

Feature

Building Toward a Global Company

Santen creates a significant variety of new drug candidates and generates growth in promising regions by leveraging its strengths.



Santen announced the 2006-2010 Medium-term Management Plan in July 2006. The plan aims to create a significant variety of new global strategic drug candidates and generate growth in promising regions by leveraging our strengths. We have positioned this plan as the first phase toward our long-term vision to become a global company by 2015.

For the final year of the new plan, 2010, we have set minimum performance targets of ¥115 billion in net sales, operating income of ¥32 billion, net income of ¥22 billion and an ROE of 13%. We plan stable and continuous returns to our shareholders during this period.

R&D expenses for the plan period are estimated at ¥16 billion annually. We will seek approvals for new drug candidates in our development pipeline, thereby securing our revenue base. By using an effective drug discovery approach, we will develop and enhance our internationally competitive pipeline allowing Santen to accelerate global growth in the second phase beginning in 2011.

Enhance the Global Strategic Product Pipeline and Accelerate R&D

Santen categorizes new drugs as global strategic products or global products. Global strategic products are drug candidates with a novel mechanism of action that have potential to generate higher sales than existing products. Our plan includes selling global strategic products in Japan, the United States and Europe. Global products are drug candidates that are an improvement of existing mechanisms and for which the anticipated sales are on par with existing products. We

generally plan to sell global products in Japan and certain overseas markets.

One of our important management initiatives is to accelerate the research and development process of global strategic products and global products and launch these drug candidates as soon as possible. Therefore, we have focused our R&D efforts on the core therapeutic areas of glaucoma, retinal and corneal disorders including dry eye. (Please see Medium-term Policy 1. on page 10.)

Medium-term Policy 1: Enhance Global Strategic Pipeline

Santen's consistent R&D strategy is to focus efforts on areas where there are significant unmet medical needs, where our strengths can be fully utilized and where there is significant growth potential. Specifically, such fields include glaucoma, retinal disorders and corneal disorders (dry eye). Developing new products in these fields represents the underlying foundation of our growth strategies.

The global strategic products currently under development are as follows:

● DE-101 (Generic name: Rivoglitazone)

【Corneal and conjunctival epithelial disorders associated with dry eye】

DE-101 is an eye drop that effectively improves conditions caused by corneal and conjunctival epithelial disorders including dry eye. With a novel mechanism of action that differs from any drugs currently on the market or under development, DE-101 works directly on the corneal and conjunctival epithelial cells. Santen and DAIICHI SANKYO COMPANY, LIMITED, entered into a contract for exclusive global development and manufacturing. Currently, the Phase II clinical trial for this drug is underway in the United States.

● DE-104 (ROCK inhibitor)

【Glaucoma and ocular hypertension】

DE-104 has a mechanism of action which differs from that of existing drugs and works directly on trabecular cells to facilitate the outflow of the aqueous humor and powerfully reduce ocular pressure. This drug is being developed through a collaboration between Santen and UBE INDUSTRIES, LTD. Currently, the Phase I clinical trial is underway in the United States.

During the period of this Medium-term Management Plan, we plan to file applications for or launch the following new drug candidates mainly in Japan.

● DE-085 (Generic name: Tafluprost)

【Glaucoma and ocular hypertension】

DE-085, which facilitates the outflow of the aqueous humor from the uveal and scleral channels, exhibits a powerful and stable effect for alleviating ocular hypertension. In July 2006, we filed for manufacturing approval in Japan and, in April 2007, we filed for marketing approval in Europe. In the United States, we will decide whether to apply for approval based on discussions of future operations.

● DE-089 (Generic name: Diquafosol tetrasodium)

【Corneal and conjunctival epithelial disorders associated with dry eye】

DE-089 is a drug to treat corneal and conjunctival epithelial disorders mainly caused by dry eye by facilitating the secretion of components of lacrimal fluid and water out of the corneal and

conjunctival epithelia. The use of DE-089 with existing drugs is also possible. Currently, the Phase III clinical trial for this drug is underway in Japan.

● MD-14 (Intraocular lenses)

【Foldable intraocular lens using acrylic materials with a high refractive index】

MD-14 is an intraocular lens developed by Advanced Vision Science, Inc., one of Santen's U.S. subsidiaries. We obtained the manufacturing and marketing approval in Japan in October 2006. In the United States, preparation for application is underway.

In this way, Santen is gradually developing and commercializing various new drug candidates. To expedite R&D and enhance the probability of commercialization, Santen adopts the following three methods for drug development.

The first method is to identify chemical compounds through in-house drug discovery. The second method, called "network-based drug discovery," is a collaborative research method that links Santen's accumulated knowledge and expertise with advanced external technologies. The third method is strategic licensing and introducing chemical compounds owned by other companies.

For each development candidate, Santen prepares backup compounds to strengthen our global portfolio and to maximize the chances of success for commercialization.



Research workers at the Nara Research Center and Development Center and Santen Oy

Clinical Trials

When safety and efficacy of candidate compounds are determined in preclinical studies, they undergo the following clinical trials. After completing the Phase III clinical trials, a new drug application (NDA) is filed for marketing approval.

- **Phase I**
Tests to check drug safety with a small number of healthy volunteers.
- **Phase II**
Tests to determine dosage and administration method with a small number of patients.
- **Phase III**
Tests to confirm safety and efficacy by comparing to existing drugs and placebo with a large number of patients.

Pipeline of prescription pharmaceuticals (Clinical studies)

As of July 31, 2007

Generic name	Brand name/ dev. code	Indication	Region	Phase I	Phase II	Phase III	NDA Filed	Approved	Launched	Characteristics
Levofloxacin (0.5%)	Cravit	Bacterial conjunctivitis	Japan	→ April-2000						Fluoroquinolone antibacterial agent. Levofloxacin + prednisolone A is a combination treatment with steroids.
	Quixin		USA	→ November-2000						
	Oftaquix		Europe	→ May-2002						
Levofloxacin + prednisolone A	DE-094	Infectious keratitis	USA	→						
Tafluprost	DE-085	Glaucoma/ Ocular hypertension	Japan	→ July-2006						Please see Page 10.
			Europe	→ April-2007						
			USA	→						
Diquafosol tetrasodium	DE-089	Corneal and conjunctival epithelial disorder associated with dry eye	Japan	→						Please see Page 10.
Olmesartan	DE-092	Glaucoma/ Ocular hypertension	Japan	Pilot study →						The angiotensin II receptor antagonist. In Japan, Europe and the USA, the Phase II studies did not demonstrate clear dose-response relationship, and therefore we decided to suspend clinical studies. We are now conducting the Phase II pilot study with different formulation.
			USA/ Europe	Pilot study →						
Lomerizine HCL	DE-090	Glaucoma	Japan	→						A new type of oral glaucoma treatment studied for inhibiting the progression of visual field defects. The only calcium antagonist in full-fledged development as a glaucoma treatment. Compared with NMDA receptor antagonists, fewer generalized side effects are expected, thus having excellent safety. Marketed by Nippon Organon as a migraine drug.
(Undetermined)	DE-096	Rheumatoid arthritis	Japan	→						An oral TNF inhibitor. Anti-rheumatic effect comparable to injectable biological agents. In addition to RA, the effect on DME was also observed in basic research, and the Phase II studies are being conducted with both diseases.
		Diabetes macular edema	Japan	→						
Gefarnate	DE-099	Corneal and conjunctival epithelial disorder associated with dry eye	Japan	→						Treats corneal and conjunctival epithelial disorder mostly associated with dry eye, by stimulating the secretion of mucin and promoting the corneal epithelial migration. Preservative-free eye ointment that can be used in combination with existing drugs.
Rivoglitazone	DE-101	Corneal and conjunctival epithelial disorder associated with dry eye	USA	→						Please see Page 10.
(Undetermined)	DE-102	Diabetes macular edema	Japan	(Phase I/IIa) →						A steroid microsphere product for a sustained release injectable drug delivery. Demonstrated sustained efficacy when injected around the affected area. In order to produce sterile microsphere in commercial scale, we collaborate with Oakwood Laboratories (USA).
(Undetermined)	DE-104	Glaucoma/ Ocular hypertension	USA	→						Please see Page 10.
(Undetermined)	DE-103	Allergic conjunctivitis	Japan	→						A PDE4 (Phosphodiesterase type 4) inhibitor for allergic conjunctivitis which has a different action mechanism from the existing drugs. Expected to be effective for allergic conjunctivitis through its inhibitory effect against PDE4.

Medium-term Policy 2: Generate Growth in Japan, Northern/Eastern Europe, Russia and China. Focus Activities on Clinical and Business Development in the United States

During the Medium-term Management Plan, Santen will concentrate its management resources in regions such as Japan, Northern/Eastern Europe, Russia and China, where it already has a business presence and its strengths can be used to achieve steady growth.

① Business Strategies in Japan

▶ Priority strategy

Maximize the product value of new products for glaucoma and corneal disorders, and new intraocular lenses, while also generating growth through promotion of existing products.

Under the current Medium-term Management Plan, we will strive to further increase our share in the Japanese prescription ophthalmic market—our core market—by introducing new products and expanding sales of existing products based on the solid promotional platform established through the 2003-2005 Medium-term Management Plan.

In fiscal 2006, we filed applications for approval to manufacture and market the glaucoma and ocular hypertension treatment drug DE-085 (Generic name: Tafluprost). In fiscal 2007, we started full-scale preparations for the launch of this product including pre-marketing to expedite market penetration and maximize product value as soon as possible after its release in fiscal 2008.

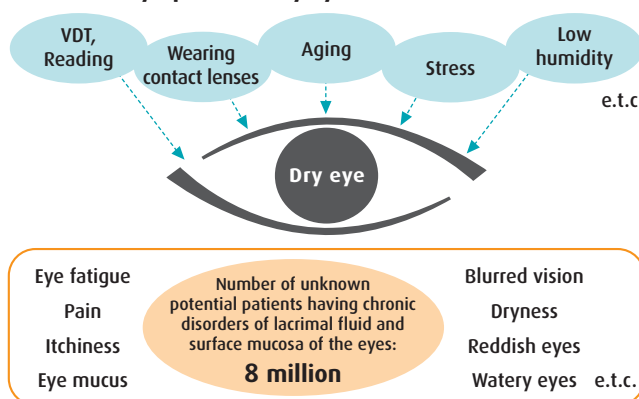
In early fiscal 2007, Santen implemented dry eye-related disease awareness activities for corneal disorders in certain regions. By promoting self-checkups and educational activities via newspapers and other media, we believe Santen's presence in the field of dry eye has been further strengthened. In the future, we will expand the regions for such activities and implement larger-scale educational efforts which we anticipate will further increase sales of *Hyalein*, that now boasts the top share in this field. *Hyalein* stabilizes the tear layer, has a moisturizing effect

and treats corneal and conjunctival epithelial disorders.

The development of several new products in the field of dry eye is also underway.

In October 2006, Santen acquired approval to manufacture and market MD-14 intraocular lenses in Japan. MD-14 is a foldable hydrophobic acrylic lens with a high refractive index. We are preparing to market in Japan in fiscal 2007.

Causes and symptoms of dry eye



Note: Visual Display Terminals (VDTs) refer to screens and display units of personal computers, TV games and mobile phones.

② Business Strategies in Northern/Eastern Europe and Russia

▶ Priority strategy

Maximize the product value of *Oftaquix* and existing products.

Santen began activities in Europe with clinical development in 1994. In 1997, we acquired an ophthalmic company in Finland, establishing our presence in Northern Europe, Eastern Europe and Russia. Under the 2003-2005 Medium-term Management Plan, we expanded sales of existing products, which raised awareness of the Santen brand and fueled a sales increase. In Northern Europe, Eastern Europe and Russia, the glaucoma and

corneal disorder fields are important in the current plan period. As a new drug candidate for glaucoma, we filed application for approval to market DE-085 for glaucoma and ocular hypertension in April 2007.

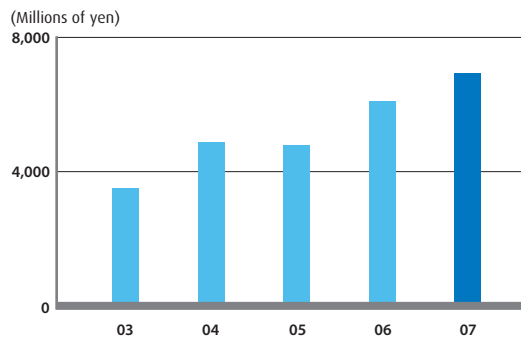
In each country, Santen will continually reinforce promotional activities for existing products, further strengthening the Santen brand. In Russia, where the prescription ophthalmic market has

expanded rapidly, we will launch the anti-infective ophthalmic *Ofstaquix* (sold as *Cravit* in Japan) in fiscal 2007. We will use the opportunity of this launch to leverage our presence in Russia.



The Nordic Congress of Ophthalmology (NOK) held in Copenhagen, Denmark, in June 2006

Transition of sales in Europe



③ Business Strategies in China

▶ Priority strategy

Improve competitiveness and growth by shifting to operations through a local manufacturing and sales subsidiary.

In China, which features tremendous and rapid economic advances, the prescription ophthalmic market will continue to see double-digit growth leveraged by both the aging society and the increasing number of insured people. A significant supporting factor of such growth is large hospitals. Although they account for only 20% of the total number of medical facilities, large hospitals account for approximately 80% of total sales. Santen has established an excellent brand image featuring high quality in large hospitals in the metropolitan areas of China, resulting in a large share of the market.

In 2006, Santen established Santen Pharmaceutical (China) in Suzhou, Jiangsu Province, integrating the entire process from manufacturing



through marketing locally, which we believe is vital to maintain a top share and enhance competitiveness in the promising Chinese market. Santen's manufacturing facility in China is scheduled for completion in 2007, and operations will begin in 2009. In addition, for the subsidiary to conduct sales activities independently, we began the education and local employment of MRs in 2007. Through sales activities providing medical information, we strive to have an increasing number of people choose our mainstay products such as *Cravit* and *Hyalein* as first-choice drugs.



Rendering of the plant in Suzhou at its completion

④ Business Strategies in the United States

▶ Priority strategy

Focus on clinical and business development.

In the United States, Santen conducts marketing activities for existing products under a sales partnership with Johnson & Johnson Vision Care, Inc. (JJVCI). We intend to maintain this sales channel. The United States is also one of our important bases for clinical development—a vital part of the process to develop new

drugs. Currently, clinical development for DE-101 to treat corneal and conjunctival epithelial disorders including dry eye and DE-104 to treat glaucoma and ocular hypertension are underway as planned.

Medium-term Policy 3: Strengthen Manufacturing Bases

▶ Priority strategy

Reorganize manufacturing lines for higher efficiency.

Santen is reorganizing manufacturing lines in Japan, Finland and China on a global basis to reinforce manufacturing capabilities on a medium- to long-term perspective. Specifically, we are addressing the following three areas:

- Enhance the efficiency of manufacturing lines by adopting a manufacturing method tailored for each area. Continually reduce costs based on our global site planning covering the Suzhou plant operation, which is scheduled to begin production in 2009.
- Develop strong, autonomous production facilities. Build a highly productive plant that can ensure the capacity to supply overseas markets through such measures as shortening lead times while maintaining and improving product quality.
- Focus on strategic manufacturing planning and technology

development. Enhance strategic management methods and technology to improve product quality and reinforce the effectiveness of new products.

During the term of this Medium-term Management Plan, we will establish three linked and cooperative manufacturing bases in Japan, Finland and China to enhance the efficiency of our global-scale manufacturing activities.



Staff at the Noto Plant, Japan

Medium-term Policy 4: Strengthen Human Resources and Organization at the Global Level

▶ Priority strategy

Develop human resources and reinforce and reorganize our system and structure.

It takes high-caliber human resources and an efficient, functional system to achieve Medium-term goals and a long-term vision. Santen is promoting a human resources education program through which an appropriate position and responsibilities are allocated to each employee according to his/her ability and potential. As a systematic reform initiative, we seek optimal decision-making and operating processes to achieve our goals.

Based on data collected and organized in 2006 from each person's specific aptitude and skills, we will formulate a specific plan to further train employees in 2007. We will develop employees who are capable of global and strategic business decisions and assign them to the appropriate positions.

We manage to optimize our organization in three areas—R&D, manufacturing and strategic marketing. In addition to independent decision making in each sector, we need to strengthen cross-functional collaboration in the future in order to approach to solve the management issues, quickly and flexibly.

Santen aggressively promotes effective employee education and systematic reform to reinforce human resource capabilities and organizational performance. We believe that creating a systematically functional organization will contribute to becoming a global company.



Meeting between an MR and a doctor



Training MRs

Status of Medium-term Management Plan

	FY2006 achievements	FY2007 plans	FY2008-10 plans
1. Enhance global strategic pipeline			
1-1. Development of global strategic product candidates	DE-101: Proceeded to Phase IIa DE-104: Proceeded to Phase I DE-085: Applied in Japan & EU* MD-14: Approved* DE-089: In Phase III* * To be applied and launched mainly in Japan.	Apply for approval of IOL injector*	DE-101: Phase III in FY09 DE-089: Apply for approval in FY08*
2. Generate growth in Japan, Northern/Eastern Europe, Russia and China. Focus activities on clinical and business development in the United States			
2-1. Japan: Successful launch of new glaucoma, corneal and IOL products and early maximization of their product value			
Glaucoma (new product)	Started DE-085 launch preparation	DE-085 full-scale preparation including pre-marketing	DE-085 launch expected in FY08; early maximization of product value
Cornea (existing products)	Increased sales	Continue	
IOL (new product)	Formulated <i>Hyalain</i> disease-awareness strategy	Conduct disease-awareness campaigns	DE-089 launch expected in FY10
IOL (existing product)	Formulated MD-14 sales strategy	Preparation and start of sales	Increase prescription
2-2. Northern/Eastern Europe and Russia: Maximize value of <i>Ofthaquix</i> and existing products; Launch DE-085			
Maximize value of new and existing products	Reinforced promotions for existing products DE-085 applied April 2007	Continue promotions; launch <i>Ofthaquix</i> in Russia Formulate DE-085 launch plan	
2-3. China: Strengthen business base and competitiveness by starting of local production and establishing direct sales organization			
Establish direct sales organization	Hired and trained sales force	Increase prescription by academic information provision	Start sales
2-4. U.S.: Focus on clinical development and business development			
3. Strengthen manufacturing bases (Strengthen manufacturing bases by reorganizing production lines and sites in Japan, Finland and China)			
3-1. Promote efficiency by reorganizing production lines	Formulated a reorganization plan Started China plant construction	Complete China plant construction	Complete line reorganization Start manufacturing in China
4. Strengthen human resources and organization at the global level (Develop human resources; reorganizations)			
4-1. Develop core human resources	Assessed human resources	Formulate human resources development plan	Implement the plan
4-2. Develop organizational capabilities		Enhance planning and business development	Enhance global organization