

J.P. Morgan Healthcare Conference – Summary Transcript



Protecting the World's Vision



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Good afternoon, everyone. I'm Shigeo Taniuchi. I'm President and COO of Santen Pharmaceutical. I joined Santen in 1996, and I became the President and COO last April, nine months ago. Since this is the first time for me to make a presentation here at the J.P. Morgan conference, I wanted to make a brief self-introduction. I joined Santen 22 years ago as a sales rep. And after that, I had been mainly working for commercialization and also on the strategy side of the company. I've been working both in Japan and also in the international business of Santen. I was head of China and Europe during my career in Santen. The reason I joined Santen, this ophthalmology-focused company, is coming back to my personal experiences about my family.

My grandfather, he passed away decades ago. My grandfather was blind due to glaucoma. I had several conversations with him when I was very young, as a kid. I asked a question about blindness to him. He answered to me blindness is a big issue, and it's a very inconvenient way to spend a life. But the hardest part is not just being unable to see something. The hardest part is you cannot see how your grandson is growing up. Because in his memory the cute grandson, me, was frozen at age six or seven. And after that, even while growing up and getting taller than him, but he couldn't see how his grandson growing up. But he can only touch and imagine how I looked. So that was a striking memory for me. And since then, I thought I will work in the life science industry, and eventually I joined Santen to protect the world's vision.

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This is our Disclosure Notice, including risks and uncertainties.

Santen Overall
- Specialized in ophthalmology since 1890

Santen

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In the first chapter, I'd like to briefly explain and introduce about Santen, who we are. We are very proud of being a specialized company in ophthalmology for about 130 years.

Santen's Values and Mission Statement

天機に参与する
*Tenki ni sanyo suru*¹

Values

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

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

Mission Statement

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

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At Santen, all discussions start from the Values and Mission Statement. Our corporate value is "Tenki ni sanyo suru" in Japanese, which is the basis of our company name, Santen. It basically describes, in English, exploring the secrets and mechanisms of nature in order to contribute to people's health. The contribution to people's health through the commitment and the focus in ophthalmology is our mission statement. And we have been working based on these values and statement and focusing on ophthalmology for 130 years.

Our Contributions to Better Serve Patients in Ophthalmology

2002: Dimple Bottle®

2012: EYLEA® (Eylea: Co-promoted product of Bayer Yakuhin, Ltd. (MAH))

2014: Acquisition of Glaucoma products from MSD

2015: ikervis®

2016: PreserFlo¹ microshunt

2018: EYBELIS DE-117 (Omidenepag isopropyl)

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¹PreserFlo is the new name of the pipeline project which has been known by dev code DE-128 and/or trade name ImFocus MicroShunt in Europe.

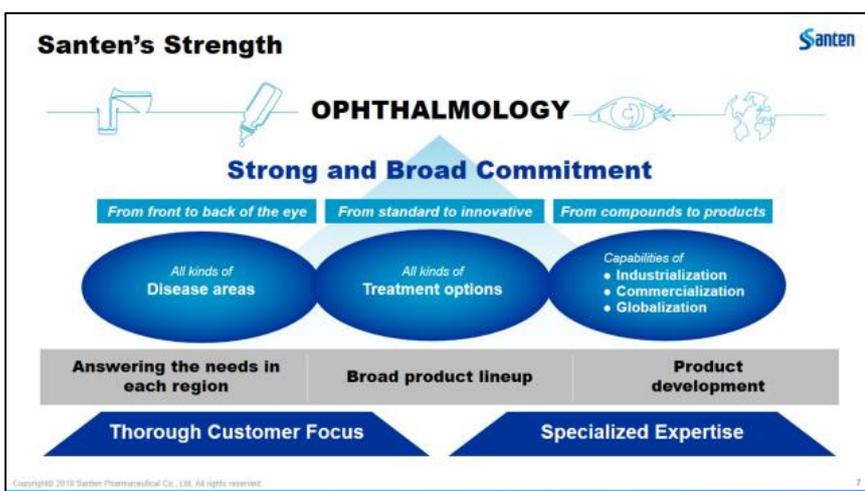
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In our long history, we have made significant steps to improve and upgrade people's quality of life through eye care. And recent examples are shown here.

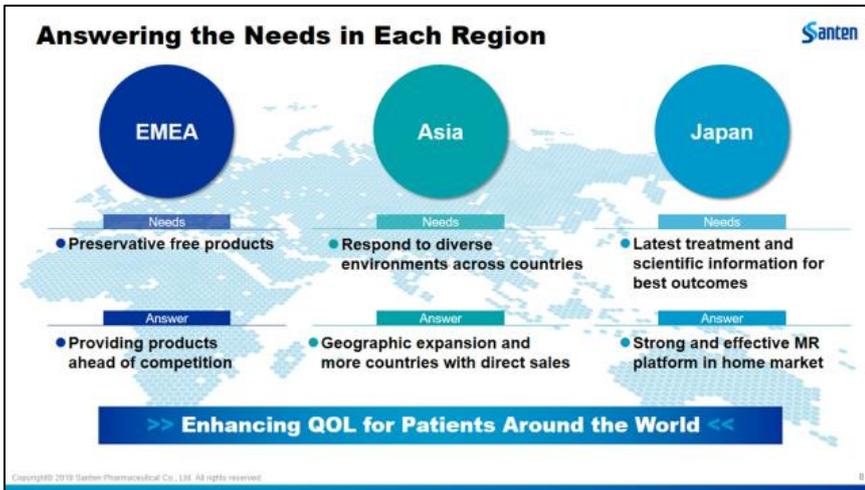
For instance, we have developed and launched the so-called Dimple Bottle, which is an eye drop container. But it's a very advanced design for better accuracy of using eye drops, and also better patient experiences and ease of use, which has improved patients' convenience for using eye drops. We have also made an investment and acquired products from Merck. We acquired their glaucoma franchise in 2014 in order to expand our reach to glaucoma patients. We have also launched and introduced new technologies such as *EYLEA* in Japan, or *Ikervis* in Europe, which is the first and only prescription product in Europe for severe dry eye. Another recent example, including *PreserFlo MicroShunt*, which was previously known as *InnFocus MicroShunt*. Also, a recent example is *EYBELIS* (DE-117), the brand-new mode of action glaucoma medication for selectively targeting EP2 receptors.



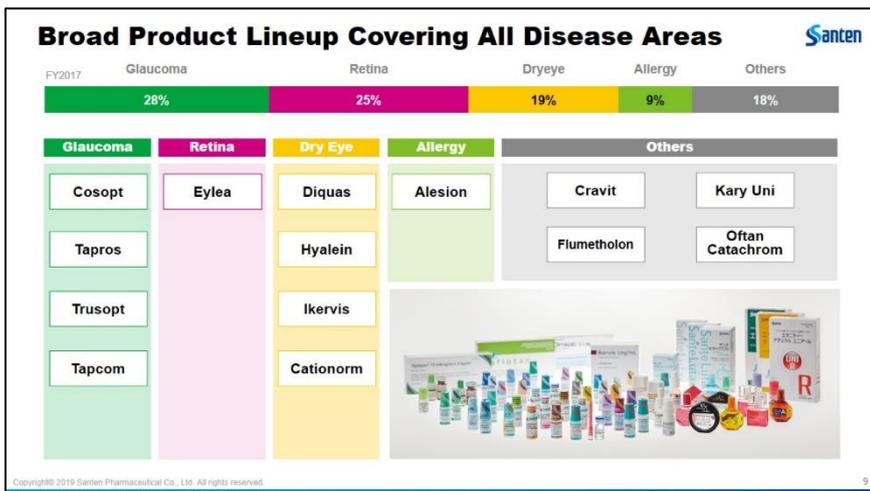
Since 2010, when we developed our long-term strategic vision, we have more than doubled our top line, up to 225 billion Japanese yen, or 2.1 billion US dollars in the last fiscal year 2017. Our growth was mainly driven by aggressive expansion of the business outside of Japan particularly in Asia and Europe. Eventually we have covered 64 countries globally, in Asia and Europe, while at the same time we have enhanced and progressed our pipeline in the ophthalmology area.



Santen's strength is quite unique. First of all, our focus and commitment to ophthalmology gives us quite a unique positioning. We are 100% focused on ophthalmology. We are covering all kinds of disease areas in the eye disease. We are also covering all kinds of technology and innovation to cover different and all kinds of treatment options, ranging from essential diagnosis to innovative surgical treatment. Throughout 130 years of history and dedication to ophthalmology, we have established and polished our unique competitive advantage by excelling in industrialization and commercialization and globalization of opportunities.



In fact, the needs for eye disease and treatment is somewhat different, country by country, region by region. This is why we believe in a global approach and leveraging our global infrastructure and capabilities to answer different needs is quite important. For instance, in European countries people wish to avoid using preservatives so there is strong need for preservative-free medicines. To answer that question on the needs, we leveraged our formulation capability based in Japan to develop and launch a preservative-free versions for products in European countries. Similarly, we're also responding and listening to the market needs in Asia as well as Europe and Japan.



As a specialized company in ophthalmology, it is important to have a broad portfolio to cover all kinds of ophthalmology business needs and market needs.

Glaucoma and retina are the leading causes of blindness in many developed countries, including the United States, Japan and Europe. This is why those are two key focuses for Santen including both commercialization and R&D activities. We are commercializing and working on several projects to answer the growing market needs in these areas.

Dry eye is also a growing concern basically worldwide, including emerging countries as well, due to increased usage of screens and smart devices. We are addressing such market demands by launching a variety of the products in this area, such as *Diquas* or *Ikervis*.

Even anti-infective areas, which is a mature market in many developed countries, are actually driving our business in Asia, such as China or Korea. And *Cravit* is one of those products and a key driver in such Asian markets driving double-digit growth in Asia due to a strong demand for our high-quality products.



As a unique player in ophthalmology, the way we develop products is also quite unique. First of all, we start our journey not from technology, but from market needs. We carefully listen to the patient needs, market needs, and then we understand what's really needed. After that, we take a hybrid approach of network-based and open innovation as well as using the internal expertise Santen has. In case a particular molecule is needed for a particular disease, we are going to leverage our global network to identify ideal compounds. Then, using our formulation know-how, we are going to develop and industrialize the product. In the case of a particular formulation technology or DDS (drug delivery system) technology is needed, we may use internal expertise or partner with external companies. We are also working very closely with many research institutes in the world for specific biomarker or companion diagnosis to also make further innovations.



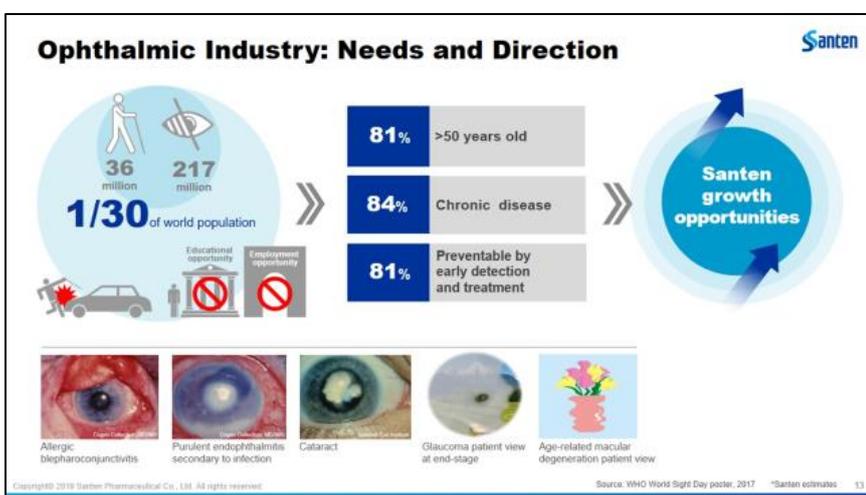
As a result, we have established a network of world-wide and industry-wide collaborations. For instance, our partnership with Boehringer Ingelheim has brought *Alesion*. *Alesion* is the leading allergy product in Japan. Also, the partnership with Ube has developed DE-117, *EYBELIS*, our new mode of action glaucoma product which just launched in Japan. Additionally, Santen is exploring game-changing innovation through the partnerships with well-known research institutes such as UCL, or Singapore Eye Research Institute, and Riken of Japan.

Capturing Growth Opportunities

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In the next chapters, I'd like to talk about what kind of opportunities in ophthalmology are ahead for Santen.



First, let's look at the situation of eye disease and its burden. While various innovation and technologies have changed the landscape of ophthalmology treatment, still the needs are huge and urgent. It is estimated that 1/30 of world's population suffers from either blindness or low vision. Many of them are either elderly or have a chronic condition. Also, many instances are preventable if proper early diagnosis and treatment are taken. But unfortunately, that's not usually the case. And once a patient becomes blind, their quality of life is significantly impaired. They will have more chance of accidents or could even face reduced educational and employment opportunities. This is becoming a big problem especially in many emerging countries. So, from that point of view, I'd like to say eye disease is a life-threatening disease. Because the needs are huge and urgent, we believe there's a huge opportunity ahead of us by focusing on ophthalmology and delivering improved solutions and innovations to the market.

Key Focus 1 Asia Region Santen

	FY2015	FY2020	FY2030	FY2015 to FY2030
Total Population	3.8 bil	4.0 bil	4.2 bil	1.1x
Over 40 Population	1.4 bil	1.5 bil	1.8 bil	1.3x
Market Scale* (USD)	1.7 bil	2.5~3.0 bil	5.0~6.0 bil	Over 3.0x

*Asia 18 countries/areas (excluding Japan)

*Asia Market Scale
 Based on IQVIA MIDAS 2015 excluding 5015, L. Korea OTC and China retail/ 10 countries + India.
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 FY2020, FY2030: Santen estimates.

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Let's do a deeper dive about how we will capture growth opportunities in ophthalmology.

The first key focus is the Asian market, where Santen has established solid presence in each country. As we all know, the population in Asia is huge and growing. But more importantly, we must focus on two facts. The first one is that Asia has already started aging. And the second fact is the economic growth in Asia is quite fast. Consequently, the life science healthcare market and ophthalmology market are growing much faster than in any other region in the world. A nice example is China, where an aging society and the economic growth has been driving double-digit growth in the market for a decade. Also, because of the developing country situation, the healthcare infrastructure in the Asian market is still premature, which means there are also growth opportunities throughout the economic development and the advancing life science infrastructure.

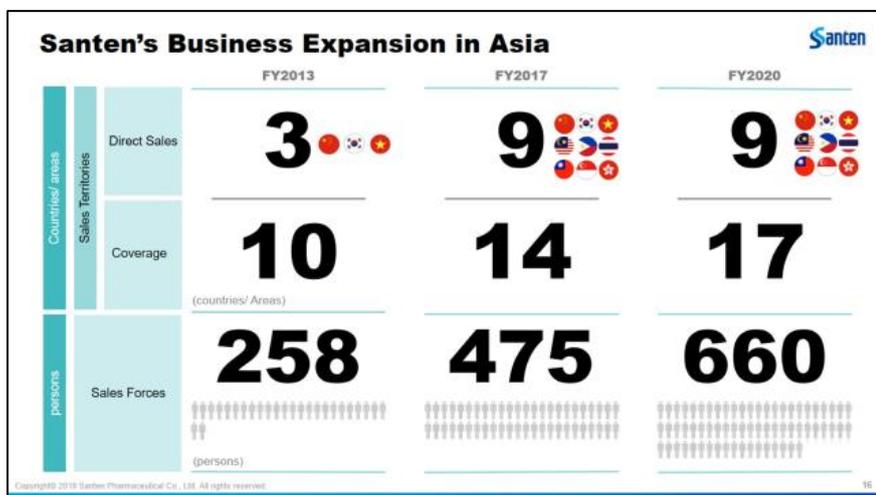


In order to capture growth in Asian countries, having a solid presence in the countries is, of course, essential. But it's not sufficient.

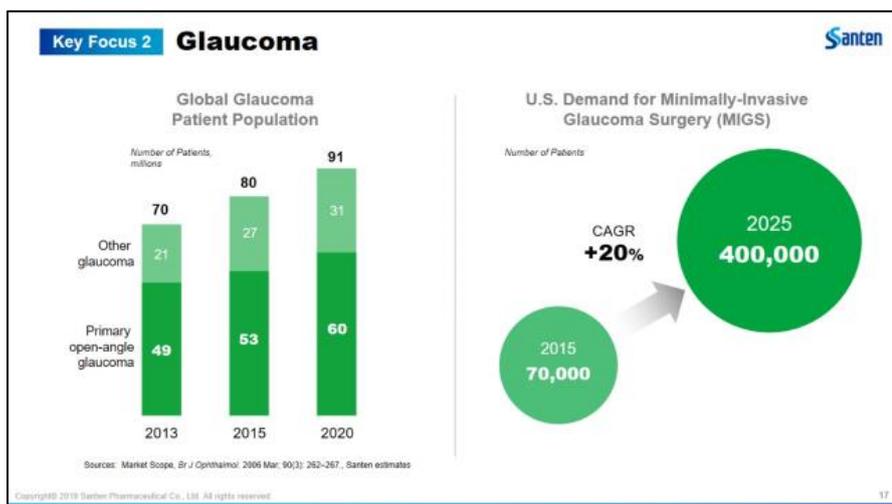
For example, Europe and the U.S. are global influencers in terms of innovation and regulation. For instance, the well-known research institutes in the United States are quite important to conduct R&D activities or scientific activities in the Asian market. Approval from the U.S. FDA is also very important when we launch the product in Asia. From Europe for instance, positive recommendation from NICE Institute of England is quite important when we are going to deal with the HTA (health technology assessment) process in the Asia market. Additionally, GxP standards in Asia markets are usually based on the European standards. Thus, having an increasing presence in Europe and the U.S. is also important in order to accelerate our business in the Asian market. And we are leveraging our strength and growing presence in Europe and the US to support the business in Asia.

From Japan, where Santen is by far the number one company with nearly 50% market share, Santen has

established quite a strong and robust execution capability, particularly in commercialization and manufacturing activities. We are sharing that knowledge and know-how with the team in Asia to support their improvement of the capability. For instance, our factory in China is the only EU-GMP approved manufacturing site for ophthalmology products. This is the one of the strengths that Santen can bring from Japan. By combining our global infrastructure and the team into Asia, we are going to accelerate the growth in Asian market.

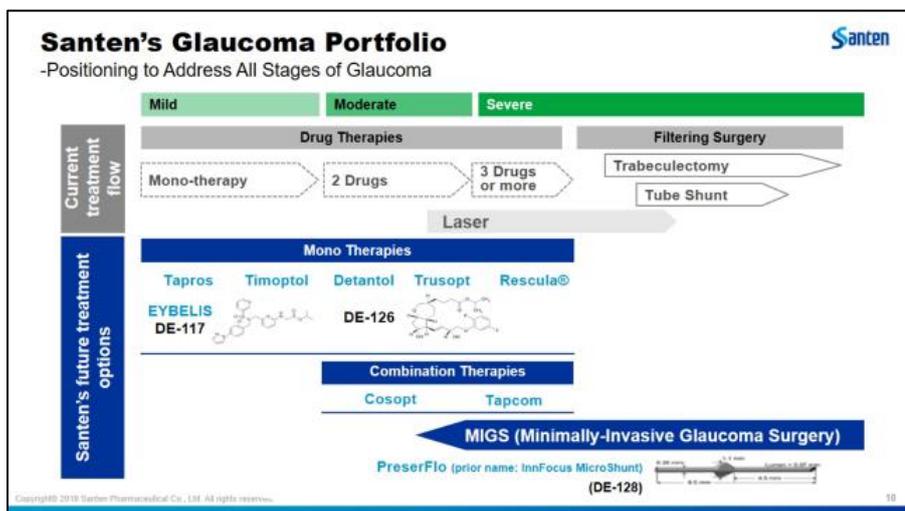


In 2010, we set the goal to become the number one player in Asia by 2020. Since then, we have been making significant progress and investment into the market. As a result, we have made significant growth much faster than the market growth in many markets. Also, we have obtained the number one position in terms of customer satisfaction survey results, which is also very important for us. Because not just the market share, but customer satisfaction result is very important for Santen. I believe our presence in Asia is already a strategic asset for Santen, and I truly hope that this strategic asset will make contribute further in the coming years.

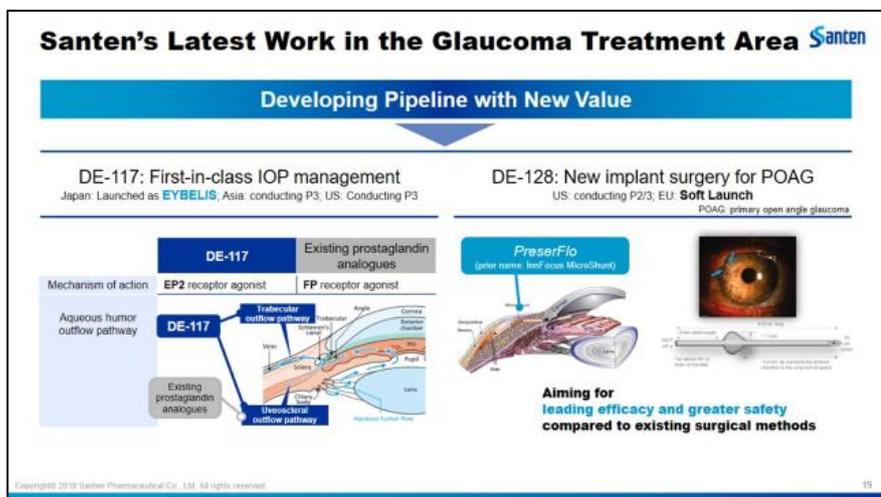


The second key focus area is Glaucoma. We believe glaucoma is one of the most important diseases in ophthalmology, not just because its market size or growth opportunity, but also its significance to the patient and patient quality of life. Glaucoma is a chronic, lifelong sight-threatening disease. Once diagnosed, a patient must undergo treatment for their entire life. In many cases, even if diagnosed it is often too late, and then the patient may become blind during their life journey. Despite various efforts made in this area, still the number of patients and also the people becoming blind due to glaucoma is increasing on a worldwide basis.

There's still unmet needs and treatment needs in the glaucoma area. Another important fact is a growing demand for minimally invasive glaucoma surgery, or MIGS. Because of the significance of glaucoma treatment, surgical approaches are becoming widely available in many markets. How to answer the need for MIGS is also becoming an important challenge for many companies, including Santen.



In order to manage glaucoma treatment, it is very important and essential to have a wide range of products, so that physicians can take a tailor-made approach depending on a patient's condition. For instance, some patients may need to take several medications at the same time all together, because of the high speed of progression of the disease, whereas some patients may need to switch to another medication because of side effects or lower response to the medication. This is why we believe it is important to have a 360-degree approach for glaucoma treatment, ranging from differentiated mono therapy to surgical devices, to answer different but all kinds of medical needs in glaucoma treatment.



Let me also highlight the two important projects that we are working on.

DE-117, or EYBELIS, is the product that we just launched in Japan last November. We are conducting Phase 3 trials in the United States as well as Asian countries. This product is a first-in-class product and uses a new mechanism of action by selectively targeting EP2 receptors. So unlike other prostaglandin F₂ analogs, this product shows a different safety profile in terms of both efficacy and safety. From an efficacy point of view this product has shown non-inferiority against latanoprost, while showing a different safety profile. And we believe this product will make a good difference for the treatment in glaucoma.

DE-128, or PreserFlo MicroShunt, is also another innovation for advanced glaucoma patients. This product

is currently in Phase 2/3, or PMA stage in the United States. Also, we have started small, “soft” launch activity in Europe. And today I'm delighted to also speak about updated schedule for *PreserFlo* MicroShunt for the US trials. We are going to complete the rolling PMA submission in this calendar year 2019, and plan to launch in 2020 once it is approved. This product is currently being tested against trabeculectomy, which is the standard care surgery. And we're hoping to show the benefit against trabeculectomy surgery. And then this product will also contribute for those advanced glaucoma patients.

Santen's Sustainable Growth into the Future

- To become a “Specialized pharmaceutical Company with a Global Presence”

Santen

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In the last chapter, I'd like to quickly talk about our company's vision and long-term future.

Vision 2020: Long-Term Vision Based on Santen's Values

Santen

2013 2017 2020

Specialized Pharmaceutical Company with a Global Presence

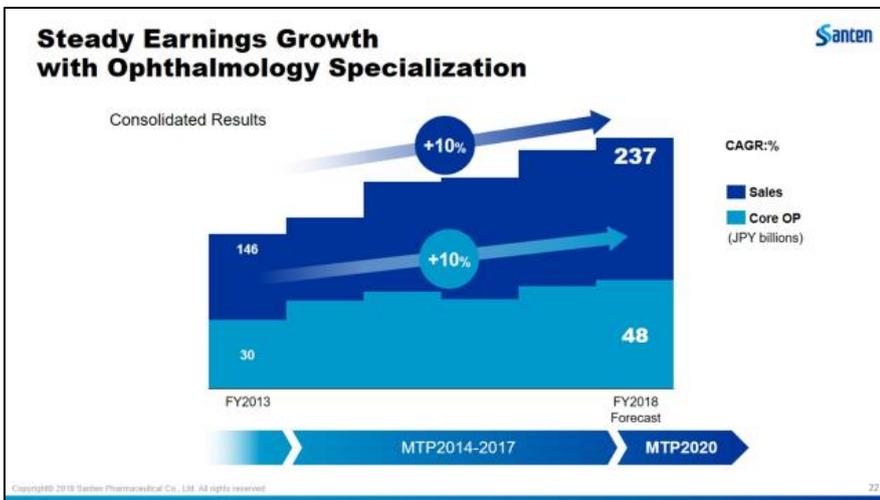
Maximize new global product value

Build and reinforce overseas businesses

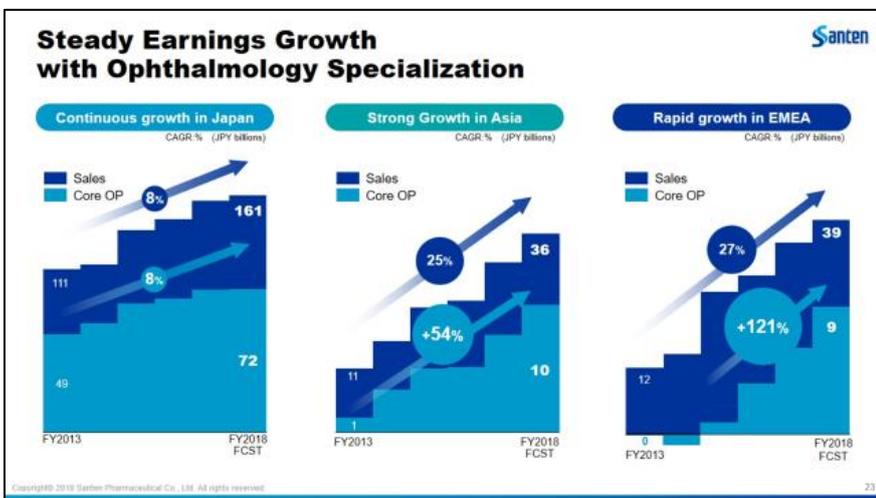
Strengthen Japan business framework and competitiveness

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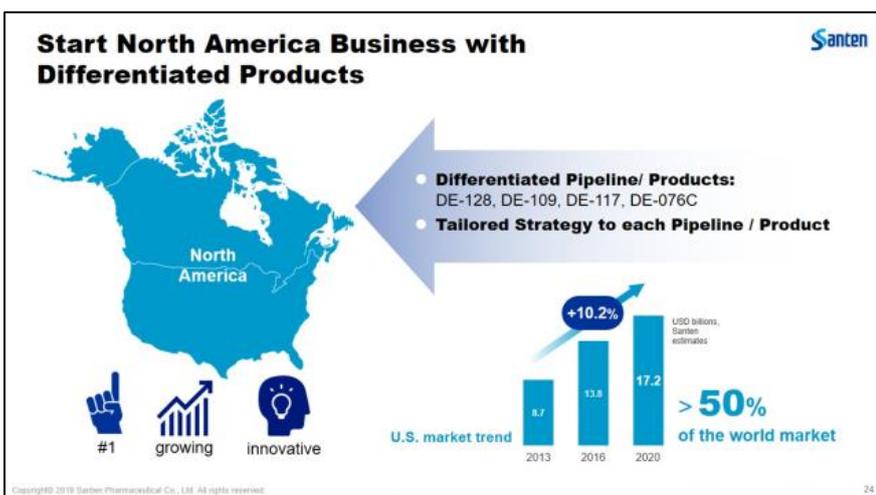
Vision 2020 is the long-term vision we set back in 2010. Based on this vision we have been developing our business mainly outside of Japan, while strengthening our business in Japan, to become a specialist pharmaceutical company with a global presence.



We believe steady growth is very important and we have been growing quite nicely, in a healthy manner, with 10% CAGR growth, in both sales and profit in the last five years, which is much faster than market average.

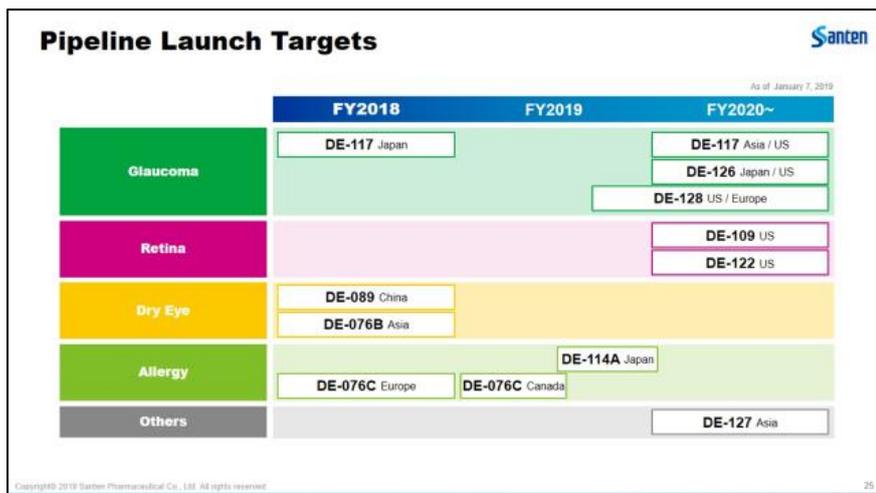


This has been driven by sustainable growth in the Japan market, as well as strong and rapid growth in Europe and Asia markets. Those two regions will continue to play a key role in Santen's globalization.

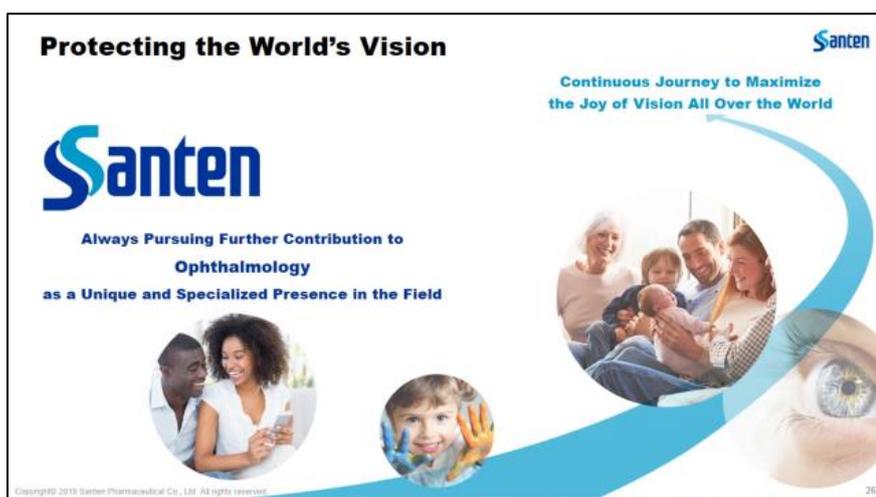


Last but not least, North America is our top priority agenda in coming years, as we are going to enter into market with *PreserFlo* MicroShunt, and hopefully DE-117. We have, of course, recognized the market environment is very tough, so we are focusing on differentiated areas, such as *PreserFlo* or DE-117 or 109 in order to become a differentiated but unique player in the market. We believe our pipeline will make a great benefit for Santen to become such a player. And we are hoping to talk about more updates in the coming

months or years.



This is summary of pipeline. As I mentioned, DE-117 was just approved and launched in Japan, and Phase 3 is ongoing in the United States. In the retina area, DE-109 additional trials have just started, while DE-122 is continuing. We have also made progress in dry eye and allergy. And we are quite confident that we can also further sustain growth with this pipeline.



Lastly, I'd like to sum up by saying we are committed to contributing to ophthalmology like no one else. Vision is very important for everyone and we hope that everyone in the world will spend a happy life with the joy of vision. Thank you very much for your time today.