

# Mission-Driven Leadership



**Annual Report**  
**2009**

CHUGAI PHARMACEUTICAL CO., LTD.

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## Forward-Looking Statements

This annual report includes forward-looking statements pertaining to the business and prospects of the Company. These statements reflect the Company's current analysis of existing information and trends. Actual results may differ from expectations based on risks and uncertainties that may affect the Company's businesses.

## Note:

The information regarding pharmaceuticals (including products under development) is not intended for advertising, promotion or medical advice. All trademarks are property of their respective holders.

# Mission-Driven Leadership

Our mission at Chugai is to add exceptional value through the creation of innovative medical products and services for the benefit of the medical community and human health around the world. This mission drives us to continually take on challenges that pave the way for new growth and to fulfill our responsibility as a life-science company as we strive to become Japan's top pharmaceutical company.



# Chugai Snapshot

Share of domestic  
oncology market (2009):

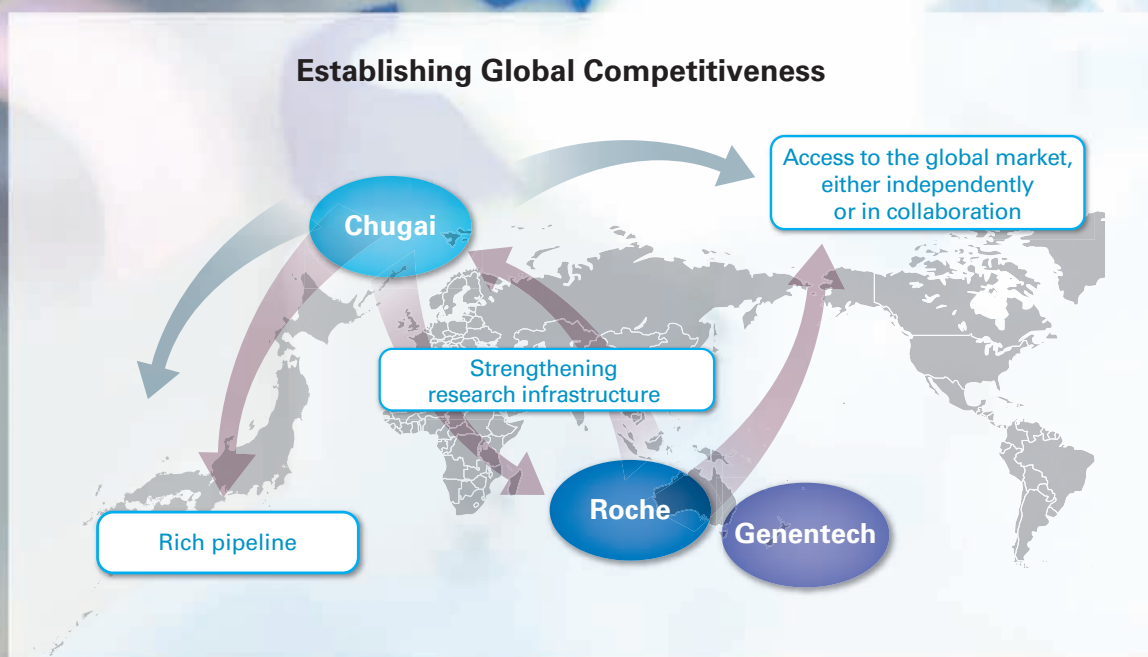
17.3%\*  
(No.1)

Share of domestic  
antibody drug market (2009):

43.2%\*  
(No.1)

Number of projects in pipeline  
(As of February 3, 2010):

34



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The scope of the market is defined by Chugai.

Revenue growth rate  
(Average for past three years):

14.7%

Operating income growth rate  
(Average for past three years):

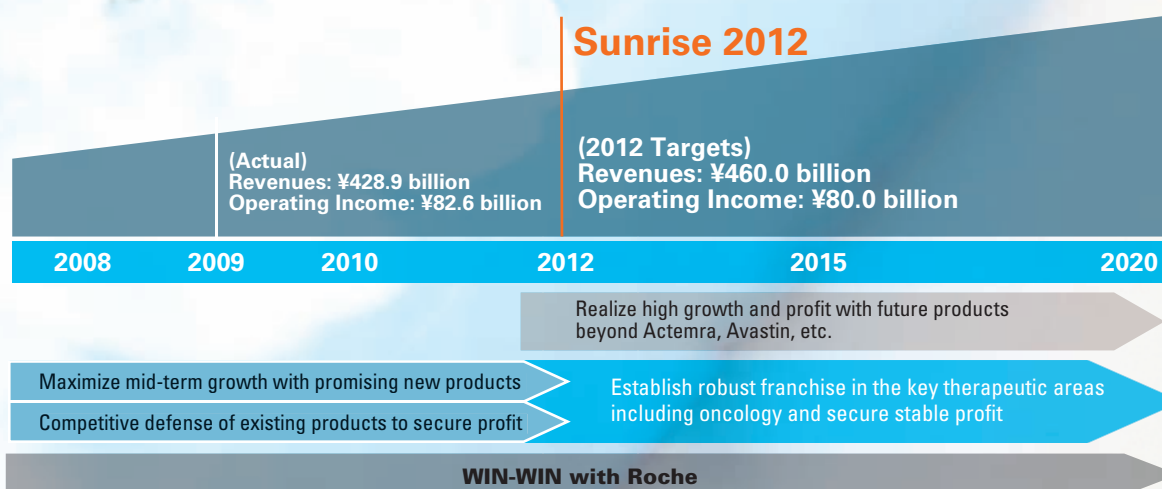
19.0%

Target payout ratio  
(Average):

40.0%

Through its partnership with Roche, Chugai has further enhanced its operating foundation and established strong global competitiveness. Annual growth in revenues and operating income has averaged more than 10 percent for the last three years. Our mainstay oncology and antibody drugs have secured the top share of the domestic market, and our development pipeline – the source of future growth – is one of the richest in Japan. With achievement of the quantitative targets of Sunrise 2012 as a waypoint, we aim to become Japan's top pharmaceutical company by continually creating innovative pharmaceuticals and meeting the expectations of patients and other stakeholders.

#### Medium-to-long-term Growth Strategy with Innovative Drugs



# Financial Highlights

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries / Years ended December 31

	Millions of yen (Except as otherwise specified)			Percent change	Thousands of U.S. dollars <sup>1</sup> (Except as otherwise specified)
	2009	2008	2007	2009/2008	2009
<b>Results for the year:</b>					
Revenues .....	¥428,947	¥326,938	¥344,808	31.2%	\$4,662,467
Operating income .....	82,613	51,563	66,703	60.2	897,967
Income before income taxes and minority interests .....	89,416	63,106	66,428	41.7	971,913
Net income .....	56,634	39,265	40,061	44.2	615,587
Research and development expenses .....	55,315	53,225	54,243	3.9	601,250
<b>Amounts per share (Yen and U.S. dollars):</b>					
Net income - basic .....	¥ 104.00	¥ 72.07	¥ 73.23	44.3%	\$ 1.13
Net income - diluted .....	103.98	72.04	73.16	44.3	1.13
Net assets .....	794.51	725.18	703.80	9.6	8.64
Cash dividends <sup>2</sup> .....	40.00	34.00	30.00	17.6	0.43
<b>Financial position at year-end:</b>					
Total assets .....	¥540,549	¥478,518	¥458,942	13.0%	\$5,875,533
Interest-bearing debt .....	154	305	775	(49.5)	1,674
Total net assets .....	434,687	397,067	385,798	9.5	4,724,859
Number of shares outstanding .....	559,685,889	559,685,889	559,636,061		
Number of employees .....	6,485	6,383	6,257		
<b>Ratios:</b>					
Operating income to revenues (%) .....	19.3	15.8	19.3		
Return on equity (%) <sup>3</sup> .....	13.7	10.1	10.4		
Shareholders' equity to total assets (%) .....	80.0	82.6	83.5		
Debt-to-equity ratio (%) <sup>4</sup> .....	0.0	0.1	0.2		
Interest coverage ratio (Times) <sup>5</sup> .....	4,620.0	517.5	461.9		
Research and development expenses to revenues (%) .....	12.9	16.3	15.7		

Notes: 1. The U.S. dollar amounts in the consolidated financial statements as of and for the year ended December 31, 2009 have been translated from Japanese yen amounts at the rate of ¥92 to U.S. \$1.00, the exchange rate prevailing on December 31, 2009.

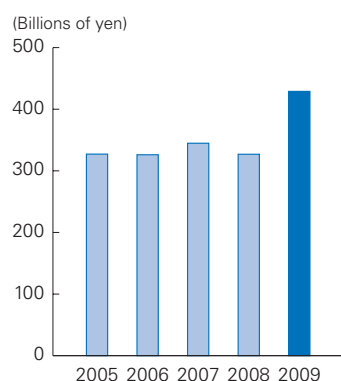
2. Dividends per share for 2009 include a special dividend of ¥6.00 per share.

3. Return on equity = Net income/Shareholders' equity (yearly average) x 100

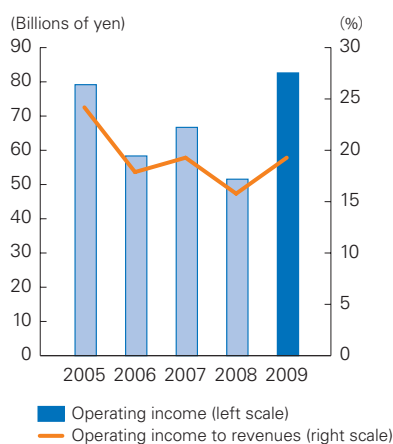
4. Debt-to-equity ratio = Interest-bearing debt (fiscal year-end)/Shareholders' equity (fiscal year-end) x 100

5. Interest coverage ratio = Net cash provided by operating activities (prior to deductions of interest paid and income taxes paid, and addition of income taxes refunded)/interest paid

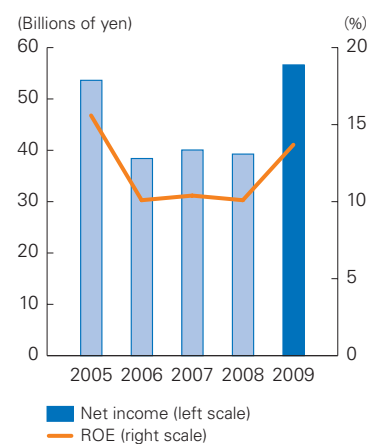
## Revenues



## Operating Income/ Operating Income to Revenues



## Net Income/Return on Equity



# 2009 in Brief

+31.2%

Revenues advanced 31.2 percent to ¥428.9 billion. In addition to strong revenue growth in oncology and bone and joint diseases, sales of Tamiflu expanded, reflecting the spread of the influenza A/H1N1 ("swine flu") virus.

+9.4%

Sales excluding Tamiflu increased 9.4 percent to ¥342.9 billion, surpassing the record set in 2008. Driving this increase was strong growth in sales of Avastin, Actemra and Herceptin.

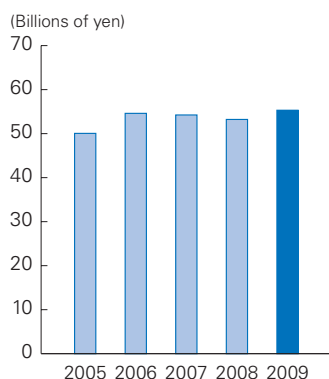
+60.1%

Cost of sales rose because Tamiflu, which has a relatively high cost-to-sales ratio, made up a larger portion of total sales. SG&A and R&D expenses also rose. Buoyed by strong sales growth, however, operating income increased 60.1 percent to a record ¥82.6 billion.

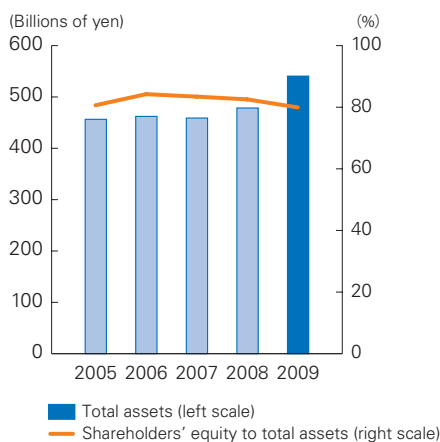
41.8%

Chugai's fundamental policy is to pay stable dividends to shareholders. Our goal is to maintain the payout ratio at around 40 percent on average, taking into account strategic funding needs and earnings prospects. In 2009, we paid an interim dividend of ¥17 per share and a year-end dividend of ¥23 per share (including a special dividend of ¥6), bringing total cash dividends to ¥40 per share for the year. The weighted average payout ratio over the past three years is 41.8 percent (38.5 percent in 2009).

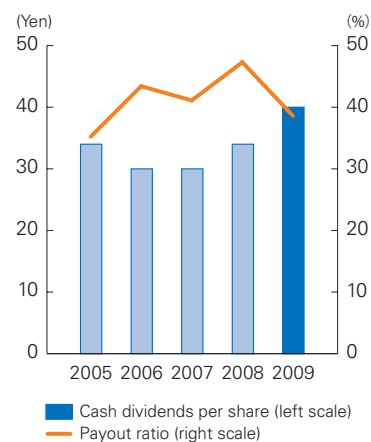
## Research and Development Expenses



## Total Assets/Shareholders' Equity to Total Assets



## Cash Dividends per Share/Payout Ratio



Note: Cash dividends per share for 2009 include a special year-end dividend of ¥6.00 per share. Cash dividends per share for 2005 include a special year-end dividend of ¥10.00 per share.

# Dear Shareholders and Investors



**Osamu Nagayama**

Representative Director,  
President and CEO

Chugai achieved record revenues and profits in 2009 as our measures to build the foundation for the next phase of growth under Sunrise 2012 began to yield results. Going forward, we will work to fulfill our mission as a leader in strategic fields and will increase our corporate value as we move toward our goal of becoming Japan's top pharmaceutical company.

## Performance in 2009

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### Record-High Financial Results

In 2009, Chugai achieved record highs in both revenues and operating income, led by the expansion of growth drivers and strong demand for Tamiflu due to the influenza A/H1N1 ("swine flu") pandemic and the increase in government stockpiles. Revenues increased 31.2 percent year-on-year to ¥428.9 billion and operating income rose 60.1 percent to ¥82.6 billion. Even excluding Tamiflu sales, which fluctuate significantly year-to-year, sales grew a substantial 9.4 percent to ¥342.9 billion. This performance is attributable to the rapid growth of new products and products approved with additional indications launched over the past several years, which are penetrating the market as planned and will form the foundation for future earnings.

Sales of Chugai's oncology products in Japan increased by a robust 20.9 percent, as sales of growth drivers including Avastin and Herceptin continued to expand. We increased the top market share we captured in Japan in 2008 by 1.5 percentage points to 17.3 percent<sup>1</sup> in 2009. In bone and joint diseases, Actemra, a product discovered and developed through Chugai research, made a significant contribution to our earnings. Domestic sales of Actemra increased

¥5.0 billion, or 147.1 percent, to ¥8.4 billion as it made steady inroads into the market. Outside Japan, sales of this product continued to grow strongly since its January 2009 launch as RoActemra in Europe. Overseas sales (exports to Roche) increased ¥5.1 billion, or 134.2 percent, to ¥8.9 billion. In renal diseases, we maintained sales at ¥61.0 billion, near the level of the previous year, as we stopped the downward trend in sales of mainstay product Epogin amid intense competition.

In addition to growth in operating income from the increase in product sales, other income also increased, mainly because of forward foreign exchange contracts used to hedge the risk associated with large foreign-currency transactions. As a result, net income rose 44.0 percent to a record ¥56.6 billion.

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## A Year of Enhancing Our Operations

In 2009, we steadily implemented initiatives to enhance our operations in research and development, sales, production and safety management.

These initiatives produced significant results. In research and development, four projects<sup>2</sup> received regulatory approval, including Actemra in Europe and Avastin for the additional indication of lung cancer. We

filed applications for five projects<sup>3</sup>, including ED-71 for osteoporosis, and started clinical trials for four new compounds.<sup>4</sup> Having completed launches of major projects licensed from Roche, such as Avastin and Tarceva, we are able to dedicate more resources to our own early-stage projects, thus improving our development capabilities. All of these achievements are due to the development of operations to achieve the original goal of our alliance with Roche: to make maximum use of the resources of the Roche Group and create new breakthrough drugs at centers of excellence in Japan, the United States and Europe. Because we target high growth from marketing innovative products worldwide, research and development is the most vital part of our business. We are pleased to see the continuous flow of drug candidates generated from our research, which is critical for our future growth. We also made steady progress in development in new fields such as diabetes and the central nervous system. All in all, it was a good year.

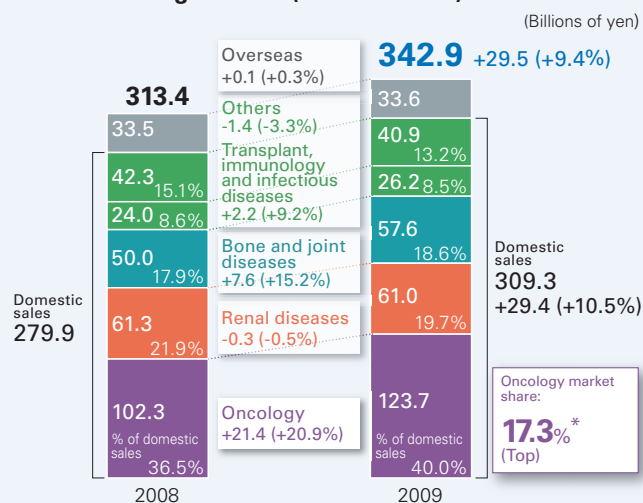
In sales, we established the Primary Unit to form a two-unit organizational structure together with the Oncology Unit. We believe this new structure has facilitated execution of product policies in each field. In oncology, where our robust lineup of products has gained the top market share in Japan, we increased

## 2009 Results

	2005*	2008	2009	YoY
(Billions of yen)				
Revenues	327.2	326.9	428.9	+31.2%
Operating income	79.2	51.6	82.6	+60.1%
% of revenues	24.2%	15.8%	19.3%	
Net income	53.6	39.3	56.6	+44.0%
% of revenues	16.4%	12.0%	13.2%	

\*Previous record profits

## Sales Excluding Tamiflu (2008 vs. 2009)



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the number of medical representatives (MRs) from 500 to 550 and further enhanced specialization by establishing the new position of Medical Associate (MA) to supply advanced scientific information.

In production, we integrated drug engineering, production planning, plant functions and other operations that had been dispersed among multiple departments into the new Pharmaceutical Technology Division. This structure will ensure consistency from product development through production.

To address global demand for more stringent safety measures, we restructured the Corporate Regulatory Compliance & Quality Assurance Division and established the Drug Safety Division to reinforce safety functions.

2. RoActemra (Rheumatoid arthritis: EU), Epogin (Partial change of API manufacturing method and pharmaceutical formulation), Avastin (Advanced or recurrent non-small cell lung cancer) and Xeloda (Advanced or recurrent colorectal cancer)
3. ED-71 (Osteoporosis), Epogin (Chemotherapy induced anemia), RG744 (Renal anemia), Avastin (Advanced or recurrent breast cancer) and Tarceva (Advanced or recurrent pancreatic cancer)
4. Actemra (Advanced or recurrent pancreatic cancer), RG1450 (Alzheimer's disease), RG3502 (Advanced or recurrent HER2-positive breast cancer) and NTZ (Chronic hepatitis C)

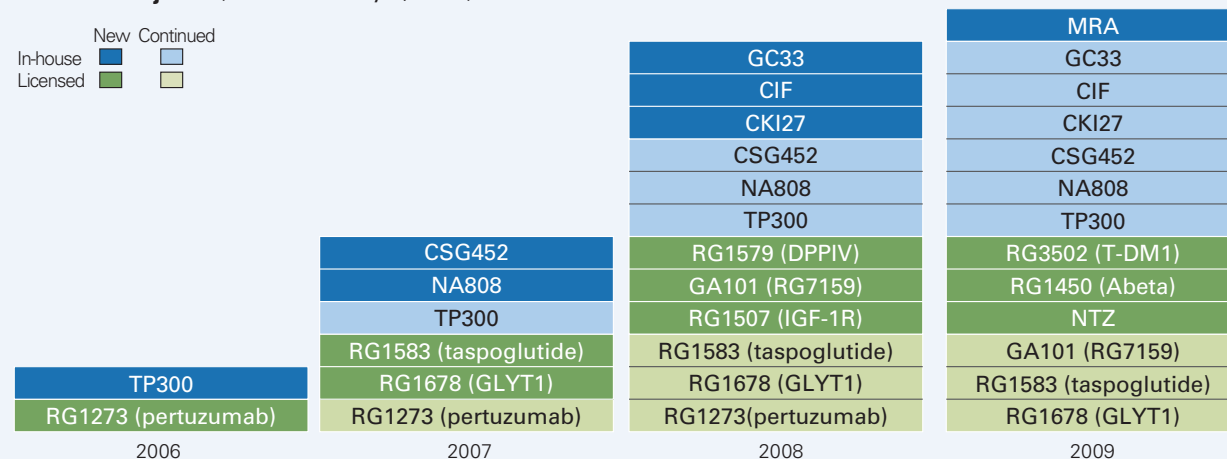
## Industry Environment and Our Position

### Creation of New Drugs Provides Major Growth Opportunities

In addition to ongoing government measures to reduce healthcare costs, pharmaceutical companies around the world are facing a host of challenges, including a shortage of new drug candidates, soaring R&D expenses and greater safety demands. Among these challenges, a wave of major patent expirations in and around 2010 is expected to have a substantial impact on the global pharmaceutical industry. In Japan, the government is implementing ongoing measures to expand the use of generics. At the same time, it has introduced measures to resolve the drug lag (the lengthy period required until new drugs launched overseas are approved in Japan). The National Health Insurance (NHI) drug price revision in April 2010 will include additional price cuts for long-listed drugs, or off-patent drugs for which generics are available. In addition, a premium to promote new drug development (the "promotional premium for new drug development") will be introduced on a trial basis.

In view of these conditions, pharmaceutical majors are concentrating their resources on areas of unmet medical needs that have high growth potential, and on development of antibodies and other biopharmaceuticals.

#### Pre-PoC Projects (As of February 3, 2010)



Competition to ensure future growth is intensifying, with companies aggressively making large acquisitions and other investments to secure new drug leads.

Chugai was among the earliest companies to focus on areas with unmet medical needs and high growth prospects such as biopharmaceuticals and oncology. Chugai has been a leader in biopharmaceutical research and development since initiating development of Epogin and Neutrogin in the 1980s. We discovered and developed Actemra, the first antibody drug originating in Japan, and successfully brought it to market as a global product. Having built a rich oncology-centered product portfolio through our alliance with Roche, we are now well ahead of our competitors in terms of biotechnological capabilities and development resources, and our share of the domestic market for antibody drugs has reached 43.2 percent. The impact of the new drug pricing system aimed at promoting the development of innovative new drugs will also give Chugai an advantage over competitors. Long-listed drugs account for a mere 20 percent of revenues, whereas new products that qualify for the promotional premium for new drug development make up more than 40 percent of revenues. The promotional premium for new drug development will enable faster recovery of R&D expenses and encourage reinvestment of those funds in subsequent new

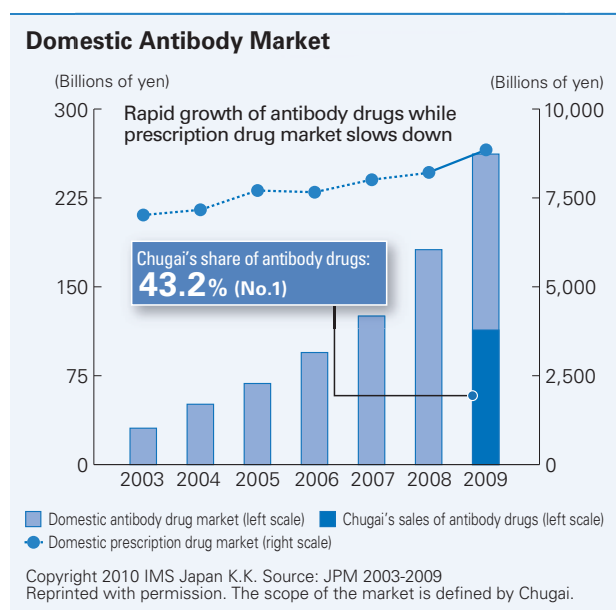


drug development. Having shifted our focus from long-lived products to growth from innovative drugs, and with a development portfolio that will underpin growth in the years ahead, Chugai is positioned to enjoy substantial benefits from this new system.

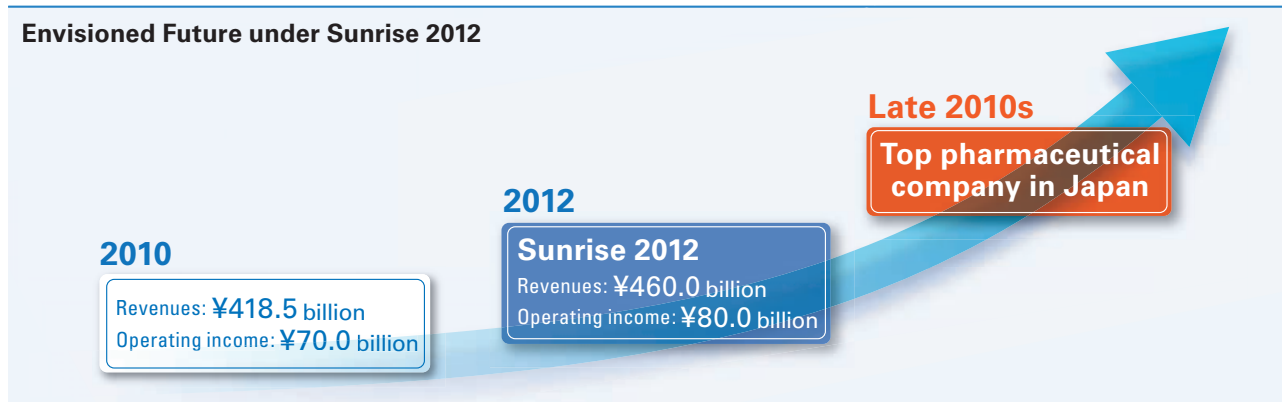
## Sunrise 2012 and Our Envisioned Future

### Toward Achievement of Sunrise 2012

Based on the operating environment, we are aiming to achieve the Sunrise 2012 targets of ¥460 billion in consolidated revenues and ¥80 billion in operating income. The plan calls for establishing a firm foundation of major products such as Actemra, Avastin, Tarceva, Herceptin, Xeloda and Pegasys/Copegus in addition to our existing base of mainstay products such as Epogin and Neutrogin. These new products have been launched on schedule and have achieved solid market positions, making an impressive contribution to our earnings. Going forward, we aim to achieve a stellar growth rate in Japan by strengthening this foundation to steadily generate earnings. At the same time, we will raise efficiency in all departments to ensure that we have the resources necessary to achieve the market penetration of new products.



## Envisioned Future under Sunrise 2012

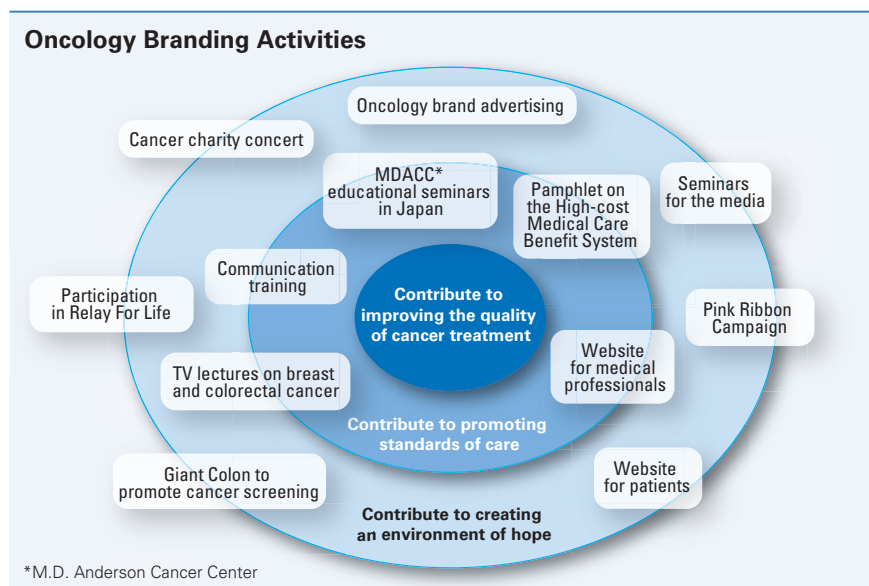


### Aiming to Become Japan's Top Pharmaceutical Company with Innovations that Benefit Patients

Achieving the objectives of Sunrise 2012 is a way-point toward our goal of becoming Japan's top pharmaceutical company in the second half of this decade. I believe that a top pharmaceutical company is one in which all employees share an awareness and sense of responsibility befitting a leading enterprise and work proactively with a global perspective. It is an enterprise that fully satisfies its stakeholders and in turn is rewarded with their active support and trust. To become such a company, we must make a high-quality contribution to patients and the medical community as a leader in our strategic fields: oncology and renal diseases, where we hold the top market share in Japan; and bone and joint diseases, where Actemra will continue to drive growth. We will also optimize internal controls, corporate ethics and compliance, environmental protection and social contribution to make sure that the quality of our business activities is suitable for a top pharmaceutical company.

The key to becoming Japan's top pharmaceutical company, though, will be ongoing innovation that benefits patients and contributes to the medical community. We have already initiated several measures to accomplish that. One example in oncology is our focus on promoting standards of care and helping to make optimal cancer treatments uniformly available to patients throughout Japan. In addition to delivering timely and useful information to healthcare providers, we provide information on an internet website, conduct cancer treatment awareness programs and hold

lectures for healthcare professionals to promote a multidisciplinary team approach to cancer care. Through these and other initiatives, we are working to create an environment that allows cancer patients to confront their disease proactively and with hope. Other medically advanced countries, especially in Europe and North America, are ahead of Japan in undertaking initiatives such as raising patients' awareness of cancer treatment, promoting collaboration with patient associations, and expanding the multidisciplinary team approach and standards of care. To bring cancer treatment in Japan up to a global level, Chugai believes that acting from a standpoint that is different from our usual corporate activities is also necessary. For that reason, in October 2009 we established the Chugai Academy for Advanced Oncology (CHAAO) in order to contribute to the development of the cancer treatment infrastructure in Japan as well as to the future advancement of cancer treatment. CHAAO will conduct various activities, such as hosting oncology forums and providing cancer research grants, to promote deeper academic exchange between the world's leading specialists in oncology and healthcare professionals who are engaged in cutting-edge research and treatment of cancer in Japan.



## 2010 Strategies and Outlook

### Continuing High Growth in Sales Excluding Tamiflu

Revenues and income are expected to decline in 2010 as Tamiflu sales retreat from the high level recorded in 2009. However, we plan to increase sales excluding Tamiflu by 9.4 percent to ¥375.3 billion. We aim to maintain the high growth rates achieved in 2009 by offsetting the negative effect of the scheduled National Health Insurance reimbursement price revision and intensifying competition for mainstay product Epogin with continued growth in sales of major oncology products and Actemra. By further expanding our presence in strategic fields, we will move more quickly toward our goal of becoming Japan's top pharmaceutical company.

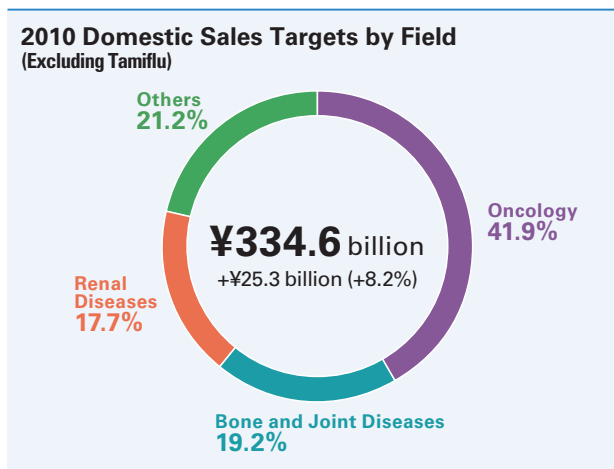
In oncology, we will focus on establishing growth drivers including Avastin, Herceptin, Tarceva and Xeloda as standard therapies. Moreover, as Japan's leading provider of oncology products, we will work to advance cancer treatment. In bone and joint diseases, we will promote further growth for Actemra around the world with Roche. In Japan, we will actively provide product information with an emphasis on safety and efficacy, and will focus on establishing Actemra's position as a first-line biologic treatment. Outside

Japan, Actemra was approved in the United States in January 2010, and is now being marketed in three regions around the world. As of the end of 2009, sales had started in more than 25 countries. Our focus now will be on sales expansion, especially in key European countries, to establish Actemra as a global blockbuster drug. In renal diseases, we will build on the expertise we have cultivated over many years as a leader in this field to contribute to treatment with a thorough understanding of clinical needs. In other areas, we will highlight the positive clinical data on Pegasys/Copegus for treatment of hepatitis C to strengthen the position of both of these medicines.

In research and development, we filed for approval of Xeloda and Herceptin for the new indication of gastric cancer in March 2010. Filing for Pegasys and Copegus for compensated liver cirrhosis caused by hepatitis C virus is also planned for this year. In early-stage development, in addition to focusing on potential growth drivers in oncology, we are also stepping up development in new fields such as diabetes and the central nervous system. In discovery research, we will take advantage of our research network, with its solid record of achievements in industry-academia partnerships, to strengthen collaboration with cutting-edge research institutions, particularly Forerunner Pharma Research Co., Ltd.



SG&A expenses are projected to rise as we implement measures to further raise the market presence of our products in Japan and co-promote Actemra in Europe. We also anticipate higher R&D expenses due to an increase in early-stage development themes and aggressive investment in discovery research. As a result, we project that operating income in 2010 will decrease 15.3 percent to ¥70.0 billion, and net income will decrease 22.3 percent to ¥44.0 billion.



## Benefiting Our Stakeholders

### Dividends of ¥40 per Share in 2009

Chugai's fundamental policy for returning profits to shareholders is to ensure stable dividends. Our goal is to maintain the payout ratio at around 40 percent of consolidated net income on average, taking into account strategic funding needs and earnings prospects. Based on this policy, in 2009 we added a special dividend of ¥6 per share, bringing total cash dividends for the year to ¥40 per share – an increase of ¥6 from the previous year. For 2010, we plan to pay total cash dividends of ¥34 per share (including an interim dividend of ¥17 per share) for a consolidated payout ratio of 42.1 percent.

### Aiming for Higher Corporate Value

As we move toward becoming Japan's top pharmaceutical company, we will raise the quality of all business activities. I believe that is the best way to increase corporate value and meet the expectations of shareholders and other stakeholders.

We are building a broad foundation to accomplish the objectives of Sunrise 2012 and ultimately to realize our vision of becoming Japan's top pharmaceutical company. The path will not be easy, but with the commitment and effort of all our employees, I am confident that we will reach our goal. I would like to thank you all for your ongoing support.

March 2010

**Osamu Nagayama**

Representative Director  
President and CEO

# Mission-Driven Leadership

## Initiatives as a Leader in Oncology

Chugai has held the top domestic market share for oncology drugs for two consecutive years, consolidating its position as a leader in this field. Here we describe Chugai's efforts to advance cancer treatment in Japan from three perspectives: research and development, lifecycle management and sales strategy.

### Creating Answers

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### Advancing the Pipeline

II. Lifecycle Management of Oncology Products 16

### Widening Our Lead

III. Oncology Sales Strategy 18

Our role is to create novel, innovative medicines that benefit as many patients as possible. That's what drives us in our daily research and development activities.

Tai Hirakura

Fuji-Gotemba Research Laboratories

## I. Oncology Research and Development

# Creating Answers

**Chugai aims to create a steady stream of innovative anticancer agents through research and development that accurately anticipates the unmet medical needs of ten years in the future.**



**Dr. Yutaka Tanaka**  
Head of Portfolio Management Unit

**Q1: Cancer treatment is evolving very rapidly thanks to advances that enable the development of molecular targeted therapies. How has research and development of anti-cancer agents changed, and what will be required going forward?**

New anticancer agents developed in recent years have significantly improved treatment outcomes, but these products are actually the fruits of technological innovations in drug research in the 1980s. That's how long it takes to bring a new drug from discovery to market.

Conventional cancer treatment focuses primarily on trying to stop the disease from progressing by inhibiting the rapid proliferation and division that is characteristic of cancer cells. Anticancer agents of this type – chemotherapy drugs – still have an important role. But because they affect normal cells as well as cancer cells, they have many side effects. Any cells that multiply rapidly, such as those involved in blood-formation, in bone marrow, the gastrointestinal tract, hair and other tissues are especially susceptible to these side effects. In contrast, advances in science and technology have allowed researchers to unravel the cellular and molecular mechanisms that give rise to disease and allow it to progress. This has led to the creation of molecular targeted therapies. These drugs are designed to selectively suppress specific protein and other molecules that play a role in the onset or progression of disease. Examples of such products in Chugai's portfolio are Avastin, Tarceva and Herceptin. These medicines represent breakthroughs in terms of efficacy and safety, both of which help improve patients' quality of life. We therefore expect they will make a major contribution to cancer care.

As for future cancer treatment, there is a global trend toward personalized healthcare. Personalized healthcare means fitting treatments to patients.

Therapeutic agents that target specific molecules are driving this treatment method and will continue to play a central role in the development of new anticancer agents. Another key element in raising acceptance of personalized healthcare in the medical community is the availability of straightforward diagnostic tools to identify the molecular characteristics of the patient's cancer. Therefore, beginning at the research stage, suitable diagnostic tools must be developed in parallel with treatments as a guide to promote effective therapy. In the case of GC33, a targeted therapy from Chugai research, we are also developing a companion diagnostic to use with this agent once it is launched.

## Q2: Many pharmaceutical companies are now expanding into oncology. How does Chugai plan to maintain its leadership in this field?

Chugai's oncology pipeline is unrivaled in Japan. It currently includes six candidate molecules from Chugai research, including GC33 for liver cancer, as well as a significant number of compounds licensed from Roche. We are making good progress in this therapeutic area thanks to our outstanding technology platform for both small-molecule and biologic medicines.

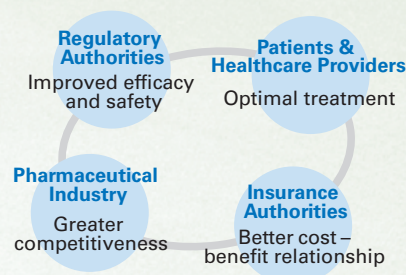
In small-molecule drug discovery, we use the advanced technology developed by Nippon Roche to modify compounds and create new drugs. Xeloda, a Nippon Roche product that has become a standard treatment around the world, is a prime example of these capabilities. We also have a major advantage in biologic medicines, with more than twenty years of research on antibodies and other biopharmaceuticals that has led to the creation of innovative drugs such as Epogin and Actemra. In addition, we focused on cancer as a target therapeutic area earlier than other companies. Our accumulated knowledge of cancer and its mechanisms gives us another significant competitive edge. We have been providing the medical community with a wealth of data and treatment options over the years. The exchange of knowledge this has enabled, coupled with our own research efforts, has deepened our understanding of the disease. This is something that our competitors cannot match. These strengths and other advantages such as our access to the research infrastructure of the Roche Group, the world's leading provider of anticancer agents and *in vitro* diagnostics, make me very confident that we can maintain our market leadership.

In my view, the main challenge for Chugai as a leader in oncology is consistently creating drugs that become standards of care. The key is research and development that anticipates the future of cancer treatment. Future market conditions will also be a critical factor as we work to develop medicines with the potential to become standards of care. And the conditions will change because of environmental factors such as reimbursement prices and the health insurance system. But I am confident that we will succeed, as long as we remain committed to addressing unmet medical needs and developing medicines that truly benefit patients. By drawing on all of our expertise in oncology to develop breakthrough medicines and promote personalized healthcare, we intend to continue to be the leading provider of cancer medicines in the future.

### Personalized Healthcare

Personalized healthcare is a treatment method in which a treatment plan is prepared and executed based on the individual patient's cell molecular and genetic information. Conventional cancer chemotherapy is a "one size fits all" approach: all patients receive the same treatment, but efficacy and side effects may vary significantly from one person to another. The aim of personalized healthcare is to give doctors the diagnostic tools and therapeutic options that enable them to select the best treatment for each patient – avoiding treatments that are unlikely to work and reducing the risk of side effects. In addition to the potential for superior efficacy and safety, it is also expected to offer economic advantages. Personalized healthcare offers the prospect of great benefit for patients, and we expect regulatory authorities and health insurers to give it high marks as well.

#### The Merits of Personalized Healthcare



## II. Lifecycle Management of Oncology Products

### Q1: Chugai's lifecycle management (LCM) system is designed to maximize product value. How are you applying LCM in the oncology field?

Chugai has one of the richest oncology pipelines in Japan. We currently have 18 projects in development, and proof of concept (PoC)<sup>1</sup> has been confirmed for 11 of them. We introduced LCM in 2005 to strategically manage these significant assets and maximize their value.

In our LCM system, a team is assembled for each product, made up of the Lifecycle Leader with overall responsibility, plus heads of clinical development, marketing, production, regulatory affairs and other functions. These cross-functional teams have to address four challenges: reduce development lead time, expand sales, extend product life and control costs.

To reduce development lead time, we collaborate with Roche in global clinical studies. We are currently taking part in six global studies. This collaboration allows us to advance development in Japan at the same

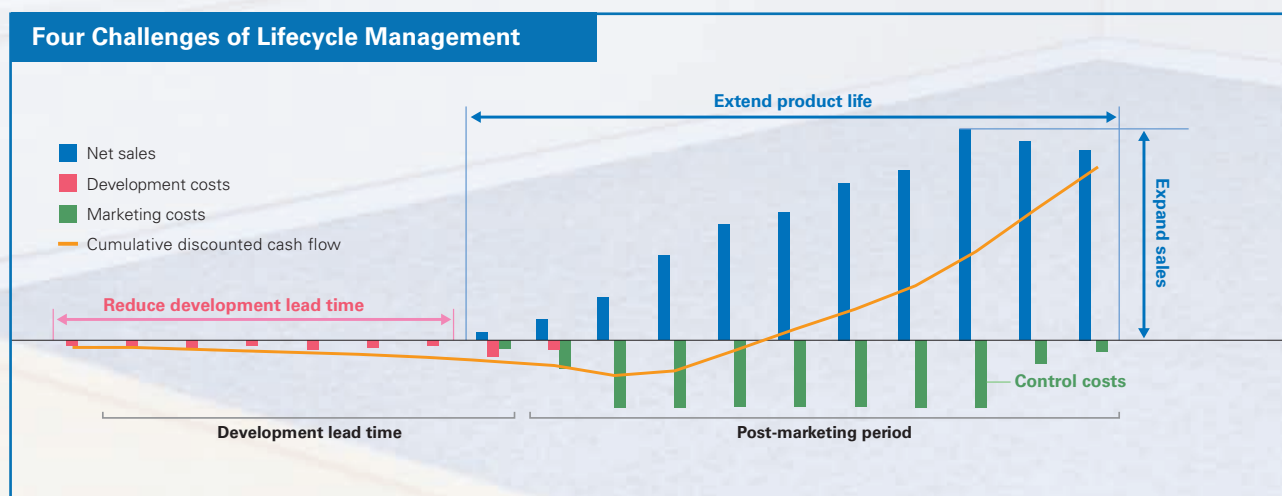
pace as global development. We also expect this approach to result in lower development costs than would be incurred if we conducted clinical trials independently in Japan.

To expand sales, we focus on promoting patient safety and appropriate use in the post-marketing period. Generally, we give priority to increasing sales growth rates in a product's first six months on the market. Many of our anticancer agents, however, have novel mechanisms of action and different safety and efficacy profiles compared with existing drugs. After product launch, we aim for steady market penetration by focusing on collecting and disseminating safety data and promoting appropriate use until sufficient clinical experience has been accumulated. This approach helps to ensure a product's long-term success.

A line extension strategy is critical for extending product life and getting the most from our assets. In the case of anticancer agents, just because a drug is effective against one type of cancer does not mean it can be used for any type. Clinical trials are required to

# Advancing the Pipeline

**With a lifecycle management system that seamlessly integrates different functions, Chugai continues to build its presence as Japan's leading provider of cancer medicines.**



obtain regulatory approval for each type of cancer and each stage of disease progression, or line of treatment. So, to maximize product value after launch, it is vital that we have a strategy that maps out how we plan to conduct development activities in different cancer types and treatment lines, as well as for combination therapy with other drugs. Having product lifecycle teams made up of specialists in different functions allows us to take a comprehensive approach – accurately assessing healthcare providers' needs, efficiently allocating resources and managing the regulatory process.

The large number of marketed products and development compounds in our portfolio makes controlling expenditure all the more important, and this includes R&D and marketing and distribution costs, and of course personnel expenses. Our goal is integrated cost management throughout a product's lifecycle, from development through to marketing.

1. Proof that a drug has the intended beneficial effect in humans.  
Normally established after the completion of early phase II clinical trials.

## Q2: Chugai has numerous oncology products. How do you plan to leverage individual product characteristics to maximize value in the oncology field as a whole?

To further strengthen our leading position in oncology, we have initiated activities at various levels to maximize value. For example, we have set up teams to formulate development and marketing strategies for each type of cancer. These teams collaborate with product lifecycle teams to systematically promote our oncology strategy.

In some cases, we have multiple products and development compounds for a single type of cancer. In breast cancer, for example, in addition to Xeloda we have Femara, for hormone receptor-positive disease, Herceptin and two development compounds, for HER2-positive cancer. We also have Avastin, which is awaiting marketing approval. To maximize the value of this portfolio, rather than conducting activities for the individual products, we need to establish how each one fits into the overall treatment of breast cancer and provide physicians with comprehensive, specialized information and treatment proposals. In addition, because

combination therapy with multiple drugs is a mainstay of cancer treatment, formulating development strategies from a cross-product perspective effectively raises the competitiveness of our entire portfolio. By having teams for each cancer type that are responsible for our entire range of anticancer medicines and for developing strategies that aim to achieve product synergies, I believe we can maximize value across our oncology portfolio.

### Tatsuro Kosaka

Head of Lifecycle Management  
& Marketing Unit



### III. Oncology Sales Strategy

#### Q1: Chugai has achieved rapid growth in the oncology field. How have sales operations contributed?

In a nutshell, with the aim of contributing to cancer treatment, we've succeeded in responding accurately to the needs of healthcare providers. Providing highly detailed information in our oncology sales activities is necessary because of the complexity of treatments and the large number of innovative drugs. With the best oncology product lineup in Japan, we are increasingly required to provide information not just about our products but also about cancer treatment in general.

With this in mind, we separated oncology sales functions into the Oncology Unit three years ago. We have since built a robust sales organization with 550 oncology medical representatives (MRs) engaged in high-level consulting and promotion. In October 2009, we also established the position of Medical Associate (MA) to provide specialized, advanced academic information in specific areas to doctors who are local opinion leaders. Cooperation between specialized MRs and MAs based in an independent unit has enabled us to

not only supply products but also provide value-added information tailored to the needs of healthcare providers.

#### Q2: What role must Chugai fulfill as the top Japanese pharmaceutical company in oncology?

As the foremost company in the field, we are expected to do more than grow our own business – we must play a leadership role in cancer treatment in Japan. We are therefore focusing on promoting standards of care and helping establish uniform access to standardized treatment throughout the country. Our goal is to realize cancer treatment that enables patients to confront their disease proactively and with hope.

We are implementing this policy in oncology branding. We have established a cancer information website for patients, publish an informational magazine for healthcare professionals and host or co-sponsor various charity events. To spread multidisciplinary team cancer care, which is still developing in Japan, we hold workshops for physicians and other healthcare professionals and actively support chemotherapy training. Moreover, we established the Chugai Academy for Advanced Oncology in October 2009 to contribute to cancer treatment from a nonbusiness standpoint.

By continuing these initiatives and leading the development of oncology in Japan, we intend to make Chugai a company not merely associated with, but synonymous with oncology.

## Widening Our Lead

**Akio Tanaka**

Head of Oncology Unit

Through its programs to deliver quality information and promote cancer awareness, Chugai seeks to promote standards of care and help establish uniform access to standardized treatment throughout Japan. We intend to make Chugai synonymous with oncology.

# Review of Operations

## Mission-Driven Leadership Gets Results

- 20 Chugai at a Glance
- 22 Oncology
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- 29 Bone and Joint Diseases
- 33 Others

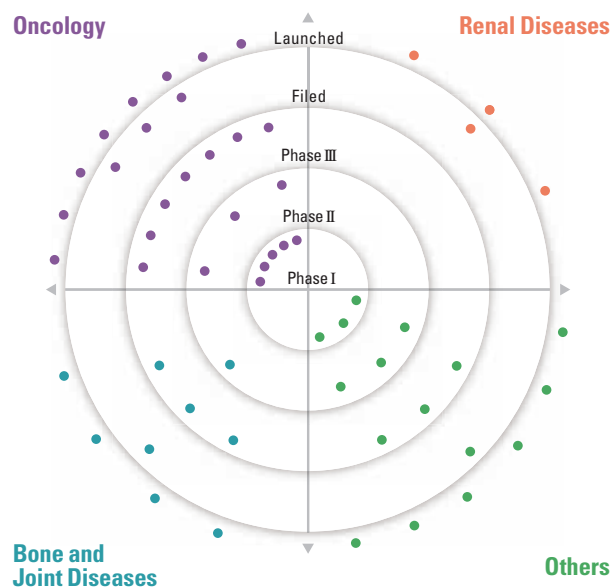
Our mission is to provide quality information to healthcare professionals and respond precisely to their needs so that patients can receive better treatment.

**Shinji Sato**

Medical Representative – Oncology Specialist  
Oncology Unit, Tokyo Branch 1

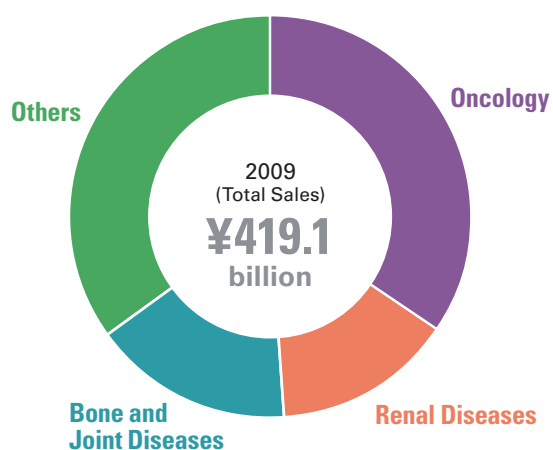
# Chugai at a Glance

## Our Pipeline



Chugai has the richest oncology pipeline in Japan with eight mainstay products and 18 development projects.

## Sales by Strategic Field



## Oncology

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## Renal Diseases

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## Bone and Joint Diseases

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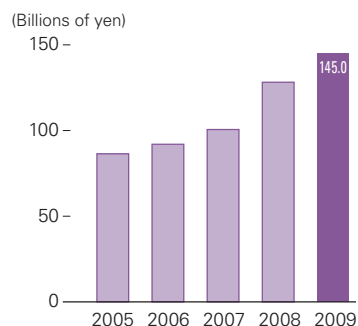


## Others

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## Sales



## Major Products

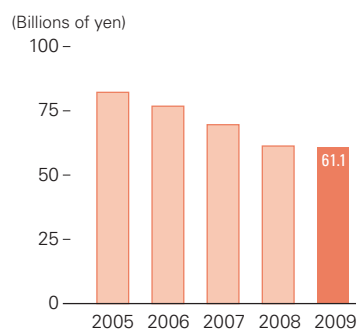
- Avastin (bevacizumab)
- Neutrogen (lenograstim)
- Herceptin (trastuzumab)
- Rituxan (rituximab)
- Kytril (granisetron)
- Xeloda (capecitabine)
- Tarceva (erlotinib)
- Femara (letrozole)

## Highlights (January 2009 – February 2010)

- Strong 13.0 percent year-on-year increase in sales
- Expanded sales of Avastin, Herceptin, Tarceva and other growth drivers
- Increased leading domestic market share to 17.3 percent\*

## Development pipeline

- ▶ Obtained approval of Xeloda (XELOX regimen) for treatment of colorectal cancer (September 2009) and Avastin for treatment of non-small cell lung cancer (November 2009)
- ▶ Filed for approval of additional indications for Epogin (November 2009), Tarceva (September 2009) and Avastin (October 2009)
- ▶ Joined global phase III study investigating RG1273 for the treatment of HER2-positive breast cancer (July 2009)
- ▶ Started overseas phase II clinical trials of TP300 (October 2009)
- ▶ Started development of Avastin for the treatment of glioblastoma (August 2009), Actemra for the treatment of pancreatic cancer (September 2009) and RG3502 for the treatment of HER2-positive breast cancer (October 2009)

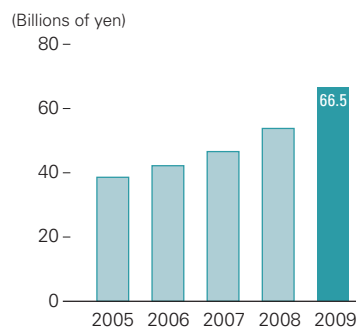


- Epogin (epoetin beta)
- Oxarol (maxacalcitol)
- Renagel (sevelamer HCl)

- Slight 0.5 percent year-on-year decrease in sales
- Stopped downward trend in sales of Epogin
- Epogin maintained top share of the domestic market at 52.7 percent\*

## Development pipeline

- ▶ Obtained approval for a new formulation of Epogin that is less painful to inject and is produced using a serum-free manufacturing process (April 2009)
- ▶ Filed for approval of RG744 for renal anemia (July 2009)

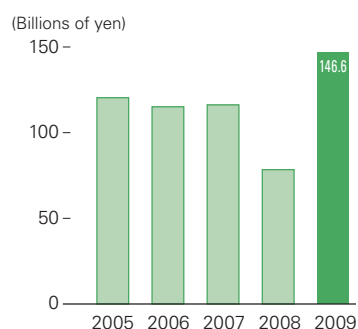


- Evista (raloxifene HCl)
- Alfamol (alfacalcidol)
- Suvenyl (sodium hyaluronate)
- Actemra (tocilizumab)

- 23.4 percent year-on-year increase in sales
- Strong growth of Actemra sales with steady penetration of the domestic market
- Actemra now available in more than 25 countries following approval in Europe (January 2009) and the United States (January 2010)

## Development pipeline

- ▶ Filed for approval of ED-71 for the treatment of osteoporosis (October 2009)
- ▶ Application filed in Europe to extend market approval of Actemra to include inhibition of the progression of joint damage and improvement of physical function in patients with rheumatoid arthritis (September 2009)
- ▶ Started domestic phase I/II clinical trials of Actemra for subcutaneous injection



- Tamiflu (oseltamivir phosphate)
- Sigmart (nicorandil)
- Pegasys (peginterferon alfa-2a)
- Rocephin (ceftriaxone)
- Copegus (ribavirin)
- Cellcept (mycophenolate mofetil)

- Tamiflu sales expanded sharply due to spread of the influenza A/H1N1 ("swine flu") virus and increase in sales for government stockpiles
- Pegasys/Copegus steadily penetrated the market and sales increased

## Development pipeline

- ▶ Global phase II study of CSG452 started (February 2009)
- ▶ Started domestic phase II clinical trials of RG1583 (July 2009)
- ▶ Started domestic phase I clinical trials of RG1450 (July 2009) and NTZ (August 2009)

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# Oncology

Chugai has the most comprehensive portfolio of oncology products in Japan, with groundbreaking anticancer agents as well as supportive care treatments.<sup>1</sup> As Japan's leading company in this field, we are focusing not just on consolidating our market position, but also on helping to advance the treatment of cancer by providing healthcare professionals with detailed information and promoting standards of care.

1. Medicines that relieve the side effects of certain cancer treatments.

## Sales of Major Products

Product Name (Generic name)	Sales (Billions of yen)	Brief Overview	Launch Year in Japan
<b>Avastin</b> (bevacizumab)	07 3.5 08 20.1 09 34.9	Humanized anti-vascular endothelial growth factor (VEGF) monoclonal antibody	Jun. 2007
<b>Neutrogin</b> (lenograstim)	07 39.2 08 37.9 09 32.6	Recombinant human granulocyte colony-stimulating factor (G-CSF)	Dec. 1991
<b>Herceptin</b> (trastuzumab)	07 16.1 08 23.7 09 29.7	Anti-HER2 humanized monoclonal antibody	Jun. 2001 (150mg) Aug. 2004 (60mg)
<b>Rituxan</b> (rituximab)	07 18.6 08 20.5 09 21.1	Anti-CD20 monoclonal antibody	Sep. 2001
<b>Kytril</b> (granisetron)	07 13.6 08 10.9 09 8.6	5-HT <sub>3</sub> receptor antagonist, antiemetic agent	May 1992 Jun. 2006 (bag)
<b>Xeloda</b> (capecitabine)	07 2.7 08 4.8 09 6.6	Fluoropyrimidine anti-tumor agent	Jun. 2003
<b>Tarceva</b> (erlotinib)	07 0.2 08 4.5 09 5.8	Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor	Dec. 2007
<b>Femara</b> (letrozole)	07 1.0 08 1.7 09 2.4	Aromatase inhibitor/agent for breast cancer in postmenopausal women	May 2006

## Development Pipeline (As of February 3, 2010)

Development Code (Product name)	Status Phase I	Phase II	Phase III	Filed	Approved	Indication	Generic Name	Dosage Form	Origin (Collaborator)
<b>EPOCH</b> (Epogin)				● Nov. 2009		Chemotherapy-induced anemia	epoetin beta	Injection	In-house
<b>RG435</b> (Avastin)				● Oct. 2009		Breast cancer	bevacizumab	Injection	Roche
			● (Global study)			Colon cancer (adjuvant)			
			● (Global study)			Gastric cancer			
			● (Global study)			Breast cancer (adjuvant)			
			● (Global study)			Glioblastoma			
		●				Glioblastoma (relapsed)			
<b>RG1415</b> (Tarceva)				● Sep. 2009		Pancreatic cancer	erlotinib	Oral	Roche / OSI
<b>RG340</b> (Xeloda)			● (Global study)			Gastric cancer	capecitabine	Oral	Roche
<b>RG597</b> (Herceptin)			● (Global study)			Gastric cancer	trastuzumab	Injection	Roche
<b>RG1273</b>			● (Global study)			Breast cancer	pertuzumab	Injection	Roche
<b>MRA</b> (Actemra)		● (I/II)				Pancreatic cancer	tocilizumab	Injection	In-house (Roche)
<b>TP300</b>		● (Overseas)				Gastric cancer, etc.	—	Injection	In-house
<b>CIF</b> (RG7167)	●					Solid tumors	—	Oral	In-house (Roche)
	● (Overseas)								
<b>CKI27</b> (RG7304)	●					Solid tumors	—	Oral	In-house (Roche)
	● (Overseas)								
<b>GC33</b>	● (Overseas)					Liver cancer	—	Injection	In-house
<b>GA101</b> (RG7159)	●					Non-Hodgkin's lymphoma	—	Injection	GlycArt
<b>RG3502</b>	●					Breast cancer	—	Injection	Roche

● Designates change in status in 2009 and thereafter.

## Review of 2009 Results

### Overview

In 2009, total sales in the oncology field rose ¥16.7 billion, or 13.0 percent, year-on-year to ¥145.0 billion. Chugai increased its leading domestic market share from 15.8 percent to 17.3 percent.<sup>2</sup> This performance was driven by steady expansion in sales of growth drivers such as Avastin, Herceptin, Tarceva and Xeloda.

Chugai gives top priority to patient safety and appropriate use of its products. In 2009 we continued to provide accurate, timely information to healthcare professionals through our 550 oncology medical representatives (MRs). Since October 2009, Chugai has also assigned Medical Associates (MAs) to convey more specialized, advanced scientific information in specific fields. Collaboration between MRs and MAs allows Chugai to offer consulting and promotion backed by specialized expertise.

2. Copyright 2010 IMS Japan K.K. Source: JPM 2008-2009. Reprinted with permission. The scope of the market is defined by Chugai.

### New Products and Additional Indications

New products and additional indications for existing products that are expected to drive Chugai's future growth are steadily penetrating the market and establishing positions as leading treatments.

Sales of Avastin, a humanized anti-vascular endothelial growth factor (VEGF) monoclonal antibody, increased ¥14.8 billion, or 73.6 percent, to ¥34.9 billion. Factors contributing to this increase included wider recognition of the product's efficacy and safety after two years on the market and its inclusion in Japan's colorectal cancer treatment guidelines, revised in July 2009. In November 2009, Avastin was approved for the additional indication of non-small cell lung cancer. Avastin is already recommended in numerous guidelines outside Japan, and Chugai expects it to contribute significantly to treatment of lung cancer in Japan as well.

Sales of Herceptin, an anti-human epidermal growth factor-2 (HER2) humanized monoclonal antibody, increased ¥6.0 billion, or 25.3 percent, to ¥29.7 billion. This growth was driven primarily by increasing use of

Herceptin in the post-operative adjuvant treatment of breast cancer, an additional indication approved in February 2008, despite the launch of a competitor product. Sales are also being helped by Chugai's focus on providing information to healthcare professionals, as well as the product's inclusion in treatment guidelines in Japan and other countries, leading to greater awareness among healthcare providers and patients of the benefits of treatment with Herceptin.

The fluoropyrimidine anti-tumor agent Xeloda posted strong sales growth, up ¥1.8 billion, or 37.5 percent, to ¥6.6 billion in a competitive market environment. Growth was driven primarily by the product's approval in September for the additional indication of advanced or recurrent colorectal cancer in combination with oxaliplatin (a regimen known as XELOX). Including oral Xeloda in the XELOX regimen lessens the burden for patients and healthcare providers compared with intravenous 5-FU therapy, as patients need to visit the hospital outpatient department only once every three weeks. XELOX and the combination of XELOX with Avastin, which was approved at the same time, are gaining acceptance as a standard of care for colorectal cancer around the world.

Sales of Tarceva, a human epidermal growth factor receptor (EGFR) tyrosine kinase



### Avastin

A molecular targeted therapy that suppresses cancer growth by inhibiting tumor angiogenesis (the formation of new blood vessels from surrounding healthy tissues)



### Herceptin

A molecular targeted therapy for breast cancer that overexpresses a protein known as HER2, which is associated with uncontrolled survival of cancer cells



### Tarceva

A molecular targeted therapy that inhibits activation of the human epidermal growth factor receptor (EGFR) pathway, which plays a role in the formation and growth of non-small cell lung and pancreatic cancers

inhibitor launched in December 2007, increased ¥1.3 billion, or 28.9 percent, to ¥5.8 billion. In the all-patient registration survey that Chugai is conducting as part of post-marketing safety surveillance, registration of patients from whom survey forms are to be collected was completed in October 2009. The data are currently being compiled and analyzed.

Sales of Neutrogin (overseas name: Granocyte), a human granulocyte colony-stimulating factor, decreased ¥5.3 billion, or 14.0 percent, to ¥32.6 billion. In Japan, sales decreased ¥0.7 billion, or 5.8 percent, to ¥11.3 billion as the market continued to contract, reflecting the growing number of facilities adopting the Diagnosis Procedure Combination- (DPC-) based payment system and increases in outpatient chemotherapy. Outside Japan, sales decreased ¥4.6 billion, or 17.8 percent, to ¥21.3 billion, due to the impact of follow-on biologics<sup>3</sup> and the effect of the stronger yen.

Sales of Kytril, a 5-HT<sub>3</sub> receptor antagonist antiemetic agent, have been impacted by the launch of several generic competitors since 2007. Sales in 2009 decreased ¥2.3 billion, or 21.1 percent, to ¥8.6 billion.

3. Follow-on versions, produced by other manufacturers, of biopharmaceutical products for which patents have expired; also called follow-on biologicals or biosimilars. Unlike generic versions of synthetic agents, follow-on biologics are not chemically identical to the original drugs.

### Existing Products

Sales of anticancer agents in Chugai's existing product portfolio continued to grow in 2009, although maintaining the market position of supportive care products is an ongoing challenge.

Sales of Rixutan, an anti-CD20 monoclonal antibody, rose ¥0.6 billion, or 2.9 percent, to ¥21.1 billion, as it consolidated its position as a standard therapy. Sales of Femara, an aromatase inhibitor for treatment of breast cancer in postmenopausal women, increased ¥0.7 billion, or 41.2 percent, to ¥2.4 billion. This was due in part to an increase in prescriptions for initial adjuvant therapy following publication in December 2008 of overseas data suggesting that Femara may prolong survival.

### Anticancer Market in Japan



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## 2010 Strategy and Outlook

In 2010, Chugai aims to consolidate its position as Japan's leading provider of anticancer medicines. Marketing activities will focus on positioning our key growth drivers as new standards of care, while we continue to give priority to patient safety and promoting appropriate product use.

We are stepping up efforts to establish Avastin as a standard treatment for colorectal cancer and lung cancer. At the same time, we will continue to highlight the drug's novel mechanism of action and the benefits of antiangiogenesis, while seeking to expand its marketing approval to include additional indications. Marketing activities to support Herceptin are being enhanced to increase efficiency and eliminate regional differences in market penetration. In addition, we are rolling out a series of lectures and other events for the medical community to promote appropriate use of Xeloda and highlight the efficacy and safety of XELOX therapy. Once completed, we will present the results of the Tarceva all-patient registration survey at scientific meetings and other forums to promote wider recognition of the product's characteristics and strengthen its market position.

As the country's leading provider of anticancer drugs, Chugai is actively supporting the national effort to further improve cancer care in Japan. We will continue to support physicians, nurses, pharmacists and other healthcare professionals and remain committed to

doing our part to promote standards of care and ensure that optimal treatment is available for all cancer patients.

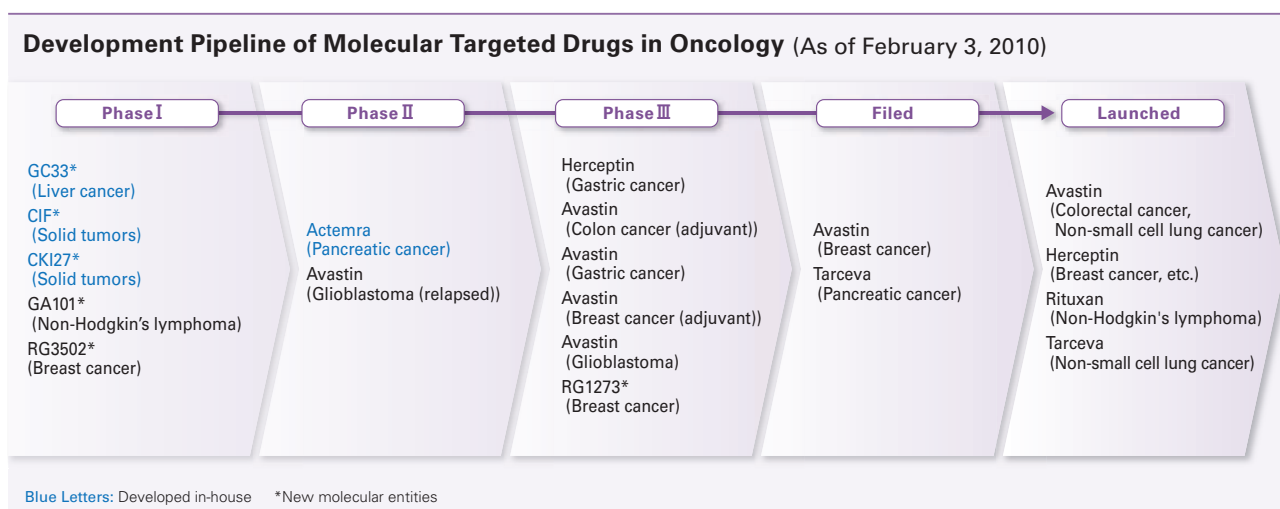
## Products under Development

### Additional Indications

Chugai is pushing ahead vigorously with the development of additional indications for key products in order to maximize their value.

In 2009, we filed for approval of additional indications for Epogin, Tarceva and Avastin. Applications were filed in November for approval of Epogin for chemotherapy-induced anemia; in September for Tarceva combined with gemcitabine in the first-line treatment of advanced or recurrent pancreatic cancer; and in October for Avastin combined with standard chemotherapy in the first-line treatment of advanced or recurrent breast cancer. In March 2010, we submitted a combined filing for approval of Herceptin plus Xeloda for the treatment of HER2-positive advanced or recurrent gastric (stomach) cancer. Development of these two agents in this indication has attracted substantial interest from healthcare professionals, as there is currently no global treatment standard for gastric cancer.

Chugai also started a number of line extension projects in 2009 that aim to address areas of substantial unmet medical needs in cancer treatment. In September, we commenced phase I/II clinical trials of Actemra in Japan for pancreatic cancer. Already



approved for rheumatoid arthritis and other autoimmune diseases, Actemra targets the immune system protein interleukin-6 (IL-6). As high levels of IL-6 are detected in many patients with pancreatic cancer, it is thought that Actemra may improve patients' clinical condition and increase life expectancy. In addition, we are collaborating in the development of Avastin in a number of indications. One of these is glioblastoma, an aggressive type of brain tumor with limited treatment options. Chugai is participating in a global phase III study with Roche and has also initiated phase II clinical trials in Japanese patients with relapsed glioblastoma. Global studies with Avastin as a post-operative adjuvant therapy for breast cancer and colon cancer, in which Chugai is also participating, are advancing as planned. In February 2010, Roche announced that a global phase III study with participation by Chugai, investigating Avastin as a treatment for gastric cancer, had not met its primary endpoint of extending overall survival.

## New Compounds

Chugai is also developing new compounds, with a focus on molecular targeted therapies. Our development pipeline currently includes four compounds from Chugai research and three licensed from Roche.

GC33, CKI27 (RG7304) and CIF (RG7167) are targeted therapies from Chugai research. All are currently in phase I clinical trials. GC33 is a humanized monoclonal antibody that targets glypican-3, a protein that is specifically expressed in liver cancer. Drawing on the results of research at PharmaLogicals Research Pte. Ltd.<sup>4</sup> and collaboration with Tokyo University and Miyazaki University, GC33 is testimony to the success of Chugai's alliance strategy with outside institutions. CKI27 and CIF, two targeted small-molecule compounds, are being co-developed by Chugai and Roche.

The topoisomerase I inhibitor TP300, a chemotherapy agent from Chugai research, entered phase II clinical trials outside Japan in October 2009. TP300 is designed to offer better pharmacokinetic and side-effect profiles than the standard treatment irinotecan, along with superior and more stable efficacy.

In October, Chugai started phase I clinical testing of RG3502 (T-DM1), an anti-HER2 antibody-drug conjugate

licensed from Roche. This novel compound links trastuzumab (the active ingredient of Herceptin) and the cytotoxic (cell-killing) agent DM1. It thus combines two anti-tumor strategies to selectively kill cancer cells more effectively. By binding to HER2, T-DM1 not only prevents the tumor cells from growing but also delivers the cell-killing agent directly to the cancerous cells to induce cell death. In addition to greater efficacy, this approach has the potential to offer improved safety compared with conventional combination therapies. In July, Chugai joined Roche's global phase III study investigating RG1273, a monoclonal antibody and HER dimerization inhibitor, in combination with Herceptin for the treatment of HER2-positive breast cancer. It is thought that the combination may provide more effective treatment of HER2-positive breast cancer, which is more aggressive than other types of cancer.

Development of the anti-CD20 monoclonal antibody GA101 (RG7159) for the treatment of non-Hodgkin's lymphoma is proceeding on track. At the end of 2009 Chugai decided to in-license the hedgehog pathway inhibitor RG3616 from Roche. We are now preparing for phase I clinical trials in Japan, which are scheduled to commence in the second half of 2010.

4. A joint venture established in Singapore by Chugai Pharmaceutical, Mitsui & Co. and the Central Institute for Experimental Animals.

# Renal Diseases

Mainstay product Epogin has been Japan's number-one treatment for renal anemia since its launch in 1990. Chugai is now emphasizing the importance of early treatment of chronic renal failure complications in pre-dialysis patients. With this approach, we aim to contribute to better treatment of renal disease while consolidating our position as the market leader.

## Sales of Major Products

Product Name (Generic name)	Sales (Billions of yen)	Brief Overview	Launch Year in Japan
<b>Epogin</b> (epoetin beta)	07 54.8 08 44.9 09 44.4	Recombinant human erythropoietin	Apr. 1990 (ampoule) May 2001 (syringe)
<b>Oxarol</b> (maxacalcitol)	07 8.7 08 10.0 09 10.6	Agent for secondary hyperparathyroidism in hemodialysis patients	Sep. 2000
<b>Renagel</b> (sevelamer HCl)	07 5.7 08 5.8 09 5.4	Agent for hyperphosphatemia	Jun. 2003

## Development Pipeline (As of February 3, 2010)

Development Code (Product name)	Status Phase I	Phase II	Phase III	Filed	Approved	Indication	Generic Name	Dosage Form	Origin (Collaborator)
<b>RG744</b>				● Jul. 2009		Renal anemia	—	Injection	Roche

● Designates change in status in 2009 and thereafter.

## Review of 2009 Results

### Overview

In 2009, sales in the renal diseases field decreased ¥0.3 billion, or 0.5 percent, year-on-year to ¥61.1 billion. The downward trend in sales of Epogin, an agent for the treatment of renal anemia and Chugai's largest-selling product, was stopped, and the overall decrease in sales of renal disease treatments slowed significantly.

Amid intense competition, sales of Epogin decreased only slightly, by ¥0.5 billion (1.1 percent), to ¥44.4 billion. Chugai's successful measures to maximize the value of this product led to a turnaround that resulted in positive sales growth in the second half compared with the same period of the previous fiscal year. Epogin maintained its leading market share in the renal anemia segment in Japan, at 52.7 percent.<sup>1</sup>

A treatment for anemia associated with chronic kidney disease (CKD), Epogin can be used in both the dialysis and pre-dialysis settings. The dialysis market has changed dramatically due to cutbacks in healthcare expenditure (see page 57) since the introduction of a flat-sum reimbursement system for erythropoietin-stimulating

agents (ESAs) in April 2006. In addition, a competitor product was launched in July 2007. Chugai has clearly maintained its position as a leading company in this intensely competitive market. The Company's sales activities are based on substantial expertise in dialysis, primarily through approximately 300 medical representatives who specialize in renal disease medicines.

Meanwhile, the pre-dialysis segment has been expanding by more than 10 percent annually in recent years. This growth is driven in part by a national education campaign to promote early diagnosis and treatment of renal anemia in pre-dialysis patients in response to the increase in CKD in patients with underlying diabetes. Revised guidelines issued by the Japanese Society for Dialysis Therapy in 2008 defined treatment standards for anemia in the pre-dialysis setting for the first time, in addition to those for dialysis patients. In addition, care guidelines issued by the Japanese Society of Nephrology in 2009 suggest that early diagnosis and treatment of renal anemia may slow the progression of CKD. As a leader in the renal diseases field, Chugai has partnered with governments, healthcare professionals, citizens' groups and other organizations



### Epogin

Epogin is a recombinant human erythropoietin biopharmaceutical developed by Chugai that has been the leading renal anemia treatment in Japan since its launch in 1990. For the new formulation introduced in 2009, the use of universal design for the packaging improved identifiability and visibility for the convenience of healthcare professionals.

to help slow the increase in the number of dialysis patients through concerted CKD education programs, including numerous conferences, lectures and community symposiums. These efforts resulted in more than ten percent year-on-year growth in sales of Epogin in the pre-dialysis segment, exceeding market growth.

In April 2009, Chugai received regulatory approval for a new formulation of Epogin. Launched in July, the new formulation is less painful to inject and is produced using a serum-free<sup>2</sup> manufacturing process. An example of Chugai's commitment to improved patient care, it offers patients increased comfort while eliminating a potential biological risk.

Sales of Oxarol, a treatment for secondary hyperparathyroidism, remained solid, backed by substantial evidence that this drug increases life expectancy. Sales of Renagel, for the treatment of hyperphosphatemia, decreased marginally due to the launch of a competitor product.

1. Copyright 2010 IMS Japan K.K. Source: JPM 2009 Reprinted with permission. The scope of the market is defined by Chugai.
2. The term "serum-free" indicates that no materials of animal origin, such as bovine serum, are used to manufacture the active ingredient. The resulting product is thus free of risks, such as bovine spongiform encephalopathy (BSE), which may be associated with animal-derived components.

## 2010 Strategy and Outlook

We anticipate even more intense competition in the key renal anemia market in 2010. In the dialysis segment, follow-on biologics containing erythropoietin are expected to be launched in Japan for the first time. Competition is also expected to intensify in the growing

pre-dialysis segment due to the emergence of a competitor product. Chugai will continue to emphasize the importance of treating renal anemia in pre-dialysis CKD patients and highlight the established safety and efficacy of Epogin. Through these measures, we aim to maintain and expand our presence in the dialysis and pre-dialysis segments as we prepare for the launch of RG744, pending regulatory approval. (See "Products under Development" and page 58 for details on RG744.)

As Japan's leading provider of renal anemia medicines, Chugai is committed not only to driving the market but also to helping to bring better treatments to patients. We will continue to focus closely on clinical needs in providing support for patients and healthcare professionals, with sales activities that are built on proposing the optimal method of treatment for each patient.

## Products under Development

In July 2009, Chugai filed for marketing approval of RG744, the first long-acting ESA. RG744 is an innovative anti-anemia medication that allows maintenance of stable hemoglobin levels with once-monthly administration, a significant reduction in treatment frequency compared with existing drugs. The decrease in administration frequency is especially beneficial for pre-dialysis renal anemia patients, as it requires fewer hospital visits. Patients and healthcare professionals have high expectations for this medicine. We believe it will play a major role in the pre-dialysis segment as the importance of earlier, more convenient anemia treatment is increasingly recognized. RG744 was launched outside Japan in 2007 under the product name Mircera.

# Bone and Joint Diseases

In the area of rheumatoid arthritis (RA), the international rollout of Actemra by Roche and Chugai continued, with market penetration progressing well. Chugai's goal is to establish Actemra – the first interleukin-6 receptor inhibiting monoclonal antibody – as a first-line biologic that offers RA patients a new treatment option and to develop it into a key revenue driver. In the area of osteoporosis and osteoarthritis, Chugai will enhance its position as a top company in the field of bone and joint diseases by steadily developing new products and maximizing the value of existing products.

## Sales of Major Products

Product Name (Generic name)	Sales (Billions of yen)	Brief Overview	Launch Year in Japan
<b>Evista</b> (raloxifene HCl)	07 16.0 08 16.5 09 17.9	Agent for postmenopausal osteoporosis	May 2004
<b>Actemra</b> (tocilizumab)	07 0.5 08 7.2 09 17.3	Humanized anti-human IL-6 receptor monoclonal antibody	Jun. 2005 (Castleman's disease) Apr. 2008 (rheumatoid arthritis)
<b>Suvenyl</b> (sodium hyaluronate)	07 11.0 08 12.0 09 13.7	Agent for knee pain associated with rheumatoid arthritis, osteoarthritis	Aug. 2000
<b>Alfarol</b> (alfacalcidol)	07 14.4 08 13.7 09 13.6	Active vitamin D <sub>3</sub> derivative (1α (OH) D <sub>3</sub> ) for improving bone metabolism	Jan. 1981 (capsule, solution) Jul. 1994 (powder)

## Development Pipeline (As of February 3, 2010)

Development Code (Product name)	Status Phase I	Phase II	Phase III	Filed	Approved	Indication	Generic Name	Dosage Form	Origin (Collaborator)
<b>ED-71</b>				● Oct. 2009		Osteoporosis	eldecalcitol	Oral	In-house (Taisho Pharmaceutical)
<b>MRA (Actemra)</b>			● (Overseas)			Systemic-onset juvenile idiopathic arthritis (sJIA)	tocilizumab	Injection	In-house (Roche)
		● (I/II)				Rheumatoid arthritis (new formulation: subcutaneous injection)			
<b>RG1594</b>			● (Global study)			Rheumatoid arthritis	ocrelizumab	Injection	Roche
<b>RG484</b>			● (II/III)			Osteoporosis	ibandronate sodium hydrate	Injection	Roche (Taisho Pharmaceutical)
		●						Oral	

● Designates change in status in 2009 and thereafter.

## Review of 2009 Results

### Overview

In 2009, Chugai's total sales in the bone and joint diseases field increased ¥12.6 billion, or 23.4 percent compared with the previous fiscal year, to ¥66.5 billion. The main revenue driver was strong growth in sales of Actemra, a humanized anti-human IL-6 receptor monoclonal antibody for treatment of RA from Chugai research. An expanding market supported relatively strong sales growth of osteoporosis and osteoarthritis treatments despite rising competition, particularly in the osteoporosis market.

### Rheumatoid Arthritis

Sales of Actemra in Japan in 2009 increased ¥5.0 billion, or 147.1 percent, to ¥8.4 billion. The first therapeutic antibody created in Japan, Actemra is a highly innovative drug with a novel mechanism of action: It is the world's first inhibitor of the signaling protein interleukin-6 (IL-6), a protein involved in regulating immune response. In 2009, Chugai's second year in the RA market, the Company's Actemra Core MRs in Japan carried out focused promotional activities, primarily targeting specialized rheumatology facilities in each region. Actemra is steadily gaining recognition among rheumatologists as the first treatment to demonstrate efficacy in preventing joint damage associated with RA in



## Actemra

A biologic discovered by Chugai and co-developed with Roche. In Japan, Actemra was first launched as a treatment for Castleman's disease in 2005 and approved for rheumatoid arthritis in 2008. It is now being made available to patients worldwide thanks to the global reach of the Roche Group.

patient enrollment target now reached, Chugai is compiling and analyzing the data for submission of the survey results to the Ministry of Health, Labour and Welfare. The adverse reactions seen to date are similar to those observed in pre-approval clinical trials.

Sales of Actemra outside Japan (exports to Roche for sale in regions other than Japan, Korea and Taiwan) increased ¥5.1 billion, or 134.2 percent, to ¥8.9 billion. Actemra received approval in Europe in January 2009 under the name RoActemra. It is now available in more than 25 countries worldwide, including Germany, the UK, France, Brazil and India. Chugai is co-promoting

Japanese patients, as well as for its high remission rate, safety profile and other benefits. Actemra is now prescribed as a first-line biologic in about 40 percent of all patients treated with the drug in Japan, helped by increasing recognition of its benefits and growing clinical experience. As with all new biologics approved in Japan, an all-patient registration survey was required for Actemra after its market launch. With the

RoActemra with Roche in Germany, the UK and France, where Chugai has marketing units, and this positive collaboration is supporting steady market penetration.

Chugai is also expanding production capacity for Actemra, which is currently manufactured only at Chugai's Utsunomiya plant. To accommodate future increases in global demand, Genentech will also manufacture the bulk drug substance in the United States under a toll manufacturing agreement. Transfer of technology to Genentech progressed as planned in 2009.

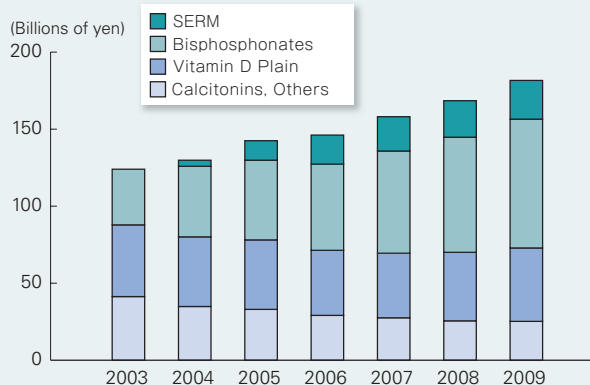
## Osteoporosis and Osteoarthritis

In the osteoporosis market, sales of the selective estrogen receptor modulator (SERM) Evista increased ¥1.4 billion, or 8.5 percent, to ¥17.9 billion, outpacing market growth. With competitor products (once-weekly bisphosphonates) gaining market share, Chugai conducted a nationwide treatment adherence program to emphasize how important it is for patients to continue taking their osteoporosis medication and based promotional activities on the product's established safety profile, which is backed up by a substantial body of data.

Despite generic erosion, the active vitamin D<sub>3</sub> derivative Alfarol maintained its position as a foundation treatment for osteoporosis. Sales decreased only ¥0.1 billion, or 0.7 percent, to ¥13.6 billion.

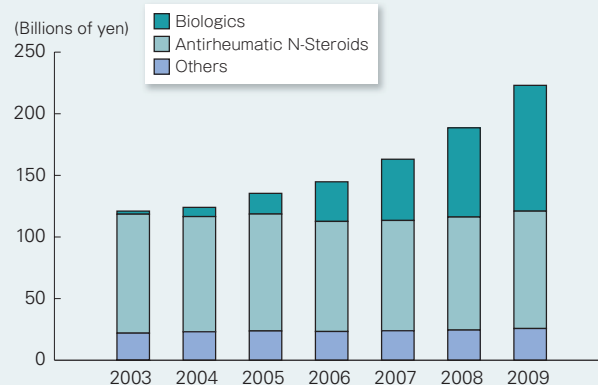
The osteoarthritis market has been growing in recent years as a result of increased awareness of the

### Osteoporosis Market in Japan



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### Rheumatoid Arthritis Market in Japan



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disease. Further market expansion in 2009 was led by sales of Suvenyl, which rose ¥1.7 billion, or 14.2 percent, to ¥13.7 billion. Growth is being driven by recognition of the clear advantages of Suvenyl, the only high molecular weight agent approved in Japan to treat osteoarthritis, over competitor products.

## 2010 Strategy and Outlook

In 2010, Chugai is stepping up promotional activities to further expand sales of Actemra.

In Japan, we will continue to focus on informing rheumatologists about the product's safety, efficacy and other advantages with the goal of positioning Actemra as a first-line biologic treatment.

Overseas, sales are expected to grow strongly as the global rollout continues. In January 2010, Actemra was approved by the U.S. Food and Drug Administration for the treatment of adult patients with moderate to severe RA who have had an inadequate response to one or more tumor necrosis factor antagonist therapies. Its U.S. launch followed later the same month. As a condition of approval, post-marketing clinical studies and the implementation of a Risk Evaluation and Mitigation Strategy (REMS)\* are required in order to collect and convey real-world safety data. The U.S. launch represents a major step forward in establishing Actemra as a key component of RA therapy. Chugai will

work closely with Roche and Genentech to highlight the strong clinical efficacy data for Actemra and its innovative mechanism of action—the key to its value—and promote its growth as a pharmaceutical product that provides a new treatment option for people around the world living with RA.

In the area of osteoporosis, Chugai's efforts will focus on maintaining its position as a leading company. While more intense competition is expected due to the launch of a competitor product, Chugai will continue working to maximize the value of Evista by highlighting the extensive efficacy and safety data available for this product after five years on the market. To secure the market presence of Alfarol until the launch of its successor, ED-71 (see "Products under Development" and page 59 for details), Chugai will re-emphasize the importance of vitamin D<sub>3</sub> therapy.

\* Comprehensive program of post-marketing safety measures provided for under the U.S. Food and Drug Administration Amendments Act of 2007 (FDAAA)

## Products under Development

In the area of RA, Roche filed applications in Europe and in the United States in September 2009 and March 2010, respectively, to extend marketing approval of Actemra to include inhibition of the progression of joint damage and improvement of physical function in RA patients. A formulation for subcutaneous injection is also under global development and is steadily advancing through phase I/II clinical trials in Japan. From October 2009, Chugai suspended administration of RG1594 (ocrelizumab), a humanized anti-CD20 monoclonal antibody in development for the treatment of RA, to patients enrolled in domestic phase I/II clinical trials and also in a global phase III trial in which Chugai is participating. This followed Roche's decision in October to suspend administration of RG1594 to patients in the Asia-Pacific region, where a higher incidence rate of opportunistic infections has been detected. In March 2010, Roche and Biogen Idec announced that the RA program for RG1594 has been put on hold and administration to all RA patients suspended.



### Alfarol

Agent for improving bone metabolism. The top brand among active vitamin D<sub>3</sub> derivatives, this original Chugai product is a foundation treatment for osteoporosis.

In the area of osteoporosis, an application was filed in October 2009 for ED-71, an active vitamin D<sub>3</sub> derivative for which Chugai has a co-development and co-marketing agreement with Taisho Pharmaceutical Co., Ltd. A direct comparison of ED-71 with alfacalcidol confirmed that ED-71 has a statistically significant effect in preventing vertebral fractures and a similar safety profile. Chugai expects ED-71 to make a significant contribution to the treatment of osteoporosis as a next-generation product.

Phase II/III clinical trials of an injectable formulation of RG484 (overseas product name: Bonviva/Boniva), a bisphosphonate medicine for the treatment of osteoporosis that is also being co-developed with Taisho, are proceeding smoothly toward planned filing in 2012. Existing oral bisphosphonates are normally taken once a week, whereas RG484 can be taken just once a month. This less-frequent dosing schedule is expected to improve adherence to treatment, a major issue in osteoporosis therapy.

### **Product under Development: ED-71**

ED-71 is an active vitamin D<sub>3</sub> derivative discovered by Chugai based on many years of in-house research on osteoporosis. It exhibits a superior effect on bones compared with existing active vitamin D<sub>3</sub> agents widely used to treat osteoporosis in Japan. Chugai is co-developing ED-71 with Taisho Pharmaceutical Co., Ltd., and an application for marketing approval was filed in October 2009.

Active vitamin D<sub>3</sub> derivatives act on the small intestine to enhance calcium absorption from food, and also stimulate renal tubular calcium reabsorption. In addition, they have gained an important position as a basic treatment for osteoporosis through demonstrated effectiveness in preventing bone fractures. In a phase III trial, ED-71 was shown to be significantly more effective than alfacalcidol (Alfarol) in preventing vertebral fractures and had a similar safety profile. We have high expectations for ED-71 as a next-generation active vitamin D<sub>3</sub> derivative.

# Others

Chugai is working to promote early detection and effective treatment of chronic hepatitis C as a way to energize the market, and developing new products to boost its market position. We are also focusing on development of treatments for diabetes and diseases of the central nervous system—two areas with substantial unmet medical needs.

## Sales of Major Products

Product Name (Generic name)	Sales (Billions of yen)	Brief Overview	Launch Year in Japan
<b>Tamiflu*</b> (oseltamivir)	07 38.7 (28.5) 08 8.4 (1.3) 09 76.2 (40.0)	Anti-influenza agent	Feb. 2001 (capsule) Jul. 2002 (dry syrup)
<b>Sigmart</b> (nicorandil)	07 17.9 08 17.0 09 16.6	Anti-anginal agent	Apr. 1984 (capsule) Jul. 1993 (injection)
<b>Pegasys</b> (peginterferon alfa-2a)	07 6.3 08 9.7 09 11.1	Peginterferon alfa-2a	Dec. 2003
<b>Rocephin</b> (ceftriaxone)	07 5.7 08 5.9 09 5.5	Cephem-type antibiotic	Aug. 1986 (0.5g and 1g IV injection) Jun. 2003 (1g IV drip bag)
<b>Copegus</b> (ribavirin)	07 2.0 08 4.2 09 4.9	Anti-viral agent in combination with Pegasys	Mar. 2007
<b>Cellcept</b> (mycophenolate mofetil)	07 3.5 08 4.0 09 4.4	Immunosuppressant	Nov. 1999

\* ( ) Sales for government stockpile.

## Development Pipeline (As of February 3, 2010)

Development Code (Product name)	Status Phase I	Phase II	Phase III	Filed	Approved	Indication	Generic Name	Dosage Form	Origin (Collaborator)
<b>RG964</b> (Copegus)			● (II/III)			Compensated liver cirrhosis caused by hepatitis C virus	ribavirin	Oral	Roche
<b>RG442</b> (Pegasys)			● (II/III)			Compensated liver cirrhosis caused by hepatitis C virus	peginterferon alfa-2a	Injection	Roche
			● (II/III)			Chronic hepatitis B			
<b>NA808</b>	●					Chronic hepatitis C	—	Injection	In-house
	● (Overseas)								
<b>NTZ</b>	●					Chronic hepatitis C	nitazoxanide	Oral	Romark Laboratories

## Other Diseases

<b>EPOCH</b> (Epopin)				● Jun. 1994		Predeposit of autologous blood transfusion	epoetin beta	Injection	In-house
<b>CSG452</b> (RG7201)		● (Global study)				Type 2 diabetes	—	Oral	In-house (Roche)
<b>RG1678</b>		● (Global study)				Schizophrenia	—	Oral	Roche
<b>RG1583</b> (ITM-077)		●				Type 2 diabetes	taspeglutide	Injection	Roche/Ipsen (Teijin)
<b>RG1450</b>	●					Alzheimer's disease	gantenerumab	Injection	Roche/Morphosys

● Designates change in status in 2009 and thereafter.

## Review of 2009 Results

### Overview

In 2009, total sales in the Others field, which covers all products other than those for oncology, renal diseases, and bone and joint diseases, increased ¥68.4 billion, or 87.5 percent, year-on-year to ¥146.6 billion. Driving this substantial growth was a more than nine-fold increase in sales of the anti-influenza agent Tamiflu due to the influenza A/H1N1 ("swine flu") pandemic and higher sales for government stockpiling. In the chronic hepatitis C segment, sales of Pegasys, a pegylated interferon-based medicine, and of Copegus (ribavirin), an antiviral agent used in combination with Pegasys, increased steadily, reflecting market expansion and growing recognition of the value of these products.

### Chronic Hepatitis C

Sales of Pegasys climbed ¥1.4 billion, or 14.4 percent, to ¥11.1 billion. The product's market share in 2009 rose to 23.8 percent, up 1.8 percentage points from the previous year.<sup>1</sup> In addition to market expansion due to government-sponsored education programs, sales benefited from a steady increase in prescriptions of combination therapy with Copegus. The unique features of Pegasys, which (unlike a competitor product) is



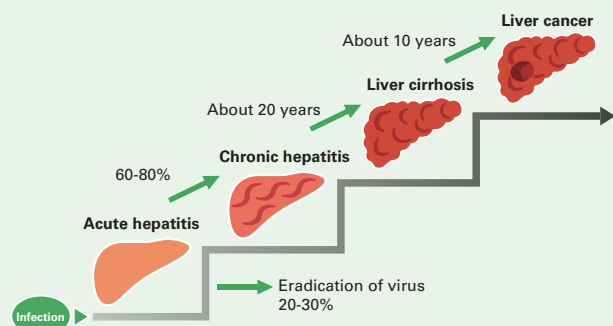
### Pegasys/Copegus

Treatment for chronic hepatitis C. Market share in Japan is expanding.

approved both as monotherapy and in combination with ribavirin, also contributed to its strong market position.

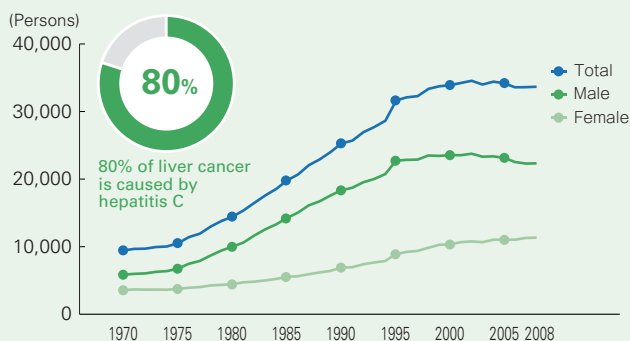
Chronic hepatitis C results from infection with the hepatitis C virus (HCV). An estimated two million patients in Japan have been infected. Untreated chronic hepatitis C may progress to liver cirrhosis and liver cancer. More than 30,000 people in Japan die from liver cancer each year, and about 80 percent of those cases are caused by chronic hepatitis C. In order to reduce its high mortality from liver cancer compared to other countries, the Japanese government is implementing numerous programs, including subsidies and other assistance, to promote early detection and treatment of hepatitis C. A joint subsidy program initiated in 2008 by

### Progression of Chronic Hepatitis C to Cancer



Source: Hamada H, et al. Cancer 95 331-9, 2002

### Number of Deaths from Liver Cancer



Source: Modified from Vital Statistics of Japan, Center for Cancer Control and Information Services, National Cancer Center, Japan.



### Tamiflu

Oral neuraminidase inhibitor for influenza A and B viruses. Available in capsule or dry syrup form.

the national and local governments in Japan for HCV patients undergoing interferon treatment was expanded in April 2009. Chugai, in addition to informing healthcare professionals of the benefits of Pegasys and Copegus, also focused on raising awareness of the disease among the general public. These activities include a website (<http://www.kanzenzero.jp>) that provides information about HCV and co-sponsoring public seminars. As a result, in 2009 sales of Pegasys grew faster than the peg-interferon market as a whole, which expanded 5.5 percent compared with 2008.

1. Copyright 2010 IMS Japan K.K. Source: JPM 2008-2009 Reprinted with permission. The scope of the market is defined by Chugai.

### Influenza

Sales of Tamiflu increased ¥67.8 billion (about nine times) to ¥76.2 billion. Seasonal sales amounted to ¥36.2 billion, an increase of ¥29.1 billion (about five times), while pandemic sales were ¥40.0 billion, an increase of ¥38.7 billion (about 30 times).

In 2009, the influenza A/H1N1 virus ("swine flu") spread rapidly worldwide, with many cases reported in the summer and fall, when influenza outbreaks are normally not expected. Responding to this public health crisis, Chugai focused on providing practical support to meet clinical needs. We provided clinical and safety data on the use of Tamiflu in high-risk patients, including pregnant women or people undergoing dialysis, and

distributed information materials for patients. The Influenza Information Service website (<http://influenza.elan.ne.jp>), which Chugai established as part of these activities, won the "2009 Best Disease Information Award,"<sup>2</sup> based on its content and user-friendliness.

In 2008, the Japanese government decided to stockpile enough anti-influenza dosage courses to cover 45 percent of the population, in line with levels in other developed countries, with the national government adding a further 13.3 million courses of Tamiflu and local governments together another 13.3 million courses to their respective stockpiles. The national government order was filled in 2009, as mentioned above, while the local government stockpile is being expanded over three years, starting in 2009.

2. Out of some 300 disease education sites in the *Byoki ga Wakaru Web Awards* program organized by QLife, Inc., a general medical media company.

## 2010 Strategy and Outlook

In the chronic hepatitis C area, the passage of the Basic Law on Hepatitis Countermeasures in November 2009 has spurred discussion regarding further enhancement of HCV treatment, including expansion of the treatment subsidy program. Chugai is working to further strengthen the position of Pegasys and Copegus by actively informing healthcare professionals about the positive clinical data from Japan and overseas for these products, as well as providing additional information on HCV to the general public.

In the influenza area, the launch of competitor products will broaden treatment options. Chugai is continuing its efforts to contribute to influenza treatment by providing information based on the clinical data the Company has accumulated since the launch of Tamiflu in 2001. In pandemic sales, we anticipate purchases of 3.2 million courses of Tamiflu by the national government in 2010, as well as additional purchases by local governments.

## Products under Development

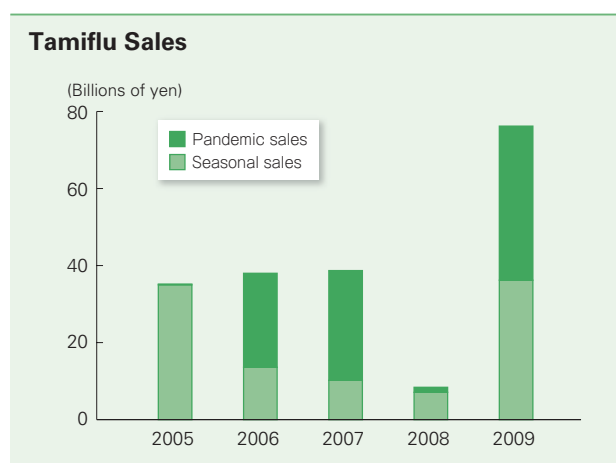
In the area of chronic hepatitis C, phase I trials of NA808, a small-molecule compound from Chugai research, are progressing as planned. NA808 is designed to inhibit HCV replication by acting on a protein found in human hepatocytes (a type of liver cell), whereas existing drugs act directly on the virus. It is hoped that this novel mechanism will reduce the development of resistant strains of HCV and demonstrate efficacy against all genotypes of the virus. In addition, in August Chugai began phase I clinical trials with NTZ (nitazoxanide), a novel anti-HCV compound licensed from U.S.-based Romark Laboratories. NTZ is being investigated in combination with Pegasys and Copegus. Expectations are rising for the potential of NA808 and NTZ because many HCV patients in Japan are intolerant or respond inadequately to interferon treatment. In addition, Chugai plans to file a marketing application in 2010 for approval of combined Pegasys and Copegus in the additional indication of compensated liver cirrhosis caused by HCV infection. Phase II/III clinical trials with Pegasys in the additional indication of chronic hepatitis B are progressing as planned.

Chugai also continued to make progress in two new fields: diabetes and central nervous system.

The number of patients with type 2 diabetes is increasing worldwide. However, achieving sustained blood sugar control can be a challenge with currently available medicines, which may also have side effects such as hypoglycemia, weight gain and edema. Chugai aims to expand the range of treatment options and develop compounds that can treat the underlying pathology. CSG452, a selective SGLT2 inhibitor, is a small-molecule compound from Chugai research. This agent is designed to achieve continuous control of blood sugar in an insulin-independent manner through excretion of glucose in the urine. In 2007, this compound was licensed out to Roche, which is participating in a global phase II study with Chugai. RG1583 (taspoglutide), licensed from Roche, is the first once-weekly human glucagon-like peptide-1 (GLP-1) hormone analogue. Chugai began phase II clinical trials of RG1583 in Japan with Teijin Pharma Limited in July 2009.

Overseas, Roche is conducting an extensive phase III development program with RG1583, involving some 7,000 patients; positive initial results from five trials in this program were reported toward the end of the year.

In the central nervous system field, Chugai has two compounds licensed from Roche in development. We began phase I clinical trials in July 2009 investigating RG1450 (gantenerumab), a human anti-amyloid beta-peptide monoclonal antibody, as a potential treatment for Alzheimer's disease. Results of a global phase II study with RG1678, a glycine transporter type 1 (GLYT-1) inhibitor currently under development for schizophrenia, were announced in November 2009. The results showed a good safety profile of the compound and statistically significant efficacy in reducing the negative symptoms of patients with schizophrenia.



# Organization and Human Resources

## Mission-Driven Leadership with Innovative Management

- 38 Research
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- 47 Board of Directors/Corporate Auditors
- 48 Executive Officers

Our foremost responsibility is stable delivery of safe, high-quality medicines to patients.

Mina Masuda  
Fujieda Plant

# Research

**Focusing on five strategic areas including oncology, Chugai seeks to benefit patients and other stakeholders by continuously creating innovative medicines that address unmet medical needs.**

## Basic Policy

Generating a steady stream of innovative medicines that address unmet medical needs for the benefit of the medical community and human health around the world is the basis of Chugai's relationship with patients and other stakeholders. In discovery research, the heart of our business, we focus on five areas: oncology, renal diseases, bone and joint diseases, diabetes and infectious diseases.

Our research organization aims not just to achieve quantitative productivity — the discovery of a certain number of new compounds in a given period — but also to create new medicines that anticipate the future environment in which they will be used. Typically, it takes more than a decade for a drug candidate to advance from the research stage through clinical trials to approved use as a medicine. We therefore begin by considering how treatment methods will evolve over the next ten to twenty years, and what challenges are likely to remain. With this approach, we believe we can create innovative medicines that will truly benefit patients.

## Chugai's Research Organization

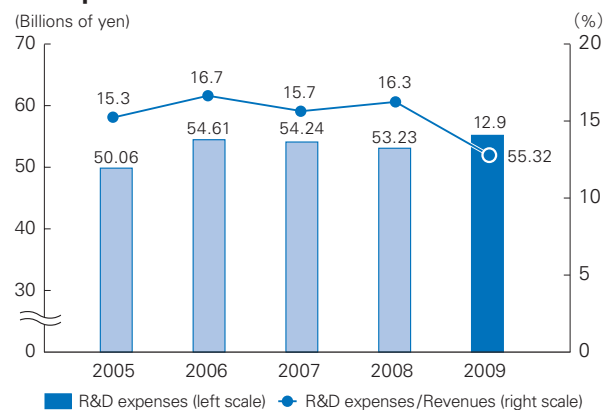
Through its strategic alliance with Roche and merger with Nippon Roche, Chugai has established a strong research organization with expertise in both biopharmaceuticals and small molecules. This is a result of combining the pre-merger strengths of the two companies: Chugai's leading position in Japan in biopharmaceuticals, including antibodies, and the Nippon Roche technology platform for discovering and developing small-molecule, chemically synthesized medicines.

The alliance with Roche and membership in the Roche Group has also enabled Chugai to dramatically improve its research infrastructure. Chugai and Roche

share research tools, including a compound library and chemical evaluation database, as well as information on the development of therapeutic antibodies. Access to world-class drug discovery platforms has enhanced Chugai's research productivity, especially in the areas of lead discovery and optimization.

Chugai's collaborative network of academic and other organizations involved in cutting-edge research represents an additional competitive advantage. Cooperating with such institutions in Japan and abroad to gain access to the latest findings in basic research is vital for the continuous development of innovative medicines at a time when scientific advances offer the prospect of developing completely new therapeutic approaches. Chugai has a long tradition of complementing its own research organization with external

### R&D Expenses

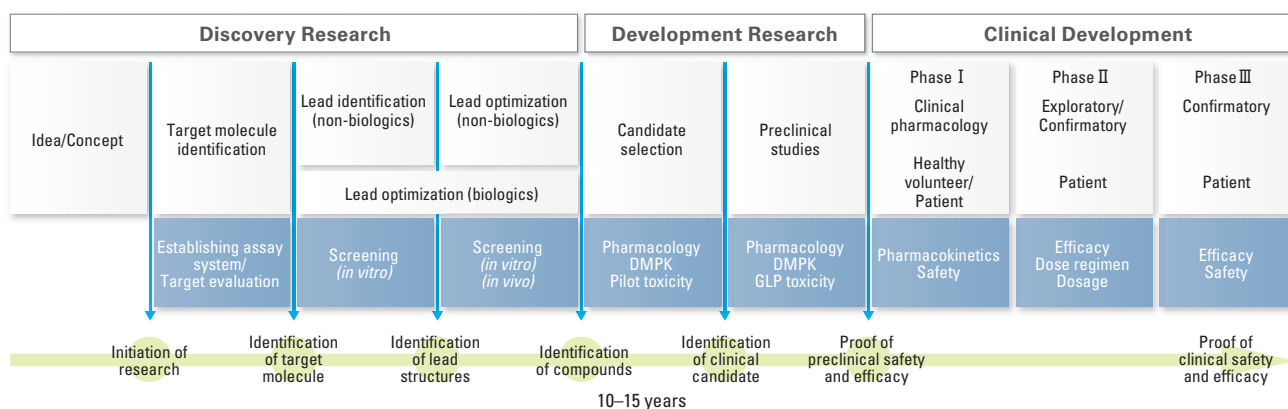


### Progress in 2009 and Thereafter

	Number of Projects	Breakdown		
		New Molecular Entities	Additional Indications	Additional Dosage and Administration / Formulations
Approved	5	—	4	1
Filed	5	2	3	—
Entered Phase III	2	1	1	—
Entered Phase II	6	3	2	1
Entered Phase I	5	5	—	—
Suspended Development	2	2	—	—

(As of February 3, 2010)

## Process and Milestones of Drug Development



institutions through close collaboration, with a focus on enhancing its ability to create innovative medicines from basic research. The success of Actemra, which was developed through joint research with Osaka University, demonstrates the value of this approach.

## Progress and Outlook

In recent years, many projects from Chugai research, including CIF, CKI27, GC33, TP300, CSG452 and NA808, have entered clinical development. The steady progress of these compounds is also testimony to the benefits of the alliance with Roche for Chugai's

Research Division. GC33 draws on research conducted at PharmaLogicals Research, our joint venture in Singapore, and with Tokyo University, and is therefore the fruit of our persistent efforts to strengthen our research organization. Chugai is also building a platform of advanced technologies focusing on biomarker research as a new approach to discovery that aims to deliver more effective, personalized healthcare solutions.

Chugai will continue to develop innovative new drugs that address unmet medical needs around the world by enhancing in-house research and fully using the resources available to it as a member of the Roche Group.

### Intellectual Property Strategy

It is not uncommon for pharmaceutical products to be covered by just a few basic patents. Intellectual property (IP) strategy can make or break a product's success and is therefore critically important. Under Chugai's IP Policy established in 2007, the IP strategy is integrated with management and R&D strategies and implemented on a companywide basis. This helps to protect the competitive advantage of our products and secure operational flexibility. We also take care to respect the intellectual property rights of other companies in our business activities.

Chugai's basic policy emphasizes high-quality patent applications and effective allocation of resources. We concentrate resources on key projects selected according to internal guidelines and aggressively file patent applications outside Japan as well. The Intellectual Property Department works closely with the Research Division from the earliest stages of research to build a network of patents that will maximize the value of products once they are on the market. In addition to the patent network, which is the foundation of product value, we strategically acquire patents to extend product life. The Intellectual Property Department also participates in lifecycle meetings and cooperates in other ways with departments involved in development. It constantly looks for new patent opportunities to add further value to existing products, including new indications and dosage forms.

# Human Resources Strategy

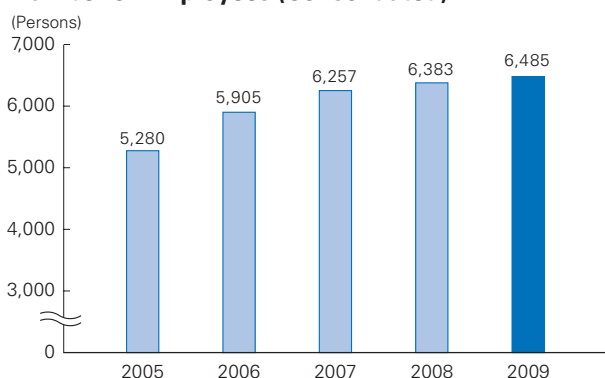
**To realize our long-term goal of growth driven by innovative drugs and establish our position as a top pharmaceutical company, we are building a strong base of human capital and creating a rewarding work environment that fosters growth of individual employees.**

## Basic Policy and the Ideal Employee Model

Chugai's guiding principle is that people are the key asset in generating growth. We offer a range of programs suited to individual employee needs, with the aim of creating a rewarding work environment that allows them to achieve personal growth. At the same time, we have established an "ideal employee" model that defines the kind of people we need to become a world-class pharmaceutical company and achieve sustained growth. We are promoting a human resources (HR) strategy to cultivate such individuals.

We recently added two new dimensions to our ideal employee model, which lies at the core of our HR strategy: a high level of expertise and communication ability, and global competency. Chugai's continued growth depends on seamless creation of innovative pharmaceuticals and maximization of the value of its products and development portfolio. To achieve these objectives, we require employees with highly specialized skills who create new value by communicating well with colleagues, medical professionals and many other stakeholders throughout our business process, from research and development to production and marketing. Developing employees with global competency who can conduct business on an equal footing with other companies around the world is also essential for Chugai as it moves to boost its international competitiveness.

**Number of Employees (Consolidated)**



## Recent Initiatives

To become a top pharmaceutical company in Japan, we also need to build programs and work environments that take advantage of the diversity of our employees. The number of female employees at Chugai has been increasing in recent years. Women now account for about 20 percent of our MRs. Creating an environment that allows them to achieve their full potential is a key theme. Chugai has already introduced various systems and programs to enable employees to continue working while raising their families: childcare leave, a working parent program, and the *wiwiw*\* program, among others. In 2008, Chugai received the "Kurumin Mark," a certification provided by the Ministry of Health, Labour and Welfare, for the Company's active support of work/life balance. In 2009, we established a new plan that enables MRs to change their working arrangements after marriage, thus allowing them to continue in the same jobs. Chugai continues to enhance these measures.

As Japan's population ages, it is also important to make effective use of the experience and expertise of seniors. Chugai had a system in place that gave senior employees the option to continue working after the mandatory retirement age of 60. However, it limited them to part-time employment and the choice of jobs was also restricted. To address these and other issues, in 2008 we decided to establish a senior employment system and are now preparing for its implementation in 2011. Under this new program, employees aged 55 or older can choose to continue working full-time as contract employees until the age of 65. This will allow senior employees to put their wealth of experience to greater use. In 2009 and 2010, we have been promoting this system to eligible employees and conducting career design training to encourage them to think about their life plans.

We will remain focused on creating a vibrant work environment that gives employees choice and independence in their careers. By taking a proactive approach to employee development, we aim to establish and enhance our base of human capital, which is vital in becoming a top pharmaceutical company in Japan.

\*An online program that provides support for employees returning to work and raising children after taking maternity or childcare leave.

# Corporate Social Responsibility

**Chugai is committed to creating innovative drugs that address unmet medical needs. At the same time, our conduct reflects our social mission to contribute to diverse stakeholders.**

## Benefiting Patients

### Developing and Providing Innovative Drugs

Chugai focuses on creating innovative drugs that contribute to medical treatment around the world, with an emphasis on unmet medical needs. To provide a continuous, stable supply of safe, high-quality medicines, we are strengthening supply chain management to optimize our activities from raw material procurement to production and distribution.

### Raising Patient Awareness

Chugai is actively involved in programs to raise disease awareness among patients. Since 2005, we have participated in the Pink Ribbon Campaign, which promotes the early detection, diagnosis and treatment of breast cancer. Since 2008 we have also operated an information website (<http://www.kanzenzero.jp>) that promotes the early detection and treatment of hepatitis C, with the hope that the number of people suffering from this disease will one day be reduced to zero. In 2009, we displayed a Giant Colon exhibit at the Relay For Life, a charity event to support cancer patients, to raise public awareness of colon cancer and the importance of early detection.

### Establishment of the Chugai Academy for Advanced Oncology

As Japan's leading supplier of oncology drugs, Chugai believes that it has an obligation to take the initiative in helping to bring cancer treatment in Japan to a world-class level as soon as possible. To that end, in October 2009 we established the Chugai Academy for Advanced Oncology. The academy will hold international forums, provide research grants and conduct other activities to contribute to the advancement of oncology research and development in Japan from a different standpoint than our usual corporate activities.

## Contributing to Society

### Donation of Vehicles with Rear Lifts to Home Welfare Services

In October 2009, Chugai donated five vehicles with rear lifts for wheelchairs to five home welfare facilities serving senior citizens and people with disabilities. The

vehicles are used as transportation for people receiving home care. Chugai has donated a total of 178 vehicles since this program began in 1985.

## Supporting Employees

### Helping Employees Build Rewarding Careers

Chugai has a robust support system to help employees build rewarding careers, including a Career Support Center, a system of leave to study abroad or obtain qualifications, an internal recruitment system and various employee training programs. In 2009, we started the Chugai FCL (Future Core Leaders) program for long-term, ongoing development of the people who will lead the Company in the future.

## Protecting the Environment

### Countering Global Warming

The Chugai Group has set the goal of reducing its CO<sub>2</sub> emissions to the level of 2003 by 2012. In addition to installing energy-saving equipment and photovoltaic power generation equipment in production facilities and research laboratories and introducing hybrid vehicles in our sales fleet, we have implemented dress codes to reduce utility costs. Our CO<sub>2</sub> emissions have been rising, however, due to factors including increased production volume and construction of new buildings. We have drawn up a medium-term reduction plan that includes installation of additional energy-saving equipment, and remain committed to reaching our goal through initiatives that are supported by employees and the general public.



For further information concerning Chugai's CSR activities, please refer to the Corporate Social Responsibility Report CSR '09. The report presents Chugai's corporate policies, including its Mission Statement and corporate governance policy, and provides stakeholders with an update on CSR initiatives and environmental protection activities undertaken in 2009.

The full report is on our website:  
<http://www.chugai-pharm.co.jp/english/csr/index.html>

# Corporate Governance

**Chugai views the enhancement of corporate governance as crucial to achieving sustained business growth. Based on this recognition, we are working continuously to ensure management transparency and strengthen our internal control system.**

## Corporate Governance

### Basic Policy

Chugai is committed to increasing corporate value continuously and responding appropriately and fairly to the requests of shareholders and other stakeholders. To fulfill this commitment, we have positioned the enhancement of corporate governance as an important management task and are building a system that emphasizes prompt decision-making, clarification of executive responsibilities and management transparency.

### Management Decision-Making, Execution and Oversight of Business Operations

To expedite business operations and clarify executive responsibilities, we have adopted an executive officer system to keep decision-making on management issues of primary importance separate from business execution. The Board of Directors is in charge of the former, while executive officers are entrusted by the board with the authority to conduct the latter. The Executive Committee makes decisions concerning business execution.

#### Board of Directors

The Board of Directors makes decisions on management issues of primary importance and receives quarterly reports on the state of business execution as well as reports on key decisions made by the Executive Committee. It is also responsible for oversight of the execution of business operations. The board consists of 12 directors, including seven outside directors. Four of the outside directors are from the Roche Group. In 2009, the Board of Directors convened 10 times.

#### Executive Committee

The Executive Committee makes important executive decisions. It consists of 14 members, including the president, key executive officers and the two full-time

corporate auditors. In addition, the IR Committee, Risk Management Committee and Corporate Social Responsibility Committee have been established under the Executive Committee.

### Introduction of Outside Perspectives

To reflect diverse stakeholder viewpoints in business decisions, Chugai has taken measures to obtain outside perspectives, such as nominating outside directors and establishing an advisory board made up of domestic and overseas specialists.

#### Outside Directors

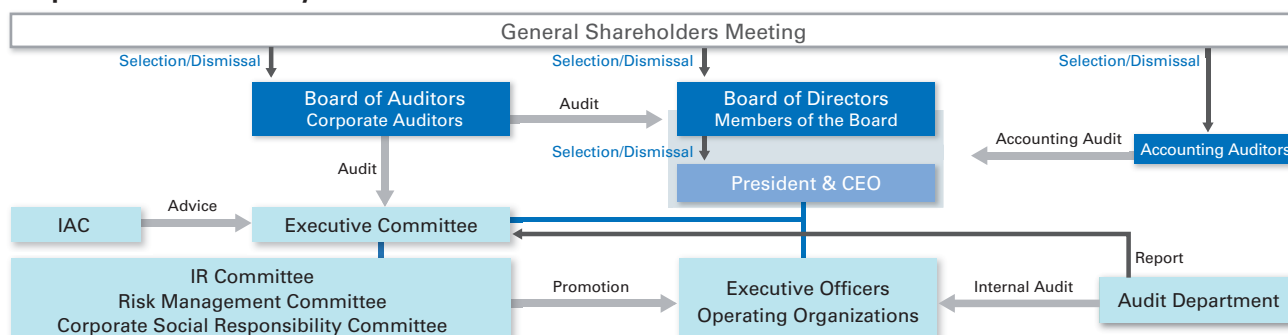
Outside directors provide timely and proactive advice concerning Chugai's management and business operations both in and outside board meetings.

Outside directors contribute to management decision-making through advice and oversight based on their abundant experience and knowledge as medical specialists or international business professionals. Because the residences of the outside directors are spread around the world, it is difficult in some cases to have the attendance of all outside directors at board meetings. The rate of attendance by outside directors at the 10 board meetings in 2009 was approximately 55 percent on average, the highest being 88 percent and the lowest 30 percent.

#### International Advisory Council

Chugai has established the International Advisory Council (IAC), an advisory board composed of industry leaders and other specialists from around the world. The IAC provides valuable advice on how to deal with changes in the global business environment and appropriate business conduct. In February 2009, the IAC meeting convened in San Francisco for a lively exchange of opinions regarding the path Chugai should take and important issues the industry will face. In addition, the council was bolstered by the nomination of three new specialists with considerable experience and knowledge primarily in the oncology field.

## Corporate Governance System



### International Advisory Council Members

- **Professor Victor Halberstadt (the Netherlands)**  
Professor, Leiden University
- **Mr. Andre Hoffmann (Switzerland)**  
Vice Chairman, Roche Holdings
- **Dr. Keith Jones (United Kingdom)**  
Former Head of the EMEA
- **Dr. Arnold J. Levine (U.S.A.)**  
Professor at the Institute for Advanced Study, Princeton University  
Discoverer of the p53 cancer suppressor protein
- **Professor Abraham D. Sofaer (U.S.A.)**  
George P. Shultz Distinguished Scholar and Senior Fellow at the Hoover Institution, Stanford University  
Former advisor to the U.S. Department of State
- **Mr. Goro Watanabe (Japan)**  
Senior Advisor, Mori Building Co., Ltd.

#### New appointments:

- **Dr. Andrew von Eschenbach (U.S.A.)**  
Former commissioner of the Food and Drug Administration
- **Mr. Robert A. Ingram (U.S.A.)**  
Vice Chairman of Pharmaceuticals, GlaxoSmithKline, plc, acting as special advisor to the Group
- **Mr. Henry L. Nordhoff (U.S.A.)**  
Chairman of the Board, Gen-Probe, Inc.

## Audit Department

The Audit Department, consisting of 14 members including certified internal auditors, conducts internal audits of operational conditions including the compliance status of various organizations within the Company. It makes reports and recommendations to the Executive Committee. In addition, it conducts a control self-assessment in every department to maintain sound operations.

## Accounting Auditors

Chugai retains Ernst & Young ShinNihon LLC to conduct accounting audits and internal control audits in accordance with the Corporation Law and Financial Instruments and Exchange Act.

## Cooperative Auditing

Corporate auditors, the Audit Department and the accounting auditors cooperate closely by regularly exchanging information to improve the effectiveness of their respective audits. Corporate auditors and the accounting auditors confirm each other's audit plans and exchange opinions on matters including quarterly and year-end audit reports. Corporate auditors also attend accounting audit reviews. The Corporate Auditors' Support Section ensures the independence of corporate auditors and enhances auditing functions.

## Auditing System

### Audits by Corporate Auditors

Chugai has a Board of Corporate Auditors, and audits of management decision-making and business execution are conducted independently from business operations by four corporate auditors, including two outside corporate auditors.

Corporate auditors express their opinions from the standpoint of appropriate corporate governance in a variety of real-time occasions including meetings of the Board of Directors, the Executive Committee (full-time auditors only) and the Board of Corporate Auditors.

## Officer Remuneration

Remuneration and bonuses paid to directors are tied to business performance, and are set within the amounts approved at the general meeting of shareholders, taking into account the operating environment, the Company's business results and individual performance. To further clarify the linkage of directors' compensation to the Company's business performance and shareholder value, and to increase the incentive for directors to improve business performance, the Company gives directors stock options as stock-based compensation in addition to stock acquisition rights. With the introduction of stock options as stock-based compensation in 2009, the directors' retirement benefits system was abolished.

### Amount of Remuneration, etc. Paid to Directors and Corporate Auditors (Millions of yen)

	Remuneration, etc.	Stock Option	
		Common Stock Option	Stock Option as Stock-based Compensation
Directors (15)	580	50	94
Outside Directors included (8)	67	—	—
Corporate Auditors (5)	84	—	—
Outside Corporate Auditors included (2)	21	—	—

(Notes)

1. The headcounts and amounts shown in the table on the left include the three Directors and one Corporate Auditor who retired during the fiscal year under review.
2. The amount of remuneration, etc. paid to all Directors was no more than ¥750 million per year as per the resolution passed in the 96th annual general meeting of shareholders held in March 2007.

The maximum amounts of compensation paid to Directors in the form of stock acquisition rights allocated as stock option, separately from the remunerations shown in the table on the left, are ¥150 million per year for stock option as stock-based compensation and ¥125 million per year for common stock option as per the resolution passed in the 98th annual general meeting of shareholders held in March 2009.

3. The amount of remuneration for all Corporate Auditors was no more than ¥100 million per year as per the resolution passed in the 95th annual general meeting of shareholders held in March 2006.
4. The amounts of remuneration, etc., shown in the table on the left include the following:

Provision for reserve for bonuses to directors for the fiscal year under review

Directors (internal)	Seven persons	¥174 million
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5. The amounts of common stock option and stock option as stock-based compensation shown in the table on the left are the amounts that were posted as expenses for the fiscal year under review.

6. A resolution was passed in the 98th annual general meeting of shareholders held in March 2009 to abolish the retirement benefits system for Directors who perform duties, and a resolution was passed in the 95th annual general meeting of shareholders held in March 2006 to abolish the retirement benefits system for Directors and Corporate Auditors who do not perform duties.

• In addition to the amounts shown in the table on the left, provision for reserve for directors' retirement benefits was accounted for as an expense, as shown below, during the fiscal year under review prior to the abolition of the system:

Directors (internal)	Six persons	¥22 million
----------------------	-------------	-------------

- In addition to the amounts shown in the table on the left, directors' retirement benefits for the period from the appointment of each until the abolition of the system, were paid as follows:

Retiring Directors (outside)	Three persons	¥10 million
Retiring Corporate Auditor (internal)	One person	¥4 million

Payment to one of the above retiring Directors was made after the end of the fiscal year under review.

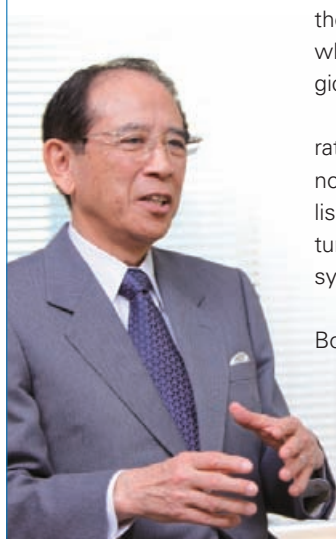
7. In the fiscal year under review, the amount of remuneration, etc. received from the Roche Group by five Directors, namely, Franz Bernhard Humer, Severin Schwan, William M. Burns, Jonathan K.C. Knowles and Erich Hunziker, totaled ¥3,072 million (converted into yen at the averages of exchange rates in the fiscal year under review).

## Outside Director Mitsuo Ohashi

Chugai is a company with a mix of cultures: the Company's original culture maintained since its foundation, the cultures of its diverse people who brought business and other experience from different industries, and the culture of Roche, with which Chugai formed a strategic alliance in 2002.

Through its unique corporate environment, Chugai is now in the process of establishing its own corporate culture and corporate governance system.

I was asked to join Chugai's Board of Directors in late



**Mitsuo Ohashi**  
Outside Director

March 2005. During my five years here, I've been feeling the significant responsibilities as a director and serving to fully perform them, not only by shedding light on questions and expressing my views in board meetings, but also through activities such as visiting Roche's headquarters and maintaining a dialogue with mid-level employees as part of Chugai's executive development plan.

Harmonizing and integrating the many valuable cultures and people in Chugai is important for maximizing its corporate value and meeting the expectations of shareholders, as well as for developing excellent medicines and contributing to mankind and society. I believe that creating a fresh corporate culture full of intensity is the most essential ingredient in achieving this.

There is no shortage of talent among the Company's employees. The key will be whether we can harness the intense energy of these varied talents. Nothing would make me happier as a director than to help shape such a corporate culture and contribute to Chugai's growth and advancement.

## Relationship with Roche

Roche, the parent company of Chugai, owns 59.9 percent of Chugai's outstanding shares, but the basic agreement establishing the alliance between the two companies restricts the extent to which Roche may increase its shareholding in Chugai for the 10-year period following the date of the merger of Chugai and Nippon Roche (October 1, 2002).<sup>1</sup> Roche and Chugai have agreed to cooperate in maintaining the listing of Chugai's common stock on the First Section of the Tokyo Stock Exchange after this 10-year period.<sup>2</sup>

Chugai makes all decisions based on the principle of self-governance and considers its management independence to be ensured by the fact that the directors from Roche constitute less than half of the members of its Board of Directors.

In addition to our capital ties, we maintain a wide-ranging partnership with Roche that includes many joint development projects and co-promotion activities in Europe. However, in our business dealings with Roche, we conduct fair transactions using third-party prices in order to protect the interests of minority shareholders.

We will continue to manage our business with autonomy and independence as a publicly listed company.

1. The restrictions do not apply to increases in Roche's shareholding that result from share repurchases by Chugai.
2. The Tokyo Stock Exchange requires delisting if the ratio of tradable shares to listed shares is less than 5 percent.

### Restrictions on Roche's Shareholding

Period	Maximum Shareholding Percentage
Oct. 1, 2002 – Sept. 30, 2007	50.1%
Oct. 1, 2007 – Sept. 30, 2012	59.9%
Oct. 1, 2012 and after	Cooperate in maintaining Chugai's listing

## Chugai's International Advisory Council

The International Advisory Council (IAC) of Chugai was formed in 2003, succeeding the International Board of Advisors established in 1995 to provide advice on international trends and policies.

The idea of having a purely advisory body to consider Chugai's place in an increasingly global industry was formed by CEO Osamu Nagayama and implemented with the approval and support of Chugai's Board of Directors. Advisors with extensive experience in the pharmaceutical industry, drug and health regulation, medical research, government and law are selected from several countries, including Japan. The advisors meet each year with the CEO and key members of his team to offer valuable suggestions and recommendations about the regulatory and business challenges faced by Chugai based on their extensive experience and achievements. With its current membership, the IAC is well suited to continue to serve the interests of Chugai and thereby benefit its shareholders and the health of consumers worldwide.

The IAC has focused on many issues of significance to Chugai, but none more important than its future as a Japanese company determined to preserve its identity while continuing to be a world-class center for the discovery of medicines to treat the most complex and devastating diseases. The talent and devotion of Chugai's leaders and personnel ultimately guarantee its success, but the Company's willingness to seek and act upon the advice of advisors and its international partner, Roche, reflects a fundamental strength that will help ensure its future.

**Professor Abraham D. Sofaer**

IAC Member



## Internal Controls

### Basic Policy

Chugai believes that maintaining good internal control is crucial to fulfilling its social responsibilities and making appropriate and timely management decisions. With this belief, we strive to enhance our internal control activities across the entire organization. The Chugai Business Conduct Guidelines (Chugai BCG) are our standards for management decision-making and employee behavior. The Corporate Social Responsibility Committee created under the Executive Committee, together with the Corporate Social Responsibility Department, ensure that the guidelines are implemented throughout the Company. Also, we established the BCG Hotline to receive employee inquiries and reports concerning compliance with laws, internal Company rules and Chugai BCG. An external hotline is also available to employees.

### Compliance

Based on a Board of Directors resolution on improvement of the internal control system, Chugai established the Risk Management & Compliance Department to preside over compliance with laws and other rules. We also put in place Compliance Regulations as the fundamental rules of our compliance system. These regulations are promoted by the Risk Management & Compliance Department and the Compliance Committee, established under the Risk Management Committee. Among specific activities, the Risk Management & Compliance Department conducts monitoring surveys on compliance status each quarter and reports the results to the Executive Committee. We also work to ensure thorough legal compliance through compliance managers and specialists in each organization.

### Financial Reporting

Chugai began preparing for the new system of internal controls over financial reporting under the Financial Instruments and Exchange Act (also known as "J-SOX").

We have formulated a basic policy for the establishment, management and assessment of internal controls over financial reporting, formulated a system of controls that ensures reliable financial reporting and implemented control design effectiveness assessments. In 2009, the first year of operation of the new system, we conducted such an assessment and concluded that our system of controls was effective.

### Risk Management

Chugai has established Risk Management Regulations to prevent risks that could affect the Company's business activities as well as to ensure prompt and appropriate handling of problems that arise. We have also established a Risk Management Committee under the Executive Committee, and Division Risk Management Committees. The Risk Management Committee draws up a comprehensive list of risks facing all divisions based on information provided by each Division Risk Management Committee, identifies companywide risks that may significantly affect management and submits a progress report to the Executive Committee concerning preventive measures for such risks.

# Board of Directors/Corporate Auditors (As of March 25, 2010)

## Representative Directors



**Osamu Nagayama**



**Motoo Ueno**

## Directors



**Ryuzo Kodama**



**Dr. Tatsumi Yamazaki**



**Tatsuro Kosaka**



**Mitsuo Ohashi**  
Chairman of the Board, SHOWA  
DENKO K.K.



**Dr. Yasuo Ikeda**  
Professor of Department of Life  
Science and Medical Bioscience of  
Graduate School of Advanced Science  
and Engineering of Faculty of Science  
and Engineering of Waseda University



**Abraham E. Cohen**  
Chairman of Chugai Pharma U.S.A.



**William M. Burns**  
Director, Roche



**Dr. Erich Hunziker**  
Chief Financial Officer, Roche



**Pascal Soriot**  
Roche Pharmaceuticals Division,  
COO



**Dr. Jean-Jacques Garaud**  
Head Roche Pharma Research &  
Early Development (pRED)

## Corporate Auditors



**Shigetoshi Matsumoto**  
(full-time)



**Dr. Yasuhiro Tsuji**  
(full-time)



**Dr. Yasunori Fujii**  
Special Assigned Professor of  
Shizuoka Sangyo University



**Toshio Kobayashi**  
Partner, The Law Offices of  
Nagashima Ohno & Tsunematsu  
Visiting Professor, University of  
Tokyo Graduate Schools for Law  
and Politics

# Executive Officers (As of March 25, 2010)



**Members of the Executive Committee:**

from left (front) Osamu Nagayama, Motoo Ueno  
(middle) Dr. Yutaka Tanaka, Tatsuro Kosaka, Ryuzo Kodama, Dr. Tatsumi Yamazaki, Naotaka Nakamura, Michiharu Abe  
(back) Shigetoshi Matsumoto, Yoshio Itaya, Dr. Hidetoshi Ushio, Shin-ya Unno, Fumihiko Kamoshida, Dr. Yasuhiro Tsuji

## Osamu Nagayama

President  
CEO / COO

## Motoo Ueno

Deputy President  
Audit

## Ryuzo Kodama

Executive Vice President  
CFO, Finance & Accounting, BPR

## Dr. Tatsumi Yamazaki

Executive Vice President

## Tatsuro Kosaka

Executive Vice President  
Head of Lifecycle Management & Marketing Unit,  
Overseas Development

## Naotaka Nakamura

Executive Vice President  
General Manager of Sales Div.

## Dr. Yutaka Tanaka

Senior Vice President  
Head of Portfolio Management Unit

## Michiharu Abe

Senior Vice President  
Head of Corporate Regulatory Compliance &  
Quality Assurance Unit

## Dr. Hidetoshi Ushio

Senior Vice President  
General Manager of Pharmaceutical Technology Div.

## Shin-ya Unno

Senior Vice President  
General Manager of Corporate Planning Supervisory Div. and  
General Manager of Corporate Planning Dept.

## Yoshio Itaya

Senior Vice President  
General Manager of Finance Supervisory Div. and  
General Manager of Finance & Accounting Dept.

## Fumihiko Kamoshida

Senior Vice President  
General Manager of Legal Dept.

## Dr. Hisafumi Okabe

Vice President  
General Manager of Research Div.

## Dr. Minoru Machida

Vice President  
Deputy General Manager of Pharmaceutical Technology Div.  
and Chugai Pharma Manufacturing Co., Ltd. (President)

## Kotaro Miwa

Vice President  
Department Manager of PT Planning Dept.

## Dr. Yasushi Ito

Vice President  
General Manager of Clinical Development Div.

## Shunji Yokoyama

Vice President  
General Manager of Drug Safety Div.

## Tetsuo Minoura

Vice President  
Deputy General Manager of Sales Div.

## Akio Tanaka

Vice President  
Deputy General Manager and Head of Oncology Unit

## Masaaki Tohaya

Vice President  
Deputy General Manager and Head of Primary Unit

## Katsuyori Kunii

Vice President  
Department Manager of Transplantation Immunology Area  
Medical Business & Science Dept.

## Keiji Shima

Vice President  
Supervisory Branch Manager of Tokyo Branch 1

## Susumu Kato

Vice President  
Supervisory Branch Manager of Osaka Branch

## Hideaki Nagai

Vice President  
General Manager of IT Supervisory Div. and  
General Manager of Information Systems Dept.

## Mitsuru Kikuchi

Vice President  
General Manager of External Affairs Dept.

## Mamoru Togashi

Vice President  
General Manager of Human Resources Supervisory Div. and  
General Manager of Human Resources Management Dept.

## Kunitoshi Watanabe

Vice President  
General Manager of General Affairs Supervisory Div. and  
General Manager of General Affairs Dept.

## Yoichi Yamanaka

Vice President  
General Manager of Corporate Social Responsibility Dept.

## Toshihiko Tsuchiya

Vice President  
General Manager of Secretarial Dept.

## Tomoyuki Nakayama

Vice President  
Chugai Research Institute for Medical Science, Inc.  
(President)

Facts and Figures

# Mission-Driven Leadership Based on the Facts

- 50 Development Pipeline
- 52 Basic Information

Kyoko Takami  
Fuji-Gotemba Research Laboratories

# Development Pipeline (As of February 3, 2010)

Development Code (*Additional Indication)	Indication	Status Phase I	Phase II	Phase III	Filed	Approved
Oncology						
EPOCH*	Chemotherapy-induced anemia	<div></div>				Nov. 2009
RG435*	Breast cancer	<div></div>				Oct. 2009
	Colon cancer (adjuvant)	<div></div>		(Global study)		
	Gastric cancer	<div></div>		(Global study)		
	Breast cancer (adjuvant)	<div></div>		(Global study)		
	Glioblastoma	<div></div>		(Global study)		
	Glioblastoma (relapsed)	<div></div>				
	RG1415*	Pancreatic cancer	<div></div>			
RG340*	Gastric cancer	<div></div>		(Global study)		
RG597*	Gastric cancer	<div></div>		(Global study)		
RG1273*	Breast cancer	<div></div>		(Global study)		
MRA*	Pancreatic cancer	<div></div>	(I / II)			
TP300	Gastric cancer, etc.	<div></div>	(Overseas)			
CIF (RG7167)	Solid tumors	<div></div>				
		<div></div>	(Overseas)			
CKI27 (RG7304)	Solid tumors	<div></div>				
		<div></div>	(Overseas)			
GC33	Liver cancer	<div></div>	(Overseas)			
GA101 (RG7159)	Non-Hodgkin's lymphoma	<div></div>				
RG3502	Breast cancer	<div></div>				
Renal Diseases						
RG744	Renal anemia	<div></div>				Jul. 2009
Bone and Joint Diseases						
ED-71	Osteoporosis	<div></div>				Oct. 2009
MRA*	Systemic onset juvenile idiopathic arthritis (sJIA)	<div></div>		(Overseas)		
	Rheumatoid arthritis (new formulation: subcutaneous injection)	<div></div>	(I / II)			
RG1594	Rheumatoid arthritis	<div></div>		(Global study)		
RG484	Osteoporosis	<div></div>		(II / III)		
		<div></div>				
Transplant, Immunology and Infectious Diseases						
RG964*	Compensated liver cirrhosis caused by hepatitis C virus	<div></div>		(II / III)		
RG442*	Compensated liver cirrhosis caused by hepatitis C virus	<div></div>		(II / III)		
	Chronic hepatitis B	<div></div>		(II / III)		
NA808*	Chronic hepatitis C	<div></div>				
		<div></div>	(Overseas)			
NTZ	Chronic hepatitis C	<div></div>				
Other Diseases						
EPOCH*	Predeposit of autologous blood transfusion	<div></div>				Jun. 1994
CSG452 (RG7201)	Type 2 diabetes	<div></div>	(Global study)			
RG1678	Schizophrenia	<div></div>	(Global study)			
RG1583 (ITM-077)	Type 2 diabetes	<div></div>				
RG1450	Alzheimer's disease	<div></div>				

Generic Name / Product Name	Origin (Collaborator)	Mode of Action
epoetin beta / Epogin	In-house	Recombinant human erythropoietin (Injection)
bevacizumab / Avastin	Roche	Anti-VEGF (vascular endothelial growth factor) humanized monoclonal antibody (Injection)
erlotinib / Tarceva	Roche / OSI	EGFR tyrosine kinase inhibitor (Oral)
capecitabine / Xeloda	Roche	Antimetabolite, 5-FU derivative (Oral)
trastuzumab / Herceptin	Roche	Anti-HER2 humanized monoclonal antibody (Injection)
pertuzumab	Roche	HER dimerization inhibitory humanized monoclonal antibody (Injection)
tocilizumab / Actemra	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody (Injection)
—	In-house	Topoisomerase I inhibitor (Injection)
—	In-house (Roche)	MEK inhibitor (Oral)
—	In-house (Roche)	(Oral)
—	In-house	Humanized anti-glypican-3 monoclonal antibody (Injection)
—	GlycArt	Humanized anti-CD20 monoclonal antibody (Injection)
—	Roche	Anti-HER2 humanized monoclonal antibody-drug conjugate (Injection)
(Overseas name: Mircera)	Roche	Continuous erythropoietin receptor activator (Injection)
eldecalcitol	In-house (Taisho Pharmaceutical)	Active vitamin D <sub>3</sub> derivative (Oral)
tocilizumab / Actemra (US), RoActemra (EU) tocilizumab / Actemra	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody (Injection)
ocrelizumab	Roche	Humanized anti-CD20 monoclonal antibody (Injection)
ibandronate sodium hydrate (Overseas name: Bonviva (US), Boniva (EU))	Roche (Taisho Pharmaceutical)	Bisphosphonate (Injection) Bisphosphonate (Oral)
ribavirin / Copegus	Roche	Anti-viral agent in combination with Pegasys (Oral)
peginterferon alfa-2a / Pegasys	Roche	Peginterferon alfa-2a agent (recombinant) (Injection)
—	In-house	Serine palmitoyl transferase inhibitor (Injection)
nitazoxanide (Overseas name: Alinia)	Romark Laboratories	Thiazolide compound (Oral)
epoetin beta / Epogin	In-house	Recombinant human erythropoietin (Injection)
—	In-house (Roche)	SGLT2 inhibitor (Oral)
—	Roche	GLYT1 inhibitor (Oral)
taspoglutide	Roche/Ipsen (Teijin)	GLP-1 analogue (Injection)
gantenerumab	Roche / Morphosys	Human anti-amyloid-beta monoclonal antibody (Injection)

# Basic Information

## Basic Information on the Pharmaceutical Industry

### Overview of Domestic Pharmaceutical Market and NHI Drug Price Revisions

#### Trends in National Medical Expenses

Without medical system reforms, Japan's national medical expenses will increase at an annual rate of approximately three percent to four percent going forward. In the year ended March 2008, national medical expenses totaled ¥34,136.0 billion, a ¥1,008.4 billion increase from the previous year. The rapid aging of Japan's society presents the serious challenge of efficiently managing the marked increase in medical expenses for the elderly.

#### National Health Insurance (NHI) Drug Price Revision

The Ministry of Health, Labour and Welfare (MHLW) generally reviews drug reimbursement prices every two years and sets standard prices (reimbursement prices) so that the prices of pharmaceuticals prescribed under the health insurance system approximate their actual market price. MHLW does this by investigating the prices and volumes of all prescription drug transactions during a given period. In the year ending March 2011, drug reimbursement prices are set to decline by 1.23

percent overall on a medical cost basis, or 5.75 percent on a reimbursement price basis.

#### Impact of National Health Insurance Price Revision

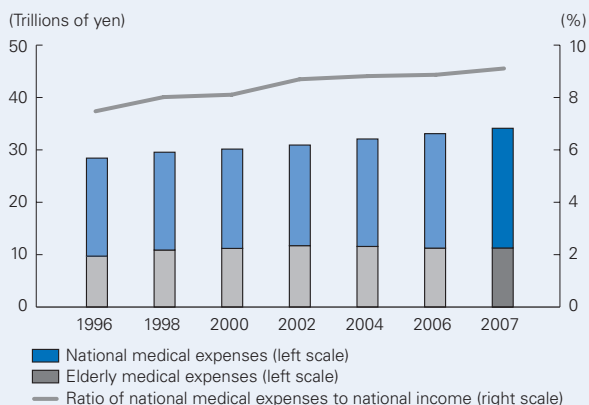
NHI Drug Price Reduction Rate (%)	2006	2008	2010
Industry Average	6.7	5.2	6.5
Chugai	7.2	7.2	6.8

Source: Chugai data

In December 2009, the Central Social Insurance Medical Council, which advises MHLW, approved the FY2010 Framework for Drug Pricing Reimbursement System Reforms. With this approval, a new pricing scheme will be implemented on a trial basis as part of the drug price revisions for the year ending March 2011 to promote the creation of innovative new drugs and solve the drug lag<sup>1</sup> problem. In this scheme, at the time of the drug price revisions a premium equal to the weighted-average percentage price difference of all listed drugs minus two percent, multiplied by 0.8, will be added to the price of drugs for which no generics<sup>2</sup> are available (provided that they have been in the NHI price list for no more than 15 years), and which satisfy certain conditions.<sup>3</sup>

1. The inability of Japanese patients to access global standard or state-of-the-art treatments because the drugs are not developed in Japan.
2. Generic drugs, which are approved after the expiry of the patents for original drugs with the same active ingredients and efficacy.
3. The percentage price difference between the current market price and the reimbursement price of the original drug must not exceed the weighted-average percentage price difference of all listed drugs.

#### Trends in National and Elderly Medical Expenses



Source: Overview of National Medical Expense by Ministry of Health, Labour and Welfare.

Note: National income is based on the actual results of the System of National Accounts (announced in December 2008 by the Cabinet office).

#### Prescription Drug Market



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### Changes to Promote Use of Generics

MHLW is instituting changes to prescription rules in line with an Action Program announced in October 2007 to promote the safe use of generics. Until now, physicians have ticked the “Can be substituted” box on the prescription form if they had determined that a generic was acceptable. However, from April 2008 they need to tick a box only if they do not agree to substitution with a generic. The Japanese government aims to trim medical expenditure by raising the generic share of prescription drug volume from approximately 17.2 percent as of 2008 to 30 percent by 2012.

## Oncology

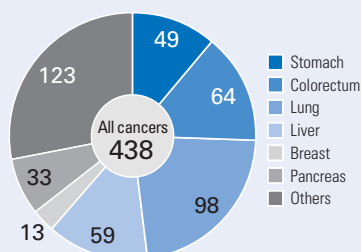
### Overview of Diseases and Treatment Methods

#### Leading Cause of Death in Japan

Cancer has been the single most common cause of death in Japan since 1981. In 2008, approximately 343,000 people died of cancer, accounting for 30.0 percent of all deaths in that year and the highest figure recorded since government surveys began in 1899.

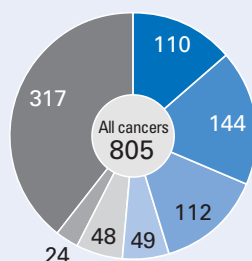
#### Cancer Mortality (Estimates for 2015)

(Thousands of cases)



#### Cancer Incidence (Estimates for 2015)

(Thousands of cases)



Source: Cancer White Paper-Incidence/Death/Prognosis-2004 (Shinohara Shuppan Shinsha).

### Establishment of the Basic Act for Anticancer Measures and Changes in the Healthcare Environment

In June 2006, the Diet enacted the Basic Act for Anticancer Measures, which stipulates the obligation of national and local governments to promote measures to fight cancer. The basic principle of the law is to develop optimal cancer treatment systems in every region of the country so that patients can receive optimal treatment in accordance with their wishes (“the availability of optimal treatment” for cancer patients). The law includes provisions for (1) improvement of cancer prevention and treatment technologies, (2) development of oncologists and “hub” institutions that specialize in cancer, and (3) enhanced provision of information to patients.

#### The Changing Cancer Treatment Environment from the Patient’s Perspective

Measures introduced as part of the patient-centered cancer treatment policy are bringing about major changes in the Japanese cancer treatment environment. The Basic Act for Anticancer Measures requires the national government to formulate a basic plan and policies to fight cancer after listening to the opinions of patients, their families and experts. As a result of these patient-centered policies, great progress is being made in the training of oncologists and other healthcare professionals such as nurses, pharmacists and nutritionists working with oncologists. Advances have also been seen in efforts such as establishing networks among local medical institutions by designating interregional hub cancer centers. Japan’s first medical oncologists were certified in 2006, and as of April 2009 there were 306 such specialists. Moreover, there is a growing multi-disciplinary approach involving oncologists and other healthcare professionals such as nurses, pharmacists and nutritionists. The drug lag problem – the inability of Japanese patients to gain access to global standard or state-of-the-art treatments – is also being addressed, and the adoption of a patient-centered approach to treatment is significantly changing oncology in Japan.

## Solving the Drug Lag Problem

In January 2005, MHLW established the Investigational Committee for Usage of Unapproved Drugs as one means of helping solve the drug lag problem. The committee is charged with investigating the clinical necessity and the appropriateness of usage of drugs already approved in Europe and the United States but not yet approved in Japan. The aim of these investigations is to promote the clinical trials of those drugs in Japan.

MHLW has also reinforced several functions of the Pharmaceutical and Medical Devices Agency, an independent administrative institution responsible for reviewing drugs and medical devices for approval. Measures include increasing the number of staff involved in the reviewing process, introducing a project management system under which a dedicated staff is appointed to oversee the progress, providing guidelines on global clinical studies, clarifying reviewing criteria and offering an improved consultancy function. The goal is to shorten the period from new drug development through approval by two-and-a-half years (development by one-and-a-half years and the review process by one year) by the year ending March 2012.

## Changes in Treatment Methods

Cancer treatment is increasingly being based on a multidisciplinary approach that combines surgery, radiation therapy and anticancer agents. In particular, the field of anticancer agents is evolving, and highly innova-

tive medications such as molecular targeted drugs have been introduced. This has brought about a dramatic improvement in treatment outcomes in colorectal, lung and breast cancer, malignant lymphoma and other forms of cancer.

As the adverse reaction profiles of these drugs differ from those of conventional anticancer agents, it is now recognized that there is a need for cancer drug therapy specialists with a thorough knowledge of drug mechanisms of action, pharmacokinetics and the effects of co-administration with other drugs. Furthermore, in recent years, there has been a rapid increase in the number of cancer patients receiving drug treatment on an outpatient basis, which allows them to maintain their normal lifestyles. To ensure the medical safety of chemotherapy for these patients, a multidisciplinary approach involving close collaboration between oncologists and other healthcare professionals has become essential.

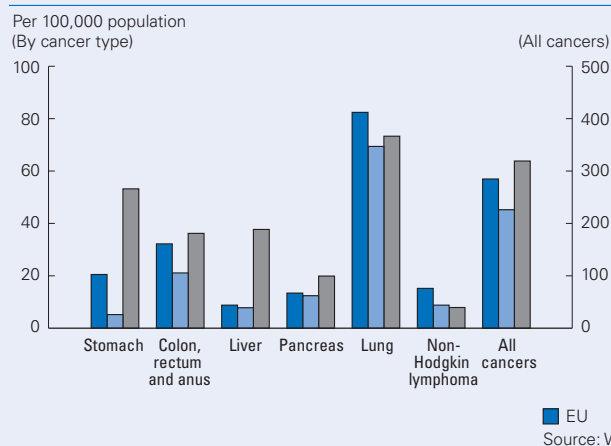
## Overview of Products and Development Projects

### Neutrogin

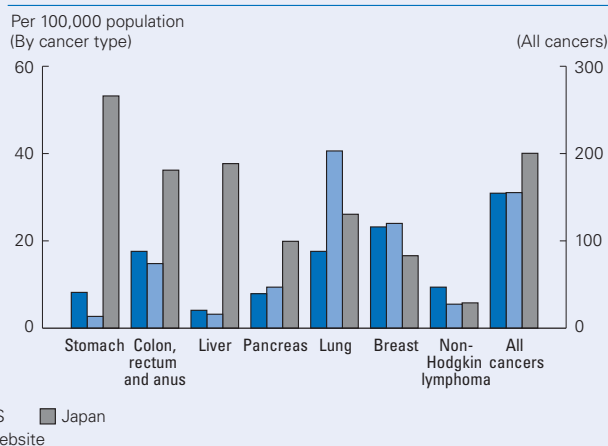
Neutrogin is a recombinant human granulocyte colony-stimulating factor (G-CSF) developed by Chugai. G-CSF is a hematopoietic factor that specifically promotes the differentiation and growth of cells of the granulocytic series (especially neutrophils) in bone marrow.

### Cancer Mortality Rate (2005)

#### Male



#### Female



Neutrogin has the effect of reducing the period when the neutrophil count is low and promoting recovery in various types of neutropenia. Neutrogin is used to treat neutropenia that occurs as a side effect of anticancer agents, mobilize peripheral blood progenitor cells, promote neutrophilia after hematopoietic cell transplantation and treat neutropenia associated with myelodysplastic syndrome, aplastic anemia, HIV infection and immunosuppressive therapy following kidney transplantation. Overseas, Neutrogin is sold under the name Granocyte.

### **Herceptin**

Herceptin is a targeted monoclonal antibody that works across all stages of human epidermal growth factor receptor type 2 (HER2)-positive breast cancer. The product specifically activates the immune system and suppresses the HER2 protein that contributes to tumor cell growth. In Japan, this product is indicated for the treatment of patients with HER2-positive metastatic breast cancer and now also for postoperative adjuvant therapy of patients with early HER2-positive breast cancer.

### **Rituxan**

Rituxan is a targeted monoclonal antibody for the treatment of CD20-positive, B-cell non-Hodgkin's lymphoma. It works by binding to a specific protein (the CD20 antigen) found on the surface of normal and malignant B cells, activating the immune system to eliminate the marked cells. These are then replaced by healthy B cells from the bone marrow. The efficacy of Rituxan has been confirmed in many overseas and domestic clinical trials, and it is now the standard therapy for non-Hodgkin's lymphoma. As a result, it has gained wide recognition internationally. In Japan, Rituxan is marketed jointly by Chugai and Zenyaku Kogyo Co., Ltd. Outside Japan and North America, Rituxan is sold under the brand name MabThera by the Roche Group.

### **Avastin**

The humanized anti-VEGF (vascular endothelial growth factor) monoclonal antibody Avastin is the first antiangiogenesis agent in the world to receive approval. Avastin inhibits angiogenesis – the growth of the network of blood vessels that supply nutrients and oxygen to cancerous tissues.

Avastin is marketed globally by Roche Group companies. Chugai plans to investigate the efficacy of combinations of Avastin and its other anticancer agents. We expect Avastin to play a key role in improving our presence in oncology in Japan. In Japan, Avastin was launched in June 2007 for the treatment of advanced or recurrent colorectal cancer. In November 2009, it received approval for the additional indication of advanced or recurrent non-squamous non-small cell lung cancer.

### **Kytril**

Kytril is a selective inhibitor of the 5-HT<sub>3</sub> (serotonin) receptors found in afferent vagal nerve endings distributed mainly along the gastrointestinal tract. It is widely prescribed as an antiemetic agent to alleviate nausea and vomiting caused by adverse reactions due to anticancer agents.

### **Xeloda**

Xeloda was developed at the Kamakura Research Laboratories of the former Nippon Roche to improve the efficacy and safety of Furtulon. After Xeloda is absorbed by the body, it is gradually metabolized by certain enzymes present in high concentrations in the liver and tumors and is eventually converted into 5-FU within tumors. It is an innovative drug with high target specificity.

Xeloda is the standard treatment for metastatic breast cancer and colorectal cancer in more than 100 countries around the world. In Japan, Xeloda is currently used to treat advanced or recurrent breast cancer and as a postoperative adjuvant chemotherapy for colon cancer. In addition, a combination of Xeloda and oxaliplatin (a regimen called XELOX) was approved in September 2009 for treating patients with advanced or recurrent colorectal cancer.

### **Tarceva**

Tarceva is a targeted, small-molecule drug that inhibits the activation of human epidermal growth factor receptor (EGFR) by blocking the enzyme tyrosine kinase. EGFR plays a key role in the growth, progression and metastasis of cancer. The product is marketed overseas by Roche, Genentech and OSI Pharmaceuticals.

It is approved in Europe and the United States for the second-line treatment of advanced non-small cell lung cancer and the first-line treatment of metastatic pancreatic cancer. In Japan, Tarceva is currently approved for the second-line or later treatment of non-small cell lung cancer.

### **Femara**

Chugai commenced joint marketing of Femara, an aromatase inhibitor, with Novartis Pharma K.K., Femara's manufacturer and distributor, in May 2006. Femara is one of the standard drugs used in endocrine therapies for breast cancer and it has already been approved in over 100 countries around the world as a breast cancer treatment for postmenopausal women. Although it is the third agent to come into the domestic market as a third-generation aromatase inhibitor, we will aim to differentiate Femara from competitor products using the strong evidence in its favor: (1) Femara is the first aromatase inhibitor shown in large-scale clinical trials to be useful as an extended adjuvant therapy (adjuvant therapy after five years of standard tamoxifen therapy after surgery for breast cancer); (2) large-scale clinical trials overseas have confirmed that Femara reduces the risk of cancer recurrence as an initial adjuvant therapy commencing immediately after surgery; and (3) large-scale clinical trials have confirmed that Femara is more effective than tamoxifen in treating advanced and recurrent breast cancer.

### **TP300**

TP300 is a topoisomerase\* I inhibitor that prevents the growth of cancer cells by obstructing the activity of an enzyme called topoisomerase I, which contributes to the replication of DNA. With existing topoisomerase I inhibitors, concentrations in the blood following administration vary from patient to patient; these agents can also cause severe diarrhea as an adverse reaction.

\*Topoisomerase inhibitors designed as anticancer agents suppress the functioning of topoisomerase I or II in order to inhibit the synthesis of deoxyribonucleic acid (DNA). Topoisomerase is an enzyme that has the function of assisting the replication of the genetic code by unknotting the double helical configuration of DNA, by temporarily loosening the binding of the DNA to manifest the genetic code. Topoisomerase I cuts one strand of DNA, and topoisomerase II cuts two strands.

TP300 is designed to overcome these disadvantages, and we expect that it will demonstrate a high level of safety and efficacy. Phase II overseas clinical trials started in October 2009.

### **CIF (RG7167)/CKI27 (RG7304)**

CIF and CKI27 are targeted small-molecule agents developed by Chugai. Chugai has licensed them to Roche, and we are working on their development overseas. Phase I clinical trials are currently under way.

### **GC33**

GC33, a humanized antibody from Chugai research, targets glypican-3 proteins, which are specifically expressed in liver cancer. The project involves joint research between Chugai and Tokyo University, as well as clinical proteomics work by PharmaLogicals Research, a joint venture in which Chugai participates. Phase I overseas clinical trials are currently under way.

### **RG1273**

RG1273 (pertuzumab) is a monoclonal antibody licensed from Roche. It is the first in a new class of targeted agents known as HER dimerization inhibitors. Chugai is participating in Roche's global phase III study for the indication of HER2-positive breast cancer.

### **GA101 (RG7159)**

GA101 is a humanized monoclonal antibody licensed from Roche. Chugai is conducting phase I domestic clinical trials investigating GA101 as a potential treatment for non-Hodgkin's lymphoma.

### **RG3502**

RG3502 (trastuzumab-DM1) is an antibody-drug conjugate combining the anti-HER2 monoclonal antibody trastuzumab (active ingredient of Herceptin) with the chemotherapy agent DM1. Chugai started a phase I domestic clinical trial for the treatment of HER2-positive breast cancer in October 2009.

## Renal Diseases

### Overview of Diseases and Treatment Methods

#### Chronic Kidney Disease

Chronic kidney disease (CKD) is defined as the continuation for three months or more of “manifestations showing the existence of renal disease, such as positive proteinuria” or “presence of kidney damage (a glomerular filtration rate of less than 60 ml/min).”

Recently, reports containing ample evidence of the major risk posed by chronic kidney disease in end-stage renal failure and cardiovascular disease have prompted efforts to address this disease around the world. In Japan, too, measures are fully under way to deal with the problem. For example, the Japanese Society of Nephrology issued a CKD Clinical Practice Guidebook in 2007 and CKD Clinical Practice Guidelines in 2009. MHLW has initiated strategic research through The Kidney Foundation, Japan with the objective of achieving a 15 percent reduction in five years of the number of dialysis patients compared with current forecasts.

#### Chronic Renal Failure and Renal Anemia

Chronic renal failure is a disease in which renal function is significantly reduced due to a variety of causes, including diabetes-related renal disease, chronic glomerulonephritis, nephrosclerosis and polycystic kidney disease. In recent years, the rise in the number of diabetes patients has led to a corresponding increase in chronic renal failure in patients with underlying diabetes-related renal disease; this has become the primary reason for dialysis use.

For dialysis patients and end-stage renal failure patients, the treatment of serious complications of advanced renal dysfunction, such as renal anemia, secondary hyperparathyroidism, and abnormal calcium and phosphorus metabolism, is a major issue. Of these complications, renal anemia is one of the most frequent, occurring not only in dialysis patients but also in pre-dialysis patients. Renal anemia, in turn, is thought to be responsible for a wide range of further complications

suffered by renal failure patients, including deterioration in heart, brain and hemostatic functions. The importance of treating renal anemia and secondary hyperparathyroidism was indicated in Guidelines for the Management of Secondary Hyperparathyroidism in Chronic Dialysis Patients (2006) and the Guideline for Renal Anemia in Chronic Kidney Disease (2008) issued by the Japan Society for Dialysis Therapy and in the CKD Clinical Practice Guidelines (2009) issued by the Japanese Society of Nephrology.

#### Erythropoietin

Erythropoietin (EPO) is a hemopoietic factor produced mainly in the kidneys. It speeds up erythrocyte production by acting on normoblastic progenitor cells found in bone marrow. EPO preparations are effective in treating renal anemia caused primarily by the decline in erythropoietin production due to chronic renal failure. In addition, by correcting and controlling anemia, the drug is also thought to help improve the secondary complications listed above. Large-scale studies have shown that correction of anemia with EPO preparations helps reduce the length of hospital stays and improves both quality of life and life expectancy. It is estimated that EPO preparations are currently used by approximately 80 percent of dialysis patients and the majority of pre-dialysis renal failure patients with serum creatinine levels of 2mg/dL or more. Chugai's Epogin is thus an essential drug for the treatment of renal anemia.

#### A Flat-sum Reimbursement System for Erythropoietin Preparations

The number of patients receiving dialysis treatment in Japan has increased by about four percent annually, reaching 283,000 people as of December 2008, partly due to increased use of dialysis in patients with diabetes-related renal disease. Expenses for EPO preparations (about ¥140 billion<sup>1)</sup>, essential for dialysis treatment, accounted for 8.8 percent of all dialysis-related expenses in 2005.

Consequently, the government decided in its 2006 revisions of medical fees that the administration of erythropoietin in dialysis treatment would be comprehensively incorporated as a flat-sum reimbursement within the medical fee points<sup>2</sup> for “artificial kidney” (dialysis

treatment). The government changed the previous mechanism under which the number of fee points awarded depended on the amount of erythropoietin used. The new mechanism provides an integrated fee structure by adding the average amount of erythropoietin used per dialysis session to the medical fee points for one session.

1. Copyright 2010 IMS Japan K.K. Source: JPM 2005 Reprinted with permission. The scope of the market is defined by Chugai.
2. Formerly, the average amount of erythropoietin used per patient was approximately 4,500 international units per week, on the basis of three dialysis sessions per week. The new system adds points equivalent to 1,500 international units to the artificial kidney medical fee points and provides an integrated fee structure. The integrated fee points were set for review in 2008 and 2010.

## Overview of Products and Development Project

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### Epogin

Epogin is a human erythropoietin formulation that uses epoetin beta, produced through Chugai's unique gene recombinant technology, as its main active ingredient. Erythropoietin is effective in improving renal anemia primarily caused by the decline in erythropoietin production due to chronic renal failure. It also contributes to the improvement of a wide range of complications arising from anemia.

### RG744 (overseas product name: Mircera)

RG744 is a new anemia treatment with a very long serum half-life, enabling stable and sustained control of haemoglobin. Chugai filed for approval of RG744 in July 2009. RG744 stimulates erythropoiesis by a different interaction with the erythropoietin receptor on progenitor cells in the bone marrow. The serum half-life of RG744 is virtually the same for subcutaneous administration or intravenous injection, and the drug demonstrates effectiveness in relieving the symptoms of anemia when administered at four-week intervals during the maintenance period. Consequently, it may reduce the cost of hospital visits for patients with pre-dialysis chronic renal failure and may contribute to better treatment adherence. Furthermore, as a dialysis-related treatment, RG744 is expected to reduce medical costs such as drug administration costs and medical waste by dramatically reducing administration frequency. The

product thus has the potential to expand the range of options for the treatment of renal anemia.

### Renagel

Renagel is used to treat hyperphosphatemia. Because depressed renal functions impair the ability of dialysis patients to eliminate phosphorous excretions, phosphorous intake is controlled by phosphorous-eliminating dialysis and strictly controlled diets. However, these methods are not 100 percent effective in correcting oversupplies of phosphorous, so a phosphate binder is required to eliminate the excess phosphorous. Renagel differs from conventional calcium carbonates used to treat this condition, and there is almost no possibility of hypercalcemia occurring with Renagel use, as it is a new type of treatment, free of aluminum and calcium. Therefore, synergies with Chugai's other products can be expected. For instance, it becomes easier to use vitamin D<sub>3</sub> derivatives, in particular Oxarol, an agent for the treatment of secondary hyperparathyroidism.

### Oxarol

Synthesized by Chugai, Oxarol is the first intravenous active vitamin D<sub>3</sub> derivative agent in Japan. It treats secondary hyperparathyroidism – a result of prolonged dialysis – by acting directly on the parathyroid gland to control parathyroid hormone synthesis and secretion, and by acting to improve osteitis fibrosa and excess remodeling. Oxarol is proving to be effective in cases where previous oral vitamin D<sub>3</sub> derivatives were not.

## Bone and Joint Diseases

### Osteoporosis

Osteoporosis is considered to be a serious disease, as fractures caused by the disease, especially compression fractures of the spine and femoral neck, can decrease quality of life, leave patients bedridden and increase mortality risks. It is estimated that over 12 million people suffer from osteoporosis throughout Japan, with one in every two women aged 65 or over said to suffer from the disease. However, the treatment rate stands at around only 30 percent of the estimated number of sufferers due to a lack of readily noticeable symptoms. Consequently, the appearance of a new drug acts to expand the osteoporosis treatment market by exposing more patients.

#### Treatment Methods

In the past, drug treatment of osteoporosis mainly involved active vitamin D<sub>3</sub> derivatives, bisphosphonates and calcitonin preparations. Since 2005, however, there has been an increase in the use of Evista, a selective estrogen receptor modulator (SERM).

#### Regulatory Trends

National guidelines for osteoporosis treatment underwent major revision in October 2006 for the first time in about four years, with the aim of improving quality of life of the elderly and containing medical costs. Among the main points of the new guidelines are: (1) emphasis on the prevention of fractures; (2) a new focus on “bone quality” as an indicator of bone strength; and (3) establishment of criteria for the initiation of drug treatment that are separate from the criteria for diagnosis. The Ministry of Health, Labour and Welfare also seeks to promote diagnosis by urging local governments to provide periodic bone density testing for women from the age of 40.

### Overview of Products and Development Projects

#### Evista

Evista, a new category of osteoporosis treatment called SERM, has an estrogen-like effect on bones while reducing the occurrence of gynecological adverse reactions that are associated with existing estrogen drugs. In Japan, Evista has been jointly marketed by Chugai and Eli Lilly Japan since May 2004.

The results of large-scale overseas clinical trials conducted by Eli Lilly have established Evista as an evidence-based medicine. The drug reduces vertebral fractures and has low risk of causing breast cancer. New treatment guidelines implemented in October 2006 designated Evista as a grade-A recommended agent.

#### Alfarol

Alfarol, an active vitamin D<sub>3</sub> derivative, is positioned as the base drug for osteoporosis treatment. Alfarol inhibits the decline of bone mass by adjusting calcium and bone metabolism, and therefore is effective in preventing vertebral fractures. The latest treatment guidelines also indicate the drug's effect on prevention of falls, focusing attention on this feature that other osteoporosis treatments do not have.

#### ED-71

ED-71 (eldecalcitol) is a vitamin D<sub>3</sub> preparation born out of Chugai's many years of research in vitamin D. Currently, Chugai is developing it as the successor drug to Alfarol. In May 2008, we concluded a co-development and co-marketing agreement with Taisho Pharmaceutical Co., Ltd. Clinical trials have confirmed that ED-71 has a similar safety profile to the existing D<sub>3</sub> derivatives but a statistically significant greater effect in preventing fractures. Chugai filed for approval in October 2009.

#### RG484 (overseas product name: Bonviva/Boniva)

RG484 (ibandronate sodium hydrate) is a bisphosphonate that requires less frequent administration than existing medicines of the same class. It is available overseas in two dosage forms: a tablet that needs to be taken only once a month, and an injection that is given once every three months. These more convenient treatment schedules are expected to enable patients to take

a more active role in their treatment, thus improving adherence. In order to expedite development and maximize sales of RG484, Chugai concluded a co-development and co-marketing agreement with Taisho Pharmaceutical in September 2006.

## Rheumatoid Arthritis, Osteoarthritis

Rheumatoid arthritis (RA) is a systemic disease characterized by inflammation of joints leading to dysfunction, pain and deformity. A lack of appropriate treatment tends to result in deterioration of a patient's condition over time. It is estimated that there are about 600,000 to 700,000 patients in Japan suffering from RA, of whom some 350,000 are currently receiving drug treatment. The number of patients is increasing as the average age of the population rises. Systemic onset juvenile idiopathic arthritis (sJIA), the form of RA suffered by children below 16 years of age, is associated with growth disorders. It is considered even more difficult to treat than adult forms of the disease, as few suitable drugs are available.

The most common joint disease is osteoarthritis. Degeneration of the cartilage in the joints and surrounding areas causes joint pain, stiffness and loss of function. The disease is more common in older people and occurs in more than 80 percent of people over 60 years of age.

### Treatment Methods and Market Conditions

RA has been conventionally treated with antirheumatic drugs and anti-inflammatory analgesics, but biologics (anti-tumor necrosis factor (TNF) agents) targeting cytokines, proteins involved in the process of inflammation, have recently entered the market and expanded the range of treatment choices. Research in recent years implies that the administration of biologics at the early onset stage is effective in inhibiting bone and joint damage. The global market for these agents exceeded US\$6 billion in 2008, and the Japanese market also continues to grow.

sJIA is a serious and potentially fatal disease. While it is rare, with only a few hundred patients in Japan, no

effective treatment is available. Current therapy relies on steroid drugs, which can cause growth impairment and other adverse reactions. Accordingly, the approval and launch of Actemra in April 2008 is expected to provide a significant step forward in therapy.

The main drug therapies for osteoarthritis include non-steroidal anti-inflammatory analgesics, steroids and hyaluronic acid preparations. However, the level of satisfaction with these therapies is low, and more useful drugs are needed.

### Regulatory Trends

In October 2005, the Ministry of Health, Labour and Welfare released the Report of the Rheumatism and Allergy Countermeasure Committee. The report calls for the following measures to prevent rheumatism from becoming severe: (1) promotion of early diagnosis and the development of highly effective treatment methods; (2) establishment of medical service systems to provide appropriate care; and (3) improvement of the patient environment, including consultation opportunities and access to information.

The 2001-2010 period has been designated as the Bone and Joint Decade, and academic societies and other players are aggressively promoting research, diagnosis and treatment of osteoarthritis.

### Overview of Products and Development Project Suvenyl

Suvenyl, a drug that improves joint function through injection into the joint cavity, is a high molecular weight hyaluronate sodium drug that alleviates knee joint pains caused by knee osteoarthritis and RA. The superior performance of Suvenyl over low molecular weight hyaluronic acid, due to its physical and chemical properties being close to that of natural hyaluronic acid, has begun to widen the understanding among clinicians of the value of high molecular weight.

### Actemra

Actemra, the first antibody drug created in Japan, blocks the activity of interleukin-6 (IL-6), a type of cytokine. The high expectations placed by physicians in this new drug are shared by patients for whom conven-

tional treatments for RA, including existing biologics, have failed to be effective.

In April 2008, we obtained domestic approval for the additional indications of RA, polyarticular-course juvenile idiopathic arthritis and sJIA. In the European Union, Actemra (European product name: RoActemra) was approved for the treatment of RA in January 2009. In the United States, Actemra was approved in January 2010 for the treatment of adult patients with moderately to severely active RA who have had an inadequate response to one or more TNF antagonist therapies.

### RG1594

RG1594 (ocrelizumab) is a second-generation humanized anti-CD20 monoclonal antibody that binds to a particular protein (the CD20 antigen) on the surface of human B cell lymphocytes, activating the immune system to eliminate the marked cells. RG1594 is expected to be effective in treating diseases that involve B cells. Japan had been participating in a global phase III study by Roche; however, the study is currently suspended, as safety risks associated with infectious diseases were judged to outweigh the benefits.

## Others

### Chronic Hepatitis C

Chronic hepatitis C is a liver disease caused by persistent infection by the hepatitis C virus (HCV). In Japan, this disease has been designated a “21st century national health issue,” as there are over two million HCV carriers. Early detection and treatment of HCV is particularly important because approximately 70 percent of those infected develop chronic hepatitis, which gradually progresses to liver cirrhosis and then liver cancer.

#### Treatment Methods and Market Conditions

There are two methods of treating chronic hepatitis C: antiviral therapy to eradicate HCV from the body, and liver-support therapy to improve liver function and prevent the hepatitis from worsening.

Interferon therapy is the main antiviral treatment. However, the limited efficacy of conventional interferon drugs has led to an increase in the use of liver-support therapy in Japan, where about 80 percent of chronic hepatitis C patients do not receive interferon treatment. Since 2001, the introduction of interferon/ribavirin combination therapy and of peginterferon<sup>1</sup> has increased the treatment options available for patients with hepatitis C. Overseas, combined peginterferon and ribavirin is now the standard of care.

1. Interferon conjugated with polyethylene glycol, which makes the medication longer-acting.

#### Regulatory Trends

The Japanese government is aiming to double the number of hepatitis patients treated with interferon in the seven years from April 2008. It has been cooperating with local governments to implement a comprehensive seven-year program for hepatitis treatment. In order to diagnose potential patients who are unaware of their infection due to a lack of symptoms, public health-care centers have been offering free testing since 2008 to people aged 20 or older. Also, regional hospitals in each prefecture are designated as hub centers for hepatitis C treatment in order to provide patients with a

framework for treatment and consultation. Additionally, to ease the financial burden on hepatitis patients, the government is subsidizing medical fees by setting the upper limit of copayments depending on the patient's income level.

Furthermore, in January 2010, a new law went into effect to promote comprehensive measures against hepatitis. This law establishes a new Hepatitis Countermeasures Promotion Council in the Ministry of Health, Labour and Welfare (MHLW) to formulate basic policies for promoting measures against hepatitis, including prevention and medical treatment. The law also includes necessary provisions for the national and local governments to ease the financial burden on hepatitis patients to ensure that they can get appropriate treatment when necessary.

## Overview of Products and Development Projects

### Pegasys/Copegus

Pegasys is a pegylated interferon-based drug that enables sustained therapeutic concentrations to be achieved with once-weekly<sup>2</sup> administration, with fewer adverse reactions than standard interferon preparations. The guidelines for chronic hepatitis C treatment published by MHLW recommend Pegasys as monotherapy for patients with a low viral load or those who cannot use ribavirin.

Copegus is a chronic hepatitis C treatment that synergistically strengthens the antiviral effect when used in combination with interferon. Chugai obtained approval for Copegus in January 2007 and launched it in March in combination with Pegasys for the treatment of patients with chronic hepatitis C serogroup 1 infection<sup>3</sup> and high viral load, or those who have either not responded to, or have relapsed following, interferon monotherapy. This approval makes Chugai the only pharmaceutical company in Japan that can offer peginterferon for both monotherapy and combination therapy. The Company plans to use this advantage to maximize the value of the two products by seeking to expand its market share in the treatment of chronic hepatitis C and further expanding the range of indications. Pegasys is establishing its position as monotherapy for patients who are unable to use ribavirin.

2. Conventional interferon must be injected three or more times per week.
3. Genotypes I (1a) and II (1b), with which approximately 70 percent of HCV patients in Japan are infected.

### NA808

NA808 is a small-molecule compound that is expected to prove effective as a treatment for chronic hepatitis C. The drug acts on the body, not the virus, to inhibit the growth of the virus.

### NTZ

NTZ (nitazoxanide) is an oral thiazolide compound with broad-spectrum activity against parasites, anaerobic bacteria and viruses. Romark Laboratories, L.C. markets the product overseas under the brand name Alinia for diarrhea caused by parasites and is also developing it as a treatment for chronic hepatitis C. Chugai entered into a licensing agreement with Romark Laboratories in February 2009 and started phase I clinical trials in Japan in August 2009.

## Influenza

Influenza is an acute infectious disease characterized by the rapid onset of high fever (38 degrees centigrade or more) and severe systemic symptoms. It is highly infectious, and epidemics can develop quickly. In some cases, secondary infections can lead to very serious illness. Influenza is classified into types A, B and C based on differences in the antigenicity of the underlying virus. Types A and B can infect humans and cause major outbreaks.

## Overview of Product

### Tamiflu

Tamiflu is the only oral anti-influenza agent that is effective against both type A and type B infections. It inhibits viral replication by binding to and blocking the action of neuraminidase, an enzyme essential for the multiplication of the influenza virus. Launched in capsule form in February 2001 and dry syrup form in July 2002, dosages are available for patients one year of age and older.

Since March 2007, restrictions on the use of Tamiflu in teenage patients with seasonal influenza have been in force in Japan. The measure was introduced as a safety precaution following several reports of abnormal behavior in influenza patients who had taken Tamiflu. The interim report of an epidemiological survey published by a working group of MHLW suggested that there are no findings to date that point to a causal association between Tamiflu and the abnormal behavior of patients taking the drug. MHLW concluded that further investigations were needed and is continuing the restriction on the use of Tamiflu.

## Angina Pectoris

Hardening of the coronary artery or coronary spasms can cause constriction of the artery and lead to ischemia, a condition in which the heart does not receive sufficient blood flow. Clinical symptoms of angina pectoris include chest pain and pressure that accompany temporary ischemia. Nitric acid is used to treat angina pectoris, enlarging the coronary artery and increasing blood flow to the ischemia-affected areas. In addition, beta blocker agents are used for exertional angina pectoris treatment, and calcium blockers are used for coronary spasm related angina pectoris.

### Overview of Product

#### Sigmat

Anti-anginal agent Sigmart is a drug that overcomes the flaws of nitric acid compounds such as nitroglycerin and is effective in treating various types of angina pectoris. In October 2007, additional approval was obtained for acute heart failure.

## Castleman's Disease

Castleman's disease is a lymphoproliferative disease characterized by symptoms such as systemic lymphadenopathy, fever and general fatigue, as well as various abnormal laboratory test values including anemia, hypergammaglobulinemia and hypoalbuminemia. It has

been confirmed that these manifestations result from the excessive production of interleukin-6 (IL-6), one of the proteins that causes inflammation. Castleman's disease is very rare, affecting approximately 1,500 people in Japan.

### Overview of Product

#### Actemra

Actemra, a humanized anti-human IL-6 receptor monoclonal antibody produced using genetic recombination technology, is the first antibody drug created in Japan. With a mechanism of action that inhibits the receptor for IL-6, a type of cytokine, the drug improves Castleman's disease symptoms. An estimated 160 patients in Japan are eligible for Actemra treatment because they cannot be treated by surgery due to the presence of multiple enlarged lymph nodes and show resistance to traditional therapies.

## Diabetes

The number of patients suffering from diabetes is increasing worldwide. In Japan, the 2007 National Health and Nutrition Survey issued by MHLW put the total number of "persons strongly suspected of having diabetes" and "persons for which having diabetes cannot be denied" at approximately 22.1 million. Patients with type 2 diabetes have higher than normal blood sugar levels due to difficulty in controlling blood sugar caused by a diminished insulin secretory function or lower insulin sensitivity. Treatment using various kinds of oral diabetic drugs becomes necessary as the disease progresses, and further deterioration necessitates insulin replacement therapy.

### Overview of Development Projects

#### CSG452 (RG7201)

An oral preparation from Chugai research that reduces blood sugar level, CSG452 is expected to be effective in the treatment of type 2 diabetes. Chugai licensed the drug to Roche in January 2007 and started phase I domestic clinical trials in September 2007. Chugai is currently conducting a global phase II clinical

study with Roche. CSG452 uses an insulin-independent mechanism to achieve blood glucose control through direct glucose excretion in the urine. Compared with existing diabetes treatments, CSG452 reduces the risk of hypoglycemia, a serious side effect. Moreover, it is not accompanied by gastrointestinal side effects or weight gain and may have a weight loss effect.

### **RG1583 (ITM-077)**

RG1583 (ITM-077, taspoglutide) is a new compound that mimics GLP-1 (glucagon-like peptide 1), a hormone that stimulates the secretion of insulin. As GLP-1 stimulates insulin secretion only when blood sugar levels are too high, there is little risk of the drug causing hypoglycemia. RG1583 is formulated using technology from Ipsen that enables maintenance of stable therapeutic concentrations for extended periods, and is expected to allow less frequent administration compared to existing medications. RG1583 is being co-developed in Japan with Teijin Pharma Limited. Phase II clinical trials started in July 2009.

## **Schizophrenia**

It is estimated that about one percent of the population suffers from schizophrenia, a disease characterized by persistent disturbances of thought, communication, perceptions, emotions and behavior. Patients become detached from reality and may experience delusions, hallucinations or uncontrollable thoughts.

### **Overview of Development Project**

#### **RG1678**

RG1678, a small-molecule compound licensed from Roche, is expected to be effective in treating schizophrenia. Chugai joined Roche's global phase II clinical study in May 2008.

## **Alzheimer's Disease**

Alzheimer's disease (AD) is the most common form of dementia. Pathologically, it is a progressive neurodegenerative disease that causes neuron death in the brain and brain atrophy. It leads to a general and progressive loss of memory and other cognitive functions, which can interfere with daily life. The amyloid hypothesis, which points to the accumulation of amyloid-beta-peptide deposits in the brain as the primary factor in AD pathogenesis, has been proposed but is not yet proven. While existing AD treatments have some effect in slowing disease progression by several months, they are unable to stop the neuron death, and thus do not treat the underlying cause. Consequently, the level of satisfaction with these treatments is low, and there is strong demand for a more effective drug.

### **Overview of Development Project**

#### **RG1450**

RG1450 (gantenerumab) is a human anti-amyloid-beta-peptide monoclonal antibody licensed from Roche. In July 2009, Chugai started phase I clinical trials investigating RG1450 as a potential treatment for AD.

## Financial Section

# Mission-Driven Leadership for Sound, Steady Growth

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# 11-Year Financial Summary

	2009/12	2008/12	2007/12	2006/12
Revenues	428,947	326,938	344,808	326,109
Sales	419,106	321,836	332,943	—
Other operating revenues	9,841	5,102	11,865	—
Cost of sales	192,851	127,029	137,293	133,086
(Percentage of revenues)	45.0%	38.9%	39.8%	40.8%
Selling, general and administrative expenses	98,168	95,121	86,569	80,067
(Percentage of revenues)	22.9%	29.1%	25.1%	24.6%
Research and development expenses	55,315	53,225	54,243	54,609
(Percentage of revenues)	12.9%	16.3%	15.7%	16.7%
Operating income	82,613	51,563	66,703	58,347
(Percentage of revenues)	19.3%	15.8%	19.3%	17.9%
Net income (loss)	56,634	39,265	40,061	38,418
(Percentage of revenues)	13.2%	12.0%	11.6%	11.8%
Total assets	540,549	478,518	458,942	462,124
Property, plant and equipment, net	93,663	98,346	92,495	85,150
Interest-bearing debt	154	305	775	1,300
Total shareholders' equity	437,493	401,623	378,734	389,598
Net income per share (basic) (Yen)	104.00	72.07	73.23	69.35
Net income per share (diluted) (Yen)	103.98	72.04	73.16	69.26
Cash dividends per share <sup>2</sup> (Yen)	40.00	34.00	30.00	30.00
Number of employees	6,485	6,383	6,257	5,905

1. In June 2003, the Company changed its fiscal year-end from March 31 to December 31. As a result of this change, the nine months ended December 31, 2003 are presented as a transitional period.

2. Cash dividends per share for 2009 include a special year-end dividend of ¥6.00 per share. Cash dividends per share for 2005 include a special year-end dividend of ¥10.00 per share.

Note: The accompanying notes to the consolidated financial statements are an integral part of this summary.

Millions of yen except per share amount and other statistics

2005/12	2004/12	2003/12 <sup>1</sup>	2003/3	2002/3	2001/3	2000/3
327,155	294,671	232,748	237,391	211,705	203,005	195,506
—	—	—	—	—	—	—
—	—	—	—	—	—	—
119,423	111,108	83,541	79,385	64,962	62,046	58,995
36.5%	37.7%	35.9%	33.4%	30.7%	30.6%	30.2%
78,505	83,900	62,963	79,178	72,189	69,527	66,540
24.0%	28.5%	27.1%	33.4%	34.1%	34.2%	34.0%
50,058	48,166	43,525	48,511	47,845	41,189	39,993
15.3%	16.3%	18.7%	20.4%	22.6%	20.3%	20.5%
79,169	51,497	42,719	30,317	26,709	30,243	29,978
24.2%	17.5%	18.4%	12.8%	12.6%	14.9%	15.3%
53,632	34,117	28,446	(20,135)	14,598	15,500	8,761
16.4%	11.6%	12.2%	—	6.9%	7.6%	4.5%
456,442	411,449	405,197	425,301	349,226	340,174	321,087
79,460	90,051	91,970	93,969	81,445	77,798	80,225
2,549	6,167	10,761	12,108	70,093	70,402	75,181
368,306	320,847	296,717	277,254	200,779	190,257	170,972
97.00	62.27	51.73	(51.75)	57.93	61.70	35.53
96.33	61.34	50.94	—	49.09	52.18	30.49
34.00	18.00	13.00	16.00	16.00	16.00	13.00
5,280	5,313	5,619	5,743	4,912	4,886	4,831

# Management's Discussion and Analysis

## Operating Environment

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In 2009, the operating environment of the pharmaceutical industry became increasingly challenging due to factors including the promotion of generics and other ongoing government policies to reduce medical costs, and the increasingly stringent approval process for new pharmaceuticals worldwide. Under these conditions, growth rates generally slowed in the pharmaceutical markets of developed countries including Japan, the United States and Europe.

On the other hand, pharmaceutical markets that address unmet medical needs are expected to continue growing strongly, with growth of biopharmaceuticals and oncology drugs forecast at over 10 percent.

In Japan, the government has implemented policies to promote the creation of innovative drugs and bring new drugs to the market. Since 2008, the regulatory system has been strengthened in an effort to shorten the time required to approve a new drug. Moreover, while the drug price revisions of April 2010 will further reduce the prices of long-listed drugs, a new drug price system with a premium for the development of new drugs that satisfy specified conditions will be introduced on a trial basis.

## Management Policies

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Based on a strategic alliance with Roche, a leading global pharmaceutical company, Chugai's mission is to dedicate itself to adding exceptional value through the creation of innovative medical products and services for the benefit of the medical community and human health around the world. Chugai's primary management goal is to become a top Japanese pharmaceutical company capable of continuously delivering innovative drugs. We have been working to fulfill our mission and achieve our goals by concentrating on building a highly unique R&D platform that employs advanced technologies based on our specialized organization for the prescription drug business. Concurrently, we have been cooperating with Roche to enhance our clinical development pipeline and our product lineup in order to build a foundation for top-class competitiveness in Japan.

Chugai has positioned consolidated revenues and consolidated operating income as key management indicators, and has formulated Sunrise 2012, a mid-term business plan ending 2012, with the aim of expanding shareholder value through growth and enhanced productivity. The targets of this plan are consolidated revenues of ¥460 billion and consolidated operating income of ¥80 billion.

## Results

### Revenues

In 2009, revenues increased 31.2 percent compared with the previous fiscal year to a record ¥428.9 billion, driven by steady growth in sales of major products and a substantial increase in sales of the anti-influenza agent Tamiflu. Excluding sales of Tamiflu, which vary widely from year to year, and other operating revenues, sales increased 9.4 percent to ¥342.9 billion.

Domestic sales excluding Tamiflu increased 10.5 percent compared with the previous fiscal year to ¥309.3 billion. Sales in the oncology field increased a substantial 20.9 percent to ¥123.7 billion, and Chugai maintained the number-one share (17.3 percent)\* of the domestic oncology market for the second consecutive year. This achievement was the result of steady market penetration for new drugs and drugs approved with additional indications, including Avastin, an anti-vascular endothelial growth factor (VEGF) receptor humanized monoclonal antibody that is steadily establishing a position as a first- and second-line treatment, and Herceptin, an anti-HER2 humanized monoclonal antibody approved for the additional indication of post-operative adjuvant therapy of HER2-positive breast cancer.

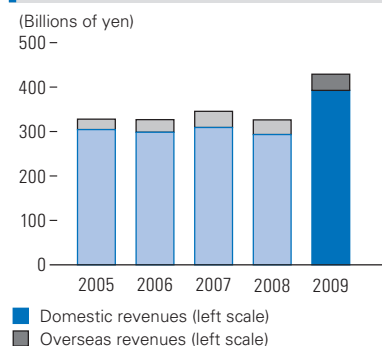
In the bone and joint diseases field, sales increased 15.2 percent compared with the previous fiscal year to ¥57.6 billion. Actemra, a humanized anti-human IL-6 receptor monoclonal antibody that is increasingly being used as a first-line biologic treatment, made a substantial contribution. Increased recognition of osteoarthritis also resulted in greater market penetration and increased sales for Suvenyl, an agent that improves joint function by alleviating pain associated with this disease.

In the renal diseases field, sales decreased 0.5 percent compared with the previous fiscal year to ¥61.0 billion. While sales of the recombinant human erythropoietin Epogin decreased in the dialysis market, its share expanded steadily in the pre-dialysis market. Epogin sales increased period-on-period during the second half of 2009 (July to December).

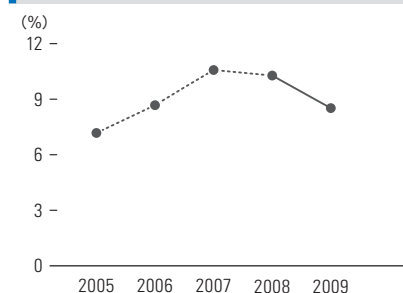
In the transplant, immunology and infectious diseases field, sales (excluding Tamiflu) increased 9.2 percent compared with the previous fiscal year to ¥26.2 billion. Sales of peginterferon alfa-2a Pegasys and antiviral treatment Copegus increased as a result of the spread of a system initiated by the government in April 2008 for subsidizing medical fees associated with interferon treatment, as well as an increase in prescriptions for Pegasys/Copegus combination therapy for chronic hepatitis C.

Sales of anti-influenza agent Tamiflu increased about nine-fold compared with the previous fiscal year to ¥76.2 billion. Spurred by the influenza A/H1N1 ("swine flu") pandemic, seasonal sales totaled ¥36.2 billion, and sales to the government for pandemic stockpiles totaled ¥40.0 billion.

### Revenues



### Overseas Sales Ratio



Overseas product sales increased 0.3 percent compared with the previous fiscal year to ¥33.6 billion. Sales of recombinant human granulocyte colony-stimulating factor Neutrogin decreased mainly due to appreciation of the yen, but exports of Actemra to Roche (for sale in regions other than Japan, Korea and Taiwan) were robust because in January 2009 this drug received approval from the European Medicines Evaluation Agency (EMA).

Other operating revenues increased 92.2 percent compared with the previous fiscal year to ¥9.8 billion due to factors including advance payments resulting from the January 2009 approval of Actemra (European product name: RoActemra) by the EMA.

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The scope of the market is defined by Chugai.

### Cost of Sales and Gross Profit

Cost of sales increased 51.9 percent compared with the previous fiscal year to ¥192.9 billion. Primary factors included the increase in revenues and strong expansion in sales of Roche products including Tamiflu, which have a relatively high cost of sales. Other factors in the increase in cost of sales included loss on inventories of old stock following the launch of a new formulation of Epogin that is less painful to inject and produced using a serum-free manufacturing process. Higher payments related to technology transfer to Genentech of the United States associated with Actemra toll manufacturing also contributed to the cost of sales increase. The cost-to-sales ratio increased 6.5 percentage points to 46.0 percent.

As a result of the above, gross profit increased 18.1 percent compared with the previous fiscal year to ¥236.1 billion.

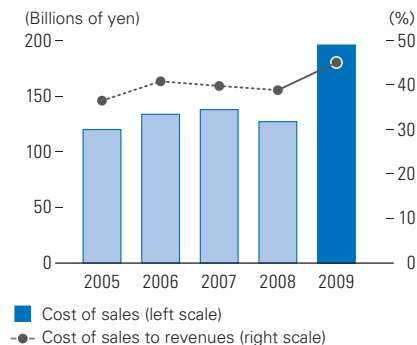
Effective the year ended December 31, 2009, the Company has applied "Accounting Standard for Measurement of Inventories" (Accounting Standards Board of Japan ("ASBJ") Statement No. 9, issued on July 5, 2006). Accordingly, loss on inventories, which was formerly included in other expenses, has been reclassified as cost of sales.

### Selling, General and Administrative Expenses and Operating Income

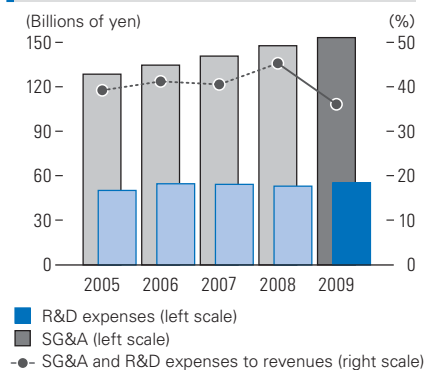
Selling, general and administrative (SG&A) expenses increased 3.3 percent year-on-year to ¥98.2 billion due to factors including higher personnel expenses such as increased reserves for performance-linked bonuses, higher expenses associated with a line extension of Avastin and increasing market penetration in Japan and overseas of Actemra, and expenses related to post-marketing surveillance. Research and development (R&D) expenses increased 3.9 percent to ¥55.3 billion because of an increase in the number of projects in early-stage development and higher depreciation expenses resulting from enhancements to pharmaceutical research facilities.

While cost of sales increased substantially, SG&A expenses did not. As a result, operating income increased 60.1 percent compared with the previous fiscal year to ¥82.6 billion, and the ratio of operating income to revenues increased 3.5 percentage points to 19.3 percent.

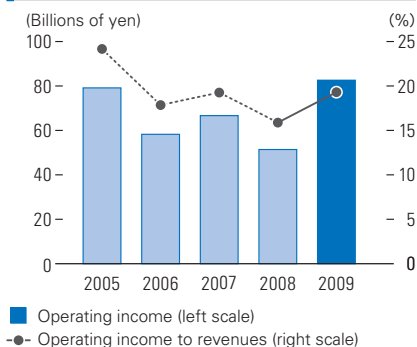
#### Cost of Sales/ Cost of Sales to Revenues



#### SG&A and R&D Expenses



#### Operating Income/ Operating Income to Revenues



### Other Income, Income before Income Taxes and Minority Interests

Other income decreased 40.9 percent compared with the previous fiscal year to ¥6.8 billion. Chugai uses forward foreign exchange contracts to cover substantial foreign currency transactions, centered on imports from Roche. In 2009, these forward foreign exchange contracts contributed to other income. In addition, other expenses decreased because of the reclassification of loss on inventories to cost of sales from other expenses. On the other hand, loss on restructuring costs, net, primarily associated with the closure of the Kamakura plant, totaled ¥1.2 billion, and gain on settlement of co-development costs for Actemra with Roche totaling ¥6.3 billion in the previous fiscal year did not recur. Consequently, income before income taxes and minority interests increased 41.7 percent to ¥89.4 billion.

### Net Income

Income taxes totaled ¥31.2 billion and minority interests totaled ¥1.6 billion. As a result, net income increased 44.0 percent compared with the previous fiscal year to ¥56.6 billion.

### Profitability (Consolidated Basis)

	2009	2008	2007	2006	2005
Gross profit ratio (%)	55.0	61.1	60.2	59.2	63.5
Operating income to revenues (%)	19.3	15.8	19.3	17.9	24.2
Return on assets (%)	17.7	12.2	14.7	13.3	18.9
Return on equity (%)	13.7	10.1	10.4	10.1	15.6

Notes: 1. Return on assets = (Operating income + interest and dividend income)/Total assets (yearly average) x 100  
2. Return on equity = Net income/Shareholders' equity (yearly average) x 100

## Financial Position

### Assets, Liabilities and Net Assets

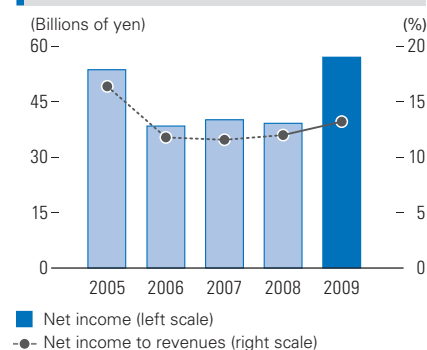
#### Assets

As of December 31, 2009, total assets were ¥540.5 billion, an increase of ¥62.0 billion, or 13.0 percent, compared with the end of the previous fiscal year. Primary factors in the increase included increases in trade accounts and inventories due to higher revenues, and an increase in cash and cash equivalents due to record income.

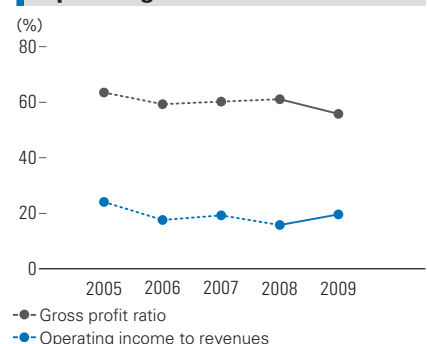
Current assets increased ¥66.9 billion, or 19.4 percent, compared with the end of the previous fiscal year to ¥411.3 billion. Cash and cash equivalents increased ¥36.2 billion, or 51.1 percent, to ¥107.0 billion. Trade notes and accounts increased ¥13.1 billion, or 12.1 percent, to ¥121.6 billion. Trade receivables turnover decreased to 3.1 months from 3.7 months for the previous fiscal year.

Inventories increased ¥13.9 billion, or 17.7 percent, compared with the end of the previous fiscal year to ¥92.6 billion. Key factors included growth

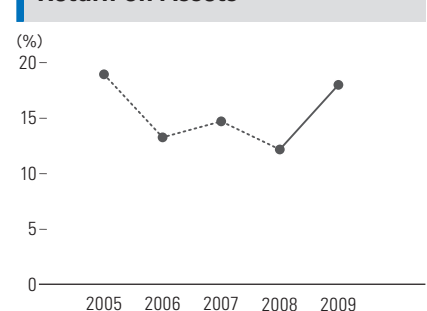
### Net Income/ Net Income to Revenues



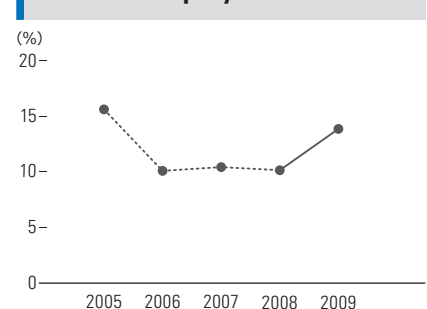
### Gross Profit Ratio/ Operating Income to Revenues



### Return on Assets



### Return on Equity



in inventories to support increased demand for new products and products approved with additional indications, such as overseas shipments of Actemra, as well as stockpiling of products associated with the closure of the Kamakura plant. The manufacturing site transfer began at the end of 2009, with completion scheduled for the end of 2012. The Kamakura plant will cease production at the end of 2010 and close in the first quarter of 2011.

Property, plant and equipment, net decreased ¥4.6 billion, or 4.7 percent, compared with the end of the previous fiscal year to ¥93.7 billion, because of higher accumulated depreciation. Capital investments such as the solid agent facility at the Fujieda plant and injection products building No. 3 at the Utsunomiya plant increased, but have peaked.

### Liabilities

Total liabilities increased ¥24.4 billion, or 29.9 percent, compared with the end of the previous fiscal year to ¥105.9 billion. Primary factors included an increase in current liabilities of ¥22.0 billion, or 28.0 percent, to ¥100.5 billion stemming from increases in income taxes payable, trade accounts payable and accrued consumption taxes included in other current liabilities.

Income taxes payable increased ¥10.7 billion, or 93.9 percent, compared with the end of the previous fiscal year to ¥22.1 billion, primarily reflecting comparatively lower income taxes payable for 2008 and the substantial increase in income for 2009.

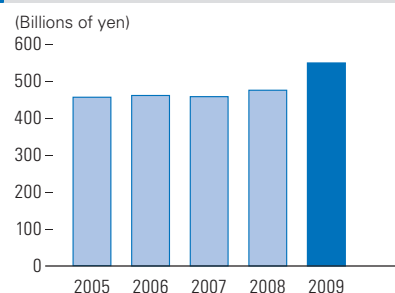
Trade notes and accounts payable increased ¥5.5 billion, or 19.1 percent, compared with the end of the previous fiscal year to ¥34.3 billion. This increase was primarily the result of a rise in payables associated with Tamiflu, approximately 80 percent of which were owed to Roche as of December 31, 2009. Trade payables turnover decreased to 1.9 months from 2.4 months mainly due to the timing of purchasing.

### Net Assets

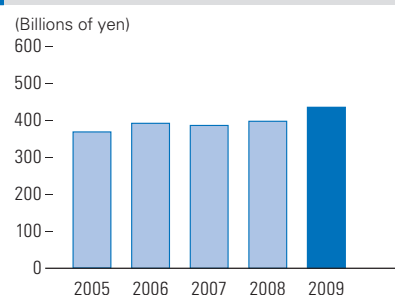
As of December 31, 2009, net assets totaled ¥434.7 billion, an increase of ¥37.6 billion, or 9.5 percent, compared with the end of the previous fiscal year. This increase was primarily the result of an increase of ¥37.0 billion in retained earnings. Net unrealized holding gain on securities totaled ¥1.6 billion, up slightly from ¥1.4 billion a year earlier.

The ratio of shareholders' equity to total assets decreased 2.6 percentage points from the end of the previous fiscal year to 80.0 percent. Net working capital (current assets minus current liabilities) totaled ¥310.8 billion, and the current ratio was 409.3 percent, reflecting the Company's sound financial position.

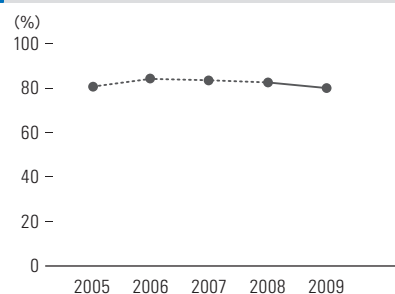
### Total Assets



### Net Assets



### Shareholders' Equity to Total Assets



**Stability (Consolidated Basis)**

	2009	2008	2007	2006	2005
Current ratio (%)	409.3	438.5	472.5	517.3	418.6
Fixed assets ratio (%)	29.9	34.0	33.7	32.0	34.8
Interest coverage ratio (times)	4,620.0	517.5	461.9	283.0	284.8
Debt-to-equity ratio (%)	0.0	0.1	0.2	0.3	0.7
Shareholders' equity to total assets (%)	80.0	82.6	83.5	84.3	80.7
Market value equity ratio (%)	175.2	196.2	189.9	294.4	306.7

Notes: 1. Current ratio = Current assets (fiscal year-end)/Current liabilities (fiscal year-end) x 100  
 2. Fixed assets ratio = Fixed assets (fiscal year-end)/Shareholders' equity (fiscal year-end) x 100  
 3. Interest coverage ratio = Net cash provided by operating activities (prior to deductions of interest paid and income taxes paid, and addition of income taxes refunded)/Interest paid  
 4. Debt-to-equity ratio = Interest-bearing debt (fiscal year-end)/Shareholders' equity (fiscal year-end) x 100  
 5. Market value equity ratio = Total market capitalization/Total assets (fiscal year-end) x 100

**Efficiency (Consolidated Basis)**

	2009	2008	2007	2006	2005
Total assets turnover (times)	0.84	0.70	0.75	0.71	0.75
Trade receivables turnover (times)	3.53	3.01	3.22	3.08	2.75
Inventories turnover (times)	4.63	4.15	6.25	5.30	6.90
Trade payables turnover (times)	12.52	11.37	19.90	11.59	15.59

Notes: 1. Total assets turnover = Revenues/Total assets (yearly average)  
 2. Trade receivables turnover = Revenues/(Trade notes receivable + Trade accounts receivable)  
 3. Inventories turnover = Revenues/Inventories  
 4. Trade payables turnover = Revenues/(Trade notes payable + Trade accounts payable)

**Cash Flows****Cash and Cash Equivalents**

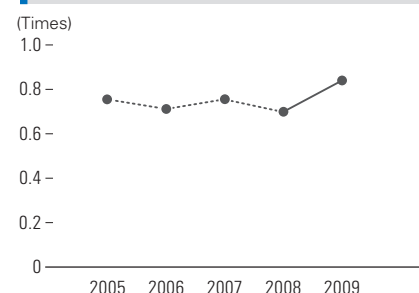
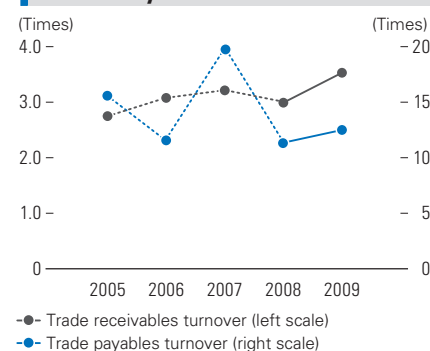
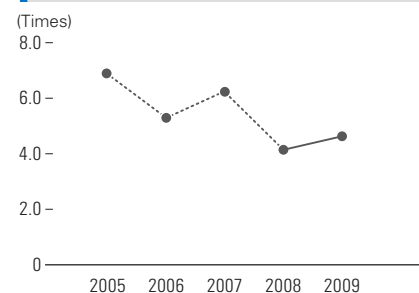
Cash and cash equivalents as of December 31, 2009 totaled ¥94.5 billion, an increase of ¥23.8 billion from a year earlier.

**Cash Flows from Operating Activities**

Net cash provided by operating activities totaled ¥66.5 billion, up ¥27.2 billion from ¥39.3 billion provided in the previous fiscal year. Income before income taxes and minority interests of ¥89.4 billion was a primary source of cash. Depreciation and amortization totaled ¥19.5 billion. Reflecting expansion in sales, increase in notes and accounts receivable used cash totaling ¥13.0 billion, and increase in inventories used cash totaling ¥13.5 billion.

**Cash Flows from Investing Activities**

Net cash used in investing activities totaled ¥20.3 billion, up ¥6.2 billion from ¥14.1 billion used in the previous fiscal year. Net proceeds from sales of marketable and investment securities provided cash totaling ¥7.6 billion, while net purchases of time deposits used cash totaling ¥12.2 billion. Purchases of fixed assets used cash totaling ¥16.1 billion. These purchases consisted of capital investments for the solid agent facility at the Fujieda plant and injection products building No. 3 at the Utsunomiya plant.

**Total Assets Turnover****Trade Receivables Turnover / Trade Payables Turnover****Inventories Turnover**

## Free Cash Flow

Free cash flow totaled ¥46.2 billion, up ¥21.0 billion from ¥25.2 billion in the previous fiscal year.

## Cash Flows from Financing Activities

Net cash used in financing activities totaled ¥22.3 billion, up ¥3.9 billion from the previous fiscal year. A primary factor was an increase of ¥3.3 billion in cash dividends paid to ¥19.6 billion.

## Cash Flows (Consolidated Basis)

(Millions of yen)

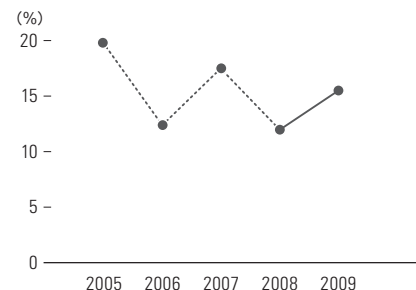
	2009	2008	2007	2006	2005
Net cash provided by operating activities	66,461	39,277	60,365	40,539	64,663
Net cash used in investing activities	(20,261)	(14,122)	(7,510)	(29,371)	(35,460)
Net cash used in financing activities	(22,252)	(18,361)	(47,173)	(18,797)	(12,557)
Effect of exchange rate changes on cash and cash equivalents	(128)	(9,865)	(292)	1,581	354
Net increase (decrease) in cash and cash equivalents	23,820	(3,071)	5,390	(6,048)	17,000
Cash and cash equivalents at beginning of year	70,652	73,723	68,333	74,381	57,381
Increase in cash and cash equivalents resulting from merger with unconsolidated subsidiaries	6	—	—	—	—
Cash and cash equivalents at end of year	94,478	70,652	73,723	68,333	74,381
Net cash provided by operating activities to revenues (%)	15.5	12.0	17.5	12.4	19.8
Interest-bearing debt to net cash provided by operating activities (years)	0.0	0.0	0.0	0.0	0.0

Note: Interest-bearing debt to net cash provided by operating activities  
= Interest-bearing debt/Net cash provided by operating activities (prior to interest and income tax deductions)

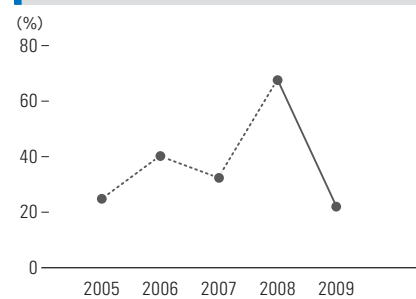
## Capital Investments

Capital investments decreased 45.1 percent compared with the previous fiscal year to ¥14.6 billion because investment has peaked in the solid agent facility at the Fujieda plant and injection products building No. 3 at the Utsunomiya plant. In addition, depreciation increased 0.5 percent to ¥19.5 billion. In 2010, Chugai projects capital investments of about ¥16.0 billion and depreciation of about ¥18.9 billion.

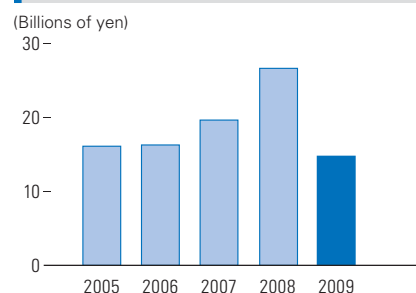
## Net Cash Provided by Operating Activities to Revenues



## Capital Investments to Net Cash Provided by Operating Activities



## Capital Investments



## Fundamental Profit Distribution Policy and Dividends

Chugai aims to provide shareholders with stable dividends. Our goal is to maintain the consolidated payout ratio at around 40 percent on average, taking into account strategic funding needs and earnings prospects.

Internal reserves will be used to fund research and development in Japan and overseas as well as for making capital investments related to new products in order to further increase corporate value.

Based on the above policy, cash dividends for 2009 totaled ¥40.00 per share, consisting of an interim dividend of ¥17.00 per share, a regular year-end dividend of ¥17.00 per share, and a special year-end dividend of ¥6.00 per share. Thus, cash dividends per share for 2009 increased ¥6.00 compared with the previous fiscal year, and the consolidated payout ratio was 38.5 percent. Chugai projects total cash dividends of ¥34.00 per share for 2010, including an interim dividend of ¥17.00 per share, and a consolidated payout ratio of 42.1 percent.

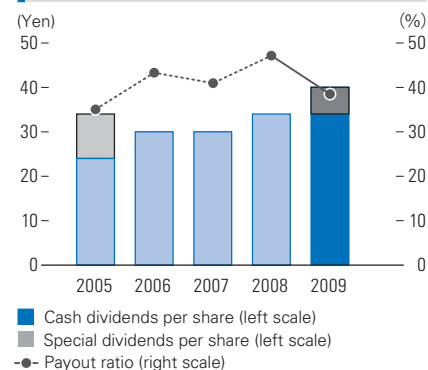
## Per Share Data (Consolidated Basis)

Net income per share for 2009 increased ¥31.93 compared with the previous fiscal year to ¥104.00. Net income per share on a fully diluted basis was ¥103.98. Net assets per share (BPS) increased ¥69.33 compared with the previous fiscal year to ¥794.51.

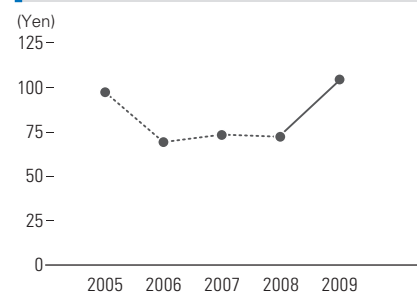
	(Yen)				
	2009	2008	2007	2006	2005
Net income per share (basic)	104.00	72.07	73.23	69.35	97.00
Net income per share (diluted)	103.98	72.04	73.16	69.26	96.33
Net assets per share	794.51	725.18	703.80	703.08	665.29
Cash dividends per share	40.00	34.00	30.00	30.00	34.00
Payout ratio (%)	38.5	47.2	41.0	43.3	35.1

Note: Cash dividends per share for 2009 include a special year-end dividend of ¥6.00 per share. Cash dividends per share for 2005 include a special year-end dividend of ¥10.00 per share.

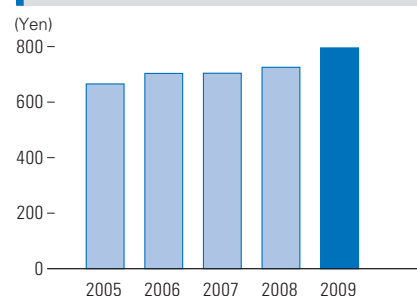
### Cash Dividends per Share / Payout Ratio



### Net Income per Share



### Net Assets per Share



## Business Risks

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Chugai's corporate performance is subject to major impact from a range of possible future events. Below, we list what we consider the principal sources of risk to the development of our business. We recognize the possibility of these risk events actually occurring, and have prepared policies to forestall such events and take appropriate measures when they do occur. The categories of risk identified in this section are based on assessments made by the Company as of December 31, 2009.

### **New Product Development**

With the goal of becoming a top Japanese pharmaceutical manufacturer capable of continuously delivering innovative new drugs, Chugai aggressively pursues research and development in Japan and overseas. Our development pipeline is well stocked, especially in the fields of oncology, bone and joint diseases, and renal diseases. However, bringing all drug candidates smoothly through to the market from the development stage may not be possible, and we expect to have to abandon development in some cases. When such a situation occurs, there is a possibility of major impact on our business performance and financial position, depending on the product under development.

### **Changes in Product Environments**

In recent years, there have been rapid technological advancements in the pharmaceutical industry, and the Company faces fierce competition from pharmaceutical companies in Japan and overseas. The Company's business performance and financial status may be significantly affected by changes in product environments caused by the sale of competitor products and generics and also by changes in marketing and technology license contracts concluded by the Company.

### **Side Effects**

Pharmaceutical products are approved in Japan by the Ministry of Health, Labour and Welfare after stringent screening. However, advances in science and technology and years of careful post-marketing monitoring of pharmaceutical product use mean that side effects are discovered in a good number of drugs. In cases where unexpected side effects occur after marketing, there is a risk of significant impact on our business performance and financial position.

### **Reform of Japan's Medical System**

Japan's health insurance system is being reformed against a backdrop of rapid demographic change, with a falling birthrate and an increasing

number of elderly people. As part of this process, measures are being taken to curb medical expenses. Revisions have been made to the system of reimbursement of medical fees, and debate is continuing in such areas as drug price reform. The Company's business performance could be significantly affected by future developments in medical system reform, including drug price reform.

### **Intellectual Property Rights**

The Company recognizes that it applies intellectual property rights in pursuing its business activities, and takes care to distinguish its own proprietary intellectual property rights and licensing arrangements recognized under law. However, the possibility remains of unintentional infringement on third-party intellectual property rights. Major disputes related to intellectual property rights relating to our business could have major impact on our business performance.

### **Strategic Alliance with Roche**

In line with its strategic alliance with Roche, Chugai is the only pharmaceutical partner of Roche in the Japanese market and has licensed many products and projects from Roche. Changes in Chugai's strategic alliance with Roche for any reason could have a major impact on the Company's operating results and financial position.

### **International Business Activities**

With the goal of continuously delivering new drugs in Japan and overseas, Chugai actively conducts international operations including overseas marketing and research and development, and export and import of bulk drug products. These international business activities expose Chugai to risks associated with legal and regulatory changes, political instability, economic uncertainty, local labor-management relations, changes in and interpretations of systems of taxation, changes in foreign currency markets, differences in commercial practices and other issues that could significantly affect the Company's operating results and financial position.

# Consolidated Financial Statements

## Consolidated Balance Sheets

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries/December 31,

Assets	Millions of yen		Thousands of U.S. dollars (Note 4)
	2009	2008	2009
Current assets:			
Cash and cash equivalents (Note 19) .....	¥ 106,978	¥ 70,768	\$ 1,162,804
Marketable securities including short-term investments (Note 13) .....	52,158	54,715	566,935
Receivables (Note 20):			
Trade notes.....	17	24	185
Trade accounts .....	121,590	108,435	1,321,630
Other .....	11,902	6,561	129,370
Reserve for doubtful accounts .....	(35)	(61)	(380)
Inventories (Note 5).....	92,642	78,736	1,006,978
Deferred tax assets (Note 10) .....	21,059	21,835	228,902
Other.....	4,992	3,341	54,261
Total current assets .....	411,303	344,354	4,470,685
Property, plant and equipment, at cost (Note 16):			
Land .....	9,894	9,938	107,543
Buildings and structures.....	124,162	122,969	1,349,587
Machinery and equipment .....	121,621	111,035	1,321,967
Construction in progress.....	1,530	5,488	16,630
Other.....	18	—	197
	257,225	249,430	2,795,924
Accumulated depreciation (Note 6) .....	(163,562)	(151,084)	(1,777,848)
Property, plant and equipment, net .....	93,663	98,346	1,018,076
Investments and other assets:			
Investment securities (Note 13).....	9,596	14,158	104,304
Unconsolidated subsidiaries and affiliates .....	61	230	663
Long-term loans .....	33	45	359
Lease deposits.....	4,032	4,091	43,826
Deferred tax assets (Note 10) .....	14,594	12,198	158,631
Other.....	7,267	5,096	78,989
Total investments and other assets.....	35,583	35,818	386,772
Total assets .....	¥ 540,549	¥ 478,518	\$ 5,875,533

See accompanying notes to consolidated financial statements.

Liabilities and net assets	Millions of yen		Thousands of U.S. dollars (Note 4)
	2009	2008	2009
Current liabilities:			
Payables (Note 20):			
Trade notes.....	¥ 1	¥ 6	\$ 11
Trade accounts .....	34,263	28,760	372,424
Construction .....	6,203	6,035	67,424
Other .....	396	1,019	4,304
Income taxes payable (Note 10).....	22,142	11,382	240,674
Accrued liabilities .....	31,870	29,133	346,413
Other .....	5,607	2,189	60,946
Total current liabilities .....	100,482	78,524	1,092,196
Long-term liabilities:			
Deferred tax liabilities (Note 10) .....	—	1	—
Reserve for employees' retirement benefits (Note 11) .....	2,710	2,084	29,457
Reserve for officers' retirement benefits.....	762	773	8,283
Other .....	1,908	69	20,738
Total long-term liabilities .....	5,380	2,927	58,478
Contingent liabilities (Note 17)			
Net assets (Notes 8, 18 and 22):			
Shareholders' equity:			
Common stock, without par value:			
Authorized: 799,805,050 shares			
Issued:			
December 31, 2009 and 2008 – 559,685,889 shares .....	72,967	72,967	793,120
Additional paid-in capital.....	92,815	92,815	1,008,859
Retained earnings .....	307,985	271,009	3,347,663
Treasury stock, at cost:			
December 31, 2009 – 15,497,079 shares .....			
December 31, 2008 – 14,872,196 shares .....	(36,274)	(35,168)	(394,283)
Total shareholders' equity .....	437,493	401,623	4,755,359
Valuation, translation adjustments and others:			
Net unrealized holding gain on securities .....	1,636	1,355	17,783
Translation adjustments.....	(6,767)	(7,889)	(73,555)
Total valuation, translation adjustments and others.....	(5,131)	(6,534)	(55,772)
Stock subscription rights.....	537	326	5,837
Minority interests in consolidated subsidiaries .....	1,788	1,652	19,435
Total net assets .....	434,687	397,067	4,724,859
Total liabilities and net assets .....	¥540,549	¥478,518	\$5,875,533

See accompanying notes to consolidated financial statements.

# Consolidated Statements of Income

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries/Year ended December 31,

	Millions of yen			Thousands of U.S. dollars (Note 4)
	2009	2008	2007	2009
Revenues (Note 20):				
Sales .....	¥419,106	¥321,836	¥332,943	\$4,555,500
Other operating revenues .....	9,841	5,102	11,865	106,967
	428,947	326,938	344,808	4,662,467
Cost of sales (Note 20) .....	192,851	127,029	137,293	2,096,206
Gross profit .....	236,096	199,909	207,515	2,566,261
Selling, general and administrative expenses .....	98,168	95,121	86,569	1,067,044
Research and development expenses (Note 20) .....	55,315	53,225	54,243	601,250
Operating income .....	82,613	51,563	66,703	897,967
Other income (expenses):				
Interest and dividend income .....	753	2,034	1,444	8,185
Interest expense (Note 20) .....	(20)	(135)	(177)	(218)
Other (Note 9) .....	6,070	9,644	(1,542)	65,979
	6,803	11,543	(275)	73,946
Income before income taxes and minority interests .....	89,416	63,106	66,428	971,913
Income taxes (Note 10) .....	(31,183)	(22,276)	(24,537)	(338,946)
Minority interests .....	(1,599)	(1,565)	(1,830)	(17,380)
Net income (Note 22) .....	¥ 56,634	¥ 39,265	¥ 40,061	\$ 615,587

See accompanying notes to consolidated financial statements.

# Consolidated Statements of Changes in Net Assets

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries/Years ended December 31, 2009, 2008 and 2007

	Thousands	Millions of yen										
		Shareholders' equity (Note 8)					Valuation, translation adjustments and others					
	Number of shares issued (Note 18)	Common stock	Additional paid-in capital	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gain on securities	Translation adjustments	Total valuation, translation adjustments and others	Stock subscription rights	Minority interests in consolidated subsidiaries	Total net assets
Balance at December 31, 2006..	559,493	¥72,893	¥92,747	¥226,209	¥ (7,590)	¥384,259	¥ 3,236	¥ 2,103	¥ 5,339	¥ —	¥2,006	¥391,604
Conversion of convertible bonds (Note 19) .....	143	55	54			109						109
Purchases of treasury stock .....					(27,615)	(27,615)						(27,615)
Disposition of treasury stock .....			(5)	(26)	97	66						66
Net income .....				40,061		40,061						40,061
Cash dividends paid .....				(18,146)		(18,146)						(18,146)
Net changes in items other than shareholders' equity .....							(478)	(159)	(637)	140	216	(281)
Balance at December 31, 2007..	559,636	72,948	92,796	248,098	(35,108)	378,734	2,758	1,944	4,702	140	2,222	385,798
Conversion of convertible bonds (Note 19) .....	50	19	19			38						38
Purchases of treasury stock .....					(87)	(87)						(87)
Disposition of treasury stock .....				(9)	27	18						18
Net income .....				39,265		39,265						39,265
Cash dividends paid .....				(16,345)		(16,345)						(16,345)
Net changes in items other than shareholders' equity .....							(1,403)	(9,833)	(11,236)	186	(570)	(11,620)
Balance at December 31, 2008..	559,686	72,967	92,815	271,009	(35,168)	401,623	1,355	(7,889)	(6,534)	326	1,652	397,067
Effect of changes in accounting policies of foreign subsidiaries ..				(26)		(26)					(11)	(37)
Purchases of treasury stock .....					(1,161)	(1,161)						(1,161)
Disposition of treasury stock .....				(19)	55	36						36
Net income .....				56,634		56,634						56,634
Cash dividends paid .....				(19,613)		(19,613)						(19,613)
Net changes in items other than shareholders' equity .....							281	1,122	1,403	211	147	1,761
Balance at December 31, 2009..	559,686	¥72,967	¥92,815	¥307,985	¥(36,274)	¥437,493	¥ 1,636	¥(6,767)	¥ (5,131)	¥537	¥1,788	¥434,687

	Thousands of U.S. dollars (Note 4)											
	Shareholders' equity (Note 8)					Valuation, translation adjustments and others						
	Common stock	Additional paid-in capital	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gain on securities	Translation adjustments	Total valuation, translation adjustments and others	Stock subscription rights	Minority interests in consolidated subsidiaries	Total net assets	
Balance at December 31, 2008 .....	\$793,120	\$1,008,859	\$2,945,750	\$(382,261)	\$4,365,468	\$14,728	\$(85,750)	\$(71,022)	\$3,543	\$17,957	\$4,315,946	
Effect of changes in accounting policies of foreign subsidiaries .....			(283)		(283)					(120)	(403)	
Purchases of treasury stock .....				(12,620)	(12,620)						(12,620)	
Disposition of treasury stock .....			(206)	598	392						392	
Net income .....			615,587		615,587						615,587	
Cash dividends paid .....			(213,185)		(213,185)						(213,185)	
Net changes in items other than shareholders' equity .....						3,055	12,195	15,250	2,294	1,598	19,142	
Balance at December 31, 2009 .....	\$793,120	\$1,008,859	\$3,347,663	\$(394,283)	\$4,755,359	\$17,783	\$(73,555)	\$(55,772)	\$5,837	\$19,435	\$4,724,859	

# Consolidated Statements of Cash Flows

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries/Year ended December 31,

	Millions of yen			Thousands of U.S. dollars (Note 4)
	2009	2008	2007	2009
<b>Cash flows from operating activities</b>				
Income before income taxes and minority interests.....	¥ 89,416	¥ 63,106	¥ 66,428	\$ 971,913
Adjustments to reconcile income before income taxes and minority interests to net cash provided by operating activities:				
Depreciation and amortization .....	19,506	20,080	14,914	212,022
Loss on impairment of fixed assets.....	27	748	32	293
Increase (decrease) in reserve for employees' retirement benefits .....	600	(510)	(1,535)	6,522
Interest and dividend income .....	(753)	(2,034)	(1,444)	(8,185)
Interest expense.....	20	135	177	218
Loss on disposal of fixed assets.....	212	357	327	2,304
Loss (gain) on sales of fixed assets .....	(264)	(411)	35	(2,870)
Loss on sales and revaluation of investment securities .....	13	20	21	141
Increase in notes and accounts receivable .....	(12,966)	(2,504)	(1,257)	(140,935)
Decrease (increase) in inventories.....	(13,484)	(25,562)	6,174	(146,565)
Increase (decrease) in notes and accounts payable ....	5,345	12,291	(10,709)	58,098
Increase (decrease) in accrued consumption taxes.....	4,447	(2,036)	1,128	48,337
Others.....	(2,294)	4,236	5,639	(24,934)
Subtotal .....	89,825	67,916	79,930	976,359
Interest and dividends received .....	736	1,586	1,366	8,000
Interest paid .....	(20)	(134)	(176)	(218)
Income taxes paid .....	(24,080)	(30,091)	(20,755)	(261,739)
Net cash provided by operating activities.....	66,461	39,277	60,365	722,402
<b>Cash flows from investing activities</b>				
Purchases of time deposits.....	(23,399)	(138)	—	(254,337)
Proceeds from withdrawal of time deposits .....	11,235	—	—	122,120
Purchases of marketable securities .....	(118,151)	(187,595)	(225,852)	(1,284,250)
Proceeds from sales of marketable securities .....	126,400	202,000	242,900	1,373,913
Purchases of investment securities .....	(631)	(4,005)	(3,504)	(6,859)
Proceeds from sales of investment securities .....	—	379	1,336	—
Purchases of fixed assets .....	(16,068)	(25,223)	(22,597)	(174,652)
Proceeds from sales of fixed assets .....	330	429	191	3,587
Other .....	23	31	16	250
Net cash used in investing activities .....	(20,261)	(14,122)	(7,510)	(220,228)
<b>Cash flows from financing activities</b>				
Net decrease in long-term debt.....	—	(305)	(0)	—
Net increase in treasury stock.....	(1,125)	(69)	(27,517)	(12,228)
Cash dividends paid.....	(19,620)	(16,335)	(18,137)	(213,261)
Cash dividends paid to minority interests .....	(1,503)	(1,652)	(1,519)	(16,337)
Other .....	(4)	—	—	(44)
Net cash used in financing activities .....	(22,252)	(18,361)	(47,173)	(241,870)
Effect of exchange rate changes on cash and cash equivalents .....	(128)	(9,865)	(292)	(1,391)
Net increase (decrease) in cash and cash equivalents ....	23,820	(3,071)	5,390	258,913
Cash and cash equivalents at beginning of year .....	70,652	73,723	68,333	767,957
Increase in cash and cash equivalents resulting from merger with unconsolidated subsidiaries .....	6	—	—	65
Cash and cash equivalents at end of year (Note 19) .....	¥ 94,478	¥ 70,652	¥ 73,723	\$ 1,026,935

See accompanying notes to consolidated financial statements.

# Notes to Consolidated Financial Statements

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries / December 31, 2009

## 1 Basis of Presentation of Financial Statements

Chugai Pharmaceutical Co., Ltd. (the "Company") and its domestic consolidated subsidiaries maintain their books of account in accordance with accounting principles generally accepted in Japan, and its overseas consolidated subsidiaries maintain their books of account in conformity with those of their countries of domicile.

Effective the year ended December 31, 2009, the Company adopted the "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements" (PITF No. 18). In accordance with PITF No. 18, the accompanying consolidated financial statements for the year ended December 31, 2009 have been prepared by using the accounts of foreign consolidated subsidiaries prepared in accordance with either International Financial Reporting Standards (IFRS) or accounting principles generally accepted in the United States. Until December 31, 2008, the

accompanying consolidated financial statements had been prepared by using the accounts of foreign consolidated subsidiaries prepared in accordance with accounting principles generally accepted in their countries of domicile. See Note 3(viii).

The accompanying consolidated financial statements of 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 IFRS, and have been compiled from the consolidated financial statements prepared by the Company as required by the Financial Instruments and Exchange Law of Japan. Certain modifications of, and reclassifications in, the presentation of the accompanying consolidated financial statements have been made to facilitate understanding by readers outside Japan.

## 2 Significant Accounting Policies

### (a) Basis of consolidation and accounting for investments in unconsolidated subsidiaries and affiliates

The accompanying consolidated financial statements include the accounts of the Company and significant companies which it controls directly or indirectly. All significant intercompany accounts and transactions have been eliminated in consolidation. As of December 31, 2009 and 2008, the number of consolidated subsidiaries was 15.

Investments in companies which are neither consolidated nor accounted for by the equity method are carried at cost or less. Where there has been a permanent decline in the value of such investments, the Company has written them down.

### (b) Foreign currency translation

The revenue and expense accounts of the overseas consolidated subsidiaries are translated into Japanese yen at the average exchange rate in effect for the year. Their balance sheet accounts, except for the components of net assets excluding minority interests in consolidated subsidiaries, are translated into Japanese yen at the rates of exchange in effect at the balance sheet date. The components of net assets excluding minority interests in consolidated subsidiaries are translated at their historical rates. Translation differences are presented as translation adjustments and minority interests in consolidated subsidiaries in net assets.

### (c) Cash and cash equivalents

Cash and cash equivalents consist principally of cash in banks and highly liquid investments with maturities of three months or less when purchased.

### (d) Inventories

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

### (e) Depreciation and amortization

Depreciation of property, plant and equipment is calculated primarily by the declining-balance method at rates based on the estimated useful lives of the respective assets.

Amortization of intangible assets is calculated primarily by the straight-line method. Amortization of software for internal use is calculated based on the usable period (five years).

### (f) Leases

Finance leases are capitalized in the balance sheet except that leases for which ownership is not transferred to the lessee and commenced prior to January 1, 2009. Amortization of finance leases is calculated primarily by straight-line method over the lease period assuming no residual value.

### (g) Securities

Securities other than equity securities issued by subsidiaries and affiliates are classified into three categories: trading, held-to-maturity and other securities. Trading securities are carried at fair value and held-to-maturity securities are carried 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, included directly in net assets. Non-marketable securities classified as other securities are carried at cost. If the value of marketable securities classified as other securities declines significantly, such securities are written down to their respective fair value thus establishing a new cost basis, and the amount of each writedown is charged to income as an impairment loss unless the fair value is deemed to be recoverable.

### (h) Retirement benefits

The reserve for employees' retirement benefits is stated at the amount required to cover the liability as of the balance sheet date and is based on the Company's estimate of its liability for retirement benefits and its pension fund assets as of the balance sheet date.

The retirement benefit obligation is primarily attributed to each period by the straight-line method over the estimated years of service of the eligible employees. Certain domestic consolidated subsidiaries adopt the simplified method in their calculation of the retirement benefit obligations.

Prior service cost is being amortized as incurred by the declining-balance method over a period (10 years) which is shorter than the average remaining years of service of the active participants in the plans.

Actuarial gain or loss is principally amortized in the year following the year in which the gain or loss is recognized by the declining-balance method over a period (10 years) which is shorter than the average remaining years of service of the active participants in the plans.

Directors and corporate auditors are not covered by the retirement benefit plans referred to above. However, the liability for their retirement benefits is calculated based on management's estimate of the amounts which would be payable if these corporate officers resigned their offices as of the balance sheet date. Amounts payable to directors and corporate auditors upon retirement are subject to the approval of the shareholders. Accompanying the abolishment of retirement benefit programs for directors and corporate auditors in 2009, the reserve for officers' retirement benefits at December 31, 2009 represented the amount payable to those officers corresponding to services provided until the date the program was terminated.

#### (i) Research and development expenses

Research and development expenses are charged to income when incurred.

#### (j) Income taxes

Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax bases of the assets and liabilities and are measured using the statutory tax rates which will be in effect when the differences are expected to be realized.

#### (k) Derivative financial instruments

The Company enters into various derivative transactions in order to manage certain risk arising from adverse fluctuation in foreign currency exchange rates and interest rates. Derivatives are carried at fair value with any changes in unrealized gain or loss charged or credited to income.

#### (l) Distribution of retained earnings

Under the Corporation Law of Japan (the "Law"), 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 such financial period. The accounts for that period do not, therefore, reflect such distributions. Refer to Note 18.

### 3 Accounting Changes

- (i) Effective January 1, 2007, the Company has adopted a new accounting standard for stock options.

As a result, both operating income, and income before income taxes and minority interests decreased by ¥139 million for the year ended December 31, 2007 from the corresponding amounts which would have been recorded under the previous method.

- (ii) Until the year ended December 31, 2006, the Company recorded patents and licensing-related income as non-operating income or extraordinary income in the consolidated statements of income. Due to the recent economic success of R&D activities, it is probable that the patents and licensing-related income will increase in the future and those income has been becoming material, the Company has started to record them as revenue effective January 1, 2007.

As a result of this change, both revenue and operating income increased by ¥11,864 million for the year ended December 31, 2007 over the corresponding amounts which would have been recorded under the previous method. This change had no impact on income before income taxes and minority interests.

- (iii) Effective the year ended December 31, 2007, the Company and its domestic consolidated subsidiaries have changed their method of depreciation for all tangible fixed assets aside from buildings (excluding leasehold improvements to such buildings) acquired on or after April 1, 2007 to reflect the revisions to the Corporation Tax Law.

As a result of this change, both operating income and income before income taxes and minority interests decreased by ¥362 million for the year ended December

31, 2007 from the corresponding amounts which would have been recorded under the previous method.

- (iv) Effective the year ended December 31, 2007, the Company has changed its method of accounting for foreign currency translation into yen to using the annual average exchange rates in effect with respect to revenues and expenses of overseas consolidated subsidiaries. Until the year ended December 31, 2006, the Company used spot rates in the foreign currency exchange market at the balance sheet dates to translate those revenues and expenses. This change was made to properly reflect the related gains and losses that occur throughout the accounting period in the consolidated financial statements by averaging the impacts of temporary fluctuations in exchange rates.

As a result of this change, revenues, operating income and income before income taxes and minority interests increased by ¥1,249 million, ¥408 million and ¥447 million, respectively, for the year ended December 31, 2007 over the corresponding amounts which would have been recorded under the previous method.

- (v) Effective the year ended December 31, 2008, in relation to revisions to the Corporation Tax Law, for those tangible fixed assets, other than buildings (excluding building fixtures and equipment) that were purchased on or before March 31, 2007, the Company and its consolidated subsidiaries depreciate the difference between 5% of the acquisition cost and nominal value by the straight line method over a period of five years from the year following the year in which accumulated depreciation reached 95% of acquisition cost.

As a result, operating income and income before income taxes and minority interests were each ¥410 million lower than they would have been in the absence of this change in the method of calculating depreciation.

- (vi) Effective the year ended December 31, 2009, following revisions to the Corporation Tax Law, the Company and certain of its consolidated subsidiaries have revised the useful lives of property, plant and equipment, primary machinery and equipment.

As a result, operating income and income before income taxes and minority interests increased by ¥634 million (\$6,891 thousand) respectively from the corresponding amounts which would have been recorded under the previous method.

- (vii) Effective the year ended December 31, 2009, the Company has applied "Accounting Standard for Measurement of Inventories" (Accounting Standards Board of Japan ("ASBJ") Statement No. 9, issued on July 5, 2006). Due to the application of this standard, losses on inventories, which were formerly included in other expenses, have been reclassified as cost of sales.

As a result, operating income was ¥1,251 million (\$13,598 thousand) lower compared to what would have been recorded under the previous method. There was no effect on income before income taxes and minority interests.

- (viii) Effective the year ended December 31, 2009, the Company adopted PITF No. 18.

As a result, retained earnings at the beginning of the period decreased by ¥26 million (\$283 thousand) compared

to what would have been recorded under the previous method. Also, revenue and operating income decreased by ¥312 million (\$3,391 thousand) and ¥7 million (\$76 thousand), respectively, and income before income taxes and minority interests increased by ¥983 million (\$10,685 thousand) over the corresponding amounts which would have been recorded under the previous method.

- (ix) Effective the year ended December 31, 2009, accompanying the application of the "Accounting Standard for Lease Transactions" (ASBJ Statement No. 13, originally issued by the Business Accounting Deliberation Council on June 17, 1993, and revised by the ASBJ on March 30, 2007) and "Implementation Guidance on Accounting Standard for Lease Transactions (ASBJ Guidance No. 16, originally issued by the Audit System Committee of the Japanese Institute of Certified Public Accountants on January 18, 1994, and revised on March 30, 2007), finance leases for which ownership is not transferred to the lessee, other than finance leases that were entered into on or before December 31, 2008, have been capitalized.

The effect of this change was not material.

- (x) Effective the year ended December 31, 2009, the Company has early adopted "Partial Amendments to Accounting Standard for Retirement Benefits (Part 3)" (ASBJ Statement No. 19, issued on July 31, 2008).

The application of this standard had no effect on the consolidated financial statements.

## 4 U.S. Dollar Amounts

The U.S. dollar amounts in the accompanying consolidated financial statements as of and for the year ended December 31, 2009 have been translated from Japanese yen amounts at ¥92 = U.S.\$1.00, the exchange rate prevailing on December

31, 2009. This translation is presented for convenience only and should not be construed as a representation that Japanese yen have been, could have been, or could in the future be, converted into U.S. dollars at that or any other rate.

## 5 Inventories

Inventories at December 31, 2009 and 2008 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2009	2008	2009
Finished products.....	¥45,373	¥38,760	\$ 493,185
Work in process and semifinished products.....	26,337	22,987	286,272
Raw materials and supplies .....	20,932	16,989	227,521
	¥92,642	¥78,736	\$1,006,978

## 6 Depreciation

Depreciation of property, plant and equipment for the years ended December 31, 2009, 2008 and 2007 amounted to ¥18,047 million (\$196,163 thousand), ¥17,493 million and ¥11,507 million, respectively.

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

The Company had no short-term bank loans and long-term debt as of December 31, 2009 and 2008.

The Company has entered into loan commitment agreements amounting to ¥40,000 million (\$434,783 thousand) with ten banks. There were no loans payables outstanding at December 31, 2009 under these loan commitment agreements.

## 8 Legal Reserve and Additional Paid-in Capital

The Law provides that an amount equal to 10% of the amount to be disbursed as distributions of capital surplus (other than the additional paid-in capital) and retained earnings (other than the legal reserve) be transferred to the additional paid-in capital and the legal reserve, respectively, until the sum of the

additional paid-in capital 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.

## 9 Other Income (Expenses)

The components of "Other" in "Other income (expenses)" for the years ended December 31, 2009, 2008 and 2007 were as follows:

	Millions of yen			Thousands of U.S. dollars
	2009	2008	2007	2009
Gain on sales of fixed assets .....	¥ 264	¥ 421	¥ —	\$ 2,870
Gain on liquidation of an affiliate .....	—	—	294	—
(Loss) gain on foreign exchange .....	(1,027)	6,255	—	(11,163)
Gain on settlement of co-development costs .....	—	6,341	—	—
Subsidies received for construction of a plant .....	—	500	—	—
Retirement benefit expenses .....	—	(107)	—	—
Gain (loss) on derivatives .....	7,328	(1,341)	—	79,652
Loss on disposal of fixed assets .....	(212)	(357)	(327)	(2,304)
Loss on impairment of fixed assets .....	(27)	(748)	(32)	(293)
Loss on restructuring costs, net .....	(1,228)	(536)	(1,521)	(13,348)
Loss on inventories (Note 3 vii) .....	—	(1,915)	(2,236)	—
Loss on sales of fixed assets .....	(1)	(10)	(35)	(11)
Other .....	973	1,141	2,315	10,576
	<u>¥ 6,070</u>	<u>¥ 9,644</u>	<u>¥(1,542)</u>	<u>\$ 65,979</u>

## 10 Income Taxes

Income taxes in Japan applicable to the Company and its domestic consolidated subsidiaries consist of corporation tax, inhabitants' taxes and enterprise tax. Income taxes of the foreign consolidated subsidiaries are based generally on the tax rates applicable in their countries of incorporation. The approximate aggregate statutory tax rate was 40.4% for the years ended December 31, 2009, 2008 and 2007. Income taxes for the years ended December 31, 2009, 2008 and 2007 consisted of the following:

	Millions of yen			Thousands of U.S. dollars
	2009	2008	2007	2009
Income taxes:				
Current .....	¥32,989	¥25,966	¥30,387	\$358,576
Deferred .....	(1,806)	(3,690)	(5,850)	(19,630)
	<u>¥31,183</u>	<u>¥22,276</u>	<u>¥24,537</u>	<u>\$338,946</u>

The significant components of deferred tax assets and liabilities at December 31, 2009 and 2008 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2009	2008	2009
Deferred tax assets:			
Prepaid expenses .....	¥10,323	¥ 8,531	\$112,207
Depreciation .....	5,780	5,214	62,826
Reserve for employees' retirement benefits .....	5,160	4,838	56,087
Amortization of deferred charges .....	4,367	3,146	47,467
Reserve for bonuses to employees .....	2,309	1,766	25,098
Enterprise tax payable .....	1,751	978	19,033
Unrealized profit on inventories .....	1,362	2,924	14,804
Reserve for sales rebates .....	1,229	1,482	13,359
Valuation loss on securities .....	1,222	1,171	13,283
Supplies .....	1,213	2,207	13,185
Reserve for officers' retirement benefits .....	308	312	3,348
Impairment loss on fixed assets .....	153	377	1,663
Other .....	4,436	4,157	48,216
Gross deferred tax assets .....	39,613	37,103	430,576
Valuation allowance .....	(2,292)	(1,569)	(24,913)
Amount offset by deferred tax liabilities .....	(1,668)	(1,501)	(18,130)
Deferred tax assets, net .....	¥35,653	¥34,033	\$387,533
Deferred tax liabilities:			
Unrealized gain on securities .....	¥ 1,108	¥ 917	\$ 12,043
Deferred gain on sales of properties for tax purposes .....	560	584	6,087
Other .....	0	1	0
Total deferred tax liabilities .....	1,668	1,502	18,130
Amount offset by deferred tax assets .....	(1,668)	(1,501)	(18,130)
Deferred tax liabilities, net .....	¥ —	¥ 1	\$ —

A reconciliation of the statutory and effective tax rates for the years ended December 31, 2009, 2008 and 2007 is summarized as follows:

	2009	2008	2007
Statutory tax rate .....	40.4%	40.4%	40.4%
Permanently non-deductible expenses for tax purposes such as entertainment expenses .....	1.9	2.8	2.3
Permanently non-taxable income such as dividend income .....	(0.0)	(0.1)	(0.0)
Inhabitants' per capita taxes .....	0.1	0.2	0.2
Different tax rates applied to overseas subsidiaries .....	(1.8)	(1.7)	(1.3)
Tax credit for research and development expenses .....	(5.9)	(5.0)	(6.5)
Change in valuation allowance .....	0.1	(1.5)	2.1
Other .....	0.0	0.2	(0.3)
Effective tax rates .....	34.9%	35.3%	36.9%

## 11 Retirement Benefits

### (a) Overview of retirement benefits

The Company has various retirement benefit plans such as defined contribution pension plans and certain types of defined benefit pension plans comprising corporate pension fund and lump-sum retirement benefit plans. The Company's domestic consolidated subsidiaries participate in the lump-sum retirement benefit plan. The Company's overseas consolidated subsidiaries participate in the defined benefit or defined contribution pension plans.

Certain employees may be entitled to additional special retirement benefits (which have not been provided for) based

on the conditions under which termination occurs.

The Company has a retirement benefit trust to fund the lump-sum retirement benefit plan.

### (b) Retirement benefit obligation

The following table sets forth the funded and accrued status of the plans, and the amounts recognized in the accompanying consolidated balance sheets as of December 31, 2009 and 2008 for the Company's and the consolidated subsidiaries' defined benefit plans:

	Millions of yen		Thousands of U.S. dollars
	2009	2008	2009
Retirement benefit obligation.....	¥(65,350)	¥(63,061)	\$(710,326)
Plan assets at fair value.....	60,434	58,069	656,891
Funded status .....	(4,916)	(4,992)	(53,435)
Unrecognized prior service cost.....	(1,846)	(2,324)	(20,065)
Unrecognized actuarial loss.....	4,313	5,502	46,880
Net amount .....	(2,449)	(1,814)	(26,620)
Prepaid pension expense .....	261	270	2,837
Reserve for employees' retirement benefits .....	¥ (2,710)	¥ (2,084)	\$ (29,457)

#### (c) Retirement benefit expenses

	Millions of yen			Thousands of U.S. dollars
	2009	2008	2007	2009
Service cost (*) .....	¥ 2,572	¥ 2,600	¥ 2,587	\$ 27,957
Interest cost.....	1,402	1,372	1,345	15,239
Expected return on pension plan assets.....	(1,271)	(1,377)	(1,380)	(13,815)
Amortization of actuarial differences .....	1,142	(134)	(537)	12,413
Amortization of prior service cost .....	(479)	(603)	(759)	(5,207)
Contribution payments to a defined contribution pension plan.....	803	754	741	8,728
Additional retirement benefits paid.....	55	—	658	598
Effect of application of the standard method for calculation of retirement benefit obligation (*2).....	—	107	—	—
Total .....	¥ 4,224	¥ 2,719	¥ 2,655	\$ 45,913

(\*) Retirement benefit expenses of consolidated subsidiaries which adopted the simplified method are included in this amount.

(\*2) During the year ended December 31, 2008, certain domestic consolidated subsidiary changed its calculation method of retirement benefit obligations from the simplified method to the standard method. In this connection, unrecognized obligations at the beginning of the fiscal year in amount of ¥107 million were fully charged to income.

#### (d) The assumptions utilized in accounting for the retirement benefit plans are summarized as follows:

	2009	2008	2007
(1) Discount rates.....	Principally 2.25%	2.25%	2.25%
(2) Expected rates of return on plan assets .....	0.8% - 2.5%	0.7% - 2.5%	0.7% - 2.5%

## 12 Leases

The Company holds certain machinery, equipment and software under finance leases which do not transfer ownership of the leased assets to the lessee. As discussed in Note 3(ix), finance lease transactions commencing on or before December 31, 2008 that do not transfer ownership are accounted for as

operating leases. If these leases had been capitalized, the acquisition costs, accumulated depreciation/amortization and net book value of such leased assets at December 31, 2009 and 2008 would have been as follows:

	Millions of yen			Thousands of U.S. dollars		
	Equipment	Software	Total	Equipment	Software	Total
2009						
Acquisition costs.....	¥1,637	¥3	¥1,640	\$17,793	\$33	\$17,826
Accumulated depreciation/amortization.....	924	1	925	10,043	11	10,054
Net book value .....	¥ 713	¥2	¥ 715	\$ 7,750	\$22	\$ 7,772
2008						
Acquisition costs.....	¥1,944	¥3	¥1,947			
Accumulated depreciation/amortization.....	839	1	840			
Net book value .....	¥1,105	¥2	¥1,107			

Rental expenses, primarily for office space and equipment, amounted to ¥4,310 million (\$46,848 thousand), ¥4,358 million and ¥4,092 million for the years ended December 31, 2009, 2008, and 2007, respectively.

Lease payments relating to finance leases accounted for as operating leases included in the above amounts totaled ¥386 million (\$4,196 thousand), ¥387 million and ¥453 million for the

years ended December 31, 2009, 2008 and 2007, respectively, which are equal to the depreciation/amortization expense of the leased assets computed by the straight-line method over the respective lease terms. Future minimum lease payments subsequent to December 31, 2009 for finance leases accounted for as operating leases are summarized as follows:

Year ending December 31,	Millions of yen	Thousands of U.S. dollars
2010 .....	¥306	\$3,326
2011 and thereafter.....	409	4,446
	<u>¥715</u>	<u>\$7,772</u>

Future minimum lease payments subsequent to December 31, 2009 for noncancelable operating leases are summarized as follows:

Year ending December 31,	Millions of yen	Thousands of U.S. dollars
2010 .....	¥2,443	\$26,554
2011 and thereafter.....	2,453	26,663
	<u>¥4,896</u>	<u>\$53,217</u>

### 13 Securities

Securities consisted of marketable securities and non-marketable securities classified as other securities. The acquisition cost, carrying value and unrealized gain (loss) on marketable securities at December 31, 2009 and 2008 are summarized by type of security as follows:

#### (a) Other securities with determinable market value

	Millions of yen			Thousands of U.S. dollars		
	Acquisition cost	Carrying value	Unrealized gain (loss)	Acquisition cost	Carrying value	Unrealized gain (loss)
2009						
Securities whose carrying value exceeds their acquisition cost:						
Stocks .....	¥ 2,331	¥ 5,134	¥2,803	\$ 25,337	\$ 55,804	\$30,467
Bonds .....	1,698	1,699	1	18,456	18,468	12
Other .....	28,000	28,005	5	304,348	304,402	54
Subtotal .....	32,029	34,838	2,809	348,141	378,674	30,533
Securities whose carrying value does not exceed their acquisition cost:						
Stocks .....	1,134	1,131	(3)	12,326	12,293	(33)
Bonds .....	14,492	14,430	(62)	157,522	156,848	(674)
Other .....	11,000	11,000	(0)	119,565	119,565	(0)
Subtotal .....	26,626	26,561	(65)	289,413	288,706	(707)
Total .....	<u>¥58,655</u>	<u>¥61,399</u>	<u>¥2,744</u>	<u>\$637,554</u>	<u>\$667,380</u>	<u>\$29,826</u>

	Millions of yen		
	Acquisition cost	Carrying value	Unrealized gain (loss)
2008			
Securities whose carrying value exceeds their acquisition cost:			
Stocks .....	¥ 2,780	¥ 5,761	¥2,981
Bonds .....	2,000	2,000	0
Other .....	25,000	25,000	0
Subtotal .....	29,780	32,761	2,981
Securities whose carrying value does not exceed their acquisition cost:			
Bonds .....	30,400	29,690	(710)
Other .....	6,000	6,000	(0)
Subtotal .....	36,400	35,690	(710)
Total .....	<u>¥66,180</u>	<u>¥68,451</u>	<u>¥2,271</u>

**(b) Sales of securities classified as other securities**

Sales proceeds from, and aggregate gain and loss on, sales of securities classified as other securities for the years ended December 31, 2009, 2008 and 2007 are summarized as follows:

	Millions of yen			Thousands of U.S. dollars
	2009	2008	2007	2009
Sales proceeds .....	¥ —	¥ —	¥972	\$ —
Aggregate gain .....	—	—	2	—
Aggregate loss .....	¥ —	¥ —	¥ (20)	\$ —

**(c) Securities without determinable market value**

	Millions of yen		Thousands of U.S. dollars
	2009	2008	2009
Other securities:			
Unlisted securities, except for those traded on the OTC market and other .....	¥355	¥422	\$3,859

**(d) The redemption schedule for other securities with maturity dates is summarized as follows:**

	Millions of yen		Thousands of U.S. dollars	
	Due in one year or less	Due after one year through five years	Due in one year or less	Due after one year through five years
2009				
Other securities with maturity dates:				
Corporate bonds .....	¥ 5,466	¥2,976	\$ 59,413	\$32,348
Other bonds .....	7,687	—	83,554	—
Other .....	39,005	—	423,968	—
Total .....	¥52,158	¥2,976	\$566,935	\$32,348

	Millions of yen	
	Due in one year or less	Due after one year through five years
2008		
Other securities with maturity dates:		
Corporate bonds .....	¥12,721	¥7,975
Other bonds .....	10,994	—
Other .....	31,000	—
Total .....	¥54,715	¥7,975

## 14 Derivatives

The Company utilizes derivative financial instruments such as forward foreign exchange contracts, currency swaps and interest-rate swaps for the purpose of hedging its foreign currency and interest rate risks, but does not enter into such transactions for speculative trading purposes.

The Company is exposed to certain market risk arising from the forward foreign exchange contracts and swap agreements referred to above. The Company is also exposed to the risk of credit loss in the event of non-performance by its counterparties to these derivatives positions; however, the Company does not

anticipate non-performance by any of its counterparties, all of whom are financial institutions with high credit ratings.

The Company enters into these derivatives transactions in accordance with the policies and strategies established by management. Routine operations involving derivatives transactions are subject to strict oversight by management.

The contract amounts of the derivatives in the table below are nominal amounts or notional principal amounts and thus do not fully reflect the potential risk associated with these open derivatives positions.

**(a) Currency-related transactions**

	Millions of yen			Thousands of U.S. dollars		
	Notional amounts	Estimated fair value	Unrealized gain	Notional amounts	Estimated fair value	Unrealized gain
2009						
Currency swap:						
Swiss francs .....	¥20,571	¥21,278	¥708	\$223,598	\$231,283	\$7,696
Total .....	¥20,571	¥21,278	¥708	\$223,598	\$231,283	\$7,696
2008						
Currency swap:						
Swiss francs .....	¥2,468	¥2,588	¥120			
Total .....	¥2,468	¥2,588	¥120			

**(b) Interest rate-related transactions**

There were no open derivatives positions of interest rate-related transactions at December 31, 2009 or 2008.

**15 Segment Information**

The Company and its consolidated subsidiaries are engaged principally in the manufacture and sales of pharmaceutical products in Japan and overseas.

**Business segments**

For the years ended December 31, 2009, 2008 and 2007, as the Company and its consolidated subsidiaries operated solely in the pharmaceutical business segment, the disclosure of business segment information has been omitted.

**Geographical segments**

As revenues and total assets of the overseas consolidated subsidiaries constituted less than 10% of the consolidated

totals for the years ended December 31, 2009, 2008 and 2007, the disclosure of geographical segment information has been omitted.

**Overseas sales**

As overseas sales was ¥36,390 million (\$395,543 thousand) and less than 10% of total consolidated revenues for the year ended December 31, 2009, the disclosure of overseas sales information has been omitted.

Overseas sales for the years ended December 31, 2008 and 2007 were as follows:

	Millions of yen	
	2008	2007
Overseas sales .....	¥ 33,804	¥ 36,444
Total consolidated revenues .....	¥326,938	¥344,808
Overseas sales as a percentage of total consolidated revenues .....	10.3%	10.6%

**16 Loss on Impairment of Fixed Assets**

The Company and its domestic consolidated subsidiaries determined that substantially the entire business constitutes a single cash generating unit since the Company and its consolidated subsidiaries are engaged principally in the manufacture and sales of pharmaceutical products. However, the Company and its consolidated subsidiaries determine whether an asset is impaired on an individual asset basis if the asset is considered idle or to be disposed of.

Loss on impairment of idle assets and assets to be disposed of, which was recognized by reducing the book value of such

assets to their respective net realizable value, for the years ended December 31, 2009, 2008 and 2007 amounted to ¥27 million (\$293 thousand), ¥748 million and ¥32 million, respectively. Loss on impairment of idle assets and assets to be disposed of for the year ended December 31, 2008 mainly consisted of losses on land in the aggregate amount of ¥178 million, buildings and structures in the aggregate amount of ¥447 million, and others in the aggregate amount of ¥123 million.

**17 Contingent Liabilities**

The Company was contingently liable as guarantor of loan obligations for its employees of ¥424 million (\$4,609 thousand) and ¥500 million in the aggregate at December 31, 2009 and 2008, respectively.

## 18 Supplementary Information for Consolidated Statements of Changes in Net Assets

### (a) Type and number of outstanding shares

2009 Type of shares	Number of shares			
	Balance at beginning of year	Increase in shares during the year	Decrease in shares during the year	Balance at end of year
Issued stock:				
Common stock .....	559,685,889	—	—	559,685,889
Total .....	559,685,889	—	—	559,685,889
Treasury stock:				
Common stock (*1,2) .....	14,872,196	648,466	23,583	15,497,079
Total .....	14,872,196	648,466	23,583	15,497,079

(\*1) Treasury stock increased by 648,466 shares due to the repurchase of 640,800 shares of common stock and the repurchase of 7,666 fractional shares of less than one unit.

(\*2) Treasury stock decreased by 23,583 due to the exercise of stock options resulting in a decrease of 23,100 shares and the sale of 483 fractional shares of less than one unit.

2008 Type of shares	Number of shares			
	Balance at beginning of year	Increase in shares during the year	Decrease in shares during the year	Balance at end of year
Issued stock:				
Common stock (*1) .....	559,636,061	49,828	—	559,685,889
Total .....	559,636,061	49,828	—	559,685,889
Treasury stock:				
Common stock (*2,3) .....	14,831,246	52,309	11,359	14,872,196
Total .....	14,831,246	52,309	11,359	14,872,196

(\*1) The number of outstanding shares of common stock increased by 49,828 shares due to the conversion of convertible bonds.

(\*2) Treasury stock increased by 52,309 shares due to the repurchase of fractional shares of less than one unit.

(\*3) Treasury stock decreased by 11,359 due to the exercise of stock options resulting in a decrease of 3,600 shares and the sale of 7,759 fractional shares of less than one unit.

2007 Type of shares	Number of shares			
	Balance at beginning of year	Increase in shares during the year	Decrease in shares during the year	Balance at end of year
Issued stock:				
Common stock (*1) .....	559,493,113	142,948	—	559,636,061
Total .....	559,493,113	142,948	—	559,636,061
Treasury stock:				
Common stock (*2,3) .....	5,363,173	9,512,367	44,294	14,831,246
Total .....	5,363,173	9,512,367	44,294	14,831,246

(\*1) The number of outstanding shares of common stock increased by 142,948 shares due to the conversion of convertible bonds.

(\*2) Treasury stock increased by 9,512,367 shares due to the repurchase of 9,500,000 shares of common stock and the repurchase of 12,367 fractional shares of less than one unit.

(\*3) Treasury stock decreased by 44,294 due to the exercise of stock options resulting in a decrease of 43,400 shares and the sale of 894 fractional shares of less than one unit.

### (b) Stock subscription rights

2009		Millions of yen	Thousands of U.S. dollars
Company	Description	Balance at end of year	Balance at end of year
Parent company	Share subscription rights as stock options .....	¥537	\$5,837
	Total .....	¥537	\$5,837

2008		Millions of yen
Company	Description	Balance at end of year
Parent company	Share subscription rights as stock options .....	¥326
	Total .....	¥326

2007		Millions of yen
Company	Description	Balance at end of year
Parent company	Share subscription rights as stock options .....	¥140
	Total .....	¥140

**(c) Dividends****(1) Dividends paid to shareholders**

2009

Date of approval	Resolution approved by	Type of shares	Amount (Millions of yen)	Amount (Thousands of U.S. dollars)	Amount per share (Yen)	Amount per share (U.S. dollars)	Shareholders' cut-off date	Effective date
March 25, 2009	Annual general meeting of shareholders	Common stock	¥10,351	\$112,511	¥19	\$0.21	December 31, 2008	March 26, 2009
July 23, 2009	Board of directors	Common stock	¥9,262	\$100,674	¥17	\$0.18	June 30, 2009	September 8, 2009

2008

Date of approval	Resolution approved by	Type of shares	Amount (Millions of yen)	Paid from	Amount per share (Yen)	Shareholders' cut-off date	Effective date
March 27, 2008	Annual general meeting of shareholders	Common stock	¥8,172		¥15	December 31, 2007	March 28, 2008
July 31, 2008	Board of directors	Common stock	¥8,173		¥15	June 30, 2008	September 9, 2008

2007

Date of approval	Resolution approved by	Type of shares	Amount (Millions of yen)	Paid from	Amount per share (Yen)	Shareholders' cut-off date	Effective date
March 23, 2007	Annual general meeting of shareholders	Common stock	¥9,974		¥18	December 31, 2006	March 26, 2007
July 31, 2007	Board of directors	Common stock	¥8,172		¥15	June 30, 2007	September 7, 2007

**(2) Dividends with a shareholders' cut-off date during the current fiscal year but an effective date subsequent to the current fiscal year**

2009

Date of approval	Resolution approved by	Type of shares	Amount (Millions of yen)	Amount (Thousands of U.S. dollars)	Paid from	Amount per share (Yen)	Amount per share (U.S. dollars)	Shareholders' cut-off date	Effective date
March 25, 2010	Annual general meeting of shareholders	Common stock	¥12,516	\$136,043	Retained earnings	¥23	\$0.25	December 31, 2009	March 26, 2010

2008

Date of approval	Resolution approved by	Type of shares	Amount (Millions of yen)	Paid from	Amount per share (Yen)	Shareholders' cut-off date	Effective date
March 25, 2009	Annual general meeting of shareholders	Common stock	¥10,351	Retained earnings	¥19	December 31, 2008	March 26, 2009

2007

Date of approval	Resolution approved by	Type of shares	Amount (Millions of yen)	Paid from	Amount per share (Yen)	Shareholders' cut-off date	Effective date
March 27, 2008	Annual general meeting of shareholders	Common stock	¥8,172	Retained earnings	¥15	December 31, 2007	March 28, 2008

## 19 Supplementary Cash Flow Information

(a) Cash and cash equivalents at December 31, 2009 and 2008 classified by account on the balance sheets were as follows:

	Millions of yen		Thousands of U.S. dollars
	2009	2008	2009
Cash on hand and at bank .....	¥106,978	¥70,768	\$1,162,804
Time deposits over three months .....	(12,500)	(116)	(135,870)
Cash and cash equivalents .....	¥ 94,478	¥70,652	\$1,026,935

(b) Significant non-cash transactions were as follows:

Convertible bonds and stock subscription rights

	Millions of yen			Thousands of U.S. dollars
	2009	2008	2007	2009
Decrease in convertible bonds resulting from conversion .....	¥—	¥38	¥109	\$—

## 20 Related Party Transactions

The Company is substantively a 61.6%-owned consolidated subsidiary of Roche Pharmholding B.V. (the "parent company"). The parent company is indirectly owned by Roche Holding Ltd. ("Roche Holding"). The Company principally purchases raw materials from F. Hoffmann-La Roche Ltd. ("Roche"), a consolidated subsidiary of Roche Holding.

Significant balances at December 31, 2009 and 2008 and transactions for the years ended December 31, 2009, 2008 and 2007 with related parties are summarized as follows:

	Millions of yen		Thousands of U.S. dollars
	2009	2008	2009
Balances:			
Roche:			
Trade payables .....	¥26,744	¥21,452	\$290,696
Trade receivables .....	6,390	2,357	69,457
Accrued receivables .....	8,329	4,049	90,533

	Millions of yen			Thousands of U.S. dollars
	2009	2008	2007	2009
Transactions:				
Parent company:				
Interest expense on bonds .....	¥ —	¥ 2	¥ 3	\$ —
Roche:				
Purchases of raw materials .....	120,159	69,695	54,279	1,306,076
Sales of products .....	11,227	3,952	5,065	122,033
Sharing of co-development costs .....	9,545	6,030	4,922	103,750

## 21 Stock Option Plans

At December 31, 2009, 2008 and 2007, the Company had the following stock option plans approved by its shareholders in accordance with the Law:

December 31, 2009	2009 plan (stock-based compensation plan)	2009 plan	2007 plan	2006 plan	2005 plan
Date of approval by shareholders	May 11, 2009	April 9, 2009	April 9, 2007	April 3, 2006	April 1, 2005
Grantees	6 directors	6 directors and 101 employees of the Company and 2 directors and 5 employees of a subsidiary	6 directors and 110 employees of the Company and 3 directors and 4 employees of a subsidiary	6 directors and 111 employees of the Company	6 directors and 24 employees of the Company
Type of stock	Common stock	Common stock	Common stock	Common stock	Common stock
Number of shares granted	78,500	330,000	355,000	344,000	252,000
Exercise price (yen)	¥1	¥1,696	¥3,039	¥2,245	¥1,649
Exercise price (U.S. dollars)	\$0.01	\$18.43	\$33.03	\$24.40	\$17.92
Exercisable period	May 11, 2009 - April 24, 2039	April 11, 2011 - March 25, 2019	April 1, 2009 - March 23, 2017	April 1, 2008 - March 23, 2016	April 1, 2007 - March 23, 2015

December 31, 2009	2004 plan	2003 plan
Date of approval by shareholders	April 5, 2004	August 5, 2003
Grantees	6 directors and 19 employees of the Company and 1 director of a subsidiary	5 directors and 23 employees of and 1 director of a subsidiary
Type of stock	Common stock	Common stock
Number of shares granted	232,000	231,000
Exercise price (yen)	¥1,675	¥1,454
Exercise price (U.S. dollars)	\$18.21	\$15.80
Exercisable period	April 1, 2006 - March 25, 2014	July 1, 2005 - June 25, 2013

December 31, 2009	2009 plan (stock-based compensation plan)	2009 plan	2007 plan	2006 plan	2005 plan
<b>Non-vested (number of shares)</b>					
Outstanding at the beginning of the year	—	—	355,000	—	—
Granted during the year	78,500	330,000	—	—	—
Forfeited during the year	—	—	4,000	—	—
Vested during the year	—	—	351,000	—	—
Outstanding at the end of the year	78,500	330,000	—	—	—
<b>Vested (number of shares)</b>					
Outstanding at the beginning of the year	—	—	—	344,000	252,000
Vested during the year	—	—	351,000	—	—
Exercised during the year	—	—	—	—	2,800
Forfeited during the year	—	—	1,000	6,000	—
Outstanding at the end of the year	—	—	350,000	338,000	249,200
Weighted-average market price (yen)	—	—	—	—	¥1,724
Weighted-average market price (U.S. dollars)	—	—	—	—	\$18.74

December 31, 2009	2004 plan	2003 plan
<b>Non-vested (number of shares)</b>		
Outstanding at the beginning of the year	—	—
Granted during the year	—	—
Forfeited during the year	—	—
Vested during the year	—	—
Outstanding at the end of the year	—	—
<b>Vested (number of shares)</b>		
Outstanding at the beginning of the year	218,000	127,600
Vested during the year	—	—
Exercised during the year	7,100	13,200
Forfeited during the year	—	8,000
Outstanding at the end of the year	210,900	106,400
Weighted-average market price (yen)	¥1,739	¥1,733
Weighted-average market price (U.S. dollars)	\$18.90	\$18.84

December 31, 2008	2007 plan	2006 plan	2005 plan	2004 plan	2003 plan
Date of approval by shareholders	April 9, 2007	April 3, 2006	April 1, 2005	April 5, 2004	August 5, 2003
Grantees	6 directors and 110 employees of the Company and 3 directors and 4 employees of a subsidiary	6 directors and 111 employees of the Company	6 directors and 24 employees of the Company	6 directors and 19 employees of the Company and 1 director of a subsidiary	5 directors and 23 employees of the Company and 1 director of a subsidiary
Type of stock	Common stock	Common stock	Common stock	Common stock	Common stock
Number of shares granted	355,000	344,000	252,000	232,000	231,000
Exercise price (yen)	¥3,039	¥2,245	¥1,649	¥1,675	¥1,454
Exercisable period	April 1, 2009 - March 23, 2017	April 1, 2008 - March 23, 2016	April 1, 2007 - March 23, 2015	April 1, 2006 - March 25, 2014	July 1, 2005 - June 25, 2013

December 31, 2008	2007 plan	2006 plan	2005 plan	2004 plan	2003 plan
<b>Non-vested (number of shares)</b>					
Outstanding at the beginning of the year	355,000	344,000	—	—	—
Granted during the year	—	—	—	—	—
Forfeited during the year	—	—	—	—	—
Vested during the year	—	344,000	—	—	—
Outstanding at the end of the year	355,000	—	—	—	—
<b>Vested (number of shares)</b>					
Outstanding at the beginning of the year	—	—	252,000	218,000	131,200
Vested during the year	—	344,000	—	—	—
Exercised during the year	—	—	—	—	3,600
Forfeited during the year	—	—	—	—	—
Outstanding at the end of the year	—	344,000	252,000	218,000	127,600
Weighted-average market price (yen)	—	—	—	—	¥1,665

December 31, 2007	2007 plan	2006 plan	2005 plan	2004 plan	2003 plan
Date of approval by shareholders	April 9, 2007	April 3, 2006	April 1, 2005	April 5, 2004	August 5, 2003
Grantees	6 directors and 110 employees of the Company and 3 directors and 4 employees of a subsidiary	6 directors and 111 employees of the Company	6 directors and 24 employees of the Company	6 directors and 19 employees of the Company and 1 director of a subsidiary	5 directors and 23 employees of the Company and 1 director of a subsidiary
Type of stock	Common stock	Common stock	Common stock	Common stock	Common stock
Number of shares granted	355,000	344,000	252,000	232,000	231,000
Exercise price (yen)	¥3,039	¥2,245	¥1,649	¥1,675	¥1,454
Exercisable period	April 1, 2009 - March 23, 2017	April 1, 2008 - March 23, 2016	April 1, 2007 - March 23, 2015	April 1, 2006 - March 25, 2014	July 1, 2005 - June 25, 2013

December 31, 2007	2007 plan	2006 plan	2005 plan	2004 plan	2003 plan
<b>Non-vested (number of shares)</b>					
Outstanding at the beginning of the year	—	344,000	252,000	—	—
Granted during the year	355,000	—	—	—	—
Forfeited during the year	—	—	—	—	—
Vested during the year	—	—	252,000	—	—
Outstanding at the end of the year	355,000	344,000	—	—	—
<b>Vested (number of shares)</b>					
Outstanding at the beginning of the year	—	—	—	225,000	167,600
Vested during the year	—	—	252,000	—	—
Exercised during the year	—	—	—	7,000	36,400
Forfeited during the year	—	—	—	—	—
Outstanding at the end of the year	—	—	252,000	218,000	131,200
Weighted-average market price (yen)	—	—	—	¥2,971	¥2,511

The fair value of options granted is estimated by using the binominal model with the following weighted average assumptions.

	2009		2007
	2009 plan (stock-based compensation plan)	2009 plan	2007 plan
Expected volatility <sup>(*)</sup> .....	35%	35%	33%
Expected holding period <sup>(*)</sup> .....	5 years	10 years	10 years
Expected dividend <sup>(*)</sup> .....	34 yen	34 yen	30 yen
Risk-free rate <sup>(*)</sup> .....	0.86%	1.45%	1.69%

(\*) The volatility of the share price for the expected life of the option is estimated by taking into account the volatility of the characteristics of the company's stock, while drawing upon the actual share price in the past.

(\*) Because there is not enough data to make a reasonable estimation, expected life of the option of 2009 plan and 2007 plan is based on the assumption that the options are exercised at the end of the exercisable period, and expected life of the option of 2009 plan (stock-based compensation plan) is based on the age at the time of retirement according to the past record.

(\*) This is based the Company's dividend paid for the last fiscal year.

(\*) Risk-free interest rate is the yield on government bonds for the period that corresponds to the remaining life of the option.

Because it is difficult to reasonably estimate the number of options that will expire in the future, the number of vested options is calculated based on historical data for the options that have not yet been vested, and the number of options that have actually forfeited for the options that have already been vested.

## 22 Amounts Per Share

	Millions of yen			U.S. dollars
	2009	2008	2007	2009
Net income:				
Basic.....	¥104.00	¥72.07	¥73.23	\$1.13
Diluted.....	¥103.98	¥72.04	¥73.16	\$1.13

	Millions of yen		U.S. dollars
	2009	2008	2009
Net assets.....	¥794.51	¥725.18	\$8.64

Basic net income per share is computed based on the net income available for distribution to shareholders of common stock and the weighted-average number of shares of common stock outstanding during each year. Diluted net income per share is computed based on the net income available for distribution to the shareholders and the weighted-average number of shares of common stock outstanding during each year after giving effect to the dilutive potential of shares of common stock to be issued upon the conversion of convertible bonds, and the exercise of stock subscription rights and stock options. The potential dilutive

impact of 107,488 shares, 202,440 shares and 544,350 shares of common stock has been included in the computation of the weighted-average number of shares for the years ended December 31, 2009, 2008 and 2007, respectively.

Net assets per share are computed based on the net assets available for distribution to the shareholders of common stock (i.e., net assets excluding minority interests and stock subscription rights) and the number of shares of common stock outstanding at each balance sheet date.

# Report of Independent Auditors



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## Report of Independent Auditors

The Board of Directors  
Chugai Pharmaceutical Co., Ltd.

We have audited the accompanying consolidated balance sheets of Chugai Pharmaceutical Co., Ltd. and consolidated subsidiaries as of December 31, 2009 and 2008, and the related consolidated statements of income, changes in net assets, and cash flows for each of the three years in the period ended December 31, 2009, 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 Chugai Pharmaceutical Co., Ltd. and consolidated subsidiaries at December 31, 2009 and 2008, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2009 in conformity with accounting principles generally accepted in Japan.

### *Supplemental Information*

As disclosed in Note 3 (ii), effective January 1, 2007, the Company has changed its classification of patents and licensing-related income in the consolidated statements of income.

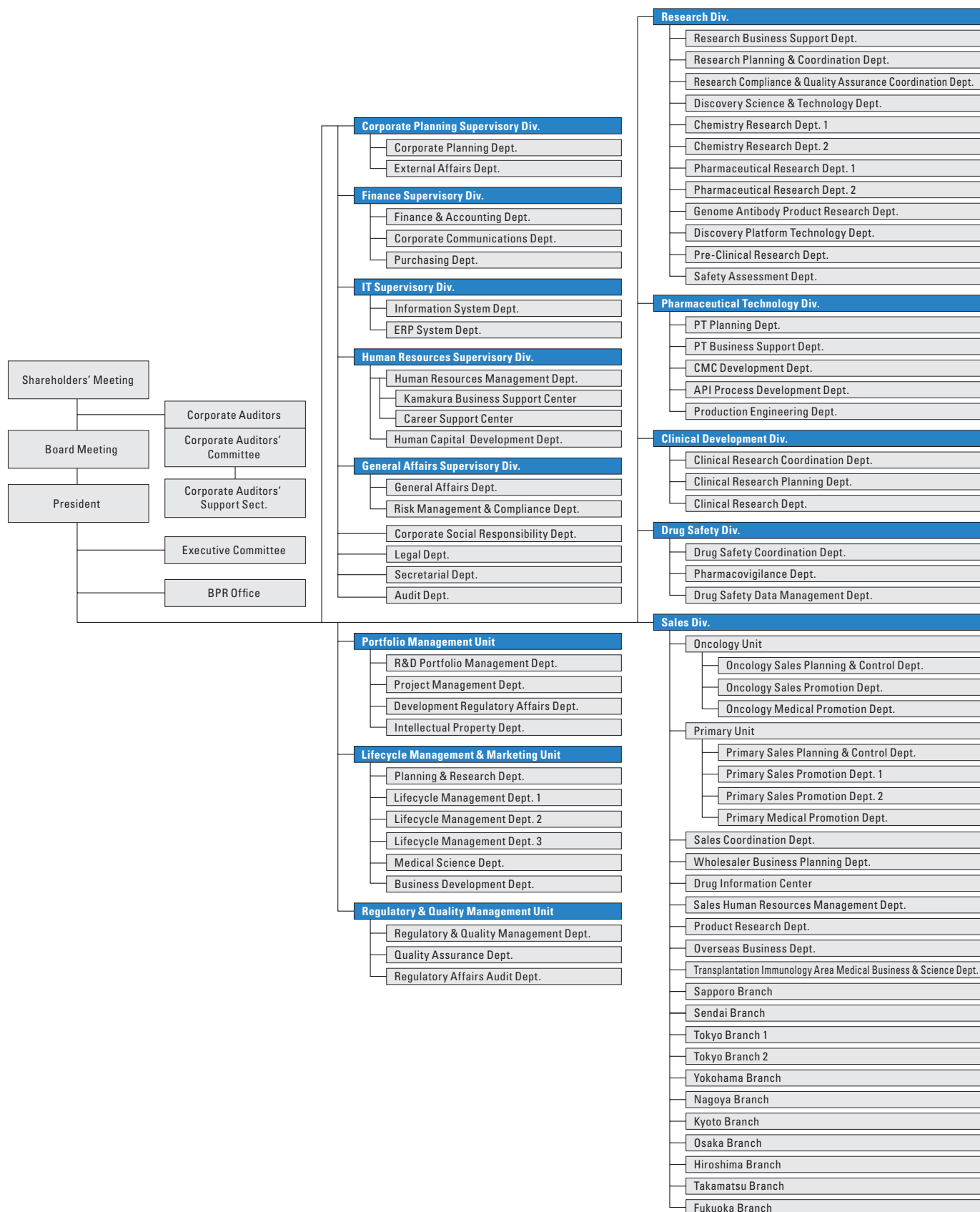
The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended December 31, 2009 are presented solely for convenience. Our audit also included the translation of yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 4.

*Ernst & Young ShinNihon LLC*

March 25, 2010

A member firm of Ernst & Young Global Limited

# Organization (As of March 25, 2010)



# Network (As of April 2010)

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Yokohama, Nagoya, Kyoto, Osaka,  
Hiroshima, Takamatsu, Fukuoka

## Plants

Ukima (Tokyo), Fujieda (Shizuoka),  
Utsunomiya (Tochigi),  
Kamakura (Kanagawa)

## Research Laboratories

Fuji-Gotemba (Shizuoka),  
Kamakura (Kanagawa), Ukima (Tokyo)

## Overseas Representative Office

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## Domestic Subsidiaries

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Chugai Business Support Co., Ltd.

Medical Culture Inc.

Chugai Distribution Co., Ltd.

Chugai Pharma Manufacturing Co., Ltd.

Chugai Clinical Research Center Co., Ltd.

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Tokyo 153-0041, Japan  
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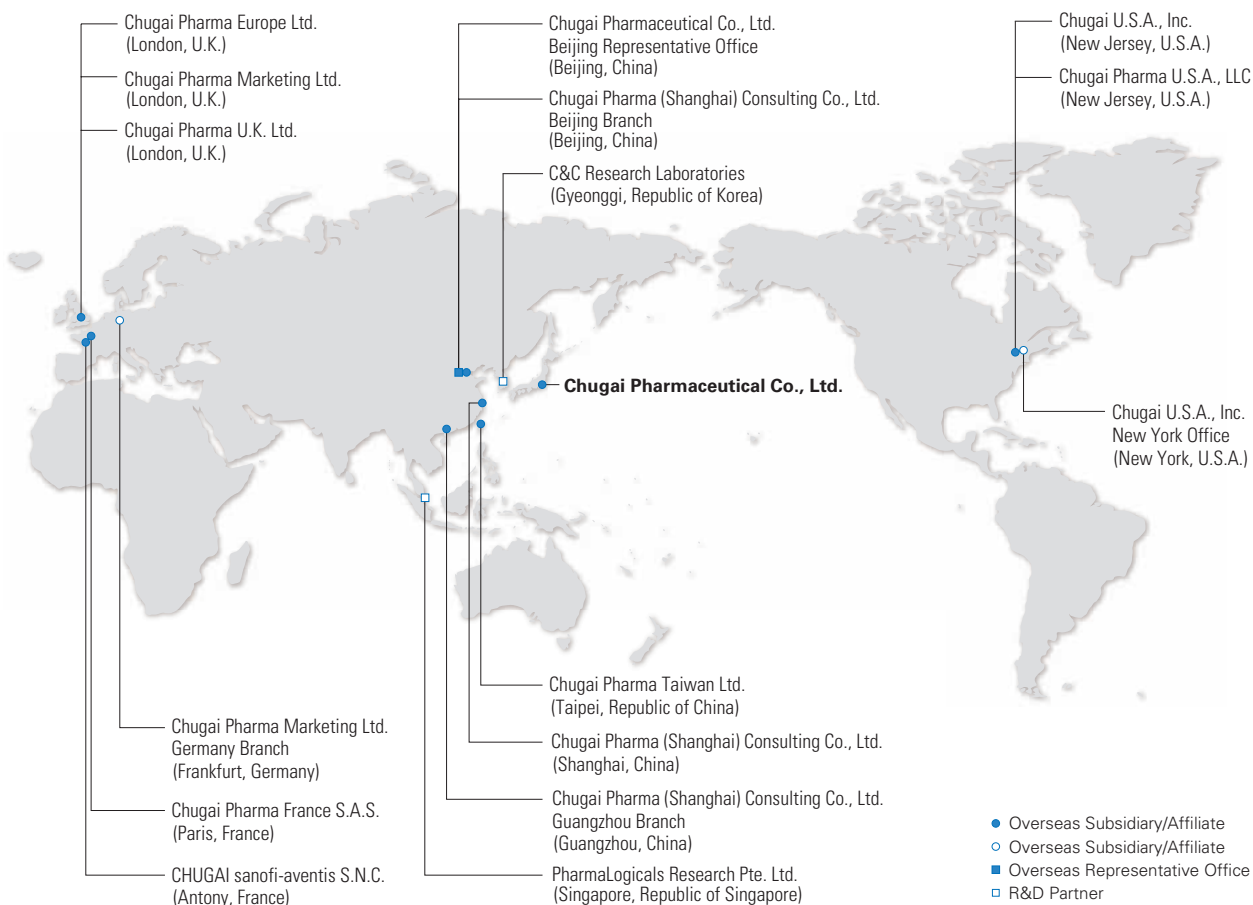
**PharmaLogicals Research Pte. Ltd.**

No.11 Biopolis Way #05-08/09 Helios,  
Singapore 138667  
Telephone: +65-(0) 6776-6556

**C&C Research Laboratories**

146-141 Annyeong-dong, Hwaseong-si,  
Gyeonggi-do, 445-380 Republic of Korea  
Telephone : +82-(0) 31-230-6542

**Chugai's Global Network**



# Corporate Data (As of December 31, 2009)

**Company Name**

Chugai Pharmaceutical Co., Ltd.

**Year of Foundation**

1925

**Year of Establishment**

1943

**Address**

1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku, Tokyo 103-8324, Japan

**Stated Capital**

¥72,966,826,000

**Number of Employees**

6,485 (Consolidated)

**Number of Shares Issued of  
Common Stock**

559,685,889

**Number of Shareholders**

55,513

**Stock Listing**

Tokyo Stock Exchange, First Section

**Fiscal Year-End**

December 31

**General Meeting of Shareholders**

March

**Transfer Agent**

Mitsubishi UFJ Trust and Banking Corporation

**Public Notices**

Public notices are to be made electronically on the Chugai website (<http://www.chugai-pharm.co.jp/ir>). In case electronic communications are unavailable, public notices will be made in the newspaper *Nihon Keizai Shimbun*.

**For further information, please contact:****Investor Relations**

Tel: +81-(0) 3-3273-0554

Fax: +81-(0) 3-3281-6607

E-mail: [ir@chugai-pharm.co.jp](mailto:ir@chugai-pharm.co.jp)

Chugai Pharmaceutical Co., Ltd. provides information on its website:

URL: <http://www.chugai-pharm.co.jp/english>

# Shareholder Information (As of December 31, 2009)

## Major Shareholders\*

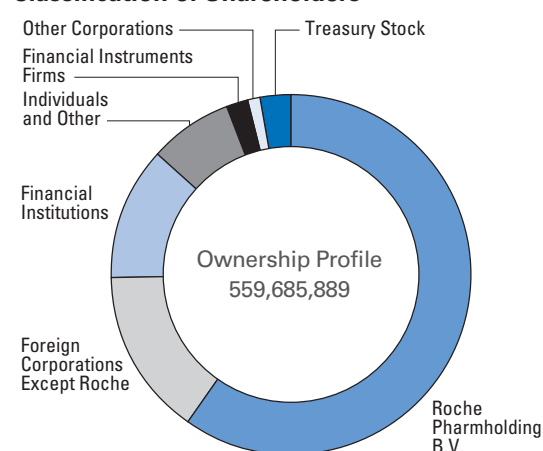
Name	Number of Shares Held (Thousands)	Percentage of Voting Rights (%)
Roche Pharmholding B.V.	335,223	61.62
The Master Trust Bank of Japan, Ltd. (trust account)	13,544	2.49
Japan Trustee Services Bank, Ltd. (trust account)	13,327	2.45
The Chase Manhattan Bank, N.A. London Secs Lending Omnibus Account	5,955	1.09
Tokio Marine & Nichido Fire Insurance Co., Ltd.	5,150	0.94
Mellon Bank, N.A. as Agent for its Client Mellon Omnibus US Pension	3,973	0.73
JP Morgan Securities Japan Co., Ltd.	3,122	0.57
Trust & Custody Services Bank, Ltd. (Securities Investment Trust Account)	3,037	0.55
Sumitomo Life Insurance Company	3,000	0.55
Chugai Pharmaceutical Employee Shareholders' Association	2,836	0.52

\* 15,497,079 shares of treasury stock held by the Company are not included in the above breakdown of major shareholders.

## Stock Price Information

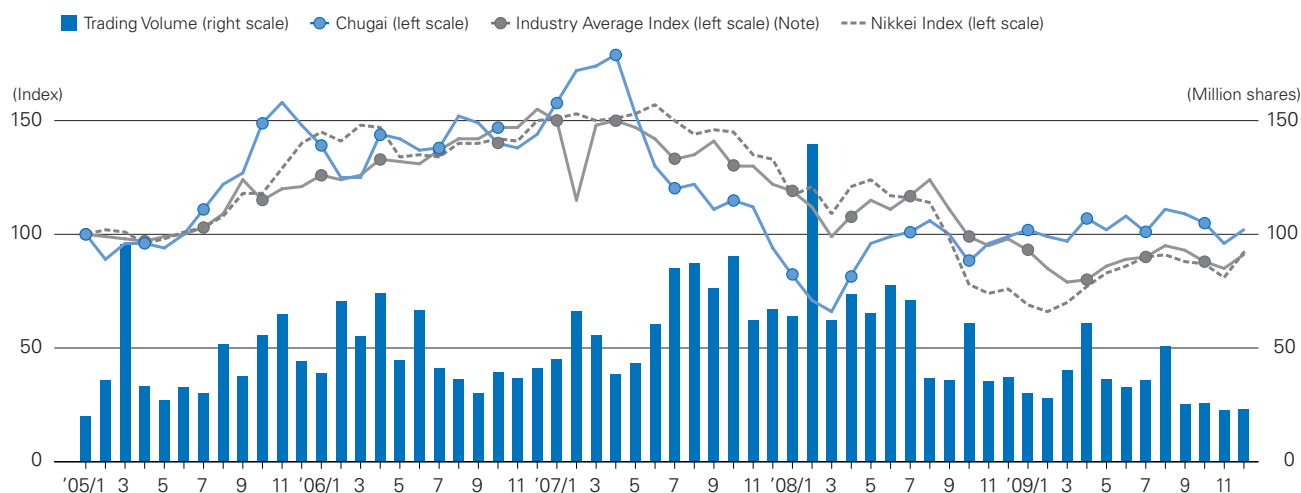
	Stock Price	
	High	Low
From January 1, 2009 to December 31, 2009		
First Quarter	¥1,764	¥1,410
Second Quarter	1,996	1,591
Third Quarter	1,942	1,716
Fourth Quarter	1,856	1,612

## Classification of Shareholders



<b>Roche Pharmholding B.V.</b>	Shares: 335,223,645	59.90% (Shareholders: 1)
<b>Foreign Corporations except Roche</b>	Shares: 83,381,987	14.90% (Shareholders: 461)
<b>Financial Institutions</b>	Shares: 67,433,327	12.05% (Shareholders: 75)
<b>Individuals and Other</b>	Shares: 42,507,295	7.59% (Shareholders: 54,570)
<b>Financial Instruments Firms</b>	Shares: 9,421,324	1.68% (Shareholders: 76)
<b>Other Corporations</b>	Shares: 6,221,232	1.11% (Shareholders: 329)
<b>Treasury Stock</b>	Shares: 15,497,079	2.77% (Shareholders: 1)

## Share Performance of Chugai



Note:

Share price on January 4, 2005 (¥1,710) = 100

Industry average index is calculated as below (because of mergers and delistings):

From Oct. 2007: A total of eight companies (Takeda, Daiichi-Sankyo, Astellas, Shionogi, Eisai, Mitsubishi-Tanabe, Dainippon-Sumitomo, Chugai)

From Oct. 2005: A total of eight companies (Takeda, Daiichi-Sankyo, Astellas, Shionogi, Eisai, Tanabe, Dainippon-Sumitomo, Chugai)

Sep. 2005: A total of seven companies (Takeda, Astellas, Shionogi, Eisai, Tanabe, Dainippon, Chugai)

Mar. to Aug. 2005: A total of nine companies (Takeda, Sankyo, Astellas, Shionogi, Eisai, Daiichi, Tanabe, Dainippon, Chugai)

Mar. 2005: A total of ten companies (Takeda, Sankyo, Yamanouchi, Shionogi, Eisai, Daiichi, Fujisawa, Tanabe, Dainippon, Chugai)



CHUGAI

**CHUGAI PHARMACEUTICAL CO., LTD.**



A member of the Roche group

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Tokyo 103-8324, Japan

Printed in Japan