



Roche Roche Group

# Turning Vision into Value

Annual Report

**2010**

Fiscal year ended  
December 31, 2010

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 Chugai Pharmaceutical Co., Ltd. ("Chugai" or "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 the property of their respective holders.



# Turning Vision into Value

Chugai's mission 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. Our research and development organization, which excels in developing antibody drugs, and our access to a global infrastructure through our strategic alliance with Roche support our continuing efforts to become a top Japanese pharmaceutical company.

Our steadfast vision is to continually develop innovative medicines that address unmet medical needs in our strategic fields, primarily oncology. By accelerating the advancement of future growth drivers, we are working to realize this vision and create value for patients and all our stakeholders.



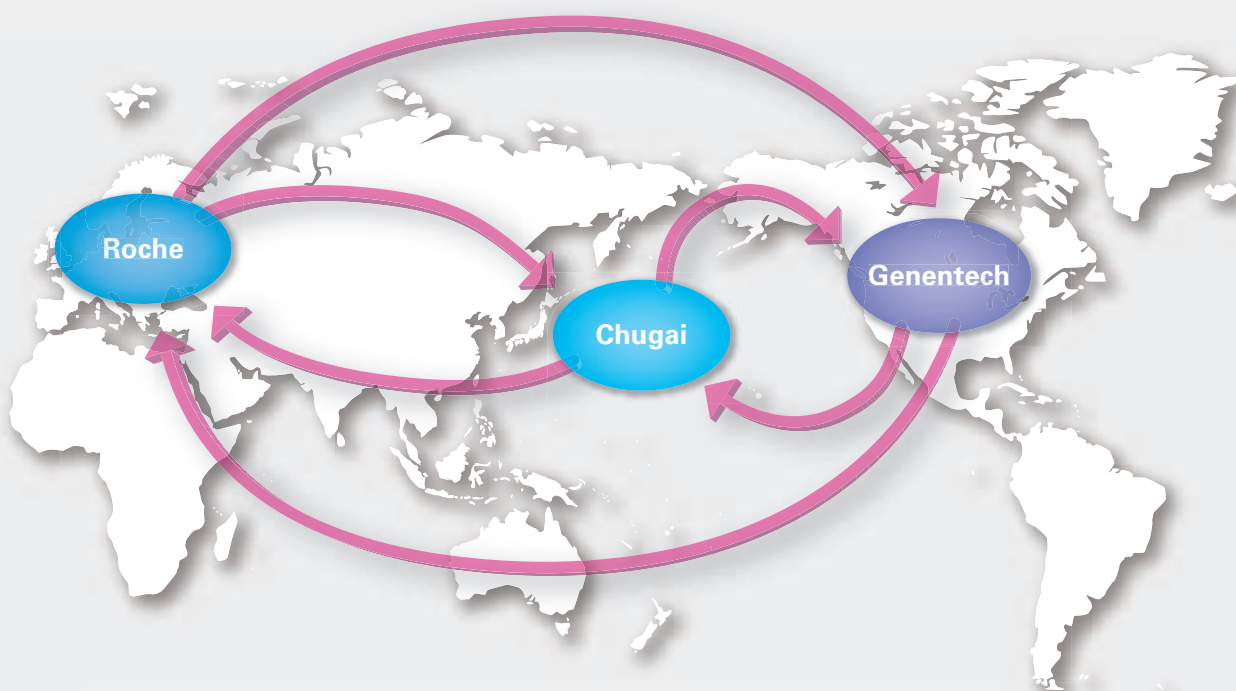
# Chugai Snapshot

# 1

## Our Network

We have used the network of the Roche Group to establish **strong global competitiveness.**

### Use of the Roche Group Network



Chugai's strategic alliance with Roche has significantly boosted its competitiveness in terms of research, development and marketing. In research and development, we are taking advantage of the Roche Group's global R&D infrastructure in ways such as participating in global clinical studies with Roche and partnering with Genentech, Inc. of the US, a member of the Roche Group as a wholly owned subsidiary. In addition, compounds licensed from the Roche Group have enhanced our pipeline, and in recent years we have licensed a growing number of compounds out to Roche, making this a WIN-WIN relationship. In marketing, access to the Roche Group's global marketing network has raised the international competitiveness of Chugai products.

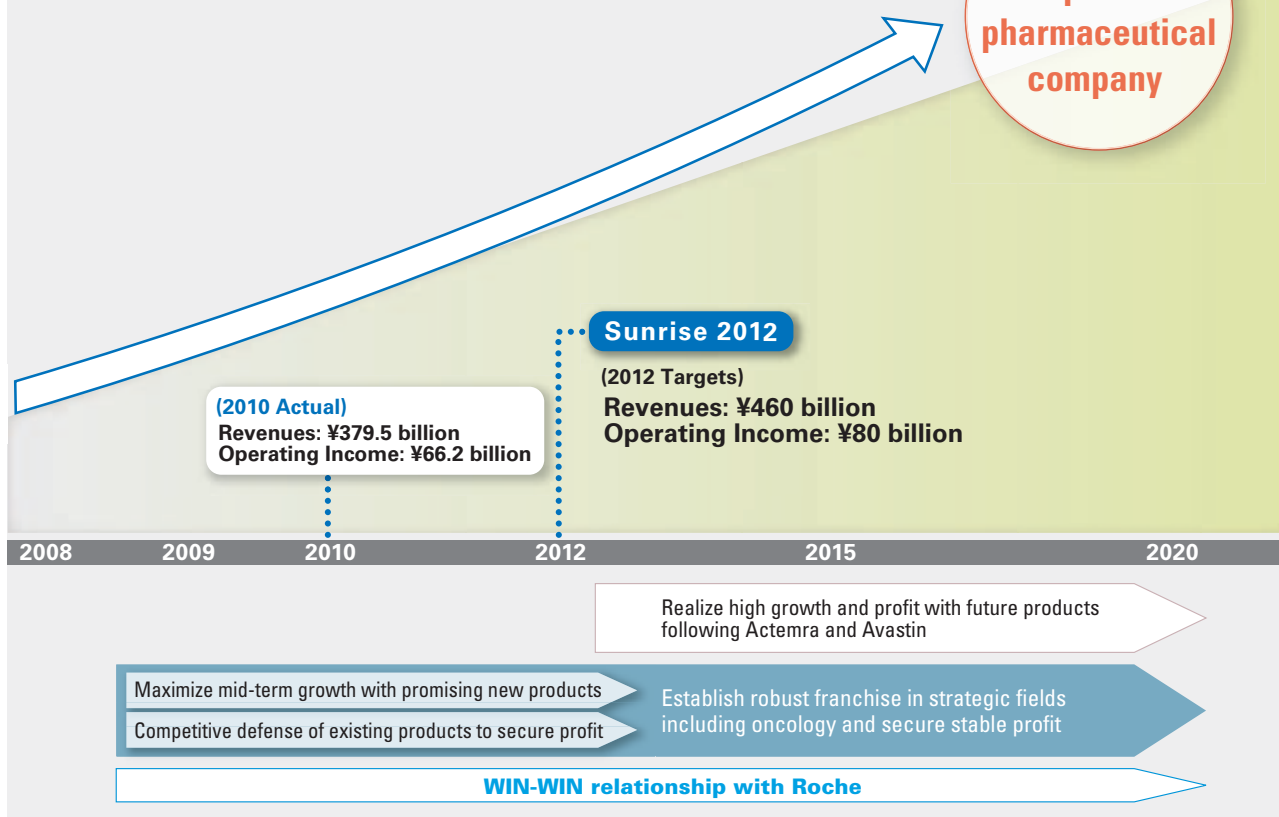
# 2

## Our Strategy

Our goal is to become  
a top Japanese  
pharmaceutical company  
by creating innovative new drugs.

Medium-to-Long-Term Growth Strategy  
Based on Innovative Drugs

A top  
Japanese  
pharmaceutical  
company



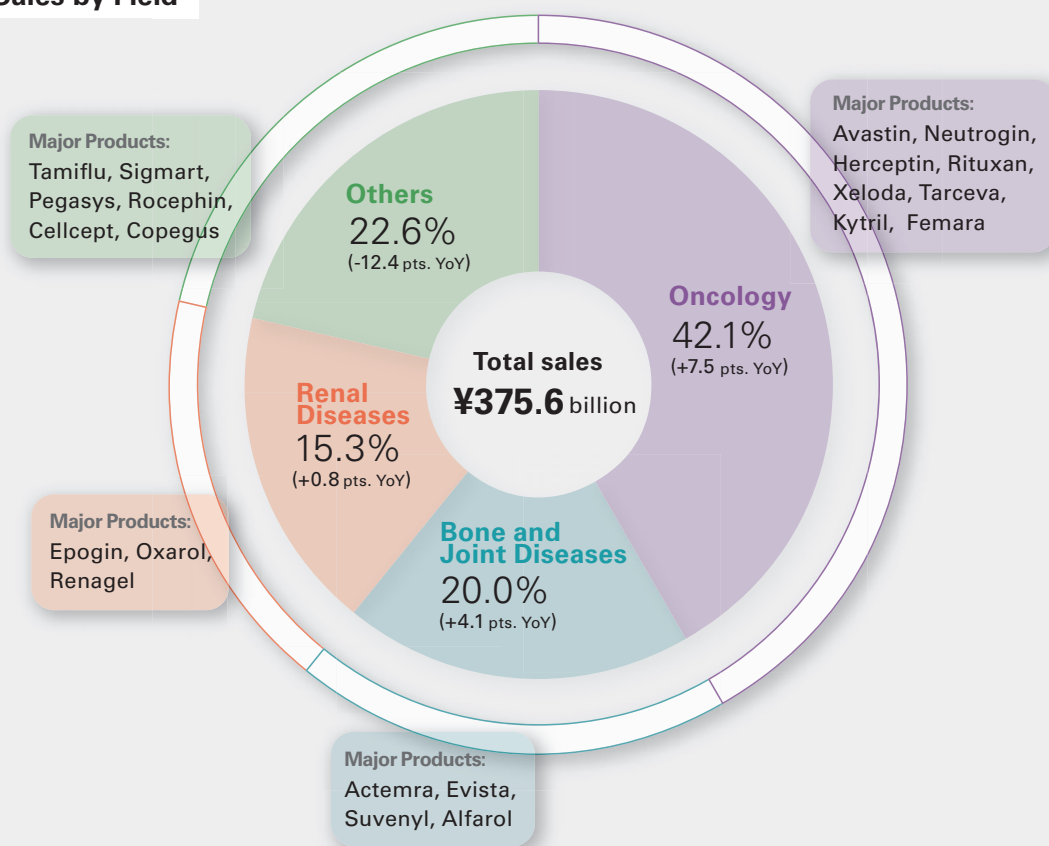
The objectives of Sunrise 2012, our mid-term business plan, are to establish Chugai as a leading presence in Japan, achieve the highest growth rate among domestic pharmaceutical companies and strengthen Chugai's WIN-WIN relationship with Roche. The plan also includes the quantitative targets of ¥460 billion in consolidated revenues and ¥80 billion in consolidated operating income in 2012. Our goal is to become a top Japanese pharmaceutical company by developing a steady flow of innovative drugs to meet the expectations of patients and all other stakeholders.

# 3

## Our Business Fields

We are prioritizing expansion in **strategic fields** with significant unmet medical needs.

2010 Sales by Field



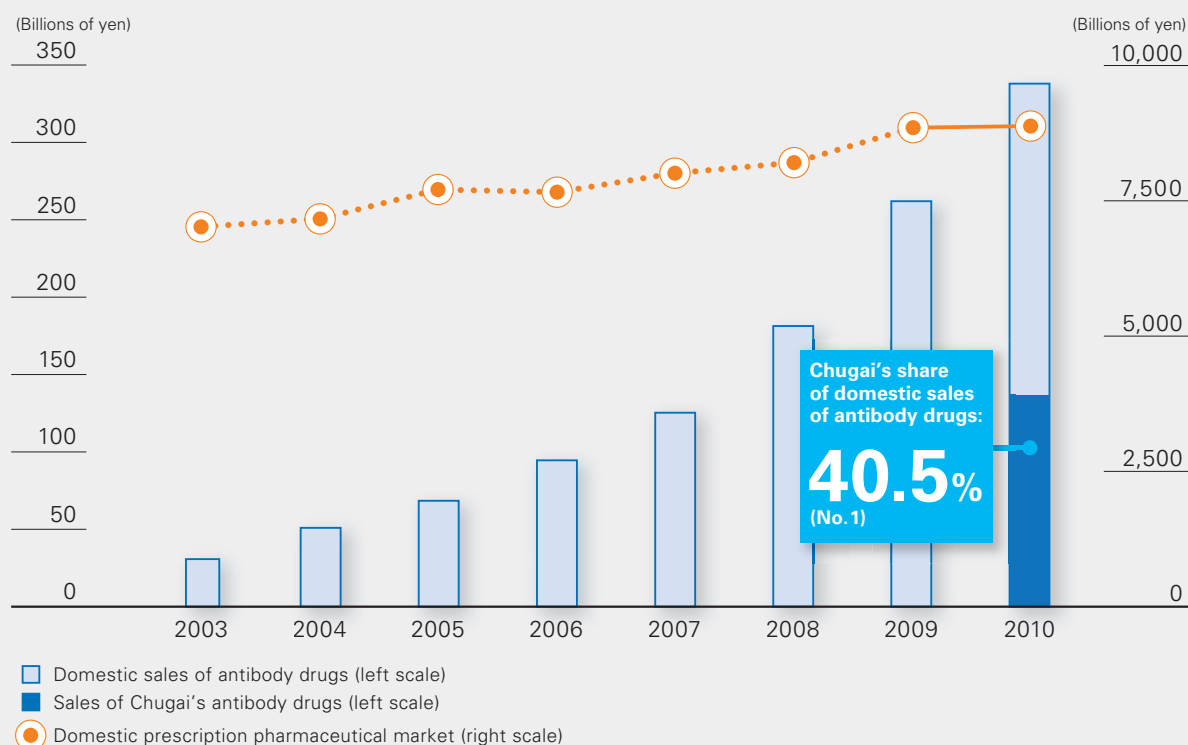
Chugai has defined oncology, bone and joint diseases, renal diseases, and others (diabetes and central nervous system diseases) as its strategic fields. In the field of oncology, where we hold the top market share in Japan, we have a portfolio of major products including Avastin, as well as the country's most robust development pipeline. The field of bone and joint diseases accounts for an increasing share of our total revenues owing to the rapid growth of Actemra. We will remain committed to delivering products that address unmet medical needs.

## 4

## Our Market Position

Chugai ranks **first in Japan** in the growing market for antibody drugs.

### Growth of the Domestic Prescription Pharmaceutical Market and Antibody Drug Sales



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The market for antibody drugs, a Chugai strength, has expanded rapidly amid a flat market for prescription pharmaceuticals in recent years and has excellent growth potential. One of Chugai's competitive advantages is its leadership in this market in Japan, with a share of 40.5 percent. We are currently developing a next-generation product to follow Actemra, the first antibody drug manufactured in Japan, in our drive to secure the dominant position in this market.

# 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* (Except as otherwise specified)
	2010	2009	2008	2010/2009	2010
<b>Results for the year:</b>					
Revenues .....	¥379,510	¥428,947	¥326,938	(11.5)%	\$4,628,171
Operating income .....	66,238	82,613	51,563	(19.8)	807,780
Income before income taxes and minority interests.....	65,686	89,416	63,106	(26.5)	801,049
Net income .....	41,433	56,634	39,265	(26.8)	505,280
Research and development expenses.....	54,703	55,315	53,225	(1.1)	667,110
<b>Sales:</b> .....	¥375,560	¥419,106	¥321,836	(10.4)%	\$4,580,000
Sales (Excluding Tamiflu) .....	357,408	342,899	313,440	4.2	4,358,634
Oncology .....	158,159	145,011	128,226	9.1	1,928,768
Bone and Joint Diseases .....	75,307	66,468	53,872	13.3	918,378
Renal Diseases .....	57,373	60,958	61,330	(5.9)	699,671
Others (Including Tamiflu) .....	84,721	146,670	78,408	(42.2)	1,033,183
<b>Financial position at year-end:</b>					
Total assets .....	¥508,016	¥540,549	¥478,518	(6.0)%	\$6,195,317
Interest-bearing debt .....	150	154	305	(2.3)	1,829
Total net assets .....	449,395	434,687	397,067	3.4	5,480,427
<b>Cash flows:</b>					
Net cash provided by operating activities .....	¥ 15,572	¥ 66,461	¥ 39,277	—	\$ 189,902
Net cash used in investing activities .....	(20,192)	(20,261)	(14,122)	—	(246,244)
Net cash used in financing activities .....	(23,055)	(22,252)	(18,361)	—	(281,159)
Cash and cash equivalents at end of year .....	65,144	94,478	70,652	—	794,439
<b>Amounts per share (Yen and U.S. dollars):</b>					
Net income - basic .....	¥ 76.14	¥ 104.00	¥ 72.07	(26.8)%	\$ 0.93
Net income - diluted .....	76.12	103.98	72.04	(26.8)	0.93
Net assets .....	821.87	794.51	725.18	3.4	10.02
Cash dividends <sup>2</sup> .....	40.00	40.00	34.00	—	0.49
<b>Number of shares outstanding</b> .....	559,685,889	559,685,889	559,685,889		
<b>Number of employees</b> .....	6,709	6,485	6,383		
<b>Ratios:</b>					
Operating income to revenues (%) .....	17.5	19.3	15.8		
Return on equity (%) <sup>3</sup> .....	9.4	13.7	10.1		
Shareholders' equity to total assets (%) .....	88.0	80.0	82.6		
Debt-to-equity ratio (%) <sup>4</sup> .....	0.0	0.0	0.1		
Interest coverage ratio (Times) <sup>5</sup> .....	8,214.4	4,620.0	517.5		
Research and development expenses to revenues (%) .....	14.4	12.9	16.3		
Payout ratio (%) .....	52.5	38.5	47.2		

Notes: 1. The U.S. dollar amounts in the consolidated financial statements as of and for the year ended December 31, 2010 have been translated from Japanese yen amounts at the rate of ¥82 to U.S. \$1.00, the exchange rate prevailing on December 31, 2010.

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

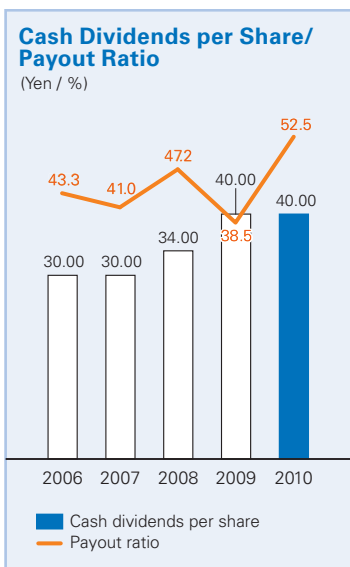
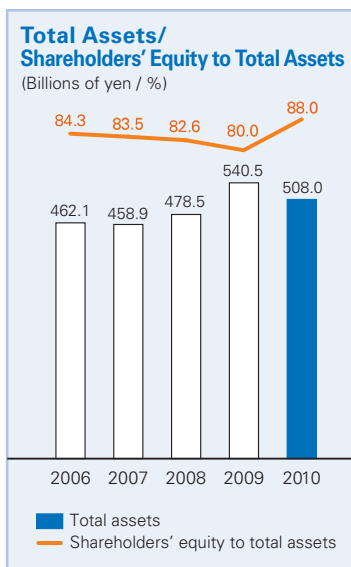
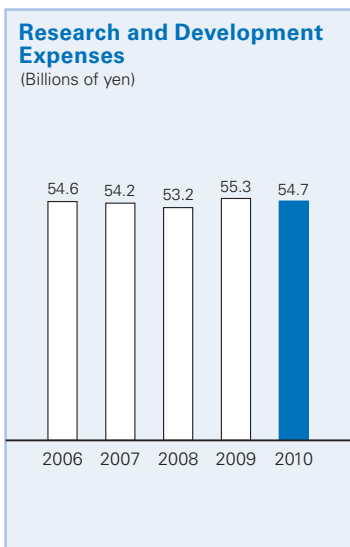
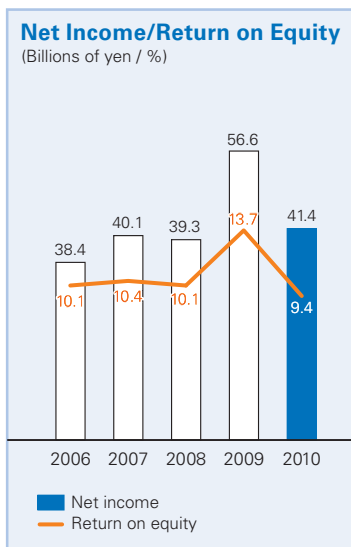
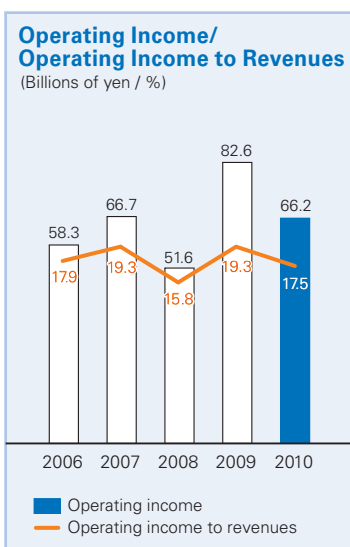
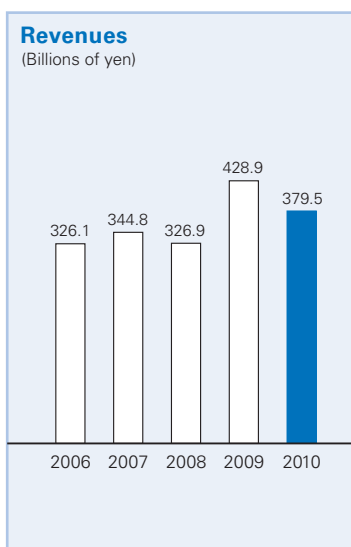
3. Return on equity = Net income/Shareholders' equity (average of beginning and end of fiscal year) x 100

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

For more detailed information, see "11-Year Financial Summary" on pages 72-73.





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

## 2010 in Brief

Revenues and profits were down in 2010 due to a sharp decline in sales of Tamiflu. However, sales excluding Tamiflu increased 4.2 percent, absorbing the impact of National Health Insurance (NHI) drug price revisions. We maintained the leading domestic market share\* for our mainstay oncology and antibody drugs, and advanced projects steadily through our robust development pipeline, the source of future growth.

Sales  
(Excluding Tamiflu) **+4.2%**

Return on equity **9.4%**

Payout ratio **52.5%**

Share of domestic  
antibody  
drug market\* **40.5%**

Share of domestic  
oncology  
market\* **18.4%**

Number of  
projects  
in pipeline **34**

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# Interview with the President

**Chugai steadily augmented its revenue base in 2010, with solid growth in its lineup of major products. From 2011, our strategic alliance with Roche enters a new stage, and we will maximize our strengths as a member of the Roche Group as we continue to work toward our goal of becoming a top Japanese pharmaceutical company.**



**Osamu Nagayama**

Representative Director  
President and CEO



**Q. Please review Chugai's performance in 2010, including the impact of the National Health Insurance (NHI) drug price revisions in Japan.**

**Continued growth in sales excluding Tamiflu offset the impact of NHI drug price revisions.**

In 2010, revenues decreased 11.5 percent compared with the previous year to ¥379.5 billion and operating income fell 19.9 percent to ¥66.2 billion due to a sharp decline in Tamiflu sales as the swine flu pandemic subsided. Excluding Tamiflu sales, which vary widely year to year, sales rose 4.2 percent to a record ¥357.4 billion. Operating income excluding Tamiflu also increased. This performance reflects the

strong expansion of our growth drivers, led by Avastin and Actemra, which offset the impact of NHI drug price revisions for Herceptin, Epogin and other products. Recently launched products and existing products with new indications are making inroads into the market and steadily contributing to overall growth. By therapeutic field, sales of products for oncology and bone and joint diseases were particularly strong. In the oncology field, sales grew at a double-digit pace for the second consecutive year, and our market share in Japan rose by 1.1 percentage points from 2009, to 18.4 percent.<sup>1</sup>

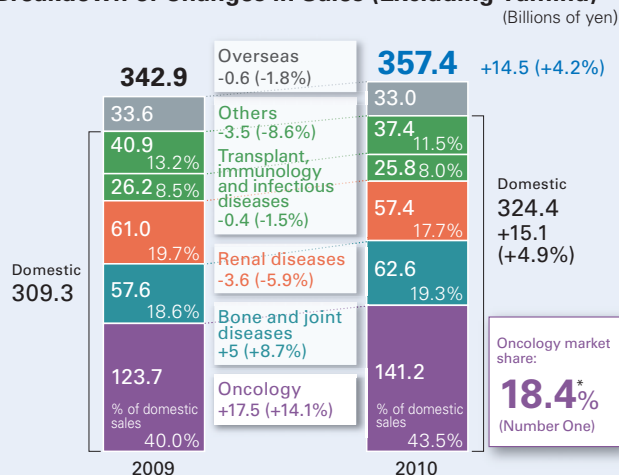
Net income decreased 26.9 percent to ¥41.4 billion due to an increase in loss on foreign exchange.

1. Copyright 2011 IMS Japan K.K. Source: JPM 2009-2010.  
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## 2010 Results

	2009	2010	YoY
(Billions of yen)			
Revenues	428.9	379.5	-11.5%
Sales (Excluding Tamiflu)	342.9	357.4	+4.2%
Gross profit	236.1	217.1	-8.0%
% of revenues	55.0%	57.2%	
Operating income	82.6	66.2	-19.9%
% of revenues	19.3%	17.5%	
Net income	56.6	41.4	-26.9%
% of revenues	13.2%	10.9%	
Tamiflu sales	76.2	18.2	-76.1%
Ordinary sales	36.2	1.6	-95.6%
Govt. stockpile, etc.	40.0	16.6	-58.5%

## Breakdown of Changes in Sales (Excluding Tamiflu)



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## Q. What progress has Chugai made in strengthening its research and development, the source of future growth?

**We made impressive progress in the past year, filing for regulatory approval of four projects as well as accelerating in-house development and establishing a breakthrough antibody technology.**

Chugai's research and development had a highly productive year in 2010. We started the year by obtaining FDA approval of Actemra for rheumatoid arthritis (RA) in January, followed by approval of Epogin in Japan for the additional indication of autologous blood transfusion in June. In addition, our pipeline has continued to grow, with numerous projects advancing to the next stage of development. We filed for approval of four projects,<sup>2</sup> and three others<sup>3</sup> demonstrated proof of concept.<sup>4</sup> Three additional novel compounds<sup>5</sup> started clinical trials. In our pipeline, we have significantly accelerated development of compounds from our own research. All three projects that started clinical trials in 2010 originated in-house. In the field of oncology, seven Chugai-discovered compounds have started clinical trials in the last several years. This is the fruition of our efforts

to date to strengthen our research organization.

We also made a notable technological breakthrough. In October 2010, we announced an innovative antibody engineering technology that enables a single antibody molecule to bind to a target antigen multiple times. By applying this technology to Actemra, preclinical studies demonstrated more than a four-fold increase in the duration of IL-6 receptor blockade. We expect this technology not only to substantially broaden the possibilities for our own antibody drug discovery, but also to contribute to the pharmaceutical industry worldwide.

2. Xeloda, Herceptin (gastric cancer) and combination therapy of Pegasys and Copegus (compensated type C liver cirrhosis)
3. T-DMI (RG3502) (breast cancer), GA101 (RG7159) (non-Hodgkin's lymphoma), and tofogliflozin (CSG452) (type 2 diabetes: in-house)
4. Proof that the drug is effective in humans as conceived in the research stage. Generally after the end of phase II clinical trials.
5. AF802 (non-small cell lung cancer: in-house), PA799 (solid tumors: in-house) and SA237 (rheumatoid arthritis: in-house)

**Q. What are your thoughts on Chugai's position in a pharmaceutical industry that faces major changes in market conditions?**

**We are the industry leader in Japan in antibody drugs and oncology and we have a solid foundation in fields with unmet medical needs, which give us a powerful competitive advantage.**

Along with growth in generic drugs and expansion of newly industrialized markets, two trends in particular are gaining momentum in today's pharmaceutical industry: the focus on addressing unmet medical needs and the shift to biopharmaceuticals. Even major pharmaceutical companies are transforming their structures through mergers, acquisitions and other approaches to concentrate their resources on these areas and continuously generate new drugs. It is estimated that the size of the biopharmaceuticals market, which was roughly US\$100 billion in 2009, will grow to US\$160 billion<sup>6</sup> in 2016. These trends will be favorable for Chugai, which has continued to focus on creating innovative drugs primarily in fields with unmet medical needs.

In Japan, Chugai has a 40.5 percent share<sup>1</sup> of the market for antibody drugs and an 18.4 percent share<sup>1</sup> of the oncology market. As the leader in both of these markets, we have a substantial competitive advantage. We have led biopharmaceutical research and development in Japan since the 1980s, and have

built Actemra, the first antibody drug originating in Japan, into a global product. Our research and development organization for antibody drugs is unquestionably in the top tier of the industry. The knowledge, technologies and other strengths we have accumulated are resources that will support growth now and in the future. The key as we go forward will be continuous innovation to further entrench our current advantage.

6. Source: EvaluatePharma

**Q. How is Chugai working to achieve its goal of becoming a top Japanese pharmaceutical company under Sunrise 2012, its mid-term business plan?**

**We seek to become a top Japanese pharmaceutical company by meeting the expectations of our stakeholders as well as our quantitative targets.**

Our goal for the second half of this decade is to become a top Japanese pharmaceutical company, continuously supplying innovative new drugs to the world by responding effectively to the various changes in our operating environment and maximizing our strengths and value as a company. A top pharmaceutical company is one in which all employees share an awareness and sense of responsibility as part of a leading enterprise, and work proactively with a global perspective. It fully satisfies its stakeholders and in turn is rewarded with their active support and trust.

**Definition of "A Top Japanese Pharmaceutical Company" (Chugai's Goal for the Second Half of This Decade)**

**Quantitative Aspects**

**1. One of the Top Three Pharmaceutical Companies in Japan in Each of the Following Categories**

- ◆ Domestic market share
- ◆ Consolidated operating margin
- ◆ Consolidated operating income per employee
- ◆ Domestic revenues per medical representative

**2. Top Domestic Market Share in Each of Our Strategic Fields**

**3. Increase in Proportion of Sales from Overseas Business**

- ◆ RoActemra/Actemra
- ◆ New drugs following the above

**Qualitative Aspects**

**1. A Company That Satisfies All Its Stakeholders and Receives Their Active Support and Trust**

**2. Works Proactively on a Global Level**

- ◆ Continuous creation/development/domestic and overseas launches of products with a competitive advantage in clinical results
- ◆ Contribution to the Roche Group's results through product-appropriate fostering and sales
- ◆ Leadership in pharmaceutical industry activities
- ◆ Activities in which all employees have an awareness, sense of responsibility and pride as part of a top pharmaceutical company

In terms of quantitative targets, our objective is to be among the top three in Japan in four categories: domestic market share, operating margin, operating income per employee, and domestic revenues per medical representative. We will also aim for the top domestic market share in each of our strategic fields and focus on the proportion of sales from overseas business as a core indicator.

The key to achieving these objectives is to meet the ever-increasing expectations placed on our company by making ongoing patient-oriented innovations and working to contribute to the medical community. In oncology, for example, we are fulfilling our leadership role by promoting standards of care and helping to make optimal cancer treatments uniformly available to patients throughout Japan. In addition to holding lectures and other activities to inform healthcare professionals and promote a multidisciplinary approach to cancer care, we also furnish information about cancer on a website for patients and their families.

In moving toward our goal of becoming a top Japanese pharmaceutical company, two milestones we are targeting under our mid-term business plan Sunrise 2012 are consolidated revenues of ¥460 billion and consolidated operating income of ¥80 billion in 2012. To reach these milestones, we will place priority on rapidly building the market presence of Ediol and Mircera (RG744), which we plan to launch in 2011; maximizing the value of our major oncology products; and expanding the market share of Actemra in Japan while building it into a major product overseas. We see significant potential for further market penetration of our oncology products, especially Actemra, from which we expect continued growth. To secure the necessary resources for this expansion, we plan to make efficiency improvements throughout the Company to raise productivity and reduce costs.

## Q. Please discuss Chugai's strategy and outlook for 2011.

**We plan to increase revenues and profits by expanding sales of our growth drivers Actemra and Avastin.**

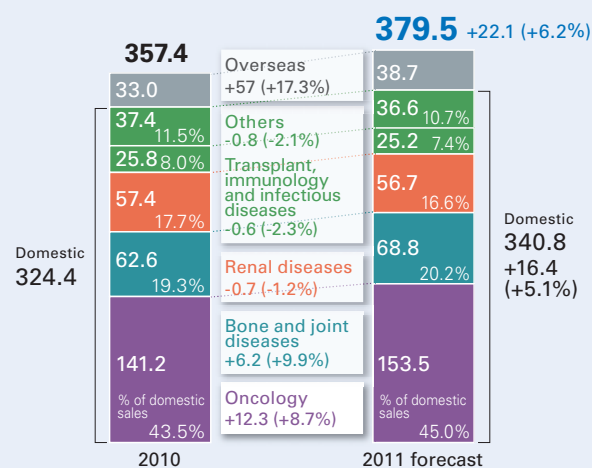
Achieving our targets for 2011 will be critical to successfully reaching the targets of Sunrise 2012.

In 2011, we expect total revenues of ¥403.0 billion (up 6.2 percent from 2010), with sales excluding Tamiflu totaling ¥379.5 billion (up 6.2 percent).

We will step up our initiatives as the leader in the domestic oncology market and generate strong revenue growth by establishing Avastin, Herceptin and Xeloda as standards of care. In the field of bone and joint diseases, we are aiming for double-digit sales growth by promoting the rapid market penetration of Ediol, which obtained approval in January 2011, and further expanding sales of Actemra. In Japan, the requirement for all-patient registration surveillance for Actemra was lifted last year, which should help to accelerate its market penetration in 2011. We will focus on providing information backed by the extensive data obtained from that surveillance to establish Actemra as a first-line biologic. Overseas, we will concentrate on building Actemra into a global blockbuster drug, particularly in the key US and

### 2011 Sales Forecast (Excluding Tamiflu)

(Billions of yen)







European markets. In the field of renal diseases, our priority will be reinforcing our market presence amid intensifying competition by promoting the rapid growth of Mircera (RG744) after its planned launch in 2011. In other fields, we plan to use the positive clinical data for Pegasys/Copegus therapy

for hepatitis C to expand the market share of these medicines.

Operating expenses are expected to rise as we build the market presence of new drugs and existing drugs with new indications. Research and development (R&D) expenses will also increase with the advancement of our development projects. Incorporating these factors, we project that operating income for 2011 will rise 13.3 percent to ¥75.0 billion and net income will increase 2.7 percent to ¥42.5 billion.

**Q. What are your thoughts on shareholder returns? Please explain Chugai's dividend policy.**

**Our fundamental policy is to deliver stable dividends to shareholders, with an average consolidated payout ratio over 40 percent.**

Chugai's fundamental policy is to ensure stable dividends for shareholders. Our goal is to maintain a payout ratio over 40 percent of consolidated net income on average, taking into account strategic funding needs and earnings.

Based on this policy, we kept total cash dividends for 2010 unchanged from the previous year at ¥40 per share, including the interim dividend of ¥17 per share, for a consolidated payout ratio of 52.5 percent. For 2011, we plan to pay total cash dividends of ¥40 per share, including an interim dividend of ¥20 per share, for a projected payout ratio of 51.2 percent.

**Q. Do you have any closing message for stakeholders?**

**We welcome your interest and support as we continue our drive to become a top Japanese pharmaceutical company.**

Chugai has made significant progress since it entered its strategic alliance with Roche in 2002. In addition to increasing revenues and profits, we have taken actions to enhance our business operations, including restructuring our manufacturing facilities, upgrading product lifecycle management and strengthening our research and development organization. Launching and expanding the market presence of products licensed from Roche has significantly enriched our product portfolio and pipeline. Our human resources have also grown in tandem with these accomplishments.

We view the period through 2010, in which we have achieved these successes, as the first stage of the strategic alliance. This year marks the beginning of a new stage in which we will fulfill our major role of contributing to the Roche Group with products from our own research and leveraging our advantages as part of the world's largest biotech group to continue providing innovative drugs. For example, working in partnership with the Roche Group, a world leader in diagnostics, we can promote the parallel development of companion diagnostics for targeted molecular therapies. This will help to realize the potential of personalized healthcare, an emerging trend in cancer treatment (see page 29 for details on personalized healthcare).

We continue to move steadily toward becoming a top Japanese pharmaceutical company. That will not be an easy task by any means, but with the spirit of innovation and challenge we have fostered at Chugai, I am confident that we will reach our goal.

I want to thank all our stakeholders, including shareholders and investors.



## The Advantages and Further Acceleration of In-House Development

# Turning Vision into Value

Chugai is promoting initiatives that have led to notable progress of its products developed in-house as it aims to become a top Japanese pharmaceutical company. This section examines Chugai's original research organization and its competitive advantages against the backdrop of its accelerating in-house development with a look at Actemra, which is growing as a global drug.

<b>I. Chugai's Research Capabilities and Development Platform</b>	<b>14</b>
<b>II. Accelerating In-House Development: The Success of Actemra</b>	<b>17</b>

# I. Chugai's Research Capabilities and Development Platform

Through original discovery research geared to unmet medical needs, many compounds discovered by Chugai have started clinical development in recent years. We will make full use of our research capabilities, enhanced by our strategic alliance with Roche, to continue to create innovative products.

## Acceleration of Products from Chugai Research

Compounds originating from Chugai's own research have shown remarkable progress in its development pipeline over the past few years. We currently have seven oncology projects in development, comprising five molecular targeted therapies – GC33, CKI27, CIF, AF802 and PA799 – plus TP300 and WT4869 (co-developed with Daiippon Sumitomo Pharma Co., Ltd.). Of these projects, AF802 and PA799 started clinical trials from 2010. In the field of bone and joint diseases, SA237 for the indication of rheumatoid arthritis (RA) started phase I clinical trials in Japan in December 2010. In other therapeutic fields, CSG452 for the treatment of type 2 diabetes is currently in phase III clinical trials in Japan. All of these compounds have started clinical development since

2006. As of February 2011, compounds from Chugai research make up about 40 percent of our pipeline.

Actemra symbolizes the recent results of our research. Since its launch in April 2008 for the additional indication of RA, it has brought about a groundbreaking advance in treatment of the disease.

Two important factors underlie these advances in Chugai-originated drugs. First, we have been committed to developing original compounds. Second, our strategic alliance with Roche has entered a new stage. Immediately after forming the alliance in 2002, we prioritized development of Roche products that had not yet obtained approval in Japan, such as Avastin, Tarceva and Xeloda, to quickly resolve the drug lag issue. We have successively introduced these products in the Japanese

**Pre-PoC Projects\*** (As of February 2, 2011)

New Continued  
In-house  
Licensed

2006	TP300	2007	CSG452 (tofogliflozin)	2008	GC33	2009	MRA	2010	AF802
	RG1273 (pertuzumab)		NA808		CIF		GC33		PA799
			TP300		CKI27		CIF		SA237
			RG1583 (taspoglutide)		CSG452 (tofogliflozin)		NA808		MRA
			RG1678 (GLYT1)		TP300		TP300		GC33
			RG1273 (pertuzumab)		RG1579 (DPPIV)		RG3502 (T-DM1)		CIF
					GA101 (RG7159)		RG1450 (Abeta)		CKI27
					RG1507 (IGF-1R)		NTZ		TP300
					RG1583 (taspoglutide)		GA101 (RG7159)		RG1450 (Abeta)
					RG1678 (GLYT1)		RG1583 (taspoglutide)		RG1583 (taspoglutide)
					RG1273 (pertuzumab)				

\*PoC (Proof of Concept): Proof that a drug has the intended beneficial effect in humans.

market. At the same time, our research laboratories continuously worked on original discovery research aimed at creating drugs with first-in-class<sup>1</sup> or best-in-class<sup>2</sup> potential. These efforts are now coming to fruition.

1. An original drug that is highly novel and useful, has a chemical structure different from that of existing drugs and basic skeletons, and significantly changes the therapeutic system.
2. A drug that offers clear advantages over other existing drugs.

## Competitive Research Organization

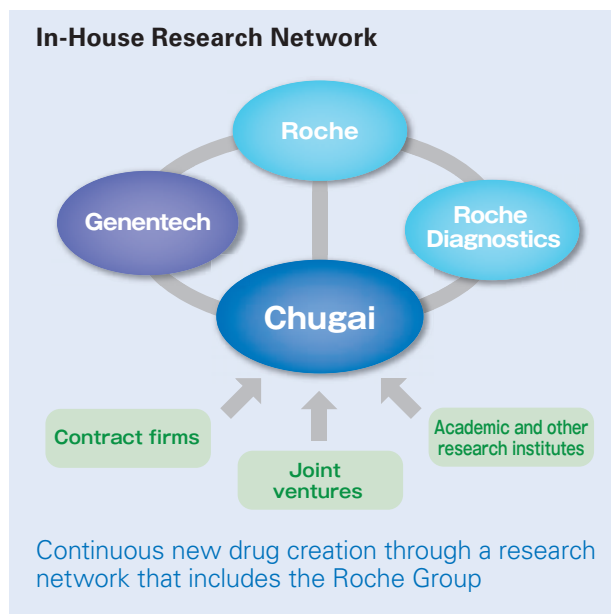
In recent years, Chugai's research activities have produced a range of results from a research organization with three defining characteristics.

The first is Chugai's integration with Nippon Roche, which combined the strengths of the two companies. Chugai has been a pioneer in biotechnology since the 1980s with the development of products such as Epogin and Neutrogin. Nippon Roche operated the Kamakura Research Laboratories where Xeloda, positioned as the global standard of care for chemotherapy, was discovered, and had focused on small-molecule compounds. The integration of these two companies as part of the strategic alliance with Roche broadened our options in discovery research. Both companies' strengths have played a role in the discovery of our nearly 20 projects in clinical development, primarily in the area of oncology. We outpaced our competitors in developing an advanced antibody technology that led to our creation of a next-generation antibody. We were also quick to recognize the importance of 3D analysis of target proteins, and set up the necessary infrastructure. As a result, we have now established the technologies to create high-quality drugs, including technology for identifying molecules that have high target specificity.

The second characteristic is our access to Roche's global research organization. Roche's world-class drug discovery platform, which includes bioinformatics<sup>3</sup> tools for genomic research, a compound library and compound evaluation database, and an assay robot that performs high throughput screening<sup>4</sup>, represents a significant advantage for Chugai in terms of cost and efficiency. While we enjoy the benefits of these assets of the Roche

Group, our discovery research is a distinctive feature that has secured our independence. The ability to use Roche's research infrastructure while freely pursuing our own original ideas has increased our research productivity.

Third is our longstanding culture of open innovation. The importance of open innovation in discovery research has been recognized in recent years, but collaboration with outside institutions has long been a pillar of Chugai's research strategy. We have an extensive record of alliances, joint research and other ties with universities and cutting-edge research institutions, and work with them to identify new research themes and to secure technologies. Many of our compounds have been developed for practical use together with outside researchers. Actemra, for example, is a product of collaboration with Osaka University, and we drew on





research at a joint venture and collaboration with Tokyo University and Miyazaki University to develop GC33, a compound now in phase I clinical trials. The free atmosphere and unique network fostered by open innovation are invaluable assets that Chugai has built up over many years.

3. Processing of data to gain understanding of biological processes by searching for information on specific gene functions from a vast database of gene mapping information.
4. A technology for selecting active chemical compounds for drug creation targets from a library consisting of a vast number of compound types using automated robots or other means.

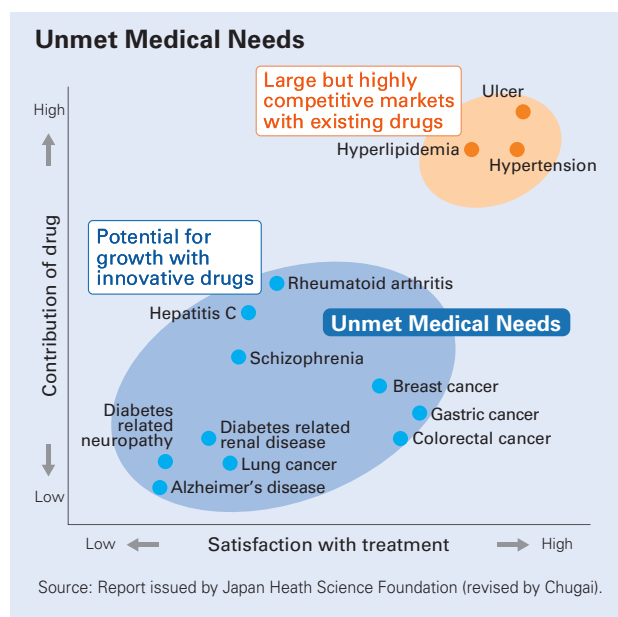
## Enhancement of Research Capabilities and Future In-House Development

Of the five strategic fields that Chugai targets – oncology, renal diseases, bone and joint diseases, diabetes, and infectious diseases – oncology is the most important. Cancer takes a variety of serious and life-threatening forms. Understanding cancer pathology and medical needs is therefore critical. Chugai's unique strength in incorporating extensive real-world information into research and development has led to the most robust oncology pipeline in Japan. In the area of bone and joint diseases, our many years of research into vitamin D culminated in obtaining approval of Edrol in January 2011 (see page 33 for details). In the field of renal diseases, the extensive

experience in the dialysis market we have developed with erythropoietin-stimulating agents is a key asset.

We believe that breakthrough pharmaceuticals are created when innovative solutions to meet underlying medical needs are matched with drug discovery technology that can turn those ideas into reality. Making the most of our research organization, coupled with our researchers' total dedication to developing first-in-class and best-in-class medicines, has resulted in the creation of compounds from Chugai research in recent years. After acquiring a technique for producing genetically engineered proteins with erythropoietin, we developed a technology for creating antibodies that bind to antigens with high specificity. This in turn led to the development of a next-generation antibody technology. In October 2010, Chugai announced its innovative antibody engineering technology that disproves the conventional wisdom about monoclonal antibodies by enabling a single antibody molecule to block the function of a target antigen multiple times (see page 42 for details). This breakthrough is just one result of this series of innovations.

Chugai's research capabilities will unquestionably drive its future growth. Creating first-in-class and best-in-class products from our own research requires outside-the-box thinking and a keen perception of various possibilities. Chugai is fostering creative researchers who will lead the research of tomorrow as we work to generate innovative, world-class drugs.





## II. Accelerating In-House Development: The Success of Actemra

Actemra, the first therapeutic antibody created in Japan and the result of joint research and development with Osaka University, epitomizes the success of Chugai research in recent years. Actemra lifecycle leaders from Chugai and Roche and the leader of the original team that developed the production process share their perspectives on the rise of Actemra to worldwide recognition as a treatment for rheumatoid arthritis (RA), initiatives to promote sales growth, and the medicine's future prospects.

### Advantages as a Product

Thanks to the consistently high remission rates<sup>1</sup> it delivers, Actemra is rapidly becoming a global success story, just three years since its initial launch in Japan.

**Yoshizawa:** Actemra is the only drug in the world that targets interleukin-6 (IL-6), a cytokine involved in regulating the immune response. We started marketing Actemra as a treatment for RA in April 2008. Total sales (Chugai's sales in Japan plus income from exports for sale overseas)<sup>2</sup> in the first year were ¥7.2 billion. They grew to ¥26.8 billion in 2010, making Actemra our fourth largest-selling product after Avastin, Epogin and Neutrogin.

**MacLean:** Thanks to market launches in Europe, North America and elsewhere over the past two years, Actemra is now available in some 50 countries around the world. The rollouts in Europe and North America will be complete in 2011, so we expect sales this year

to grow again significantly. Actemra is the first drug from Chugai research that has been developed for global sale, and it is rapidly becoming one of the Roche Group's key pharmaceutical products.

**Yoshizawa:** The primary reason for the rapid market penetration of Actemra is its clear-cut effect in inhibiting the progress of joint damage. To give you an idea of the high remission rates that Actemra delivers, the interim analysis of all-patient registration surveillance in Japan showed that 45.0 percent of 2,072 patients who had exhibited high disease activity were in remission after 28 weeks of treatment. Five-year follow-up data have already been published – just two-and-a-half years after launch. We can now present this data, including long-term safety information, to physicians. That gives us a huge advantage and has been a key factor behind the current level of market penetration.

**MacLean:** Thanks to the excellent follow-up data, the safety and efficacy of Actemra are also becoming widely known in Roche's global markets. The most important markets will be Europe's top five countries in terms of sales (Germany, the UK, France, Italy and Spain) and the United States, with the addition of China in the future.

**Akamatsu:** Setting up a system to ensure a stable supply globally is essential to meet growing worldwide



**Donald MacLean**  
Lifecycle Leader - Actemra  
F. Hoffmann-La Roche Ltd.

**Katsunori Yoshizawa**  
Lifecycle Leader - Actemra  
Lifecycle Management Dept. 2

**Ken-ichi Akamatsu**  
Department Manager in Charge of  
Biotechnology  
API Process Development Dept.,  
Pharmaceutical Technology Division

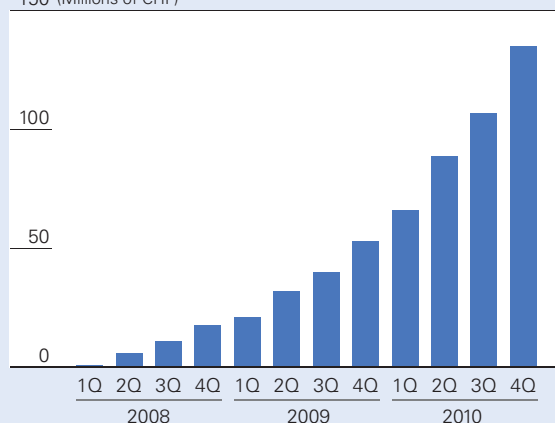
demand. There's also a risk in relying entirely on our Utsunomiya plant for all production. Because of that, we are now transferring technology to Genentech, which will manufacture Actemra bulk drug substance under a toll manufacturing agreement.

**Yoshizawa:** Changes in RA treatment practices are also working in favor of Actemra. Previously, doctors generally took a wait-and-see approach, using biologics only in patients who did not respond to treatment with nonsteroidal anti-inflammatories and disease-modifying antirheumatic drugs. But recent research has shown that joint damage begins soon after the onset of disease, so treatment goals are shifting to early treatment and early remission. Clinical trials have shown that Actemra is effective in inhibiting the progression of joint damage, and we intend to position it as a drug that fits the new treatment goals. One quality that makes Actemra very valuable is its sustained efficacy, which sets it apart from biologics that lose their effectiveness with continued treatment.

1. The proportion of patients who experience suppression of disease signs and symptoms.
2. Includes sales for the indications Castleman's disease, systemic-onset juvenile idiopathic arthritis (sJIA) and polyarticular-course juvenile idiopathic arthritis (pJIA). Does not include other operating revenues from milestone income.

#### Total Roche Group Sales of Actemra

150 (Millions of CHF)



Note: Exchange rates for Swiss francs (CHF) as of December 31, 2010 are provided for the reader's convenience.  
CHF1 = ¥87 = U.S. \$1.07

## Behind the Scenes: Discovery and Development

*The discovery of Actemra was made possible because Chugai researchers tackled and overcame unprecedented challenges.*

**Yoshizawa:** Our research for a groundbreaking RA treatment started around 1984, a time when no one thought that antibodies could be medicines. In 1986, researchers at Osaka University successfully cloned IL-6. Chugai researchers started collaborating with their Osaka University colleagues because they saw in IL-6 the seed of an innovative therapy.

**MacLean:** Aside from those involved in the research, no one at that time even imagined that blocking IL-6 could be effective against RA, did they? It's impressive that they saw that potential.

**Yoshizawa:** Development was achieved through one of the largest clinical trial programs ever conducted in Japan, involving 601 patients in Japan and 4,009 patients overseas. Of particular note is that in all the trials, the treatment was administered continuously right up until approval was obtained. This had significant ethical implications, because normally patients go back to their previous treatment once a trial is over. But in the case of Actemra, patients who had responded to the



medicine continued to receive it even after the trial ended. This contributed greatly to the treatment of these patients and also enabled us to accumulate long-term follow-up data quickly.

**Akamatsu:** While development went smoothly, in manufacturing we had to overcome the obstacles of securing production volume and improving production efficiency in order to deliver this breakthrough drug to patients. An antibody has a high molecular weight, and about 1,000 times the volume of conventional pharmaceuticals is required to achieve the equivalent efficacy. Coupled with projected market trends and demand forecasts for the drug, it was obvious that the output from two 2,500-liter cell culture tanks at our Ukima plant would not be adequate. So we undertook a major expansion of production capacity, building eight new 10,000-liter cell culture tanks at the Utsunomiya plant. Then we decided to adopt what at the time was a new technique to increase batch yields. This technique is now the norm around the world, but implementing it was a significant challenge for Chugai.

**MacLean:** After co-development with Roche was formally decided in 2003, we assembled a joint technical development team from the manufacturing divisions of both companies.

**Akamatsu:** Setting up manufacturing of a new biologic destined for global distribution involves all sorts of issues and challenges. As team leader at the time, I led weekly videoconferences in which we worked out how to resolve them. I believe the fact that we overcame all the obstacles as a unified team – colleagues from Chugai and Roche working together – led to the success of Actemra today.

## Post-Marketing Development

*We will continue to improve Actemra to make it an even better product and achieve further growth.*

**MacLean:** One key to the growth of Actemra will be to make it more convenient to administer. Right now we're working on developing a formulation that can be given by subcutaneous injection. This new dosage form is in phase III clinical trials in Japan and other countries, and we want to launch it as soon as possible. A subcutaneous formulation will significantly benefit patients because it can be administered anywhere in a short time, offering an alternative to the current intravenous (IV) formulation. We expect it to give market acceptance of Actemra a strong push.

**Yoshizawa:** The volume of a subcutaneous injection has to be smaller than for an IV infusion, and we went through a trial-and-error process to obtain the right antibody concentration.

**Akamatsu:** In manufacturing, we've worked on developing new methods to boost production volume. So far, we've gone through five changes in production method and raised efficiency nearly four-fold. Under Japan's Pharmaceutical Affairs Law, every time you change the production method, you have to prove that the resulting product is equivalent in order to get approval. There were challenges to overcome, but we made it. It was also worthwhile because



we are now creating a platform of technologies built up through that process. We've already used this platform to develop a new method that is still at the pilot stage but already surpasses the production yield of the current Actemra process.

## The Future That Actemra Will Create

*We will leverage the knowledge gained with Actemra to accelerate in-house development.*

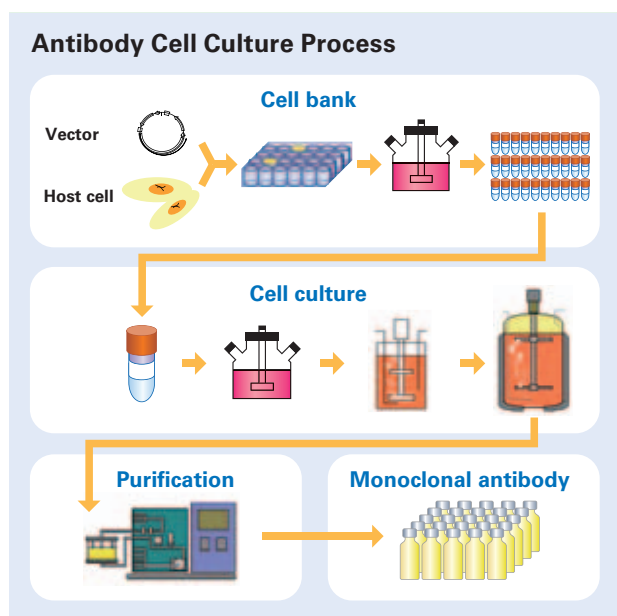
**Yoshizawa:** Biologics will definitely play a major role in future RA treatment approaches. At Chugai, which leads the world in IL-6 expertise, we want to strengthen the Actemra brand and eventually bring out a successor product. If the successor to Actemra is also well accepted, I think we'll have a very attractive IL-6 inhibitor franchise. Moreover, the successor drug will dramatically broaden our freedom at all development stages. IL-6 is thought to be involved in the pathogenesis of a variety of diseases. We believe we can contribute to the treatment

of many patients suffering from diseases other than RA by developing Actemra for additional indications.

**MacLean:** Providing information to the medical community is another key factor for Actemra to grow substantially as a global drug. In particular, competing anti-TNF-alpha agents are used more widely overseas than in Japan, so we will concentrate on raising recognition of Actemra and increasing awareness among physicians that inhibiting IL-6 is effective against RA. Actemra has exceptional efficacy data, and we need to take advantage of that. We also want to explore indications for which anti-TNF-alpha agents are not approved.

**Akamatsu:** In manufacturing, we want to enhance our basic technology for developing new types of antibodies while maintaining production volume, quality and development time at the current level. In providing medicines to patients, ensuring quality is our top priority. Therefore, our mission will be to improve the manufacturing technology platform needed to continue creating high-quality pharmaceuticals.

**Yoshizawa:** Actemra has really helped Chugai to grow in many ways. We've accumulated valuable experience and refined our technologies in every phase – research, development, manufacturing and marketing. The real significance of the Actemra success story is that our platform for advancing in-house development has been raised to a higher level. Over the long term, Chugai intends to make the most of the knowledge it has gained to accelerate development of medicines that satisfy unmet medical needs.







# Progressing

## Review of Operations

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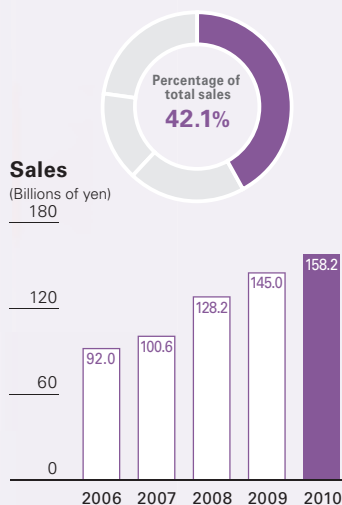
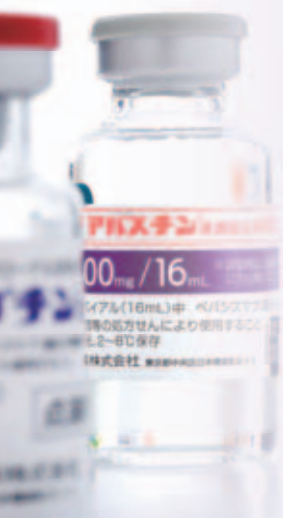
# Chugai at a Glance

## Oncology

▶ page 24

### Performance Highlights

- Oncology sales continued to grow, rising 9.1 percent year-on-year.
- Sales of growth drivers Avastin, Xeloda and Tarceva expanded strongly.
- Chugai maintained the leading share of the domestic oncology market at 18.4 percent.\*



### Major Products

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

### Key Developments

(January 2010 – February 2011)

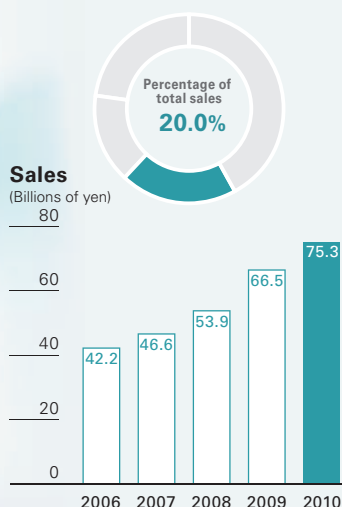
- Filed for approval of combination therapy of Xeloda and Herceptin for the additional indication of gastric cancer (March 2010)
- Filed for approval of Xeloda for gastric cancer based on evidence in the public domain (September 2010)
- Started phase II clinical trials of RG3502 for breast cancer (October 2010)
- Started phase I/II clinical trials of AF802 for non-small cell lung cancer (September 2010)
- Started clinical trials of CKI27 (RG7304) for solid tumors (January 2010), Tarceva as a first-line treatment for non-small cell lung cancer (April 2010), PA799 for solid tumors (August 2010), and GC33 for liver cancer (October 2010)

### Our Pipeline and



### Performance Highlights

- Sales continued to expand with a 13.2 percent increase year-on-year.
- Actemra sales in Japan grew by a robust 67.9 percent as a result of steady market penetration.



### Key Developments

(January 2010 – February 2011)

- Obtained approval of Ediol (ED-71) for osteoporosis (January 2011)
- Obtained FDA approval of Actemra for rheumatoid arthritis (January 2010)
- Filed applications overseas for an additional indication of Actemra for the treatment of systemic juvenile idiopathic arthritis (October 2010)
- Started phase III clinical trials in Japan (May 2010) and overseas (September 2010) of subcutaneous injection of Actemra for rheumatoid arthritis
- Started domestic phase I clinical trials of SA237 for rheumatoid arthritis (December 2010)

Chugai has the most product portfolio and 21 development

### Major Products

- Actemra (tocilizumab)
- Evista (raloxifene HCl)
- Suvenyl (sodium hyaluronate)
- Alfaryl (alfacalcidol)
- Ediol (eldecalcitol)

## Bone and Joint Diseases ▶ page 30

\* Copyright 2011 IMS Japan K.K. Source: JPM 2010.  
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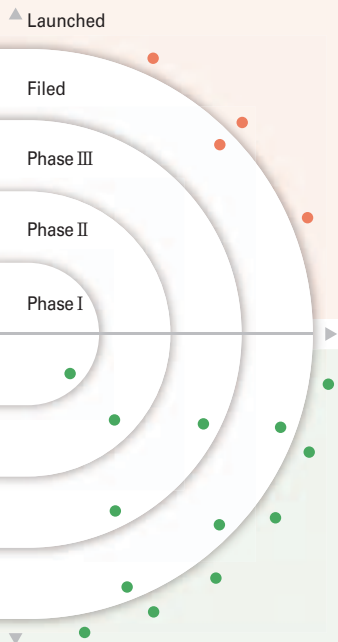
**Major Products**

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

**Key Developments**

(January 2010 – February 2011)

- Obtained approval of Epogin for the additional indication of autologous blood transfusion (June 2010)

**Major Products**

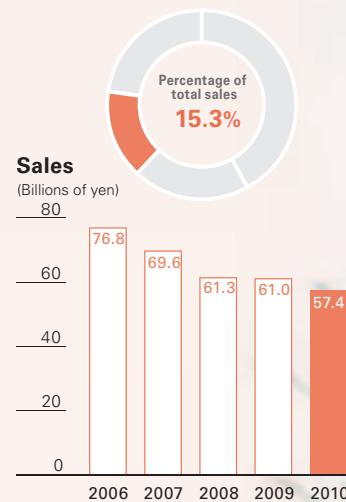
robust oncology  
pipeline in Japan with  
projects.

**Major Products**

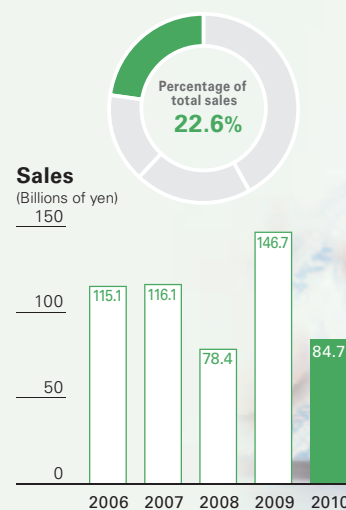
- Tamiflu (oseltamivir phosphate)
- Sigmart (nicorandil)
- Pegasys (peginterferon alfa-2a)
- Rocephin (ceftriaxone)
- Cellcept (mycophenolate mofetil)
- Copegus (ribavirin)

**Performance Highlights**

- Sales declined 5.9 percent year-on-year as a result of intense competition.

**Performance Highlights**

- Tamiflu sales, which fluctuate significantly from year to year, declined 76.1 percent.
- Pegasys/Copegus sales declined slightly due to market contraction and other factors despite steady market penetration.



# Oncology

Chugai has built a top-class portfolio of oncology products in Japan, with groundbreaking targeted 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 cancer treatment by providing healthcare professionals with detailed information and promoting standards of care.

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

## Domestic Sales of Major Products

Product Name (Generic name)	Sales (Billions of yen)	Brief Overview	Launch in Japan
<b>Avastin</b> (bevacizumab)	08: 20.1 09: 34.9 10: 52.6	Anti-VEGF (vascular endothelial growth factor) humanized monoclonal antibody	Jun. 2007
<b>Neutrogin*</b> (lenograstim)	08: 12.0 09: 11.3 10: 10.4	Recombinant human granulocyte colony-stimulating factor (G-CSF)	Dec. 1991
<b>Herceptin</b> (trastuzumab)	08: 23.7 09: 29.7 10: 25.3	Anti-HER2 humanized monoclonal antibody	Jun. 2001 (150mg) Aug. 2004 (60mg)
<b>Rituxan</b> (rituximab)	08: 20.5 09: 21.1 10: 23.0	Anti-CD20 monoclonal antibody	Sep. 2001
<b>Xeloda</b> (capecitabine)	08: 4.8 09: 6.6 10: 10.7	Fluoropyrimidine anti-tumor agent	Jun. 2003
<b>Tarceva</b> (erlotinib HCl)	08: 4.5 09: 5.8 10: 7.9	EGFR (epidermal growth factor receptor) tyrosine kinase inhibitor	Dec. 2007
<b>Kytril</b> (granisetron HCl)	08: 10.9 09: 8.6 10: 5.5	5-HT <sub>3</sub> receptor antagonist, antiemetic agent	May 1992 Jun. 2006 (bag)
<b>Femara</b> (letrozole)	08: 1.7 09: 2.4 10: 3.2	Aromatase inhibitor	May 2006

\* □ Overseas sales

## Development Pipeline (As of February 2, 2011)

Development Code (Product name)	Status Phase I	Phase II	Phase III	Filed	Approved	Indication	Generic Name	Dosage Form	Origin (Collaborator)
<b>RG435</b> (Avastin)				● Oct. 2009		Breast cancer	bevacizumab	Injection	Roche
			● (Multinational study)			Gastric cancer			
			● (Multinational study)			Breast cancer (adjuvant)			
			● (Multinational study)			Glioblastoma			
		●				Glioblastoma (relapsed)			
<b>EPOCH</b> (Epogin)				● Nov. 2009		Chemotherapy-induced anemia	epoetin beta	Injection	In-house
<b>RG340</b> (Xeloda)				● Sep. 2010		Gastric cancer	capecitabine	Oral	Roche
<b>RG597</b> (Herceptin)				● Mar. 2010		Gastric cancer	trastuzumab	Injection	Roche
<b>RG1415</b> (Tarceva)				● Sep. 2009		Pancreatic cancer	erlotinib HCl	Oral	Roche / OSI
		●				Non-small cell lung cancer (first-line treatment)			
<b>RG1273</b>			● (Multinational study)			Breast cancer	pertuzumab	Injection	Roche
<b>RG3502</b>		●				Breast cancer	—	Injection	Roche
<b>TP300</b>		● (Overseas)				Gastric cancer, etc.	—	Injection	In-house
<b>MRA</b> (Actemra)		● (I / II)				Pancreatic cancer	tocilizumab	Injection	In-house (Roche)
<b>AF802</b>		● (I / II)				Non-small cell lung cancer	—	Oral	In-house
<b>WT4869</b>		● (I / II)				Myelodysplastic syndromes	—	Injection	Chugai / Daiippon Sumitomo Pharma
<b>CIF (RG7167)</b>	●					Solid tumors	—	Oral	In-house (Roche)
	● (Overseas)								
<b>CKI27 (RG7304)</b>	●					Solid tumors	—	Oral	In-house (Roche)
	● (Overseas)								
<b>GC33</b>	●					Liver cancer	—	Injection	In-house (Roche)
	● (Overseas)								
<b>PA799</b>	● (Overseas)					Solid tumors	—	Oral	In-house
<b>GA101 (RG7159)</b>	●					Non-Hodgkin's lymphoma	—	Injection	Roche

● Designates change in status in 2010 and thereafter.

## Review of 2010 Results

### Overview

In 2010, total sales in the oncology field rose ¥13.2 billion, or 9.1 percent, year-on-year to ¥158.2 billion. This substantial increase was driven by strong growth in sales of the key products Avastin, Xeloda and Tarceva, which more than offset negative factors, including a reduction of the National Health Insurance (NHI) drug price for Herceptin and growing generic competition for Kytril. Chugai maintained its leading domestic market share, which increased to 18.4 percent from 17.3 percent in 2009.<sup>2</sup>

2. Copyright 2011 IMS Japan K.K. Source: JPM 2009-2010. Reprinted with permission. The scope of the market is defined by Chugai.

### New Products and Additional Indications

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

Sales of the anti-vascular endothelial growth factor (VEGF) humanized monoclonal antibody Avastin exceeded expectations, increasing ¥17.7 billion, or 50.7 percent, to ¥52.6 billion. This very strong growth was driven by continued uptake for colorectal and lung cancer. Surveillance data for Avastin helped expand recognition of the medicine's safety and efficacy, resulting in increased uptake for the treatment of both first- and second-line colorectal cancer and despite the launch of a competitor product in the second-line segment. Sales of Avastin also benefited from NHI revisions introduced

in April 2010 that made Avastin eligible for reimbursement on a partial fee-for-service basis instead of being included in flat-sum payments under the Diagnosis Procedure Combination (DPC) system. In addition, as a result of updated lung cancer treatment guidelines published in October 2010 that now include recommendations on treatment with Avastin, the medicine is also steadily gaining acceptance as a first-line treatment for non-small cell lung cancer.

Sales of Herceptin, an anti-human epidermal growth factor receptor-2 (HER2) humanized monoclonal antibody, decreased ¥4.4 billion, or 14.8 percent, to ¥25.3 billion. The price of Herceptin was cut significantly under the Japanese government's policy of recalculating prices of drugs based on the expansion of the market. Volume growth has also slowed somewhat, as Herceptin is already in use at many hospitals, reflecting high awareness of the benefits of treatment with this drug.

Sales of the fluoropyrimidine anti-tumor agent Xeloda rose a substantial ¥4.1 billion, or 62.1 percent, to ¥10.7 billion. In addition, the combination of Xeloda and oxaliplatin (a regimen called XELOX), which obtained approval in September 2009 for the treatment of patients with advanced or recurrent colorectal cancer, also captured a significantly larger market share. XELOX using oral Xeloda is becoming a standard of care for colorectal cancer worldwide, in part because it lessens the burden for patients and healthcare providers compared with intravenous 5-FU therapy. The combination of XELOX with Avastin is also replacing combination therapy with FOLFOX<sup>3</sup> and Avastin.



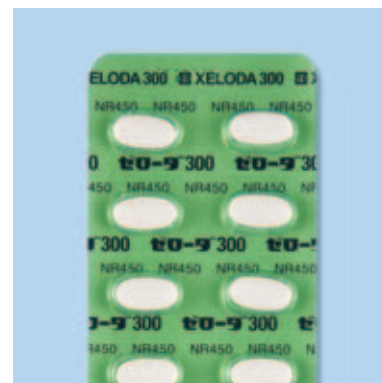
**Avastin**

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



**Xeloda**

The standard of care for metastatic breast cancer and colorectal cancer in more than 100 countries around the world



### 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

Sales of Tarceva, an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor, increased ¥2.1 billion, or 36.2 percent, to ¥7.9 billion. This reflects the efforts made by Chugai to communicate the results of all-patient registration surveillance for Tarceva to health-care professionals in order to further deepen understanding of the drug's safety and efficacy.

3. A combination therapy consisting of fluorouracil, folinic acid and oxaliplatin

### Existing Products

Sales of anticancer agents in Chugai's existing product portfolio continued to grow in 2010, although maintaining the market position of supportive care products remained a challenge.

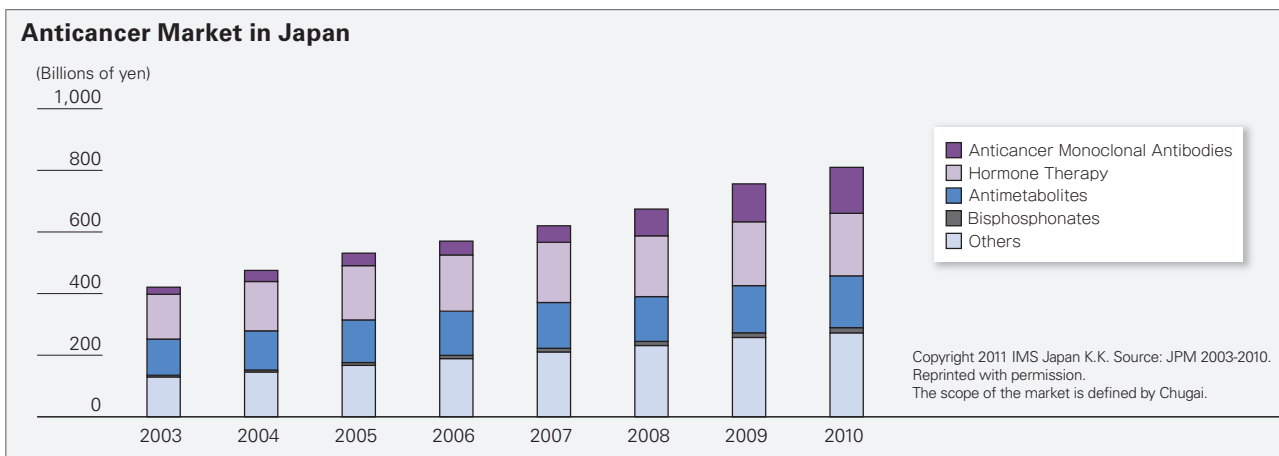
Sales of Rituxan, an anti-CD20 monoclonal antibody, showed a solid increase of ¥1.9 billion, or 9.0 percent, to ¥23.0 billion, as it consolidated its position as a standard therapy. Sales of Femara, an aromatase inhibitor for the treatment of breast cancer in postmenopausal women, increased ¥0.8 billion, or

33.3 percent, to ¥3.2 billion, driven by expanding use in initial adjuvant therapy. Because Femara is administered over a long period of time, its use in new patients is key, and this drug is gaining a substantial share of new prescriptions.

Sales of Neutrogen (overseas name: Granocyte), a recombinant human granulocyte colony-stimulating factor, decreased ¥5.2 billion, or 16.0 percent, to ¥27.4 billion. In Japan, sales decreased ¥0.9 billion, or 8.0 percent, to ¥10.4 billion, reflecting market contraction due to the growing number of facilities adopting the DPC-based payment system and an increase in outpatient chemotherapy. Outside Japan, competition from follow-on biologics<sup>4</sup> and the impact of the stronger yen led to a decrease in sales of ¥4.3 billion, or 20.2 percent, to ¥17.0 billion.

The challenging market environment for Kytril, a 5-HT<sub>3</sub> receptor antagonist antiemetic, continued due to generic erosion, with an additional competitor product launched in 2010. As a result, sales decreased ¥3.1 billion, or 36.0 percent, to ¥5.5 billion.

4. 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.





## Marketing

Chugai's approximately 550 oncology medical representatives (MRs) provide accurate, timely information to healthcare professionals, giving top priority to patient safety and appropriate use of Chugai's products. In 2007, we established a system to train our top oncology MRs in consulting-based promotion backed by a high level of expertise. Currently, our 71 top oncology MRs are building comprehensive professional partnerships with healthcare providers by offering advice on treatment of individual cases, holding study sessions in hospitals, and providing other support services. Our target is to have 120 top oncology MRs in the field by 2012.

As Japan's leading company in the field of oncology, Chugai is promoting the establishment of uniform standards of care and approaches to cancer treatment nationwide. Our efforts include providing information for patients as well as organizing or co-sponsoring a variety of charity events. Other initiatives include conducting workshops, training and other programs for doctors and other healthcare professionals to familiarize them with the emerging multidisciplinary approach to cancer care. Surveys among participants indicate strong support for this approach from the medical community.

## 2011 Strategy and Outlook

In 2011, Chugai will focus on positioning its key cancer medicines as standards of care to drive further growth and reinforce its leadership position in oncology. We will continue our efforts to promote the safe and appropriate use of our products and build a solid foundation for expanding our franchise in an increasingly competitive market environment.

One of our key focus areas will be establishing Avastin as a standard therapy for colorectal cancer and lung cancer, backed by a wealth of data on its safety and efficacy. In addition to increasing the number of colorectal cancer patients taking Avastin, we intend to grow sales substantially by promoting its use in accordance with the new lung cancer treatment guidelines.

Our strategy for Herceptin will focus on faster expansion of its use in adjuvant therapy for breast cancer and on improved HER2 testing.<sup>5</sup>

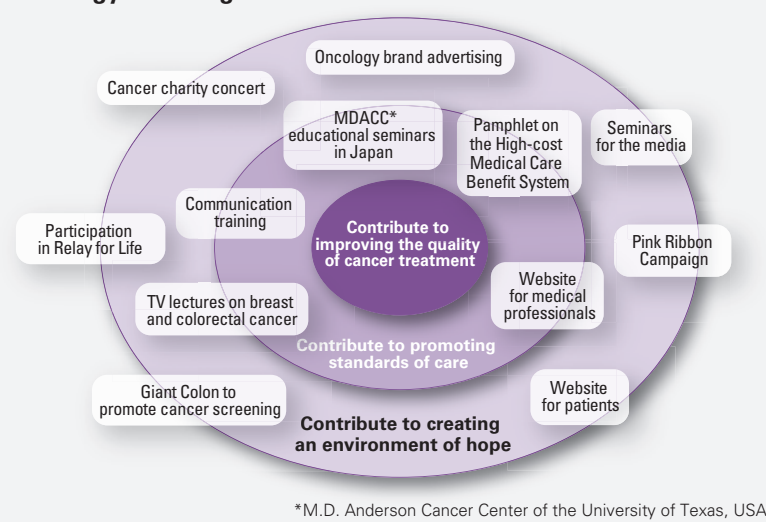
Promotion of Xeloda will emphasize its efficacy and safety as a component of the XELOX treatment regimen mentioned previously and in postoperative adjuvant chemotherapy for colon cancer. Activities will focus on the medicine's convenience as an oral treatment and the importance of side effect management. We will continue to promote wider awareness of the benefits of Tarceva in the treatment of lung cancer and strengthen its market position.

5. A test to determine the presence of a protein called HER2. Herceptin, which targets HER2, is administered only to patients who test positive for HER2.



Giant Colon exhibit at Relay for Life 2010, an event to support cancer patients held at 10 locations throughout Japan. The exhibit is intended to raise public awareness of early detection of colorectal cancer.

### Oncology Branding Activities



## 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. Line extension projects designed to address areas of significant unmet medical need in cancer treatment are progressing steadily and are expected to help further expand Chugai's franchise in oncology.

In March 2010, we filed an application for approval of Herceptin for the additional indication of HER2-positive advanced or recurrent gastric cancer. The Ministry of Health, Labour and Welfare (MHLW) designated it for priority review in June 2010 and we obtained approval in March 2011. In September 2010, we filed an application based on evidence in the public domain for Xeloda for the additional indication of advanced or refractory gastric cancer in patients who are not candidates for curative surgery. We obtained approval for this indication in February 2011. These new indications will allow Chugai to vigorously promote the combinations of Herceptin and Xeloda for patients with HER2-positive disease and Xeloda and cisplatin for HER2-negative disease. Herceptin and Xeloda are the first innovative drugs in more than a decade to obtain approval for the treatment of gastric cancer, an area in which no global standard of care is yet established, and expectations among healthcare professionals are correspondingly high.

In September 2009, Chugai filed an application for approval of Tarceva as a first-line treatment for pancreatic

cancer in combination with gemcitabine chemotherapy. Positive results of clinical trials, including a clear decrease in patient mortality, are attracting strong interest in the medical community.

Chugai is collaborating in the development of Avastin for the additional indication of glioblastoma, an aggressive type of brain tumor with limited treatment options. We are currently participating in a multinational phase III study, and are conducting domestic phase II clinical trials in patients with relapsed glioblastoma.

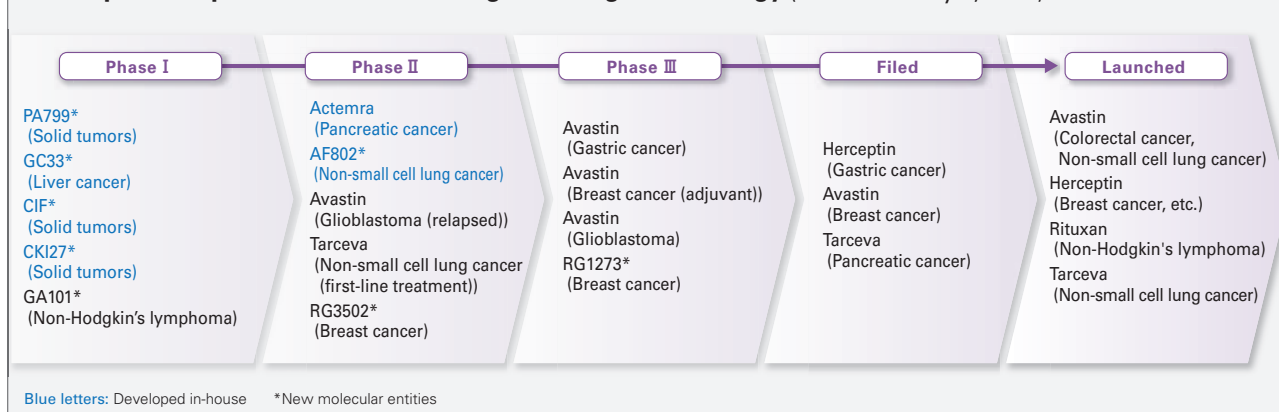
The development of Xeloda for advanced or refractory gastric cancer and Tarceva for advanced or refractory pancreatic cancer described above was requested by the MHLW. Both were identified by the ministry's Investigational Committee for Usage of Unapproved Drugs as treatments approved for use in Western countries but not yet approved in Japan for diseases that represent areas of particularly high unmet medical need.

### New Compounds

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

From 2010, phase I clinical trials started for two compounds from Chugai research: AF802 and PA799. AF802, a targeted, highly selective inhibitor of anaplastic lymphoma kinase (ALK) with a promising safety profile, is being developed for the treatment of non-small cell lung cancer. Domestic phase I/II clinical trials started in September 2010, and preparations are under way

### Development Pipeline of Molecular Targeted Drugs in Oncology (As of February 2, 2011)



for the start of phase I clinical trials overseas in 2011. PA799 is a targeted small-molecule compound that Chugai is developing for the treatment of solid tumors. Phase I clinical trials started overseas in August 2010 and are progressing as planned.

In 2011, Chugai and Dainippon Sumitomo Pharma Co., Ltd. will start joint domestic phase I/II clinical trials of the therapeutic cancer vaccine WT4869, for the treatment of patients with myelodysplastic syndromes. WT4869 is a novel peptide that targets a protein known as WT1, which is thought to play a key role in leukemia and other cancers.

Another compound from Chugai research is GC33, 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. Chugai has licensed this compound to Roche for joint development, and a multinational phase II study is being prepared. Chugai has also licensed the small-molecule targeted therapies CIF (RG7167) and CKI27 (RG7304) to Roche, and joint phase I clinical trials have started. CIF is a MEK inhibitor; CKI27 is a dual Raf and MEK inhibitor.

Chugai has been participating in a phase II trial of the anti-HER2 antibody-drug conjugate RG3502 (T-DM1) that started in October 2010. This novel compound links trastuzumab (T), the active ingredient of Herceptin, and the potent 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 an improved safety profile compared with conventional combination therapies. Chugai is also participating in Roche's multinational phase III study investigating RG1273 (pertuzumab), a monoclonal antibody and HER dimerization inhibitor, in combination with Herceptin for the treatment of HER2-positive breast cancer. Patient enrollment is complete, and preparations are under way to file for regulatory approval in 2012. Development of the anti-CD20 monoclonal antibody GA101 (RG7159) for the treatment of non-Hodgkin's lymphoma is proceeding on track.

## 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.

Chugai has already launched four such medicines in the field of oncology alone and is working to expand access to treatment. In addition, we have nine projects in clinical development. We will apply our biopharmaceutical knowledge and technical expertise in areas such as structural analysis to accelerate development of molecular targeted therapies.

Chugai is developing diagnostic tools by taking advantage of the powerful resources of the Roche Group, the global leader in *in vitro* diagnostics. We are currently collaborating with Roche Diagnostics K.K. to develop a companion diagnostic for use with GC33, a targeted therapy from Chugai research. This is one example of how we are working to support the rapid uptake of molecular targeted therapies once they are launched. Personalized healthcare enables physicians to give highly effective drugs to the patients most likely to benefit from them, not to patients who are unlikely to respond. Thus it can also contribute to the reduction of overall medical costs.

# Bone and Joint Diseases

In the area of rheumatoid arthritis (RA), we aim to leverage the potential of Actemra to drive growth and establish a strong market position in Japan and internationally. In the osteoporosis and osteoarthritis segments, Chugai will enhance its leading market position by focusing on maximizing the value of existing products and promoting the rapid market penetration of new product Ediol.

## Domestic Sales of Major Products

Product Name (Generic name)	Sales (Billions of yen)	Brief Overview	Launch in Japan																
<b>Actemra*</b> (tocilizumab)	<table border="1"> <thead> <tr> <th>Year</th> <th>Domestic Sales</th> <th>Overseas Sales</th> <th>Total Sales</th> </tr> </thead> <tbody> <tr> <td>08</td> <td>3.4</td> <td>3.8</td> <td>7.2</td> </tr> <tr> <td>09</td> <td>8.4</td> <td>8.9</td> <td>17.3</td> </tr> <tr> <td>10</td> <td>14.1</td> <td>12.7</td> <td>26.8</td> </tr> </tbody> </table>	Year	Domestic Sales	Overseas Sales	Total Sales	08	3.4	3.8	7.2	09	8.4	8.9	17.3	10	14.1	12.7	26.8	Humanized anti-human IL-6 receptor monoclonal antibody	Jun. 2005 (Castleman's disease) Apr. 2008 (rheumatoid arthritis)
Year	Domestic Sales	Overseas Sales	Total Sales																
08	3.4	3.8	7.2																
09	8.4	8.9	17.3																
10	14.1	12.7	26.8																
<b>Evista</b> (raloxifene HCl)	<table border="1"> <thead> <tr> <th>Year</th> <th>Domestic Sales</th> <th>Overseas Sales</th> <th>Total Sales</th> </tr> </thead> <tbody> <tr> <td>08</td> <td>16.5</td> <td>0.0</td> <td>16.5</td> </tr> <tr> <td>09</td> <td>17.9</td> <td>0.0</td> <td>17.9</td> </tr> <tr> <td>10</td> <td>18.7</td> <td>0.0</td> <td>18.7</td> </tr> </tbody> </table>	Year	Domestic Sales	Overseas Sales	Total Sales	08	16.5	0.0	16.5	09	17.9	0.0	17.9	10	18.7	0.0	18.7	Agent for postmenopausal osteoporosis	May 2004
Year	Domestic Sales	Overseas Sales	Total Sales																
08	16.5	0.0	16.5																
09	17.9	0.0	17.9																
10	18.7	0.0	18.7																
<b>Suvenyl</b> (sodium hyaluronate)	<table border="1"> <thead> <tr> <th>Year</th> <th>Domestic Sales</th> <th>Overseas Sales</th> <th>Total Sales</th> </tr> </thead> <tbody> <tr> <td>08</td> <td>12.0</td> <td>0.0</td> <td>12.0</td> </tr> <tr> <td>09</td> <td>13.7</td> <td>0.0</td> <td>13.7</td> </tr> <tr> <td>10</td> <td>13.6</td> <td>0.0</td> <td>13.6</td> </tr> </tbody> </table>	Year	Domestic Sales	Overseas Sales	Total Sales	08	12.0	0.0	12.0	09	13.7	0.0	13.7	10	13.6	0.0	13.6	Agent for joint function improvement	Aug. 2000
Year	Domestic Sales	Overseas Sales	Total Sales																
08	12.0	0.0	12.0																
09	13.7	0.0	13.7																
10	13.6	0.0	13.6																
<b>Alfarol</b> (alfacalcidol)	<table border="1"> <thead> <tr> <th>Year</th> <th>Domestic Sales</th> <th>Overseas Sales</th> <th>Total Sales</th> </tr> </thead> <tbody> <tr> <td>08</td> <td>13.7</td> <td>0.0</td> <td>13.7</td> </tr> <tr> <td>09</td> <td>13.6</td> <td>0.0</td> <td>13.6</td> </tr> <tr> <td>10</td> <td>12.3</td> <td>0.0</td> <td>12.3</td> </tr> </tbody> </table>	Year	Domestic Sales	Overseas Sales	Total Sales	08	13.7	0.0	13.7	09	13.6	0.0	13.6	10	12.3	0.0	12.3	Active vitamin D <sub>3</sub> derivative (1α(OH) D <sub>3</sub> ) for improving bone metabolism	Jan. 1981 (capsule, solution) Jul. 1994 (powder)
Year	Domestic Sales	Overseas Sales	Total Sales																
08	13.7	0.0	13.7																
09	13.6	0.0	13.6																
10	12.3	0.0	12.3																

\* □ Overseas sales

## Development Pipeline (As of February 2, 2011)

Development Code (Product name)	Status	Phase I	Phase II	Phase III	Filed	Approved	Indication	Generic Name	Dosage Form	Origin (Collaborator)
<b>ED-71</b> (Ediol)						Jan. 2011	Osteoporosis	eldecalcitol	Oral	In-house (Taisho Pharmaceutical)
<b>MRA</b> (Actemra)						(Overseas / US) Jan. 2010	Rheumatoid arthritis	tocilizumab	Injection	In-house (Roche)
					(Overseas) Oct. 2010		Systemic-onset juvenile idiopathic arthritis (sJIA)			
					(Overseas)		Rheumatoid arthritis (new formulation: subcutaneous injection)			
<b>RG484</b>							Osteoporosis	ibandronate sodium hydrate	Injection	Roche (Taisho Pharmaceutical)
									Oral	
<b>SA237</b>							Rheumatoid arthritis	—	Injection	In-house

● Designates change in status in 2010 and thereafter.

## Review of 2010 Results

### Overview

In 2010, Chugai's total sales in the bone and joint diseases field increased ¥8.8 billion, or 13.2 percent compared with the previous fiscal year, to ¥75.3 billion. The main revenue driver was strong growth in sales of Actemra, a humanized anti-human IL-6 receptor monoclonal antibody for the treatment of RA, which continued to gain acceptance in the market. Chugai focused on maintaining the market position of its osteoporosis and osteoarthritis treatments, including Alfarol, Evista and Suvenyl, in an intensely competitive environment, and sales were basically at the same level as the previous year.

### Rheumatoid Arthritis

Sales of Actemra in Japan increased ¥5.7 billion, or 67.9 percent, to ¥14.1 billion, expanding steadily despite intensifying competition that included the launch of a rival product. Actemra originated from Chugai research and is the first therapeutic antibody created in Japan. A highly innovative drug with a novel mechanism of action, Actemra is the world's first inhibitor of interleukin-6 (IL-6), a signaling protein involved in regulating the immune response (see pages 17-20 for details).

In 2010, the third year since the approval of Actemra in Japan for the treatment of RA, an interim report was issued on the post-marketing all-patient registration

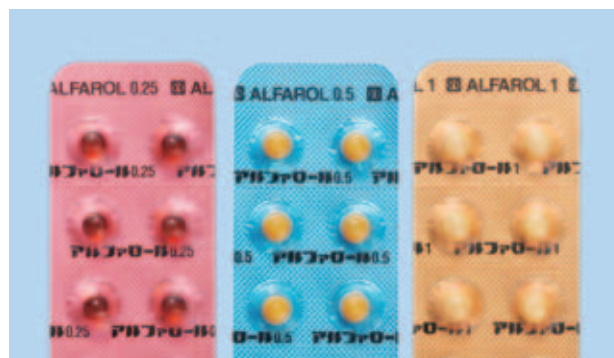
surveillance that was a condition of the drug's approval. Data on 3,987 patients were collected and analyzed, forming the basis of detailed information for healthcare professionals. As a result, Actemra's safety and efficacy profile, including its effectiveness in preventing joint destruction and its high remission and treatment adherence rates, gained wide recognition among rheumatologists. Based on a review of the interim report, the regulatory authorities lifted the condition for approval (all-patient registration surveillance) in August 2010, and market uptake of Actemra continues to expand. In marketing, medical representatives (MRs) specializing in Actemra have been conducting focused promotional activities, primarily targeting approximately 500 specialized rheumatology facilities throughout Japan. Since the lifting of Actemra's condition for approval, other MRs have also started promoting the drug to other healthcare facilities. The success of these efforts is shown by the fact that Actemra is now prescribed as a first-line biologic for about 40 percent of patients treated with the drug in Japan.

Sales of Actemra outside Japan (exports to Roche for sale in regions other than Japan, Korea and Taiwan) rose ¥3.8 billion, or 42.7 percent, to ¥12.7 billion. Following regulatory approval in January 2009 in the European Union, where it is known as RoActemra, Actemra obtained approval in January 2010 in the United States, the world's largest market for pharmaceuticals. Uptake of the medicine in the US and other global launch markets in 2010 was very encouraging. Around 60 percent of US rheumatologists have already



### 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 obtained approval for rheumatoid arthritis in 2008. It is now being made available to patients worldwide thanks to the global reach of the Roche Group.



### 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.

prescribed Actemra. Chugai co-promotes RoActemra with Roche in Germany, the UK and France through its own marketing units. As of the end of December 2010, Actemra had been approved for sale in some 90 countries around the world and launched in about 50.

Chugai has expanded production capacity for Actemra at its Utsunomiya plant in Japan. To meet future growth in global demand, Genentech will also manufacture Actemra's bulk drug substance in the United States under a toll manufacturing agreement. The transfer of production technology to Genentech is proceeding smoothly.

## Osteoporosis and Osteoarthritis

In the osteoporosis segment, the selective estrogen receptor modulator Evista performed well, with sales increasing ¥0.8 billion, or 4.5 percent, to ¥18.7 billion. With competitor products (once-weekly bisphosphonates) gaining market share, Chugai's marketing efforts emphasized the benefits of Evista as a clinically differentiated medicine associated with excellent patient adherence to treatment (continued use as directed). Our sales force also concentrated on providing information based on post-marketing surveillance data from 6,967 patients (number of patients subject to safety evaluation) in the six years since the product was launched, further promoting physician understanding of Evista's safety profile.

Sales of the active vitamin D<sub>3</sub> derivative Alfarol



decreased ¥1.3 billion, or 9.6 percent, to ¥12.3 billion due to generic erosion. In a challenging market environment, Chugai worked to maintain Alfarol's position as a basic treatment for osteoporosis with a proven record of safety and efficacy in over 30 years on the market.

In the osteoarthritis segment, sales of Suvenyl decreased ¥0.1 billion, or 0.7 percent, to ¥13.6 billion. Suvenyl maintained its market share despite slightly slower market expansion and the launch of a rival product. This is attributable to recognition of the clear advantages of Suvenyl, the only natural, high molecular weight hyaluronate preparation that has obtained approval in Japan to treat osteoarthritis.

## 2011 Strategy and Outlook

In 2010, Chugai established the foundation for the future growth of Actemra with a substantial body of clinical data supporting its safety and efficacy and a marketing platform that extends outside Japan. In 2011, we will build on this to achieve full-fledged growth.

In Japan, we remain committed to establishing Actemra as a leading biologic treatment for RA and related disorders. As the goal of RA therapy shifts to achieving and maintaining clinical remission, we will emphasize the high rates of prolonged remission that can be reached with Actemra treatment: In domestic clinical trials, 55.3 percent of patients were still in remis-

sion after five years. We will vigorously promote increasing recognition of Actemra as a drug that can help achieve current therapeutic goals.

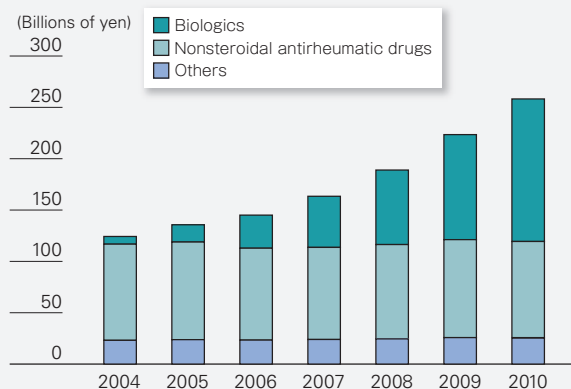
Outside Japan, Chugai will continue to cooperate closely with Roche and Genentech to develop global sales of Actemra. We anticipate strong growth, primarily in the critical US and European markets.

Chugai will also focus on strengthening its position as a leading provider of osteoporosis treatments. We expect Evista to face increased competition from launches of rival products but will work to further expand its market share by emphasizing the extensive safety and efficacy data available for this product after six years on the market.

In January 2011, we obtained approval of Ediol for the treatment of osteoporosis. A result of Chugai's many years of research on vitamin D, Ediol is a next-generation active vitamin D<sub>3</sub> derivative that significantly reduces bone fractures. (See the column on page 33 for details on Ediol). We aim to leverage the strong clinical data on the drug's safety and efficacy and our extensive experience in this disease area to achieve rapid market penetration and establish Ediol as a foundation treatment for osteoporosis.

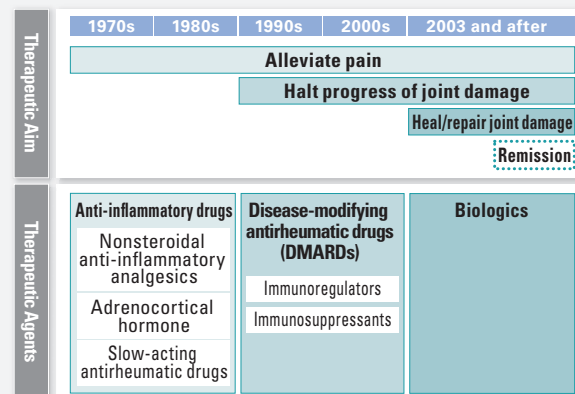
In the area of osteoarthritis, we plan to introduce a new dosage form of Suvenyl in 2011 to enhance patient convenience. This will involve switching from the current glass syringe to a plastic syringe designed for easier use.

### Rheumatoid Arthritis Market in Japan



Copyright 2011 IMS Japan K.K. Source: JPM 2004-2010. Reprinted with permission. The scope of the market is defined by Chugai.

### Changes in Rheumatoid Arthritis Drug Therapy



With the advent of biologics, the aim of therapy for rheumatoid arthritis has shifted to achieving and maintaining remission.

## Products under Development

In the area of RA, development of a new formulation of Actemra for subcutaneous injection is progressing as planned, and domestic phase III clinical trials started in May 2010. Actemra is currently administered by intravenous infusion, and a subcutaneous dosage form has the potential to increase convenience for patients and healthcare providers alike. In the United States, Genentech obtained approval in January 2011 to expand marketing for Actemra to include reduction or inhibition of progression of joint damage and improvement of physical function in adults with RA. In October 2010, Roche and Genentech filed applications in the US and Europe for the additional indication of systemic juvenile idiopathic arthritis (sJIA). The filings were supported by data from the overseas phase III TENDER study, which showed that treatment with Actemra significantly improved disease signs and symptoms; the study also showed that Actemra was well tolerated in children with sJIA, with a safety profile similar to that seen in adult RA patients.

In the osteoporosis segment, Chugai is co-developing RG484 (overseas product name: Bonviva/Boniva), a bisphosphonate medicine, with Taisho Pharmaceutical Co., Ltd. Phase II/III clinical trials with an injectable

formulation and phase II trials with an oral formulation of the medicine are progressing on track. Unlike existing oral bisphosphonates, which are normally taken once a week, RG484 can be taken just once a month. Less-frequent dosing is expected to improve patient adherence to treatment, a major issue in osteoporosis therapy. Once approved, RG484 will give Chugai a full lineup of osteoporosis medicines and will offer healthcare providers greater flexibility to tailor treatments to patient needs.

### Active Vitamin D3 Derivative Edirol: A Next-Generation Treatment Option for Osteoporosis

Chugai has been involved in vitamin D research for many years and, through Alfarol, has established a strong presence in the osteoporosis market. Following approval of Edirol in January 2011, we are now commencing the market rollout of this next-generation active vitamin D3 derivative for the treatment of osteoporosis.

Active vitamin D3 derivatives act on the small intestine to enhance the absorption of calcium from food. Through this and other beneficial effects, they have an important role as a basic treatment for osteoporosis. In addition to promoting calcium absorption like conventional vitamin D3 products, Edirol is significantly more effective in increasing bone density and inhibiting bone resorption. A large-scale comparative phase III clinical trial conducted in Japan confirmed the superiority of Edirol over Alfarol (alfacalcidol), another vitamin D3 analogue, in reducing the incidence of bone fractures.

As Japan's leading provider of vitamin D3 preparations for 30 years, Chugai will use its extensive experience to vigorously promote Edirol as a product backed by convincing clinical data, and will give high priority to ensuring its rapid availability to patients.



# Renal Diseases

Chugai is committed to maintaining its market presence as a leader in the field of renal diseases, with an emphasis on defending the position of its core product Epogin in dialysis. In addition, Chugai will step up its activities in the pre-dialysis setting by promoting early intervention in renal anemia and launching new products that contribute to better treatment.

## Domestic Sales of Major Products

Product Name (Generic name)	Sales (Billions of yen)	Brief Overview	Launch in Japan
<b>Epogin</b> (epoetin beta)	08 44.9 09 44.4 10 40.0	Recombinant human erythropoietin	Apr. 1990 (ampoule) May 2001 (syringe)
<b>Oxarol</b> (maxacalcitol)	08 10.0 09 10.6 10 12.0	Agent for secondary hyperparathyroidism in hemodialysis patients	Sep. 2000
<b>Renagel</b> (sevelamer HCl)	08 5.8 09 5.4 10 4.9	Agent for hyperphosphatemia	Jun. 2003

## Development Pipeline (As of February 2, 2011)

Development Code (Product name)	Status Phase I	Phase II	Phase III	Filed	Approved	Indication	Generic Name	Dosage Form	Origin (Collaborator)
<b>EPOCH</b> (Epogin)					● Jun. 2010	Chemotherapy-induced anemia	epoetin beta	Injection	In-house
<b>RG744</b> (Mircera)				● Jul. 2009		Renal anemia	epoetin beta pegol	Injection	Roche

● Designates change in status in 2010 and thereafter.

## Review of 2010 Results

### Overview

In 2010, sales in the renal diseases field decreased ¥3.6 billion, or 5.9 percent, year-on-year to ¥57.4 billion. The primary factor was a decrease in sales of mainstay product Epogin, an agent for the treatment of renal anemia, due to reduction of the NHI drug price and strong competition from other products. Epogin sales fell ¥4.4 billion, or 9.9 percent, to ¥40.0 billion. Sales volume of Epogin remained solid, however.

A treatment for anemia associated with chronic kidney disease (CKD), Epogin is used in both the dialysis and pre-dialysis settings.

In the dialysis segment, Chugai has focused on defending the product's position since the introduction of a flat-sum reimbursement system for erythropoietin-stimulating agents (ESAs) in 2006 (see page 67 for details) and intense competition from rival drugs. Based on its expertise in the dialysis market, Chugai continued careful follow-up of patients in 2010, in addition to conducting promotional activities that highlighted the

safety and efficacy of Epogin. These included a series of academic conferences at 40 sites across Japan to commemorate the twentieth anniversary of the Epogin launch. These promotional activities helped to minimize the decrease in sales despite the launch of follow-on biologics and competitor products.

The pre-dialysis segment has expanded by about 10 percent annually in recent years. This growth is being driven in part by a national education campaign to promote early diagnosis and treatment of renal anemia in the pre-dialysis setting, in response to an increase in CKD in patients with diabetes. In July 2009, Chugai launched a new formulation of Epogin that uses a serum-free<sup>1</sup> manufacturing process and reduces the pain of subcutaneous administration. The new formulation has obtained high approval ratings from patients and healthcare providers alike.

In June 2010, Chugai obtained marketing approval for a 24,000-unit formulation of Epogin Injection for use in autologous blood transfusion.<sup>2</sup> This market is expected to grow as Japan's low birth rate and aging population lead to blood shortages while the need for



## Epogin

A recombinant human erythropoietin biopharmaceutical developed by Chugai that has been the leading renal anemia treatment in Japan since its launch in 1990

transfusions increases.

Substantial clinical evidence that treatment with Oxarol can increase life expectancy in patients with secondary hyperparathyroidism drove strong sales of the medicine, which rose ¥1.4 billion, or 13.2 percent, to ¥12.0 billion. Sales of Renagel, for hyperphosphatemia, decreased ¥0.4 billion, or 7.5 percent, to ¥4.9 billion, due in part to the launch of a competitor product.

1. 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.
2. A procedure in which a patient’s own blood is collected in advance and stored for transfusion during scheduled surgery.

## 2011 Strategy and Outlook

Chugai anticipates that competition in the key renal anemia market will continue to intensify in 2011. In the expanding pre-dialysis market, sales of a new competitor product are expected to gain momentum.

Chugai plans to reinforce its market presence with the rollout in 2011 of Mircera (RG744), an ESA (see the next section and page 67 for details). Our marketing activities will continue to focus on proposing optimal treatment approaches for individual patients. We will promote the use of our pioneering system for managing each patient’s course of treatment, combined with our comprehensive pharmacovigilance system. In addition, results of a survey of 3,287 pre-dialysis patients – part of the larger all-patient registration surveillance for Epogin that has been ongoing since 2005 – revealed a

statistically significant survival benefit. We plan to use these data to support a full-scale expansion of Epogin sales in the pre-dialysis market.

Revisions to treatment guidelines in 2011 are expected to emphasize the benefits of early treatment of secondary hyperparathyroidism in improving life expectancy. This represents an opportunity to expand the market for Oxarol, and we will focus on informing healthcare professionals about the wealth of clinical data confirming the benefits of the product in this setting.

## Products under Development

Following its submission of a marketing application in mid-2009, Chugai is preparing for the planned launch in 2011 of the long-acting ESA Mircera (RG744). This product 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 patients, as it requires fewer hospital visits. An added benefit is that the drug’s half-life is similar after both intravenous and subcutaneous administration, which enables a smooth transition in patients moving from the pre-dialysis to the dialysis setting. Patients and healthcare providers have high expectations for Mircera (RG744), and we believe it will drive expansion of the renal anemia market.



# Others

Chugai aims to strengthen its position in the hepatitis C segment and is supporting promotion of early detection and effective treatment of chronic hepatitis C. In addition, we are focusing on developing treatments in areas of significant unmet medical need such as diabetes and diseases of the central nervous system.

## Domestic Sales of Major Products

Product Name (Generic name)	Sales (Billions of yen)	Brief Overview	Launch in Japan
<b>Tamiflu</b> *1 (oseltamivir)	08 7.1 1.3 8.4 09 16 10 16.6 18.2 36.2 40.0 76.2	Anti-influenza agent	Feb. 2001 (capsule) Jul. 2002 (dry syrup)
<b>Sigmar</b> *2 (nicorandil)	08 15.0 2.0 17.0 09 14.7 1.9 16.6 10 13.0 2.2 15.2	Anti-anginal agent	Apr. 1984 (capsule) Sep. 1993 (injection)
<b>Pegasys</b> (peginterferon alfa-2a)	08 9.7 09 11.1 10 10.5	Peginterferon alfa-2a agent	Dec. 2003
<b>Rocephin</b> (ceftriaxone)	08 5.9 09 5.5 10 5.4	Cephem-type antibiotic	Aug. 1986 (0.5g and 1g IV injection) Jun. 2003 (1g IV drip bag)
<b>Cellcept</b> (mycophenolate mofetil)	08 4.0 09 4.4 10 5.2	Immunosuppressant	Nov. 1999
<b>Copegus</b> (ribavirin)	08 4.2 09 4.9 10 4.5	Anti-viral agent	Mar. 2007

\*1 Sales for government stockpile

\*2 Overseas sales

## Development Pipeline (As of February 2, 2011)

Development Pipeline (As of January 2, 2017)							Indication	Generic Name	Dosage Form	Origin (Collaborator)
Development Code (Product name)	Status Phase I	Phase II	Phase III	Filed	Approved					
Transplant, Immunology and Infectious Diseases										
RG964 (Copegus)				<div><div></div></div> Oct. 2010		Compensated liver cirrhosis caused by hepatitis C virus	ribavirin	Oral	Roche	
RG442 (Pegasys)				<div><div></div></div> Oct. 2010		Compensated liver cirrhosis caused by hepatitis C virus	peginterferon alfa-2a	Injection	Roche	
				<div><div></div></div> Jan. 2011		Chronic hepatitis B				

### Other Diseases

<b>CSG452 (RG7201)</b>			●		Type 2 diabetes	tofogliflozin	Oral	In-house (Roche)
<b>RG1678</b>			● (Multinational study)		Schizophrenia	—	Oral	Roche
<b>RG1583 (ITM-077)</b>		●			Type 2 diabetes	tasoglutide	Injection	Roche / Ipsen (Teijin)
<b>RG1450</b>	●				Alzheimer's disease	gantenerumab	Injection	Roche / Morphosys

● Designates change in status in 2010 and thereafter.

## Review of 2010 Results

### Overview

In 2010, total sales in the Others field, which covers all products other than those for oncology, bone and joint diseases, and renal diseases, decreased ¥62.0 billion, or 42.3 percent, year-on-year to ¥84.7 billion. Sales of the anti-influenza agent Tamiflu were down ¥58.0 billion, or

76.1 percent, as the influenza A/H1N1 ("swine flu") pandemic of 2009/2010 subsided quickly, and there was no major seasonal flu outbreak up to the end of 2010.

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, decreased in comparison with 2009.



### Pegasis/Copegus

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



### Tamiflu

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

## Chronic Hepatitis C

Sales of Pegasis declined ¥0.6 billion, or 5.4 percent, to ¥10.5 billion due to the impact of an NHI drug price revision and market contraction, although government-sponsored education programs had a positive effect. On the other hand, sales of Pegasis benefited from a steady increase in prescriptions of combination therapy with Copegus and the market share of this combination increased. The unique features of Pegasis, which (unlike a competitor peginterferon product) has obtained approval both as monotherapy and in combination with ribavirin, also contributed to its strong market position.

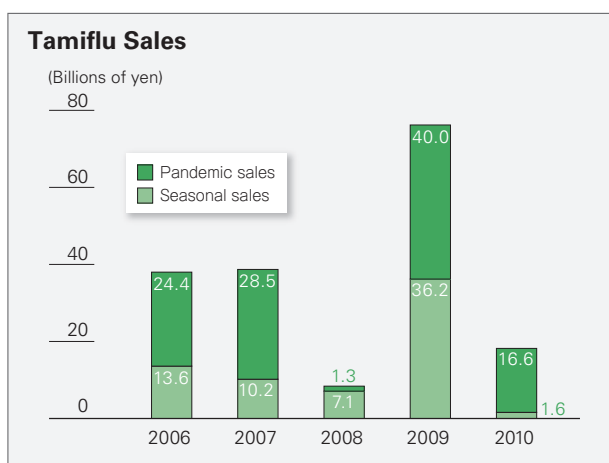
Chronic hepatitis C results from infection with the hepatitis C virus (HCV). An estimated two million patients in Japan are currently infected. Untreated chronic hepatitis C may progress to liver cirrhosis and liver cancer. More than 30,000 people in Japan die from liver cancer each year, and about 80 percent of those cases are thought to be caused by chronic hepatitis C. In order to reduce the country's comparatively high rate of mortality from liver cancer, 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 started in 2008 by the national and local governments for HCV patients undergoing interferon treatment was expanded in April 2010. In addition to informing healthcare professionals of the benefits of Pegasis and Copegus, Chugai is helping to raise public awareness of the disease. Activities include a website

(<http://www.kanenzero.jp>) that provides information about HCV and co-sponsorship of public seminars.

## Influenza

Sales of Tamiflu decreased ¥58.0 billion, or 76.1 percent, to ¥18.2 billion. Seasonal sales amounted to ¥1.6 billion, a decrease of ¥34.6 billion (95.6 percent), while pandemic sales were ¥16.6 billion, a decrease of ¥23.4 billion (58.5 percent).

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. This process is due to be completed in 2011.



## 2011 Strategy and Outlook

In the chronic hepatitis C field, 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 supporting these products, as well as providing additional information on HCV to the general public.

In the influenza field, the expected launch of competitor products in 2011 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 the pandemic sales segment, we anticipate additional stockpiling purchases by local governments in 2011.

## Products under Development

An application filed by Chugai in October 2010 for approval of Pegasys/Copegus combination therapy for patients with compensated liver cirrhosis caused by chronic hepatitis C has been designated for priority review by the Japanese health authorities. In addition, in January 2011, Chugai applied for approval of Pegasys for the additional indication of chronic hepatitis B.

Development of NA808, a small-molecule compound from Chugai research, was suspended after it failed to meet efficacy criteria. In addition, reprioritization of our development portfolio led to a decision to suspend development of NTZ (nitazoxanide), a novel anti-HCV compound licensed from US-based Romark Laboratories, L.C. Romark will continue to develop NTZ in Japan as part of its international program.

Chugai continued to make progress in two new fields in 2010: diabetes and diseases of the central nervous system.

The number of patients with type 2 diabetes is increasing worldwide. However, many currently availa-

ble medicines 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 is a selective SGLT2 inhibitor from Chugai research. This small-molecule compound is designed to achieve continuous control of blood sugar in an insulin-independent manner through excretion of glucose in the urine. CSG452 was licensed out to Roche in 2007, and phase **III** clinical trials started in November 2010. Chugai is considering terminating development of RG1583 (taspoglutide), an investigational type 2 diabetes drug licensed from Roche, following Roche's decision early in 2011 to discontinue its phase **III** program and return the rights to the compound to the original developer.

In the central nervous system field, Chugai has two compounds licensed from Roche in development. We started 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 multinational phase **II** study with RG1678, a first-in-class glycine reuptake inhibitor currently under development for schizophrenia, were announced in November 2009. The results showed that this novel compound has a favorable safety profile and produced a clinically meaningful reduction in negative symptoms in patients with schizophrenia. A multinational phase **III** study started in January 2011.



# Sustaining

## Organization and Human Resources

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# Research

**Chugai seeks to continuously create innovative medicines that address unmet medical needs for the benefit of the medical community and human health around the world. Leveraging the research organization and technology platform that we have been steadily enhancing, we focus on original research that will drive Chugai's future growth.**

## Basic Policy and Allocation of Resources

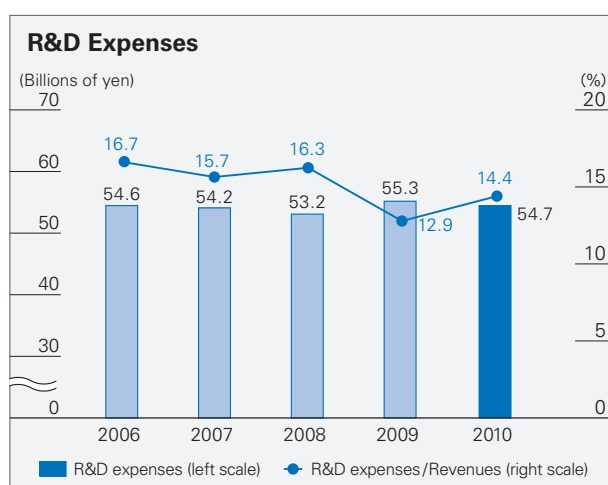
Generating a steady stream of innovative medicines that address unmet medical needs for the benefit of the medical community and human health around the world is Chugai's raison d'être as well as the basis of its relationship with patients and other stakeholders.

Chugai conducts research in five strategic fields – oncology, bone and joint diseases, renal diseases, diabetes and infectious diseases – focusing primarily on creating new drugs with first-in-class or best-in-class potential. Typically, it takes more than a decade for a drug candidate to advance from the research stage to approved use as a medicine. In conducting research, therefore, Chugai always considers factors such as how healthcare systems will be structured, how the market environment will change, and how treatment methods will evolve in the future.

In allocating research resources, we prioritize projects based on criteria such as a compound's potential for development as a novel, first-in-class medicine; a high level of scientific feasibility for the target product profile; and whether speedy development can be expected. At various decision points during research, we focus first and foremost on patient needs, not on the drug's short-term commercial potential. This reflects our belief that creating medicines that patients and healthcare providers truly need will drive Chugai's medium-to-long-term growth.

## Strengths of Chugai's Research Organization

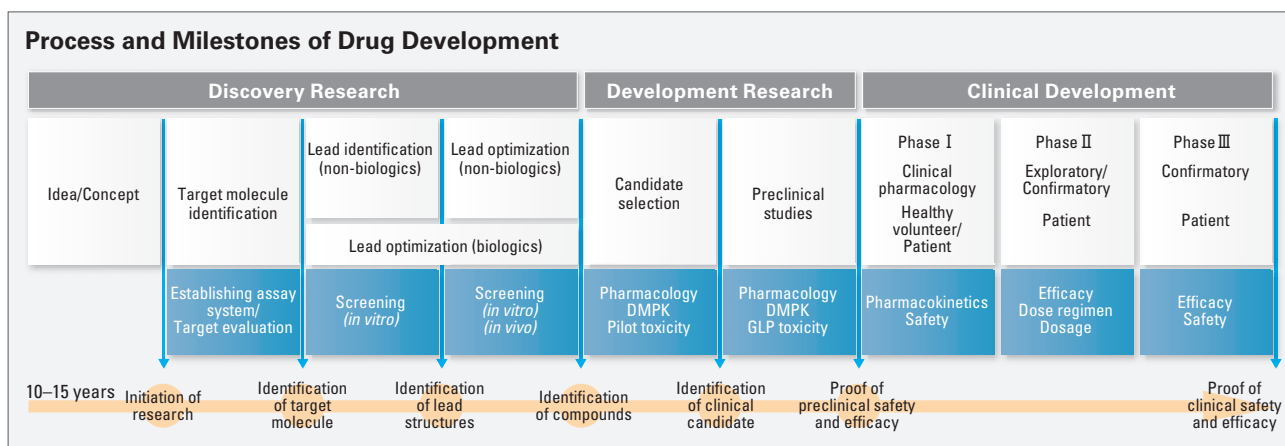
Through its strategic alliance with Roche and merger with Nippon Roche, Chugai has become a research and development leader in Japan by building a strong research organization and technology platform with expertise in both biopharmaceuticals and small molecules. As a member of the Roche Group, Chugai has access to a world-class research infrastructure, giving it a major advantage over its competitors. Access to Roche's research platform, with tools including a compound library and chemical evaluation database as well as information on the development of therapeutic



### Progress in 2010 and Thereafter

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

(As of February 2, 2011)



antibodies, has dramatically increased our research productivity, especially in the lead discovery and optimization stages.

Chugai's collaborative network of academic and other organizations involved in cutting-edge research is another key resource supporting its research organization. As the discovery of new drug candidates becomes more and more challenging, 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 with global potential. Chugai has complemented its own research organization with external institutions through close collaboration aimed at creating innovative medicines from basic research. The success of Actemra, which was developed through years of joint research with Osaka University, demonstrates the value of this approach, and Chugai is determined to continue pursuing alliances and joint research with external networks.

## Progress and Outlook

In the last several years, many projects from Chugai research, mainly in the field of oncology, have entered clinical development, including GC33, CKI27, CIF, AF802 and PA799. The number of projects from Chugai research advancing to the pre-proof-of-concept stage has risen from one in 2006 to seven in 2009 and eight in 2010. This steady progress is testimony to the benefits

of the strategic alliance with Roche for Chugai's Research Division.

Personalized healthcare, which tailors treatment based on individual patients' molecular and genetic profiles, is expected to play an increasingly prominent role in the years ahead. Chugai intends to promote this approach by systematically creating molecular targeted therapies. In addition, Chugai is partnering with Roche Diagnostics to develop diagnostics that screen for specific molecules, which will be pivotal in advancing personalized healthcare.

Chugai will continue to develop innovative new drugs that contribute to healthcare around the world through its own research while fully utilizing the resources available as a member of the Roche Group.

## Intellectual Property Strategy

Intellectual property (IP) strategy is an important part of product lifecycle management and a key to maintaining the competitive advantage of a company's technology platform. Chugai's Intellectual Property Department exchanges information on the progress of research and development and the status of IP rights in close contact with research and development operations. This cooperative approach helps to maximize the value of Chugai's products and technologies.

## Behind the Development of a Next-Generation Antibody Engineering Technology

In October 2010, Chugai announced in the November issue of *Nature Biotechnology* its establishment of an innovative antibody engineering technology that will greatly advance antibody drug discovery worldwide. The new technology enables a single antibody molecule to bind with a target antigen multiple times, which was previously impossible for conventional monoclonal antibodies.

The impetus for creating the new technology was Chugai's desire to create a "next-generation Actemra" that would significantly improve convenience for patients. Bringing the substantial benefits of Actemra to a larger number of patients requires a smaller-dose formulation with a sustained effect to supplement the existing intravenous formulation. In developing next-generation Actemra, we devised measures to extend the serum half-life, and used repeated trial and error to create an antibody with an affinity hundreds of times stronger than Actemra. Despite these efforts, we were unable to come close to our target using conventional antibody engineering technology.

Our options were limited with conventional monoclonal antibodies, which can bind to a target antigen only once. We wondered if there was any way to get a single antibody to block a target antigen repeatedly. From that thought, the project team came up with an idea: Using the difference in the pH of plasma and cells, an antibody that has bound to a target antigen in plasma could enter a cell, where only the antigen would be released and degraded. The antibody would then be "recycled"

back extracellularly, where it would be able to bind to another target antigen. I decided that we should go all-out to test this idea, which could potentially overturn the conventional wisdom on antibody engineering. However, the only way to prove our hypothesis was to create and validate antibodies that actually had this property. Based on the amino acid sequence of Actemra, we simply kept repeating the research cycle of designing, producing and evaluating modified antibodies, one after another. In total, we evaluated some 2,000 different modified antibodies. It was a race against time. One day, after spending a year and a half on this, we finally succeeded in producing an antibody with the target property. Preclinical studies demonstrated a more than four-fold improvement in the duration of antigen receptor blockade compared with Actemra.

The factors that enabled us to accomplish this technological breakthrough are the extensive experience and knowledge of antibody drugs that Chugai had amassed over 20 years, and the conviction and tenacity of its researchers who are experts on the properties of antibodies. In the course of developing this new technology, we also built up the world's leading antibody molecular structure optimization system to evaluate large numbers of modified antibodies. That system has become a new framework supporting our antibody technology.

Our development of antibody drugs is especially intense now, because it will determine whether we have a groundbreaking technology that can differentiate our products. The technology we established will bring significant benefits for patients, such as a lower dosage and reduced dosing frequency. It will also play a pivotal role in the discovery of first-in-class drugs because it opens up the possibility of targeting antigens that are present in large quantities in the body, which was impossible with conventional monoclonal antibodies. In addition to being of great significance for our discovery of innovative new drugs in terms of competitive advantage, it is also a technology that should be universally applied when developing antibody drugs, and thus represents a major contribution to the advancement of this field. We plan to take steps to improve this new technology, including licensing it out to other companies, and aim to create a system for it be applied routinely in antibody drug discovery.



**Kunihiro Hattori**  
Department Manager,  
Genome Antibody Product  
Research Department,  
Research Division

# Drug Safety

**Enhancing safety evaluations and providing extensive safety information are important for promoting appropriate use of pharmaceuticals and acceptance by patients and healthcare providers. Chugai has linked its drug safety operations directly with management as it works to fortify its safety evaluation system and bring it to a world-class level.**

## Drug Safety Approach and System

It is the duty of companies that manufacture and sell pharmaceuticals to collect, analyze and study data on drug safety (including the incidence of adverse drug reactions) and efficacy even after the drug is launched in the market. The April 2005 revision of Japan's Pharmaceutical Affairs Law clarifies the responsibilities of drug manufacturers, requiring them to establish three key manufacturing and marketing positions<sup>1</sup> and to carry out Good Vigilance Practice<sup>2</sup> and Good Quality Practice.<sup>3</sup>

One of Chugai's characteristics as a drug manufacturing and sales company is that it handles numerous biopharmaceuticals, molecular targeted therapies and other pharmaceuticals with novel mechanisms of action. Innovative drugs draw attention for their high efficacy, but promoting appropriate use and providing adequate safety information so that they are accepted by patients and healthcare providers are also key issues. In July 2009, therefore, Chugai separated the Drug Safety Unit from the Corporate Regulatory Compliance & Quality Assurance Division and established the Drug Safety Division to directly link drug safety operations to management. The managers in the three key manufacturing and marketing positions will continue to maintain solid coordination while working to build a world-class safety system.

1. General Marketing Authorization Holder (MAH) Manager, Pharmacovigilance Manager, and Quality Assurance Manager

2. Standards for pharmacovigilance management

3. Standards for quality assurance management of pharmaceuticals and other products

## Measures to Evaluate Safety

### Post-Marketing Studies

The objectives of post-marketing studies are to collect and evaluate information on the safety and efficacy of drugs after their market launch. They must be conducted according to Good Post-Marketing Study Practice<sup>4</sup> guidelines.

At Chugai, the Drug Safety Division is responsible

for planning post-marketing studies, managing their progress and analyzing the results in coordination with product lifecycle teams and the Sales Division. Medical representatives (MRs) handle tasks such as requests to medical institutions, data collection and follow-up. Like clinical studies, post-marketing studies are conducted according to fixed protocols under binding agreements with medical institutions. We collect the data forms through electronic systems and other means, and analyze the aggregate data. MRs then share this evaluated safety information with the medical institutions when the final report is published.

4. Standards for conducting surveillance and studies after market launch.

### Adverse Drug Reaction Reports and Information Disclosure

In general, adverse drug reactions reported by medical institutions are evaluated from three aspects: 1) the cause-and-effect relationship with the drug administered; 2) whether or not the adverse drug reaction was previously known (for example, whether or not it was listed on the package insert); and 3) the severity of the adverse drug reaction. In the case of serious adverse drug reactions for which a causal relationship cannot be ruled out, we issue individual reports to domestic and overseas regulatory authorities within a specified period. Adverse events that were previously unknown and are not serious are included in periodic reports.

In addition to reports to regulatory authorities, Chugai compiles information on and typical examples of potential risk factors for the inherent adverse drug reactions of each product. We distribute leaflets containing information on adverse drug reactions to patients and medical institutions and post similar information on our website, while MRs respond to inquiries from medical institutions individually. These activities help to reduce the incidence of serious adverse drug reactions and facilitate early detection by enabling healthcare providers to monitor high-risk patients for any adverse events.



## Global Safety Evaluation System

Pharmacovigilance has become increasingly important worldwide in recent years. There is a growing consensus that companies should collect and analyze information continuously from the pre-clinical stage and conduct comparative evaluations that consider the risk/benefit profile, rather than the previous approach of focusing on post-marketing surveillance alone. The European Medicines Evaluation Agency (EMA), the US Food and Drug Administration (FDA) and other regulatory agencies are also placing greater emphasis on pharmacovigilance in the drug approval process.

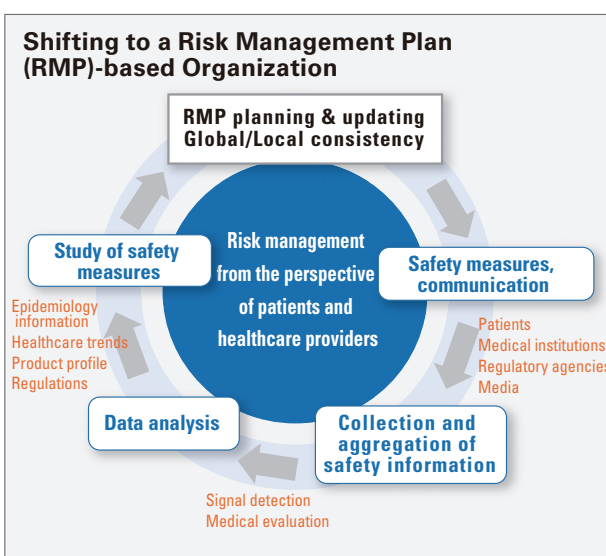
In light of these trends, Chugai has set up a world-class safety management system that can accommodate the different review procedures of regulatory agencies in Japan, the United States and Europe. We have also made pharmacovigilance agreements with Roche and other alliance partners. By establishing uniform safety evaluation standards for each product, compiling individually evaluated data in a safety information database, and creating a shared platform, we can accumulate and assess safety information on a global scale. Strengthening such collaborative arrangements will enhance the quality of our pharmacovigilance activities.

## Enhancing Drug Safety

Chugai recognizes that implementing the plan-do-check-act cycle in pharmacovigilance is a key to maintaining and improving world-class drug safety functions. We are shaping our organizational structure to

ensure that safety operations are executed in accordance with our risk management plan, including enhancement of our analytical capabilities from an epidemiological perspective. In January 2011, we set up an internal group in charge of epidemiology functions, with the aim of quickly improving the precision of data analysis. In addition, we are actively recruiting medical doctors to strengthen medical evaluation of safety information.

Making sure that healthcare providers and patients understand the risks is critical for the safe use of pharmaceutical products. Chugai is proactively building a more robust safety evaluation system because we realize that contributing to better care for patients involves not just looking at the benefits, but also reducing the risks of a given treatment.



### All-Patient Registration Surveillance

All-patient registration surveillance is post-marketing surveillance aimed at promoting appropriate use by quickly obtaining information on a drug's safety and efficacy. It covers all treatment facilities and all patients using the drug, so pharmaceutical manufacturers give substantial attention to aspects such as thorough distribution management and verification of usage conditions. Real-time submission of reports is required due to the necessity of simultaneous safety measures. Due to the significant burden the surveillance places on medical institutions, a key issue going forward will be how to lessen the burden on healthcare professionals while ensuring the quality of surveillance results.

For innovative drugs, all-patient registration surveillance is often imposed as a condition when the drug is approved. Chugai has conducted large-scale surveillance for Avastin, Actemra and Tarceva. This condition was lifted for Avastin and Actemra in 2010, and Chugai is now providing information based on the safety and efficacy data obtained from the surveillance so that more patients can use these drugs appropriately.

# Human Resources Strategy

**At Chugai, we understand that our employees are invaluable assets and the key to our continued progress toward becoming a top Japanese pharmaceutical company. We are striving to build a solid base of human capital and to create rewarding work environments that develop the capabilities of individual employees.**

## Basic Policy and the Ideal Employee Model

Chugai's fundamental principle is that its employees are invaluable assets for generating the growth of the company. We offer a range of programs suited to individual employee needs, with the aim of creating work environments where employees have rewarding jobs that let them develop personally.

At the same time, for continuous development toward becoming a top Japanese pharmaceutical company, we have defined our ideal employee in terms of not only skills, but also fundamental attributes that we call the "three contributions": contribution to patients, contribution to pharmaceuticals, and contribution to colleagues. We create and organize all our employee training programs based on this concept. In developing skill sets, five types of development opportunities – on-the-job training, off-the-job training and self-development, personnel treatment, career development, and reassignment and promotion – are organically linked so that human resources development can be conducted on a daily basis.

### Number of Employees (Consolidated)

2006	2007	2008	2009	2010
5,905	6,257	6,383	6,485	6,709

## Recent Initiatives

We believe that creating a vibrant workplace that gives employees choice and self-reliance in their careers is vital in becoming a top Japanese pharmaceutical company. Chugai offers various career development programs that include the opportunity to take up to three years leave for education or to acquire professional qualification, and an internal recruiting system for advertising job openings inside the Company. Our goal is to create a work environment that allows Chugai to take advantage of the diversity of its employees.

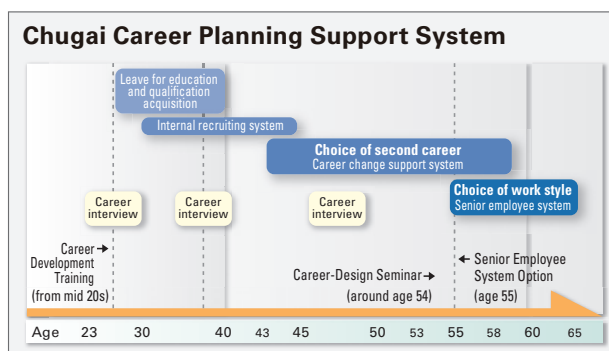
The number of female employees at Chugai is increasing, and creating an environment that allows them to maximize their potential has been a key theme in recent years. We have introduced various systems and programs to enable these employees to continue working while raising their families: childcare leave, a

working parent program, and an internet program that supports employees on maternity leave or childcare leave in returning to work. In 2008, Chugai received the "Kurumin Mark," a certification given by Japan's Ministry of Health, Labour and Welfare, for the Company's active support of work/life balance. Since then, Chugai has continued to enhance these measures. We have established a new plan that enables MRs to change their working arrangements after marriage, thus allowing them to continue in the same jobs, and held a forum for female MRs to think about their career paths.

Against the backdrop of Japan's aging population, we are creating a working environment that effectively uses the experience and expertise of senior employees. Chugai's former system, which gave senior employees the option to continue working after the mandatory retirement age of sixty, will be replaced with a new senior employee system in 2011. The new system revises the previous restrictions on employment status and job type to offer more flexible ways of working to employees from age 55 up to age 65. We believe this will give seniors a forum in which to contribute while broadening each employee's options.

Fostering an environment in which contract employees can make use of their skills with a high degree of motivation is also important. In 2011, we introduced a system that allows contract employees to convert to permanent employee status after working at Chugai and consistently demonstrating their abilities for a certain length of time.

In order to become a top Japanese pharmaceutical company, we are building a solid base of human capital by creating a rewarding work environment for every employee and by taking a proactive approach to human resources.



# 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.**

## Contribution for Patients

### Developing and Providing Innovative Drugs

Chugai creates innovative drugs and develops technologies that contribute to medical treatment around the world, with an emphasis on unmet medical needs. In 2010, Chugai researchers established an innovative antibody engineering technology that disproves the conventional wisdom about monoclonal antibodies. This technology greatly broadens the scope of possibilities in antibody drug discovery.

### Raising Patient Awareness

To support cancer patients and their families, Chugai participates in and sponsors a variety of activities. In 2010, we helped to promote accurate knowledge and awareness about cancer by serving as a special sponsor for "Medicine and Humor," a charity event for psychological care for cancer patients.

We also energetically provide information to the public. Chugai's Cancer Information Guide, a website for patients launched in 2009, received the grand prize in the medical information category of the *Gan ga Wakaru* ("Understanding Cancer") Web Awards.<sup>1</sup> This website was recognized for its usefulness to visitors, with the industry's first navigation tool that guides users to easy-to-understand explanations suited to the patient's specific condition by physicians. In January 2011, Chugai also launched a disease awareness website for rheumatoid arthritis (RA) where visitors can find the latest information on RA and easily comprehensible explanations of topics such as the importance of early treatment.

1. Presented by QLife, Inc., a general healthcare media company, to promote the diffusion of information on cancer. Winners were selected from more than 100 disease awareness sites.

## Contribution for Society

### Collecting Funds for Social Contributions

In May and June 2010, Chugai participated in the Roche Children's Walk, a charity event conducted globally by the Roche Group. More than 4,000 employees from the Chugai Group<sup>2</sup> took part in the sponsored walk, collecting funds for Roche to support children in Malawi, Africa who have lost parents to AIDS and other diseases.

2. Chugai Pharmaceutical Co., Ltd. and its domestic consolidated subsidiaries

## Contribution for Employees

### Supporting Employees in Building Rewarding Careers

Chugai has a variety of support programs to help employees build rewarding careers. The Career Support Center, established in 2007, made a new start in July 2010 as the Human Resources Management Department's Career Support Group. It will continue to provide multifaceted support to meet the diverse career needs of Chugai employees.

## Protection of the Environment

### Countering Global Warming

The Chugai Group set the goal of reducing its CO<sub>2</sub> emissions to the level of 2003 by 2012, and had been taking energy-reduction initiatives at its plants and research laboratories. However, CO<sub>2</sub> emissions have been on the rise due to new construction and expansion of facilities, making achievement of the goal difficult.

Following the new, legally mandated amount for CO<sub>2</sub> emission reduction introduced in 2010, Chugai revised its medium-term plan to set a new target for reducing emissions (GJ per employee), i.e., 10 percent reduction of 2009 CO<sub>2</sub> emission levels in 2014.<sup>3</sup> All Chugai employees will make a concerted effort to achieve this new target. In addition to ongoing measures to reduce energy consumption at all our business sites, we will also continue to introduce hybrid cars and energy-saving equipment to help reduce CO<sub>2</sub> emissions.

3. The Roche Group's target for reduction of energy consumption per employee, including vehicle gasoline consumption and business trip flights (1.8GJ/1,000km per employee) (GJ: gigajoule, or 10<sup>9</sup> joules)



Chugai's Corporate Social Responsibility Report CSR '10 presents the Company'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 2010.

**The full report is on our website:**

<http://www.chugai-pharm.co.jp/english/csr/index.html>

# Corporate Governance and Internal Controls

**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.

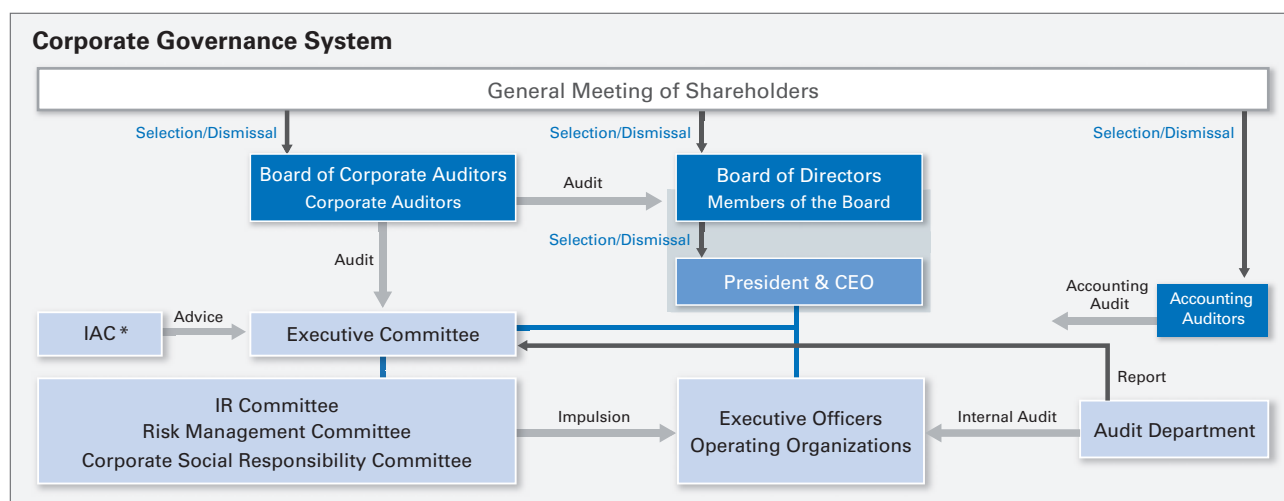
### Board of Directors

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 2010, the Board of Directors convened eight times.

### Executive Committee

The Executive Committee makes important executive decisions. It consists of 14 members, including the president, key executive officers and the 2 full-time corporate auditors.

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



\*See page 49 for details.

## 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 eight board meetings in 2010 was approximately 62 percent on average, the highest being 100 percent and the lowest 33 percent.

### Reasons for Election of Outside Directors

Name	Outside Position	Reason for Election
<b>Mitsuo Ohashi</b>	Adviser, SHOWA DENKO K.K.	Recommended or appointed as the Company expects that he would provide advice and monitoring by leveraging his abundant experience and knowledge of corporate management and other fields. Designated as independent director based on the Company's judgment that such position is not applicable to the provisions of stock exchange regulations and that there is no risk of conflict with the interests of shareholders in general.
<b>Yasuo Ikeda</b>	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	Recommended or appointed as the Company believes that he can properly execute the duties of an outside director by leveraging his abundant experience and knowledge of medicine and medical care as a doctor and university professor.
<b>Abraham E. Cohen</b>	Chairman, Chugai Pharma USA, LLC	Recommended or appointed as the Company expects that he would provide advice and monitoring by leveraging his abundant experience and knowledge of management in the global pharmaceutical business.
<b>William M. Burns</b>	Director, Roche Holding Ltd.	Board and managerial members of the Roche Group, to which the Company belongs. Recommended or appointed as the Company expects that members would point out issues and provide advice with respect to management and business of the Company, leveraging their abundant experience and knowledge of the Roche global perspective in the management of the pharmaceutical business.
<b>Pascal Soriot</b>	COO, Roche Pharmaceuticals and Member of the Corporate Executive Committee	
<b>Jean-Jacques Garaud</b>	Head of Roche Pharma Research & Early Development (pRED) and Member of the Enlarged Corporate Executive Committee	
<b>Daniel Zabrowski</b>	Head of Roche Partnering and Member of the Enlarged Corporate Executive Committee	

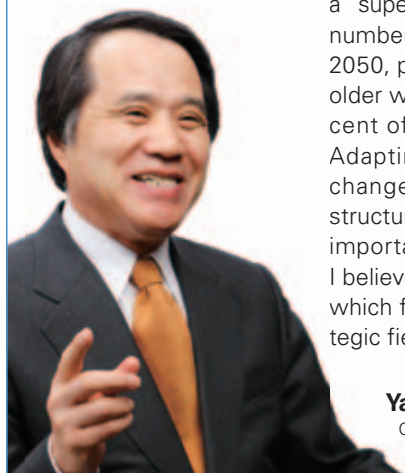
### Outside Director's Comment

Nearly a year has passed since I became a director of Chugai. I realize I am expected not only to apply my experience as a medical researcher and clinician to R&D, post-marketing development and other operations, but also to play a major role in establishing the corporate governance necessary to be a global leader in the pharmaceutical industry.

Japan is rapidly becoming a "super-aging society." The numbers tell the story: By 2050, people aged 65 and older will make up 40 percent of the population. Adapting healthcare to changes in the disease structure will be critically important. In that context, I believe that Chugai – which focuses on the strategic fields of oncology,

bone and joint diseases, renal diseases, diabetes and the central nervous system – is well-positioned to become one of Japan's top companies and an industry leader around the world in the near future. One key to supporting efficient development of safe, highly effective new medicines will be fostering human resources who can put Chugai's corporate philosophy into practice. We also hope to establish a system for efficient collaboration with researchers and healthcare professionals in Japan and abroad.

In recent years, healthcare providers have diversified, but it is important for everyone involved in the field to remember that patients are at the center of everything we do, and to constantly think about what we can do for them. I also want Chugai employees to think of themselves as healthcare professionals at the forefront of Japan's pharmaceutical industry and medical community under the strong leadership of President Nagayama. As a director, I am delighted to have the opportunity to support Chugai's progress by maintaining a dialogue with employees.



**Yasuo Ikeda**  
Outside Director



## 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 2010, the IAC meeting convened in Kyoto for a lively exchange of opinions regarding the path Chugai should take and important issues the industry will face.

### IAC Chairman

- **Mr. Abraham E. Cohen**  
Chairman, Chugai Pharma USA, LLC

### IAC Advisors

- **Dr. Andrew von Eschenbach**  
Former commissioner of the Food and Drug Administration
- **Professor Victor Halberstadt**  
Professor, Leiden University
- **Mr. Andre Hoffmann**  
Vice Chairman, Roche Holdings
- **Mr. Robert A. Ingram**  
Vice Chairman of Pharmaceuticals, GlaxoSmithKline plc, acting as special advisor to the Group
- **Dr. Keith Jones, M.D.**  
Former Head of the EMEA
- **Dr. Arnold J. Levine**  
Professor at the Institute for Advanced Study, Princeton University  
Discoverer of the p53 cancer suppressor protein
- **Mr. Henry L. Nordhoff**  
Chairman of the Board, Gen-Probe, Inc.
- **Professor Abraham D. Sofaer**  
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**  
Senior Advisor, Mori Building Co., Ltd.

## 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.

## Audit Department

The Audit Department, consisting of 16 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 internal control assessments based on the Financial Instruments and Exchange Act (informally known as J-SOX) to maintain sound operations.

## Accounting Auditors

From 2011, Chugai has changed its accounting auditors from Ernst & Young ShinNihon LLC to KPMG AZSA & Co., which conducts accounting audits and internal control audits in accordance with the Corporation Law and the 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.

## Officer Remuneration

Chugai's fundamental policy for remuneration of directors and corporate auditors is to facilitate maximization of the Chugai Group's corporate value. Remuneration levels and the remuneration system are designed to link compensation of officers with the Company's performance and promote shared values with shareholders.

Remuneration of directors consists of three components: regular compensation, which is fixed; bonuses paid according to performance; and stock options granted as a long-term incentive. These components are paid by resolution of the Board of Directors based on the Company's criteria within the limits on remuneration approved by the general meeting of shareholders. The Remuneration Committee, composed of outside directors and people with experience as outside directors,

sets policies and details concerning remuneration of executive directors to ensure the objectivity and transparency of the compensation setting process.

Remuneration of outside directors and corporate auditors (including outside corporate auditors), which consists solely of fixed regular compensation, is paid by resolution of the Board of Directors for outside directors and through consultation with the Board of Corporate Auditors for corporate auditors. The amounts

are set within the limits approved by the general meeting of shareholders.

A resolution was passed in the 98th annual general meeting of shareholders held in March 2009 to abolish the retirement benefits system for directors. A resolution was passed in the 95th annual general meeting of shareholders held in March 2006 to abolish the retirement benefits system for outside directors and corporate auditors (including outside corporate auditors).

## Amount of Remuneration, etc., Paid to Directors and Corporate Auditors

(Millions of yen)

	Amount of Remuneration, etc.	Total Compensation by Type			
		Regular Compensation	Bonuses	Common Stock Options	Stock Options as Stock-based Compensation
Directors (8) (excluding outside directors)	695	299	216	64	114
Outside Directors (4)	53	53	—	—	—
Total (12)	749	569		64	114
Corporate Auditors (2) (excluding outside corporate auditors)	62	62	—	—	—
Outside Corporate Auditors (2)	21	21	—	—	—
Total (4)	84	84		—	—

1. The table includes three directors 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 options, separately from the amount of remuneration, are ¥150 million per year for stock options as stock-based compensation and ¥125 million per year for common stock options 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 common stock options and stock options as stock-based compensation shown in the table are the amounts that were posted as expenses during the fiscal year under review.
5. The amount of bonuses shown in the table is the amount of the provision for bonuses to directors for the fiscal year under review.
6. Bonuses to directors for 2009 include ¥62 million paid to seven directors (internal) in addition to the ¥174 million provision for bonuses to directors.
7. 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 to make a final lump-sum payment equivalent to the retirement benefits that accrued up until the abolishment of the system to those directors whose terms extended past the conclusion of the 98th annual general meeting of shareholders. This payment will be made when the directors in question retire.  
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, and to make a final lump-sum payment equivalent to the retirement benefits that accrued up until the abolishment of the system to those directors and corporate auditors whose terms extended past the conclusion of the 95th annual general meeting of shareholders. This payment will be made when the directors and corporate auditors in question retire.  
In addition to the amounts shown in the table, directors' retirement benefits for the period from the appointment of each until the abolition of the system, based on the resolutions mentioned above, were paid as follows: Retiring Directors (internal) Two persons ¥34 million
8. In the fiscal year under review, the amount of remuneration, etc. received from the Roche Group by four directors, namely, Severin Schwan, William M. Burns, Erich Hunziker and Pascal Soriot, totaled ¥1,322 million (converted into yen at the averages of exchange rates in the fiscal year under review).

## 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 thereafter	Cooperate in maintaining Chugai's listing

## Disclosure Policy

Chugai pursues interactive corporate communication activities in an attempt to deepen mutual understanding and further enhance trust with its stakeholders, such as shareholders, investors, consumers, patients and health-care service providers. In order to achieve this objective, Chugai ensures that information related to its business activities is made available in a transparent, fair, and consistent manner to all stakeholders.

Chugai's policy for disclosing information to shareholders and investors is to make timely, consistent and fair disclosure of information in accordance with the Financial Instruments and Exchange Act and relevant rules of the stock exchange on which shares of Chugai are listed in order to receive fair valuation in the capital markets. In addition, measures to allow easy access to disclosed information have been established to ensure transparency.

The Corporate Communications Department is in charge of the internal framework for information disclosure. The IR Committee, chaired by the executive officer in charge of investor relations, formulates information disclosure policies and supervises disclosure activities.

Note: For further details on policies for disclosure to shareholders and investors, securities analysts and other capital market participants, please refer to Chugai's website (<http://www.chugai-pharm.co.jp/hc/ss/english/ir/policy/disclosure.html>)

## Communication with Shareholders and Investors

### General Meeting of Shareholders

Unlike many Japanese companies, which have fiscal years ending in March, Chugai's fiscal year ends in December. As a result, we are able to avoid holding our general meeting of shareholders on a day when many other companies' meetings are held. Convocation notices for the general meeting are sent out promptly, at least 20 days prior to the date of the general meeting of shareholders each year.

The 100th annual general meeting of shareholders was held on March 24, 2011. After the presentation of the business report through narration and materials, shareholders deliberated on agenda items such as appropriation of retained earnings and election of directors and corporate auditors. All agenda items were approved and passed by a majority.

### IR Activities

Chugai holds information meetings and conference calls for analysts and investors coinciding with the announcement of results for each quarter. In 2010, in addition to these regular IR events, we held an information meeting on rheumatoid arthritis treatment Actemra in September and an information meeting presented by President and CEO Osamu Nagayama and Roche Group CEO Severin Schwan in October. For overseas investors, Chugai's management holds roadshows in Europe, the United States and Asia. Additionally, we conduct information meetings for individual investors at branches of securities companies throughout Japan.

The Chugai website contains news releases, financial results, presentation materials and other information in Japanese and English, as well as webcasts of major IR events.

### External Recognition

Chugai is listed on the FTSE4Good Index Series, a representative global index for socially responsible investment (SRI). The FTSE4Good Index Series is maintained by the FTSE Group in the UK, which offers a variety of stock and other investment indices. This index tracks the stocks of about 2,400 listed companies in 23 countries worldwide that meet international criteria related to the environment and society. Chugai has been selected for this global SRI index in recognition of its corporate social responsibility initiatives relating to the environment, society and human rights.



## Internal Controls

### Basic Policy

Chugai believes that maintaining good internal controls 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.

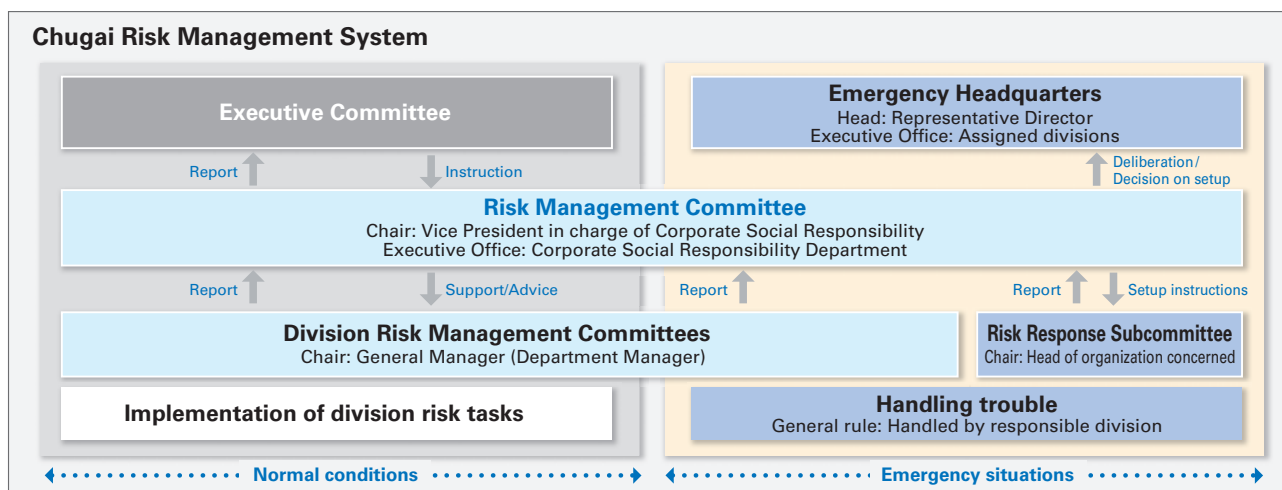
### Financial Reporting

Chugai has prepared for the new system of internal controls over financial reporting under the Financial Instruments and Exchange Act. 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. We select business processes to be assessed based on the results of the assessments of company-wide internal controls, and evaluate the design and operation of internal controls after identifying and analyzing financial reporting risks.

### Risk Management

(See pages 82-83 for details on business risks.)

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 24, 2011)

## Representative Directors



Osamu Nagayama



Motoo Ueno

## Directors



Ryuzo Kodama



Tatsumi Yamazaki



Tatsuro Kosaka



Mitsuo Ohashi  
Adviser,  
SHOWA DENKO K.K.



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 USA,  
LLC



William M. Burns  
Director of Roche Holding Ltd.



Pascal Soriot  
COO of Roche Pharmaceuticals and  
Member of the Corporate Executive  
Committee



Jean-Jacques Garaud  
Head of Roche Pharma Research & Early  
Development (pRED) and Member of the  
Enlarged Corporate Executive Committee



Daniel Zabrowski  
Head of Roche Partnering and  
Member of the Enlarged Corporate  
Executive Committee

## Corporate Auditors



Yasuhiro Tsuji  
(full-time)



Koutaro Miwa  
(full-time)



Yasunori Fujii  
Special Assigned Professor of  
Shizuoka Sangyo University



Toshio Kobayashi  
Partner, The Law Offices of  
Nagashima Ohno & Tsunematsu



# Executive Officers (As of April 1, 2011)



## Members of the Executive Committee:

from left (front) Tatsuro Kosaka, Ryuzo Kodama, Osamu Nagayama, Motoo Ueno, Tatsumi Yamazaki

(back) Koutaro Miwa, Shunji Yokoyama, Yoshio Itaya, Hidetoshi Ushio, Naotaka Nakamura, Yutaka Tanaka, Shin-ya Unno, Fumihiko Kamoshida, Yasuhiro Tsuji

## Executive Committee Members

### Osamu Nagayama

President  
CEO / COO

### Motoo Ueno

Deputy President  
Corporate Social Responsibility, Audit

### Ryuzo Kodama

Deputy President  
General Manager of IT Supervisory Div.

### Tatsumi Yamazaki

Deputy President

### Tatsuro Kosaka

Executive Vice President  
Business Development

### Naotaka Nakamura

Executive Vice President  
Wholesaler Business Planning

### Yutaka Tanaka

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

### 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  
CFO, General Manager of Finance Supervisory Div. and  
General Manager of Finance & Accounting Dept.

### Fumihiko Kamoshida

Senior Vice President  
General Manager of Legal Dept.

### Shunji Yokoyama

Vice President  
Head of Regulatory & Quality Management Unit and  
General Manager of Drug Safety Div.

## Executive Officers (Non-Executive Committee Members)

### Keiji Kono

Vice President  
Deputy Head of Lifecycle Management & Marketing Unit

### Hisafumi Okabe

Vice President  
General Manager of Research Div.

### Minoru Machida

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

### Yasushi Ito

Vice President  
General Manager of Clinical Development Div.

### Masaaki Tohaya

Vice President  
General Manager of Sales Div. and Head of Primary Unit

### Tetsuo Minoura

Vice President  
Deputy General Manager of Sales Div.

### Akio Tanaka

Vice President  
Deputy General Manager of Sales Div. and Head of Oncology Unit

### Katsuyori Kunii

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

### Toshitaka Uto

Vice President  
Supervisory Branch Manager of Tokyo Branch 1

### Susumu Kato

Vice President  
Supervisory Branch Manager of Osaka Branch

### 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 Dept.

### Toshihiko Tsuchiya

Vice President  
General Manager of Secretarial Dept.



# Supporting

## Facts and Figures

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# Development Pipeline (As of February 2, 2011)

Development Code (*Additional Indication)	Indication	Status Phase I	Phase II	Phase III	Filed	Approved
<b>Oncology</b>						
RG435*	Breast cancer					Oct. 2009
	Gastric cancer				(Multinational study)	
	Breast cancer (adjuvant)				(Multinational study)	
	Glioblastoma				(Multinational study)	
	Glioblastoma (relapsed)					
EPOCH*	Chemotherapy-induced anemia					Nov. 2009
RG340*	Gastric cancer					Sep. 2010
RG597*	Gastric cancer					Mar. 2010
RG1415*	Pancreatic cancer					Sep. 2009
	Non-small cell lung cancer (first-line treatment)					
RG1273*	Breast cancer				(Multinational study)	
RG3502	Breast cancer					
TP300	Gastric cancer, etc.		(Overseas)			
MRA*	Pancreatic cancer		(I / II)			
AF802	Non-small cell lung cancer		(I / II)			
WT4869	Myelodysplastic syndromes		(I / II)			
CIF (RG7167)	Solid tumors					
		(Overseas)				
CKI27 (RG7304)	Solid tumors					
		(Overseas)				
GC33	Liver cancer					
		(Overseas)				
PA799	Solid tumors		(Overseas)			
GA101 (RG7159)	Non-Hodgkin's lymphoma					
<b>Bone and Joint Diseases</b>						
MRA*	Systemic onset juvenile idiopathic arthritis (sJIA)					Oct. 2010 (Overseas)
	Rheumatoid arthritis (new formulation: subcutaneous injection)					
					(Overseas)	
RG484	Osteoporosis				(II / III)	
SA237	Rheumatoid arthritis					
<b>Renal Diseases</b>						
RG744	Renal anemia					Jul. 2009
<b>Transplant, Immunology and Infectious Diseases</b>						
RG964*	Compensated liver cirrhosis caused by hepatitis C virus					Oct. 2010
RG442*	Compensated liver cirrhosis caused by hepatitis C virus					Oct. 2010
	Chronic hepatitis B					Jan. 2011
<b>Other Diseases</b>						
CSG452 (RG7201)	Type 2 diabetes					
RG1678	Schizophrenia				(Multinational study)	
RG1583 (ITM-077)	Type 2 diabetes					
RG1450	Alzheimer's disease					

Generic Name / Product Name	Origin (Collaborator)	Mode of Action
bevacizumab / Avastin (Overseas name: Avastin)	Roche	Anti-VEGF (vascular endothelial growth factor) humanized monoclonal antibody (Injection)
epoetin beta / Epogin	In-house	Recombinant human erythropoietin (Injection)
capecitabine / Xeloda (Overseas name: Xeloda)	Roche	Antimetabolite, 5-FU derivative (Oral)
trastuzumab / Herceptin (Overseas name: Herceptin)	Roche	Anti-HER2 humanized monoclonal antibody (Injection)
erlotinib HCl / Tarceva (Overseas name: Tarceva)	Roche / OSI	EGFR tyrosine kinase inhibitor (Oral)
pertuzumab / Product name undetermined	Roche	HER dimerization inhibitory humanized monoclonal antibody (Injection)
—	Roche	Anti-HER2 humanized monoclonal antibody-drug conjugate (T-DM1) (Injection)
—	In-house	Topoisomerase I inhibitor (Injection)
tocilizumab / Actemra	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody (Injection)
—	In-house	ALK inhibitor (Oral)
—	In-house / Dainippon Sumitomo Pharma	WT1 peptide cancer vaccine (Injection)
—	In-house (Roche)	MEK inhibitor (Oral)
—	In-house (Roche)	Raf and MEK dual inhibitor (Oral)
—	In-house (Roche)	Humanized anti-Glypican-3 monoclonal antibody (Injection)
—	In-house	(Oral)
—	Roche	Humanized anti-CD20 monoclonal antibody (Injection)
tocilizumab / Actemra (Overseas name: Actemra (US), RoActemra (EU))	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody (Injection)
ibandronate sodium hydrate / Product name undetermined (Overseas name: Boniva (US), Bonviva (EU))	Roche (Taisho Pharmaceutical)	Bisphosphonate (Injection) Bisphosphonate (Oral)
—	In-house	Humanized anti-human IL-6 receptor monoclonal antibody (Injection)
epoetin beta pegol (Overseas name: Mircera)	Roche	Continuous erythropoietin receptor activator (Injection)
ribavirin / Copegus (Overseas name: Copegus)	Roche	Anti-viral agent, in combination with Pegasys (Oral)
peginterferon alfa-2a / Pegasys (Overseas name: Pegasys)	Roche	Peginterferon alfa-2a agent (recombinant) (Injection)
tofogliflozin / Product name undetermined	In-house (Roche)	SGLT2 inhibitor (Oral)
—	Roche	GLYT1 inhibitor (Oral)
taspoglutide / Product name undetermined	Roche / Ipsen (Teijin)	GLP-1 analogue (Injection)
gantenerumab / Product name undetermined	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 2009, national medical expenses totaled ¥34,808.4 billion, a ¥672.5 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. The 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 declined by 1.23 percent overall on a medical cost basis, or 5.75 percent on a reimbursement price basis.

#### Impact of NHI Drug Price Revision

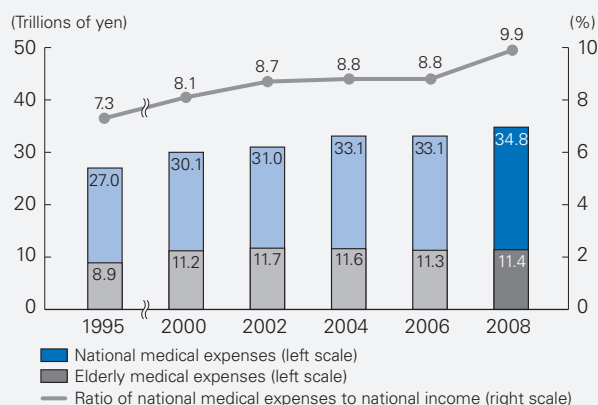
NHI Drug Price Reduction Rate (%)	2006	2008	2010
Industry Average	6.7	5.2	6.5
Chugai	7.2	7.2	6.8

Source: Chugai data

#### Incentives to Promote New Drug Development

In December 2009, the Central Social Insurance Medical Council, which advises the MHLW, approved the FY2010 Framework for Drug Pricing Reimbursement System Reforms. With this approval, a new pricing scheme has been implemented on a trial basis as part of the NHI 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 NHI drug price revisions a premium equal to the weighted-average percentage price difference of all listed drugs minus 2 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> Companies receiving the premium pricing will be requested to develop drugs selected by a panel of the MHLW that have not yet obtained approval in Japan or are approved for other indications. This system was introduced on a trial basis for the NHI drug price revisions for the year ending March 2011 only. For revisions in the year ending March 2013 and thereafter, it is expected that decisions

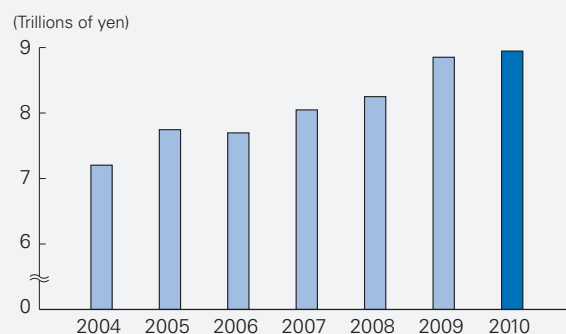
#### Trends in National and Elderly Medical Expenses



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 2009 by the Cabinet office).

#### Prescription Drug Market



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will be made based on the status of efforts to develop unapproved drugs or drugs approved for other indications, financial condition and other factors.

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.

### Changes to Promote Use of Generics

The 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 20.3 percent as of March 2010 to 30 percent or more by the year ending March 2013.

## Oncology

### Overview of Diseases and Treatment Methods

#### Leading Cause of Death in Japan

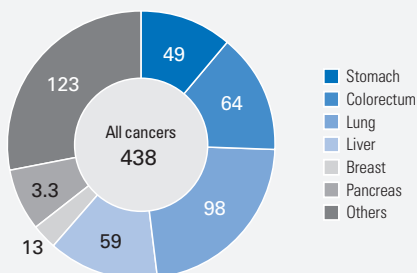
Cancer has been the single most common cause of death in Japan since 1981. In 2009, 344,105 people died of cancer, accounting for 30.1 percent of all deaths in that year and the highest figure recorded since government surveys began in 1899.

#### 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.

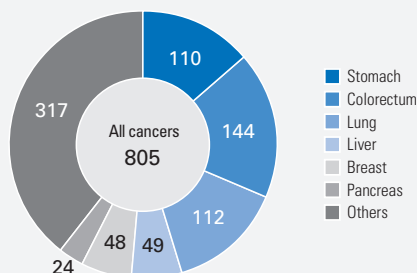
#### Cancer Mortality (Estimates for 2015)

(Thousands of cases)



#### Cancer Incidence (Estimates for 2015)

(Thousands of cases)



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

## 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. Major 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 October 2010 there were 451 such specialists. Moreover, there is a growing multidisciplinary 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, the 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 development of those drugs in Japan.

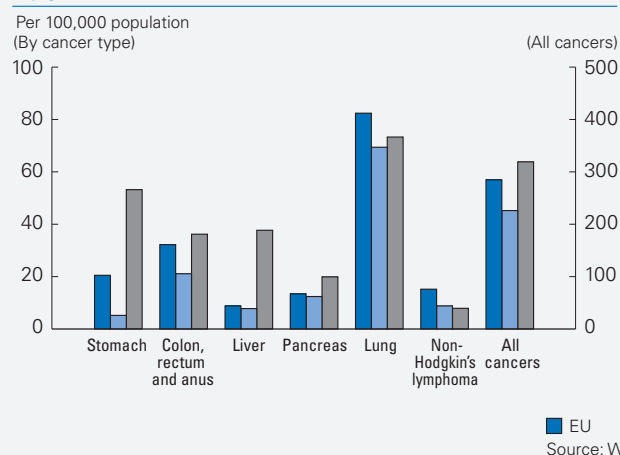
MHLW has also reinforced several functions of the Pharmaceutical and Medical Devices Agency, an independent administrative institution responsible for reviewing drugs and medical devices for approval. Measures include increasing the number of staff involved in the reviewing process, introducing a project management system under which a dedicated staff is appointed to oversee the progress, providing guidelines on multinational 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

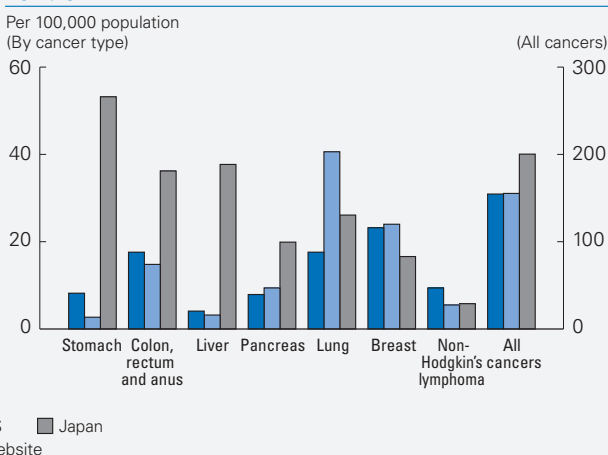
Cancer treatment is increasingly being based on a multidisciplinary approach that combines surgery, radiation therapy and anticancer agents. In particular, the field of anticancer agents is evolving, and highly innovative medications such as molecular targeted drugs have been introduced. This has brought about a dramatic

## International Comparison of Cancer Mortality Rates (2005)

### Male



### Female



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. 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.

In March 2010, Chugai filed an application in Japan seeking additional approval of a combination therapy of Herceptin and Xeloda for the treatment of HER2-positive advanced or recurrent gastric cancer. In May 2010, the MHLW designated this application for priority review based on a comprehensive evaluation of the severity of the disease and the therapeutic value of the products, and Chugai obtained approval in March 2011.

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

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, Chugai obtained approval for the additional indication of advanced or recurrent non-squamous non-small cell lung cancer. As a condition of Avastin's approval for the treatment of advanced or recurrent colorectal cancer,

post-marketing surveillance of all patients was required. This condition was lifted in September 2010 after Chugai submitted safety and efficacy data on 2,699 patients to the MHLW.

### 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 anti-cancer 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) has obtained approval for treating patients with advanced or recurrent colorectal cancer. In February 2011, Xeloda obtained approval for advanced or recurrent gastric 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 by Roche, Genentech and OSI Pharmaceuticals in Europe and the United States, where it has obtained approval for the second-line treatment of advanced non-small cell lung cancer and the first-line treatment of metastatic pancreatic cancer. In Japan, Tarceva has obtained approval 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 has already obtained approval in over 100 countries around the world as a breast cancer treatment for postmenopausal women and it is a standard of care in endocrine therapy. 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 the standard five years of endocrine therapy to prevent recurrence 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. 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 are currently under way.

\* 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.

**CIF (RG7167)**

CIF is a targeted small-molecule agent from Chugai research. Chugai has licensed CIF to Roche overseas, and the two companies are co-developing it for the treatment of solid tumors. Phase I clinical trials are currently under way in Japan and overseas.

**CKI27 (RG7304)**

CKI27 is a dual Raf and MEK inhibitor from Chugai research. Chugai has licensed CKI27 to Roche overseas, and the two companies are co-developing it for the treatment of solid tumors. Phase I clinical trials are currently under way in Japan and overseas.

**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. GC33 was licensed out to Roche in January 2011, and Phase I clinical trials are currently under way in Japan and overseas.

**RG1273**

RG1273 (pertuzumab) is a monoclonal antibody licensed from Roche. This is the first in a new class of targeted agents known as HER dimerization inhibitors. Chugai is participating in Roche's multinational 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. A phase II domestic clinical trial for the treatment of HER2-positive breast cancer started in October 2010.

**AF802**

AF802 is a targeted molecular therapy from Chugai research that is being developed for the treatment of non-small cell lung cancer. It inhibits the activity of EML4-ALK, a recombinant kinase expressed in about 5 percent of non-small cell lung cancers. Phase I/II clinical trials started in Japan in September 2010.

**PA799**

PA799 is an oral agent from Chugai research that is being developed for the treatment of solid tumors. Overseas phase I clinical trials started in August 2010.

**WT4869**

A product of joint research with Dainippon Sumitomo Pharma Co., Ltd. based on the results of clinical research by Dr. Haruo Sugiyama, Professor of Osaka University Graduate School of Medicine. WT4869 is a cancer peptide vaccine for patients with myelodysplastic syndromes that targets the WT1 protein, a product of Wilms' tumor gene 1. It induces WT1-specific cytotoxic T-lymphocytes (CTLs), which attack tumor cells that express the WT1 protein. It is thus expected to demonstrate therapeutic efficacy against leukemia and other types of cancer that express WT1.

## 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 MHLW 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 K.K. 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.

### Edirol (ED-71)

Edirol (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 entered into 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 of Edirol in Japan in October 2009 and obtained approval in January 2011.

### RG484

**(overseas product name: Bonviva/Boniva)**

RG484 (ibandronate sodium hydrate) is a bisphosphonate licensed from Roche 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 entered into a co-development and co-marketing agreement with Taisho Pharmaceutical in September 2006. Phase II clinical trials for the oral formulation and phase II/III clinical trials for the injectable formulation are currently under way.

## 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 is thought to occur in 80 percent or more of people 60 years of age or older.

### Treatment Methods and Market Conditions

RA has been conventionally treated with antirheumatic drugs, anti-inflammatory analgesics and steroids, 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\$7 billion in 2009, 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 provided 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 not high, and more useful drugs are needed.

### Regulatory Trends

In October 2005, the MHLW 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 was designated as the Bone and Joint Decade, and academic societies and other players aggressively promoted research, diagnosis and treatment of osteoarthritis.

### Overview of Products and Development Projects 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. Because its physical and chemical properties are close to that of natural hyaluronic acid, the superior performance of Suvenyl over low molecular weight hyaluronic acid has been recognized.

### Actemra

Actemra, the first antibody drug created in Japan, blocks the activity of interleukin-6 (IL-6), a type of cytokine. It was first launched in Japan in 2006 as a treatment for Castleman's disease. In April 2008, we obtained domestic approval for the additional indications of RA, polyarticular-course juvenile idiopathic arthritis (pJIA) and sJIA. The high expectations placed by physicians in this new drug are shared by patients for whom conventional RA treatments, including existing biologics, have failed to be effective.

Actemra is marketed globally through Roche. In the European Union, where it is known as RoActemra, sales of the drug have started for the treatment of RA. In the United States, Actemra obtained approval 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.

The requirement for post-marketing all-patient registration surveillance as a condition of Actemra's approval in Japan was lifted in August 2010 for RA and pJIA. All-patient registration surveillance for sJIA and Castleman's disease is ongoing, and patient registration continues.

## SA237

SA237, a compound from Chugai research, is a next-generation antibody drug that has shown success in blocking IL-6 receptors for an extended period of time. It is being developed as a treatment for RA. A novel antibody technology established by Chugai enables a single antibody molecule to block the target antigen multiple times. Chugai created SA237 by applying this technology to Actemra, a humanized anti-human IL-6 receptor monoclonal antibody. Preclinical studies have verified that SA237 can continuously block IL-6 receptors more than four times longer than Actemra. This sustained efficacy is expected to lead to greater convenience for patients by allowing them to take smaller, less frequent doses. A phase I clinical trial started in December 2010.

## 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 60ml/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. The MHLW has started 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 approximately 291,000 people as of December 2009, partly due to increased use of dialysis in patients with diabetes-related renal disease. Expenses for EPO preparations, 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\* 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.

\* 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

### 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. Since its launch in 1990, Epogin has been widely used in the clinical setting for its approved indications of renal anemia under dialysis and before dialysis, and anemia of prematurity. In June 2010, Epogin Subcutaneous Injection Syringe 24000 obtained approval for autologous blood transfusion of 800ml or more for a patient's scheduled surgery with a blood collection period of more than one week.

### 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. It 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. Chugai filed for approval of RG744 in July 2009.

### 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 insufficient.

## 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 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. In April 2010, the hepatitis B and C medical expense subsidy program was expanded.

#### 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 the 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. Chugai is 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.

In October 2010, Chugai applied for approval of the combination therapy of Pegasys and Copegus for the additional indication of compensated liver cirrhosis caused by hepatitis C virus. The MHLW designated this application for priority review in January 2011 based on a comprehensive evaluation of the severity of the disease and the therapeutic value of the drugs.

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.

## 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 the 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. The 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 Sigmart

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 an injectable formulation 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 the 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)

A compound from Chugai research, CSG452 (tofogliflozin) is an oral hypoglycemic agent that is expected to be effective in the treatment of type 2 diabetes. Chugai licensed the drug to Roche in January 2007. 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. Phase III clinical trials started in November 2010.

## 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 Projects

### RG1678

RG1678, a small-molecule compound licensed from Roche, is expected to be effective in treating schizophrenia. Chugai joined Roche's multinational phase III clinical study in January 2011.

## 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 Projects

### RG1450

RG1450 (gantenerumab) is a human anti-amyloid-beta-peptide monoclonal antibody licensed from Roche. Phase I clinical trials investigating RG1450 as a potential treatment for AD are currently under way.



# Performing

## **Financial Section**

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# 11-Year Financial Summary

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

	2010/12	2009/12	2008/12	2007/12
Revenues	379,510	428,947	326,938	344,808
Sales	375,560	419,106	321,836	332,943
Other operating revenues	3,950	9,841	5,102	11,865
Cost of sales	162,418	192,851	127,029	137,293
(Percentage of revenues)	42.8%	45.0%	38.9%	39.8%
Selling, general and administrative expenses	96,151	98,168	95,121	86,569
(Percentage of revenues)	25.3%	22.9%	29.1%	25.1%
Research and development expenses	54,703	55,315	53,225	54,243
(Percentage of revenues)	14.4%	12.9%	16.3%	15.7%
Operating income	66,238	82,613	51,563	66,703
(Percentage of revenues)	17.5%	19.3%	15.8%	19.3%
Net income (loss)	41,433	56,634	39,265	40,061
(Percentage of revenues)	10.9%	13.2%	12.0%	11.6%
Total assets	508,016	540,549	478,518	458,942
Property, plant and equipment, net	87,954	93,663	98,346	92,495
Interest-bearing debt	150	154	305	775
Total net assets <sup>2</sup>	449,395	434,687	397,067	385,798
Return on equity <sup>3</sup>	9.4%	13.7%	10.1%	10.4%
Return on assets <sup>4</sup>	7.9%	11.1%	8.4%	17.4%
Net income per share (basic) (Yen)	76.14	104.00	72.07	73.23
Net income per share (diluted) (Yen)	76.12	103.98	72.04	73.16
Net assets per share (Yen)	821.87	794.51	725.18	703.80
Cash dividends per share <sup>5</sup> (Yen)	40.00	40.00	34.00	30.00
Payout ratio	52.5%	38.5%	47.2%	41.0%
Shareholders' equity to total assets	88.0%	80.0%	82.6%	83.5%
Capital investments	12,662	14,630	26,570	19,609
Depreciation and amortization	17,983	19,506	20,080	14,914
Number of employees	6,709	6,485	6,383	6,257

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. Net assets include minority interests from 2006 in accordance with a revision to regulations for consolidated financial statements in Japan.

3. Return on equity = Net income/Shareholders' equity (average of beginning and end of fiscal year) x 100

4. Return on assets = Net income/Total assets (average of beginning and end of fiscal year) x 100

5. 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 as otherwise specified)

2006/12	2005/12	2004/12	2003/12 <sup>1</sup>	2003/3	2002/3	2001/3
326,109	327,155	294,671	232,748	237,391	211,705	203,005
—	—	—	—	—	—	—
—	—	—	—	—	—	—
133,086	119,423	111,108	83,541	79,385	64,962	62,046
40.8%	36.5%	37.7%	35.9%	33.4%	30.7%	30.6%
80,067	78,505	83,900	62,963	79,178	72,189	69,527
24.6%	24.0%	28.5%	27.1%	33.4%	34.1%	34.2%
54,609	50,058	48,166	43,525	48,511	47,845	41,189
16.7%	15.3%	16.3%	18.7%	20.4%	22.6%	20.3%
58,347	79,169	51,497	42,719	30,317	26,709	30,243
17.9%	24.2%	17.5%	18.4%	12.8%	12.6%	14.9%
38,418	53,632	34,117	28,446	(20,135)	14,598	15,500
11.8%	16.4%	11.6%	12.2%	—	6.9%	7.6%
462,124	456,442	411,449	405,197	425,301	349,226	340,174
85,150	79,460	90,051	91,970	93,969	81,445	77,798
1,300	2,549	6,167	10,761	12,108	70,093	70,402
391,604	368,306	320,847	296,717	277,254	200,779	190,257
10.1%	15.6%	11.0%	9.9%	—	7.5%	8.6%
8.4%	12.4%	8.4%	6.9%	—	4.2%	4.7%
69.35	97.00	62.27	51.73	(51.75)	57.93	61.70
69.26	96.33	61.34	50.94	—	49.09	52.18
703.08	665.29	583.61	542.96	503.41	796.97	754.99
30.00	34.00	18.00	13.00	16.00	16.00	16.00
43.3%	35.1%	28.9%	25.1%	—	27.6%	25.9%
84.3%	80.7%	78.0%	73.2%	65.2%	57.5%	55.9%
16,344	16,129	9,865	11,819	17,815	14,292	9,689
13,815	16,981	14,383	10,514	14,905	12,939	14,408
5,905	5,280	5,313	5,619	5,743	4,912	4,886



# Management's Discussion and Analysis

## Operating Environment

In April 2010, a new National Health Insurance (NHI) drug price system was introduced on a trial basis with the goal of promoting the creation of innovative drugs and eliminating the time lag in approval of new drugs developed overseas. However, 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.

## Management Policies

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.

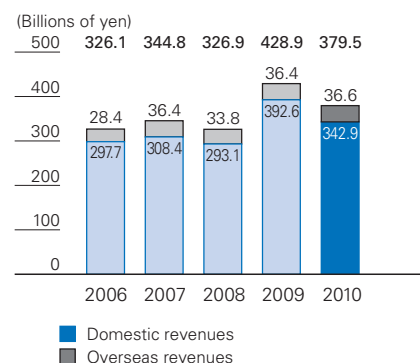
## Results

### Revenues

#### Overview of Revenues

In 2010, revenues decreased 11.5 percent compared with the previous fiscal year to ¥379.5 billion, due to a substantial decrease in sales of the anti-influenza agent Tamiflu, which vary widely from year to year. However, excluding sales of Tamiflu and other operating revenues, sales absorbed the impact of NHI drug price revisions, increasing 4.2 percent to a record ¥357.4 billion.

### Revenues



## Domestic Sales by Field

Domestic sales excluding Tamiflu increased 4.9 percent compared with the previous fiscal year to ¥324.4 billion. Sales in the oncology field increased a substantial 14.1 percent to ¥141.2 billion, and Chugai maintained the number-one share (18.4 percent)\* of the domestic oncology market. This achievement was the result of the steady market penetration of core products including Avastin, an anti-vascular endothelial growth factor (VEGF) humanized monoclonal antibody that is steadily establishing a position as a first- and second-line treatment. Increased sales of these products more than compensated for lower sales of Herceptin, an anti-HER2 humanized monoclonal antibody that underwent an NHI drug price recalculation, and Kytril, a 5-HT<sub>3</sub> receptor antagonist that has been affected by the large number of competing generics.

In the bone and joint diseases field, sales continued their upward trend with an 8.7 percent increase compared with the previous fiscal year to ¥62.6 billion. The market share of Actemra, a humanized anti-human IL-6 receptor monoclonal antibody, has steadily increased since Chugai obtained approval for additional indications including rheumatoid arthritis in April 2008.

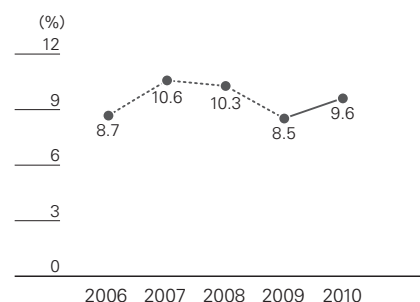
In the renal diseases field, sales decreased 5.9 percent compared with the previous fiscal year to ¥57.4 billion. Sales of the recombinant human erythropoietin Epogin decreased due to an NHI drug price revision and intensifying competition.

In the transplant, immunology and infectious diseases field, sales (excluding Tamiflu) decreased 1.5 percent compared with the previous fiscal year to ¥25.8 billion due to the impact of NHI drug price revisions and market contraction. However, peginterferon alfa-2a Pegasys and anti-viral agent Copegus both captured solid market share gains as a result of the spread of Pegasys/Copegus combination therapy for chronic hepatitis C since April 2008.

Sales of anti-influenza agent Tamiflu decreased a substantial 76.1 percent compared with the previous fiscal year to ¥18.2 billion. The influenza A/H1N1 ("swine flu") pandemic of the 2009/2010 season quickly receded, while 2010/2011 seasonal influenza had not appeared by the end of the year. Seasonal sales totaled ¥1.6 billion, and sales to the government for pandemic stockpiles totaled ¥16.6 billion.

\* Copyright 2010 IMS Japan K.K. Source: JPM 2010.  
Reprinted with permission. The scope of the market is defined by Chugai.

## Overseas Sales Ratio



## Overseas Sales and Other Operating Revenues

Overseas sales decreased 1.8 percent compared with the previous fiscal year to ¥33.0 billion. Sales of recombinant human granulocyte colony-stimulating factor Neutrogin decreased significantly due to the impact of follow-on biologics and the appreciation of the yen. However, exports of Actemra to Roche (for sale in regions other than Japan, Korea and Taiwan) increased; this product obtained approval in the United States in January 2010 and is sold in more than 50 countries.

Other operating revenues decreased 60.2 percent compared with the previous fiscal year to ¥3.9 billion because of a decrease in milestone revenues.

## Cost of Sales and Gross Profit

Cost of sales decreased 15.8 percent compared with the previous fiscal year to ¥162.4 billion. Factors included the substantial decrease in sales of Tamiflu; growth in sales of Actemra, which Chugai created in-house; and the appreciation of the yen compared with previous fiscal year. The cost-to-sales ratio decreased 2.8 percentage points to 43.2 percent.

As a result of the above, gross profit decreased 8.0 percent compared with the previous fiscal year to ¥217.1 billion.

## Selling, General and Administrative Expenses and Operating Income

Selling, general and administrative (SG&A) expenses decreased 2.0 percent year-on-year to ¥96.2 billion. Chugai implemented detailed cost controls that included revising IT investment periods and adjusting advertising expenses. R&D expenses decreased 1.1 percent to ¥54.7 billion because Chugai introduced fewer large-scale themes than in the previous fiscal year.

As a result, operating income decreased 19.9 percent compared with the previous fiscal year to ¥66.2 billion, and the ratio of operating income to revenues decreased 1.8 percentage points to 17.5 percent.

## Other Income (Expenses) and Income before Income Taxes and Minority Interests

Other expenses totaled ¥0.6 billion, compared with other income of ¥6.8 billion for the previous fiscal year. Chugai uses forward foreign exchange contracts to cover substantial foreign currency transactions, centered on imports from Roche. In 2010, these forward foreign exchange contracts generated a loss on derivatives of ¥2.8 billion. Chugai recognized a net gain on restructuring costs of ¥0.5 billion associated with the closure of the Kamakura plant, compared with a net loss on restructuring costs totaling ¥1.2 billion in the previous fiscal year. Consequently, income before income taxes and minority interests decreased 26.5 percent to ¥65.7 billion.

## Net Income

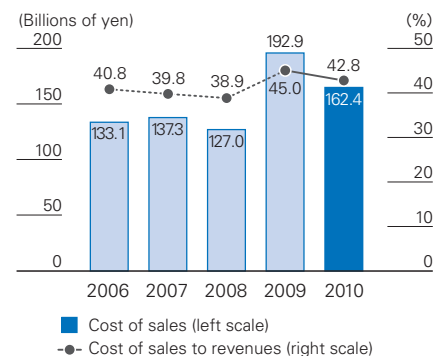
Income taxes totaled ¥23.1 billion and minority interests totaled ¥1.2 billion. As a result, net income decreased 26.9 percent compared with the previous fiscal year to ¥41.4 billion.

## Profitability Indicators (Consolidated Basis)

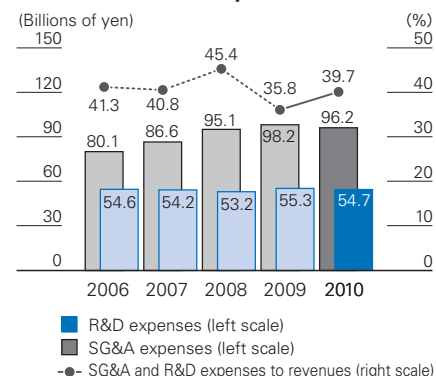
	2010	2009	2008	2007	2006
Gross profit ratio (%)	57.2	55.0	61.1	60.2	59.2
Operating income to revenues (%)	17.5	19.3	15.8	19.3	17.9
Return on assets (%)	7.9	11.1	8.4	17.4	8.4
Return on equity (%)	9.4	13.7	10.1	10.4	10.1

Notes: 1. Return on assets = Net income/Total assets (average of beginning and end of fiscal year) x 100  
2. Return on equity = Net income/Shareholders' equity (average of beginning and end of fiscal year) x 100

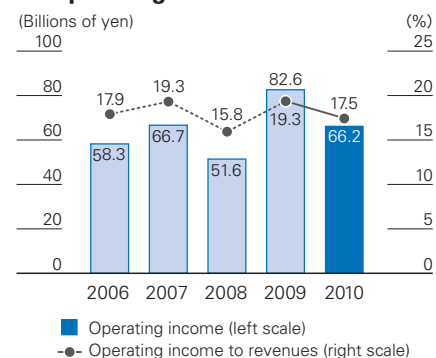
## Cost of Sales/ Cost of Sales to Revenues



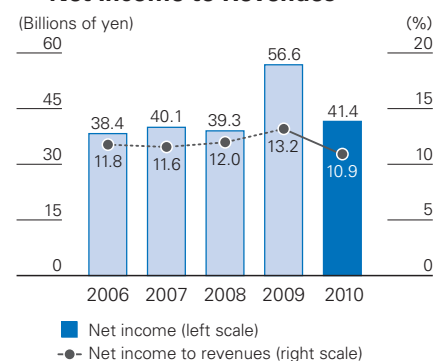
## SG&A and R&D Expenses/ SG&A and R&D Expenses to Revenues



## Operating Income/ Operating Income to Revenues



## Net Income/ Net Income to Revenues



## Financial Position

### Assets, Liabilities and Net Assets

#### Assets

As of December 31, 2010, total assets were ¥508.0 billion, a decrease of ¥32.5 billion, or 6.0 percent, compared with the end of the previous fiscal year. While inventories increased, cash and cash equivalents and trade notes and accounts receivable decreased.

Current assets decreased ¥24.8 billion, or 6.0 percent, compared with the end of the previous fiscal year to ¥386.5 billion. Cash and cash equivalents decreased ¥30.8 billion, or 28.8 percent, to ¥76.2 billion because of an increase in working capital and increased tax payments. Trade notes and trade accounts receivable decreased ¥8.2 billion, or 6.7 percent, to ¥113.4 billion. Trade receivables turnover decreased to 3.35 times from 3.53 times for the previous fiscal year.

Inventories increased ¥12.3 billion, or 13.3 percent, compared with the end of the previous fiscal year to ¥104.9 billion. Key factors included a year-on-year decrease in shipments of Tamiflu, which increased inventories of this product. In addition, Chugai prepared for increased demand for Actemra and other new products and products that have obtained approval for new indications by expanding inventories.

Property, plant and equipment, net decreased ¥5.7 billion, or 6.1 percent, compared with the end of the previous fiscal year to ¥88.0 billion. Depreciation exceeded the increase in assets from capital investments.

#### Liabilities

Total liabilities as of December 31, 2010 decreased ¥47.3 billion, or 44.7 percent, compared with the end of the previous fiscal year to ¥58.6 billion. Primary factors included a decrease in current liabilities of ¥45.9 billion, or 45.7 percent, to ¥54.6 billion due to decreases in income taxes payable and in trade notes and trade accounts payable.

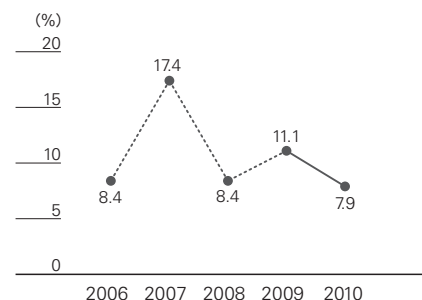
Trade notes and trade accounts payable decreased ¥14.8 billion, or 43.1 percent, compared with the end of the previous fiscal year to ¥19.5 billion. This decrease was primarily the result of reduced purchases of Tamiflu and products involved in the production site change resulting from the closure of the Kamakura plant. Trade payables turnover increased to 19.47 times from 12.52 times.

Income taxes payable decreased ¥18.4 billion, or 83.3 percent, compared with the end of the previous fiscal year to ¥3.7 billion. The main reason was that income taxes payable at the end of the previous fiscal year were greater because of the substantial increase in income for 2009.

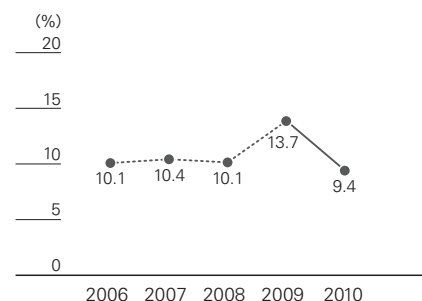
#### Net Assets

As of December 31, 2010, net assets totaled ¥449.4 billion, an increase of ¥14.7 billion, or 3.4 percent, compared with the end of the previous fiscal year. This increase was primarily the result of an increase of ¥19.6 billion in retained earnings. Net unrealized holding gain on securities totaled ¥1.3 billion, about the same level as a year earlier.

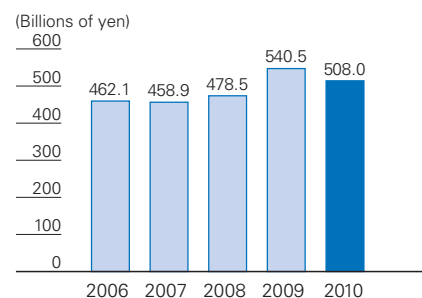
#### Return on Assets



#### Return on Equity



#### Total Assets



The ratio of shareholders' equity to total assets increased 8.0 percentage points from the end of the previous fiscal year to 88.0 percent. Net working capital (current assets minus current liabilities) totaled ¥332.0 billion, and the current ratio was 708.2 percent, reflecting the Company's sound financial position.

### Stability Indicators (Consolidated Basis)

	2010	2009	2008	2007	2006
Current ratio (%)	708.2	409.3	438.5	472.5	517.3
Fixed assets ratio (%)	27.2	29.9	34.0	33.7	32.0
Interest coverage ratio (times)	8,214.4	4,620.0	517.5	461.9	283.0
Debt-to-equity ratio (%)	0.0	0.0	0.1	0.2	0.3
Shareholders' equity to total assets (%)	88.0	80.0	82.6	83.5	84.3
Market value equity ratio (%)	159.6	175.2	196.2	189.9	294.4

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 Indicators (Consolidated Basis)

	2010	2009	2008	2007	2006
Total assets turnover (times)	0.72	0.84	0.70	0.75	0.71
Trade receivables turnover (times)	3.35	3.53	3.01	3.22	3.08
Inventories turnover (times)	3.62	4.63	4.15	6.25	5.30
Trade payables turnover (times)	19.47	12.50	11.37	19.90	11.59

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

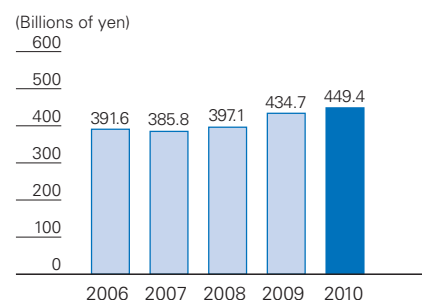
### Cash and Cash Equivalents

Cash and cash equivalents as of December 31, 2010 totaled ¥65.1 billion, a decrease of ¥29.4 billion from a year earlier.

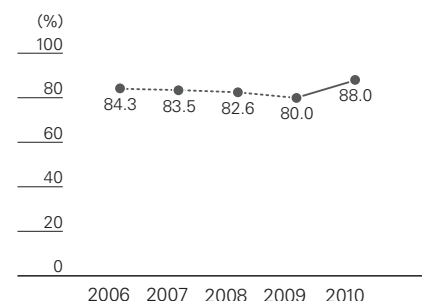
### Cash Flows from Operating Activities

Net cash provided by operating activities totaled ¥15.6 billion, down ¥50.9 billion from ¥66.5 billion provided in the previous fiscal year. Income before income taxes and minority interests of ¥65.7 billion was a primary source of cash. Depreciation and amortization totaled ¥18.0 billion. While reducing supplies for and shipments of Tamiflu, Chugai used cash totaling ¥14.7 billion to reduce notes and accounts payable. Increase in inventories used cash totaling ¥12.7 billion. Income taxes paid used cash totaling ¥38.9 billion.

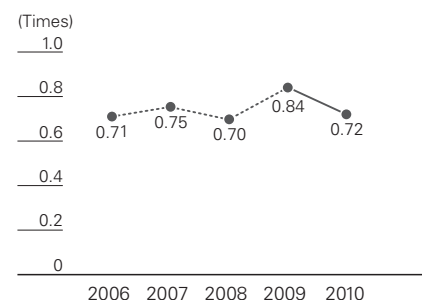
### Net Assets



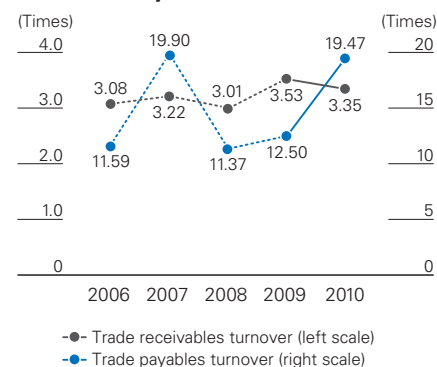
### Shareholders' Equity to Total Assets



### Total Assets Turnover



### Trade Receivables Turnover/Trade Payables Turnover





### Cash Flows from Investing Activities

Net cash used in investing activities totaled ¥20.2 billion, down ¥0.1 billion from ¥20.3 billion used in the previous fiscal year. Net proceeds from sales of marketable and investment securities used cash totaling ¥5.9 billion. Purchases of fixed assets less proceeds from sales of fixed assets used net cash totaling ¥13.5 billion. Purchases of fixed assets included capital investments to enhance research facilities and equipment at the Fuji-Gotemba Research Laboratories and the solid agent facility at the Fujieda plant.

### Free Cash Flow

Free cash flow was negative ¥4.6 billion, a year-on-year change of ¥50.8 billion compared to free cash flow of ¥46.2 billion for the previous fiscal year.

### Cash Flows from Financing Activities

Net cash used in financing activities totaled ¥23.1 billion, up ¥0.8 billion from the previous fiscal year. A primary factor was cash dividends paid totaling ¥21.8 billion, reflecting a special cash dividend of ¥6.00 per share in addition to the year-end dividend for 2009 and the interim dividend for 2010.

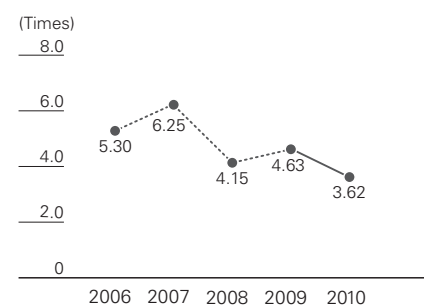
### Cash Flows (Consolidated Basis)

(Millions of yen)

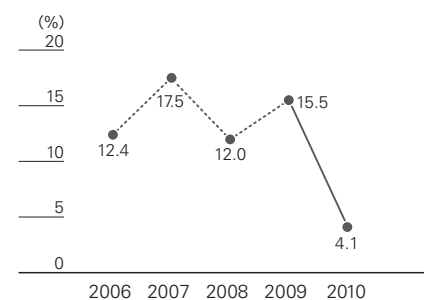
	2010	2009	2008	2007	2006
Net cash provided by operating activities	15,572	66,461	39,277	60,365	40,539
Net cash used in investing activities	(20,192)	(20,261)	(14,122)	(7,510)	(29,371)
Net cash used in financing activities	(23,055)	(22,252)	(18,361)	(47,173)	(18,797)
Effect of exchange rate changes on cash and cash equivalents	(1,660)	(128)	(9,865)	(292)	1,581
Net increase (decrease) in cash and cash equivalents	(29,335)	23,820	(3,071)	5,390	(6,048)
Cash and cash equivalents at beginning of year	94,478	70,652	73,723	68,333	74,381
Increase in cash and cash equivalents resulting from merger with unconsolidated subsidiaries	—	6	—	—	—
Cash and cash equivalents at end of year	65,144	94,478	70,652	73,723	68,333
Net cash provided by operating activities to revenues (%)	4.1	15.5	12.0	17.5	12.4
Capital investments to net cash provided by operating activities (%)	81.3	21.9	67.6	32.5	40.3
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)

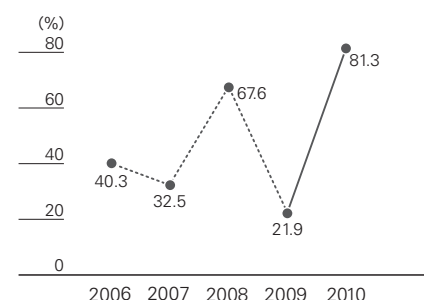
### Inventories Turnover



### Net Cash Provided by Operating Activities to Revenues



### Capital Investments to Net Cash Provided by Operating Activities

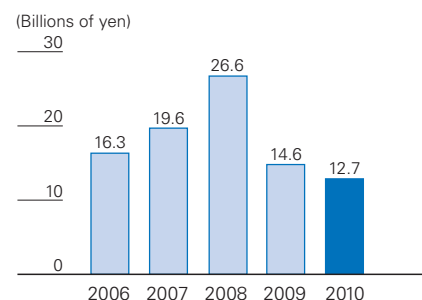


## Capital Investments

Capital investments decreased 13.0 percent compared with the previous fiscal year to ¥12.7 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 and amortization decreased 7.7 percent to ¥18.0 billion.

In 2011, Chugai projects capital investments of about ¥14.0 billion and depreciation of about ¥17.0 billion.

### Capital Investments



## Per Share Data

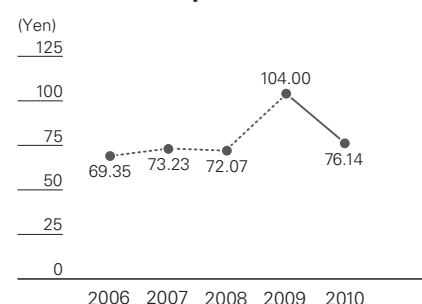
Net income per share for 2010 decreased ¥27.86 compared with the previous fiscal year to ¥76.14. Net income per share on a fully diluted basis was ¥76.12. Net assets per share increased ¥27.36 compared with the previous fiscal year to ¥821.87.

### Per Share Data (Consolidated Basis)

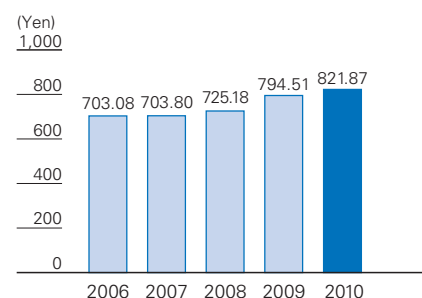
	2010	2009	2008	2007	2006
Net income per share (basic)	76.14	104.00	72.07	73.23	69.35
Net income per share (diluted)	76.12	103.98	72.04	73.16	69.26
Net assets per share	821.87	794.51	725.18	703.80	703.08
Cash dividends per share	40.00	40.00	34.00	30.00	30.00
Payout ratio (%)	52.5	38.5	47.2	41.0	43.3

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

### Net Income per Share



### Net Assets per Share



## Outlook for 2011

### Forecast Assumptions

For 2011, Chugai assumes exchange rates of ¥85/CHF, ¥110/EUR, ¥85/USD, and ¥131/GBP, and that the scale of seasonal influenza will be about the same as the average for the past 10 years, excluding the influenza A/H1N1 pandemic in the 2009/2010 season. Please note that this forecast also assumes that the statutory tax rate will be reduced 5 percentage points from the fiscal year beginning April 1, 2011, according to FY2011 Tax Reform (Main Points).

### Results Forecast

Chugai expects revenues to increase 6.2 percent year-on-year to ¥403.0 billion.

Chugai forecasts that domestic sales, excluding Tamiflu, will increase 5.1 percent compared with the previous fiscal year to ¥340.8 billion, supported by continued year-on-year growth in sales of Avastin and other oncology drugs, as well as sales of Actemra, and the launch of Edirol. Overseas sales are forecast to increase 17.3 percent to ¥38.7 billion as a result of factors including an increase in exports due to growth in overseas sales of Actemra.

R&D expenses and SG&A expenses are expected to increase, reflecting

increased activities to promote the proper use of new products and products with extended indications, and progress in development themes. However, growth in gross profit is expected to exceed growth in expenses. Consequently, operating income for the fiscal year is forecast to increase 13.3 percent compared with the previous fiscal year to ¥75.0 billion. The application of the Accounting Standard for Asset Retirement Obligations and a temporary increase in the effective tax rate accompanying tax reform will offset improvement in other income and expenses absent the impact of the foreign exchange loss for 2010. As a result, Chugai forecasts that net income will increase 2.7 percent to ¥42.5 billion.

## Fundamental Profit Distribution Policy and Dividends

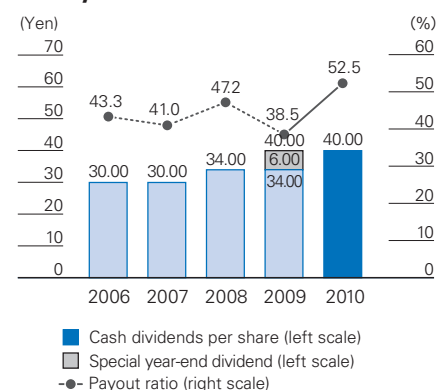
Chugai aims to provide shareholders with stable dividends. The Company's goal is to maintain the consolidated payout ratio at 40.0 percent or more on average, taking into account strategic funding needs and earnings prospects.

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 2010 totaled ¥40.00 per share, consisting of an interim dividend of ¥17.00 per share and a year-end dividend of ¥23.00 per share. Thus, cash dividends per share for 2010 were the same as for the previous fiscal year, and the consolidated payout ratio was 52.5 percent.

Chugai projects total cash dividends of ¥40.00 per share for 2011, including an interim dividend of ¥20.00 per share, and a consolidated payout ratio of 51.2 percent.

**Cash Dividends per Share/ Payout Ratio**



## 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, 2010.

### 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)
	2010	2009	2010
Current assets:			
Cash and cash equivalents (Notes 13 and 20) .....	¥ 76,213	¥ 106,978	\$ 929,427
Marketable securities including short-term investments (Notes 13 and 14).....	59,700	52,158	728,049
Receivables (Notes 13 and 21):			
Trade notes .....	17	17	207
Trade accounts .....	113,374	121,590	1,382,610
Other .....	7,902	11,902	96,366
Reserve for doubtful accounts .....	(6)	(35)	(73)
Inventories (Note 5) .....	104,885	92,642	1,279,085
Deferred tax assets (Note 10).....	19,927	21,059	243,012
Other.....	4,526	4,992	55,195
Total current assets .....	386,538	411,303	4,713,878
Property, plant and equipment, at cost (Note 17):			
Land .....	9,894	9,894	120,659
Buildings and structures .....	125,874	124,162	1,535,049
Machinery and equipment .....	127,512	121,621	1,555,024
Construction in progress.....	2,010	1,530	24,512
Other.....	45	18	549
	265,335	257,225	3,235,793
Accumulated depreciation (Note 6).....	(177,381)	(163,562)	(2,163,183)
Property, plant and equipment, net.....	87,954	93,663	1,072,610
Investments and other assets:			
Investment securities (Notes 13 and 14) .....	7,527	9,596	91,793
Unconsolidated subsidiaries and affiliates .....	61	61	743
Long-term loans .....	19	33	232
Lease deposits.....	4,229	4,032	51,573
Deferred tax assets (Note 10).....	14,939	14,594	182,183
Other.....	6,749	7,267	82,305
Total investments and other assets .....	33,524	35,583	408,829
Total assets.....	¥ 508,016	¥ 540,549	\$ 6,195,317

See accompanying notes to consolidated financial statements.

Liabilities and net assets	Millions of yen		Thousands of U.S. dollars (Note 4)
	2010	2009	2010
Current liabilities:			
Payables (Notes 13 and 21):			
Trade notes .....	¥ 1	¥ 1	\$ 12
Trade accounts .....	19,489	34,263	237,671
Construction .....	5,301	6,203	64,646
Other .....	632	396	7,707
Income taxes payable (Note 10) .....	3,679	22,142	44,866
Accrued liabilities .....	23,492	31,870	286,488
Other .....	1,986	5,607	24,220
Total current liabilities .....	54,580	100,482	665,610
Long-term liabilities:			
Reserve for employees' retirement benefits (Note 11) .....	2,596	2,710	31,659
Reserve for officers' retirement benefits .....	729	762	8,890
Other .....	716	1,908	8,731
Total long-term liabilities .....	4,041	5,380	49,280
Contingent liabilities (Note 18)			
Net assets (Notes 8, 19, 22 and 23):			
Shareholders' equity:			
Common stock, without par value:			
Authorized: 799,805,050 shares			
Issued:			
December 31, 2010 and 2009 – 559,685,889 shares .....	72,967	72,967	889,841
Additional paid-in capital .....	92,815	92,815	1,131,890
Retained earnings .....	327,642	307,985	3,995,635
Treasury stock, at cost:			
December 31, 2010 – 15,491,466 shares .....	(36,256)	—	(442,146)
December 31, 2009 – 15,497,079 shares .....	—	(36,274)	—
Total shareholders' equity .....	457,168	437,493	5,575,220
Valuation, translation adjustments and others:			
Net unrealized holding gain on securities .....	1,341	1,636	16,354
Translation adjustments .....	(11,252)	(6,767)	(137,220)
Total valuation, translation adjustments and others .....	(9,911)	(5,131)	(120,866)
Stock subscription rights .....	775	537	9,451
Minority interests in consolidated subsidiaries .....	1,363	1,788	16,622
Total net assets .....	449,395	434,687	5,480,427
Total liabilities and net assets .....	¥508,016	¥540,549	\$6,195,317

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)
	2010	2009	2008	2010
Revenues (Note 21):				
Sales .....	¥375,560	¥419,106	¥321,836	\$4,580,000
Other operating revenues .....	3,950	9,841	5,102	48,171
	379,510	428,947	326,938	4,628,171
Cost of sales (Note 21) .....	162,418	192,851	127,029	1,980,708
Gross profit .....	217,092	236,096	199,909	2,647,463
Selling, general and administrative expenses .....	96,151	98,168	95,121	1,172,573
Research and development expenses (Note 21) .....	54,703	55,315	53,225	667,110
Operating income .....	66,238	82,613	51,563	807,780
Other income (expenses):				
Interest and dividend income .....	450	753	2,034	5,488
Interest expense (Note 21) .....	(4)	(20)	(135)	(49)
Other (Note 9) .....	(998)	6,070	9,644	(12,170)
	(552)	6,803	11,543	(6,731)
Income before income taxes and minority interests .....	65,686	89,416	63,106	801,049
Income taxes (Note 10) .....	(23,096)	(31,183)	(22,276)	(281,659)
Minority interests .....	(1,157)	(1,599)	(1,565)	(14,110)
Net income (Note 23) .....	¥ 41,433	¥ 56,634	¥ 39,265	\$ 505,280

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, 2010, 2009 and 2008

	Thousands						Millions of yen					
	Number of shares issued (Note 19)	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
<b>Balance at December 31, 2007..</b>	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 20) .....	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)
<b>Balance at December 31, 2008..</b>	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
<b>Balance at December 31, 2009..</b>	559,686	72,967	92,815	307,985	(36,274)	437,493	1,636	(6,767)	(5,131)	537	1,788	434,687
Purchases of treasury stock .....					(10)	(10)						(10)
Disposition of treasury stock .....				(8)	28	20						20
Net income .....				41,433		41,433						41,433
Cash dividends paid .....				(21,768)		(21,768)						(21,768)
Net changes in items other than shareholders' equity .....							(295)	(4,485)	(4,780)	238	(425)	(4,967)
<b>Balance at December 31, 2010..</b>	<b>559,686</b>	<b>¥72,967</b>	<b>¥92,815</b>	<b>¥327,642</b>	<b>¥(36,256)</b>	<b>¥457,168</b>	<b>¥1,341</b>	<b>¥(11,252)</b>	<b>¥(9,911)</b>	<b>¥775</b>	<b>¥1,363</b>	<b>¥449,395</b>

	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
<b>Balance at December 31, 2009.....</b>	\$889,841	\$1,131,890	\$3,755,915	\$(442,366)	\$5,335,280		\$19,951	\$ (82,524)	\$ (62,573)	\$6,549	\$21,805	\$5,301,061
Purchases of treasury stock .....				(122)	(122)							(122)
Disposition of treasury stock .....			(97)	342	245							245
Net income .....			505,280		505,280							505,280
Cash dividends paid .....			(265,463)		(265,463)							(265,463)
Net changes in items other than shareholders' equity .....							(3,597)	(54,696)	(58,293)	2,902	(5,183)	(60,574)
<b>Balance at December 31, 2010.....</b>	<b>\$889,841</b>	<b>\$1,131,890</b>	<b>\$3,995,635</b>	<b>\$(442,146)</b>	<b>\$5,575,220</b>		<b>\$16,354</b>	<b>\$(137,220)</b>	<b>\$(120,866)</b>	<b>\$9,451</b>	<b>\$16,622</b>	<b>\$5,480,427</b>

# 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)
	2010	2009	2008	2010
<b>Cash flows from operating activities</b>				
Income before income taxes and minority interests .....	¥ 65,686	¥ 89,416	¥ 63,106	\$ 801,049
Adjustments to reconcile income before income taxes and minority interests to net cash provided by operating activities:				
Depreciation and amortization .....	17,983	19,506	20,080	219,305
Loss on impairment of fixed assets .....	41	27	748	500
Increase (decrease) in reserve for employees' retirement benefits .....	(107)	600	(510)	(1,305)
Interest and dividend income .....	(450)	(753)	(2,034)	(5,488)
Interest expense .....	4	20	135	49
Loss on disposal of fixed assets .....	210	212	357	2,561
Gain on sales of fixed assets .....	(18)	(264)	(411)	(220)
Loss (gain) on sales and revaluation of investment securities .....	(91)	13	20	(1,110)
(Increase) decrease in notes and accounts receivable ....	7,896	(12,966)	(2,504)	96,293
Increase in inventories .....	(12,716)	(13,484)	(25,562)	(155,073)
Increase (decrease) in notes and accounts payable ....	(14,676)	5,345	12,291	(178,976)
Increase (decrease) in accrued consumption taxes ....	(3,803)	4,447	(2,036)	(46,378)
Others .....	(5,947)	(2,294)	4,236	(72,524)
Subtotal .....	54,012	89,825	67,916	658,683
Interest and dividends received .....	432	736	1,586	5,268
Interest paid .....	(7)	(20)	(134)	(85)
Income taxes paid .....	(38,865)	(24,080)	(30,091)	(473,964)
Net cash provided by operating activities .....	15,572	66,461	39,277	189,902
<b>Cash flows from investing activities</b>				
Purchases of time deposits .....	(23,363)	(23,399)	(138)	(284,915)
Proceeds from withdrawal of time deposits .....	22,512	11,235	—	274,537
Purchases of marketable securities .....	(125,384)	(118,151)	(187,595)	(1,529,073)
Proceeds from sales of marketable securities .....	117,900	126,400	202,000	1,437,805
Purchases of investment securities .....	(5)	(631)	(4,005)	(61)
Proceeds from sales of investment securities .....	1,613	—	379	19,671
Purchases of fixed assets .....	(13,565)	(16,068)	(25,223)	(165,427)
Proceeds from sales of fixed assets .....	89	330	429	1,085
Other .....	11	23	31	134
Net cash used in investing activities .....	(20,192)	(20,261)	(14,122)	(246,244)
<b>Cash flows from financing activities</b>				
Net decrease in long-term debt .....	—	—	(305)	—
Net increase in treasury stock .....	(9)	(1,125)	(69)	(110)
Cash dividends paid .....	(21,759)	(19,620)	(16,335)	(265,354)
Cash dividends paid to minority interests .....	(1,277)	(1,503)	(1,652)	(15,573)
Other .....	(10)	(4)	—	(122)
Net cash used in financing activities .....	(23,055)	(22,252)	(18,361)	(281,159)
Effect of exchange rate changes on cash and cash equivalents .....	(1,660)	(128)	(9,865)	(20,243)
Net increase (decrease) in cash and cash equivalents ...	(29,335)	23,820	(3,071)	(357,744)
Cash and cash equivalents at beginning of year .....	94,478	70,652	73,723	1,152,183
Increase in cash and cash equivalents resulting from merger with unconsolidated subsidiaries .....	—	6	—	—
Cash and cash equivalents at end of year (Note 20) .....	¥ 65,144	¥ 94,478	¥ 70,652	\$ 794,439

See accompanying notes to consolidated financial statements.



# Notes to Consolidated Financial Statements

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries / December 31, 2010

## 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 years ended December 31, 2010 and 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(d).

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, 2010 and 2009, 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

Receivables and payables denominated in foreign currencies are translated into yen at the rates of exchange in effect at the balance sheet date, and differences arising from the translation are included in the consolidated statements of income.

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 which can easily be converted to cash and are subject to little risk of change in value.

### (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 plan assets as of the balance sheet date, as adjusted for unrecognized actuarial gain or loss and unrecognized prior service cost.

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 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 derivative transactions in order to manage certain risk arising from adverse fluctuation in foreign currency exchange 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 19.

### 3 Accounting Changes

- (a) 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.

- (b) 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 respectively from the corresponding amounts which would have been recorded under the previous method.

- (c) 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 lower compared to what would have been recorded under the

previous method. There was no effect on income before income taxes and minority interests.

- (d) 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 compared to what would have been recorded under the previous method. Also, revenue and operating income decreased by ¥312 million and ¥7 million, respectively, and income before income taxes and minority interests increased by ¥983 million over the corresponding amounts which would have been recorded under the previous method.

- (e) 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.

- (f) 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, 2010 have been translated from Japanese yen amounts at ¥82 = U.S.\$1.00, the exchange rate prevailing on December 31,

2010. 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, 2010 and 2009 consisted of the following:

December 31,	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Finished products .....	¥ 55,291	¥45,373	\$ 674,280
Work in process and semifinished products.....	34,177	26,337	416,793
Raw materials and supplies .....	15,417	20,932	188,012
	<u>¥104,885</u>	<u>¥92,642</u>	<u>\$1,279,085</u>

#### 6 Depreciation

Depreciation of property, plant and equipment for the years ended December 31, 2010, 2009 and 2008 amounted to ¥17,413 million (\$212,354 thousand), ¥18,047 million and ¥17,493 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, 2010 and 2009.

The Company has entered into loan commitment agreements amounting to ¥40,000 million (\$487,805 thousand) with ten banks. There were no loans payables outstanding at December 31, 2010 and 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, 2010, 2009 and 2008 were as follows:

Year ended December 31,	Millions of yen			Thousands of U.S. dollars
	2010	2009	2008	2010
Gain on sales of fixed assets .....	¥ 18	¥ 264	¥ 421	\$ 220
Gain (loss) on foreign exchange.....	877	(1,027)	6,255	10,695
Gain (loss) on sales of investment securities .....	94	—	—	1,134
Gain on settlement of co-development costs.....	—	—	6,341	—
Subsidies received for construction of a plant.....	50	—	500	610
Retirement benefit expenses .....	—	—	(107)	—
Gain (loss) on derivatives .....	(2,762)	7,328	(1,341)	(33,683)
Loss on disposal of fixed assets.....	(210)	(212)	(357)	(2,561)
Loss on impairment of fixed assets.....	(41)	(27)	(748)	(500)
Gain (loss) on restructuring costs, net .....	480	(1,228)	(536)	5,854
Loss on inventories (Note 3 (c)).....	—	—	(1,915)	—
Loss on sales of fixed assets.....	(0)	(1)	(10)	(0)
Other.....	497	973	1,141	6,061
	<u>¥ (998)</u>	<u>¥ 6,070</u>	<u>¥ 9,644</u>	<u>\$ (12,170)</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, 2010, 2009 and 2008. Income taxes for the years ended December 31, 2010, 2009 and 2008 consisted of the following:

Year ended December 31,	Millions of yen			Thousands of U.S. dollars
	2010	2009	2008	2010
Income taxes:				
Current .....	¥22,130	¥32,989	¥25,966	\$269,878
Deferred .....	966	(1,806)	(3,690)	11,781
	¥23,096	¥31,183	¥22,276	\$281,659

The significant components of deferred tax assets and liabilities at December 31, 2010 and 2009 were as follows:

December 31,	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Deferred tax assets:			
Prepaid expenses .....	¥ 8,567	¥10,323	\$104,476
Depreciation .....	6,202	5,780	75,634
Reserve for employees' retirement benefits .....	5,132	5,160	62,585
Amortization of deferred charges .....	4,636	4,367	56,537
Supplies .....	2,493	1,213	30,402
Reserve for bonuses to employees .....	1,783	2,309	21,744
Valuation loss on securities .....	1,231	1,222	15,012
Reserve for sales rebates .....	983	1,229	11,988
Unrealized profit on inventories .....	956	1,362	11,659
Enterprise tax payable .....	445	1,751	5,427
Reserve for officers' retirement benefits .....	294	308	3,585
Impairment loss on fixed assets .....	157	153	1,915
Other .....	5,626	4,436	68,609
Gross deferred tax assets .....	38,505	39,613	469,573
Valuation allowance .....	(2,149)	(2,292)	(26,207)
Amount offset by deferred tax liabilities .....	(1,490)	(1,668)	(18,171)
Deferred tax assets, net .....	¥34,866	¥35,653	\$425,195
Deferred tax liabilities:			
Unrealized gain on securities .....	¥ 905	¥ 1,108	\$ 11,037
Deferred gain on sales of properties for tax purposes .....	540	560	6,585
Other .....	45	0	549
Total deferred tax liabilities .....	1,490	1,668	18,171
Amount offset by deferred tax assets .....	(1,490)	(1,668)	(18,171)
Deferred tax liabilities, net .....	¥ —	¥ —	\$ —

A reconciliation of the statutory and effective tax rates for the years ended December 31, 2010, 2009 and 2008 is summarized as follows:

Year ended December 31,	2010	2009	2008
Statutory tax rate .....	40.4%	40.4%	40.4%
Permanently non-deductible expenses for tax purposes such as entertainment expenses .....	2.6	1.9	2.8
Permanently non-taxable income such as dividend income .....	(0.0)	(0.0)	(0.1)
Inhabitants' per capita taxes .....	0.2	0.1	0.2
Different tax rates applied to overseas subsidiaries .....	(1.1)	(1.8)	(1.7)
Tax credit for research and development expenses .....	(6.9)	(5.9)	(5.0)
Change in valuation allowance .....	0.1	0.1	(1.5)
Other .....	(0.1)	0.0	0.2
Effective tax rates .....	35.2%	34.9%	35.3%

## 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, 2010 and 2009 for the Company's and the consolidated subsidiaries' defined benefit plans:

December 31,	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Retirement benefit obligation .....	¥(66,208)	¥(65,350)	\$(807,415)
Plan assets at fair value .....	62,602	60,434	763,439
Funded status .....	(3,606)	(4,916)	(43,976)
Unrecognized prior service cost .....	(1,465)	(1,846)	(17,866)
Unrecognized actuarial loss .....	2,730	4,313	33,293
Net amount .....	(2,341)	(2,449)	(28,549)
Prepaid pension expense .....	255	261	3,110
Reserve for employees' retirement benefits .....	¥ (2,596)	¥ (2,710)	\$ (31,659)

### (c) Retirement benefit expenses

Year ended December 31,	Millions of yen			Thousands of U.S. dollars
	2010	2009	2008	2010
Service cost (*) .....	¥ 2,684	¥ 2,572	¥ 2,600	\$ 32,731
Interest cost .....	1,454	1,402	1,372	17,732
Expected return on pension plan assets .....	(1,312)	(1,271)	(1,377)	(16,000)
Amortization of actuarial differences .....	895	1,142	(134)	10,915
Amortization of prior service cost .....	(380)	(479)	(603)	(4,634)
Contribution payments to a defined contribution pension plan .....	832	803	754	10,146
Additional retirement benefits paid .....	—	55	—	—
Effect of application of the standard method for calculation of retirement benefit obligation (*) .....	—	—	107	—
Total .....	¥ 4,173	¥ 4,224	¥ 2,719	\$ 50,890

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

(\*) 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:

Year ended December 31,	2010	2009	2008
(1) Discount rates .....	Principally 2.25%	Principally 2.25%	2.25%
(2) Expected rates of return on plan assets .....	0.6% - 2.5%	0.8% - 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(e), 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, 2010 and 2009 would have been as follows:

December 31, 2010	Millions of yen			Thousands of U.S. dollars		
	Equipment	Software	Total	Equipment	Software	Total
Acquisition costs.....	¥1,068	¥3	¥1,071	\$13,024	\$37	\$13,061
Accumulated depreciation/amortization.....	662	2	664	8,073	25	8,098
Net book value.....	¥ 406	¥1	¥ 407	\$ 4,951	\$12	\$ 4,963

December 31, 2009	Millions of yen			Thousands of U.S. dollars		
	Equipment	Software	Total	Equipment	Software	Total
Acquisition costs.....	¥1,637	¥3	¥1,640			
Accumulated depreciation/amortization.....	924	1	925			
Net book value.....	¥ 713	¥2	¥ 715			

Rental expenses, primarily for office space and equipment, amounted to ¥4,131 million (\$50,378 thousand), ¥4,310 million and ¥4,358 million for the years ended December 31, 2010, 2009, and 2008, respectively.

Lease payments relating to finance leases accounted for as operating leases included in the above amounts totaled ¥303 million (\$3,695 thousand), ¥386 million and ¥387 million for the

years ended December 31, 2010, 2009 and 2008, 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, 2010 and 2009 for finance leases accounted for as operating leases are summarized as follows:

December 31,	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Due within one year.....	¥204	¥306	\$2,488
Due after one year.....	203	409	2,475
	¥407	¥715	\$4,963

Future minimum lease payments subsequent to December 31, 2010 and 2009 for noncancelable operating leases are summarized as follows:

December 31,	Millions of yen		Thousands of U.S. dollars
	2010	2009	2010
Due within one year.....	¥2,325	¥2,443	\$28,353
Due after one year.....	3,315	2,453	40,427
	¥5,640	¥4,896	\$68,780

## 13 Financial Instruments

### (a) Policies for financial instruments

The Company and its consolidated subsidiaries (collectively, the "Group") manage temporarily cash surpluses mainly through low risk and highly liquid financial assets. The Group makes use of derivatives to reduce risk, as explained below, and does not enter into derivatives for speculative or trading purposes.

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

In the course of its business activities, the Group is exposed to credit risk associated with trade notes and accounts receivable. In addition, the Group is exposed to foreign currency exchange risk arising from operating receivables denominated in foreign currencies.

Through its holdings of marketable securities and investment securities, the Group is exposed to market price risk. Those securities are composed of mainly bonds held for the investment of cash surpluses and the stocks of other companies with which it has business relationships.

The Group is exposed to foreign currency exchange risk arising from trade notes and accounts payable denominated in foreign currencies.

Regarding derivatives, the Group enters into forward foreign exchange contracts to reduce the risk of foreign currency exchange movements that arise from the receivables and payables denominated in foreign currencies.

**(c) Policies and processes for risk management****(1) Credit risk management**

In accordance with the internal policies prepared by the Company, regarding receivables, the management administration sections of operating units monitor the conditions of their main customers periodically, and monitor due dates and outstanding balances by individual customers. In addition, the Group is making efforts to identify and mitigate risks of bad debts from customers who are having financial difficulties.

When making use of derivatives, the Company arranges such transactions with highly creditworthy financial institutions to minimize counterparty risk.

**(2) Market risk management**

To manage foreign currency exchange risk arising from receivables and payables denominated in foreign currencies, the Company hedges such risk, mainly by entering into forward foreign exchange contracts. For marketable securities and investment securities, the Company reviews the market value of such securities periodically and monitors the financial position of the issuers (transaction partners). Also, for securities other than those classified as held-to-maturity, the Company reviews its portfolio of such securities on a continuing basis, taking into account market conditions and relationships with transactions partners. When making use of derivatives, the Company conducts such operations in accordance with its internal policies, and

monthly reports are prepared including the balances of such transactions, valuation gains and losses, and other related information. Furthermore, the consolidated subsidiaries do not utilize derivative transactions.

**(3) Liquidity risk management**

The Company manages liquidity risk by using its cash flow plans on a timely basis prepared and updated by the finance and accounting departments based on reports from each operational division.

**(d) Supplemental information on fair values**

The fair value of financial instruments is based on their quoted market price, if available. When there is no quoted market price available, fair value is reasonably estimated. Since various assumptions and factors are reflected in estimating the fair value, different assumptions and factors could result in a different fair value. The notional amounts of derivatives in Note 15 are not necessarily indicative of the actual market risk involved in derivative transactions.

**(e) Fair value of financial instruments**

The carrying value, the fair value and the difference of those values for financial instruments on the consolidated balance sheet as of December 31, 2010 are shown in the following table. The following table does not include financial instruments for which obtaining a fair value is deemed to be extremely difficult. (Refer to Note (2) below.)

December 31, 2010	Millions of yen			Thousands of U.S. dollars		
	Carrying value	Fair value	Difference	Carrying value	Fair value	Difference
Cash and cash equivalents .....	¥ 76,213	¥ 76,213	¥ —	\$ 929,427	\$ 929,427	\$ —
Trade notes and accounts receivables.....	113,391	113,391	—	1,382,817	1,382,817	—
Marketable securities and investment securities .....	66,975	66,975	—	816,768	816,768	—
Total .....	¥256,579	¥256,579	¥ —	\$3,129,012	\$3,129,012	\$ —
Trade notes and accounts payables.....	¥ 19,490	¥ 19,490	¥ —	\$ 237,683	\$ 237,683	\$ —
Total .....	¥ 19,490	¥ 19,490	¥ —	\$ 237,683	\$ 237,683	\$ —
Derivatives (*).....	¥ 52	¥ 52	¥ —	\$ 634	\$ 634	\$ —
Total .....	¥ 52	¥ 52	¥ —	\$ 634	\$ 634	\$ —

(\*) The value of assets and liabilities arising from derivative transactions is shown on a net basis.

**Notes:**

(1) Methods for computing the estimated fair value of financial instruments and other matters related to assets, liabilities, and derivatives are as follows:

**[Assets]**

Cash and cash equivalents, Trade notes and accounts receivables: Since these items are settled in a short period of time, their carrying value approximates fair value.

Marketable securities and investment securities: Stocks are valued at the quoted market price. Bonds are valued at the quoted market price or at the price provided by the financial institutions making markets in these securities. For information on securities classified by holding purpose, please refer to Note 14 of the notes to the consolidated financial statements.

**[Liabilities]**

Trade notes and accounts payables: Since these items are settled in a short period of time, their carrying value approximates fair value.

**[Derivatives]**

Estimates of the fair value of derivatives are based on the prices provided by the financial institutions making markets in these instruments.

(2) Financial instruments for which it is extremely difficult to determine the fair value are as follows:

	Millions of yen	Thousands of U.S. dollars
December 31,	2010	2010
Unlisted securities .....	¥313	\$3,817

Since quoted market prices are not available for these financial instruments and estimating their fair value is deemed to be extremely difficult, they are not included within "Marketable securities and investment securities" in the previous table.

(3) The redemption schedule for monetary claims and securities with maturity dates is summarized as follows:

	Millions of yen				Thousands of U.S. dollars			
December 31, 2010	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Cash and cash equivalents.....	¥ 76,213	¥ —	¥ —	¥ —	\$ 929,427	\$ —	\$ —	\$ —
Trade notes and accounts receivables...	113,391	—	—	—	1,382,817	—	—	—
Marketable securities and investment securities								
Other securities with maturity dates:								
Corporate bonds .....	1,000	1,499	—	—	12,195	18,280	—	—
Other bonds .....	4,695	—	—	—	57,256	—	—	—
Other .....	54,005	—	—	—	658,598	—	—	—
Total .....	¥249,304	¥1,499	¥ —	¥ —	\$3,040,293	\$18,280	\$ —	\$ —

## 14 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, 2010 and 2009 are summarized by type of security as follows:

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

	Millions of yen			Thousands of U.S. dollars		
December 31, 2010	Acquisition cost	Carrying value	Unrealized gain (loss)	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:						
Stocks .....	¥ 2,337	¥ 4,737	¥2,400	\$ 28,500	\$ 57,768	\$29,268
Bonds.....	2,000	2,001	1	24,390	24,402	12
Other.....	39,000	39,004	4	475,610	475,659	49
Subtotal.....	43,337	45,742	2,405	528,500	557,829	29,329
Securities whose carrying value does not exceed their acquisition cost:						
Stocks .....	1,195	1,039	(156)	14,573	12,671	(1,902)
Bonds.....	5,197	5,194	(3)	63,378	63,342	(36)
Other.....	15,000	15,000	(0)	182,927	182,927	(0)
Subtotal.....	21,392	21,233	(159)	260,878	258,940	(1,938)
Total .....	¥64,729	¥66,975	¥2,246	\$789,378	\$816,769	\$27,391

December 31, 2009	Millions of yen		
	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:			
Stocks .....	¥ 2,331	¥ 5,134	¥2,803
Bonds .....	1,698	1,699	1
Other .....	28,000	28,005	5
Subtotal .....	32,029	34,838	2,809
Securities whose carrying value does not exceed their acquisition cost:			
Stocks .....	1,134	1,131	(3)
Bonds .....	14,492	14,430	(62)
Other .....	11,000	11,000	(0)
Subtotal .....	26,626	26,561	(65)
Total .....	¥58,655	¥61,399	¥2,744

**(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, 2010, 2009 and 2008 are summarized as follows:

Year ended December 31,	Millions of yen			Thousands of U.S. dollars
	2010	2009	2008	2010
Sales proceeds .....	¥613	¥ —	¥ —	\$7,476
Aggregate gain .....	95	—	—	1,159
Aggregate loss .....	(3)	—	—	(37)

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

December 31, 2009	Millions of yen
Other securities:	
Unlisted securities, except for those traded on the OTC market and other .....	¥355

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

December 31, 2009	Millions of yen	
	Due in one year or less	Due after one year through five years
Other securities with maturity dates:		
Corporate bonds .....	¥ 5,466	¥2,976
Other bonds .....	7,687	—
Other .....	39,005	—
Total .....	¥52,158	¥2,976

## 15 Derivatives

### (a) Derivative transaction for which hedge accounting has not been applied

Summarized below are the notional amounts and the estimated fair value of the derivative instruments outstanding at the balance sheet date.

#### (1) 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
December 31, 2010						
Currency swap:						
Swiss francs.....	¥1,822	¥52	¥52	\$22,220	\$634	\$634
Total .....	¥1,822	¥52	¥52	\$22,220	\$634	\$634

	Millions of yen		
	Notional amounts	Estimated fair value	Unrealized gain
December 31, 2009			
Currency swap:			
Swiss francs.....	¥20,571	¥708	¥708
Total .....	¥20,571	¥708	¥708

#### (2) Interest rate-related transactions

There were no open derivatives positions of interest rate-related transactions at December 31, 2010 or 2009.

### (b) Derivative transaction for which hedge accounting has been applied

There were no open derivatives positions for which hedge accounting has been applied at December 31, 2010 or 2009.

## 16 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, 2010, 2009 and 2008, 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, 2010, 2009 and 2008, the disclosure of geographical segment information has been omitted.

### Overseas revenues

As overseas revenues were ¥36,567 million (\$445,939 thousand), ¥36,390 million and less than 10% of total consolidated revenues for the years ended December 31, 2010 and 2009, respectively, the disclosures of overseas revenues information have been omitted.

Overseas revenues for the year ended December 31, 2008, was as follows:

	Millions of yen
Year ended December 31,	2008
Overseas revenues.....	¥ 33,804
Total consolidated revenues .....	¥326,938
Overseas revenues as a percentage of total consolidated revenues .....	10.3%

## 17 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, 2010, 2009 and 2008 amounted to ¥41 million (\$500 thousand), ¥27 million and ¥748 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.



## 18 Contingent Liabilities

The Company was contingently liable as guarantor of loan obligations for its employees of ¥352 million (\$4,293 thousand) and ¥424 million in the aggregate at December 31, 2010 and 2009, respectively.

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

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

Year ended December 31, 2010 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).....	15,497,079	6,118	11,731	15,491,466
Total .....	15,497,079	6,118	11,731	15,491,466

(\*1) Treasury stock increased by 6,118 shares due to the repurchase of fractional shares of less than one unit.

(\*2) Treasury stock decreased by 11,731 shares due to the exercise of stock options resulting in a decrease of 11,500 shares and the sale of 231 fractional shares of less than one unit.

Year ended December 31, 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.

Year ended December 31, 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 shares 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.

### (b) Stock subscription rights

Year ended December 31, 2010		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 .....	¥775	\$9,451
	Total .....	¥775	\$9,451

Year ended December 31, 2009		Millions of yen
Company	Description	Balance at end of year
Parent company	Share subscription rights as stock options .....	¥537
	Total .....	¥537

Year ended December 31, 2008		Millions of yen
Company	Description	Balance at end of year
Parent company	Share subscription rights as stock options .....	¥326
	Total .....	¥326

### (c) Dividends

#### (1) Dividends paid to shareholders

Year ended December 31, 2010

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, 2010	Annual general meeting of shareholders	Common stock	¥12,516	\$152,634	¥23	\$0.28	December 31, 2009	March 26, 2010
July 22, 2010	Board of directors	Common stock	¥ 9,252	\$112,829	¥17	\$0.21	June 30, 2010	September 1, 2010

Year ended December 31, 2009

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

Year ended December 31, 2008

Date of approval	Resolution approved by	Type of shares	Amount (Millions of yen)	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

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

Year ended December 31, 2010

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 24, 2011	Annual general meeting of shareholders	Common stock	¥12,516	\$152,634	Retained earnings	¥23	\$0.28	December 31, 2010	March 25, 2011

Year ended December 31, 2009

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, 2010	Annual general meeting of shareholders	Common stock	¥12,516	Retained earnings	¥23	December 31, 2009	March 26, 2010

Year ended December 31, 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

## 20 Supplementary Cash Flow Information

(a) Cash and cash equivalents at December 31, 2010, 2009 and 2008 classified by account on the balance sheets were as follows:

December 31,	Millions of yen			Thousands of U.S. dollars
	2010	2009	2008	2010
Cash on hand and at bank.....	¥ 76,213	¥106,978	¥ 70,768	\$ 929,427
Time deposits over three months.....	(11,069)	(12,500)	(116)	(134,988)
Cash and cash equivalents .....	¥ 65,144	¥ 94,478	¥ 70,652	\$ 794,439

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

Convertible bonds and stock subscription rights

Year ended December 31,	Millions of yen			Thousands of U.S. dollars
	2010	2009	2008	2010
Decrease in convertible bonds resulting from conversion.....	¥ —	¥ —	¥38	\$ —

## 21 Related Party Transactions

The Company is substantively a 61.6%-owned (Percentage of Voting rights) 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, 2010 and 2009 and transactions for the years ended December 31, 2010, 2009 and 2008 with related parties are summarized as follows:

	Millions of yen		Thousands of U.S. dollars
December 31,	2010	2009	2010
Balances:			
Roche:			
Trade payables .....	¥11,874	¥26,744	\$144,805
Trade receivables .....	3,161	6,390	38,549
Accrued receivables (Sharing of co-development costs) .....	4,923	8,329	60,037
	Millions of yen		Thousands of U.S. dollars
Year ended December 31,	2010	2009	2010
Transactions:			
Parent company:			
Interest expense on bonds .....	¥ —	¥ —	\$ 2
Roche:			
Purchases of raw materials.....	87,840	120,159	1,071,220
Sales of products .....	15,538	11,227	189,488
Sharing of co-development costs .....	5,932	9,545	72,341
Directors of the Company:			
Exercise of stock option			
Osamu Nagayama .....	—	12	—
Motoo Ueno .....	—	12	—

## 22 Stock Option Plans

At December 31, 2010, 2009 and 2008, the Company had the following stock option plans approved by its shareholders in accordance with the Law:

December 31, 2010	2010 plan (stock-based compensation plan)	2010 plan	2009 plan (stock-based compensation plan)	2009 plan	2007 plan
Date of grant	May 11, 2010	May 11, 2010	May 11, 2009	April 9, 2009	April 9, 2007
Grantees	5 directors	5 directors and 96 employees of the Company and 4 employees of a subsidiary	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
Type of stock	Common stock	Common stock	Common stock	Common stock	Common stock
Number of shares granted	71,600	324,000	78,500	330,000	355,000
Exercise price (yen)	¥1	¥1,881	¥1	¥1,696	¥3,039
Exercise price (U.S. dollars)	\$0.01	\$22.94	\$0.01	\$20.68	\$37.06
Exercisable period	May 11, 2010 - April 23, 2040	April 25, 2012 - April 23, 2020	May 11, 2009 - April 24, 2039	April 11, 2011 - March 25, 2019	April 1, 2009 - March 23, 2017

December 31, 2010	2006 plan	2005 plan	2004 plan	2003 plan
Date of grant	April 3, 2006	April 1, 2005	April 5, 2004	August 5, 2003
Grantees	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
Number of shares granted	344,000	252,000	232,000	231,000
Exercise price (yen)	¥2,245	¥1,649	¥1,675	¥1,454
Exercise price (U.S. dollars)	\$27.38	\$20.11	\$20.43	\$17.73
Exercisable period	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, 2010	2010 plan (stock-based compensation plan)	2010 plan	2009 plan (stock-based compensation plan)	2009 plan	2007 plan
<b>Non-vested (number of shares)</b>					
Outstanding at the beginning of the year	—	—	78,500	330,000	—
Granted during the year	71,600	324,000	—	—	—
Forfeited during the year	—	—	—	2,000	—
Vested during the year	—	—	11,500	—	—
Outstanding at the end of the year	71,600	324,000	67,000	328,000	—
<b>Vested (number of shares)</b>					
Outstanding at the beginning of the year	—	—	—	—	350,000
Vested during the year	—	—	11,500	—	—
Exercised during the year	—	—	11,500	—	—
Forfeited during the year	—	—	—	—	5,000
Outstanding at the end of the year	—	—	—	—	345,000
Weighted-average market price (yen)	—	—	¥1,790	—	—
Weighted-average market price (U.S. dollars)	—	—	\$21.83	—	—

December 31, 2010	2006 plan	2005 plan	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	338,000	249,200	210,900	106,400
Vested during the year	—	—	—	—
Exercised during the year	—	—	—	—
Forfeited during the year	5,000	4,000	4,000	—
Outstanding at the end of the year	333,000	245,200	206,900	106,400
Weighted-average market price (yen)	—	—	—	—
Weighted-average market price (U.S. dollars)	—	—	—	—

December 31, 2009	2009 plan (stock-based compensation plan)	2009 plan	2007 plan	2006 plan	2005 plan
Date of grant	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
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 grant	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 the Company 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
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

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



December 31, 2008	2007 plan	2006 plan	2005 plan	2004 plan	2003 plan
Date of grant	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

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

Year ended December 31,	2010		2009	
	2010 plan (stock-based compensation plan)	2010 plan	2009 plan (stock-based compensation plan)	2009 plan
Expected volatility (*1).....	35%	33%	35%	35%
Expected holding period (*2).....	4 years	10 years	5 years	10 years
Expected dividend (*3).....	34 yen	34 yen	34 yen	34 yen
Risk-free rate (*4).....	0.38%	1.31%	0.86%	1.45%

(\*1) 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.

(\*2) Because there is not enough data to make a reasonable estimation, expected life of the option of 2010 plan and 2009 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 2010 plan and 2009 plan (stock-based compensation plan) is based on the age at the time of retirement according to the past record.

(\*3) This is based the Company's dividend paid for the last fiscal year.

(\*4) 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.

**23 Amounts Per Share**

Year ended December 31,	Yen			U.S. dollars
	2010	2009	2008	2010
Net income:				
Basic .....	¥76.14	¥104.00	¥72.07	\$0.93
Diluted.....	¥76.12	¥103.98	¥72.04	\$0.93

December 31,	Yen		U.S. dollars
	2010	2009	2010
Net assets.....	¥821.87	¥794.51	\$10.02

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 exercise of stock subscription rights and stock options.

The potential dilutive impact of 124,760 shares, 107,488 shares and 202,440 shares of common stock has been included in the computation of the weighted-average number of shares for the years ended December 31, 2010, 2009 and 2008, 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.

**24 Subsequent Event**

Due to the Tohoku District-off the Pacific Ocean Earthquake on March 11, 2011, some damage has occurred mainly at the Utsunomiya Plant of Chugai Pharma Manufacturing Co., Ltd. The amount of losses and the impact on Chugai's business performance are undetermined at this time.

# 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, 2010 and 2009, 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, 2010, 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, 2010 and 2009, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2010 in conformity with accounting principles generally accepted in Japan.

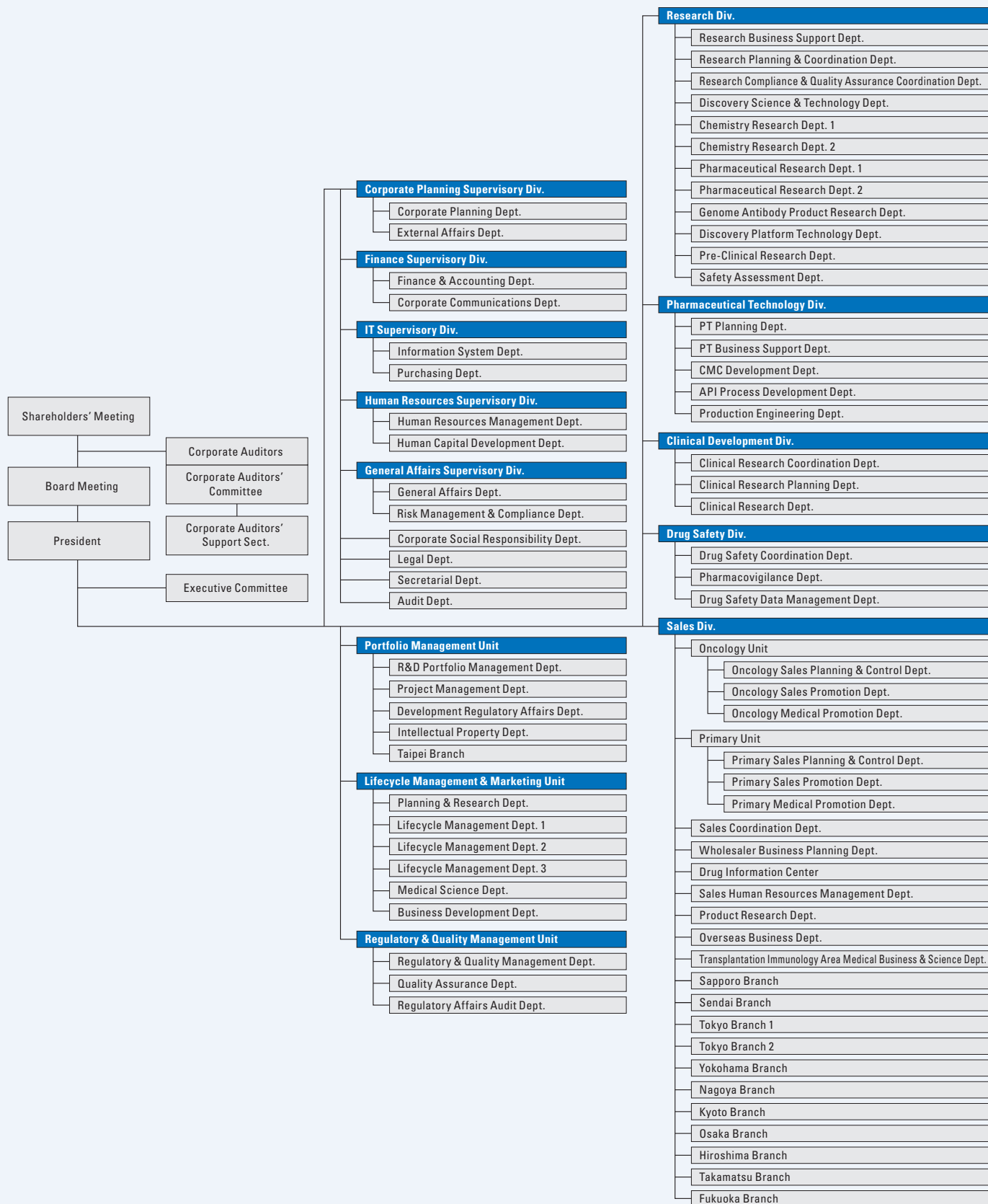
The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended December 31, 2010 are presented solely for convenience. Our audit also included the translation of yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 4.

*Ernst & Young ShinNihon LLC*

March 24, 2011

A member firm of Ernst & Young Global Limited

# Organization (As of March 24, 2011)



# Network (As of March 24, 2011)

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Chuo-ku, Tokyo 103-8324, Japan  
Telephone: +81-(0) 3-3281-6611  
Facsimile: +81-(0) 3-3281-2828  
URL: <http://www.chugai-pharm.co.jp/english>

## Branches

Sapporo, Sendai, Tokyo 1, Tokyo 2,  
Yokohama, Nagoya, Osaka, Kyoto,  
Hiroshima, Takamatsu, Fukuoka

## Plants

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

## Research Laboratories

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

## Overseas Representative Office

**Beijing Representative Office**  
2101 Beijing Fortune Bldg.  
No. 5, Dong San Huan Bei Lu,  
Chao Yang District,  
Beijing 100004, China  
Telephone: +86-(0) 10-6590-8061

## Domestic Subsidiaries

Chugai Research Institute  
for Medical Science, Inc.

Chugai Business Support Co., Ltd.

Medical Culture Inc.

Chugai Distribution Co., Ltd.

Chugai Pharma Manufacturing Co., Ltd.

Chugai Clinical Research Center Co., Ltd.

## Overseas Subsidiaries and Affiliates

**Chugai Pharma Europe Ltd.**  
Mulliner House, Flanders Road,  
Turnham Green, London W4 1NN, U.K.  
Telephone: +44-(0) 20-8987-5600

**Chugai Pharma U.K. Ltd.**  
Mulliner House, Flanders Road,  
Turnham Green, London W4 1NN, U.K.  
Telephone: +44-(0) 20-8987-5680

**Chugai Pharma Marketing Ltd.**  
Mulliner House, Flanders Road,  
Turnham Green, London W4 1NN, U.K.  
Telephone: +44-(0) 20-8987-5656

**Germany Branch**  
Lyoner Strasse 15 60528  
Frankfurt am Main, Germany  
Telephone: +49-(0) 69-663000-0

**Chugai Pharma France S.A.S.**  
Tour Franklin, La Defense 8,  
100/101 Quartier Boieldieu  
92042 Paris La Defence Cedex, France  
Telephone: +33-(0) 1-56-37-05-20

**CHUGAI sanofi-aventis S.N.C.**  
20 Avenue Raymond Aron,  
92165 Antony Cedex, France  
Telephone: +33-(0) 1-41-24-75-52

**Chugai U.S.A., Inc.**  
300 Connell Drive, Suite 3100  
Berkeley Heights, NJ 07922, U.S.A.  
Telephone: +1-908-516-1350

**New York Office**  
444 Madison Avenue  
New York, NY 10022, U.S.A.  
Telephone: +1-212-486-7780

**Chugai Pharma U.S.A., LLC**  
300 Connell Drive, Suite 3100  
Berkeley Heights, NJ 07922, U.S.A.  
Telephone: +1-908-516-1350



**Chugai Pharma (Shanghai)  
Consulting Co., Ltd.**  
Unit 2901, Central Plaza  
381, Huaihai Road Centre,  
Shanghai 200020, China  
Telephone: +86-(0) 21-6319-0388

#### Beijing Branch

2102 Beijing Fortune Bldg.  
No. 5, Dong San Huan Bei Lu,  
Chao Yang District,  
Beijing 100004, China  
Telephone: +86-(0) 10-6590-8066

#### Guangzhou Branch

Unit 2508B, Yian Plaza,  
No. 33 Jian She 6th Road,  
Guangzhou, 510060 China  
Telephone: +86-(0) 20-8363-3468

**Chugai Pharma Taiwan Ltd.**  
3Fl., No.73, ZhouZi Street,  
Neihu District, Taipei 11493, Taiwan  
Telephone: +886-(0) 2-2658-8800

#### Taipei Branch

8Fl., No.73, ZhouZi Street,  
Neihu District, Taipei 11493, Taiwan  
Telephone: +886-(0) 2-2659-8030

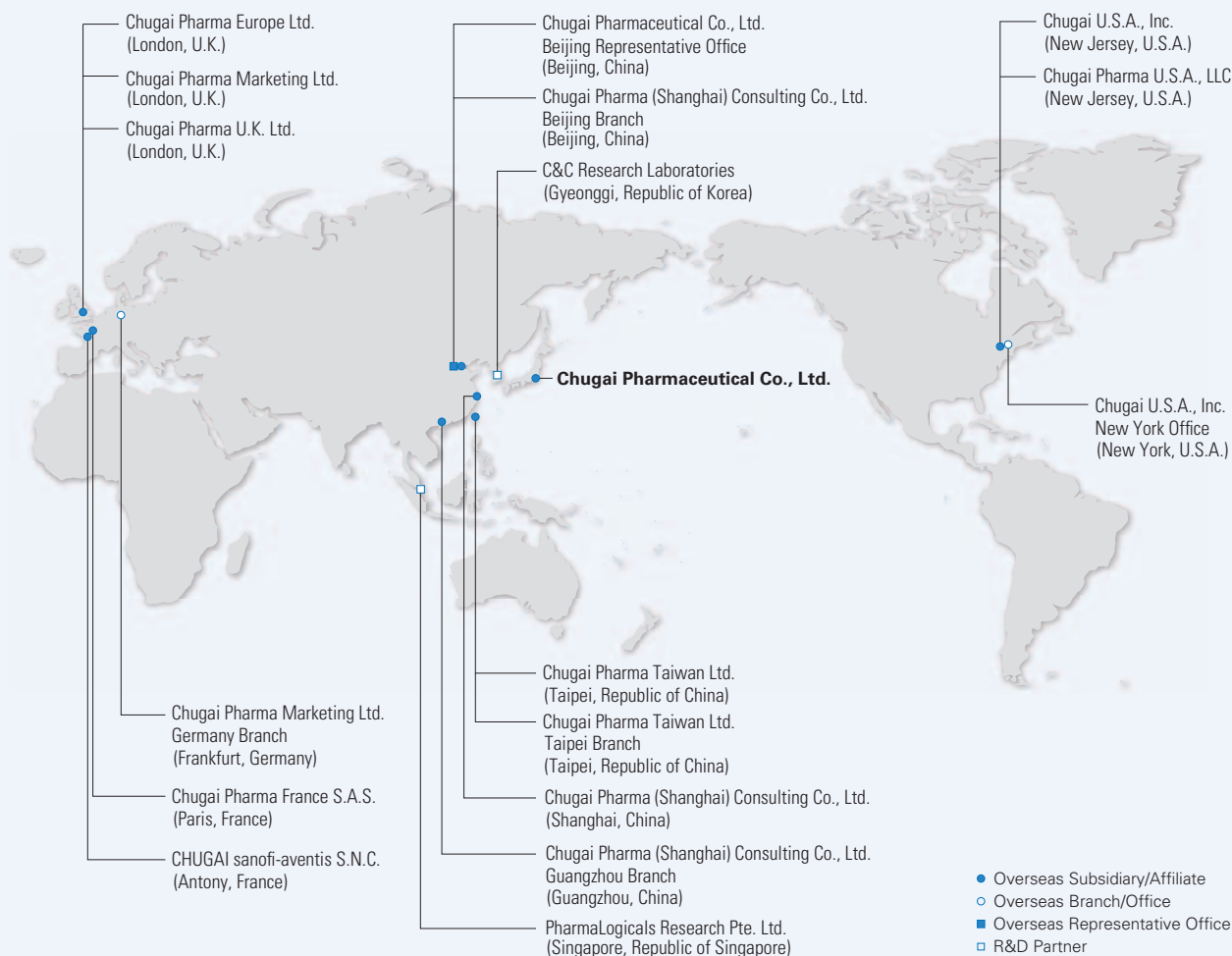
## R&D Partners

**Forerunner Pharma Research Co., Ltd.**  
2-16 Komaba 4-chome, Meguro-ku,  
Tokyo 153-0041, Japan  
Telephone: +81-(0) 3-5465-0871

**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, 2010)

**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**

6,709 (Consolidated)

**Number of Shares Issued of Common Stock**

559,685,889

**Number of Shareholders**

50,418

**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/english/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, 2010)

## Major Shareholders\*

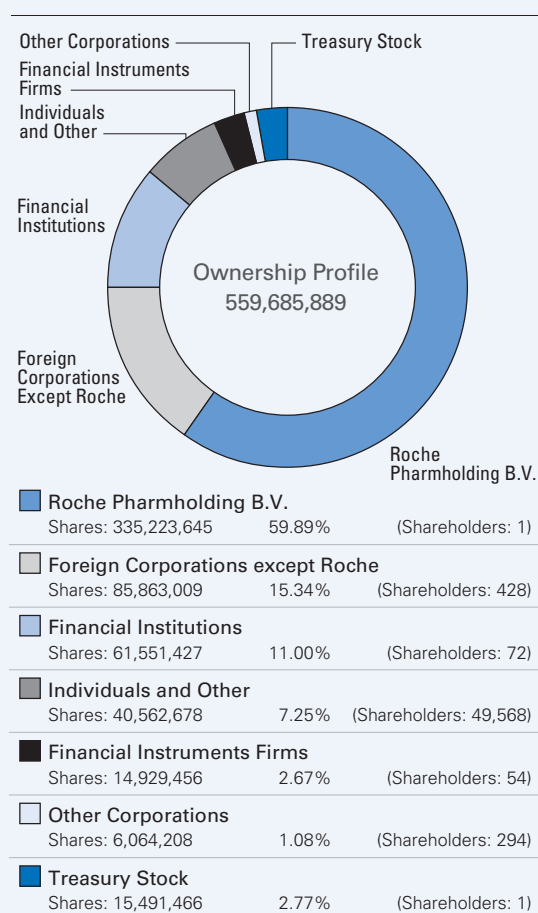
Name	Number of Shares Held (Thousands)	Percentage of Voting Rights (%)
Roche Pharmholding B.V.	335,223	61.62
Japan Trustee Services Bank, Ltd. (trust account)	12,460	2.29
The Master Trust Bank of Japan, Ltd. (trust account)	12,229	2.24
Tokio Marine & Nichido Fire Insurance Co., Ltd.	4,668	0.85
JP Morgan Chase Bank 385147	4,651	0.85
JP Morgan Chase Bank 385078	4,281	0.78
JP Morgan Securities Japan Co., Ltd.	4,146	0.76
Mellon Bank, N.A. as Agent for its Client Mellon Omnibus US Pension	3,735	0.68
State Street Bank and Trust Company 505225	3,567	0.65
Chugai Pharmaceutical Employee Shareholders' Association	3,197	0.58

\* 15,491,466 shares of treasury stock held by the Company are not included in the above breakdown of major shareholders.

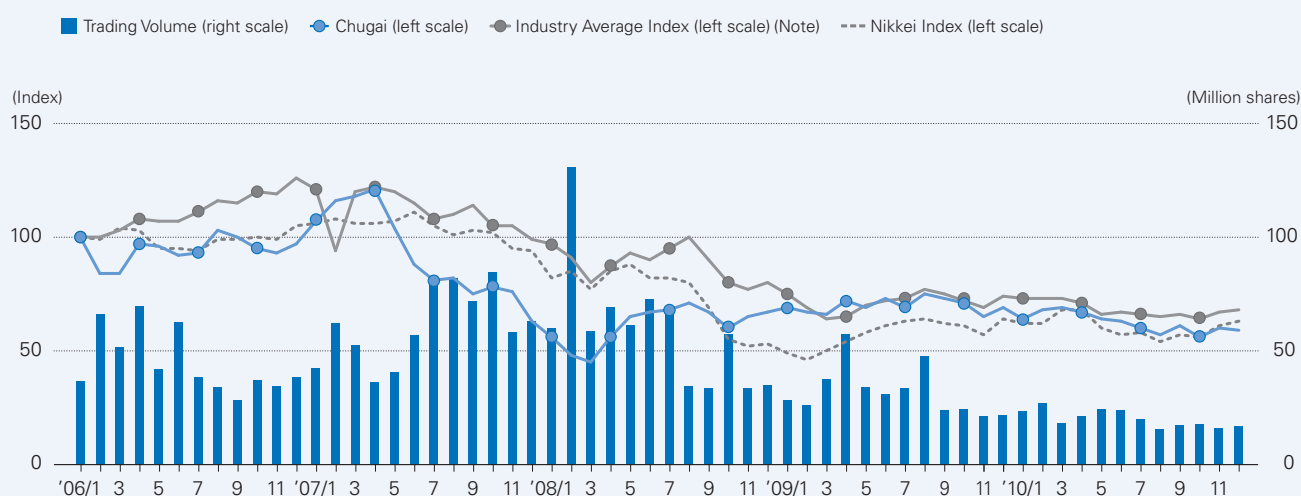
## Stock Price Information

	Stock Price	
	High	Low
From January 1, 2010 to December 31, 2010		
First Quarter	¥1,801	¥1,594
Second Quarter	1,835	1,544
Third Quarter	1,621	1,424
Fourth Quarter	1,570	1,390

## Classification of Shareholders



## Share Performance of Chugai



Note:

Share price on January 4, 2006 (¥2,530) = 100

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

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

From January 2006: A total of eight companies (Takeda, Daiichi-Sankyo, Astellas, Shionogi, Eisai, Tanabe, Daiippon-Sumitomo, Chugai)



CHUGAI

**CHUGAI PHARMACEUTICAL CO., LTD.**



A member of the Roche group

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