen's enhancing its growing presence in Asia, as well as United States.

## Japan: Extension of *Eylea*\* Sales Contract and Launch of *Alesion LX*

**EYLEA®**  
(afibercept) Injection

**Alesion LX**

**Strong business base**

\*Eylea: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

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Now I'd like to touch upon two important updates for Japan. Santen has marketed *Eylea* in Japan since its launch, and it's quite successfully growing. Now, we agreed with Bayer to extend our contract so that we can continue our leading position in back of the eye segment in Japan. Also, we can continue our contribution to patient in this key area.

Additionally, I am proud of introducing new addition in allergy market. Seasonal allergy market is quite big in Japan due to seasonal pollen. By launching twice daily *Alesion LX*, an extension to the *Alesion*, we could further secure our dominant position in Japan.

## China / Asia: Unlocking Potential for Further Growth



**4 Billion Population** × **Aging Population** × **Improving Diagnosis and Access**

Source: UN World Population Prospects 2019

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11

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Rapidly growing business in China and Asia, it's critical element for Santen's longer-term growth. Santen started to focus on Asian countries back to '90s. Currently, we have established solid presence and platform in almost all Asian markets, with leading position in many markets, including China and Korea, establishing very strong brand in the market.

Fastest growing business is China, which actually I launched direct marketing more than 10 years ago. I have to say the business has grown much faster than expected with uncomparable speed. Even now, the market seems quite large and attractive.

We predict the market will grow further due to increasing diagnostics and improving access to healthcare, to the medication. Hence, we have started multiple initiatives to capture future opportunities.

Biggest growth driver in Asia is its population, four billion. Additionally, Asia is rapidly aging, which eventually causing various type of eye disease. Furthermore, thanks to economic growth and also urbanization, access to medication is improving very fast.

In here, we can take optimistic view that the market is growing nicely. However, we could also consider pessimistic scenario that we're going to face catastrophic consequence unless we take some additional actions. Why is that?

Because ophthalmology infrastructure in many Asian market is quite vulnerable or insufficient. Number of ophthalmologists, trained nurse, specifically trained for ophthalmology diagnosis, as well as ophthalmology institute are much, much less compared to those in developed countries.

Without having sufficient hard and soft infrastructures, it is impossible to deal with exponential demand increase in Asian market in very near future. Or, because manufacturing capacity may be not sufficient to deal with four billion population. Therefore, Santen has determined to deal with those issues as a responsible leading company in ophthalmology.

Santen has decided to provide various solution to deal with those issues, such as strengthening the partnership with local association to increase the ophthalmology training for instance, so that we can improve the treatment paradigm in Asian markets.

## Establishment of a Second Plant in Suzhou, China to Meet Demand from Increase in Patients



Our Suzhou First Plant in China

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12

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As one of solutions to deal with those future challenges, we decided to build the second factory in China.

Perhaps it will become the biggest manufacturing site for ophthalmology product in the world, so that we can deal with future demand increase from China, as well as Asian markets. We strongly believe that having the capacity and the capability for high-quality manufacturing will become a competitive advantage.

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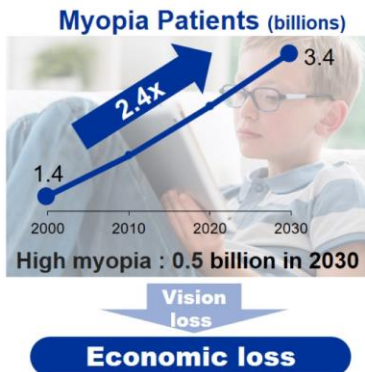
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13

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As the last chapter, I'd like to explore how we are going to capture additional growth opportunity for the future.

## Tackling Unmet Needs: Myopia



**DE-127:  
Low dose atropine**



**Phase 2 trial met  
primary endpoint**

Source: WHO World report on vision

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14

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Our first focus is myopia, especially for Asian markets. WHO urged, the number of myopia patient will increase up to 3.4 billion in 2030. An estimated economic impact related to productivity loss due to myopia is even 244 billion USD. Having a such sharp increase may multiply tremendous the social and economic impact around the globe, particularly in Asian countries where myopia is growing massively. Santen has focused on this growing concern and has initiated a project with SERI, Singapore Eye Research Institute, that's commencing new development project for myopia. We have concluded successful study in Asian countries and also started the trials in Japan. Additionally, we are investigating additional treatment options to further contribute to patient suffering from myopia.

## Tackling Unmet Needs: Ophthalmic Rare Diseases

Inherited retinal diseases, etc.



**Vision loss / blindness**

**Gene Therapy**

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Oxford Biomedica

Kobe Eye Center

Source: US National Library of Medicine National Institutes of Health Translational Vision & Science Technology <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6052953/>

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15

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In ophthalmology area, there are diseases such as myopia where a number of patient are quite massive. At the same time, there are many rare diseases causing blindness due to lack of treatment option. Santen has started project to find out a gene therapy for retinal diseases with strong partnership with RIKEN of Japan, as well as Oxford Biomedica in UK. We hope that we can bring about innovation, innovative treatment option to prevent from blindness.

**Partnership with ITU**  
To support ITU and WHO for “Be He@lthy, Be Mobile”

**Raise awareness of the prevention and management of non-communicable diseases**

ITU: International Telecommunication Union (a specialized agency of the United Nations)  
WHO: World Health Organization

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In order to deal with social challenges related to ophthalmology, developing new medicine is very important, but not maybe sufficient to make a change happen. Therefore, Santen is also approaching various type of innovation that could change the world.

Digital health or cutting-edge medical device might be an answer. In fact, Santen had decided to start various project to capture next-generation digital health solution through the partnership. We strongly believe that not only conventional Rx medication, but also digital will play a significant role in ophthalmology in very near future.

We also believe it is very important to increase awareness about eye disease by improving access to disease and treatment information. Particularly ophthalmology area is far behind compared to the other therapeutic area in terms of awareness and attention from general public.

In order to deal with such a challenge, Santen has decided to participate joint initiative led by ITU and WHO, both famous UN organization. The project is called “Be Healthy, Be Mobile”, which is a part of key initiatives for achieving SDGs, sustainable development goals, led by United Nation.

As a partner in ophthalmology field, Santen is hoping to play a key role to promote eye health across the world.

**Focus on the Eye:  
Toward the Next Growth Phase**

- Increase in ophthalmic patients
- Aim to resolve issues in the ophthalmology field
- Taking on the challenge of new fields

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Going forward, Santen continues its focus on ophthalmology while transforming from traditional eye drop manufacturer to innovative ophthalmology company.

As I mentioned, the number of patients suffering from eye disease is increasing and the importance of vision is also increasing together with social/economic growth. Based on importance of vision, Santen will continue our journey toward innovation and value-adding solution. We'll continue our contribution through end-to-end company activity from research and development to commercialization.

I'm really hoping that you are going to have more interest on us and support our challenges toward next decade. Santen is trying whatever we can do to make the world brighter and better. Thank you very much.