

Tatsuya Kaihara – Corporate Officer, Head of North America Business, Santen Pharmaceutical Co., Ltd. & CEO, Santen Inc.



This is a very exciting moment for the Santen US affiliate

20.10.2020

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Tatsuya Kaihara, head of US operations for Japanese eyecare specialist Santen, describes his excitement at bringing two new ophthalmic advancements to the US market, the similarities, differences, and synergies of Japanese and American innovation, and the challenges of building a unified corporate culture.

Tatsuya, you were appointed president and head of North America in April 2020, but you have been with Santen’s US operations in various capacities since 2017, after a 16-year stint with Astellas. What brought you to Santen and what is your mission now as head of Santen’s North American affiliate?

During my time with Astellas, I had the chance to work across Japan, Belgium and the US. Astellas’s US operations had been established since the 1990s and I spent seven years in the US. On the other hand, while Santen also entered the US in the early 2000s, its focus was more on R&D and clinical development. The idea was to understand the market better, build a team with the right experience and expertise, and start product launches at the right time. The best-case scenario is always to launch products with an in-house team.

Our global R&D and clinical development functions have been headquartered in North America, in our Emeryville, California location for a while now. The R&D team built in the US has done a great job of working toward entering the next stage in the US: commercialization.

During the past three years with Santen in the US, I have served in different roles including chief strategy officer and chief investment officer of Santen Inc. During this time, I have been building the commercial team and portfolio for the US. My mission now as head of North America Business of Santen Pharmaceutical Co., Ltd. and president of Santen Inc. is to start Santen's US commercial business, beginning with our two anticipated product launches. We are hopeful about bringing promising ophthalmic advancements to patients and the doctors who treat them.

Globally, Santen has announced a new 2030 corporate strategy, including the adoption of a new slogan "to become a social innovator". How will this be seen in the North American market?

Fundamentally, Santen's vision places patients as our first priority. Santen is continuously looking at how we can bring more value to patients—encapsulated in our new slogan "Imagine Your Happiness." As one team, Santen strives to take on the challenge of resolving social issues related to eye health and bringing more values to our patients as a specialized company dedicated to ophthalmology. There are many patients requiring better prevention, diagnosis and treatment and we want to use our science and knowledge to deliver better outcomes for them. We endeavour not simply to make functional improvements in eyesight, but to improve experience value, contribute to society and thereby achieve happiness for each individual by focusing on vision.

We aim to connect with patients, their families and society as a whole. This means we need to listen to their concerns and expectations, and then provide patients with possible solutions including products and treatments focused on their eye health.

In other parts of the world where Santen's business is already established like Japan, Asia including China, and the Europe, Middle East and Africa (EMEA) region, Santen has already connected with patients and other stakeholders and surely expanded our business, but in the US we are not at that point yet. The US market is the largest ophthalmology market in the world, and we're ready to tap into this market that is so very important to our business.

We are very motivated to launch our first two products on the US market over the next year so that we can start connecting with stakeholders and engage with the market. Our goal is to deliver the best solutions within the ophthalmology space and to bring value to improve society. Once we have our products on the market, we will be in a better position to understand and meet market needs. From there, we can then move forward to develop concrete ideas on becoming a social innovator in the US market. This is a very exciting moment for the Santen US affiliate.

What are the first two products Santen will deliver to the US market?

With a strong focus on glaucoma, Santen North America's product pipeline is well-positioned to help address a significant unmet need in the US. Pending a positive decision from the US Food and Drug Administration (FDA), the first is DE-128 (PRESERFLO MicroShunt), an investigational surgical glaucoma implant designed to reduce intraocular pressure (IOP) in patients with primary open-angle glaucoma (POAG) whose IOP is not controlled when using maximum tolerated glaucoma medications. This was developed by InnFocus, a company we invested in and subsequently

acquired in 2016.

The second is a glaucoma pharmaceutical product that we plan to commercialize with the help from EyeVance, the US ophthalmology company we acquired in September 2020.

How has COVID-19 affected your market launch plans and, more generally, Santen's operations in the US?

Around March or April everything really slowed down. For instance, it became more difficult or even impossible to visit healthcare practitioners. The situation started improving in the summer and now, based on what I have heard from external stakeholders, people are discussing timelines for cautiously returning to the office as appropriate. We have proven that we can flexibly adapt to a new work environment and operate seamlessly by leveraging digital platforms and tools.

In terms of conferences and other networking events, they have all gone virtual, which have their pros and cons. In terms of scheduling and budgets, virtual conferences are beneficial since you do not have to arrange accommodation or transport, and you probably have more

time to fit more meetings in the day. While face-to-face communication is important, we would like to take advantage of the new virtual environment to further enhance our communication with others.

For Santen's operations, in March I decided to shut down our Emeryville headquarters office. With very few exceptions, everyone started working remotely, and those who had to be in the office would wear masks and use other personal protective equipment (PPE). We also have two manufacturing facilities in the US—in Santa Barbara and Miami—and both are still operating but with COVID-19 protocols in place to ensure the safety of our employees and patients.

What are the commercial expectations for Santen in the US for the next couple of years?

The US ophthalmology market is growing and we are very excited for the opportunity to enter this important region—the largest ophthalmology market in the world. There is of course some pricing pressure, as is the case in every market, but as long as you can deliver best-in-class or

first-in-class products and treatments that deliver value to patients, the outlook is good. Santen is an R&D-focused company delivering innovations to markets globally so we feel positively about our future in the US.

We continue to demonstrate and deliver differentiated value to grow this market. Through the recent EyeVance acquisition, which is very significant to us, we have gained part of their portfolio as well as their strong salesforce and marketing capabilities to help accelerate our business growth. This will further expand our commercial infrastructure, bring patients and doctors the latest innovations in ophthalmology, and provide opportunities for sustainable growth for Santen as a leading ophthalmology company. My goal is to integrate EyeVance into the Santen organization in order to successfully introduce a number of products into the US market over the next two to three years. This is a starting point of our next journey toward future growth.

One of Santen's strategic focuses for the US market is also to become a partner of choice for innovative companies and products in the US. You spent nearly two years as

head of innovation at Santen Ventures, Santen's venture investment arm in the US. What is Santen's strategy here?

This role was a great opportunity for me to oversee both the technology and commercial development of innovative products. The US is one of the most innovative science and technology markets, and the Bay Area is one of the top networking and innovation hubs which we are able to tap into through our North America headquarters. We connect with both academic and start-ups, and in general, we monitor market developments constantly. The moment we see an interesting opportunity that could benefit patients, we reach out to the team involved to explore the possibilities for collaboration. Typically, for interesting technology, we would invest first and monitor their growth before developing partnerships and/or acquisitions.

InnFocus, the company we acquired in 2016, is an example. Their MicroShunt is now being commercialized and is anticipated to be our first product approved in the US. The whole process took around five years in total.

Of course, Santen is a global company so we have R&D functions located globally. Ultimately, we are looking for solutions that can bring value to patients. What is the future of the sector and what kind of investments do we need? We have to be smart and think about what the business case for each product could be.

The US is seen as the most innovative healthcare market in the world but Japan is also well-recognized for its biomedical innovation. What do you see as similarities and differences between US innovation and Japanese innovation?

From my perspective, Japanese innovation is very organized while American innovation is more opportunistic. Both have their merits. This is, however, more apparent in the early stages of discovery and development because different countries approach science and research differently. But I believe companies from different regions are all equally driven by innovation. Great products have been developed by companies of different origins. In addition, for global companies, their teams are all international, incorporating different ways of working and cultures.

Having worked in different regions, I think while markets and cultures can differ, the fundamentals for pharma companies are the same everywhere: how can we deliver the best solutions to patients?

With Santen's US presence having been built in part through acquisitions, including EyeVance most recently in 2020 and InnFocus in 2016, how will you build a Santen corporate culture in North America?

This is very important. I have experience with post-M&A integration, as I was actually part of the project management team overseeing the merger of Yamanouchi and Fujisawa into Astellas in 2005. Though both are Japanese companies, one was based in Osaka and one was based in Tokyo, and the cultures in both companies were very different. My advantage was that I am personally from Tokyo but I work for Fujisawa, the company in Osaka, so I was able to understand both sides. This helped me appreciate how to create a new corporate culture for Astellas.

Thus, when Santen acquired InnFocus an East Coast company I was able to lead the integration of the company while working on the development of their MicroShunt product.

For Eyevance, I have been working to understand the Eyevance culture and to see how we can best integrate it with our ownâ??to build a new, enhanced culture at Santen in North America. We have a great culture today but we can always learn more. If we see positive elements in the companies we acquire, we should incorporate those qualities into our corporate culture, which would lead to building a stronger organization.

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