

REPORTS FROM THE FRONT LINE: FIRST-YEAR RESULTS OF THE "2003-2005 MEDIUM-TERM MANAGEMENT PLAN"

During the year under review, Santen took aggressive actions to improve earnings from our U.S. ophthalmics business. And, in an effort to counter the impact of the prolonged sluggish Japanese prescription ophthalmics market, we carried out full implementation of the Santen Activity Improved Navigator (SAIN), a sales force automation system, and completed restructuring of the sales offices.

for growth...

TO IMPROVE EARNINGS POWER

FOR FUTURE GROWTH

In the United States, our eye care products are now available to help more people in market segments that we earlier were not able to penetrate – namely pediatrics and primary care – through our recent agreement with Johnson & Johnson Vision Care, Inc. (JJVCI). The agreement was signed in December 2003. JJVCI started sales of the products in February 2004, and we are completing the transition of distribution, sales and marketing activities to JJVCI during the first half of the current fiscal year.

One benefit of the agreement with JJVCI is the positive impact on earnings in the U.S. Another benefit of the agreement is that many of the former Santen sales representatives were hired by JJVCI so there was no disruption in the high level of service provided to physicians.



Adrienne Graves, Ph.D.
President and CEO
Santen Inc.

We are now better focused on our core strength of research and development in the U.S. We have brought three significant drugs to the U.S. ophthalmic market in less than four years. In March of this year, we received FDA approval for *Iquix*, a levofloxacin ophthalmic solution of 1.5% concentration, indicated for the treatment of bacterial corneal ulcer. Levofloxacin's high solubility at neutral pH allows the solution to be formulated at a concentration that is three times higher than any other ophthalmic fluoroquinolone on the

market, and thus provides physicians and patients with a safe and powerful new option in the anti-infective market. We will continue to focus on the development of the products in our pipeline and will work to strengthen our strategic marketing and business development efforts in the U.S.

ACHIEVING THE BENEFITS OF SALES FORCE AUTOMATION

While we have had a digital reporting system before, SAIN is now more convenient as our reports are automatically entered into a database.

Furthermore, should a medical representative (MR) transfer to another location, for example, SAIN should reduce the time required for handing over existing work to a new MR. For our team meetings, we have already incorporated the effective sharing of information by projecting the data in SAIN in a visually broad image for group viewing and discussion. And, most valuable, SAIN has virtually eliminated the need for producing materials for meetings. It is a tremendous efficiency for MRs who are typically under heavy time constraints.

These user-friendly improvements of the SAIN for MRs still require continuous company-wide efforts. For example, our experienced MRs enjoy the strong trust of customers, and our goal is for all MRs to share their individual expertise and know-how. Once we can make full organizational use of SAIN, our top position in the Japanese prescription ophthalmics market will become increasingly solid.

Finally, SAIN also allows us to access all kinds of in-house databases from our mobile laptop computers. When we are with customers, we are now able to provide the latest academic information immediately. By utilizing SAIN, we no longer have to report back to our office to access information, giving us a greater degree of mobility in MR activities.



Takashi Kawano
Medical Representative
Osaka South Team
Kansai Area

LOOKING FORWARD TO SYNERGISTIC EFFECTS

With only a half-year since full implementation of SAIN, I believe real benefits and real results are yet to come. From the perspective of the basic flow of sales activities (i.e., Research, Plan, Do, Check and Act), we are in the Research phase of database building. As a "system," it requires constant improvements; in fact, we upgrade the version after reviewing the feedback from our users at the sales front line.

Medical representative work with SAIN will provide value-added information to customers in a timely manner through accurately understanding their needs as we take advantage of the Santen brand strength. For this objective, SAIN is a very valuable tool. Specifically, it is very useful to develop and assess our team strategies as we can follow up each of our six MRs' activities in chronological order. Regarding the change to satellite offices resulting from the restructuring of sales bases, those MRs who cover a wide area now have additional benefits, including reduced distances to customers. However, the real benefits will come about in tandem with mobile computing and SAIN.



Hidehiko Kanaya
Team Manager
Ibaragi Team
Kansai Area



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For any pharmaceuticals firm, success depends on the strength and speed of research and development programs. During the year, we stepped up the pace of clinical trials on compounds for glaucoma treatment and enhanced our in-house development capabilities in high-priority research areas, including retinal disorders. In the clinical trial phase, we are adding to our global presence in the high-growth glaucoma market by advancing development of our prostaglandin (PG) compounds. Tafluprost (development code: DE-085) is expected to show an improved reduction of intraocular pressure, compared to PG products available on the market today.

for the future...

TO LEVERAGE R&D EXPERTISE

SUCCEEDING WITH SHARED COMMITMENT

Thanks to the cooperation both internally and externally at Santen, our group was able to accelerate the clinical trials for tafluprost (DE-085) and move into Phase III at the end of last year. Medical institutions have both begun to deepen their understanding of clinical studies and establish better internal systems, which have allowed us to expedite our process. In addition to the substantially increased number of patients from Phase II to Phase III, we are conducting three different clinical trials concurrently. We added 10 people to our clinical group to conduct the Phase III clinical trials.

Most of the additional clinical manpower has been transferred from our research division. While researchers usually focus on specialized experiments, clinical employees must coordinate the activities of physicians and medical institutions in order to successfully conduct clinical trials. Since clinical development requires different skills and competency from basic research, we offer new clinical employees in-house training for approximately one month after transferring. After the training program, new clinical employees train under the supervision of

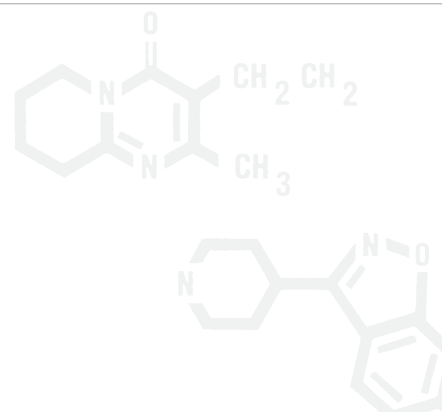


Yoshikazu Matsumoto
General Manager
Clinical Development Group 2
Clinical Development Center

experienced staff, and are evaluated for their communication skills with the staff of medical institutions. This interpersonal skills training sometimes includes discussions with physicians who call for immediate responses to their questions.

To accelerate our clinical development, we have increased the speed of our decision-making and strengthened internal collaboration with our research centers, production departments, sales departments, academics, regulatory affairs, statistical analysis, quality control and assurance. A high degree of mutual commitment by all those involved allowed us to succeed in this project.

Development of pharmaceuticals is much like a long-distance relay race. Once the medical value and safety of our compounds created by our researchers are confirmed, we then seek to complete clinical trials successfully and on time before moving on to the registration process for the final course of the race. Working towards the same goal, each "runner" is passing the baton of the shared commitment to success.



TAKING UP THE CHALLENGE OF GLOBAL DEVELOPMENT

Because glaucoma treatments, from a global perspective, represent the largest market and are the highest priority for Santen, we have been promoting concurrent clinical development of tafluprost (DE-085) in Japan, the U.S. and Europe. Tafluprost represents our first major global project. To succeed, consistent, detailed collaboration among our project teams in our three geographic regions is extremely important.

In Phase we are conducting multiple clinical trials concurrently in Japan, the U.S. and Europe, making our collaboration more complex. Our global project teams are working very closely to advance clinical trials in



Koji Yamamoto, Ph.D.

Project Manager
R&D Project Planning and
Coordination Group
R&D Planning Integration Department

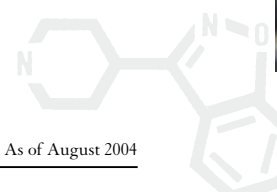
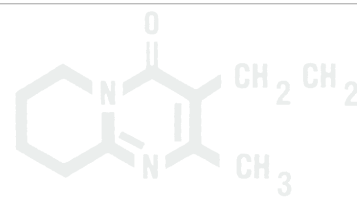
each area, with the goal of utilizing the trial results obtained in one region for registration purposes in other regions of the world as quickly as possible. To complete the trials and file an application in each region in the shortest time, all other related operations such as non-clinical research, regulatory, quality assurance, project management and statistics are also collaborating closely.

From an operational standpoint, when Japanese pharmaceutical companies develop international products, they first get approvals in the U.S. or Europe and use their clinical

trial results for application in Japan. This process – and the success thereof – should become an important asset of the Santen Group.



▲ Laboratory of Santen Oy



Prescription Pharmaceuticals in Development

As of August 2004

Generic name	Brand Name/ Development Code	Indication	Region	Pre-clinical	Phase I	Phase II	Phase III	NDA Filed	Approved	Characteristics
Levofloxacin 1.5%	<i>Iquix</i>	Bacterial corneal ulcer	USA							Antibacterial ophthalmic solution containing the active ingredient fluoroquinolone three times higher than current product (<i>Quixin</i>). Exhibits potent antibacterial action. Approved in March 2004.
Ciclosporin	DE-076	Vernal keratoconjunctivitis	Japan							An orphan drug ^{*2} . Expected to treat advanced vernal keratoconjunctivitis for which existing anti-allergy agents are not effective. NDA filed in August 2003.
Tafluprost	DE-085	Glaucoma and ocular hypertension	Japan USA/Europe							Prostaglandin glaucoma treatment that is expected to have greater efficacy in reducing intraocular pressure than other prostaglandin glaucoma treatments. Can be stored at room temperature.
Olmesartan	DE-092	Glaucoma and ocular hypertension	Japan USA/Europe			*				The only angiotensin receptor antagonist in full-fledged development as a glaucoma treatment. Comparable to prostaglandin products in reducing intraocular pressure.
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.
Diquafosol tetrasodium	DE-089	Dry eye	Japan							A dry eye treatment that stimulates corneal and conjunctival epithelial secretion of tear fluid and moisture.
Levofloxacin and prednisolone A	DE-094	Infectious keratitis	USA							Combination of levofloxacin and steroid.
Sodium hyaluronate	<i>Hyalain</i>	Dry eye	USA			*				Ophthalmic solution containing sodium hyaluronate for dry eye.
(Undetermined)	DE-096	Rheumatoid arthritis	Japan							An oral TNF inhibitor. Anti-rheumatic effect comparable to injectable biological agents has been observed in basic research.
Gefarnate	DE-099	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	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 ointment that can be used in combination with existing drugs.
(Undetermined)	DE-098	Rheumatoid arthritis	Japan							Anti-APO-1 antibody. Joint injection that induces apoptosis in diseased joints of rheumatoid arthritis patients. Bulk pharmaceutical manufacturing process for actual production scale has been established, and drug development is being studied.
Bucillamine	<i>Rimatil</i>	Osteoarthritis (additional indication)	Japan							Shown to be effective on joint inflammation caused by osteoarthritis.

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

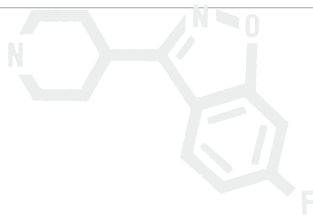
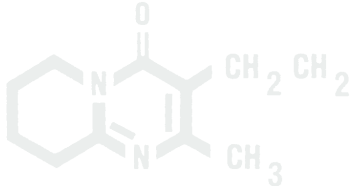
Phase : Tests to check drug safety with a small number of healthy volunteers.

Phase : Tests to determine dosage and administration method with a small number of patients.

Phase : Tests to confirm safety and efficacy by comparing to existing drugs and placebo with a large number of patients.

*1 In preparation

*2 Orphan drug: A drug with an indication for treating a relatively small number of patients. Orphan drug R&D expenses are eligible for government subsidies in Japan.



UPDATING PROGRESS IN DISCOVERY RESEARCH

Over the past several years, unmet medical needs in ophthalmologic diseases have shifted focus for research from the anterior segment (cornea and conjunctiva) to the posterior segment (retina and optic nerve). Rheumatoid arthritis shares common etiological and pathological symptoms, such as angiogenesis, cell growth, edema and inflammation with retinal and other diseases in the posterior segment of the eye. By deploying our accumulated knowledge gained in rheumatism research over the years, we are working to establish efficient, unique drug-discovery techniques to develop breakthrough ophthalmic pharmaceuticals.

During the year, we advanced our drug discovery efforts in the priority fields of retinal disorder and osteoarthritis. In the ophthalmic field, we placed special emphasis on reinforcing our in-house drug discovery capabilities.

Today, the mainstream glaucoma treatments are prostaglandin products that lower intraocular pressure by promoting the outflow of aqueous humor through the uveal and scleral channels. At Santen, we are currently making steady progress in the preclinical development of a protein kinase inhibitor, as a new mechanism of action that promotes the outflow of aqueous humor through the trabecular channel. This channel is responsible for 80% of the outflow of aqueous humor. We have positioned this pharmaceutical agent as a treatment possibility to replace surgery. Another approach to glaucoma treatment is protection of the optic nerve. There are two ways to protect the optic nerve: improvement of retinal circulation and direct action on the optic nerve. We have already embarked on discovery research and preclinical experiments in both methods.

In the field of retinal disorders, we have been advancing preclinical studies of candidate compounds designed to treat age-related macular degeneration (AMD) and other retinal disorders, diseases with which the number of patients increases as the population ages.

In the osteoarthritis field, we have discovered an oral tumor necrosis factor (TNF) inhibitor (DE-096) and have initiated Phase I clinical trials in Japan.



REINFORCING INTELLECTUAL PROPERTY STRATEGIES

The importance of intellectual property strategies has been growing in the prescription pharmaceuticals market today. From candidate compounds under development to basic research results, we are developing and implementing our intellectual property strategies on a global scale in order to maximize the value of our products and technologies.



▲ The ninth worldwide intellectual property committee meeting was held in Osaka in February 2004.

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We at Santen have continued our efforts to strengthen corporate governance and employee training as important measures to maximize corporate value. For corporate governance, we shortened the term for directors to one year from two, and appointed Mr. Kosei Furukawa as an outside director. For employee training, the Company conducted the Santen Innovation Project (SIP), an in-house business school launched in 2001. Since 2003, middle management personnel have participated in SIP and engaged in the research, development and implementation of reform programs designed to meet the current needs of the Company.

for strength...

TO ENHANCE ORGANIZATIONAL PERFORMANCE

INTERVIEW WITH KOSEI FURUKAWA,
OUTSIDE DIRECTOR OF SANTEN
PHARMACEUTICAL

Q: Please tell us what brought you to Santen.

Furukawa: During my thirty-odd years of teaching at Keio Business School, many managers and manager candidates from Santen Pharmaceutical attended the MBA program and various intensive management development programs of Keio University. Mr. Morita, President, for example, is a 1981 graduate of the MBA program. In my classes at Keio University over the years, I had come to learn about Santen's sincere pursuit of the mission of offering excellent products and services to ophthalmologists and consumers, first in the domestic market and then in various overseas markets as well.

Six years ago, Mr. Morita invited me to take the position of an outside auditor at Santen. His invitation appealed to me as an exciting challenge for several reasons. First, for many years, I had maintained academic interest in the historical patterns of global competition led largely by major European and American competitors in the knowledge-intensive pharmaceutical industry. Secondly, I had been aware of the aspirations and expectations of Japanese industry leaders, economic



Kosei Furukawa

Born in 1935, Mr. Furukawa is currently Professor of Business Administration at Nakamura Gakuen University, Visiting Professor at the University of the Air, and Professor Emeritus of Keio University. He specializes in management policy, technology management, and management of small business. Mr. Furukawa was appointed Outside Auditor of Santen Pharmaceutical in June 1998, and was appointed Outside Director in June 2003.

planners, analysts, investors and scholars at large, for the growth of Japan-based pharmaceutical companies as competitive entities in the global arena. Thirdly, I had come to regard Santen as a promising and attractive contender in the Japanese and overseas pharmaceutical market with its clearly focused product-market strategy. I did not hesitate to accept Mr. Morita's invitation.

Q: Please describe the roles you played as an outside auditor for five years and as an outside director for the year under review. Please also share your impressions about Santen with us.

Furukawa: At various official corporate meetings, I posed questions to directors about their basic management policies, and to corporate officers about their management objectives, planned activities and specific outcomes. I occasionally visited research centers, factories, and subsidiaries to observe corporate teams in action. I tried also to meet with Santen managers outside of formal meeting rooms in order to learn about individual managers and their thoughts.

Through all these activities, I gained clear appreciation for top management's proactive attitudes towards the challenges of developing overseas markets, reinforcing and expanding Santen's tech-

nological expertise, and expanding management capabilities through adoption of IT applications.

As an outside director during the last fiscal year, I considered my important Board role to be offering objective views and suggestions that reflect my teaching and research experience, as well as my information contacts in other industries. I also believed I should be drawing the Board's attention to matters that are too sensitive for employees to express themselves. I can assure you that our Board always seeks to make Santen attractive to a diverse range of stakeholders. Our Board also aims to enhance Santen's corporate value.

Q: *What do you think Santen needs most at this point?*

Furukawa: I believe Santen needs to keep strengthening its domestic and overseas human resource development activities. In

order to become a competitive worldwide manufacturer-marketer of pharmaceutical products and services, Santen needs to identify and motivate talents in the R&D areas. We also need to expand capabilities in managing global activities in all areas other than R&D.

Santen needs to increase interaction among professionals in the Japanese headquarters and in our family companies in the U.S., Europe, the Asian countries, and in Japan with a common goal of establishing a creative environment for everyone in the Santen family.

In both the ophthalmic and rheumatoid arthritis markets, Santen must aim to become a company recognized by patients and medical professionals around the world as their trustworthy partner. Fortunately, Santen is a capable and action-oriented company. We should be able to achieve all of our immediate goals in technology and in business on schedule.

IMPROVING INTERNAL COMMUNICATION

The Santen Innovation Project (SIP) was launched to accelerate the pace of personnel development and self-driven management reforms. Since then, some 100 employees have participated in the program. Certain suggestions from the SIP have already been implemented, such as the "town hall" meetings held at 19 locations nationwide, since March 2002. During the meetings, President Morita explained Santen's results and strategies directly to employees and exchanged candid opinions.

The current SIP in which I participate is designed exclusively for middle management employees and features a small group of 15 participants. In the first half session, we studied cases of other companies. In our second half session, we are developing and implementing our own project tailored to improving the actual work conditions in our departments. My project task is to explore ways to improve the understanding of management messages aimed at all employees, such as Santen's core value, business plans, fiscal strategies and follow-up reports.



Masao Tanaka
General Manager
Corporate Communication Group
Corporate Development &
Administration Division

First, I compared the results of two employee attitude surveys, one conducted in 2002 and one more recent, and reaffirmed that a gap still remained between the intentions of information providers and the recognition and understanding of information receivers. I am currently identifying the issues and possible countermeasures. At the same time, I have also felt the strong need to develop a corporate culture in which employees take initiative to seek information. A virtual meeting system was installed as part of the sales office reform at the end of last year, and a LAN-based portal site is scheduled to launch in October this year. I would like to use IT solutions to achieve low-cost, interactive communications for all employees and develop an environment where everyone can share important management information.

Meanwhile, conventional face-to-face communications remain particularly important for middle management, including myself, to ensure accurate understanding of management philosophy and strategies among our staff members.