

Interview with President Isao Teshirogi, Ph.D.



Isao Teshirogi, who has been Shionogi's president since April 2008, explains the results of business measures implemented during fiscal 2008, as well as the management strategies the Company will be implementing in fiscal 2009, which is the final year of the second medium-term management plan.

How would you characterize the operating environment and Shionogi's performance in fiscal 2008?

Fiscal 2008 was a very noteworthy year regarding Shionogi's overseas expansion. We had already for some time considered building a marketing network in the United States to be an important objective. Now, having also augmented our global R&D pipeline of drug candidates that meet global standards as a result of our concerted, Company-wide efforts to implement the second medium-term management plan, we have successfully acquired U.S. pharmaceutical company Sciele Pharma, Inc.

Concerning net sales, because of challenges stemming from continued difficult conditions in the Japanese pharmaceuticals market, we did not meet our domestic sales target and were disappointed to have to revise down our performance forecast. Ultimately, however, we were able to increase our net sales, reflecting such factors as the contribution of Sciele Pharma to consolidated performance and a rise in royalty income associated with Crestor®. However, our profitability decreased due to business combination accounting associated with the Sciele Pharma acquisition, particularly our one-time booking of in-process R&D expenses, as well as our amortization of intangible fixed assets and goodwill. If we calculate just the consolidated performance of previously existing Shionogi Group units and exclude the impact of our Sciele Pharma acquisition, however, then we find that we realized increases in both net sales and profit.

There are still many challenges that Shionogi has to overcome, but the year was highly memorable, due to the huge stride we made in global business development. We expect our global business development to be a key factor enabling our sustained viability and independence going forward.

What are the main management strategies you will be implementing in fiscal 2009, the final year of Shionogi's second medium-term management plan?

The most important tasks that we must accomplish to achieve the targets of the second medium-term management plan are further strengthening our domestic marketing systems, sustaining the augmentation of our R&D pipeline, and building global development and marketing systems.

Regarding domestic marketing, we plan to further expand sales of our hyperlipidemia treatment Crestor®, on which we have already concentrated considerable resources, and intensify our promotional activities for the hypertension treatment Irbetan®. At the same time, we will step up our marketing of new products, such as Differin® Gel, a topical treatment for acne vulgaris, and the idiopathic pulmonary fibrosis treatment Pirespa®. In the therapeutic areas of infectious diseases and pain, we are striving to increase our sales while efficiently arranging related lecture programs for medical professionals and carrying out activities aimed at increasing patient awareness.



With respect to our development pipeline, we have the objective of launching 10 new products during the period of our second medium-term management plan, and we need only one more product to reach our target, for which we have an application pending for the indication of depression. We are confident that we will realize our development pipeline goals.

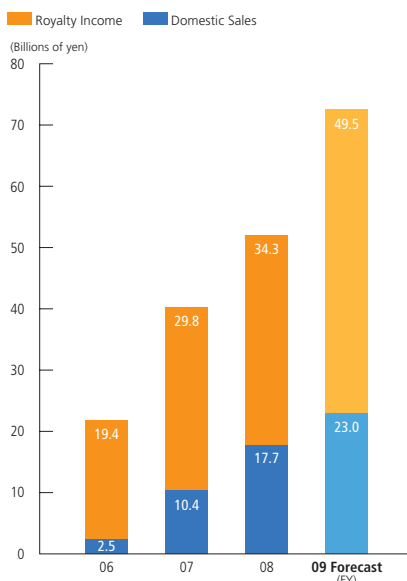
In overseas operations, we have already begun the smooth flight for the combination with Sciele Pharma, and we intend to provide support for expanding Sciele Pharma's operations in the United States during fiscal 2009. Looking at the development network, we will continue focusing our overseas development systems on our U.S. development subsidiary, Shionogi USA, Inc., while expanding capabilities in Europe.

Please explain the most important tasks you must handle in domestic operations to support Shionogi's globalization process going forward.

Aiming to maintain the momentum of our globalization, we consider it very important to realize steady sales growth in the Japanese market, which is our primary revenue base. To strengthen our domestic marketing operations, we have to shift emphasis from acute diseases to chronic diseases, and we have to expand our presence in the hospital market. However, our marketing organization was unable to fully attain these objectives in fiscal 2008, and this was a major factor behind our inability to reach our marketing targets for the year.

To take our place among the pharmaceutical industry's top companies with respect to productivity, the first thing we must do is successfully shift our marketing focus away from acute diseases and toward chronic diseases. Next, because we have been centering our marketing efforts on general practitioners and weakened our presence in the hospital market, we must reinforce our marketing programs focused on hospitals. Further, we must move ahead with efforts to develop stronger demand for our products, particularly new products, by providing appropriate product information. In particular, we must find ways to more proactively use scientific evidence from such long-term studies as JUPITER (Justification for the Use of statins in Primary prevention: an Intervention Trial Evaluating Rosuvastatin) or COSMOS (COronary atherosclerosis Study Measuring effects Of rosuvastatin using intravascular ultrasound in Japanese Subjects) to promote Crestor®. And then, the long-term prescription of Irbetan® has already begun from July 2009, and we seek a full-scale expansion in Irbetan®. In April 2009, we established the Sales Resources Management Department, which is responsible for the strategic training and posting of Medical Representatives (MRs). We want to maximize our human resource productivity by changing our methods for evaluating MRs, as well as placing and training personnel.

Growth in Crestor® Revenues: Domestic Sales and Royalty Income in Fiscal 2009



Could you describe the management vision you have regarding the shape of Shionogi 5 or 10 years from now?

Currently, our royalty income associated with Crestor® is steadily increasing, and we anticipate that it will rise to approximately ¥50 billion in fiscal 2009. We project that the peak level of annual royalty income associated with Crestor® will be even higher, but our patents on the product will be expiring in the period through 2016 and 2017. Accordingly, it is crucial that we develop a principal management base to sustain our growth over the next seven to eight years before the Crestor® patents expire. I will explain our management vision for the future with respect to domestic marketing, R&D, overseas business development, and programs to find the drug discovery seeds that will support Shionogi over the long term.

Looking at marketing, we are bolstering our presence in our emphasized targeted therapeutic areas with particular focus on strategic products and drug candidates that are expected to be launched in the near future. Specifically, we are preparing three products—Crestor®, Irbetan®, which has been available for long-term prescription since July 2009; and duloxetine hydrochloride, which is expected to be approved for the indication of depression during fiscal 2009—to be principal drivers of Shionogi's corporate growth over the medium-to-long term. We are also intent on maximizing the marketing shares of such mainstay products as Finibax® carbapenem antibiotic, Avelox® new quinolone antibiotic, the anti-allergic Claritin®, and the cancer pain analgesic OxyContin®.

With regard to R&D, in addition to making sure we maintain progress in domestic development programs, we believe it is crucial to discover and develop a continual flow of globally competitive drug candidates and then launch the approved drugs in the United States and Europe. We are anticipating the marketing of the anti-obesity drug S-2367 and the anti-HIV drug S-349572 in the period from 2013 to 2014, and we will be emphasizing these global strategic products as we work to expand our sales through Sciele Pharma in the U.S. market.

Of these, the top priorities are placed on S-2367 and another R&D program of neuropeptide Y Y5 receptor antagonists. The results of Phase IIb trials have confirmed that S-2367 is safe and has great potential for therapeutic applications related to obesity and metabolic syndrome. We are expecting S-2367 or its follow-up compounds to become the first-in-class therapeutic drug for obesity. Currently, we are in the process of selecting partners for collaborative overseas development and marketing, and bringing Sciele Pharma into the Shionogi Group has given us systems that enable us to market S-2367 in the important U.S. market ourselves. It has expanded the range of our options.

Besides the previously mentioned S-2367 and S-349572, we are now proceeding with the overseas development of such drug candidates as S-555739, a treatment for allergic diseases, and S-888711, a treatment for thrombocytopenia.

We plan to continue to proactively enter into strategic alliances, such as our cooperative research programs with U.S.-based Purdue Pharma L.P., Hokkaido University, Osaka University, and others as well as our cooperation with OncoTherapy Science, Inc., for our in-licensing of cancer vaccines. By searching for drug discovery seeds and strengthening these alliances, we intend to realize a sustained expansion of our development pipeline.

Major Strides in Fiscal 2008

2008	April	President Motozo Shiono became Chairman and was succeeded as president by Isao Teshirogi, Ph.D.
	May	The Shionogi Innovation Center for Drug Discovery was established (on the campus of Hokkaido University).
	July	Irbetan® 50mg and 100mg tablets were launched.
	October	Sciele Pharma, Inc., was converted into a consolidated subsidiary. Differin® Gel 0.1% was launched.
	November	A new solid formulation manufacturing and packaging facility was completed at the Settsu Plant.
December	Pirespa® tablets 200mg were launched.	
2009	February	A licensing agreement on peptide vaccines for cancer treatment was concluded with OncoTherapy Science, Inc. A preliminary report on Phase IIb clinical trials of velneperit (S-2367) was announced.
	March	Ezose Sciences, Inc., was established. A basic agreement was reached on the establishment of a Medicinal Molecular Imaging Center (tentative name).

In light of the various points I have just explained, it should be clear that if Shionogi launches its in-house developed products over the next 5-to-10 years as planned and expands its overseas sales while concurrently achieving steady growth in domestic sales, then the Company will be able to completely offset the drop in operating income associated with the expiry of Crestor® patents in the period from 2016 through 2017. In this way, I believe we can also get Shionogi on track for growth over the medium-to-long term.

Having acquired Sciele Pharma last year as a means of building marketing capabilities in the U.S. market, what other measures is Shionogi planning to make to expand its overseas presence?

For Shionogi, Sciele Pharma is not just a means of building U.S. marketing systems and fostering the development of human resources able to meet needs associated with globalization; it is also an ideal partner with which Shionogi can share long-term growth plans.

In 2008, we created a new governance system for operations in the United States by establishing Shionogi USA Holdings, Inc. Two business companies—Shionogi USA, Inc., and Sciele Pharma—are under the umbrella of that holding company. Going forward, besides making efficient use of management resources and engaging in consultations to ensure the Shionogi Group's smooth operations, the Group also intends to orchestrate concerted Group efforts to promote a continuous increase in its presence in the U.S. market.

One of the goals of our second medium-term management plan is to develop multiple in-house products simultaneously in Japan, the United States, and Europe. In line with this goal, we will not restrict ourselves to our recent initiatives in the United States. We are planning to move ahead with measures to also build the requisite infrastructure in Europe.

Please explain Shionogi's fundamental Corporate Social Responsibility (CSR) and corporate governance policies.

All our CSR activities are based on Shionogi's purpose—"Shionogi strives constantly to provide medicine of the best possible kind essential for protection of the health of the people." In other words, we want to make the products we supply useful to as many patients and medical practitioners as possible. We think it is important to realize this fundamental policy by giving due consideration to society and the natural environment.

Regarding corporate governance, to ensure that our operational management is flexible and that our management processes are transparent, we have streamlined our Board of Directors and introduced an executive officer system. In addition, from fiscal 2009 we brought outside directors, a corporate manager, and a lawyer who both have considerable experience with and knowledge about international affairs onto the Board. We expect that this move will further strengthen the Board's supervisory capabilities and promote prudent management decisions.

We will pay close attention to trends in society and strive to build operational execution systems that are highly efficient and responsive.



What measures is Shionogi taking regarding compliance systems?

Recently, the media have covered a series of problematic events concerning the operations of certain companies that give cause for reconsidering key corporate compliance issues, as well as the ideal nature of compliance-related systems. We recognize that giving additional consideration to compliance issues is particularly important for us at this time—when Shionogi is striving to accelerate its global business development and ensure that it is on track for sustained corporate growth over the medium-to-long term. Specific measures we have taken include those to establish a Compliance Committee, which is working to ensure rigorous legal compliance and corporate ethics performance throughout the Shionogi Group. In addition, our corporate auditors and Internal Control Unit have augmented their monitoring of management and operational execution processes with the introduction of internal and external compliance issue reporting systems. We are working to expedite the discovery of any problems that may exist and to prevent the recurrence of such problems.

Naturally, we are also emphasizing activities to promote the appropriate use of pharmaceutical products and maintain rigorous quality standards. In fiscal 2008, the Shionogi Group had zero cases of product recalls due to the discovery of patient health issues or product quality issues. In this way, we are fulfilling our social responsibility to offer stable supplies of products, and we have made great efforts to ensure our strict conformance with the Pharmaceutical Affairs Law and other relevant regulations.

Determined to never be complacent about our compliance performance, we intend to further intensify our compliance promotion activities, striving to prevent even apparent cases of noncompliance that turn out to be groundless.

What is Shionogi's stance on shareholder returns, and do you have any closing message for shareholders?

To increase its corporate value in the medium-to-long term, Shionogi is proactively undertaking business investments while aiming to disburse dividends at levels that are commensurate with its business performance, as well as being generally stable and rising over time. Our plans call for measures to realize a 35% consolidated dividend payout ratio in fiscal 2009.

Shionogi is getting on track for global growth. The second medium-term management plan that we are now implementing is designed to ensure that we stay on track for considerable corporate growth and that our current strategies will effectively promote our corporate development over the medium-to-long term, as well as the maximization of our corporate value. We ask that shareholders be frank in sharing their opinions with us and continue to be wholehearted in providing us with support.

