

Toward a New Stage: The 2006–2010 Medium-term Management Plan

An interview with Chairman and CEO, Takakazu Morita on Santen's new medium-term management plan

“By leveraging our unique strengths, we aim to be a company that makes a significant and worthwhile contribution to patients worldwide.”

Takakazu Morita Chairman and CEO



Q.1

Before we discuss the new medium-term management plan, could you first tell us where you see Santen now? What has the company achieved to date?

Santen has concentrated in the fields of ophthalmology and rheumatology. As a specialty company, we have deliberately focused our resources in areas where we can leverage our strengths. This approach has helped us carve out a distinctive identity.

In research and development, which is the source of our growth, we have channeled our resources by concentrating on research themes in the core therapeutic segments with unmet medical needs. These priority areas are glaucoma, corneal conditions such as dry eye, and retinal disorders. This focus has yielded a steady stream of new drug candidates, principally in these core therapeutic segments. We have also targeted acceleration of new drug development, and have succeeded in substantially reducing the time required for preclinical and clinical studies.

Next, in our Japanese business, we have secured the number-one position in the prescription ophthalmics market. These operations are now firmly established as the mainstay of our revenues. Our sales and marketing capabilities in our chosen fields are second to none in Japan. We have a full product portfolio, and extensive experience and expertise which allow us to meet the market needs in Japan.



Nara Research and Development Center

In overseas markets, we began developing operations at an early stage to support our goal of becoming a global company. We started clinical development of drugs in the United States in 1993 and in Europe the following year. In 1997, we acquired a Finnish ophthalmic pharmaceutical manufacturer. We have achieved notably high market positions in Northern Europe, Eastern Europe and Russia. Today, we are also the market leader in China.

On the production front, besides consistent cost-reduction efforts, we have also succeeded in raising manufacturing productivity through the introduction of the new *Dimple Bottle*. This has improved patient utility and drug identification. We can manufacture ophthalmic pharmaceuticals of world-class quality at a highly competitive cost.

Q.2

You have always emphasized Santen’s global development as a long-term theme. Please elaborate.

Long-term Vision:

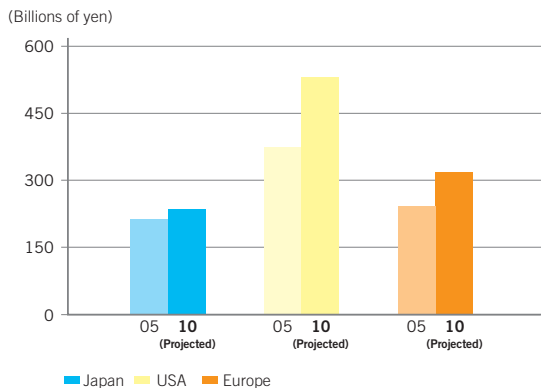
- World-class company
- Leader in the ophthalmic and anti-rheumatic fields
- R&D-oriented pharmaceutical company specializing in ophthalmology and other areas where we can leverage our strengths

There are two reasons why we have made Santen’s global development a long-term theme. First, this thinking is based on our core value.

Our mission is to focus on specific areas of expertise, such as eye care, developing our unique capabilities and technologies, and contributing to the health and quality of life of patients and their loved ones, and society as a whole. Today, although our products are prescribed widely in Japan, that is certainly not the case in many other markets. There are still many countries where we can use our experience and expertise to improve the medical treatments available to doctors and patients.

The second reason for global development is its commercial importance. The global ophthalmic market is growing at very different rates in various regions. For instance, in the period from 2005 to 2010, annual growth in the ophthalmic market is projected to average 6% around the world. But looking at this in terms of countries and regions, the compound annual growth rate (CAGR) is expected to be a relatively low 2% in Japan. This compares with the United States and Europe, where CAGRs of 7% and 6%, respectively, are predicted and growth is expected to be at least 10% in China and Russia. In all of these important geographic regions the growth rates are consistently higher than in Japan. This shows that we cannot afford to limit our efforts to the Japanese market if we want to achieve higher growth for the corporation. Our continued ability to fulfill our mission of providing improved health and quality of life to patients depends on our ability to meet the challenge of achieving success in overseas markets.

Ophthalmic Pharmaceutical Market Size by Region (Actual and Projected)



Source: Santen analysis based on IMS data
 IMS MIDAS (U.S., Major Western European Countries, Northern Europe, Eastern Europe), 2005, Copyright IMS 2006
 IMS JPM (Japan), 2005, Copyright IMS 2006. All rights reserved.

Q.3

What is the plan for Santen's development as a global company?

We have set fiscal 2015—10 years from now—as the target date for realizing our plans for Santen's global development. We view our path as a two-stage process.

We have positioned the five-year period from fiscal 2006 to the end of fiscal 2010 as the first stage. During this time, our aims are to further Santen's global development by creating a strong pipeline of new drug candidates and by actively developing operations in regions where we can leverage our strengths. We have formulated four medium-term strategic policies to guide our efforts during this period. First, we aim to enhance the global strategic product pipeline through internal discovery and development, joint development projects and in-licensing efforts. Second, we will generate growth mainly in Japan, Northern/Eastern Europe, Russia and China while focusing our U.S. activities on clinical and business development. Third, we are strengthening our manufacturing bases. Fourth, we aim to strengthen human resources and organizational capabilities on a global basis. Based on this strategy, we aim to achieve solid growth in the first stage.

In the second five-year period from fiscal 2011 to the end of fiscal 2015, we hope to reap the fruits of our investments in R&D. During this stage, we aim to achieve higher rates of growth as we realize our global ambition, which includes continuing to expand our business in the U.S. market.

Q.4

What is Santen's fundamental R&D strategy?

The fundamental strategy that we have applied consistently over the years is to invest selectively and to concentrate resources on research themes in those areas where there are significant unmet medical needs which we can meet with our unique capabilities and where there is significant growth potential. This strategy is unchanged in the medium-term management plan.

In drug discovery, we focus on areas where there is high medical demand and where we can demonstrate our competitive edge. Our basic aim is to increase the number of new drug candidates that are highly competitive internationally, focusing primarily on next-generation drugs.

Turning to specifics, our core therapeutic segments are glaucoma, corneal conditions and retinal disorders. The network-based approach that we have developed for drug discovery aims to leverage the benefits of collaborative development activities. This means that we combine competitive internal resources with advanced technology from external sources to search for drug discovery targets and to acquire development compounds.

On the development side, we are devoting the majority of our efforts to ensuring that we properly develop those compounds that are likely to drive the growth of our prescription pharmaceuticals business.

Our immediate priority is to gain manufacturing and marketing approvals for the three products that we plan to launch within the period of the new medium-term management plan. These are DE-085, a treatment for glaucoma and ocular hypertension; DE-089, a treatment for corneal and conjunctival disorders; and MD-14, which is an intraocular lens.

Next in the development pipeline are a group of global strategic products that we are planning to launch from 2011 onward (DE-104 for glaucoma and ocular hypertension; DE-096 for retinal disorders that is also an anti-rheumatic; and DE-101 for corneal and conjunctival disorders) and a group of global products (DE-102 for retinal disorders; and DE-099 for corneal and conjunctival disorders).

We have also taken steps to strengthen our global portfolio by creating a strong development pipeline including back-up candidates. In this way we hope to maximize the chances of success for each product in our pipeline.

In addition, we have continued to work on improving our research and development processes. Between fiscal 2003 and the end of fiscal 2005, we specifically targeted an acceleration of clinical development. In the period from fiscal 2006 through fiscal 2010, in addition to maintaining our focus on accelerating our development process, we aim to integrate the drug development processes across our regional R&D centers in Japan, the U.S. and Europe, with additional links to major countries within the Asian market. This is vital in order to create an effective process for developing global strategic products.

Santen's definition of a "global strategic product":

A drug candidate with a novel mechanism of action that has the potential to generate higher sales than current products. Such a product would be marketed in Japan, the U.S. and Europe.

Santen's definition of a "global product":

A drug candidate with an improved mechanism of action compared with existing drugs and that has the potential to generate sales on a par with current products. Such a product would be marketed in Japan and some overseas markets.

Q.5

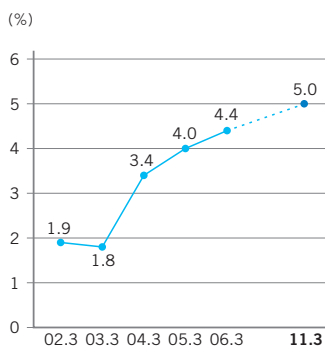
Could you tell us about Santen's policies on dividends and other profit distributions to shareholders?

Santen treats the distribution of profit to shareholders as a key management focus. To date, our policy has been to set dividends at a level that is commensurate with performance while at the same time maintaining capital efficiency and keeping a sound and flexible financial position that will allow us to pursue product acquisition, licensing and alliance activities and to build up sufficient retained earnings to fund our long-term growth strategy. We have also made effective use of share buybacks and retirements in a flexible manner. Going forward, this approach will remain our profit distribution strategy.

In the 2006–2010 Medium-term Management Plan, with the aim of generating a future stream of profits to fund more consistent and stable dividends to shareholders, we have adopted the dividend-on-equity (DOE) ratio as a new performance indicator to measure dividends. DOE is calculated by multiplying the payout ratio by return on equity (ROE). We aim to raise DOE to 5.0% by fiscal 2010. This approach is a good way of boosting returns to shareholders in the form of dividends while also improving capital efficiency.

Furthermore, in addition to dividends, we plan to be more proactive in undertaking share buybacks. Our aim over the next five years is thus to have a consistent management focus on providing an appropriate return of profits to our shareholders.

DOE Ratio



An interview with President and COO, Akira Kurokawa on Santen's new medium-term management plan

“We aim to achieve growth by successful launch of new products by focusing resources on those regions where we can make the most of our strengths.”

Akira Kurokawa President and COO



Q.1

What are the sales and profit targets in the new plan?

For the final year of the new plan, fiscal 2010, we have set minimum performance targets of ¥115 billion in net sales, operating income of ¥32 billion, net income of ¥22 billion and ROE of 13%. Compared to our results in fiscal 2005, these targets equate to prospective CAGRs of over 3% for net sales and 8% for operating income.

There are three factors that we see contributing to the higher growth rate for operating income relative to net sales. First, during the plan period, we expect to launch products that we have developed in-house for glaucoma, for corneal disorders, and in intraocular lenses. Second, our strategy is to generate growth increasingly from high-value-added products for which there is substantial untapped market demand. Third, we expect to generate ongoing cost savings from the continuing rationalization of our production lines. I believe that these various initiatives will more than absorb higher spending on R&D and promotion. I feel confident that we can hit the targets we have set.

Q.2

How do you aim to develop Santen's prescription pharmaceuticals operations in Japan, and what are the major business objectives?

We forecast a CAGR of approximately 2% for the Japanese prescription ophthalmics market in the period from 2006 through 2010. How we expand sales and raise profitability in this market will be a major determinant of Santen's overall financial performance during the next five years.

We have already established a strong promotional base in Japan in the specialized areas of ophthalmic medicine and rheumatology. Our basic strategy in these fields—in both of which I believe we can maximize our strengths—is to launch new products while at the same time working to expand sales of the existing product portfolio.

Turning first to the glaucoma market, we expect this market to achieve a CAGR in volume terms of 5% over the next five years. In the plan period we expect to launch DE-085, a prostaglandin treatment for glaucoma that we developed in-house. Our objective is to effectively market this drug so that we can derive

the maximum market value as quickly as possible. Using our overwhelming sales presence in this market—one of our greatest strengths—we plan to quickly raise awareness for the new drug and thus maximize prescription numbers.

Next, in the market for corneal conditions, a volume CAGR of approximately 8% is forecast. This reflects a number of factors driving growth in the dry eye market, such as increasing numbers of people wearing contact lenses or using personal computers or other equipment with display monitors for long periods, plus the ongoing aging of the population. In this segment, one goal is to expand sales of our existing product *Hyalein*. We also expect to launch DE-089 as a new treatment for corneal disorders in the latter half of the plan period. Once we have both drugs on the market, this will improve our ability to offer medical professionals a wide range of treatment options for varying medical conditions within this segment. We also plan to conduct campaigns to boost awareness of dry eye among patients. Through an effective combination of these approaches, we intend to realize increased sales and profits from this segment.

We expect the needs of medical professionals to become more diverse. We also anticipate fiercer competition due to the entry of rival companies. In such a competitive business environment, it is critical that we continue to raise the quality of our promotional activities so we can ensure a successful launch for all new products. To this end, we are increasing the number of specialist medical representatives in both ophthalmology and rheumatology as well as further enhancing training programs focused on scientific knowledge and professional skills in both fields.

Q.3

What is Santen's business development strategy in overseas markets?

In the five years to 2010, our overseas business strategy is, first, to concentrate on priority regions. We are tailoring the development of each of these regions to their specific characteristics.

In terms of actual regions, we plan to focus most of our development efforts on countries where growth is expected, where we have already built up a certain commercial presence and where we can make the most of our strengths. These regions are Northern Europe, Eastern Europe, Russia, Germany and China.

In Northern Europe, Eastern Europe and Russia, we are using in-licensing of local European products to supplement the sales of our existing lineup so that we can boost our overall market presence. Over the next five years, we aim to increase sales within this region to ¥9.0 billion, which is equivalent to a CAGR of approximately 8%. In particular, we plan to enhance our position within the growing Russian market for prescription ophthalmics through the launch of our anti-infective *Ofthaquix*. This will add to the growth that we have achieved with our existing lineup of cataract treatments. In Northern Europe, Eastern Europe and Germany, we will boost promotional efforts to increase sales, particularly in the two key therapeutic segments of glaucoma and corneal disorders.

In China, we aim to achieve sales of ¥4.5 billion within five years, which is equivalent to a CAGR of about 25%. We have been targeting the huge potential of the Chinese market for many years now. We began exporting to China in 1988, and today we are the market leader in our target segments. We are also taking the steps necessary to build a robust base of in-house operations within the country. In 2005, we

established a local subsidiary Santen Pharmaceutical (China) Co., Ltd., to conduct manufacturing and direct sales and marketing in China. Using this new base, we have adopted sales and marketing techniques based on academic studies and other medical information. Our promotional goals are to make our main-stay products *Cravit* and *Hyalein* first-choice prescription drugs within the Chinese market.

In the United States, while continuing to develop the business by promoting our existing product lineup through the sales partnership with Johnson & Johnson Vision Care, Inc., we are also focusing on further development of our in-house capabilities for both clinical development and business development.

Q.4

What is Santen's strategy in HR and organizational management?

Whether you are trying to create and manufacture a product or whether you are trying to achieve your plan targets, my personal belief is that people and organization are vital.

It is important to tap the potential of employees and develop their abilities in order to create a strong organization. We value an open and fair atmosphere in which employees can work proactively.

We are strengthening development of Santen's human resources in Japan. This is critical if we are to stake claim to an even higher position in our home market, particularly with overseas firms providing much stiffer competition these days. I believe that we also have to put a lot of effort into overall HR development so that we can forge the internal talent pool needed to realize Santen's transformation into a global company.

In terms of upgrading our organizational management, we are focusing on three areas: R&D, production and strategic marketing.

Within R&D, we are developing integrated clinical development functions across Japan, Europe, the U.S. and Asia with the aim of sharing data between regions and making our clinical development more efficient. Our goal is to upgrade our R&D capabilities so that we have a high-quality, high-speed global clinical development capacity. We are also working to integrate regulatory functions within global drug development.

We are seeking to integrate capabilities worldwide on the production side, too. We plan to optimize production across our three regional manufacturing bases in Japan, Finland and China.

Finally, in strategic marketing, our goal is to establish a global marketing function to ensure our product development efforts support our commercialization goals and prepare for the launch of the global strategic products currently in development.

Through these strategic initiatives we aim to create a stronger and more talented organization. Besides helping us to achieve the medium-term plan objectives, these moves will also help us to further improve our corporate value.