



## 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.

**Mission** 

**Value** 

Vision

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

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

### **Editorial Policy**

### **Period under Review**

Fiscal 2009 (April 1, 2009 - March 31, 2010)

Certain activities continuing into fiscal 2009 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).

The section entitled Shionogi's Environmental Activities 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 two domestic manufacturing subsidiaries (Bushu Pharmaceuticals Ltd. and Nichia Pharmaceutical Industries 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.

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.

## Eleven-Year Consolidated Financial Highlights

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

	2000	2001	2002	2003	2004	
			Millions of yen			
For the year ended March 31:						
Net sales	¥400,281	¥412,664	¥420,188	¥285,232	¥200,485	
Cost of sales	253,202	263,629	273,692	153,402	79,856	
Selling, general and administrative expenses	121,658	125,126	130,312	112,564	100,337	
Operating income	25,421	23,909	16,184	19,266	20,292	
Income before income taxes						
and minority interests	27,697	24,556	18,755	9,139	5,178	
Net income	12,868	12,614	8,456	5,904	2,204	
Research and development expenses	27,027	29,255	30,602	31,284	29,808	
Capital investments	9,355	8,331	8,810	9,012	4,404	
As of March 31:						
Property, plant and equipment, net	¥ 86,613	¥ 87,971	¥ 86,387	¥ 75,585	¥ 71,993	
Total assets	442,547	496,591	480,668	371,704	376,161	
Total long-term liabilities	50,812	67,592	58,971	49,145	49,005	
Total net assets	257,596	288,919	281,123	274,996	292,387	
Working capital	192,656	197,686	155,239	162,926	179,382	
			Yen			
Per share amounts:						
Net income	¥ 37.07	¥ 36.29	¥ 24.28	¥ 16.66	¥ 6.06	
Net assets	735.14	823.27	806.02	789.91	844.53	
Cash dividends applicable to the year	8.50	8.50	8.50	8.50	8.50	

<sup>\*</sup> US dollar figures have been calculated, for convenience only, at the rate of ¥93.04 = US\$1.00, the approximate rate of exchange on March 31, 2010.

### First medium-term business plan

Fiscal 2000

April First medium-term business plan starts

February the US subsidiary Shionogi USA, Inc. established

Fiscal 2001

October Agrochemical operations transferred

October Overseas joint venture Shionogi-GlaxoSmithKline Pharmaceuticals, LLC established

March Clinical testing operations transferred

Fiscal 2002

April Animal health operations transferred

August Anti-allergic product Claritin® 10mg Tablets launched

October Ohmori Co., Ltd. merged with Suzuken Co., Ltd.

Fiscal 2003

uly Controlled-release oral analgesic for cancer pain OxyContin® Tablets launched

October Industrial chemical operations transferred

Fiscal 2004

November Allergy medication Claritin® RediTabs® 10mg Tablets launched Fiscal 2005

April Second mediumterm business plan starts

Hyperlipidemia treatment Crestor® Tablets launched



September Carbapenem antibiotic Finibax® 0.25g IV solution launched

October Capsule operations sold **December New quinolone** 

New quinolone antibiotic Avelox® Tablet 400mg launched

January Multi-year research and worldwide comarketing agreement for novel analgesic drug compounds signed with Purdue Pharma L.P. Fiscal 2006

ne Rapid BNP test
Shionospot® BNP
and associated
measurement system
Shionospot® Reader
launched



June Carbapenem antibiotic Finibax® 0.25g IV solution kit launched

September Premature ovulation inhibitor Cetrotide® 0.25mg and 3mg for injection launched

February Cancer pain analgesic OxiNorm® Powder 0.5% launched

March License agreement concluded with BioCryst Pharmaceuticals, Inc. for anti-influenza drug Peramivir

scal 2007

Results of PRIME Program "Crestor® clinical experience investigation study of investigation study of Japanese patients" reported

May Shionogi's drug discovery competition started

January Shionogi Analysis Center Co., Ltd. Established

January Allergic diseases treatment Claritin® Dry Syrup 1% launched

<sup>\*</sup> 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. Figures for fiscal years through the year ended March 31, 2006 have been calculated in conformity with the new standard.

2005	2006	2007	2008	2009	2010	2010
		Millions	of yen			Thousands of US dollars
¥199,365	¥196,389	¥ 199,759	¥ 214,268	¥227,512	¥ 278,503	\$2,993,368
74,069	68,708	67,542	68,594	70,929	76,264	819,690
96,567	98,455	103,354	105,275	124,568	149,801	1,610,071
28,729	29,226	28,863	40,399	32,015	52,438	563,607
31,655	38,798	31,723	39,963	30,786	58,541	629,202
18,942	22,735	18,595	25,064	15,661	38,626	415,155
29,409	32,257	37,456	40,290	52,822	51,808	556,836
5,424	5,386	11,411	11,661	10,875	12,547	134,855
¥ 68,191	¥ 64,251	¥ 67,815	¥ 70,378	¥ 71,812	¥ 62,448	\$ 671,195
396,999	427,683	429,569	413,704	501,853	540,762	5,812,145
27,783	38,371	36,282	29,024	114,955	131,956	1,418,272
300,065	337,434	345,752	342,236	310,094	341,976	3,675,580
152,914	156,449	161,355	152,520	125,920	183,834	1,975,860
		Ye	n			US dollars
¥ 54.64	¥ 66.55	¥ 54.61	¥ 74.21	¥ 46.75	¥ 115.33	\$ 1.24
879.79	989.76	1,014.73	1,020.31	924.43	1,019.71	10.96
12.00	16.00	16.00	22.00	28.00	36.00	0.39

### Second medium-term business plan

## Fiscal 2008

April Cancer Pain Relief Consortium established

May Joint research facility with Hokkaido University, Shionogi Innovation Center for Drug Discovery,

established

July Hypertension treatment Irbetan® 50mg and 100mg Tablets launched

October Sciele Pharma, Inc. acquired

October Acne vulgaris treatment Differin® Gel 0.1% launched

November New facility for formulation and packaging of solid dosage forms completed at Settsu plant

December Idiopathic pulmonary fibrosis treatment Pirespa® 200mg Tablets launched

February Licensing agreement on

Peptide vaccines for cancer treatment concluded with OncoTherapy Science, Inc.

February Serum glycan analysis service joint venture Ezose Sciences, Inc. established in the US

## Fiscal 2009

October Agreement on international industry-academic collaboration initiative signed with United Kingdom

November Sciele Pharma, Inc. acquires the US specialty pharmaceutical company Addrenex Pharmaceuticals, Inc.

January Sciele Pharma, Inc. changes name to Shionogi Pharma, Inc.

January Anti-viral drug for influenza Rapiacta® 300mg Bag for Intravenous Drip Infusion and Rapiacta® 150mg Vial for Intravenous Drip Infusion launched



March Exclusive license agreement concluded with QuatRx
Pharmaceuticals Company to market post-menopausal
vulvovaginal atrophy treatment Ospemifene

March Bushu Pharmaceuticals Ltd. sold

### Third medium-term business plan

## Fiscal 2010

April Third medium-term business plan starts

April Antidepressant drug Cymbalta® Capsules 20mg and 30mg launched



July Shionogi Inc. established as the US group headquarters



**Motozo Shiono** Chairman and Representative Director

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

The Shionogi Group completed its second medium-term business plan (April 2005 to March 2010), which positioned the Company to make significant strides for the long term. During this period, we put in place a structure for ensuring that the Shionogi Group is able to achieve sustained growth, centered on pharmaceutical operations. Over the past five years, we focused on "building global R&D systems," "strengthening domestic marketing systems" and "establishing global marketing systems." Our achievements included better-than-targeted progress on the development of global pipeline products, the launch of new products, and the growth of our hyperlipidemia treatment, Crestor®, into a core Shionogi product; as well as the establishment of a strong the US marketing network.

In April 2010, we launched our third medium-term business plan covering the next five years. Under this new plan, we are implementing various measures aimed at achieving growth and progress over the medium and long term.

### **Business Performance**

In Japan's pharmaceutical industry, National Health Insurance (NHI) drug price system reforms were implemented in April 2010, resulting in an average downward revision of 6.5% in drug prices across the industry. A new system called "NHI Drug Price Premiums for Promoting the Creation of New Drugs and the Elimination of Off-label Drug Use" was also introduced on a trial basis. For new drugs that have no generic alternatives and meet certain conditions, these premiums will temporarily ease drug price reductions based on actual market prices until generic drugs are available. In this manner, the system is designed to accelerate the creation of innovative new drugs, while resolving off-label drug use and other issues. In response to the new drug price calculation method, it has become clear to us that new measures will be required of pharmaceutical companies, and that those companies that are unable to address these issues will be forced to withdraw from the market. Furthermore, the major Japanese pharmaceutical companies must address the so-called "2010 issue," which refers to a concentration of patent expirations for core products in 2010.

Overseas, newly emerging markets centered in China and India are experiencing substantial growth. Meanwhile, the Health Insurance Reform Bill was enacted in the US, the world's largest pharmaceutical market. While further expansion in the US market is projected, pharmaceutical companies are expected to face many different challenges, including an increase in rebates and tax obligations commensurate with their market share. In light of these significant shifts in the global pharmaceutical market, a diverse range of responses are now required of pharmaceutical companies.

## **Shionogi's Current Status and Initiatives Ahead**

Shionogi surpassed its target by launching 11 products in Japan during the five-year period of its second medium-term business plan. The key to maximizing "NHI Drug Price Premiums for Promoting the Creation of New Drugs and the Elimination of Off-label Drug Use," which were introduced on a trial basis as part of the latest round of drug price system reforms, is to focus on selling new drugs at appropriate prices that justify their product value, and expanding these sales. Seeing this new system as an opportunity, Shionogi will work to achieve growth by expanding new drug sales in the Japanese market.

Meanwhile, globalization is crucial to achieving future growth. Pharmaceutical companies must continuously launch a steady stream of products developed internally on a global basis in order to develop overseas business. Crestor® is one of our core products in the domestic market, and is expanding worldwide. However, Shionogi will face the expiration of patents for Crestor® in 2016-2017. In response, we aim to achieve long-term growth by maximizing royalty income from Crestor®, which is currently expanding globally, and to actively invest in R&D activities that will create future growth products for Shionogi.

Shionogi has designed its third medium-term business plan as a roadmap 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®.

In terms of concrete strategies, we will first build a strong earnings base by maximizing sales of new products centered on Crestor® in the domestic market, our main growth platform. At the same time, we will pursue the enhancement and development of our pipeline products on a global scale. Furthermore, through the concentration of R&D resources on priority diseases, we aim to develop pipeline products and rapidly bring them to market. We have also started working to explore new priority domains to achieve long-term growth. With regard to establishing global marketing systems, we will enhance our the US business through Shionogi Inc., which was established in July, in order to increase the consolidated overseas sales ratio. Meanwhile, we will bolster our development framework spanning the four regions of Japan, the US, Europe and Asia, and will begin considering entering additional Asian markets.

Shionogi is determined to make concerted efforts to advance to a new stage of real growth that is clear for all to see.

We look forward to the continued commitment and support of all our shareholders and other stakeholders.

**Motozo Shiono** 

Chairman and Representative Director

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



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

Q \_\_\_\_\_ 01

# First, could you give us an overview of the second medium-term business plan, which ended in fiscal 2009?

The second medium-term business plan was about Shionogi making significant strides for the long term. We set the three targets for the five-year plan of "building global R&D systems," "strengthening domestic marketing systems" and "establishing global marketing systems." In research and development, we exceeded our goal by progressing seven compounds as far as Phase II development or beyond. While reinforcing Shionogi's presence in infectious diseases, where the Company has been traditionally strong, we also bolstered our presence in the therapeutic domains of metabolic syndrome and pain. Most significantly, we were able to achieve sufficient growth to develop global pipeline products.

In Japan, we exceeded our development goal by launching 11 new products (compared with an initial target of 10). I think we can be proud of this industry-leading achievement, which is testament to the high quality and speed of Shionogi's R&D capabilities.

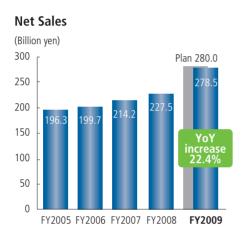
With regard to strengthening domestic marketing systems, we gradually shifted our marketing focus from acute to chronic diseases. We expanded sales of our hyperlipidemia treatment Crestor® to the point where it is now our top-selling product in Japan, while successfully expanding sales of the hypertension treatment Irbetan®. In overseas developments, we acquired Sciele Pharma, Inc. (now Shionogi Pharma, Inc.)

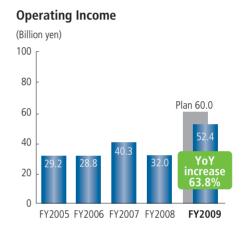
to achieve our long-awaited goal of building a strong the US marketing network. Our exports of antibacterials expanded steadily to Europe, the US and Asia, with sales in fiscal 2009 approximately four times that of fiscal 2004, the final year of the first medium-term business plan.

On the other hand, in terms of business performance, we did not achieve our numerical targets of net sales of ¥280.0 billion and operating income of ¥60.0 billion, despite posting higher sales and earnings in fiscal 2009. This was mainly

the result of a drop in seasonal prescription drug sales in Japan, as well as the fact that the full-year sales contribution from Shionogi Pharma, Inc. did not register any year-on-year growth due to the impact of the recession triggered by the bankruptcy of Lehman Brothers. In this manner, although we delivered major achievements during the second medium-term business plan, we recognize that there are still many issues outstanding.

## Results of the Second Medium-Term Business Plan (Consolidated)





Q \_\_\_\_ 02

### What issues remain outstanding from the second medium-term business plan?

First, we need to develop a management structure that is not reliant on royalty income. While it is true that we have actively increased R&D expenses in step with growth in royalty income, I believe that our top priority is to shift to a structure that is able to remain profitable without royalties. To this end, we must bolster our domestic marketing base while continuously creating a steady stream of globally competitive products developed internally. In research, our early-stage drug discovery programs to find greater numbers of promising new chemical entities (NCEs) are a bit weak. To boost our success rates with compounds in development, we must achieve greater accuracy in terms of clinical predictability. On the development side, we can proudly say that our domestic development team has grown into one of the strongest in Japan. We must now make our development capabilities as strong on a global scale as they are in Japan. In production technology, we renamed the former Sciele

Pharma, Inc. in the US to Shionogi Pharma, Inc. and began selling products under the Shionogi brand. We must now develop "Shionogi quality" on a global scale. Furthermore, in domestic sales, while our top priority is to develop systems for achieving sales growth centered on new products, the optimization of selling expenses is just as urgent. In regard to reducing costs, our administrative divisions seek to streamline the head office. I believe there is substantial scope to do this. Finally, I believe that the development of globally competitive human resources is crucial. I had wanted to start doing this much earlier. We stationed around 10 employees at Shionogi Pharma, Inc. from the second half of 2009, and intend to increase their number to several tens of employees going forward.

We intend to address all of the issues I have just outlined in the third medium-term business plan, which began in April 2010.

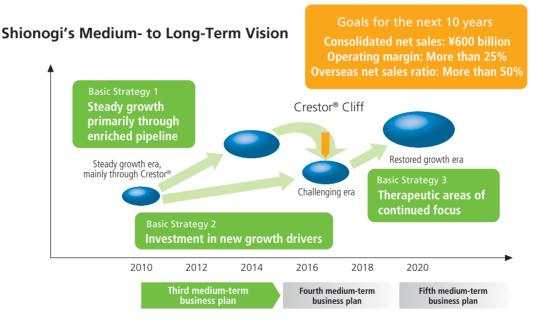
7



# What are the basic principles underlying the formulation of Shionogi's third medium-term business plan?

When formulating the plan, we first considered our vision for the Company ten years from now. We chose 13 relatively young, general-manager level employees from the Company's business divisions to think about and debate where Shionogi needed to be in the next 10 years, and report back their conclusions. Naturally, from a 10-year perspective, we realized that the most important issue we face is how to overcome the cliff represented by the expiration of Crestor® patents that is, the drop in royalty income resulting from these patent expirations in 2016-2017—and restore growth thereafter. In light of this, we formulated three basic strategies for preparing for this transition over the next five years: 1. Maximize sales of existing products; 2. Invest in new growth drivers to surmount the cliff represented by the expiration of Crestor® patents; and, 3. Discover the next generation of new molecular entities (NMEs), which must be enhanced when looking ahead ten years from now.

We also established "SONG for the Real Growth" as our slogan for the third medium-term business plan. "SONG" stands for **S**peed (Quick decision and implementation), **O**pen Mind (Flexible mind and out of box thinking), **N**ever-failing Passion (Persistent passion), and **G**lobal Perspective (Higher and broader perspective). These four phrases were chosen taking into consideration the type of corporate culture that we must develop in order for Shionogi to achieve substantial growth over the next five years. On reflection, we believe that the basic strategies of the first and second medium-term business plans were not defined clearly enough within the Company. Therefore we want everybody in Shionogi to feel a part of this third medium-term plan so that it underscores what we do on a daily basis, as we work to achieve its goals.



04

### Please explain the first basic strategy, "steady growth primarily through enriched pipeline."

Shionogi launched 11 new drugs during the second mediumterm business plan. Therefore, I believe the "NHI Drug Price Premiums for Promoting the Creation of New Drugs and the Elimination of Off-label Drug Use," which were introduced as part of drug price system reforms in April, provide a strong tail wind for Shionogi even though the system is still at a trial stage. We have positioned three products, namely Crestor®, Irbetan® and Cymbalta®, as our core strategic products, and we aim to increase total sales from these three products from ¥27.9 billion in fiscal 2009 to ¥100 billion in fiscal 2014. We have also defined five additional strategic products as Pirespa®, Differin®, Rapiacta®, Finibax® and OxyContin®/ OxiNorm®. We aim to increase combined sales from these 8 strategic products, as a percentage of total domestic sales, from approximately 30% in fiscal 2009 to at least 70% in fiscal 2014. We believe these targets are well within reach

in view of the characteristics, evaluation and market scale of each product. To achieve these goals, Medical Representative evaluations will be based primarily on these eight products. In this manner, we will vigorously implement the selectivity and concentration of resources.

We expect Crestor® sales to continue growing in Japan and overseas markets. Based on the catchphrase of "Challenge 1000," we are working together with AstraZeneca to reach our target of increasing Crestor® sales to ¥100 billion in Japan. On a standalone basis, Shionogi is targeting Crestor® sales of ¥50 billion, half the combined target, in fiscal 2014. Our conservative projection is that royalty income from Crestor® will reach ¥75 billion in fiscal 2014. Based on this outlook, we will formulate our internal strategies going forward.



Q \_\_\_\_ 05

Please explain the second basic strategy, "investment in new growth drivers." What specific goals will you pursue in this regard?

In order to surmount the cliff represented by the expiry of Crestor® patents, we must continuously develop and bring to market a steady stream of original products. The goal of our first strategy is to maximize sales from existing products. Our second strategy is focused on the creation of new internally developed drugs that can drive future growth. The plan objective is to progress at least five compounds as far as late-stage clinical development (defined as Phase III or Phase IIb clinical trials) on a global basis. We also aim to make submissions for overseas regulatory approval of four compounds that we originally discovered in Japan and launch at least one of these products within the plan period. High-level development portfolio management skills will be

essential to achieve these goals. To conduct effective drug development activities with a limited R&D budget, we will reevaluate the development potential of each compound every 6 months, and review investment allocation by prioritizing compounds. We will constantly consider back-up strategies, instead of considering the next step only after terminating development activities, while pursuing a proactive in-licensing strategy. In terms of our in-licensing strategy, we unified the business development functions of our the US subsidiaries and head office in Japan in April 2010 to create a dynamic global business development function. Looking ahead, we will establish a Global Development Office to create a global strategic decision-making function.



Could you please provide a clear explanation of the third basic strategy, "therapeutic areas of continued focus?"

In order to continue achieving long-term growth, we must accurately identify trends in new therapeutic areas, and discover the seeds of new drugs that satisfy unmet medical



Research facility dedicated to drug discovery (Rendering)

needs. Shionogi's three priority therapeutic areas at present are metabolic syndrome, infectious diseases and pain. However, we should also note that trends change over time in terms of the types of drugs targeted in R&D and the diseases that require new pharmaceutical therapies. In the third medium-term business plan, Shionogi aims to develop pipeline products and rapidly bring them to market by focusing R&D resources on obesity/diabetes and viral infections. Furthermore, to identify new future trends, we will further advance various joint research programs with various academic institutions, in order to flexibly address medical needs and take on the challenge of budding research in new therapeutic areas.

Q \_\_\_\_ 07

### Please tell us about Shionogi's efforts to establish global marketing systems going forward.

We are strengthening our the US marketing network by realigning the business model of Shionogi Pharma, Inc. so that it is focused on developing and marketing Shionogibranded pharmaceuticals in the US In addition, through the establishment of Shionogi Inc. on July 1, 2010, we are working to integrate our the US subsidiaries and centralize local business functions. Furthermore, our aim is to globalize our drug development capabilities by creating a network of development bases across Europe, the US and Asia going forward. In particular, we intend to build up Shionogi's

development and sales operations in Asia, where the market is growing, during the period covered by the third medium-term business plan.

In regard to our numerical targets, we aim to increase overseas sales from ¥49.1 billion in fiscal 2009 to ¥87 billion in fiscal 2014. This increase will be supported mainly by expanded sales at Shionogi Pharma, Inc., the launch of an anti-HIV drug currently under development, an increase in drug exports, and other factors.

08

### What are the third medium-term business plan's numerical targets?

In the final year of the plan, fiscal 2014, we are targeting net sales of ¥375 billion and operating income of ¥110 billion. As I mentioned earlier, these targets assume purely organic growth and do not reflect any projected increases from strategic business development initiatives. We basically plan to control R&D expenses between 17% and 18% of net sales, with an R&D budget of ¥65 billion. Naturally, we will continue to actively make investments as deemed necessary for strategic reasons. In principle, however, we will prioritize R&D projects within the scope of our R&D

budget. Cost controls will be rigorously enforced. Over the course of the plan, we are targeting a reduction in the ratio of selling, general and administrative (SG&A) expenses to net sales of approximately 8 percentage points compared with fiscal 2009. We see the cost of sales remaining mostly unchanged as a percentage of sales.

Based on lessons learned from the first and second medium-term business plans, we are focused on achieving our targets one year at a time to ensure that we attain the five-year targets.

09

# What measures are being taken in fiscal 2010, the first year of the third medium-term business plan?

In regard to domestic sales, as I mentioned earlier, we are working to expand sales by focusing on our eight strategic products. In Japan, we saw an average industry-wide drug price reduction of 6.5% in the April 2010 NHI drug price revision. The impact across our domestic product range was slightly more than 6%. We plan to absorb the negative impact on revenue with growth in sales of these strategic products. On the development front, in July we reported extremely favorable results in Phase IIb trials of our anti-HIV drug, and plan to commence Phase III trials by the end of the year. In regard to obesity treatments, we expect to obtain the results of clinical trials that are now under way within the current fiscal year. Other drug candidates are also progressing steadily on the whole.

Furthermore, we are rigorously enforcing cost controls. The Corporate Planning Department, Financial & Accounting Department and Human Resources Department are engaged in a project that will rigorously control costs through joint monitoring of the operations and costs of each division.



10

# Compliance has recently become more and more important to the continued existence of corporations. What is Shionogi's approach to compliance?

In order for Shionogi to develop its operations into a global enterprise, we recognize that corporate integrity will be strongly demanded of us, in addition to growth in sales and profits. I take advantage of every opportunity that I can to remind our employees that now that Shionogi is returning to a growth path, their actions must be based on a constant awareness of the enforcement of compliance. I see compliance as not merely the observance of laws and

regulations, but also covering ethical conduct befitting a corporation and a member of society. In other words, through the enforcement of compliance, I want everyone that works for the Shionogi Group to become a first-rate businessperson and member of society. I personally chair the Compliance Committee. In this role, I am actively promoting activities designed to promote compliance.

Q \_\_\_\_ 11

### Finally, what is your thinking on shareholder returns?

Shionogi is working to strengthen operational fundamentals and return profits to shareholders by simultaneously implementing three priorities in a well-balanced manner: investment for the future, shareholder returns, and strategic balance sheet improvement. Through this process, we believe that we can continuously drive growth at Shionogi and meet the expectations of our shareholders. Specifically, we will actively make business investments through R&D spending and capital investments and enhance our corporate value, to achieve growth over the medium and long terms. In regard to dividends, we aim to pay dividends that deliver the tangible benefits of growth to shareholders with a view to maintaining a dividend payout ratio of 35%. In addition, we see the third medium-term business plan as a period for strengthening our balance sheet. In this regard, we will actively pursue the repayment of debt.

We must stay true to Shionogi's basic corporate policies on a global basis to achieve future growth. My message to employees has been that the third medium-term business plan contains a practical course of action for globalizing our business over the next five years. This period is set to be a productive period when the Company and all of its employees will experience significant growth. I hope that all of our shareholders will continue to lend us their support and share in the benefits of that growth.

Strengthen operational fundamentals and shareholder returns in a well-balanced manner by simultaneously implementing three priorities

### Investment for the future

- R&D expenses: ¥305 billion
- Capital investments: ¥75 billion

### Shareholder returns

- Maintain dividend payout ratio of 35%
   Projected total dividend amount: ¥94 billion
- Dividends that deliver the tangible benefits of growth to shareholders
   Projected dividend per share: ¥36 to ¥78

### Strategic balance sheet improvements

- Debt repayment/bond redemption: ¥111 billion Term-end balance: ¥121 billion to ¥10 billion
- Strategic business development funds: ¥150 billion
   Term-end balance: ¥100 billion to ¥250 billion

\*Figures represent either five-year totals or targets for fiscal 2014.

# 3rd Medium-Term Business Plan

In April 2010, under the slogan, "SONG for the Real Growth," Shionogi redoubled its resolve and launched the 3rd Medium-Term Business Plan covering the next five years.

Based on the achievements and outstanding issues of the 2nd Medium-Term Business Plan, Shionogi will work to realize its Company Policy from a global perspective, as follows:

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

Shionogi has begun measures to advance toward the new stage where we can all feel the Real Growth.

## 2nd Medium-Term Business Plan

(From April 2005 to March 2010)

## **Making Significant Strides** for the Long Term

1st Medium-Term Business Plan

(From April 2000 to March 2005)

Laying the Foundation

beyond

2005



## 2nd Medium-Term Business Plan **Achievements** Advanced 7 compounds to Phase II and beyond Advance 5 compounds to Phase II and In addition to infectious disease, strengthened metabolic syndrome and pain • Build-up of priority therapeutic areas Achieved solid results for anti-HIV drug through co-development with GSK

- - Maximize the value of Crestor®

Proactively form alliances

Continuously launch new products (Launch 10 products in Japan)

Targets



- Crestor® has grown into the core product with net sales of ¥24.2 billion
- Launched 11 products in Japan

Steady overseas business development



- · Established marketing network in the US through acquisition of Sciele Pharma, Inc.
- Expanded export of antibiotics to Europe, the US and Asia

12

## **3rd Medium-Term Business Plan**

(From April 2010 to March 2015)

# **SONG** for the Real Growth

Speed:

Never-Failing Passion:

**Quick decision and implementation** 

mentation Persistent passion

Open Mind:

Flexible mind and out of box thinking

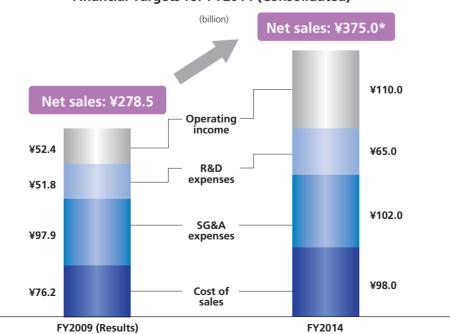
Global Perspective:

Higher and broader perspective

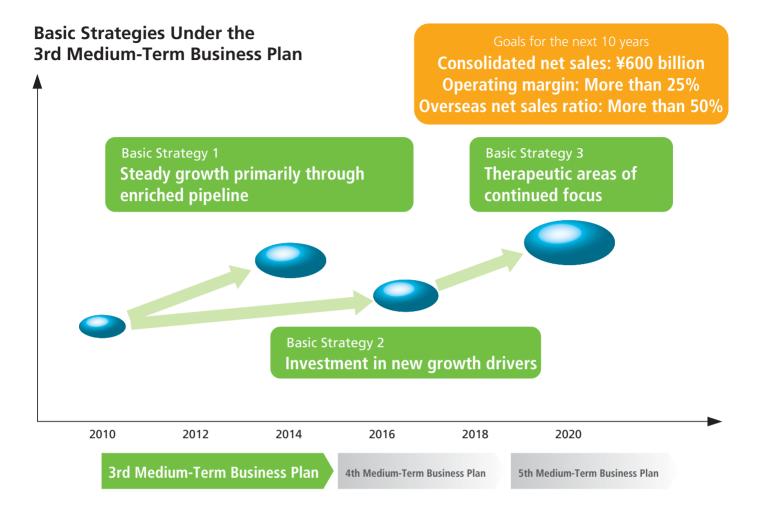
2015

2010

### Financial Targets for FY2014 (Consolidated)



\*Excluding additional sales through strategic business development deals



# Basic Strategy 1: Steady growth primarily through enriched pipeline

# Realize Positive Revenue Spiral Through "New Drugs"

- Realize steady growth by expanding sales of 8 new products: Crestor®, Irbetan®, Cymbalta®, Pirespa®, Differin®, Rapiacta®, Finibax®, and OxyContin®/OxiNorm®
- Domestic net sales target: ¥200 billion
- Generate more than 70% of net sales from 8 new products

### **Maximize the Value of Globally Proven Products**

- Position Crestor®, Irbetan®, and Cymbalta® as the core strategic products among 8 new products
- Net sales target: Total of ¥100 billion from 3 products

### Global Growth of Crestor®

- Embracing the challenge of becoming No.1 in the domestic market
   FY2011 Establish top share in statin market
  - FY2014 Net sales target: ¥50 billion
- Increase in royalty income
   FY2014 forecast: More than ¥75 billion

## Overseas Sales Expansion

- Net sales target for marketed products and products in development: ¥87 billion
- Expand consolidated overseas net sales ratio, excluding royalties, to approximately 30%

### Basic Strategy 2: Investment in new growth drivers

# Rigorous Management of Development Portfolio Contingency Plan

- Globally develop more than 5 products in the late stage (Phase IIb and beyond)
- Achieve NDA submission overseas for 4 products (originating from Shionogi or Japanese research institutes), and launch of at least one product

### **Basic Strategy 3: Therapeutic areas of continued focus**

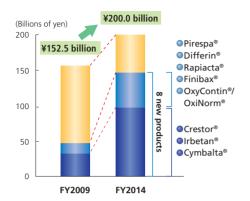
# Respond to "Multi-Layered Wave Structure" of Diseases

- Sustainability: Maintain strengths in target areas
   Concentrate sales capabilities on the 3 priority therapeutic areas, namely metabolic syndrome, infectious diseases and pain, and contribute to medical care by maximizing product potential.
- Flexibility: Adapt to change in each target area By focusing R&D capabilities on priority obesity/diabetes and viral infection fields, we aim to enrich pipelines and launch them as soon as possible.
- Foresight: Prepare for the waves of next generation

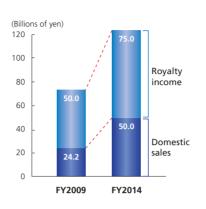
Accurately forecast the waves of next generation and make future investments to discover drug seeds.

## **Segment Sales Forecast**

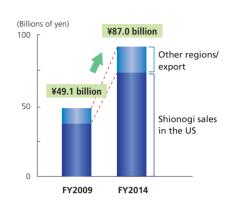
### **Domestic Sales Forecast**



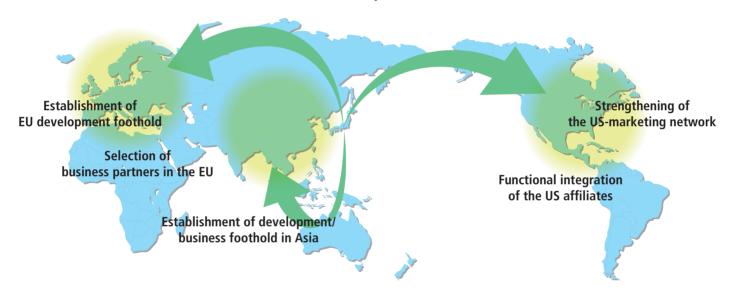
### Global Growth of Crestor®



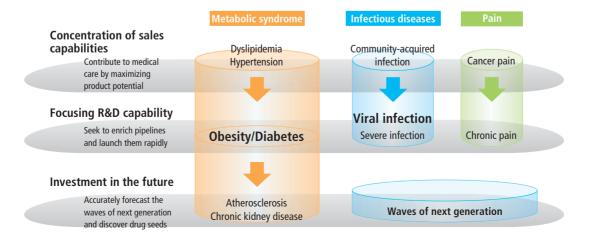
### **Overseas Sales Forecast**



## **Global Expansion**



## **Therapeutic Areas of Continued Focus**





## Pharmaceutical Research

our core goal is to realize global growth. At this juncture, I believe human health and rigorously pursue the search for the best sustained increases in quality and productivity at the divisional

Executive General Manager, Pharmaceutical Research Division Kohii Hanasaki, Ph.D.

### Review of the second medium-term business plan achievements

The Pharmaceutical Research Division focused on achieving three goals: augmenting our array of drugs for treating infectious diseases, and positioning pain and metabolic syndrome as new strategic drug discovery domains; generating at least five new drug candidates to enter at least Phase II clinical trials by fiscal 2009; and proactively leveraging outside resources to increase the efficiency and success rate of research programs. Our in-house drug discovery efforts resulted in a steady stream of new molecular entities (NMEs) in all three strategic domains. Over the five-year plan period, a total of seven NMEs entered Phase II clinical studies and ten compounds reached the FTIH (First Time in Human) stage. During the final year of fiscal 2009, we reached FTIH with two drug candidates (S-707106 for diabetes and S-234462 for obesity) and also discovered two new molecular entities, including one potential pain medicine. The high level of research productivity we have achieved in a short period of time is due to various factors. These include focusing on strategic therapeutic areas linked to unmet medical needs; achieving highspeed, high-quality revolution of the cycle of synthesis, pharmacological evaluation and ADMET\*1, based on the establishment of SAR\*2 processes for small molecule drug discovery; and our proactive use of joint global research programs and external resources.

## Targeting the goals of the third medium-term business plan

Based on the drug discovery capabilities we have cultivated to date and our strengths in therapeutic areas, the Pharmaceutical Research Division will focus on rebuilding Shionogi's strategic research franchise. Over the course of the new plan, we aim to achieve world-class drug discovery research quality and productivity by focusing our resources in three areas: upgrading the early drug discovery portfolio; improving

the level of clinical predictability; and combining functional concentration with enhanced flexibility. We have set two numerical performance targets: first, to generate at least four new development candidates per year; and, second, to demonstrate PoC\*3 for molecular entities with a success rate of at least 50%.

In terms of rebuilding the strategic research franchise, we will continue to invest our resources primarily in our three core domains, based on an assessment of changes in disease-related needs and our in-house drug discovery platform. In particular, we will focus on expanding the development pipeline for obesity/diabetes and viral infection. At the same time, we will take up the challenge of furthering our nascent research in new therapeutic areas so that we can adapt flexibly to shifts in medical needs over the medium to long term.

To upgrade Shionogi's early drug discovery portfolio, we have been highly proactive in targeting joint research programs with outside institutions. Our aim is to seek out the seeds of innovative drug discovery that are essential to our continued growth. Our network of in-house and joint research projects is expanding around the hub of the Shionogi Innovation Center for Drug Discovery, which we established on the campus of Hokkaido University. The Shionogi's drug discovery competition program that we began to unearth seeds of research innovation matched to our requirements has led to the germination of five full-scale joint research programs. The FLASH\*4 initiative with the Osaka University Graduate School of Medicine that we began in fiscal 2009 to find further drug discovery seeds has also spawned 9 joint research projects. This collaboration between industry and academia promises to generate a steady stream of new research possibilities. Going forward, we plan to seek out new international research partners by expanding the Shionogi's drug discovery competition initiative. The aim is to pursue various avenues to find seeds of innovative drug discovery while maintaining balance with in-house research.



To improve clinical predictability, we aim to boost the probability of R&D success by accelerating our translational research programs. In May 2010, we established the PET Molecular Imaging Center at the Osaka University Graduate School of Medicine as a joint institution focusing on molecular imaging technology. We believe that this approach will help yield breakthroughs in this field. Combined with our joint research programs with Osaka University, this facility promises to dramatically improve our capabilities in translational research and help Shionogi to achieve world-class PoC demonstration success rates.

Finally, to combine functional concentration with enhanced flexibility, we have begun building a new research complex to bring together the capabilities of various disparate research facilities under one roof. The new building is due to become operational in fiscal 2011, by which time we plan to have established an integrated research set-up spanning molecular screening to CMC\*<sup>5</sup> research. Enhanced research efficiency and greater coordination among researchers will help to foster industry-leading research productivity at Shionogi. Ahead of this, at the beginning of fiscal 2010 we clarified missions and delineated the organizational set-up between the three research functions of diseases, drug discovery and development. Including the emerging synergy benefits from the Global Research Leader Training program, we are in the process of creating a robust yet flexible drug discovery research set-up with global potential.

- \*1 ADMET: Absorption, Distribution, Metabolism, Excretion and Toxicity
- \*2 SAR: Structure-Activity Relationship
- \*3 PoC: Proof of Concept
- \*4 FLASH: Pharma-Link between Academia and SHionogi
- \*5 CMC: Chemistry, Manufacturing and Controls

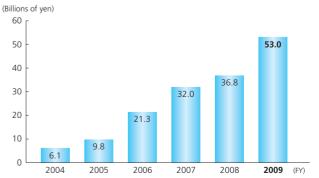
## **Intellectual Property**

Shionogi recognizes that coordinated R&D and intellectual property (IP) strategies are the foundation of corporate growth and earnings in the pharmaceutical sector. IP activities are conducted on a global basis.

Substance patent acquisition efforts continued as efficiently as possible for the broad range of new compounds originated in-house. The future patentability of drug discovery targets and basic research technologies was also given appropriate consideration. A total of approximately 110 patent filings were completed in fiscal 2009 (of which about 60% were for foreign patents).

Shionogi reviews its patent portfolio periodically and manages it from a cost-conscious perspective. As of the end of March 2010, Shionogi owned approximately 230 patents in Japan and 140 families of patents in overseas jurisdictions (registered patents based on original invention filings).

### Patent and licensing revenues





## **Pharmaceutical Development**

medium-term business plan, as a year that holds the key to the

We achieved the domestic development goals contained in the number of drug candidates in late-stage global clinical to set up the Global Development Office (GDO) in due course to

Executive General Manager, Pharmaceutical Development Division Takuko Sawada

### Review of the second medium-term business plan achievements

Notable achievements in fiscal 2009 included securing world-first manufacturing and marketing approval for Peramivir, a neuraminidase inhibitor that we in-licensed from the US-based BioCryst Pharmaceuticals, Inc. as a treatment for influenza virus infections. We launched this drug in January 2010 under the brand name Rapiacta®. We also gained domestic manufacturing and marketing approval for Duloxetine, a serotonin and noradrenaline reuptake inhibitor (SNRI) in-licensed from the US-based Eli Lilly and Company that we have developed for the treatment of depression and depressive symptoms. This product was launched in Japan in April 2010 under the brand name Cymbalta®. Amid heightened social concerns about the possible threat of pandemic due to new strains of the influenza virus, Rapiacta® has helped to underline our contribution to society as one of the world's leading makers of drugs to treat infectious diseases. Meanwhile, Cymbalta® is expected to become one of the core strategic products supporting Shionogi's future growth alongside Crestor® and Irbetan®.

Having demonstrated excellent efficacy and tolerability in Phase IIa studies in the US and Europe, our global strategic product S-349572 (integrase inhibitor for treatment of HIV) is currently in Phase IIb trials. This compound is our top-priority clinical development project, and we expect Phase III trials to commence during 2010. S-2367, a neuropeptide Y Y5 (NPY5) receptor antagonist for the treatment of obesity, demonstrated compliance with the US FDA standards for weight management drugs in Phase IIb trials conducted in the US. Based on these results, it is currently undergoing further clinical trials in the US to determine whether coadministration with Orlistat produces additional weight-reduction benefits to meet market needs. A parallel clinical development program is underway in Japan, where S-2367 is in Phase II trials for the treatment of obesity associated with other conditions such as diabetes, dyslipidemia or hypertension.

During the five-year period of the second medium-term business plan, we were able to demonstrate clinical efficacy for three global development compounds that were discovered in-house (the two drugs mentioned above, plus the thrombocytopenia treatment S-888711). We also gained regulatory approval in Japan for no less than 12 products, as listed below.

These achievements are the tangible result of efficiency-boosting initiatives such as human resource development programs, the creation of target management systems using time-based PDCA cycles, and an Asian multi-national clinical study that included South Korea and Taiwan.

Going forward, we plan to build on these achievements to date. The key issue for us is to strengthen Shionogi's global development capabilities by expanding and upgrading our worldwide network of clinical development operating bases.

Main products gaining Japanese regulatory approval

iviant products gaining supartese regulatory approval				
Product name	t name Indication/drug type			
Crestor®	Hyperlipidemia			
Finibax®	Bacterial infection			
Cetrotide®	Premature ovulation inhibitor			
OxiNorm®	Cancer pain			
Irbetan®	Hypertension			
Differin®	Acne vulgaris			
Pirespa®	Idiopathic interstitial pulmonary fibrosis			
Rapiacta <sup>®</sup>	Influenza antiviral agent			
Cymbalta <sup>®</sup>	Depression and depressive symptoms			

### Targeting the goals of the third medium-term business plan

(Improved strategic decision-making capabilities and development of tri-regional base network)

Under the third medium-term business plan, we aim to build a late-



stage (Phase IIb onwards) global development pipeline of at least five products. Our goal is to file regulatory applications in overseas markets for four drugs discovered in Japan and gain approval for at least one compound during the plan period. This will demand highlevel pipeline management skills. We plan to evaluate the potential of the entire development portfolio every six months and re-allocate resources accordingly so that we can accelerate investment of development resources in high-priority projects.

To upgrade our global development set-up, we plan to integrate the development functions of Shionogi's US subsidiaries while also consolidating within the GDO the development strategy functions that to date have been divided between Japan and the US. Separating strategic and operational management functions in this way will help to clarify lines of responsibility. Integrating development strategy functions will promote faster and more flexible decision-making, which in turn will help speed up global clinical development.

In addition, to make global development faster and more efficient, we plan to choose the regions where we conduct clinical trials based on the specific development phase. For early-stage clinical studies, we plan to develop a tri-regional global system where we conduct such studies in Japan, the US and Europe. During the period of the second medium-term management plan, we were able to achieve a high success rate with advanced PoM/PoC\* studies using our development capabilities in Japan. By tapping into these capabilities, we aim to make go/no go development decisions on compounds at an early stage. In late-stage clinical development, we aim to be able to conduct trials in Japan, the US, Europe and Asia to enable development of pharmaceuticals with high speed and efficiency at relatively low cost.

\*PoM: Proof of Mechanism; PoC: Proof of Concept

## Pipeline overview

# ◆S-349572 (integrase inhibitors for treatment of HIV)

This compound is being developed by joint venture Shionogi-ViiV Healthcare LLC., and combines potent antiviral activity with excellent resistance and pharmacokinetic profiles and a low probability of causing drug-drug interactions. S-349572 was shown in Phase Ila trials to suppress HIV plasma virus levels in treatment-naive HIV subjects and was well tolerated. This effect was reproduced in Phase Ilb trials. In concurrent trials, antiviral suppression was also observed in treatment-experienced patients resistant to the leading integrase inhibitor Raltegravir, along with an excellent resistance profile. S-349572 is expected to move into Phase III trials during 2010.

# ◆S-2367/S-234462 (Neuropeptide Y Y5 receptor antagonists for treatment of obesity)

In Phase IIb trials in the US, S-2367 demonstrated weight-reduction efficacy along with a serum lipid improving effect. No weight rebound or any significant safety issues, including neurological or psychological symptoms, were observed among patients in the 12-month administration study. S-2367 is now undergoing further trials in combination with Orlistat to gauge additional weight-reduction benefits. In Japan, the drug is in Phase II trials for obesity associated with other conditions such as dyslipidemia and diabetes or dyslipidemia and hypertension. The follow-up compound S-234462, which shows strong efficacy at lower doses than S-2367, is currently in Phase I trials in the US.

## **Pipeline**

### **Pipeline overview**

# ◆S-888711 (non-peptide TPO mimetic for treatment of thrombocytopenia)

S-888711 elicited rapid increases in platelet count on once-daily administration in Phase I studies and was well tolerated. It is currently in Phase II dosing studies in the US and Europe for immune thrombocytopenic purpura (ITP). Future plans call for its development for other disorders associated with thrombocytopenia.

# ◆S-444823 (cannabinoid receptor agonist for atopic dermatitis)

This drug is a topical application that is expected to relieve inflammation and itching without any of the side effects of topical steroids. In Phase I studies it demonstrated good tolerability and safety along with high rates of skin absorption. Phase IIa studies are currently underway in Japan.

# ◆S-297995 (peripheral opioid receptor antagonist for alleviating opioid-induced adverse effects)

There are currently no effective medications for treating gastrointestinal side effects of opioids such as constipation, nausea and vomiting.

Co-administration of this compound with an opioid promises to relieve the latter's side effects without altering any of an analgesic effects. Phase IIa studies are currently underway in the US.

# ◆S-288310 (peptide cancer vaccine for bladder cancer)

This vaccine is a peptide derived from genes that are selectively expressed by cells in proliferating bladder cancer. Efficacy was demonstrated in translational research in Japan on patients with bladder cancer. The peptide works by binding to specific HLA on white blood cells, thus stimulating an immune response. Patients with the right type of HLA could benefit from this therapy. Phase I/II studies in Japan are currently underway, targeting patients with bladder cancer.

# ◆S-707106 (agent for improving insulin resistance to treat Type 2 diabetes)

Animal studies have demonstrated improvements in terms of reductions in blood sugar levels, insulin resistance and abnormal lipid metabolism, combined with a lower incidence of side effects observed with existing therapies such as weight gain, edema, abnormal bone metabolism and lactic acidosis. Phase I studies are currently underway in the US, and the compound is expected to enter Phase IIa studies during 2010.

Areas	Code No. or generic name [Product name]	Category (Administration)		
	Pravastatin/Fenofibrate (Pravastatin/fenofibrate combination)	Statin-HMG-CoA reductase inhibitors/ fenofibrate lipid regulating agent combination (Oral)		
	Jenloga XR (Clonidine hydrochloride)	Alpha 2 specific adrenergic agonist (Oral)		
Meta	S-474474 (Irbesartan/trichlormethiazide combination)	Angiotensin receptor blocker diuretic combination (Oral)		
Metabolic Syndrome	S-2367 (Velneperit)	Neuropeptide Y Y5 receptor antagonist (Oral)		
from	ADX415	Alpha 2 specific adrenergic agonist (Oral)		
Ü	S-234462	Neuropeptide Y Y5 receptor antagonist (Oral)		
	S-707106	Insulin sensitizer (Oral)		
Infe	Peramivir 【Rapiacta®】	Neuraminidase inhibitor (Injection)		
ctious	Doripenem hydrate [Finibax®]	Carbapenem antibiotic (Injection)		
Infectious Diseases	Doripenem hydrate [Finibax®]	Carbapenem antibiotic (Injection)		
ases	S-349572/S-265744/S-247303	Integrase inhibitor (Oral)		
	Duloxetine hydrochloride 【Cymbalta®】	SNRI (Serotonin & noradrenaline reuptake inhibitor) (Oral)		
Pain	S-811717 (Oxycodone hydrochloride)	Natural opium alkaloids (Injection)		
<del>s</del> ï	S-297995	Peripheral opioid receptor antagonist (Oral)		
Wor	PSD502 (Lidocaine/prilocaine)	Eutectic mixture of anesthetics (Metered-dose topical aerosol spray)		
Women's Health	Ospemifene	Selective estrogen receptor modulator		
Pediatrics	Glycopyrrolate 【Cuvposa™】	Anticholinergic (Oral)		
atrics	Clonidine HCL	Alpha 2 specific adrenergic agonist (Oral)		
	S-888711	Small molecule TPO mimetic (Oral)		
	S-288310	Peptide cancer vaccine (Injection)		
Other	S-555739	Prostaglandin D2 receptor antagonist (Oral)		
	S-444823	Cannabinoid receptor agonist (Topical)		
	S-222611	Her2/EGFR dual inhibitor (Oral)		
	S-488410	Peptide cancer vaccine (Injection)		

### **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))

Indication	Stage  PhaseII PhaseIIb PhaseIII Submission Approved	Origin	Development
Lowering non-HDL cholesterol and triglycerides	USA: NDA filed (November 2009)	Galephar, PR Inc. (Puerto Rico)/ SMB Laboratories (Belgium)	Shionogi/ SMB Laboratories
Hypertension	USA: Phase Ⅲ	In-house	In-house
Hypertension	Japan: Phase III	Irbesartan: Sanofi Aventis (France) Trichlormethiazide: Shionogi	In-house
Obesity	USA: Phase II  Japan: Phase II	- In-house	In-house
Hypertension	USA: Phase II (in preparation)	In-house	In-house
Obesity	USA: Phase I	In-house	In-house
Type 2 Diabetes	USA: Phase I	In-house	In-house
Pediatric influenza infection	Japan: NDA submission (February 2010)	BioCryst Pharmaceuticals, Inc. (USA)	In-house
Addition of new dosage regimen (1g t.i.d. for serious infection)	Japan: NDA submission (March 2010)	In-house	In-house
Pediatric infection	Japan: Phase III	In-house	In-house
HIV infection	USA, Europe: Phase Ib (the most advanced phase)	Shionogi & GlaxoSmithKline	Shionogi-ViiV Healthcare LLC
Diabetic peripheral neuropathic pain	Japan: NDA submission (September 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 (in preparation)	Napp Pharmaceuticals Limited (UK)	In-house
Alleviation of opioid-induced adverse effect	USA: Phase IIa  Japan: Phase I	- In-house	In-house
Premature ejaculation	USA, Europe: Phase III	Plethora Solutions Holdings PLC (UK)	Shionogi/Plethora Solutions Holdings PL
Post-menopausal vaginal atrophy	USA: Phase III	QuatRx Pharmaceuticals Company (USA)	Shionogi/QuatRx Pharmaceuticals Compar
Chronic severe drooling in pediatric patients	USA: Approved (July 2010)	In-house	In-house
Attention Deficit Hyperactivity Disorder	USA: SNDA filed (October 2009)	In-house	In-house
Thrombocytopenia	USA, Europe: Phase II  Japan: Phase I	In-house	In-house
Bladder cancer	Japan: Phase I/II	OncoTherapy Science, Inc. (Japan)	In-house
Allergic rhinitis	Japan: Phase IIa	In-house	In-house
Allergic militis	Europe: POM (Proof of Mechanism)	III-House	In-house
Atopic dermatitis	Japan: Phase IIa	In-house	In-house
Malignant tumor	Europe: Phase Ib	In-house	In-house
	Japan: Phase I/II (in preparation)	OncoTherapy Science, Inc.	In-house

USA: NDA submission (June 2007) Hospital-acquired (nosocomial) pneumonia including ventilator-associated pneumonia

Europe: Approved (July 2008)

USA, Europe: Phase **Ⅲ** 

Japan : Phase  ${\mathbb I}$ 

Bacterial infection

Acute coronary syndromes Mixed dyslipidemia

Spinocerebellar ataxia

In-house

In-house

Shionogi/ Eli Lilly and Company (USA) Johnson & Johnson (USA)

Anthera Pharmaceuticals Inc. (USA)

Kissei Pharmaceutical Co., Ltd.



## **Manufacturing & Technology**

Technology Division steadily advanced production and CMC plan to redouble our focus on safety and quality in daily

Executive General Manager, Manufacturing & Technology Division Takuo Fukuda

### Review of the second medium-term business plan achievements

The Manufacturing & Technology Division completed major reforms in the second medium-term business plan. First, the CMC\*1 QA Unit was established to reinforce the quality assurance framework so that it can address global regulations. Another fairly notable achievement was the worldwide supplying of an in-house-developed antibiotic, Finibax®, from the Kanegasaki Plant through a licensee. The division also played a significant role in the development and production of other major new products such as OxiNorm®, Irbetan®, Pirespa®, Rapiacta® and Cymbalta®.

A new facility for formulation and packaging of solid dosage forms was built at the Settsu Plant to facilitate the manufacture and packaging within a single building of products ranging from drugs for clinical trials to commercial products. The facility supported the launch of Cymbalta® and is set to play a role going forward in supplying domestic and overseas markets with other new products. At the Kuise Site, we built a new facility for APIs\*2 used in producing drugs for clinical trials to strengthen our systems for ensuring smooth and rapid development of a growing number of pipeline candidates



## Targeting the goals of the third medium-term business plan

Shionogi has constantly striven to ensure reliable supplies of products with high Shionogi quality. Under the third medium-term business plan, we aim to improve quality standards while continuing to supply Shionogi products overseas. By matching and exceeding global standards in production technology to boost product competitiveness and enhance production efficiency, we will ensure reliable, cost-competitive supplies of all Shionogi pharmaceuticals, especially the core strategic lines such as Irbetan® and Cymbalta®.

Our CMC research activities will continue to contribute to speeding up of drug development and play a key role in product life cycle management. We also intend to focus efforts on establishing core technical expertise (formulation development as well as production engineering) in peptides and other biopharmaceuticals to contribute to drug development and production in this field going

We are putting in place new infrastructure to support these activities. For example, we began construction on a new formulation facility for beta-lactam injectable products at the Kanegasaki Plant. We are also planning to build a D&M\*3 facility for manufacturing APIs in late stage trials. The facility will also be used for commercial APIs in initial production.

In these various ways, the Manufacturing & Technology Division will conduct daily operations with untiring enthusiasm in order to help achieve the goals of the third medium-term business plan.

- \*1 CMC: Chemistry, Manufacturing and Controls
- \*2 API: Active Pharmaceutical Ingredient
- \*3 D&M: Development & Manufacturing



# Quality, Safety and Regulatory Affairs Management

We have entered the critical first year of Shionogi's third medium-term business plan. As part of its concerted efforts to achieve the plan, the division is targeting three main goals: First, we will build and implement a global quality assurance system. Second, we will upgrade predictive and preventive risk management. Third, we will focus on human resource development. As the entire division takes concrete actions to achieve these goals, we must answer the following questions more clearly: "What must be done, and by when?"; "What must be provided to whom?"; and "What can we voluntarily propose and how can we contribute to the success of the third medium-term business plan?" We are convinced that developing highly reliable QA processes globally, and identifying risks in a predictive and preventive mapper, are crucial to Shionogi's continued advancement.

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

# Review of the second medium-term business plan achievements

In April 2005, when Shionogi's second medium-term business plan began, the amended Pharmaceutical Affairs Act came into force. The amended legislation enabled drug manufacturers to outsource the entire production process for the first time, but also put all the responsibility for product quality, safety, stable supply and so forth on the commissioning manufacturer and seller. This led to a decline in the proportion of drugs manufactured in-house, and attached greater importance to the quality assurance function for Shionogirelated bulk pharmaceuticals and formulations manufactured at third-party production facilities both in Japan and overseas. Therefore, we have actively conducted QA audits of our supply chain and taken other steps to ensure product quality.

April 2005 also marked the first launch of Crestor®, one of Shionogi's most important products. Giving top priority to patient safety, we conducted post-marketing surveillance (PMS) studies to gather safety-related data on patients taking the product during its first 18 months on the market. Once the safety evidence was obtained, regular commercial sales commenced in September 2006.



A new facility for formulation and packaging of solid dosage forms

This marked the first time in Japan that a drug manufacturer gathered PMS data from around 10,000 patients based on a predictive and preventive approach, which was just as difficult as clinical trials. Shionogi received extensive praise from outside the company for this initiative.

In December 2008, we completed the Japanese launch of Pirespa®, which is the world's first drug approved for the treatment of idiopathic pulmonary fibrosis. In this case, we enrolled all patients taking the drug in a PMS study to ensure safety by promoting correct usage. Enrollments were completed in October 2009 and extensive results were obtained from the PMS study by early 2010.

In January 2010, we received regulatory approval for Rapiacta®, the world's first injectable antiviral agent for treating influenza. We plan to enroll all patients taking this drug in a PMS study for a certain period after launch to promote correct usage.

In this manner, during the five-year period of the second medium-term business plan, Shionogi proactively worked to ensure drug quality and safety and scored a number of notable achievements in this area.

# Targeting the goals of the third medium-term business plan

In fiscal 2010, as part of preparations to build global quality assurance systems, we will first deepen our collaboration with Shionogi USA, Inc. and Shionogi Pharma, Inc. for the purpose of sharing information relating to the Shionogi Group's global safety management and quality assurance framework. In addition, as part of upgrading risk management to adopt a more predictive and preventive approach, we will revise current safety management and quality assurance procedures and formulate a human resources development plan to help us identify global risks based on such an approach. In line with these efforts, we will also formulate Shionogi product policies, strengthen divisional planning functions and begin work on constructing a global quality assurance framework for Shionogi.



## **Human Health Care**

changes in the pharmaceutical sales and marketing environment patent drugs that have been NHI-listed for many years, we need

Executive General Manager, Human Health Care Division Masaaki Goshima

### Review of the second medium-term business plan achievements

Under the second medium-term business plan, we focused on strengthening our sales and marketing activities in Japan with the aim of reinforcing Shionogi's overall sales and marketing presence.

In the field of metabolic syndrome, in collaboration with AstraZeneca we finished the intermediate endpoint analysis for the PRIME (Post-marketing Surveillance Study for Rosuvastatin: Innovative Medical Experience) PMS study for Crestor® and submitted it for regulatory approval a full six months ahead of schedule. Consequently, we were able to launch regular commercial sales of the drug in September 2006. Since then, we have continued to gather evidence relating to the clinical efficacy and safety of Crestor® via long-term studies such as JUPITER (Justification for the Use of statins in Primary prevention: an Intervention Trial Evaluating Rosuvastatin) and COSMOS (COronary atherosclerosis Study Measuring effects Of rosuvastatin using intravascular ultrasound in Japanese Subjects). Reflecting the fierce competition in the market for cardiovascular drugs, we created new teams to provide additional sales support for our medical representatives. While leveraging Shionogi's strengths in one-on-one sales activities, we also collected other clinical data from hospitals and joined forces with opinion leaders to share this evidence with a wider audience of health professionals through lectures, seminars and other events. This helped us to further shift Shionogi's operations from acute disorders to treatment of chronic diseases. By fiscal 2009, the final year of the plan, Crestor® had grown to become Shionogi's topselling product.

In the field of infectious diseases, we launched new products such as Finibax® and also succeeded in expanding the market presence of Flomox® based on a consistent program of detailing activities

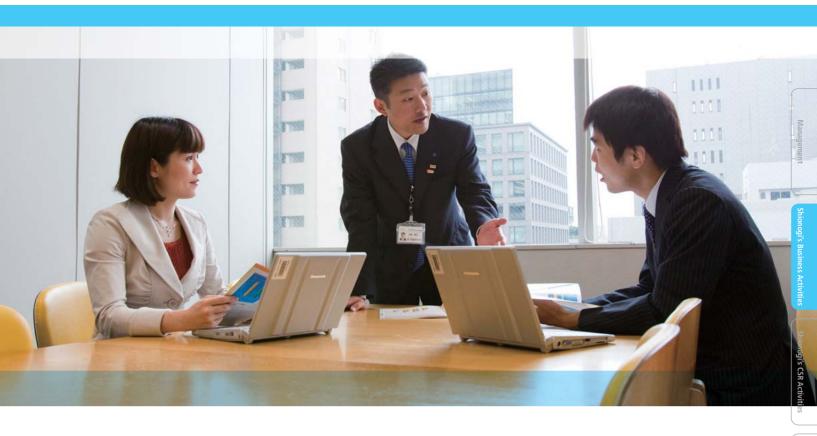
In the field of pain, we introduced OxiNorm® in an immediaterelease powder formulation. Combined use of sustained-release and immediate-release analgesics with the same active ingredient and administration route is a method for treating cancer pain recommended by the World Health Organization and others. We have followed this advice by marketing OxiNorm® Powder in conjunction with sustained-release OxyContin® Tablets for more effective relief of cancer-related pain.

### Targeting the goals of the third medium-term business plan

During the second medium-term business plan we developed the cardiovascular field into a new area of strength. Leveraging this strength, we will build up our earnings base by maximizing profits from new drugs. We have positioned three products, namely Crestor®, Irbetan® and Cymbalta®, as our core strategic products, and we aim to increase total sales from these three products to ¥100 billion in fiscal 2014. We also have five additional new products, namely Pirespa®, Differin®, Rapiacta®, Finibax® and OxyContin®/OxiNorm®. We aim to increase combined sales from these 8 new drugs, as a percentage of total domestic sales, to at least 70% in fiscal 2014.

### Three core strategic products: Crestor®, Irbetan® and Cymbalta®

In fiscal 2010, we plan to vigorously convey the unique characteristics of our three core strategic products Crestor®, Irbetan® and Cymbalta® by concentrating sales resources on these products and enhancing the impact of detailing activities. In fiscal 2010, we are targeting sales of Crestor®, Irbetan® and Cymbalta® (launched April 2010) of ¥30 billion, ¥8.3 billion and ¥1.8 billion, respectively. In fiscal 2009, Crestor® and Irebetan® sales were ¥24.2 billion and ¥3.8 billion, respectively. To achieve our fiscal 2010 sales targets, we believe that it is important to increase physicians' understanding of the features of each product. That is why we will actively hold small doctor meetings and other presentation events.



### **Initiatives for other products**

With Differin®, we plan to continue our public awareness campaign through television and other media to broadly convey that dermatologists can now prescribe a novel therapy for acne. We hope to encourage more acne sufferers to visit a dermatologist as a result.

In the case of Pirespa®, our foremost marketing message is that "earlier is better" when it comes to treating pulmonary fibrosis. By promoting the drug's unique characteristics, we aim to boost prescriptions for Pirespa®. We plan to continue organizing physician seminars hosted by doctors with extensive experience in prescribing the drug.

Rapiacta® is an effective influenza treatment based on a single injection received on an outpatient basis. It offers guaranteed medication compliance, and it can also be used widely in severe influenza cases or where oral administration is difficult. Our marketing campaign will emphasize the usefulness of injections in ensuring the correct frequency of administration and dosage, and the role Rapiacta® can play in broadening the range of therapeutic



options for influenza.

Finibax® and OxyContin®/OxiNorm® are both products that are mainly prescribed in hospital. Co-prescription is a strong possibility in the case of cancer patients. In our marketing campaign, we plan to derive synergies by focusing on the complete relief from cancer pain that can be achieved while also treating infections early.

# **Unit for Judicious Use of Antibiotics Established**

Measures to fight infectious diseases are a crucial risk management issue at the national level. The Japanese Society for Bacteriology has advocated the importance of promoting the appropriate use of antibiotics along with its significance as a national government policy. However, only a handful of pharmaceutical companies are now directly addressing this issue in their R&D, manufacturing and sales activities.

Shionogi believes that part of its social significance lies in contributing to the therapeutic area of infectious diseases. Activities ranging from R&D to sales in the infectious disease area have remained a key focus. In July 2010, we established the Unit for Judicious Use of Antibiotics. This unit was set up for the purpose of conveying information intended to prevent the emergence of antibiotic-resistant bacteria. Our approach is to encourage patients to take the best antibiotic for treating a given infectious disease using the most appropriate method of administration, and thus use antibiotics in a safer manner.

Shionogi takes this proposal seriously. The Company will remain actively engaged in awareness-raising activities aimed at promoting the appropriate use of antibiotics, and will make every effort to make a greater contribution to the treatment of infectious diseases.



## **Overseas Business Activities**

a global drug development foundation. As a result, steady progress was obesity treatment and made steady progress on the development of an anti-HIV drug through Shionogi-ViiV Healthcare LLC. In 2008, we

Shionogi Inc. President and Chief Executive Officer Sapan Shah, Ph.D.

# Shionogi Inc.: A new the US headquarters to lead commercial and R&D growth

On July 1, 2010 Shionogi announced the formation of Shionogi Inc. as its consolidated the US corporate headquarters based in New Jersey. Dr. Sapan Shah was named as President and Chief Executive Officer of Shionogi Inc., having previously led Shionogi USA, Inc., as President and Chief Executive Officer since 2002.

The rationale behind the formation of Shionogi Inc. is to create a fully-integrated headquarters and leadership team that can direct both the commercial and R&D activities of Shionogi in the US. The decision to maintain two centers of excellence in the US under a single Shionogi Inc. leadership team, with Atlanta, Georgia focused on sales, marketing and distribution through our Shionogi Pharma, Inc. subsidiary, and New Jersey containing group headquarters, corporate strategy, clinical development and regulatory functions, will ensure efficient the US operations and close coordination of all activities.

Over the past several years, Shionogi's the US activities have increased significantly in scale, with the acquisition of Sciele Pharma, Inc. in 2008 providing an established commercial

platform which can be leveraged to maximize the potential of our robust pipeline of clinical stage drug candidates originated by Shionogi & Co., Ltd. and partners worldwide. The reorganization of the US operations under Shionogi Inc. will allow us to fully capitalize on the significant scale of our the US platform and build efficiently for future growth.

Our strategy for the US makes the most of our current commercial portfolio and late stage pipeline assets through efficient commercial operations and best-in-class launch preparation and execution, and builds a bridge to the robust pipeline of in-house new chemical entities under development. This strategy translates into leveraging the core sales, marketing, and distribution capabilities of our Shionogi Pharma, Inc. subsidiary (formerly Sciele Pharma, Inc.) and continuing to build the global product development capabilities, which have been initiated under Shionogi USA, Inc. Our unified the US leadership team under Shionogi Inc. will allow us to deliver on our objectives for future growth.



In terms of specific activities in fiscal year 2010, the US group will continue to move forward aggressively with efforts to optimize our current the US infrastructure and maximize our current marketed portfolio, including the launch of Glycopyrrolate for chronic drooling Cuvposa™ and Clonidine for ADHD. We will also focus on making further progress towards regulatory approval and launch of near-term products, including PSD502 for premature ejaculation and Ospemifene for vaginal atrophy. These products will provide an important bridge to our clinical pipeline of new chemical entities originated by Shionogi's research labs in Japan. To that end, in 2010 we will also continue our global clinical development efforts in support of numerous drug candidates, including S-2367/S-234462 for obesity, S-888711 for thrombocytopenia, S-297995 for alleviation of opioid-induced side effects, S-707106 for diabetes, and our integrase inhibitor S-349572 for HIV in collaboration with ViiV Healthcare LLC.

In summary, with the formation of Shionogi Inc. we have taken another important step towards establishing Shionogi & Co., Ltd., as a global pharmaceutical company. The team of dedicated professionals we have assembled under Shionogi Inc. is truly committed to our success as a company, which is firmly grounded in our overall corporate goal of providing important medicines in areas of unmet medical need to patients worldwide.

## **Major Products**

### **Prescription Drugs**

In the third medium-term business plan, we have positioned three products, namely Crestor®, Irbetan® and Cymbalta®, as our core strategic products. We have also defined five additional strategic products as Pirespa®, Differin®, Rapiacta®, Finibax® and OxyContin®/OxiNorm®. With a total of eight strategic drugs, Shionogi is targeting further growth by expanding new drug sales.

### Crestor® Tablet (Hyperlipidemia Treatment)

The clinical effectiveness of Crestor® for preventing atherosclerotic diseases has been confirmed by many large-scale clinical studies in Japan and overseas, such as JUPITER and COSMOS. Crestor® is a statin formulation supported by a broad range of accumulated evidence of efficacy and safety for patients. Crestor® is particularly attractive due to the current evidence improvement in the ratio of LDL cholesterol to HDL cholesterol, an indicator related to atherosclerosis, and is expected to drive the statin therapy forward.



# Irbetan® Tablet (Antihypertensive)

Irbetan® is a long-acting angiotensin II receptor blocker (ARB) with a superior antihypertensive effect for minor to severe hypertension. Combining superior tissue penetration and a PPAR-gamma activation effect, Irbetan® is a first-choice ARB for treatment of metabolic syndrome, obesity, diabetes and hypertension with chronic kidney disease (CKD). Irbetan® shows evidence of a renoprotective effect and encephalopathy evidence, and is contributing to the treatment of hypertension in 88 countries around the world.



### Cymbalta® Capsule (Treatment for depression and depressive symptoms)

Depression is a disease that causes physical symptoms such as fatigue, headaches and lower back pain, in addition to emotional symptoms such as depressive states, lack of motivation and anxiety. Launched in April 2010 as a dual-action serotonin-norepinephrine reuptake inhibitor (SNRI), Cymbalta® is expected to be a useful drug formulation for relieving symptoms and promoting recovery due to its effectiveness in treating a broad range of depressive symptoms. Overseas, it has been approved in 99 countries since its launch in the US in 2004.



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

Finibax® is a carbapenem antibacterial agent for infusion with a broad spectrum of superior antibacterial activity against various bacteria. Antibacterial activity especially against *Pseudomonas aeruginosa* is the most potent among carbapenem antibacterial agents, and it was revealed recently that Finibax® had an inhibitory action on the formation of carbapenem resistance in *Pseudomonas aeruginosa*. Finibax® is being recognized as a highly useful drug for the treatment of serious infections.



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

Offering the effect of inhibiting pulmonary fibrosis, Pirespa® is the only drug that is indicated for idiopathic pulmonary fibrosis. Shionogi became the first company in the world to obtain manufacturing and marketing approval of the drug in Japan, and launched the product in December 2008. Shionogi provides information on correct usage primarily to respiratory specialists in order to make some contribution to the treatment and understanding of idiopathic pulmonary fibrosis, which remains an intractable illness.



### Rapiacta® Bag for Intravenous Drip Infusion Rapiacta® Vial for Intravenous Drip Infusion (Antiviral drug for influenza)

Rapiacta® is an influenza treatment for shortening infection periods and inhibiting severe symptoms that can be administered through a single-dose intravenous drip infusion. Shionogi received the world's first manufacturing and marketing approval for the drug in Japan and launched the product in January 2010. The emergence of this injectable influenza treatment that promises guaranteed medication compliance has expanded treatment options.



### Differin® Gel (Acne Vulgaris Treatment)

Differin® Gel is the first topical retinoid preparation to be approved for the indication of acne vulgaris in Japan. Marketed since October 2008, it is being jointly promoted by Shionogi in cooperation with Galderma KK, giving top priority to improving the quality of life and satisfaction of patients suffering from acne vulgaris. In guidelines on the treatment of acne vulgaris issued by the Japanese Dermatological Association in 2008, Differin® Gel received an A grade recommendation for the treatment of light to severe symptoms of comedo and inflammatory skin rashes. Differin® Gel is gaining recognition as a key drug for the treatment of acne vulgaris primarily among dermatologists.



### OxyContin® Tablet OxiNorm® Powder (Cancer Pain Analgesic)

The World Health Organization recommends treating cancer-related pain with oral drugs that include immediate-release and extendedrelease formulations of the same active ingredient. Shionogi's extended-release OxyContin® Tablets and immediate-release OxiNorm® Powder, both of which are cancerpain analgesics, are oral drugs that share the same active ingredient, enabling treatment in line with WHO recommendations. Shionogi does its utmost to appropriately promote these products so as to liberate patients from cancer pain.

## **OTC Drugs**

Shionogi's OTC drug business will contribute to the promotion of self-medication by returning the benefits of pharmaceutical resources developed in the pharmaceutical drugs business to patients, along with providing proper information on each product as required by patients.

# Sedes® (Analgesic Antipyretics)

The four items in Shionogi's Sedes® line of analgesic antipyretics allow users to choose the most appropriate product for their pain. In spring 2009, the Company renovated the packaging design for these products. These include New Sedes®, designed for household use in treating fevers and headaches; Sedes®—Hi, which is effective for treating intolerable headaches and toothaches; Sedes® V, which relieves the pain of stiff shoulders and related headaches; and Sedes® Cure, an effective means of countering menstrual pains and sore throats. In this manner, these products are designed to ease the particular form of pain faced by each user.



# Popon® (Vitamin Compounds)

Offered in redesigned packaging from the summer of 2010, Popon® S is a well-balanced comprehensive vitamin supplement including eight vitamins as well as calcium and magnesium. The Popon® line includes Popon® C White, which helps to moderate blemishes and freckles, and Popon® B Fresh, which helps to relieve muscular fatigue. In addition, in March 2010 Shionogi also launched two products addressing eye problems caused by PC work and other factors: Popon® Pumeri Eye Drop R, which alleviates eye fatigue and Popon® Pumeri Tablets VB, which helps to relieve eye strain.







# Locusta® (Hyperlipidemia Treatment)

Hyperlipidemia is known as a risk factor for arteriosclerosis. To mitigate this risk factor and contribute to patients' future health, Shionogi launched the Locusta® hyperlipidemia treatment in December 2009. By having patients add Locusta® to regular cholesterol-reducing habits such as exercise and a good diet, Shionogi helps patients to properly manage their cholesterol levels.



### **Diagnostics**

Shionogi's Diagnostics Division aims to create high value-added diagnostics that make a broad contribution to society, in fields ranging from diagnosis to treatment. To this end, we are promoting the development of new testing items in the fields of cardiovascular and metabolic syndrome, as well as in the fields of immunology and allergies. Efforts are also focused on developing reagents that can be used by not only traditional testing centers and hospitals, but also private practitioners.

### MI02 Shionogi BNP Shionospot® BNP (Human BNP Kit)

Because blood levels of BNP will 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. MI02 Shionogi BNP and Shionospot® BNP are reagents used to measure the BNP level, while MI02 and Shionospot® Reader are diagnostic instruments that use those reagents to perform actual measurements.



### Allerport® TARC (Th2 Chemokine/TARC Kit)

Allerport® TARC is a reagent used to measure serum levels of TARC, a process that has been covered by Japan's national health insurance system since July 2008. For patients with atopic dermatitis symptoms, serum levels of TARC rise in step with worsening skin condition. Guidelines for the treatment of atopic dermatitis also refer to the clinical utility of serum TARC diagnosis. Thus, this diagnostic product is a useful indicator for evaluating the severity of atopic dermatitis symptoms.



### Quick Chaser® Flu A,B (Influenza Virus Diagnostic Kit)

Quick Chaser® Flu A,B is a reagent for determining whether a patient is infected by the influenza virus, featuring a product design that is easy for patients and medical professionals to understand. The reagent was launched in March 2010 around the same time as the release of Rapiacta®, an anti-viral drug for influenza, in order to facilitate a full-line of support, ranging from the diagnosis to treatment of influenza.





# Fundamental Policy on CSR

Shionogi'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 enduring and unwavering corporate philosophy is a statement of our vision and value to society. Our activities as a pharmaceutical company inherently contribute to society, and we believe that implementing our corporate philosophy promotes our fulfillment of social responsibilities.

To help realize the Company Policy, we have created Shionogi's Action Guidelines, which all people working at Shionogi 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.

### Trus

- 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

### **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 at the Company's website.

In fiscal 2009, the total number of inquiries was approximately 87,800, increasing roughly 10% from fiscal 2008.

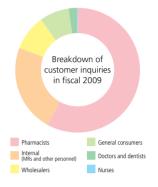
Drug Information Center is our contact point for inquiries. Here, we gather information on not only Shionogi products but also peripheral areas, in order to promptly provide accurate information in response to inquiries. We collect, compile and store as well as analyze information on inquiries received, and provide feedback on this information to the relevant departments. In this way, we strive to share and make good use of 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 analyses 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.

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 use of information



## **Measures to Improve Quality of Life**

## **◆**Supporting Dermatological Treatment for Acne

Acne vulgaris afflicts many in their teens and 20s. It mainly appears on the face and can leave scars, significantly affecting quality of life. Yet despite these consequences, few sufferers seek medical attention.

Shionogi provides acne patients with accurate information and encourages them to seek dermatological treatment to restore their confidence and improve their quality of life.

On May 21, 2010, we registered that date of the year as Acne Day with the Japan Anniversary Association. The significance is that the numbers 5 (for the month) and 2 and 1 (for the day) can be used to express a reading in Japanese to the effect that acne sufferers should always consult dermatologists. On that day, we began airing a television commercial featuring entertainer Kanako Yanagihara in fiscal 2010 as part of our positive, multifaceted approach to educating the public about the issue of acne.



## Cancer Pain Management Outreach

A survey of cancer patients in 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 is 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 three years, achieving high awareness of its message and increasing visits to our cancer pain therapy website.

We participate in the Cancer Pain Relief Consortium, a collaborative initiative of industry entities that promotes pain care. We also support 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 2010 marking the fourth 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

# 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. One of the results of this approach is seen in the share of Shionogi MRs who pass the MR accreditation test of the MR Education and Accreditation Center of Japan—while the industry average is some 80%, the rate for Shionogi employees is close to 100%.

Furthermore, besides education and training programs, Shionogi implements a "youthful employee interview" program for employees in their second and fourth years with the Company. Human resource staff undertake interviews with all the youthful employees throughout Japan and their bosses concerning routine tasks and problems and provide advice with an emphasis on educational issues as a means of tailoring human resource development activities to each individual employee's needs.

## **Fair and Equitable Personnel Evaluations**

Shionogi has rigorously aligned Company targets 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 treatment. In view of this, besides creating evaluation standards and disclosing them to employees, Shionogi is increasing the transparency and objectivity of its evaluation methodology by providing extensive educational programs for evaluators. In addition, by gathering 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.

## **Human Resources System**

We revised our human resources structure in April 2010 in recognition of our need to deploy our basic policy globally to survive and continue growing as a Company. It is essential for all employees to play an even greater role in such efforts and produce results. Structural improvements included creating an evaluation system that increases the weight given to employees' roles. Employees are scored based on their assigned roles and their displayed ability levels. We then move to improve their abilities by assigning greater roles, and help them grow further by performing new tasks. The end result is a continuous and positive cycle of improvement. This approach aims to motivate employees to take on greater challenges and thereby improve their skills.

## **Occupational Safety and Health**

In line with its corporate purpose of "protection of 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 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.

	2007	2008	2009
Number of occupational illnesses/injury incidents	18	12	16
Occupational illness/injury incident frequency rate	0.33%	0.108%	0.22%
Occupational illness/injury incident severity rate	0.002%	0.0002%	0.001%

Concerning employee health, Shionogi has introduced 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, 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 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" (self-care, managerial care, on-site industrial staff health care, and external resource-based care).

Beginning in fiscal 2009, we promoted efforts to end smoking inside of the Company, and plan to phase in the complete elimination of smoking by employees during business hours in April 2011.

## **Employment of Persons with Disabilities**

To help normalize the lives of persons with disabilities, Shionogi has been making ongoing efforts to hire such persons. In fiscal 2009, the share of Shionogi's employees with disabilities was 2.0%, 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.

	2005	2006	2007	2008	2009
Share of employees with disabilities	2.16%	2.19%	2.29%	2.17%	2.00%

## **Human Rights Initiatives**

Shionogi has clearly articulated its employee rights concept 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 designated 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.

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.

Shionogi donated ¥2 million through the Japanese Red Cross Society to support relief efforts for victims of a massive earthquake that struck Haiti in January 2010.

## **Shionogi Inc. Activities**

Shionogi Inc. has made donations of pharmaceutical products to MAP International, an NPO that provides medicines throughout the world to people who live in poverty and lack adequate medical care. The Company also made a financial donation to MAP International for the victims of the Haiti earthquake in January 2010.

Shionogi Inc. makes donations to the American Diabetes Association and participates in the Tour de Cure, a bicycle race to raise money for diabetes patients.



Shionogi Inc. is also donating to AID Atlanta. This is an organization that raises awareness of HIV and provides medical services such as medical care, pharmaceutical products, vaccine research, housing, meals, and counseling.

We also provide various educational grants in the US.



## Commemorating 2300th Broadcast of Shionogi Music Fair

Since August 1964, Shionogi has sponsored the music program Shionogi Music Fair, which airs on Saturdays from 6:00 PM to 6:30 PM on a television station associated with Fuji Television Network. To commemorate the 2300th broadcast in March 2010, the show was taped in front of a live audience at Wel City Osaka Koseinenkin Kaikan Hall.

Shionogi remains committed to offering this program so that audiences can enjoy songs by top singers in a wonderful environment with the best sound effects, lighting and sets.

Going forward, the Company will continue to sponsor high-quality musical programs that help promote the musical culture of Japan as one way to contribute to society.



# Investor Relations

### **Interactive Communications**

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



Financial results presentation

### **Efforts to Preserve the Environment**

In promoting its business activities, the Shionogi Group are aware that, as a company, we have an important social responsibility to give appropriate consideration to the global and local environments. To lessen our environmental impact in all of its 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. Despite increased production activities in fiscal 2009 reflecting the full-scale operation of a new drug formulation facility, we continued to reduce the environmental impact of all our 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**

We promote environmental preservation activities under the group-wide supervision of the Chief Environmental Supervisor and the Chief Environmental Management Supervisor. All major business sites 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.

Head Office & Manufacturing &

**Branch Offices** 

President Corporate Executive Meeting Chief Environmental Supervisor Shionogi Group Central Environmental Committee Chief Environmental Management Supervisor **Environmental Management** Committee Pharmaceutical Pharmaceutical Subsidiaries Technology Division Research Division **Development Division** 

### FY2009 Results

## Measures for Resource Conservation and Wastes • Amount of Waste Generated

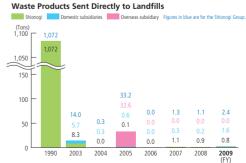
In recent years, the establishment of a recycling-oriented society has become a necessity, partly because there is a limit to the capacity of waste processing plants. In response, Shionogi has worked to reduce the volume of waste products generated and promote the reuse and recycling of resources. Principal waste products included waste oil generated from manufacturing processes, sludge generated from wastewater treatment processes, and plastics used in product containers. In fiscal 2009, the volume of waste products generated rose, mainly reflecting an increase from expanded production activities accompanying the full-scale operation of a new drug

formulation facility, and realignment of existing research facilities in line with construction plans of new research facilities. Going forward, however, we will continue working to reduce wastes. We define the goal of reducing the amount of waste products from our business sites that are directly disposed of in landfills to zero as "zero emissions," and, with this goal in mind, we are working to reduce the amount of waste. Although we fell short of this target in fiscal 2009, we are promoting steps to achieve zero emissions through the incineration of

certain waste formerly sent to landfill, among other means.

In addition, to prevent illegal dumping of waste products, we carefully select the companies to which we consign waste processing and transport tasks, verifying their industrial permit acquisition situation as well as their treatment facilities, operational situation, document management situation, and other items listed on company evaluation sheets to provide a basis for deliberations on whether or not to employ a particular company. After work is consigned, we appropriately manage the relevant contracts, permit certificates, and manifests, and undertakes an onsite check of the waste processing company one or more times each year.

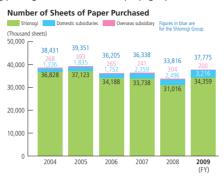




# • Copy Paper and Printing Paper

We are reducing the amount of copy paper and printing paper used by means of various initiatives, including printing double-sided or multiple pages per sheet,

shifting to paperless faxing, and promoting the use of scanners and management of documents in electronic form. In fiscal 2009, paper usage increased mainly due to sales promotion activities. Going forward, however, we will continue working to reduce paper usage.



# Green Purchasing

Regarding office supplies, we make efforts to purchase environment-friendly products. We have built an intranet-based purchasing system that facilitates green

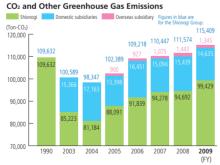
purchasing when ordering by searching for and identifying eco-friendly products. In fiscal 2009, the green purchasing ratio declined partly due to changes in sticker mark standards for environmental labels, but we will continue working to enhance this ratio going forward.



# • Prevention of Global Warming

In recent years, a casual relationship has been identified between the increased frequency of abnormal weather events around the world and rising greenhouse gas concentrations in the atmosphere. In response, Shionogi has taken measures to reduce its greenhouse gas emissions. In fiscal 2009, we continued to take systematic steps, including upgrading such equipment as high-voltage transformers, freezers, and lighting equipment to energy-saving models, and reviewing our use of air conditioners. However, through expansion of production, such as the start of full-scale operations at a new drug formulation facility the volume of greenhouse gas emissions rose. We will continue considering ways to curb our output of greenhouse gases and improve our environmental efficiency. Furthermore, plans for new research facilities

at our Development Research Laboratories include more extensive measures built in to enhance energy efficiency and reduce greenhouse gas emission volume. This initiative has been well received by the public, and culminated in it being named as a "fiscal 2009 model CO2 reduction enterprise" by Japan's Ministry of Land, Infrastructure, Transport and Tourism.

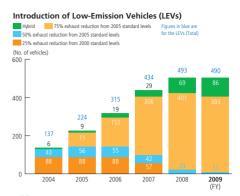


- \* From fiscal 2005, figures for all greenhouse gas emissions are included on
- \* From fiscal 2006, the Tokyo Branch Office expanded the scope of its calculations

# • Low-Emission Vehicles

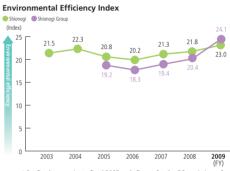
We continue to introduce low-emission vehicles for use by medical representatives (MRs). In fiscal 2009—following the introduction of 86 hybrid vehicles, low-emission vehicles, and other vehicles that meet specified fuel economy standards—all 490 of the Company's marketing-use cars were low-emission vehicles that have exhaust

emissions 50% or more below the 2005 standard level. Going forward, while focusing mainly on hybrid cars, plans call for partially introducing electric vehicles as well as promoting greater use of public transportation within Tokyo.



# Environmental Efficiency

Environmental efficiency, which is based on greenhouse gas emissions and net sales, has been improved. Going forward, we will strive to improve environmental efficiency further through efficient business activities.



- \*Environmental efficiency is calculated as net sales divided by the amount of greenhouse gas emissions. Therefore, higher numbers indicate more environment-friendly business activities.
- For fiscal years prior to fiscal 2005, only figures for the CO<sub>2</sub> emissions of Shionogi & Co.'s sites are used.
- From fiscal 2005, figures for all greenhouse gas are included on a Group-wide basis.

# • Chemical Substance Management

Because many chemical substances have an impact on human health, ecosystems, and the global environment, the pharmaceutical industry is autonomously implementing such measures as those to survey the amount of chemical substances used and reduce atmospheric emissions. We properly manage our emissions of chemical substances into the atmosphere and wastewater and otherwise undertake the appropriate management of harmful chemical substances. In addition, we have a reagent control system in place for appropriate inventory management regarding chemicals used in R&D as well as access controls concerning poisonous and/or hazardous chemicals. In other areas, Shionogi files reports based on the Pollutant Release and Transfer Register (PRTR) Law, which requires companies to measure, compile and announce data on hazardous chemicals released into the environment. Going forward, we will continue to properly monitor the amount of such chemicals we use, release and transfer.

# Environmental Accounting

We have been conducting environmental accounting based on guidelines from Japan's Ministry of the Environment. The purpose of environmental accounting is to quantitatively manage environmental preservation activities by recognizing their cost and the effect they achieve.

## **Environmental Management Evaluation Report**

Experts at the Institute for Environmental Management Accounting (IEMA) provide us with their opinion on our efforts to improve the reliability and transparency

of disclosure of our environmental activities. We also receive advice on our environmental friendliness, environmental management status, and future activities.





For further details on our environmental and other activities, please visit our website at

URL:http://www.shionogi.co.jp/environment/eco/

# **Phase 3 Shionogi Group Environmental Protection Plan**

Shionogi initially worked to reduce its environmental impact based on a company-wide two-stage Environmental Protection Plan, with Phases 1 and 2 covering the periods Fiscal 1995–2000 and Fiscal 2000–2004, respectively. The scope of the plan's Phase 3, which covers Fiscal 2005–2010, was expanded to include Shionogi Group companies to strengthen the company's environmental activities.

# Targets and Results of Phase 3 Shionogi Group Environmental Protection Plan

Pha	ase 3 Shionogi Group Environmental Protection Plan Targets	Fiscal 2009 Targets
1	Strengthen conservation of resources and waste disposal measures  • Reduce amount of waste generated by 38% (to 4,990 tons) [42% reduction to 4,460 tons]  • Reduce waste 40% by Fiscal 2015 (to 4,830 tons) [44% reduction to 4,350 tons]	12% reduction (to 7,109 tons) [24% reduction to 5,907 tons]  • Make efforts to offset natural increase in environmental impact accompanying the start of operations at new facility (Settsu Plant)  • Reduce waste product volume 145 tons below the Fiscal 2008 level despite an increase in production volume (Kanegasaki Plant)
	Promote zero emissions	Waste sent directly to landfills: 0.79 tons [0.79 tons]  • Promote appropriate treatment methods (Nichia Pharmaceutical Industries)  • Thoroughly implement waste separation and decreasing the volume of non-burnable waste (Nagoya branch office)
	Reduce use of copy paper and printing paper by 5% (to 36.5 million sheets) [7% reduction to 34.3 million sheets] Reduce 8% in Fiscal 2015 (to 35.3 million sheets) [10% reduction to 33.1 million sheets]	<ul> <li>8.6% reduction (to 35.127 million sheets)</li> <li>[12.6% reduction to 32.177 million sheets]</li> <li>Employ diverse printing machine functions, information sharing, and other measures to sustain progress toward paper-free operations</li> </ul>
2	Implement measures to counter global warming  • Maintain greenhouse gas emissions at level of benchmark year (to 102,500 ton-CO <sub>2</sub> ) [8% reduction to 84,000 ton-CO <sub>2</sub> ]  • Reduce 1% in Fiscal 2015 (to 101,500 ton-CO <sub>2</sub> ) [8% reduction to 84,000 ton-CO <sub>2</sub> ]  • Promote energy conservation	Limit to 14.3% increase (to 117,235 ton-CO <sub>2</sub> ) [9.6% increase to 100,581 ton-CO <sub>2</sub> ]  • Reduce to below the Fiscal 2008 level (Kuise Site)  • Further raise environmental efficiency targets (Kanegasaki Plant)
3	Strengthen management of chemical substances  • Monitor and reduce use, emissions and transfer of hazardous chemicals	Continue to monitor use, emissions, and transfer of hazardous chemicals and undertake appropriate management Respond to Osaka's chemical substance management system Increase capacity utilization rate of processes employing dichloromethane as a means of reducing emissions to below 95 tons (Kanegasaki Plant) Sustain use of environment-friendly experiment methods (Shionogi Research Laboratories)
	Completely eliminate specified CFCs (applies to equipment holding more than 20kg)	Renovate two freezers (Kuise Site) Renovate one freeze-drying equipment (Settsu Plant) Renovate one freezer (Kanegasaki Plant)
	Set and manage voluntary control levels for atmosphere, wastewater, soil and underground water	Continue periodic measurement and evaluation of atmosphere, wastewater and soil
4	Enhance system for evaluating safety of chemical processes	Continue to manage chemical process safety evaluation system (Kuise Site)
5	Promote Product Life Cycle Assessment	Continue considering selection of packaging materials, methods, etc., based on results of environmental impact surveys (Kuise Site)
5	Implement environmental accounting	Continue to collect data in accordance with environmental accounting guidelines
7	Expand green purchasing  Raise rate of green purchasing of office supplies to 75% [75%] Raise rate to 80% in Fiscal 2015 [80%]	Green purchasing rate 78% [76%] • Promote green purchasing
В	Contribute to society	Promote communication with surrounding communities
9	Disclose environmental information	Publish environmental information as part of the Annual Report

Scope of application: Shionogi Group companies (domestic and overseas)
Benchmark year: Fiscal 1990 (or Fiscal 2004)
Figures in [] apply to parent company
Fiscal year targets: Fiscal 2010 targets were set in line with expanded production and R&D activity levels, despite Fiscal 2010 being the final year of the medium-term environmental plan.

Fiscal 2009 Results

**Fiscal 2010 Targets** 

<ul> <li>2% increase (to 8,194 tons)</li> <li>[11% reduction to 6,912 tons]</li> <li>Rose due to the full-scale operation of new drug formulation facility, but the overall increase was curbed mainly through a review of manufacturing processes (Settsu Plant)</li> <li>Waste products increased in line with expanding production volume (Kanegasaki Plant)</li> <li>Promoted the purchasing of organic solvents in containers and volumes (Shionogi Research Laboratories)</li> <li>Recycling contract was changed to treat metal scrap waste as valuable materials (Aburahi Laboratories)</li> </ul>	<ul> <li>21% reduction (to 6,372 tons)</li> <li>[23% reduction to 5,996 tons]</li> <li>Raise eco-efficiency targets for waste emissions (Kanegasaki Plant)</li> <li>Promote re-use of unneeded or underutilized equipment and office supplies stemming from plans for a new research facility (Aburahi Laboratories)</li> </ul>
<ul> <li>Waste sent directly to landfill: 2.45 tons [0.81 tons]</li> <li>One-off increase due to disposal of mixed wastes and ion-exchange membranes (Nichia Pharmaceutical Industries)</li> <li>Strict waste separation employed and volume of non-combustible waste reduced (Nagoya Branch Office)</li> </ul>	Waste sent directly to landfill: 0.76 tons [0.76 tons]  • Switch to incinerating ion-exchange membranes to reduce landfill waste (Nichia Pharmaceutical Industries)  • Use strict waste separation and cut volume of non-combustible waste (Nagoya Branch Office)
1.7% reduction (to 37.775 million sheets) [6.7% reduction to 34.359 million sheets]  • Usage increase due to large number of overseas inspections (Kanegasaki Plant)  • Usage increase mainly due to internalization of some copying requests and sales promotion activities (Settsu Plant, Head Office)	14.2% reduction (to 32.962 million sheets) [12.9% reduction to 32.077 million sheets]  • Continue promoting paperless operations using various printer functions, document sharing and other measures
12.5% increase (to 115,409 ton-CO <sub>2</sub> ) [8.3% increase to 99,429 ton-CO <sub>2</sub> )  • Reduced year on year through change of water coolers and freezers and enhancement of transformer efficiency (Kuise Site) • Improvement in environmental efficiency benchmark (Kanegasaki Plant) • Changed the operating hours of production-line air conditioners (Kanegasaki Plant) • Replaced incandescent light bulbs with fluorescent light bulbs (Kanegasaki Plant) • Thinned windbreak forest (Aburahi Laboratories) • NOx/SOx reducing photo-catalytic and heat-blocking paint used on external walls (Bushu Pharmaceuticals) • Plans for new research facilities adopted as model CO <sub>2</sub> reduction enterprise by the Ministry of Land, Infrastructure, Transport and Tourism (Developmental Research Laboratories)	7.7% reduction (to 94,670 ton-CO <sub>2</sub> ) [0.6% increase to 92,317 ton-CO <sub>2</sub> ]  • Raise greenhouse-gas-related environmental efficiency targets (Kanegasaki Plant)  • Review operation of air-conditioning systems (Aburahi Laboratories)  • Establish an Energy Efficiency Committee and promote energy conservation and CO <sub>2</sub> countermeasures company-wide.
<ul> <li>Hazardous chemicals use, emissions and transfers monitored and managed properly</li> <li>Submission made on Osaka's chemical substance management system</li> <li>Atmospheric dichloromethane emissions rose to 119.5 tons, in line with higher operation rates (Kanegasaki Plant)</li> <li>Lecture by an outside expert on proper chemicals management performed (Shionogi Research Laboratories)</li> <li>Format miniaturization promoted for screening of development compounds (Shionogi Research Laboratories)</li> <li>Warehouse facilities subject to asbestos enclosure work were properly dismantled and removed (Developmental Research Laboratories)</li> </ul>	Continue monitoring use, emissions and transfers of hazardous chemicals and manage properly  Cut atmospheric dichloromethane emissions to 91 tons or less (Kanegasaki Plant)  Sustain use of environment-friendly experiment methods (Shionogi Research Laboratories)
Two freezers renovated (Kuise Site) One freeze-drying unit renovated (Settsu Plant) One freezer renovated (Kanegasaki Plant)	Renovate one freeze-drying equipment (Settsu Plant)     Renovate four freezers (Kanegasaki Plant)
<ul> <li>Periodic measurement and evaluation of atmosphere, wastewater and soil conducted based on voluntary control levels</li> </ul>	Continue periodic measurement and evaluation of atmosphere, wastewater and soil
<ul> <li>Safety of chemical processes evaluated for 25 development compounds and 49 processes (Kuise Site)</li> <li>Chemical process safety evaluated for 3 new product manufactures as well as carrying out pre-production training (Nichia Pharmaceutical Industries)</li> </ul>	Continue to manage chemical process safety evaluation system (Kuise Site)     Continue chemical process safety evaluation for new product manufactures as well as carrying out pre-production training (Nichia Pharmaceutical Industries)
<ul> <li>Film usage cut by about 20% by switching from strip packaging to more eco-friendly stick packaging (Kuise Site)</li> </ul>	Continue selecting packaging materials and methods based on environmental impact survey results (Kuise Site)
Environmental accounting data collected for our Group and individual operating sites in accordance with environmental accounting guidelines	Continue collecting data in accordance with environmental accounting guidelines
Green purchasing rate 74% [71%]	Green purchasing rate 75% [75%]
Rate was decreased due to changes in sticker mark standards for environmental labels and increased usage of higher-grade paper	Promote green purchasing
<ul> <li>Participated in cleanup campaigns near sites and main roads in vicinity, as well as environmental activities</li> <li>Sponsorship of "Kanegasaki Greenery and Flower Bank" (Kanegasaki Plant)</li> <li>Wastepaper and newspapers donated to local children's groups (Developmental Research Laboratories)</li> <li>Cooperation with work experience program for local junior high school students (Aburahi Laboratories)</li> <li>PET bottle caps donated to the NPO EcoCap Movement (Bushu Pharmaceuticals, Kuise Site)</li> <li>Began consideration of biodiversity initiatives         <ul> <li>(Kanegasaki Plant, Shionogi Research Laboratories, Developmental Research Laboratories)</li> </ul> </li> </ul>	Promote communications with neighboring communities at operating sites     Promote biodiversity initiatives
<ul> <li>Annual Report published online and as booklet</li> <li>Contributed article on environmental activities to the Osaka Environmental Management Newsletter ("Naniwa No Kankyo Keiei Kawaraban") (Shionogi Research Laboratories)</li> </ul>	Publish environmental information in an Annual Report format

# Corporate Governance

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 gives top priority to carrying out sound and transparent management 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 six 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 the human resources selected as 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 build a flexible operational execution structure able to rapidly respond to changes in the operating environment. 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.

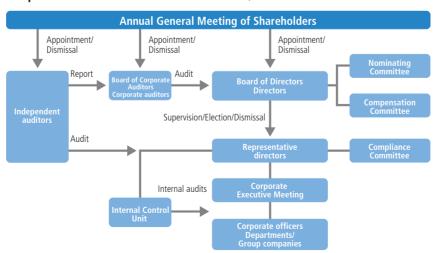
The Company has two standing corporate auditors and two outside corporate auditors. The corporate auditors attend meetings of the Board of Directors, Corporate Executive Meetings, and other important meetings, offering opinions when necessary. In addition, by conducting operational and accounting audits 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 Internal Control Unit, 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 has worked to establish internal control systems throughout the Shionogi Group. The Board of Directors annually evaluates the state of internal control systems and the progress in implementing the basic policy 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 has worked to optimize its IT environment and is moving ahead with measures to build and improve internal controls over financial reporting. As part of these efforts, the president of Shionogi has sent a message 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.

# Corporate Governance Structure (As of April 2010)



# **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.

#### **Framework for Information Disclosure**

Shionogi has established internal systems for the timely, appropriate, and fair disclosure of accurate corporate information to investors and all other kinds of stakeholders, and the Company continues to make necessary revisions to these systems with the goal of maintaining and improving them.

#### **Thorough Compliance**

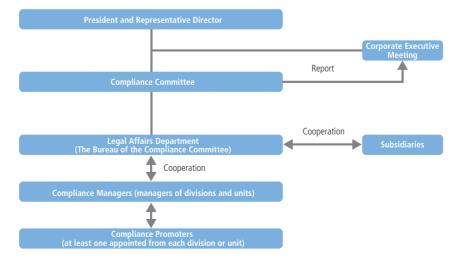
Shionogi promotes compliance in all departments and units, including domestic and global subsidiaries, through measures centered on those of the Compliance Committee, which is chaired by the president and for which the Legal Affairs Department serves as the secretariat. In line with the formulation of the aforementioned outline of essential countermeasures for corporate scandals, the Corporate Scandal Risk Deliberation Committee was established under the Compliance Committee. The Deliberation Committee analyzes and assesses the possible risks due to such incidents, and is responsible for enacting advance measures to prevent their occurrence.

Not limited to conformance with laws and regulations, Shionogi's broad definition of compliance also requires ethical behavior. Each year,

the Company engages in the following types of activities aimed at promoting outstanding compliance consciousness and compliance performance among all employees.

- 1. As the designated Compliance Manager, the manager of each department or unit cooperates with an assistant—designated the Compliance Promoter—in undertaking activities that promote comprehensive compliance consciousness, identifying risks and considering related responses, drafting and submitting reports regarding implementation and improvement measures, and taking various other measures.
- 2. Besides drafting compliance measure proposals, the Legal Affairs Department provides support for promotion activities of each department or unit 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 awareness-raising messages, and conduct employee attitude surveys.
- 3. Shionogi has established an internal reporting system, 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 amelioration and prevention of compliance violations through the early discovery of breaches. In conjunction with this system, the Company, in accordance with the intent of Japan's Whistleblower Protection Act, has established internal protection regulations 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 prevent the inappropriate usage or 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 consultations and complaints, and helping employees who handle personal information to participate in educational programs and acquire related certifications.

# Compliance Promotion Structure (As of April 2010)





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

# **Directors**

Chairman of the Board and Representative Directo

# **Motozo Shiono**

President and Representative Director

Isao Teshirogi, Ph.D.

Sachio Tokaji

Director

Yasuhiro Mino

# **Outside Directors**

## **Akio Nomura**

June 1998:	Representative Director and President of Osaka
	Gas, Ltd.

Director of West Japan Railway Company Representative Director and Chairman of Osaka June 2000: June 2003:

Director of the Royal Hotel, Ltd. (incumbent) Director of Shionogi & Co., Ltd. (incumbent) June 2008: June 2009:

# 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: Lecturer, Kobe University Graduate School

of Law (incumbent) Director of Shionogi & Co., Ltd. (incumbent) June 2009:

# **Corporate Auditors**

Standing Corporate Auditor

Mitsuaki Ohtani, Ph.D.

Standing Corporate Auditor

Satoshi Komatsu

Outside Corporate Auditor

Takeharu Nagata

Outside Corporate Auditor

Shinichi Yokoyama

#### **Corporate Officers**

Senior Executive Officer

Sachio Tokaji

Senior Executive Officer Yasuhiro Mino

Executive Officer

Takuo Fukuda

Executive Officer

Ryuichi Kume, Ph.D.

Executive Officer

Takuko Sawada

Corporate Officer

Hirosato Kondo, Ph.D.

Corporate Officer

Masaaki Goshima

Corporate Officer

Yoshiaki Kamoya

Corporate Officer

Kohji Hanasaki, Ph.D.

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# Management's Discussion and Analysis

# **Overview of Results**

The introduction of the fiscal 2010 reforms to the National Health Insurance (NHI) drug pricing system was a key issue affecting the Japanese pharmaceutical industry in fiscal 2009, the year ended March 31, 2010. As part of these pricing reforms the government introduced on a trial basis new NHI pricing premiums to promote the discovery of new drugs and provide reimbursement for off-label drug use. The actions demanded by these reforms will differ between pharmaceutical manufacturers. Going forward, companies unable to respond to the new challenges may be forced to exit the Japanese market. Overseas, major reforms were introduced to the health insurance system in the US, the world's largest market for pharmaceuticals. These reforms are expected to affect the market in future in a variety of ways.

Amid this operating environment, the Shionogi Group (comprising Shionogi & Co., Ltd. and its consolidated subsidiaries) focused its collective efforts on implementing the second medium-term business plan. Covering the period from April 2005 to March 2010, this plan is positioned as the first stage of the Group's drive to promote significant long-term growth centered on the core prescription drug business. Steady progress was made in a number of areas, including the establishment of a global drug development pipeline and the acquisition of a sales network in the US based around Shionogi Pharma, Inc. (formerly Shionogi Pharma, Inc.), which has helped form a bridgehead for future global business development. Crestor®, the Group's mainstay product for treating hypercholesterolemia, generated further growth. The Group also faced a number of headwinds in fiscal 2009, which resulted in financial performance falling short of the targets set for the second medium-term business plan's final year. In April 2010, the Group embarked on the third medium-term business plan, a five-year plan beginning in fiscal 2010 that targets further significant growth based on the progress made and issues that arose during the second medium-term business plan.

Contract manufacturing subsidiary Bushu Pharmaceuticals Ltd. was sold in March 2010. This divestment was aimed at concentrating Group resources in pharmaceutical operations while also allowing Bushu Pharmaceuticals scope to develop in the future.

#### **Net Sales**

Net sales of ¥278,503 million were 22.4% ahead of the previous year. The mainstay prescription drugs Crestor® and Irbetan®, a treatment for hypertension, both posted significant increases in sales. Other products contributing to sales growth included the topical acne treatment Differin® and the idiopathic pulmonary fibrosis treatment Pirespa®. Offsetting this, sales of antibiotics and other seasonal drugs were affected by a contraction in the market for winter medications more than normal. Overall, the Group's sales of prescription drugs were slightly less than in fiscal 2008. However, royalty income rose substantially, reflecting higher overseas sales of Crestor® by AstraZeneca. Shionogi Pharma, Inc. also made its first full-year contribution to sales.

#### **Gross Profit**

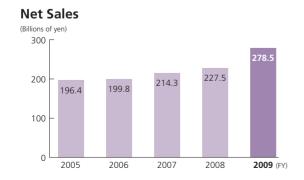
The cost of sales increased by ¥5,335 million in year-on-year terms to ¥76,264 million. The cost of sales ratio declined from 31.2% to 27.4%, reflecting increased royalty income and the sales contribution by Shionogi Pharma, Inc.

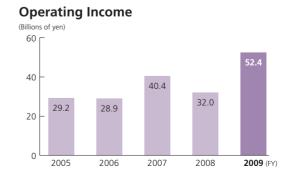
As a result, gross profit increased 29.2% to ¥202,239 million.

# **Operating Expenses and Operating Income**

Selling, general and administrative (SG&A) expenses increased 20.3% to ¥149,801 million and the ratio of SG&A expenses to net sales fell from 54.7% to 53.8%.

Operating income grew 63.8% to ¥52,438 million. This largely reflected the SG&A expenses of ¥9,669 million that the Group had booked in fiscal 2008 under business combination accounting rules in recognition of intellectual property and inprocess R&D expenses arising from the acquisition of Shionogi Pharma, Inc.





# Other Income (Expenses)

Net other income amounted to ¥6,103 million in fiscal 2009, compared with net other expenses of ¥1,229 million recorded in the previous year.

Net interest and dividend income (after the deduction of interest expense) amounted to ¥66 million, compared with ¥1,634 million in the previous year. In other expenses, gains derived from the sale of Bushu Pharmaceuticals Ltd. and the exchange of shares in affiliates were offset by losses on valuation of investment securities and losses due to asset impairments.

# Income before Income Taxes and Minority Interests and Net income

Income before income taxes and minority interests rose 90.2% to ¥58,541 million. Including income tax adjustments, income taxes rose 31.9% to ¥19,900 million.

Net income increased 146.6% on a year-on-year basis to ¥38,626 million. The net income ratio was 13.9%, compared with 6.9% in the previous year. Net income per share increased from ¥46.75 to ¥115.33.

# **Segment Information**

# **Performance by Geographic Segment**

#### **Japan**

Net sales in Japan were ¥238,191 million, an increase of 10.3% compared with fiscal 2008. Operating income rose 31.1% to ¥52,973 million.

## **North America**

Net sales and operating income in North America were ¥38,642 million and ¥2,913 million, respectively. Net sales were approximately four times the figure recorded in the previous year, mainly because Shionogi Pharma, Inc. only made a three-month contribution to sales in fiscal 2008 following its acquisition. The segment recorded an operating loss in fiscal 2008 due to the recognition of ¥9,669 million in in-process R&D expenses associated with the acquisition of the US operations.

#### Other

This segment primarily represents operations in Asia. Net sales fell 4.7% to \$1,670 million and operating income declined 32.0% to \$314 million.

#### **Overseas Sales**

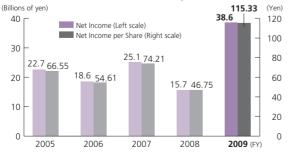
Reflecting increased royalty income and the full-year sales contribution by Shionogi Pharma, Inc., the ratio of overseas sales to consolidated net sales was 35.8% in fiscal 2009, an increase of 11.9 percentage points compared with the prior year. Overseas sales increased to ¥99,842 million.

# **Research and Development Expenses**

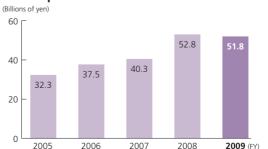
In Japan, Shionogi received manufacturing and marketing approval in January 2010 for Rapiacta®, an antiviral agent for influenza. The product was launched in the same month amid heightened social concerns about influenza in this field. Rapiacta® is expected to make a significant contribution to the future treatment of influenza. Shionogi also received manufacturing and marketing approval for the antidepressant Cymbalta® in January 2010. This product was launched in April 2010. Shionogi also made a submission for Japanese regulatory approval of Cymbalta® for the additional indication of diabetic neuropathic pain in September 2009. Including the overseas development pipeline. Shionogi is currently developing drugs to treat obesity, HIV/AIDS, thrombocytopenia and atopic dermatitis, among others. R&D facility investments during fiscal 2009 included the start of construction work on a newly planned research facility in Toyonaka, Osaka. On completion in April 2011, the new building will consolidate a number of research functions. This is expected to boost R&D productivity and further enhance the Group's drug discovery capabilities.

As a result of these activities, overall Group R&D expenses totaled ¥51,808 million. This figure represented 18.6% of net sales.

## Net Income and Net Income per Share



# **R&D Expenses**



#### **Cash Flows**

Net cash provided by operating activities of ¥52,902 million represented an increase of ¥23.782 million in year-on-year terms. Major factors in the growth of operating cash flow included a significant increase in income before income taxes and minority interests and higher non-cash items such as depreciation and amortization of goodwill.

Net cash used in investing activities amounted to ¥826 million. The cash proceeds from the sale of Bushu Pharmaceuticals were offset by facility investments and other factors.

Net cash used in financing activities equaled ¥4,979 million. Debt repayments, dividend payments and other items offset funds raised via corporate bond issuance.

The balance of cash and cash equivalents at the fiscal yearend was ¥97,663 million, an increase of ¥46,127 million compared with the previous year-end.

#### **Capital Investments**

Capital investments by the Shionogi Group in fiscal 2009 totaled ¥12.5 billion. 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, 2010, total assets equaled ¥540,762 million, an increase of ¥38,908 million from a year earlier. Current assets increased by ¥47,939 million to ¥250,664 million; property, plant and equipment declined by ¥9,363 million to ¥62,448 million; and investments and other assets increased by ¥333 million to ¥227,650 million.

Within current assets, cash and cash equivalents increased by ¥46,127 million. Within investments and other assets, investments in securities increased by ¥3,123 million and prepaid pension costs declined by ¥1,561 million.

(Billions of yen) 600 400 427.7 429.6 413.7

**Total Assets** 

501.9 200 2005 2006 2007 2008 2009 (FY)

The growth in cash principally reflected the receipt of proceeds from the divestment of consolidated subsidiary Bushu Pharmaceuticals. This transaction also resulted in a decline in property, plant and equipment.

Total liabilities at the fiscal year-end amounted to ¥198,785 million, an increase of ¥7,026 million compared with a year earlier

Current liabilities decreased by ¥9,974 million to ¥66,830 million, while long-term liabilities increased by ¥17.001 million to ¥131.956 million.

Principal factors behind the rise in total liabilities included the issuance of corporate bonds worth ¥30.000 million, which was offset by declines in short-term bank loans and long-term debt of ¥10,000 million and ¥14,000 million, respectively.

Net assets totaled ¥341,976 million at the fiscal year-end, an increase of ¥31,882 million compared with a year earlier.

Total shareholders' equity, net unrealized holding gain on securities and translation adjustments all increased compared with a year earlier, by ¥27,828 million, ¥2,154 million and ¥1,887 million, respectively.

In addition to higher retained earnings, the principal factors behind the increase in net assets included an increase in net unrealized holding gain on securities due to higher share prices and an increase in translation adjustments that reflected a weaker yen.

Reflecting these various factors, the ratio of total net assets to total assets increased from 61.7% to 63.2%.

#### 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 in fiscal 2009 included exceptional profit items. The gains arising from the exchange of shares between Omwell Co., Ltd. and Toho Holdings Co., Ltd., which were booked in line with Japanese business combination accounting rules, were excluded for the purposes of determining the underlying level of profits in fiscal 2009. Taking this and future earnings prospects into consideration, the final dividend was set at ¥18 per share. Including the interim dividend, total dividends in fiscal 2009 were ¥36 per share. The consolidated dividend payout ratio for the year was 31.2%.

# **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, 2010.

# 1 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.

# 3 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.

# **4** 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.

#### **5** Risk of Dependence on Certain Products

The Shionogi Group obtains approximately 35% of its product sales and royalty income from two of its products, Crestor® and Flomox® (as of fiscal 2009). 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 prescription drug industry's R&D and sales operations is becoming increasingly intense.

# **7** 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 outlicensing 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.

#### (8) 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.

# **9** 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.

### **10 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, 2010 and 2009

	Millions of yen		Thousands of U.S. dollars (Note 3)	
	2010	2009	2010	
Assets				
Current assets:				
Cash and cash equivalents (Notes 9 and 12)	¥ 97,663	¥ 51,536	\$ 1,049,688	
Short-term investments (Notes 5 and 12)	6,546	7,267	70,357	
Notes and accounts receivable (Note 12):				
Affiliates	1,314	4,333	14,123	
Trade	78,101	71,047	839,435	
Other	4,287	3,161	46,077	
Allowance for doubtful accounts	(11)	(12)	(119	
	83,691	78,529	899,516	
Inventories (Note 6)	49,341	43,028	530,320	
Deferred income taxes (Note 14)	5,418	5,189	58,233	
Other current assets	8,005	17,175	86,039	
otal current assets	250,664	202,724	2,694,153	
Property, plant and equipment:				
Land (Note 21)	10,089	14,809	108,437	
Buildings and structures (Note 21)	100,040	100,296	1,075,236	
Machinery, equipment and vehicles	83,503	87,771	897,496	
Furniture and fixtures	33,863	32,933	363,962	
Construction in progress	6,842	8,408	73,538	
Accumulated depreciation	(171,889)	(172,405)	(1,847,474	
Property, plant and equipment, net	62,448	71,812	671,19	
nvestments and other assets:				
Investments in securities (Notes 5 and 12)	65,276	62,153	701,591	
Investments in affiliates	6,594	4,661	70,873	
Prepaid pension costs (Note 16)	24,411	25,972	262,371	
Goodwill	69,874	71,625	751,010	
Marketing rights (Note 13)	40,720	42,153	437,661	
Long-term prepaid expenses	11,292	12,736	121,367	
Deferred income taxes (Note 14)	81	97	87	
Other assets	9,402	7,920	101,053	
otal investments and other assets	227,650	227,317	2,446,797	

	Million:	Millions of yen	
	2010	2009	2010
Liabilities and net assets			
Current liabilities:			
Notes and accounts payable (Note 12):			
Affiliates	¥ 1,699	¥ 1,728	\$ 18,261
Trade	11,706	13,716	125,817
Construction	1,970	2,961	21,174
Short-term bank loans (Note 7)		10,000	_
Current portion of long-term debt (Notes 7 and 12)	14,000	14,000	150,473
Allowance for employees' bonuses	6,473	5,325	69,572
Accrued expenses	4,851	10,956	52,139
Accrued income taxes (Note 14)	13,061	7,929	140,380
Other current liabilities (Notes 8 and 9)	13,070	10,189	140,477
Total current liabilities		76,804	718,293
Long-term liabilities:	407.000	01.000	4 450 043
Long-term debt (Notes 7 and 12)		91,000	1,150,043
Accrued retirement benefits for employees (Note 16)		7,793	86,812
Accrued retirement benefits for directors and corporate auditors		156	_
Deferred income taxes (Note 14)		13,999	165,918
Long-term accounts payable – other		891	4,202
Other long-term liabilities		1,116	11,297
Total long-term liabilities	131,956	114,955	1,418,272
Contingent liabilities (Note 10)			
Net assets:			
Shareholders' equity (Note 11):			
Common stock:			
Authorized: 1,000,000,000 shares			
Issued: 351,136,165 shares in 2010 and 2009	21,280	21,280	228,719
Capital surplus	20,227	20,227	217,401
Retained earnings	332,670	304,762	3,575,559
Less treasury stock, at cost	(19,733)	(19,653)	(212,092)
Total shareholders' equity	354,444	326,616	3,809,587
Valuation and translation adjustments:			
Net unrealized holding gain on securities	10,362	8,208	111,371
Translation adjustments		(25,189)	(250,451)
Total valuation and translation adjustments		(16,981)	(139,080)
is an indication and translation adjustments	(12,370)	(10,501)	(133,000)
Minority interests	472	459	5,073
Total net assets (Note 24)	341,976	310,094	3,675,580
Total liabilities and net assets	¥540,762	¥501,853	\$5,812,145

# Consolidated Statements of Income

Shionogi & Co., Ltd. and Consolidated Subsidiaries Years ended March 31, 2010 and 2009

	Million	Millions of yen	
	2010	2009	2010
Net sales (Notes 21 and 26)	¥278,503	¥227,512	\$2,993,368
Cost of sales (Notes 17 and 21)	-	70,929	819,690
Gross profit		156,583	2,173,678
Selling, general and administrative expenses (Note 18)		124,568	1,610,071
Operating income (Note 26)		32,015	563,607
Other income (expenses):	32,436	32,013	303,007
Interest and dividend income	1,609	2,336	17,294
		(702)	(18,003)
Interest expense		(427)	
Loss on revaluation of inventories		, ,	(2,698)
		(89)	E7 E12
Gain on sale of business		_	57,513
Gain on exchange from business combination		212	52,666
Gain on sales of investments in securities (Note 5)		213	(20.004)
Impairment loss on devaluation of investments in securities (Note 5)		_	(20,884)
Impairment loss on fixed assets (Note 13)		(700)	(2,150)
Special contract expenses (Note 19)		(700)	_
Special retirement expenses		(363)	_
Casualty losses (Note 20)		(254)	_
Loss on sales of investments in securities (Note 5)		(25)	_
Other, net		(1,218)	(18,143)
	6,103	(1,229)	65,595
Income before income taxes and minority interests	58,541	30,786	629,202
Income taxes (Note 14):			
Current	21,146	14,718	227,278
Deferred	(1,246)	369	(13,392)
	19,900	15,087	213,886
Income before minority interests	38,641	15,699	415,316
Minority interests	15	38	161
Net income (Note 24)	¥ 38,626	¥ 15,661	\$ 415,155

# Consolidated Statements of Changes in Net Assets

Shionogi & Co., Ltd. and Consolidated Subsidiaries Years ended March 31, 2010 and 2009

					Millions	of yen				
	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gain on securities	Translation adjustments	Total valuation and translation adjustments	Minority interests	Total net assets
Balance at March 31, 2008	¥21,280	¥20,227	¥297,812	¥ (19,281)	¥320,038	¥ 22,068	¥ (178)	¥ 21,890	¥308	¥342,236
Net income	_	_	15,661	_	15,661	_	_	_	_	15,661
Dividends	_	_	(8,711)	_	(8,711)	_	_	_	_	(8,711)
Purchases of treasury stock	_	_	_	(372)	(372)	_	_	_	_	(372)
Other changes	_	_	_	_	_	(13,860)	(25,011)	(38,871)	151	(38,720)
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

-				-	Thousands of c	dollars (Note 3)				
_	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gain on securities	Translation adjustments	Total valuation and translation adjustments	Minority interests	Total net assets
Balance at March 31, 2009	\$228,719	\$ 217,401	\$ 3,275,602	\$ (211,232)	\$ 3,510,490	\$ 88,220	\$ (270,733)	\$ (182,513)	\$4,933	\$ 3,332,910
Net income	_	_	415,155	_	415,155	_	_	_	_	415,155
Dividends	_	_	(115,198)	_	(115,198)	_	_	_	_	(115,198)
Purchases of treasury stock	_	_	_	(860)	(860)	_	_	_	_	(860)
Other changes	_	_	_	_	_	23,151	20,282	43,433	140	43,573
Balance at March 31, 2010	\$228,719	\$217,401	\$3,575,559	\$(212,092)	\$3,809,587	\$111,371	\$(250,451)	\$(139,080)	\$5,073	\$3,675,580

# Consolidated Statements of Cash Flows

Shionogi & Co., Ltd. and Consolidated Subsidiaries Years ended March 31, 2010 and 2009

	Million	ns of yen	Thousands of U.S. dollars (Note 3)
	2010	2009	2010
Operating activities			
Income before income taxes and minority interests	¥ 58,541	¥ 30,786	\$ 629,202
Adjustments for:			
Depreciation and amortization		13,468	193,981
Impairment loss on fixed assets		_	2,150
Amortization of goodwill		907	40,101
Gain on sale of business		_	(57,513)
Impairment loss on devaluation of investment securities		_	20,884
Write-off of purchased in-process research and development costs		9,669	(
Gain on exchange from business combination		(188)	(52,666)
Increase (decrease) in accrued retirement benefits		(2,802)	18,164
Interest and dividend income		(2,336)	(17,294)
Interest expense	•	702	18,003
Other	1,438	938	15,456
Changes in operating assets and liabilities:	(4 7 40)	(2.440)	(=0.046)
Notes and accounts receivable		(2,419)	(50,946)
Inventories	,	(7,361)	(84,544)
Other current assets.		(2,756)	60,341
Notes and accounts payable		1,393	(22,528)
Accrued expenses		(3,823)	(68,981)
Other current liabilities		3,867	71,012
Subtotal		40,045	714,822
Interest and dividends received		2,386	17,691
Interest paid	,	(780)	(16,262)
Income taxes paid		(12,531)	(147,657)
Net cash provided by operating activities	52,902	29,120	568,594
Investing activities			
Increase in short-term investments		(4,233)	(56,245)
Proceeds from sales and redemption of short-term investments		8,094	103,687
Increase in investments in securities		(5,583)	(47,238)
Proceeds from sales and redemption of investments in securities		18,345	53,740
Purchases of property, plant and equipment		(11,200)	(141,402)
Increase in investment in an affiliate	(3,203)	(1,921)	(34,426)
Acquisition of investment in subsidiaries resulting in change in scope of			
consolidation (Note 23)	(2,506)	(146,767)	(26,935)
Proceeds from sales of investments in a subsidiary resulting in change			
in scope of consolidation (Note 23)			86,984
Other		(5,791)	52,957
Net cash used in investing activities	(826)	(149,056)	(8,878)
Financing activities			
(Decrease) increase in short-term bank loans, net	(10,000)	10,000	(107,481)
Proceeds from long-term debt	988	105,000	10,619
Repayment of long-term debt	(14,000)	_	(150,473)
Proceeds from bond issuance		_	322,442
Purchases of treasury stock	(80)	(372)	(860)
Repayment of installment accounts payable		(746)	(11,092)
Cash dividends paid	(10,702)	(8,702)	(115,026)
Issuance of shares of common stock to minority shareholders of			
consolidated subsidiaries		116	_
Other		(2)	(1,644)
Net cash (used in) provided by financing activities	(4,979)	105,294	(53,515)
Effect of exchange rate changes on cash and cash equivalents		(1,431)	(10,425)
Net increase (decrease) in cash and cash equivalents	46,127	(16,073)	495,776
Cash and cash equivalents at beginning of year	51,536	67,609	553,912
Cash and cash equivalents at end of year	¥ 97,663	¥ 51,536	\$1,049,688

# 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.

Certain reclassifications of previously reported amounts have been made to conform the consolidated financial statements for the year ended March 31, 2009 to the 2010 presentation. Such reclassifications had no effect on consolidated net income or net assets.

# 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 and two affiliates for the years ended March 31, 2010 and 2009, respectively.

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.

Most of the overseas consolidated subsidiaries close their accounts on December 31 and one closes its accounts on September 30. These year ends differ from that of the Company. The company whose year end date is September 30 prepares the financial statements as of and for the year ended December 31 solely for consolidation purposes. As a result, adjustments have been made for any significant intercompany transactions which took place during the period from January 1 to March 31.

# (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 net assets in the consolidated balance sheets.

# 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 has 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 (\$6,793 thousand), operating income decreased by ¥67 million (\$720 thousand) and income before income taxes and minority interests increased by ¥9 million (\$97 thousand) 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-to-maturity 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 net assets. Non-marketable securities classified as other securities are carried at cost determined by the moving average method. Investments in investment partnerships are stated at the amount of net assets attributable to the ownership percentage of the Company.

#### (e) Inventories

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

#### Change in accounting policy

Effective April 1, 2008, the Company and its domestic consolidated subsidiaries adopted "Accounting Standard for Measurement of Inventories" (Accounting Standards Board of Japan ("ASBJ") Statement No. 9 issued on July 5, 2006). This standard requires that inventories held for sale in the ordinary course of business be measured at the lower of cost or net selling value, which is defined as the selling price less additional estimated manufacturing costs and estimated direct selling expenses. The replacement cost may be used in place of the net selling value, if appropriate.

As a result of this change, operating income decreased by ¥316 million and income before income taxes decreased by ¥135 million for the year ended March 31, 2009 from the corresponding amounts which would have been recorded under the previous method.

# (f) 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.

# Supplemental information

Effective the year ended March 31, 2009, the Company and its domestic consolidated subsidiaries changed the useful lives of machinery and equipment as allowed under the revisions of the Corporation Tax Law. The effect of this change was to decrease depreciation expense by ¥423 million and increase operating income and income before income taxes by the same amount for the year ended March 31, 2009 from the corresponding amounts which would have been recorded under the previous method.

# (g) Intangible assets (other than leased assets)

Intangible assets are amortized by the straight-line method.

#### (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.

#### Change in accounting policy

Effective the year ended March 31, 2009, the Company and its domestic consolidated subsidiaries applied "Accounting Standard for Lease Transactions" (ASBJ Statement No.13 issued on March 30, 2007) and "Guidance on Accounting Standard for Lease Transactions" (ASBJ Guidance No.16 issued on March 30, 2007). Under this accounting standard, finance lease transactions that do not transfer ownership, which had previously been accounted for as operating leases, are capitalized and recognized as fixed assets. As a result, leased assets of ¥3 million, which are included in property, plant and equipment, were recognized. There was no impact on operating income and income before income taxes and minority interests.

#### (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 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 consolidated subsidiaries have defined contribution pension plans.

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 (\$1,182 thousand) was reclassified to other long-term liabilities at March 31, 2010.

## Change in accounting policy

Effective from the year ended March 31, 2010, the Company has 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 interest. 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 assets and liabilities and interest rates of loans. Hedging instruments are forward foreign currency exchange contracts and interest rate swap agreements. Hedged items are foreign currency assets and liabilities 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.

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.

# (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 29.)

#### 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 ¥93.04 = U.S.\$1.00, the approximate rate of exchange in effect on March 31, 2010. 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) Application of accounting standards for business combinations

Effective the year ended March 31, 2010, the Company has 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).

# (b) Accounting treatment of overseas subsidiaries

Effective the year ended March 31, 2009, the Company and its consolidated subsidiaries applied "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for the Consolidated Financial Statements" (ASBJ Practical Issues Task Force (PITF) No.18, May 17, 2006) and made necessary adjustments in the consolidation process. The effect of this change was to decrease operating income and income before income taxes by ¥906 million for the year ended March 31, 2009 from the corresponding amounts which would have been recorded under the previous method.

# 5. Short-Term Investments and Investments in Securities

(1) Marketable securities classified as held-to-maturity debt securities at March 31, 2010 and 2009 were as follows:

	Millions of yen					
	2010					
	Carrying value	Gross unrealized gain	Gross unrealized loss	Fair value		
Government bonds,						
municipal bonds, etc	¥20	¥—	¥—	¥20		

	Millions of yen					
	2009					
	Carrying value	Gross unrealized gain	Gross unrealized loss	Fair value		
Government bonds,						
municipal bonds, etc	¥20	¥—	¥O	¥20		

	Thousands of U.S. dollars			
	2010			
	Carrying value	Gross unrealized gain	Gross unrealized loss	Fair value
Government bonds,				
municipal bonds, etc	\$215	<b>\$</b> —	<b>\$</b> —	\$215

(2) Marketable securities classified as other securities at March 31, 2010 and 2009 were as follows:

	Millions of yen			
	2010			
	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

	Millions of yen			
	2009			
	Acquisition cost	Gross unrealized gain	Gross unrealized loss	Carrying value
Equity securities	¥21,003	¥13,870	¥(761)	¥34,112
Government bonds,				
municipal bonds, etc	19,856	784	(8)	20,632
Other securities	10,022	_	(74)	9,948
	¥50,881	¥14,654	¥(843)	¥64,692

	Thousands of U.S. dollars			
	2010			
	Acquisition cost	Gross unrealized gain	Gross unrealized loss	Carrying value
Equity securities	\$288,317	\$181,621	\$(3,257)	\$466,681
Government bonds,				
municipal bonds, etc	207,567	5,793	(150)	213,210
Other securities	53,740	3,332	_	57,072
	\$549,624	\$190,746	\$(3,407)	\$736,963

(3) Proceeds from sales of, and gross realized gain and loss on, held-to-maturity debt securities for the year ended March 31, 2009 is summarized as follows:

	Millions of yen
	2009
Proceeds from sales	¥18,197
Gross realized gain	213
Gross realized loss	(25)

(4) Proceeds from sales of, and gross realized gain and loss on, other securities for the year ended March 31, 2009 is summarized as follows:

	Millions of yen
	2009
Proceeds from sales	¥2
Gross realized gain	1
Gross realized loss	_

(5) The carrying value of investments in non-marketable securities at March 31, 2009 is summarized as follows:

	Millions of yen
	2009
Other securities:	
Unlisted equity securities	¥2,592

(6) Impairment of marketable securities

Impairment losses are 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 has recognized an impairment loss on devaluation of investment in securities of ¥1,943 million (\$20,884 thousand) for the year ended March 31, 2010.

(7) Change in holding purpose of securities

During the year ended March 31, 2009, the Company sold a certain portion of its held-to-maturity debt securities prior to maturity. Under "Practical Guideline of Accounting Standards for Financial Instruments," the Company was required to transfer the remaining held-to-maturity debt securities to other securities. As a result, all remaining held-to-maturity debt securities totaling ¥20,144 million were transferred to other securities due to change in holding purpose of securities.

The effect of this transfer was to increase short-term investments by ¥19 million, investments in securities by ¥219 million and net unrealized holding gain on securities by ¥141 million as of March 31, 2009 as compared to the corresponding amounts which would have been recorded under the previous categorization.

#### 6. Inventories

Inventories at March 31, 2010 and 2009 were as follows:

	Million	s of yen	Thousands of U.S. dollars
	2010	2009	2010
Merchandise	¥ 4,339	¥ 3,239	\$ 46,636
Finished goods	16,744	12,770	179,966
Semi-finished goods and			
work in process	19,908	17,180	213,972
Raw materials and			
supplies	8,350	9,839	89,746
	¥49,341	¥43,028	\$530,320

# 7. Short-Term Bank Loans and Long-Term Debt

The annual average interest rate applicable to short-term bank loans at March 31, 2009 was 1.1%.

Long-term debt at March 31, 2010 and 2009 consisted of the following:

	Millio	ons of yen	Thousands of U.S. dollars
	2010	2009	2010
Unsecured loans from			
banks and financial			
institutions due			
through 2019 with			
an average interest			
rate of 1.3%	¥ 91,000	¥ 105,000	\$ 978,0745
Unsecured bonds due			
in 2012 with an			
average interest rate			
of 0.8%	10,000	_	107,481
Unsecured bonds due			
in 2014 with an			
average interest rate			
of 1.1%	20,000		214,961
	121,000	105,000	1,300,516
Less current portion	(14,000)	(14,000)	(150,473)
	¥107,000	¥ 91,000	\$1,150,043

The aggregate annual maturities of long-term debt subsequent to March 31, 2010 are summarized as follows:

Year ending March 31,	Millions of yen	Thousands ( U.S. dollars	
2011	¥ 14,000	\$ 150,47	73
2012	14,000	150,47	73
2013	24,000	257,95	54
2014	39,000	419,17	75
2015	20,000	214,96	51
2016 and thereafter	10,000	107,48	30
	¥121,000	\$1,300,51	16

# 8. Installment Accounts Payable

The current portion of installment accounts payable was included in "Other current liabilities" at March 31, 2009. The current and long-term portions of installment accounts payable at March 31, 2009 were as follows:

	Millions o	f yen
	2009	
Current portion	¥	748
Long-term portion		573
	¥	1,321

# 9. Pledged Assets

Assets pledged as collateral at March 31, 2010 were as follows:

	Millions of yen	Thousands of U.S. dollars
	2010	2010
Cash and cash equivalents	¥7	\$75

The corresponding liabilities secured by such collateral at March 31, 2010 were as follows:

	Millions of yen	Thousands of U.S. dollars
	2010	2010
Deposits received from employees		
(included in "Other current liabilities")	¥7	\$75

# 10. Contingent Liabilities

The Company was contingently liable for the guarantee of employees' housing loans of ¥29 million (\$312 thousand) at March 31, 2010.

# 11. 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, 2010 and 2009 amounted to ¥5,388 million (\$57.911 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, 2010 and 2009 are summarized as follows:

		Number	of shares	•
		20	10	
	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
		Number	of charac	
		20	09	
	March 31, 2008	Increase	Decrease	March 31, 2009
Issued shares of				
common stock	351,136,165	_	_	351,136,165

The Company has purchased 41,420 shares and 176,697 shares of common stock from shareholders who had fractional shares of less than one unit for the years ended March 31, 2010 and 2009, respectively.

176,697

16,189,825

16,013,128

Treasury stock ......

#### 12. 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 nine years, at the longest, subsequent to March 31, 2010.

Derivative transactions are made for hedging foreign currency fluctuation risk of trade receivables and trade payables denominated in foreign currencies by using forward foreign exchange 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 March 31, 2010 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 for hedging to mitigate fluctuation risk identified by each foreign currency of trade receivables payables. 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 (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 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

53 percent of outstanding trade receivables at March 31, 2010 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 sheet as of March 31, 2010, their fair values and their differences are shown in the following table. The following table does not include financial instruments for which it is extremely difficult to determine the fair value.

	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				
investments in securities	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 payable	30,000	30,404	404	
Long-term loans	77,000	77,049	49	
Total liabilities	¥132,706	¥133,162	¥456	

	Tho	ousands of U.S. doll	ars	
	2010			
	Carrying value	Fair value	Difference	
Cash and cash equivalents	\$1,049,688	\$1,049,688	\$ —	
Notes and accounts				
receivable-trade and				
affiliates	853,558	852,558	(1,000)	
Short-term investments and				
investments in securities	759,415	759,415		
Total assets	\$2,662,661	\$2,661,661	\$(1,000)	
Notes and accounts				
payable-trade	\$ 125,817	\$ 125,817	\$ —	
Current portion of				
long-term debt	150,473	150,505	32	
Long-term debt:				
Bonds payable	322,442	326,784	4,342	
Long-term loans	827,601	828,128	527	
Total liabilities	\$1,426,333	\$1,431,234	\$ 4,901	

# (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.
- 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 price 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 payable

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

# **Derivative transactions**

Please refer to Note 25 "Derivative Transactions."

# (b) Financial instruments for which it is extremely difficult to determine the fair value

	Millions of yen	Thousands of U.S. dollars
	2010	2010
Unlisted equity securities, exclusive of		
over-the-counter securities	¥7,760	\$83,405

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, 2010.

	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	¥ 97,663	¥ —	¥ —	¥ —	
Notes and accounts					
receivable-trade					
and affiliates	75,950	2,310	1,155	_	
Short-term investments					
and investments in					
securities:					
Bonds held to maturity	20	_	_	_	
Other securities with					
maturity dates	6,527	10,238	5,142		
Total	¥180,160	¥12,548	¥6,297	¥ —	
		Thousands of	U.S. dollars  Due after		

	Thousands of U.S. dollars			
		Due after	Due after	
	Due in 1 year	1 year through	,	Due after
	or less	5 years	10 years	10 years
Cash and				
cash equivalents	\$1,049,688	s —	\$ —	\$ —
Notes and accounts				
receivable-trade				
and affiliates	816,316	24,828	12,414	_
Short-term investments				
and investments in				
securities:				
Bonds held to maturity	215	_	_	_
Other securities with				
maturity dates	70,152	110,039	55,267	_
Total	\$1,936,371	\$134,867	\$67,681	\$ —

Effective from the year ended March 31, 2010, the Company and its consolidated subsidiaries have 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).

# 13. Impairment Loss on Fixed Assets

The Company and its consolidated subsidiaries group fixed assets used for business assets based on its management segment such as by product lines. They also group assets for rent and idle assets individually.

Because a contract related to exclusive marketing rights for ethical pharmaceutical products will be cancelled in the next fiscal year, the Company has reduced its carrying value of ¥200 million (\$2,150 thousand) to its recoverable value of zero and recognized impairment loss of ¥200 million (\$2,150 thousand) for the year ended March 31, 2010.

Loss on impairment of fixed assets for the year ended March 31, 2010 is summarized as follows:

			Millions of yen	Thousands of U.S. dollars
Location	Use	Classification	2010	2010
	Exclusive marketing			
Chuo-ku,	rights for ethical			
Osaka Prefecture	pharmaceutical	Marketing		
and other	products	rights	¥200	\$2,150

#### 14. 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, 2010 and 2009.

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, 2010 and 2009 differ from the above statutory tax rate for the following reasons:

	2010	2009
Statutory tax rate	40.6%	40.6%
Expenses not deductible for		
income tax purposes	1.8	4.0
Dividends not taxable for		
income tax purposes	(1.2)	(8.0)
Amortization of goodwill	2.2	1.0
Inhabitants' per capita taxes	0.2	0.4
Tax credits	(10.8)	(8.6)
Difference in statutory tax rates		
of overseas subsidiaries	(0.4)	1.1
Consolidation adjustment for the		
sales of a consolidated subsidiary	2.3	_
In-process R&D costs	_	11.1
Change in valuation allowance	(0.3)	_
Other	(0.4)	0.2
Effective tax rates	34.0%	49.0%

The tax effects of temporary differences at March 31, 2010 and 2009 which gave rise to significant deferred tax assets and liabilities are presented below:

	Millions	of yen	Thousands of U.S. dollars
	2010	2009	2010
Deferred tax assets:			
Allowance for employees'			
bonuses	¥ 2,398	¥ 2,107	\$ 25,774
Retirement benefits	_	63	_
Accrued enterprise taxes	1,354	796	14,553
Research and			
development costs	2,617	2,541	28,128
Reserve for sales rebates	276	347	2,966
Loss on revaluation of			
investments in securities	520	440	5,589
Tax loss carry forwards			
of a consolidated			
subsidiary	753	362	8,093
Accrued expenses and			
other current liabilities	1,215	_	13,059
Other	6,756	5,749	72,614
Valuation allowance	(2,147)	(754)	(23,076)
Total deferred tax assets	13,742	11,651	147,700
Deferred tax liabilities:			
Unrealized gain on			
other securities	(7,077)	(5,610)	(76,064)
Marketing rights	(7,307)	(4,628)	(78,536)
Specially recognized			
depreciation reserve			
fund	(121)	(189)	(1,301)
Prepaid pension costs	(6,339)	(7,087)	(68,132)
Investments in securities	(2,581)	_	(27,741)
Other	(255)	(2,850)	(2,740)
Total deferred tax liabilities	(23,680)	(20,364)	(254,514)
Net deferred tax liabilities	¥ (9,938)	¥ (8,713)	\$(106,814)

#### 15. Leases

The Company and its consolidated subsidiaries lease principally equipment and vehicles and have entered into a number of finance lease contracts that do not transfer the ownership of the leased property to the Company and its consolidated subsidiaries.

The following pro forma amounts represent the acquisition costs, accumulated depreciation and net book value of the property leased to the Company and its consolidated subsidiaries at March 31, 2010 and 2009, 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 Company and its consolidated subsidiaries (which were accounted for as operating leases) had been capitalized:

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

		Millions of yen	
	2009		
	Acquisition costs	Accumulated depreciation	Net book value
Machinery, equipment			
and vehicles	¥ 800	¥ 674	¥126
Other	1,397	1,004	393
Total	¥2,197	¥1,678	¥519

	Thousands of U.S. dollars				
	2010				
	Acquisition Accumulated Net boo costs depreciation value				
Machinery, equipment					
and vehicles	\$312	\$290	\$ 21		
Other	505	333	172		
Total	\$817	\$623	\$193		

Depreciation of the leased assets, which is computed by the straight-line method over the respective lease terms assuming a nil residual value, amounted to ¥476 million (\$5,116 thousand) and ¥501 million for the years ended March 31, 2010 and 2009, respectively.

Finance lease payments of the Company and its consolidated subsidiaries for the years ended March 31, 2010 and 2009 were as follows:

	Millions	of yen	Thousands of U.S. dollars
	2010	2009	2010
Lease payments	¥476	¥501	\$5,116

Future minimum lease payments (including the interest portion thereon) subsequent to March 31, 2010 under finance lease transactions that do not transfer the ownership of the leased property to the Company and its consolidated subsidiaries are summarized as follows:

	Millions of yen	Thousands of U.S. dollars
Due within one year	¥ 9	\$ 97
Due after one year	9	97
Total	¥18	\$194

The acquisition costs and future minimum lease payments under finance leases presented in the above tables include the imputed interest expense.

There are no losses on impairment of leased assets for the years ended March 31, 2010 and 2009.

# **16. Retirement Benefits**

The following table sets forth the retirement benefit obligation, plan assets and the funded status of the Company's and its consolidated subsidiaries' defined benefit pension plans at March 31, 2010 and 2009:

	Millions	of yen	Thousands of U.S. dollars
_	2010	2009	2010
Retirement benefit			
obligation at			
end of year	¥(86,498)	¥(88,167)	\$(929,686)
Fair value of plan assets			
at end of year	89,013	80,639	956,717
Plan assets in excess of			
retirement benefit			
obligation	2,515	_	27,031
Unfounded status	_	(7,528)	_
Unrecognized			
actuarial loss	22,101	36,663	237,543
Unrecognized prior			
service costs	(8,282)	(10,956)	(89,015)
Net retirement benefit			
obligation	16,334	18,179	175,559
Prepaid pension costs	24,411	25,972	262,371
Accrued retirement			
benefits for employees	¥ (8,077)	¥ (7,793)	\$ (86,812)

The components of retirement benefit expenses for the years ended March 31, 2010 and 2009 are outlined as follows:

		Millior	ıs of yeı	1	ousands of
-		2010	.5 0. ye.	2009	 2010
Service cost	¥	1,865	¥	1,828	\$ 20,045
Interest cost		1,763		1,788	18,949
Expected return					
on plan assets		(2,530)		(3,891)	(27,193)
Amortization of					
actuarial loss		5,857		2,869	62,951
Amortization of					
prior service costs		(2,674)		(2,674)	(28,740)
Contributions to the					
defined contribution					
pension plan		1,045		825	11,232
Retirement benefit					
expenses	¥	5,326	¥	745	\$ 57,244

The assumptions used in accounting for the defined benefit pension plans for the years ended March 31, 2010 and 2009 were as follows:

	2010	2009
Discount rate	2.0%	2.0%
Expected rates of return on plan assets	3.1%	3.6%

# 17. Cost of Sales

Cost of sales included loss on devaluation of inventories of ¥474 million (\$5,095 thousand) and ¥317 million for the years ended March 31, 2010 and 2009, respectively.

# 18. Research and Development Expenses

Research and development expenses included in selling, general and administrative expenses for the years ended March 31, 2010 and 2009 amounted to ¥51,808 million (\$556,836 thousand) and ¥52,822 million, respectively.

# 19. Special Contract Expenses

Special contract expenses represented payment for the extension of a sales license contract that stipulates the release of the obligation to dispose of the licensed products.

# 20. Casualty Losses

Casualty losses included construction costs for recovery and loss on disposal of inventories and fixed assets damaged by earthquakes.

# 21. Investment and Rental Properties

The Company and its consolidated subsidiaries own 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 ¥1,652 million (\$17,756 thousand) for the year ended March 31, 2010. The rental income is principally recorded in net sales and the rental expenses are principally recorded in cost of sales.

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

Millions of yen				
Carrying value			Fair value	
March 31, 2009	Net change	March 31, 2010	March 31, 2010	
¥6,398	¥(164)	¥6,234	¥25,960	
	Thousands	of U.S. dollars		
	Carrying value		Fair value	
March 31, 2009	Net change	March 31, 2010	March 31, 2010	
\$68,766	\$(1,763)	\$67,003	\$279,020	

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

Fair value at March 31, 2010 is 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 Company and its consolidated subsidiaries have 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, 2010 and 2009 are summarized as follows:

Transaction with a director

	Millions	of yen	Thousands of U.S. dollars
	2010	2009	2010
Shunjusha Co., Ltd.:			
Rent received —			
land and office building	¥ 45	¥ 45	\$ 484
Rent expense-building	143	143	1,537
Management fee for			
leased property	3	4	32

Shunjusha Co., Ltd. is 99.9% directly owned by a relative of a director of the Company and has been engaged in the real estate leasing business. Shunjusha Co., Ltd. is located in Chuo-ku, Osaka with a capital amount of \$701 million (\$7,534 thousand) and \$701 million as of March 31, 2010 and 2009, 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, 2010 and 2009.

Effective the year ended March 31, 2009, the Company adopted "Accounting Standard for Related Party Disclosures" (ASBJ Statement No.11 issued on October 17, 2006) and "Guidance on Accounting Standard for Related Party Disclosures" (ASBJ Guidance No.13 issued on October 17, 2006).

As a result of the adoption of this accounting standard, transactions involving the Company, its consolidated subsidiaries or affiliates and any related parties were disclosed effective the year ended March 31, 2009.

# 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 are summarized as follows:

	Millions of ye	en		ands of dollars
	2010 20		20	10
Current assets	¥ 4	7	\$	505
In-process research and development costs	2,82	9	3	0,406
Goodwill	1,06	3	1	1,425
Current liabilities	(14	(141) (1,51		1,515)
Non-current liabilities	(770) (8,2		8,276)	
Interest which the Company				
already owned	(33	80)	(	3,547)
Acquisition cost	¥2,69	8	\$ 2	8,998
Net of advance payments	(14	6)	(	1,569)
Cash and cash equivalents of Addrenex	(4	6)		(494)
Cash disbursement	¥2,50	16	\$ 2	6,935

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		ousands of .S. dollars
	2010		2010
Current assets	¥ 4,187	\$	45,002
Non current assets	11,556		124,205
Current liabilities	(2,378)	(25,559)	
Non-current liabilities	(10,599)	(113,919)	
Expenses for sale of shares of Bushu	438		4,708
Gain on sale of business	5,351		57,513
Sales amount of shares of Bushu	¥ 8,555	\$	91,950
Cash and cash equivalents of Bushu	(462)		(4,966)
Proceeds from sale of investment	¥ 8,093	\$	86,984

On October 9, 2008, the Company purchased shares of Sciele Pharma, Inc. ("Sciele" currently, Shionogi Pharma, Inc.)

and initially consolidated the accounts of Sciele as of and for the year ended March 31, 2009. The assets and liabilities included in consolidation were summarized as follows:

	Millions of yen
•	2009
Current assets	¥ 27,051
Intangible assets	44,525
In-process research and development costs	9,669
Goodwill	79,664
Other non-current assets	2,228
Current liabilities	(13,446)
Non-current liabilities	(5,076)
Foreign currency translation adjustment	11,998
Acquisition cost	¥156,613
Cash and cash equivalents of Sciele	(9,846)
Cash disbursement	¥146,767

# 24. Amounts per Share

Amounts per share as of and for the years ended March 31, 2010 and 2009 were as follows:

	Ye	U.S. dollars	
	2010	2009	2010
Net income	¥ 115.33	¥ 46.75	\$ 1.24
Net assets	1,019.71	924.43	10.96
Cash dividends applicable			
to the year	36.00	28.00	0.39

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

Net income per share has been 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, 2010 and 2009 in the table above is summarized as follows:

	Millions	Thousands of U.S. dollars	
_	2010	2009	2010
Information used in			
computation of basic			
net income per share:			
Net income	¥38,626	¥15,661	\$415,155
		Thousands of shares	
		2010	2009
Weighted-average number of	shares of		
common stock outstanding		334,915	335,022

The financial data used in the computation of net assets per share at March 31, 2010 and 2009 in the above table is summarized as follows:

	Millions of yen		Thousands of U.S. dollars
_	2010	2009	2010
Total net assets  Amounts deducted from total net assets  (Amounts attributed to	¥341,976	¥310,094	\$3,675,580
minority interests in total net assets):  Net assets used in the calculation of net	472	459	5,073
assets per share	¥341,504	¥309,635	\$3,670,507
		Thousand	ds of shares
		2010	2009
Number of shares used in the of net assets per share		334.904	334.946

# 25. Derivative Transactions

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

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

# 2. Derivative transactions to which hedge accounting applies

Millions of yen

Contract value

(i) Currency-related transactions

Method of hedge accounting	Transaction	Principal hedged item	Notional amount	More than one year	Fair value
Forward foreign currency exchange rates applied to underlying transactions	Forward foreign currency exchange contracts Buying: EUR	Accounts payable- trade	¥133	¥—	(*)
			Thous	sands of U.S. do	llars
				2010	
				Contract value	
Method of hedge accounting	Transaction	Principal hedged item	Notional amount	More than one year	Fair value
Forward foreign currency exchange rates applied to underlying transactions	Forward foreign currency exchange contracts Buying: EUR	Accounts payable- trade	\$1,429	\$—	(*)

(\*): Since the forward foreign currency exchange contracts were accounted for by the allocation method (refer to Note 2(o)), their fair value is included in that of the accounts payable – trade disclosed in Note 12 "Financial Instruments."

# (ii) Interest rate-related transactions

				Millions of yen	
				2010	
				Contract value	
Method of hedge accounting	Transaction	Principal hedged item	Notional amount	More than one year	Fair value
Swap rates applied to	Interest rate swaps				
underlying debt	Pay: fixed/ Receive: floating	Long-term debt	¥25,000	¥25,000	(*)

			Thous	sands of U.S. do	lars
			2010		
				Contract value	
Method of hedge accounting	Transaction	Principal hedged item	Notional amount	More than one year	Fair value
Swap rates applied to	Interest rate swaps				
underlying	Pay: fixed/	Long-term			
debt	Receive: floating	debt	\$268,702	\$268,702	(*)

(\*): 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(o)), their fair value is included in that of the long-term debt disclosed in Note 12 "Financial Instruments."

# 26. Segment Information

The Company and its consolidated subsidiaries are engaged primarily in the manufacture and sale of pharmaceutical products and in related marketing activities in Japan and overseas, principally in North America and Asia, in two major segments.

The pharmaceuticals and related businesses includes more

than 90% of the total sales, operating income and total assets of all business segments. Therefore, the disclosure of business segment information has been omitted for the years ended March 31, 2010 and 2009.

The geographical segment information of the Company and its consolidated subsidiaries for the years ended March 31, 2010 and 2009 are outlined as follows:

_			Millions of	yen		
			2010	)		
	Japan	North America	Total	Eliminations or corporate Consolic		
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
I. Total assets	¥287,603	¥85,803	¥3,818	¥377,224	¥ 163,538	¥540,762
			Millions of	ven		
-			2009	·		
_					Eliminations or	
-	Japan	North America	Other	Total	corporate	Consolidate
Sales and operating income (loss):						
Sales to third parties	¥215,875	¥ 9,885	¥1,752	¥227,512	¥ —	¥227,512
Intragroup sales and transfers	436	3,253	56	3,745	(3,745)	_
Net sales	216,311	13,138	1,808	231,257	(3,745)	227,512
Operating expenses	175,916	21,072	1,348	198,336	(2,839)	195,497
Operating income (loss)	¥ 40,395	¥ (7,934)	¥ 460	¥ 32,921	¥ (906)	¥ 32,015
l. Total assets	¥276,221	¥ 67,846	¥3,741	¥347,808	¥154,045	¥501,853
_			Thousands of U	.S. dollars		
_			2010	)		
	Japan	North America	Other	Total	Eliminations or corporate	Consolidate
Sales and operating income:						
Sales to third parties	\$2,560,092	\$415,327	\$17,949	\$2,993,368	s —	\$2,993,368
Intragroup sales and transfers	4,439	31,459	624	36,522	(36,522)	
Net sales	2,564,531	446,786	18,573	3,029,890	(36,522)	2,993,368
Operating expenses	1,995,174	415,477	15,198	2,425,849	3,912	2,429,76
Operating income	\$ 569,357	\$ 31,309	\$ 3,375	\$ 604,041	\$ (40,434)	\$ 563,607

\$922,216

\$3,091,176

\$41,036

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

II. Total assets

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 has changed the

translation method of revenues and expenses of overseas subsidiaries using the average exchange rate for the fiscal year.

\$1,757,717

\$5,812,145

\$4,054,428

The effect of this change was to increase sales in the "North America" segment by ¥644 million (\$6,922 thousand) and to decrease sales in the "Other" segment by ¥11 million (\$118 thousand). In addition, this change was to increase operating expenses in the "North America" segment by ¥644 million (\$6,922 thousand), "Eliminations or corporate" by ¥62

million (\$666 thousand) and to decrease operating expenses in the "Other" segment by ¥7 million (\$75 thousand). Furthermore, this change was to decrease operating income by ¥0 million (\$0 thousand) in the "North America" segment, the "Other" segment by ¥4 million (\$43 thousand) and the "Eliminations or corporate" by ¥62 million (¥666 thousand) from the corresponding amount which would have been recorded under the previous method.

As described in Note 2(e), effective the year ended March 31, 2009, the Company has applied "Accounting Standard for Measurement of Inventories" (ASBJ Statement No. 9 issued on July 5, 2006). The effect of this change was to increase operating expenses in the "Japan" segment by ¥316 million and decrease operating income by the same amount for the year ended March 31, 2009 from the corresponding amounts which would have been recorded under the previous method.

As described in Note 2(h), effective the year ended March 31, 2009, the Company has applied "Accounting Standard for Lease Transactions" (ASBJ Statement No.13; Business Accounting Council Committee No.1 issued on June 17, 1993 revised on March 30, 2007) and "Guidance on Accounting Standard for Lease Transactions" (ASBJ Guidance No. 16; the Japanese Institute of Certified Public Accountants, Accounting Committee issued on January 18, 1994 revised on March 30, 2007). The effect of this change is to increase assets in the "Japan" segment by ¥3 million as at March 31, 2009 from the corresponding amount which would have been recorded under the previous method. There was no effect on operating expenses and income.

As described in Note 4, effective the year ended March 31, 2009, the Company has applied "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for the Consolidated Financial Statements" (ASBJ Practical Issues Task Force No.18 issued on May 17, 2006). The effect of this change was to increase operating expenses included in the "Eliminations and general corporate assets" segment by ¥906 million and decrease operating income by the same amount for the year ended March 31, 2009 from the corresponding amounts which would have been recorded under the previous method.

As described in Note 2(f), effective the year ended March 31, 2009, the Company and its consolidated subsidiaries have changed the useful lives of machinery and equipment. The effect of this change was to decrease operating expenses in the "Japan" segment by ¥423 million and increase operating income by the same amount for the year ended March 31, 2009 from the corresponding amounts which would have been recorded under the previous method.

Overseas sales for the years ended March 31, 2010 and 2009 are outlined as follows:

		Millions	of yon		
-	Millions of yen				
-	Europe North America Other		Total		
I. Overseas sales	¥51,040	¥44,653	¥4,149	¥ 99,842	
II. Consolidated net sales	_	_	_	¥278,503	
III. Overseas sales as a					
percentage of					
consolidated net sales	18.3%	16.0%	1.5%	35.8%	
-		Millions	of yen		
		200			
=	Europe Other		Total		
I. Overseas sales	¥36,180	) ¥18	3,306	¥ 54,486	
II. Consolidated net sales	_	-	_	¥227,512	
III. Overseas sales as a					
percentage of					
consolidated net sales	15.9%		3.0%	23.9%	
-		Thousands of			
-	2010				
-	Europe	North America	Other	Total	
I. Overseas sales	\$548,581	\$479,933	\$44,594	\$1,073,108	
II. Consolidated net sales	_	_	_	2,993,368	

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 were as follows:

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

Up to the year ended March 31, 2009, overseas sales had been categorized into "Europe" and "Other." Effective the year ended March 31, 2010, sales for "North America" are independently disclosed because sales of this category accounted more than 10% of the consolidated net sales. Overseas sales of "North America" for the year ended March 31, 2009 amounted to ¥14,567 million and represented 6.4% of consolidated net sales.

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 has 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 (\$6,922 thousand) and to decrease overseas sales to "Other" segment by ¥11 million (\$118 thousand), which resulted in the increase of consolidated net sales by ¥632 million (\$6,793 thousand) 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. Business Combinations

On October 9, 2008, the Company acquired all the outstanding shares of Sciele for \$1,446 million in cash. Sciele was engaged in research, development and sales of pharmaceuticals. The Company determined that the acquisition would enable it to enhance the market presence as well as sales structure in the United States of America, which would contribute to realizing the value of the Company's original products and ensure long-term growth in the future.

The acquisition was accounted for using the purchase method of accounting. Goodwill of \$718 million was recognized and to be amortized during the period of 20 years.

The assets acquired and liabilities assumed as of the acquisition date were as follows:

	Millions of yen	Thousands of U.S. dollars
Current assets	¥ 27,051	\$ 270,553
Non-current assets	126,418	1,264,309
Total assets	¥153,469	\$1,534,862
Current liabilities	13,446	134,478
Non-current liabilities	5,076	50,765
Total liabilities	¥ 18,522	\$ 185,243

The transaction was made in U.S. dollars and the amounts in yen in the above table represent amounts booked in the consolidated financial statements.

In connection with this acquisition, the Company allocated \$96 million and \$445 million from acquisition cost (see Note 23) to research and development cost and marketing rights, respectively. Marketing rights are being amortized over a period of 3 to 12 years.

The effect on the consolidated statement of income for the year ended March 31, 2009, assuming that this acquisition had been completed at April 1, 2008, was as follows:

	Millions of yen	Millions of U.S. dollars	
	(Unau	ited)	
Net sales	¥36,780	\$404	
Operating income	7,283	80	
Income before income taxes and			
minority interest	6,646	73	

These amounts represent the consolidated statement of income for the year ended December 31, 2008 of Sciele and its consolidated subsidiaries. The exchange rate to Japanese yen amounts was ¥91.04 = U.S.\$1.00, the approximate rate of exchange in effect on December 31, 2008.

# 28. Litigation

In December 2007, the Company brought a patent infringement action jointly with AstraZeneca against seven generic drug companies (another company was added later) including Cobalt Pharmaceuticals, Inc. and Apotex, Inc., which had filed Abbreviated New Drug Applications for generic drugs of "Crestor," to prevent such companies from selling any generic drugs under the patent owned by the Company in the U.S.A. The trial was conducted from late February to early March 2010. A decision is expected to be made around June or July 2010.

Furthermore, in September 2009, the Company brought, in collaboration with AstraZeneca Canada, a patent infringement action against two companies, namely Novopharm Limited and Apotex, Inc., which had filed Abbreviated New Drug Applications for generic drugs of "Crestor" in Canada, to prevent such companies from selling any generic drugs under the patent owned by the Company in Canada.

In May 2008, a suit was brought against the Company in Osaka District Court by Cellectis SA who is the exclusive licensee of the patent owned by Institute Pasteur claiming that the use of the technology relating to the genetically modified mice for research would infringe the patent and the Company should pay ¥970 million (\$10,426 thousand). The suit is pending in court.

In February 2009, the Company brought a patent infringement action under its patent of the crystal of Cefcapene Pivoxil Hydrochloride monohydrate, the active ingredient of Flomox®, an antibiotic developed by the Company, against ITOCHU CHEMICAL FRONTIER Corporation, who is the importer of such active ingredient and simultaneously initiated the procedures to petition for a provisional deposition order thereunder.

Furthermore, in August 2009, the Company brought a patent infringement action against Sawai Pharmaceutical Co., Ltd. which had been selling a generic version of Flomox® since May 2009 and simultaneously initiated the procedures to petition for a provisional deposition order thereunder. 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 the abovementioned two companies as appellants.

# 29. 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, 2010, was approved at a shareholders' meeting held on June 24, 2010:

	Millions of yen	Thousands of U.S. dollars
	IVIIIIOTIS OT YELL	U.S. uoliais
Cash dividends		
(¥18.00 = U.S.\$0.19 per share)	¥6,028	\$64,789

# 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, 2010 and 2009, and the related consolidated statements of income, changes in net assets, and cash flows for the years then ended, 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, 2010 and 2009, 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, 2010 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, 2010

Ernst & Young Shim Nihon LLC

# Corporate Information (As of March 31, 2010)

Company Name Shionogi & Co., Ltd.

Established March 17, 1878

Incorporated June 5, 1919

Paid-in Capital ¥21,279,742,717

Website http://www.shionogi.co.jp/
Head Office 1-8, Doshomachi 3-chome,

Tel: +81-6-6202-2161 Fax: +81-6-6229-9596 **Number of Employees** Consolidated: 5,887

Non-consolidated: 4,124

**Category of Business** Marketing and manufacturing of drugs

Manufacture and sale of pharmaceutical products, diagnostics, and other related

products

Fiscal Year-End March 31

Net Sales Consolidated: ¥278,502 million,

Non-consolidated: ¥228,585 million (Year ended March 31, 2010)

Stock (Securities) Listings

**Common Stock** 

ctings Osaka, Tokyo (#4507)

Authorized: 1,000,000,000 shares

Issued: 351,136,165 shares Number of shareholders: 29,439

Chuo-ku, Osaka 541-0045, Japan

**Transfer Agent** 

Type of Business

The Sumitomo Trust & Banking Co., Ltd. Stock Transfer Agency Department,

5-33, Kitahama 4-chome,

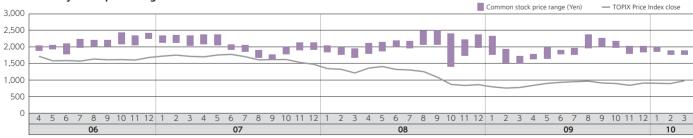
Chuo-ku, Osaka 541-0041, Japan

#### **Major Shareholders**

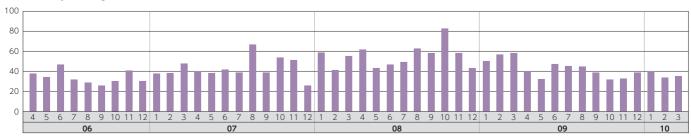
Name	Number of shares (Thousands)	Percentage of total shares
Japan Trustee Services Bank, Ltd. (trust account)	21,609	6.45
The Master Trust Bank of Japan, Ltd. (trust account)	20,261	6.04
Sumitomo Life Insurance Company	18,604	5.55
Nippon Life Insurance Company	13,138	3.92
JP Morgan Chase Bank 385147	10,126	3.02
JP Morgan Chase Bank 380055	10,109	3.01
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	6,657	1.98
Japan Trustee Services Bank, Ltd. (trust account 9)	6,596	1.96

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

#### Monthly stock price range



#### Monthly trading volume (Million shares)



# **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

#### **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**

SKÝ OÁSIS 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

Daisan Kouan Bldg., 13, Minami Nanajo Nishi 1-chome, Chuo-ku, Sapporo, Hokkaido 064-0807, Japan Tel: +81-11-530-0360

#### Laboratories

#### Shionogi Research Laboratories

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

# **Developmental Research Laboratories**

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

# **Plants**

#### **Settsu Plant**

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

## Kanegasaki Plant

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

#### iite

# **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**

#### Nichia Pharmaceutical Industries 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

#### 4 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

#### Shionogi General Service Co., Ltd.

Shionogi Doshomachi Bldg., Doshomachi 4-chome, Chuo-ku, Osaka 541-0045, Japan Tel: +81-6-6227-0815

#### Aburahi AgroResearch Co., Ltd.

1405, Gotanda, Koka-cho, Koka, Shiga 520-3423, Japan Tel: +81-748-88-3215

# Taiwan Shionogi & Co., Ltd.

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

# Shionogi Inc.

100 Campus Drive, Florham Park, NJ 07932, U.S.A. Tel: +1-973-966-6900

## Shionogi USA, Inc.

100 Campus Drive, Florham Park, NJ 07932, U.S.A. Tel: +1-973-966-6900

# Shionogi Pharma, Inc.

5 Concourse Parkway, Suite 1800, Atlanta, GA 30328, U.S.A. Tel: +1-800-461-3696









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





