Based on its strategic business objectives, Santen transformed its R&D organization during fiscal 2012. This included anchoring global clinical development and medical affairs functions in the U.S. In addition, our European subsidiary, Santen S.A.S. (formerly Novagali Pharma S.A.S.), was fully integrated with the Santen Group in January 2012. This achievement will allow us to leverage our expertise in ophthalmic formulations to effectively and efficiently formulate best-in-class molecules for accelerated development worldwide.

During fiscal 2012, we also continued to improve our decision-making processes whilst improving collaboration and work ethics across R&D worldwide. In fiscal 2013, translational studies to establish POC1 will continue to be conducted in the U.S. These integrations will improve decision-making, consolidate resources, and maintain the cost of development in an adequate manner. In order to accelerate the development of products, Santen will focus on developing “differentiated” products based on a deep understanding of unmet medical needs in all regions. To reduce risk and accelerate development we will also develop a global network of partners.

One of our major challenges going forward is to supplement our in-house research through network-based drug development, which is to in-license compounds from external sources so that we can expand the number of inputs into our screening programs and early-stage clinical studies. In addition, based on our product portfolio strategy for each region, we aim to maximize returns on R&D investment by using benefit and risk assessments to gauge the value of each product.
In April 2013, we began a new system designed to further speed up global clinical development. As Chief Scientific Officer (CSO), it is my job to develop a global strategic and tactical R&D plan. The plan will consist of short-, medium- and long-term objectives. The immediate focus will be on the fiscal 2014 through fiscal 2017 time frame. The cornerstone of the plan will be to better understand unmet medical needs in the various regions of interest to Santen. This will be followed by prioritization with an eye on deliverables to ensure that business objectives are met. As time is of the essence, strategies to accelerate development while keeping costs to a minimum will be developed and implemented.

1. Proof of Concept (POC) is the realization of a certain method or idea to demonstrate efficacy or safety in clinical trials.

Forging Seamless Collaboration between Bases in Japan, the U.S. and Europe Based on Synchronized Sharing of R&D Results and Development Progress

Within Santen’s new R&D system, my role is to manage globally the execution of specific measures based on our product portfolio strategy. In fiscal 2012, we created a system that makes the most of our diverse, specialist resources based on seamless links between bases in Japan, the U.S. and Europe, notably at pre-clinical stages. We are also pushing on with our “KANAME” project, which is enhancing R&D efficiency by capturing the progress and results of development projects and related issues across regions. Continuing to develop our organization efficiently and increase the productivity of our global development will remain a key priority for us going forward.

Targeting Continuous Growth through Steady Development of the Late-Stage Clinical Pipeline

We are making steady progress in the development of our late-stage clinical pipeline. In the field of glaucoma, we applied for manufacturing and marketing approval for our combination drug DE-111 (tafluprost/timolol maleate) in Japan and Europe in October 2012 and June 2013, respectively. DE-118 (tafluprost) in a preservative-free, unit-dose, single-use formulation gained Japanese regulatory approval in January 2013. In the field of retinal disorders, we are conducting Phase 3 clinical trials in the U.S., Japan and Europe with DE-109 (sirolimus). In the field of corneal and conjunctival epithelial disorders, Phase 3 clinical trials are progressing steadily with Cyclokat (ciclosporin), which is indicated for the treatment of severe dry eye.

We are applying a “network-based drug discovery” approach to make effective use of external resources to supplement Santen’s original in-house research. We are also using a product life cycle management2 approach to ensure that we maximize the value derived from our current portfolio of compounds. To target continuous growth, we plan to continue to take a variety of steps while contributing to medical treatment as a company specializing in ophthalmic pharmaceuticals.

Maximizing Product Value Based on Specific Market Needs

Santen is engaged in proprietary drug discovery research mainly in the three fields of corneal disorders, glaucoma and retinal disorders. Since medical needs vary significantly in different markets around the world, developing a competitive drug portfolio must be driven by the needs of customers and not by the products if we are to extract maximum therapeutic value. Currently, we are planning to introduce a system to enable us to gain scientific data from ophthalmologists and patients worldwide so that we can better define our investment priorities based on an idea of customers’ real needs.