CHUGAI
Roche Group

Annual Report 2012

(Integrated Edition Including CSR Report)

Fiscal year ended December 31, 2012

CHUGAI PHARMACEUTICAL CO., LTD.

The mission of Chugai Pharmaceutical Co., Ltd. and its consolidated subsidiaries ("Chugai" or "the Company") 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.

We at Chugai believe that the realization of this mission will result in the creation and improvement of corporate value. Based on the business philosophy of "innovation all for the patients," we will continue to work tirelessly to become a top Japanese pharmaceutical company.

Editorial Policy

Chugai has adopted integrated reporting to communicate its corporate value, which includes both financial and non-financial aspects. From *Annual Report 2012*, we are combining the traditional annual report with the print version of the corporate social responsibility (CSR) report.

For CSR information, we are taking advantage of the attributes of different media by focusing on the main initiatives of 2012 in this annual report and providing our action policies and more detailed information on the Chugai website (scheduled for publication at the end of June 2013).

Scope of This Report

This report presents information on Chugai Pharmaceutical Co., Ltd. and its consolidated subsidiaries. In some places, however, it gives data specifically pertaining to Chugai Pharmaceutical Co., Ltd.

Timeframe and Reference Guidelines (CSR Information)

The timeframe for CSR data in the section titled "Organization and Human Resources" is January to December 2012, and the contents were prepared with reference to the Environmental Reporting Guidelines (Fiscal Year 2007 Edition) of the Ministry of the Environment of Japan and the 2006 Sustainability Reporting Guidelines of the Global Reporting Initiative (GRI).

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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. and its consolidated subsidiaries ("Chugai" or "the Company"). These statements reflect the Company's current analysis of existing information and trends. Actual results may differ from expectations due to 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.

Message from the CEO

—Innovation all for the patients—
This philosophy is the source of Chugai's strengths, which will drive further growth as we move toward becoming a top Japanese pharmaceutical company with global-level capabilities.

Chugai is steadily advancing toward its fundamental management goal of becoming a top Japanese pharmaceutical company by providing a continuous flow of innovative new medicines in Japan and internationally. Ten years have elapsed since the start of our strategic alliance with Roche. Over that time, we have built a solid position in the market, with a robust research infrastructure and well-stocked development pipeline, and Chugai has become known for its leading presence in oncology and biopharmaceuticals. As a result, we can now see the way forward to becoming a top Japanese pharmaceutical company. We were able to make such dramatic progress not only because of the alliance with Roche, but because we have continuously embraced the challenge of innovation that derives from our integral business philosophy: "innovation all for the patients." And it is the patient-oriented initiatives we have executed in all areas of our operations that have enabled us to create the powerful business platform that is unique to Chugai.

One example is in research, where we place top priority on generating new compounds with the potential to be developed into first-in-class[1] or best-in-class[2] medicines. This approach stems from our belief that Chugai grows when it creates drugs that benefit patients by addressing unmet medical needs[3] and improving satisfaction of treatment. We developed cutting-edge antibody technologies ahead of our competitors in Japan. As a result, we have achieved international competitiveness in this field, exemplified by our technologies for identifying molecules and for comprehensive analysis of proteins. The advantage of this technology platform was evident in Chugai's development of recycling antibody and sweeping antibody technologies announced in 2010 and 2011, respectively, and technologies for engineering a bispecific antibody for hemophilia A and establishing stable cell lines of cancer stem cells, both of which were announced in 2012.

In clinical development, our goal is to make new medicines available to patients as quickly as possible. We have established speedy and sophisticated development operations with world-class, cutting-edge quality. Similarly, we have persistently pursued innovation in our production operations, where we have integrated investigational new drug production and post-marketing production, and created biological active pharmaceutical ingredient production facilities that feature world-class product quality and stability. As a result, we have established a production system that combines scale and quality.

In marketing, we have built a leading position in Japan while contributing to acceptance of the multidisciplinary team approach to healthcare and the preparation of treatment guidelines, with the aim of promoting standards of care and establishing nationwide access to optimal cancer treatment. These efforts are backed by Chugai's three decades of experience not only in oncology, where we are the leading Japanese pharmaceutical company, but also in renal diseases and bone and joint diseases.

To develop the people who drive these initiatives, we are putting various work environments and systems in place and enhancing our personnel assignment and skill development programs to secure diverse human resources, regardless of gender or nationality. Initiatives include adoption of new personnel systems, such as a talent management system for ascertaining the capabilities of employees from multiple perspectives in order to place them in the most suitable positions.

Yet even with Chugai's many strengths, a look at the business environment tells us we have much to do. We must move ahead quickly to successfully deal with the pressure on the industry stemming from rapid changes in our operating environment, such as financial problems and policies to control healthcare costs in various countries. It is imperative that we visualize Chugai's strengths, which are backed by our business philosophy of "innovation all for the patients," and transform those strengths into a solid foundation for medium-to-long-term growth.

That thinking is the basis for ACCEL 15, the mid-term business plan we launched in 2013. Under ACCEL 15, we will improve the quality of the products and services we provide through constant innovation to ensure a foundation for realizing our goal of becoming a top Japanese pharmaceutical company. To establish a strong presence in marketing, we will raise productivity while enhancing consulting-based promotion and generating robust post-marketing data. In addition, we will leverage our strong development framework and extensive know-how to accelerate global development. We will also focus on conducting world-leading research by further strengthening our network with academia and advancing the work of our subsidiary Chugai Pharmabody Research Pte. Ltd. in Singapore, which specializes in generating novel antibodies. At the same time, we will build a more cost efficient and flexible production framework predicated on high quality. In conjunction with these operational innovations, we will work to improve our cost structure. Finally, our initiatives in corporate social responsibility (CSR), which encompasses environmental protection and contribution to society, will be reinforced.

Another priority will be enhancing returns to shareholders while flexibly making strategic investments for future growth and conducting balanced cash flow management aimed at increasing shareholder value.

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. Fulfilling that mission is a never-ending process. We are fully committed to continuous innovation for the benefit of patients in every area of our business and advancing to a new stage of growth because we believe these efforts will create value for all of our stakeholders.

I hope that our shareholders and investors are as excited as I am about Chugai's future prospects, and will continue to support us as we accelerate our initiatives for further growth.

1. An original drug that is highly novel and useful, has a chemical structure different from that of existing drugs, and significantly changes the therapeutic system
2. A drug that offers clear advantages over other existing drugs
3. Therapeutic areas in which satisfaction with treatment is low and that offer potential to create new markets with innovative medical products

Osamu Nagayama

Representative Director,
Chairman & CEO

Chugai's Unique Strengths

Chugai's business philosophy of "innovation all for the patients" is shared by every employee. As a result, we have established unique strengths that increase our corporate value. Since forming the strategic alliance with Roche in 2002, quality and efficiency have improved dramatically throughout our operations, and the combination of our own achievements and those from the alliance with Roche has created synergy. With these strengths, Chugai has built an organization that ranks among the industry leaders in consistently creating and delivering innovative medicines.


Presence
Efficiency
Creation
Stability

Marketing strength stemming from a high level of expertise supports our leading market share in our core fields and has contributed to the advancement of medical care.

Top domestic market share in therapeutic antibodies*

36.4% (2012)

Top domestic market share in oncology*

19.4% (2012)

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We have cultivated clinical development know-how and a solid development platform through efforts to develop and launch needed medicines.

Enhanced system for simultaneous global development

25 new products and additional indications approved (2008-2012)

Extensive licensing from Roche

19 compounds licensed (2008-2012)

Numerous Personalized Healthcare (PHC)-based development projects

Cooperating on 14 projects (2012)

We have raised our drug discovery technologies and network to a world-class level in our quest to create innovative drugs.

Extensive lineup of drugs from Chugai

11 products from in-house research (2012)

Next-generation antibody technologies and other cutting-edge technologies

Enhanced system for accelerated drug discovery

Chugai Pharmabody Research Pte. Ltd. established in Singapore (2012)

Our strong, environmentally conscious production system meets global standards for safety and quality management.

Global-standard safety and quality management system

Cross-functional risk management system

Strong therapeutic antibody production facilities

Eight 10,000-liter bioreactors at the Utsunomiya plant and four 2,500-liter bioreactors at the Ukima plant

Presence

In Japan, Chugai holds the top share of the therapeutic antibody market as well as in oncology and osteoporosis. This presence stems from our portfolio of high-value products coupled with the success of our consulting-based promotion for individual cases, which reflects our strong focus on patients. Our rich product franchise enables us to collect and analyze useful clinical data. This accumulated high-level expertise allows Chugai's medical representatives and medical associates[1] to provide precise information. We also focus on contributing to the advancement of medical care overall. For example, in oncology we hold numerous lectures and study sessions aimed at promoting equal accessibility to optimal cancer treatment nationwide and acceptance of the multidisciplinary team approach to care. In bone and joint diseases and renal diseases, we are contributing to the creation of treatment guidelines as a pioneer in these fields.

Efficiency

Based on its steadfast commitment to delivering useful medicines to patients as quickly as possible, Chugai has submitted applications and obtained approvals for a large number of development compounds in the last several years. As a result, our development operations have built exceptionally high levels of accuracy, speed and productivity. We now have one of the richest pipelines in Japan. In development, our effective lifecycle management system ensures consistent management of all functions, from clinical development to marketing, production and regulatory affairs. In addition, we have established a system for parallel development of new medicines and companion diagnostics in cooperation with the Diagnostics Division of the Roche Group. This will position Chugai to lead the establishment of PHC, an emerging trend in medical care.

Creation

Chugai has secured a unique competitive advantage in research by focusing primarily on creating drugs with first-in-class or best-in-class potential to address unmet medical needs. In particular, our industry-leading research technologies in therapeutic antibodies and oncology, stemming from our experience and know-how as a pioneer in biopharmaceutical development, have led to breakthroughs such as our recycling antibody and bispecific antibody technologies. Our open innovation[2] environment based on a powerful external network and access to the world-class research platform of the Roche Group are also major strengths.

Stability

One of Chugai's key responsibilities is ensuring thorough safety and quality management and stable supply so that patients can use its high-quality medicines properly and with peace of mind. We were quick to establish a global-standard quality and safety management system capable of meeting the differing review requirements of regulatory agencies in Japan, the United States and the European Union. Moreover, we have created a cross-functional risk management system based on the perspective of patients and healthcare providers to effectively implement the plan-do-check-act (PDCA) cycle in pharmacovigilance. In supply, as a result of our aggressive capital investments focused on production efficiency and safety, we have established leadership in Japan in both quality and capacity at our bioreactors for biological active pharmaceutical ingredients (APIs) and other facilities. All of these facilities are managed in accordance with Chugai's own strict environmental standards based on the Chugai Environmental Policy.

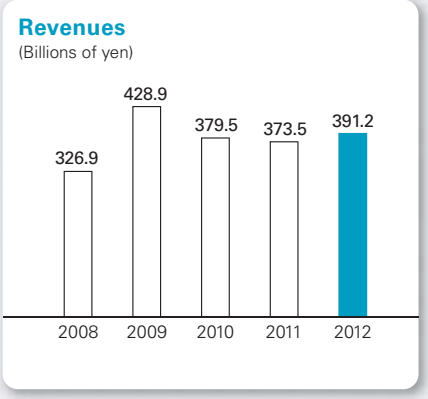
1. A position responsible for conveying more specialized, advanced information in specific fields and specific regions.
2. Cooperation and partnerships in joint research with academia, venture businesses and other advanced research institutions outside the industry in addition to in-house research to discover new lead compounds and drugs.

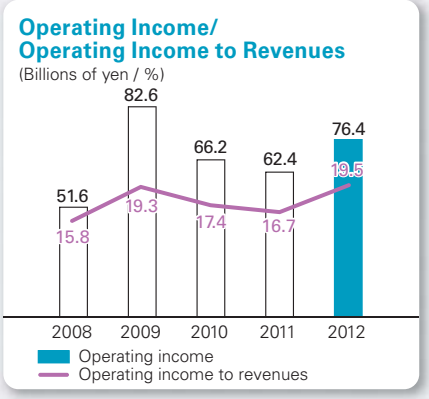
Financial Highlights

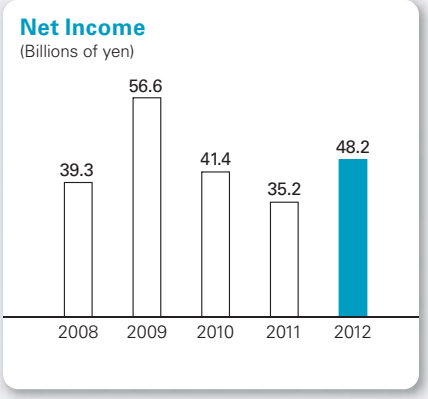
Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries / Years ended December 31

- **Sales excluding Tamiflu were up 2.3 percent year on year, driven by the solid performance of oncology products and growth of new products in Japan, which more than offset the effect of National Health Insurance (NHI) drug price revisions, and a sharp increase in exports of Actemra on a volume basis.**
- **Overall revenues rose 4.7 percent reflecting an increase in other operating revenues, primarily from out-licensing of compounds under development.**
- **Operating income was up 22.4 percent as operating expenses decreased owing to more efficient use of resources. Net income increased 36.9 percent.**
- **The ratio of shareholders' equity to total assets was 83.0 percent as Chugai continued to maintain a strong financial position.**
- **Cash dividends totaled ¥40.00 per share (interim and year-end dividends of ¥20.00 yen per share each), and the payout ratio was 45.2 percent.**

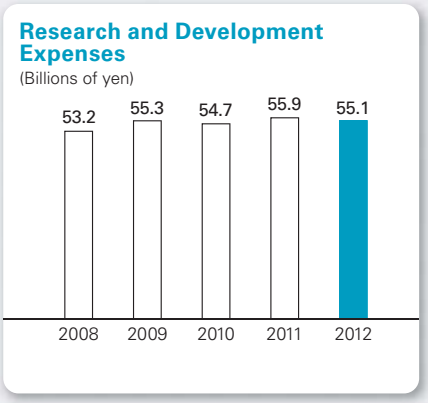
For more detailed information, see "11-Year Financial Summary" on pages 110-111.

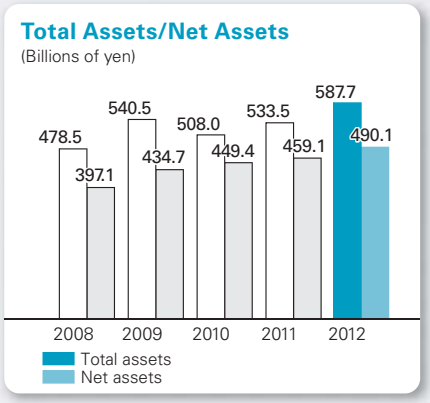


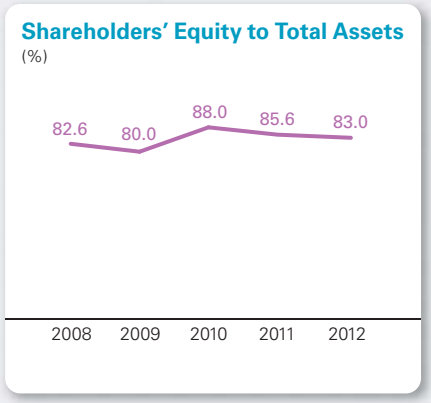


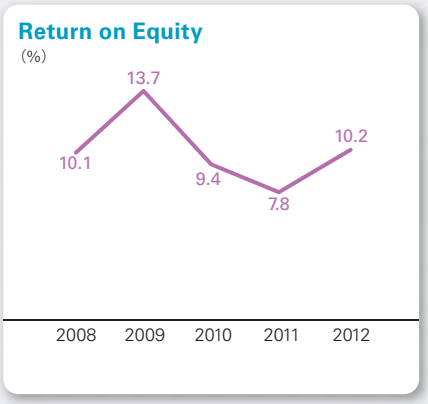


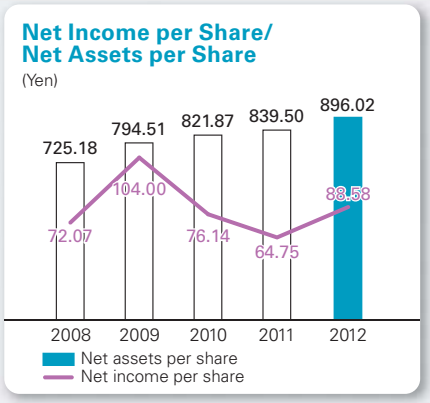
	Millions of yen (Except as otherwise specified)			Percent change	Thousands of U.S. dollars[1] (Except as otherwise specified)
	2012	2011	2010	2012／2011	2012
Results for the year:					
Revenues	¥391,220	¥373,517	¥379,510	4.7%	$4,549,070
Operating income	76,413	62,430	66,238	22.4	888,523
Income before income taxes and minority interests	75,322	57,131	65,686	31.8	875,837
Net income	48,206	35,235	41,433	36.8	560,535
Research and development expenses	55,107	55,856	54,702	(1.3)	640,780
Sales:	¥375,234	¥363,622	¥375,560	3.2%	$4,363,186
Sales (Excluding Tamiflu)	363,195	354,912	357,408	2.3	4,223,198
Oncology	170,050	157,540	158,159	7.9	1,977,326
Bone and Joint Diseases	91,857	86,688	75,306	6.0	1,068,105
Renal Diseases	48,131	50,768	57,372	(5.2)	559,663
Others (Including Tamiflu)	65,194	68,623	84,721	(5.0)	758,070
Financial position at year-end:					
Total assets	¥587,720	¥533,483	¥508,016	10.2%	$6,833,953
Interest-bearing debt	158	154	150	2.5	1,837
Total net assets	490,075	459,073	449,394	6.8	5,698,547
Cash flows:					
Net cash provided by operating activities	¥ 77,300	¥ 69,594	¥ 15,572	—	$ 898,837
Net cash used in investing activities	(54,769)	(15,135)	(20,192)	—	(636,849)
Net cash used in financing activities	(22,720)	(24,551)	(23,055)	—	(264,186)
Cash and cash equivalents at end of year	95,445	94,474	65,144	—	1,109,826

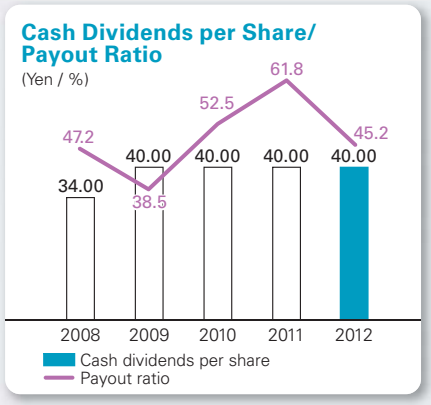












Note: Cash dividends per share for 2009 include a special year-end dividend of ¥6.00 per share.

	Millions of yen (Except as otherwise specified)			Percent change	Thousands of U.S. dollars[1] (Except as otherwise specified)
	2012	2011	2010	2012/2011	2012
Amounts per share (Yen and U.S. dollars):					
Net income – basic	¥ 88.58	¥ 64.75	¥ 76.14	36.8%	$ 1.03
Net income – diluted	88.54	64.73	76.12	36.8	1.03
Net assets	896.02	839.50	821.87	6.7	10.42
Cash dividends	40.00	40.00	40.00	—	0.47
Number of shares outstanding	559,685,889	559,685,889	559,685,889		
Number of employees	6,836	6,779	6,709		
Ratios:					
Operating income to revenues (%)	19.5	16.7	17.5		
Return on equity (%)[2]	10.2	7.8	9.4		
Shareholders' equity to total assets (%)	83.0	85.6	88.0		
Debt-to-equity ratio (%)[3]	0.0	0.0	0.0		
Interest coverage ratio (Times)[4]	21,734.9	20,032.2	8,214.4		
Research and development expenses to revenues (%)	14.1	15.0	14.4		
Payout ratio (%)	45.2	61.8	52.5		

Notes: 1. The U.S. dollar amounts in the consolidated financial statements as of and for the year ended December 31, 2012 have been translated from Japanese yen amounts at the rate of ¥86 to U.S. $1.00, the approximate exchange rate prevailing on December 31, 2012.

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

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

4. 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

Visualizing Our Challenge

Over the last ten years, Chugai has built a number of unique strengths, including both visible and behind-the-scenes value, using its business philosophy of "innovation all for the patients."

Chugai now plans to evolve and link these strengths to further expand its corporate value. Under our new mid-term business plan, ACCEL 15, we will establish a formidable competitive advantage by accelerating innovation.

We will continue to move toward our goal of being a company that can meet the expectations of all stakeholders – in other words, a top Japanese pharmaceutical company.

Motoo Ueno
Representative Director &
Deputy Chairman

Osamu Nagayama
Representative Director,
Chairman & CEO

Tatsuro Kosaka
Representative Director,
President & COO

What were the highlights of 2012, the final year of the previous mid-term business plan, Sunrise 2012?

President & COO Kosaka:

Steady market penetration of core products and new products drove sales and profit growth as we emphasized speed.

We started 2012 facing a tough environment, and ended up slightly short of our initial plan for the year. But we achieved sales and profit growth by focusing on aggressively increasing the market uptake of our products in each therapeutic area, with an emphasis on speed.

Although prices of Chugai products were reduced by an average of 6.0 percent overall in the Japanese government's National Health Insurance (NHI) price revisions, our business gradually recovered from the effects of the Great East Japan Earthquake of 2011 as core products and new products drove growth. In particular, the market penetration of core products such as Avastin and Actemra increased, and sales of new products such as Mircera and Edirol also grew. Outside Japan, Actemra sales continued to expand. In Japan, re-calculation of market expansion for Actemra resulted in a downward NHI drug price revision of 25 percent, but sales growth accelerated on a volume basis, which enabled us to maintain sales at the level of the previous year.

We worked to manage costs more efficiently in every area, and succeeded in holding down expenses even as sales grew. As a result, revenues rose 4.7 percent to ¥391.2 billion, operating income grew 22.4 percent to ¥76.4 billion and net income increased 36.9 percent to ¥48.2 billion.

Ten years have passed since the start of the strategic alliance with Roche. Please summarize the achievements of Sunrise 2012.

President & COO Kosaka:

Our biggest achievement was the establishment of highly profitable operations capable of continuously creating and providing innovative new drugs.

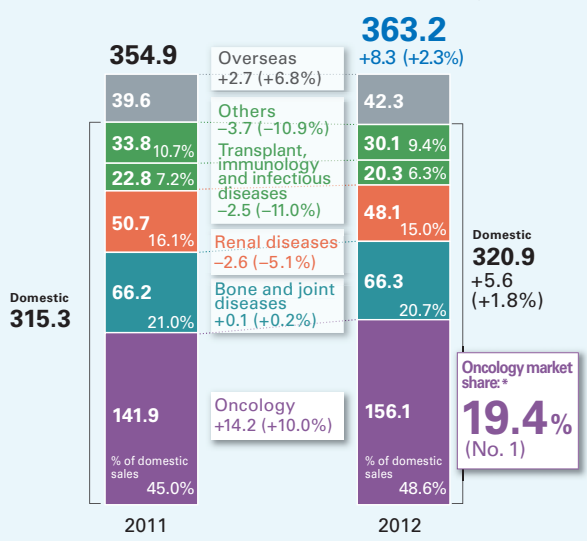
Our targets for 2012, the final year of Sunrise 2012, were revenues of ¥418.5 billion[1] and operating income of ¥80.0 billion. We fell slightly short of both of those targets. Problems in responding to intensifying competition and the slow penetration of new products are issues we take very seriously, and we intend to implement measures for improvement. But looking back at our decade-long alliance with Roche, I think our key achievement during Sunrise 2012 was the establishment of the infrastructure to create and provide a steady flow of innovative medicines.

Looking at the numbers, sales excluding Tamiflu are about twice what they were in 2002, before the alliance, and operating income has expanded approximately 2.5 times. While the cost-to-sales ratio has risen in tandem with the increase in products licensed from Roche, restructuring following the merger with Nihon Roche and subsequent improvements to our cost structure reduced the ratio of expenses to revenues by more than 16 points to 37.6 percent in 2012 from 53.8 percent in 2002. As a result, we have built an operating structure that is among the most profitable in our industry in Japan.

1. The original target of ¥460.0 billion was revised in February 2012 in response to changes in the external environment, including the effects of the Great East Japan Earthquake and the delayed launch of Actemra in the United States.

Breakdown of Changes in Sales (Excluding Tamiflu)

(Billions of yen)



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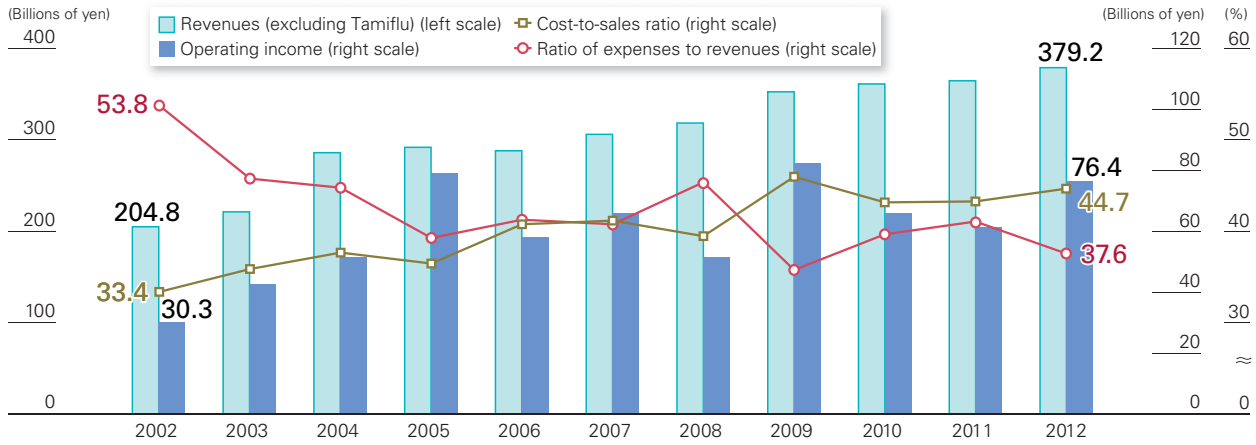
Results from 2002



What advantages has Chugai established for future growth?

Chairman & CEO Nagayama:

Chugai's business philosophy has taken firm root across the Company, and we have established numerous unique strengths, which include both visible and behind-the-scenes value.

Over the past decade we have strengthened our operations in every area, including research, development, production and marketing, as planned at the start of the alliance with Roche. We have established strengths unique to Chugai, which include value both visible and behind-the-scenes. Looking at specific outcomes, during the five years of Sunrise 2012, we advanced 10 new projects from Chugai into the clinical phase of development, licensed 19 new compounds from Roche, and launched a total of 25 new products and additional indications. In the oncology field in Japan, we are now the leading company in name and reality, with a market share of almost 20 percent. In addition, we captured the top share of the osteoporosis market in 2012 and maintained our number-one domestic market share for therapeutic antibodies. Moreover, we are leading the Japanese market in the discovery and development of new drugs based on Personalized Healthcare (PHC), an emerging trend in medical treatment.

We were able to establish these unique strengths due to a variety of factors in addition to the knowledge and expertise we have cultivated over many years. For example, the partnership between Chugai and Roche has increased our corporate strength. But I think the single largest factor is that our employees have embraced our business philosophy of "innovation all for the patients," which is Chugai's point of origin.

Deputy Chairman Ueno:

We have strengthened our foundations in research, development, production, marketing and human resources, using our business philosophy as a source of growth.

We continue to innovate with a thorough focus on patients. This approach is a source of our growth. For example, in research, we have created next-generation research technologies and platforms, including our recycling antibody, sweeping antibody and bispecific antibody technologies, and the establishment of stable cell lines of cancer stem cells. In development, we have dramatically increased productivity and speed through a large number of regulatory filings and product launches, and our development pipeline is now among the richest in Japan. We are also ahead of our competitors in building powerful biopharmaceutical production capacity, robust production functions, and safety and quality functions that meet regulatory standards in Japan, the United States and the European Union. In marketing, we are doing more than just trying to achieve the top market share; we are also contributing to the improvement of healthcare overall with efforts that include the promotion of equal availability of optimal treatment and multidisciplinary team care for cancer patients. Against that backdrop, I have sensed a dramatic change in the outside perception of the Company.

One thing I want to emphasize is the growth of our

people. The unprecedented creation, clinical development and launch of new products have dramatically raised the level of our employees. In addition, global co-development and promotion of PHC has helped to increase the number of Chugai employees who can work in the international arena. Such talent is sure to be an extremely valuable asset for the continued growth of the Company.

Rapid change in the environment surrounding the pharmaceutical industry is expected to continue. What is your view on the operating environment over the medium to long term?

Chairman & CEO Nagayama:

Amid sharper and more rapid change, creating the conditions for true market leadership will require us to grow and evolve further.

We are heading into a period of even sharper and more rapid change. Around the world, the operating environment is characterized by declining birth rates, aging populations, ongoing policies to control healthcare costs, and a dearth of new drug candidates. Given these conditions, industry players will concentrate on the limited growth areas remaining in the pharmaceutical market, including oncology, therapeutic antibodies and emerging countries. In Japan, shifts in healthcare provision such as cooperation between hospitals and clinics and the trend toward home care are also changing the expectations and needs of patients, which has made new business approaches necessary. Dealing with upcoming patent expirations will also be critical. It is important that we steadily address all of these challenges.

Going forward, the social mission required of the pharmaceutical industry will no longer be limited to just

providing innovative drugs. The solutions needed to address the challenges facing healthcare providers, such as individualized treatment and rehabilitation of patients, involve more than medicine. For example, it is important to assess the role that pharmaceutical companies should fulfill in light of advances in life science, including regenerative medicine, and to provide patients with what they need to overcome illness. For that reason, we believe that we must grow and evolve further before we are in a position to truly lead the market.

Please summarize and explain the positioning of the new mid-term business plan that started in 2013.

President & COO Kosaka:

By accelerating innovation, Chugai will establish a formidable competitive advantage. We also plan to enhance shareholder returns.

To realize our goal of becoming a top Japanese pharmaceutical company by the second half of this decade, it is vital that we establish a strong position

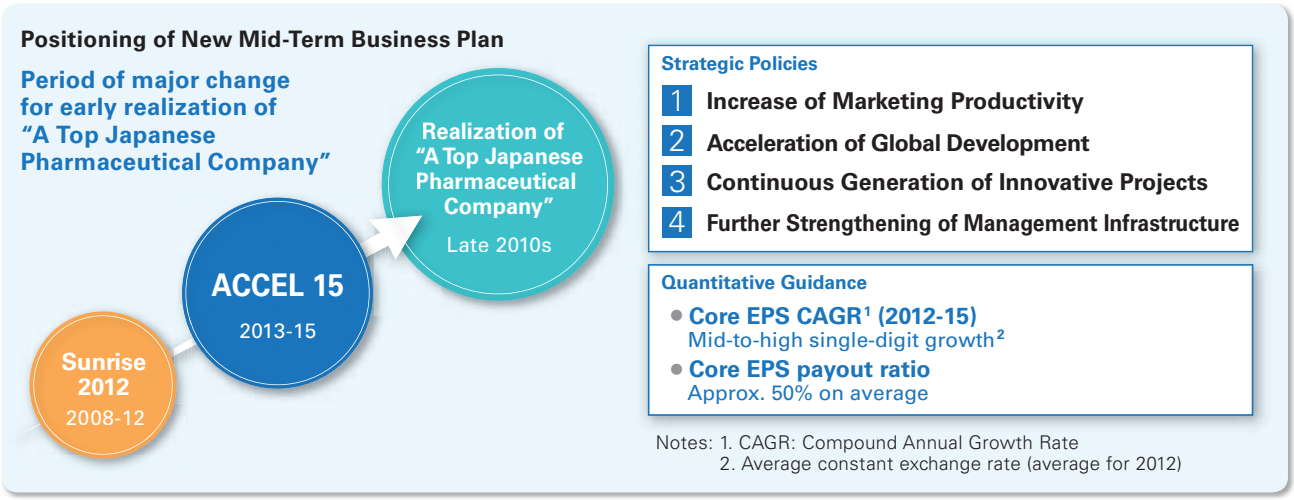
Definition of "A Top Japanese Pharmaceutical Company" (Chugai's Goal for the Second Half of This Decade)

Quantitative Aspects

1. **One of the Top Three Pharmaceutical Companies in Japan in Each of the Following Categories**
   - ◆ Domestic share
   - ◆ Consolidated operating income margin
   - ◆ Consolidated operating income per employee
   - ◆ Domestic sales 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



unrivaled by our competitors by staying ahead of changes in the external environment, further developing the strengths we have cultivated and building new strengths.

Accordingly, we positioned the new mid-term business plan as a period of transition toward the early realization of our goal and named the plan "ACCEL 15" – an acronym for the phrase "Accelerate Continuous Creation and Evolution Leading to 'Top Pharmaceutical Company.'" The name signifies our intent to speed up, to accelerate innovation and our evolution into a top Japanese pharmaceutical company.

The central idea of the plan is to reach a level where we can exercise a formidable competitive advantage by raising the quality of the products and services we provide through constant innovation.

As quantitative guidance, we are aiming for average annual growth of core earnings per share (EPS)[2] in the mid-to-high single digits. In a rapidly changing environment, expressing performance forecasts for three years from now in concrete figures could cause misunderstandings. Therefore, we have decided to announce the plan in terms of this growth rate and single-year performance forecasts.

Since we have established a steady growth platform, we will also enhance returns to shareholders. While maintaining our policy of paying stable dividends with no dividend reductions in principle, we will raise our consolidated payout ratio target from 40 percent or higher to approximately 50 percent of core EPS on average.

2. With the adoption of International Financial Reporting Standards (IFRS), Chugai internally and externally discloses core operating profit, core net income and core EPS as indicators to represent profit trends. Core operating profit is IFRS-based operating income less the impact of acquisition of intangible assets and business combinations (managed as investments) and other non-recurring items (including major restructuring expenses, litigation expenses and any other extraordinary items arising outside of the Company's core pharmaceutical business).

What are some specific actions Chugai will take in ACCEL 15?

President & COO Kosaka:

We will focus on four strategic policies that will evolve and link our current strengths to further expand Chugai's corporate value.

To evolve and link our current strengths and further expand Chugai's corporate value, we have set four strategic policies in ACCEL 15.

The first is "increase of marketing productivity." To establish a dominant presence, we will focus on strengthening consulting-based promotion in all therapeutic areas and generating extensive post-marketing data. We will also make proactive efforts to further advance PHC, standards of care and regional healthcare. To ensure profits while we undertake these

initiatives, we must increase productivity in marketing and all other Company operations. In marketing, we will focus on integrating product strategies with customer strategies and raising efficiency through measures including the use of contract medical representatives (MRs) and deployment of information and communications technology. Key growth drivers over the next three years will include Actemra, for which we have expanded the market by filing for approval of a new subcutaneous formulation and obtaining approval for use as a first-line biologic treatment in the United States; Avastin, which has established a position as a standard of care; Mircera, which is backed by a growing body of clinical data and is highly regarded for the convenience of its once-every-four-weeks dosing frequency; and Edirol, which has the leading market share for oral osteoporosis drugs owing to strong clinical data. In addition, we have a number of promising projects in late-stage clinical development, including RG1273, RG3502 and RG484. We also expect growth from the launch of these new products.

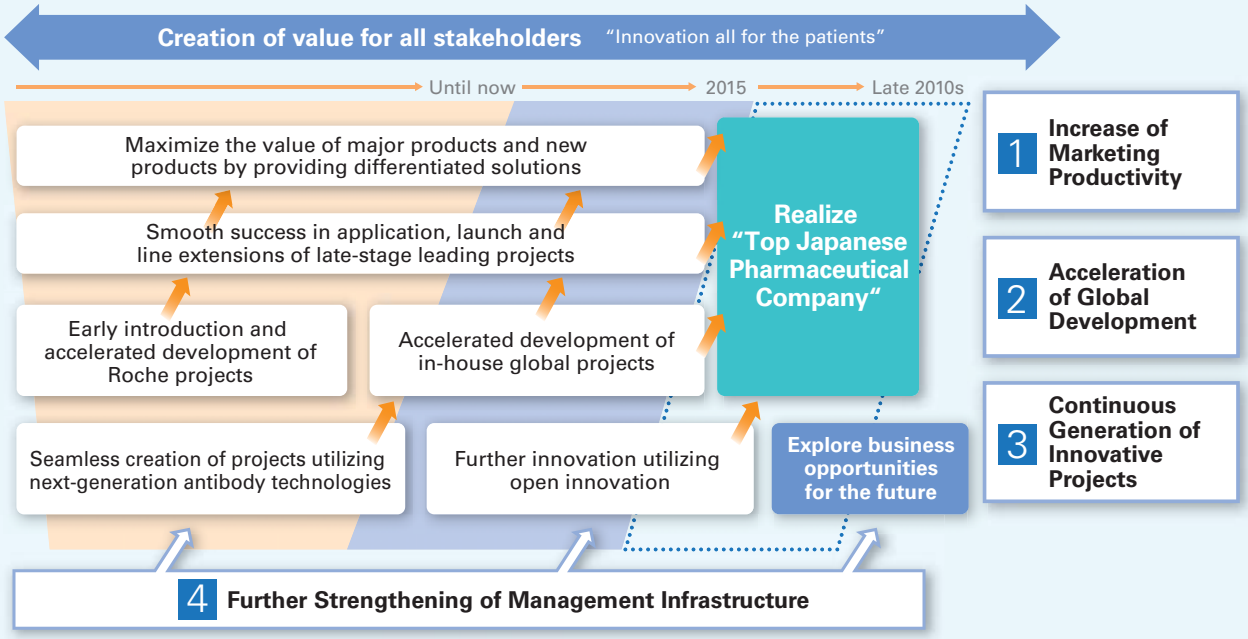
The second strategic policy is "acceleration of global development" to leverage our strong development framework and wide-ranging know-how to compete at the global level. We plan to enhance clinical science functions, set up a system for collaboration with Roche from the early stages of development, and create a development system that seamlessly integrates research, development, production and other functions. These approaches will help to speed up development as we aim for the early launch of the next global drug to follow Actemra.

The third strategic policy is "continuous generation of innovative projects." A key challenge going forward will be to quickly generate results from our next-generation antibody engineering and other world-leading proprietary technologies and our original research platform. We will prioritize allocation of resources to the antibody engineering subsidiary we established in Singapore in 2012. This subsidiary will use our next-generation antibody technologies to accelerate generation and development of new antibody projects. In open innovation, an approach in which we have a notable track record, we will leverage our proprietary antibody engineering technologies and our library of more than two million compounds to further enhance our global network. Through these approaches, we intend to bring an average of three to five new projects into the clinical phase each year during ACCEL 15.

Our fourth strategic policy is "further strengthening of management infrastructure" to promote and

ACCEL 15 Agenda for Value Creation

Further enhancing the flow of value creation by evolving and linking Chugai's current strengths



actualize the other three strategic policies. To create a more efficient and flexible cost structure that can effectively cope with rapid changes in the environment, we will further improve our high operating profitability by expanding use of external resources and controlling fixed expenses such as personnel costs and capital expenditures. In addition, we plan to promote flexible and strategic investments in order to ensure that we secure future business opportunities. Furthermore, we believe that diverse values and expertise drive innovation. We will therefore place greater emphasis on diversity management to evolve into an organization that pursues constant innovation and speed.

Deputy Chairman Ueno:

We will continue to improve our management infrastructure, the backbone of value creation and innovation.

We have covered the areas that we will focus on changing as the key measures of ACCEL 15. But what will not change is our commitment to improving every function in our management infrastructure, which is the backbone of value creation and innovation.

These days, the social value of corporations is emphasized in addition to their financial value. Companies must earn the trust of stakeholders with proactive efforts to increase qualitative corporate value, including corporate governance and reduction of environmental impact. At Chugai, we regard all efforts to realize our mission as our corporate social responsibility and will perform and enhance our corporate activities based on the Chugai BCG, the Company's code of conduct.

To earn the trust of stakeholders, we will continually strive to provide a stable supply of safe, high-quality pharmaceuticals and carry out information and awareness activities that contribute to medical care overall. Diligent risk management is also important. We will focus on efforts such as improving the business continuity plan and ensuring thorough compliance. In recent years, in addition to the provisions of the Foreign Corrupt Practices Act in the United States and the Japan Pharmaceutical Manufacturers Association Guideline for the Transparent Relation between Corporate Activities and Medical Institutions, there have been growing calls for fairness and transparency, including the start of requirements to disclose the details of payments to healthcare providers. These fundamental ideas are meant to guarantee patient-oriented medical choices by ensuring fair business practices, and should go beyond the framework of business risks. We want to set an example by increasing fairness and transparency as an approach that respects the rights of patients. We believe that through these activities, we will consistently earn the trust of stakeholders and continue to be a trusted enterprise, which we view as our raison d'etre.

What is the outlook for results in 2013?

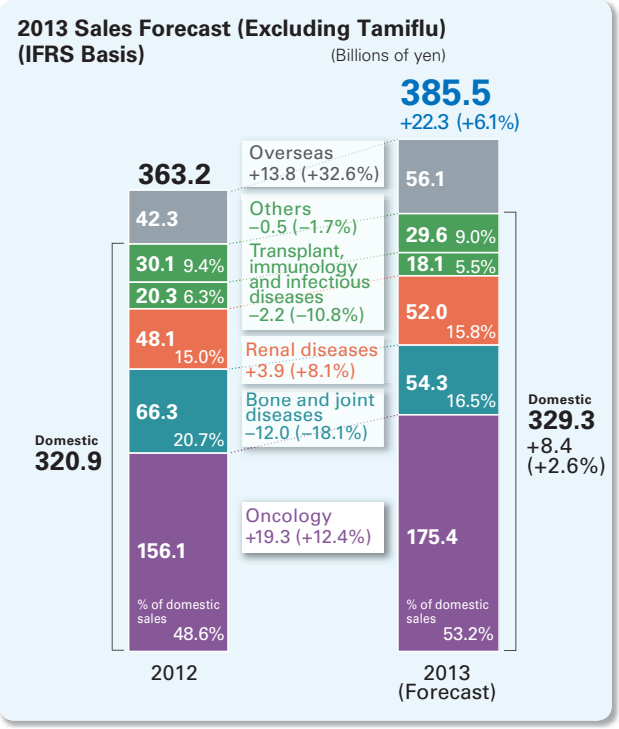
President & COO Kosaka:

In the first year of ACCEL 15, we will accelerate initiatives in every area, with the aim of increasing revenues and profit.

In 2013, the first year of ACCEL 15, we will accelerate initiatives in every area of our operations, with the aim of increasing revenues and profit. We expect to achieve revenues of ¥416.0 billion (a 7.6 percent increase over 2012), core operating profit of ¥77.5 billion (a 2.5 percent increase) and core EPS of ¥92.57 (an 8.1 percent increase). In oncology, we plan to expand sales 12.4 percent in Japan by working to further increase the market penetration and presence of major products such as Avastin and Xeloda. In bone and joint diseases, we expect an 18.1 percent decrease in sales due to the expiration of our co-marketing tie-up for Evista, although worldwide growth in sales of Actemra is expected. In renal diseases, we aim to increase sales 8.1 percent by highlighting the convenience of Mircera to quickly establish this drug in the market.

As for cash dividends, we plan to increase total dividends per share by ¥5.00 from 2012 to ¥45.00, for a payout ratio of 48.6 percent of core EPS.

To enhance convenience for domestic and overseas investors and align our management indicators with overseas metrics, we have voluntarily adopted International Financial Reporting Standards (IFRS) as of 2013. The forecasts for 2013 and comparisons with 2012 results are based on IFRS.



Forecast of Key Management Indicators (Billions of yen)

	2012 Results	2012 Results (IFRS Core Basis)*	2013 Forecast (IFRS Core Basis)*
Revenues	**391.2**	**386.6**	**416.0**
Sales	375.2	375.2	394.3
Excluding Tamiflu	363.2	363.2	385.5
Royalties and other operating revenues	16.0	11.3	21.7
Cost of sales	167.7	167.3	183.2
Gross profit	**223.5**	**219.3**	**232.8**
Operating expenses	147.1	143.7	155.3
Operating Income (Core operating profit)	**76.4**	**75.6**	**77.5**
Net income per share (Core EPS) (Yen)	88.58	85.64	92.57

* Chugai voluntarily applied IFRS from 2013. Consequently, forecast amounts for 2013 are calculated based on IFRS (core basis). In addition, key management indicators for disclosure purposes have been changed to core operating profit, core net income and core EPS.

Any closing words for shareholders and investors?

Chairman & CEO Nagayama:

Chugai will continue to push toward the early realization of its goal of becoming a top Japanese pharmaceutical company.

Ten years have elapsed since the start of the strategic alliance with Roche. Chugai has reached a stage that requires further development. With the innovations we have built up, we have established unique strengths and gradually put in place the framework for pursuing new achievements. However, an examination of each area of our business – research, development, production and marketing – tells us we must evolve further in order to be a top company in the context of international standards.

In the three years of ACCEL 15, we will create the conditions to reach the top level in every function by accelerating the innovation of all divisions and employees based on our business philosophy of "innovation all for the patients." We believe that this approach will lead to higher corporate value.

Chugai will push toward its goal of being a company that can meet the expectations of all stakeholders, including shareholders and investors – in other words, a top Japanese pharmaceutical company that delivers innovation. Thank you for your ongoing support.

Feature


Innovation
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Innovation

Visualizing Our Innovation

Feature: Growth Driven by Behind-the-Scenes Value

The Four Strategic Policies of the Mid-Term Business Plan

"Innovation all for the patients" — Under this business philosophy, Chugai has cultivated unique strengths. What kinds of innovation will Chugai generate by leveraging this unseen value in marketing, development, research and its management infrastructure to generate further growth? This feature explains the strategic policies of the new mid-term business plan ACCEL 15, which focuses on further innovation for the benefit of patients.

Strategic Policy 1

Increase of Marketing Productivity

Current Strengths

- **Dominant market share and consulting-based promotion in oncology**
- **Contribution to establishment of standards of care and team care approach in oncology**
- **Trusted as a pioneer in treatment of renal diseases and osteoporosis**
- **Know-how in gathering and providing large amounts of safety data**
- **Presence of Actemra as a global drug**

Masaaki Tohaya
Senior Vice President, General Manager of Marketing & Sales Division

A Strong Position in Strategic Fields

In its drive to become a top Japanese pharmaceutical company, Chugai aims to gain the top domestic market share in its strategic fields. In oncology, we have held a dominant market share as the industry leader in Japan since 2008. (Our share in 2012 was 19.4 percent*). We also regained the top share in osteoporosis medicines in 2012 and have established a prominent position in treatments for renal diseases and hepatitis.

Chugai's strong presence in its strategic fields is a tribute to its marketing style, which is firmly patient-oriented. Besides having a rich portfolio of innovative products, we have adopted "consulting-based promotion" to make sure that patients use those products appropriately and effectively.

*Copyright 2013 IMS Japan K.K. Source: JPM 2012.
Reprinted with permission. The scope of the market is defined by Chugai.

Strengthening Our Commitment to Patients while Staying Ahead of Changes

To become a top Japanese pharmaceutical company, it is critical that Chugai creates higher added value by staying ahead of changes in the external environment while remaining firmly focused on patients. In the external environment, we need to keep a close watch on patient trends and needs in addition to government healthcare policies and industry trends.

In Japan, the rise in active cooperation between hospitals and clinics and the increase in hospitals that are subject to the Diagnosis Procedure Combination (DPC) system are changing the way hospitals are managed. The information available to patients is also increasing. Where patients are, and how they act, have been changing, which is increasing the importance of responding to needs with a broad-based rather than individual facility-based approach as in the past.

Chugai's lineup of core products is also changing and expanding. Our core therapeutic fields now encompass chronic diseases. That means we must broaden our marketing reach from intensive marketing concentrated at acute care hospitals, regional hub hospitals, dialysis centers and other such facilities.

Moving to Establish a Dominant Presence

Under ACCEL 15, the new mid-term business plan that started in 2013, Chugai aims to respond to these changes by building an even more dominant presence in strategic areas. We will focus on generating additional evidence to enhance and accelerate consulting-based promotion in all of our strategic fields.

To support the generation of evidence, in 2012 we established the Medical

"We will create added value by establishing a stronger marketing organization with a patient-oriented perspective."

Strengths to Be Further Enhanced

- **Further accumulation and provision of evidence**
- **Powerful consulting-based promotion capabilities in all strategic fields**
- **Flexible and efficient MR organization**
- **Further contribution to standards of care, regional healthcare and Personalized Healthcare (PHC)**

Affairs Division as an independent unit to enhance medical affairs and facilitate more intensive efforts in that area. Setting targets from the time of development, not just in post-marketing surveillance, is also important in generating evidence. We will therefore step up cooperation with development operations and move forward with a focus on speed and effectiveness.

Outside Japan, we will also be targeting a wider market in the future because Actemra obtained approval as a first-line treatment for rheumatoid arthritis in the United States in 2012, and an application for regulatory approval has been filed for a subcutaneous formulation. Generating and using powerful evidence will help to further advance Actemra as a global drug.

Expanding Our Role in Healthcare Overall

As Chugai's position in the industry and medical settings becomes stronger, its role and responsibilities in healthcare overall will increase. Up to now, we have made concentrated efforts such as holding lectures and study sessions to promote the spread of standards of care and multidisciplinary team care, and informing and educating patients. We plan to reinforce these activities. As a pioneer of PHC in Japan, we need to take the lead in promoting its adoption. We will make a contribution consistent with future healthcare needs by serving as a liaison between hospitals and clinics and other care facilities to energize regional healthcare.

Transforming for Higher Productivity

To increase profitability while carrying out these activities, we will also need to transform our marketing organization. Raising productivity to even higher levels is going to be our biggest challenge.

In addition to measures to increase speed, including more efficient material production and use of information technology, we will build a more dynamic and flexible personnel structure. To foster high-quality MRs, we will conduct intensive human resource development, including strengthening our training system, to enhance their expertise and ability to handle a wide range of therapeutic fields. We plan to raise efficiency further with strategic use of contract MRs, something we began partially implementing in 2012.

Chugai's operating environment is expected to continue to change drastically. With ACCEL 15, we aim to create a powerful, resilient marketing organization that can restore results in a short time and generate even higher profit, no matter what challenges we face from the external environment.

Strategic Policy 2

Acceleration of Global Development

Current Strengths

- A rich development pipeline
- Sophisticated, fast-moving development operations that handle a large number of clinical trials and regulatory approval filings
- Advanced production operations functions that reduce development time
- System for simultaneous development of PHC-based therapeutics and companion diagnostics
- Consistent lifecycle management (LCM) over all functions

Yutaka Tanaka
Senior Vice President
Head of Project & Lifecycle Management Unit

The Second Stage of Clinical Development

Through the strategic alliance with Roche, Chugai's development pipeline has expanded into one of the largest in Japan, and the proportion of compounds from Chugai has increased. By executing an exceptional number of development projects – 25 have obtained regulatory approval in the last five years – we have increased clinical development productivity and speed dramatically.

Our strategic alliance with Roche is now entering the second stage. As the operating environment changes and competition in development intensifies, we will need to leverage our strengthened clinical development platform and make additional innovations to drive new advances. Accordingly, under ACCEL 15, the new mid-term business plan, we will work to further enhance our development pipeline by fortifying global development and maximizing project value to bring useful products to patients quickly.

Aiming for the Fastest Global Development

The functions that Chugai must fulfill under ACCEL 15 will also change. For example, up until now we have focused on licensing products from Roche and quickly and steadily bringing them to market in Japan to help eliminate the drug lag. Going forward, though, development projects for medicines not yet available in the market will increase, as will compounds from Chugai, so it will be necessary to simultaneously develop and file applications for regulatory approval of these projects worldwide. Since this process involves obtaining preclinical data, designing competitive clinical trials and producing investigational drugs, we will require creativity in addition to greater productivity and speed. We plan to establish a framework for co-development with Roche from the early-stage development phase and set up a system that will enable a smooth transition into global development. For PHC-based projects, which now account for the majority of Chugai's development projects, the comprehensive agreement we formed with Roche in 2012 gives Chugai access to Roche's world-class diagnostic technology. We intend to take advantage of this technology to develop and file applications for regulatory approval of drug therapies and companion diagnostics simultaneously.

Evolving Our Lifecycle Management System

Chugai has established a product lifecycle management (LCM) system for consistent management of every function on a project level, including nonclinical and clinical development, production, marketing, regulatory affairs and safety. This system is essential for ensuring that our extensive development operations progress on schedule. Under ACCEL 15, we will evolve the system to maximize

“We will evolve our development functions to bring valuable products to patients quickly.”

Strengths to Be Further Enhanced

- **Global development capability through closer collaboration with Roche**
- **World-leading clinical science capabilities**
- **Enhanced LCM system that seamlessly connects functions from research to production and marketing**

value. To speed up clinical development, we will implement an innovative development strategy that shortens the duration of phase II clinical trials by including patients with the target disease in phase I studies, which are normally conducted on healthy subjects.

Another measure we will focus on is upgrading early drug development and establishing a faster and more flexible investigational drug (IND) supply system through stronger interdivisional cooperation. In 2012, in the course of developing ACE910, which uses bispecific antibody technology that requires more advanced production technology than conventional antibodies, we launched a collaborative task force comprising members from relevant divisions to speed up supply of active pharmaceutical ingredients (APIs) for safety studies. As a result, we shortened the lead time for phase I clinical trials. Before clinical trials can start, the IND must be delivered to the clinical study setting. Numerous production issues must first be cleared, such as developing the process and scaling up. Therefore, our success in shortening preclinical development of ACE910, which is even harder to produce than conventional therapeutic antibodies, exemplifies Chugai’s production technologies, which it has cultivated over many years.

We will also establish seamless in-house production facilities that cover scale-up in stages from development to post-marketing production. This integration will enable more flexible allocation of staff and facilities, which until now were separate for IND production and post-marketing production. We think this initiative will further enhance our strengths in production technologies and contribute significantly to boosting development speed and productivity.

Increasing Our Human Resource Advantage to Successfully Compete in Development

A key to the evolution of our development functions will be fortifying clinical science.

Conducting development and obtaining approvals globally will require not only stringent GMP*-based production in line with global standards but also consultation and cooperation with regulatory authorities, clinicians and clinical trial partners around the world. Planning clinical development strategies to successfully compete in global development is also important. I believe that participation in projects builds people’s skills, as illustrated by our rapid accumulation of know-how through the many development operations we have conducted in the past. In addition to upgrading our employee development system, we want to increase our human resource advantage through projects that are more innovative.

* Good Manufacturing Practice: Standards for pharmaceutical production management and quality control

Hitoshi Kuboniwa
Vice President
General Manager of Pharmaceutical Technology Division

Strategic Policy

3

Continuous Generation of Innovative Projects

Current Strengths

- **Experience and expertise in biopharmaceutical development as a pioneer in Japan**
- **Enhanced drug discovery technologies (antibody engineering and small-molecule technologies)**
- **Groundbreaking, proprietary research technologies (recycling antibody, sweeping antibody, bispecific antibody)**
- **Successes such as establishment of stable cancer stem cell lines**
- **Domestic and overseas research network including academia**

Hisafumi Okabe
Vice President
General Manager of Research Division

Our Original Research Platform: A Great Asset in Drug Discovery

I feel that Chugai research has steadily yielded results, including an increasing number of products from Chugai (11 have advanced to the clinical phase since 2008) and the original, innovative technologies we have announced since 2010.

Chugai has focused on therapeutic antibody discovery, producing notable successes. A key factor behind this is the experience we have accumulated in developing advanced antibody technologies ahead of our competitors, starting with our development of biopharmaceuticals such as Epogin and Neutrogin in the 1980s. Our ability to develop original research technologies is among the best in the industry. Examples include our antibody engineering technologies such as recycling antibody technology, as well as conformational analysis of target proteins and the establishment of stable cancer stem cell lines. On top of that is the tremendous significance of our access to the world-leading drug discovery infrastructure of the Roche Group, which includes the world's largest compound library and bioinformatics tools.

Looking back at the last 10 years, our pipeline has become one of the largest in Japan, and we have enhanced our research platform by investing management resources even in early stage research. By further developing the original research technologies and research materials we have created, we will work to generate first-in-class and best-in-class drugs to address unmet medical needs.

Accelerating Research of Antibody Projects at Our Singapore Subsidiary

One focus of ACCEL 15, our new mid-term business plan, is quickly converting our technologies into results.

Target molecules that were previously undruggable or on which sufficient therapeutic effects could not be elicited using conventional technologies can now be treated as drug targets with our recycling antibody, sweeping antibody and bispecific antibody technologies. These antibody technologies are potentially applicable to a broad spectrum of diseases.

In 2012, we established Chugai Pharmabody Research Pte. Ltd. (CPR), an antibody discovery subsidiary in Singapore with a short-term, intensive mission. Under ACCEL 15, we will maximize our use of CPR's functions and prioritize allocation of resources to this subsidiary to accelerate generation of novel antibodies. The company has established the human resource structure as planned, and its advisory committee consisting of outside experts is functioning effectively. CPR is currently conducting about 10 projects in parallel but will create the capacity to conduct 10 to 15 projects at any given time. It aims to create ten therapeutic antibody candidates in five years.

"We will build an original research platform to continuously generate innovative new drugs that address unmet medical needs."

Strengths to Be Further Enhanced

- **Ability to continuously generate projects by leveraging Chugai's proprietary antibody engineering technologies**
- **Technology platform to create drugs based on new concepts**
- **Efficient joint research system using networks**

Expanding Open Innovation

Open innovation, a Chugai strength, is another approach we will use to bring in drug leads and business opportunities from outside the Company. Chugai has focused on joint research with academic and other entities for many years. As a result, we have built a powerful external research network and currently have nearly 50 joint research projects with academia on matters including safety and kinetic research. In recent years, recognition of the value of Chugai's original research technologies and research materials has become a unifying force that has energized joint research. We will leverage these strengths to accelerate the expansion of open innovation.

Moreover, the technologies Chugai has developed are highly versatile, so they can be applied to a wide range of target molecules. Therefore, in addition to using these technologies ourselves, we plan to out-license them to other companies as a way of maximizing their value.

Development of Next-Generation Technologies and Continuous Innovation

Because we have worked to build an original technology platform and create new drug candidates from our own research rather than just in-licensing technologies and drug candidates from other companies, we can build up our knowledge base, which enables continuous technological development and innovation. In fact, we developed the sweeping antibody technology based on our recycling antibody technology. But we are not content to keep our technology platform as it is. We intend to lead the industry by developing and applying next-generation technologies to create innovative new medicines.

Strengthening our human resources will be essential in moving these efforts forward. We will therefore redouble our commitment to help individuals enhance their skills and upgrade our human resource development system. In addition, the high level of expertise and research management capabilities cultivated at global locations such as CPR will be a major asset. More vigorous joint research with academia will also play a role in the acquisition of new knowledge and technologies. We will actively foster researchers who can perform globally in order to build Chugai into the company it needs to be five to ten years in the future.

Strategic Policy

4

Further Strengthening of Management Infrastructure

Current Strengths

▶ Top-class profitability among domestic peers

- Business model that balances risk and return
- Positive impact from strong product portfolio (many drugs that qualify for the Premium to Promote the Development of New Drugs and Eliminate Off-Label Use, low percentage of long-listed drugs)
- Low overhead expenses due to consistent cost reduction initiatives such as business process reengineering

▶ Shared commitment to "innovation all for the patients"

Shin-ya Unno
Senior Vice President
General Manager of Corporate Planning Department

Strengthening the Management Infrastructure That Underpins Value Creation and Innovation

In the mid-term business plan ACCEL 15, which we have positioned as a period of major change to quickly become a top Japanese pharmaceutical company, it is vitally important to strengthen the management infrastructure that underpins value creation and innovation. Innovation is something that can and should be generated by every division and all employees, not just by research operations. In line with this thinking, under ACCEL 15 we will not only continuously enhance the various foundations that support Chugai's growth, but will focus particularly on initiatives in areas such as further improving our cost structure, exploring and creating future business opportunities, and enhancing organizational and human resource strategies.

Evolving Our Cost Structure for Further Value Creation

Chugai's ratio of operating income to revenues is among the highest in the industry in Japan. While the cost-to-sales ratio has been increasing as we license more products from Roche, reductions in operating, R&D and other expenses have lowered the ratio of expenses to revenues. The resulting high operating profitability has become a powerful advantage. This improvement in profitability can be attributed to the business process reengineering initiatives we have implemented since 2006, strengthened purchasing operations and our constant efforts to optimize variable costs, general expenses, capital expenditures and other outlays, in addition to our efficient business model based on collaboration with Roche. The characteristics of our product portfolio also contribute to higher profitability: Many of our products have obtained the Premium to Promote the Development of New Drugs and Eliminate Off-Label Use, and we have relatively few long-listed drugs.

We expect the volume of work to continue increasing with the expansion of our product portfolio and development pipeline, so to achieve formidable competitiveness in a rapidly changing market environment, we must make our cost structure even more efficient and flexible. We will therefore keep fixed cost increases in check by controlling headcount and capital expenditures through effective use of external resources such as organizations that develop, manufacture and sell drugs on a contract basis.

"We will speed up structural and organizational innovation to generate a formidable competitive advantage."

Strengths to Be Further Enhanced

- **Creation of a more efficient and flexible cost structure through effective use of external resources and reduction of fixed costs**
- **Strategic and flexible investments to strengthen strategic areas and maximize growth opportunities**
- **Acceleration of diversity to generate innovation**
- **Continual enhancement of management infrastructure that supports growth**

Exploring Future Business Opportunities and Promoting Aggressive Investment

Greater intelligence capabilities and strategic, flexible advance investments will be essential to stay ahead of and respond appropriately to technological innovation and changes in the market environment. We plan to aggressively pursue investment opportunities such as in-licensing of third-party products and compounds in development to maintain a strong advantage in our current strategic fields. Taking a longer view, though, we also need to start building the foundations for medium-to-long-term growth now by making investments to deal with patent expirations, expand into new therapeutic areas, obtain access to outside innovations, and explore business opportunities in pioneering areas such as regenerative medicine.

Continuing to Take on Challenges in Pursuit of Innovation and Speed

Our shared commitment to "innovation all for the patients" and awareness that this principle underpins all of our business activities are Chugai strengths.

Under ACCEL 15, we intend to evolve into an organization that pursues constant innovation and speed so that this basic principle will lead to even greater value creation. We will build a corporate culture that encourages risk-taking through trial and error, and execute a fast PDCA cycle that will be a competitive advantage. In our human resource strategy, we will focus on fortifying the operation of the talent management system we started in 2012 to develop and turn out the next generation of leaders and core staff. We also plan to emphasize diversity management. Promoting diversity to foster a corporate culture that secures the talents of a variety of people and unleashes their full potential will help to drive innovation at Chugai. Concrete initiatives for gender diversity, including upgrading various workplace systems and holding in-house forums and lectures to transform employee awareness and behavior, are now gaining speed. We are also planning initiatives to promote nationality and age diversity.

If we can accelerate innovation in all of our operations and evolve and link our current strengths, the value that Chugai creates should expand further. We will continue striving to quickly make Chugai a top Japanese pharmaceutical company and accomplish our mission.

Review of Operations

Visualizing Our Progress

At Chugai, we never stop advancing. Dedicated to a thoroughly patient-oriented approach, we aim to deliver medicines that address an ever-widening range of unmet medical needs. This section covers operating results for 2012 and the outlook and strategies for 2013 in each strategic field. It also includes descriptions of products under development that will be the sources of future growth in each field.

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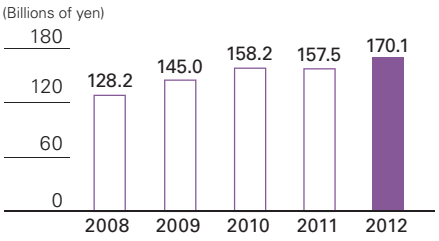
Chugai at a Glance

Sales

Therapeutic Fields | **Performance Highlights**

Oncology

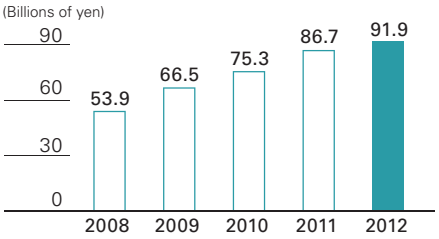
- Sales of oncology products were up 8.0 percent year on year with steady growth of core products.
- Chugai maintained its market leadership with a 19.4 percent* share of the Japanese market.



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

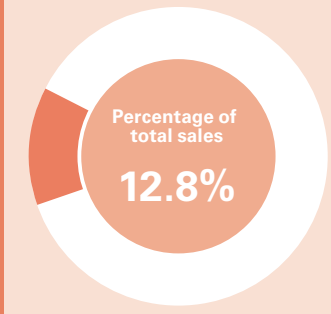
Bone and Joint Diseases

- Sales continued to rise, increasing 6.0 percent year on year.
- Actemra sales were down 2.3 percent in Japan due to the NHI drug price revision, but rose 24.9 percent overseas with steady market penetration.

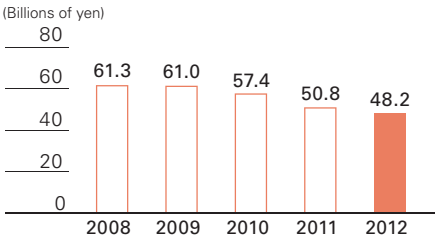


- Actemra (tocilizumab)
- Evista (raloxifene HCl)
- Suvenyl (sodium hyaluronate)
- Alfarol (alfacalcidol)
- Edirol (eldecalcitol)

Renal Diseases

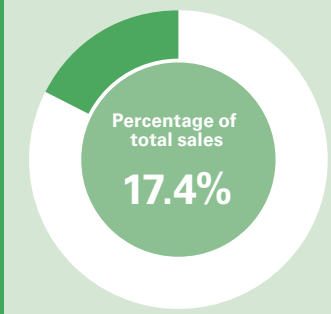


- Sales decreased 5.1 percent year on year.
- Sales growth from market penetration of new product Mircera did not fully offset the decrease in sales of Epogin.

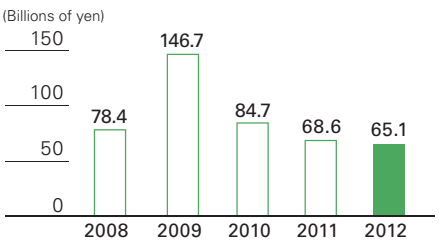


- Mircera (epoetin beta pegol)
- Epogin (epoetin beta)
- Oxarol (maxacalcitol)
- Renagel (sevelamer HCl)

Others



- Sales decreased 5.1 percent year on year.
- Despite higher sales of Tamiflu, sales declined overall due to a contracting market for Pegasys and Copegus and the impact of competition.



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

(As of January 30, 2013)

Research and Development

	Phase I	Phase II	Phase III	Filed
Oncology	**CIF (RG7167)** Solid tumors **CKI27 (RG7304)** Solid tumors **PA799** Solid tumors **WT4869** Myelodysplastic syndromes (I/II) Solid tumors **WT2725** Advanced cancer **RG7204** Melanoma (I/II)	**AF802 (RG7853)** Non-small cell lung cancer (I/II) **GC33 (RG7686)** Liver cancer **RG340 (Xeloda)** Gastric cancer (adjuvant) **RG3502** Gastric cancer (II/III)	**RG435 (Avastin)** Glioblastoma Breast cancer (adjuvant) **RG1273** Breast cancer (adjuvant) **GA101 (RG7159)** Indolent non-Hodgkin's lymphoma Aggressive non-Hodgkin's lymphoma **RG3638** Non-small cell lung cancer	**RG435 (Avastin)** Glioblastoma (recurrent) Ovarian cancer **RG1273** Breast cancer **RG1415 (Tarceva)** Non-small cell lung cancer (1st line) **RG3502** Breast cancer
Bone and Joint Diseases			**NRD101 (Suvenyl)** Enthesopathy **RG484** Osteoporosis (oral)	**RG484** Osteoporosis (injection)
Autoimmune Diseases	**SA237** Rheumatoid arthritis **RG7415** Systemic lupus erythematosus			**MRA (Actemra) (Japan)** Rheumatoid arthritis (subcutaneous injection) **MRA (Actemra) (Overseas)** Rheumatoid arthritis (subcutaneous injection)
Central Nervous System	**RG1450** Alzheimer's disease	**RG7090** Major depressive disorder	**RG1678** Schizophrenia	
Others	**ACE910** Hemophilia A **CIM331** Atopic dermatitis **RG3637** Asthma **RG7652** Hyperlipidemia		**CSG452** Type 2 diabetes	

Originated in-house Designates change in status in 2012 and thereafter.

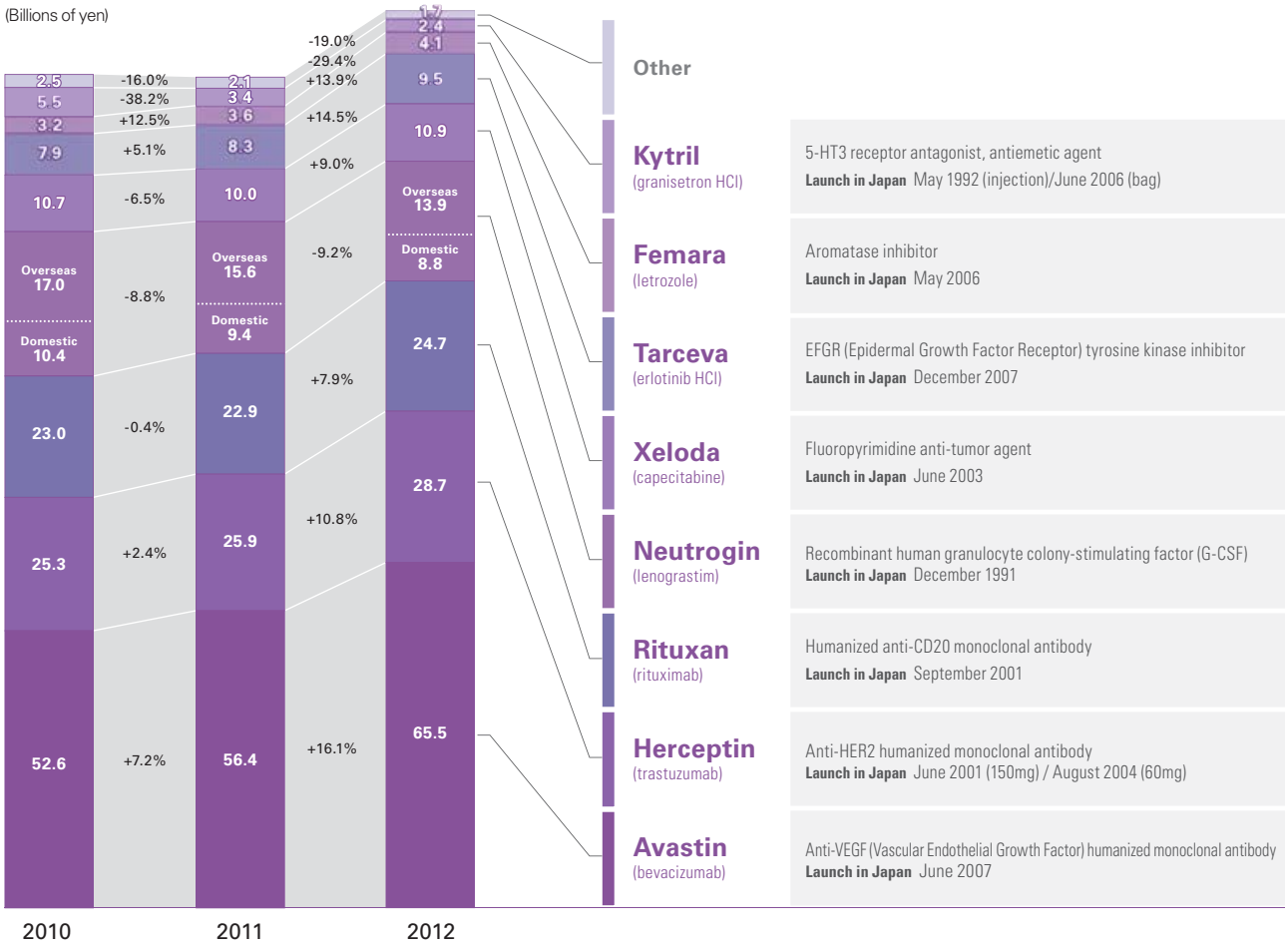
For more detailed information on diseases, products and development projects by therapeutic field, see "Development Pipeline" on pages 92-93 and "Basic Information" on pages 94-107.

Business Review

Oncology

With a first-class product portfolio, Chugai holds the top share of the Japanese oncology market. In addition to reinforcing our strong market position, we will fulfill our responsibility as a leader in the field of oncology by sharing specialized information with healthcare professionals and promoting the standards of care to contribute to cancer treatment in Japan.

Sales of Major Products



Review of 2012 Results

Overview

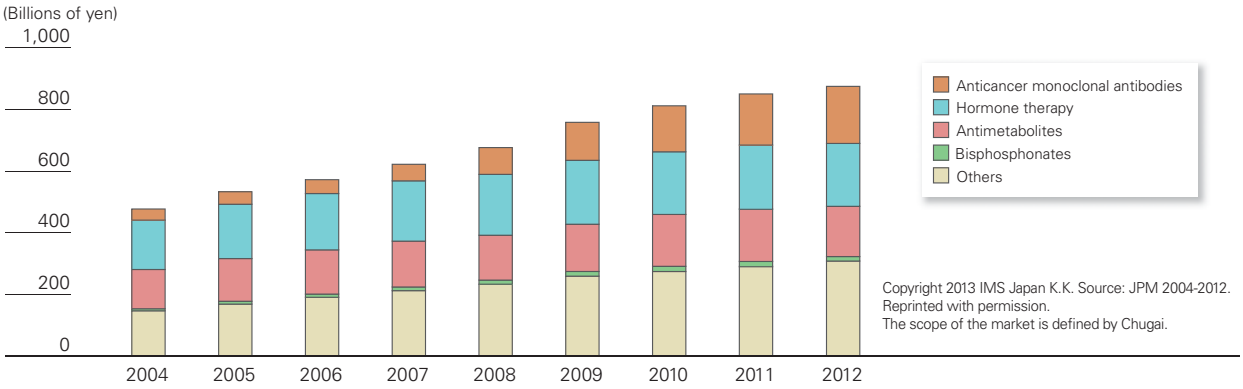
In 2012, net sales in the oncology field increased ¥12.6 billion, or 8.0 percent, year-on-year to ¥170.1 billion. In an increasingly competitive environment, growth was driven by steady expansion in sales of major oncology products such as Avastin, Herceptin and Rituxan. We maintained our leading share of the Japanese oncology market at 19.4 percent.[1]

1. Copyright 2013 IMS Japan K.K. Source: JPM 2012. Reprinted with permission. The scope of the market is defined by Chugai.

New Products and Additional Indications

Sales of the anti-vascular endothelial growth factor (VEGF) humanized monoclonal antibody Avastin increased ¥9.1 billion, or 16.1 percent, to ¥65.5 billion. Avastin maintained its market share in metastatic colorectal cancer (mCRC) despite increasing competition in the first- and second-line treatment settings, reflecting recognition of the drug's efficacy, which is backed by a substantial body of evidence. Avastin's leading market position was reinforced by data from a phase III study (ML18147) announced by Roche in June 2012 that evaluated continued administration of Avastin with first-line and second-line chemotherapy in

Anticancer Market in Japan



mCRC. Market uptake of Avastin for use in non-small cell lung cancer also progressed as Chugai stepped up consulting-based promotion regarding safety management, held medical conferences, and took other measures to broaden the range of patients who can benefit from Avastin. Uptake was also faster than expected in the area of advanced or recurrent breast cancer, an indication for which Avastin was approved in 2011, as Chugai leveraged its wealth of knowledge on breast cancer.

Sales of Herceptin, an anti-human epidermal growth factor receptor-2 (HER2) humanized monoclonal antibody, increased ¥2.8 billion, or 10.8 percent, to ¥28.7 billion. In addition to its indication of metastatic breast cancer and post-operative adjuvant chemotherapy, Herceptin obtained approval for the indication of neoadjuvant chemotherapy in HER2-positive metastatic breast cancer in November 2011. Herceptin has now established itself as the standard of care for patients with HER2-positive breast cancer.

Use of Herceptin as a neoadjuvant and an adjuvant therapy has led to a reduction of tumor recurrence rates to the point where the market for metastatic breast cancer medicine is shrinking. Uptake of Herceptin has also been steady due to active promotion of HER2 testing[2] for advanced or recurrent gastric cancer.

Sales of Xeloda, a fluoropyrimidine anti-tumor agent, increased ¥0.9 billion, or 9.0 percent, to ¥10.9 billion. Combination therapy with oral Xeloda and oxaliplatin (a regimen called XELOX) has become a highly regarded standard of care for colorectal cancer worldwide, in part because it lessens the burden for both patients and healthcare providers compared with intravenous 5-FU therapy. Xeloda continued to steadily penetrate the market for its indication of advanced or recurrent gastric cancer, helped by uptake of combined Xeloda and Herceptin. To address the side effect issues, we provide consultation for each individual patient. DVDs and booklets are also made available to help patients and healthcare professionals self-manage the side effects. We are seeing steady uptake of Xeloda as a result of these measures.

Avastin
(bevacizumab)

Herceptin
(trastuzumab)

Rituxan
(rituximab)

Neutrogin
(lenograstim)

Sales of Tarceva, an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor, increased ¥1.2 billion, or 14.5 percent, to ¥9.5 billion. Market penetration is increasing steadily, reflecting increased understanding by oncologists of the medicine's safety and efficacy.

2. A diagnostic test can determine if a patient's breast or gastric cancer expresses abnormally high levels of a protein called HER2. Herceptin targets HER2 and is administered only to patients whose tumors are identified as being HER2-positive.

Existing Products

Anticancer agents in Chugai's product portfolio posted a steady growth in sales. However, maintaining the market position of supportive care products remained a challenge.

Sales of Rituxan, a humanized anti-CD20 monoclonal antibody, increased ¥1.8 billion, or 7.9 percent, year-on-year to ¥24.7 billion. This medicine has established a solid position as a standard therapy for non-Hodgkin's lymphoma.

Sales of Femara, an aromatase inhibitor for the treatment of breast cancer in postmenopausal women, increased ¥0.5 billion, or 13.9 percent, to ¥4.1 billion, driven by steady market uptake for use in initial adjuvant therapy. High-quality evidence differentiated Femara from competitor products.

Sales in Japan of Neutrogin (overseas name: Granocyte), a recombinant human granulocyte colony-stimulating factor (G-CSF), decreased ¥0.6 billion, or 6.4 percent, to ¥8.8 billion. The decrease reflected market contraction due to expansion of outpatient chemotherapy as well as marketing of competitor products. Outside Japan, competition from follow-on biologics[3] and the impact of the stronger yen led to a decrease in sales of ¥1.7 billion, or 10.9 percent, to ¥13.9 billion.

In a challenging market environment, continued generic erosion and competition from rival products resulted in lower sales of Kytril, a 5-HT3 receptor antagonist antiemetic, which decreased ¥1.0 billion, or 29.4 percent, to ¥2.4 billion.

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

Marketing

Consulting-based promotion is the basis of Chugai's MR activities, reflecting our business philosophy of "innovation all for the patients."

Over recent years, there has been a shift toward a more patient-oriented approach to treatment. A multidisciplinary team, including physicians and other medical professionals such as nurses, pharmacists and nutritionists, coordinates treatment and care depending on the needs of each individual patient. Chugai will help popularize the multidisciplinary approach by holding workshops at hub hospitals in each region of Japan and conducting study sessions at individual hospitals to encourage the concept of multidisciplinary care.

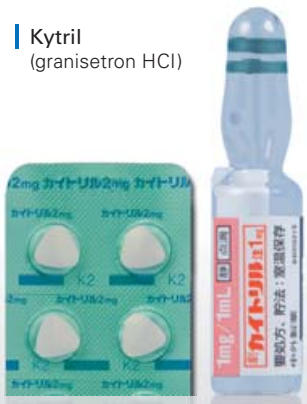
Chugai's marketing system is centered on approximately 550 oncology MRs, who provide accurate and timely information for healthcare professionals. We established a special training program for oncology MRs in 2007. As of the end of 2012, approximately 120 MRs have finished the program. We also started equipping all MRs with tablet computers in 2012 so that they can leverage information technology in their marketing activities. MRs use the tablets to display various data

Xeloda
(capecitabine)

Tarceva
(erlotinib HCl)

Femara
(letrozole)

Kytril
(granisetron HCl)



and evidence, which helps them explain Chugai's products to physicians. In addition, we have established the new position of medical associate (MA). We currently have approximately 80 MAs who work together with our MRs to offer value-added information tailored to the needs of healthcare professionals.

2013 Strategy and Outlook

We expect new data on the use of Avastin to treat metastatic colorectal cancer as well as two novel breast cancer medicines to support our oncology portfolio.

In 2013, we will work to further increase the penetration of our products and strengthen their positions by providing detailed information and treatment suggestions with a focus on consulting-based promotion that addresses the individual needs of as many patients as possible.

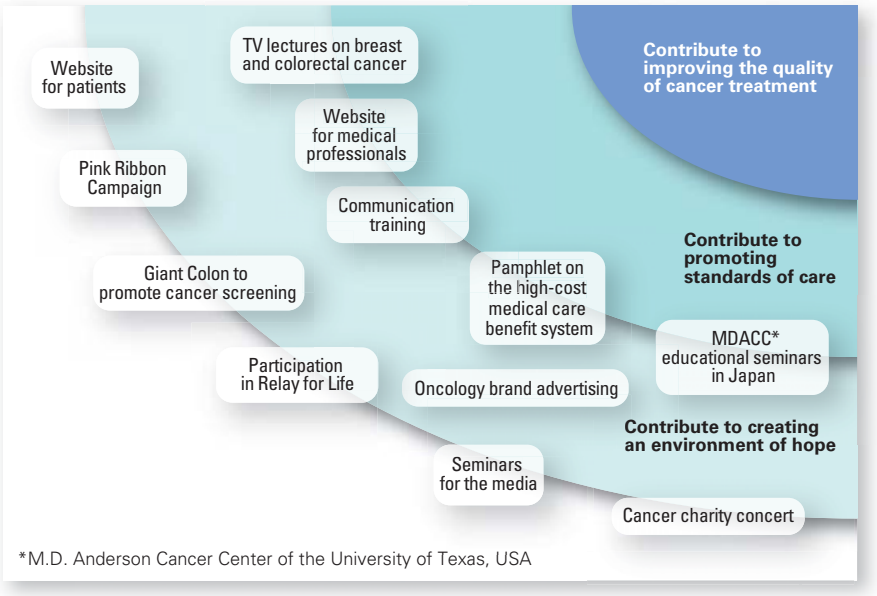
We will take steps to further build the market presence of our key growth driver, Avastin. New study data on Avastin's safety and efficacy in the treatment of metastatic colorectal cancer scheduled to be announced in 2013 will underpin our efforts to increase this product's competitive advantage and solidify its position. For lung cancer, we will provide detailed information on Avastin's safety profile to support continued growth. For breast cancer, we aim for further market penetration by continuing to highlight the effectiveness of Avastin in reducing tumor size.

Our strategy for Herceptin will focus on accelerating expansion of its use in neoadjuvant therapy for breast cancer. In addition, we will prepare our marketing organization for the smooth uptake penetration of RG1273 and RG3502, two medications targeting HER2 that are expected to obtain regulatory approval in 2013 or 2014. We will also continue our efforts to promote more widespread use of HER2 testing for gastric cancer and the penetration of appropriate testing methods.

Marketing of Xeloda will focus on encouraging more physicians to switch from FOLFOX therapy[4] by highlighting the convenience and safety of the XELOX regimen in colorectal cancer. We will also provide support and information to patients and physicians on side-effect management. For gastric cancer, we will continue to promote the use of combination therapy with Herceptin in HER2-positive disease.

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

Oncology Branding Activities



*M.D. Anderson Cancer Center of the University of Texas, USA

Actemra

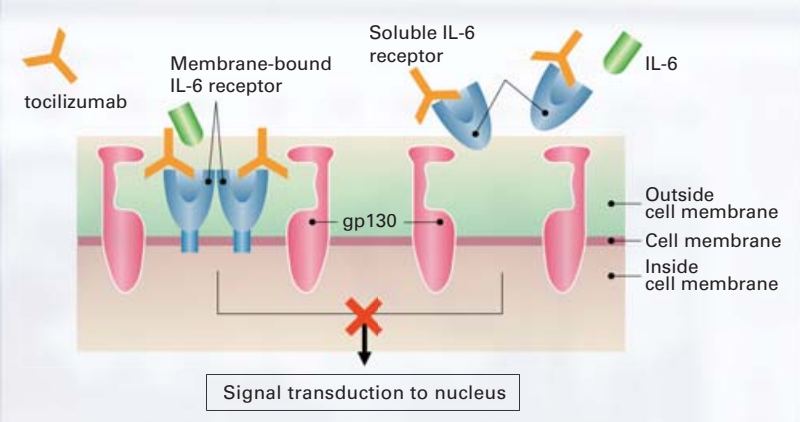
Humanized anti-human IL-6 receptor monoclonal antibody (generic name: tocilizumab)

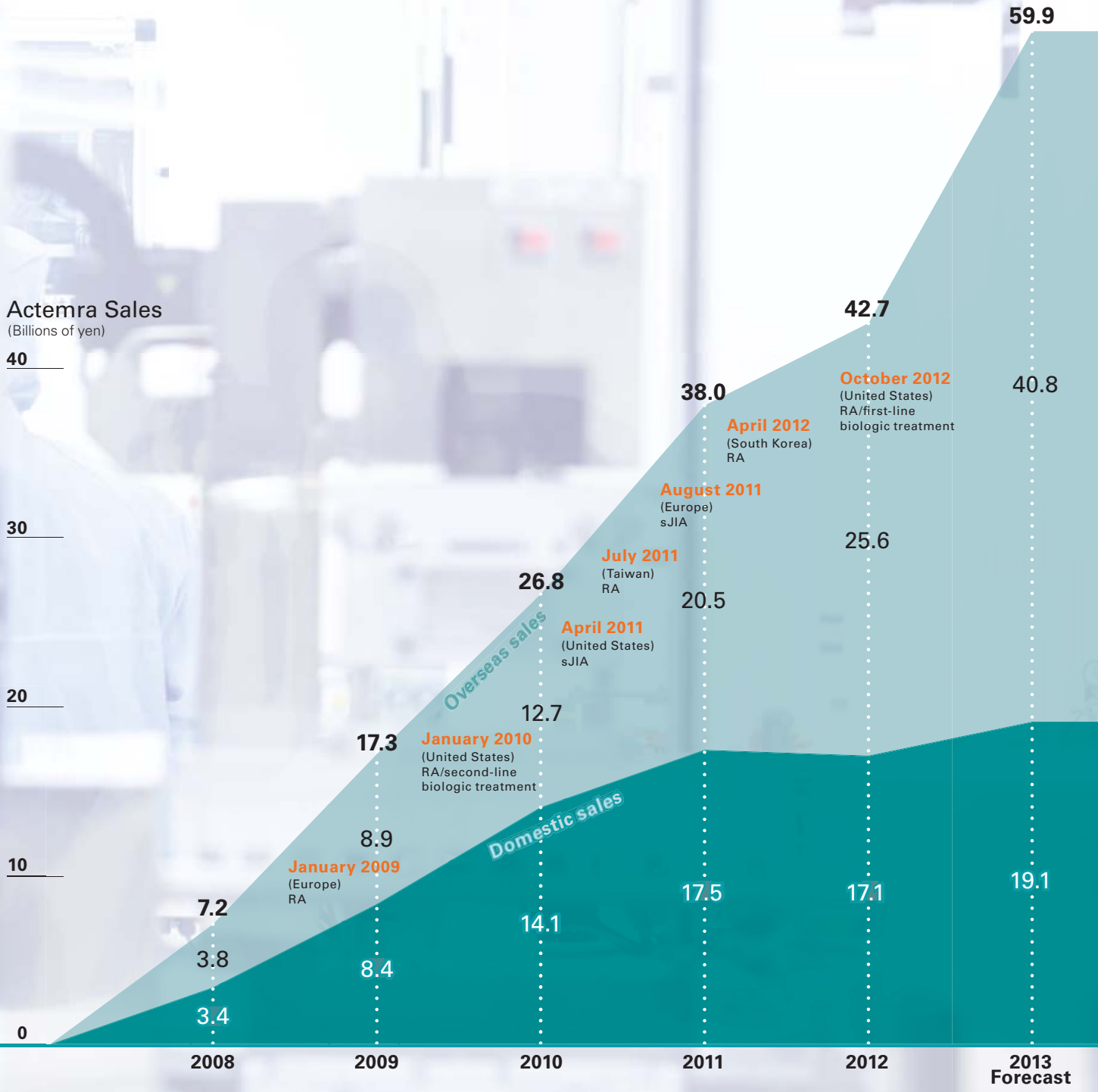
Developed in-house, Actemra is a growth driver for Chugai. With a novel mechanism of action, it has achieved rapid market growth and is advancing as a representative global Chugai product.

Filing for Regulatory Approval/Market Launch (Japan)

June 2005	Castleman's disease
April 2008	Rheumatoid arthritis (RA)
	Systemic-onset juvenile idiopathic arthritis (sJIA)
	Polyarticular-course juvenile idiopathic arthritis (pJIA)
March 2012	(Filed) RA (new dosage form: subcutaneous injection)
	(Filed overseas in December 2012)

Mechanism of Action





The world's first antibody targeting interleukin-6 (IL-6) and the first therapeutic antibody created in Japan, Actemra is currently approved in more than 100 countries, and rapid market growth continues worldwide. Its steady market uptake is the result of the clear efficacy it has shown in achieving high rates of long-term remission and treatment retention. Actemra's reputation for efficacy and safety is growing, backed by data from a wealth of sources including post-marketing all-case surveillance and direct comparison tests with competitor products in addition to clinical data.

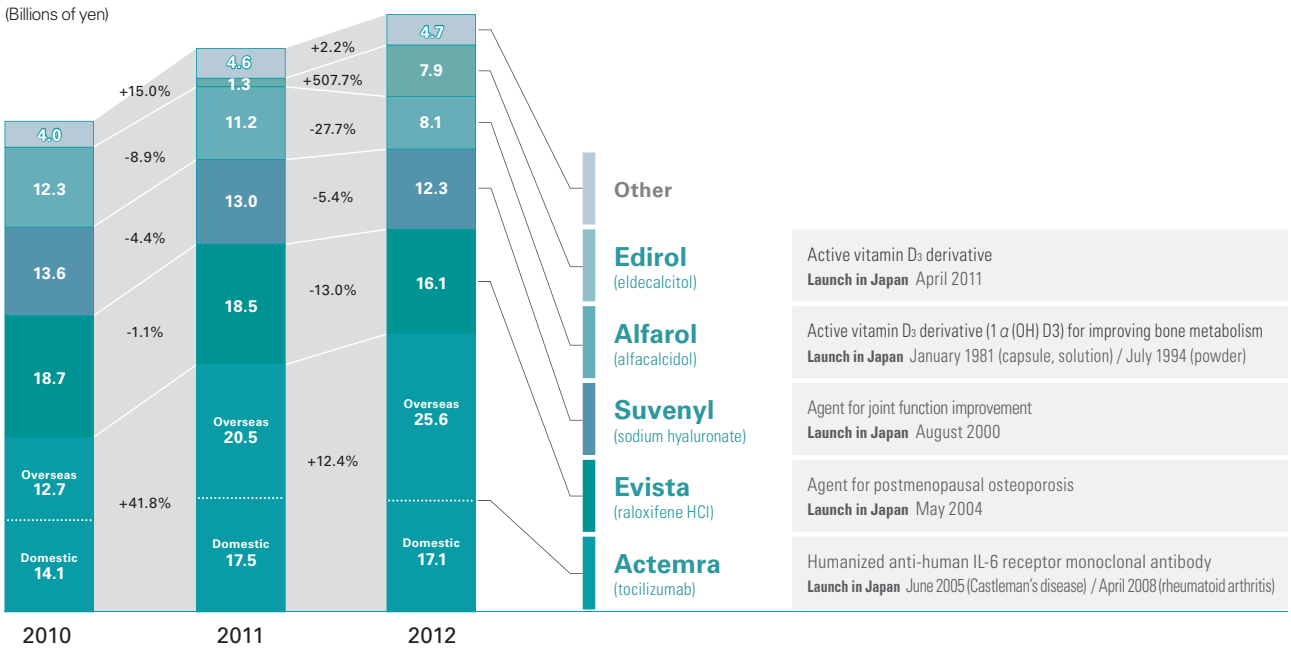
With its novel mechanism of action, Actemra has received a high level of scholarly interest from healthcare professionals, and is among the top products in its field in the number of related presentations at scientific conferences.

Further growth is expected with the March 2012 filing in Japan of an application for a subcutaneous formulation (applications also filed overseas). In addition, a phase I clinical trial is progressing smoothly in Japan for SA237, which applies recycling antibody technology to Actemra, representing a further step in Actemra's evolution.

Bone and Joint Diseases

Chugai aims to expand in this key future growth field by promoting rapid market penetration and building a strong market presence for two products originating from its own research: our main growth driver, Actemra, and our new next-generation osteoporosis therapeutic drug, Edirol.

Sales of Major Products



Edirol (eldecalcitol)
Active vitamin D_3 derivative
Launch in Japan April 2011

Alfarol (alfacalcidol)
Active vitamin D_3 derivative (1 α (OH) D3) for improving bone metabolism
Launch in Japan January 1981 (capsule, solution) / July 1994 (powder)

Suvenyl (sodium hyaluronate)
Agent for joint function improvement
Launch in Japan August 2000

Evista (raloxifene HCl)
Agent for postmenopausal osteoporosis
Launch in Japan May 2004

Actemra (tocilizumab)
Humanized anti-human IL-6 receptor monoclonal antibody
Launch in Japan June 2005 (Castleman's disease) / April 2008 (rheumatoid arthritis)

Review of 2012 Results

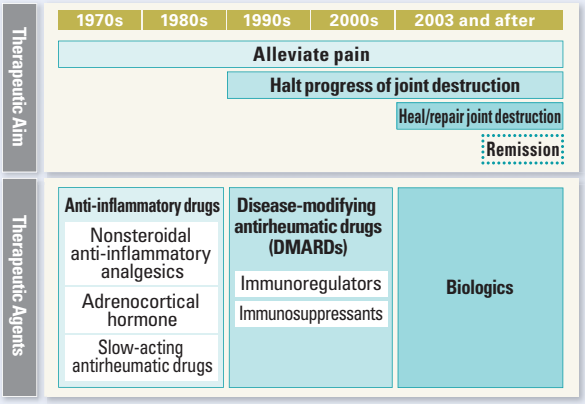
Overview

In 2012, Chugai's total sales in the bone and joint diseases field increased ¥5.2 billion, or 6.0 percent, compared with the previous year to ¥91.9 billion. Sales of Actemra, a humanized anti-human IL-6 receptor monoclonal antibody for the treatment of rheumatoid arthritis (RA), continued to grow, offsetting the impact on sales from the revision of National Health Insurance (NHI) drug prices. Sales of Edirol, an osteoporosis treatment based on many years of research on vitamin D and launched in 2011, grew significantly, putting Edirol in the leading position in the market for active vitamin D_3 derivatives. The market positions of Alfarol and Evista remained steady in an intensely competitive environment, with only slight declines in sales.

Rheumatoid Arthritis

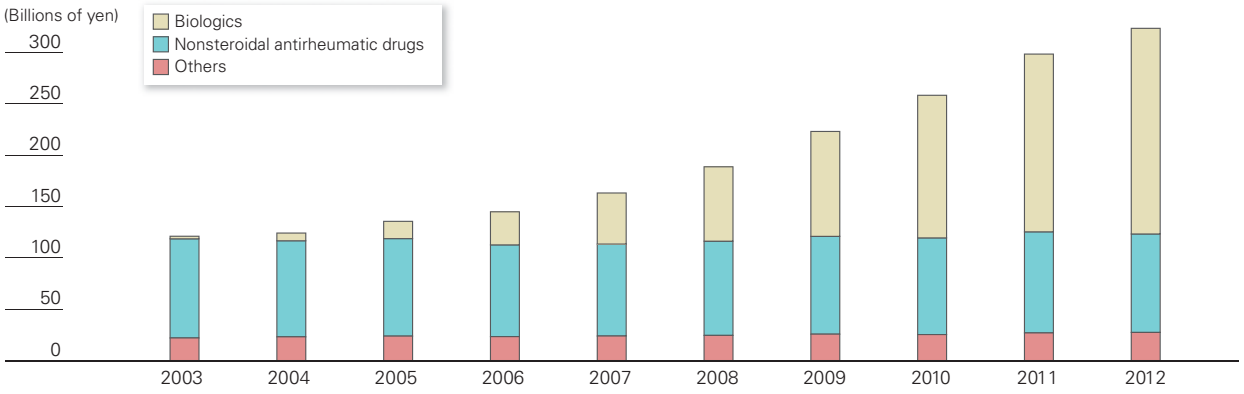
Actemra, which originated from Chugai, is the first therapeutic antibody created in Japan, with a novel mode of action as the world's first drug targeting interleukin-6 (IL-6). Sales in Japan in 2012 decreased ¥0.4 billion, or 2.3 percent, to ¥17.1 billion. The Japanese market for biologic medicines continues to expand, with estimated growth of about 30 percent* in 2012. On the

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.

Rheumatoid Arthritis Market in Japan

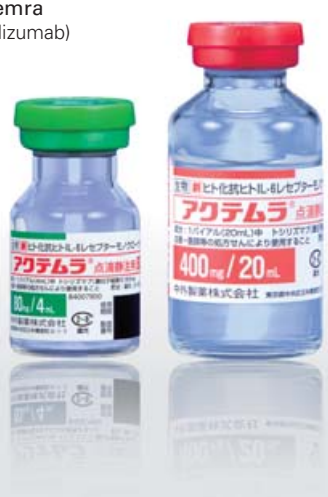


other hand, the launch of competitor products in recent years has further intensified competition. Under these conditions, a recalculation for the market expansion of Actemra resulted in a 25.0 percent reduction of the NHI drug price. However, sales grew substantially on a volume basis, reflecting steady market penetration. On a value basis, Actemra's market share remained at the level of the previous year. The growth of its share among biologic medicines used as first-line treatments was particularly impressive, increasing approximately 1.5 times.

The main factor behind these results was growing recognition of Actemra's profile as a medicine with effectiveness in preventing joint destruction, a high remission rate and sustained long-term efficacy. In 2012, it was announced at the Annual European Congress of Rheumatology (EULUAR) and the annual meeting of the American College of Rheumatology (ACR) that Actemra monotherapy showed superior improvement in rheumatoid arthritis signs and symptoms versus adalimumab monotherapy. This data adds to the growing body of evidence supporting the benefit of Actemra monotherapy when methotrexate is not appropriate. Analysis of approximately 7,900 cases from all-case registration surveillance in the ADACTA trial also contributed to solid recognition of the product's safety. This data was requested by the FDA to grant Actemra its first-line label.

In marketing, Chugai increased the number of medical associates (MAs), who convey advanced scientific information, and conducted intensive training in cooperation with the Medical Affairs Division to enhance the expertise of its medical representatives (MRs) and MAs. By deepening our multilayered marketing organization of MRs and MAs backed by head and branch offices, we are able to provide information and follow-up tailored to each patient.

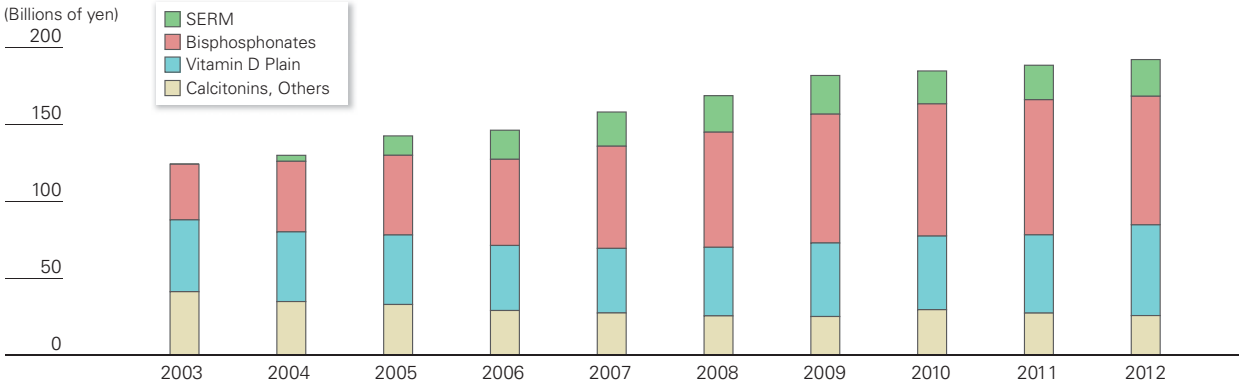
Actemra
(tocilizumab)



Evista
(raloxifene HCl)

Suvenyl
(sodium hyaluronate)

Osteoporosis Market in Japan



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The scope of the market is defined by Chugai.

Sales of Actemra outside Japan (exports to Roche for sale in regions other than Japan, Korea and Taiwan) rose ¥5.1 billion, or 24.9 percent, to ¥25.6 billion. The product was approved in the European Union, where it is known as RoActemra, in 2009 and in the United States in 2010. Actemra/RoActemra is now a global medicine approved for sale in more than 100 countries. In October 2012, it also obtained approval as a first-line biologic treatment in the US. Moreover, in addition to the evidence on efficacy and safety accumulated in Japan, the release of a consensus statement that pointed to the high level of efficacy and manageable safety profile of IL-6 inhibitors boosted recognition of these drugs in the highly competitive European and US markets. As a result, market uptake has been rapid.

To meet the increasing global demand for Actemra and prepare for the planned launch of a new subcutaneous formulation, Chugai is outsourcing manufacturing of the active pharmaceutical ingredient (API) of Actemra to Genentech in the United States under a toll manufacturing agreement. FDA approval has already been obtained, and commercial production is under way.

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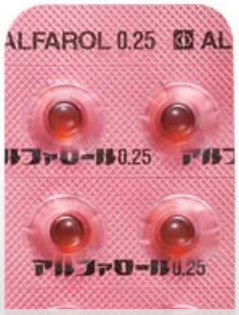
The scope of the market is defined by Chugai.

Alfarol
(alfacalcidol)



Edirol
(eldecalcitol)

Osteoporosis and Osteoarthritis

Chugai is the market leader in the osteoporosis segment in Japan. In 2012, sales increased ¥6.6 billion, or 507.7 percent compared with the previous year, to ¥7.9 billion, as Edirol, an active vitamin D_3 derivative from Chugai research launched in 2011, continued to penetrate the market. (Edirol sales for 2011 are for April to December because the product was launched in April 2011). Conditions for Edirol were challenging in 2011 because major launch promotions were canceled or postponed in the wake of the Great East Japan Earthquake. However, with the rapid increase in use, primarily for new patients, after restrictions on long-term prescriptions ended in April 2012 and the 2011 revision of osteoporosis prevention and treatment guidelines took effect, Edirol has become the leading active vitamin D_3 derivative on the market. The first vitamin D_3 derivative to receive a grade A recommendation in the revised guidelines, Edirol is highly regarded for its superior effectiveness in increasing bone mass and preventing bone fractures compared with conventional therapeutics.

Sales of Alfarol decreased ¥3.1 billion, or 27.7 percent, to ¥8.1 billion due to the shift to Edirol and generic competition, despite the product's strong reputation after 30 years on the market as a basic treatment for osteoporosis.

Sales of Evista decreased ¥2.4 billion, or 13.0 percent, to ¥16.1 billion. While the market share of competitor products increased due to the end of restrictions on long-term prescriptions, Chugai worked to maintain the position of Evista by highlighting the substantial data on its safety and efficacy as well as the benefits of continuous administration. Chugai and Eli Lilly Japan K.K. terminated their co-marketing agreement for Evista at the end of December 2012. As of January 2013, Eli Lilly Japan is solely responsible for the distribution and marketing of Evista in Japan.

In the osteoarthritis segment, sales of Suvenyl decreased ¥0.7 billion, or 5.4 percent, to ¥12.3 billion. Sales were impacted by the revision of NHI drug prices, but the clear benefits of Suvenyl as the straight-chain hyaluronic acid preparation with the highest molecular weight remained well recognized. Sales volume grew as a result of Suvenyl's recognized benefits and the change in dosage form to a plastic syringe in 2011.

2013 Strategy and Outlook

In 2013, competition in the RA market is likely to increase worldwide due to the expected launch of an oral JAK inhibitor. In response, Chugai, in collaboration with Roche, will work to further increase sales by establishing Actemra as a first-line treatment based on substantial clinical data and study findings.

Data have shown that Actemra can result in high rates of prolonged remission. In domestic clinical trials, 55.3 percent of patients were still in remission after five years. Moreover, rheumatologists are moving from the conventional "wait-and-see" approach to a "treat-to-target" approach in which the patient's response to treatment is assessed after a short period and patients who have not responded are switched to a new therapy. The treatment objective is shifting to early and sustained remission.

In 2013, the interim report of FIRST-BIO, a post-marketing surveillance study, is scheduled to be released. We plan to use this report to expand Actemra's market share by promoting it as a first-line biologic treatment. The launch of a new subcutaneous formulation is also expected in 2013. We will focus on quickly establishing its use as a more convenient treatment option for patients.

Outside Japan, Chugai will continue to cooperate closely with the Roche Group in further expanding Actemra's sales and market share as a global medicine that contributes to the treatment of RA worldwide. A key focus will be on the monotherapy use of Actemra following the strong data from the ADACTA trial. This study showed that Actemra monotherapy leads to a significantly and clinically meaningful improvement in disease activity compared to adalimumab monotherapy. Introducing the subcutaneous formulation will be even more important in the US and European markets, where subcutaneous injections constitute the majority of RA treatments. As in Japan, we will make focused efforts to provide information highlighting the efficacy and safety of Actemra with a view to obtaining approval of the new subcutaneous formulation in the future. Obtaining approval as a first-line treatment is of particular significance in the US market, which accounts for about half of the global market for biologic medicines.

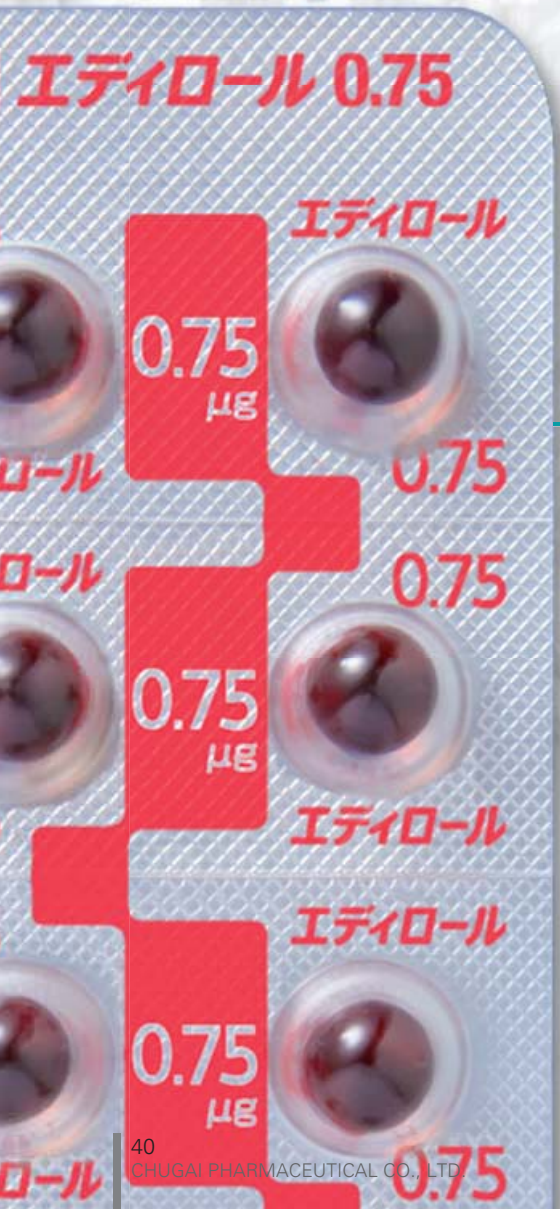
In the osteoporosis segment, we will focus on accelerating the market penetration of Edirol and increasing sales by continuing to raise awareness of the effectiveness of vitamin D in increasing bone mass and preventing bone fractures, backed by powerful evidence. Chugai has established a strong presence in the osteoporosis segment through extensive research into vitamin D. The establishment of Edirol will solidify our presence as a leading pharmaceutical company and drive expansion of the vitamin D_3 market.

In the osteoarthritis segment, we will emphasize the safety and efficacy of Suvenyl and the convenience of the new dosage form to maintain market share. Moreover, we will work to expand the market by promoting awareness of the importance of early treatment.

Edirol

Active vitamin D_3 derivative (generic name: eldecalcitol)

Developed in-house, Edirol is a next-generation treatment for osteoporosis that has brought together Chugai's many years of research into vitamin D. Market uptake has been strong since the drug's launch in 2011.

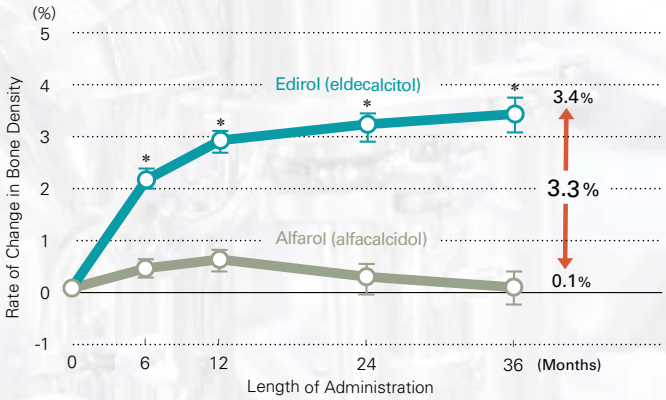


Filing for Regulatory Approval/Market Launch (Japan)

October 2009	Filed
January 2011	Approved
April 2011	Launched

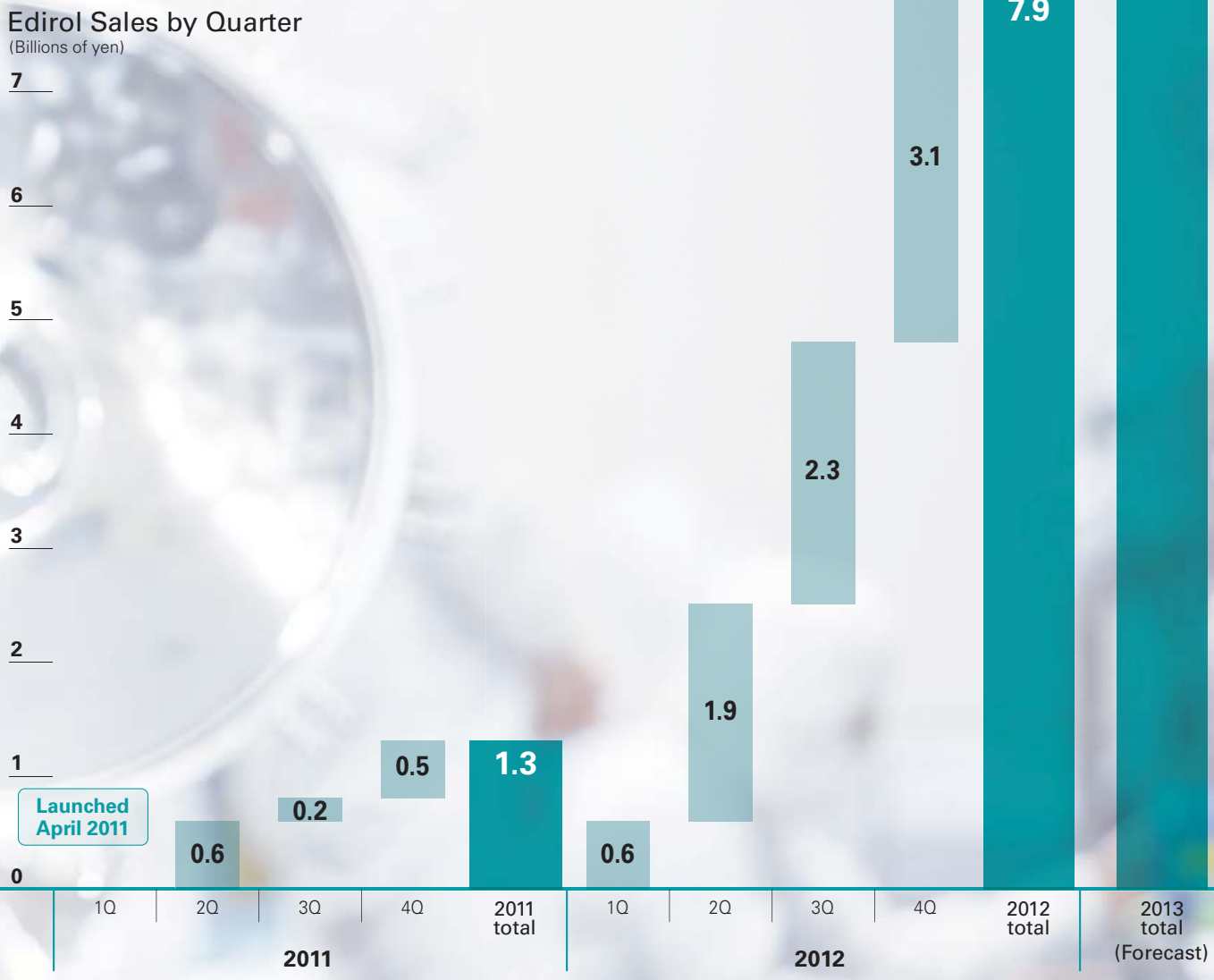
(Chugai entered into a co-development and co-marketing agreement with Taisho Pharmaceutical Co., Ltd. in May 2008.)

Rate of Change in Bone Density



Average± S.E.
* : p < 0.001(Eldecalcitol vs. alfacalcidol)
Student t-test

Source: Adapted from Matsumoto T, et al, Bone 2011; 49; 605-12.



In addition to promoting calcium absorption like its predecessor product Alfarol, Edirol is a next-generation osteoporosis treatment that also inhibits bone resorption and is significantly more effective in preventing bone fractures and increasing bone density.

Active vitamin D_3 derivatives function in the small intestine to promote efficient absorption of calcium ingested in food, giving them an important position as a base treatment for osteoporosis. As a leading company in vitamin D_3 derivatives for 30 years, Chugai has focused on research and market expansion, and Edirol can be regarded as the culmination to date of Chugai's research and expertise.

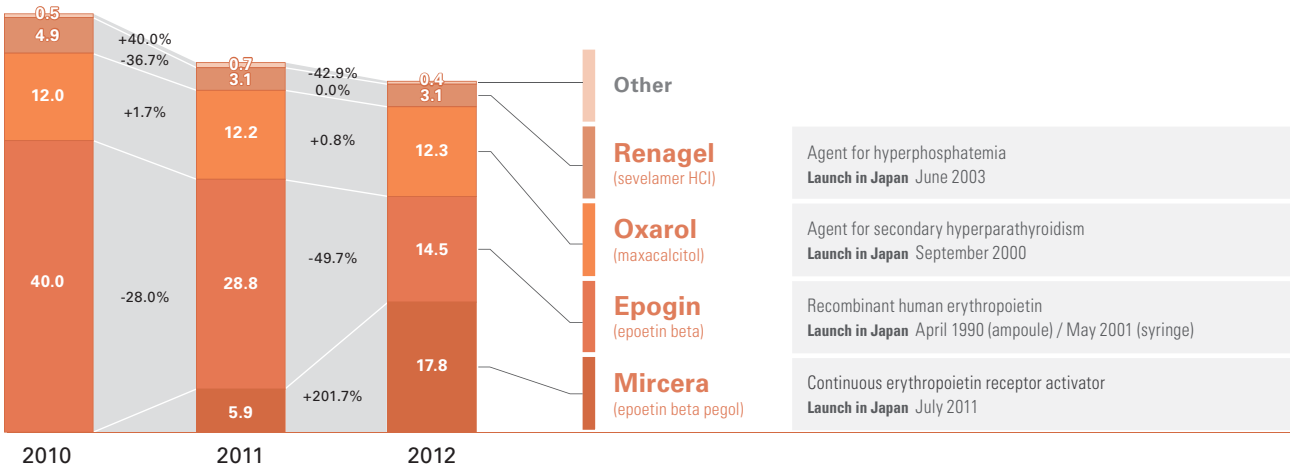
As a result of Chugai's efforts to compile useful data from the clinical development stage, Edirol received a grade A recommendation in the osteoporosis treatment guidelines in December 2011 — a first for a vitamin D_3 derivative. In addition to growing awareness of these guidelines and the lifting of restrictions on long-term prescriptions in April 2012, Edirol is rapidly penetrating the market. Currently, Edirol holds the top share in Japan among vitamin D_3 preparations, and is becoming a new growth driver for Chugai.

Renal Diseases

As a leader in the field of renal diseases, Chugai will further increase its market presence by promoting the rapid establishment of its innovative new medicine Mircera, and will drive market expansion and contribute to overall treatment by providing education on the importance of early treatment of renal anemia and contribute to overall treatment.

Sales of Major Products

(Billions of yen)



Review of 2012 Results

Overview

In 2012, sales in the renal diseases field decreased ¥2.6 billion, or 5.1 percent, year-on-year to ¥48.2 billion. Sales of Epogin, our established erythropoietin-stimulating agent (ESA) for the treatment of renal anemia, continued to decline due to competitive pressure and because patients were switched to Mircera, a long-acting ESA and new growth driver launched in 2011. At the same time, sales of Mircera grew more slowly than we expected, reflecting the pace of market uptake.

In renal anemia associated with chronic kidney disease (CKD), in the dialysis segment, medical costs have been under pressure since the government introduced a flat-sum reimbursement system for ESAs in 2006, while the market growth generated by Japan's elderly population has slowed and competition has intensified. In contrast, the pre-dialysis segment has grown in recent years, driven in part by a national education campaign to promote early diagnosis and treatment of renal anemia in response to an increase in CKD in patients with diabetes.

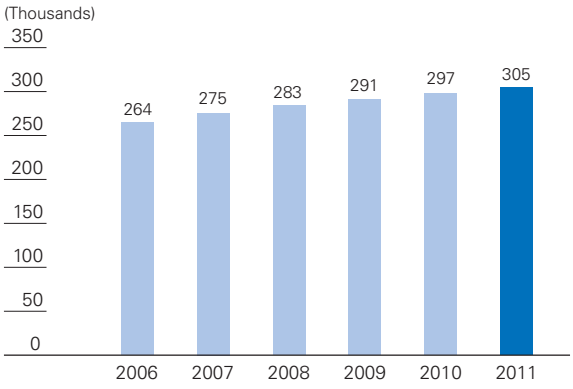
Sales of Mircera increased ¥11.9 billion, or 201.7 percent, year on year to ¥17.8 billion, making this medication one of Chugai's key growth drivers. (Sales of Mircera in the year earlier are for July through December because the product was launched in July 2011.) Like Epogin, Mircera can be used in both the dialysis and pre-dialysis settings. An innovative medication, Mircera allows maintenance of stable hemoglobin levels with administration once every four weeks, a significant reduction in treatment frequency compared with existing medicines. In addition, the serum half-life of Mircera is similar after both intravenous and subcutaneous administration, allowing consistent treatment from the pre-dialysis to the dialysis setting. In the dialysis segment, although Mircera is expected to offer advantages such as more efficient patient management and lower treatment costs, market uptake has been slower than expected due to the time needed to establish methods of switching from existing drugs. However, the number of healthcare providers who have seen Mircera's effects firsthand and recognized its usefulness has steadily increased. In the pre-dialysis segment, where the characteristics of Mircera are demonstrated more effectively, market uptake has advanced steadily as planned. Mircera has been well received for the convenience it offers patients, such as a longer dosing interval and long duration of action. It is already establishing a solid position, particularly for use in new patients.

Sales of Epogin decreased ¥14.3 billion, or 49.7 percent, to ¥14.5 billion due to the switch to Mircera and aggressive competition from rival products including follow-on biologics.

Sales of Oxarol, an agent for secondary hyperparathyroidism, grew ¥0.1 billion, or 0.8 percent, to ¥12.3 billion. Under flat market growth that partly reflected a higher target range for parathyroid hormone in the revised treatment guidelines, sales growth was driven by substantial clinical data showing that treatment with Oxarol can increase life expectancy.

Sales of Renagel, for hyperphosphatemia, were flat at ¥3.1 billion. In 2011, the Great East Japan Earthquake had a significant impact on Renagel sales, but in 2012 the product's market position recovered to almost the pre-earthquake level based on many years of evidence that it increases life expectancy.

Number of Chronic Dialysis Patients in Japan



Source: Overview of Regular Dialysis Treatment in Japan (as of December 31, 2011) by Statistical Survey Committee, The Japanese Society for Dialysis Therapy

2013 Strategy and Outlook

In 2013, while the pre-dialysis segment is forecast to continue to expand, Chugai expects intense competition, including price competition, from rival products and follow-on biologics in the dialysis segment. We will focus on rapidly establishing Mircera in the pre-dialysis segment and also work to increase its use in the dialysis segment by highlighting the advantage of consistent treatment from pre-dialysis to dialysis. In addition, we will continue our efforts to expand the market by emphasizing the benefits of Mircera (long duration of action, administration once every four weeks) and educating potential renal anemia patients about the importance of early treatment. At the same time, we will establish clinical evidence from large-scale surveillance data that Mircera can control iron levels, and will work to generate evidence of the drug's benefits from the standpoint of medical costs as well as the quality of life of patients. Our goal is to build a leading position for Mircera by establishing a solid advantage in terms of efficacy. Marketing activities will continue to focus on proposing optimal treatment approaches for individual patients using our pioneering electronic system for managing each patient's course of treatment, combined with our comprehensive pharmacovigilance system.

For Oxarol, we aim to establish a solid market position ahead of the expected launch of competitor products and generics over the next several years. In addition to highlighting Oxarol's effects on bones, we will focus on providing education about the benefits of early treatment of hyperparathyroidism, which is emphasized in treatment guidelines. Promotional efforts for Renagel will highlight its globally recognized effectiveness in improving life expectancy and its safety as a metal-free phosphate binder.

Mircera
(epoetin beta pegol)

Epogin
(epoetin beta)

Oxarol
(maxacalcitol)

Renagel
(sevelamer HCl)

Mircera

Continuous erythropoietin receptor activator (generic name: epoetin beta pegol)

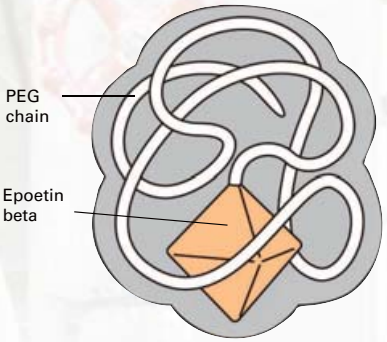
Mircera is an innovative long-acting treatment for anemia that allows stable and sustained control of the disease. It is penetrating the market as a new major product for Chugai.

Filing for Regulatory Approval/Market Launch (Japan)

July 2009	Filed
April 2011	Approved
July 2011	Launched

(Launched outside Japan by Roche in 2007.
Currently sold in over 100 countries.)

Characteristics of Pegylation and the Structure of Mircera

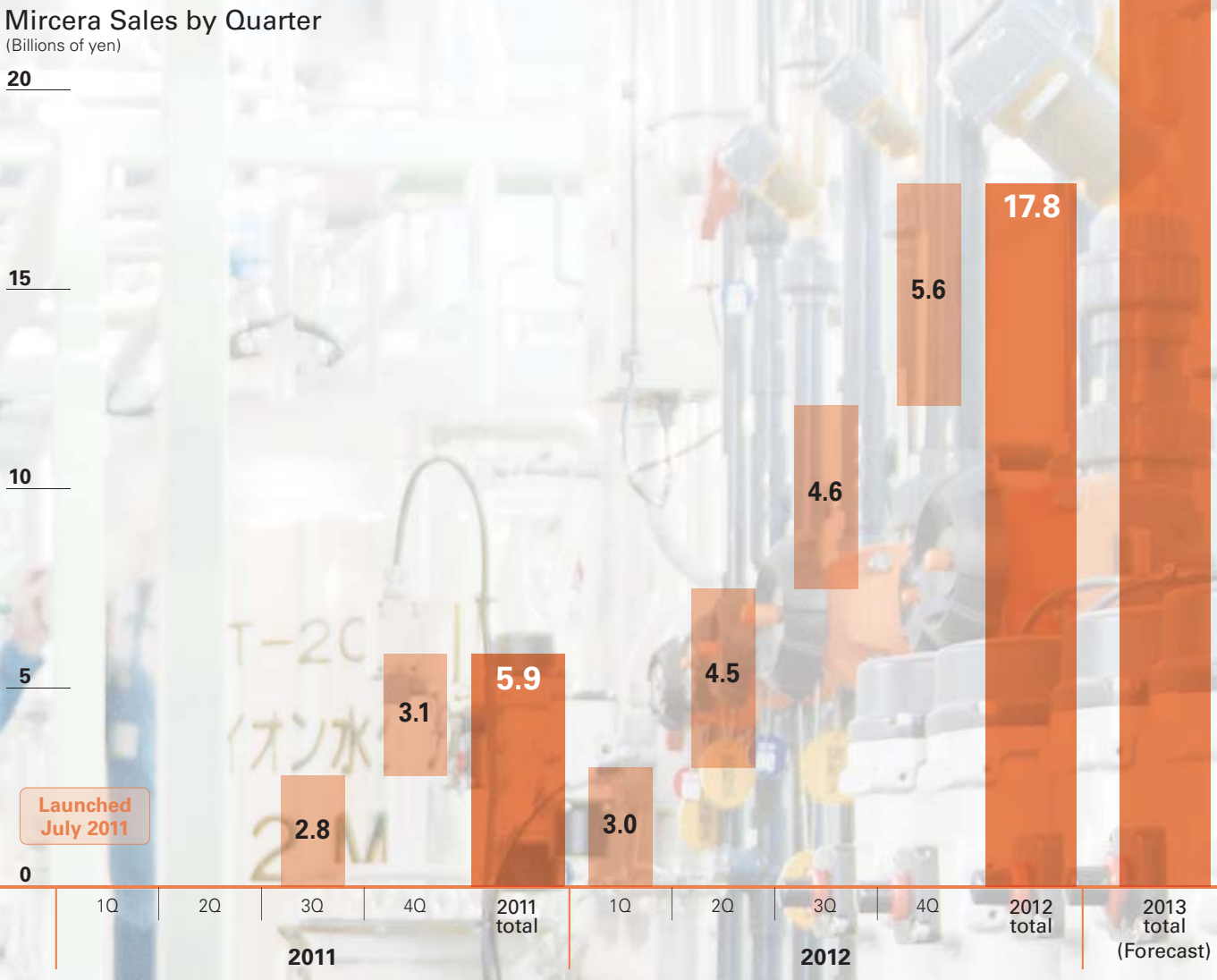


(Conceptual diagram)

General Characteristics of Pegylation

Increasing molecular weight leads to:

1. Extended serum half-life
2. Reduced antigenicity
3. Sustained effect due to slow in vivo absorption from subcutaneous tissue at injection site
4. More limited serum and hepatic distribution



Mircera is an innovative anemia treatment that allows maintenance of stable, sustained hemoglobin levels. With a longer serum half-life than conventional products, the drug enables a significant reduction in dosing frequency to once every four weeks. In addition, the serum half-life is virtually the same after both intravenous and subcutaneous administration. This allows consistent treatment from the pre-dialysis to the dialysis setting. As a result, expectations are high not just for its convenience and reduction of medical costs, but also in terms of control of the disease.

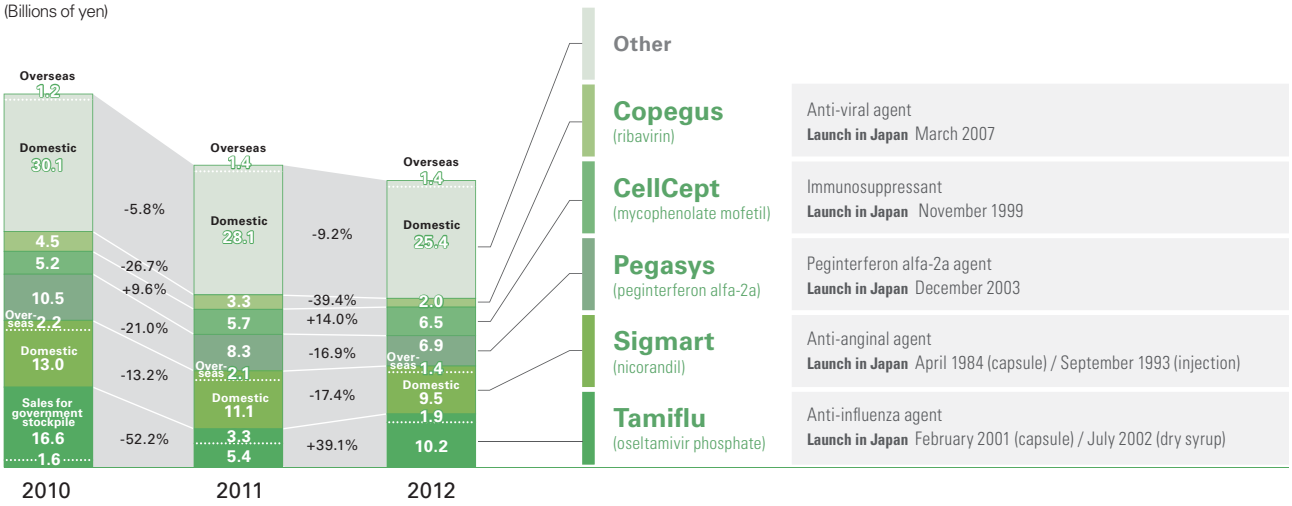
For a period after launch, market uptake was slower than expected due to the impact of the Great East Japan Earthquake and other factors. However, Mircera's reputation among healthcare professionals is rising, and sales are growing steadily, particularly in the pre-dialysis segment, where long-acting erythropoietin-stimulating agents (ESAs) are becoming the mainstream treatment. Mircera is building a leading position in its field, and has grown into a major product for Chugai, with sales in Japan just behind Avastin, Herceptin and Rituxan in 2012, one year after its launch. As a pioneer in ESAs with a powerful presence in the field, Chugai will make the most of its knowledge and reliability to achieve further market penetration.

Others

In the chronic hepatitis C segment, Chugai aims to establish a stronger market position and expand market share by enhancing efforts to provide information to healthcare professionals to accelerate the penetration of its products. In addition, Chugai is preparing its marketing organization for its upcoming entry into the central nervous system (CNS) field, an area of significant unmet medical need.

Sales of Major Products

(Billions of yen)



Copegus (ribavirin)	Anti-viral agent **Launch in Japan** March 2007
CellCept (mycophenolate mofetil)	Immunosuppressant **Launch in Japan** November 1999
Pegasys (peginterferon alfa-2a)	Peginterferon alfa-2a agent **Launch in Japan** December 2003
Sigmart (nicorandil)	Anti-anginal agent **Launch in Japan** April 1984 (capsule) / September 1993 (injection)
Tamiflu (oseltamivir phosphate)	Anti-influenza agent **Launch in Japan** February 2001 (capsule) / July 2002 (dry syrup)

Review of 2012 Results

Overview

In 2012, total sales in the Others field, which covers all products excluding oncology, bone and joint diseases, and renal diseases, decreased ¥3.5 billion, or 5.1 percent, year-on-year to ¥65.1 billion. The decrease was mainly due to lower sales of Pegasys (peginterferon alfa-2a) and Copegus (ribavirin), an antiviral agent used in combination with Pegasys, in a contracting market for chronic hepatitis C drugs. This decrease outweighed an increase in sales of the anti-influenza agent Tamiflu from the previous year, reflecting an outbreak of seasonal influenza in the 2011/2012 season.

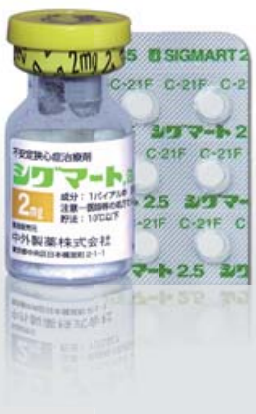
Chronic Hepatitis C

Chronic hepatitis C results from infection with the hepatitis C virus (HCV). An estimated 2 million people 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. It is therefore important to detect and treat chronic hepatitis C early.

Sales of Pegasys decreased ¥1.4 billion, or 16.9 percent, to ¥6.9 billion. However, the additional indication of compensated liver cirrhosis caused by hepatitis C in combination therapy with Copegus was approved in 2011, ahead of competitor products, and

Tamiflu
(oseltamivir phosphate)

Sigmart
(nicorandil)

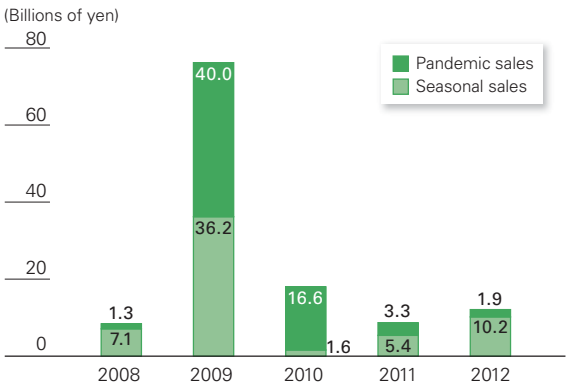


market uptake has steadily advanced. Pegasys also obtained approval in 2011 as monotherapy for chronic hepatitis B. It is the only peginterferon agent indicated for that condition, which is commonly treated with nucleic acid analogues.

Influenza

Sales of Tamiflu increased ¥3.3 billion, or 37.9 percent, to ¥12.0 billion. Seasonal sales were ¥10.2 billion, an increase of ¥4.8 billion (88.9 percent), while pandemic sales were ¥1.9 billion, a decrease of ¥1.4 billion (42.4 percent), due to replacements of Tamiflu supplied in fiscal 2005 (April 2005–March 2006) that had reached its expiration date. Sales of Tamiflu proved largely resilient to competition due to the drug's effectiveness and the benefits of its unique dry syrup formulation.

Tamiflu Sales



2013 Strategy and Outlook

The market for chronic hepatitis C medicines is projected to continue to contract because of an expected increase in patients postponing treatment in anticipation of the launch of new drugs. Under these conditions, Chugai will continue to focus on promoting the positive clinical data supporting Pegasys and Copegus and will work to expand market share by establishing their use in the newly approved indication of compensated liver cirrhosis caused by hepatitis C. For chronic active hepatitis B, we will encourage switching from treatment with nucleic acid analogues by highlighting the efficacy of treatment, including improved quality of life, with a peginterferon agent.

In the market for anti-influenza drugs, while intense competition is expected to continue, we will contribute to influenza treatment by making steady efforts to provide information on Tamiflu's safety and effectiveness, including prevention, based on the extensive clinical data accumulated since the drug's launch in 2001.

In preparation for our entry into the CNS field with the expected approval of products starting in the late 2010s, we will provide education and training to MRs to give them a high level of expertise in order to quickly build our presence in this area. We will work to establish the necessary marketing organization and other functions.

Pegasys
(peginterferon alfa-2a)

CellCept
(mycophenolate mofetil)

Copegus
(ribavirin)

Products under Development

Oncology

Development Pipeline (As of January 30, 2013)

Development Code (Product name)	Indication	Status	Generic Name	Dosage Form	Origin (Collaborator)
RG1273	Breast cancer	Filed	pertuzumab	Injection	Roche
	Breast cancer (adjuvant)	Phase III (Multinational study)			
RG1415 (Tarceva)	Non-small cell lung cancer (1st line)	Filed	erlotinib HCl	Oral	Roche / OSI
RG435 (Avastin)	Recurrent glioblastoma	Filed	bevacizumab	Injection	Roche
	Ovarian cancer	Filed			
	Glioblastoma	Phase III (Multinational study)			
	Breast cancer (adjuvant)	Phase III (Multinational study)			
RG3502	Breast cancer	Filed	trastuzumab emtansine	Injection	Roche
	Gastric cancer	Phase II / III (Multinational study)			
RG3638	Non-small cell lung cancer	Phase III (Multinational study)	onartuzumab	Injection	Roche
GA101 (RG7159)	Indolent non-Hodgkin's lymphoma	Phase III (Multinational study)	obinutuzumab	Injection	Roche (Nippon Shinyaku)
	Aggressive non-Hodgkin's lymphoma	Phase III (Multinational study)			
GC33 (RG7686)	Liver cancer	Phase II (Multinational study)	—	Injection	In-house (Roche)
RG340 (Xeloda)	Gastric cancer (adjuvant)	Phase II	capecitabine	Oral	Roche (Yakult Honsha)
AF802 (RG7853)	Non-small cell lung cancer	Phase I / II	—	Oral	In-house (Roche)
		Phase I / II (Overseas)			
RG7204	Melanoma	Phase I / II	vemurafenib	Oral	Roche
WT4869	Myelodysplastic syndromes	Phase I / II	—	Injection	In-house / Dainippon Sumitomo Pharma
	Solid tumors	Phase I			
WT2725	Advanced cancer	Phase I (Overseas)	—	Injection	In-house / Dainippon Sumitomo Pharma
CIF (RG7167)	Solid tumors	Phase I	—	Oral	In-house (Roche)
		Phase I (Overseas)			
CKI27 (RG7304)	Solid tumors	Phase I	—	Oral	In-house (Roche)
		Phase I (Overseas)			
PA799	Solid tumors	Phase I (Overseas)	—	Oral	In-house

● Designates change in status in 2012 and thereafter

Additional Indications

Line extension projects are expected to further expand Chugai's oncology franchise.

Three line extension projects for existing products are in progress. We received a request from the Japanese Ministry of Health, Labour and Welfare to develop Avastin for the treatment of recurrent glioblastoma and ovarian cancer, two indications of high medical need. We filed applications for approval of these additional indications in September and October 2012, respectively. Phase II clinical trials of Xeloda in adjuvant chemotherapy for gastric cancer began in July 2012. For Tarceva, we filed an application in June 2012 for approval of the additional indication of first-line chemotherapy for non-small cell lung cancer. Approval is expected in 2013.

New Compounds

Chugai is developing new compounds with a focus on molecular targeted therapies. Our pipeline currently includes eight projects from Chugai and eight licensed from Roche. All of these are projects are based on Personalized Healthcare (PHC).

Among those compounds from Chugai is a joint phase II multinational study with Roche started in March 2012 for GC33 (RG7686), which Chugai licensed to Roche in 2011. GC33 is a humanized monoclonal antibody that targets glypican-3, a protein that is expressed in liver cancer. Parallel development of a companion diagnostic to detect glypican-3 with an immunohistochemical (IHC) staining method is also ongoing.

Phase I/II clinical trials are currently under way in Japan for AF802, a potential treatment of non-small cell lung cancer. Chugai has decided to license this compound to Roche. Both companies are preparing

to file for regulatory approval. A targeted highly selective inhibitor of anaplastic lymphoma kinase (ALK), AF802 is expected to make a significant contribution to treatment based on data that has shown a very high response rate.

WT4869 is a therapeutic peptide vaccine that targets the WT1 protein, which is thought to play a key role in leukemia and other cancers. Chugai is co-developing this compound with Dainippon Sumitomo Pharma Co., Ltd. Domestic phase I/II clinical trials for patients with myelodysplastic syndromes and domestic phase I clinical trials for solid tumors are ongoing. Phase I clinical trials started overseas in August 2012 for WT2725, another WT1 peptide cancer vaccine that Chugai is co-developing with Dainippon Sumitomo Pharma. This compound uses a different WT1-derived peptide from WT4869, and is being developed as a potential treatment for advanced cancer.

Chugai has licensed CIF (RG7167) and CKI27 (RG7304) to Roche, and joint phase I clinical trials are under way. CIF is a MEK inhibitor; CKI27 is a Raf and MEK dual inhibitor.

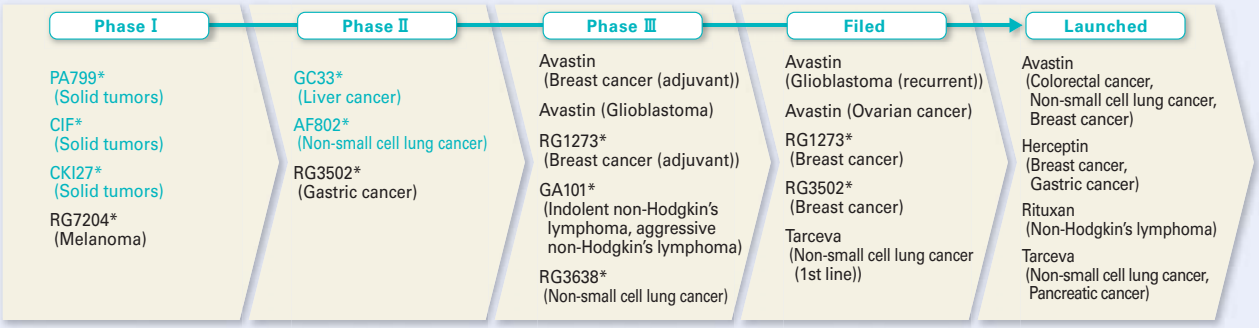
PA799, a PI3K class I inhibitor that Chugai is developing for the treatment of solid tumors, is also advancing through phase I clinical trials overseas.

Among the compounds licensed from Roche, we are confident that RG1273 (overseas product name: Perjeta) and RG3502, which were both recently launched in the United States to treat HER2-positive metastatic breast cancer, will obtain regulatory approval in 2013 or 2014. We will also work to ensure HER2 testing in gastric cancer continues. RG1273 is a monoclonal antibody and HER dimerization inhibitor for the treatment of HER2-positive metastatic breast cancer. It has been shown to extend overall survival in patients with this type of breast cancer. A phase III multinational study for adjuvant therapy in HER2-positive breast cancer (APHINITY study) started in April 2012.

RG3502 is a novel compound designed to selectively kill cancer cells more effectively and safely than the current standard combination of Herceptin plus chemotherapy. It combines the therapeutic effect of trastuzumab (the active substance of Herceptin) with intracellular delivery of DM1, a chemotherapy agent. A phase II/III multinational study of RG3502 started in September 2012 for the treatment of gastric cancer is ongoing. Development of RG3638, a humanized anti-MET antibody, as a potential treatment for non-small cell lung cancer is progressing faster than planned. A phase III multinational study started in November 2012 and is expected to be fully enrolled in 2013. This compound is expected to offer a new therapeutic option for patients with MET-positive advanced non-small cell lung cancer, which has a poor prognosis with currently available treatments. GA101 (RG7159) is a glycoengineered, type II anti-CD20 monoclonal antibody that is being developed for the indications of indolent and aggressive non-Hodgkin's lymphoma (NHL). Multinational phase III studies for both indications are progressing as planned. In November 2012, Chugai entered into an agreement with Nippon Shinyaku Co., Ltd. to co-develop and co-market this compound in Japan. Phase I/II clinical trials started in Japan in September 2012 for RG7204 (overseas product name: Zelboraf). A BRAF inhibitor for the treatment of metastatic melanoma, this compound is already approved in the United States and the European Union. Chugai is expediting development of RG7204 as a medicine that prolongs life expectancy and addresses unmet medical needs.

Development Pipeline of Molecular Targeted Drugs in Oncology (As of January 30, 2013)

Blue letters: Developed in-house *New molecular entities



Bone and Joint Diseases/Autoimmune Diseases

Development Pipeline (As of January 30, 2013)

Development Code (Product name)	Indication	Status: Phase I	Phase II	Phase III	Filed	Approved	Generic Name	Dosage Form	Origin (Collaborator)
Bone and Joint Diseases									
RG484	Osteoporosis				●		ibandronate sodium hydrate	Injection	Roche (Taisho Pharmaceutical)
				●				Oral	
NRD101 (Suvenyl)	Enthesopathy (lateral epicondylitis, patellar tendinitis, achilles tendinopathy, plantar fasciitis)						sodium hyaluronate	Injection	In-house
Autoimmune Diseases									
MRA (Actemra)	Rheumatoid arthritis (new formulation: subcutaneous injection)				●		tocilizumab	Injection	In-house (Roche)
					●	(Overseas)			
SA237	Rheumatoid arthritis						—	Injection	In-house
RG7415	Systemic lupus erythematosus (SLE)	●					rontalizumab	Injection	Roche

● Designates change in status in 2012 and thereafter

In the area of rheumatoid arthritis (RA), applications for regulatory approval of a new subcutaneous formulation for Actemra were filed in Japan in March 2012 and overseas in December 2012 based on positive data from the SUMMACTA and BREVACTA* trials. The SUMMACTA trial has demonstrated comparable and clinically meaningful efficacy of the subcutaneous formulation of Actemra given weekly compared to Actemra given intravenously every four weeks. BREVACTA has demonstrated that the subcutaneous formulation of Actemra given every two weeks is superior in efficacy to placebo in the setting of background disease-modifying antirheumatic drugs (DMARDs). We believe that making the more convenient subcutaneous formulation available in addition to the intravenous formulation will be beneficial for both patients and healthcare providers. Moreover, a phase I clinical trial of SA237 is under way in Japan. This compound from Chugai is a next-generation antibody drug developed by applying recycling antibody technology, one of Chugai's innovative antibody engineering technologies, to Actemra. (For more detailed information, see "Focus: Chugai's Proprietary Technologies" on pages 59-61.) The phase I trial has verified that SA237 can continuously block IL-6 receptors more than four times longer than Actemra. SA237 is expected to improve convenience for patients by enabling smaller, less frequent doses.

In the osteoporosis segment, Chugai is co-developing the bisphosphonate medicine RG484 (overseas product name: Bonviva/Boniva) with Taisho Pharmaceutical Co., Ltd. An application for regulatory approval was filed for an injectable formulation in July 2012, and phase III clinical trials of an oral formulation started in October 2012. Existing oral bisphosphonates are normally taken once a week, but oral RG484 can be taken just once a month and is thus expected to improve patient adherence to treatment.

Development of Suvenyl as a potential treatment for enthesopathy is progressing smoothly, and we aim to file an application for regulatory approval in 2013. Enthesopathy is a painful condition characterized by degeneration in the attachment of tendons and ligaments to bone. Examples include lateral epicondylitis, patellar tendinitis, achilles tendinopathy and plantar fasciitis.

* BREVACTA is a randomized, double-blind, parallel-group study of RoActemra subcutaneous formulation versus placebo subcutaneous formulation in combination with traditional DMARDs in patients with moderate to severe, active RA who had an inadequate response to DMARD therapy. BREVACTA was designed to assess the efficacy of treatment with RoActemra 162mg subcutaneous formulation given every two weeks versus placebo given every two weeks, both in combination with DMARDs, based on ACR20 response at Week 24. Safety profile was assessed with regard to adverse events and laboratory assessments.

Central Nervous System/Other Diseases

Development Pipeline (As of January 30, 2013)

Development Code (Product name)	Indication	Status	Generic Name	Dosage Form	Origin (Collaborator)
Central Nervous System					
RG1678	Schizophrenia	Phase III (Multinational study)	bitopertin	Oral	Roche
RG7090	Major depressive disorder	Phase II (Multinational study)	—	Oral	Roche
RG1450	Alzheimer's disease	Phase I	gantenerumab	Injection	Roche / Morphosys
Other Diseases					
CSG452	Type 2 diabetes	Phase III	tofogliflozin	Oral	In-house (Kowa, Sanofi)
RG3637	Asthma	Phase I (Overseas)	lebrikizumab	Injection	Roche
CIM331	Atopic dermatitis	Phase I	—	Injection	In-house
ACE910	Hemophilia A	Phase I	—	Injection	In-house
RG7652	Hyperlipidemia	Phase I (Overseas)	—	Injection	Roche

● Designates change in status in 2012 and thereafter

In 2012, development projects in the fields of CNS, diabetes and inflammatory diseases advanced steadily. We further enhanced our development pipeline with the addition of two new projects.

In the CNS field, Chugai has three projects in development: one for depression, one for Alzheimer's disease and another for schizophrenia. In September 2012, we began participating in Roche's phase II multinational study of RG7090, an mGluR5 antagonist, as a potential treatment for major depressive disorder. This small-molecule compound with a novel mechanism of action shows promise as a first-in-class medicine and is being investigated together with a companion biomarker as a potential Personalized Healthcare solution. RG1450, a human anti-amyloid-beta monoclonal antibody for the treatment of Alzheimer's disease, continues to advance through phase I clinical trials. A phase III multinational study of RG1678, a glycine reuptake inhibitor under development for schizophrenia, is progressing as planned.

In the diabetes field, CSG452, a selective SGLT2 inhibitor, is advancing smoothly through phase III clinical trials, with filing for regulatory approval planned in 2013. This small-molecule compound is designed to achieve continuous control of blood glucose in an insulin-independent manner through excretion of glucose in the urine. In October 2012, Chugai entered into an agreement with Kowa Company, Ltd. and Sanofi K.K. to co-develop this compound in Japan, as well as licensing agreements under which Kowa and Sanofi will file applications for marketing authorization under their own brand names.

In the respiratory diseases field, overseas phase I clinical trials are under way for the treatment of asthma with RG3637, a humanized anti-IL-13 antibody licensed from Roche. This compound has the potential to become a Personalized Healthcare treatment. Parallel development of a companion diagnostic is also progressing steadily. RG3637 has demonstrated particular efficacy in patients with elevated levels of serum periostin.* It is being investigated for its potential to improve the daily symptoms of asthma and prevent asthmatic attack in patients with moderate to severe asthma that is uncontrolled with existing treatment options.

In other fields, CIM331, an injectable formulation originating from Chugai, started phase I clinical trials in Japan in September 2011 as a potential treatment for atopic dermatitis. In addition, ACE910, a bispecific antibody to factors IXa and X that employs Chugai's innovative antibody engineering technologies, started phase I clinical trials in August 2012 for the treatment of hemophilia A. ACE910 shows promise as an antibody drug that can prevent bleeding with once-weekly subcutaneous administration and may provide a novel treatment option for hemophilia A patients. (See "Focus: Chugai's Proprietary Technologies" on pages 59–61 for more details on bispecific antibody technology.) In addition, RG7652, a human anti-PCSK9 monoclonal antibody licensed from Roche, started phase I clinical trials overseas in October 2012 as a potential treatment for hyperlipidemia.

* An extracellular matrix protein that is induced by IL-13 and is considered to be related with fibrosis of bronchial cells in patients with asthma. Periostin levels can be measured with a blood test.

Organization and Human Resources

Visualizing Our Value

Chugai meets its corporate social responsibility by executing its mission. This section describes the foundations that create Chugai's value, including its CSR philosophy, research, drug safety, initiatives by stakeholder type and corporate governance.

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Chugai's Approach to CSR

Chugai will help to build public trust in corporations and contribute to the sustainable development of society by working to create innovative drugs that address unmet medical needs.

Our View of CSR

To realize its mission, Chugai has established a Mission Statement that includes seven Core Values to be shared as individuals and as a company in order to ensure sound business activities as we work toward our Envisioned Future. The Core Values also form the basis of the Chugai Business Conduct Guidelines (Chugai BCG), a code of behavior for management decision-making and employees. The Chugai BCG are reflected in the activities of each business unit and serve as a foundation to support the execution of our new mid-term business plan, ACCEL 15. We believe that corporate activities consistent with our Mission Statement and the Chugai BCG are the essence of our CSR.

Mission Statement

Mission

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.

Core Values

1. The primary focus of all our activities is patients and consumers.
2. In all our activities we are committed to the highest ethical and moral standards.
3. We value employees who develop profound expertise and broad perspectives and pursue innovation and challenges without fear of failure.
4. Wherever we operate around the world we seek to understand and respect people and cultures and to behave as good corporate citizens.
5. We promote an open and active corporate culture that respects individuality, ability and teamwork.
6. We care about the global environment.
7. We aim to achieve a fair return for our shareholders and to disclose information appropriately and in a timely manner.

Envisioned Future

As a most important member of the Roche group, we aim to become a top Japanese pharmaceutical company by providing a continuous flow of innovative new medicines domestically and internationally.

Chugai Business Conduct Guidelines

- **Responsibility to Patients and Consumers**
We will always put the patient and the consumer first, and provide high-quality products and services of superior safety and efficacy.
- **Strict Adherence to the Law**
In all our business activities, we will strictly adhere to all laws and their underlying principles.
- **Respect for Human Rights**
We will respect human rights in every aspect of our business activities.
- **Fair Trade**
We will engage in fair and transparent transactions with medical institutions and organizations, suppliers and customers.
- **Management of Corporate Assets**
We will achieve our management objectives through the optimal and appropriate management and use of corporate assets.
- **Disclosure of Information**
We will actively and fairly disclose corporate information in accordance with both legal requirements and the principles of social justice.
- **Social Contribution**
We will remain aware of our responsibility as a good corporate citizen and actively continue with our social action programs.
- **Protection of the Global Environment**
We believe the supreme value to the future of "one and only Earth" and, therefore, we continue our efforts to reconcile our business activity with nature and environments.
- **Relations with Governmental and Administrative Bodies**
We will maintain fair and transparent relations with policymakers and administrative bodies.
- **Relations with External Bodies**
We will maintain fair and transparent relations, within reason, with external bodies.

Framework for Promoting Corporate Social Responsibility

The Corporate Social Responsibility Committee, chaired by the Deputy Chairman of the Board, deliberates and makes decisions on tasks, policies, targets and action plans concerning social responsibility for all of Chugai's business activities. The Corporate Social Responsibility Department is in charge of implementing the committee's decisions and presiding over daily activities, and works to provide support for CSR activities while assessing their results.

The department manager of each business unit is responsible for spreading and establishing the Chugai BCG in his or her workplace to promote CSR. The manager assigns a BCG promotion assistant, and they work together to resolve issues arising in the promotion of the Chugai BCG, enhancement of human rights and other activities.

The safety and environmental action plans decided by the Corporate Social Responsibility Committee are shared with the general safety and health managers and environmental protection managers at each facility and reflected in the facility's action plans.

Framework for Promoting Corporate Social Responsibility (As of January 1, 2013)

Research

Leveraging its solid technology platform, Chugai is pushing forward on cutting-edge research to continuously generate innovative medical products that address unmet medical needs for the benefit of the medical community and human health around the world.

Basic Policy and Allocation of Resources

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

Based on this stance, Chugai's research activities prioritize creating new drugs with first-in-class or best-in-class potential. In addition, Personalized Healthcare (PHC), which tailors treatment based on individual patients' molecular and genetic profiles, will play an increasingly prominent role in the years ahead. In recognition of this trend, Chugai is focusing on the creation of innovative molecular targeted therapeutics. We are also partnering with the Roche Group's Diagnostics Division to develop diagnostics that detect specific molecules.

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 to address unmet medical needs; and the potential for differentiation of efficacy through development using biomarkers for PHC. 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.

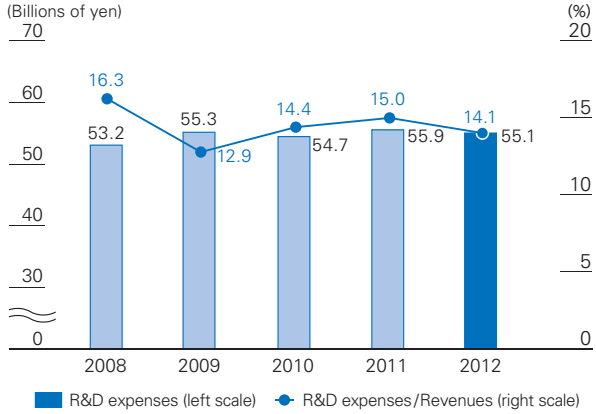
Recent Outcomes of Chugai's Research Activities

In the last several years, many projects from Chugai in oncology and other fields have entered clinical development. One project entered clinical development in 2006, 12 in 2011 and 15 in 2012. Out of 23 new compounds currently in the development pipeline, approximately 50 percent were developed in-house, evidence of the strength of Chugai's research organization.

Moreover, as a pioneer in PHC in Japan, Chugai is devoted to promoting the field. Including projects where biomarker discovery research is in progress, PHC-related projects account for approximately 80 percent of the total pipeline, a particularly high proportion (includes projects licensed from Roche).

In addition to this track record in new drug creation, Chugai has announced a series of innovative, proprietary research technologies and results in recent years. In 2010, Chugai announced in a scientific journal its antibody recycling technology that enables a single antibody molecule to bind to a target antigen multiple times, which was impossible with conventional monoclonal antibodies. Preclinical studies have

R&D Expenses



Progress in 2012 and Thereafter

(January 1, 2012 - January 30, 2013)

	Number of Projects	Breakdown		
		New Molecular Entities	Additional Indications	Additional Dosage and Administration/ Formulations
Approved*	2	2	—	—
Filed	8	3	3	2
Started Phase Ⅲ	3	3	—	—
Started Phase Ⅱ	4	3	1	—
Started Phase Ⅰ	5	5	—	—
Development Suspended	2	—	2	—

* Two projects not in Chugai's pipeline for which filings have been submitted based on evidence in the public domain for drugs that are not yet approved in Japan or are approved for other indications. (Pulmozyme for the improvement of pulmonary function in patients with cystic fibrosis and Bactramin for the treatment and prevention of pneumocystis pneumonia.)

demonstrated that applying this technology to Actemra increases the duration of IL-6 receptor blockade by more than four times. In 2011, Chugai further evolved this technology by accelerating its intracellular incorporation to break down a large number of antigens, and thus developed sweeping antibody technology to eliminate target antigens from plasma. Collectively, Chugai calls these two technologies SMART-Ig. In October 2012, Chugai announced in a scientific journal its development of ART-Ig, a technology for producing bispecific antibodies, which have two different antigen binding sites that can respectively bind different antigens. Bispecific antibodies have a complex molecular structure, and to date no recombinant IgG bispecific antibody has been brought to market due to the difficulty of commercially producing IgG molecular medicines using conventional technology. Also in October 2012, Chugai announced in a scientific journal that it was the first in the world to succeed in establishing stable cell lines of colon cancer stem cells. It has been extremely difficult to isolate and elucidate the detailed nature of cancer stem cells because they are rare in cancer tissues. However, Chugai established cancer stem cell lines capable of being stably cultured in a highly pure form, which it believes will lead to the development of an unprecedented new type of anticancer drug that targets cancer stem cells. In addition, Chugai has announced a series of new technologies including ART-Fc, which uses ART-Ig to enhance the potency of ADCC (antibody-dependent cell cytotoxicity); TRAB T-cell recruiting antibody, which also uses ART-Ig technology; TwoB-Ig, which enhances selective binding to inhibitory Fcγ receptors; and ACT-Ig, which engineers the charge of antibodies to extend their serum half-life. (See "Focus: Chugai's Proprietary Technologies" on pages 59-61 for details on Chugai's innovative proprietary technologies.)

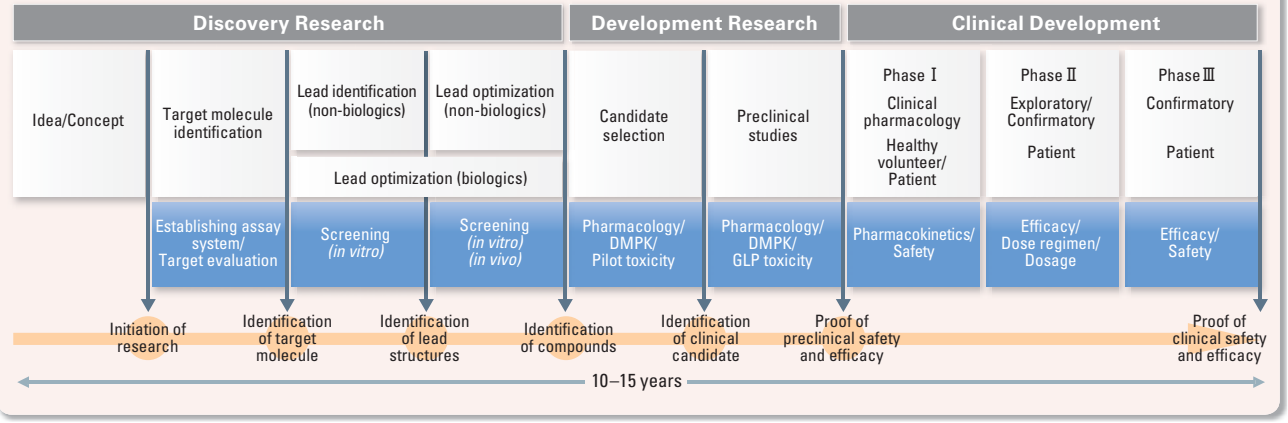
Background of Chugai's Research Organization

Chugai has many unique strengths in the area of research, including the achievements listed above. Three of these strengths have underpinned the creation of this robust research organization.

The first is our years of accumulated knowledge and the benefits of the merger with Nippon Roche. Before its strategic alliance with Roche, Chugai had been engaged in research and development of biopharmaceuticals for more than 30 years and had the foremost research platform in Japan for biopharmaceuticals and therapeutic antibodies. Nippon Roche, meanwhile, operated the Kamakura Research Laboratories, which discovered Xeloda, the global standard of care for cancer, and had established a world-class technology platform for the discovery of synthetic agents. The merger of these two companies created a research organization excelling in both biopharmaceuticals and synthetic agents, which expanded options in drug discovery. The result is a world-class technology platform.

The second strength is access to Roche's global research infrastructure. Roche's world-class drug discovery platform, which includes bioinformatics[1] tools for genomic research, a compound library and chemical evaluation database, and an assay robot that performs high throughput screening,[2] represents a significant advantage for Chugai in terms of cost and efficiency. It has dramatically increased our research productivity, particularly in the lead discovery and optimization

Process and Milestones of Drug Development



stages. While we enjoy the benefits of these assets of the Roche Group, our discovery research is a distinctive feature that has ensured our independence.

The third strength is our research system's environment of open innovation. With the paucity of promising new drug candidates worldwide, the pharmaceutical industry is emphasizing cooperation and partnerships with cutting-edge research institutions outside the industry. Chugai has steadily engaged in joint research, including research at the facilities of partner institutions, while contributing its own technology and know-how. Combined with recognition of our proprietary technologies, this has helped us to build strong external networks. The success of Japan's first therapeutic antibody Actemra, which originated from joint research with Osaka University, demonstrates the value of this approach. Chugai also conducts research using a joint-venture model aimed at further reducing development lead time and continuously creating innovative R&D themes. Numerous findings have resulted from research in joint ventures with the University of Tokyo Research Center for Advanced Science and Technology; Forerunner Pharma Research Co., Ltd., a multidisciplinary research institution adjacent to RIKEN Yokohama Institute; Chugai Pharmabody Research Pte. Ltd. in Singapore, which specializes in the creation of new therapeutic antibodies using Chugai's recycling, sweeping and other proprietary antibody technologies; PharmaLogicals Research Pte. Ltd., also in Singapore; and C&C Research Laboratories in South Korea.

1. 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.
2. A technology that uses automated robots or other means to select active chemical compounds for drug creation targets from a library consisting of a vast number of compound types.

Intellectual Property Strategy

In the pharmaceutical industry, the drug approval success rate is extremely low given the time and expense required for research and development. Moreover, corporate profits are heavily dependent on blockbuster products and the length of their period of exclusivity. These characteristics are unique to the pharmaceutical industry. Therefore, intellectual property (IP) strategy is a vital part of product lifecycle management and a key to maintaining the competitive advantage of a company's technology platform.

Under Chugai's IP policy established in 2007, the IP strategy is integrated with business and R&D strategies and implemented throughout the Company. This helps to protect the competitive advantage of our products and secure operational flexibility. We also take care to respect the IP rights of others in our business activities.

Chugai's basic policy emphasizes high-quality patent applications and effective allocation of resources. We concentrate resources on key projects selected according to internal guidelines and aggressively file patent applications outside Japan as well, with a view toward global co-development with the Roche Group. The Intellectual Property Department and the Research Division share information closely and cooperate to maximize the value of products and technologies. We also protect broadly applicable technologies, such as the innovative antibody technologies that have emerged from our research activities, with IP rights and we have set up the foundation to deploy them effectively. In 2012, we granted permission through licensing agreements for the use of three of our proprietary technologies outside the Company: ART-Ig, a technology for producing bispecific antibodies; TwoB-Ig, which enhances selective binding to inhibitory Fcγ receptors; and ACT-Ig, which engineers the charge of antibodies to extend their serum half-life.

We are also establishing a scheme that enables the use of IP rights to protect findings that emerge from our research network activities with universities, research institutions and other outside parties. In addition, we defend our brands using trademarks and logos that protect our products directly, as well as measures to prevent counterfeiting. To execute IP activities more efficiently, we are also focusing on establishing and maintaining internal environments and systems for IP information, including a system for sharing information with Roche.

Chugai's Proprietary Technologies

Through continuous development of advanced technologies, Chugai has built a solid technology platform that gives it powerful advantages. This section introduces some of Chugai's innovative antibody technologies for enabling the generation of antibodies unrivaled by competitors.

SMART-Ig Recycling antibody and sweeping antibody technology

Sequential **M**onoclonal **A**ntibody **R**ecycling **T**echnology - **I**mmuno**g**lobulin

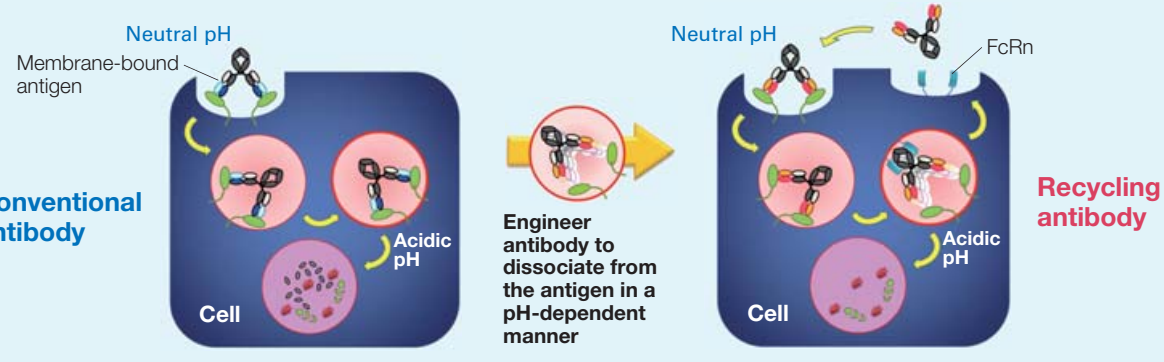
A conventional antibody derived from known technology, regardless of how high its affinity to a target antigen is, has two limitations: 1) the antibody can bind to the antigen only once; and 2) the antibody can only bind to the antigen and cannot eliminate it from plasma. SMART-Ig, developed by Chugai, is an entirely new technology that overcomes these two limitations. It enables the targeting of previously untargetable antigens and achieves a product profile that previously could not be realized with a conventional antibody.

Recycling Antibody

The recycling antibody is engineered so that a single antibody molecule can bind to an antigen multiple times. Binding to the neonatal Fc receptor (FcRn) after being taken up by vascular endothelial cells or other cells contributes to a long half-life for an antibody in plasma compared with other proteins by recycling the antibody back to plasma. However, when a conventional antibody binds to a membrane-bound antigen such as a cytokine receptor, the antibody-antigen complex is transferred to lysosome and degraded by protease. In the case of a soluble antigen such as a cytokine ligand, the antigen bound to the antibody is recycled back to plasma by FcRn as an antibody-antigen complex. Since antigens would be degraded by lysosome in the absence of the antibody, the antibody would accumulate the antigens in plasma, requiring administration of a large amount of antibodies for long-term blockade of the antigen function.

Conversely, the recycling antibody has been engineered to dissociate from an antigen in acidic conditions within the cell. Since the antibody bound to a membrane-bound antigen dissociates from the antigen

Effect of Recycling Antibody on Membrane-Bound Antigen



- Can bind to the antigen only once
- Binds to the antigen and is rapidly cleared

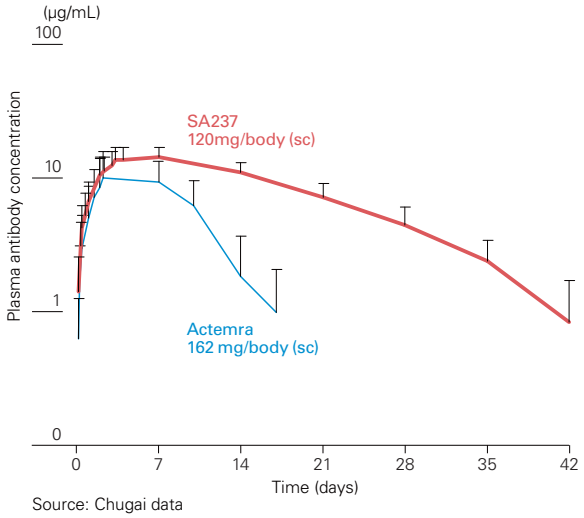
- Can bind to the antigen multiple times
- Able to reduce the antibody clearance

in a pH-dependent manner, a dissociated antibody would be recycled by FcRn while the antigen is transferred to lysosome and degraded, enabling the antibody to bind to other antigens repeatedly in plasma and reducing the antibody clearance.

This antibody technology arose from an idea to prolong the duration of efficacy of Actemra. The engineering of Actemra led to the generation of SA237 (currently in phase I clinical trials in Japan). In preclinical studies, SA237 exhibited plasma persistence four times that of Actemra, and a phase I clinical trial has demonstrated significant improvement in the effective duration. SA237 is expected to offer substantial convenience of subcutaneous administration at a dosing interval of longer than once a month.*

* Actemra has been approved for once-a-month intravenous administration, and applications have been filed in Japan and overseas for approval of subcutaneous administration once every week or two weeks.

Comparison of Plasma Persistence of SA237 and Actemra



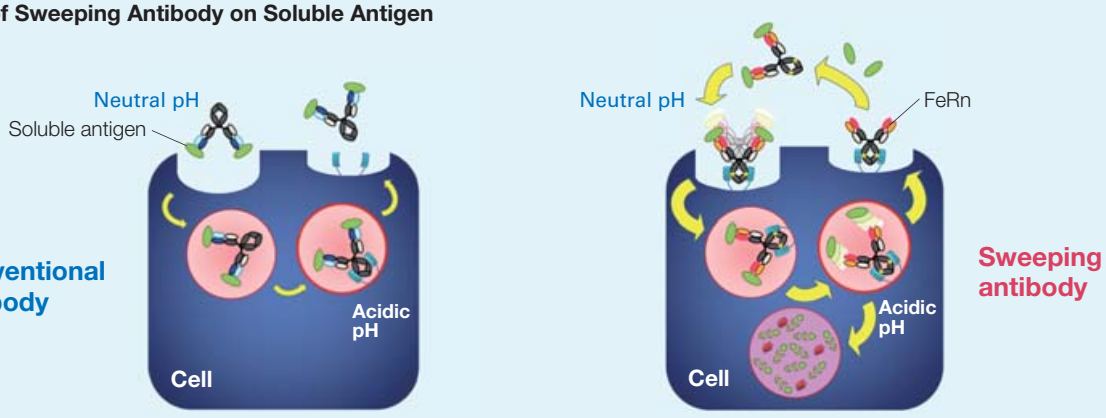
Source: Chugai data

Sweeping Antibody

The sweeping antibody is a recycling antibody that has been further engineered to bind to FcRn at neutral pH. Accordingly, when the target is a soluble antigen present in plasma such as cytokine, the antigen bound to the antibody is actively taken up into the cell by FcRn. This accelerates the turnover rate of antigen degradation, enabling the antibody to eliminate, or sweep, the antigen from plasma. In addition, by modulating the binding affinity for FcRn to modify the turnover rate, the sweeping antibody can be customized with properties appropriate to the antigen or disease it targets.

With these characteristics, a sweeping antibody can be administered in smaller doses with a longer dosing interval that cannot be achieved by conventional antibodies, and it is can antagonize antigens present in large amounts in plasma that cannot be antagonized by conventional antibodies. Moreover, even if it does not block an antigen's activity by binding with it, a sweeping antibody can be effective by directly eliminating antigens from plasma, giving it potential for a wide range of applications in medicines.

Effect of Sweeping Antibody on Soluble Antigen



- Can bind to the antigen only once
- Antigen persists in plasma as an antibody-bound form, and antigen accumulates in plasma

- Can bind to the antigen multiple times
- Can actively degrade antigen
- Can eliminate or sweep antigen from plasma

ART-Ig

Bispecific antibody manufacturing technology

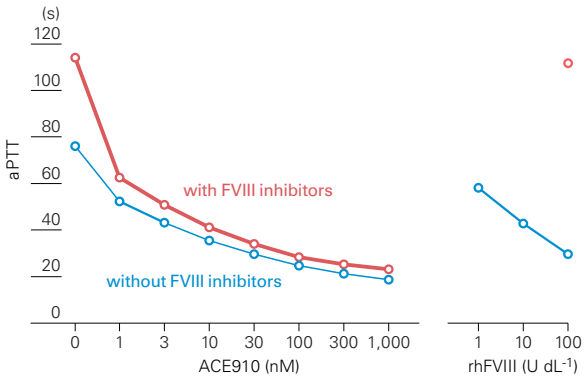
Asymmetric **R**e-engineering **T**echnology - **Ig**lobulin

A conventional IgG antibody has two antigen binding sites that bind to the same antigen. In contrast, a bispecific antibody (BiAb) has two different binding sites consisting of two different heavy chains and two different light chains, which can respectively bind to two different antigens. Due to various issues regarding the manufacturability of BiAb, no recombinant immunoglobulin G (IgG) BiAbs have been approved yet. However, Chugai's antibody engineering technologies have enabled large scale manufacturing of BiAbs, resulting in the generation of a BiAb expected to treat hemophilia A.

With many years of experience and expertise in the field of hematology, including research into erythropoiesis stimulating agent (ESA) and granulocyte-colony stimulating factor (G-CSF), Chugai felt a sense of mission in dealing with hemophilia, an area of high unmet medical needs. Hemophilia A results from an inherited deficiency or a functional abnormality in clotting factor VIII (FVIII) that causes bleeding disorder. Replacement therapy with concentrates of FVIII is the most common treatment, but problems with the therapy include the need for frequent intravenous injections (three times a week) and the creation of antibodies that neutralize FVIII activity. To deal with these issues, Chugai began development of ACE910 (phase I clinical trials currently under way in Japan), a BiAb that mimics the cofactor function of FVIII by binding to factor IX (FIX) and factor X (FX). Large-scale manufacturing of BiAbs results in many different antibody species, making the manufacturing of highly pure target BiAb nearly impossible. Chugai overcame this problem with a proprietary technology called ART-Ig. ART-Ig incorporates three antibody engineering technologies: 1) introduction of a common light chain to reduce the number of combinations of light and heavy chains; 2) introduction of difference in the charges of two heavy chains to facilitate purification of the target BiAb; and 3) use of electrostatic steering of the two heavy chains to facilitate expression of the target BiAb. The application of these three technologies resulted in a process capable of producing a target BiAb on a 2,500-liter scale with productivity and purity similar to conventional antibodies.

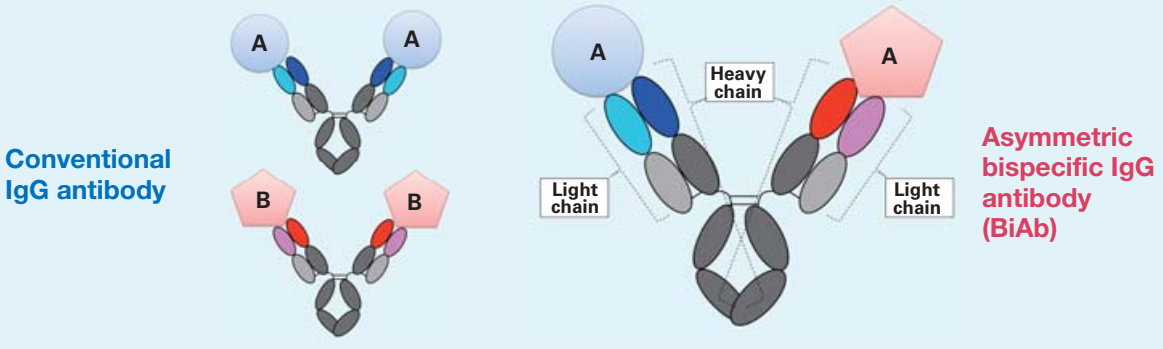
The establishment of ART-Ig technology has enabled the use of IgG BiAbs as a practical method for drug discovery. As such, it is expected to lead to the generation of drugs with a new mode of action that enhances efficacy by simultaneously binding with two types of antigen or provides new pharmacology by bridging two antigens.

Plasma Coagulation Accelerating Action of ACE910



Source: Chugai data

Differences between Conventional Antibody and Bispecific Antibody



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 further strengthen its world-class operations.

Drug Safety Approach and System

Companies that manufacture and market pharmaceuticals have a duty to collect, analyze and investigate 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[1] and to be compliant with Good Vigilance Practice[2] and Good Quality Practice.[3]

One of Chugai's characteristics as a drug manufacturing and marketing company is that it handles numerous biopharmaceuticals, molecular targeted therapies and other pharmaceuticals with novel mechanisms of action. Innovative medical products draw attention for their high efficacy, but providing adequate safety information is a key issue for the promotion of appropriate use of the products and acceptance by patients and healthcare providers. With this in mind amid the rising need to ensure safety in Japan and overseas, a drug safety division has been established in Chugai as an essential organizational unit of a pharmaceutical company. By carefully evaluating the risk/benefit balance and continuously representing drugs accurately to healthcare providers and patients, Chugai aims to increase trust.

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 surveillance are to collect and evaluate information on the safety and efficacy of drugs after their market launch. This surveillance must be conducted in compliance with Good Post-Marketing Study Practice[4] guidelines.

At Chugai, the Drug Safety Division is responsible for planning post-marketing surveillance, managing its progress and analyzing the results in coordination with product lifecycle teams and the Marketing & Sales Division. Medical representatives (MRs) handle tasks such as requests to medical institutions, data collection and follow-up. Like clinical studies, post-marketing surveillance is conducted according to fixed protocols after entering into agreements with medical institutions. The data forms are collected through electronic systems and other means, and the accumulated data are analyzed. This evaluated safety information is shared with medical institutions by MRs and officially announced inside and outside the Company.

4. Standards for conducting post-marketing surveillance and testing of pharmaceuticals

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 drug reactions 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 their early detection by enabling healthcare providers to monitor high-risk patients.

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 studies alone. The European Medicines 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.

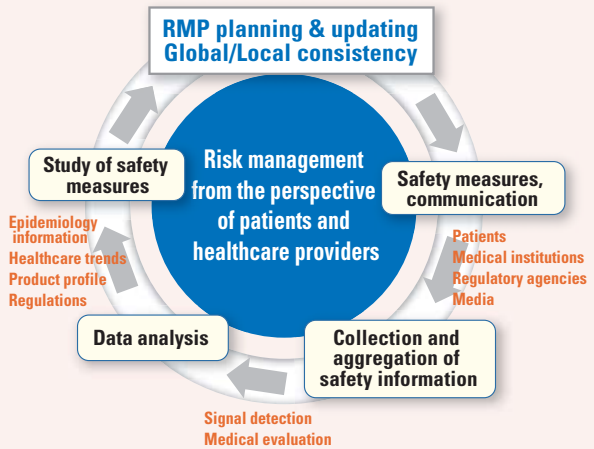
In light of these trends, Chugai has set up a world-class safety management system that can accommodate the different review procedures of regulatory agencies in Japan, the United States and Europe. We have also made pharmacovigilance agreements and specified communication methods with Roche and other alliance partners in Japan and overseas, and we are working to implement them smoothly. 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. In advance of the Risk Management Plan (RMP) Guidance becoming effective in April 2013, we began applying RMP measures to five products in 2012. To enhance our epidemiological-based analytical capabilities for safety data, we are working to improve the precision of analysis through a specialized internal group in charge of epidemiology functions and began a new initiative for signal detection and assessment tools for adverse events. In addition, we are actively recruiting physicians to strengthen medical evaluation of safety information.

Making sure that healthcare providers and patients understand the risk/benefit balance is critical for the acceptance of pharmaceutical products. We are proactively building a more robust safety evaluation system because we realize that contributing to better care for patients involves not just looking at the effectiveness, but also reducing the risks of a given treatment.

Shifting to a Risk Management Plan (RMP)-Based Organization



Quality Assurance

Placing top priority on patients, Chugai seeks to provide high-quality products and services that offer outstanding efficacy and safety. Quality assurance functions are critical from this perspective, and Chugai's Quality Assurance Department has been working closely with each manufacturing site to improve product quality.

However, with the increase in our affiliated manufacturing sites in recent years, quality assurance functions have diversified, as reflected in the broader scope of cooperation between our quality assurance and development operations for smoother product development. In addition, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), which covers Japan, the United States and the EU, is placing increasingly stringent requirements on quality, including the start of implementation of its international Pharmaceutical Quality System guideline.

In view of these trends, Chugai consolidated the quality assurance functions of its development operations into the Quality Assurance Department in October 2011 to promote more rigorous and high-level quality assurance. This new structure supports consistent GMP[5] throughout the product lifecycle from development to manufacturing, and strengthens oversight of GMP management. As part of its efforts to strengthen oversight, Chugai is working to create and maintain a world-class system for pharmaceutical quality.

Chugai's products are provided to people worldwide, and we have affiliated production sites around the world, including Roche's production facilities. We carry out GMP consistently from the development stage and promote it at our global affiliated production sites to ensure that we continue to deliver high-quality medicines to patients everywhere.

5. Good Manufacturing Practice: Standards for pharmaceutical production management and quality control

Initiatives by Stakeholder Type

CSR Activities in 2012

Below is a summary of Chugai's CSR activities for stakeholders in various areas, centered on provision of innovative pharmaceutical products and services.

Items	Main initiatives	Main performance indicators in 2012
High ethical and moral standards	• Fostering high ethical standards through training on the Chugai BCG; making continuous efforts to build human rights awareness • Maintaining high animal welfare standards in accordance with international guidelines • Promoting compliance with the Pharmaceutical Affairs Law, fair competition codes, promotion codes, and other laws and regulations	• BCG and Human Rights training attendees: 13,399 (includes repeat attendees; Chugai Group in Japan) • In-house education and training for people who handle laboratory animals: 46 sessions attended by 591 people • Status of ethical and legal compliance survey within the Sales Division: Responses received from 2,297 people
Patients and consumers	• Pursuing the development and provision of innovative pharmaceuticals • Conducting activities to build awareness of disease in priority fields • Conducting support activities for patients • Providing support for researchers from Asia • Responding to inquiries and disclosing information	• Launch of Pulmozyme (for improvement of pulmonary function in patients with cystic fibrosis) • R&D expenses/Sales: 14.1% (Consolidated) • Special sponsorship of a cancer charity event: "WAHAHA HONPO Special Live Show - Heal with Laughter"; participation in Relay For Life • Cumulative number of countries receiving free therapeutic drugs for treating children with lymphangiomas: 78 (program in its 22nd year)
Shareholders and investors	• Disclosing information in an unbiased and highly transparent manner • Holding frequent dialogues with investors in and outside Japan • Holding general meetings of shareholders • Realizing steady dividend payments	• Briefings for the media and investors: 18 • Individual responses to information requests from securities analysts and others: 300 • Institutional investors outside Japan visited in person by top executives: 77
Business partners	• Continuously standardizing and optimizing purchasing processes to build fair, transparent relationships • Promoting purchasing that balances compliance, business efficiency and purchasing cost reduction	• Promotion of fairness and transparency and cataloging of indirect materials in the electronic purchasing system • Number of companies that held supplier relationship management meetings: 38
Society	• Conducting welfare initiatives for the elderly and people with disabilities • Nurturing the next generation of individuals who will carry science and technology forward • Supporting employee volunteer activities • Contributing to communities where Chugai Group facilities and sites are located	• Donation of welfare vehicles to provide transportation for home welfare services: a total of 193 vehicles over 28 years (total of five vehicles to five organizations in 2012) • Video presentations given at Dr. Kitanomaru's Bio Pharmaceutical Laboratory exhibit: 20,384 (January to December, 2012)
Employees	• Fostering human assets who are competent in the global arena • Building work environments that are motivating and fulfilling for every employee • Building sound labor-management relations • Creating safe, pleasant workplaces	• Leader development program, all-employee program, division programs, Self-Innovation Program (SIP) • Number of employees taking childcare leave: 55 • Users of wiwiw (an online tool that supports employees who return to work after taking childcare leave): 55 • Percentage of employees with disabilities: 1.99%
Environmental protection and occupational safety and health	• Promoting global warming countermeasures • Pursuing resource conservation and waste reduction • Enhancing environmental awareness • Making environment-related contributions to local communities • Disclosing environmental information • Thoroughly managing chemical substances	• Energy consumption per employee compared with 2009: Down 11% (Chugai Group in Japan) • Ratio of hybrid sales vehicles: 49.3% • Amount of waste generated compared with 2011: Down 28.0% (Chugai Group in Japan) • Amount of landfill waste compared with 2011: Down 12% (Chugai Group in Japan)

	Page reference	Items described in detail on website
	66	Commitment to Ethical Promotional Activities/ Creating a Corporate Culture of Respect for Self and Others/Sexual Harassment Consultation Training/Creating Workplaces Free from Power Harassment/Chugai's View of Animal Welfare/ Bioethics Initiatives in R&D/Conduct of Clinical Trials/BCG Hotline
• Disease awareness activities and co-sponsored events held: 16 • Customer inquiries answered by Chugai's Drug Information Center: 60,240 (includes telephone, e-mail and fax inquiries)	67-69	Innovative R&D/Executing Global Supply Chain Management/Reliable Distribution of Pharmaceuticals and Promotional Samples/Enhancement of Safety Information/Ensuring Traceability/A Global-Standard Regulatory Compliance and Quality Assurance System/ Policy for Regulatory Compliance and Quality Assurance/Post-marketing All-Case Surveillance/Drug Information Center/Sponsorship of Anticancer Charity/NPO Shuhei Ogita Fund Supporting Patients with Lymphatic Malformations/Chugai Academy for Advanced Oncology Holds International Forum/ Supporting Researchers from Asia
• General meeting of shareholders: 729 participants at the Royal Park Hotel in Tokyo on March 28, 2012 • Return on equity (ROE): 10.2% (Consolidated) • Dividend per share: ¥40 (annual)	80-85 Please refer to "Corporate Governance."	General Meeting of Shareholders
• Number of companies that conducted questionnaires and interviews of suppliers: 24 • Number of key materials for which required improvements were mutually confirmed with in-house users: 12	70	
• Summer Biotech-Lab for Kids at the Japan Science Foundation's Science Museum in Tokyo: 88 participants in lab, 502 at hands-on corner • Employees taking volunteer holiday: 26 • Continuation of endowed course at Waseda University: Total of 15 lectures; establishment of endowed course at Keio University: Total of 14 lectures	71	Private-Sector Training for Teachers/ Environmental Protection Activities/Chugai Becomes Official Partner of National Museum of Emerging Science and Innovation (Miraikan)/ Co-Sponsorship of Youngsters' Science Festival 2012/Chugai Eco-Kids Program
	72-73	Systems and Frameworks to Support Life Events/ Basic Cycle of Career Development/Career Policies 1-4/Help Lines/Sound Labor-Management Relations/Dialogue between Management and Employees
• Occupational incident rate: 2.26 (No. of occupational injuries and deaths/No. of hours actually worked) X 1,000,000 • Accidents accompanied by lost worktime: 6 (Chugai Group in Japan) • Lost workdays resulting from occupational accidents: 33.5 (Chugai Group in Japan)	76-79	Environmental Action Plans/Framework for Promoting Health and Safety/Health Management/Mental Health/Power-Saving Measures/Waste Generated in Significant Quantities/Proper Disposal of Waste Materials

Commitment to High Ethical and Moral Standards

Corporate Ethics Take Priority over Profit

When the new Chugai was created in October 2002, the president issued a message to all employees concerning the need to prioritize corporate ethics over profit. The Company also published a Mission Statement declaring its path to becoming a company that meets stakeholders' expectations and fulfills its social responsibilities, and established the Chugai Business Conduct Guidelines (Chugai BCG) to accompany the statement.

Chugai places paramount importance on respect for life and strives for fair and transparent corporate activities based on high ethical standards, along with sincere scientific initiatives. Specifically, through corporate ethics training and other programs, all Chugai employees share the Core Values of the Company. They understand the ethical standards necessary to execute the business of a healthcare company and follow those standards every day, based on the guidance of the Chugai BCG.

Conduct of Clinical Trials

Clinical trials are essential for verifying the safety and efficacy of investigational products, and they must be performed with respect for the rights of trial subjects. At Chugai, clinical trials are closely monitored for patient safety, following stringent scientific methodology based on the highest ethical standards.

Chugai is committed to evaluating the real merit of investigational products using established, reputable procedures, starting with the Protocol Review Committee, in compliance with Japan's Pharmaceutical Affairs Law and other related legislation, as well as the Declaration of Helsinki[1] and ICH-GCP,[2] which are global standards.

1. The "Ethical Principles for Medical Research Involving Human Subjects" first adopted at the World Medical Association in 1964. Biomedical research must ultimately include testing on human subjects in order to contribute to healthcare. The 1964 Declaration of Helsinki is the ethical foundation of modern clinical trials. (Source: The Pharmaceutical Society of Japan)
2. Good Clinical Practice (GCP) guidelines adopted by the International Conference on Harmonisation (ICH) for conducting pharmaceutical clinical trials in the European Union, the United States and Japan

Bioethics Initiatives in R&D

Chugai has established Ethical Guidelines for Research That Uses Human-Derived Test Material. We also have a Research Ethics Committee to ensure that research using human-derived test material is carried out appropriately, with human dignity, respect for human rights and the understanding and cooperation of society. About one-quarter of the members of this committee are people from the humanities and social sciences, including ethics and law, as well as people with a more general background. The composition and operation of the committee help to ensure that it carries out fair, objective evaluations from an interdisciplinary and pluralistic frame of reference and is responsive to changes in social conditions.

Chugai's View of Animal Welfare

In guidelines enacted in 1988, Chugai established a basic philosophy on how to treat laboratory animals in research: "We must consider both ethical and scientific issues when undertaking animal experiments by taking into account issues including animal physiology, ecology and behavior as they affect animal welfare, and rearing animals with compassion, respecting animal life and taking measures to minimize pain." We have consistently practiced ethical animal testing in line with this philosophy.

The Institutional Animal Care and Use Committee has clarified the lines of responsibility. To make appropriate improvements that reflect changes in the social environment and scientific advances, it has also added nonaffiliated voting committee members to ensure objective ethical reviews of the validity and rationality of animal testing. At the same time, an institutional qualification program was adopted for researchers and animal handlers to provide appropriate education and training designed to cultivate the ethical treatment of animals. In 2007, these initiatives were evaluated by AAALAC International,[3] a global independent evaluation organization. Chugai obtained full accreditation, which was renewed in 2010.

3. Association for Assessment and Accreditation of Laboratory Animal Care International, a private nonprofit organization that promotes the humane treatment of animals in scientific research through voluntary inspection and accreditation programs. More than 870 facilities in 36 countries have been accredited.

Commitment to Ethical Promotional Activities

Pharmaceutical companies have a responsibility to pursue quality, effectiveness and safety in all their operations, from product R&D to sales. They must also rapidly collect and disseminate accurate information on pharmaceuticals in an appropriate manner.

Chugai actively supports the efforts of the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry and the Japan Pharmaceutical Manufacturers Association's Promotion Code Committee, the institutions that administer self-regulated industry rules. In addition, we have voluntarily established our own code of conduct for pharmaceutical promotion, and full-time monitors at the head office and branches ensure proper adherence to the Chugai promotion code and the industry's fair competition agreement. In these ways, we are taking steps to make sure that all of our marketing activities are highly ethical.

Initiatives for Patients and Consumers

Ensuring a Stable Supply of High-Quality Pharmaceuticals

Stable Procurement of Raw Materials and Packaging Materials

Raw material procurement is a key business activity in providing a stable and continuous supply of high-quality pharmaceuticals to healthcare providers and patients. However, the stable procurement of raw materials is constantly exposed to risks such as discontinued production due to the merger or closing of suppliers, spikes in prices or problems with availability due to fluctuations in the balance of raw material supply and demand, or delays in delivery caused by accidents at suppliers. Chugai takes a number of measures to avoid these risks and maintain a stable supply of raw materials. For each raw material, we monitor market trends and the financial condition of suppliers; conduct quality assessments, price analysis and delivery management; and analyze risks at production facilities, such as natural disasters. In this way, we ensure a stable supply of pharmaceuticals to the market.

To further ensure the quality and stable procurement of raw materials, Chugai is optimizing the supply chain on a global basis and will strive for mutual trust and growth through even more detailed information sharing with suppliers.

Reliable Distribution of Pharmaceuticals

Chugai is strengthening its supply chain management to optimize all activities, from raw material procurement to production and distribution, to ensure a stable and continuous supply of safe, high-quality pharmaceuticals. As part of that effort, we established a global supply chain, leveraging our experience as the supplier of Japan's first original therapeutic antibody to overseas markets. Through our supply chain leader, we shared worldwide demand information with Roche and jointly developed a Global Demand & Supply Control System for suitable supply planning and management. This system started in 2008.

When importing Roche products, Chugai must deal with the increasingly complex and global nature of supply chain management. For example, we must make purchase plans to meet Japanese demand and routinely monitor product temperature during transportation. We are therefore strengthening our risk management, including earthquake countermeasures, while constantly striving to provide a stable supply of medicines from and into Japan.

Chugai Distribution Co., Ltd. distributes pharmaceuticals and promotional samples in Japan. Its mission is to consistently provide high-quality distribution services, with a commitment to putting delivery recipients first. To fulfill this mission, Chugai Distribution performs computerized inventory management and utilizes solutions devised by employees.

Pre-shipment inspection of sample packs

Packaging of sample packs

Sorting of case units for shipment

Promotional sample shipping

Contributing to Patient-Centered Healthcare

Disease Awareness Activities

Chugai participates in and co-sponsors a variety of activities to support cancer patients and their families.

The Relay For Life is an awareness support campaign that forges ties in the fight against cancer. A 24-hour walk-a-thon in which cancer patients, their families and supporters compete as relay teams, this event was held in 36 locations throughout Japan in 2012. Chugai employees have participated in the Relay For Life as volunteers since 2007. A total of 630 employees participated as "Team Chugai" at 27 locations in 2012. At 16 of these locations, we set up our Giant Colon exhibit to educate visitors about colon cancer. Visitors deepened their understanding of colon cancer by reading explanations of tumors, polyps and other subjects inside the tunnel-shaped exhibit and searching for answers to quiz questions on their way through.

Chugai employees participate as volunteers in the Relay For Life.

In December 2012, Chugai sponsored "WAHAHA HONPO Special Live Show - Heal with Laughter," an anticancer charity event held in Tokyo. The eighth such event, the show was organized by an executive committee comprising patient associations and support group members and by Nippon Broadcasting System, Inc. It provided accurate information on cancer and familiarized people with patient associations. The aim of this event is to create a society in which no one has to face cancer alone. The 2012 program featured a medical lecture followed by live entertainment by the WAHAHA HONPO comedy troupe.

Anticancer charity event "WAHAHA HONPO Special Live Show"

Fundraising Activities

Chugai conducts fundraising activities to assist children in need around the world and patients suffering from rare intractable diseases.

Chugai participated in the Roche 2012 Children's Walk, a global charity event, and collected donations from June 11 to 15, 2012. The Children's Walk raises funds to help children in the Republic of Malawi, Africa who have been orphaned by AIDS or for other reasons, and children in need of assistance around the world.

More than 3,300 Chugai employees helped raise funds, which were matched by the Company. As in 2011, half of the funds were donated to the Tohoku Rainbow House, a facility that the organization Ashinaga is building to provide psychological care for children orphaned by the Great East Japan Earthquake. The

Children's Walk 2012 near Chugai's head office

Chugai companies and sites throughout Japan conduct fundraising activities.

other half was donated through Roche to assist orphaned children in Malawi.

For 20 years Chugai has provided OK-432, an anticancer agent and agent for treating lymphangiomas,[1] free of charge to children worldwide suffering from incurable lymphatic malformations, working with the nonprofit organization Shuhei Ogita Fund (http://www.fund-ogita.org/). This fund, which was originally established as the Little Carlos Fund[2] in 1992, helps to make this treatment available to children around the world who suffer from this disease, regardless of their local medical situation or financial difficulties.

1. A rare disease in which lymphatic fluid abnormally pools in the lymphatic vessels to form cysts in parts of the body. In many cases, it is found at birth. Unlike cancer, lymphatic malformations are benign, but can retard children's development, and occasionally the cysts compress the respiratory tract and become life-threatening.
2. A fund established by Dr. Ogita in 1992 after he learned about the travel expenses a family from Mexico had to come up with to get OK-432 local injection therapy for their 14 month-old boy Carlos.

Academic Support Activities

Chugai actively promotes exchanges with authorities from around the world and the development of young researchers in Asia.

The Chugai Academy for Advanced Oncology (CHAAO)[3] promotes deeper academic ties between the world's top oncologists, researchers and clinicians who play a leading role in cutting-edge cancer treatment in Japan. The International Academy for Advanced Oncology (IAAO) 2012, the largest CHAAO event, took place over two days in Tokyo in August 2012. The main topic of this third annual forum was "The Dynamism of Therapeutic Strategy from the New Oncology Paradigm." Thirteen influential oncologists working in the forefront of oncology gave impassioned lectures on subjects including the latest information on advanced molecular targeted therapies and development strategies for anticancer agents.

3. Established in October 2009 to contribute to the establishment and advancement of infrastructure for cancer treatment in Japan. To bring cancer treatment in Japan to a world-class level, CHAAO promotes deeper academic exchange between the world's top specialists in oncology and healthcare professionals who play a leading role in cutting-edge research and treatment of cancer in Japan.

IAAO 2012, a CHAAO event

In addition, Chugai conducts an international joint research fellowship program through the Tokyo Biochemical Research Foundation (TBRF). Each year, the foundation invites young postdoctoral researchers from Asia to conduct joint research at universities and scientific research institutions in Japan for one to two years. Since its launch in 1995, the program has supported 64 researchers from 13 Asian countries and regions. At a meeting in March 2012, 10 researchers invited from China, South Korea, Thailand, Bangladesh, Kazakhstan and Egypt presented their findings. (For detailed information on the program, see the TBRF website at http://www.tokyobrf.or.jp/english/)

Researchers from Asia supported through TBRF present their findings.

Working with Business Partners

Initiatives for Building Fair, Transparent Relationships

Chugai emphasizes cooperation with its business partners and works on a daily basis to promote various initiatives to ensure fair and transparent relationships with them as equals.

In 2011, we restructured our electronic purchasing system, which was introduced in 2005 as an optimal mechanism for building fair and transparent business relationships. In addition, we have been standardizing and optimizing our process for purchasing indirect materials, such as office supplies, to ensure healthy competition.

Purchasing Policy

The Chugai Group Purchasing Policy is designed to build fair and transparent relationships with business partners and strengthen cooperation with them.

Chugai Group Purchasing Policy

Ethics, compliance with laws and regulations	Comply with laws and regulations, social norms, Chugai Business Conduct Guidelines (BCG), and Chugai ethical purchasing standards to conduct fair purchasing activities and healthy business transactions.
Impartial, fair, open policy	Provide the opportunity for Japanese and overseas business partners to conduct business with Chugai openly, impartially, and fairly regardless of management size or trading performance.
Environment	Promote procurement activities that take into account the global environment by conducting green procurement with our business partners.
Quality	Respect the spirit of GMP and pursue high quality and safe material alongside our business partners.
Cost	Set appropriate prices and promote lower costs by considering volume discounts realized through the consolidation of business partners as well as the change of business partners.
Mutual trust and growth, protect intellectual property	Fulfill our obligations faithfully under the contracts with our business partners, establish equally cooperative relationships, and aim for mutual growth. Do not disclose confidential information related to business transactions to third parties without the relevant supplier's permission.
Select and evaluate business partners	Select business partners based on an overall objective evaluation of their quality, price, timing, information, stable supply of material and products, and consideration towards social responsibility.

Chugai Ethical Purchasing Standards

The Chugai Ethical Purchasing Standards outline the principles for ethical conduct for all companies and individuals participating in its purchasing process in order to build and maintain sound transaction relationships with business partners. For example, the standards specify actions that should be taken with regard to gifts and invitations for entertainment, including dining together.

Gifts

Any gifts that are offered must be declined, and the incident must be reported to the head of the organization concerned. Any gifts received by delivery must be returned with a polite letter of decline.

However, generally distributed promotional articles, such as hand towels, calendars and datebooks, may be accepted within commonly accepted limits.

Entertainment

Any offers of entertainment, including dining together, must be declined, and the incident must be reported to the head of the organization concerned.

Initiatives in 2012

Based on its experience in purchasing, Chugai balanced compliance, business efficiency and cost reduction in its purchasing activities by following purchasing processes that correspond to the characteristics of each particular commodity group and transaction type.

We also actively communicated with everyone involved in purchasing activities, both in and outside the Company to discover problems and improve business processes.

We will continue our efforts to conduct purchasing activities that maintain a good balance of compliance, operational efficiency and cost reduction.

Initiatives for Society

Endowed Courses on Medical Treatment

As a way of contributing to society, Chugai has established endowed courses at universities to provide health-related education for the next generation.

One of these was a course based on the theme of "health" at the Keio University Global Security Research Institute from April to September 2012. In addition to general lectures on various topics including government healthcare policy and health management from both local and global perspectives, the course included practical lectures from the standpoints of pharmaceutical companies, hospital management and sports promotion. Students from various fields of study deepened their understanding of the current situation regarding "health" and collaborated in considering ways to solve social issues.

Lecture at Keio University

The course at Waseda University, which Chugai established in 2011, was held again from October 2012 to January 2013 with lectures on the theme of medical treatment, particularly cancer treatment. Some of Japan's leading clinical physicians and researchers as well as securities analysts gave lectures on the current state, challenges and future of cancer treatment in Japan. The course also featured lectures by Chugai employees on initiatives at pharmaceutical companies, including drug safety and the activities of MRs.

Ongoing Donations of Welfare Vehicles

The number of seniors and persons with disabilities in Japan who need nursing care continues to increase as the population ages. Since 1985, Chugai has maintained a program to donate specially equipped welfare vehicles to organizations that provide welfare services to these people.

This program is conducted in cooperation with the Japan National Council of Social Welfare and Central Community Chest of Japan, and through it vehicles have been donated to recipients in all of Japan's 47 prefectures. In 2012, a total of five vehicles were donated – one to each of five organizations operating in prefectures damaged in the Great East Japan Earthquake. A total of 193 vehicles have been donated since 1985.

Welfare services are provided at day service centers and other facilities so that people needing nursing care can lead independent lives with peace of mind in a familiar environment. The welfare vehicles donated by Chugai are used to transport these people between such facilities and their homes.

Donation ceremony in Minamisanrikucho, Miyagi Prefecture

Donated vehicle

Biotech-Lab to Show Children the Fun of Science

Chugai hosts the Summer Biotech-Lab for Kids to show children that science can be fun. In 2012, 88 children chosen by lot out of 453 applicants participated. The program is co-sponsored by the Japan Science Foundation, with cooperation from Leave a Nest Co., Ltd.

In the lab class, Chugai employees playing the role of a doctor of pharmacy gave the children experiment "missions." One child said, "It made me enjoy science more," and another remarked, "In the future, I want to be a Chugai researcher." The children's guardians also made positive comments.

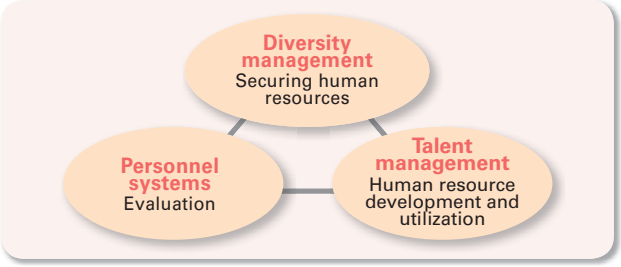
Nineteen Chugai employees volunteered at an interactive corner set up at the event. They explained to the 502 visitors how cell samples are collected, provided explanations when the children were viewing their own cells, and gave quizzes.

A volunteer explains how buccal swabs are taken.

Engagement with Employees

Human Resource Strategy to Become a Top Japanese Pharmaceutical Company

People are an invaluable asset in generating a company's growth and development. Based on that fundamental principle, Chugai is building its human resource management on three pillars – diversity management, talent management and personnel systems – to ensure achievement of its goal of becoming a top Japanese pharmaceutical company, as expressed in its Mission Statement.



Career Development That Supports Self-Directed Careers

Having already revised its personnel system and introduced diversity management and talent management systems, Chugai revamped its career development framework in 2012.

Our career policy is to "Support employee autonomy and mutual growth by placing importance on providing employees with opportunities to realize and nurture their own value." With the career declaration system as the basic cycle, we focus on workplace dialogue and management centering on the awareness of the employee concerned and the support and advice of his or her superior to facilitate self-directed career development. We also supplement the basic cycle with various measures to promote further autonomy and mutual growth.

Talent Management According to Each Person's Capabilities and Aptitude

Chugai revised its talent management system in 2012. Specifically, in April 2012, each organization held discussions on medium-to-long-term human resource development policy, drafted a human resource development plan and created a talent pool.* Based on the development plans, the organizations carried out strategic employee placement and training designed to strengthen leadership.

In addition, we clarified our succession plan by selecting successor candidates for a total of 88 general manager and department manager positions in Japan. We are currently implementing development plans for these candidates to help them hone the various skills and cultivate the management perspective that these positions require.

This talent management system will enable Chugai to systematically and continuously develop and turn out the next generation of leaders and core employees while strengthening human resources and boosting motivation throughout the Company.

*A group of candidates for the next generation of leaders

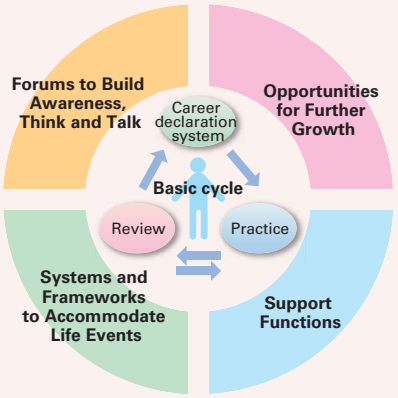
Three Goals of the Talent Management System

Goal 1	**Formulate and implement human resource development plans** according to the capabilities and aptitude of individual employees
Goal 2	**Build and manage a talent pool** from which to select successor candidates
Goal 3	**Formulate and implement a succession plan** to serve as a framework for evaluation, selection, development and assignment

Overview of Career Development

Create forums for employees to realize their own value and think and talk about their careers
- Training (including career development)
- Forums to talk about careers

Promote further growth by providing various opportunities
- Talent management
- Leadership competency program (LCP), training to strengthen expertise, self-improvement program (SIP)



Enhance systems and frameworks for life events that are significantly related to career development
- Life event-related systems
- Diversity measures

Provide individual support through career consultation and post relevant information on website
- Career consultation
- Career Web

Equal Opportunity and Fairness in Recruiting

Based on its equal opportunity policy, Chugai treats and compensates its employees equally regardless of gender, age, nationality or whether or not they have disabilities. In accordance with this policy, we actively seek to hire persons with disabilities in addition to hiring new university graduates, mid-career professionals and non-Japanese. As of December 1, 2012, the ratio of employees with disabilities in the Company was 1.99 percent.

Moreover, we maintain fair and impartial hiring practices by using a diverse team of interviewers to evaluate candidates' abilities, skills and experience.

Facilitating Work/Life Balance

Based on the desire to retain employees and support family life, Chugai has developed a full range of programs, including childcare leave and a part-time working system for childcare, that allow employees to continue working, for example, during child-rearing years.

Chugai formulated a general employer action plan in 2005 pursuant to Japan's Act on Advancement of Measures to Support Raising Next-Generation Children, and has taken measures such as introducing a program to support employees who return to work after childcare leave and improving the part-time working system for childcare. In recognition of these measures, since 2008 Chugai has continued to receive the "Kurumin" mark from Japan's Ministry of Health, Labour and Welfare, certifying the Company as one that actively supports the balance between work and family life.

In its Phase 3 Action Plan (April 1, 2011 – December 31, 2014), Chugai is making efforts to create work environments that enable both male and female employees to balance work and family life. In 2012, we began lending Company PCs to employees on leave for childbirth or childcare to facilitate a smooth return to the workplace, and introduced a telecommuting system to allow these employees to fully utilize their abilities while raising their children.

Occupational Safety and Health, Health Maintenance and Mental Healthcare Initiatives

In December 2011, Chugai established basic rules on occupational safety and health. Based on our policy of placing priority on ensuring employee safety in all operations, we are taking proactive measures to upgrade our safety and health system, ensure safety, prevent occupational injuries, promote health maintenance and create comfortable work environments. In creating a framework to give individualized attention to employees' issues, we have set up physical and mental health counseling services in which specialists including occupational health physicians, nurses and psychologists cooperate with managers and supervisors. Employees at all facilities can freely access these services.

BCG and Human Rights Training

Chugai conducts annual training for all employees. In the first half of the year, the content focuses on corporate ethics, and in the second, on respect for human rights.

The theme for the first half of 2012 was "Living up to the expectations and trust of society." Drawing on case studies, the training enabled employees to consider the idea that companies must not only comply with laws and regulations but also meet public expectations, and that by doing so consistently over time, they will earn the respect and trust of society. The training emphasized the importance of having a high level of awareness as well as knowledge in living up to the expectations and trust of society, and the value of concern and sensitivity when executing business. It also confirmed that checking with colleagues about any questions or doubts and making adjustments according to the situation rather than adhering to conventional methods will help build trust.

In the second half, training covered power harassment (i.e. abuse of power), under the theme of "Aiming for a harassment-free workplace." In bridging communication gaps that can easily trigger harassment, listening to the real intentions and points of other people and thinking about their feelings can inspire self-reflection and bring people closer, thus building good relationships. The training provided an opportunity to consider the idea that creating a harassment-free workplace depends on every employee.

Enabling Diverse Employees to Realize Their Potential

Promoting Diversity Management

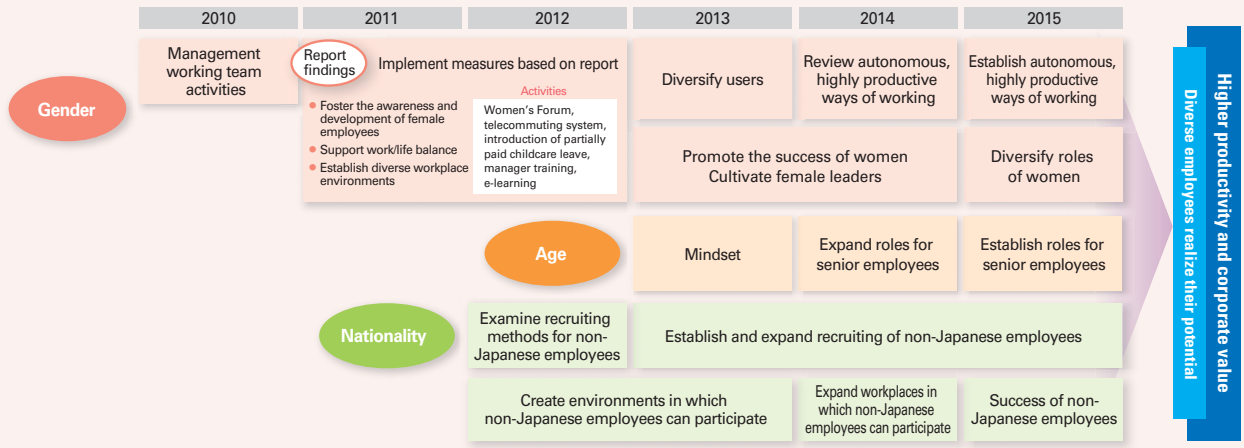
Human resource management that promotes diversity of gender, nationality and age will help Chugai become a top Japanese pharmaceutical company.

Chugai has placed priority on diversity management to enable a rich variety of employees to work enthusiastically and create new value. Our first step was to launch a management working team in 2010 to promote gender diversity.

In January 2012, we established the Diversity Office to strengthen these efforts and implement them more broadly. This office focuses on fostering awareness and improving systems and environments. Forums have been held in every division to give women the opportunity to think about their careers and ways of working. Talks by employees with different experiences, lunchtime gatherings and other such activities have also been held. Initiatives implemented to balance life events and work include a telecommuting system, lending of Company PCs to employees on childcare or nursing care leave so they stay current with developments at the Company and thereby smooth their return to the workplace, and partially paid childcare leave to encourage male employees to take paternity leave. We are also making efforts in areas other than personnel systems, including an e-learning program to deepen understanding of diversity in general, and manager training for overseeing diverse employees. Our objective is to make a workplace environment in which all employees can play important roles.

Going forward, we will carry out activities to address nationality and age in addition to gender in order to promote the success of non-Japanese employees with diverse values and senior employees with a wealth of useful experience.

Diversity Promotion Roadmap



I feel that our flexible activities have raised interest and awareness.

Gender diversity activities are primarily conducted by designated members of each division. As a result, activities have been flexible, taking into account the issues and conditions of each division. I feel that interest in employee diversity has also been steadily rising. To ensure the promotion of diversity, I believe we need to encourage greater participation by all employees.

Since various people with different views and work constraints carry out their tasks together, adjustments and decisions will probably take extra time. However, I think it could also be a good opportunity for organizational growth, as people are inspired by other departments' solutions. Looking at diversity from a broader perspective, we will not only develop ourselves, but also strive to bolster the activities of a diverse range of employees so that autonomous, highly productive talent and the organization can make innovations that contribute to the Company's performance.

Seiko Nohara
Manager, Diversity Office, Human Resources Management Department

Key Activities in 2012

Women's Forum and Lunchtime Gatherings

As of June 2012, all divisions have held a Women's Forum for giving female employees the opportunity to think about their careers and ways of working. The forum was the first step toward changing the mindset and culture of the Company. Among the comments heard were "This was a good opportunity to think about how I work" and "It was helpful to exchange views with people who are having problems."

The Women's Forum has evolved into other forms of activity in divisions and at facilities, such as working groups and lunchtime gatherings. Participation of male employees has also increased, making these meetings an opportunity to gain more recognition.

Interaction with Overseas Employees at the "Roundtable Conference on Diversity Management"

In July 2012, Chugai started promoting diversity of nationality with the "Roundtable Conference on Diversity Management." Taking advantage of the opportunity provided by Chugai's employee exchange program with overseas marketing subsidiaries, 12 employees from the U.K., Germany, France, China and Japan participated in the conference, sharing and discussing the cultural aspects and diversity initiatives of each country. The event was a meaningful reminder of the importance of communication and trust in intercultural exchanges.

"Mutual trust and respect" is a vital ingredient in promoting diversity.

Ruth Currie

Managing Director,
Chugai Pharma U.K. Ltd.

I felt very privileged to participate in the Roundtable Conference on Diversity Management. As part of the open discussion, we looked at approaches to transcultural management. We reached certain conclusions: to understand diversity you need to consider different backgrounds, nationalities, culture and gender. It's not enough to scratch the surface; you need to dig deeper and "more than" understand the differences. In fact, we should look for and understand similarities, recognize competing views and perspectives, and then it's easier to understand each other as individuals. Communication is thus based on "mutual trust and respect," which is a vital ingredient in promoting diversity. We felt it essential to actively listen to understand others and encourage others to understand, ensuring clarity in our communication. This will achieve successful international business.

New perspectives and ideas come from promoting diversity.

Kunihiko Yukimatsu

Manager,
Business Operations Group,
Overseas Business Department

What impressed me was that the approach to diversity was different in each country. For example, when an employee goes on educational leave in Japan, people assume that another regular employee usually fills in, but in Europe it's more common for a temporary worker to be brought in to provide support. I believe diverse employment arrangements are a prerequisite for gender diversity. Being aware of these differences in assumptions can give people the perspective to come up with the best approach in their own country. This opportunity to interact with overseas employees was very stimulating because I was able to experience the process of getting new ideas by recognizing differences. I expect Chugai to make progress on diversity, including nationality, as a global company.

Environmental and Safety Initiatives

Chugai conducts environmental activities in line with the Chugai Environmental Policy, Guidelines for Environmental Protection and Guidelines for Health and Safety, which were all established in December 2011.

Basic Approach

Chugai's environmental and safety initiatives are based on Chugai's Environmental Action Plan and Annual Safety and Health Plan. These plans take the employees' perspective when considering not only business activities but also the various environments around us.

Chugai Environmental Policy

We believe the supreme value to the future of "one and only Earth" and, therefore, we continue our efforts to reconcile our business activity with nature and the environment.

Regulatory Compliance
Chugai complies with all legislation and regulations, internal regulations and self-imposed standards relating to environmental protection.

System to Facilitate Action
Each year Chugai sets an environmental action plan and goals, and is continuously working to protect the environment.

Environmental Protection Activities
To minimize its impact on the environment, Chugai works to prevent global warming, conserve resources, reduce waste and prevent environmental pollution at every stage of the product lifecycle, from research and development to manufacturing, transportation, marketing and disposal.

Education and Training
Chugai provides regular education and training to its employees to deepen their knowledge and appreciation of environmental protection.

Information Disclosure
Chugai actively discloses information about its environmental protection activities both internally and externally and works to improve communication with communities.

2012 Environmental Action Plans and Performance

Evaluation: ○ Goal achieved △ Goal 75% or more achieved

Item		2012 Goal or Mid-Term Plan	2012 Result	Evaluation
Global warming countermeasures	Achievement of the reduction target for CO_2 emissions	Reduce energy consumption per employee by 10% from the 2009 level by 2014	Reduced energy consumption per employee by 10.6%	○
	Introduction of more hybrid vehicles in MR fleet	Raise the ratio of hybrid vehicles or conventional vehicles with comparable fuel efficiency in our fleet to 50% or more by 2012	Introduced 243 hybrid vehicles and conventional vehicles with comparable fuel efficiency; hybrid vehicle ratio of 49.3% in 2012	△
Waste reduction	Reduction in the amount of waste generated	Limit the amount of waste generated in 2012 to the 2011 level	Reduced to 72% of the 2011 level	○
	Reduction in the amount of landfill waste	Limit the amount of landfill waste in 2012 to 70 tons or less	Landfill waste in 2012 was 67 tons	○
Resource conservation	Reduction in the amount of PPC paper purchased	Reduce the amount of PPC paper purchased in 2012 by 5% from the 2011 level	Decreased by 8% from the 2011 level	○
	Improvement in the recycling ratio of PPC paper	Maintain a recycling ratio of 80% or higher for PPC paper in 2012	Achieved a recycling ratio of 85.5% for PPC paper in 2012	○

For further details, please refer to the "CSR" section of the Chugai website.
http://www.chugai-pharm.co.jp/hc/ss/english/csr/index.html

Measures to Prevent Global Warming

Reducing Energy Consumption

Chugai has set the goal of reducing energy consumption in 2014 by 10 percent from the 2009 level of 357 GJ per employee.

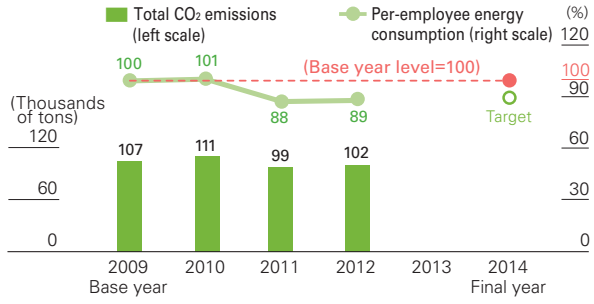
Energy use in 2012 was 316 GJ per employee, or 89 percent of the base-year level, meeting the target for the second consecutive year.

The conversion of an aging refuse-derived fuel (RDF) boiler[1] to a heavy oil boiler (reduction of 18,900 GJ of energy from 2011) and power-saving measures at each facility contributed to this reduction.

The trend of total CO_2 emissions is similar to that of total energy consumption.

1. A specialized boiler for power generation, fueled by RDF that has been pre-processed, dried, shredded and sorted, then chemically treated, compressed and solidified into pellet form.

Total CO_2 Emissions and Per-Employee Energy Consumption

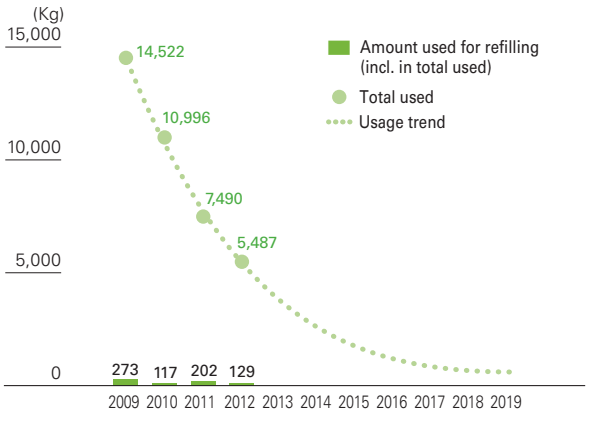


Discontinuation of Use of and Conversion from Halogenated Hydrocarbons

By 2020, Chugai plans to eliminate equipment that uses chlorofluorocarbons (CFCs) and hydrochlorofluorocarbons (HCFCs), which have a high global warming potential and deplete the ozone layer.

In 2012, the total amount of CFCs and HCFCs used to fill equipment decreased to 5,487 kg as a result of our conversion to equipment that uses less ozone-depleting hydrocarbons. We are also closely monitoring the amount of hydrocarbons used to replenish the portion that leaked from equipment (the amount of CFCs and HCFCs refilled in 2012).

CFCs and HCFCs Used to Fill Equipment



Introduction of Fuel-Efficient Vehicles

Chugai began introducing hybrid vehicles to its MR fleet in 2003. We have been increasing the ratio of hybrid vehicles to reach the goal we set in 2006 of 50 percent of our MR fleet by the end of 2012.

At the end of 2012, we had nearly achieved the target with a total of 974 hybrid vehicles and conventional vehicles with similar fuel efficiency. These vehicles account for 49.3 percent of our fleet.

Chemical Substance Management

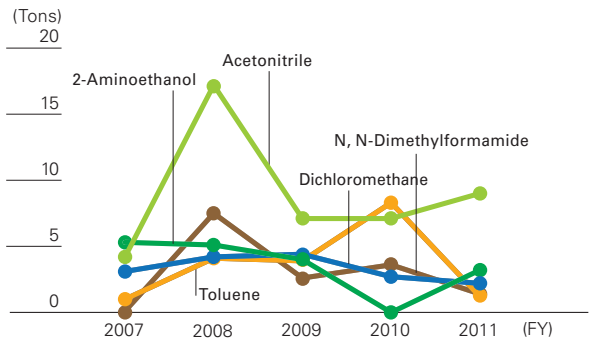
To protect employees from exposure to chemical substances and prevent health hazards, Chugai has established voluntary rules for chemical substance management and provides suitable work environments based on the results of risk assessments on the substances handled and the type of work. After protective equipment is selected, operations and procedures are determined.

We also provide material safety data sheets (MSDS) and Yellow Cards (cards with emergency measures and contact information) in an effort to ensure the safety of outside parties such as toll manufacturers.

In the one-year period from April 2011 to March 2012 (fiscal 2011), Chugai handled more than one ton each of five chemical substances covered by the PRTR Law.[2] These substances were Acetonitrile, Dichloromethane, Toluene, 2-Aminoethanol and N,N-Dimethylformamide. The amount of PRTR substances handled is shown in the graph. The amount of Acetonitrile and 2-Aminoethanol handled increased, but the total amount of these five substances handled decreased by 24 percent.

2. Pollutant Release and Transfer Register Law. Requires companies to monitor and report the release of designated chemical substances into the environment and promotes improvement of management.

Handled Amounts of Chemical Substances Covered by PRTR Law

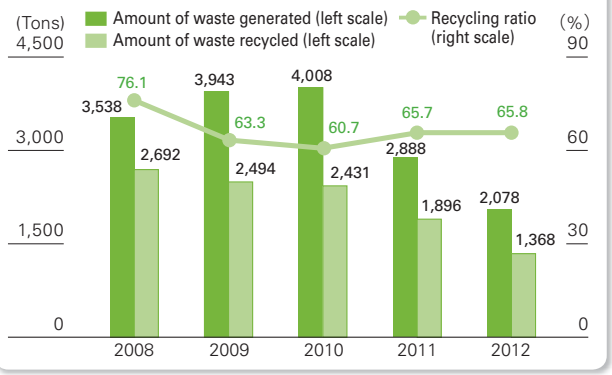


Waste Reduction

Results in 2012

The amount of waste generated in 2012 decreased by 28 percent compared with 2011 as a result of Chugai's efforts to achieve its goal of limiting the amount of waste generated to 2,888 tons. The key factors in this decrease were the absence of incinerated ash due to the shutdown of the RDF boiler at Fuji Gotemba Research Laboratories and a decrease in the amount of organic sludge generated at the Utsunomiya plant.

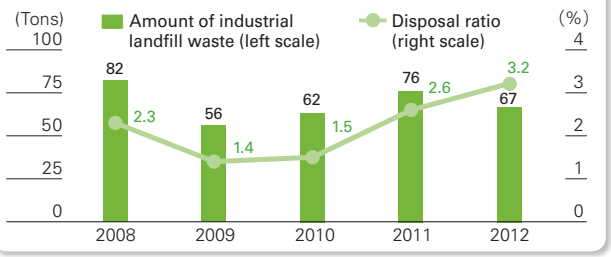
Industrial Waste Generation and Recycling Ratio[1]



1. Amount of waste recycled/(Amount of waste disposed + Amount of waste recycled)

The amount of landfill waste decreased by 12 percent compared with 2011 to 67 tons, below the target of 70 tons. However, the final disposal ratio was 3.2 percent, up 0.6 percentage points from 2011 due to the decrease in total waste generated.

Amount of Industrial Landfill Waste and Final Disposal Ratio[2]



2. Amount of landfill waste/Amount of waste generated

Disposal of Capacitors Containing PCBs

In June 2012, 14 capacitors containing PCBs that had been stored at the Fujieda plant of Chugai Pharma Manufacturing Co., Ltd. (CPMC) were disposed of at the Toyota facility of Japan Environmental Safety Corporation (JESCO). In December 2012, seven capacitors containing PCBs at the Ukima plant were disposed of at JESCO's Tokyo facility.

Removal of equipment containing PCBs (Fujieda plant of CPMC)

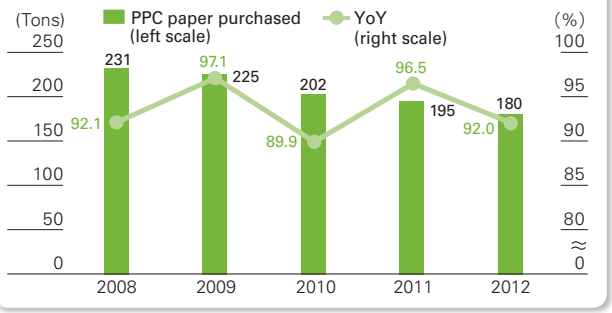
(Ukima plant)

Reduction in PPC Paper Used

The amount of PPC paper purchased decreased by 8 percent compared with 2011 as a result of efforts including reduction of handouts at meetings, multi-page printing and duplex printing.

We are also promoting the purchase of PPC paper that meets green purchasing criteria (100% recycled paper, FSC certification, etc.).

PPC Paper Purchased



Dismantling and Removal of RDF Boiler

In July 1998, Fuji Gotemba Research Laboratories installed an RDF boiler fueled by solid refuse from the cities of Gotemba and Oyama in Shizuoka Prefecture as part of its local social contribution program. The boiler was put into service in July 2000. However, due to the aging of the boiler and the associated increase in maintenance costs, the boiler was shut down in 2011 with the agreement of the city of Gotemba. Starting in April 2012, we dismantled and removed the boiler while taking precautionary steps such as dioxin countermeasures and soil surveys to confirm that there were no problems related to the work. Removal was completed in October 2012.

Before dismantling

Dismantling in progress

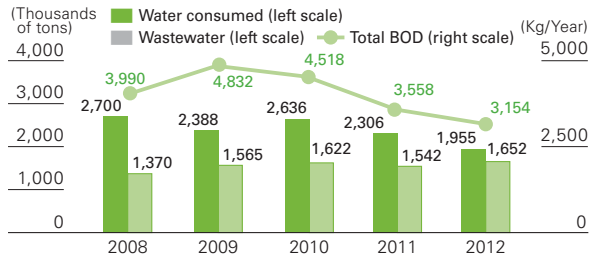
After removal

Prevention of Water and Air Pollution

Amount of Water Consumed and Wastewater

The amount of water consumed decreased by 351 tons compared with 2011. Nominal wastewater discharge at all Chugai plants and research laboratories was significantly below the prescribed environmental limits, and total biochemical oxygen demand (BOD) decreased by 404 kg compared with 2011.

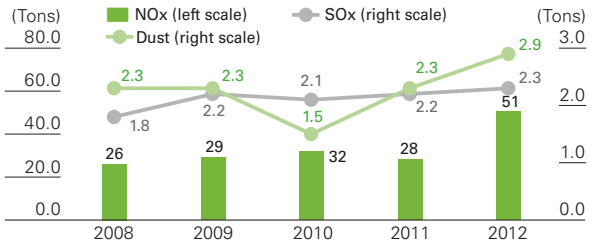
Water Consumed, Wastewater and Total BOD



Air Pollutants Emitted

Air pollutants emitted by Chugai sites were significantly below the prescribed environmental limits at each site. However, NOx emissions increased by 22 tons because the shutdown of the RDF boiler resulted in increased operation of other boilers.

Air Pollutants Emitted



Environmental Accounting

Environmental accounting data compiled in 2012 are shown below. Investments in 2012 totaled ¥410 million, while costs were ¥1,878 million.

Major investments included energy-saving equipment and wastewater management equipment.

The economic benefit was ¥49 million.

2012 Investments and Costs for Environmental Protection

(Millions of yen)

Breakdown of costs	Investments	Costs
(1) Business area costs	383	1,544
(1)-1 Pollution prevention costs	239	786
(1)-2 Global environmental protection costs	144	585
(1)-3 Resource recycling costs	—	173
(2) Upstream and downstream costs	—	25
(3) Administration costs	27	285
(4) R&D costs	—	1
(5) Social activity costs	—	23
(6) Environmental remediation costs	—	—
Total	**410**	**1,878**

Internal Environmental and Safety Audits

Internal audit at the Ukima site

In 2012, Chugai conducted internal environmental and safety audits at one research laboratory, two sites and four branches. At the research laboratory, the 5Ss (*seiri, seiton, soji, seiketsu* and *shitsuke*, which translate respectively as "put in order," "tidy up," "clean up," "be neat and clean," and "be disciplined") were applied throughout the laboratories and lounges and have led to substantial improvements. Activities continued to be implemented smoothly at plants in 2012, and no serious problems were found, including at branches. In 2012, environmental audits were separated from safety and health audits, and were conducted simultaneously. This move allowed for a more detailed understanding of efforts in each of these areas.

Environmental Education

Advanced training seminar for internal environmental auditors

In 2012, internal environmental auditor training was conducted for employees of ISO 14001-certified factories. In addition, more advanced training was provided for employees who had already taken the internal environmental auditor training. As a result of this ongoing training, these sites now have more than 300 internal environmental auditors. Advanced training will continue.

Occupational Safety and Health

In January 2012, Chugai established its Guidelines for Health and Safety as the basis for health and safety management in the Chugai Group. We are improving and implementing safety and health management systems under our policy of placing priority on ensuring employee safety in all business operations.

In addition to the management system centered on the Safety and Health Committee at each site, we have clarified the Company-wide safety and health management structure with the Corporate Social Responsibility Committee at its core. These committees help to ensure that safety management, health management and mental health programs are carried out uniformly at all sites.

Results of Occupational Accidents in 2012

	Number of accidents	Incidence rate*
Lost worktime	6	0.48
No lost worktime	22	1.77
Total	**28**	**2.26**

Total number of lost workdays: 33.5

*Incidence rate = (No. of occupational injuries and deaths/ No. of hours actually worked) X 1,000,000

Corporate Governance

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 with prompt decision-making, clarification of executive responsibilities and management transparency as the key points.

Management Decision-Making, Execution and Oversight of Business Operations

To expedite business operations and clarify executive responsibilities, Chugai has 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. In execution of business, starting in March 2012, the chief executive officer (CEO) has ultimate responsibility for decisions on Company-wide management strategies and other important matters, and the chief operating officer (COO) is responsible for decisions on 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 ten directors, including five outside directors. Three of the outside directors are from the Roche Group. In 2012, the Board of Directors convened seven times.

Executive Committee

The Executive Committee makes important executive decisions. It consists of key executive officers, including the CEO and COO, and the full-time Audit & Supervisory Board Members.

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

Introduction of Outside Perspectives

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

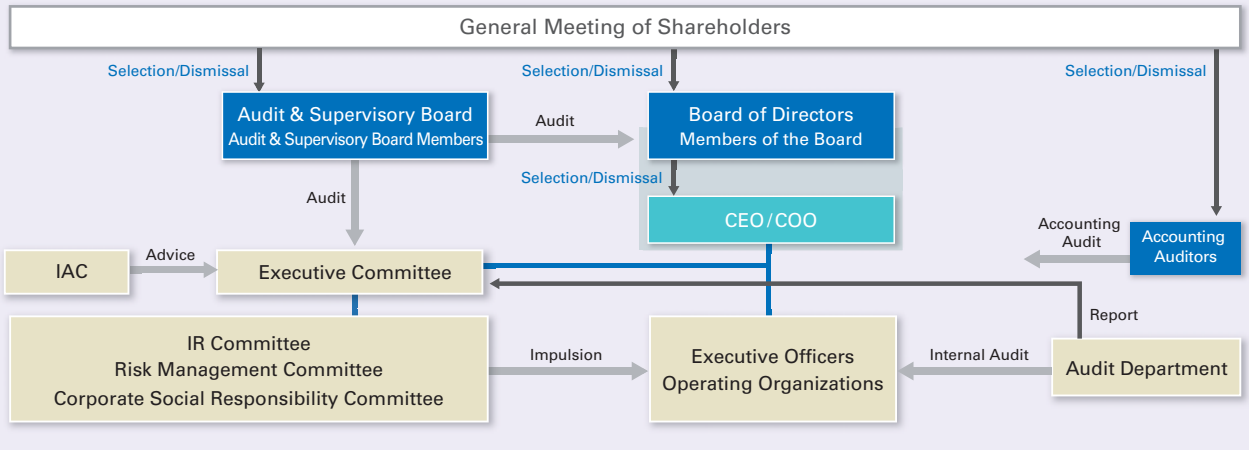
International Advisory Council (IAC)

Chugai has established the International Advisory Council (IAC), an advisory board composed of industry leaders and other professionals from around the world. The IAC works to enhance decision-making by providing valuable advice on how to deal with changes in the global business environment and appropriate business conduct.

Outside Directors

Chugai has appointed outside directors to reflect the views of a broader range of stakeholders in management decision-making. Outside directors from Roche provide appropriate advice and oversight with

Chugai's Corporate Governance System



IAC Chairman

- **Henry L. Nordhoff (US)**
  Former Chairman of the Board, Gen-Probe, Inc.

IAC Advisors

- **Virginia Bottomley (UK)**
  Former Health Secretary
- **Andrew von Eschenbach (US)**
  Former Commissioner of the Food and Drug Administration
- **Victor Halberstadt (Netherlands)**
  Professor, Leiden University
- **Andre Hoffmann (Switzerland)**
  Vice Chairman, ROCHE HOLDING LTD
- **Dr. Franz B. Humer (Switzerland)**
  Chairman, ROCHE HOLDING LTD
- **Robert A. Ingram (US)**
  Former Vice Chairman of Pharmaceuticals, GlaxoSmithKline plc
- **Arnold J. Levine (US)**
  Professor at the Institute for Advanced Study, Princeton University
  Discoverer of the p53 cancer suppressor protein
- **Abraham D. Sofaer (US)**
  George P. Shultz Distinguished Scholar and Senior Fellow at the Hoover Institution, Stanford University
  Former legal advisor to the US Department of State
- **Sonosuke Kadonaga (Japan)**
  President, Intrinsics

regard to management and business from a global perspective. Other outside directors contribute to management decision-making through advice and monitoring based on their abundant experience and knowledge as corporate executives or medical specialists.

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. However, they point out issues and give advice concerning Chugai's management as required outside board meetings as well.

The rate of attendance by outside directors at the seven board meetings in 2012 was approximately 88.6 percent on average, the highest being 100 percent and the lowest 71.4 percent.

Auditing System

Audits by Audit & Supervisory Board Members

Chugai has an Audit & Supervisory Board, and audits of management decision-making and business execution are conducted independently from business operations by four Audit & Supervisory Board Members, including two outside members.

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

Audit Department

The Audit Department, staffed by approximately 16 members including certified internal auditors, conducts internal audits of operational conditions including the compliance status of various organizations within the Company. It conducts audits of the Chugai Group's business execution from various standpoints, including effectiveness, efficiency of business activities and compliance; reports and makes recommendations to the Executive Committee; and reports to the Audit & Supervisory Board. In 2012, the internal audit process underwent an independent evaluation by a third-party institution (Ernst & Young ShinNihon LLC), which concluded that Chugai's internal audits conformed well to international standards. In addition, the Audit Department conducts internal control assessments based on the Financial Instruments and Exchange Act (informally known as J-SOX) to help maintain sound operations.

Accounting Auditors

KPMG AZSA LLC handles accounting audits and internal control audits. Audit & Supervisory Board Members and the accounting auditors confirm each other's audit plans and exchange opinions on matters including the results of quarterly audit reports. Audit & Supervisory Board Members also attend accounting audit reviews.

Reasons for Election of Outside Directors

Name	Outside Position	Reason for Election
Mitsuo Ohashi	Senior Advisor, SHOWA DENKO K.K.	Recommended or appointed as the Company expects that he will provide advice and monitoring by leveraging his abundant experience and knowledge of corporate management and other fields. Designated as independent director based on the regulations of Tokyo Stock Exchange, Inc., to which notification has been submitted.
Yasuo Ikeda	Professor Emeritus of Keio University 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 based on the Company's judgment that he will provide appropriate advice and monitoring with respect to the Company's management and business by leveraging his abundant experience and knowledge as a doctor and university professor and can properly execute the duties of an outside director. Designated as independent director based on the regulations of Tokyo Stock Exchange, Inc., to which notification has been submitted.
William M. Burns	Board Member of ROCHE HOLDING LTD	Board member of the Roche Group, to which the Company belongs. Recommended or appointed based on the Company's judgment that he will provide appropriate advice and monitoring with respect to the Company's management and business from a global perspective and can properly execute the duties of an outside director.
Daniel O'Day	Chief Operating Officer of Roche Pharmaceuticals Division, Member of the Roche Corporate Executive Committee and Member of the Genentech Board of Directors	Board member of the Roche Group, to which the Company belongs. Recommended or appointed based on the Company's judgment that he can properly execute the duties of an outside director, including providing advice and monitoring with respect to the Company's management from a global perspective.
Sophie Kornowski-Bonnet	Head of Roche Partnering and Member of the Enlarged Roche Corporate Executive Committee	Managerial member of the Roche Group, to which the Company belongs. Recommended or appointed based on the Company's judgment that she can provide appropriate advice and monitoring with respect to the Company's management and business from a global perspective and can properly execute the duties of an outside director.

Cooperative Auditing

Audit & Supervisory Board Members, the Audit Department and the accounting auditors cooperate closely by regularly exchanging information to improve the effectiveness of their respective audits. The Office of Audit & Supervisory Board Members ensures the independence of Audit & Supervisory Board Members and enhances auditing functions.

Officer Remuneration

Chugai's fundamental policy for remuneration of directors and Audit & Supervisory Board Members 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 Audit & Supervisory Board Members (including outside members), which consists solely of fixed regular compensation, is paid by resolution of the Board of Directors for outside directors and through consultation with the Audit & Supervisory Board for Audit & Supervisory Board Members. 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 Audit & Supervisory Board Members (including outside members).

Relationship with Roche

Roche, the parent company of Chugai, owns 59.9 percent of Chugai's outstanding shares based on the strategic alliance agreement between the two companies. 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.*

The aim of this alliance is to establish a new business model that differs from conventional corporate acquisitions and joint ventures. Although ROCHE HOLDING LTD includes Chugai in its consolidated accounts, Chugai functions as an independent listed company and makes all of its own management decisions based on the principle of self-governance. In its business dealings with the Roche Group, Chugai conducts all transactions fairly using third-party prices to protect the interests of minority shareholders.

Three of Chugai's ten directors are from the Roche

Amount of Remuneration Paid to Directors and Audit & Supervisory Board Members

(Millions of yen)

	Amount of Remuneration, etc.	Total Remuneration by Type			
		Regular Compensation	Bonuses	Common Stock Options	Stock Options as Stock-based Compensation
Directors (6) (excluding outside directors)	669	301	198	56	112
Outside Directors (4)	52	52	—	—	—
Total (10)	721	553		56	112
Audit & Supervisory Board Members (2) (excluding outside members)	62	62	—	—	—
Audit & Supervisory Board Members (outside)(4)	21	21	—	—	—
Total (6)	84	84		—	—

1. The table above includes two directors and two Audit & Supervisory Board Members who retired during 2012.
2. The amount of remuneration, etc. (regular remuneration and bonuses) paid to all directors was no more than ¥750 million per year as per the resolution passed in the Annual General Meeting of Shareholders for the year ended December 31, 2006 held in March 2007.
   Apart from this, the maximum amounts of compensation paid to directors in the form of stock acquisition rights allocated as stock options are ¥125 million per year for common stock options and ¥150 million per year for stock options as stock-based compensation as per the resolution passed in the Annual General Meeting of Shareholders for the year ended December 31, 2008 held in March 2009.
3. The amount of remuneration for all Audit & Supervisory Board Members was no more than ¥100 million per year as per the resolution passed in the Annual General Meeting of Shareholders for the year ended December 31, 2005 held in March 2006.
4. The amounts of bonuses shown in the table above are the amount of provision for reserve for bonuses to directors during 2012.
5. The amounts of common stock options and stock options as stock-based compensation shown in the table above are the amounts that were posted as expenses for 2012.
6. In addition to the amounts of total remuneration, etc. shown in the table above, the following amounts were paid as retirement benefits corresponding to the period from the time each officer assumed office to the abolishment of the retirement benefits system for directors or Audit & Supervisory Board Members (including Audit & Supervisory Board Members (outside)).

One retired director	¥70 million
One retired outside director	¥11 million
Two retired Audit & Supervisory Board Members (outside)	¥4 million

   A resolution was passed in the Annual General Meeting of Shareholders for the year ended December 31, 2008 held in March 2009, to abolish the retirement benefits system for directors with executive power, and to pay retirement benefits corresponding to their residual term up to the abolishment of the system to each concerned director remaining in office after the closing of the Annual General Meeting of Shareholders for the year ended December 31, 2008, at the respective time of their retirement.
   Also, a resolution was passed in the Annual General Meeting of Shareholders for the year ended December 2005 held in March 2006, to abolish the retirement benefits system for directors and Audit & Supervisory Board Members with no executive power, and to pay retirement benefits corresponding to their residual term up to the abolishment of the system to each concerned director and Audit & Supervisory Board Member remaining in office after the closing of the Annual General Meeting of Shareholders for the year ended December 31, 2005, at the respective time of their retirement.
7. In 2012, the amount of remuneration, etc., received by two outside directors, namely William M. Burns, and Pascal Soriot, as an officer from the parent company of the Company or subsidiaries of the said parent company totaled ¥305 million (converted into yen at the average exchange rate in 2012).

Group. However, they do not comprise a majority of the Board of Directors, and thus Chugai considers its management independence to be secure.

Chugai will continue to manage its business with autonomy and independence as a publicly listed company.

* 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

Maintenance and Management of Internal Controls

Chugai seeks to fulfill its mission by conducting transparent, fair and ethical corporate activities. In maintaining its internal control system, Chugai established the Chugai Business Conduct Guidelines (Chugai BCG) as 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.

In addition, Chugai has prepared for the 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

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 identifies Company-wide risks that may significantly affect management and submits a progress report to the Executive Committee concerning preventive measures for such risks. Division Risk Management Committees summarize and create risk maps of all the risks facing their divisions, make proactive efforts to prevent such risks, and submit reports on the progress of those efforts to the Risk Management Committee. (See page 119 for details of business risks.)

Compliance

Chugai has put in place Compliance Regulations as the fundamental rules of its compliance system. These regulations are promoted by the Corporate Social Responsibility Committee and the Corporate Social Responsibility Department. In 2012, the Corporate Social Responsibility Department conducted monitoring surveys on compliance status each quarter and reported the results to the Corporate Social Responsibility Committee. We also worked to ensure thorough legal compliance through managers and specialists in charge of promoting the Chugai BCG in each organization. The Corporate Social Responsibility Committee and the Corporate Social Responsibility Department, in cooperation with BCG promotion staff, hold regular business ethics training for all employees, and conducted such training twice in 2012.

The BCG Hotline has been established to receive employee inquiries and reports concerning compliance with laws, internal Company rules and the Chugai BCG. An external hotline is also available to employees.

Chugai Risk Management System

Disclosure Policy

Overview

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 healthcare 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 Chugai's shares are listed in order to receive fair valuation in capital markets. In addition, measures to allow easy access to disclosed information have been established to ensure transparency.

Chugai has established an IR Committee composed of the CFO and general managers of the Corporate Communications Department, the Corporate Planning Department, the Finance & Accounting Department, the Corporate Social Responsibility Department and the General Affairs Department as an executive advisory committee. The IR Committee holds regular meetings and is responsible for the establishment, revision and internal dissemination of the information disclosure policy, and for the management and promotion of information collection, disclosure and other related activities.

Top management, including the Chairman and key executive officers, has primary accountability for disclosure. In addition, the Corporate Communications Department takes the lead in coordinating with relevant departments to disclose information promptly.

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 of shareholders are sent out promptly. We sent the notice for the 102nd annual meeting more than four weeks prior to the meeting date.

The 102nd annual general meeting of shareholders was held on March 27, 2013. After the presentation of the business report through narration and materials, shareholders deliberated on agenda items concerning appropriation of retained earnings and election of directors and Audit & Supervisory Board Members. All agenda items were approved and passed by a majority.

IR Activities

Chugai holds information meetings and conference calls for analysts, investors and the media coinciding with financial results announcements. These meetings provide opportunities to explain the state of the Company's business directly to shareholders and investors. In 2012, we held an information meeting in December that covered the innovative antibody engineering technologies Chugai has developed in recent years. We explained Chugai's unique drug discovery technologies, such as its recycling antibody technology, and the activities of Chugai Pharmabody Research Pte. Ltd. Webcasts of IR events such as these are made available on our website as part of efforts to provide full information to stakeholders.

Senior management also holds overseas roadshows and in 2012 visited investors in Europe, the United States and Asia. Moreover, in addition to participating in domestic and overseas conferences hosted by securities companies to enhance IR activities, Chugai is increasing its outreach to individual investors by holding information meetings for them at branches of securities companies throughout Japan.

The Chugai website is another tool we use to

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 2,000 listed companies in 25 countries worldwide and selects candidates that meet international criteria related to the environment and society. As of December 31, 2012, 735 companies were listed, including 181 Japanese companies. 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.

provide timely and fair disclosure to shareholders and other investors. Information on our website includes news releases, financial results, the status of our development pipeline, presentation materials, an IR event calendar and annual reports. We focus on convenience for individual investors by offering the option of receiving e-mail notices whenever news releases and other updates are posted on the IR section of the website.

Chugai emphasizes fair information disclosure for domestic and overseas investors alike. As a rule, we post presentation materials and other information on our website and send out information by e-mail simultaneously in Japanese and English.

Countermeasures against Large-Scale Earthquakes

Formulation and Revision of Chugai Earthquake BCP

Chugai formulated the Chugai Earthquake BCP* in 2010 to avoid disruption of critical operations in the event of a disaster, or to restore operations within an acceptable timeframe if they are disrupted.

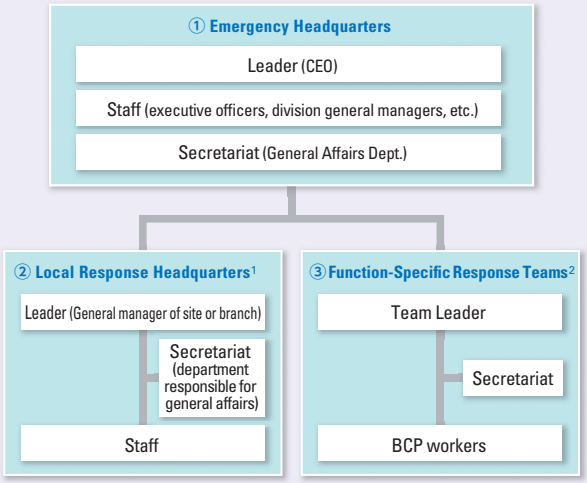
The basic policy of the Chugai Earthquake BCP is to place top priority on the safety and security of employees, and then to ensure the stable supply of products and protect research resources and other key assets. The Chugai Earthquake BCP includes provisions for organizational frameworks, action guidelines, a response manual, preparedness measures and other procedures in the event of a major earthquake.

We continuously strive to improve the effectiveness of these measures through training, verification and updating as needed.

*Business continuity plan

Organizational Framework in the Event of a Major Earthquake

Under the Chugai Earthquake BCP, the following organizational hierarchy is to be set up to respond if a large-scale earthquake with an intensity of 6 or higher occurs in the vicinity of a Chugai business site.



1. Organized at damaged sites or branches
2. Separate teams organized for SCM, manufacturing, safety, IT and payment functions

Promoting Awareness within the Company

A handbook for responding to large-scale earthquakes and a wallet-sized card with action guidelines are distributed to all employees to inform them about the Company-wide emergency response system and what to do in the event of an earthquake. In addition, information on the Chugai Earthquake BCP is provided in the in-house newsletter.

To ensure an early first response to an earthquake, safety confirmation drills are conducted for all employees three times a year.

Measures to Ensure Stable Product Supply

Reliably delivering products to patients is one of Chugai's most important missions. We therefore focus in particular on measures to ensure stable product supply. Under the Chugai Earthquake BCP, response teams are established for different functions, such as supply chain management (SCM), manufacturing and safety, following a major earthquake. These teams take immediate action to restore and maintain functions. Tasks include restoring manufacturing equipment and clean environments at plants, adjusting inventory and shipping at distribution centers, and ensuring business continuity at alternate sites.

Using the lessons from the Great East Japan Earthquake, we re-analyzed risks in the supply chain of each product and are implementing a plan for stable supply that incorporates proactive risk mitigation measures, including inventory buildup, production at more than one site, and storage of inventories at dispersed locations.

Seismic Diagnosis and Retrofitting of Production Facilities

Chugai launched a facility seismic retrofitting project in 2011 to strengthen buildings and facilities. We conducted comprehensive seismic diagnosis and risk assessments for plants, research laboratories and distribution centers, and identified approximately 3,000 rooms requiring retrofitting from the standpoint of risk to human life or business. Retrofitting work began in September 2012 and will be completed in March 2014. Measures are also being taken at 69 facilities to prevent furniture and fixtures from falling over.

Board of Directors / Audit & Supervisiory Board

(As of March 27, 2013)

Representative Directors

Osamu Nagayama

Motoo Ueno

Tatsuro Kosaka

Directors

Tatsumi Yamazaki

Yoshio Itaya

Mitsuo Ohashi
Senior Advisor,
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

William M. Burns
Member of the Board of Directors,
ROCHE HOLDING LTD

Daniel O'Day
Chief Operating Officer of Roche Pharmaceuticals Division, Member of the Roche Corporate Executive Committee

Sophie Kornowski-Bonnet
Head of Roche Partnering and Member of the Roche Enlarged Corporate Executive Committee

Audit & Supervisory Board Members

Kotaro Miwa
(full-time)

Kunitoshi Watanabe
(full-time)

Hisashi Hara
Chairman, Attorney at Law,
Nagashima Ohno & Tsunematsu

Michio Ishizuka
Ishizuka Certified Public Accountant Office

Board of Directors (As of March 27, 2013)

Osamu Nagayama

1978 Entered the Company
1985 Deputy General Manager of Development and Planning Div. and Director
1987 Director & Senior Vice President
1989 Representative Director & Deputy President
1992 Representative Director, President & CEO
2012 Representative Director, Chairman & CEO (to present)

Motoo Ueno

1984 Entered the Company
1991 General Manager of London Representative Office
1993 Director
1994 Director and General Manager of Medical Information Div.
1995 Director and General Manager of Clinical Research & Development Division
1996 Director and Deputy General Manager of Research and Development Division
1997 Director & Senior Vice President
1998 Senior Vice President
2000 Director & Senior Vice President
2002 Director & Deputy President
2003 Director & Deputy President
2004 Representative Director & Deputy President
2006 Representative Director & President, Chugai Pharma Manufacturing Co., Ltd.
2012 Representative Director & Deputy Chairman (to present)

Tatsuro Kosaka

1976 Entered the Company
1995 Deputy President of Chugai Pharma Europe Ltd. (UK)
2000 General Manager of Business Strategy Planning Office
2002 Vice President & General Manager of Corporate Planning Dept.
2004 Senior Vice President & General Manager of Corporate Planning Dept.
2005 Senior Vice President & Deputy Managing Director of Sales & Marketing Group
Senior Vice President & Head of Strategic Marketing Unit
2008 Senior Vice President & Head of Lifecycle Management & Marketing Unit
2010 Director & Executive Vice President and Head of Lifecycle Management & Marketing Unit
2011 Director & Executive Vice President
2012 Representative Director, President & COO (to present)

Tatsumi Yamazaki

1980 Entered the Company
1993 Head of Laboratory of Molecular Science
1996 Department Manager of Research Planning & Coordination Dept.
1997 Department Manager of Research Administration Dept.
1998 Vice President
2002 Senior Vice President & General Manager of Research Div.
2003 Senior Vice President & Managing Director of Research & Development Div.
2004 Director & Executive Vice President
2011 Director & Deputy President (to present)

Yoshio Itaya

2003 Entered the Company
Senior Specialist of Finance & Accounting Div.
2006 Vice President and General Manager of Finance & Accounting Div.
2007 Vice President and General Manager of Corporate Planning Dept.
2010 Senior Vice President and General Manager of Finance Supervisory Div. and Finance & Accounting Dept.
2012 Director, Executive Vice President & CFO (to present)

Mitsuo Ohashi

1959 Entered The Mitsui Bank Limited.
1961 Entered Showa Denko K.K. (SDK)
1989 Director and Chief Manager, Corporate Planning Department, SDK
1993 Managing Director, SDK
1995 Senior Managing Director, SDK
1997 Representative Director and President (CEO), SDK
2005 Representative Director and Chairman of the Board of Directors, SDK
Director of the Company (to present)
2010 Senior Advisor, SDK (to present)

Yasuo Ikeda

1979 Director of Keio University Hospital Blood Center
1991 Professor of Internal Medicine of Keio University School of Medicine
2001 Director of Keio University Center for Integrated Medical Research
2005 Dean of Keio University School of Medicine
2009 Professor Emeritus of Keio University (to present)
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 (to present)
2010 Director of the Company (to present)

William M. Burns

1969 Entered Beecham Pharmaceuticals
1986 Director of Sales & Marketing, Roche UK
1988 Head of Pharmaceuticals Division, Roche UK
1991 Global Head of Strategic Marketing & Business Development, F. Hoffmann-La Roche Ltd, Basel
1998 Head of Pharma Europe/International
2000 Member of Corporate Executive Committee of the Roche Group
2001 Head of Pharmaceuticals Division
2002 Board Member of the Company (to present)
2004 Board Member of Genentech, USA (to present)
2005 Chief Executive Officer Division Roche Pharmaceuticals
2010 Board Member of ROCHE HOLDING LTD (to present)

Daniel O'Day

1987 Entered Roche Pharma USA
1995 Director Human Resources, Roche Pharma USA
1996 Director Product Marketing, Roche Pharma USA
1998 Business Unit Head, Arthritis and Respiratory, Roche Pharma Headquarters
1999 Lifecycle Leader Tamiflu, Roche Pharma Headquarters
2001 Head Corporate Planning, Roche Pharma Japan
2003 General Manager, Roche Pharma Denmark
2006 President & CEO of Roche Molecular Diagnostics
2010 COO Roche Diagnostics Division, Member of the Corporate Executive Committee
2012 COO Roche Pharmaceuticals Division, Member of the Corporate Executive Committee, Member of the Genentech Board of Directors (to present)
2013 Director of the Company (to present)

Sophie Kornowski-Bonnet

1985 Abbott Diagnostic Division – Paris - France
Scientific Manager
1989 Abbott Pharmaceutical Products – Chicago, USA
Marketing Research Analyst
1990 Abbott Pharmaceutical Products – New York, USA
Neuroscience Sales Representative
1991 Sanofi Winthrop – New York, USA
Director, Strategic Marketing, Diagnostic Imaging
1994 Sanofi Winthrop – Paris, France
Director, Neuroscience Business Unit
1996 Merck Sharp & Dohme Paris, France
Director, Marketing Research and Strategic Planning
1997 Merck Sharp & Dohme Israel Managing Director
2000 Vice-President Arthritis and Analgesia Franchise, Merck & Co. Inc. USA
2002 Merck Sharp & Dohme Paris, France
Director, Rheumatology Division
2006 Merck Sharp & Dohme Paris, France
Director, Cardiovascular Division
2007 Roche Pharma, France
General Manager
2012 Head of Roche Partnering and Member of the Roche Enlarged Corporate Executive Committee (to present)
Director of the Company (to present)

Executive Officers

(As of April 1, 2013)

Executive Committee Members

Members of the Executive Committee
From left (front) Motoo Ueno, Osamu Nagayama, Tatsuro Kosaka
(back) Kotaro Miwa, Fumihiko Kamoshida, Shin-ya Unno, Shunji Yokoyama, Naotaka Nakamura, Tatsumi Yamazaki, Yoshio Itaya, Yutaka Tanaka,

Osamu Nagayama
Representive Director, Chairman
CEO

Motoo Ueno
Representive Director, Deputy Chairman
Corporate Social Responsibility, Audit

Tatsuro Kosaka
Representive Director, President
COO

Tatsumi Yamazaki
Director, Deputy President

Yoshio Itaya
Director, Executive Vice President
CFO, General Manager of Finance Supervisory Div. and
General Manager of Finance & Accounting Dept.

Naotaka Nakamura
Executive Vice President

Yutaka Tanaka
Senior Vice President
Head of Project & Lifecycle Management Unit

Shunji Yokoyama
Senior Vice President
Head of Regulatory & Quality Management Unit

Masaaki Tohaya
Senior Vice President
General Manager of Marketing & Sales Div.

Masaaki Tohaya, Hitoshi Kuboniwa, Mitsuru Kikuchi, Kunitoshi Watanabe

Shin-ya Unno
Senior Vice President
General Manager of Corporate Planning Dept.

Mitsuru Kikuchi
Senior Vice President
General Manager of External Affairs Dept.

Fumihiko Kamoshida
Senior Vice President
General Manager of Legal Dept.

Hitoshi Kuboniwa
Vice President
General Manager of Pharmaceutical Technology Div.

Executive Officers
(Non-Executive Committee Members)

Toshihiko Komori
Vice President
Deputy Head of Project & Lifecycle Management Unit and
Department Manager of R&D Portfolio Management Dept.
(Business Assessment, Regulatory Affairs, Intellectual Property,
Overseas Development)

Hisafumi Okabe
Vice President
General Manager of Research Div.

Minoru Machida
Vice President
Deputy General Manager of Pharmaceutical Technology Div.

Yasushi Ito
Vice President
General Manager of Clinical Development Div.

Shin-ichi Nihira
Vice President
General Manager of Medical Affairs Div.

Toshitaka Uto
Vice President
Head of Primary Unit

Susumu Kato
Vice President
Supervisory Branch Manager of Tokyo Branch 1

Keiji Kono
Vice President
General Manager of IT Supervisory Div.

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

Toshihiko Tsuchiya
Vice President
General Manager of General Affairs Dept. and
General Manager of Secretarial Dept.

Visualizing Our Potential

Understanding trends in the pharmaceutical industry and medical care is important when exploring Chugai's potential. This section presents details on Chugai's pharmaceutical products, including an overview of Chugai's development pipeline and basic information, as well as information on the newest treatments and other topics.

Development Pipeline 92

Basic Information 94


Potential
Potential
Potential
Potential
生物 劇 ミルセラ® 注シリンジ 100μg
生物 劇 ヒト化抗ヒトIL-6レセプ
アクテムラ®
成分：1バイアル(20mL)中
注意－医師等の処方せんにより使用
400mg/20mL
中外製薬株式会社

Development Pipeline (As of January 30, 2013)

Development Code (*Additional Indication)	Indication	Status: Phase I	Phase II	Phase III	Filed	Approved
Oncology						
RG1273	Breast cancer					
	Breast cancer (adjuvant)			(Multinational study)		
RG1415*	Non-small cell lung cancer (1st line)					
RG435*	Recurrent glioblastoma					
	Ovarian cancer					
	Glioblastoma			(Multinational study)		
	Breast cancer (adjuvant)			(Multinational study)		
RG3502	Breast cancer					
	Gastric cancer			(II / III) (Multinational study)		
RG3638	Non-small cell lung cancer			(Multinational study)		
GA101 (RG7159)	Indolent non-Hodgkin's lymphoma			(Multinational study)		
	Aggressive non-Hodgkin's lymphoma			(Multinational study)		
GC33 (RG7686)	Liver cancer			(Multinational study)		
RG340*	Gastric cancer (adjuvant)					
AF802 (RG7853)	Non-small cell lung cancer			(I / II)		
				(I / II) (Overseas)		
RG7204	Melanoma		(I / II)			
WT4869	Myelodysplastic syndromes		(I / II)			
	Solid tumors					
WT2725	Advanced cancer		(Overseas)			
CIF (RG7167)	Solid tumors					
			(Overseas)			
CKI27 (RG7304)	Solid tumors					
			(Overseas)			
PA799	Solid tumors		(Overseas)			
Bone and Joint Diseases						
RG484	Osteoporosis					
NRD101*	Enthesopathy (Lateral epicondylitis, Patellar tendinitis, Achilles tendinopathy, Plantar fasciitis)					
Autoimmune Diseases						
MRA*	Rheumatoid arthritis (new formulation: subcutaneous injection)					
						(Overseas)
SA237	Rheumatoid arthritis					
RG7415	Systemic lupus erythematosus (SLE)					
Central Nervous System						
RG1678	Schizophrenia			(Multinational study)		
RG7090	Major depressive disorder			(Multinational study)		
RG1450	Alzheimer's disease					
Other Diseases						
CSG452	Type 2 diabetes					
RG3637	Asthma		(Overseas)			
CIM331	Atopic dermatitis					
ACE910	Hemophilia A					
RG7652	Hyperlipidemia		(Overseas)			

Designates change in status in 2012 and thereafter

Generic Name / Product Name	Origin (Collaborator)	Mode of Action
pertuzumab / Product name undetermined (Overseas name: Perjeta)	Roche	HER dimerization inhibitory humanized monoclonal antibody (Injection)
erlotinib HCl / Tarceva (Overseas name: Tarceva)	Roche / OSI	EGFR tyrosine kinase inhibitor (Oral)
bevacizumab / Avastin (Overseas name: Avastin)	Roche	Anti-VEGF (Vascular Endothelial Growth Factor) humanized monoclonal antibody (Injection)
trastuzumab emtansine / Product name undetermined	Roche	Anti-HER2 antibody-drug conjugate (T-DM1) (Injection)
onartuzumab / Product name undetermined	Roche	Humanized anti-Met monoclonal antibody (Injection)
obinutuzumab / Product name undetermined	Roche (Nippon Shinyaku)	Glycoengineered type II anti-CD20 monoclonal antibody (Injection)
—	In-house (Roche)	Humanized anti-Glypican-3 monoclonal antibody (Injection)
capecitabine / Xeloda (Overseas name: Xeloda)	Roche (Yakult Honsha)	Antimetabolite, 5-FU derivative (Oral)
—	In-house (Roche)	ALK inhibitor (Oral)
vemurafenib / Product name undetermined (Overseas name: Zelboraf)	Roche	BRAF inhibitor (Oral)
—	In-house / Dainippon Sumitomo Pharma	WT1 peptide cancer vaccine (Injection)
—	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	PI3K class I inhibitor (Oral)
ibandronate sodium hydrate / Product name undetermined (Overseas name: Boniva (US), Bonviva (EU))	Roche (Taisho Pharmaceutical)	Bisphosphonate (Injection) Bisphosphonate (Oral)
sodium hyaluronate / Suvenyl	In-house	Sodium hyaluronate (Injection)
tocilizumab / Actemra (Overseas name: Actemra (US), RoActemra (EU))	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody (Injection)
—	In-house	Humanized anti-human IL-6 receptor monoclonal antibody (Injection)
rontalizumab / Product name undetermined	Roche	Humanized anti-interferon alpha monoclonal antibody (Injection)
bitopertin / Product name undetermined	Roche	Glycine reuptake inhibitor (Oral)
—	Roche	mGluR5 antagonist (Oral)
gantenerumab / Product name undetermined	Roche / MorphoSys	Human anti-amyloid-beta monoclonal antibody (Injection)
tofogliflozin / Product name undetermined	In-house (Kowa, Sanofi)	SGLT2 inhibitor (Oral)
lebrikizumab / Product name undetermined	Roche	Humanized anti-IL-13 monoclonal antibody (Injection)
—	In-house	— (Injection)
—	In-house	Anti-factor IXa x anti-factor X humanized bispecific antibody (Injection)
—	Roche	Human anti-PCSK9 monoclonal antibody (Injection)

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 3 to 4 percent going forward. In the year ended March 2011, national medical expenses totaled ¥37,420.2 billion, a ¥1,413.5 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 ended March 2013, drug reimbursement prices declined by 1.26 percent overall on a medical cost basis, or 6.00 percent on a reimbursement price basis.

Impact of NHI Drug Price Revision

NHI Drug Price Reduction Rate (%)	2008	2010	2012
Industry Average	5.2	6.5	6.25
Chugai	7.2	6.8	6.0

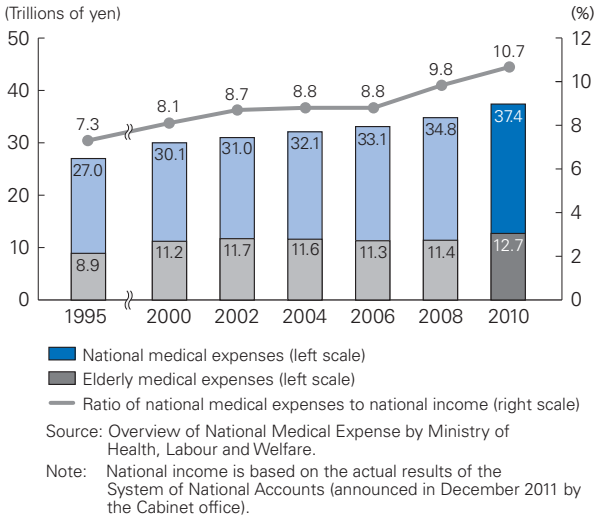
Source: Chugai data

Premium to Promote the Development of New Drugs and Eliminate Off-label Use

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 was implemented on a trial basis as part of the NHI drug price revisions for the year ended March 2011 to promote the creation of innovative medical products and solve the drug lag[1] 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, is added to the price of drugs for which no generics[2] are available (provided that they have been in the NHI price list for no more than 15 years), and which satisfy certain conditions.[3] Companies receiving the premium pricing are 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 (off-label use). In the year ended March 2013, 367 compounds and 702 products received premium pricing.

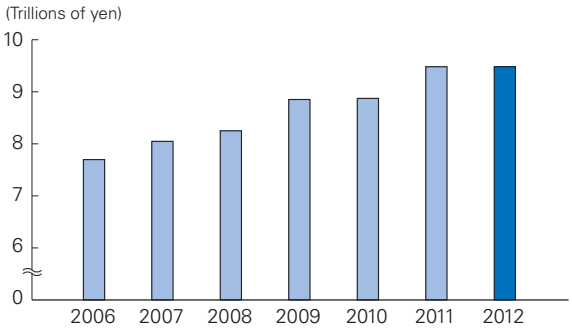
1. The inability of Japanese patients to gain access to global standard or state-of-the-art treatments because the drugs are not developed in Japan.
2. Generic drugs, which are approved after the expiry of the patents for original drugs with the same active ingredients and efficacy.
3. The percentage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

Trends in National and Elderly Medical Expenses



Source: Overview of National Medical Expense by Ministry of Health, Labour and Welfare.
Note: National income is based on the actual results of the System of National Accounts (announced in December 2011 by the Cabinet office).

Prescription Drug Market



Changes to Promote Use of Generics

The MHLW has instituted changes to prescription rules in line with an Action Program announced in October 2007 to promote the safe use of generics. Previously, physicians ticked the "Can be substituted" box on the prescription form if they determined that a generic was acceptable. However, since 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 23.3 percent as of March 2012 to 30 percent or more by the year ended March 2013.

Solving the Drug Lag Problem

In January 2005, the MHLW established the Study Group on Unapproved and Off-label Drugs of High Medical Need as one means of helping solve the drug lag problem. The study group 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.

The 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 using a dedicated staff, providing guidelines on multinational clinical studies, clarifying reviewing criteria and offering an improved consultancy function. The goal was 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) during the period from the year ended March 2010 to the year ended March 2012. The median total review time for new drugs in the year ended March 2012 was 11.5 months.

Current Situation of Requests Made by the MHLW Study Group on Unapproved and Off-label Drugs of High Medical Need (As of January 30, 2013)

Date for request	Product	Indication	Development status
First development request	Xeloda	Advanced or recurrent gastric cancer	Approved in Feb. 2011
	Tarceva	Advanced or recurrent pancreatic cancer	Approved in Jul. 2011
	Avastin	Advanced or recurrent breast cancer	Approved in Sep. 2011
	Herceptin	Q3W dosage HER2+ metastatic breast cancer	Approved in Nov. 2011
		HER2+ neoadjuvant breast cancer	
	CellCept	Child renal transplant	Approved in Sep. 2011
	Kytril	Gastrointestinal symptoms associated with radiotherapy	Approved in Dec. 2011
	Avastin	Ovarian cancer	Filed in Oct. 2012
	Pulmozyme	Improvement of pulmonary function in patients with cystic fibrosis	Approved in Jun. 2012
	Bactramin	Treatment and prevention of pneumocystis pneumonia	Approved in Aug. 2012
Second development request	Avastin	Recurrent glioblastoma	Filed in Sep. 2011
	Herceptin	Q1W dosage postoperative adjuvant breast cancer overexpressing HER2	Plan to file in Feb. 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 2011, 357,305 people died of cancer, accounting for 28.5 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.

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 medical staff such as nurses, pharmacists and nutritionists who work 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 December 2012 there were 710 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.

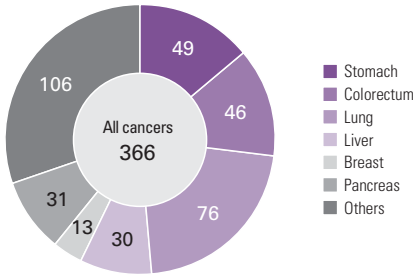
Changes in Treatment Methods

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 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

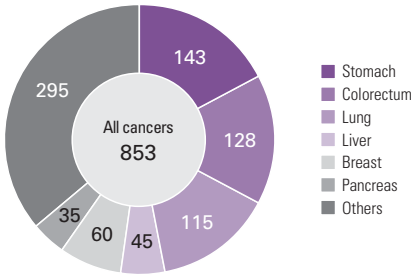
Cancer Mortality (Estimates for 2015)

(Thousands of cases)



Cancer Incidence (Estimates for 2015)

(Thousands of cases)

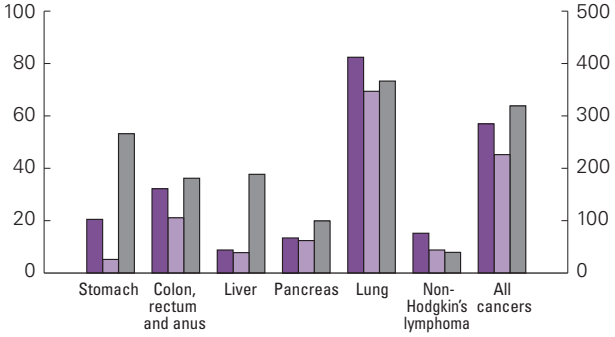


Source: Cancer White Paper-Incidence/Death/Prognosis-2012 (Shinohara Shuppan Shinsha).

International Comparison of Cancer Mortality Rates (2005)

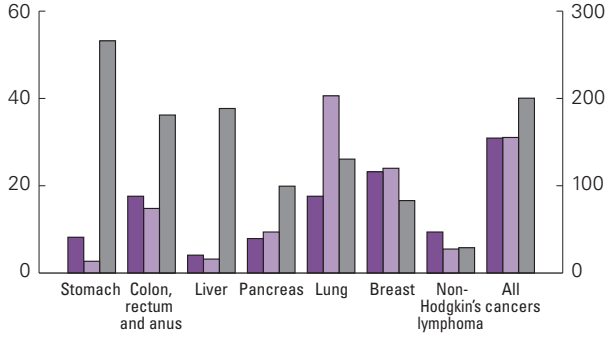
Male

Per 100,000 population
(By cancer type)



Female

Per 100,000 population
(By cancer type)



EU US Japan

Source: WHO website

drug treatment on an outpatient basis, which allows them to maintain normal lifestyles. To ensure the medical safety of chemotherapy for these patients, a multidisciplinary approach involving close collaboration between oncologists and medical staff essential.

Overview of Products and Development Projects

Avastin

The anti-VEGF (vascular endothelial growth factor) humanized monoclonal antibody Avastin is the first antiangiogenesis 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. Chugai obtained approval for the additional indications of advanced or recurrent non-squamous non-small cell lung cancer in November 2009, and inoperable or recurrent breast cancer in combination with paclitaxel in September 2011. Chugai also filed for approval of the additional indications of relapsed glioblastoma and ovarian cancer in September and October 2012, respectively.

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 for postoperative adjuvant therapy of patients with HER2-positive early breast cancer. In 2011, Herceptin obtained approval for the additional indications of HER2-positive advanced or recurrent gastric cancer and neoadjuvant chemotherapy in HER2-positive early breast cancer. As a result, Herceptin has gained approval for all stages of breast cancer that overexpresses HER2.

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.

Neutrogin

Neutrogin is a recombinant human granulocyte colony-stimulating factor (G-CSF) developed by Chugai. G-CSF is a hematopoietic factor that specifically stimulates 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 and aplastic anemia. Overseas, Neutrogin is sold under the name Granocyte.

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 inoperable 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. Xeloda has also obtained additional approval for advanced or recurrent gastric cancer not amenable to curative resection. In addition, phase II clinical trials started in Japan in July 2012 for the additional indication of postoperative adjuvant chemotherapy for gastric cancer (co-development with Yakult Honsha Co., Ltd.).

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 is used for the second-line or later treatment of non-small cell lung cancer, but in June 2012 Chugai filed for approval for use in first-line treatment. In July 2011, Tarceva obtained approval for the additional indication of pancreatic cancer not amenable to curative resection.

Kytril

Kytril is a selective inhibitor of the 5-HT3 (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 to anticancer agents.

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 aim to differentiate Femara from competitor products using the strong evidence in its favor: its usefulness as an extended adjuvant therapy (adjuvant therapy after the standard five years of endocrine therapy to prevent recurrence after surgery for breast cancer); the low risk of cancer recurrence when it is used as an initial adjuvant therapy commencing immediately after surgery; and the confirmation of its benefits compared with tamoxifen in treating advanced and recurrent breast cancer.

RG1273 (overseas product name: Perjeta)

RG1273 (pertuzumab) is a humanized monoclonal antibody licensed from Roche. This is the first in a new class of targeted agents known as HER dimerization inhibitors. Chugai filed an application for regulatory approval for the indication of HER2-positive breast cancer in May 2012. In addition, a phase III multinational study for RG1273 as a potential postoperative adjuvant chemotherapy for HER2-positive breast cancer started in April 2012.

RG3502

RG3502 (trastuzumab emtansine, T-DM1) is an antibody-drug conjugate combining the anti-HER2 monoclonal antibody trastuzumab (active ingredient of Herceptin) with the chemotherapy agent DM1. Chugai filed an application for regulatory approval for the treatment of HER2-positive breast cancer in January 2013. In addition, a phase II/III multinational study of RG3502 as a potential treatment of HER2-positive gastric cancer started in September 2012.

RG3638

RG3638 (onartuzumab), a humanized anti-Met antibody licensed from Roche, targets Met, a hepatocyte growth factor (HGF) receptor. A phase III multinational study of RG3638 as a potential treatment for non-small cell lung cancer started in November 2012. This compound can be used in combination with erlotinib hydrochloride (Tarceva), and is expected to show efficacy in patients with high Met expression, which is associated with poor outcomes using existing therapies.

GA101 (RG7159)

GA101 (obinutuzumab) is a humanized monoclonal antibody licensed from Roche. Chugai is currently participating in Roche's phase III multinational studies of GA101 as a potential treatment for aggressive non-Hodgkin's lymphoma and indolent non-Hodgkin's lymphoma. In November 2012, Chugai entered into an agreement with Nippon Shinyaku Co., Ltd. to co-develop and co-market this compound in Japan.

GC33 (RG7686)

GC33, a humanized antibody from Chugai, 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 Pte. Ltd., a joint venture in which Chugai participates. A phase II multinational study started in March 2012.

AF802

AF802 is a targeted molecular therapy from Chugai 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 are under way in Japan and overseas. Chugai has decided to license this compound to and is currently co-developing it with Roche.

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 that targets the WT1 protein, a product of Wilms' tumor gene 1. Clinical trials are under way in Japan for myelodysplastic syndromes (phase I/II) and solid tumors (phase I). WT4869 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.

WT2725

Like WT4869, WT2725 is a cancer peptide vaccine candidate that targets the WT1 protein and was discovered in joint research with Dainippon Sumitomo Pharma Co., Ltd. WT2725 has the same mechanism of action as WT4869, but is suited to different patients. Phase I clinical trials of this compound as a potential treatment for advanced cancer started overseas in August 2012.

CIF (RG7167)

CIF is a targeted small-molecule agent from Chugai. 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 Raf and MEK dual inhibitor from Chugai. 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.

PA799

PA799, a PI3K class I inhibitor, is an oral agent from Chugai that is being developed for the treatment of solid tumors. Overseas phase I clinical trials are currently under way.

RG7204 (overseas product name: Zelboraf)

RG7204 (vemurafenib), licensed from Roche, is a BRAF inhibitor for the treatment of metastatic melanoma. It is an oral small-molecule drug that selectively inhibits a mutated form of the BRAF protein that is present in about half of melanoma patients. Phase I/II clinical trials started in Japan in September 2012.

Bone and Joint Diseases/Autoimmune 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 revealing more patients.

Treatment Methods

Bone resorption inhibitors and bone formation stimulants, drugs with two different mechanisms of action, are used in the treatment of osteoporosis. In the past, active vitamin D_3 derivatives, bisphosphonates, calcitonin preparations and selective estrogen receptor modulators (SERMs), which are bone resorption inhibitors, were the primary drug treatments used. However, the use of human parathyroid hormone (PTH) therapy, which stimulates bone formation, has been increasing since it was approved in 2010.

Regulatory Trends

National guidelines for osteoporosis treatment underwent major revision in October 2006 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. Over the following five years, notable advances have been made in basic and clinical research into osteoporosis, evaluation of fracture risk and criteria for the initiation of drug treatment have been reviewed, and osteoporosis caused by lifestyle-related diseases has been addressed. In addition, Edirol and other medicines are covered by insurance. New guidelines were issued in December 2012 with revised content to accommodate these current conditions, which adds preventative and diagnostic items from the standpoint of the importance of early treatment to broaden the overall scope of osteoporosis treatment.

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 was jointly marketed by Chugai

and Eli Lilly Japan K.K. from May 2004 until the expiration of their joint marketing agreement in December 2012.

Alfarol

Alfarol, an active vitamin D_3 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

Edirol (eldecalcitol) is a vitamin D_3 preparation born out of Chugai's many years of research in vitamin D. Chugai started sales of Edirol in April 2011 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 Edirol has a similar safety profile to the existing D_3 derivatives but a statistically significant greater effect in preventing fractures. Edirol received a grade A recommendation in the treatment guidelines for vitamin D_3 preparations for the first time in December 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. In December 2011, it was announced that efficacy for osteoporosis was demonstrated in phase II/III clinical trials for the injectable formulation. Based on the results of these trials, Chugai filed an application for regulatory approval for the injectable formulation in July 2012. In addition, phase III clinical trials for the oral formulation started in Japan in October 2012.

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 suggests 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$19 billion in 2011, 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 2000-2010 period was designated as the Bone and Joint Decade, and academic societies and other players have been aggressively promoting research, diagnosis and treatment of osteoarthritis. In 2010, it was decided to extend these activities for ten more years through 2020.

Overview of Products and Development Projects

Actemra

Actemra, the first therapeutic antibody 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. In March 2012, Chugai filed an application for regulatory approval of a new subcutaneous formulation.

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, and obtained approval in October 2012 as a first-line treatment. Applications for regulatory approval of the subcutaneous formulation were filed in the United States and the European Union in December 2012.

Actemra obtained approval for the additional indication of treatment of sJIA in the United States in April 2011 and the European Union in August 2011. In Asia, where Chugai has local sales branches, Actemra obtained approval in Taiwan in July 2011 and in South Korea in April 2012.

The requirement for post-marketing all-case registration surveillance as a condition of Actemra's approval in Japan was lifted in August 2010 for RA and pJIA, and is expected to be lifted in 2012 for Castleman's disease. All-case registration surveillance for sJIA is ongoing, and patient registration continues.

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. Phase III clinical trials are currently underway in Japan for the additional indication of enthesopathy.

SA237

SA237, a compound from Chugai, is a next-generation therapeutic antibody 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 (recycling 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 antihuman 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 is currently under way in Japan.

Systemic Lupus Erythematosus

Systemic lupus erythematosus (SLE), a connective tissue disease, is an autoimmune disorder in which the immune system turns on the body due to an immune abnormality, causing various types of inflammation throughout. This intractable disease affects an estimated 20,000 to 40,000 patients in Japan, with a 9:1 female-to-male ratio. Generalized symptoms include fever and fatigue, as well as skin and joint conditions and organ damage. Steroids and immunosuppressants are used in current therapies.

RG7415

RG7415 (rontalizumab) is a humanized anti-interferon alpha monoclonal antibody licensed from Roche. It binds to and neutralizes all 12 human interferon alpha subtypes, and thus is expected to inhibit the processes that cause chronic inflammation. Phase I clinical trials of RG7415 as a potential treatment for SLE started in July 2012.

Renal Diseases

Renal Anemia

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 the 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 2 to 3 percent annually, reaching approximately 305,000 people as of December 2011, 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, 2010 and 2012.

Overview of Products and Development Projects

Mircera

Mircera is a new anemia treatment with a very long plasma half-life, enabling stable and sustained control of hemoglobin. It stimulates erythropoiesis by a different interaction with the erythropoietin receptor on progenitor cells in the bone marrow. Mircera was launched in Japan in July 2011 as a treatment for anemia. Outside Japan, Mircera obtained approval in the European Union in 2007 and is currently sold in more than 100 countries.

The plasma half-life of Mircera 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 is expected to contribute to better treatment adherence. Furthermore, as a dialysis-related treatment, Mircera 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.

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.

Oxarol

Synthesized by Chugai, Oxarol is the first intravenous active vitamin D_3 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_3 derivatives were insufficient.

Renagel

Renagel is used to treat hyperphosphatemia. Because depressed renal functions impair the ability of dialysis patients to excrete phosphorous, phosphorous intake is controlled by phosphorous-eliminating dialysis and strictly controlled diets. However, these methods are not 100 percent effective in correcting oversupplies of phosphorus, so a phosphate binder is required to eliminate the excess phosphorus. 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_3 derivatives, in particular Oxarol, an agent for the treatment of secondary hyperparathyroidism.

Others (Central Nervous System/Other Diseases)

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 2 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, its limited efficacy 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[1] has increased the treatment options available for patients with hepatitis C. Moreover, the approval in 2012 of a protease inhibitor that suppresses the growth of HCV now makes triple combination therapy with peginterferon and ribavirin possible.

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.

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[2] administration, with fewer adverse reactions than conventional 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. In 2011, Pegasys obtained approval for the additional indications of compensated liver cirrhosis caused by hepatitis C (in combination with Copegus) in July and chronic active hepatitis B (as a monotherapy) in September.

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[3] 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.

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 therapeutic antibody 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 2009 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 22.65 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 Project

CSG452

A compound from Chugai, CSG452 (tofogliflozin) is an oral hypoglycemic agent that is expected to be effective in the treatment of type 2 diabetes. 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 2010. In October 2012, Chugai entered into license agreements with Kowa Company, Ltd. and Sanofi K.K. for the co-development of this compound in Japan and for regulatory filing and marketing of the product.

Schizophrenia

It is estimated that about 1 percent of the population suffers from schizophrenia, a disease characterized by persistent disturbances of thought, communication, perceptions, emotions and behavior. Patients become detached from reality and may experience delusions, hallucinations or uncontrollable thoughts.

Overview of Development Project

RG1678

RG1678 (bitopertin), a small-molecule compound licensed from Roche, is expected to be effective in treating schizophrenia. Chugai joined Roche's phase III multinational study in 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. While existing AD treatments have some effect in slowing disease progression by several months, they are unable to stop the neuron death, and thus do not treat the underlying cause. Consequently, the level of satisfaction with these treatments is low, and there is strong demand for a more effective drug.

Overview of Development Project

RG1450

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

Depression

Depression is a condition associated with brain dysfunction. It is classified by type, including exogenous, psychogenic, endogenous, reactive or situational, depending on the cause. Severe depression is called major depressive disorder. For treatment of depression, if the cause of the depressive state is clear, removal of the cause may be considered. However, if the cause is undetermined, or the depressive state is severe, drug therapy with an antidepressant is carried out. The number of patients in Japan with mood disorders including depression was estimated at 1.04 million in 2008, and has been trending upward year by year.

Overview of Development Project

RG7090

RG7090 is an oral mGluR5 antagonist licensed from Roche. Since September 2012, Chugai has been participating in Roche's phase II multinational study for the treatment of major depressive disorder.

Asthma

Asthma is a disease in which the sensitive airways become inflamed and narrow, hindering the passage of air and causing attacks of breathing difficulty. It is accompanied by symptoms such as coughing, mucus production, wheezing and shortness of breath. In Japan, asthma affects an estimated 4 million people, and about 10 percent of patients have symptoms that are not adequately controlled with existing treatments.

Overview of Development Project

RG3637

Licensed from Roche, RG3637 (lebrikizumab) is a humanized anti-IL-13 antibody under development for the treatment of asthma. It is expected to improve asthma symptoms and prevent asthma attacks in patients with moderate to severe asthma who are unable to adequately control their symptoms with existing treatments. This agent has demonstrated particular efficacy in patients with high serum periostin[4] levels. Overseas phase I clinical trials started in August 2011.

4. An extracellular matrix protein induced by IL-13, periostin is thought to be involved in fibrosis of the airways of asthma patients.

Atopic Dermatitis

A type of allergic disorder, atopic dermatitis is a skin disease characterized by a chronic itchy rash. The basic treatment method is drug therapy using topical steroid preparations and/or topical immunosuppressants to control the inflammation and a skin care regimen to prevent the inflammation from recurring.

Overview of Development Project

CIM331

CIM331 is an injectable formulation originating from Chugai that is being developed as a potential treatment for atopic dermatitis. Phase I clinical trials started in Japan in September 2011.

Hemophilia

Hemophilia is a disease that leads to bleeding in the joints, muscles and other areas in the body due to a congenital deficiency or abnormal function of blood coagulation factors. A low level or absence of blood coagulation factor VIII is known as hemophilia A, while a low level or absence of blood coagulation factor IX is referred to as hemophilia B. Treatment is centered on replacement therapy to supplement factor VIII or IX. However, patients must be watched for the development of autoantibodies, called inhibitors, to the supplemented factor. Patients with inhibitors are treated by other means, such as bypass therapy or immune tolerance therapy.

Overview of Development Project

ACE910

ACE910 is a promising bispecific antibody to factor IXa and factor X that employs Chugai's innovative antibody engineering technologies. Factor VIII promotes blood clotting by simultaneously binding to factor IXa and factor X. The bispecific antibody generated by Chugai mimics the function of factor VIII by simultaneously binding to factor IXa and factor X, and thus can stimulate blood clotting in patients lacking factor VIII, even if an inhibitor is present. ACE910 is expected to prevent bleeding with once-weekly subcutaneous injections, regardless of the presence of inhibitors. Phase I clinical trials started in Japan in August 2012.

Hyperlipidemia

Hyperlipidemia is a type of lifestyle disease characterized by abnormally high levels of lipids (fat) such as cholesterol and triglycerides in the blood. Increased blood lipids can cause atherosclerosis, and can also lead to myocardial infarction and cerebral infarction. Because hyperlipemia has no subjective symptoms, the number of patients in Japan, including potential patients, is estimated at about 22 million.

Overview of Development Project

RG7652

RG7652 is a human anti-PCSK9 monoclonal antibody licensed from Roche. It lowers LDL cholesterol by inhibiting the action of PCSK9, which promotes LDL receptor degradation. Phase I clinical trials for the treatment of hyperlipidemia started overseas in October 2012.

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Message from the CFO

ACCEL 15 will accelerate all of Chugai's activities. In addition, cash flow management will promote aggressive investment for future growth and enhance shareholder returns.

Yoshio Itaya
Director, Executive Vice President & CFO

The aim of our new mid-term business plan, ACCEL 15, is to evolve and link Chugai's unique strengths and deploy its formidable advantages to rapidly achieve the goal of becoming a top pharmaceutical company in Japan.

Chugai's efforts to date have strengthened various functions, including research, development, manufacturing and marketing, and built a foundation for further growth. The same is true of its finances. With an efficient business model concentrated on its core pharmaceutical business and the ongoing implementation of cost reductions, Chugai has established a robust structure capable of maintaining a high ratio of operating income to revenues. In addition, with the voluntary application of International Financial Reporting Standards (IFRS) from 2013, the application of income smoothing when conducting strategic investment will set up a foundation that promotes investment for future growth.

Another feature of Chugai's current finances is ample net cash. With net cash of approximately ¥200 billion, or about half of revenues, and the prospect of generating net cash of ¥20 to ¥30 billion annually, management of cash flow for future growth has become an important issue.

With this in mind, ACCEL 15 is intended to build a more efficient and flexible cost structure while deploying a cash flow strategy of aggressive investment to explore future business opportunities and continuous, appropriate shareholder returns.

The keys for our investment policy are "Diversified investment" and "Focusing on areas where we can expand our strength." Our targets range from in-licensing and expanding our fields and sales channels for products to dealing with the coming expiration of patents on our existing products, incorporating research results from external sources, and exploring business opportunities in cutting-edge medical treatment and other areas. While appropriate analysis and evaluation of such new business opportunities are essential, we will tackle these issues with the sense that we urgently need to lay the groundwork for future growth.

As for shareholder returns, while maintaining our policy of providing stable dividends, we will raise our core earnings per share (EPS)-based payout ratio to approximately 50 percent on average from our previous target of 40 percent or more on average on a consolidated basis.

Merely increasing speed will not widen the gap between us and our competitors sufficiently to establish a solid lead. Accelerating all of our activities, as the title of our mid-term business plan states, is essential.

11-Year Financial Summary

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

	2012/12	2011/12	2010/12	2009/12
Revenues	391,220	373,517	379,510	428,947
Sales	375,234	363,622	375,560	419,106
Other operating revenues	15,986	9,895	3,950	9,841
Cost of sales	167,727	157,507	162,418	192,851
(Percentage of revenues)	42.9%	42.2%	42.8%	45.0%
Selling, general and administrative expenses	91,973	97,723	96,151	98,168
(Percentage of revenues)	23.5%	26.2%	25.3%	22.9%
Research and development expenses	55,107	55,857	54,703	55,315
(Percentage of revenues)	14.1%	15.0%	14.4%	12.9%
Operating income	76,413	62,430	66,238	82,613
(Percentage of revenues)	19.5%	16.7%	17.5%	19.3%
Net income (loss)	48,206	35,235	41,433	56,634
(Percentage of revenues)	12.3%	9.4%	10.9%	13.2%
Total assets	587,720	533,483	508,016	540,549
Property, plant and equipment, net	82,272	82,936	87,954	93,663
Interest-bearing debt	158	154	150	154
Total net assets[2]	490,075	459,073	449,395	434,687
Return on equity[3]	10.2%	7.8%	9.4%	13.7%
Return on assets[4]	8.6%	6.8%	7.9%	11.1%
Net income per share (basic) (Yen)	88.58	64.75	76.14	104.00
Net income per share (diluted) (Yen)	88.54	64.72	76.12	103.98
Net assets per share (Yen)	896.02	839.50	821.87	794.51
Cash dividends per share[5] (Yen)	40.00	40.00	40.00	40.00
Payout ratio	45.2%	61.8%	52.5%	38.5%
Shareholders' equity to total assets	83.0%	85.6%	88.0%	80.0%
Capital investments	14,172	11,927	12,662	14,630
Depreciation and amortization	15,330	15,900	17,983	19,506
Number of employees	6,836	6,779	6,709	6,485

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)

2008/12	2007/12	2006/12	2005/12	2004/12	2003/12[1]	2003/3
326,938	344,808	326,109	327,155	294,671	232,748	237,391
321,836	332,943	—	—	—	—	—
5,102	11,865	—	—	—	—	—
127,029	137,293	133,086	119,423	111,108	83,541	79,385
38.9%	39.8%	40.8%	36.5%	37.7%	35.9%	33.4%
95,121	86,569	80,067	78,505	83,900	62,963	79,178
29.1%	25.1%	24.6%	24.0%	28.5%	27.1%	33.4%
53,225	54,243	54,609	50,058	48,166	43,525	48,511
16.3%	15.7%	16.7%	15.3%	16.3%	18.7%	20.4%
51,563	66,703	58,347	79,169	51,497	42,719	30,317
15.8%	19.3%	17.9%	24.2%	17.5%	18.4%	12.8%
39,265	40,061	38,418	53,632	34,117	28,446	(20,135)
12.0%	11.6%	11.8%	16.4%	11.6%	12.2%	—
478,518	458,942	462,124	456,442	411,449	405,197	425,301
98,346	92,495	85,150	79,460	90,051	91,970	93,969
305	775	1,300	2,549	6,167	10,761	12,108
397,067	385,798	391,604	368,306	320,847	296,717	277,254
10.1%	10.4%	10.1%	15.6%	11.0%	9.9%	—
8.4%	17.4%	8.4%	12.4%	8.4%	6.9%	—
72.07	73.23	69.35	97.00	62.27	51.73	(51.75)
72.04	73.16	69.26	96.33	61.34	50.94	—
725.18	703.80	703.08	665.29	583.61	542.96	503.41
34.00	30.00	30.00	34.00	18.00	13.00	16.00
47.2%	41.0%	43.3%	35.1%	28.9%	25.1%	—
82.6%	83.5%	84.3%	80.7%	78.0%	73.2%	65.2%
26,570	19,609	16,344	16,129	9,865	11,819	17,815
20,080	14,914	13,815	16,981	14,383	10,514	14,905
6,383	6,257	5,905	5,280	5,313	5,619	5,743

Management's Discussion and Analysis

Operating Environment

In 2012, despite recovery from the impact of the Great East Japan Earthquake that occurred on March 11, 2011, the operating environment of the pharmaceutical industry remained difficult due to ongoing government policies to reduce medical costs. In addition, global conditions are changing dramatically, with factors such as the increasing complexity of research and development to treat more intractable diseases and rising pressure on prices against a backdrop of financial crises in various countries.

On the other hand, continued expansion is forecast in pharmaceutical markets that address unmet medical needs, with expectations for ongoing growth of biopharmaceuticals and oncology drugs.

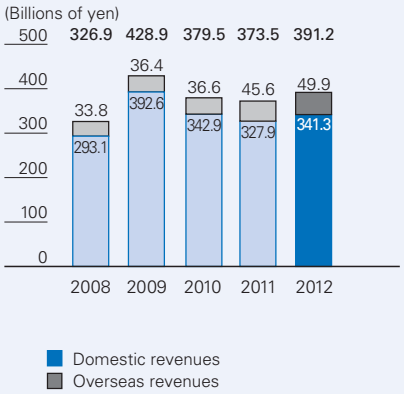
Management Policies

Based on our 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. Our fundamental management goal is to become a top Japanese pharmaceutical company by providing a continuous flow of innovative new medicines in Japan and internationally. We have been working to fulfill this mission and achieve our goal by leveraging our close relationship with Roche to in-license products from Roche's rich development pipeline, promote global development and sales and Personalized Healthcare (PHC), and undertake other activities to build systems capable of efficiently and continuously developing and marketing new drugs. We have also been working to refine our own strengths, and have achieved leading-edge drug discovery technology, represented by our next-generation antibody technologies, and captured the top share of the domestic oncology field by practicing consulting-based promotion.

Sunrise 2012, Chugai's mid-term business plan for the period from 2008 to 2012, targeted consolidated revenues of ¥460 billion and consolidated operating income of ¥80 billion for its final year. However, consolidated revenues fell short of this target by ¥68.8 million as a result of discrepancies between actual conditions and the initial assumptions used to formulate Sunrise 2012, such as the delay in approval of Actemra in the United States and restrictions on its usage at the time of launch, as well as the protracted adjustments to shipping due to the Great East Japan Earthquake. On the other hand, although operating income was ¥3.6 billion below the target due to the shortfall in revenues, the ratio of operating income to revenues was 2.1 percentage points above the Sunrise 2012 target. This was the result of the readjustment of burden-sharing with Roche at the time of National Health Insurance (NHI) drug price revisions, an improved cost-to-sales ratio because the Premium to Promote the Development of New Drugs and Eliminate Off-Label Use applies to many of our products, and ongoing efforts to increase efficiency in all divisions. In addition, compared with 2007, the year before the start of Sunrise 2012, we have substantially strengthened the foundation for growth. The number of major products with annual sales of ¥20 billion or more has increased from two to five (excluding Tamiflu, sales of which vary widely from year to year with the scale of influenza outbreaks), and the number of new active ingredients in phase III trials or later stages of development has increased from four to seven.

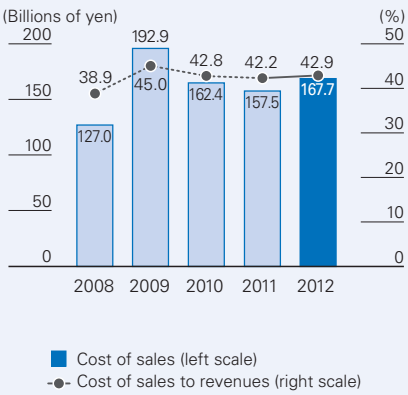
ACCEL 15, our new mid-term business plan for the period from 2013 to 2015, positions this period as a turning point for accelerating our progress toward becoming a top Japanese pharmaceutical company. To further augment the competitive advantages we have built up and to promote sustained growth in corporate

Revenues



Overseas Sales Ratio

Cost of Sales/ Cost of Sales to Revenues



value, we will deal with four reform themes: increase of marketing productivity; acceleration of global development; continuous generation of innovative projects; and further strengthening of management infrastructure.

Results

Revenues

Overview of Revenues

In 2012, revenues increased 4.7 percent compared with the previous fiscal year to ¥391.2 billion. Although the revision of NHI drug prices had an impact, sales of core products and new products increased. Excluding sales of Tamiflu, which are seasonal, and other operating revenues, product sales increased 2.3 percent to ¥363.2 billion.

Domestic Sales by Field

Domestic sales excluding Tamiflu increased 1.8 percent compared with the previous fiscal year to ¥320.9 billion. Sales in the oncology field continued to increase, rising 10.0 percent to ¥156.1 billion as we maintained the number-one share (19.4 percent)* of the domestic oncology market. The steady growth in sales of the anticancer agents Avastin, an anti-vascular endothelial growth factor (VEGF) humanized monoclonal antibody, Herceptin, an anti-HER2 humanized monoclonal antibody, and Tarceva, an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor, resulted in a double-digit increase in this field overall. Although a recalculation of market expansion for Avastin resulted in a downward NHI drug price revision of 8.8 percent, this drug maintained a high market share for treatments for colorectal cancer and showed faster penetration of the markets for lung and breast cancer due to more active promotional activities, resulting in an increase in sales.

In the bone and joint diseases field, sales increased 0.2 percent compared with the previous fiscal year to ¥66.3 billion. Edirol, a second-generation active vitamin D_3 derivative launched in April 2011, has steadily penetrated the market since the removal of long-term prescription restrictions in April 2012, and sales grew significantly. On the other hand, sales of Alfarol, a calcium/bone metabolism stimulator 1α(OH)D_3 derivative, decreased, and sales of Evista, an agent for the treatment of osteoporosis, declined as competition intensified. In addition, a recalculation of market expansion for Actemra, a humanized anti-human IL-6 receptor monoclonal antibody, resulted in a downward NHI drug price revision of 25.0 percent, but sales were flat year on year because the drug maintained strong growth in volume terms.

In the renal diseases field, sales decreased 5.1 percent compared with the previous fiscal year to ¥48.1 billion. Sales of the recombinant human erythropoietin Epogin decreased sharply due to a shift to use of Mircera, a long-acting erythropoietin-stimulating agent (ESA) launched in July 2011, and competition from other products, including follow-on biologics. At the same time, market uptake of Mircera lagged because more time is required to spread awareness of its characteristics.

In the transplant, immunology and infectious diseases field, sales (excluding Tamiflu) decreased 11.0 percent compared with the previous fiscal year to ¥20.3 billion. The decrease resulted from lower sales of peginterferon alfa-2a Pegasys and anti-viral agent Copegus due to contraction of the market for interferon treatments and the launch of competing products.

Sales of anti-influenza agent Tamiflu increased 37.9 percent compared with the previous fiscal year to ¥12.0 billion. Seasonal sales totaled ¥10.2 billion, and sales to the government for pandemic stockpiles totaled ¥1.9 billion.

* Copyright 2013 IMS Japan K.K. Source: JPM 2012.
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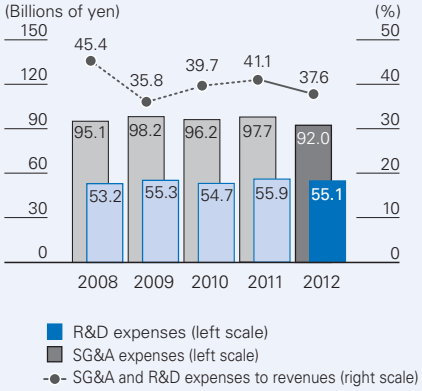
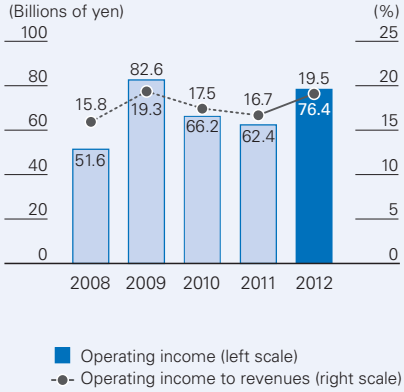
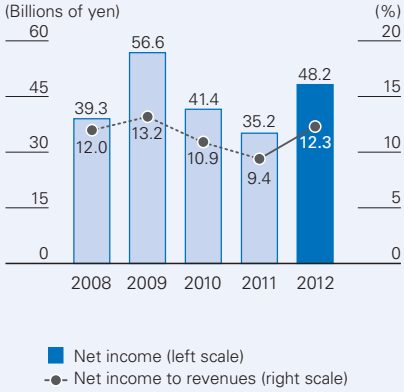
SG&A and R&D Expenses/ SG&A and R&D Expenses to Revenues



Operating Income/ Operating Income to Revenues



Net Income/ Net Income to Revenues



Overseas Sales and Other Operating Revenues

Overseas sales increased 6.8 percent compared with the previous fiscal year to ¥42.3 billion. Although the appreciation of the yen caused an overall decline in overseas sales, exports of Actemra to Roche increased substantially in terms of volume.

Other operating revenues increased 61.6 percent compared with the previous fiscal year to ¥16.0 billion, reflecting increases in lump-sum payments for out-licensing of products developed in-house, royalties on overseas sales of Actemra and profit sharing in European countries where Chugai is co-promoting Actemra with Roche.

Cost of Sales and Gross Profit

Cost of sales increased 6.5 percent compared with the previous fiscal year to ¥167.7 billion due to the increase in product sales. The cost-to-sales ratio increased 1.4 percentage points to 44.7 percent.

As a result of the above, gross profit increased 3.5 percent compared with the previous fiscal year to ¥223.5 billion.

Selling, General and Administrative Expenses and Operating Income

Selling, general and administrative (SG&A) expenses decreased 4.2 percent to ¥147.1 billion, reflecting more efficient allocation of outlays in sales activities. R&D expenses decreased 1.4 percent to ¥55.1 billion.

As a result, operating income increased 22.4 percent compared with the previous fiscal year to ¥76.4 billion, and the ratio of operating income to revenues increased 2.8 percentage points to 19.5 percent.

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

Other expenses totaled ¥1.1 billion, compared with ¥5.3 billion for the previous fiscal year. Chugai uses forward foreign exchange contracts to cover substantial foreign currency transactions, centered on imports from Roche. In 2012, gain on derivatives associated with these forward foreign exchange contracts was ¥1.3 billion, compared with loss on derivatives of ¥30 million in the previous fiscal year. Loss on foreign exchange totaled ¥3.2 billion. A loss on disaster of ¥4.7 billion in connection with the Great East Japan Earthquake, which Chugai recorded in the previous fiscal year, did not recur in 2012. Consequently, income before income taxes and minority interests increased 31.9 percent to ¥75.3 billion.

Net Income

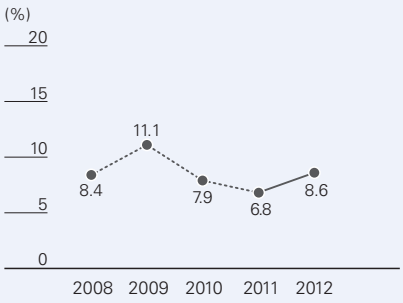
Income taxes totaled ¥26.3 billion and minority interests totaled ¥0.8 billion. As a result, net income increased 36.9 percent compared with the previous fiscal year to ¥48.2 billion.

Profitability Indicators (Consolidated Basis)

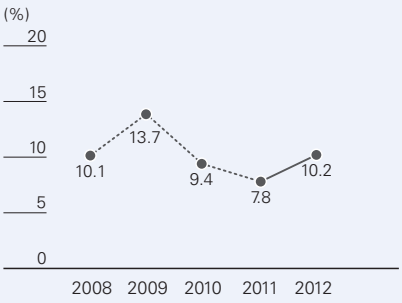
	2012	2011	2010	2009	2008
Gross profit ratio (%)	57.1	57.8	57.2	55.0	61.1
Operating income to revenues (%)	19.5	16.7	17.5	19.3	15.8
Return on assets (%)	8.6	6.8	7.9	11.1	8.4
Return on equity (%)	10.2	7.8	9.4	13.7	10.1

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

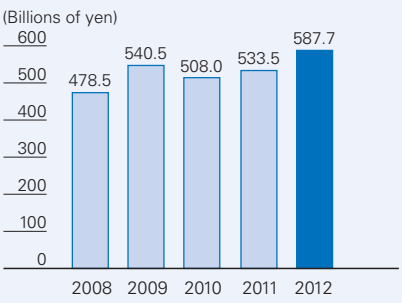
Return on Assets



Return on Equity



Total Assets



Financial Position

Assets, Liabilities and Net Assets

Assets

As of December 31, 2012, total assets were ¥587.7 billion, an increase of ¥54.2 billion, or 10.2 percent, compared with the end of the previous fiscal year. The primary reason for the increase was an increase in marketable securities including short-term investments.

Current assets increased ¥56.3 billion, or 13.4 percent, compared with the end of the previous fiscal year to ¥475.7 billion. Cash and deposits increased ¥3.7 billion, or 3.5 percent, to ¥110.9 billion. Trade notes and trade accounts receivable increased ¥9.1 billion, or 8.2 percent, to ¥120.0 billion. Trade receivables turnover decreased to 3.26 times from 3.37 times for the previous fiscal year.

Inventories increased ¥3.9 billion, or 3.7 percent, compared with the end of the previous fiscal year to ¥108.9 billion due to an increase in raw materials and supplies, despite efforts to adjust the timing of purchasing and production plans and rightsize inventory to meet demand and other conditions.

Property, plant and equipment, net decreased ¥0.6 billion, or 0.7 percent, compared with the end of the previous fiscal year to ¥82.3 billion.

Liabilities

Total liabilities as of December 31, 2012 increased ¥23.2 billion, or 31.2 percent, compared with the end of the previous fiscal year to ¥97.6 billion. This increase was primarily the result of an increase in current liabilities of ¥22.8 billion, or 33.1 percent, to ¥91.6 billion due to increases in trade notes and trade accounts receivable.

Trade notes and trade accounts payable increased ¥24.3 billion, or 139.7 percent, compared with the end of the previous fiscal year to ¥41.7 billion. Trade payables turnover decreased to 9.38 times from 21.53 times.

Income taxes payable decreased ¥2.3 billion, or 16.2 percent, compared with the end of the previous fiscal year to ¥11.9 billion.

Net Assets

As of December 31, 2012, net assets totaled ¥490.1 billion, an increase of ¥31.0 billion, or 6.8 percent, compared with the end of the previous fiscal year. This increase was primarily the result of an increase of ¥26.5 billion in retained earnings. Net unrealized holding gain on securities totaled ¥1.6 billion, while translation adjustments reduced net assets by ¥9.7 billion.

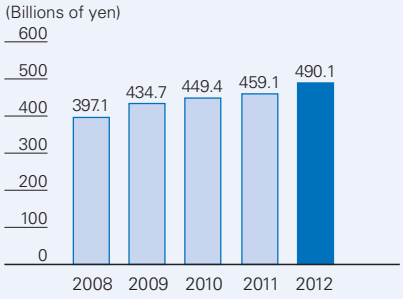
The ratio of shareholders' equity to total assets decreased 2.6 percentage points from the end of the previous fiscal year to 83.0 percent. Net working capital (current assets minus current liabilities) totaled ¥384.1 billion, and the current ratio was 519.1 percent, as Chugai maintained a sound financial position.

Stability Indicators (Consolidated Basis)

	2012	2011	2010	2009	2008
Current ratio (%)	519.1	609.4	708.2	409.3	438.5
Fixed assets ratio (%)	23.0	25.0	27.2	29.9	34.0
Interest coverage ratio (times)	21,734.9	20,032.2	8,214.4	4,620.0	517.5
Debt-to-equity ratio (%)	0.0	0.0	0.0	0.0	0.1
Shareholders' equity to total assets (%)	83.0	85.6	88.0	80.0	82.6
Market value equity ratio (%)	152.9	129.4	159.6	175.2	196.2

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

Net Assets



Shareholders' Equity to Total Assets

Total Assets Turnover

Efficiency Indicators (Consolidated Basis)

	2012	2011	2010	2009	2008
Total assets turnover (times)	0.70	0.72	0.72	0.84	0.70
Trade receivables turnover (times)	3.26	3.37	3.35	3.53	3.01
Inventories turnover (times)	3.59	3.56	3.62	4.63	4.15
Trade payables turnover (times)	9.38	21.53	19.47	12.50	11.37

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, 2012 totaled ¥95.4 billion, an increase of ¥0.9 billion from a year earlier.

Cash Flows from Operating Activities

Net cash provided by operating activities totaled ¥77.3 billion, up ¥7.7 billion from ¥69.6 billion in the previous fiscal year. Income before income taxes and minority interests of ¥75.3 billion was a primary source of cash. Depreciation and amortization totaled ¥15.3 billion. Partially offsetting these items were a ¥11.7 billion increase in working capital and income taxes paid of ¥25.5 billion. Chugai recorded payments for loss on disaster totaling ¥1.1 billion.

Cash Flows from Investing Activities

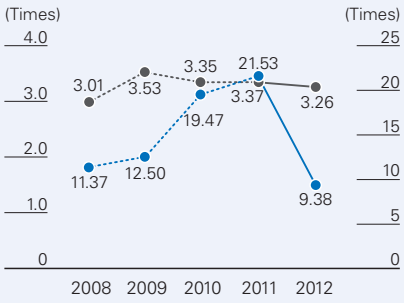
Net cash used in investing activities totaled ¥54.8 billion, an increase of ¥39.7 billion from ¥15.1 billion

Cash Flows (Consolidated Basis)

	2012	2011	2010	2009	2008
Net cash provided by operating activities	77,299	69,594	15,572	66,461	39,277
Net cash used in investing activities	(54,769)	(15,135)	(20,192)	(20,261)	(14,122)
Net cash used in financing activities	(22,720)	(24,551)	(23,055)	(22,252)	(18,361)
Effect of exchange rate changes on cash and cash equivalents	1,121	(578)	(1,660)	(128)	(9,865)
Net increase (decrease) in cash and cash equivalents	931	29,330	(29,335)	23,820	(3,071)
Cash and cash equivalents at beginning of year	94,474	65,144	94,478	70,652	73,723
Increase in cash and cash equivalents resulting from merger with unconsolidated subsidiaries	39	—	—	6	—
Cash and cash equivalents at end of year	95,445	94,474	65,144	94,478	70,652
Net cash provided by operating activities to revenues (%)	19.8	18.6	4.1	15.5	12.0
Capital investments to net cash provided by operating activities (%)	18.4	17.1	81.3	21.9	67.6
Interest-bearing debt to net cash provided by operating activities (years)	0.0	0.0	0.0	0.0	0.0

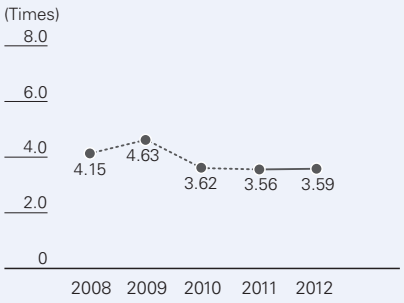
Note: Interest-bearing debt to net cash provided by operating activities = Interest-bearing debt/Net cash provided by operating activities (prior to interest and income tax deductions)

Trade Receivables Turnover/ Trade Payables Turnover

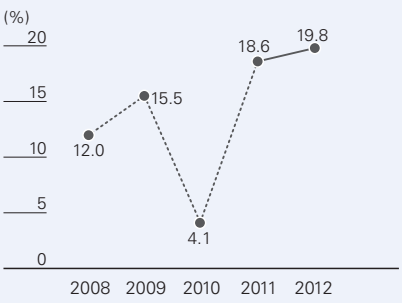


-●- Trade receivables turnover (left scale)
-●- Trade payables turnover (right scale)

Inventories Turnover



Net Cash Provided by Operating Activities to Revenues



used in the previous fiscal year. Net purchases of time deposits and purchases of marketable and investment securities used cash totaling ¥39.7 billion. Purchases of fixed assets less proceeds from sales of fixed assets used net cash totaling ¥15.1 billion.

Free Cash Flow

Free cash flow was ¥22.5 billion, a year-on-year decrease of ¥32.0 billion from ¥54.5 billion for the previous fiscal year.

Cash Flows from Financing Activities

Net cash used in financing activities totaled ¥22.7 billion, down ¥1.9 billion from the previous fiscal year. The primary factor was cash dividends paid totaling ¥21.8 billion.

Capital Investments

Capital investments increased 19.3 percent compared with the previous fiscal year to ¥14.2 billion, mainly due to investment in construction of research and other facilities at Chugai Pharmabody Research Pte. Ltd. in Singapore. In addition, depreciation and amortization decreased 3.8 percent to ¥15.3 billion.

In 2013, Chugai projects capital investments of ¥15.5 billion and depreciation of ¥13.5 billion (forecasts are based on International Financial Reporting Standards (IFRS) due to Chugai's voluntary application of IFRS from 2013).

Per Share Data

Net income per share for 2012 increased ¥23.83 compared with the previous fiscal year to ¥88.58. Net income per share on a fully diluted basis was ¥88.54. Net assets per share increased ¥56.52 compared with the previous fiscal year to ¥896.02.

Per Share Data (Consolidated Basis)

	2012	2011	2010	2009	2008
Net income per share (EPS)	88.58	64.75	76.14	104.00	72.07
Net income per share (EPS)	88.54	64.72	76.12	103.98	72.04
Net assets per share	896.02	839.50	821.87	794.51	725.18
Cash dividends per share	40.00	40.00	40.00	40.00	34.00
Payout ratio (%)	45.2	61.8	52.5	38.5	47.2

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

Outlook for 2013

To increase the comparability of its financial information on an international level for the convenience of investors in Japan and overseas, Chugai will voluntarily apply IFRS from 2013, and disclosures from the first quarter of 2013 will be based on these standards. Consequently, forecast amounts in this outlook for 2013 were calculated based on IFRS (core basis).

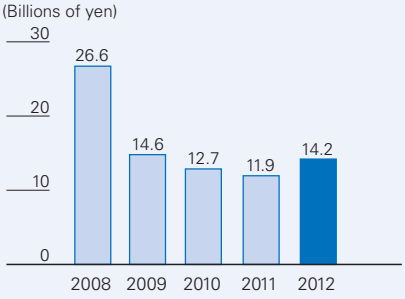
In addition, in the transition to IFRS, Chugai has changed from operating income, which was previously used as a management indicator, to core operating profit. Core operating profit, which excludes non-core items (impact of acquisition of intangible assets and business combinations, other extraordinary events, etc.) from results based on IFRS, will be used as an indicator to represent recurring profit trends.

Forecast Assumptions

For 2013, Chugai assumes exchange rates of ¥95/CHF, ¥115/EUR, and ¥88/USD, and that the scale of seasonal influenza will be about the same as the average for the past 10 years, excluding the influenza pandemic in the 2009/2010 season.

Capital Investments to Net Cash Provided by Operating Activities

Capital Investments



Net Income per Share

Results Forecast

Chugai forecasts revenues of ¥416.0 billion, an increase of 7.6 percent compared with 2012 results restated using IFRS.

Domestic sales, excluding Tamiflu, are forecast to rise steadily to ¥329.3 billion, an increase of 2.6 percent year on year. Although sales of Evista (¥16.1 billion in 2012), a treatment for post-menopausal osteoporosis, will be lost due to the expiration of a co-marketing agreement with Eli Lilly Japan K.K. on December 31, 2012, sales of Avastin and other drugs in the oncology field and sales of Edirol and Mircera will contribute to continued growth. In addition, Chugai plans to launch a number of new products and expand indications for existing products in 2013, and the contribution from these sources has been incorporated into the forecast with certain assumptions. Exports to Roche are expected to increase steadily to ¥40.6 billion, a year-on-year increase of 58.6 percent, with growth in sales of Actemra outside Japan. On the other hand, sales outside Japan of other products are forecast to decrease 6.6 percent year on year to ¥15.6 billion as sales of Neutrogin decline as a result of competition from follow-on biologics. Royalties and other operating revenues are forecast to rise 92.0 percent year on year to ¥21.7 billion because of increases in revenues from out-licensing and from Roche for co-promotion and royalties for Actemra.

As for profits, the growth in revenues is expected to increase gross profit, but budgeted costs have been increased to reflect higher expenses for activities to promote the proper use of new products and products with additional indications, progress in development themes and the commencement of activities of Chugai Pharmabody Research Pte. Ltd. in Singapore, which began operations in 2012. As a result, core operating profit is forecast to be ¥77.5 billion, an increase of 2.5 percent year on year. Core earnings per share (EPS)* is forecast to be ¥92.57, an increase of 8.1 percent year on year.

* Core EPS is net income per share attributable to shareholders of Chugai Pharmaceutical after subtraction, at Chugai Pharmaceutical's discretion, of non-recurring profit and loss items and after full dilution for latent shares.

Fundamental Profit Distribution Policy and Dividends

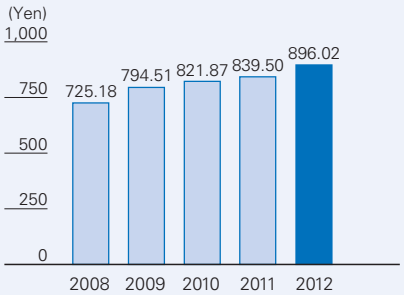
In 2013, Chugai will make the transition to disclosure under IFRS and therefore will use core earnings per share (EPS) in calculating its dividend payout ratio beginning in 2013. Chugai will increase its target consolidated payout ratio from the previous 40 percent or higher, and the policy for the distribution of profit will be as follows.

After taking strategic funding needs and the results forecast into account, Chugai aims for a consolidated payout ratio of approximately 50 percent of core EPS on average to provide for stable allocation of profit to all shareholders. Internal reserves will be used to increase corporate value through investments for further growth in existing strategic fields and to explore future business opportunities.

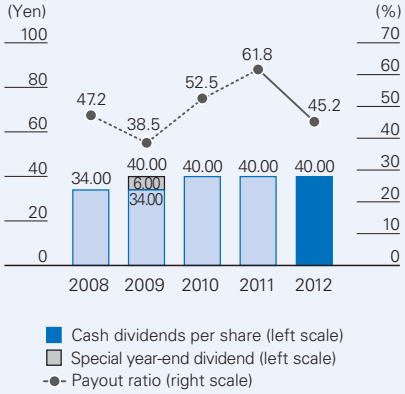
Total dividends for 2012 were ¥40.00 per share, the same as for the previous fiscal year, and the consolidated payout ratio was 45.2 percent, with an average of 47.8 percent over the past five years.

Taking into account the new dividend policy and the performance forecast for the year, Chugai forecasts total dividends for 2013 of ¥45.00 per share, including an interim dividend of ¥22.00 per share. This estimate assumes a forecast for the payout ratio of 48.6 percent of core EPS in 2013. This will bring the three-year average payout ratio to 47.8 percent, based on payout ratios for 2011 and 2012 calculated using core EPS.

Net Assets per Share



Cash Dividends per Share/ Payout Ratio



Business Risks

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 Chugai Pharmaceutical as of December 31, 2012.

New Product Research and Development

With the goal of becoming a top Japanese pharmaceutical company 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 field of oncology. 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 a major impact on Chugai's 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 Chugai faces fierce competition from pharmaceutical companies in Japan and overseas. Chugai's business performance and financial position 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 Chugai.

Side Effects

Pharmaceutical products are approved in Japan by the Ministry of Health, Labour and Welfare after stringent screening. However, because of the characteristics of these products, it is difficult to completely prevent side effects from their use even if all possible safety measures are taken. In cases where side effects occur, in particular newly discovered serious side effects, there is a risk of a major impact on Chugai's 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 NHI drug price reform. Chugai's business performance could be significantly affected by future developments in medical system reform, including NHI drug price reform.

Intellectual Property Rights

Chugai 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 a major impact on Chugai's business performance and financial position.

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 its business performance and financial position.

International Business Activities

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 have a major impact on Chugai's business performance and financial position.

Impact from Large-Scale Disasters and Other Contingencies

In the event of natural disasters such as earthquakes or typhoons, or accidents such as fires or other contingencies, damage to Chugai's business sites or sales locations, or those of its business partners, could interrupt its operations. In addition, Chugai could incur significant expenses for the repair of damaged buildings and facilities. Such circumstances could therefore have a major impact on Chugai's business performance and financial position.

Consolidated Balance Sheets

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

	Millions of yen	
Assets	2012	2011
Current assets:		
Cash and deposits (Notes 11 and 18)	¥ 110,936	¥ 107,163
Marketable securities including short-term investments (Notes 11 and 12)	100,994	60,995
Receivables (Notes 11 and 19):		
Trade notes	14	11
Trade accounts	119,982	110,902
Other	8,120	8,494
Reserve for doubtful accounts	(7)	(3)
Total	128,109	119,404
Inventories (Note 4)	108,894	104,984
Deferred tax assets (Note 8)	20,214	22,743
Other	6,549	4,141
Total current assets	475,696	419,430
Property, plant and equipment, at cost:		
Land	10,149	10,177
Buildings and structures	125,254	120,014
Machinery and equipment	132,776	126,438
Construction in progress	472	2,717
Other	192	61
	268,843	259,407
Accumulated depreciation	(186,571)	(176,471)
Property, plant and equipment, net	82,272	82,936
Intangible assets:		
Software	238	328
Other	1,464	1,633
Total intangible assets	1,702	1,961
Investments and other assets:		
Investment securities (Notes 11 and 12)	6,142	6,370
Investments in unconsolidated subsidiaries and affiliates	61	61
Long-term loans	129	7
Lease deposits	4,386	4,323
Deferred tax assets (Note 8)	12,822	14,034
Other	4,510	4,361
Total investments and other assets	28,050	29,156
Total assets	¥ 587,720	¥ 533,483

See accompanying notes to consolidated financial statements.

Liabilities and net assets	Millions of yen 2012	2011
Current liabilities:		
Payables (Notes 11 and 19):		
Trade notes	¥ —	¥ 1
Trade accounts	41,725	17,350
Construction	4,753	7,442
Other	267	445
Total	46,745	25,238
Income taxes payable (Note 8)	11,853	14,156
Accrued liabilities	28,958	26,316
Other	4,077	3,112
Total current liabilities	91,633	68,822
Long-term liabilities:		
Reserve for employees' retirement benefits (Note 9)	3,048	2,599
Reserve for directors and corporate auditors' retirement benefits	649	729
Other	2,315	2,260
Total long-term liabilities	6,012	5,588
Contingent liabilities (Note 15)		
Net assets (Notes 6,16 and 20):		
Shareholders' equity:		
Common stock, without par value:		
Authorized: 799,805,050 shares		
Issued:		
December 31, 2012 and 2011 – 559,685,889 shares	72,967	72,967
Capital surplus	92,815	92,815
Retained earnings	365,965	339,477
Treasury stock, at cost:		
December 31, 2012 – 15,440,438 shares	(36,133)	—
December 31, 2011 – 15,494,118 shares	—	(36,261)
Total shareholders' equity	495,614	468,998
Accumulated other comprehensive income:		
Net unrealized holding gains on securities	1,639	842
Foreign currency translation adjustments	(9,721)	(12,992)
Deferred gains or losses on hedges	120	—
Total accumulated other comprehensive income	(7,962)	(12,150)
Stock subscription rights	1,220	1,016
Minority interests in consolidated subsidiaries	1,203	1,209
Total net assets	490,075	459,073
Total liabilities and net assets	¥587,720	¥533,483

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		
	2012	2011	2010
Revenues (Note 19):			
Sales	¥375,234	¥363,622	¥375,560
Other operating revenues	15,986	9,895	3,950
	391,220	373,517	379,510
Cost of sales (Note 19)	167,727	157,507	162,418
Gross profit	223,493	216,010	217,092
Selling, general and administrative expenses	91,973	97,723	96,151
Research and development expenses (Note 19)	55,107	55,857	54,703
Operating income	76,413	62,430	66,238
Other income (expenses):			
Interest and dividend income	480	501	450
Interest expense	(5)	(4)	(4)
Other (Note 7)	(1,566)	(5,796)	(998)
	(1,091)	(5,299)	(552)
Income before income taxes and minority interests	75,322	57,131	65,686
Income taxes (Note 8)	(26,330)	(20,856)	(23,096)
Income before minority interests	48,992	36,275	42,590
Minority interests	(786)	(1,040)	(1,157)
Net income	¥ 48,206	¥ 35,235	¥ 41,433

Per share information (Note 21)

	Yen		
	2012	2011	2010
Basic net income per share	¥88.58	¥64.75	¥76.14
Diluted net income per share	88.54	64.73	76.12
Cash dividends per share	40.00	40.00	40.00

See accompanying notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income

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

	Millions of yen		
	2012	2011	2010
Income before minority interests	¥48,992	¥36,275	—
Other comprehensive income:			
Unrealized gains (losses) on securities	797	(499)	—
Deferred gains (losses) on hedges	120	—	—
Foreign currency translation adjustments	3,409	(1,809)	—
Total other comprehensive income	4,326	(2,308)	—
Comprehensive income	¥53,318	¥33,967	—
Comprehensive income attributable to:			
Owners of the parent	52,394	32,996	—
Minority interests	924	971	—

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, 2012, 2011 and 2010

	Thousands	Millions of yen											
		Shareholders' equity (Note 6)					Accumulated other comprehensive income						
	Number of shares issued (Note 16)	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gain on securities	Deferred gains or losses on hedges	Foreign currency translation adjustments	Total accumulated other comprehensive income	Stock subscription rights	Minority interests in consolidated subsidiaries	Total net assets
Balance at January 1, 2010	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)
Disposal 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)
Balance at December 31, 2010	559,686	72,967	92,815	327,642	(36,256)	457,168	1,341		(11,252)	(9,911)	775	1,363	449,395
Purchases of treasury stock					(5)	(5)							(5)
Net income				35,235		35,235							35,235
Cash dividends paid				(23,400)		(23,400)							(23,400)
Net changes in items other than shareholders' equity							(499)		(1,740)	(2,239)	241	(154)	(2,152)
Balance at December 31, 2011	559,686	72,967	92,815	339,477	(36,261)	468,998	842		(12,992)	(12,150)	1,016	1,209	459,073
Purchases of treasury stock					(5)	(5)							(5)
Disposal of treasury stock				(51)	133	82							82
Net income				48,206		48,206							48,206
Cash dividends paid				(21,768)		(21,768)							(21,768)
Change of scope of consolidation				101		101							101
Net changes in items other than shareholders' equity							797	¥120	3,271	4,188	204	(6)	4,386
Balance at December 31, 2012	559,686	¥72,967	¥92,815	¥365,965	¥(36,133)	¥495,614	¥1,639	¥120	¥ (9,721)	¥ (7,962)	¥1,220	¥1,203	¥490,075

See accompanying notes to consolidated financial statements.

Consolidated Statements of Cash Flows

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

	Millions of yen		
	2012	2011	2010
Cash flows from operating activities			
Income before income taxes and minority interests	¥ 75,322	¥ 57,131	¥ 65,686
Adjustments to reconcile income before income taxes and minority interests to net cash provided by operating activities:			
Depreciation and amortization	15,330	15,900	17,983
Loss on impairment of fixed assets	117	145	41
Increase (decrease) in reserve for employees' retirement benefits	439	245	(107)
Interest and dividend income	(480)	(501)	(450)
Interest expense	5	4	4
Loss on disposal of fixed assets	257	659	210
(Gain) loss on sales of fixed assets	(1)	8	(18)
(Gain) loss on sales and revaluation of investment securities	4	217	(91)
Loss on disaster	—	4,723	—
(Increase) decrease in receivables – trade notes and trade accounts	(8,886)	2,357	7,896
(Increase) decrease in inventories	(3,675)	(1,877)	(12,716)
Increase (decrease) in payables – trade notes and trade accounts	24,265	(1,949)	(14,676)
Increase (decrease) in accrued consumption taxes	1,432	1,926	(3,803)
Others	(624)	2,340	(5,947)
Subtotal	103,505	81,328	54,012
Interest and dividends received	441	500	432
Interest paid	(5)	(4)	(7)
Proceeds from insurance income	—	2,966	—
Payments for loss on disaster	(1,140)	(3,384)	—
Income taxes paid	(25,501)	(11,812)	(38,865)
Net cash provided by operating activities	77,300	69,594	15,572
Cash flows from investing activities			
Purchases of time deposits	(27,502)	(22,393)	(23,363)
Proceeds from withdrawal of time deposits	26,485	19,769	22,512
Purchases of marketable securities	(169,991)	(119,989)	(125,384)
Proceeds from sales of marketable securities	131,500	118,700	117,900
Purchases of investment securities	(159)	(6)	(5)
Proceeds from sales of investment securities	3	—	1,613
Purchases of fixed assets	(15,053)	(11,239)	(13,565)
Proceeds from sales of fixed assets	30	12	89
Other	(82)	11	11
Net cash used in investing activities	(54,769)	(15,135)	(20,192)
Cash flows from financing activities			
Net (increase) decrease in treasury stock	41	(4)	(9)
Cash dividends paid	(21,778)	(23,397)	(21,759)
Cash dividends paid to minority interests	(930)	(1,125)	(1,277)
Other	(53)	(25)	(10)
Net cash used in financing activities	(22,720)	(24,551)	(23,055)
Effect of exchange rate changes on cash and cash equivalents	1,121	(578)	(1,660)
Net increase (decrease) in cash and cash equivalents	932	29,330	(29,335)
Cash and cash equivalents at beginning of year	94,474	65,144	94,478
Increase in cash and cash equivalents resulting from merger with unconsolidated subsidiaries	39	—	—
Cash and cash equivalents at end of year (Note 18)	¥ 95,445	¥ 94,474	¥ 65,144

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries / December 31, 2012

1 Basis of Presentation of Financial Statements

The accompanying consolidated financial statements of Chugai Pharmaceutical Co., Ltd. (the "Company") and its consolidated subsidiaries (collectively, the "Group") are prepared on the basis of accounting principles generally accepted in Japan, which are different in certain respects as to the application and disclosure requirements of International Financial Reporting Standards (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.

The Company and its domestic consolidated subsidiaries maintain their books of account in accordance with accounting principles generally accepted in Japan, and its foreign consolidated subsidiaries maintain their books of account in conformity with those of their countries of domicile.

Effective the year ended December 31, 2010, the Company adopted "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements" (PITF No. 18, issued by the Accounting Standards Board of Japan (ASBJ) on May 17, 2006). In accordance with PITF No. 18, the accompanying consolidated financial statements have been prepared by using the accounts of foreign consolidated subsidiaries prepared in accordance with either IFRS or accounting principles generally accepted in the United States.

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. The number of consolidated subsidiaries was 18 as of December 31, 2012, 16 as of December 31, 2011 and 15 as of December 31, 2010.

During the fiscal year ended December 31, 2012, the Company established one new subsidiary, Chugai Pharmabody Research Pte. Ltd. (Singapore)

The closing date of all subsidiaries is the same as the Company's closing date.

Investments in subsidiaries and affiliates which are neither consolidated nor accounted for by the equity method are carried at cost and subject to write-down if there has been a permanent decline in the value of such investments.

(b) Foreign currency translation

Receivables and payables denominated in foreign currencies are translated into Japanese 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 foreign 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 foreign currency translation adjustments and minority interests in consolidated subsidiaries in net assets.

(c) Cash and cash equivalents

Cash and cash equivalents in the consolidated statements of cash flows 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 over the estimated useful lives of the respective assets. Amortization of software for internal use is calculated based on the usable period (5 years).

(f) Leases

Leased assets under finance leases are capitalized in the balance sheet except for leases for which ownership of the leased asset is not transferred to the lessee that commenced prior to January 1, 2009. Depreciation of leased assets is calculated primarily by the 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 for defined benefit schemes is based on the projected benefit obligation and the estimated fair value of 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 a 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 from 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 directors and corporate auditors 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 directors and corporate auditors' retirement benefits represents the amount payable to those directors and corporate auditors 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 assets and liabilities and are measured using the statutory tax rates which will be in effect when the differences are expected to be realized. Refer to Note 8.

(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. Derivative instruments are stated at fair value, and accounted for using deferred hedge accounting. Recognition of gains and losses resulting from changes in the fair values of derivative financial instruments are deferred until the related losses and gains on the hedged items are recognized if the derivative financial instruments are used as hedges and meet certain hedging criteria.

(l) Distribution of retained earnings

Under the Japanese Corporate Law and regulations (the "Corporate 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 16.

3 Accounting Changes

(a) Effective the fiscal year ended December 31, 2012, the Company has adopted "Accounting Standard for Earnings Per Share" (Accounting Standards Board of Japan (ASBJ) Statement No. 2, revised on June 30, 2010) and "Guidance on Accounting Standard for Earnings Per Share" (ASBJ Guidance No. 4, revised on June 30, 2010).

When calculating diluted net income per share including adjustment for latent shares for the fiscal year ended December 31, 2012, the Company has changed its method for computing the amount that is assumed to be paid to the Company due to the exercise of stock option rights, which require a specified term of service before holders can secure exercise rights, to take account of the amount for service that will be provided to the Company in the future in the fairly assessed value of the stock options.

(b) In view of major fluctuations in foreign exchange rates in recent years and the rise in the Company's transactions denominated in foreign currencies, the Company has made further changes in its risk management regulations regarding foreign exchange forward contracts and now reflects the effects of hedge accounting in the consolidated financial statements. To present the Company's operating results more accurately, beginning with the fiscal year ended December 31, 2012, the Company has adopted hedge accounting to a portion of foreign exchange forward contracts and adopted deferred hedge treatment. This change in accounting policy accompanies further changes in the Company's risk management regulations regarding foreign exchange forward contracts beginning with the fiscal year ended December 31, 2012, and it has no effect on previous fiscal years. As a result, for the fiscal year ended December 31, 2012, consolidated operating income was ¥345 million lower, consolidated income before income taxes and minority interests was ¥39 million lower than they would have been in the absence of this change.

(c) Accompanying revisions in the Corporation Tax Act of Japan, the Company and its consolidated subsidiaries in Japan have changed their method of accounting for depreciation of tangible fixed assets other than buildings and structures (except for building fixtures) that were purchased on or after April 1, 2012, to reflect tax act revisions. As a result, for the fiscal year ended December 31, 2012, consolidated operating income and consolidated income before income taxes and minority interests were each ¥233 million higher than they would have been in the absence of this change.

(d) The Company and its consolidated subsidiaries in Japan have adopted "Accounting Standard for Accounting Changes and Error Corrections" (ASBJ Statement No. 24,

December 4, 2009) and "Guidance on Accounting Standard for Accounting Changes and Error Corrections" (ASBJ Guidance No. 24, December 4, 2009) for accounting changes and error corrections of prior period errors which are made from the fiscal year beginning on January 1, 2012.

(e) Effective the fiscal year ended December 31, 2011, the Company has adopted "Accounting Standard for Presentation of Comprehensive Income" (ASBJ Statement No. 25, issued on June 30, 2010) and "Revised Accounting Standard for Consolidated Financial Statements" (ASBJ Statement No. 22, revised on June 30, 2010).

As a result, the Company has presented a consolidated statement of comprehensive income in the consolidated financial statements for the fiscal year ended December 31, 2011.

(f) Effective the fiscal year ended December 31, 2011, the Company and its consolidated subsidiaries in Japan have adopted "Accounting Standard for Asset Retirement Obligations" (ASBJ Statement No. 18, issued on March 31, 2008) and "Guidance on Accounting Standard for Asset Retirement Obligations" (ASBJ Guidance No. 21, issued on March 31, 2008).

As a result, operating income decreased by ¥90 million, and income before income taxes and minority interests decreased by ¥1,092 million for the fiscal year ended December 31, 2011 compared with the amounts which would have been recorded under the previous method.

(g) Effective the year ended December 31, 2011, the Company has adopted the following accounting standards. All of these accounting standards, partial amendments to existing accounting standards, and guidance were issued by the ASBJ on December 26, 2008.

- "Accounting Standard for Business Combinations" (ASBJ Statement No. 21)
- "Accounting Standard for Consolidated Financial Statements" (ASBJ Statement No. 22)
- "Partial Amendments to the Accounting Standard for Research and Development Costs" (ASBJ Statement No. 23)
- "Revised Accounting Standard for Business Divestitures" (ASBJ Statement No. 7)
- "Revised Accounting Standard for Equity Method of Accounting for Investments" (ASBJ Statement No. 16)
- "Revised Guidance on Accounting Standard for Business Combinations and Accounting Standard for Business Divestitures" (ASBJ Guidance No. 10)

As a result, the method of accounting for the assets and liabilities of consolidated subsidiaries was changed from the partial fair market value method to the full fair market value method from the fiscal year ended December 31, 2011. There was no effect from this accounting change on the consolidated financial statements for the fiscal year ended December 31, 2011.

4 Inventories

Inventories at December 31, 2012 and 2011 consisted of the following:

	Millions of yen	
December 31,	2012	2011
Finished goods and merchandise	¥ 51,775	¥ 58,983
Work in process and semi-finished goods	27,524	28,281
Raw materials and supplies	29,595	17,720
	¥108,894	¥104,984

5 Short-Term Bank Loans and Long-Term Debt

The Company had no short-term bank loans and long-term debt as of December 31, 2012 and 2011.

The Company has entered into loan commitment agreements amounting to ¥40,000 million with nine banks. There were no loan payables outstanding at December 31, 2012 and 2011 under these loan commitment agreements.

6 Net Assets

Under the Corporate Law, the entire amount paid for new shares is required to be designated as common stock. However, a company may, by a resolution of its Board of Directors, designate an amount not exceeding half of the price of the new shares as additional paid-in capital, which is included in capital surplus.

The Corporate Law requires that an amount equal to 10% of dividends must be appropriated as a legal reserve (a component of retained earnings) or as additional paid-in capital (a component of capital surplus) depending on the equity account charged upon the payment of such dividends until the total aggregate amount of legal reserve and additional paid-in capital equals 25% of the common stock.

The maximum amount that a company can distribute as dividends is calculated based on its unconsolidated financial statements in accordance with the Corporate Law.

7 Other Income (Expenses)

The components of "Other" in "Other income (expenses)" for the years ended December 31, 2012, 2011 and 2010 were as follows:

	Millions of yen		
Year ended December 31,	2012	2011	2010
Gain (loss) on foreign exchange	¥(3,197)	¥ 566	¥ 877
Gain (loss) on derivatives	1,336	(34)	(2,762)
Gain (loss) on sales of investment securities	(4)	—	93
Loss on revaluation of investment securities	—	(217)	(2)
Loss on disposal of fixed assets	(257)	(659)	(210)
Gain on sales of fixed assets	2	0	18
Loss on sales of fixed assets	(1)	(8)	(0)
Loss on impairment of fixed assets	(117)	(145)	(41)
Restructuring cost, charge and reversal	(11)	(69)	480
Loss on disaster (*)	—	(4,723)	—
Loss on adjustment for changes of Accounting Standard for Asset Retirement Obligations	—	(1,002)	—
Life insurance dividend income	342	341	—
Provision for environmental measures	—	(280)	—
Subsidies received for construction of a plant	46	—	50
Other	295	434	499
	¥(1,566)	¥(5,796)	¥ (998)

(*) The Company and its domestic subsidiaries incurred certain damage as a result of the Great East Japan Earthquake in March 2011, mainly at the Utsunomiya Plant. The expenses incurred mainly included inventory loss, write-off of damaged property, plant and equipment, restoration and demolition costs for damaged assets, and fixed cost during shutdown. The above amount represents the gross costs incurred net of insurance proceeds received.

8 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 foreign consolidated subsidiaries are based generally on the tax rates applicable in their countries of incorporation. The approximate aggregate statutory tax rate for the Company was 40.4% for the fiscal years ended December 31, 2012, 2011 and 2010.

Following the enactment on December 2, 2011 of "Act for Partial Revision of the Income Tax Act, etc. for the Purpose of Creating Taxation System Responding to Changes in Economic and Social Structures" (Act No. 114 of 2011) and "Act on Special Measures for Securing Financial Resources Necessary to Implement Measures for Reconstruction following the Great East Japan Earthquake" (Act No. 117 of 2011), the corporate tax rate will be reduced and a special recovery tax will be imposed effective from the fiscal year beginning on and after April 1, 2012.

In accordance with this reform, the effective statutory tax rates, which are used to measure deferred tax assets and deferred tax liabilities, will be reduced to 38.0% from 40.4% for temporary differences that are expected to be eliminated during the fiscal year beginning on January 1, 2013 through the fiscal year beginning on January 1, 2015, and to 35.6% for temporary differences that are expected to be eliminated in and after the fiscal year beginning on January 1, 2016.

Income taxes for the fiscal years ended December 31, 2012, 2011 and 2010 consisted of the following:

	Millions of yen		
Year ended December 31,	2012	2011	2010
Income taxes:			
Current	¥22,943	¥22,212	¥22,130
Deferred	3,387	(1,356)	966
	¥26,330	¥20,856	¥23,096

The significant components of deferred tax assets and liabilities at December 31, 2012 and 2011 were as follows:

	Millions of yen	
December 31,	2012	2011
Deferred tax assets:		
Prepaid expenses	¥ 8,385	¥ 9,173
Reserve for employees' retirement benefits	4,854	4,678
Depreciation	4,485	4,759
Supplies	4,179	4,154
Amortization of deferred charges	3,400	3,852
Reserve for bonuses to employees	2,171	2,089
Net operating loss carryforwards	1,423	1,939
Valuation loss on securities	1,273	1,274
Enterprise tax payable	1,086	1,219
Unrealized profit on inventories	900	1,171
Reserve for sales rebates	608	803
Asset retirement obligations	544	536
Reserve for directors and corporate auditors' retirement benefits	231	260
Impairment loss on fixed assets	150	170
Other	3,419	4,469
Gross deferred tax assets	37,108	40,546
Valuation allowance	(2,693)	(2,748)
Amount offset by deferred tax liabilities	(1,380)	(1,021)
Deferred tax assets, net	¥33,035	¥36,777
Deferred tax liabilities:		
Unrealized gain on securities	¥ 773	¥ 455
Deferred gain on sales of properties for tax purposes	410	422
Other	312	249
Total deferred tax liabilities	1,495	1,126
Amount offset by deferred tax assets	(1,380)	(1,021)
Deferred tax liabilities, net	¥ 115	¥ 105

A reconciliation of the statutory and effective tax rates for the fiscal years ended December 31, 2012, 2011 and 2010 is summarized as follows:

Year ended December 31,	2012	2011	2010
Statutory tax rate	40.4%	40.4%	40.4%
Permanently non-deductible expenses for tax purposes such as entertainment expenses	1.2	2.8	2.6
Permanently non-taxable income such as dividend income	(0.0)	(0.0)	(0.0)
Per capita inhabitants' taxes	0.2	0.2	0.2
Different tax rates applied to foreign subsidiaries	(0.6)	(1.0)	(1.1)
Tax credit for research and development expenses	(7.9)	(8.8)	(6.9)
Change in valuation allowance	(0.1)	1.1	0.1
Effect of revised corporate tax rate	1.7	2.6	—
Other	0.1	(0.8)	(0.1)
Effective tax rate	35.0%	36.5%	35.2%

9 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 a corporate pension fund and lump-sum retirement benefit plans. The Company's domestic consolidated subsidiaries participate in lump-sum retirement benefit plans. The Company's foreign consolidated subsidiaries participate in 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, 2012 and 2011 for the Company's and the consolidated subsidiaries' defined benefit plans:

	Millions of yen	
December 31,	2012	2011
Retirement benefit obligation	¥(69,242)	¥(67,041)
Plan assets at fair value	66,269	62,448
Funded status	(2,973)	(4,593)
Unrecognized prior service cost	(1,248)	(1,572)
Unrecognized actuarial loss	1,173	3,566
Net amount	(3,048)	(2,599)
Prepaid pension expense	—	—
Reserve for employees' retirement benefits	¥ (3,048)	¥ (2,599)

(c) Retirement benefit expenses

	Millions of yen		
Year ended December 31,	2012	2011	2010
Service cost (*)	¥ 2,792	¥ 2,686	¥ 2,684
Interest cost	1,487	1,473	1,454
Expected return on pension plan assets	(1,388)	(1,432)	(1,312)
Amortization of actuarial loss	747	578	895
Amortization of prior service cost	(324)	(349)	(380)
Contribution payments to a defined contribution pension plan	860	844	832
Additional retirement benefits paid	—	26	—
Total	¥ 4,174	¥ 3,826	¥ 4,173

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

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

Year ended December 31,	2012	2011	2010
(1) Discount rates	Principally 2.25%	Principally 2.25%	Principally 2.25%
(2) Expected rates of return on plan assets	0.8% – 2.5%	1.3% – 2.5%	0.6% – 2.5%

10 Leases

The Company holds certain machinery, equipment and software under finance leases which do not transfer ownership of the leased assets to the lessee. 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, 2012 and 2011 would have been as follows:

	Millions of yen		
December 31, 2012	Machinery and equipment	Other	Total
Acquisition costs	¥293	—	¥293
Accumulated depreciation/amortization	230	—	230
Net book value	¥ 63	—	¥ 63

	Millions of yen		
December 31, 2011	Machinery and equipment	Other	Total
Acquisition costs	¥820	¥3	¥823
Accumulated depreciation/amortization	614	3	617
Net book value	¥206	¥0	¥206

Lease payments relating to finance leases accounted for as operating leases as noted above totaled ¥131 million, ¥209 million and ¥303 million for the fiscal years ended December 31, 2012, 2011 and 2010, 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, 2012 and 2011 for finance leases accounted for as operating leases are summarized as follows:

	Millions of yen	
December 31,	2012	2011
Due within one year	¥40	¥137
Due after one year	23	69
	¥63	¥206

Future minimum lease payments subsequent to December 31, 2012 and 2011 for non-cancelable operating leases are summarized as follows:

	Millions of yen	
December 31,	2012	2011
Due within one year	¥ 3,407	¥ 3,015
Due after one year	11,330	11,729
	¥14,737	¥14,744

11 Financial Instruments

(a) Policies for financial instruments

The Group manages temporary 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. These securities are composed mainly of bonds held for the investment of cash surpluses and the stocks of other companies with which the Group has business relationships.

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

The Company 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 (counterparts). 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, consolidated subsidiaries do not utilize derivative transactions.

(3) Liquidity risk management

The Company manages liquidity risk by monitoring its cash flow forecasts 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 13 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 in those values for significant financial instruments on the consolidated balance sheet as of December 31, 2012 and 2011 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).

	Millions of yen		
December 31, 2012	Carrying value	Fair value	Difference
Cash and deposits	¥110,936	¥110,936	¥—
Receivables – trade notes and trade accounts	119,996	119,996	—
Marketable securities and investment securities	106,735	106,735	—
Total	¥337,667	¥337,667	¥—
Payables – trade notes and trade accounts	¥ 41,725	¥ 41,725	¥—
Total	¥ 41,725	¥ 41,725	¥—
Derivatives (*)	¥ 1,701	¥ 1,701	¥—
Total	¥ 1,701	¥ 1,701	¥—

	Millions of yen		
December 31, 2011	Carrying value	Fair value	Difference
Cash and deposits	¥107,163	¥107,163	¥—
Receivables – trade notes and trade accounts	110,913	110,913	—
Marketable securities and investment securities	67,114	67,114	—
Total	¥285,190	¥285,190	¥—
Payables – trade notes and trade accounts	¥ 17,351	¥ 17,351	¥—
Total	¥ 17,351	¥ 17,351	¥—
Derivatives (*)	¥ 18	¥ 18	¥—
Total	¥ 18	¥ 18	¥—

(*) 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 deposits, receivables - trade notes and trade accounts: 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 counterpart. For information on securities classified by holding purpose, please refer to Note 12 of the notes to the consolidated financial statements.

[Liabilities]

Payables – trade notes and trade accounts: 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 counterpart.

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

	Millions of yen	
December 31,	2012	2011
Unlisted securities	¥462	¥312

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			
December 31, 2012	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 deposits	¥110,936	¥ —	¥ —	¥ —
Receivables – trade notes and trade accounts	119,996	—	—	—
Marketable securities and investment securities				
Other securities with maturity dates:				
Corporate bonds	1,000	—	—	—
Other bonds	—	—	—	—
Other	95,000	—	—	—
Total	¥326,932	¥ —	¥ —	¥ —

	Millions of yen			
December 31, 2011	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 deposits	¥107,163	¥ —	¥ —	¥ —
Receivables – trade notes and trade accounts	110,913	—	—	—
Marketable securities and investment securities				
Other securities with maturity dates:				
Corporate bonds	5,000	1,500	—	—
Other bonds	5,000	—	—	—
Other	51,000	—	—	—
Total	¥279,076	¥1,500	¥ —	¥ —

12 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, 2012 and 2011 are summarized by type of security as follows:

(a) Other securities with determinable market value

December 31, 2012	Millions of yen		
	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:			
Stocks	¥ 2,192	¥ 4,765	¥2,573
Bonds	—	—	—
Other	30,000	30,000	0
Subtotal	32,192	34,765	2,573
Securities whose carrying value does not exceed their acquisition cost:			
Stocks	1,134	976	(158)
Bonds	5,997	5,994	(3)
Other	65,000	65,000	(0)
Subtotal	72,131	71,970	(161)
Total	¥104,323	¥106,735	¥2,412

December 31, 2011	Millions of yen		
	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:			
Stocks	¥ 1,732	¥ 3,279	¥1,547
Bonds	5,499	5,501	2
Other	31,000	31,000	0
Subtotal	38,231	39,780	1,549
Securities whose carrying value does not exceed their acquisition cost:			
Stocks	1,589	1,348	(241)
Bonds	5,997	5,986	(11)
Other	20,000	20,000	(0)
Subtotal	27,586	27,334	(252)
Total	¥65,817	¥67,114	¥1,297

(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, 2012, 2011 and 2010 are summarized as follows:

Year ended December 31,	Millions of yen		
	2012	2011	2010
Sales proceeds	¥ 3	¥ —	¥613
Aggregate gain	—	—	95
Aggregate loss	(4)	—	(3)

13 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.

Currency-related transaction

	Millions of yen		
December 31, 2012	Notional amounts	Estimated fair value	Unrealized gain (loss)
Forward foreign exchange contract:			
Buy:			
Swiss francs	¥11,898	¥655	¥655
U.S. dollars	¥ 851	¥ 26	¥ 26
Total	¥12,749	¥681	¥681

	Millions of yen		
December 31, 2011	Notional amounts	Estimated fair value	Unrealized gain (loss)
Forward foreign exchange contract:			
Buy:			
Swiss francs	¥2,493	¥(11)	¥(11)
U.S. dollars	¥5,365	¥ 29	¥ 29
Total	¥7,858	¥ 18	¥ 18

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

Currency-related transaction

	Millions of yen		
December 31, 2012	Notional amounts	Estimated fair value	Unrealized gain (loss)
Forward foreign exchange contract:			
Buy:			
Swiss francs	¥ 9,596	¥ —	¥ 858
U.S. dollars	¥ 1,827	¥ —	¥ 162
Total	¥11,423	¥ —	¥1,020

14 Segment Information

The Group is engaged principally in the manufacture and sales of pharmaceutical products in Japan and overseas.

Related segment information for the fiscal year ended December 31, 2012 and 2011 are described in (a) below, while segment information for the fiscal years ended December 31, 2012 and 2011 are described in (b).

(a) Related information for the fiscal year ended December 31, 2012

(1) Information by product and service

	Millions of yen	
Year ended December 31,	2012	2011
Revenues from external customers:		
Avastin (Sales)	¥ 65,456	¥ 56,367
Actemra (Sales)	42,689	38,041
Other	283,075	279,109
Total	¥391,220	¥373,517

(2) Information by geographical area

Revenues

Year ended December 31,	Millions of yen 2012	2011
Revenues:		
Japan	¥341,323	¥ 327,874
Europe	46,979	42,579
Other	2,918	3,064
Total	¥391,220	¥373,517

Note: Revenues are classified by country or region where customers are located.

Property, plant and equipment for the fiscal years ended December 31, 2012 and 2011

As the carrying value of the property, plant and equipment of the Group that are located in Japan accounts for more than 90% of the Group's total consolidated property, plant and equipment, disclosure of geographical segment information has been omitted.

(3) Information on principal customers

Customer name	Revenue Millions of yen 2012	2011	Relevant company segment
Alfresa Corporation	¥89,954	¥87,818	Pharmaceuticals
Mediceo Corporation	75,378	73,920	Pharmaceuticals
Suzuken Co., Ltd.	46,295	44,970	Pharmaceuticals
Toho Pharmaceutical Co., Ltd.	40,343	37,917	Pharmaceuticals

(b) Business segments for the fiscal years ended December 31, 2012 and 2011

As the Group operated solely in the pharmaceutical business segment, the disclosure of business segment information has been omitted.

15 Contingent Liabilities

The Company was contingently liable as guarantor of loan obligations for its employees of ¥216 million and ¥271 million at December 31, 2012 and 2011, respectively.

16 Supplementary Information for the Consolidated Statements of Changes in Net Assets

(a) Type and number of outstanding shares

Year ended December 31, 2012 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)	15,494,118	3,010	56,690	15,440,438
Total	15,494,118	3,010	56,690	15,440,438

(*1) Treasury stock increased by 3,010 shares due to the repurchase of fractional shares of less than one unit.
(*2) Treasury stock decreased by 56,690 shares due to the exercise of stock options resulting in a decrease of 56,500 shares and the sale of 190 fractional shares of less than one unit.

Year ended December 31, 2011 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)	15,491,466	2,834	182	15,494,118
Total	15,491,466	2,834	182	15,494,118

(*1) Treasury stock increased by 2,834 shares due to the repurchase of fractional shares of less than one unit.
(*2) Treasury stock decreased by 182 shares due to the sale of fractional shares of less than one unit.

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.

(b) Stock subscription rights

December 31, 2012 Company	Description	Millions of yen Balance at end of year
The Company	Share subscription rights as stock options	¥1,220
	Total	¥1,220

December 31, 2011 Company	Description	Millions of yen Balance at end of year
The Company	Share subscription rights as stock options	¥1,016
	Total	¥1,016

(c) Dividends

(1) Dividends paid to shareholders

Year ended December 31, 2012

Date of approval	Resolution approved by	Type of shares	Amount (Millions of yen)	Amount per share (Yen)	Shareholders' cut-off date	Effective date
March 28, 2012	Annual general meeting of shareholders	Common stock	¥10,884	¥20	December 31, 2011	March 29, 2012
July 26, 2012	Board of directors	Common stock	¥10,884	¥20	June 30, 2012	August 31, 2012

Year ended December 31, 2011

Date of approval	Resolution approved by	Type of shares	Amount (Millions of yen)	Amount per share (Yen)	Shareholders' cut-off date	Effective date
March 24, 2011	Annual general meeting of shareholders	Common stock	¥12,516	¥23	December 31, 2010	March 25, 2011
July 21, 2011	Board of directors	Common stock	¥10,884	¥20	June 30, 2011	September 1, 2011

Year ended December 31, 2010

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, 2010	Annual general meeting of shareholders	Common stock	¥12,516	¥23	December 31, 2009	March 26, 2010
July 22, 2010	Board of directors	Common stock	¥9,252	¥17	June 30, 2010	September 1, 2010

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

Year ended December 31, 2012

Date of approval	Resolution approved by	Type of shares	Amount (Millions of yen)	Paid from	Amount per share (Yen)	Shareholders' cut-off date	Effective date
March 27, 2013	Annual general meeting of shareholders	Common stock	¥10,885	Retained earnings	¥20	December 31, 2012	March 28, 2013

17 Supplementary Information for the Consolidated Statement of Comprehensive Income

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

Year ended December 31, 2010	Millions of yen
Comprehensive income attributable to:	
Owners of the parent	¥36,652
Minority interests	852
Total	¥37,505

Year ended December 31, 2010	Millions of yen
Other comprehensive income	
Unrealized gains (losses) on securities	¥ (295)
Foreign currency translation adjustments	(4,789)
Total	¥(5,084)

Reclassification to profit or loss and tax effects of comprehensive income for the fiscal year ended December 31, 2012.

Amounts reclassified to profit or loss in the current period that were recognized in other comprehensive income in the current period and tax effects for each component of other comprehensive income are as follows:

Year ended December 31, 2012	Millions of yen
Unrealized gains (losses) on securities:	
Arising during the year	¥1,114
Reclassification to profit or loss for the year	—
Sub-total, before tax	1,114
Tax effects	(317)
Sub-total, net of tax	797
Deferred gains (losses) on hedges:	
Arising during the year	406
Adjustment for the acquisition cost of assets	500
Reclassification to profit or loss for the year	(712)
Sub-total, before tax	194
Tax effects	(74)
Sub-total, net of tax	120
Foreign currency translation adjustments:	
Arising during the year	3,409
Total other comprehensive income	¥4,326

18 Supplementary Cash Flow Information

Cash and cash equivalents at December 31, 2012, 2011 and 2010 in the consolidated statements of cash flows classified by account on the consolidated balance sheets were as follows:

	Millions of yen		
December 31,	2012	2011	2010
Cash and deposits	¥110,936	¥107,163	¥ 76,213
Time deposits over three months	(15,491)	(12,689)	(11,069)
Cash and cash equivalents	¥ 95,445	¥ 94,474	¥ 65,144

19 Related Party Transactions

The Company is substantively a 61.6%-owned (Percentage of Voting rights) consolidated subsidiary of 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, 2012 and 2011 and transactions for the fiscal years ended December 31, 2012, 2011 and 2010 with related parties are summarized as follows:

		Millions of yen	
December 31,		2012	2011
Balances:			
Roche:	Payables – Trade accounts	¥31,960	¥9,914
	Receivables – Trade accounts	10,495	6,001
	Payables – Other (Sharing of co-development costs)	6,134	—
	Receivables – Other (Sharing of co-development costs)	5,487	5,311

		Millions of yen		
Year ended December 31,		2012	2011	2010
Transactions:				
Roche (*):	Purchases of raw materials	¥84,272	¥75,742	¥87,840
	Sales of products	32,708	25,678	15,538
	Sharing of co-development costs (receivable)	4,992	5,334	5,932
	Sharing of co-development costs (payable)	5,623	—	—
Directors of the Company:				
	Excise of stock options: Osamu Nagayama	11	—	—

(*) Business transactions are determined on an arm's-length basis at the same price as general transactions based on considering market value. Sharing of co-development costs is determined based on the license contracts concluded with Roche.

20 Stock Option Plans

At December 31, 2012, 2011 and 2010, the Company had the following stock option plans approved by its shareholders in accordance with the Corporate Law:

December 31, 2012	2012 plan (stock-based compensation plan)	2012 plan	2011 plan (stock-based compensation plan)	2011 plan	2010 plan (stock-based compensation plan)	2010 plan	2009 plan (stock-based compensation plan)	2009 plan
Date of grant	May 10, 2012	May 10, 2012	June 14, 2011	June 14, 2011	May 11, 2010	May 11, 2010	May 11, 2009	April 9, 2009
Grantees	5 directors	5 directors and 108 employees of the Company and 2 employees of a subsidiary	5 directors	5 directors and 102 employees of the Company and 2 employees of a subsidiary	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
Type of stock	Common stock	Common stock	Common stock	Common stock	Common stock	Common stock	Common stock	Common stock
Number of shares granted	81,700	334,000	88,800	325,000	71,600	324,000	78,500	330,000
Exercise price (yen)	¥1	¥1,528	¥1	¥1,397	¥1	¥1,881	¥1	¥1,696
Exercisable period	May 10, 2012 – April 24, 2042	April 26, 2014 – April 24, 2022	June 14, 2011 – May 27, 2041	May 29, 2013 – May 27, 2021	May 11, 2010 – April 23, 2040	April 25, 2012 – April 23, 2020	May 11, 2009 – April 24, 2039	April 11, 2011 – March 25, 2019

December 31, 2012	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, 2012	2012 plan (stock-based compensation plan)	2012 plan	2011 plan (stock-based compensation plan)	2011 plan	2010 plan (stock-based compensation plan)	2010 plan	2009 plan (stock-based compensation plan)	2009 plan
Non-vested (number of shares)								
Outstanding at the beginning of the year	—	—	88,800	325,000	71,600	324,000	67,000	—
Granted during the year	81,700	334,000	—	—	—	—	—	—
Forfeited during the year	—	1,000	—	1,000	—	—	—	—
Vested during the year	—	—	10,800	—	6,900	324,000	7,600	—
Outstanding at the end of the year	81,700	333,000	78,000	324,000	64,700	—	59,400	—
Vested (number of shares)								
Outstanding at the beginning of the year	—	—	—	—	—	—	—	—
Vested during the year	—	—	10,800	—	6,900	324,000	7,600	328,000
Exercised during the year	—	—	10,800	—	6,900	—	7,600	—
Forfeited during the year	—	—	—	—	—	1,000	—	1,000
Outstanding at the end of the year	—	—	—	—	—	323,000	—	327,000
Weighted-average market price (yen)	—	—	—	—	—	—	—	—

December 31, 2012	2007 plan	2006 plan	2005 plan	2004 plan	2003 plan
Non-vested (number of shares)					
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	—	—	—	—	—
Vested (number of shares)					
Outstanding at the beginning of the year	345,000	333,000	245,200	206,900	106,400
Vested during the year	—	—	—	—	—
Exercised during the year	—	—	—	—	31,200
Forfeited during the year	1,000	—	—	—	—
Outstanding at the end of the year	344,000	333,000	245,200	206,900	75,200
Weighted-average market price (yen)	—	—	—	—	—

December 31, 2011	2011 plan (stock-based compensation plan)	2011 plan	2010 plan (stock-based compensation plan)	2010 plan	2009 plan (stock-based compensation plan)	2009 plan	2007 plan
Date of grant	June 14, 2011	June 14, 2011	June 11, 2010	May 11, 2010	May 11, 2009	April 9, 2009	April 9, 2007
Grantees	5 directors	5 directors and 102 employees of the Company and 2 employees of a subsidiary	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	Common stock	Common stock
Number of shares granted	88,800	325,000	71,600	324,000	78,500	330,000	355,000
Exercise price (yen)	¥1	¥1,397	¥1	¥1,881	¥1	¥1,696	¥3,039
Exercisable period	June 14, 2011 – May 27, 2041	May 29, 2013 – May 27, 2021	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, 2011	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
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, 2011	2011 plan (stock-based compensation plan)	2011 plan	2010 plan (stock-based compensation plan)	2010 plan	2009 plan (stock-based compensation plan)	2009 plan	2007 plan
Non-vested (number of shares)							
Outstanding at the beginning of the year	—	—	71,600	324,000	67,000	328,000	—
Granted during the year	88,800	325,000	—	—	—	—	—
Forfeited during the year	—	—	—	—	—	—	—
Vested during the year	—	—	—	—	—	328,000	—
Outstanding at the end of the year	88,800	325,000	71,600	324,000	67,000	—	—
Vested (number of shares)							
Outstanding at the beginning of the year	—	—	—	—	—	—	345,000
Vested during the year	—	—	—	—	—	328,000	—
Exercised during the year	—	—	—	—	—	—	—
Forfeited during the year	—	—	—	—	—	—	—
Outstanding at the end of the year	—	—	—	—	—	328,000	345,000
Weighted-average market price (yen)	—	—	—	—	—	—	—

December 31, 2011	2006 plan	2005 plan	2004 plan	2003 plan
Non-vested (number of shares)				
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	—	—	—	—
Vested (number of shares)				
Outstanding at the beginning of the year	333,000	245,200	206,900	106,400
Vested during the year	—	—	—	—
Exercised during the year	—	—	—	—
Forfeited during the year	—	—	—	—
Outstanding at the end of the year	333,000	245,200	206,900	106,400
Weighted-average market price (yen)	—	—	—	—

December 31, 2010	2010 plan (stock-based compensation plan)	2010 plan	2009 plan (stock-based compensation plan)	2009 plan	2007 plan	2006 plan	2005 plan
Date of grant	May 11, 2010	May 11, 2010	May 11, 2009	April 9, 2009	April 9, 2007	April 3, 2006	April 1, 2005
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	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	Common stock	Common stock
Number of shares granted	71,600	324,000	78,500	330,000	355,000	344,000	252,000
Exercise price (yen)	¥1	¥1,881	¥1	¥1,696	¥3,039	¥2,245	¥1,649
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	April 1, 2008 – March 23, 2016	April 1, 2007 – March 23, 2015

December 31, 2010	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, 2010	2010 plan (stock-based compensation plan)	2010 plan	2009 plan (stock-based compensation plan)	2009 plan	2007 plan	2006 plan	2005 plan
Non-vested (number of shares)							
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	—	—	—
Vested (number of shares)							
Outstanding at the beginning of the year	—	—	—	—	350,000	338,000	249,200
Vested during the year	—	—	11,500	—	—	—	—
Exercised during the year	—	—	11,500	—	—	—	—
Forfeited during the year	—	—	—	—	5,000	5,000	4,000
Outstanding at the end of the year	—	—	—	—	345,000	333,000	245,200
Weighted-average market price (yen)	—	—	¥ 1,790	—	—	—	—

December 31, 2010	2004 plan	2003 plan
Non-vested (number of shares)		
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	—	—
Vested (number of shares)		
Outstanding at the beginning of the year	210,900	106,400
Vested during the year	—	—
Exercised during the year	—	—
Forfeited during the year	4,000	—
Outstanding at the end of the year	206,900	106,400
Weighted-average market price (yen)	—	—

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

Year ended December 31, 2012	2012 plan (stock-based compensation plan)	2012 plan
Expected volatility (*1)	22%	32%
Expected holding period (*2)	3 years	10 years
Expected dividend per share (*3)	40 yen	40 yen
Risk-free rate (*4)	0.12%	0.85%

(*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) Since there is insufficient data to make a reasonable estimation, the expected holding period of the options of the 2012 plan is based on the assumption that the options are exercised at the end of the exercisable period, and the expected holding period of the options of the 2012 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 holding period 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.

21 Amounts Per Share

Effective the fiscal year ended December 31, 2012, the Company has adopted "Accounting Standard for Earnings Per Share" (ASBJ Statement No. 2, revised on June 30, 2010) and "Guidance on Accounting Standard for Earnings Per Share" (ASBJ Guidance No. 4, revised on June 30, 2010).

When calculating diluted net income per share after adjustment for latent shares for the fiscal year ended December 31, 2012, the Company has changed its method for computing the amount that is assumed to be paid into the Company due to the exercise of stock option rights, which require a specified term of service before holders can secure exercise rights, to take account of the amount for service that will be provided to the Company in the future in the fairly assessed value of the stock options. Diluted net income per share for the fiscal year ended December 31, 2011 has been restated applying the same method as the current fiscal year.

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 260,206 shares, 173,814 shares and 124,760 shares of common stock has been included in the computation of the weighted-average number of shares for the years ended December 31, 2012, 2011 and 2010, respectively.

Diluted net income per share including adjustment for latent shares for the fiscal year ended December 31, 2011 amounted to ¥64.72 based on the method adopted in the previous fiscal year compared to ¥64.73 applying the new method.

Independent Auditors' Report

Independent Auditors' Report

To the Board of Directors of Chugai Pharmaceutical Co., Ltd.:

We have audited the accompanying consolidated financial statements of Chugai Pharmaceutical Co., Ltd. and its consolidated subsidiaries, which comprise the consolidated balance sheets as at December 31, 2012 and 2011, and the related consolidated statements of income, comprehensive income, changes in net assets and cash flows for the years then ended, and a summary of significant accounting policies and other explanatory information.

Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in Japan, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatements, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. The consolidated statement of income, changes in net assets and cash flows for the year ended December 31, 2010 were audited by other auditors whose report dated March 24, 2011, expressed an unqualified opinion on those statements. We conducted our audits in accordance with auditing standards generally accepted in Japan. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on our judgement, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, while the objective of the financial statement audit is not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Chugai Pharmaceutical Co., Ltd. and its consolidated subsidiaries as at December 31, 2012 and 2011, and their financial performance and cash flows for the years then ended in accordance with accounting principles generally accepted in Japan.

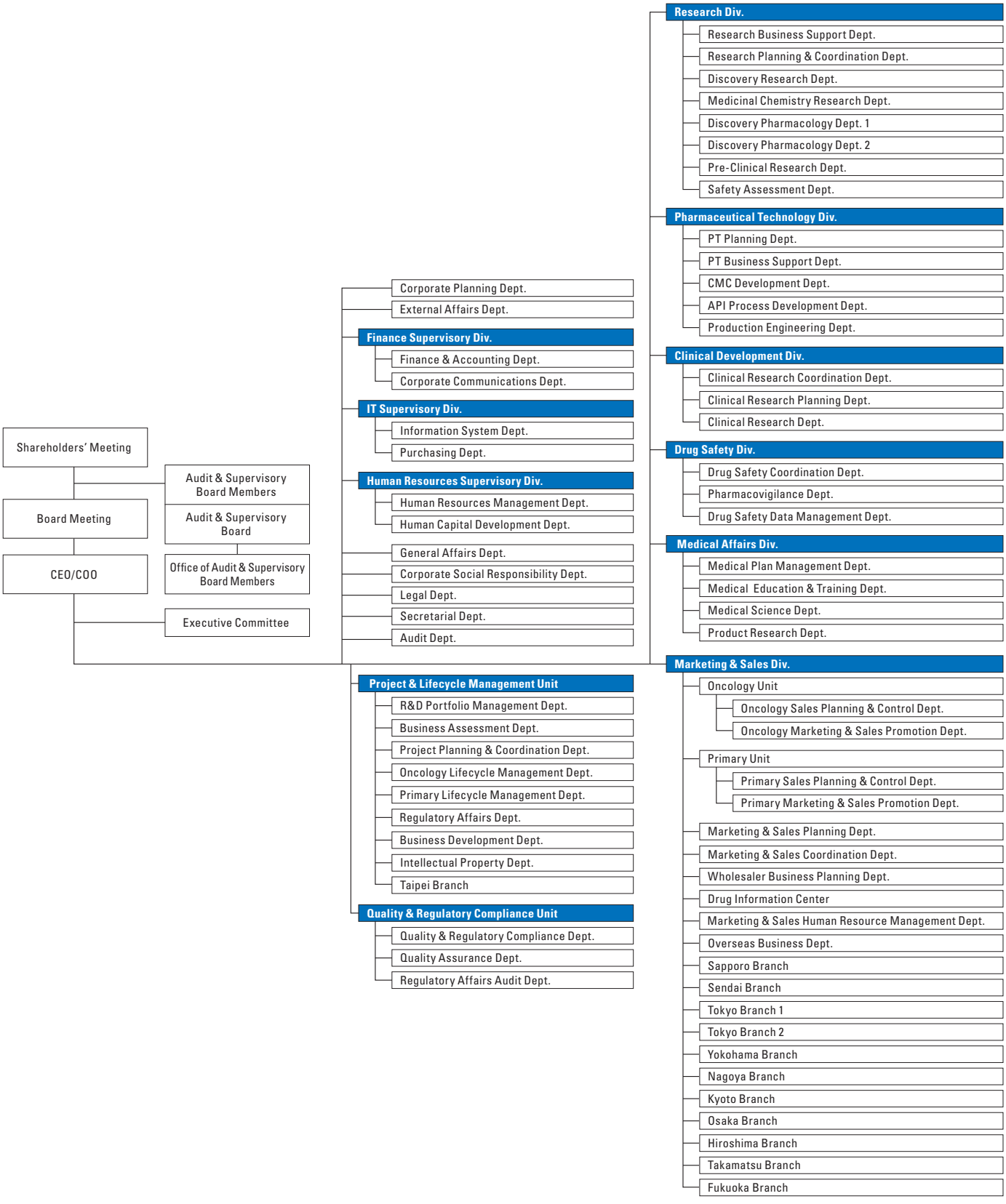
Emphasis of Matter

Without qualifying our opinion, we draw attention to Note 17 to the consolidated financial statements, in which the comprehensive income for the year ended December 31, 2010 is disclosed.

KPMG AZSA LLC

March 27, 2013
Tokyo, Japan

Organization (As of April 1, 2013)



Network (As of March 27, 2013)

Chugai Pharmaceutical

Head Office

1-1 Nihonbashi-Muromachi 2-chome,
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Kamakura Research Laboratories
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Chugai Business Support Co., Ltd.
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Medical Culture Inc.
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Forerunner Pharma Research Co., Ltd.
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Chugai Pharma Marketing Ltd.
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Tel +1-212-486-7780

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Tel +65-(0)6776-6556

Chugai Pharmabody Research Pte. Ltd.
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Tel +65-(0)6933-4888

C&C Research Laboratories

Discovery Research Center
DRC Natural Sciences Campus,
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Suwon-si, Gyeonggi-do 440-746 Korea
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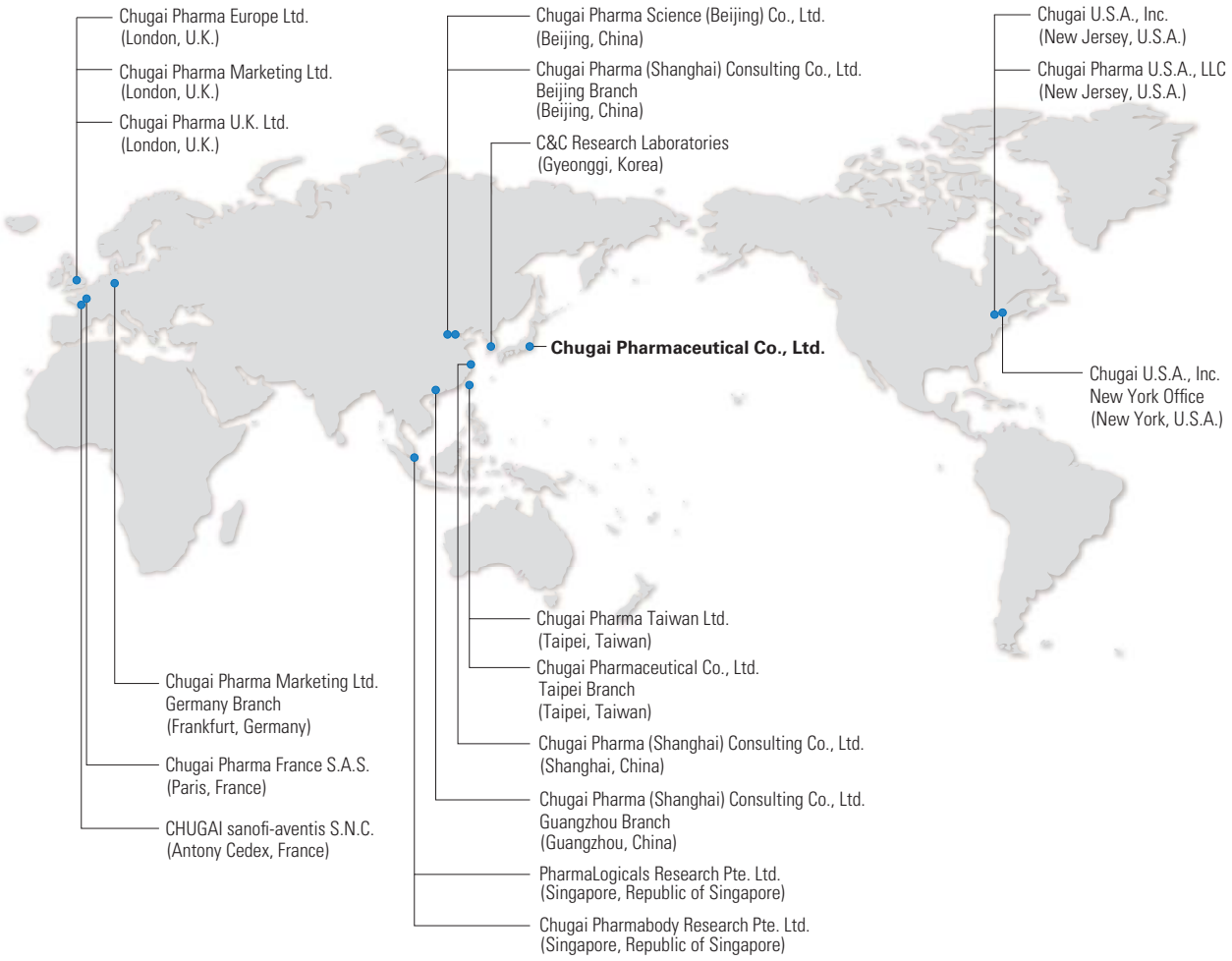
Clinical Research Center
903 E&C Venture Dream Tower 3Cha,
197-33 Guro-Dong, Guro-Gu,
Seoul 152-719 Korea
Tel +82-(0)2-858-6226

Chugai's Global Network



Shareholder Information (As of December 31, 2012)

Major Shareholders*

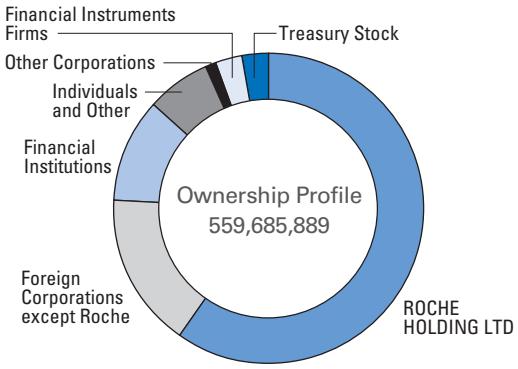
Name	Number of Shares Held (Thousands)	Percentage of Voting Rights (%)
ROCHE HOLDING LTD	335,223	61.62
The Master Trust Bank of Japan, Ltd. (Trust account)	14,837	2.72
Japan Trustee Services Bank, Ltd. (Trust account)	12,691	2.33
JP Morgan Chase Bank 385147	5,621	1.03
SSBT OD05 OMNIBUS ACCOUNT - TREATY CLIENTS	4,478	0.82
Mizuho Securities Co., Ltd.	4,275	0.78
State Street Bank and Trust Company 505225	4,040	0.74
Chugai Pharmaceutical Employee Shareholders' Association	3,920	0.72
Tokio Marine & Nichido Fire Insurance Co., Ltd.	3,787	0.69
Mellon Bank, N.A. as Agent for its Client Mellon Omnibus US Pension	3,499	0.64

* 15,440,000 shares of treasury stock held by the Company are not included in the above breakdown of major shareholders.

Stock Price Information

	Stock Price	
	Low	High
From January 1, 2012 to December 31, 2012		
First Quarter	¥1,176	¥1,527
Second Quarter	1,379	1,538
Third Quarter	1,466	1,665
Fourth Quarter	1,550	1,718

Classification of Shareholders



ROCHE HOLDING LTD
Shares: 335,223,645 59.89% (Shareholders: 1)

Foreign Corporations except Roche
Shares: 89,818,994 16.05% (Shareholders: 447)

Financial Institutions
Shares: 60,692,122 10.84% (Shareholders: 70)

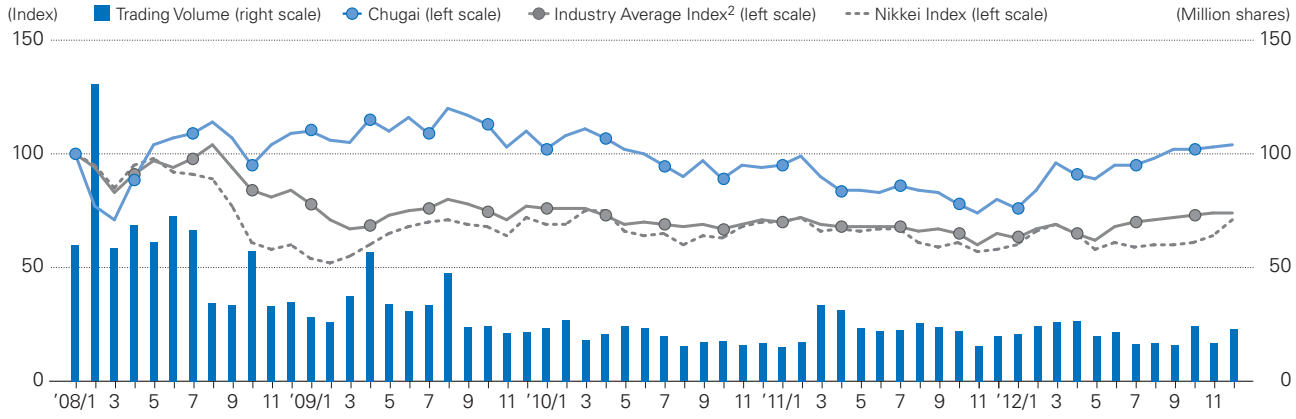
Individuals and Other
Shares: 38,064,938 6.80% (Shareholders: 43,100)

Other Corporations
Shares: 5,904,091 1.05% (Shareholders: 242)

Financial Instruments Firms
Shares: 14,541,661 2.60% (Shareholders: 48)

Treasury Stock
Shares: 15,440,438 2.76% (Shareholders: 1)

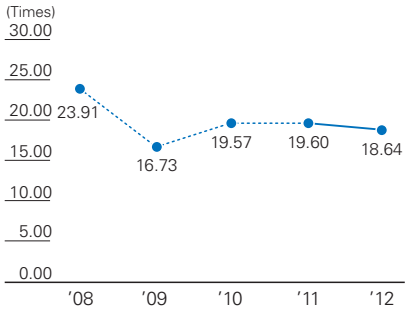
Share Performance[1]



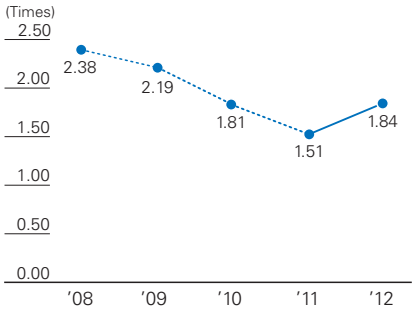
1. Share price on January 4, 2008 (¥1,586) = 100
2. Industry average index is calculated as below (because of mergers):
From October 2007: A total of eight companies (Takeda, Daiichi Sankyo, Astellas, Shionogi, Eisai, Mitsubishi Tanabe, Dainippon Sumitomo, Chugai)

Share Price Indicators

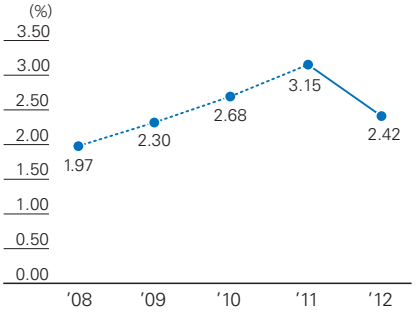
Price/Earnings Ratio
Year-end share price ÷ Net income per share



Price/Book Ratio
Year-end share price ÷ Net assets per share



Dividend Yield
Dividends per share ÷ Year-end share price



Corporate Data (As of December 31, 2012)

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
6,836 (Consolidated)

Number of Shares Issued of Common Stock
559,685,889

Number of Shareholders
43,909

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 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*.

IR website
http://www.chugai-pharm.co.jp/english/ir

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Corporate Social Responsibility Department
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CHUGAI PHARMACEUTICAL CO., LTD.

A member of the Roche group

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Tokyo 103-8324, Japan