# SHIONOGI & CO., LTD.

SONG for the Real Growth

# The Company Policy of Shionogi

### Shionogi's purpose

Shionogi strives constantly to provide medicine of the best possible kind essential for protection of the health of the people.

### For this purpose, Shionogi will need to

Pursue the search for even better medicine. Produce even better medicine.

Promote the word of even better medicine to an even greater number of people so that an even greater number of people will be able to use such medicine. Pursue, produce, and promote in an even more economical manner.

### For this purpose, Shionogi people will need to

Strive ceaselessly day after day to improve their skills. Strive ceaselessly day after day to improve as human beings.

### As a result, Shionogi people will

Find even greater satisfaction in their daily work and in their daily lives. Find even greater improvement in the quality of their lives. Find even greater prosperity in their lives.

(Established in 1957)

# Shionogi's Action Guidelines

Mission

#### Mission

Value

We will deliver pharmaceuticals that offer an even higher level of satisfaction to patients, their families, and healthcare providers and improve the quality of life for patients and their families.

Value

individual

Customer focus, Trust,

Professionalism, On-site

orientation, Respect for the

### Vision

A company with a strong presence worldwide A company that has pride and dreams and embraces challenges

### **Editorial Policy**

Period under Review Fiscal 2010 (April 1, 2010 - March 31, 2011) Certain activities continuing into fiscal 2010 and thereafter are also included.

#### Scope and Organization

The Annual Report encompasses the activities of Shionogi & Co., Ltd. and its 22 Group companies (17 consolidated subsidiaries and 4 affiliates).

Vision

The section entitled Efforts to Preserve the Environment covers all business facilities of Shionogi & Co., Ltd. and eight of its domestic and overseas subsidiaries. In this report, "Shionogi" refers to Shionogi & Co., Ltd. and all its on-site subsidiaries. "Domestic subsidiaries" refers to the one domestic manufacturing subsidiary (Shionogi Pharma Chemicals Co., Ltd.) and two domestic non-manufacturing subsidiaries (Shionogi General Service Co., Ltd. and Saishin Igaku Co., Ltd.), and "overseas subsidiary" refers to Taiwan Shionogi & Co., Ltd. "Shionogi Group" refers to all the aforementioned companies.

#### Notes Concerning Numerical Values and Graphs

All numerical values are rounded to the nearest unit, as applicable. Totals may not match due to rounding.

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### Forward-Looking Statements

This report contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks, and uncertainties which could cause actual results to differ materially from these statements

Risks and uncertainties include general domestic and international economic conditions, such as general industry and market conditions, and changes of interest rates and currency exchange rates.

These risks and uncertainties particularly apply to forward-looking statements concerning existing products and those under development. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms; and changes of laws and regulations.

For existing products, there are also manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials, and competition with other companies' products

The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events, or otherwise.

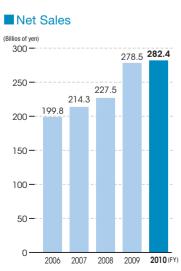
This report contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy of these pharmaceuticals nor provide medical advice of any kind.

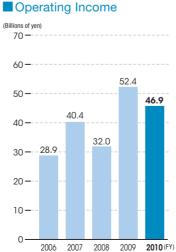
# Shionogi Fiscal 2010 Snapshot

# Consolidated Financial Highlights

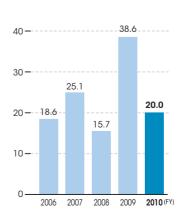
	FY2008	FY2009	FY2010	FY2010
-		Millions of yen		Thousands of U.S. dollars
For the year ended March 31:				
Net sales	¥227,512	¥ 278,503	¥ 282,350	\$3,395,671
Cost of sales	70,929	76,264	81,737	983,007
Selling, general and administrative expenses	124,568	149,801	153,721	1,848,719
Operating income	32,015	52,438	46,892	563,945
Income before income taxes and minority interests-	30,786	58,541	33,135	398,497
Net income	15,661	38,626	20,027	240,854
Research and development expenses	52,822	51,808	50,921	612,399
Capital investments	10,875	12,547	17,967	216,079
As of March 31:				
Property, plant and equipment, net	¥ 71,812	¥ 62,448	¥ 70,221	\$ 844,510
Total assets	501,853	540,762	523,242	6,292,748
Total long-term liabilities	114,955	131,956	115,326	1,386,963
Total net assets	310,094	341,976	328,096	3,945,833
Working capital	125,920	183,834	177,118	2,130,102
		Yen		U.S. dollars
Per share amounts:				
Net income	¥ 46.75	¥ 115.33	¥ 59.80	\$ 0.72
Net assets	924.43	1,019.71	979.69	11.78
Dividends per share	28.00	36.00	40.00	0.48

\* U.S. dollar figures have been calculated, for convenience only, at the rate of ¥83.15 = US\$1.00, the approximate rate of exchange on March 31, 2011.

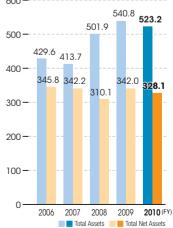








#### Total Assets / Total Net Assets (Billions of yen) 600 ------



Management



2010

Speed

Quick decision and implementation

2012

Open Mind

Flexible mind and out of box thinking

2014

2016

Persistent passion

2018

2020 (FY)

5th medium-te

Never-Failing Passion Global Perspective

Higher and broader perspective

# Main Achievements in Fiscal 2010

FY2014 (Target)



# Fiscal 2011 Targets

#### **Domestic sales**

Focus on 8 strategic products

FY2010 (Results)

\*Excluding additional sales through strategic business development deals

SONG for the Real Growth

- Strengthen sales to hospitals
- Improve productivity per MR

#### Shionogi Inc.

 Achieve operational integration benefits and stable operations

#### Cost contro

- Reduce cost of sales
- Rigorously prioritize selling & general expenses and manage expense budget according to changes in the business environment

#### Jomestic sales

- Increase and enhance R&D pipeline by setting appropriate priorities.
   Main pipeline milestones
   ⇒S-349572 : Completion of enrollment for global Phase III clinical trials.
   ⇒Ospemifene : Filing of NDA following completion of bioequivalence study
   in the US.
   ⇒S-297995 : Initiation of Phase IIb trials in Japan and the US.
  - ⇒S-707106 : Completion of Phase IIa trials in the US. Go/No-Go decision

# To Our Stakeholders

First of all, along with extending our heartfelt condolences to those affected by the Great East Japan Earthquake that struck on March 11, 2011, we pray for those who lost their lives. We also hope the affected areas recover from the disaster as soon as possible.

Shionogi employees and facilities were affected by the earthquake; in particular our Kanegasaki Plant in Iwate Prefecture was forced to suspend all operations. However, an all-out effort by our employees saw production resume roughly a month later, and by July operations were completely restored. Fiscal 2010 marked the first year of our third mediumterm business plan, under which we are implementing various measures aimed at realizing our basic corporate policies on a global basis. We believe tangible progress was made toward our goals, including year-on-year growth in domestic sales, advances in R&D, and recovery from the Great East Japan Earthquake. It was also a year, though, in which we were made keenly aware of the challenges ahead, such as the need to flesh out our development pipeline, and restructure our US operations.



Corporate Information

In Japan, in addition to stretched public finances as the population ages and the birth rate declines, there is also the problem of how to pay for the nation's rebuilding in the aftermath of the Great East Japan Earthquake. Due to these factors, National Health Insurance (NHI) drug price revisions scheduled for next fiscal year are expected to be steeper. If pharmaceutical companies are to achieve sustained growth in the domestic market, we think it important that the new system called "NHI Drug Price Premiums for Promoting the Creation of New Drugs and the Elimination of Off-Label Drug Use" be made permanent after being introduced on a trial basis in April 2010. Along with ramping up development of innovative new drugs, it is imperative, in our view, that pharmaceutical companies in general strive to maximize the value of new drugs by attracting such premiums, and work to ensure that medical professionals truly grasp the value of these products.

Turning to the international stage, mega-pharma companies and Japanese drug majors are leading the way in mapping out individual responses to change in the business climate and in company-specific circumstances. These include specialization in treatments for areas of high unmet medical needs, conditions for which there remains no satisfactory method of treatment (such as cancer, psychiatric and nervous system disorders, and orphan diseases), diversification into vaccine and generic drug businesses, and expansion into emerging markets.

In this era of rapid-fire change in the prescription drug market, companies have some difficult decisions to make to ensure ongoing viability at home and abroad.

### Our Initiatives Ahead

We think it important that Shionogi continue expanding and strengthening its earnings base if it is to realize further growth. But with little prospect of marked expansion in the domestic market, it is essential that we launch on the global market a stream of products developed internally. Crestor<sup>®</sup> is one of our core products in the domestic market, and sales are also expanding worldwide. However, Shionogi will face the expiration of patents for Crestor<sup>®</sup> in 2016–2017, giving rise to the so-called "Crestor Cliff" in five years time. In response, we aim to achieve long-term growth by maximizing royalty income from Crestor<sup>®</sup>, which is currently expanding globally, and by actively investing in R&D activities worldwide with a view to creating future growth products.

Shionogi has designed its new medium-term plan as a road map for achieving substantial growth in the next five years based on our vision for the company ten years from now, while preparing to maintain growth after the expiration of patents for Crestor<sup>®</sup>. In the domestic market, we aim to expand and enhance our earnings base by maximizing sales of new products, while in R&D we will concentrate resources on priority diseases with the goal of expanding and advancing our pipeline on a global basis. We are striving to speedily develop and market such pipeline products as S-349572 for HIV treatment, ospemifene for vulvar and vaginal atrophy, S-297995 for alleviating opioid-induced adverse effects, and S-707106 for diabetes treatment. In addition, we plan to redouble our efforts to improve research productivity and generate a sustained flow of products developed internally at Shionogi. We expect the new pharmaceutical research building completed in July 2011 to play a key role in this regard.

At Shionogi we are determined to make concerted efforts to achieve the objectives of the new medium-term plan, enabling us to "provide medicine of the best possible kind essential for protection of the health of people," on a global basis as expressed in our basic corporate policies, and achieve real growth that is clear for all to see.

We look forward to receiving continued support and guidance from all our shareholders and other stakeholders.

Motozo Shiono Chairman of the Board



**Isao Teshirogi, Ph.D.** President and CEO

# Interview with the President

Isao Teshirogi, Ph.D. President and CEO

# First, would you mind looking back over fiscal 2010, the first year of Shionogi's third five-year medium-term business plan?

I believe that in fiscal 2010, we made solid progress as a whole in implementing our basic strategies. By focusing resources on the 8 drugs we identified as strategic products, we grew combined sales of these 8 products by 32% year on year. These 8 products accounted for 37% of our sales of prescription drugs in the Japanese market, compared with 29% in the previous fiscal year. With regard to new growth drivers, we achieved progress in domestic and overseas development of several compounds including S-349572 (anti-HIV drug), ospemifene (treatment for vulvar and vaginal atrophy), S-297995 (for alleviating opioid-induced adverse effects), and S-707106 (anti-diabetes drug). In terms of business performance, however, we ended up reporting decreased profits, as a consequence of structural reforms at Shionogi Inc. and booking quake-related extraordinary losses.

Our new medium-term plan, which kicked off in April 2010, is essentially a five-year transition program preparing the Company to surmount the "Cliff" represented by the expiration of Crestor® patents in 2016 and 2017.

The first of our three basic strategies—that of "steady growth mainly through enriched pipeline"—is geared toward establishing a robust earnings base independent from "legacy products," including off-patent drugs. To achieve this goal, we are concentrating resources on the eight new drugs we have identified as strategic products, including the hyperlipidemia treatment Crestor® and the antidepressant Cymbalta® (launched in April 2010). Although "selectivity" and "focus" have long been the watchwords for our domestic marketing effort, we have

become dependent on antibiotics such as Flomox<sup>®</sup>, as a result of which productivity has dwindled alongside market share. In fiscal 2010, however, we consistently reported domestic sales in excess of the market average. As a consequence, combined sales of our 8 strategic products grew 32% year on year, such that these drugs now account for 37% of Shionogi's prescription drug sales in Japan, up from 29% a year earlier.

The goal of our second basic strategy—that of "investments in the new growth drivers" with an eye to surmounting the "Crestor Cliff"—is to develop globally more than five late-stage products. Our anti-HIV drug S-349572 is currently in Phase III clinical trials, with a view to filing for regulatory approval during fiscal 2012. S-297995, for the alleviation of

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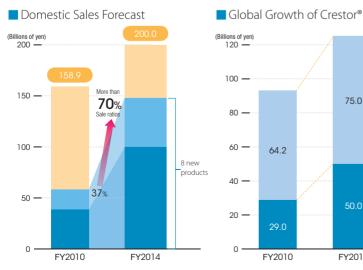
opioid-induced adverse effects, offers hope that a single drug will prove effective in treating both nausea/vomiting and constipation. This drug is now in Phase IIb trials in Japan and the US. The diabetes treatment S-707106 has entered Phase IIa trials in the US. In January and April of 2011, meanwhile, Shionogi Inc. launched Kapvay<sup>™</sup> for the treatment of attention deficit hyperactivity disorder (ADHD) and Cuvposa™ for chronic drooling in children. Following the completion of Phase III trials on our vulvar and vaginal atrophy treatment ospemifene, we have also commenced a bioequivalence study that leaves submission for regulatory approval just around the corner. However, in a combination

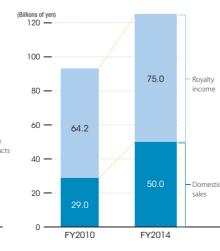
Phase II study with the existing weight-loss pill orlistat, our anti-obesity drug S-2367 fell short of the expected level of efficacy. Based also on the outcome of recent applications to have anti-obesity drugs approved in the US and Europe, we made the difficult decision to halt development in those markets.

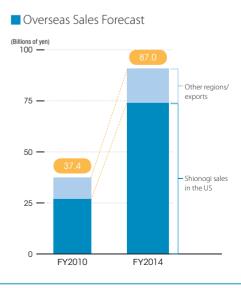
Among initiatives supporting our third basic strategy of "therapeutic areas to be focused on," and the discovery of development candidates capable of underpinning an era of renewed growth ten years from now, we inked a joint research agreement concerning Gram-negative cephems with GlaxoSmithKline, launched a collaboration with Purdue Pharma L.P. in the field of pain management, and undertook research into treating Alzheimer's disease.

In terms of our business performance in fiscal 2010, domestic prescription drug sales increased year on year despite the adverse impact of NHI drug price revisions, in addition to which AstraZeneca achieved solid growth in global sales of Crestor<sup>®</sup>, resulting in higher royalty revenues. As a consequence, net sales rose 1.4% year on year in fiscal 2010, to ¥282.4 billion. However, operating income decreased 10.6% year on year to ¥46.9 billion. One reason was an increase in selling, general and administrative (SG&A) expenses. Furthermore, the cost of sales ratio worsened in line with a decrease in sales at Shionogi Inc. and a shortfall versus plan in companywide activities to reduce the cost of sales. Ordinary income decreased 10.6% to ¥45.2 billion. Net income decreased 48.2% to ¥20.0 billion as a result of extraordinary losses, including losses relating to the Great East Japan Earthquake, business structure reform expenses and impairment losses at Shionogi Inc.

### Shionogi Growth Indicators in the Third Medium-Term Business Plan







# What issues came to light in this first year that stand in the way of achieving the objectives of the new medium-term plan?

While I think the first year proved that we are heading in the right direction with the various initiatives undertaken as part of the new medium-term plan, it became clear that further action is needed to support global growth. One thing we need to do is to control costs. Second, we need to enhance our R&D pipeline. In these regards, we must enhance the Group's drug discovery capabilities, as well as improve and accelerate strategic decision-making about global products under development.

Although results from the first year of the new medium-term plan appear to validate the initiatives undertaken to support the first basic strategy, "steady growth mainly through enriched pipeline," we think there is still room for improvement in productivity per Medical Representative (MR) and in detailing\* to hospitals. Also, we cannot claim that our goals have been met if sales are on target but profits fall short. As has already been announced, for fiscal 2014 we are targeting net sales of ¥375 billion and operating income of ¥110 billion. If we are to meet those objectives, we must continue making a concerted effort to enforce cost controls across the Shionogi Group, including domestic marketing.

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With regard to our second basic strategy, "investments in the new growth drivers," development of our anti-HIV drug is proceeding apace. Unfortunately, though, we were obliged to halt development in the US and Europe of S-2367, an anti-obesity drug that we had hoped would play a role in us surmounting the "Crestor Cliff." We have no choice now but to quicken the pace of pipeline development to fill the hole left by this discontinuation, all the more so because we envisioned S-2367 fitting the bill of an internally developed drug with global market potential, and had acquired the former Sciele Pharma, Inc. with the specific goal of building a US marketing network. It was for this reason, too, that we established the Global Development in April 2011, in order to create a

unified global development strategy.

On the subject of our third basic strategy, "therapeutic areas to be focused on," we are taking steps to flesh out our drug discovery portfolio through joint research with other pharmaceutical companies and bioventures to create new development candidates. With a view to securing new drug seeds, we believe it is important to continue our collaboration with Hokkaido University and Osaka University, along with the FLASH\* drug discovery initiatives. In a move to enhance research productivity by consolidating research functions, we also undertook to build a new research building on the grounds of the Shionogi Pharmaceutical Research Center in Toyonaka City, Osaka Prefecture, which was completed in July 2011.

It may go without saying, but if we are to market original products in the US market and in other countries worldwide, we must further strengthen our in-house R&D capacity. We see this as critical to our capacity for survival in this industry, and our ability to realize global growth.

#### Glossary

#### \* Detailing

Providing doctors or other healthcare professionals with detailed information about drugs in a timely fashion.

<sup>\*</sup> FLASH (PHarma-Link between Academia and SHionogi)



The new pharmaceutical research building was completed in July 2011

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# What are the key points for realizing the goals set in the new medium-term plan?

We believe a change of approach is necessary if these goals are to be met. We must change our approach and our employees must better control costs. We are therefore taking steps to achieve the plan's goals from the dual perspectives of operational reform and corporate culture.

We recognize that holding on to past practices and attitudes would make it difficult to meet the objectives of our new medium-term plan. When kicking off our new medium-term plan, we also instigated Project SING (Shionogi Innovative New-DNA Generator), a two-pronged companywide initiative comprising an "operational reform project" aimed at changing business practices and optimizing resource allocation, and a "corporate culture reform project" geared toward upending a corporate culture that has consistently seen Shionogi fall short of its goals.

In particular, we hope that actions such as these will instill greater cost awareness among our employees. Sales are often at the mercy of external factors, but cost control is something that can be pursued internally. We plan to be unstinting in our cost-control efforts, devolving management objectives into targets for individual divisions and working toward those targets by clarifying the order of priorities, enabling optimal allocation of limited resources.

Under continual pressure from daily business operations, it is conceivable that employees may lose sight of their goal. For that reason, I



have taken to marking the first day of each quarter with a message to employees. I also endeavor to address our employees directly when something significant has taken place. It is my hope that conveying my thoughts in this manner will promote unity within the "Shionogi family," thereby aiding in the realization of our plan's goals.

# What lessons have you learned from halting development of the anti-obesity drug S-2367 in the US and Europe?

In drug development, the Go/No Go decision is critical. Halting development of S-2367 reaffirmed for me that you must always be prepared so as to respond flexibly in the event a drug candidate is dropped.

While halting development is a matter for great regret, in pharmaceutical development it is imperative that compounds be assigned priority according to their perceived potential and marketability. Dropping a drug candidate must be regarded as one of the options available. At Shionogi, we will be evaluating all development candidates every six months, reviewing our investment allocation and order of priority, as part of our approach to ensuring we are always prepared to respond flexibly in the event a development candidate is dropped. We believe that pharmaceutical companies derive a competitive advantage from being ever-ready to respond flexibly in the event a drug candidate is dropped. Based on this

belief, we create back-up compounds and focus on priority projects.

With the anti-obesity drug S-2367, while continuing with Phase II trials in Japan, our Pharmaceutical Research Division is accelerating development of backup compounds. S-2367 had been garnering attention as a global development compound originated internally, but we made the decision to discontinue development in the US and Europe in light of recent decisions on other obesity drugs by regulatory authorities; in addition, S-2367 fell short of its 6% weight loss goal. We think the right decision was made, based on the massive cost involved in continuing development, and the risks likely to be encountered on the road to seeking approval.



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### What expectations do you have for the Global Development?

We expect it to result in faster and more efficient development due to the unification of strategic functions for global development compounds.

We established the Global Development in April 2011. The Global Development was created as one initiative under our new medium-term plan and is charged with speeding up global development through timely and flexible decision-making. It will oversee the unification of development strategies aimed at creating highly marketable new drugs across Europe, the US and Asia (including Japan). The establishment of the Global Development should maximize the value of development compounds. And with a framework for global development and an integrated strategy, we expect development to be faster and more efficient.

### Please comment on US operations (Shionogi Inc.) and the outlook.

In fiscal 2010, we revamped Shionogi Inc.'s business model and implemented operational structure reforms in response to changes in the business environment. As a result, Shionogi Inc. experienced a marked drop in sales, which was caused by terminating marketing agreements for some primary care products. Going forward, management in Japan and the US will work as a committed team to steer the company's operations.

In the US, we acquired Sciele Pharma, Inc. (now Shionogi Inc.) in 2008 as a bridgehead toward globalization. Initially, our plan was to continue selling Sciele Pharma products while we instilled the "Shionogi spirit" and later market Shionogi-developed products in the US, the largest pharmaceutical market, through Sciele Pharma marketing channels. However, we brought forward transformation into a business model based on new drugs similar to Shionogi; Sciele Pharma's previous business model was that of a specialty pharma licensing in late-stage products and adding value to them before launching. We took this action because of changes in the business environment such as the rapid emergence of generics and price negotiations with insurers. A reshuffling of the product lineup and cuts in the work force resulting from this move gave rise to extraordinary losses, while in the process some shipments were affected by quality assurance issues.

We are keenly aware of the disappointment and dissatisfaction our shareholders experienced in regard to the US business, and I personally became acutely aware of how difficult it is to get an overseas operation on the right track. We took a number of steps to enhance communication throughout the company (including at the operational level), such as moving up the schedule for consolidating our US operations on one site, conducting a management reshuffle, and also newly establishing the Overseas Business Unit to enable those in Japan to at all times have a solid grasp of conditions at the US operation. Looking ahead, we aim to ensure stable business operations by marketing ospemifene (treatment for vulvar and vaginal atrophy), S-297995 (for alleviating opioid-induced adverse effects) and then other in-house developed drugs through Shionogi Inc.

As regards our future plans for business overseas, I am sometimes asked whether we should maintain a focus on out-licensing drugs. It is my belief, though, that if we are to achieve true globalization we must construct our own sales channels. Crestor® sales grew more than 20% year on year in fiscal 2010, but this was an exceptional result attributable in large part to AstraZeneca's marketing efforts, which reflect its appreciation for the drug's clinical advantages. As far as globalization is concerned, we believe that organic growth is not possible unless we have our own sale channels and are able to harness our own strengths and ideas in marketing internally developed products. While development of our anti-obesity drug has been discontinued in the US and Europe, if all goes well we expect to be ready in fiscal 2012 to seek approval for our anti-HIV drug S-349572 as a monotherapy and in combination regimens. This compound is being developed by joint venture Shionogi–ViiV Healthcare LLC, but as Shionogi now has its own sales channels overseas, we can approach negotiations over a sales scheme on an equal footing.

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### Please describe the impact of the Great East Japan Earthquake.

Although our Kanegasaki Plant in Iwate Prefecture sustained damage in the earthquake, we continue to regard this plant as having a key role to play in ensuring a stable supply of pharmaceuticals.

Shionogi's Kanegasaki Plant in Iwate Prefecture as well as sales bases and a Distribution Center in eastern Japan were damaged in the earthquake. The Kanegasaki Plant was forced to halt operations, while operations were disrupted at the sales bases and the Distribution Center. While I am sure that the key plant's location in Iwate Prefecture has caused our shareholders to worry, fortunately there was no loss of life or injury. Employees at the Kanegasaki Plant and related departments made a concerted effort to restore operations, and as a result sales activities and distribution center operations quickly resumed, and the Kanegasaki Plant recommenced production approximately one month after the disaster. In terms of ensuring a stable supply of pharmaceuticals, we were helped by having appropriate inventory levels prior to the earthquake. Thanks also to our wholesalers' efforts and the calm response of medical professionals, fears of product shortages proved unfounded. Whereas some Japanese companies have moved to transfer production since the earthquake, at Shionogi we plan to continue using the Kanegasaki Plant as a key production facility.

Across the Company we will also work to save power. We are extending the annual Cool Biz period, cutting the use of lighting, and controlling overtime, among other measures. While our top priority as a pharmaceutical manufacturer is to ensure a stable supply of drugs, we will be doing our utmost to achieve the goal set by The Federation of Pharmaceutical Manufacturers' Associations of Japan, namely to reduce electricity consumption by at least 15% year on year.

# Finally, what is your thinking on shareholder returns?

Shionogi seeks to strike the correct balance between strengthening business fundamentals and returning profits to shareholders in order to meet shareholders' expectations and maximize corporate value.

Our new medium-term plan identifies three key priorities: investment for the future, shareholder returns, and strategic balance sheet improvement. By simultaneously implementing these three priorities, we will balance the strengthening of operational fundamentals and returning profits to shareholders. We believe that we can drive growth at Shionogi as a result and meet the expectations of our shareholders. Steep yen appreciation and a protracted economic slump have kept the Nikkei Average pinned below 10,000 yen, while the earthquake is also likely to leave lingering effects. Against this backdrop, we plan to actively make necessary business investments in such forms as R&D spending on in-house developed drugs, as we believe we must increase and enhance our drug pipeline in order to achieve medium- to long-term growth. In regard to dividends, our new medium-term plan calls for the Company to maintain a dividend payout ratio of 35% and to return to shareholders any income from business activities that is incremental to our initial expectations. In addition, we will repay debt and take other actions with a view to further improving the health of our balance sheet.

We must stay true to Shionogi's basic corporate policies on a global



basis if we are to continue growing. This new medium-term plan contains a practical course of action for globalizing our business. I hope that all of our shareholders will continue to lend us their support in this endeavor, such that together we can experience the tangible benefits of growth.

### Shionogi's Business Activities



Executive General Manager, Pharmaceutical Research Divisio Kohji Hanasaki, Ph.D.

# Pharmaceutical Research Division

In fiscal 2010, which marked the first year of Shionogi's third medium-term business plan, we took our first step toward realizing global growth—generating several new development candidates and undertaking three initiatives aimed at strengthening our operation. As a leading maker of drugs to treat infectious diseases, one of our notable achievements was the successful generation of potential new antibiotics targeting multidrug-resistant Gramnegative bacteria, identified as a major problem both in Japan and overseas. In fiscal 2011, the second year of the new medium-term plan, we will seek to fully capitalize on the Shionogi Pharmaceutical Research Center (SPRC) due for completion in summer. By encouraging active communication among researchers, we aim to consistently turn out high-quality drug candidates, contributing to global realization of our basic strategies.

### Review of fiscal 2010 (first year of the new medium-term plan)

The Pharmaceutical Research Division aims to achieve world-class drug discovery research quality and productivity by focusing our resources in three areas: enhancement of early phase research portfolio; improvement of predictive performance for clinical efficacy; and centralization of functions and strengthening of flexibility. We have set two numerical performance targets: first, to select four or more new molecular entities (NMEs) for drug candidate selection per year, and second, to create NMEs with a success rate of 50% or more in POC\* studies.

During the first year of our new medium-term plan, we advanced two compounds to clinical trials—the HIV integrase inhibitor S-265744 LAP\* and peptide cancer vaccine S-488410 (for esophageal cancer, head and neck cancer, etc.)—as well as progressing several new development candidates (including one for Alzheimer's disease) to preclinical studies. We also succeeded in generating three new development candidates in our focused therapeutic areas: two candidates of antibiotics for serious infectious diseases and a drug candidate for treatment of chronic pain. In the field of cephem antibiotics targeting Gram-negative bacteria, the unmet medical needs\* in treatments to combat drug-resistant bacteria has been increasing in recent years. Against this backdrop, Shionogi has leveraged its strength in antibiotic research to successfully discover effective antibiotics against a broad array of multidrug-resistant Gram-negative bacteria, including Pseudomonas aeruginosa and Acinetobacter baumannii. In order to convey the results of this research to medical settings worldwide as guickly as possible, we have formed a global R&D partnership with GlaxoSmithKline.

### Initiatives in fiscal 2011 (second year of the new medium-term plan) Enhancement of early phase research portfolio

We think that if Shionogi is to overcome the "Crestor Cliff" and further grow our operations worldwide, we must create groundbreaking new drugs addressing unmet medical needs. To upgrade our early drug discovery portfolio, the Pharmaceutical Research Division has focused on seeking out new seeds of research innovation through external alliances with academia and bioventures in Japan. Thus far, these efforts have spawned several new drug discovery programs; besides the Shionogi Science Program, there is also the FLASH\* initiative with the Osaka University Graduate School of Medicine to find further drug discovery seeds, and a network of joint research projects around the hub of the Shionogi Innovation Center for Drug Discovery, established on the campus of Hokkaido University. We plan to take our search for the seeds of drug discovery worldwide by deepening our ties with overseas academia, especially in Europe. In addition to small molecule drug discovery, which we consider to be an area of our strength, we are conducting joint research with bioventures such as OncoTherapy Science, Inc. and AnGes MG, Inc., with a view to accelerating development of highly innovative large molecule drugs.

### Improvement of predictive performance for clinical efficacy

In May 2010, we opened the Osaka University PET Molecular Imaging Center, a joint initiative with the Osaka University Graduate School of Medicine. Equipped with the latest cyclotron and radio/image analysis devices, the Center has already succeeded in the synthesis of a novel positron probe and in imaging analysis in pharmacokinetics and drug efficacy experiments. In fiscal 2011, we plan to press ahead with these initiatives, as well as promoting translational research to facilitate microdosing clinical trials. To further improve clinical predictability, we will fully analyze and make practical use of POC data concerning the compounds we develop in-house, creating enhanced predictive animal models and screening evaluation systems for assessing drug efficacy and toxicity.

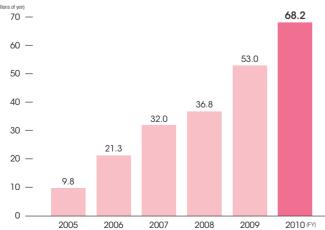
### Centralization of functions and strengthening of flexibility

July 2011 marks the scheduled completion of the much-awaited new research building in Toyonaka, Osaka. The SPRC will bring the company's various disparate research functions—from basic research to exploratory research, synthetic research and early-stage formulation research—under one roof. Our aim in doing so is to achieve top-class global research productivity, with the aid of cutting-edge research facilities and intensive scientific discussion yielded by greater coordination among researchers. In cooperation with other members of the Shionogi value chain, the Pharmaceutical Research Division will work to realize our company policy from a global perspective, at every stage of research from sales and development support to new drug creation.

### **Intellectual Property**

The Intellectual Property Department is focused on developing a global patent strategy closely coordinated with Shionogi's R&D strategies. In fiscal 2010, as in past years, the Department put emphasis on acquiring substance patents for a broad range of new compounds in a large number of countries. As a result of these efforts, approximately 100

### Patent and Licensing Revenues





patents were filed, of which around 30% were for foreign patents (original invention filings).

In the US, several generic drug companies filed Abbreviated New Drug Applications for generic drugs of the hyperlipidemia treatment Crestor<sup>®</sup>. In response to these filings, the Company brought a patent infringement action against these generic drug companies in the US. In July 2010, a US district court ruled that the substance patent was valid and enforceable. This matter is still being contested because the generic drug companies subsequently appealed the ruling. Separate from the above, the Company is contesting the filing of generic applications by another manufacturer in a district court. In Japan, the Company is a defendant in a pending lawsuit concerning technology relating to genetically modified mice for research.

The emergence of generics manufacturers in recent years has seen generics launched to coincide with the expiry of substance patents. In light of this situation, Shionogi plans to efficiently acquire patents regarding indication, crystalline form, manufacturing method, formulation and in other areas in various countries commensurate with cost. In this way, the Company is determined to do its utmost to continue maximizing the length of patent terms and protecting its earnings.

As of March 31, 2011, Shionogi owned approximately 240 patents in Japan and approximately 120 families of patents in overseas jurisdictions (registered patents based on original invention filings).

#### Glossary

- \* POC (Proof of Concept)
   POC studies are human clinical trials designed to demonstrate early signs of a product's efficacy.
   \* LAP (Long acting parenteral formulation)
- \* Unmet medical needs
- This refers to conditions for which there remains no satisfactory method of treatment.
- \* FLASH (PHarma-Link between Academia and SHionogi)

### Shionogi's Business Activities



Executive General Manager, Global Development Takuko Sawada

# Global Development

Among the goals outlined in Shionogi's third medium-term business plan, one is to file for overseas regulatory approval for four products by fiscal 2014. Our mission in fiscal 2011 will be to select the candidate compounds holding the key to Shionogi's future growth, and subject them to efficient global development. To this end, we established the Global Development as an organizational body for planning and overseeing new drug development globally. The Global Development, along with subordinate bodies the Global Project Management and the New Product Planning, will step up the pace of development of highly marketable compounds.

# Mission and role of the Global Development and its two subordinate departments

Under Shionogi's new medium-term plan, the mission assigned to the Development Division was first to make submissions for overseas regulatory approval of four compounds originating from Shionogi or Japanese research institutes, and launch more than one product, and second to globally develop at least five late-stage products (Phase IIb and beyond). To achieve these missions, we will give top priority to carefully screening for highly marketable drug candidates that can drive future growth, and pursuing global development of the chosen compounds with high speed and efficiency and relatively low cost. The Global Development is positioned as an organizational body charged with consolidating control over important decisions concerning "when," "where," "who," and "what studies at what cost."

Unified management enables us to prioritize—that is, to selectively allocate resources to projects that we believe have higher added value and will confer a competitive advantage. Additionally, the Global Development is putting in place systems and processes for global project management, including budgetary allocation and control based on the

#### Target Milestones for FY2011

Code No.	Milestones for FY2011
S-349572 (Dolutegravir)*	Global: Phase III registration completed
S-2367 (Japan) S-234462	Go/No-Go decision
Ospemifene	US: BE study completion, NDA filing
S-555739	Japan: Phase IIa completion, Go/No-Go decision
S-297995	US: Phase IIa completion, Phase IIb initiation Japan: Phase IIb initiation
S-707106	US: Phase IIa completion, Go/No-Go decision
S-888711	Japan: Phase IIa completion, Go/No-Go decision
S-288310	Japan: Phase I/II in progress (registration completed)
S-488410	Japan: Phase I/II in progress (registration completed)
S-222611	EU: Phase Ib in progress (registration completed)
S-265744 LAP	US: Phase I completion
ETHI / Einst Time a im I	

FTIH (First Time in Human): more than new 3 compounds

\*Developed by Shionogi-ViiV Healthcare LLC

aforementioned prioritization, and information on the progress of projects.

In order to speed up global development through timely and flexible decision-making, we arranged the Global Steering Committee (approval of development strategy and clinical trial plans for global compounds) and established the Global Product Strategy Meeting (evaluation and prioritization of the global development compound portfolio). This has enabled speedier strategic decision-making and development.

The functions of the Global Project Management and the New Product Planning, which were established under the Global Development, are as follows. The Global Project Management and its constituent Global Project Leaders are responsible for planning, implementing and supervising development strategies geared toward speedy and efficient global development in three regions: the US, Europe and Asia, including Japan. In specific terms, the Global Project Management is formulating plans for late-stage clinical development of global compounds once POC has been demonstrated in early-stage clinical studies domestically and overseas by the Pharmaceutical Development Division and our US subsidiary Shionogi Inc. Meanwhile, the New Product Planning conducts research on each therapeutic area and competing products, the goal being to create high added-value, namely, distinctive new products that can succeed through



building a competitive advantage after launch.

The Global Development will work even more with the Pharmaceutical Development Division and Shionogi Inc. in an increasingly cross-organizational and borderless fashion, to ensure that all organizations act in unison and agreement, thereby generating maximum value from global development compounds.

#### Goals for the Third Medium-Term Business Plan (1)



# Speed Up Global Clinical Development

Submit NDAs overseas for 4 products (originate from Shionogi or Japanese research institutes) and launch at least one product by FY2014

Globally develop at least 5 late-stage (Phase IIb and beyond) products

Establish the Global Development in April 2011 Unify global clinical development strategy Enhance development functions worldwide

Unify development function in the US: Completed

Establish development footholds in EU Enhance clinical developments in Asia



Executive General Manager, Pharmaceutical Development Division Takayuki Yoshioka, Ph.D.

# Pharmaceutical Development Division

In fiscal 2011, the Pharmaceutical Development Division will engage in further collaboration with the Pharmaceutical Research Division, with a view to conducting early-stage development (to the point of determining POC) swiftly and accurately, and proceeding to clinical development resulting in regulatory approval in Japan and Asia. We will work actively to support attainment of the goals set in the new medium-term plan, providing backup to the Global Development while also assisting with application procedures in Japan and Asia, in terms of data analysis, handling of regulatory affairs and document preparation.

# Review of fiscal 2010 (first year of the new medium-term plan) and prospects

In fiscal 2010, we scored notable achievements with three drugs: Rapiacta<sup>®</sup>, S-349572, and S-297995.

Rapiacta®, the influenza antiviral drug in-licensed from BioCryst Pharmaceuticals, Inc., gained Japanese regulatory approval for the additional indication for pediatric use. In children as in adults, this drug is expected to prove sufficiently effective with just a single dose. As it can also be used on patients with severe influenza virus infection and in cases where oral administration is difficult, we expect the drug to play a key role in preparedness efforts against pandemic influenza, which tends to involve a broad range of patients including children.

In Phase IIb trials, our global strategic product S-349572 (anti-HIV drug) showed strong antiviral activity not just in treatment-naive HIV patients, but also in treatment-experienced patients resistant to the existing integrase inhibitors. The drug is currently in Phase III trials around the world.

In a Phase IIa POC study in the US, S-297995 (for alleviating opioidinduced adverse effects) demonstrated efficacy against constipation, and entered Phase IIb trials in Japan and the US.

In other development news, the type 2 diabetes treatment S-707106 was observed to lower blood sugar levels in an exploratory Phase lb study in the US, and a Phase lla POC study is ongoing in the US. In the field of peptide cancer vaccine therapy, which is expected to become the fourth major form of cancer treatment alongside surgery, chemotherapy, and radiotherapy. S-288310 (bladder cancer) and S-488410 (esophageal cancer, head and neck cancer, etc.) are undergoing Phase I/II trials in Japan and are poised to enter clinical trials in Asia as well. All these drugs have the potential to become growth drivers, but in order to uncover new engines for growth we have been enriching our pipeline through the in-licensing of drugs such as S-524101 (for treating allergic rhinitis caused by house dust mite allergen), and peptide vaccines for ophthalmic disease (age-related macular degeneration and other retinal disorders).

Shionogi has received approval for carbapenem antibiotic Finibax® in Japan for a new dosage regimen in adult patients with serious and intractable bacterial infections, and our next step is to seek authorization for the additional indication of pediatric infection in order to maximize product potential. Furthermore, we have also filed applications for regulatory approval for the additional indication of diabetic neuropathic pain for the antidepressant Cymbalta®, as well as for a cancer pain analgesic, and an additional formulation of oxycodone hydrochloride for injection, as part of product life-cycle management.

### Overseas Business Activities

# Shionogi Inc.



President and CEO, Shionogi Inc. John Keller, Ph.D

A core component of Shionogi's globalization strategy, Shionogi Inc. is a US subsidiary of Shionogi & Co., Ltd. and has fully integrated capabilities spanning clinical development, registration and regulatory affairs, business development, and commercialization. Aided by the establishment of the Global Development, we will work in close collaboration with research and development divisions in Japan—while also independently developing, registering, and marketing our own products in the US, the world's largest pharmaceutical market—to contribute globally to maximizing Shionogi value.

# Shionogi Inc.'s role and mission within the Shionogi Group

Shionogi Inc. is intensively pursuing business development opportunities with a view to helping the Shionogi Group attain the goals set in its third medium-term business plan. We have more than ten marketed products in the US, including two new products launch in early 2011—Kapvay<sup>™</sup> and Cuvposa<sup>™</sup>.

In April 2011, we completed the integration of our operations from Atlanta into one site in New Jersey, and clarified the targets of Shionogi Inc. We expect that achieving the goals of "managing our costs to stabilize our earnings," "maximizing the commercial value of our existing portfolio," "expanding the US portfolio through business development," and "supporting the development of Shionogi pipeline products," will not only bring financial stability but also create a platform for Shionogi Inc. to grow.

Key to the future success of Shionogi Inc. is our focus on new products. We believe that products in-licensed through current business development activities will establish a strong base for the marketing and sale in the US of internally discovered compounds. To that end, it is important also to pursue alliances with leading global companies possessing both deep expertise and stability. Globally, Shionogi has an excellent track record of innovative and successful alliances, based on respect for the expertise and vision of our partners. As Shionogi Inc. pursues new US commercialization partnerships, it is imbued with the same spirit as its parent. In that sense we are seeking out growth-stage pharmaceutical companies and proposing what we believe to be mutually beneficial alliances.

Shionogi Inc. also has a key role in the US development and registration of Shionogi pipeline compounds, and following the establishment of the Global Development, all development efforts throughout Shionogi have become more tightly integrated. With this, the entire Shionogi Inc. workforce will work as one to further strengthen the US operation and enhance the Shionogi Group's growth prospects.





# Pipeline

# Attention Products

# **S-349572**

### (HIV integrase inhibitor)

S-349572 displays stronger antiviral activity than existing integrase inhibitors, as well an excellent resistance profile and favorable pharmacokinetics (maintaining sufficient plasma concentration with once-daily administration without a booster). It is moreover an oral drug that can be administered in combination with other HIV medications. As there is still a need for additional treatment options for HIV, including concomitant administration and combination therapies, Shionogi is concurrently developing a drug combining S-349572 with Epzicom® (abacavir/ lamivudine). This combination therapy is currently the subject of several Phase III trials.

# **S-297995**

# (Peripheral opioid receptor antagonist for alleviating opioid-induced adverse effects)

S-297995 is an oral medication that has minimal CNS effect and selectively targets peripheral opioid receptors. It is therefore effective in alleviating opioid-induced adverse effects including nausea/vomiting and constipation, yet exerts no adverse impact on the analgesic effect of opioids. It is distinguished from existing treatments by being effective at smaller doses not only for nausea/vomiting but also constipation. Phase lla studies in the US confirmed the drug's safety and efficacy, in light of which a Phase llb study has now commenced in Japan and the US.

# Ospemifene

#### (Selective estrogen receptor modulator for post-menopausal vulvar and vaginal atrophy)

Ospemifene is an oral medication that stimulates estrogen receptors in the vaginal mucosa. It is being developed as a treatment for post-menopausal vulvar and vaginal atrophy, a condition in which declining estrogen levels have adversely affected the thickness of vaginal epithelial cells, elasticity, and vaginal secretion. Ospemifene differs from currently available selective estrogen receptor modulators (SERMs) like raloxifene and tamoxifen, which have an antagonistic action on estrogen receptors, and therefore lacks the side effects associated with traditional estrogen-related products, such as thromboembolism and endometrial thickening. Phase III studies are complete and a study is now under way to determine bioequivalence to the commercial product.

Areas	Code No. (Generic name) [Product name]	Category (Administration)
Met	S-474474 (Irbesartan/trichlormethiazide combination)	Angiotensin receptor blocker/diuretic combination (Oral)
abolic	S-2367 (Velneperit)	Neuropeptide Y Y5 receptor antagonist (Oral)
Metabolic Syndrome	S-707106	Insulin sensitizer (Oral)
ome	S-234462	Neuropeptide Y Y5 receptor antagonist (Oral)
	S-4661 (Doripenem hydrate) [Finibax®]	Carbapenem antibiotic (Injection)
Infectious Diseases	S-349572 <sup>+</sup> (Dolutegravir)	Integrase inhibitor (Oral)
S IS	S-265744 LAP	Integrase inhibitor (Injection; Long acting parenteral formulation)
	LY248686 (Duloxetine hydrochloride) [Cymbalta <sup>®</sup> ]	SNRI (Serotonin & noradrenaline reuptake inhibitor) (Oral)
Pain	S-811717 (Oxycodone hydrochloride)	Natural opium alkaloids (Injection)
	S-297995*	Peripheral opioid receptor antagonist (Oral)
Wom Hea	PSD502 (Lidocaine/prilocaine)	Eutectic mixture of anesthetics (Metered-dose topical aerosol spray)
lien's alth	Ospemifene*	Selective estrogen receptor modulator (Oral)
	S-555739	Prostaglandin D2 receptor antagonist (Oral)
Other	S-888711	Small molecule TPO mimetic (Oral)
	S-288310	Peptide cancer vaccine (Injection)
	S-488410	Peptide cancer vaccine (Injection)
	S-222611	HER2/EGFR dual inhibitor (Oral)
	S-524101	Sublingual tablet of house-dust mite allergen extracts for immunotherapy

#### **Out-Licensing Activity**

S-4661 (Doripenem hydrate)	Carbapenem antibiotic (Injection)
S-3013 (Varespladib methyl)	Secretory PLA2 (sPLA2) inhibitor (Oral)
S-0373	Non-peptide mimetic of TRH (Oral)

	(As of August 2011)							
	Indication	Stage		Origin	Development			
		Phase I	Phase IIa	Phase IIb	Phase III	Submission		
	Hypertension	Japan: Phase	e				Irbesartan: Sanofi Aventis (France) Trichlormethiazide: Shionogi	In-house
	Obesity	Japan: Phase	e				In-house	In-house
	Type 2 Diabetes	USA: Phase	la				In-house	In-house
	Obesity	USA: Phase					In-house	In-house
	Pediatric infection	Japan: NDA	submission (in	preparation)			In-house	In-house
	HIV infection	Global: Phas	e III				Shionogi-GlaxoSmithKline	Shionogi-ViiV Healthcare LLC
	HIV infection	USA: Phase					Shionogi-GlaxoSmithKline	Shionogi-ViiV Healthcare LLC
	Diabetic peripheral neuropathic pain	Japan: NDA	submission (Se	ptember 2009)	)		Eli Lilly and Company (USA)	Shionogi/Eli Lilly Japan K.K.
	For the treatment of moderate to severe pain in patients with cancer pain	Japan: NDA	submission (Se	ptember 2010)	)		Napp Pharmaceuticals Limited (UK)	In-house
Alleviation of opioid- induced adverse effects	Japan: Phase	e IIb				In-house	In-house	
	USA: Phase	lb				III-II0036		
	Premature ejaculation	USA, Europe	Phase III				Plethora Solutions Holdings PLC (UK)	Shionogi/Plethora Solutions Holdings PLC
	Post-menopausal vaginal atrophy	USA: Phase	II				QuatRx Pharmaceuticals Company (USA)	Shionogi/QuatRx Pharmaceuticals Company
		Japan: Phase	e IIb (in prepara	ition)				
	Allergic disease	Europe: PON	e: POM (Proof of Mechanism)		In-house	In-house		
		USA: NDA su	bmission (in pi	eparation)				
	Thrombocytopenia	USA, Europe	: Phase II				In-house	In-house
		Japan: Phase	e IIa					
	Bladder cancer	Japan: Phase	e I/II				OncoTherapy Science, Inc. (Japan)	In-house
	Esophageal cancer	Japan: Phase	e I/II				OncoTherapy Science, Inc. (Japan)	In-house
	Malignant tumor	Europe: Phas	e Ib				In-house	In-house
	Allergic rhinitis caused by house-dust mite allergen	Japan: Phase	91				Stallergenes SA (France)	In-house

Bacterial infection	USA: NDA submission (June 2007) Hospital-acq	uired (nosocomial) pneumonia including ventilator-associat	In-house	Johnson & Johnson (USA)	
				III-HOUSE	
Acute coronary syndromes	USA, Europe: Phase III			Shionogi/	Anthera Pharmaceuticals Inc. (USA)
				Eli Lilly and Company (USA)	Anthera Finannaceuticais Inc. (USA)
Spinocerebellar ataxia	Japan: Phase II			In-house	Kissei Pharmaceutical Co., Ltd.
				In-nouse	(Japan)

### Shionogi's Business Activities



Executive General Manager, Human Health Care Division Masaaki Goshima

# Human Health Care Division

In fiscal 2010, the first year of our third medium-term business plan, the trial introduction of a new drug pricing system (NHI Drug Price Premiums for Promoting the Creation of New Drugs and the Elimination of Off-Label Drug Use) triggered dramatic change in the pharmaceutical sales and marketing environment in Japan. Despite the drug price revisions, Shionogi outpaced the market average in terms of growth in sales of prescription drugs in Japan for the first time in 12 years. Rather than relying on the offpatent drugs\* that have been NHI-listed for many years, we will continue putting our all into promoting and carrying out educational activities on the new products, especially Crestor® (hyperlipidemia treatment), Irbetan® (antihypertensive) and Cymbalta® (antidepressant).

### Review of fiscal 2010 (first year of the new medium-term plan)

We intend to achieve the goals set in our new medium-term plan by continuing to grow sales at a pace outstripping the average for the pharmaceutical market. In fiscal 2010, the first year of our new business plan, Shionogi's prescription drug sales grew 4.3% year on year, versus 2.5% growth for the market as a whole, according to Crecon data\*. In this manner, growth outstripped that of the Japanese market for the first time in 12 years. We attribute our success in growing sales according to plan to strategic expansion in sales of eight strategic products: Crestor\*, Irbetan\*, Cymbalta\*, OxyContin\*/OxiNorm\*, Finibax\*, Differin\*, Pirespa\*, and Rapiacta\*.

While leveraging Shionogi's long-standing strength in one-on-one sales activities by medical representatives (MRs), we also held a number of small seminars to promote "doctor to doctor" communication. We believe this action provided doctors, who share their experiences actually treating patients, with the information they need.

Shionogi's new medium-term plan also targets closer relationships with hospitals. This will require improved communication between Shionogi and hospitals (doctors), toward which end we have been holding web conferences with highly topical themes specifically catering for busy hospital doctors. These seminars offer doctors the convenience of participating online while remaining at their hospitals, and in fiscal 2010 our web conferences continued to attract large numbers of medical professionals.

In terms of initiatives undertaken to promote individual products, for Crestor<sup>®</sup> and Differin<sup>®</sup> we conducted our first direct-to-consumer educational campaigns. Based in part on television commercials, these programs were aimed at increasing public awareness of the two therapies, encouraging asymptomatic dyslipidemia patients and acne sufferers to seek help from medical institutions.

In April 2010, we entered the area of treatments for central nervous system (CNS) disorders when launching the antidepressant Cymbalta®, at which time we formed a special team of MRs dedicated to Cymbalta® detailing\*. We will continue using MRs to maximize sales of our eight strategic products, while at the same time conducting marketing activities specifically tailored to each product's attributes.

### Initiatives in fiscal 2011 (second year of new medium-term plan)

It goes without saying that our performance in fiscal 2011, the second year of our new medium-term plan, will be critical to achieving the plan's objectives. The Human Health Care Division will again concentrate its resources on expanding sales of Shionogi's eight strategic products, with the goal of achieving detailing synergies between products. We have positioned three products—Crestor® above all, followed by Irbetan® and Cymbalta®—as our core strategic products and aim to increase total sales



from them to ¥100 billion in fiscal 2014.

In marketing targeted at patients suffering from both dyslipidemia and hypertension, we anticipate detailing synergies between Crestor<sup>®</sup> and Irbetan<sup>®</sup>. In May 2011, approval was given for long-term prescription of Cymbalta<sup>®</sup>. As many depression sufferers are found to be afflicted also by lifestyle diseases such as metabolic syndrome or hypertension, we envision an increase in efficiency through concurrent detailing of Cymbalta<sup>®</sup>, Crestor<sup>®</sup>, and Irbetan<sup>®</sup>.

In terms of the other five strategic products, we conduct detailing activities, always aware of total care for patients. Although OxyContin<sup>®</sup>/ OxiNorm<sup>®</sup>, both developed as analgesics for cancer pain, could relieve pain of most cancer patients when applied with appropriate dose setting, some cancer patients are still suffering from pain. Shionogi is therefore inspiring public opinion through multiple advertisements to make patients aware that cancer pain could be relieved with oral medication. At the same time, our MRs hold seminars for physicians as well as other medical professionals such as pharmacists and nurses. We are thus using every opportunity to provide information about cancer pain treatment. Moreover, Shionogi is tackling infectious diseases head-on, in an



environment where various infectious diseases have become social problems in recent years. We have produced a booklet called "What is SHIONOGI," which looks back at our efforts in respect of infectious diseases over the past 100 years. Through this publication, we are providing information about Shionogi's corporate commitment. In the context of treatments for infectious diseases, in April 2011 our carbapenem antibiotic Finibax® obtained or gained approval for an additional dosage and administration regimen (3g as a maximum daily dose), which we think will produce increased efficacy in patients with serious infections. At the 51st Annual Meeting of The Japanese Respiratory Society, new guidelines were released for NHCAP (nursing and healthcare-associated pneumonia). As an antipseudomonal drug, Finibax<sup>®</sup> (generic name: doripenem hydrate) was recommended at the meeting for patients at risk of infection with drugresistant pathogens, and for those requiring treatment in intensive care unit settings. In fiscal 2011, we plan to continue the public awareness campaign begun in fiscal 2010 for Differin®, a topical treatment for acne vulgaris. We hope to return smiles to the faces of acne sufferers by encouraging them to seek help from dermatologists. With Pirespa®, the only drug indicated for idiopathic pulmonary fibrosis, receipt of regulatory approval in Europe has also had a favorable impact on domestic sales. Finally, Rapiacta® demonstrated the usefulness of injections in the treatment of influenza. In fiscal 2011, we will ramp up detailing activities with a view to carving out a role for Rapiacta® in treating all influenza patients.

#### Glossary

- \* Off-patent drugs Off-patent drugs for which generic equivalents exist
- \* Crecon data Market analysis data provided by pharmaceutical industry research organization Crecon Research & Consulting Inc.
- \* Detailing

Providing doctors or other healthcare professionals with detailed information about drugs in a timely fashion.

### Shionogi's Business Activities



 $\label{eq:constraint} \begin{array}{l} {\sf Executive General Manager, Manufacturing \& {\sf Technology Division} \\ {\sf Takuo Fukuda} \end{array}$ 

# Manufacturing & Technology Division

Under the third medium-term business plan, the Manufacturing & Technology Division has the goal of strengthening the production system and ensuring a stable supply to support the global launch of in-house products. In fiscal 2010, the first year of our new medium-term plan, our emphasis was on putting in place new infrastructure to support these activities.

The Great East Japan Earthquake in March 2011 damaged the Kanegasaki Plant in Iwate Prefecture, where some of our key products are manufactured. It was not long, however, before production resumed after a concerted effort to get the plant up and running again.

Employees showed enormous passion and adaptability in undertaking restoration efforts and determination to make up for time lost due to the natural disaster. These qualities are strengths of the Manufacturing & Technology Division. I am convinced that they will enable us to speed up globalization and ensure stable product supplies, without affecting victims of the disaster.

# Review of fiscal 2010 (first year of the new medium-term plan) and prospects

At the Manufacturing & Technology Division, we are actively working to bolster our existing manufacturing infrastructure and technology base in order to ensure reliable global supplies. In fiscal 2010, we enhanced the production line at the Settsu Plant in Osaka to support Cymbalta<sup>®</sup>, which was launched in April 2010, and also instigated a project to improve global GMP\* compliance. At the Kanegasaki Plant, we began construction of a new formulation facility for injectable betalactam antibiotics in a move designed to consolidate and increase production.

In CMC\* research activities so as to manufacture newly developed products and raise quality further, we embarked on construction of a D&M\* facility that will be used for manufacturing APIs\* in late-stage trials, and for commercial APIs in initial production. We also strove to establish technical expertise in biopharmaceuticals.

As part of our program to further develop the manufacturing infrastructure and technology base, we made consolidated subsidiary an API manufacturer Nichia Pharmaceutical Industries Ltd. a wholly owned subsidiary and renamed it Shionogi Pharma Chemicals Co., Ltd., as well as merging it with another wholly owned subsidiary, Shionogi Engineering Service Co., Ltd., to strengthen engineering functions.

In the field of infectious diseases, which is a priority therapeutic area for Shionogi, in 2010 we inked an agreement with GlaxoSmithKline to conduct joint research, development and commercialization regarding cephem antibiotics targeting Gram-negative bacteria. We intend to quicken the pace of development by appropriate manufacturing technologies at the early stage of R&D.

# Impact of Great East Japan Earthquake and efforts to restore manufacturing facilities

The Great East Japan Earthquake on March 11, 2011 caused damage to our Kanegasaki Plant, where we manufacture mainstay antibiotics and cancer pain analgesics. At one point, we suspended all operations.

Thereafter, the entire company pitched in to aid the manufacturing division in restoring the plant, because it is precisely in circumstances such as this that we have a responsibility to provide patients with reliable access to Shionogi products. Production recommenced approximately a month later and has since been progressively ramped up as a result of prompt action to secure essential supplies, repair damaged facilities, accurately ascertain plant inventory levels, procure raw materials, and reschedule and redeploy manpower for resuming production. While we are still grappling with various issues in the aftermath of the natural disaster, the Manufacturing & Technology Division will continue making every possible effort to reinforce Shionogi quality while ensuring the stable supply of products.

#### Glossary

- \* GMP (Good Manufacturing Practice)
- \* CMC (Chemistry, Manufacturing and Controls)
- \* D&M (Development & Manufacturing)
- \* APIs (Active Pharmaceutical Ingredients)



Executive General Manager, Quality, Safety and Regulatory Affairs Management Division Hirosato Kondo, Ph.D.

# Quality, Safety and Regulatory Affairs Management Division

The first year of our third medium-term business plan has come to an end, and we are now into the second year. At the Quality, Safety and Regulatory Affairs Management Division we set three main goals in the first year of the new medium-term plan. First, to build and implement a global quality assurance system. Second, to upgrade predictive and preventive risk management. Third, to focus on human resource development. Each individual is working to advance the Company's pursuit of globalization, and the fruits of those efforts are considerable.

At the same time, we made it clear as to what aspects we should strengthen. For example, in our bid to build and implement a global quality assurance system, we consider it to be essential that the quality assurance and safety and regulatory affairs management for the Shionogi brand should function properly to ensure that patients around the world are able to use Shionogi products with confidence.

In the year ending March 2012, for a little closer to that objective, we will work cohesively to transform the Quality, Safety and Regulatory Affairs Management Division into an organization that acts rather than responds, viewing continued innovation as our overarching goal.

### Review of fiscal 2010 (first year of the new medium-term plan)

In January 2010, in relatively quick time, we received regulatory approval for Rapiacta®, the world's first injectable treatment for influenza virus infections. To promote correct and safe usage after launch, the Quality, Safety and Regulatory Affairs Management Division is collecting data on all patients who receive the drug after launch to ensure safety, something never before undertaken in Japan.

In July 2010, we established a planning office to oversee the entire division, focusing specifically on our efforts to build a global quality assurance system, upgrade predictive and preventive risk management of Shionogi products, and engage in the necessary human resource development.

As the upshot of a joint project begun in early 2010 with Shionogi Inc. to build a new system for managing safety information globally, in March 2011 we also introduced and launched the Argus safety database for storing and managing adverse event information. This has enabled unified management of adverse event information and expedited the sharing of such information between Japan and the US, thereby allowing the Shionogi Group to take a cohesive approach to evaluating, ruling on, and responding to, adverse events. And, in November 2010, we established the "Shionogi Product Policy" to serve as an important guideline for Shionogi products. This policy emphasizes the pursuit of globally acceptable product quality.

On the other hand, fiscal 2010 saw us recall the OTC product Belix® and diagnostic agent Shionospot® BNP. After finding the cause of the problems based on information obtained from a contract manufacturer and an overseas manufacturer, we quickly recalled the products and took all the necessary improvement steps. Fortunately, there was no damage to human health. In light of these recall experiences, however, we will redouble our efforts to reinforce quality assurance for Shionogi products.

### Initiatives in fiscal 2011 (second year of the new medium-term plan)

Under the aegis of the Global Development established in fiscal 2011 to steer and oversee global drug development, the Quality, Safety and Regulatory Affairs Management Division plans to work more closely with Shionogi's overseas affiliates to further strengthen quality assurance and ensure that patients worldwide can use Shionogi products with peace of mind. Following a management review conducted in accordance with international quality assurance guidelines, top management now has active involvement in this aspect of operations.

Turning to the Great East Japan Earthquake, we sustained damage to one manufacturing facility—the Kanegasaki Plant—and also to our Tokyo Distribution Center. In the event of future emergencies we may be required to make some changes to manufacturing processes. However, as a pharmaceutical manufacturer we will continue to devote every possible resource to ensuring the "quality," "safety," and "reliability" of our products, and to doing our utmost to achieve stable supply.

# Major Products

### Prescription Drugs

In fiscal 2011, which marks the second year of Shionogi's third medium-term business plan, we are targeting further growth through strategic expansion of sales for the eight core products underpinning our first basic strategy.

### **Crestor® Tablet** (Hyperlipidemia Treatment)

Evidence from many clinical studies in Japan and overseas indicates that the statin therapy Crestor<sup>®</sup>, developed internally by Shionogi, is a leader among dyslipidemia treatments. Crestor<sup>®</sup> has been proven highly effective in lowering LDL cholesterol, thereby helping more dyslipidemia patients to reduce their risk of atherosclerotic diseases, and affording physicians and patients alike a greater sense of satisfaction and reliance.



### Irbetan<sup>®</sup> Tablet (Antihypertensive)

Irbetan<sup>®</sup> is a long-acting angiotensin II receptor blocker (ARB) suited for use as a first-line therapy for hypertension. In addition to its superior antihypertensive effect, Irbetan<sup>®</sup> is also a first-choice treatment for the growing number of Japanese suffering from a combination of hypertension and metabolic syndrome. As a second-generation ARB, Irbetan<sup>®</sup> is the subject of much anticipation, and is also referred to as "metabosartan."



### **Cymbalta® Capsule** (Treatment for Depression and Depressive Symptoms)

Cymbalta®, which won domestic approval in January 2010 after receiving US and European regulatory approval in 2004, is a serotonin and noradrenaline reuptake inhibitor (SNRI) approved in 99 countries around the world for the treatment of depression. It is expected to be a useful drug formulation for relieving the symptoms of depression and enabling those who suffer to achieve remission, recovery and a return to society.



### Finibax<sup>®</sup>, Finibax<sup>®</sup> Kit (Carbapenem Antibiotic)

Developed in-house by Shionogi, Finibax<sup>®</sup> is a carbapenem antibiotic for injection with broad antibacterial activity against various bacteria. In April 2011, Finibax<sup>®</sup> received approval in Japan (ahead of elsewhere in the world) for an additional dosage (3g as a maximum daily dose). Shionogi is confident that this product will be effective for patients with serious infections.

### **Differin® Gel** (Acne Vulgaris Treatment)

Differin<sup>®</sup> Gel, which uses adapalen and received an A grade recommendation for treating comedo as well as light to severe symptoms of inflammatory skin rashes in guidelines on the treatment of acne vulgaris, is Japan's first novel topical acne treatment with retinoid-like activity. We hope it will return smiles to the faces of acne sufferers.

### **Pirespa® Tablet** (Idiopathic Pulmonary Fibrosis Treatment)

Offering the effect of inhibiting pulmonary fibrosis, Pirespa® (general name: pirfenidone) is the only drug that is indicated for idiopathic pulmonary fibrosis. In 2008, Shionogi became the first company in the world to obtain manufacturing and marketing approval of the drug in Japan. US company InterMune, Inc. received approval for pirfenidone in Europe in March 2011, and now plans to launch it across the region.







# Shionogi's Business Activities

### OTC Drugs

#### OxyContin<sup>®</sup> Tablet, OxiNorm<sup>®</sup> Powder (Cancer Pain Analgesic)

The World Health Organization recommends treating cancer-related pain with oral analgesics that include immediate-release and sustainedrelease formulations of the same active ingredient. A combination of Shionogi's 12-hour sustained-release OxyContin® Tablet and immediaterelease OxiNorm® Powder is clinically proven to be highly effective in cancer pain management.

Rapiacta<sup>®</sup> Bag,

**Rapiacta® Vial** 

(Antiviral Drug for Influenza) Rapiacta<sup>®</sup> was launched in January

2010, as the world's first influenza

treatment administrable through a

single-dose intravenous drip infusion.

As an intravenous injection, Rapiacta®

be administered to seriously ill patients as well as patients who have difficulty

swallowing tablets. These attributes

anti-influenza drug, that of protecting

aid it in fulfilling the mission of an

the life of the patient.

can be used to treat all age groups, from children to the elderly, and can

#### Sedes<sup>®</sup> First (Non-pyrazolone Analgesic Antipyretics)

We regard Sedes<sup>®</sup> First as a frontline analgesic antipyretic, in that it combines the three attributes patients demand from such drugs: it does not make you sleepy, is gentle on the stomach, and has a film coating that renders it easy to swallow.



#### Sedes<sup>®</sup> Hi G (Pyrazolone Analgesic Antipyretics)

Sedes<sup>®</sup> Hi G is the first granular formulation in the Sedes<sup>®</sup> series, and like its predecessor Sedes<sup>®</sup> Hi contains isopropylantipyrine, which has an excellent antipyretic and analgesic effect. In its capacity as an analgesic antipyretic, Sedes<sup>®</sup> Hi G combines the clinical efficacy of Sedes<sup>®</sup> Hi with a granular formulation's ease of ingestion.



### **Pylon®** (Vitamin C-based Combination Cold Remedy)

Soluble in either hot or cold water, the lemon-flavored Pylon<sup>®</sup> is easy to ingest. Its seven active ingredients, starting with the analgesic antipyretic acetaminophen, and also including vitamin C, levels of which are quickly depleted during a cold, are effective in easing various cold symptoms including fever, chills, and sore throat.



Quick Chaser<sup>®</sup> Flu A,B

Quick Chaser® Flu A,B is a reagent for

design that is easy for patients and

medical professionals to understand.

Together with Rapiacta®, Shionogi's

Flu A,B is helping to improve patients'

(Influenza Virus Diagnostic Kit)

determining whether a patient is infected

by the influenza virus, featuring a product

anti-viral drug for influenza, Quick Chaser®

quality of life through the early detection

and treatment of influenza virus infection.

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### MIO2 Shionogi® BNP, Shionospot® BNP (BNP Kit)

Because blood levels of the hormone BNP (human brain natriuretic peptide) rise when heart functions are even lightly impaired, BNP is a useful indicator when diagnosing and assessing cardiac insufficiency. With recent therapeutic guidelines citing testing of BNP blood levels as a useful means of screening people with hypertension for signs of cardiac insufficiency, BNP has gained a strong reputation at the frontlines of medicine.

### Allerport<sup>®</sup> TARC (Th2 Chemokine/TARC Kit)

TARC (thymus and activation-regulated chemokine) is believed to play a key role in the pathogenesis of atopic dermatitis, as serum levels of TARC are observed rising in step with worsening skin condition. Action to normalize serum TARC levels has proven highly effective in treating atopic dermatitis and for this reason such levels are regarded in clinical settings as an objective indicator of the condition. As a reagent used to measure serum levels of TARC, Allerport\* TARC can be used to support treatment of atopic dermatitis.



### Allerport<sup>®</sup> HRT (HRT Kit)

Launched in May 2011, Allerport<sup>®</sup> HRT (Histamine Release Test) is a reagent for use in automated assays measuring the histamine released due to allergens, of which 32 are now listed as causing food allergies in the Japanese Pediatric Guideline for Oral Food Challenge Test in Food Allergy.



# Fundamental Policy on CSR

The Shionogi Group's purpose, as expressed in the beginning of the Company Policy instituted in 1957, is "to strive constantly to provide medicine of the best possible kind essential for protection of the health of the people." This eternal and unwavering corporate philosophy is a statement of our vision and value to society. Our operations as a pharmaceutical company inherently contribute to society, and we believe that implementing this philosophy promotes the fulfillment of our social responsibilities as a corporation.

To help realize the Company Policy, we have created Action Guidelines, which all Shionogi employees share and embrace as norms for daily activities. These guidelines also describe the ideal nature of all our current and future activities.

By acting in accordance with the Company Policy and the Action Guidelines, we can contribute to patients, physicians, and other healthcare professionals who need the medicines we provide as well as to shareholders, other investors, and society as a whole. We are confident that this contribution, in turn, leads to the Company's development and to the personal growth of Shionogi employees as fellow human beings.

# The Company Policy of Shionogi

# Shionogi's Action Guidelines

Mission

We will deliver pharmaceuticals that offer an even higher level of satisfaction to patients, their families, and healthcare providers and improve the quality of life for patients and their families.

# Vision

A company with a strong presence worldwide A company that has pride and dreams, and embraces challenges

# Value

Customer Focus, Trust, Professionalism, On-Site Orientation, Respect for the Individual

### **Customer Focus**

- Shionogi understands that the greatest joy comes from bringing joy to patients, their families, and healthcare professionals by relieving their suffering and concerns.
- For this reason, the Company places the highest priority on relationships with these people, and takes meticulous care to meet their demands.

#### Trust

- Shionogi understands that the only way to gain the trust of society is to steadily provide original medicines in a proper manner to the maximum number of people
- To do this, employees must build relationships of mutual trust both inside and outside the Company.

#### Professionalism

- Shionogi understands that maintaining the highest level of professionalism in attitude and conduct is crucial for ensuring that it provides the best medicines to patients and healthcare professionals.
- For this reason, Shionogi's employees work steadily, overcoming major challenges with a positive mind set and accomplishing the goals they have set in order to achieve the highest level of competence in every field.

#### **On-Site Orientation**

- Shionogi understands that its laboratories, plants, and the places where it sells its products are a focus of expertise and fact, and that the Company's activities at these sites reflect whether the Company' s efforts are benefiting patients, their families, and healthcare professionals
- For these reasons, Shionogi places a priority on information from these sites, and uses such information as a basis for action.

#### **Respect for the Individual**

- Shionogi understands that respect for individuals and the recognition of diversity result in a higher level of creative value, and that this allows the Company to provide patients, their families, and healthcare workers with greater value.
- For this reason, Shionogi's employees maintain maximum respect for each other and everyone they deal with.

# Relationships with Patients and Medical Professionals

# Responding to Inquiries

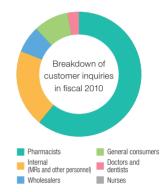
To respond to various inquiries regarding Shionogi products, Shionogi has two different toll-free telephone numbers—one for medical professionals and the other for general consumers and patients. Inquiries are also accepted round the clock on the Company's website.

In fiscal 2010, the total number of inquiries was approximately 78,400, decreasing roughly 9% from fiscal 2009. This decrease can be accounted for by the 1,500 or so inquiries made in fiscal 2009 regarding our newly approved thiazide antihypertensive diuretic, Fluitran<sup>®</sup> 1mg. Such inquiries receded in fiscal 2010.

The Drug Information Center is our contact point for inquiries. Here, we gather information on not only Shionogi products but also peripheral areas, in order to promptly provide accurate information in response to inquiries. We collect, compile and store information on inquiries received, and provide feedback on analysis of this information to the relevant departments. Through this feedback, we strive to share and make good use of all of this information. By sharing this information, we not only monitor current conditions but also conduct company-wide risk management and implement prompt and proper responses to risk. At the same time, these efforts ultimately help us to prevent the materialization of future risks.

Looking ahead, we will focus on multifaceted application of information. For example, we will gauge the extent to which current strategies have become established through the analysis of inquiries related to various product strategies, which will enable us to identify new directions for future strategies.

Furthermore, by responding promptly and accurately to inquiries from within and outside the Company, we will work to expand and promote the appropriate use of Shionogi products and contribute to the health of even more patients, while increasing our contribution through the optimized use of information.



# Measures to Improve Quality of Life

### Cancer Pain Management Outreach

Japan reported that two thirds of those experiencing pain from cancer did not seek relief (see source below). Oral therapeutic narcotics can eliminate pain in many cases. Therefore, Shionogi has been running a pain management campaign that includes television commercials and newspaper advertisements in which actor Shunji Fujimura, himself a cancer survivor, emphasizes that patients do not have to simply tolerate pain. This initiative has proved successful over the past four years, achieving high awareness of its message and increasing visits to our cancer pain therapy website.

Shionogi has participated in the Cancer Pain Relief Consortium (http://www.toutu.jp/, Japanese only), a collaborative initiative of industry entities that promotes pain care through a variety of activities, since its founding in April 2008. In February 2011, Shionogi hosted a media forum

along with representatives from the government, patient groups, academia, and the media, together with a range of people affected one way or another by cancer, to discuss ways to effectively disseminate accurate information on, and



thus increase awareness of pain care for cancer sufferers. Shionogi also supports a project promoted by the Ministry of Labour, Health and Welfare called the Orange Balloon Project, which disseminates palliative care information. These and other ongoing initiatives seek to increase overall social interest in cancer pain therapy and improve quality of life.

With April 2011 marking the fifth year of publicity in this arena, Shionogi is determined to continue taking diverse steps to help eliminate cancer patients' pain as swiftly as possible. Source: MMJ June 2008, Vol. 4, No.6, p. 534

Supporting Dermatological Treatment for Acne

Acne vulgaris afflicts many people, and, as it mainly appears on the face and can leave scars, significantly affects quality of life. Yet despite these consequences, few sufferers seek the attention of a dermatologist, and instead turn to skincare products and commercially available treatments.

Indeed, the notion that acne is a medical condition requiring medical attention is not a common one.

Shionogi continues to provide acne patients with accurate information and encourages them to seek



Corporate Informat

### Shionogi's CSR Activities

dermatological treatment to restore their confidence and improve their quality of life.

Fiscal 2011 will see Shionogi conitune with our advertising campaign featuring entertainer Kanako Yanagihara. This campaign will include television commercials aimed at dispelling fallacies surrounding the treatment of acne and advising acne patients of the benefits of seeking medical help, as well as coverage of acne treatment under health insurance.

Going forward, we intend to step up this awareness campaign to encourage more acne patients to seek greater quality of life through treatment by a dermatologist.

# Relationship with Employees

### Human Resource Development

Shionogi considers people to be its most important resource, and it does its utmost to create an environment in which employees can proactively improve and exercise their skills. And, in doing so, create a workforce that will support Shionogi's basic policy on a global scale.

Shionogi believes that it is this development of individual employees that leads to the growth of the company as a whole. Human resource development at Shionogi is composed of an organic mix of elements, including on-the-job training, off-site training, and personal development. In terms of scope, the strands of HR policy at Shionogi cover a wide range: from company-wide programs, business divisionspecific content and overseas postings, to intra-company rotation (career development). Furthermore, besides education and training programs, Shionogi also implements a regular "youthful employee interview" program to provide guidance for younger employees.

### Human Resources System

In order to continue growing as a Company, we need to deploy our basic policy globally. It is essential for all employees to play an even greater role in such efforts and produce results.

The evaluation system at Shionogi places great emphasis on employees' roles. Employees are scored based on their assigned roles, the difficulty of that role, and their displayed ability levels. The next step in improving their abilities involves assigning to them greater roles to help them grow further through performing new tasks. The end result is a continuous and positive cycle of improvement. This approach aims to motivate employees through the setting and completion of key targets, and thereby improve their skills.

### Fair and Equitable Personnel Evaluations

Shionogi has rigorously aligned Company strategy with individual employee targets and has built a target management system that emphasizes Plan-Do-Check-Act (PDCA) management.

To maximize employees' motivation and capabilities, we believe it is crucial to properly evaluate the abilities employees display, the roles they undertake to play, and results they achieve in their areas of responsibility, so that we can give them appropriate jobs, remuneration, and other benefits. In view of this, besides clarifying evaluation standards, disclosing information to employees on a fair and equitable basis, and providing extensive educational programs for evaluators, Shionogi is increasing the transparency and objectivity of its evaluation methodology. In addition, by gathering appropriate feedback on evaluation results, the Company is working to increase employee satisfaction in the evaluation system and to operate the system in a manner that effectively promotes human resource development.

### Occupational Safety and Health

In line with its corporate purpose of "providing the best possible medical products for protecting the health of the people," Shionogi recognizes the primary importance of its employees' safety and health, which the Company works to ensure through a variety of initiatives centered on the safety and health committees of each workplace.

Regarding safety, because many chemicals are used at its research and production facilities, the Company strictly enforces appropriate handling and storage management, and is also strengthening its internal check system. In addition, to prevent occupational injury or illness, Shionogi regularly conducts rigorous safety inspections, promptly rectifies any problems identified, and works to raise employee safety awareness.

Concerning employee health, Shionogi is promoting a work information system to facilitate the management of working hours and thereby create a framework for preventing the incidence of chronically excessive work hours. We are also cooperating with a health insurance association to augment our efforts to maintain and improve employee health. Specifically, we work to ensure employees take part in the regular annual health checkup (99.7% of employees have had checkups), and encourage employees to receive testing for adult-onset and gynecological illnesses. Based on the results, industrial physicians, nurses and other health maintenance staff undertake detailed follow-up work regarding each individual employee with a pre-existing or newly diagnosed condition. Moreover, we organize such events as health seminars and fitness walks to improve employees' awareness of their own health situations.

To address mental health, Shionogi has a specialized physician working full-time as an industrial physician and has established a counseling system that includes a counseling room and outside services. In these and other ways, the Company is implementing a comprehensive

range of measures in line with the Japanese Ministry of Health, Labour and Welfare's "four care policy" (selfcare, managerial care, on-site industrial staff health care, and external resource-based care).

	2007	2008	2009	2010 (FY)
Number of occupational illnesses/injury incidents	18	12	16	10
Occupational illness/injury incident frequency rate	0.33%	0.108%	0.22%	0.209%
Occupational illness/injury incident severity rate	0.002%	0.0002%	0.001%	0.0007%

### Employment of Persons with Disabilities

To help normalize the lives of persons with disabilities, Shionogi has been making proactive, ongoing efforts to hire such persons. In fiscal 2010, the share of Shionogi's employees with disabilities was 1.92%, above the legally mandated share of 1.8%. Shionogi has received recognition from the Osaka Employment Development Association as a distinguished employer. This association also annually presents disabled Shionogi employees with longtime service awards that reflect the Company's high retention rate for employees with disabilities.

### Human Rights Initiatives

Shionogi has clearly articulated its policy on employee rights in the "Conduct at Shionogi" section of the Shionogi Charter of Conduct, stating that "Shionogi respects the rights and individuality of its employees and works to ensure their comfort and fulfillment." In line with this, Shionogi has implemented various training programs and established a consultation service to ensure that there is no discrimination either inside or outside the Company on the grounds of race, national origin, religion, creed, beliefs, gender, age, education, disability, illness or other factors, nor any sexual harassment, power harassment, or other types of harassment. In addition, as stated in one of the five values of Shionogi's Action Guidelines, "Respect for the individual," maintaining maximum respect for the diverse individualities of everyone involved with Shionogi is one of the Company's most important values.

# Community Relations

### Socie—Our Social Contribution Support Association

Shionogi established Socie in 1997. The Company, its employees and the employee labor union cooperate in supporting Socie members' voluntary social contribution activities. Management and employees work together in carrying out social contribution activities, using funds provided by Shionogi and the labor union at the time Socie was established, and through monthly contributions from employees and the Company.

Socie provides assistance to areas affected by earthquakes, storms, volcanic eruptions and other disasters as deemed necessary by Japan's Disaster Relief Act, as well as surrounding regions in Japan and overseas when deemed necessary by the executive board. It also makes annual

donations to groups that contribute to society, such as the Japanese Red Cross Society and the Japan Guide Dog Association.

Socie donated ¥20 million through the Japanese Red Cross Society to support relief efforts for victims of the Great East Japan Earthquake that struck in March 2011, and to promote recovery of the affected regions. Shionogi also donated ¥100 million to the prefectural governments of Iwate, Miyagi, and Fukushima Prefectures.

In addition, Shionogi supports the voluntary social contribution activities of employees by helping raise their consciousness of volunteer work with time off or leaves of absence for such activities or for bone marrow donation. 

# Investor Relations

### Interactive Communications

Shionogi endeavors in various ways to improve communications with all our shareholders. Top management holds semiannual and annual results briefings and first- and third-quarter conference calls for domestic institutional investors and analysts. We also distribute audio recordings of briefings and conference calls. We convene annual briefings on research and development, which is vital for pharmaceutical manufacturers, reporting on R&D progress, presenting new compounds, and providing other useful information.

We welcome visits from Japanese and overseas institutional investors and analysts, and visit these investors ourselves. Meanwhile, management itself goes to see these investors and participate in brokerage-run conferences. In addition, we endeavor to disclose all corporate data, such as progress in research and development projects, and new product launches, that are useful for determining the corporate value of Shionogi.

# Efforts to Preserve the Environment

Due to electricity supply shortages in the wake of the Great East Japan Earthquake and social needs arising from these, Shionogi business locations within the service areas of The Tokyo Electric Power Company, Inc. and Tohoku Electric Power Co., Inc. have taken a range of actions to save electricity mindful of their social mission to ensure a stable supply of pharmaceuticals. Initiatives include installing generators, raising capacity utilization, starting shifts earlier, asking staff to wear cool business attire earlier than normal, and upgrading to LED lighting. Moreover, in business facilities and offices, including Head Office, Shionogi is promoting efforts to save electricity and conserve energy in accordance with a power-saving plan.

# Efforts to Preserve the Environment

In promoting its business activities, the Shionogi Group is aware that, as a Company, it has an important social responsibility to give appropriate consideration to the global and local environments. To lessen the environmental impact of all of our business activities, we established "The Shionogi Group's Basic Environmental Policy." In line with this policy, we have established the Shionogi Group Environmental Protection Plan and conduct a growing range of environmental preservation activities.

### The Shionogi Group's Basic Environmental Policy

#### 1. Environmental Management System

The Shionogi Group will promote high-quality environmental protection activities by assigning the Director in charge of the environment to the post of Chief Environmental Supervisor and clarifying organizational responsibilities and authority for environmental management.

2. Compliance with Laws and Regulations

The Shionogi Group will work to protect the environment by complying with environmental laws and regulations as well as setting voluntary management standards.

3. Reduction of Environmental Impact

In its research and development, manufacturing, distribution, marketing, and other business activities, the Shionogi Group will set and periodically revise targets in areas such as energy and resource conservation, waste reduction, and strengthening management of chemical substances, striving for continual improvement.

#### 4. Education and Training

The Shionogi Group will raise the awareness of all employees toward environmental protection by conducting environmental education and training and providing environment-related information.

5. Coexistence with Society

From its standpoint as a corporate citizen, the Shionogi Group will cooperate in environmental protection activities of regional communities. In addition, we will disclose our environmental information to promote mutual understanding with society.

6. Disclosure of Our Basic Environmental Policy

The Shionogi Group will disclose the Basic Environmental Policy both inside and outside the Group.

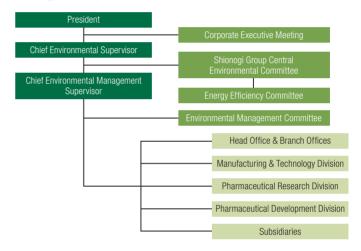
April 1, 2008 Isao Teshirogi, President and Representative Director Shionogi & Co., Ltd.



### Environmental Management Organization

The Shionogi Group promotes environmental preservation activities under the group-wide supervision of the Chief Environmental Supervisor and the Chief Environmental Management Supervisor. All major business sites and affiliates have environmental committees chaired by the Environmental Supervisor and composed of the Environmental Management Supervisor, environmental supervisors from each department, and others. The committees deliberate on and approve the operations of the environmental management system.

To coincide with the full enforcement of the Amended Act on Temporary Measures for Promotion of Rational Uses of Energy and Recycled Resources in Business Activities, Shionogi made a number of changes designed to manage energy use and control greenhouse gas emissions across the Group as a whole. These changes included the election of an Energy Management Supervisor and an Energy Management Plan Coordinator, as well as the establishment of an Energy Efficiency Committee under the Central Environment Committee.



### Environmental Management System

◆ISO 14001 (International Standard for Environmental Management Systems) Shionogi has acquired ISO 14001 certification for six production divisions and R&D divisions with a high environmental impact (Kuise Site, Settsu Plant, Kanegasaki Plant, Shionogi Research Laboratories, Shionogi Pharmaceutical Research Center, and Aburahi Laboratories) as well as an onsite affiliate, Shionogi Analysis Center Co., Ltd. Domestic production subsidiary Shionogi Pharma Chemicals Co., Ltd. also acquired certification in 2001, which it continues to maintain.

In order to ensure proper adherence to ISO 14001, we appoint internal auditors at each business location to conduct internal audits. At the same time, we train and certify internal auditors in the ISO 14001 standard and offer advanced training courses so as to further improve the capabilities of internal auditors.



Internal auditor training

### Environmental Audits

The Shionogi Group conducts environmental audits at all manufacturing plants, research laboratories and domestic production subsidiaries to confirm that environment-related laws and regulations are being complied with, environmental risks are being properly managed, and improvements to management systems are being made on an ongoing basis. In fiscal 2010, environmental audits were conducted at the Kuise Site and Aburahi Laboratories, where there were changes in management systems.

### Compliance with Laws and Regulations

Environment-related regulations cover prevention of atmospheric pollution and water contamination, management of chemical substances, and a range of other areas. Shionogi shares information about them with all business sites to obtain up-to-date information on relevant regulatory revisions and ensure proper compliance. In addition, periodically we formally assess whether there is proper compliance with laws and regulations.

We continue to have no environment-related legal action or fines to report.

### Reducing Environmental Impact

### Environmental Protection Plan

We set targets for energy and resource efficiency, reducing waste, strengthening chemical substance management and other areas for all business activities, from research and development to production, distribution, and sales, and we work to make improvements on an ongoing basis. The targets below were set and promoted from fiscal 2005 through fiscal 2010 under the Phase 3 Shionogi Group Environmental Protection Plan. In the meantime, Shionogi has found it difficult to reduce the volume of waste products generated and also greenhouse gases, due to the construction of new manufacturing facilities for drugs for clinical trials and commercial products and higher production volume. However, the Company made steady progress as a whole with other targets such as chemical substance management and green purchasing. Shionogi has been unable to compile data for the main Kanegasaki Plant, due to the impact of the Great East Japan Earthquake, but will post data on its website when able to do so.

- 1. Strengthen conservation of resources and waste disposal measures
- 2. Implement measures to counter global warming
- 3. Strengthen management of chemical substances
- 4. Enhance system for evaluating safety of chemical processes
- 5. Promote Product Life Cycle Assessment
- 6. Implement environmental accounting
- 7. Expand green purchasing
- 8. Contribute to society
- 9. Disclose environmental information

From fiscal 2011, Shionogi has set new targets under Phase 4 of the Shionogi Group Environmental Protection Plan in line with the action plans and charters of corporate behavior of Keidanren (Japan Business Federation) and The Federation of Pharmaceutical Manufacturers' Associations of Japan, including reducing the volume of final waste disposed, and reducing CO<sub>2</sub> emissions. Shionogi is working to achieve these targets as part of its ongoing environmental activities.

#### Resource Conservation and Waste Disposal Measures

Shionogi promotes the 3Rs—reduce, reuse, and recycle—in order to help create a recycling-oriented society. The Company's efforts in this regard include turning waste liquid and waste plastics into items of value, and reducing the volume of waste products that are directly disposed of in landfills to zero (zero emissions).

### Prevention of Global Warming

Shionogi is implementing measures to reduce greenhouse gas emissions, such as upgrading freezers and lighting equipment to energy-saving models, and reviewing air-conditioner equipment. The Company has also formed the Energy Efficiency Committee, which is examining the Company's policies and mediumto long-term plans, and creating management standards for upgrading environmental equipment, changing operating methods and so forth, as well as evaluating compliance status. Through these actions, Shionogi is promoting measures to conserve energy and reduce CO<sub>2</sub> across the company.

### Chemical Substance Management

Shionogi is working to control atmospheric and wastewater emissions by setting voluntary standards, as well as properly managing harmful chemical substances and reducing the amount transferred with an awareness that chemical substances can have an adverse impact on people's health, ecosystems, and the natural environment. The Shionogi Pharmaceutical Research Center has also introduced a supplies takeout control system (STOC), which is allowing it to visually track the movement, use, and disposal of general-purpose agents.

#### Biodiversity

The Company engages in environmental activities with an awareness of biodiversity, based on the declaration of the tenth meeting of the Conference of the Parties (COP10) held in Nagoya in October 2010 and Keidanren's Declaration of Biodiversity. Shionogi is conducting employee education programs, managing research based on the Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms and Invasive Alien Species Act, and conserving rare plants and endangered species at the botanical gardens of Aburahi Laboratories.



Botanical gardens of Aburahi Laboratories



# Corporate Governance System

In line with the Company Policy of Shionogi, we recognize that it is our social mission to continually discover, develop, and provide effective and safe medicines. Shionogi is also aware that sustaining its implementation of this social mission will increase corporate value. Accordingly, it believes strongly in carrying out sound management practices through the corporate governance system it has established.

### Corporate Governance System

Shionogi has adopted a "company with corporate auditors" corporate governance system that includes a board of directors, a board of corporate auditors, and independent accounting auditors.

To further enhance the effective functioning of corporate governance, two outside directors were elected to the Board of Directors in fiscal 2009 to promote comprehensive decision-making incorporating an objective, outside perspective. Both directors recognize their role as independent directors in helping the Company to fulfill its corporate responsibilities, making decisions with the interest of general shareholders in mind and contributing to highly transparent management. The Board of Directors is composed of five directors, including the two outside directors. It meets once a month, in principle, to make decisions on important matters affecting management. To facilitate rapid responses to changes in the operating environment and clarify management responsibilities, the directors' term in office has been set at one year.

In addition, to further increase management transparency and accountability to stakeholders, the Company has established a nomination advisory committee and a compensation advisory committee as advisory bodies to the Board of Directors. Both committees are chaired by outside directors, ensuring that management decisions in these areas are examined from a fair and honest perspective, as well as that selected directors are vetted and evaluated from multiple angles, including assessment of aptitude, impact on management, and quality of work performance.

Moreover, the Company has introduced a corporate officer system to allow management policy to be reflected in operations without delay, and has built a flexible operational execution structure able to rapidly respond to changes in the operating environment. Furthermore, the Corporate Executive Meeting is a unit created to conduct deliberations regarding operational execution issues. It is composed of the directors and managers responsible for operation, and, in principle, it meets every week.

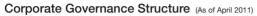
The Company has two standing corporate auditors and three outside corporate auditors. The corporate auditors attend meetings of the Board of Directors, Corporate Executive Meetings, and other important meetings, offering opinions when necessary. In addition, by conducting operational and accounting audits in accordance with corporate auditing standards, they check and evaluate the legality and propriety of operations executed by directors and corporate officers, and thereby work to enhance the implementation of oversight. While implementing audits and providing advice and suggestions, the corporate auditors work to coordinate their activities with the independent accounting auditors and the Internal Control Department, an internal auditing department. In addition, by regularly exchanging opinions with the representative directors, the corporate auditors endeavor to ensure the appropriateness and effectiveness of audits.

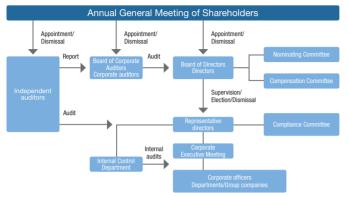
# Strengthening the Internal Control System

In accordance with the Basic Policy for Building an Internal Control System approved by the Board of Directors based on the Corporate Law, Shionogi

Management

has worked to establish internal control systems throughout the Shionogi Group. The Board of Directors annually evaluates the state and management of internal control systems based on consideration of the operational situation during the previous year and continually works to





strengthen and augment the internal control systems.

Sincere efforts to ensure the reliability of financial statements are necessary for maintaining management transparency and integrity. To comply with the J-SOX internal control report system under the Financial Instruments and Exchange Act, Shionogi is moving ahead with measures to build and improve internal controls over financial reporting. As part of these efforts, a message has been sent to all domestic and global Group employees regarding the need to emphasize the reliability of financial reporting, and the Company is working to promote greater and broader-spread awareness of this issue.

### **Risk Management**

Each of the Company's organizational units recognizes the intrinsic risk factors associated with its activities, determines response strategies in line with the degree of risk related to each factor, and takes measures to avoid or mitigate those risks. Responses to important risks that could significantly impact the Company's management are discussed at the Corporate Executive Meeting and other meetings and, based on the response policies determined at those meetings, the responsible units cooperate with relevant departments to respond as necessary. Regarding risks associated with disasters, accidents, corporate scandals, and other situations requiring emergency responses, Shionogi has formulated a Crisis Management Policy, as well as separate sets of critical measures and contact chains pertaining specifically to disasters, pandemics, and corporate scandals. In this way, Shionogi is promoting crisis management processes that emphasize respect for human lives, demonstrate consideration for and contributions to local communities, and mitigate potential damage to corporate value. Moreover, we have formulated a business continuity plan and system for each risk factor in order to fulfill our mission as a pharmaceuticals manufacturer of ensuring the stable and continuous provision of essential medicines.

### Framework for Information Disclosure

Shionogi has established internal systems for the timely, appropriate, and

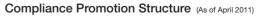
fair disclosure of accurate corporate information to all kinds of stakeholders, and the Company continues to make necessary revisions to these systems with the goal of maintaining and improving them.

### Thorough Compliance

Shionogi promotes compliance in all departments and units, including domestic and overseas subsidiaries, through measures centered on those of the Compliance Committee, which is chaired by the president and for which the Legal Affairs Department serves as the secretariat.

In order to further enhance the assurance of compliance of which Shionogi's broad definition does not mean only compliance with laws and regulations but also requires ethical behavior, the Company engages in the following types of activities aimed at promoting outstanding compliance consciousness and compliance performance among all employees.

- As the designated Compliance Manager, the manager of each department or unit cooperates with an assistant—designated the Compliance Promoter—in undertaking activities, including the drafting and submitting of compliance risk management action plans that identify risks and consider related responses, and the drafting and submitting of reports regarding the promotion of compliance consciousness, implementation, and improvement measures based on these action plans, in order to ensure thorough compliance.
- 2. Besides drafting compliance measure proposals, the Legal Affairs Department provides support for promotion activities of the entire Shionogi Group through such measures as those to implement and facilitate compliance education programs for executives and all Shionogi Group employees, prepare and distribute Shionogi's Compliance Handbook, disseminate messages and reminders regarding compliance, conduct employee attitude surveys, and feed back survey results internally.
- 3. Shionogi has established an internal reporting system comprising an internal reporting desk in the Legal Affairs Department, and an external reporting desk at the office of its outside legal counsel, and makes risk management efforts designed to promote the early discovery as well as the amelioration and prevention of compliance violations utilizing the system. In conjunction with this system, the Company, in accordance with the intent of Japan's Whistleblower Protection Act, has established internal protection regulations within the rules for its internal reporting system aimed at preventing whistleblowers from being subjected to disadvantageous situations.
- 4. Concerning the protection of personal information, Shionogi has established an information management system based on its Information Security Policy and employs this system to manage information assets. In addition, the Company has established a standing committee headed by the General Manager of the Legal Affairs Department that takes various measures to assure the appropriate usage of and to prevent leakage of personal information, including implementation of the Company's privacy policy, disclosing the scope of personal information usage objectives, establishing a dedicated consulting line to handle personal information related questions and complaints, and helping employees who handle personal information to participate in educational programs.





# Members of the Board (As of June 24, 2011)



Front row from left: Motozo Shiono, Isao Teshirogi. Back row from left: Teppei Mogi, Akio Nomura, Yasuhiro Mino.

# Directors

Chairman of the Board Representative Director Motozo Shiono

President and CEO Representative Director Isao Teshirogi, Ph.D.

Director Yasuhiro Mino

# **Outside Directors**

#### Akio Nomura

June 1998:	Representative Director and President of Osaka Gas, Ltd.
June 2000:	Director of West Japan Railway Company
June 2003:	Representative Director and Chairman of Osaka Gas, Ltd.
June 2008:	Director of the Royal Hotel, Ltd. (incumbent)
June 2009:	Director of Shionogi & Co., Ltd. (incumbent)

### Teppei Mogi

April 1989:	Admitted to Osaka Bar Association
August 2002	: Partner of Oh-Ebashi LPC & Partners (incumbent)
April 2004:	Professor, Kwansei Gakuin University Law School
April 2005:	Part-time lecturer, Kobe University Graduate School of Law (incumbent)
	· · · · · · · · · · · · · · · · · · ·
June 2009:	Director of Shionogi & Co., Ltd. (incumbent)
April 2010:	Part-time instructor, Kwansei Gakuin University Law School (incumbent)

### **Corporate Auditors**

Standing Corporate Auditor Sachio Tokaji

Standing Corporate Auditor Mitsuaki Ohtani, Ph.D. Outside Corporate Auditor Takeharu Nagata Outside Corporate Auditor Shinichi Yokoyama Outside Corporate Auditor Kenji Fukuda

### **Corporate Officers**

Vice President Officer Senior Executive Officer Executive Officer Executive Officer Executive Officer Corporate Officer Corporate Officer Corporate Officer Corporate Officer Corporate Officer

Yasuhiro Mino Takuko Sawada Takuo Fukuda Ryuichi Kume, Ph.D. Yoshiaki Kamoya Hirosato Kondo, Ph.D. Masaaki Goshima Kohji Hanasaki, Ph.D. Takayuki Yoshioka, Ph.D. Kiyoshi Nagata, Ph.D.

# Six-Year Consolidated Financial Highlights

Shionogi & Co., Ltd. and Consolidated Subsidiaries Years ended March 31

	2006	2007	2008	2009	2010	2011	2011
			Millions	s of yen			Thousands of U.S. dollars
For the year ended March 31:							
Net sales	¥196,389	¥ 199,759	¥214,268	¥227,512	¥278,503	¥ 282,350	\$3,395,671
Cost of sales	68,708	67,542	68,594	70,929	76,264	81,737	983,007
Selling, general and administrative expenses	98,455	103,354	105,275	124,568	149,801	153,721	1,848,719
Operating income	29,226	28,863	40,399	32,015	52,438	46,892	563,945
Income before income taxes and minority interests	38,798	31,723	39,963	30,786	58,541	33,135	398,497
Net income	22,735	18,595	25,064	15,661	38,626	20,027	240,854
Research and development expenses	32,257	37,456	40,290	52,822	51,808	50,921	612,399
Capital investments	11,132	11,107	13,069	10,875	12,547	17,967	216,079
Depreciation and amortization	8,653	8,798	10,666	13,468	18,048	17,966	216,067
As of March 31:							
Property, plant and equipment, net …		¥ 67,815	¥ 70,378	¥ 71,812	¥ 62,448	¥ 70,221	\$ 844,510
Total assets	427,683	429,569	413,704	501,853	540,762	523,242	6,292,748
Total long-term liabilities	38,371	36,282	29,024	114,955	131,956	115,326	1,386,963
Total net assets	337,434	345,752	342,236	310,094	341,976	328,096	3,945,833
			Ye	n			U.S. dollars
Per share amounts:							
Net income	¥ 66.55	¥ 54.61	¥ 74.21	¥ 46.75	¥ 115.33	¥ 59.80	\$ 0.72
Net assets	989.76	1,014.73	1,020.31	924.43	1,019.71	979.69	11.78
Dividends per share	16.00	16.00	22.00	28.00	36.00	40.00	0.48
Other:							
Total asset turnover (Time)	0.48	0.47	0.51	0.50	0.53	0.53	
Equity ratio (%)	78.8	80.4	82.7	61.7	63.2	62.7	
Return on equity [ROE] (%) ······	7.1	5.4	7.3	4.8	11.9	6.0	
Return on assets [ROA] (%)	7.2	6.6	9.5	7.0	9.7	8.5	
Payout ratio (%)	24.0	29.3	29.6	59.9	31.2	66.9	

\* U.S. dollar figures have been calculated, for convenience only, at the rate of ¥83.15 = US\$1.00, the approximate rate of exchange on March 31, 2011.
 \* From the fiscal year ended March 31, 2007, the Company has adopted a new accounting standard for the presentation of net assets in the balance sheet, which reclassifies former shareholders' equity, valuation and translation adjustments, and minority interests as total net assets.

# Management's Discussion and Analysis

# Overview of Results

In the fiscal year ended March 31, 2011 (fiscal 2010), the market environment of Japan's pharmaceutical industry was increasingly severe, in part due to the April 2010 implementation of National Health Insurance (NHI) drug price revisions. Conditions were exacerbated by competition among pharmaceutical companies faced with the expiration of patents. Overseas, due to reform of the US health insurance system, conditions in the pharmaceutical market are expected to remain severe.

Under these circumstances, the Shionogi Group began the first year of its five-year third medium-term business plan in fiscal 2010. Despite NHI drug price revisions, the Group achieved growth in sales of prescription drugs in Japan that outpaced the market average and recovered market share. With regard to the Great East Japan Earthquake that occurred on March 11, 2011, the Group incurred an extraordinary loss of approximately ¥3.0 billion related to the substantial impact on operations at the Kanegasaki Plant in Iwate Prefecture and sales activities in East Japan. Thereafter, the Group worked tirelessly to restore operations, restarting production about one month later. For the Group's US operations, it was a challenging year. Following instability in operating results from the previous year, the Shionogi Group implemented a host of measures. These included integration of the Group's US development subsidiary; structural reform of expenses, including personnel cutbacks; a review of the product lineup, including discontinuing certain products; and adoption of more conservative accounting policies. As a result of these initiatives, the Group recorded an extraordinary loss of approximately ¥15.0 billion. With these measures, the Shionogi Group laid the platform for more stable business operations in fiscal 2011 and beyond.

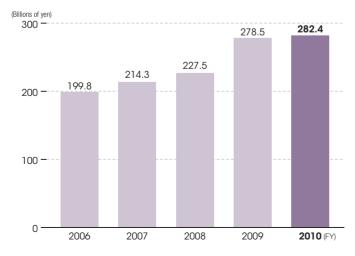
# Net Sales

Net sales rose 1.4% year on year to ¥282,350 million. In core prescription drugs in Japan, sales of Crestor®, a hyperlipidemia treatment, and Irbetan®, a hypertension treatment, grew substantially, and Cymbalta®, an antidepressant drug launched in April 2010, contributed to the increase in sales. Sales of other strategic drugs also increased. As a result, overall sales of prescription drugs rose 4.2% year on year. In addition, royalty income increased significantly due to overseas sales growth of Crestor® by AstraZeneca. On the other hand, sales decreased at US subsidiary Shionogi Inc.

#### **Gross Profit**

The cost of sales increased by ¥5,473 million in year-on-year terms to ¥81,737 million. The cost of sales ratio increased from 27.4% to 28.9%,

#### Net Sales



reflecting a higher cost of sales than the Group's target due mainly to lower sales at Shionogi Inc.

As a result, gross profit declined 0.8% year on year to ¥200,613 million despite increases in domestic sales of prescription drugs and royalty income.

#### **Operating Expenses and Operating Income**

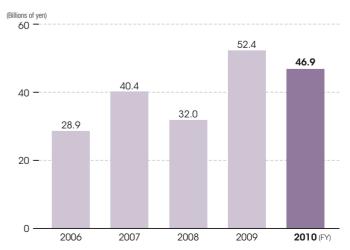
Selling, general and administrative (SG&A) expenses increased 2.6% to ¥153,721 million. The ratio of SG&A expenses to net sales increased from 53.8% to 54.4%.

Operating income declined 10.6% to ¥46,892 million.

#### **Other Income (Expenses)**

In the year ended March 31, 2011, net other expenses of ¥13,757 million were recorded. This compared with net other income of ¥6,103 million in

#### Operating Income



Management

the year ended March 31, 2010.

Net interest and dividend income (after the deduction of interest expense) amounted to ¥204 million, compared with net expenses of ¥66 million in the previous fiscal year. In the year ended March 31, 2011, Shionogi incurred extraordinary losses including a loss relating to disasters caused by the Great East Japan Earthquake, business structure improvement expenses for Shionogi Inc. and impairment losses.

# Income before Income Taxes and Minority Interests and Net Income

Income before income taxes and minority interests decreased 43.4% to ¥33,135 million. Including income tax adjustments, income taxes decreased 34.3% to ¥13,078 million.

Net income declined 48.2% to ¥20,027 million. The net income ratio was 7.1%, compared with 13.9% in the previous year. Net income per share declined from ¥115.33 to ¥59.80.

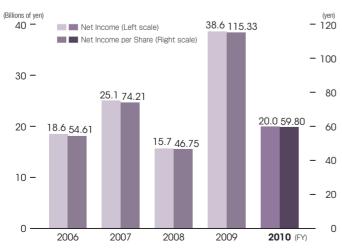
## Segment Information

The Shionogi Group operates as a single business segment related to prescription drugs, involving research and development, purchasing, manufacturing, distribution and related businesses for prescription drugs. While Shionogi performs analysis of sales by product and evaluations of performance by group companies, decisions on business strategy, and the allocation of management resources, especially the allocation of research and development expenses, are made on a Group-wide basis. Therefore, disclosure of segment information for the year ended March 31, 2011 has been omitted.

## Research and Development Expenses

Regarding research and development activities in Japan, the Shionogi Group launched Cymbalta<sup>®</sup> in April 2010. The Group has also filed an application for this drug for the additional indication of diabetic neuropathic pain. In addition, Shionogi received manufacturing and marketing approval in October 2010 for the additional indication of pediatric use of Rapiacta<sup>®</sup>, an antiviral drug for influenza. Drugs currently

#### Net Income and Net Income per Share



under development in and outside Japan include an anti-HIV drug, a drug to alleviate opioid-induced adverse effects, and a drug for the treatment of diabetes. Regarding research facilities, the Shionogi Pharmaceutical Research Center (SPRC) in Toyonaka City, Osaka, was completed in July 2011. This is expected to further strengthen drug discovery capabilities through a projected consolidation of research functions and improvement in productivity. Moreover, in April 2011 the Shionogi Group reviewed its development organization and established a Global Development to enhance and accelerate strategic decision-making about global products under development.

As a result of these activities, overall Group R&D expenses for the fiscal year ended March 31, 2011 totaled ¥50,921 million. This figure represented 18.0% of net sales.

## Cash Flows

For the fiscal year ended March 31, 2011, net cash provided by operating activities totaled ¥56,528 million, an increase of ¥3,626 million compared with the previous fiscal year. Although income before income taxes and minority interests decreased, non-cash items such as impairment loss and a provision for damages due to the Great East Japan Earthquake rose substantially, and notes and accounts receivable decreased.

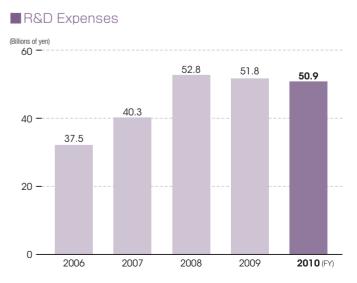
Net cash used in investing activities totaled ¥13,947 million. This was largely attributable to capital investment in the SPRC.

Net cash used in financing activities totaled ¥27,011 million. The major components were repayment of long-term debt and cash dividends paid.

As a result, cash and cash equivalents at the end of the fiscal year were ¥110,692 million, an increase of ¥13,029 million from the end of the previous fiscal year.

## Capital Investments

Capital investments by the Shionogi Group in fiscal 2010 totaled ¥17,967 million. The Group made proactive investments mainly in new research facilities and manufacturing facility upgrades, including the construction of a new research building.



# Assets, Liabilities and Net Assets

As of March 31, 2011, total assets stood at ¥523,242 million, ¥17,519 million less than at March 31, 2010. Current assets increased ¥6,274 million to ¥256,937 million. Property, plant and equipment, net increased ¥7,773 million to ¥70,221 million. Total investments and other assets decreased ¥31,566 million to ¥196,084 million.

Within current assets, cash and cash equivalents increased by ¥13,028 million. Within investments and other assets, marketing rights declined ¥6,464 million and investments in securities declined ¥11,459 million.

In terms of the main reasons for changes in assets, property, plant and equipment increased due to capital investment for construction of the SPRC. On the other hand, assets were reduced as a result of the amortization of marketing rights as well as impairment losses. Moreover, investments in securities and foreign currency-denominated assets declined due to lower stock market prices and the yen's appreciation.

Total liabilities at the fiscal year-end amounted to ¥195,146 million, down ¥3,640 million from a year earlier. Current liabilities increased ¥12,990 million to ¥79,820 million. Total long-term liabilities decreased ¥16,630 million to ¥115,326 million.

In terms of principal changes in liabilities, there was an increase in accounts payable-other, which are included in other current liabilities, while repayments led to a decrease in long-term debt.

Net assets totaled ¥328,096 million at the fiscal year-end, a decrease of ¥13,880 million from the year earlier.

Total shareholders' equity increased ¥7,289 million to ¥361,733 million. However, net unrealized holding gains on securities decreased ¥6,629 million to ¥3,733 million and translation adjustments increased ¥13,779 million in year-on-year terms to negative ¥37,081 million.

The decrease in net assets was largely due to the decline in net unrealized holding gains on securities resulting from the drop in stock market prices, and an increase in translation adjustments reflecting the strong yen.

Reflecting these various factors, the ratio of total net assets to total assets decreased from 63.2% to 62.7%.

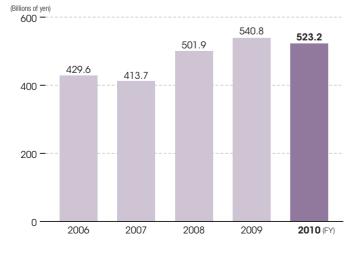
## Dividends

Shionogi aims to raise dividends steadily in line with performance while proactively making business investments to increase corporate value from a medium-to-long-term perspective. The Group has adopted a consolidated dividend payout ratio of 35% as a performance target going forward.

Shionogi's Articles of Incorporation stipulate twice-yearly distributions of retained earnings as interim and final dividends wherever possible. The General Meeting of Shareholders must approve the final dividend, while the Board of Directors approves any interim dividend.

Consolidated net income for the fiscal year ended March 31, 2011 includes the effect of one-off, non-cash flow-related losses for damage due to the Great East Japan Earthquake, and the business integration of Shionogi Inc., which occurred during the period. Taking into consideration the Company's steady progress toward achieving the goals of its third medium-term business plan through its business activities, including sales and marketing in Japan, and its policy of ensuring a stable increase in cash dividends, Shionogi set the year-end cash dividend at ¥20 per share for the fiscal year ended March 31, 2011, as planned. Together with the interim cash dividend, the total annual dividend was ¥40 per share. The consolidated dividend payout ratio was 66.9%.

# Total Assets



# Business and Other Risks

The main types of risk that might have a significant impact on the Shionogi Group's management performance and financial condition are listed below.

Forward-looking statements in the text reflect the Group's judgment as of March 31, 2011.

#### Systemic and Regulatory Risk

In the pharmaceutical industry, revisions to the National Health Insurance (NHI) system are being considered, including revisions to the NHI drug price system. These trends could affect the results of the Shionogi Group. In addition, an increase in the strictness of Japanese or overseas regulations concerning such items as the development and manufacture of pharmaceuticals could present the Group with additional expenses or make it difficult for its products to comply with regulations, and there is a possibility that this might have an impact on the Group's performance.

#### 2 Risk of Adverse Drug Reactions

Pharmaceuticals entail the risk of unanticipated adverse drug reactions that could involve termination of sales, product recalls, and other outcomes that could affect the results of the Shionogi Group.

#### B Pharmaceutical R&D Risk

Pharmaceutical R&D requires substantial commitment of resources and time. In addition, new drugs are subject to numerous uncertainties prior to the start of actual sales.

#### Intellectual Property Risk

The Shionogi Group uses patents as intellectual property to protect the pharmaceuticals it discovers and generate income from them. However, the various types of intellectual property may be unable to provide adequate protection, or may infringe on the intellectual property of third parties.

#### S Risk of Dependence on Certain Products

The Shionogi Group obtains approximately 41% of its product sales and royalty income from two of its products, Crestor<sup>®</sup> and Flomox<sup>®</sup> (as of fiscal 2010). If the incidence of an unexpected factor were to cause a drop in or the discontinuation of the sales of one of these products, there is a possibility that this might have an impact on the Group's performance.

#### **6** Intensification of Global Competition

Global competition involving non-Japanese companies in the pharmaceutical industry's R&D and sales operations is becoming increasingly intense.

#### Risk of Alliances with Other Companies

The Shionogi Group engages in diverse forms of alliances with other companies with respect to joint research, joint development, joint marketing, and other activities, including cooperation in such forms as cooperative research projects, cooperative development projects, the in-licensing and out-licensing of technologies, and cooperative marketing projects. If some situation were to change or eliminate these cooperative relationships, it might have an impact on the Group's performance.

#### **18** Plant Closure and Shutdown Risk

The sudden occurrence of natural disasters or other unforeseen incidents could dictate the closure or shutdown of plants, which could affect the results of the Shionogi Group.

#### O Capital Market and Foreign Exchange Risk

Fluctuations in stock and foreign exchange markets that exceed the projected range could affect the results and financial position of the Shionogi Group.

#### Other Risks

In addition to the above-listed risks, the Shionogi Group's business activities involve the risk of lawsuits, risks related to regulatory and economic factors, and diverse other risks. The above list of risks does not include all the types of risks the Shionogi Group is exposed to.

# Consolidated Balance Sheets Shionogi & Co., Ltd. and Consolidated Subsidiaries March 31, 2011 and 2010

	Millions	Thousands of U.S. dollars (Note 3)	
	2011	2010	2011
Assets			
Current assets:			
Cash and cash equivalents (Notes 8 and 11)	¥110,692	¥ 97,663	\$1,331,233
Short-term investments (Notes 5 and 11)	5,802	6,546	69,778
Notes and accounts receivable (Note 11):			
Affiliates	939	1,314	11,293
Trade	68,559	78,101	824,522
Other	6,440	4,287	77,450
Allowance for doubtful accounts	(13)	(11)	(156)
	75,925	83,691	913,109
Inventories (Note 6)	47,339	49,341	569,320
Deferred income taxes (Note 13)	7,873	5,418	94,684
Other current assets	9,306	8,005	111,918
Total current assets	256,937	250,664	3,090,042
Property, plant and equipment:			
Land (Note 21)	9,915	10,089	119,242
Buildings and structures (Note 21)	99,491	100,040	1,196,524
Machinery, equipment and vehicles	82,798	83,503	995,767
Furniture and fixtures	33,999	33,863	408,888
Construction in progress	19,353	6,842	232,748
Accumulated depreciation	(175,335)	(171,889)	(2,108,659)
Property, plant and equipment, net	70,221	62,448	844,510
Investments and other assets:			
Investments in securities (Notes 5 and 11)	53,817	65,276	647,228
Investments in affiliates (Note 11)	6,837	6,594	82,225
Prepaid pension costs (Note 15)	23,331	24,411	280,589
Goodwill	58,831	69,874	707,529
Marketing rights (Note 12)	34,256	40,720	411,978
Long-term prepaid expenses ·····	9,097	11,292	109,405
Deferred income taxes (Note 13)	2,462	81	29,609
Other assets (Note 12)	7,453	9,402	89,633
Total investments and other assets	196,084	227,650	2,358,196
Total assets (Note 26) ······	¥523,242	¥540,762	\$6,292,748

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	Millions	Thousands of U.S. dollars (Note 3)	
	2011	2010	2011
Liabilities and net assets			
Current liabilities:			
Notes and accounts payable (Note 11):			
Affiliates	¥ 1,365	¥ 1,699	\$ 16,416
Trade	11,521	11,706	138,557
Construction	8,654	1,970	104,077
Current portion of long-term debt (Notes 7 and 11)	14,000	14,000	168,370
Allowance for employees' bonuses	7,059	6,473	84,895
Accrued expenses	4,607	4,851	55,406
Accrued income taxes (Note 13)	13,209	13,061	158,858
Other current liabilities (Note 8)	19,405	13,070	233,373
Total current liabilities	79,820	66,830	959,952
Long-term liabilities:			
Long-term debt (Notes 7 and 11)	93,000	107,000	1,118,461
Accrued retirement benefits for employees (Note 15)	8,573	8,077	103,103
Deferred income taxes (Note 13)	6,624	15,437	79,663
Long-term accounts payable – other	5,884	391	70,763
Other long-term liabilities	1,245	1,051	14,973
Total long-term liabilities	115,326	131,956	1,386,963
Contingent liabilities (Note 9)			
Net assets:			
Shareholders' equity (Note 10):			
Common stock:			
Authorized: 1,000,000,000 shares			
Issued: 351,136,165 shares in 2011 and 2010	21,280	21,280	255,923
Capital surplus	20,227	20,227	243,259
Retained earnings ·····	339,970	332,670	4,088,635
Less treasury stock, at cost ••••••	(19,744)	(19,733)	(237,450)
Total shareholders' equity	361,733	354,444	4,350,367
Accumulated other comprehensive income (loss):			
Net unrealized holding gains on securities (Note 5)	3,733	10,362	44,895
Deferred losses on hedges (Note 25)	(289)		(3,476)
Translation adjustments	(37,081)	(23,302)	(445,953)
Accumulated other comprehensive loss, net	(33,637)	(12,940)	(404,534)
Minority interests	(00,007)	472	(-0-,00-)
Total net assets (Note 24)	328,096	341,976	3,945,833
Total liabilities and net assets	¥523,242	¥540,762	\$6,292,748

See accompanying notes to consolidated financial statements.

# Consolidated Statements of Income Shionogi & Co., Ltd. and Consolidated Subsidiaries Years ended March 31, 2011 and 2010

	Millions	Thousands of U.S. dollars (Note 3)	
	2011	2010	2011
Net sales (Notes 21 and 26)	¥282,350	¥278,503	\$3,395,671
Cost of sales (Notes 16 and 21)	81,737	76,264	983,007
Gross profit	200,613	202,239	2,412,664
Selling, general and administrative expenses (Note 17)	153,721	149,801	1,848,719
Operating income (Note 26)	46,892	52,438	563,945
Other income (expenses):			
Interest and dividend income	1,683	1,609	20,241
Interest expense	(1,479)	(1,675)	(17,787)
Loss on disposal of property, plant and equipment	(371)	(251)	(4,462)
Gain on sales of land •••••	4,067		48,912
Gain on sales of investments in securities (Note 5)	1,647		19,808
Gain on forgiveness of debt (Note 18)	280		3,367
Gain on recognition of negative goodwill ••••••	244		2,934
Gain on sale of business	—	5,351	—
Gain on exchange from business combination	—	4,900	—
Impairment losses on fixed assets (Note 12)	(7,343)	(200)	(88,310)
Business structure improvement expenses (Note 19)	(4,829)		(58,076)
Loss on disaster (Note 20)	(2,826)		(33,987)
Bad debt expenses ·····	(1,769)		(21,275)
Loss on devaluation of investments in securities (Note 5)	(172)	(1,943)	(2,069)
Other, net	(2,889)	(1,688)	(34,744)
	(13,757)	6,103	(165,448)
Income before income taxes and minority interests ••••••	33,135	58,541	398,497
Income taxes (Note 13):			
Current •••••	20,207	21,146	243,019
Deferred	(7,129)	(1,246)	(85,737)
	13,078	19,900	157,282
Income before minority interests	20,057	38,641	241,215
Minority interests	30	15	361
Net income (Note 24)	¥ 20,027	¥ 38,626	\$ 240,854

See accompanying notes to consolidated financial statements.

# Consolidated Statement of Comprehensive Loss

Shionogi & Co., Ltd. and Consolidated Subsidiaries Year ended March 31, 2011

	Millions of yen	Thousands of U.S. dollars (Note 3)
	2011	2011
Income before minority interests	¥ 20,057	\$ 241,215
Net unrealized holding losses on securities (Note 5)	(6,629)	(79,723)
Deferred losses on hedges (Note 25)	(289)	(3,476)
Translation adjustments	(13,779)	(165,713)
Total other comprehensive loss	(20,697)	(248,912)
Comprehensive loss ·····	¥ (640)	\$ (7,697)
Comprehensive income (loss) attributable to:		
Shareholders of Shionogi & Co., Ltd.	¥ (670)	\$ (8,058)
Minority interests ·····	30	361

See accompanying notes to consolidated financial statements.

# Consolidated Statements of Changes in Net Assets

Shionogi & Co., Ltd. and Consolidated Subsidiaries Years ended March 31, 2011 and 2010

	Millions of yen										
	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gains on securities	Deferred losses on hedges	Translation adjustments	Accumulated other comprehensive loss, net	Minority interests	Total net assets
Balance at March 31,2009	¥21,280	¥20,227	¥304,762	¥(19,653)	¥326,616	¥8,208	¥ —	¥(25,189)	¥(16,981)	¥459	¥310,094
Net income ••••••	_	_	38,626	—	38,626	_	_	_	_	_	38,626
Dividends •••••	_	_	(10,718)	—	(10,718)	_	_	_	_	_	(10,718)
Purchases of treasury stock •••	_	_	—	(80)	(80)	_	_	_	_	_	(80)
Other changes •·····	_	_	—	—	—	2,154	_	1,887	4,041	13	4,054
Balance at March 31, 2010 ···	21,280	20,227	332,670	(19,733)	354,444	10,362	—	(23,302)	(12,940)	472	341,976
Net income ••••••	—		20,027	—	20,027	—	—	—	—	—	20,027
Dividends	—	—	(12,727)	—	(12,727)	—	—	—	—	—	(12,727)
Purchases of treasury stock ••••	—	—	_	(11)	(11)	—	—	—	—	_	(11)
Other changes ••••••	—	—	—	—	—	(6,629)	(289)	(13,779)	(20,697)	(472)	(21,169)
Balance at March 31, 2011	¥21,280	¥20,227	¥339,970	¥(19,744)	¥361,733	¥3,733	¥(289)	¥(37,081)	¥(33,637)	¥—	¥328,096
		Thousands of U.S. dollars (Note 3)									

	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gains on securities	Deferred losses on hedges	Translation adjustments	Accumulated other comprehensive loss, net	Minority interests	Total net assets
Balance at March 31, 2010 ···	\$255,923	\$243,259	\$4,000,842	\$ (237,318)	\$4,262,706	\$124,618	\$ —	\$ (280,240)	\$(155,622)	\$ 5,676	\$4,112,760
Net income ••••••	—	—	240,854	—	240,854	—	—	—	—	—	240,854
Dividends •••••	—	—	(153,061)	—	(153,061)	—	—	—	—	—	(153,061)
Purchases of treasury stock ••••	—	—	—	(132)	(132)	—	—	—	—	—	(132)
Other changes •·····	—	—	—	—	—	(79,723)	(3,476)	(165,713)	(248,912)	(5,676)	(254,588)
Balance at March 31, 2011 ···	\$255,923	\$243,259	\$4,088,635	\$(237,450)	\$4,350,367	\$ 44,895	\$(3,476)	\$(445,953)	\$(404,534)	\$ —	\$3,945,833

See accompanying notes to consolidated financial statements.

# Consolidated Statements of Cash Flows Shionogi & Co., Ltd. and Consolidated Subsidiaries Years ended March 31, 2011 and 2010

	Millions	Thousands of U.S. dollars (Note 3)	
	2011	2010	2011
Operating activities			
Income before income taxes and minority interests ••••••	¥ 33,135	¥ 58,541	\$ 398,497
Adjustments for:			
Depreciation and amortization	17,966	18,048	216,067
Impairment losses on fixed assets	7,343	200	88,310
Amortization of goodwill, net	4,390	3,731	52,796
Gain on sale of business	_	(5,351)	_
Gain on sales of investments in securities	(1,647)	—	(19,808)
Loss on devaluation of investments in securities	172	1,943	2,069
Gain on exchange from business combination ••••••	_	(4,900)	_
Provision for loss on disaster ••••••	1,492		17,944
Increase in accrued retirement benefits	1,576	1,690	18,954
Interest and dividend income	(1,683)	(1,609)	(20,241)
Interest expense	1,479	1,675	17,787
Other	(2,297)	1,438	(27,625)
Changes in operating assets and liabilities:			
Notes and accounts receivable	9,140	(4,740)	109,922
Inventories •••••	1,722	(7,866)	20,710
Other current assets ·····	3,082	5,614	37,066
Notes and accounts payable	(382)	(2,096)	(4,594)
Accrued expenses ·····	(145)	(6,418)	(1,744)
Other current liabilities	3,491	6,607	41,984
Subtotal	78,834	66,507	948,094
Interest and dividends received	1,692	1,646	20,349
Interest paid	(1,493)	(1,513)	(17,956)
Income taxes paid ••••••	(22,505)	(13,738)	(270,655)
Net cash provided by operating activities	¥ 56,528	¥ 52,902	\$ 679,832

	Millions	Thousands of U.S. dollars (Note 3)	
	2011	2010	2011
Investing activities			
Increase in short-term investments	¥ (15,626)	¥ (5,233)	\$ (187,926)
Proceeds from sales and redemption of short-term investments	19,376	9,647	233,025
Increase in investments in securities	(4,340)	(4,395)	(52,195)
Proceeds from sales of investments in securities	2,074	5,000	24,943
Purchases of property, plant and equipment	(11,274)	(13,156)	(135,586)
Increase in investments in an affiliate	(2,349)	(3,203)	(28,250)
Acquisition of investment in a subsidiary resulting in change in scope of consolidation	—	(2,506)	-
Proceeds from sales of investments in a subsidiary resulting in change in scope of	—	8,093	-
Other •••••	(1,808)	4,927	(21,744)
Net cash used in investing activities	(13,947)	(826)	(167,733)
Financing activities			
Decrease in short-term bank loans, net	_	(10,000)	_
Proceeds from long-term debt ••••••	_	988	_
Repayment of long-term debt	(14,000)	(14,000)	(168,371)
Proceeds from bond issuance	—	30,000	—
Purchases of treasury stock	(10)	(80)	(120)
Repayment of installment accounts payable ••••••	—	(1,032)	—
Cash dividends paid ••••••	(12,707)	(10,702)	(152,820)
Other •••••	(294)	(153)	(3,536)
Net cash used in financing activities	(27,011)	(4,979)	(324,847)
Effect of exchange rate changes on cash and cash equivalents	(2,541)	(970)	(30,559)
Net increase in cash and cash equivalents ••••••	13,029	46,127	156,693
Cash and cash equivalents at beginning of year ••••••	97,663	51,536	1,174,540
Cash and cash equivalents at end of year •••••••	¥ 110,692	¥ 97,663	\$ 1,331,233

Management

See accompanying notes to consolidated financial statements.

# Notes to Consolidated Financial Statements Shionogi & Co., Ltd. and Consolidated Subsidiaries

## 1. Basis of Preparation

The accompanying consolidated financial statements of Shionogi & Co., Ltd. (the "Company") and consolidated subsidiaries are prepared on the basis of accounting principles generally accepted in Japan, which are different in certain respects as to the application and disclosure requirements of International Financial Reporting Standards, and are compiled from the consolidated financial statements prepared by the Company as required by the Financial Instruments and Exchange Act of Japan.

In addition, the notes to the consolidated financial statements include certain information which is not required under accounting principles generally accepted in Japan but is presented herein as additional information.

# 2. Summary of Significant Accounting Policies

# (a) Principles of consolidation and accounting for investments in affiliates

The accompanying consolidated financial statements include the accounts of the Company and all companies controlled directly or indirectly by the Company. Companies over which the Company exercises significant influence in terms of their operating and financial policies have been included in the consolidated financial statements on an equity basis. The Company has applied the equity method to its investment in one affiliate for the years ended March 31, 2011 and 2010.

Investments in affiliates not accounted for by the equity method are carried at cost.

All significant intercompany accounts and transactions have been eliminated in consolidation.

The fiscal year end of one overseas consolidated subsidiary is December 31, which is different from that of the Company. This subsidiary is consolidated by using the financial statements as of and for the year ended December 31. As a result, adjustments are made for any significant intercompany transactions taking place during the period from January 1 to March 31.

Effective the year ended March 31, 2011, Shionogi, Inc. (formerly, Shionogi USA Holdings, Inc., name changed in July 2010) and other consolidated subsidiaries changed their fiscal year end from December 31 to March 31. As a result, the consolidated financial statements of the Company for the year ended March 31, 2011 included the results for a 15-month period of those subsidiaries from January 1, 2010 to March 31, 2011.

As a result of this change in fiscal year end, net sales increased by ¥9,563 million (\$115,009 thousand), operating income decreased by ¥602 million (\$7,240 thousand), income before income taxes and minority interests decreased by ¥1,001 million (\$12,038 thousand) and net income decreased by ¥624 million (\$7,505 thousand) for the year ended March 31, 2011 from the corresponding amounts which would have been recorded under the previous method, respectively.

#### (b) Foreign currency translation

All monetary assets and liabilities denominated in foreign currencies are translated into yen at the rates of exchange in effect at the balance sheet date and the gain or loss on each translation is credited or charged to income.

Revenue and expense items arising from transactions denominated in foreign currencies are generally translated into Japanese yen at the rates of exchange in effect at the respective transaction dates. Gain or loss on foreign exchange is credited or charged to income in the period in which such gain or loss is recognized for financial reporting purposes.

Assets and liabilities of the overseas subsidiaries are translated into yen at the rates of exchange in effect at the balance sheet date. Revenues and expenses of the overseas subsidiaries are translated into yen at the average exchange rates. The components of net assets excluding minority interests are translated at their historical exchange rates. Adjustments resulting from translating the foreign currency financial statements are not included in the determination of net income and are reported as "Translation adjustments" in accumulated other comprehensive income (loss) in the consolidated balance sheets and consolidated statement of comprehensive loss.

#### Change in accounting policy

Up to the year ended March 31, 2009, revenues and expenses of the overseas subsidiaries were translated into yen at the rates of exchange in effect at the balance sheet dates of the overseas subsidiaries.

Effective the year ended March 31, 2010, the Company changed the translation method of revenues and expenses of overseas subsidiaries using the average exchange rates.

This change was made in order to reflect the substantive results of the transactions of the overseas subsidiaries more accurately in the consolidated statements of income by mitigating unusual effects in the case of rapid changes of foreign currency exchange rates at the balance sheet date.

As a result of this change, sales increased by ¥632 million, operating income decreased by ¥67 million and income before income taxes and minority interests increased by ¥9 million for the year ended March 31, 2010 from the corresponding amounts which would have been recorded under the previous method.

#### (c) Cash and cash equivalents

Cash and cash equivalents include cash on hand and in banks and other highly liquid investments with maturities of three months or less when purchased.

#### (d) Short-term investments and investments in securities

Securities are classified into three categories: trading securities, held-tomaturity debt securities or other securities. Trading securities, consisting of debt and marketable equity securities are stated at fair value. Gain and loss, both realized and unrealized, are charged to income. Held-to-maturity debt securities are stated at amortized cost. Marketable securities classified as other securities are carried at fair value with any changes in unrealized holding gain or loss, net of the applicable income taxes, reported as a separate component of accumulated other comprehensive income (loss). Non-marketable securities classified as other securities are carried at cost determined by the moving average method except for investments in investment partnerships which are stated at the amount of net assets attributable to the ownership percentage of the Company.

#### (e) Derivatives

Derivatives are carried at fair value.

#### (f) Inventories

Inventories are principally stated at lower of cost, determined by the average method, or net selling value.

#### (g) Property, plant and equipment (other than leased assets)

Property, plant and equipment are stated at cost.

Depreciation of buildings (except for structures attached to the buildings) acquired on or subsequent to April 1, 1998 is calculated principally by the straight-line method over the estimated useful lives of the respective assets. Depreciation of other property, plant and equipment is calculated principally by the declining-balance method over the estimated useful lives of the respective assets.

The useful lives of property, plant and equipment are summarized as follows:

Buildings and structures	2 to 60 years
Machinery, equipment and vehicles	2 to 17 years

Significant renewals and additions are capitalized at cost. Maintenance and repairs are charged to income as incurred.

#### (h) Leases

Finance lease transactions that do not transfer ownership are depreciated to a nil residual value over the period of the lease contract using the straight-line method.

The finance lease transactions entered into on or before March 31, 2008 that do not transfer ownership continue to be accounted for as operating leases.

#### (i)Goodwill

Goodwill is amortized over 20 years by the straight-line method.

#### (j) Research and development expenses and computer software

Research and development expenses are charged to income when incurred. Expenditures relating to computer software developed for internal use are charged to income as incurred unless these are deemed to contribute to the generation of future income or cost savings. Such expenditures are capitalized as assets and amortized by the straight-line method over their respective estimated useful lives, generally a period of 5 years.

#### (k) Income taxes

Income taxes are calculated based on taxable income and charged to income on an accrual basis. Certain temporary differences exist between taxable income and income reported for financial statement purposes which enter into the determination of taxable income in a different period. The Company has recognized the tax effect of such temporary differences in the accompanying consolidated financial statements.

#### (I) Allowance for doubtful accounts

The Company and its consolidated subsidiaries (the "Group") provide an allowance for doubtful accounts at an amount calculated based on their historical experience of bad debts on ordinary receivables plus an additional estimate of probable specific bad debts from customers experiencing financial difficulties.

#### (m) Allowance for employees' bonuses

Allowance for employees' bonuses is provided at the estimated amount of bonuses to be paid to the employees in the following year.

#### (n) Retirement benefits

The Company has a defined benefit pension plan known as a "cash balance plan," which allows pension benefits to fluctuate in accordance with market interest rates, and also has a lump-sum payment plan and a defined contribution pension plan. Certain domestic consolidated subsidiaries have lump-sum payment plans and defined contribution pension plans. In addition, certain overseas subsidiary has defined contribution pension plan.

Accrued retirement benefits are provided based on the amount of the projected benefit obligation reduced by the pension plan assets at fair value at the year end.

Prior service cost is amortized by the straight-line method over a period of 10 years, which is within the estimated average remaining years of service of the eligible employees.

Actuarial gain or loss is amortized each year following the year in which the gain or loss is recognized, principally by the straight-line method over a period of 10 years, which falls within the estimated average remaining years of service of the eligible employees.

#### Supplemental information

The retirement benefits system for directors and corporate auditors was abolished in June 2004 and the shareholders' meeting of the Company held on June 25, 2009 approved a resolution to pay the remaining balance of retirement benefits to directors and corporate auditors. As a result, accrued retirement benefits for directors and corporate auditors of ¥110 million was reclassified to other long-term liabilities at March 31, 2010.

#### Change in accounting policy

Effective the year ended March 31, 2010, the Company adopted "Partial Amendments to Accounting Standard for Retirement Benefits" (Part 3) (ASBJ Statement No. 19, July 31, 2008). The adoption of this accounting standard had no effect on operating income or income before income taxes and minority interests. In addition, the adoption of this accounting standard had no effect on the unrecognized actuarial gain or loss.

#### (o) Hedge accounting

The Company utilizes derivative transactions for mitigating the fluctuation risks of foreign currency receivable and payable, forecasted transactions and interest rates of loans. Hedging instruments are forward foreign currency exchange contracts, currency option contracts and interest-rate swap agreements. Hedged items are foreign currency receivable and payable, forecasted transactions and interest rates on loans from financial institutions.

Gain or loss on derivatives positions designated as hedges is deferred until the loss or gain on the respective underlying hedged items is recognized. Interest-rate swaps which meet certain conditions are accounted for as if the interest rates applied to the swaps had originally applied to the underlying debt (special accounting treatment).

Forward foreign exchange contracts which meet certain criteria are accounted for by the allocation method, which requires that recognized foreign currency receivables or payables be translated at the corresponding contract rates.

The Company evaluates effectiveness of its hedging activities as compared with the movements of cash flows of hedging instruments and the corresponding movement of cash flows of hedged items. However, with regard to the forward foreign exchange contracts accounted for by the allocation method and the interest-rate swaps accounted for by the special accounting treatment, the evaluation of effectiveness is omitted.

#### (p) Distribution of retained earnings

Under the Corporation Law of Japan, the distribution of retained earnings with respect to a given financial period is made by resolution of the shareholders at a general meeting held subsequent to the close of the financial period. The accounts for the period do not reflect such distributions. (Refer to Note 28).

## 3. U.S. Dollar Amounts

The translation of yen amounts into U.S. dollar amounts is included solely for convenience, as a matter of arithmetic computation only, at ¥83.15 = U.S.\$1.00, the approximate rate of exchange in effect on March 31, 2011. This translation should not be construed as a representation that yen have been, could have been, or could in the future be, converted into U.S. dollars at the above or any other rate.

## 4. Changes in Accounting Policies

#### (a) Adoption of accounting standard for comprehensive income

Effective the year ended March 31, 2011, the Company adopted "Accounting Standard for Presentation of Comprehensive Income" (ASBJ Statement No. 25 issued on June 30, 2010). Under this accounting standard, "Accumulated other comprehensive income (loss)" and "Accumulated other comprehensive loss, net," in the accompanying consolidated balance sheets as of March 31, 2011 and 2010 were newly presented in place of "Valuation and translation adjustments" and "Total valuation and translation adjustments" in the prior years' consolidated financial statements.

Comprehensive income and other comprehensive income for the year ended March 31, 2010 were as follows:

	Millions of yen
	2010
Income before minority interests ••••••	¥38,641
Other comprehensive income:	
Net unrealized holding gains on securities •••••••••	2,154
Translation adjustments ••••••	1,887
Total other comprehensive income •••••••	4,041
Comprehensive income	¥42,682
Comprehensive income attributable to:	
Shareholders of the Company ••••••	¥42,667
Minority interests ••••••	15

#### (b) Application of accounting standards for business combinations

Effective the year ended March 31, 2010, the Company applied the following revised accounting standards for business combinations and business divestitures: "Accounting Standard for Business Combinations" (ASBJ Statement No. 21, issued on December 26, 2008), "Accounting Standard for Consolidated Financial Statements" (ASBJ Statement No. 22, issued on December 26, 2008), "Partial Amendments to Accounting Standard for Research and Development Costs" (ASBJ Statement No. 23, issued on December 26, 2008), "Accounting Standard for Business Divestitures" (ASBJ Statement No. 7, issued on December 26, 2008), "Accounting Standard for Equity Method of Accounting for Investments" (ASBJ Statement No. 16, issued on December 26, 2008), and "Guidance on Accounting Standard for Business Combinations and Accounting Standard for Business Divestitures" (ASBJ Guidance No. 10, issued on December 26, 2008).

# 5. Short-Term Investments and Investments in Securities

(1) Marketable securities classified as held-to-maturity debt securities at March 31, 2011 and 2010 were as follows:

		Millions of yen			
		2011			
	Carrying value	Gross unrealized gain	Gross unrealized loss	Fair value	
Government bonds, municipal bonds, etc.	¥20	¥—	¥—	¥20	
		Millions	s of yen		
		2010			
	Carrying value	Gross unrealized gain	Gross unrealized loss	Fair value	
Government bonds, municipal bonds, etc.	¥20	¥—	¥—	¥20	
		Thousands o	of U.S. dollars		
		20	11		
	Carrying value	Gross unrealized gain	Gross unrealized loss	Fair value	
Government bonds,	\$241	\$—	\$—	\$241	

(2) Marketable securities classified as other securities at March 31, 2011 and 2010	
as follows:	

as 101101/05.				
	Millions of yen			
		20	11	
	Acquisition cost	Gross unrealized gain	Gross unrealized loss	Carrying value
Equity securities •••••••	¥26,698	¥8,035	¥(2,960)	¥31,773
Government bonds, municipal bonds, etc.	19,106	417	(22)	19,501
Other securities	5,013	631	_	5,644
	¥50,817	¥9,083	¥(2,982)	¥56,918
			s of yen	
			010	
	Acquisition cost	Gross unrealized gain	Gross unrealized loss	Carrying value
Equity securities	¥26,825	¥16,898	¥(303)	¥43,420
Government bonds, municipal bonds, etc.	19,312	539	(14)	19,837
Other securities	5,000	310	_	5,310
	¥51,137	¥17,747	¥(317)	¥68,567
			of U.S. dollars	
		20	)11	
	Acquisition cost	Gross unrealized gain	Gross unrealized loss	Carrying value
Equity securities ••••••	\$321,082	\$96,633	\$(35,598)	\$382,117
Government bonds, municipal bonds, etc.	229,778	5,015	(265)	234,528
Other securities ••••••	60,289	7,588	_	67,877
	\$611,149	\$109,236	\$(35,863)	\$684,522

(3) Proceeds from sales of, and gross realized gain and loss on, other securities for the years ended March 31, 2011 and 2010 were summarized as follows:

	Millions of yen		Thousands of U.S. dollars
	2011	2010	2011
Proceeds from sales	¥2,075	¥ —	\$24,955
Gross realized gain •·····	1,647	_	19,808
Gross realized loss ••••••	0	—	0

(4) Loss on devaluation of investments in securities

Loss on devaluation of investments in securities is recorded for securities whose fair value has declined by 30% or more if the decline is deemed to be irrecoverable considering the financial position of the securities' issuer and other factors.

The Company recognized losses on devaluation of investments in securities of ¥172 million (\$2,069 thousand) and ¥1,943 million for the years ended March 31, 2011 and 2010, respectively.

### 6. Inventories

Inventories at March 31, 2011 and 2010 were as follows:

	Millions of yen		Thousands of U.S. dollars
-	2011	2010	2011
Merchandise	¥ 4,155	¥ 4,339	\$ 49,970
Finished goods ••••••	14,120	16,744	169,813
Semi-finished goods and	19,389	19,908	233,181
Raw materials and supplies	9,675	8,350	116,356
	¥47,339	¥49,341	\$569,320

# 7. Long-Term Debt

Long-term debt at March 31, 2011 and 2010 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2011	2010	2011
Unsecured loans from banks and financial institutions due through 2019 with an average interest rate of 1.3%	¥77,000	¥ 91,000	\$ 926,037
Unsecured bonds due in 2012 with an average interest rate of 0.8%	10,000	10,000	120,265
Unsecured bonds due in 2014 with an average •••••••• interest rate of 1.1%	20,000	20,000	240,529
	107,000	121,000	1,286,831
Less current portion ••••••	(14,000)	(14,000)	(168,370)
	¥93,000	¥107,000	\$1,118,461

The aggregate annual maturities of long-term debt subsequent to March 31, 2011 were summarized as follows:

Year ending March 31,	Millions of yen	Thousands of U.S. dollars	
2012••••••	¥ 14,000	\$ 168,370	
2013 • • • • • • • • • • • • • • • • • • •	24,000	288,635	
2014 • • • • • • • • • • • • • • • • • • •	39,000	469,032	
2015••••••	20,000	240,529	
2016 and thereafter ••••••	10,000	120,265	
	¥107,000	\$1,286,831	

## 8. Pledged Assets

Assets pledged as collateral at March 31, 2011 were as follows:

	Millions of yen	Thousands of U.S. dollars	
	2011	2011	
Cash and cash equivalents ••••••	¥7	\$84	

The corresponding liabilities secured by such collateral at March 31, 2011 were as follows:

	Millions of yen	Thousands of U.S. dollars
	2011	2011
Deposits received from employees (included in "other current liabilities")	¥7	\$84

## 9. Contingent Liabilities

The Company was contingently liable for the guarantee of employees' housing loans of ¥20 million (\$241 thousand) at March 31, 2011.

## 10. Shareholders' Equity

The Corporation Law of Japan (the "Law") provides that an amount equal to 10% of the amount to be disbursed as distributions of capital surplus (other than the capital reserve) and retained earnings (other than the legal reserve) be transferred to the capital reserve and the legal reserve, respectively, until the sum of the capital reserve and the legal reserve equals 25% of the capital stock account. Such distributions can be made at any time by resolution of the shareholders, or by the Board of Directors if certain conditions are met.

The Company's legal reserve included in retained earnings at March 31, 2011 and 2010 amounted to ¥5,388 million (\$64,799 thousand).

Under the Law, upon the issuance and sale of new shares of common stock, the entire amount of the proceeds is required to be accounted for as common stock, although a company may, by resolution of the Board of Directors, account for an amount not exceeding one-half of the proceeds of the sale of new shares as additional paid-in capital included in capital surplus.

Movements in issued shares of common stock and treasury stock during the years ended March 31, 2011 and 2010 were summarized as follows:

		Number	of shares	
		20	)11	
	March 31, 2010	Increase	Decrease	March 31, 2011
Issued shares of common stock	351,136,165	_	_	351,136,165
Treasury stock ••••••	16,231,245	6,530	_	16,237,775
		Number	of shares	
		20	010	
	March 31, 2009	Increase	Decrease	March 31, 2010
Issued shares of common stock	351,136,165	_	_	351,136,165
Treasury stock ······	16,189,825	41,420	_	16,231,245

The Company purchased 6,530 shares and 41,420 shares of common stock from shareholders who had fractional shares of less than one unit for the years ended March 31, 2011 and 2010, respectively.

# 11. Financial Instruments (1) Overview

#### (a) Policies for financial instruments

The Company obtains necessary funding principally by bank borrowings and bond issuance under the business plan for its main business, the production and sales of pharmaceuticals. Temporary surplus funds are managed by low-risk financial assets. Derivatives are utilized for mitigating risks described in the later part of this note and not utilized for speculative purpose.

#### (b) Types of financial instruments and related risk

Trade receivables, notes and accounts receivable, are exposed to the credit risk of customers. Trade receivables denominated in foreign currencies are exposed to the fluctuation risk of foreign currencies. Short-term investments and investments in securities are exposed to fluctuation risk of market price.

Trade payables, notes and accounts payable, are due within one year. Certain trade payables denominated in foreign currencies for the import of raw materials are exposed to the fluctuation risk of foreign currencies. Loans and bonds are utilized principally for necessary financing under the business plan and those maturity dates are due in eight years, at the longest, subsequent to March 31, 2011.

Derivative transactions are made for hedging foreign currency fluctuation risk of trade receivables, trade payables and forecasted transactions denominated in foreign currencies by using forward foreign exchange contracts and currency option contracts and for hedging interest rate fluctuation risk of loans by using interest rate swap agreements. Refer to "Hedge accounting" in Note 2 "Summary of Significant Accounting Policies" for information on hedge accounting such as hedging instruments, hedged items, hedging policy and so forth.

#### (c) Risk management for financial instruments

(i) Monitoring of credit risk (the risk that customers or counterparties may default)

In accordance with the procedures determined in the Company, the Accounting and Finance Department and related sections of the Company periodically monitor the conditions of major customers, manage collection due dates and balances of each customer and try to identify credit risk of customers with worsening financial conditions at the early stage and mitigate the risk. Consolidated subsidiaries perform the similar credit management in accordance with the internal rules of the Company.

The Company enters into derivative transactions with financial institutions with high credit ratings to mitigate the counterparty risk.

The maximum amount of credit risk at balance sheet date is represented as the carrying value of financial assets exposed to the credit risk.

(ii) Monitoring of market risks (the risks arising from fluctuations in foreign exchange rates, interest rates and others)

The Company utilizes forward foreign currency exchange contracts and currency option contracts for hedging to mitigate fluctuation risk identified by each foreign currency of trade receivables payables and forecasted transactions. The Company also utilizes interest rate swap agreements to control the fluctuation risk of interest rates on loans.

The Company continuously reviews securities holdings by monitoring periodically the market and financial condition of the securities' issuers

Management

(companies with business relationships with the Group) and also reviews holding conditions for securities other than held-to-maturities by evaluating the relationship of those companies.

The Accounting and Finance Department enters into derivative transactions under the rules determined in the Company and utilizes forward foreign exchange contracts, currency option contracts and interest-rate swap agreements within the normal range of transactions. The Accounting and Finance Department manages information on transactions by reporting periodically to the Board of Directors' meetings. Consolidated subsidiaries do not utilize derivative transactions.

(iii) Monitoring of liquidity risk (the risk that the Group may not be able to meet its obligations on scheduled due dates)

The Company manages liquidity risk with the Accounting and Finance Department preparing and updating cash flow plans on a timely basis and keeping necessary funds based on the reports prepared by each department.

# (d) Supplementary explanation of the estimated fair value of financial instruments

The fair value of financial instruments is based on their quoted market price, if available. When there is no quoted market price available, fair value is reasonably estimated. Since various assumptions and factors are reflected in estimating the fair value, different assumptions and factors could result in different fair value. In addition, the notional amounts of derivatives in Note 25 do not necessarily indicate the market risk of the derivative transactions.

#### (e) Concentration of credit risk

56 percent of outstanding trade receivables at March 31, 2011 represented receivables due from a specific and large-scale customer.

#### (2) Fair value of financial instruments

Carrying values of financial instruments on the consolidated balance sheets as of March 31, 2011 and 2010, their fair values and their differences are shown in the following table. The following table does not include financial instruments for which it was extremely difficult to determine the fair value.

	Millions of yen		
-		2011	
	Carrying value	Fair value	Difference
Cash and cash equivalents	¥110,692	¥110,692	¥ —
Notes and accounts receivable-trade and affiliates	69,498	69,448	(50)
Short-term investments and investments in securities	58,426	58,426	_
Total assets ·····	¥238,616	¥238,566	¥(50)
Notes and accounts payable-trade	¥11,521	¥11,521	¥ —
Current portion of long-term debt	14,000	14,004	4
Long-term debt:			
Bonds	30,000	30,324	324
Long-term loans	63,000	63,480	480
Total liabilities ••••••	¥118,521	¥119,329	¥808
Derivative transactions (*) •••••••	¥(485)	¥(485)	¥ —

	Millions of yen			
		2010		
	Carrying value	Fair value	Difference	
Cash and cash equivalents	¥ 97,663	¥ 97,663	¥ —	
Notes and accounts receivable-trade and affiliates	79,415	79,322	(93)	
Short-term investments and	70,656	70,656	_	
Total assets ·····	¥247,734	¥247,641	¥ (93)	
Notes and accounts payable-trade	¥ 11,706	¥ 11,706	¥ —	
Current portion of long-term debt	14,000	14,003	3	
Long-term debt:				
Bonds	30,000	30,404	404	
Long-term loans ·····	77,000	77,049	49	
Total liabilities •••••	¥132,706	¥133,162	¥456	

	Thousands of U.S. dollars			
	2011			
	Carrying value	Fair value	Difference	
Cash and cash equivalents	\$1,331,233	\$1,331,233	\$ —	
Notes and accounts receivable-trade and affiliates	835,815	835,214	(601)	
Short-term investments and investments in securities	702,658	702,658	_	
Total assets •••••	\$2,869,706	\$2,869,105	\$ (601)	
Notes and accounts payable-trade	\$ 138,557	\$ 138,557	\$ —	
Current portion of long-term debt	168,370	168,418	48	
Long-term debt:				
Bonds	360,794	364,690	3,896	
Long-term loans •••••	757,667	763,440	5,773	
Total liabilities •••••	\$1,425,388	\$1,435,105	\$9,717	
Derivative transaction (*)	\$ (5,833)	\$ (5,833)	\$ —	

(\*) Assets and liabilities arising from derivative transactions are shown at net value with the amount in parentheses representing net liability position.

a) Methods to determine the fair value of financial instruments, short-term investments and investments in securities and derivative transactions

#### Assets

Cash and cash equivalents

Since these items are settled in a short time period, their carrying value approximates fair value.

Since certificates of deposit issued in Japan included in cash and cash equivalents are settled in a short time period, their carrying value approximates fair value.

• Notes and accounts receivable-trade and affiliates

The fair value of accounts receivable that require a longer period for collection is determined based on the present value by each group of receivables classified by collection term computed by interest rates in consideration of the credit risk corresponding to the collection term. Since other accounts receivable are settled in a short time period, their carrying value approximates fair value.

Short-term investments and investments in securities

With regard to short-term investments and investments in securities, fair value of debt securities is determined by quoted market price or prices offered by financial institutions and that of equity securities is determined by quoted market price. Refer to Note 5 "Short-Term Investments and Investments in Securities" for the information of securities by holding purpose.

#### Liabilities

• Notes and accounts payable-trade

Since these items are settled in a short time period, their carrying value approximates fair value.

Current portion of long-term debt and long-term debt

The fair value of the current portion of long-term debt and long-term debt is based on the present value of the total of principal and interest discounted by the estimated interest rates to be applied if similar new loans are made. Long-term debt with floating interest is hedged by interest rate swap agreements and accounted for as loans with fixed interest rates. The fair value of this long-term debt is based on the present value of the total of principal, the interest and cash flows of interest rate swap agreements discounted by the reasonably estimated interest rates to be applied if similar new loans are made.

#### • Bonds

The fair value of bonds is based on quoted market prices.

#### **Derivative transactions**

Please refer to Note 25 "Derivative Transactions."

b) Financial instruments for which it was extremely difficult to determine the fair value

	Millions of yen		Thousands of U.S. dollars
	2011	2010	2011
Unlisted equity securities	¥8,030	¥7,760	\$96,573

Because no quoted market price is available and it is extremely difficult to determine the fair value, these financial instruments are not included in the preceding table.

c) The redemption schedule for monetary assets and marketable securities with maturities at March 31, 2011

	Millions of yen				
	Due in 1 year or less	Due after 1 year through 5 years	Due after 5 years through 10 years	Due after 10 years	
Cash and cash equivalents	¥110,692	¥ —	¥ —	¥ —	
Notes and accounts receivable-trade and ···· affiliates	66,745	2,577	176	_	
Short-term investments and investments in securities: Bonds held to maturity	20	_	_	_	
Other securities with maturity dates	5,722	6,000	8,748	-	
Total ·····	¥183,179	¥8,577	¥8,924	¥ —	

	Thousands of U.S. dollars				
	Due in 1 year Due after or less 5 years		Due after 5 years through 10 years	Due after 10 years	
Cash and cash equivalents	\$1,331,233	\$ —	\$ —	\$ —	
Notes and accounts receivable-trade and ···· affiliates	802,706	30,992	2,117	-	
Short-term investments and investments in securities: Bonds held to maturity	241	_	_	_	
Other securities with maturity dates	68,815	72,159	105,207	-	
Total ·····	\$2,202,995	\$103,151	\$107,324	\$ —	

Effective the year ended March 31, 2010, the Group adopted "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, issued on March 10, 2008) and "Guidance on Disclosures about Fair Value of Financial Instruments" (ASBJ Guidance No. 19, issued on March 10, 2008).

# 12. Impairment Losses on Fixed Assets

Fixed assets for business use are grouped based on their corresponding, management segment, such as product lines. Assets available for rent and idle assets are grouped individually.

Impairment losses on fixed assets for the year ended March 31, 2011 were summarized as follows:

			Millions of yen	Thousands of U.S. dollars
Location	Use	Classification	2011	2011
U.S.A.	Exclusive marketing rights for ethical pharmaceutical products	Marketing rights	¥7,135	\$85,809
U.S.A.	In-process research and development expenses for compounds developing pharmaceutical	Other assets	¥ 208	\$ 2,501

The Group decided to discontinue sales of certain ethical pharmaceutical products, for which the Company owns marketing rights. As a result, the Group reduced the related carrying value of marketing rights to a recoverable value of zero and recognized impairment loss.

The Company also concluded that no future value of use existed for certain pharmaceutical compounds, which are recorded as in-process research and development expenses included in other assets. As a result, the Group reduced the related carrying value of other assets to a recoverable value of zero and recognized impairment loss.

Impairment loss on fixed assets for the year ended March 31, 2010 was summarized as follows:

			Millions of yen
Location	Use	Classification	2010
Chuo-ku, Osaka Prefecture and other	Exclusive marketing rights for ethical pharmaceutical products	Marketing rights	¥200

Because a contract related to exclusive marketing rights for ethical pharmaceutical products would be cancelled in the next fiscal year, the Company reduced its carrying value of ¥200 million to its recoverable value of zero and recognized impairment loss of ¥200 million for the year ended March 31, 2010.

## 13. Income Taxes

Income taxes applicable to the Company and its domestic consolidated subsidiaries comprise corporation tax, inhabitants' taxes and enterprise taxes which, in the aggregate, resulted in a statutory tax rate of approximately 40.6% for the years ended March 31, 2011 and 2010.

The overseas subsidiaries are subject to the income taxes of the respective countries in which they operate.

The effective tax rates for the years ended March 31, 2011 and 2010 differed from the above statutory tax rate for the following reasons:

	2011	2010
Statutory tax rate	40.6%	40.6%
Expenses not deductible for income tax purposes	1.3	1.8
Dividends not taxable for income tax purposes ••••••	(0.8)	(1.2)
Amortization of goodwill ••••••	4.6	2.2
Inhabitants' per capita taxes	0.4	0.2
Tax credits ••••••	(13.5)	(10.8)
Difference in statutory tax rates of overseas	9.3	(0.4)
Consolidation adjustment for the sales of a	_	2.3
Change in statutory tax rates of overseas	(2.4)	_
Change in valuation allowance	_	(0.3)
Other ·····	0.0	(0.4)
Effective tax rates ••••••	<b>39.5</b> %	34.0%

The tax effects of temporary differences at March 31, 2011 and 2010 which gave rise to significant deferred tax assets and liabilities are presented below:

	Million	Millions of yen	
-	2011	2010	2011
Deferred tax assets:			
Allowance for employees' bonuses	¥ 2,858	¥ 2,398	\$ 34,372
Retirement benefits	1,125	_	13,530
Accrued enterprise taxes	1,111	1,354	13,361
Research and	5,529	2,617	66,494
Reserve for sales rebates	_	276	_
Allowance for sales returns	676	_	8,130
Losses on revaluation of	470	520	5,652
Tax loss carry forwards of a	2,646	753	31,822
Accrued expenses and	2,333	1,215	28,058
Other •••••	4,613	6,756	55,478
Valuation allowance	(441)	(2,147)	(5,304)
Total deferred tax assets	20,920	13,742	251,593
Deferred tax liabilities:			
Unrealized gain on other securities	(2,574)	(7,077)	(30,956)
Marketing rights •••••••••	_	(7,307)	-
Specially recognized depreciation reserve fund	_	(121)	_
Prepaid pension costs	(5,698)	(6,339)	(68,527)
Investments in securities	(2,581)	(2,581)	(31,040)
Deferred gain on fixed assets ••	(1,511)	_	(18,172)
Other	(4,845)	(255)	(58,268)
Total deferred tax liabilities	(17,209)	(23,680)	(206,963)
Net deferred tax assets	¥ 3,711	¥ (9,938)	\$ 44,630

## 14. Leases

The Group principally leases equipment and vehicles and has entered into a number of finance lease contracts that do not transfer the ownership of the leased property to the Group.

The following pro forma amounts represent the acquisition costs, accumulated depreciation and net book value of the property leased to the Group at March 31, 2010, for lease contracts entered into on or before March 31, 2008, that would have been reflected in the accompanying consolidated balance sheets if the finance leases that do not transfer the ownership of the leased property to the Group (which were accounted for as operating leases) were capitalized:

	Millions of yen		
	2010		
	Acquisition Accumulated Net boo costs depreciation value		
Machinery, equipment and vehicles	¥29	¥27	¥ 2
Other	47	31	16
Total	¥76	¥58	¥18

Depreciation of the leased assets, which was computed by the straight-line method over the respective lease terms assuming a nil residual value, amounted to ¥476 million for the year ended March 31, 2010.

Finance lease payments of the Group for the year ended March 31, 2010 were as follows:

	Millions of yen
	2010
Lease payments	¥476

There were no losses on impairment of leased assets for the year ended March 31, 2010.

Because the amounts related to finance lease contracts entered into on or before March 31, 2008, which do not transfer the ownership of the leased property to the Group and were accounted for as operating leases, are immaterial, disclosure information at March 31, 2011 has been omitted.

## 15. Retirement Benefits

The following table sets forth the retirement benefit obligation, plan assets and the funded status of the Group's defined benefit pension plans at March 31, 2011 and 2010:

	Millions of yen		Thousands of U.S. dollars
	2011	2010	2011
Retirement benefit obligation at end of year	¥(84,847)	¥(86,498)	\$(1,020,409)
Fair value of plan assets at end of year	79,143	89,013	951,810
Plan assets in excess of retirement benefit obligation	_	2,515	_
Unfounded status ·····	(5,704)	_	(68,599)
Unrecognized actuarial loss	26,070	22,101	313,530
Unrecognized prior service costs	(5,608)	(8,282)	(67,445)
Net retirement benefit	14,758	16,334	177,486
Prepaid pension costs ••••••	23,331	24,411	280,589
Accrued retirement	¥ (8,573)	¥ (8,077)	\$ (103,103)

The components of retirement benefit expenses for the years ended March 31, 2011 and 2010 were as follows:

	Millions of yen		Thousands of U.S. dollars
-	2011	2010	2011
Service cost	¥1,902	¥1,865	\$22,874
Interest cost ·····	1,729	1,763	20,794
Expected return on plan assets	(2,227)	(2,530)	(26,783)
Amortization of actuarial loss	4,986	5,857	59,964
Amortization of prior service costs	(2,674)	(2,674)	(32,159)
Contributions to the defined	1,033	1,045	12,424
Retirement benefit expenses ·····	¥4,749	¥5,326	\$57,114

The assumptions used in accounting for the defined benefit pension plans for the years ended March 31, 2011 and 2010 were as follows:

	2011	2010
Discount rate	2.0%	2.0%
Expected rates of return on plan assets	2.8%	3.1%

# 16. Cost of Sales

Cost of sales included losses on devaluation of inventories of ¥1,120 million (\$13,470 thousand) and ¥474 million for the years ended March 31, 2011 and 2010, respectively.

# 17. Research and Development Expenses

Research and development expenses included in selling, general and administrative expenses for the years ended March 31, 2011 and 2010 amounted to ¥50,921 million (\$612,399 thousand) and ¥51,808 million, respectively.

# 18. Gain on Forgiveness of Debt

During the year ended March 31, 2011, development activities for a certain pharmaceutical compound based on an outsourcing development agreement entered into with the Japan Science and Technology Agency ("JST") in the year ended March 31, 2005 were completed. Under this agreement, the Company was released from the obligation to repay borrowings from JST for certain costs related to the development activities. As a result, the Company recognized gain on forgiveness of debt in the amount of ¥280 million (\$3,367 thousand) for the year ended March 31, 2011.

# 19. Business Structure Improvement Expenses

Business structure improvement expenses were attributable to the reorganization of subsidiaries of the Company in the United States and mainly consisted of special retirement benefits in the amount of ¥4,006 million (\$48,178 thousand).

# 20. Loss on Disaster

The Company recorded loss on disaster in connection with the impact of the Great East Japan Earthquake. It consists of losses recorded for the year ended March 31, 2011 and a provision for losses expected to be incurred for future recovery costs.

# 21. Investment and Rental Properties

The Group owns office buildings including land for lease mainly in Tokyo and other areas.

Rental income, net of related expenses relevant to these real estate properties, amounted to ¥1,258 million (\$15,129 thousand) and ¥1,652 million for the years ended March 31, 2011 and 2010. The rental income is principally recorded under net sales and the rental expenses are principally recorded under cost of sales.

The carrying value in the consolidated balance sheets and corresponding fair value of those properties are as follows:

	Millions of yen						
	Carrying value						
March 31, 2010	March 31, 2010 Net change March 31, 2011						
¥6,234	¥(591)	¥5,643	¥21,510				

Millions of yen						
	Carrying value		Fair value			
March 31, 2009	March 31, 2010					
¥6,398	¥25,960					
	Thousands	s of U.S. dollars				
	Carrying value		Fair value			
March 31, 2010	March 31, 2010 Net change March 31, 2011					
\$74,973	\$(7,108)	\$67,865	\$258,689			

Carrying value in the table above is presented as the amount of acquisition costs less accumulated depreciation.

Fair value at March 31, 2011 was primarily calculated based on real estate appraisal standards and, in some cases, the adjusted amounts using indices and other methods.

#### Supplemental information

Effective the year ended March 31, 2010, the Group adopted "Accounting Standard for Disclosures about Fair Value of Investment and Rental Property" (ASBJ Statement No. 20, issued on November 28, 2008) and "Guidance on Accounting Standard for Disclosures about Fair Value of Investment and Rental Property" (ASBJ Guidance No. 23, issued on November 28, 2008).

# 22. Related Party Transactions

Principal transactions between a subsidiary and a related party for the years ended March 31, 2011 and 2010 were summarized as follows:

Transaction with a director

	Millions	s of yen	Thousands of U.S. dollars
-	<b>2011</b> 2010		2011
Shunjusha Co., Ltd.:			
Rent received – land and office building ····	¥ 49	¥ 45	\$ 589
Rent expense-building ••••••	145	143	1,744
Management fee for leased property	3	3	36

Shunjusha Co., Ltd. is directly owned by a director and a relative of a director of the Company and is engaged in the real estate leasing business. The percentages of voting rights owned by these two people were 85.8% and 99.9% as of March 31, 2011 and 2010, respectively. Shunjusha Co., Ltd. is located in Chuo-ku, Osaka with a capital amount of ¥701 million (\$8,431 thousand) as of March 31, 2011 and 2010, respectively.

The prices for the above related party transactions were determined with reference to market value, transactions made in the same area and so on.

There were no outstanding balances in connection with related party transactions above as of March 31, 2011 and 2010.

# 23. Supplementary Cash Flow Information

On November 13, 2009, the Company purchased shares of Addrenex Pharmaceuticals, Inc. ("Addrenex") and initially consolidated the accounts of Addrenex as of and for the year ended March 31, 2010. The assets and liabilities included in consolidation were summarized as follows:

	Millions of yen
-	2010
Current assets	¥ 47
In-process research and development costs	2,829
Goodwill ••••••	1,063
Current liabilities	(141)
Non-current liabilities ••••••	(770)
Interest which the Company already owned **********	(330)
Acquisition cost	¥2,698
Net of advance payments ••••••	(146)
Cash and cash equivalents of Addrenex ••••••	(46)
Cash disbursement ••••••	¥2,506

Effective February 22, 2010, Bushu Pharmaceuticals Ltd. ("Bushu") was excluded from the scope of consolidation because the Company's investment in Bushu had been sold. The assets and liabilities as of the date of the sale, and proceeds from sale and gain on the sale were as follows:

	Millions of yen
-	2010
Current assets	¥ 4,187
Non current assets ••••••	11,556
Current liabilities	(2,378)
Non-current liabilities ••••••	(10,599)
Expenses for sale of shares of Bushu ·····	438
Gain on sale of business ••••••	5,351
Sales amount of shares of Bushu •••••••	¥ 8,555
Cash and cash equivalents of Bushu ••••••	(462)
Proceeds from sale of investment •••••••	¥ 8,093

## 24. Amounts per Share

Amounts per share as of and for the years ended March 31, 2011 and 2010 were as follows:

	Y	U.S. dollars	
	2011	2010	2011
Net income ••••••	¥ 59.80	¥ 115.33	\$ 0.72
Net assets ••••••	979.69	1,019.71	11.78
Cash dividends applicable to the year •••	40.00	36.00	0.48

Diluted net income per share has not been presented since no potentially dilutive securities have been issued.

Net income per share is computed based on the net income available for distribution to shareholders of common stock and the weighted-average number of shares of common stock outstanding during the year. The amounts per share of net assets have been computed based on the number of shares of common stock outstanding at the year end.

Cash dividends per share represent the cash dividends proposed by the Board of Directors as applicable to the respective years together with the interim cash dividends paid.

The financial data used in the computation of basic net income per share for the years ended March 31, 2011 and 2010 in the table above was summarized as follows:

	Millions of yen 2011 2010		Thousands of U.S. dollars
-			2011
Information used in computation of basic net income per share:			
Net income ·····	¥20,027	¥38,626	\$240,854
		Thousand	ls of shares
	-	2011	2010
Weighted-average number of shares of common stock outstanding	•••••	334,902	334,915

The financial data used in the computation of net assets per share at March 31, 2011 and 2010 in the above table was summarized as follows:

	Million	s of yen	Thousands of U.S. dollars	
-	2011	2010	2011	
Total net assets	¥328,096	¥341,976	\$3,945,833	
Amounts deducted from total net assets (Amounts attributed to •• minority interests in total net assets):	_	472	_	
Net assets used in the calculation	¥328,096	¥341,504	\$3,945,833	
		Thousands	s of shares	
	-	2011	2010	
Number of shares used in the calculation net assets per share	n of	334,898	334,904	

# Shionogi's Business Activities

# 25. Derivative Transactions

#### 1. Derivative transactions for which hedge accounting does not apply

Information on derivative transactions for which hedge accounting does not apply was omitted since all outstanding derivative positions qualified for hedge accounting.

#### 2. Derivative transactions to which hedge accounting applies

(1) Currency-related transactions

			Millions of yen			ousands of U.S. dollar	S
		2011					
		Contra	act value		Contract value		
Transaction	Principal hedged item	Notional amount	More than one year	Fair value (*1)	Notional amount	More than one year	Fair value (*1)
Forward foreign currency exchange contracts Selling: USD	Forecasted transactions	¥16,105	¥ —	¥(481)	\$193,686	\$ —	\$(5,785)
Forward foreign currency exchange contracts Buying: USD	Forecasted transactions	¥ 1,626	¥ —	¥ 35	\$ 19,555	\$ —	\$ 421
Currency option contracts (*2) Selling-put: USD	Forecasted transactions	¥14,967	¥ —	¥ (73)	\$180,000	\$ —	\$ (878)
Currency option contracts (*2) Buying-call: USD	Forecasted transactions	¥14,967	¥ —	¥ 32	\$180,000	\$ —	\$ 385

(\*1) Fair values are calculated based on the prices provided by counterparty financial institutions.

(\*2) The currency option contracts are zero-cost options and no premium is received or paid.

			Millions of yen			
			Contra	act value		
Method of hedge accounting	Transaction	Principal hedged item	Notional amount	More than one year	Fair value	
orward foreign surrency exchange ates applied to underlying transactions	Forward foreign currency exchange contracts Buying: EUR	Accounts payable- trade	¥133	¥ —	(*)	

(\*) Since forward foreign exchange contracts that quality for deferral hedge accounting are included in accounts payable, their fair value is included in that of accounts payable.

(2) Interest rate-related transactions

				Millions of yen		Tho	usands of U.S. dollars	
			2011				2011	
		Contr	act value		Contr	act value		
Method of hedge accounting	Transaction	Principal hedged item	Notional amount	More than one year	Fair value	Notional amount	More than one year	Fair value
Swap rates applied to underlying debt	Interest rate swaps Pay: fixed/ Receive: floating	Long-term debt	¥25,000	¥25,000	(*)	\$300,661	\$300,661	(*)
				Millions of yen				
				2010				
			Contr	act value				
Method of hedge accounting	Transaction	Principal hedged item	Notional amount	More than one year	Fair value			
Swap rates applied to underlying debt	Interest rate swaps Pay: fixed/ Receive: floating	Long-term debt	¥25,000	¥25,000	(*)			

(\*) Since interest rate swap agreements are accounted for as if the interest rates applied to the swaps had originally applied to the underlying debt (refer to Note 2(p)), their fair value is included in that of the long-term debt disclosed in Note 11 "Financial Instruments."

# 26. Segment Information

#### 1. Segment information for the year ended March 31, 2011

The Group operates as single business segment related to prescription drugs involving research and development, purchasing, manufacturing, distribution and related businesses for prescription drugs. While analyses of sales by products and evaluation of performance by group companies is performed, decisions of business strategy and allocation of management resources, especially allocation of research and development expenses, are made on a Group-wide basis. Therefore, disclosure of segment information for the year ended March 31, 2011 was omitted.

#### 2. Related information

(1) Information on sales by product and service

As the amount of sales to third parties of only one type of product and service in a single segment accounted for more than 90% of net sales in the consolidated statement of income for the year ended March 31, 2011, information on sales by product and service for the year ended at March 31, 2011 was omitted.

#### (2) Geographical information

(a) Net sales

	Millions of yen	Thousands of U.S dollars	
-	2011	2011	
Japan ·····	¥ 177,915	\$ 2,139,688	
Europe ·····	65,912	792,688	
(of which United Kingdom) •••••	(64,962)	(781,263)	
North America ••••••	34,247	411,870	
(of which the U.S.) •••••••••	(34,179)	(411,052)	
Other •••••	4,276	51,425	
Total	¥282,350	\$ 3,395,671	

Net sales information above is classified by countries and or regions based on locations of customers. The main countries and regions included in each category are as follows:

- (1) Europe: United Kingdom, Switzerland, Germany and other
- (2) North America: United States of America and other
- (3) Other: Asia and other

(b) Property, plant and equipment

As the balances property, plant and equipment located in Japan accounted for more than 90% the balances of property, plant and equipment recognized in the consolidated balance sheet at March 31, 2011, information of property, plant and equipment at March 31, 2011 was omitted.

#### (3) Information by major customer

	Ne	t sales	
	Millions of yen	Thousands of U.S. dollars	
Customer name	2011	2011	- Related segment name
SUZUKEN CO., LTD. •••••••	¥64,489	\$775,574	Prescription drugs
AstraZeneca UK Ltd. ••••••	64,378	774,239	Prescription drugs
Toho Pharmaceutical Co., Ltd. •••	35,316	424,726	Prescription drugs

#### 3. Information regarding impairment losses on fixed assets, amount of amortization of goodwill and unamortized balance and gain on recognition of negative goodwill by reportable segments at March 31, 2011 and for the year then ended

The Group is primarily engaged in research and development, merchandising, manufacturing and marketing of ethical pharmaceuticals and related businesses. Accordingly, information regarding impairment losses on fixed assets, amount of amortization of goodwill and remaining balance and gain on negative goodwill by business segment at March 31, 2011 and for the year then ended was omitted.

#### Supplemental information

Effective the year ended March 31, 2011, the Company applied "Accounting Standard for Disclosures about Segments of an Enterprise and Related Information" (ASBJ Statement No. 17 issued on March 27, 2009) and "Guidance on Accounting Standard for Disclosures about Segment of an Enterprise and Related Information" (ASBJ Guidance No. 20 issued on March 21, 2008).

#### 4. Segment information for the year ended March 31, 2010

Under the former segmentation policy applied by the Company up to the year ended March 31, 2010, segment information for the year ended March 31, 2010 was as follows:

#### (1) Business segment information

The pharmaceuticals and related businesses included more than 90% of the total sales, operating income and total assets of all business segments. Therefore, the disclosure of business segment information was omitted for the year ended March 31, 2010.

(2) Geographical segment information

The geographical segment information of the Group for the year ended March 31, 2010 was as follows:

	Millions of yen					
	2010					
	Japan	North America	Other	Total	Eliminations or corporate	Consolidated
I.Sales and operating income:						
Sales to third parties	¥238,191	¥38,642	¥1,670	¥278,503	¥ —	¥278,503
Intragroup sales and transfers ••••••••	413	2,927	58	3,398	(3,398)	_
Net sales ••••••	238,604	41,569	1,728	281,901	(3,398)	278,503
Operating expenses ••••••	185,631	38,656	1,414	225,701	364	226,065
Operating income	¥ 52,973	¥ 2,913	¥ 314	¥ 56,200	¥ (3,762)	¥ 52,438
II.Total assets ·····	¥287,603	¥85,803	¥3,818	¥377,224	¥ 163,538	¥540,762

The above categories were based on geographic proximity. "North America" mainly represents the United States of America, and "Other" mainly represents Asian countries.

As described in Note 2(b), up to the year ended March 31, 2009, revenues and expenses of the overseas subsidiaries were translated into yen at the rates of exchange in effect at balance sheet dates of the overseas subsidiaries. Effective the year ended March 31, 2010, the Company changed the translation method of revenues and expenses of overseas subsidiaries using the average exchange rate for the fiscal year.

The effect of this change was to increase sales in the "North America" segment by ¥644 million and to decrease sales in the "Other" segment by ¥11 million. In addition, this change was to increase operating expenses in the "North America" segment by ¥644 million, "Eliminations or corporate" by ¥62 million and to decrease operating expenses in the "Other" segment by ¥7 million. Furthermore, this change was to decrease operating income by ¥0 million in the "North America" segment, the "Other" segment by ¥4 million and the "Eliminations or corporate" by ¥62 million from the corresponding amount which would have been recorded under the previous method.

#### (3) Overseas sales

Overseas sales for the year ended March 31, 2010 was as follows:

	Millions of yen 2010				
	Europe North Other Total				
I.Overseas sales ••••••	¥51,040	¥44,653	¥4,149	¥ 99,842 ¥278,503	
III.Overseas sales as a percentage of consolidated net sales	18.3%	16.0%	1.5%	35.8%	

Overseas sales represent those of the Company and consolidated subsidiaries outside Japan and include royalty revenue. The above categories are based on geographic proximity. The main countries and regions included in each category are as follows:

(1) Europe: United Kingdom, Switzerland, Germany and other
 (2) North America: United States of America and other
 (3) Other: Asia and other

As described in Note 2(b), up to the year ended March 31, 2009, revenues and expenses of the overseas subsidiaries were translated into yen the rates of exchange in effect at balance sheet dates of the overseas subsidiaries. Effective the year ended March 31, 2010, the Company changed the translation method of revenues and expenses of overseas subsidiaries using the average exchange rate.

The effect of this change was to increase overseas sales to "North America" by ¥644 million and to decrease overseas sales to "Other" segment by ¥11 million, which resulted in the increase of consolidated net sales by ¥632 million from the corresponding amount which would have been recorded under the previous method. The share of overseas sales in consolidated net sales increased by 0.2% in "North America" and the impact on "Europe" and "Other" was immaterial.

## 27. Litigation

In December 2007, the Company brought a patent infringement action jointly with AstraZeneca against seven generic drug companies and additional two other companies later including Cobalt Pharmaceuticals, Inc. and Apotex, Inc., which had filed Abbreviated New Drug Applications ("ANDAs") for a generic drug version of Crestor in the United States, in order to prevent said companies from selling any generic drug under the patent owned by the Company in the United States.

The trial was held from late February to early March 2010. In June 2010, the United States District Court for the District of Delaware rendered a judgment that the Company's patent was effective and enforceable, and prohibited eight generic drug companies from the manufacture and sales of said generic drug prior to the expiration of the patent. In August 2010, seven generic drug companies appealed the above ruling to the United States Court of Appeals for the Federal Circuit. As a result, the Company has responded to this action, which is currently pending in court.

In September 2009, the Company brought, jointly with AstraZeneca Canada, a patent infringement action against two companies, namely Novopharm Limited (currently Teva Canada Limited) and Apotex, Inc., which had filed ANDAs for a generic drug version of Crestor in Canada, in order to prevent said companies from selling generic drugs under the patent owned by the Company in Canada.

The Company has performed the necessary procedures in court, to request the relevant administrative authorities to stop the approval of ANDAs filed by the aforementioned two companies as well as six other generic drug companies.

Of the parties in the suit and procedures, a settlement was reached with and actions have been terminated against Teva Canada Limited (which absorbed Ratiopharm Inc.), Apotex, Inc., Cobalt Pharmaceuticals Company, Sandoz Canada Inc. and Mylan Pharmaceuticals ULC. Procedures against Pharmascience Inc. and Ranbaxy Pharmaceuticals Canada Inc. are still pending.

In October 2010 in the Delaware District Court and again in November 2010 in the Nevada District Court, the Company brought a patent infringement action jointly with AstraZeneca against Watson Pharmaceuticals, Inc., which had filed an ANDA for a generic drug version of Crestor in the United States, in order to prevent Watson Pharmaceuticals, Inc. from selling any generic drug under the patent owned by the Company in the United States.

In May 2008, a suit was brought against the Company in Osaka District Court by Cellectis SA, which is the exclusive licensee of the patent owned by Institut Pasteur, claiming that the use of the technology relating to genetically modified mice for research would infringe the patent and demanding that the Company pay ¥970 million (\$11,666 thousand). The trial for this suit is currently pending in court.

In February 2009, the Company brought a patent infringement action under its patent for the crystal of cefcapene pivoxil hydrochloride monohydrate, the active ingredient of Flomox<sup>®</sup>, an antibiotic developed by the Company, against ITOCHU CHEMICAL FRONTIER Corporation, which is the importer of said active ingredient, and simultaneously initiated procedures to petition for a provisional deposition order.

In August 2009, the Company also brought a patent infringement action against Sawai Pharmaceutical Co., Ltd., which had started selling a generic drug version of Flomox<sup>®</sup> in May 2009, for the same patent, and simultaneously initiated procedures to petition for a provisional deposition order. Additionally, in February 2010, the Company initiated procedures to petition for a provisional deposition order, based on infringement of this same patent, against eight generic drug companies including Towa Pharmaceutical Co., Ltd. that started selling a generic version of the drug in November 2009.

Since the Osaka District Court made a judgment to repeal the series of claims by the Company in April 2010, the Company filed an appeal to the Intellectual Property High Court with ITOCHU CHEMICAL FRONTIER Corporation and Sawai Pharmaceutical Co., Ltd. against the appellees. This suit was settled and the action was ended in October 2010.

## 28. Subsequent Event

The following distribution of retained earnings of the Company, which has not been reflected in the accompanying consolidated financial statements for the year ended March 31, 2011, was approved at a shareholders' meeting held on June 24, 2011:

	Millions of yen	Thousands of U.S. dollars
Cash dividends (¥20.00 = U.S.\$0.24 per share)	¥6,698	\$80,553

# Report of Independent Auditors

The Board of Directors Shionogi & Co., Ltd.

We have audited the accompanying consolidated balance sheets of Shionogi & Co., Ltd. and consolidated subsidiaries as of March 31, 2011 and 2010, and the related consolidated statements of income, changes in net assets, and cash flows for the years then ended and consolidated statement of comprehensive loss for the year ended March 31, 2011, all expressed in yen. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Shionogi & Co., Ltd. and consolidated subsidiaries at March 31, 2011 and 2010, and the consolidated results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in Japan.

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended March 31, 2011 are presented solely for convenience. Our audit also included the translation of yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 3.

Osaka, Japan June 24, 2011

Ernet & Young Shimkon LLC

# Shionogi Group Directory

# Major Business Locations

#### Head Office/Branch Offices

#### Head Office

1-8, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045, Japan Tel: +81-6-6202-2161 Fax: +81-6-6229-9596

#### 2 Tokyo Branch Office

Shionogi Shibuya Bldg., 17-5, Shibuya 2-chome, Shibuya-ku, Tokyo 150-0002, Japan Tel: +81-3-3406-8111

Nagoya Branch Office SKY OASIS SAKAE, 9, Shinsakaemachi 2-chome, Naka-ku, Nagoya, Aichi 460-0004, Japan Tel: +81-52-957-8271

#### Fukuoka Branch Office

Shin KBC Bldg., 1-35, Nagahama 1-chome, Chuo-ku, Fukuoka City, Fukuoka 810-0072, Japan Tel: +81-92-737-7750

#### Sapporo Branch Office

Nissay Sapporo Bldg., 1-1, Kitasanjo-Nishi 4-chome, Chuo-ku, Sapporo, Hokkaido 060-0003, Japan Tel: +81-11-252-2290

#### Laboratories

Shionogi Research Laboratories 12-4, Sagisu 5-chome, Fukushima-ku, Osaka 553-0002, Japan Tel: +81-6-6458-5861

#### Shionogi Pharmaceutical Research Center

1-1, Futaba-cho 3-chome, Toyonaka, Osaka 561-0825, Japan Tel: +81-6-6331-8081

#### Shionogi Institute for Medical Science

5-1, Mishima 2-chome, Settsu, Osaka 566-0022, Japan Tel: +81-6-6382-2612

#### Aburahi Laboratories

1405, Gotanda, Koka-cho, Koka, Shiga 520-3423, Japan Tel: +81-748-88-3281

#### Shionogi Innovation Center for Drug Discovery Kita 21, Nishi 11, Kita-ku, Sapporo, Hokkaido 001-0021, Japan Tel: +81-11-700-4700

#### **Plants**

#### Gettsu Plant

5-1, Mishima 2-chome, Settsu, Osaka 566-0022, Japan Tel: +81-6-6381-7341

#### 6 Kanegasaki Plant

7, Moriyama, Nishine, Kanegasaki-cho, Isawa-gun, Iwate 029-4503, Japan Tel: +81-197-44-5121

#### Site

#### 6 Kuise Site

1-3, Kuise Terajima 2-chome, Amagasaki, Hyogo 660-0813, Japan Tel: +81-6-6401-1221

#### **Distribution Centers**

Shionogi Distribution Center 5-1, Mishima 2-chome, Settsu, Osaka 566-0022, Japan Tel: +81-6-6381-7342

#### Shionogi Tokyo Distribution Center

1513, Funagata-Azaueharaichi, Noda, Chiba 270-0233, Japan Tel: +81-4-7127-3000

#### **Overseas Offices**

Shionogi & Co., Ltd. Taipei Office 4F, No. 2, Sec. 2, Nanking East Road, Taipei 10457, Taiwan Tel: +886-2-2551-6336

#### Shionogi & Co., Ltd. Shanghai Office

Far East International Plaza 3F, 306A No. 319 Xian Xia Road, Shanghai 200051, People's Republic of China Tel: +86-21-6235-1311

# Major Consolidated Subsidiaries

#### Shionogi Pharma Chemicals Co., Ltd.

224-20, Ebisuno Hiraishi, Kawauchi-cho Tokushima 771-0132, Japan Tel: +81-88-665-2312

#### Shionogi Analysis Center Co., Ltd. 1-3, Kuise Terajima 2-chome, Amagasaki, Hyogo 660-0813, Japan Tel: +81-6-6381-7271

Saishin Igaku Co., Ltd. Shionogi Doshomachi Bldg., 7-6, Doshomachi 4-chome, Chuo-ku, Osaka 541-0045, Japan Tel: +81-6-6222-2876

#### Shionogi Engineering Service Co., Ltd. 1-3, Kuise Terajima 2-chome, Amagasaki, Hyogo 660-0813, Japan Tel: +81-6-6401-1227

Aburahi AgroResearch Co., Ltd. 1405, Gotanda, Koka-cho, Koka, Shiga 520-3423, Japan Tel: +81-748-88-3215

#### Shionogi Techno Advance Research Co., Ltd. 3-1-1, Futaba-cho, Toyonaka, Osaka 561-0825, Japan Tel: +81-6-6331-8605

#### 🕖 Taiwan Shionogi & Co., Ltd.

4F, No. 2, Sec. 2, Nanking East Road, Taipei 10457, Taiwan Tel +886-2-2551-6336

#### 8 Shionogi Inc. 300 Campus Drive, Florham Park, NJ 07932, U.S.A.

Tel +1-973-966-6900





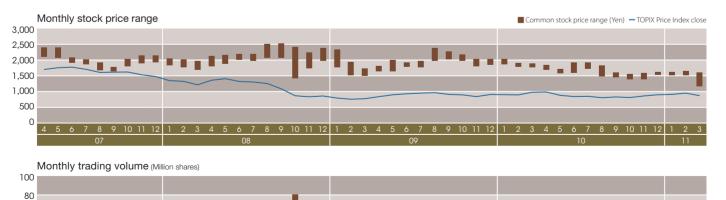
# Corporate Information (As of March 31, 2011)

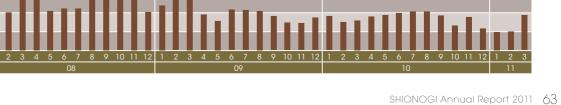
Company Name Established Incorporated Paid-in Capital Website Head Office	Shionogi & Co., Ltd. March 17, 1878 June 5, 1919 ¥21,279,742,717 http://www.shionogi.co.jp/ 1-8, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045, Japan Tel: +81-6-6202-2161 Fax: +81-6-6229-9596	Number of Employees Category of Business Type of Business Fiscal Year-End Net Sales	Consolidated: 5,277 Non-consolidated: 4,162 Marketing and manufacturing of drugs Manufacture and sale of pharmaceutical products, diagnostics, and other related products March 31 Consolidated: ¥282,350 million, Non-consolidated: ¥249,989 million (Year ended March 31, 2011)
Stock (Securities) Listings Common Stock	Osaka, Tokyo (#4507) Authorized: 1,000,000,000 shares Issued: 351,136,165 shares Number of shareholders: 34,532	Transfer Agent	The Sumitomo Trust & Banking Co., Ltd. Stock Transfer Agency Department, 5-33, Kitahama 4-chome, Chuo-ku, Osaka 541-0041, Japan

or reholders	Name	Number of shares (Thousands)	Percentage of total shares			
	Japan Trustee Services Bank, Ltd. (trust account)	19,028	5.68			
	Sumitomo Life Insurance Company	18,604	5.56			
	The Master Trust Bank of Japan, Ltd. (trust account)	15,465	4.62			
	Nippon Life Insurance Company	13,138	3.92			
	JP Morgan Chase Bank 385147	10,716	3.20			
	JP Morgan Chase Bank 380055	10,620	3.17			
	Japan Trustee Services Bank, Ltd. (Trust Account Re-entrusted by The Sumitomo Trust & Banking Co., Ltd., The Sumitomo Mitsui Banking Corporation Retirement Trust Account)	9,485	2.83			
	NIPPONKOA Insurance Co., Ltd.	7,551	2.25			
	State Street Bank and Trust Company	6,935	2.07			
	SSBT OD05 OMNIBUS ACCOUNT - TREATY CLIENTS	6,787	2.03			
	(Notes) 1. The Company holds 16.237.775 shares of treasury stock. However, this shareholding is not included in the list of top-10 shareholders.					

2. The percentage of total shares is calculated as a proportion of 334,898,390 shares, which is the total number of issued shares less treasury stock.

#### Stock Price Range and Trading Volume (Tokyo Stock Exchange)









http://www.shionogi.co.jp/



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