

# An Interview with the President and CEO

## TOWARD ACHIEVING THE MEDIUM-TERM MANAGEMENT PLAN



President and CEO  
Akira Kurokawa

### **Please tell us your thoughts about Santen's operating environment?**

First, I believe that the ophthalmic and anti-rheumatic areas in which Santen specializes will grow over the medium to long term. The reason for this is that demand for products in our areas of expertise will continue to rise as the rapid aging of populations in developed nations like Japan continues.

There are a number of important factors influencing the environment for medical services and thus Santen's operations. In Japan, these include the progressive decline in the birthrate and the concurrent aging of the population and the primary political issue of containing social security costs through NHI drug price revisions, reducing the level of remuneration for medical treatment and rationalizing medical institutions.

The restructuring of the industry on a global level through M&A and other means also affects Santen's business operations to some degree. We are truly facing the realities of an aging population and global competition.

In such an environment, Santen aims to focus our resources in areas where we can leverage our strengths as a specialty company excelling in ophthalmic and anti-rheumatic treatments to consistently provide pharmaceutical products and services that fulfill unmet medical needs and contribute to improving patients' quality of life (QOL).

### **One of the policies of the 2006–2010 Medium-term Management Plan is “generating growth in promising regions by leveraging strengths.” How is Santen progressing with this policy in relation to its principal business in domestic prescription pharmaceuticals?**

The Japanese market for prescription ophthalmic pharmaceuticals is expected to continue to grow, but due to the influence of NHI drug price revisions and other factors, the rate of growth is likely to be held to approximately 2% per annum. Competition is also

intensifying as competing companies enter the market. With these circumstances in mind, we are focusing investment of our management resources in areas with a prospectively strong growth outlook and are looking to achieve above-average growth. These areas of high potential include glaucoma and corneal disorders (dry eye), for which we forecast average annual sales increases of 4% and 7%, respectively.

In fiscal 2006 and 2007, Santen's domestic prescription ophthalmic pharmaceuticals business remained strong, despite intensifying competition. One reason was the success of our disease awareness campaign for dry eye conditions which contributed substantially to sales expansion of *Hyalein* a treatment for corneal and conjunctival epithelial disorders. We will promote our dry eye awareness campaign even more effectively in fiscal 2008.

We expect to receive approval for the glaucoma and ocular hypertension treatment DE-085 (Tafluprost) in the second half of fiscal 2008, and will work to achieve a smooth market launch and rapid uptake of this new product. In this way, we will further strengthen the foundation for our future growth. DE-085 (Tafluprost) will not make a large contribution to our results in fiscal 2008, however, it is expected to be the principal growth driver in the 2006–2010 Medium-term Management Plan. As such, I will personally take a leading and active role in ensuring its success.

### **Would you please update us on developments in Santen's overseas business?**

We are planning to expand our businesses in China, Russia, Northern Europe and Eastern Europe during the Medium-term Management Plan. These are all markets with high growth potential, where we can leverage our strengths on the foundations of our existing operations. We are targeting average annual sales growth in excess of 10% in China, Russia and Eastern Europe and approximately 5% in Northern Europe.

## “ Building toward becoming a global company, Santen creates new drug candidates and generates growth in promising regions by leveraging strengths. ”

In China, we plan to achieve a growth rate higher than the market in general, primarily as a result of strong sales of the anti-infective ophthalmic solution *Cravit*, and the corneal and conjunctival epithelial disorder treatment *Hyalein*.

We have been quite reliant until now on in-licensed products in our European businesses, but are working to change the structure of these businesses by bringing new in-house products into the lineup. We aim to maximize value in Europe with the success of the glaucoma and ocular hypertension treatment DE-085 (Tafluprost) and anti-infective ophthalmic solution *Oftaquix* (sold as *Cravit* in Japan). *Oftaquix* has already been launched in 24 countries, including Russia. DE-085 (Tafluprost) was launched in Germany in June 2008 and will be released in seven other European countries in fiscal 2008.

### How is Santen's medium-term objective of “enhancing the global strategic pipeline” progressing?

Our fundamental strategy of speeding up the process of developing, creating and marketing a final product by honing our R&D focus and allocating management resources on the core therapeutic areas of glaucoma, corneal disorders and retinal disorders remains unchanged. This strategy forms the basis of our corporate mission to create innovative and competitive new drugs that fulfill unmet medical needs and is also essential in securing future growth in sales and profits.

In the current plan, we are at the stage of preparing new, highly competitive global strategic product candidates and are concentrating on clinical development. As a result of these efforts, we have made solid progress in fiscal 2006 and 2007, with the development of the global strategic product DE-104 in the glaucoma area and DE-101 (Rivoglitazone) in the dry eye area.

We are also focusing our attention on business development activities in core areas—areas where we can leverage our strengths—and in May 2008 acquired the development and marketing rights for all ophthalmic indications in Japan and Asia of DE-109 (Sirolimus) from MacuSight, Inc. (U.S.), thus enabling us to strengthen our range of new drug candidates in the field of retinal disorder treatments.

Expansion in the global market for treatments for diseases of the back of the eye, including glaucoma and retinal disorder fields, has generated increasing competition, so in-licensing is becoming more and more difficult every year. In this environment, I believe it is vitally important for management to be able to correctly evaluate the potential of a prospective pharmaceutical product by staying informed of new developments in worldwide scientific information and grasping new trends at the medical facility level faster than anyone else.

### How is Santen moving forward with its medium-term policy of “strengthening manufacturing bases” ?

Each year, Santen manufactures approximately 250 million bottles of prescription ophthalmic solutions. On a volume basis, this is the highest number produced by any company in the world and represents 56% of the Japanese market. We are proud that in addition to the superior operational capabilities that allow us to maintain this production volume, we possess in-house technology to manufacture the Dimple Bottle<sup>1</sup>, which together makes us highly competitive in the market.

Under the current Medium-term Management Plan, we intend to further strengthen the base of our manufacturing activities on a global level by constructing a stable manufacturing and supply system with improved risk management and highly efficient operations in which every plant has a well-defined role in the system.

In 2007, our Shiga Plant was granted GMP (Good Manufacturing Practice)<sup>2</sup> certification by the European Union. I feel this is a crucial step toward Santen's globalization. In the future, we hope to create a manufacturing and supply system that is not bound by national borders and which can take full advantage on a global level of the strengths we have cultivated in our Japanese business. A notable move in this direction is the commencement in 2008, of packaging operations at our Suzhou Plant in China, construction of which was completed in 2007.

1. Developed in-house as an easy-to-hold, easy-to-use ophthalmic solution container.

“Dimple” is a registered trademark of Santen Pharmaceutical Co., Ltd.

2. A set of standards regarding manufacturing management and quality control of pharmaceuticals and quasi-drugs.