CHUGAI
Roche Roche Group

(Integrated Edition Including CSR Report)

Annual Report 2013

Fiscal year ended December 31, 2013

Passion for Innovation

Innovation all for the patients

CHUGAI PHARMACEUTICAL CO., LTD.

PROFILE

The mission of Chugai Pharmaceutical Co., Ltd. and its consolidated subsidiaries ("Chugai") 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 achieving 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 pharmaceutical company.

Chugai's Seven Strengths

- High product potential that addresses unmet medical need
- One of the richest pipelines in Japan
- Strategic alliance with the Roche Group
- Cutting-edge drug discovery technologies, especially biotechnology
- Knowledge and experience as a pioneer in personalized healthcare (PHC)
- Commitment to safety management
- Support for healthcare delivery

Mission

The mission of Chugai Pharmaceutical Co., Ltd. and its consolidated subsidiaries (“Chugai”) 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.

Business Philosophy

Innovation all for the patients

CONTENTS

Strategy

Feature: Creating Value from Chugai's Strengths

Editorial Policy

Chugai has adopted integrated reporting to communicate both the financial and non-financial aspects of its corporate value by combining the traditional annual report with the print version of the corporate social responsibility (CSR) report.

For CSR information, we are focusing on the main initiatives of 2013 in this annual report and providing our action policies and more detailed information on the Chugai website.

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

The basic timeframe for this report is the financial reporting period of January to December 2013. However, in view of the importance of providing the latest information available, some information relating to activities that occurred in 2014 is included, mainly in research and clinical development data.

Information in This Report

The information presented in this report is information that Chugai believes to be of high importance given its significance in building Chugai's corporate value over the short, medium and long term, and its degree of impact on stakeholders. More detailed CSR information is reported on the Chugai website.

Reference Guidelines

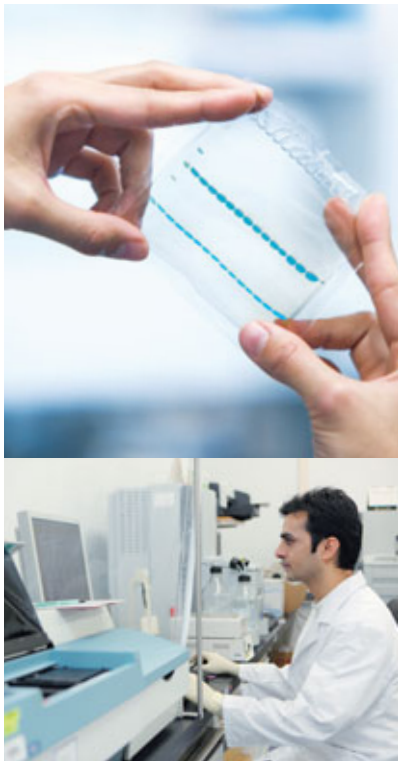
From *Annual Report 2013*, content focuses on value creation, using as reference The International Integrated Reporting Framework issued by the International Integrated Reporting Council (IIRC).* This framework is designed to promote reporting on a company's short-, medium- and long-term value creation, underpinned by the seven guiding principles below, and is consistent with Chugai's integrated reporting objectives and fundamental thinking.

A) Strategic focus and future orientation, B) Connectivity of information, C) Stakeholder relationships, D) Materiality, E) Conciseness, F) Reliability and completeness, G) Consistency and comparability

CSR information was prepared with reference to the Environmental Reporting Guidelines (Fiscal Year 2012 Edition) of the Ministry of the Environment of Japan and the 2013 Sustainability Reporting Guidelines of the Global Reporting Initiative (GRI).

* Established in 2010 to provide an international corporate reporting framework, the IIRC is a global coalition of private corporations, investors, the accounting profession, government agencies, NGOs and others. The framework was released in December 2013.

Performance Report and Future Initiatives



Data Section

Financial Section

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.

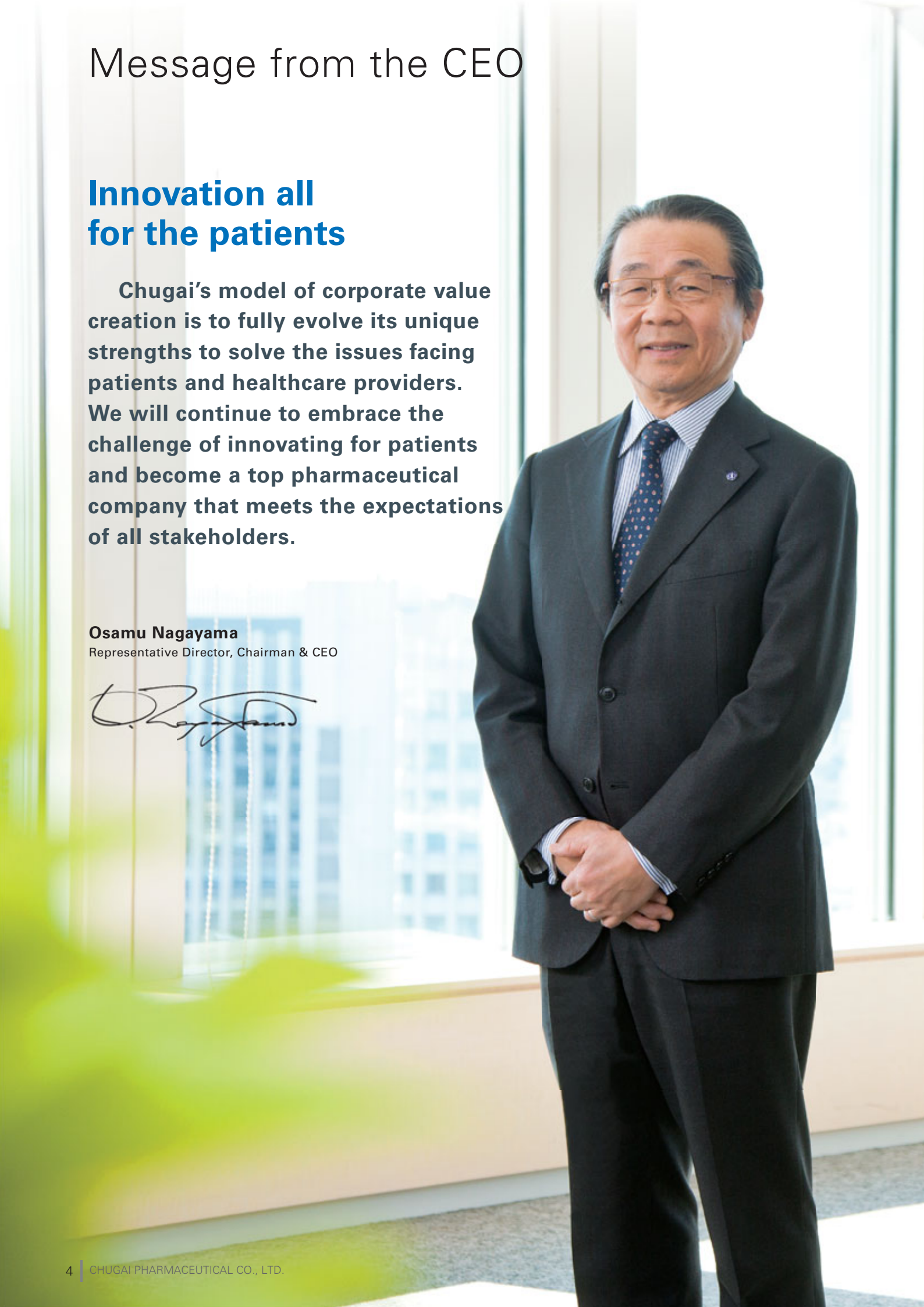
Note
The information regarding pharmaceuticals (including products under development) is not intended for advertising, promotion or medical advice. All trademarks are the property of their respective holders.

Message from the CEO

Innovation all for the patients

Chugai's model of corporate value creation is to fully evolve its unique strengths to solve the issues facing patients and healthcare providers. We will continue to embrace the challenge of innovating for patients and become a top pharmaceutical company that meets the expectations of all stakeholders.

Osamu Nagayama
Representative Director, Chairman & CEO



Chugai launched its mid-term business plan ACCEL 15 in January 2013 with a strong determination to accelerate progress toward its fundamental management goal of becoming a top pharmaceutical company. Under this plan, we are mobilizing our unique strengths to deliver value to patients and healthcare professionals even faster, while quickly building a business foundation that underpins these efforts.

In 2013, we moved forward with a number of initiatives under the theme of "acceleration," and achieved a variety of successes. Our accomplishments included launching new products and additional indications for existing products; expanding the market presence of our core products; advancing innovative in-house research projects; rolling out new overseas operations; and initiating multiple new development projects. As a result, in 2013 Chugai showed its many stakeholders that it is making progress toward becoming a top pharmaceutical company.

On the other hand, we still have a long way to go to reach our goal. My image of a top pharmaceutical company is an organization that blazes new paths by astutely identifying opportunities in the rapidly changing global market environment and offering innovative solutions. We are not at that level yet. Moreover, pharmaceutical companies are facing many challenges and competitive pressures, including declining productivity in research and development, stricter safety and quality regulations, and the transformation of marketing activities. As countries further strengthen measures to restrain healthcare costs, only companies that are truly conscious of the overall social benefit they contribute to patients and healthcare will survive.

To continue providing value under these circumstances, we at Chugai need to seek real solutions that encompass considerations of the social rehabilitation of patients and contribution to economic development. For Chugai, whose 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, fully evolving its strengths to solve the issues facing patients and healthcare providers is integral to the value creation process. Underlying this value creation are Chugai's seven Core Values,[1] which include placing the primary focus on patients and consumers and maintaining a commitment to the highest ethical and moral standards in all our activities. We will achieve sustained growth by creating corporate value that is rooted in our Core Values, being responsive to our stakeholders and continuing to conduct business activities that benefit society.

Under ACCEL 15, Chugai will continue to accelerate the value creation process. In research and development, we will advance initiatives that lead to faster results from our proprietary research centered on antibody technologies to create new medicines that address unmet medical need.[2] At the same time, we will reinforce our simultaneous global development capabilities through enhanced speed and productivity. In the area of marketing, we are striving for a higher level of flexibility and efficiency so as to respond precisely to the needs of patients and healthcare providers. By building such an organization, we will lead the promotion and adoption of regional healthcare and Personalized Healthcare (PHC),[3] which are currently key issues in medical care. To carry out these initiatives steadily and flexibly, we will focus on strengthening our management foundation, especially in human asset management. We will accelerate diversity in terms of nationality, gender and other characteristics to establish a workforce with a wide range of perspectives and skills that will stimulate innovation.

I believe our continuous efforts to deliver innovation to patients in various ways will lead directly to increased corporate value and shareholder value. But I also recognize the importance of our capital strategy. We will focus on balanced cash management to increase returns to shareholders while making strategic investments based on the medium-to-long-term outlook for the business environment.

I ask our shareholders and investors for their continuing support as we embrace new challenges.

1. For details on Chugai's view of CSR, including its Core Values, see page 7.
2. Therapeutic areas in which satisfaction with treatment is low and that offer potential to create new markets with innovative medical products
3. A treatment approach designed and implemented according to each patient's unique molecular and genetic profile

Message from the Deputy Chairman

To continue benefitting the medical community and human health around the world, we will focus on evolving as we work to increase Chugai's qualitative corporate value.

The environment of the pharmaceutical industry worldwide is changing by the minute.

We at Chugai believe that achieving our mission through corporate activities consistent with the Chugai Business Conduct Guidelines (Chugai BCG) is how we fulfill our responsibilities to society. In this rapidly changing market environment, however, we too must continue to evolve in order to fulfill these responsibilities and deliver value in the future.

To meet our fundamental management goal of becoming a top pharmaceutical company, we are likewise focusing on not only achieving numerical targets but also on qualitative evolution in achieving those targets. Under ACCEL 15, our current mid-term business plan, we are therefore innovating every function with a patient-oriented approach to earn the trust and support of all stakeholders.

In 2013, the first year of ACCEL 15, Chugai made various efforts such as launching innovative products to further contribute to the treatment of patients and advances in healthcare. But there is still much more we can do in terms of the role we play and the value we contribute. For example, Chugai should take the initiative in disseminating accurate safety information and creating an environment in which patients can receive high-quality care. In clinical contract research, which has drawn particular attention lately, we believe that it is important to raise the level of post-marketing clinical research in Japan in addition to ensuring transparency. Accordingly, we have taken proactive measures to strengthen this area, including the enhancement of our organizational structure effective since April 2012.

Chugai will continue to prioritize implementation of the strategic policies of ACCEL 15 while concentrating efforts in improving the management infrastructure that forms the backbone of value creation and innovation. By strengthening management functions across the board – from corporate governance and reduction of environmental burden to stable supply of medicines and sophistication of risk management – Chugai should be able to achieve sustained growth.

We remain committed to constantly evolving to increase Chugai's corporate value.

Motoo Ueno
Representative Director and Deputy Chairman
Corporate Social Responsibility, Audit

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 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

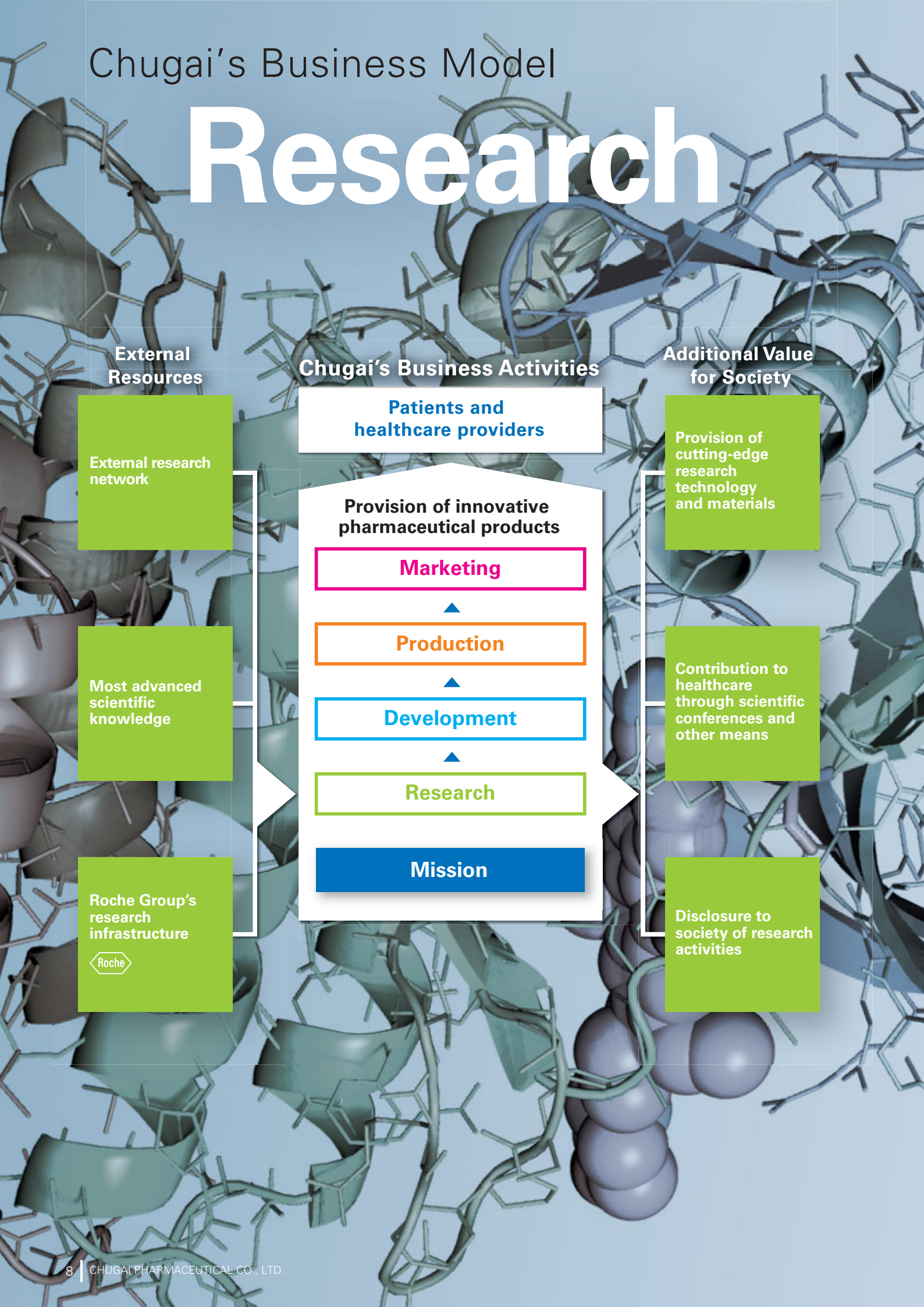
As a most important member of the Roche Group, we aim to become a top Japanese pharmaceutical company by providing a continuous flow of innovative new medicines domestically and internationally.

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.

Chugai's Business Model

Research



12

Number of in-house compounds in pipeline (As of January 30, 2014)

Business Philosophy

"Innovation all for the patients"

In research, Chugai works to continually generate new compounds with first-in-class[1] or best-in-class[2] potential to meet unmet medical need. We have industry-leading research technologies backed by the most advanced scientific knowledge. In addition to our pioneering advances in biotechnology in Japan, we have access to the Roche Group's world-class research infrastructure, including a large-scale compound library and bioinformatics tools, and a strong external research network with academia and other institutions. These advantages allow us to contribute to healthcare overall through our own drug discovery projects, scientific conference presentations of our research technologies and advanced technologies. We will continue to pursue patient-focused drug discovery to create medicines that are genuinely needed by patients and healthcare providers.

SMART-Ig
ART-Ig

Chugai's proprietary antibody technologies

25

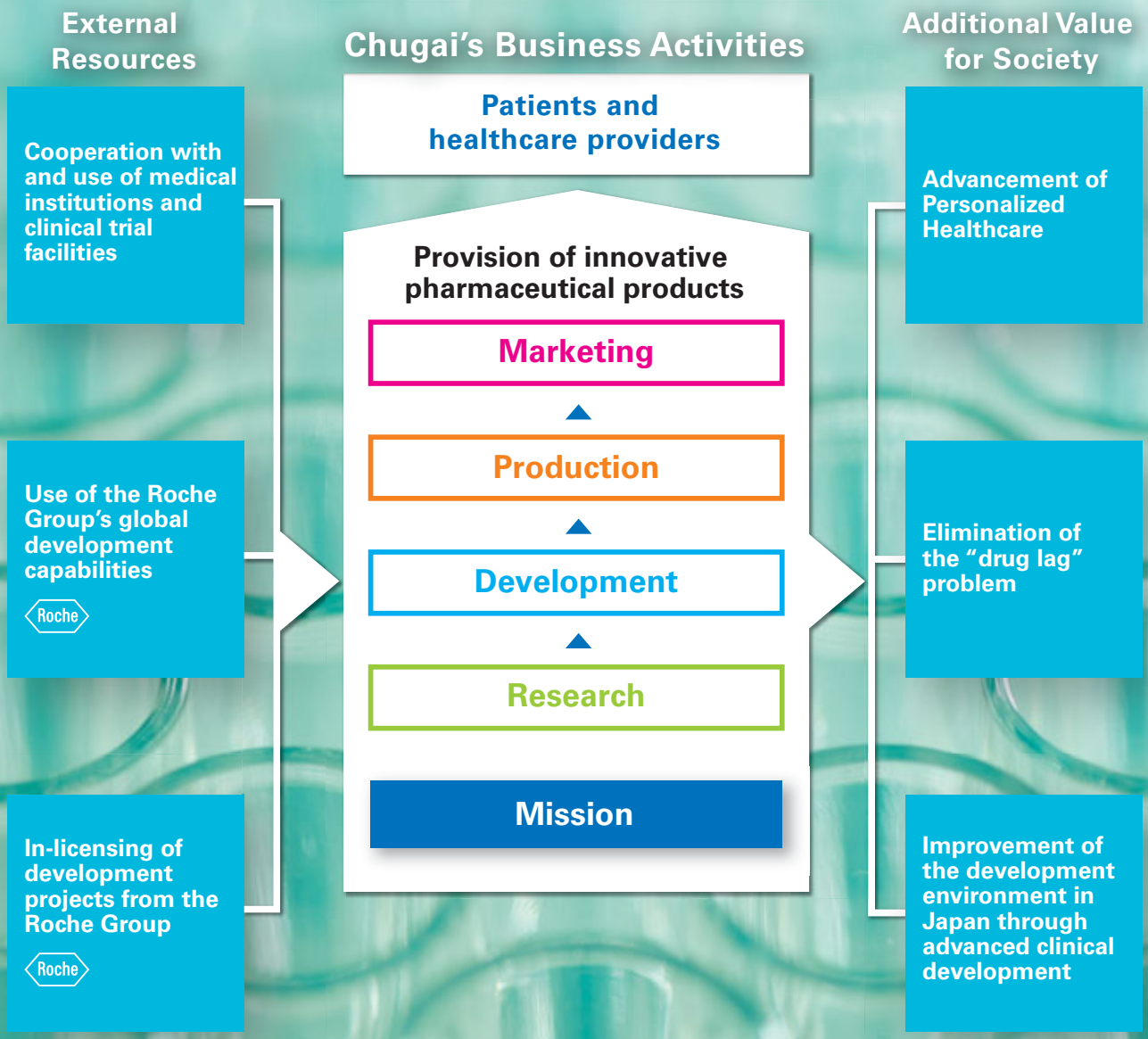
Number of presentations at scientific conferences and publications in academic papers on Chugai's innovative proprietary technologies (2010-2013)

104

Number of published articles regarding Chugai research findings (2010-2013)

1. An original drug that is highly novel and useful, which will significantly change the therapeutic system
2. A drug that offers clear advantages over other existing drugs

Development



35

Number of approvals of new products and additional indications (2008-2013)

Business Philosophy

“Innovation all for the patients”

Chugai seeks to deliver innovative medicines to patients as quickly as possible. To accomplish that end, we have established a lifecycle management system for integrated management of all functions at the project level to conduct clinical development with exceptional speed, efficiency and science, supported by the cooperation of many medical institutions and clinical trial facilities. Moreover, through our alliance with the Roche Group, we are implementing many multinational studies and strengthening the process to enable simultaneous development of therapies and corresponding diagnostic agents suitable for Personalized Healthcare (PHC). Through these initiatives, we are creating best practices in development and filing in Japan which may contribute to the advancement of the industry.

19

Number of products in-licensed from Roche (2008-2013)

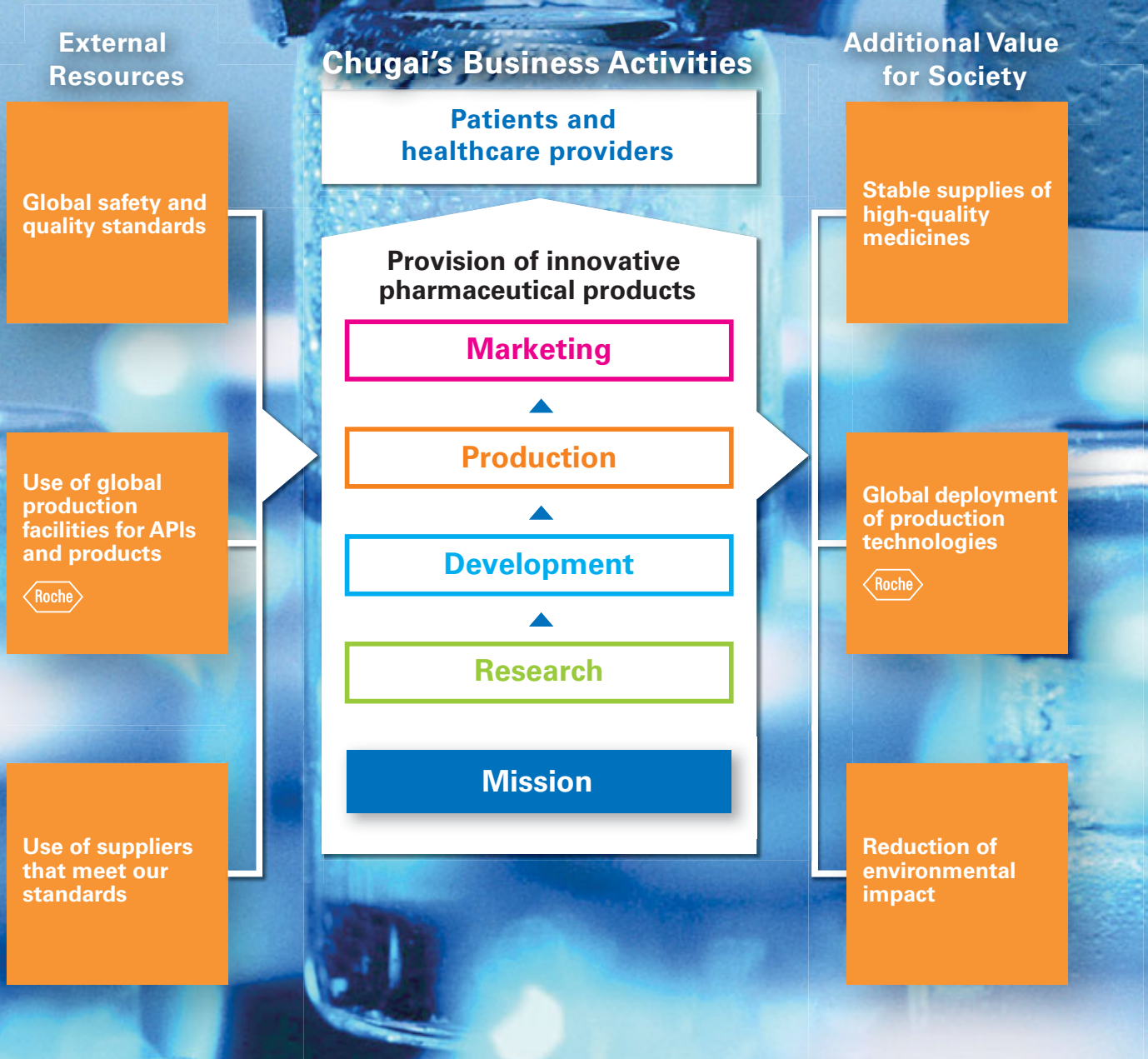
27

Number of co-development projects with the Roche Group (As of January 30, 2014)

Approx. 60 percent

Ratio of PHC projects to total development projects (As of January 30, 2014)

Production


External Resources
Global safety and quality standards
Use of global production facilities for APIs and products
Roche
Use of suppliers that meet our standards
Chugai's Business Activities
Patients and healthcare providers
Provision of innovative pharmaceutical products
Marketing
Production
Development
Research
Mission
Additional Value for Society
Stable supplies of high-quality medicines
Global deployment of production technologies
Roche
Reduction of environmental impact

10,000-liter × 8
2,500-liter × 4
bioreactor capacity

Biologcal active pharmaceutical ingredient (API) production facilities (Utsunomiya and Ukima plants)

The most important responsibility of Chugai's production functions is to ensure thorough safety and quality management and stable supplies so that patients and healthcare professionals can use our products with confidence. We have built a global-standard safety and quality management system for pharmaceutical products sold in Japan, the United States and Europe, and have established Japan's most robust pharmaceutical supply platform in terms of both quality and quantity. In addition, we in- and out-license production technologies with the Roche Group to help ensure stable supplies of our global products. To reduce our environmental footprint, our production operations are managed in accordance with stringent voluntary standards based on the Chugai Environmental Policy.

Business Philosophy

CHUGAI

Roche Roche Group

"Innovation all for the patients"

12

Number of biopharmaceutical products produced

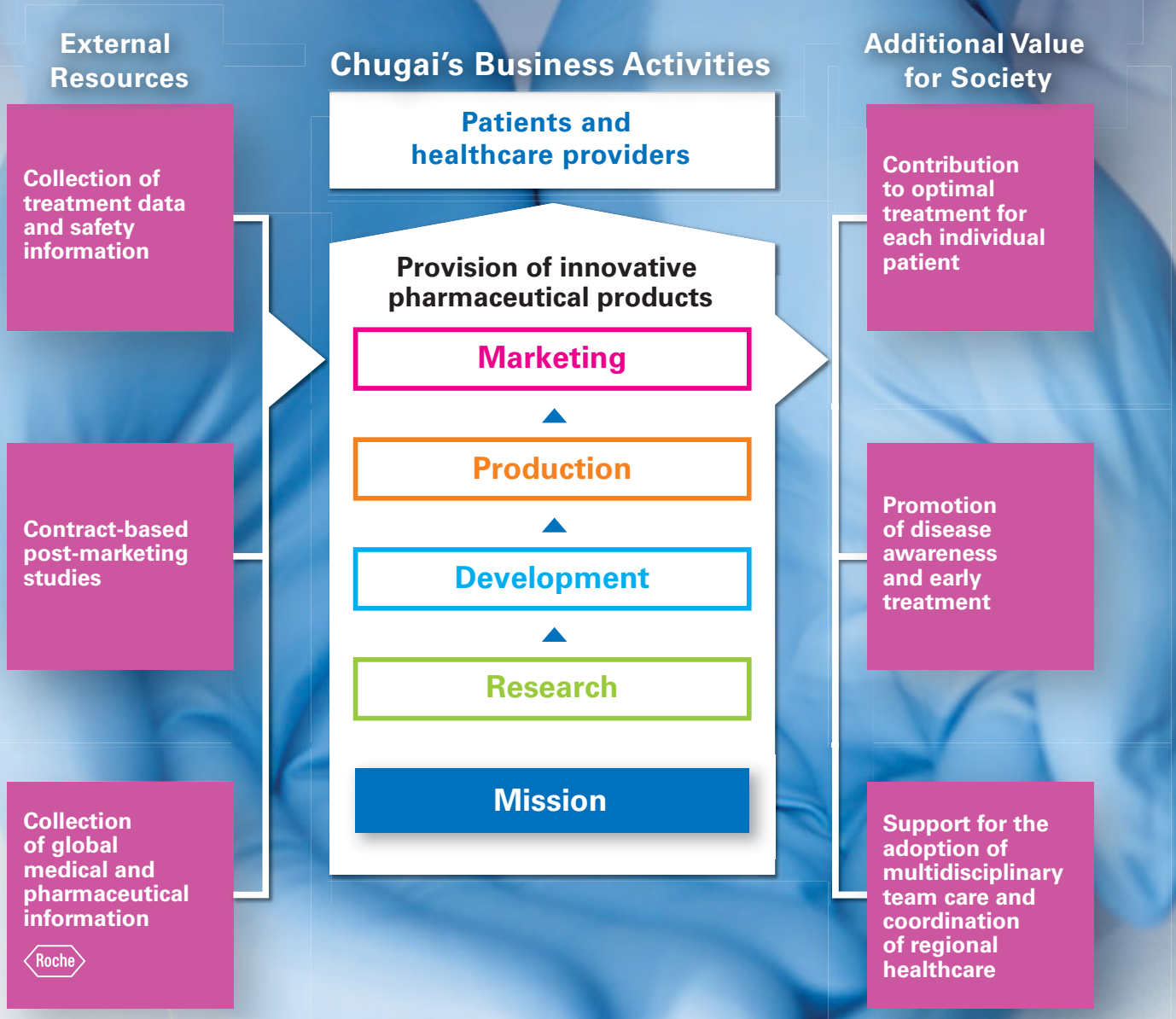
Over 90

Number of countries in which Chugai's biopharmaceutical (Actemra) is sold

-1
percent

CO_2 emissions (Compared with 2012)

Marketing


External Resources
Collection of treatment data and safety information
Contract-based post-marketing studies
Collection of global medical and pharmaceutical information
Roche
Chugai's Business Activities
Patients and healthcare providers
Provision of innovative pharmaceutical products
Marketing
Production
Development
Research
Mission
Additional Value for Society
Contribution to optimal treatment for each individual patient
Promotion of disease awareness and early treatment
Support for the adoption of multidisciplinary team care and coordination of regional healthcare

Business Philosophy

"Innovation all for the patients"

Patients' needs are placed at the center of Chugai's marketing activities, conducted by medical representatives (MRs) with a high level of expertise. The foundation of our activities in this area is consulting-based promotion geared to each individual patient. To ensure the appropriate use of the products with high value by the patients and healthcare providers, we collect and analyze safety information using extensive post-marketing surveillance. As for the medical affairs function, we work to generate data through contract-based post-marketing studies. We also contribute to the advancement of healthcare overall by supporting the adoption of multidisciplinary team care and the coordination of regional healthcare; holding lectures and study sessions; and conducting disease awareness activities. Through these and other initiatives, we will fulfill our mission as a leader in the fields of oncology and osteoporosis in Japan.

34.7[1] **percent**

Share of sales in the Japanese therapeutic antibody market (No. 1) (2013)

20.4[1] **percent**

Share of sales in the Japanese oncology market (No. 1) (2013)

146

Number of MRs with a high level of expertise[2] (As of December 31, 2013)

Approx. 140,000

Number of safety reports collected in clinical studies and post-marketing

1. Copyright 2014 IMS Japan K.K.
   Source: JPM 2013. Reprinted with permission.
   The scope of the market is defined by Chugai.
2. Chugai's internal certification system

Financial and Non-Financial Highlights

International Financial Reporting Standards (IFRS)

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

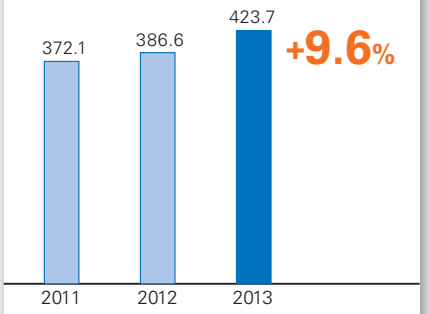
The financial and non-financial highlights shown below are key management indicators that may be of interest to various stakeholders. Core basis indicators are used for financial items, consistent with internal performance indicators. (For details, see "About Core Basis Results" on page 19.)

Key Indicators

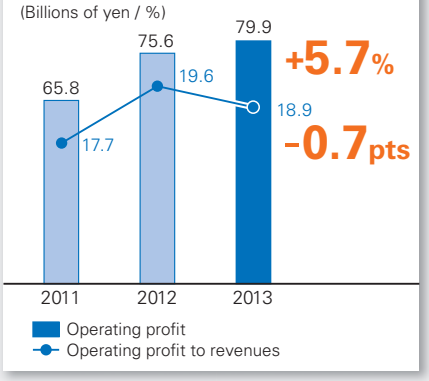
Note: Changes indicated in orange are comparisons with 2012.

Financial (Core Basis)

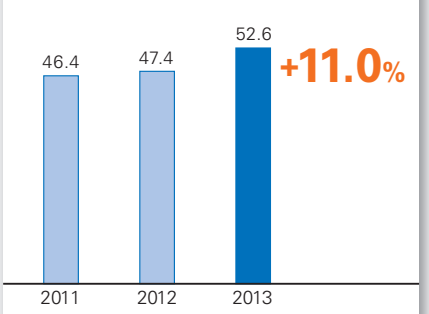
Revenues
(Billions of yen)



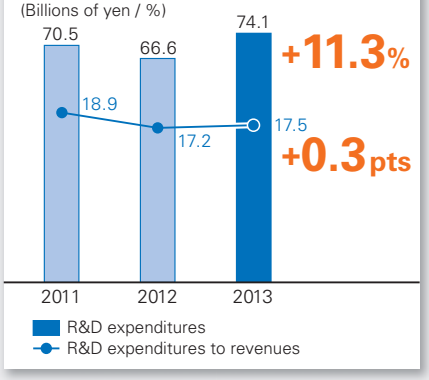
Operating Profit/ Operating Profit to Revenues
(Billions of yen / %)



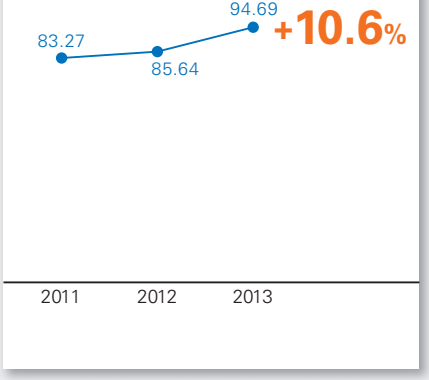
Net Income
(Billions of yen)



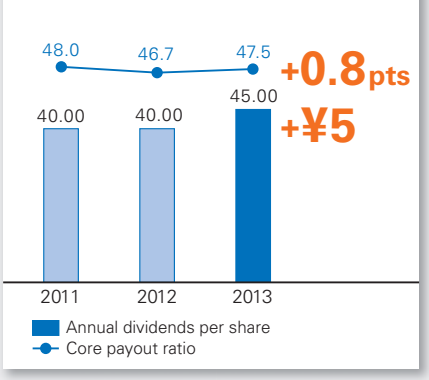
R&D Expenditures/ R&D Expenditures to Revenues
(Billions of yen / %)



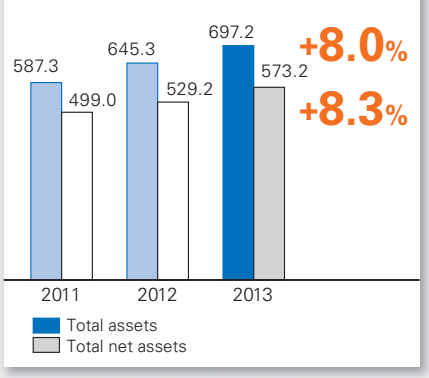
Core EPS
(Yen)



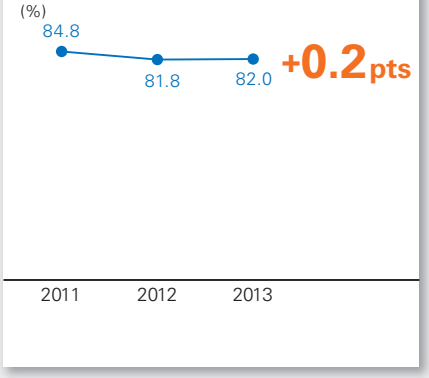
Dividends/Core Payout Ratio
(Yen / %)



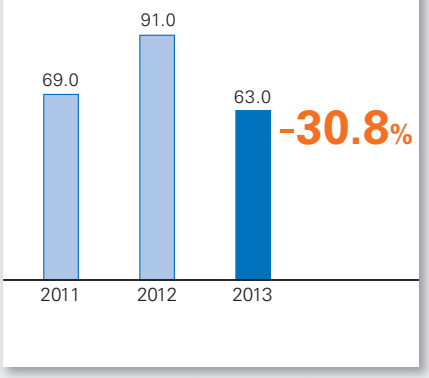
Total Assets/Total Net Assets
(Billions of yen)



Ratio of Equity Attributable to Chugai Shareholders
(%)



Operating Free Cash Flows
(Billions of yen)

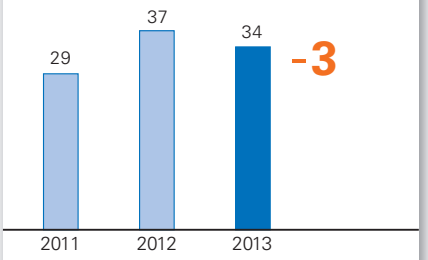


Chugai adopted International Financial Reporting Standards (IFRS) in 2013. This section presents data for 2013 and the two preceding years, retroactively adjusted for comparison purposes. For past performance trends (detailed 11-year data), see the 11-Year Financial Summary on pages 108-109.

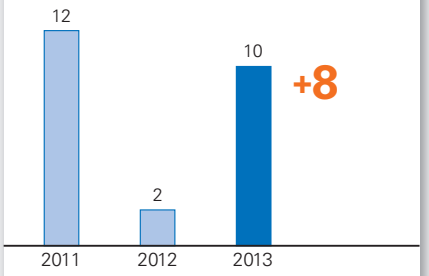
For further details on performance indicators for R&D, disease awareness, patient support, employees and the environment, see Overview of Activities in 2013 on pages 40-41.

R&D

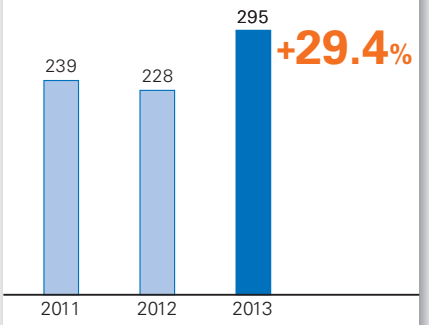
Number of Pipeline Projects



New Products and New Indications Approved

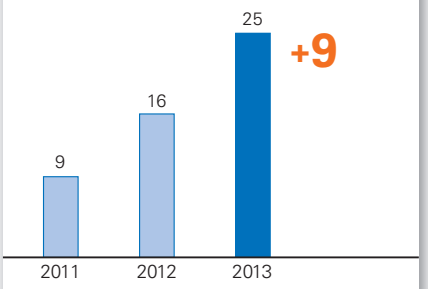


Number of Newly Granted Patents

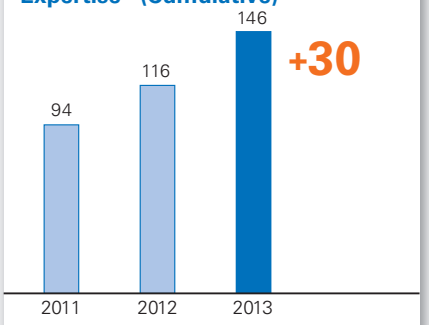


Disease Awareness and Patient Support

Disease Awareness Seminars for Patients

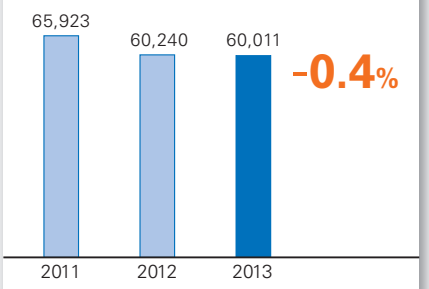


MRs With a High Level of Expertise* (Cumulative)



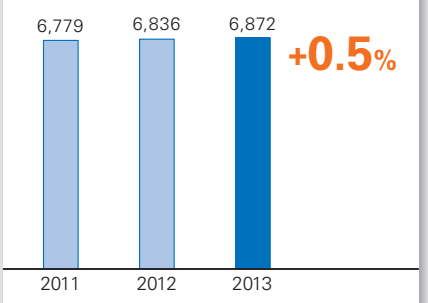
* Chugai certification system

Customer Inquiries Answered by the Drug Information Center



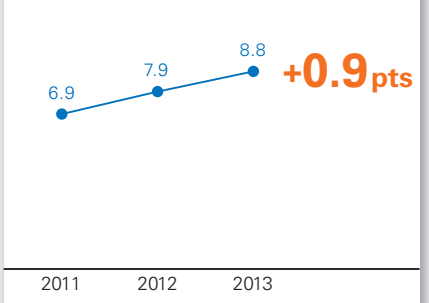
Employees and the Environment

Number of Employees



Percentage of Female Executives*

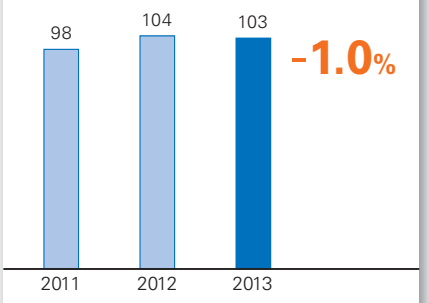
(%)



* Comparison with total number of executives

CO_2 Emissions

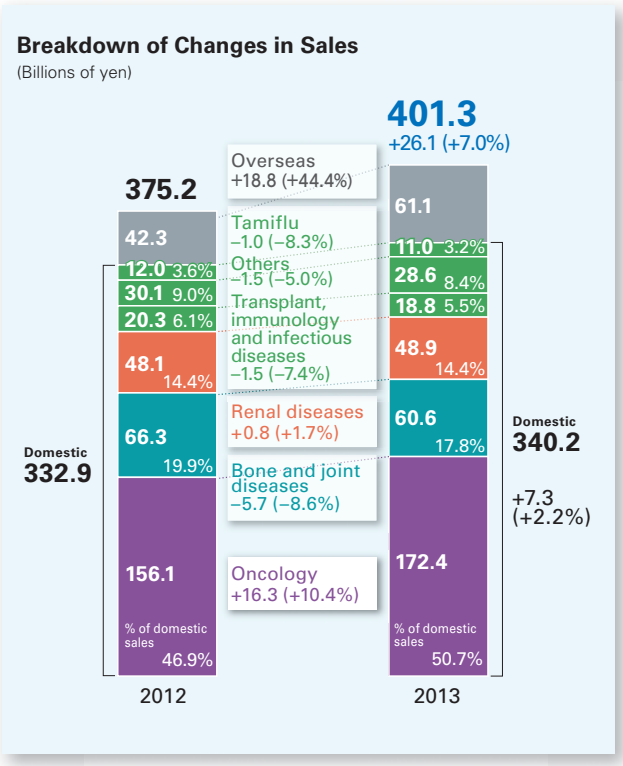
(Thousand tons)



Financial Summary (Core Basis)

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

	Billions of yen (Except as otherwise specified)			Percent change	Millions of U.S. dollars[1] (Except as otherwise specified)
	2013	2012	2011	2013/2012	2013
Results for the year:					
Revenues	¥423.7	¥386.6	¥372.1	+9.6%	$4,035
Operating profit	79.9	75.6	65.8	+5.7	761
Net income	52.6	47.4	46.4	+11.0	501
R&D expenditures	(74.1)	(66.6)	(70.5)	+11.3	(706)
Sales	¥401.3	¥375.2	¥363.5	+7.0%	$3,822
Oncology	172.4	156.1	141.8	+10.4	1,642
Bone and joint diseases	60.6	66.3	66.1	−8.6	577
Renal diseases	48.9	48.1	50.6	+1.7	466
Transplant, immunology and infectious diseases	18.8	20.3	22.8	−7.4	179
Others	28.6	30.1	33.7	−5.0	272
Overseas	61.1	42.3	39.7	+44.4	582
Royalties and other operating income	22.4	11.3	8.6	+98.2	213
Financial position at year-end:					
Total assets	¥697.2	¥645.3	¥587.3	+8.0%	$6,640
Interest-bearing debt	(0.2)	(0.3)	(0.2)	−33.3	(2)
Total net assets	573.2	529.2	499.0	+8.3	5,459
Cash flows during the year:					
Cash flows from operating activities	¥ 53.5	¥ 77.5	¥ 73.2	−31.0	$ 510
Operating free cash flows	63.0	91.0	69.0	−30.8	600



Performance in 2013 (Core Basis)

In 2013, sales and profits increased with strong revenue growth more than offsetting higher cost of sales and expenses resulting from the weaker yen. Revenues rose 9.6 percent year-on-year to ¥423.7 billion as sales, royalties and other operating income increased. In domestic sales, the launch of new products and new dosage forms, and steady growth in sales of major products exceeded the negative impact from the National Health Insurance (NHI) drug price revisions and the expiration of the co-marketing agreement for the osteoporosis treatment Evista. Outside Japan, sales growth was driven by increased milestone revenue in addition to the positive impact of the weaker yen and rising exports of Actemra.

In the oncology field, Perjeta contributed to sales from its launch in September 2013, and sales of Avastin, Tarceva and other major products expanded steadily. Sales in the bone and joint diseases field decreased overall. Excluding Evista, however, sales grew more than 20 percent year on year, led by

	Billions of yen (Except as otherwise specified)			Percent change	Millions of U.S. dollars[1] (Except as otherwise specified)
	2013	2012	2011	2013/2012	2013
Amounts per share (Yen and U.S. dollars):					
Net income	¥ 94.69	¥ 85.64	¥ 83.27	+10.6%	$0.902
Equity per share attributable to Chugai shareholders (BPS)	1,049.47	970.08	914.72	+8.2	9.995
Dividends	45.00	40.00	40.00	+12.5	0.429
Number of shares outstanding	559,685,889	559,685,889	559,685,889		
Number of employees	6,872	6,836	6,779		
Ratios:					
Operating profit to revenues (%)	18.9	19.6	17.7		
Ratio of net income to equity attributable to Chugai shareholders (ROE) (%)[2]	9.3	9.0	8.3		
Ratio of equity attributable to Chugai shareholders (%)	82.0	81.8	84.8		
R&D expenditures to revenues (%)	17.5	17.2	18.9		
Payout ratio (%)[3]	47.5	46.7	48.0		

Notes: 1. The U.S. dollar amounts have been converted from Japanese yen amounts at the rate of ¥105 to U.S.$1.00, the approximate exchange rate prevailing on December 31, 2013.

2. Ratio of net income to equity attributable to Chugai shareholders (ROE) = Net income attributable to Chugai shareholders/Capital and reserves attributable to Chugai shareholders (average of beginning and end of fiscal year)

3. Equivalent to the Total return ratio because Chugai did not implement a share repurchase.

Edirol, with contributions from the subcutaneous formulation of Actemra and Bonviva, launched in May and August 2013, respectively. In the renal diseases field, growth in sales of Mircera offset declining sales of Epogin, and sales began to increase overall during the second half of 2013. In the transplant, immunology and infectious diseases field, sales of Pegasys and Copegus decreased, reflecting the shrinking market for interferon.

Various expenses increased during 2013. Cost of sales rose primarily due to the depreciation of the yen. Promotional costs increased due to the launch of new products and new indications. R&D expenditures rose with the start of full operations at Chugai Pharmabody Research Pte. Ltd.

As a result, core operating profit increased 5.7 percent year on year to ¥79.9 billion and core net income rose 11.0 percent to ¥52.6 billion, meeting Chugai's forecast for revenues and operating profit issued at the beginning of the year.

About Core Basis Results

Chugai reports its results on a Core basis from 2013 in conjunction with its decision to adopt IFRS. Core basis results are the IFRS basis results adjusted to exclude non-Core items, and are consistent with the concept of Core basis results disclosed by Roche. Core basis results are used by Chugai as internal performance indicators, for representing recurring profit trends both internally and externally, and as indices for setting profit distributions such as returns to shareholders. No items have been excluded from the IFRS balance sheet, as the Core basis results concept only applies to the income statement.

Stra
for
Innovation

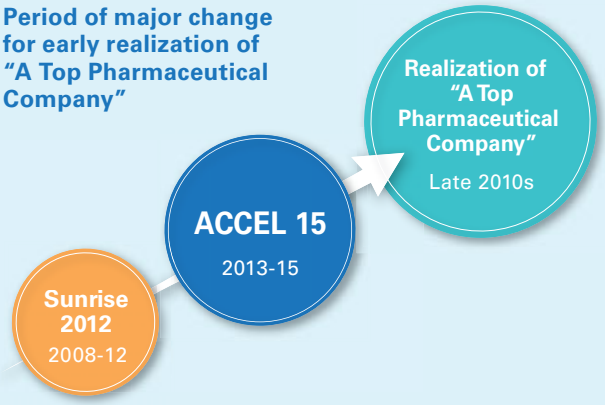
Strategy

In our mid-term business plan, ACCEL 15, we have set four strategic policies designed to further increase corporate value by evolving and linking Chugai's current strengths, and accelerating innovation. We will continue to push toward achievement of our goal of making Chugai a top pharmaceutical company that creates value for and meets the expectations of stakeholders.

Overview and Progress of ACCEL 15

Positioning of Mid-Term Business Plan

Period of major change for early realization of "A Top Pharmaceutical Company"



Strategic Policies

1. Increase of Marketing Productivity
2. Acceleration of Global Development
3. Continuous Generation of Innovative Projects
4. Further Strengthening of Management Infrastructure

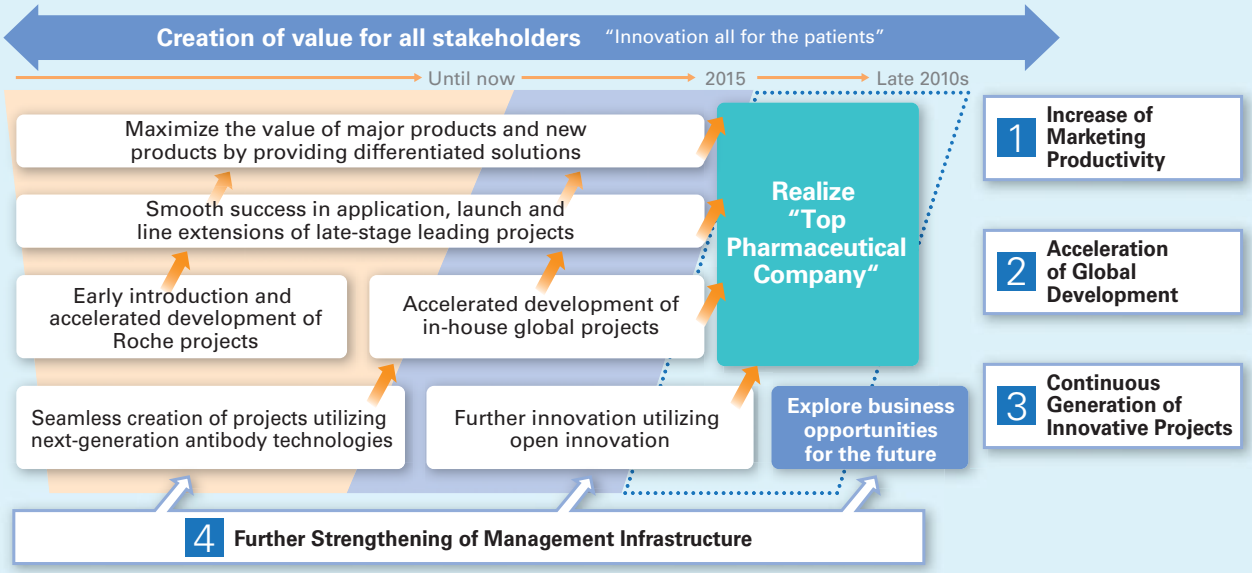
Quantitative Guidance

- **Core EPS CAGR[1] (2012-15)**
  Mid-to-high single-digit growth[2]
- **Core EPS payout ratio**
  Approx. 50% on average

Notes: 1. CAGR: Compound Annual Growth Rate
2. Average constant exchange rate (average for 2012)

ACCEL 15 Agenda for Value Creation

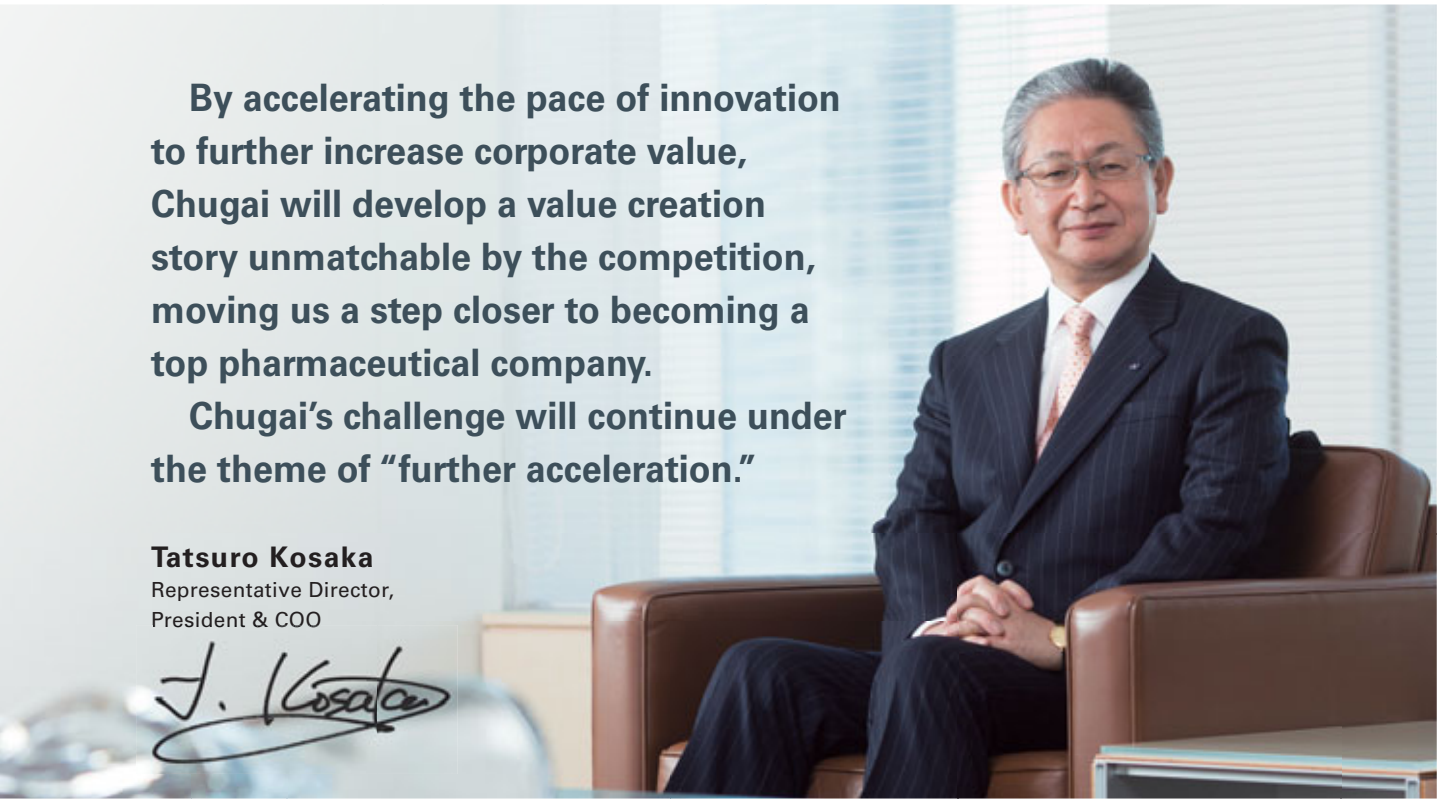
Further enhancing the flow of value creation by evolving and linking Chugai's current strengths



Progress of ACCEL 15

Strategic Policies		Achievements
1	**Increase of Marketing Productivity**	• Consulting promotion, e-promotion • Enhanced implementation of medical evidence activities • Utilization of contracted sales forces
2	**Acceleration of Global Development**	• Progress of in-house antibody projects ACE910, CIM331, SA237
3	**Continuous Generation of Innovative Projects**	• Full-fledged operations at Chugai Pharmabody Research • Advance in next-generation antibody technologies
4	**Further Strengthening of Management Infrastructure**	• Strategic capital expenditure • Expansion of overseas business • Accelerated diversity

Message from the President



By accelerating the pace of innovation to further increase corporate value, Chugai will develop a value creation story unmatchable by the competition, moving us a step closer to becoming a top pharmaceutical company.

Chugai's challenge will continue under the theme of "further acceleration."

Tatsuro Kosaka
Representative Director,
President & COO

Progress of ACCEL 15

Our strategic policies progressed steadily and produced significant achievements in 2013.

We made significant progress in 2013, the first year of mid-term business plan ACCEL 15. It was a very productive year.

Under ACCEL 15, Chugai is aiming to build an overwhelming competitive advantage by evolving and linking its unique strengths and accelerating innovation to further increase its corporate value. The plan sets out four strategic policies, and last year we achieved solid results in each one.

The first is "increase of marketing productivity." To that end, customer relationship management functions, which had been dispersed among multiple departments, were integrated into a single unit. Bringing these functions together has enabled us to offer solutions in line with the genuine needs of our customers. In addition, we established a new organizational structure that appropriately separates medical affairs and marketing activities to generate convincing clinical data and ensure a high level of scientific soundness and transparency. We also moved to build greater flexibility into our sales operations through measures such as utilizing contract sales forces as needed for new product launches.

Achievements in the First Year of ACCEL 15

- Launched three products: Perjeta, Bonviva and Actemra subcutaneous formulation
- Obtained approval for three significant additional indications: Avastin (two indications) and Tarceva
- Established Edirol as the number-one brand in oral osteoporosis drugs
- Actemra achieved blockbuster status, with global sales reaching 1 billion Swiss francs*
- Filed for approval in Japan of AF802, which was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA)
- Started development of seven new projects

*1 Swiss franc = 105 yen (Average exchange rate in 2013)

For the second strategic policy, "acceleration of global development," our in-house projects progressed substantially. One example was AF802, which we have been developing as a potential treatment for ALK-positive non-small cell lung cancer. Reflecting positive evaluation of the drug's

high response rate, our application for regulatory approval was accepted with unprecedented speed in Japan and AF802 was designated as an orphan drug. It was also granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA). Our in-house antibody projects, ACE910, CIM331 and SA237, also advanced steadily.

For our third strategic policy, "continuous generation of innovative projects," we made further progress in our recycling antibody and other proprietary next-generation antibody technologies. Novel therapeutic antibody candidates are emerging from Chugai Pharmabody Research Pte. Ltd. (CPR), which has entered full scale operations following its establishment in Singapore in 2012.

In line with our fourth strategic policy, "further strengthening of management infrastructure," we expanded production facilities for biological active pharmaceutical ingredients and investigational drugs to enhance development and production of biopharmaceuticals, an area of strength for Chugai. In addition, we invested in production facilities for injection products to support our future development strategy and meet the needs of patients. We also took steps to increase earnings outside Japan. In Europe, we in-licensed the rights to commercialize anamorelin from Switzerland-based Helsinn group, and in China, we established a sales and marketing subsidiary.

Quantitative Results in 2013

From a quantitative perspective, strong growth also became evident, both top- and bottom-line.

Tangible results of our initiatives in 2013 included the launches of Perjeta, Bonviva and a subcutaneous formulation of Actemra. All three products have shown promise as therapies with expected high efficacy or other benefits that can dramatically reduce the burden on patients. Chugai also obtained approval for important additional indications for Avastin and Tarceva. At the same time, sales of our core products also grew strongly. Edirol, which was launched in 2011, has become the number-one brand among oral osteoporosis drugs in Japan. In addition, global sales of Actemra, including sales by Roche, reached 1 billion Swiss francs for the first time. The fact that Actemra, discovered and developed by Chugai, has evolved as one of the core growth drivers of the Roche Group has a tremendous meaning for us as we maintain our independence within the group.

We also enhanced our product pipeline. Projects moved forward steadily for the most part, including those from in-house research that I mentioned earlier. Visible results included the advancement of seven new projects into clinical trials.

In financial results, strong growth in revenues offset the increase in cost of sales and operating expenses due to the depreciation of the yen. We posted solid bottom-line growth with core operating profit increasing 5.7 percent compared with the previous year and core EPS up 10.6 percent.*

* Core indicators were introduced with the application of International Financial Reporting Standards (IFRS) in 2013 to represent Chugai's profit trends internally and externally. Core results are IFRS results adjusted to exclude the impact of non-Core items such as acquisition of intangible assets (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).

ACCEL 15 and Future Initiatives

We will not settle for the status quo, and will put our full effort into further acceleration.

While we made significant progress in 2013, we are not satisfied with our current accomplishments. Continuing to innovate is our mission. We will

constantly work to achieve ACCEL 15, and then become a top pharmaceutical company to earn strong support from all of our stakeholders.

I will now explain our upcoming initiatives in line with the four strategic policies, as I did in my review of 2013.

Increase of Marketing Productivity

As major changes continue in our operating environment, high product potential, reliable quality and generation of convincing clinical evidence will become increasingly important for delivering real solutions to patients and healthcare providers. Under the consulting-based promotion system we established in 2013, we will merge our product and customer policies to carry out the measures best suited to each region and facility. This will help to expedite the market penetration of our products and enhance Chugai's reputation.

Generating strong sales growth will be a particular focus in 2014. We will work to put Perjeta and Bonviva, launched in 2013, on a steady growth path and accelerate the uptake of our growth drivers including Avastin, Edirol, Mircera and Actemra, which was recently launched in a subcutaneous formulation.

Acceleration of Global Development

Consistently generating new global drugs will be important for our future growth. Acceleration of global clinical development to overcome fierce competition will be vital for our success.

To speed up projects and reduce idle time between stages, we plan to change our development structure to foster stronger cooperation among research, development, production and other functions. In addition, we will follow the development model used for AF802, which has a higher probability of success. AF802 has yielded good results in clinical trials, and making it available to patients as early as possible is a priority for Chugai. We expect it to become our next global drug after Actemra.

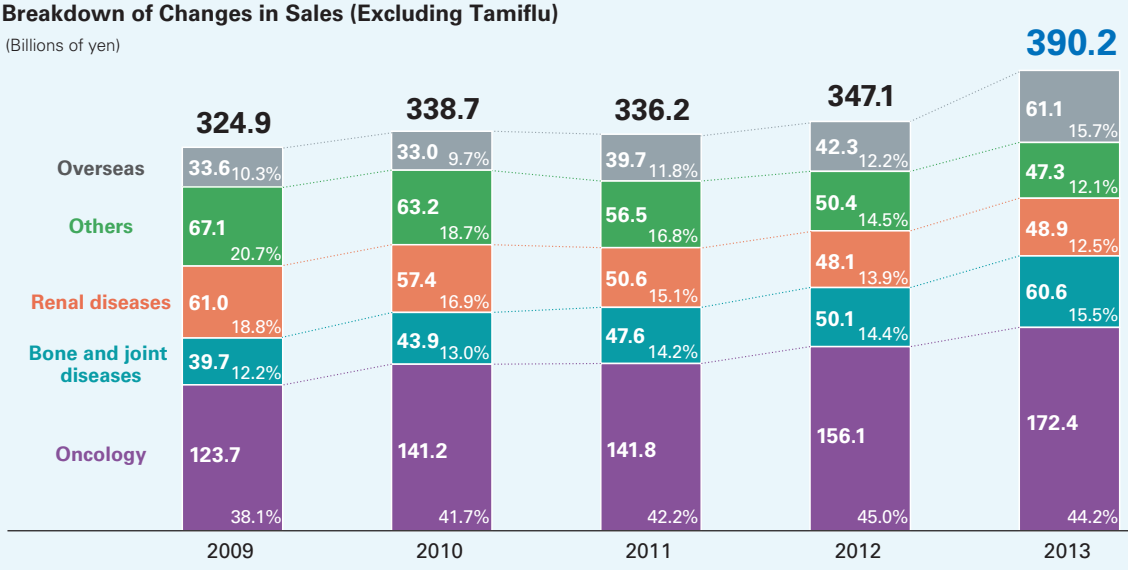
In addition, we will advance global development of in-house projects. We will take the lead in multinational studies for CIM331 and SA237, and will work to strengthen our clinical science functions and enhance our competitiveness in study design as we establish the framework for simultaneous global development.

Continuous Generation of Innovative Projects

Chugai's state-of-the-art proprietary antibody technologies, including its recycling antibody and bispecific antibody technologies, have enabled us to

Breakdown of Changes in Sales (Excluding Tamiflu)

(Billions of yen)



Note: Figures for years prior to 2013 have been restated to exclude sales of Evista.
Japanese GAAP is applied to the figures prior to 2011.

target molecules that were not possible to target with conventional antibodies. In the area of small molecules, we have also created the foundation for new advances and are poised to begin creating new drug candidates that have high expectations worldwide.

Looking ahead, while we will maintain our cutting-edge technologies at the highest level, we must apply those technologies to continuously generate new drug candidates with speed to address medical need. We will preferentially allocate resources to enhance antibody discovery at CPR and build a strong framework for rapid generation of new projects.

Further Strengthening of Management Infrastructure

In executing the three strategies above, we will create a more efficient and flexible cost structure through information technology and innovations in our procurement strategy, as well as appropriate control of headcount and capital expenditures. At the same time, we will strengthen our management infrastructure with strategic investments and other measures that position Chugai for future growth opportunities.

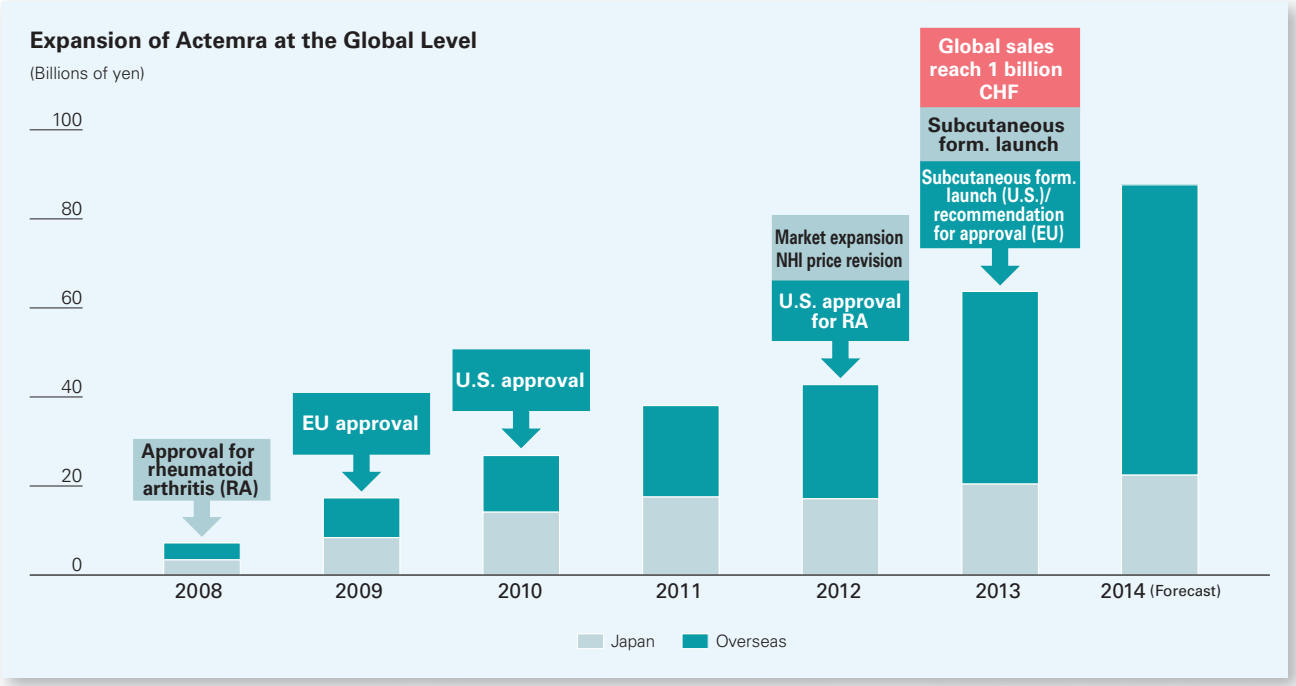
Among these measures, I place particular emphasis on changing our human assets and organizational culture, primarily by utilizing talent management and promoting diversity. These changes are essential to making Chugai a company that continues to innovate. By focusing on various measures and organizational reforms, I will ensure that Chugai evolves into a company that incorporates global perspectives and diverse values in its solutions, and undertakes innovation independently.

Performance Forecast for 2014

We expect solid revenue growth driven by core products.

In 2014, we project that solid growth in sales of core products for oncology and bone and joint diseases, royalties and other operating revenues, will offset the impact from the NHI drug price revisions. As a result, we forecast revenues of ¥451.0 billion, an increase of 6.4 percent compared with 2013. In the oncology field, we expect sales to rise 2.7 percent. Sales growth will be driven by our portfolio of products for breast cancer and greater use of Avastin, which obtained approval for two additional indications in 2013. In the bone and joint diseases field, we expect robust growth of 11.1 percent as we focus on maximizing the value of growth drivers Actemra and Edirol and expediting the market uptake of Bonviva. Overseas sales are forecast to climb 35.0 percent, led by the continued rapid growth of Actemra.

On the other hand, cost of sales and operating expenses are also expected to rise due to the weaker yen. Other factors driving up expenses will include increased spending for promotion of new products, faster development of in-house projects and the escalation of research activities at CPR. As a result,



we forecast that core operating profit will decrease 11.1 percent to ¥71.0 billion. We plan to maintain cash dividends at ¥45 per share, the same as in 2013, for a core payout ratio of 54.5 percent.

Increasing Corporate Value

We will work confidently to achieve further acceleration to increase Chugai's corporate value.

When Chugai announced ACCEL 15, it made a commitment to stakeholders that it would devote its efforts to advancing the plan's strategic policies, based on its business philosophy of "innovation all for the patients." Our stated objective was to become a "top pharmaceutical company" as early as possible in the second half of this decade.

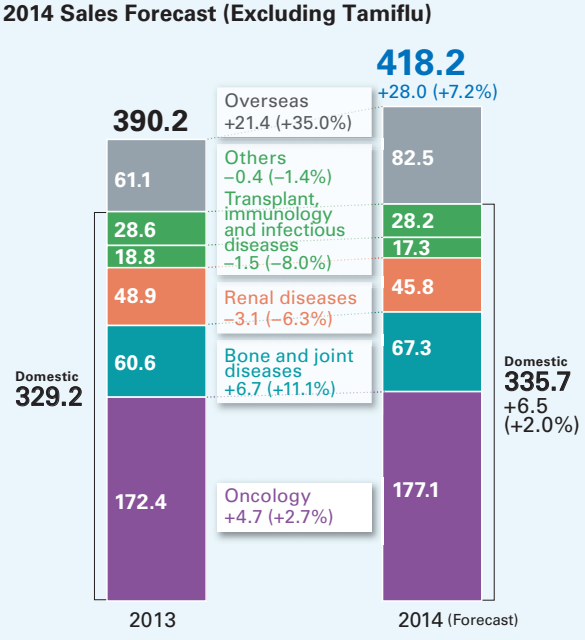
As I said, many aspects of Chugai's operating environment are changing every moment, from industry trends and economic conditions to healthcare systems and the needs of patients and healthcare facilities. I believe that the key to dealing with these changes effectively while continuing to move forward is to implement a value creation cycle that our competitors cannot imitate. ACCEL 15 is our value creation story, and we must evolve and link the strengths that Chugai has built to achieve this plan.

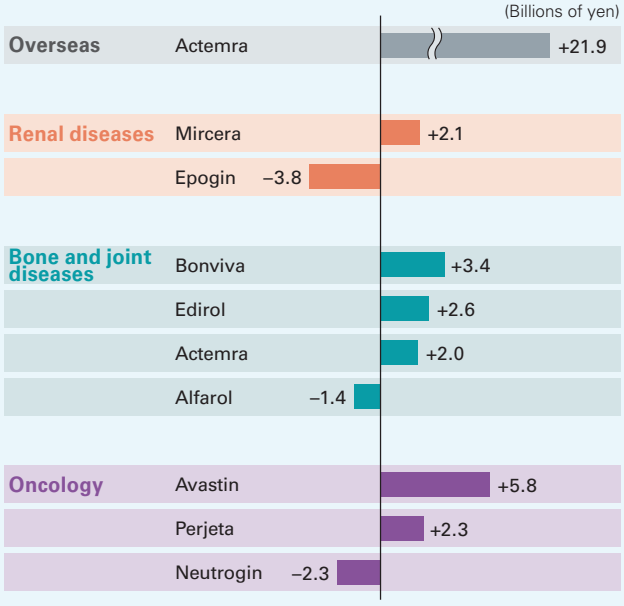
The progress Chugai has made reaffirms my belief that we are moving in the right direction.

We will work confidently to achieve further acceleration under ACCEL 15.

We ask for the ongoing support of shareholders and investors as we continue taking on new challenges to deliver value to all our stakeholders.

2014 Sales Forecast (Excluding Tamiflu)





Stren

for Innovation

Feature: Creating Value from Chugai's Strengths

Our Value Creation in Lung Cancer and IL-6 Inhibitors

Maximizing the unique set of strengths Chugai has built – strengths acquired through continuous innovation – will be essential to driving further value creation for all stakeholders. Chugai's role will be to generate new value by linking these strengths to the enhancement of corporate value.

Feature:
Creating Value from Chugai's Unique Strengths

Chugai has established a number of unique strengths that contribute to increasing its corporate value. These strengths are a result of active efforts to support our business philosophy of "Innovation all for the patients."

Our strengths can be grouped largely into the seven categories listed below. Together, they drive Chugai's efforts to become a top pharmaceutical company and fulfill its mission of contributing to the medical community and human health around the world. By further evolving these strengths, we will continue to deliver new value to society.

In this feature, we present two model cases of our efforts, in the lung cancer field and our IL-6 inhibitor, to illustrate how Chugai's unique strengths create corporate value.

Chugai's Seven Strengths

Chugai's Seven Strengths

To help stakeholders recognize and understand Chugai as it endeavors to become a top pharmaceutical company, we strove to pinpoint the source of our value. Chugai's "strengths" were identified through internal and external interviews and evaluated from the standpoint of "value to patients" and "competitive advantage," resulting in 25 categories. Then, through a process including outside analysis, we narrowed those down to seven strengths.

1. Therapeutic areas in which satisfaction with treatment is low and that offer potential to create new markets with innovative medical products
2. A treatment approach designed and implemented according to each patient's unique molecular and genetic profile

Case 1: Value Creation in the Lung Cancer Field

Characteristics of Lung Cancer

In developed countries, lung cancer is the most prominent cause of cancer death. In Japan, it is estimated that in 2015 the disease will affect about 115,000 people and be responsible for approximately 75,000 deaths. In general, the prognosis of lung cancer is poor compared with breast cancer and colon cancer, partly because the lack of specific symptoms in the early stages makes early diagnosis difficult.

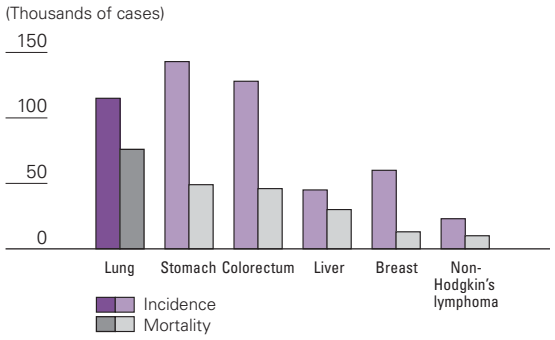
Lung cancer is treated with a multimodal approach that combines surgery, radiotherapy and drug therapy, but determining the optimal treatment regimen requires tests to examine the histological type and stage of the cancer. For example, small cell lung cancer and non-small cell lung cancer (NSCLC) are the two histological classifications, but this distinction is made because their treatment methods are markedly different.

NSCLC accounts for more than eight out of every 10 cases of lung cancer. Advanced and recurrent NSCLC are treated primarily with drug therapy, which starts with the drug initially believed to be optimal (first-line treatment). If the cancer progresses, treatment continues with second- and third-line treatment options using different drug types or combinations. In first-line treatment of non-squamous advanced or recurrent NSCLC, a combination of Avastin with other anticancer agents, a two-drug regimen known as platinum-doublet chemotherapy,[1] is one of the current standards of care (the best available evidence-based therapy).

PHC for lung cancer has advanced dramatically in recent years with the emergence of several new drugs and because it is now possible to analyze a cancer's characteristics at the genetic level in the testing stage. For example, patients whose tumors test positive for epidermal growth factor receptor (EGFR) genetic mutations can be expected to respond well to treatment with an EGFR tyrosine kinase inhibitor such as Tarceva. Those who test positive for the anaplastic lymphoma kinase (ALK) fusion gene may be treated with an ALK tyrosine kinase inhibitor. To contribute to the treatment of ALK-positive patients, Chugai has developed the ALK tyrosine kinase inhibitor AF802 (generic name: alectinib), which is currently under regulatory review in Japan.

1. Combination therapy that pairs a platinum-based agent (cisplatin or carboplatin) with one of the new anticancer agents marketed since the 1990s, such as paclitaxel, gemcitabine or pemetrexed

Incidence and Mortality by Cancer Type
(Estimates for 2015)



Source: Cancer White Paper 2012 (Shinoharashinsha Publishers Inc.)

Examples of Strengths That Enable Value Creation

[1] High product potential that addresses unmet medical need

Innovative Drug Creation and Product Lineup

Chugai provides many new medicines that address unmet medical need. Under the Premium to Promote the Development of New Drugs and Eliminate Off-Label Use introduced by the Japanese government on a trial basis in 2010, we are actively meeting development requests made through the Review Committee on Unapproved Drugs and Indications with High Medical Needs. **Seventeen of our compounds and 38 products have received premium pricing** in the 2014 NHI drug price revisions (12 obtained approval between 2011 and 2013).

[1] High product potential that addresses unmet medical need

A Dominant Presence in Oncology

Chugai has a full lineup of oncology medicines that includes both anticancer agents and supportive care agents. We have established a powerful presence in the oncology field in Japan, driven by the high market share of major products such as Avastin and Herceptin. **In 2013, we maintained our top position with a market share of 20.4 percent,* up 1 percentage point** from 2012.

* Copyright 2014 IMS Japan K.K.
Source: JPM 2013. Reprinted with permission. The scope of the market is defined by Chugai.

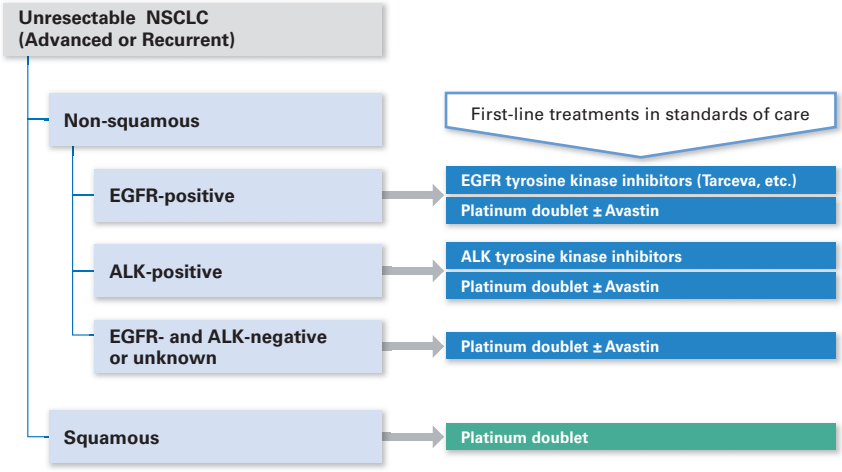
Contribution as a Leading Company in the Field of Oncology

Chugai has long contributed to the field of lung cancer through its supportive care agents such as Neutrogin, which acts against neutropenia induced by drug therapy or radiotherapy, and Kytril, an antiemetic. Supportive care agents have not only helped to make cancer treatment safer, but have also improved treatment outcomes by enabling the use of more potent anticancer agents. Chugai added anticancer agents to its product portfolio with the launch of Tarceva in 2007 and the approval of Avastin for lung cancer in 2009. Today, Chugai has an excellent reputation among healthcare professionals as a leading provider of both anticancer agents and supportive care agents for lung cancer.

Both Tarceva and Avastin are molecular targeted therapies with novel modes of action. Tarceva binds to EGFR molecules, which promote the proliferation of cancer cells, to block the signals involved in cell proliferation. Avastin acts on the environment around the tumor by inhibiting angiogenesis to slow the progression of cancer. Both drugs are scientifically proven to extend survival, one of the goals of cancer therapy, and are recommended as standards of care in treatment guidelines in Japan and other countries.

Molecular targeted therapies are less likely to cause the side effects commonly associated with conventional anticancer agents, such as neutropenia and hair loss. On the other hand, they have different types of side effects that require attention. In most cases, treatment can be continued if these side effects are dealt with appropriately. Although infrequent, some serious, life-threatening side effects have been reported. It is essential to not only treat these side effects when they develop, but also to take measures such as keeping healthcare providers well-informed of background factors in high-risk patients to help ensure appropriate use of the drugs. In handling these medicines, Chugai's medical representatives

Types and Therapies of Non-Small Cell Lung Cancer



Examples of Strengths That Enable Value Creation

[7] Support for healthcare delivery

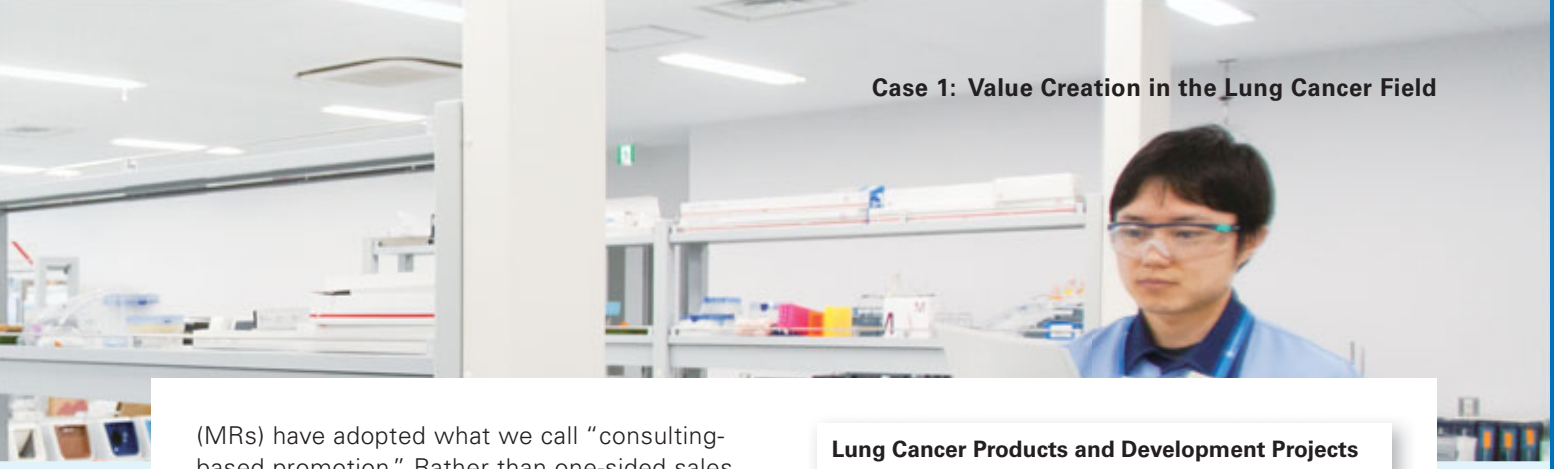
Oncology MRs with a High Level of Expertise

Our team of **approximately 500 oncology MRs**, who have specialized knowledge in areas such as pathology and treatment methods, practices **consulting-based promotion**, which entails providing information and treatment proposals. The excellent reputation they have built among healthcare professionals creates substantial value.

[7] Support for healthcare delivery

Participation and Leadership in Promoting Multidisciplinary Team Approach to Care

Chugai is focusing on promoting **multidisciplinary team care** in which various healthcare professionals, including doctors, collaborate to provide treatment and care tailored to the patient's condition. Our efforts include developing training programs for team members and holding workshops and study sessions. As a result, Chugai is earning wide recognition as a company that provides relevant support for multidisciplinary team care.



(MRs) have adopted what we call "consulting-based promotion." Rather than one-sided sales promotion to the primary physician, this approach entails proposing ideas for treatment and side-effect management while showing the various professionals involved, including pharmacists, nurses, and doctors in other specialties, the scientific basis of benefits and risks.

In ACCEL 15, our mid-term business plan, we state our commitment to further advance this patient-focused marketing strategy and tailor customer policies to the needs of each region and facility. In one such initiative, we held workshops throughout Japan in 2013 to promote the multidisciplinary team approach to care, demonstrating our value as a liaison within and outside medical institutions.

Our Strength in Safety

Chugai's consulting-based promotion is supported by an extensive body of safety information. We are among the industry leaders in Japan in terms of managing safety information and the number and quality of drugs for which a risk management plan (RMP) has been implemented, a requirement that took effect in April 2013. This is the result of our experience in conducting all-case registration surveillance when launching products such as Avastin and Tarceva, and the world-class pharmacovigilence and communication organization we have built in collaboration with the Roche Group. Chugai views the provision of safety information as a valuable contribution to the benefit of the medical community and patients worldwide. We will continue to take on new challenges such as enhancing epidemiological functions and further raising the precision of safety assessments in order to maintain a high-quality safety management system. (For details on safety information, see "Drug Safety" on pages 66-67)

Lung Cancer Products and Development Projects

Product Name	Application in Lung Cancer Treatment	Mode of Action
Avastin	Molecular targeted therapy that blocks angiogenesis	Anti-VEGF humanized monoclonal antibody
Tarceva	Molecular targeted therapy that inhibits EGFR activation	EGFR tyrosine kinase inhibitor
Neutrogin	Supportive care agent for chemotherapy-induced neutropenia	Recombinant human G-CSF
Kytril	Supportive care agent that suppresses chemotherapy-induced nausea and vomiting	Antiemetic 5-HT_3 receptor antagonist

Compound Name	Development Stage	Mode of Action
AF802 (RG7853)	Filed in Oct. 2013 (Japan)	ALK inhibitor (Oral)
RG3638	Phase III multinational study	Humanized anti-MET monoclonal antibody (Injection)

Continuously Addressing Unmet Medical Need

Research and development of new medicines is vital to maintaining Chugai's position as the leading company in the lung cancer field, which

[6] Commitment to safety management

Leadership in Safety Information Provision and Safety Measures

Chugai conducted post-marketing all-case registration surveillance and safety management of **over 20,000 cases** for three products – Avastin, Tarceva and Actemra. From this experience, Chugai has become an industry leader in collecting, analyzing and acting on safety data, and has earned **solid recognition for its safety measures** from healthcare providers.

[5] Knowledge and experience as a pioneer in PHC

Drug Discovery Platform Based on Oncology and Personalized Healthcare (PHC)

As of January 30, 2014, Chugai's development pipeline contains **12 compounds or 14 projects from its own research** (including 6 in the oncology field). In addition, **20 projects are based on PHC** (including 14 in the oncology field). With this well-stocked pipeline, we are creating new drugs that will contribute to the advancement of cancer treatment and PHC.

remains an area of high unmet medical need. Our pipeline currently includes AF802, which was developed in-house, and other compounds targeting lung cancer. As we work to promptly file for and obtain regulatory approval for these compounds, we must also create the next innovative projects.

ALK-positive lung cancer is likely to be detected in young women with no history of smoking. It is characterized by rapid progression and a limited response to chemotherapy. Chugai was able to file for regulatory approval of AF802 for this type of lung cancer with exceptional speed after the Japanese Ministry of Health, Labour and Welfare designated it as an orphan drug. Several key factors made this possible: our many years of focus on the significance of fusion genes and research on the development of kinase inhibitors; starting discovery research immediately after the publication of a research paper on ALK translocation by Professor Hiroyuki Mano et al. of Jichi Medical University in 2007; and use of the Roche Group's world-leading drug discovery platform.

Delivering Innovative Medicines to Patients as Quickly as Possible

Chugai has carried out development and filed for and obtained approval of numerous drugs in-licensed from Roche to help in solving Japan's drug lag. This experience has been instrumental in raising our clinical development productivity and speed to a high level.

Now we are working to further evolve the knowledge, infrastructure and systems we have cultivated for faster global development. Specific measures to maximize product value more quickly include leading development design to meet clinical needs worldwide and establishing a seamless supply system for investigational new drugs. By including patients with the target disease in phase I clinical trials, which are normally conducted on healthy adult subjects, we are able to determine the efficacy of a drug at an earlier stage. This is called early proof-of-concept,[2] and allows us to get a quick start on developing plans for global phase III trials.

In addition, Chugai will focus on implementing a development model with a high probability of success based on stronger scientific hypotheses. Our aim, premised on the PHC approach, is to develop medicines for areas with high unmet medical need by zeroing in on molecules that are strongly associated with the underlying cause of the disease. Our goal is to quickly file for regulatory approval based on early findings showing clear efficacy in phase I/II and phase II/III clinical trials. In the case of AF802, we achieved development (from late-stage preclinical development to filing) in just five years, remarkably fast compared to the 10 years commonly required to develop a new drug.

At Chugai, we understand that in addition to the results of these best practices, it is important to regularly raise speed and productivity. Therefore, to optimize the development process, we have assembled small molecule and biological compound task forces, which are now focusing on process improvements.

2. Demonstration that the therapeutic effect conceived in the research stage is effective in humans

Examples of Strengths That Enable Value Creation

[3] Strategic alliance with the Roche Group

In-Licensing Projects from the World's Top-Tier Company

Chugai is the main supplier in Japan of the pharmaceutical products for the Roche Group. Roche is one of the world's leading pharmaceutical companies, and Genentech, a leading biopharmaceutical company, is also a member of the Roche Group. Based on this structure, Chugai has successfully developed and launched **19 products** in-licensed from the Roche Group in the past six years.

[2] One of the richest pipelines in Japan

Pipeline and Participation in Multinational Studies in the Oncology Field

Chugai's pipeline in the oncology field is **one of the richest in Japan with 18 projects under way**, and features many projects that target diseases with high mortality rates and high unmet medical need. In addition, we have participated in multinational studies of **21 projects over the last five years**, the most for a Japanese pharmaceutical company.

Case 2: Value Creation in IL-6 Inhibitors

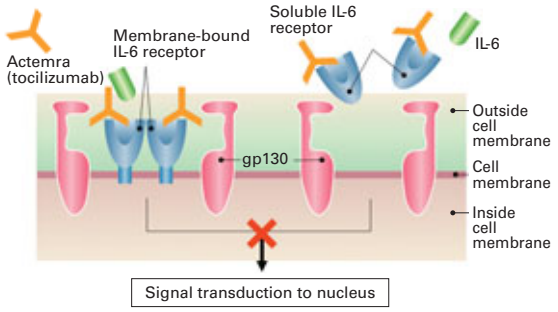
IL-6 and Actemra, the First Therapeutic Antibody Created in Japan

Interleukin-6 (IL-6) is an inflammatory cytokine produced from various cells. It plays a central role in regulating immune and inflammatory responses. However, excessive production of IL-6 has been found to cause a variety of inflammatory diseases, and IL-6 overproduction is also a cause of joint inflammation in diseases such as rheumatoid arthritis (RA).

In 1986, Dr. Tadamitsu Kishimoto's group at Osaka University succeeded in isolating the IL-6 protein. Chugai, attracted by the mechanism of IL-6, began developing an IL-6 inhibitor together with Osaka University. Based on its research platform built up over many years of bioresearch, Chugai continued to make significant progress toward the creation of a treatment, including structural elucidation of the signaling molecules of IL-6 and establishment of humanization technology for mouse antibodies. These efforts culminated in the anti-IL-6 receptor antibody Actemra, the first therapeutic antibody created in Japan and the first in the world to target IL-6.

Actemra inhibits signal transduction to the nucleus by binding to IL-6 receptors, thereby inhibiting IL-6 from binding to its receptors. As the only pharmaceutical product with a mode of action that inhibits IL-6, it has generated a high level of scholarly interest among healthcare professionals, and has been the subject of numerous conference presentations and academic papers in various fields, primarily RA.

Mode of Action



Advantages in Development and Manufacturing

Actemra obtained approval for Castleman's disease in 2005, and for RA, systemic juvenile idiopathic arthritis (sJIA) and poly-articular course juvenile idiopathic arthritis (pJIA) in 2008. In the development of Actemra, one of the largest ever clinical trial programs to test the drug on RA was planned. The clinical trial was conducted on 601 patients in Japan and 4,009 patients overseas and featured an extension study in which the drug continued to be administered to patients who had responded. An important benefit of this extension study was the accumulation of follow-up data on efficacy and safety. The expertise in therapeutic antibody development that Chugai gained through these studies provides a powerful competitive advantage today.

In addition, the antibody manufacturing capability that Chugai established through Actemra is now at a dominant level. Antibodies have a high molecular weight and require about 1,000 times

[4] Cutting-edge drug discovery technologies, especially biotechnology

Knowledge and Expertise in Creating Therapeutic Antibodies

Chugai **created the first therapeutic antibody manufactured in Japan (Actemra)**. Joint research with academia and our knowledge, expertise and technologies in antibody creation that were established through this experience have continued to evolve. For example, our subsidiary in Singapore specializes in research to create antibodies.

[4] Cutting-edge drug discovery technologies, especially biotechnology

A Leading Presence in Biopharmaceutical and Antibody Research

With more than three decades of experience in research and development of biopharmaceuticals, Chugai is among the top companies in Japan in terms of research capabilities. Our antibody research platform and technologies are at a high level, and **we rank second*** following Genentech **in the number of patents in force for therapeutic antibodies**.

* Source: Patent Result Co., Ltd.

the volume of conventional biologic medicines to obtain the equivalent effect. Only a handful of pharmaceutical companies in Japan manufacture antibodies, and none can match Chugai's production volume. This advantage stems from our substantial investment in facilities during the phase III clinical trials of Actemra, and the continuous innovations Chugai has made in cell culture methods and manufacturing processes to increase production volume and raise production efficiency.

Growth Based on Clinical Evidence

Actemra use is growing dramatically. One factor behind the rapid pace of growth is the clear value Actemra offers, including a high remission rate in RA and excellent long-term adherence to treatment. Moreover, studies such as all-case registration surveillance of approximately 7,900 cases and head-to-head comparison studies with a rival product have generated a convincing body of evidence that has led to broad recognition of the benefits Actemra can bring to patients. Based on this evidence, the European League Against Rheumatism (EULAR) issued recommendations that place Actemra on the same level as anti-tumor necrosis factor (TNF) inhibitors, its predecessors in first-line treatment with biologics.

One example of building evidence is the global ADACTA trial, announced in 2012, which compared Actemra in monotherapy with a competitive biologic. In this study, Actemra was shown to be significantly superior for reduction of signs and symptoms of RA at 24 weeks. To build further evidence, we are also conducting the FIRST-BIO study in Japan to evaluate the remission rate at 52 weeks in patients who had not previously used a biologic treatment. Moreover, we are currently considering a study to evaluate the economic benefit to Japanese patient lifestyles of treatment with Actemra. Clinical research to scientifically test pharmacoeconomic indicators is not often done in Japan, but Chugai will continue to step up its efforts to generate clinically useful data.

Our IL-6 Inhibitor Franchise

Actemra was able to demonstrate even greater value in 2013 with the launch of a new subcutaneous formulation (pre-filled syringe and auto-injector) in Japan. In the United States and Europe, the majority of drugs are available as subcutaneous injections, and the new formulation obtained regulatory approval in the United States in October 2013 and is expected to obtain approval in the EU in 2014. As the new formulation improves convenience for patients and helps to expand treatment options, uptake is expected to accelerate further in 2014. Actemra currently has four indications in Japan, and we are currently developing two additional indications overseas to expand the potential benefits of this drug.

In addition, Chugai is developing SA237 as an IL-6 inhibitor to follow Actemra. SA237 is a novel antibody developed utilizing Chugai's proprietary recycling antibody technology. The recycling antibody is molecularly engineered to enable a single antibody molecule to bind to the target antigen multiple times. This development is expected to enable the same effect to be obtained with a smaller dose and/or reduced dosing frequency.

Preclinical studies showed that by applying this groundbreaking technology, SA237 exhibited

Examples of Strengths That Enable Value Creation

[1] High product potential that addresses unmet medical need

No. 1 Position in Development and Marketing of Therapeutic Antibodies

Chugai is one of the few companies to successfully create, develop, manufacture and market therapeutic antibodies. In the growing therapeutic antibody market, Chugai is the leader in Japan, maintaining its top position with a **domestic share of 34.7 percent**.*

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Source: JPM 2013. Reprinted with permission. The scope of the market is defined by Chugai.

[4] Cutting-edge drug discovery technologies, especially biotechnology

World-Class Antibody Manufacturing Operations

In the field of biopharmaceuticals and therapeutic antibodies, Chugai's manufacturing operations are top class. Early on we set up safety and quality management systems that meet global standards and ensure we can comply with regulatory reviews in Japan, the United States and Europe. We have also established robust production facilities, including **bioreactors for biological active pharmaceutical ingredients (eight 10,000-liter and four 2,500-liter tanks)**.

plasma persistence four times that of Actemra. Phase I clinical trials have also demonstrated significant improvement in the effective duration. With its efficacy in inhibiting IL-6, SA237 is expected to have a wider range of indications than RA and Castleman's Disease, for which Actemra is currently approved. In the first half of 2014, Chugai is planning to start a phase III multinational study of SA237 with the expected indication of neuromyelitis optica, an inflammatory disorder of the central nervous system with high unmet medical need. (For details on Chugai's proprietary technologies, see "Chugai's Proprietary Technologies SMART-Ig and ART-Ig" on page 63.)

Delivering Value to the World

Actemra is a global blockbuster sold in more than 90 countries, and worldwide sales have grown to over 1 billion Swiss francs annually. Chugai is also aiming for global approval and marketing of SA237, and is now ready to start a multinational study.

Chugai's ability to deliver the value of its medicines to patients around the world is made possible by our strategic alliance with the Roche Group. Large-scale multinational studies are necessary in order to efficiently file for and obtain approvals in various countries. This is where the Roche Group's network, experience and know-how are invaluable. In addition, the Roche Group has a leading global presence with sales channels in more than 150 countries. We believe that by taking advantage of this marketing platform attuned to medical and therapeutic needs in each country, we can maximize the value of Actemra. Strengthening our cooperation with the Roche Group will therefore be a key to accelerating the expansion of our IL-6 inhibitor's presence.

The value creation model illustrated by IL-6 inhibitors can be considered an example of a major success. By combining its unique strengths in drug discovery and the Roche Group's global operating capabilities, Chugai will continue working to create value worldwide.

Timeline of Actemra Approvals

April 2005	(Japan)	Castleman's disease
April 2008	(Japan)	Rheumatoid arthritis
		Systemic juvenile idiopathic arthritis (sJIA)
		Polyarticular-course juvenile idiopathic arthritis (pJIA)
January 2009	(EU)	Rheumatoid arthritis
January 2010	(U.S.)	Rheumatoid arthritis (second-line biologic treatment)
April 2011	(U.S.)	sJIA
August 2011	(EU)	sJIA
October 2012	(U.S.)	Rheumatoid arthritis (first-line biologic treatment)
March 2013	(Japan)	Rheumatoid arthritis (new formulation: subcutaneous injection)
April 2013	(U.S.)	pJIA
October 2013	(U.S.)	Rheumatoid arthritis (new formulation: subcutaneous injection)

[7] Support for healthcare delivery

Generation of Advanced Scientific Evidence

To respond to societal demands such as appropriate use and post-marketing drug development, Chugai works to **generate scientific evidence based on clear medical plans**. We have earned a solid reputation among healthcare professionals for our efforts, resulting in high-quality evidence generation and provision of scientific information, through activities by the qualified division.

[4] Cutting-edge drug discovery technologies, especially biotechnology

Antibody Engineering and Other Next-Generation Technology

In recent years, Chugai has developed a series of innovative proprietary research technologies, including **recycling antibody, sweeping antibody and bispecific antibody**. These technologies are expected to play a key role in future antibody research by making it possible to target the molecules that were not possible to target with conventional antibodies.

Initia for Innovation

Performance Report and Future Initiatives

Under its business philosophy of "Innovation all for the patients," Chugai is innovating in all areas of its business operations. In this section, we summarize our 2013 performance and action policies in each area, and describe Chugai's value creation initiatives.

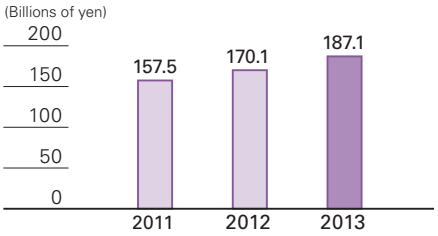
Overview of Activities in 2013

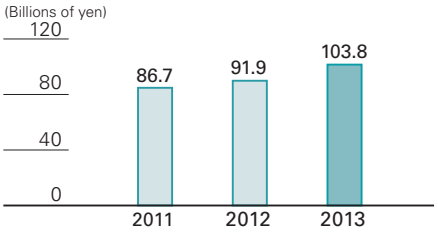
Items	Main initiatives	Main performance indicators in 2013
Marketing	• Promoting standards of care, regional healthcare and Personalized Healthcare (PHC) • Driving advances in medicine as Japan's leading oncology and therapeutic antibody company • Offering patient-centered treatment proposals through consulting-based promotion • Conducting disease awareness and patient support activities in mainstay product areas	• Share of sales in the Japanese therapeutic antibody market: 34.7%* • Share of sales in the Japanese oncology market: 20.4%* • Education and internal certification program for MRs with a high level of expertise: 140 certified Top Oncology MRs, 67 Top Non-Oncology MRs who completed training courses and 6 certified Top Non-Oncology MRs (as of the end of December 2013) • Disease awareness seminars sponsored (incl. co-sponsorship): 25 (with head office involved)
Development	• Improving clinical development of drugs to address unmet medical need • Increasing productivity and speed of global clinical development for earlier market launches • Conducting parallel development and regulatory filing of drug therapies and diagnostics that contribute to PHC • Strengthening lifecycle management to maximize product value	• Number of pipeline projects: 34 (as of January 30, 2014) • New products and new indications approved: 35 (2008-2013) • PHC-based development projects: 20 (as of January 30, 2014) • Projects in-licensed from Roche: 19 (2008-2013)
Research	• Continuously generating first-in-class and best-in-class drugs • Creating molecular targeted therapies that contribute to PHC • Strengthening innovative proprietary research technologies and creating innovative antibodies • Providing support and education for researchers from Asia	• Products from in-house research: 12 (as of January 30, 2014) • Start of full-scale operation at Singapore subsidiary Chugai Pharmabody Research (CPR) • Number of presentations at scientific conferences and publications in academic papers on Chugai's innovative proprietary technologies: 25 (2010-2013)
Intellectual property	• Protecting and effectively using rights for broadly applicable innovative technologies • Filing of high-quality patent applications and effectively allocating resources • Aggressive filing of patent applications outside Japan with a view to global co-development	• Number of patents held (including pending applications): 3,539 • Number of patents received in major countries: 295 • Construction of an antibody technology patent database • Improvement of efficiency by using electronic documents and visualizing workflows
Drug safety	• Strengthening pharmacovigilance system to meet the world's strictest standards and most comprehensive global regulations • Continuously conducting post-marketing surveillance and disseminating timely information on appropriate use • Preparing and implementing risk management plans (RMPs)	• Number of safety reports collected from Japan and overseas according to global standards for clinical trials and post-marketing studies: About 140,000 adverse drug reaction reports per year • New RMPs prepared and carried out: 5 products and 6 indications (most in the industry)
Production and procurement	• Providing a continuous stable supply of pharmaceuticals, raw materials and packaging materials • Strengthening global supply chain management • Continuously standardizing and optimizing purchasing processes to build fair, transparent relationships • Promoting purchasing that balances compliance, operational efficiency and cost reduction	• Start of investigational new drug manufacturing at the Ukima plant • Biological active pharmaceutical ingredient production facilities: Eight 10,000-liter bioreactors (Utsunomiya plant), four 2,500-liter bioreactors (Ukima plant) • Promotion of fairness and transparency that includes cataloging of indirect materials in the electronic purchasing system
Environmental protection and occupational safety	• Promoting global warming countermeasures, resource conservation and waste reduction • Thoroughly managing chemical substances • Disclosing environmental information • Enhancing environmental awareness and making environment-related contributions to local communities	• Energy consumption per employee compared with 2009: Down 7% (Chugai Group in Japan) • Amount of waste generated compared with 2012: Up 6% (Chugai Group in Japan) • Amount of landfill waste compared with 2012: Down 37% (Chugai Group in Japan) • Ratio of hybrid sales vehicles: 53.7%
Social contribution	• 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: Total of 198 vehicles over 29 years (total of five vehicles to five organizations in 2013) • Cumulative number of countries receiving free therapeutic drugs for treating lymphangiomas: 80 (program in its 23rd year) • Video presentations given at Dr. Kitanomaru's Bio Pharmaceutical Laboratory exhibit: 38,551
Human assets	• Fostering human assets who are competent in the global arena • Building work environments in which diverse people can succeed • Building sound labor-management relations • Creating safe, comfortable workplaces	• Leader development program, all-employee program, division programs, Self-Innovation Program (SIP) implemented • Percentage of female executives: 8.8% • Employees approved for telecommuting: 172
Corporate ethics and bioethics	• Fostering high ethical standards through training on the 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: 13,407 (includes repeat attendees; Chugai Group in Japan) • In-house education and training for people who handle laboratory animals: 53 sessions attended by 549 people • In-house education for people who handle human-derived test materials: 1 session attended by 450 people
Corporate governance	• Prompt decision-making, clarification of executive responsibilities and management transparency • Enhancing decision-making by introducing outside perspectives • Maintaining an internal control system • Proactive information disclosure and IR activities	• Number of Board of Directors meetings: 7 (average attendance rate of outside directors 97.1%) • Auditing system: 4 Audit & Supervisory Board Members (including 2 outside members) • Information events for the media and institutional investors: 11 • Number of security analysts and institutional investors with which individual meetings/conference calls were held: 280

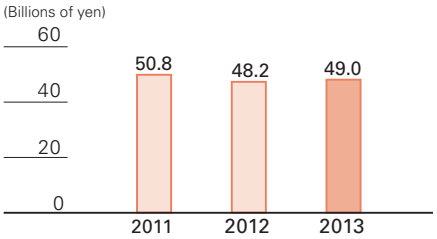
	Page reference	Items described in detail on website
• Participation in the 24-hour charity event Relay For Life • Customer inquiries answered by Chugai's Drug Information Center: 60,011 (includes telephone, e-mail and fax inquiries)	44-57	Relay For Life 2013/NPO Shuhei Ogita Fund Supporting Patients with Lymphatic Malformations/Drug Information Center
• Projects co-developed with Roche Group: 27 (as of January 30, 2014) • Projects in response to development requests for unapproved drugs/ indications: 12 (2011-2013)	58-61	Development Pipeline
• Number of published academic papers on Chugai's research activities: 104 (2010-2013) • R&D expenditures to revenues: 17.5% • Creation of new antibodies using Chugai's recycling antibody, sweeping antibody, bispecific antibody and other proprietary antibody technologies	62-64	Chugai's Proprietary Technologies/Drug Discovery/R&D Infrastructure/R&D Structure/CHAAO Sponsorship of International Forum/Supporting Researchers from Asia
• Patent infringement lawsuits filed against generic drug companies: 1 • Generic drugs blocked from market entry by exercising patent rights: 2	65	
• Number of scientific papers and conference presentations on safety based on the results of post-marketing surveillance: 24	66-67	Post-Marketing All-Case Surveillance/Feature: Ensuring That Patients and Healthcare Professionals Can Use Our Products with Confidence
• Number of key materials for which procurement strategies were developed and opinions exchanged with users: 12 • Issues of in-house newsletter *Purchasing News*: 4 • Internal e-learning held (for new employees and mid-career hires): 5 times	68-69	Purchasing Policy/Chugai Ethical Purchasing Standards/Initiatives in 2013/Stable Procurement of Raw Materials and Packaging Materials/Executing Global Supply Chain Management/Reliable Distribution of Pharmaceuticals/ Information Sharing for Quality and Safety/Ensuring Traceability/A Global-Standard Regulatory Compliance and Quality Assurance System/Policy for Regulatory Compliance and Quality Assurance
• Occupational incidence rate: 2.16 [(No. of occupational injuries and deaths/No. of hours actually worked) X 1,000,000] • Accidents accompanied by lost worktime: 1 (Chugai Group in Japan) • Lost workdays resulting from occupational accidents: 78 (Chugai Group in Japan)	70-73	Environmental Action Plans/Occupational Safety and Health System/Health Management/Mental Health/Power-Saving Measures/Introduction of Fuel-Efficient Sales Vehicles/Waste Generated in Large Amounts/Proper Disposal of Waste Materials/Environmental and Safety Audits/Environmental Education
• Biology lab classes for children at the Japan Science Foundation's Science Museum: 93 participants in 4 labs • Employees taking volunteer leave: 42 • Endowed courses at Waseda University: Total of 15 lectures; endowed course at Keio University: Total of 14 lectures	74	Guest Lessons and Co-Sponsorship of Terakoya Class at Nadeshiko Elementary School/ Private-Sector Training for Teachers/ Establishment of and Donation to Peking University Chugai Educational Foundation/Environmental Protection Activities (Higashi Toyoda Conservation Area)/Chugai Becomes Official Partner of National Museum of Emerging Science and Innovation (Miraikan)/Co-Sponsorship of Youngsters' Science Festival 2013/Biology Lab Classes to Show Children the Fun of Science/Chugai Eco-Kids Program/Response to the Great East Japan Earthquake
• Users of wiwiw (an online tool that supports employees who return to work after taking childcare leave): Total of 240 • Percentage of employees with disabilities: 2.01%	75-77	Diversity Initiatives/Performance Data Related to Diversity/Systems and Frameworks to Support Life Events/Basic Cycle of Career Development/Career Policies 1-4/Facilitating a Healthy Work/Life Balance/Help Lines/Sound Labor-Management Relations/Dialogue between Management and Employees
• Status of ethical and legal compliance survey within the Sales Division: Responses received from 2,606 people	78	Commitment to Ethical Corporate Activities/Creating a Corporate Culture of Respect for Self and Others/Creating Workplaces Free from Harassment/Chugai's View of Animal Welfare/Bioethics Initiatives in R&D/Conduct of Clinical Trials/BCG Hotline
• Institutional investors outside Japan visited in person by top executives: 46 institutions • Briefings for individual investors and shareholders: 4 • Plant tour for shareholders: 1 • General Meeting of Shareholders (March 27, 2013 at Royal Park Hotel, Tokyo; attended by 607 people)	79-85	Corporate Governance/General Meeting of Shareholders

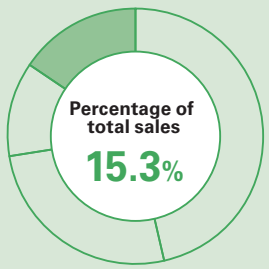
Sales

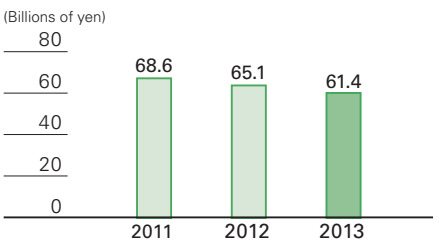
Therapeutic Fields	Performance Highlights	
Oncology	• Sales rose 10.0 percent year on year due to steady growth in sales of new products in addition to core products. • Chugai maintained its market leadership with a 20.4 percent* share of the Japanese oncology market.	• Avastin (bevacizumab) • Herceptin (trastuzumab) • Rituxan (rituximab) • Xeloda (capecitabine) • Tarceva (erlotinib) • Neutrogin (lenograstim) • Perjeta (pertuzumab)
Bone and Joint Diseases	• Sales increased 12.9 percent year on year, but sales excluding Evista increased 36.9 percent. • Sales of Actemra increased 19.3 percent in Japan and grew a substantial 68.8 percent overseas.	• Actemra (tocilizumab) • Suvenyl (sodium hyaluronate) • Edirol (eldecalcitol) • Alfarol (alfacalcidol) • Bonviva (ibandronate sodium hydrate)
Renal Diseases	• Sales increased 1.7 percent year on year. • Despite competition from rival products, sales increased due to the growing market presence of Mircera.	• Mircera (epoetin beta pegol) • Oxarol (maxacalcitol) • Epogin (epoetin beta)
Others	• Overall sales decreased 5.7 percent year on year. • Sales of CellCept increased, but sales of Pegasys and Copegus declined due to a shrinking market and competition from rival products.	• Tamiflu (oseltamivir phosphate) • Sigmart (nicorandil) • CellCept (mycophenolate mofetil) • Pegasys (peginterferon alfa-2a) • Copegus (ribavirin)











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(As of January 30, 2014)

Research and Development

	Phase I	Phase II	Phase III	Filed
Oncology	**CIF (RG7167)** Solid tumors **CKI27 (RG7304)** Solid tumors **PA799** Solid tumors **RG7414** Solid tumors **RG7321** Solid tumors **RG7446** Solid tumors	**AF802 (RG7853)** Non-small cell lung cancer (I/II) (Overseas) **GC33 (RG7686)** Liver cancer **RG340 (Xeloda)** Gastric cancer (adjuvant) **RG7204** Melanoma (I/II)	**RG435 (Avastin)** Breast cancer (adjuvant) **RG1273 (Perjeta)** Breast cancer (adjuvant) Gastric cancer **GA101 (RG7159)** Indolent non-Hodgkin's lymphoma Aggressive non-Hodgkin's lymphoma **RG3502 (Kadcyla)** Gastric cancer (II/III) **RG3638** Non-small cell lung cancer	**AF802 (RG7853)** Non-small cell lung cancer
Bone and Joint Diseases			**NRD101 (Suvenyl)** Enthesopathy **RG484** Osteoporosis (oral)	
Autoimmune Diseases	**SA237** Rheumatoid arthritis **RG7415** Systemic lupus erythematosus	**MRA (Overseas: Actemra)** Systemic sclerosis	**MRA (Overseas: Actemra)** Giant cell arteritis	**MRA (Overseas (Europe): Actemra)** Rheumatoid arthritis (subcutaneous injection)
Central Nervous System	**RG1450** Alzheimer's disease **RG1577** Alzheimer's disease	**RG7090** Major depressive disorder	**RG1678** Schizophrenia	
Others	**URC102** Gout **RG7652** Hyperlipidemia	**ACE910** Hemophilia A (I/II) **CIM331** Atopic dermatitis	**RG3637** Asthma	

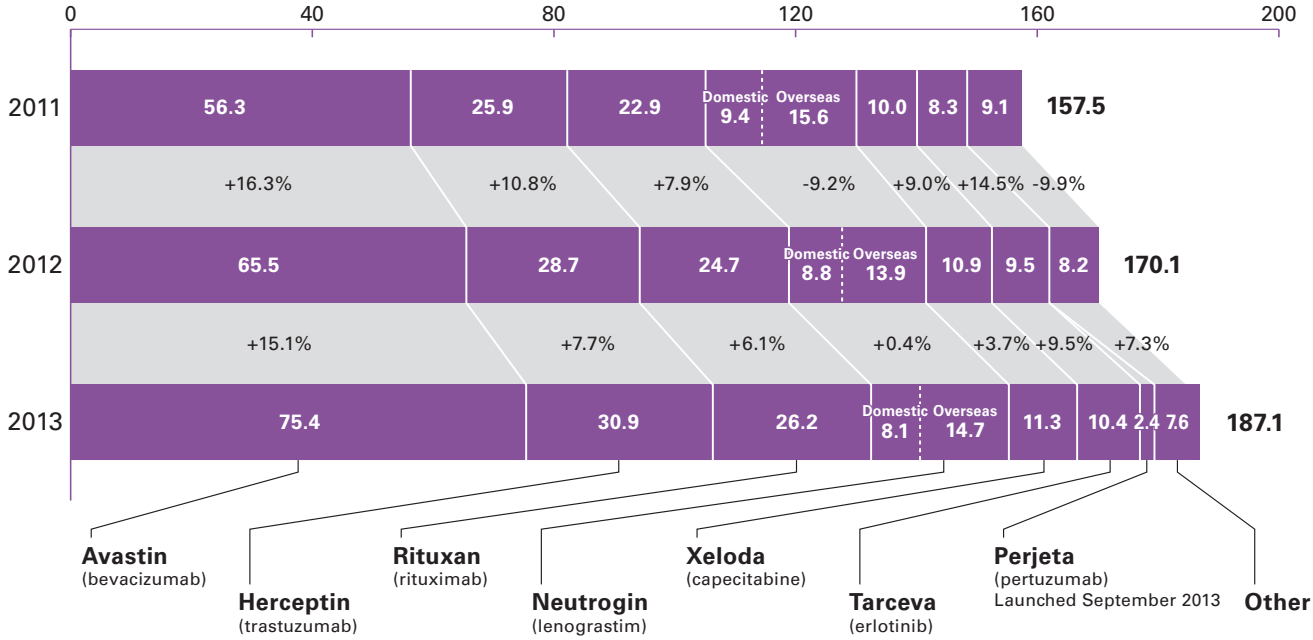
Originated in-house Status changed in or after 2013.

For more detailed information on diseases, products and development projects by therapeutic field, see "Development Pipeline" on pages 90-91 and "Basic Information" on pages 92-105.

Oncology

Sales of Major Products

(Billions of yen)



Overview

Chugai is the leading oncology company in Japan, providing innovative products and services to deliver cancer treatments that allow patients to confront their disease proactively and with hope.

Cancer is the leading cause of death in Japan with over 350 thousand patients dying every year.[1] There are many different cancer types, each with different prognoses and treatment methods. Chugai provides therapies that have been scientifically proven to prolong the time before the disease worsens, or increase the cure rate in patients with gastrointestinal, lung, breast, hematological and other types of cancer. Products in Chugai's portfolio have led to new standards of care around the world.

Our 500 oncology medical representatives (MRs) provide information to healthcare professionals to

Avastin
(bevacizumab)

Anti-vascular endothelial growth factor (VEGF) humanized monoclonal antibody
Launch in Japan: June 2007

Herceptin
(trastuzumab)

Anti-human epidermal growth factor receptor-2 (HER2) humanized monoclonal antibody
Launch in Japan: June 2001 (150mg)
August 2004 (60mg)

Rituxan
(rituximab)

Anti-CD20 monoclonal antibody
Launch in Japan: September 2001

ensure that our products are used appropriately and safely. Oncology MRs have specialized knowledge not only about Chugai products, but also about diseases, standards of care and medical systems, and must be able to offer patient-centered treatment proposals. We call this approach "consulting-based promotion" to distinguish it from conventional promotion.

1. Source: Cancer White Paper (2012), (Shinoharashinsha Publishers Inc.)

Review of 2013 Performance

General Overview

In 2013, sales in the oncology field increased ¥17.0 billion, or 10.0 percent, year on year to ¥187.1 billion. We added a newly launched product, Perjeta, to our line-up of therapeutic antibodies Avastin, Herceptin and Rituxan, which have a well-established presence as medicines with unique modes of action. Moreover, additional indications were approved for two products, Avastin and Tarceva, broadening the range of treatment options available to patients.

We made significant progress with our efforts to build market presence for oncology products in 2013, supported by favorable response from health care providers, widening our lead in the Japanese oncology market to a 20.4 percent[2] share, up 1 percentage point from 2012.

2. Copyright 2014 IMS Japan K.K. Source: JPM 2013
Reprinted with permission. The scope of the market is defined by Chugai.

Performance by Product

Sales of Avastin, an anti-vascular endothelial growth factor (VEGF) humanized monoclonal antibody, increased ¥9.9 billion, or 15.1 percent, to ¥75.4 billion. Avastin is already an established standard of care in first- and second-line treatment for colorectal cancer in many medical facilities. Accumulation of safety data in Japan is also broadening the range of lung cancer patients who can be treated with Avastin. In the third year since its launch to treat breast cancer, Avastin's recommendation grade in the treatment guidelines was raised, increasing the number of patients receiving prescriptions. In addition, as a result of a development request from the Japanese Ministry of Health, Labour and Welfare based on the findings of the MHLW Review Committee on Unapproved Drugs and Indications with High Medical Needs, Avastin received approvals for the treatment of malignant glioma (a type of brain tumor) and ovarian cancer in June and November 2013, respectively, and uptake is advancing steadily. Innovative medicines had been long awaited in both these areas, and the approval of Avastin is seen as highly significant in terms of expanding the range of treatment options.

Sales of Herceptin, an anti-human epidermal growth factor receptor-2 (HER2) humanized monoclonal antibody, increased ¥2.2 billion, or 7.7 percent, to ¥30.9 billion. Herceptin is recognized as a leading product in Personalized Healthcare, and is a mainstay in the treatment of HER2-positive breast cancer. Active promotion of HER2 testing[3] for gastric cancer has also contributed to the steady growth of Herceptin.

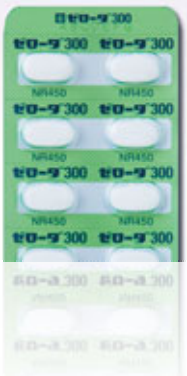
Perjeta, a HER2 dimerization inhibitory humanized monoclonal antibody, was launched in September 2013 for HER2-positive metastatic breast cancer in combination with Herceptin. Based on its data, which

Neutrogin
(lenograstim)

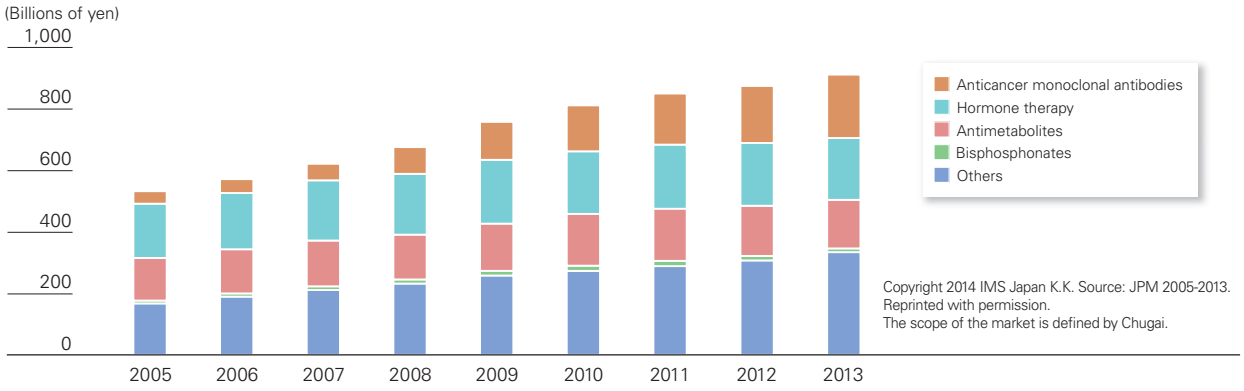
Recombinant human granulocyte colony-stimulating factor (G-CSF)
Launch in Japan: December 1991

Xeloda
(capecitabine)

Fluoropyrimidine anti-tumor agent
Launch in Japan: June 2003



Anticancer Market in Japan



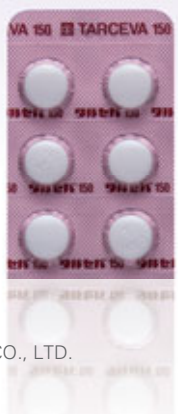
demonstrated improved overall survival (length of time from diagnosis or the start of treatment until death), Perjeta is being steadily adopted by medical facilities as a new medicine that can further improve HER2-positive breast cancer treatment. Sales in 2013 were ¥2.4 billion.

Sales of Xeloda, a fluoropyrimidine anti-tumor agent, increased ¥0.4 billion, or 3.7 percent, to ¥11.3 billion. Growth was limited despite our efforts to promote uptake of combination therapy with oral Xeloda and oxaliplatin (a regimen called XELOX), a worldwide standard of care for advanced or recurrent colorectal cancer to prevent recurrence. Xeloda has established a leading position in post-operative adjuvant chemotherapy for colon cancer, with steady uptake of both XELOX and Xeloda monotherapy. In advanced or recurrent gastric cancer, uptake of Xeloda has increased steadily as a result of our efforts to highlight its efficacy, particularly in combination with Herceptin. To address side effect management, which we have been focusing on since 2012, we provide information and offer suggestions not only to the physicians who prescribe Xeloda, but also healthcare professionals, including dispensing pharmacists and nurses, who also communicate with patients. These efforts are aimed at supporting patients with management of side effects.

Sales of Tarceva, an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor, increased ¥0.9 billion, or 9.5 percent, to ¥10.4 billion. In May 2013, Tarceva obtained regulatory approval for the additional indication of first-line treatment of non-small cell lung cancer in patients with EGFR mutations. This approval has resulted in more opportunities to use Tarceva for treating EGFR-positive patients, where efficacy is particularly high. We are also continuing to focus on management of

Tarceva
(erlotinib)

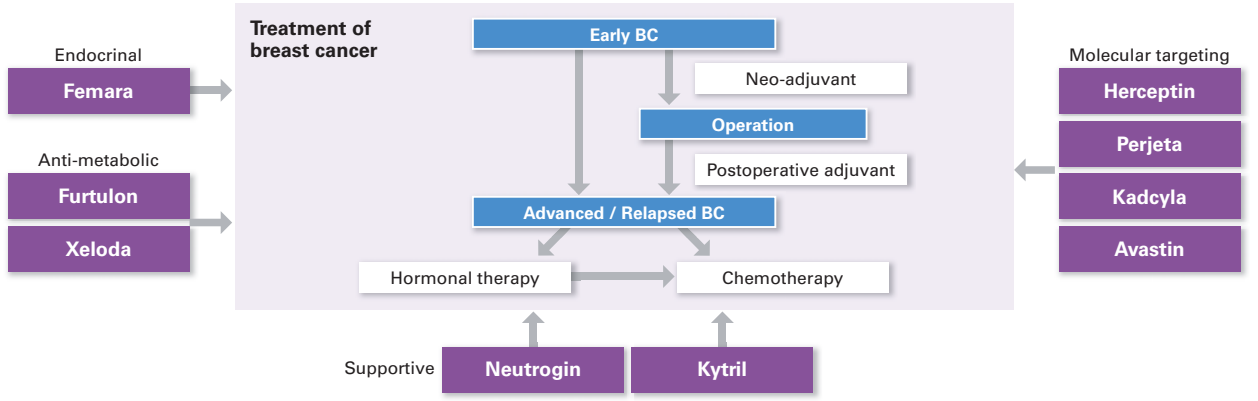
EGFR (Epidermal Growth Factor Receptor) tyrosine kinase inhibitor
Launch in Japan: December 2007



Perjeta
(pertuzumab)

HER2 dimerization inhibitory humanized monoclonal antibody
Launch in Japan: September 2013

Extensive Contribution to Cancer Treatment (Breast Cancer)



side effects, as well as building greater understanding of the product's efficacy.

Sales of Rituxan, an anti-CD20 monoclonal antibody, increased ¥1.5 billion, or 6.1 percent, to ¥26.2 billion. This medicine has a well-established position as a standard therapy for non-Hodgkin's lymphoma, and is showing solid sales growth.

Sales in Japan of Neutrogin (overseas name: Granocyte), a recombinant human granulocyte colony-stimulating factor (G-CSF), decreased ¥0.7 billion, or 8.0 percent, to ¥8.1 billion. The decrease reflected market contraction mainly due to expansion of outpatient chemotherapy. Outside Japan, sales increased ¥0.8 billion, or 5.8 percent, to ¥14.7 billion as the favorable effect of the weaker yen outweighed the impact of competition from follow-on biologics.[4]

3. A diagnostic test can determine if a patient's breast or gastric cancer has overexpression of a protein called HER2. Herceptin and Perjeta target HER2 and are administered only to patients whose tumors are identified as HER2-positive.
4. 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.

2014 Strategy and Outlook

In 2014, we will continue to promote the penetration of standards of care through the value of our products and the value-added information we provide.

We expect particularly robust growth for Avastin in the areas of lung cancer and breast cancer. For lung cancer, we will use domestic and overseas safety data to make Avastin a treatment option for a broader range of patients, as well as continue to promote the importance of evidence-based maintenance therapy. For breast cancer, we will promote uptake by highlighting the ways in which Avastin improves quality of life for patients. Avastin's anti-tumor activity can be effective from the early stages, which reduces the incidence of paraneoplastic syndromes, pain and other cancer side effects. Avastin is also the first molecular targeted therapy (a therapy that targets a specific molecule) for malignant glioma and ovarian cancer, two new indications that were added in 2013. We will continue to focus on improving understanding of its mode of action and ensuring its appropriate use.

Perjeta and Herceptin, along with Kadcyla which we plan to launch in the near future, are all antibodies targeting HER2, a protein associated with cancer cell growth. These agents have expanded the range of treatment options for HER2-positive breast cancer, which previously had a poor prognosis. We will work to ensure that they are used appropriately by calling attention to their particular characteristics and precautions.

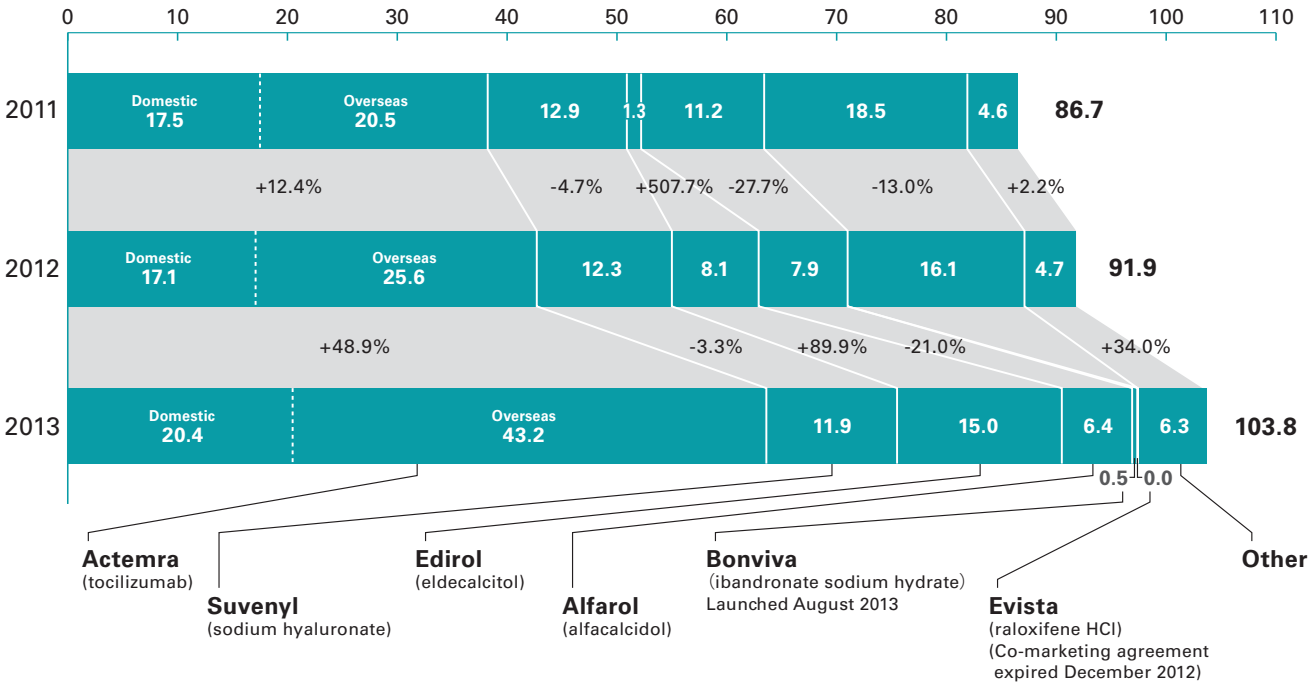
With Xeloda, we will continue to highlight the convenience and safety of the XELOX regimen in colorectal cancer. For gastric cancer, we will use the data announced in 2013 showing the increased efficacy of combination therapy with Herceptin to accelerate the market penetration of both products.

As Tarceva becomes established in first-line therapy, we expect that more patients will have access to such treatment and that longer-term treatment will be possible. We will continue to provide guidance for side effect management, which will become even more important as opportunities for use of Tarceva increase.

Bone and Joint Diseases

Sales of Major Products

(Billions of yen)



Overview

Chugai has been active in the field of bone and joint diseases for more than three decades since the launch of the osteoporosis treatment Alfarol in 1981. A key turning point was the discovery of Actemra through our joint research with Osaka University. Actemra is the world's first drug that blocks the action of interleukin-6 (IL-6), a protein that causes inflammation, and is now sold in more than 90 countries worldwide. In Japan, Actemra obtained regulatory approval for the treatment of Castleman's disease in 2005 and rheumatoid arthritis (RA) in 2008. Previously, treatment of RA mainly focused on relieving pain and other symptoms. But the appearance of biologics such as Actemra has brought new possibilities including early and sustained remission, and even prevention of joint destruction.

Actemra
(tocilizumab)

Humanized anti-human IL-6 receptor monoclonal antibody
Launch in Japan: June 2005 (Castleman's disease)
April 2008 (rheumatoid arthritis)
May 2013 (new formulation: subcutaneous injection)

Suvenyl
(sodium hyaluronate)

Agent for joint function improvement
Launch in Japan: August 2000

To contribute further to the treatment of RA, we are continuing our efforts to increase treatment options, including the launch of a subcutaneous formulation of Actemra in 2013. In the osteoarthritis segment, locomotive syndrome, which refers to the loss of mobility of the legs and back caused by advanced age or lifestyle factors, has received growing attention in Japan due to its impact on quality of life, which has boosted recognition of the importance of treatment. In 2011, we launched Edirol, a next-generation vitamin D_3 derivative that improves on Alfarol, and in 2013, we launched Bonviva, a bisphosphonate agent. These additions to our product lineup reflect our commitment to meeting the therapeutic needs of osteoporosis patients.

Review of 2013 Performance

General Overview

In 2013, total domestic sales in the bone and joint diseases field decreased ¥5.7 billion, or 8.6 percent, year on year to ¥60.6 billion. Excluding the effect of the expiration of the co-marketing agreement for the osteoporosis treatment Evista at the end of 2012, sales increased ¥10.5 billion, or 21.0 percent. The subcutaneous formulation of Actemra, which was developed to address a wide range of therapeutic needs, was launched successively in Japan and the United States with high expectations from patients and healthcare providers. In addition, we launched Bonviva for osteoporosis, and Edirol significantly exceeded sales projections in its third year on the market.

Rheumatoid Arthritis

Actemra, the first therapeutic antibody created in Japan, is in its eighth year on the market. Sold by the Roche Group in more than 90 countries, it has grown into a global medicine with sales reaching 1 billion Swiss francs in 2013. It is the only approved medicine that blocks the action of the IL-6 protein, which causes inflammation. It is also approved for rare diseases with limited treatment methods, including Castleman's disease, systemic-onset juvenile idiopathic arthritis (sJIA) and polyarticular-course juvenile idiopathic arthritis (pJIA).

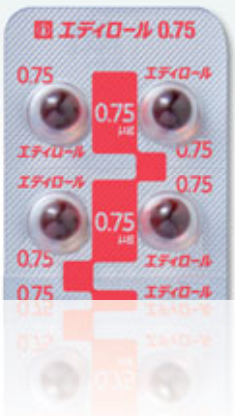
Sales of Actemra in Japan in 2013 rose ¥3.3 billion, or 19.3 percent, year on year to ¥20.4 billion. The Japanese market for biologics is expanding, driven by a growing patient population and a succession of new drug launches. Patients and healthcare providers are now able to choose from a growing array of treatments with different modes of action, dosing frequencies and routes of administration to fit treatment goals and patient lifestyles. In this changing market landscape, Actemra is increasingly being chosen as the first biologic used, and continued to post strong growth in 2013.

Actemra has received growing recognition in clinical settings for its effectiveness in maintaining a high and sustained rate of remission (decrease in or disappearance of symptoms) and preventing joint destruction in clinical trials. Moreover, data on the drug's safety profile in Japanese patients has been accumulated from all-case registration surveillance covering approximately 7,900 cases. The benefit of blocking IL-6 in RA treatment has been reported at numerous scientific conferences, and seminars on IL-6 have been held with the participation of about 400 rheumatologists from throughout Japan since 2012, helping to broaden recognition of the benefit of treatment focused on IL-6.

In May 2013 we simultaneously launched two types of subcutaneous formulation: a pre-filled

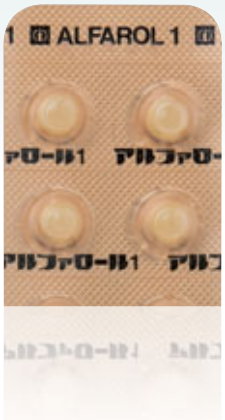
Edirol
(eldecalcitol)

Active vitamin D_3 derivative
Launch in Japan: April 2011



Alfarol
(alfacalcidol)

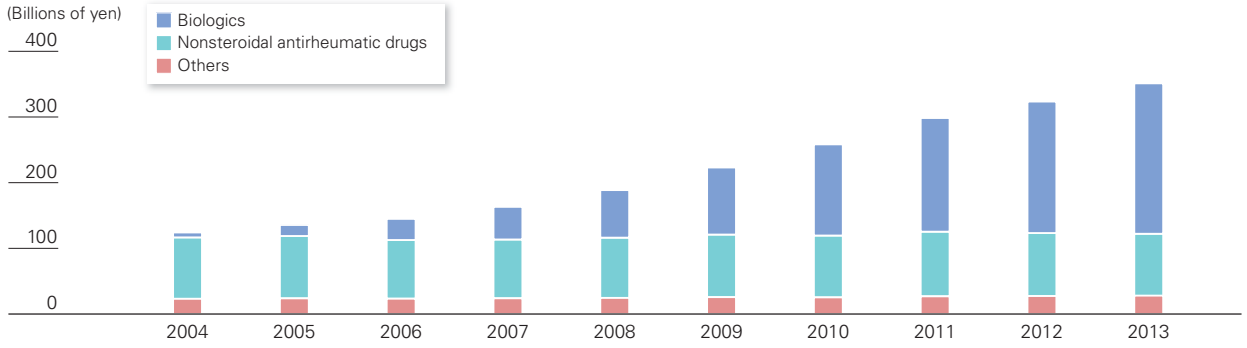
Active vitamin D_3 derivative (1α(OH) D_3) for improving bone metabolism
Launch in Japan: January 1981 (capsule, solution)
July 1994 (powder)



Bonviva
(ibandronate sodium hydrate)

Bisphosphonate
Launch in Japan: August 2013

Rheumatoid Arthritis Market in Japan



The scope of the market is defined by Chugai.

syringe and an auto-injector. The subcutaneous injection reduces administration time to about 20 seconds from the approximately one hour required for a drip infusion with the intravenous formulation. It also lessens the burden on medical staff as it eliminates the need for beds and other infrastructure that are required for infusions. As a result, the number of facilities, primarily clinics, where patients can receive treatment with Actemra has increased. For patients, the launch of the subcutaneous formulation not only shortens administration time, but is also expected to lead to reduce the number of visits to medical facilities by allowing them to choose self-injection. Moreover, the auto-injector, which was launched simultaneously with the pre-filled syringe, enables injection with the push of a button. This option was developed to allow even patients with hand impairments to inject the medicine safely and easily without fear of needles.

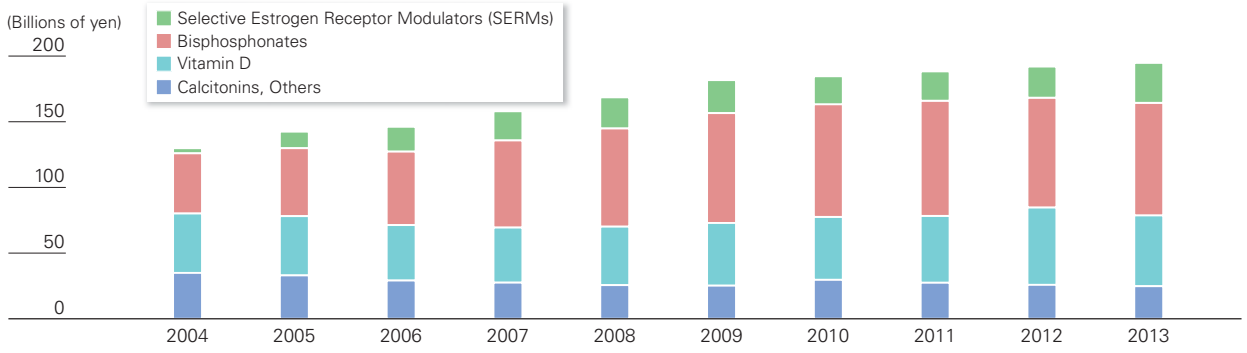
Sales of Actemra outside Japan (exports to Roche for sale in regions other than Japan, South Korea and Taiwan) increased ¥17.6 billion, or 68.8 percent, to ¥43.2 billion. Actemra IV formulation obtained regulatory approval in the European Union, where it is known as RoActemra, in 2009, and in the United States in 2010. Since the approval of an additional indication in the United States in 2012, Actemra/RoActemra has been used as a first-line biologic treatment in Europe and the United States as well as in Japan. In the U.S. and European markets, where there are more approved drugs than in Japan, the efficacy and safety of IL-6 inhibitors has been recognized, and Actemra/RoActemra posted strong growth in 2013. The drug showed superior effectiveness against a rival biologic in the ADACTA trial published in 2012, and the European League Against Rheumatism (EULAR) issued new treatment recommendations in 2013 giving Actemra/RoActemra the same grade of recommendation as earlier biologics. These factors were significant in advancing understanding of Actemra. The subcutaneous formulation obtained regulatory approval in the United States in October 2013 and is expected to obtain approval in the European Union in 2014. As a result, Actemra is the only anti-IL-6 biologic that can be used in both monotherapy and combination therapy and be administered either intravenously or subcutaneously.

Osteoporosis and Osteoarthritis

Edirol, an active vitamin D_3 derivative from Chugai research, is well recognized for its superior effectiveness in increase bone mass and preventing bone fractures compared with conventional vitamin D_3 derivatives. Sales in 2013 increased ¥7.1 billion, or 89.9 percent, year on year to ¥15.0 billion. In addition to the lifting of restrictions on long-term prescriptions in 2012, Edirol became the first vitamin D_3 derivative to receive a Grade A recommendation in the osteoporosis prevention and treatment guidelines in 2011. These and other developments have helped to broaden understanding of the importance of vitamin D_3 derivatives in osteoporosis treatment and recognition of Edirol as a base treatment for osteoporosis. Use of Edirol increased in 2013, primarily for new patients.

Bonviva IV Injection, a bisphosphonate agent, was launched in Japan in August 2013, and uptake has been steady, supported by efforts to provide information about the product, including briefings concentrated around the time of the launch. Once-monthly oral administration of bisphosphonate agents is becoming more common, but oral formulations have various issues, including problems such as a low absorption rate in the body, effect on eating and gastrointestinal side effects, and limitations on dosing methods. However, because Bonviva has demonstrated

Osteoporosis Market in Japan



The scope of the market is defined by Chugai.

effectiveness with a once-monthly intravenous injection, the new formulation is promising as a product that will improve convenience and adherence to treatment.

Sales of Alfarol decreased ¥1.7 billion, or 21.0 percent, to ¥6.4 billion, reflecting the shift to Edirol and the impact of generic competition.

In the osteoarthritis segment, sales of Suvenyl decreased ¥0.4 billion, or 3.3 percent, to ¥11.9 billion due to competition from rival products and generics. However, Suvenyl contributed to treatment as the straight-chain hyaluronic acid preparation with the highest molecular weight.

2014 Strategy and Outlook

In the RA segment, we expect 2014 to be a year of further significant advances for Actemra. We will work in Japan and elsewhere to generate additional clinical data and provide information to support Actemra's continuing contribution to RA treatment worldwide.

In Japan, our efforts will focus on establishing Actemra as a first-line treatment. To achieve this, we will promote understanding of Actemra's high and sustained remission rate and cost-effectiveness based on data accumulated in basic and clinical research, and will highlight the benefit of blocking IL-6 in RA treatment. Until May 2014, the subcutaneous formulation of Actemra will be subject to the two-week limit on prescriptions imposed on new drugs. Once that restriction is lifted in June, uptake is expected to accelerate as at-home administration reduces the frequency of visits to medical facilities. We will focus on providing information to medical institutions to enable safe, reliable self-injection by patients at home.

Outside Japan, while Actemra will face competition from an oral JAK inhibitor, particularly in the United States, we expect the rollout of the subcutaneous formulation to contribute substantially to sales growth in the United States and Europe, where the majority of RA treatments are administered subcutaneously. We will strengthen coordination with the Roche Group and continue to promote understanding of Actemra's characteristics, particularly its high efficacy in biologic monotherapy, based on powerful evidence from the ADACTA trial and other studies, along with the recommendation in EULAR guidelines. With these initiatives, we will work to promote Actemra as a first-line treatment outside Japan as well.

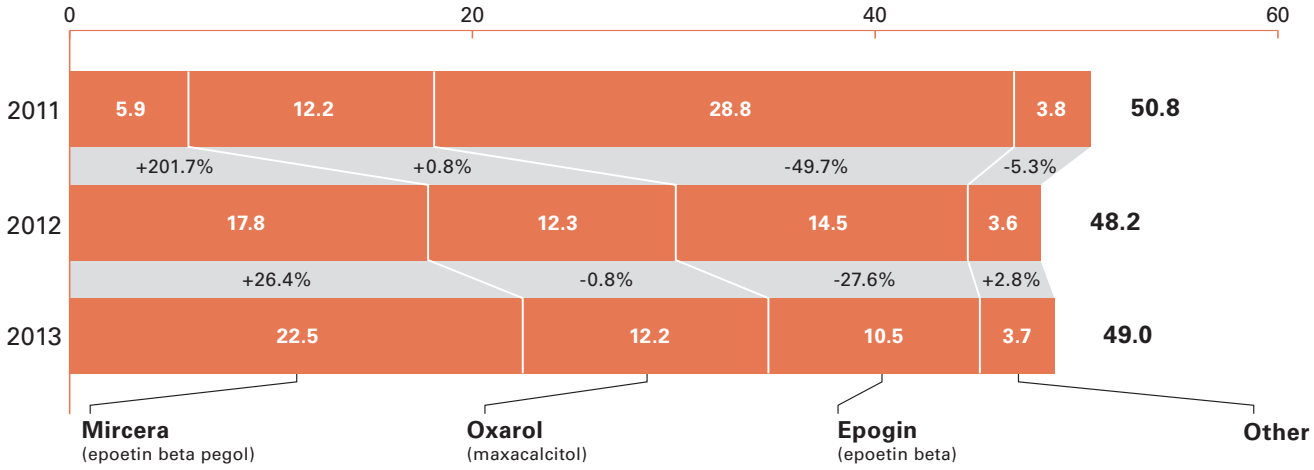
In the osteoporosis segment, in which Chugai is a leader, we will promote awareness of the importance of measuring bone density so that more patients will proactively seek treatment. We will also make treatment proposals that distinguish between the use of Edirol and Bonviva, which have different product characteristics. Another focus will be contributing to treatment of secondary osteoporosis caused by steroid use, lifestyle diseases such as diabetes or other factors. In this effort, we will work to generate further data and expand our role as a leader in the field.

In the osteoarthritis segment, we will continue to promote understanding of the straight-chain high molecular weight sodium hyaluronate preparation Suvenyl, as well as further raise awareness of the importance of early treatment.

Renal Diseases

Sales of Major Products

(Billions of yen)



Overview

Since the launch of Epogin, a renal anemia treatment, more than 20 years ago, Chugai has continued to promote awareness of the importance of early treatment of renal anemia and to improve overall treatment as a leader in this field. In 2011, we contributed to the treatment of renal disease in Japan by launching Mircera, an innovative long-acting erythropoietin-stimulating agent (ESA) with a significantly lower dosing frequency than existing medicines.

Our activities focus on proposing the optimal treatment for each patient. To support that objective, we provide detailed information to healthcare professionals and have taken the initiative in establishing a comprehensive pharmacovigilance system.

Anemia frequently occurs in patients with impaired renal function due to a deficiency of the hormone that helps generate red blood cells (erythrocytes). About 90 percent of patients beginning dialysis require treatment for anemia, and improving anemia is essential to maintain their quality of life. In pre-dialysis renal failure (patients with reduced renal function, but who do not yet require dialysis), studies suggest that early treatment of anemia may slow down disease progression. Awareness of the importance of treating anemia is also rising. Chugai provides not only agents for renal anemia but also hyperparathyroidism and

Mircera
(epoetin beta pegol)

Continuous erythropoietin receptor activator
Launch in Japan: July 2011

Oxarol
(maxacalcitol)

Agent for secondary hyperparathyroidism
Launch in Japan: September 2000

Epogin
(epoetin beta)

Recombinant human erythropoietin
Launch in Japan: April 1990 (ampule)
May 2001 (syringe)

hyperphosphatemia treatments, which are necessary in dialysis therapy. We also provide other related information that helps dialysis facilities as part of our comprehensive support.

Review of 2013 Performance

In 2013, sales in the renal diseases field increased ¥0.8 billion, or 1.7 percent year on year, to ¥48.9 billion. The impact from competing products was more than offset by the growing market presence of Mircera, a long-acting ESA launched in 2011.

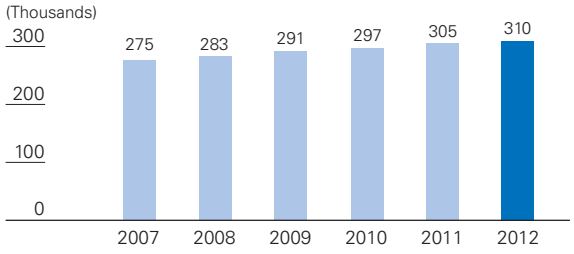
In treatments for renal anemia associated with chronic kidney disease (CKD) in the dialysis segment, medical costs have been under pressure since the government introduced a flat-sum reimbursement system for ESAs in 2006. At the same time, the number of competing products has increased. In contrast, the pre-dialysis segment has gained more attention, driven by a public awareness campaign to promote early diagnosis and treatment of renal anemia in response to an increase in CKD in patients with diabetes.

Against this backdrop, sales of Mircera, one of Chugai's mainstay products, rose ¥4.7 billion, or 26.4 percent, to ¥22.5 billion. Mircera can maintain stable hemoglobin levels with a dosing frequency of just once every four weeks, and its serum half-life is the same after both intravenous and subcutaneous administration, allowing consistent treatment from pre-dialysis to dialysis. Uptake of Mircera has progressed steadily in treatment of pre-dialysis patients, where the drug's benefits are more readily demonstrated. Use in new patients in particular is accelerating, with solid support for advantages such as convenience for patients and a long duration of action. In treatment of dialysis patients, although an increasing number of healthcare providers have seen Mircera's effects firsthand and recognize its usefulness, uptake has been slower than expected because of the delay in establishing methods of switching from existing treatments.

Sales of Epogin decreased ¥4.0 billion, or 27.6 percent, to ¥10.5 billion due to the switch to Mircera and competition from other products, including follow-on biologics. However, the decrease was smaller than expected, reflecting the solid reputation the product has built over the years.

Sales of Oxarol, an agent for secondary hyperparathyroidism, decreased ¥0.1 billion, or 0.8 percent, to ¥12.2 billion. While the number of prescriptions remained flat, partly due to revisions to treatment guidelines, sales essentially remained at the level of the previous year due to substantial clinical data showing that treatment with an active vitamin D derivative can extend survival.

Number of Dialysis Patients in Japan



Source: Overview of Regular Dialysis Treatment in Japan (as of December 31, 2012) by Statistical Survey Committee, The Japanese Society for Dialysis Therapy

2014 Strategy and Outlook

Our top priority in 2014 in the renal diseases field will be to contribute to treatment by accelerating the uptake of Mircera.

In the pre-dialysis segment, which continues to be a focus of society at large, we will leverage the usefulness of Mircera to quicken the pace of uptake, and increase awareness among potential renal anemia patients of the importance of early treatment. In addition, we are conducting a post-marketing study on renal anemia treatment and renal prognosis in pre-dialysis patients. We will use the data from these studies to promote understanding of the role that Mircera can play in treatment.

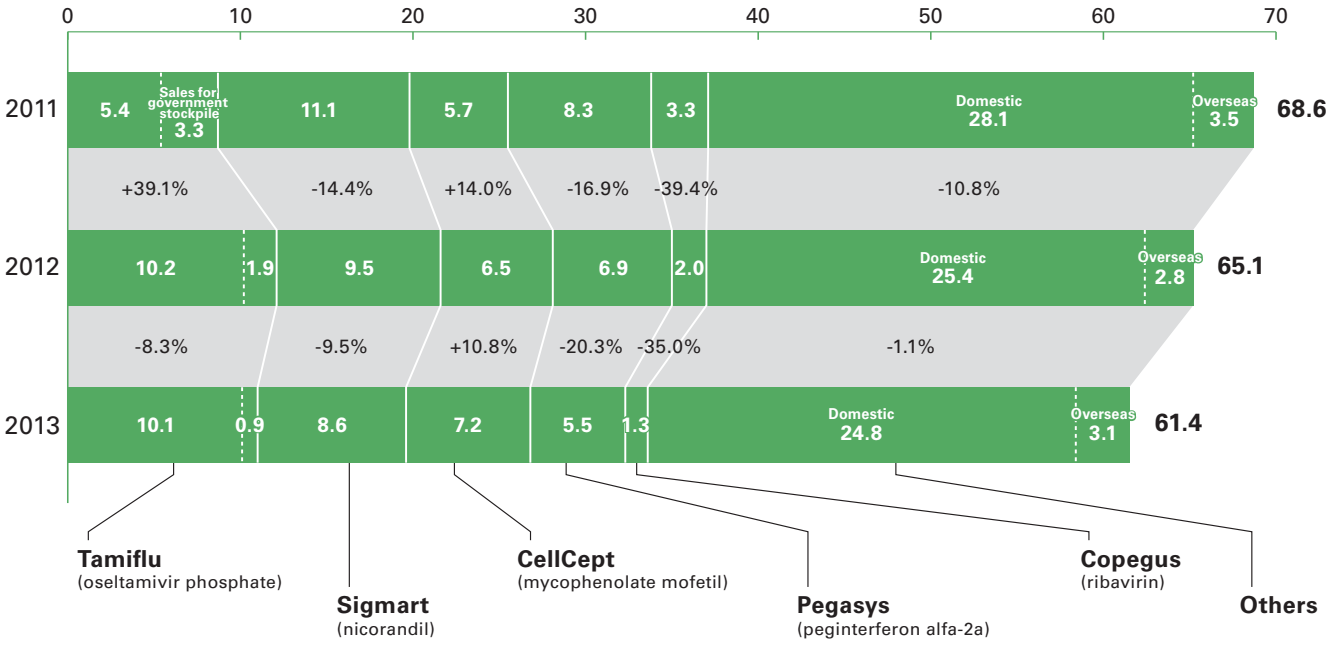
In the dialysis segment, it is expected that pharmacoeconomics will take on even greater importance with continued pressure from competing products and follow-on biologics, and with National Health Insurance drug reimbursement price revisions set to take place in 2014. For Chugai, 2014 will also be an important year for establishing Mircera's presence in the dialysis segment, so we will focus efforts in that area.

For Oxarol, we will promote further understanding of the product profile ahead of the expected launch of competitor products and generics over the next few years. In addition, we will provide education about the benefits of early treatment of hyperparathyroidism, which is emphasized in treatment guidelines.

Transplant, Immunology and Infectious Diseases, and Others

Sales of Major Products

(Billions of yen)



Overview

At Chugai, we are also active in the transplant, immunology and infectious diseases field, which includes the influenza and chronic hepatitis areas, and in the Others field. In the influenza area, Chugai plays an important role as a supplier of the anti-influenza agent Tamiflu. We contribute to influenza treatment by disseminating information on the appropriate use of Tamiflu as well as on its safety and effectiveness, including prevention, based on the extensive clinical data accumulated since the drug's launch in 2001. In chronic hepatitis, we help raise awareness of the importance of early detection and

Tamiflu
(oseltamivir phosphate)

Anti-influenza agent
Launch in Japan:
February 2001 (capsule)
July 2002 (dry syrup)

Sigmart
(nicorandil)

Anti-anginal agent
Launch in Japan:
April 1984 (capsule)
September 1993 (injection)

CellCept
(mycophenolate mofetil)

Immunosuppressant
Launch in Japan:
November 1999

Pegasys
(peginterferon alfa-2a)

Peginterferon alfa-2a agent
Launch in Japan:
December 2003

Copegus
(ribavirin)

Anti-viral agent
Launch in Japan:
March 2007

treatment for chronic hepatitis C. The peginterferon alfa-2a agent Pegasys was approved for the treatment of compensated liver cirrhosis caused by hepatitis C, and of chronic hepatitis B, ahead of competitor products, and we are working to make it available to a broader range of patients. We are also working to launch products in other areas of significant unmet medical need including severe asthma and neuroscience.

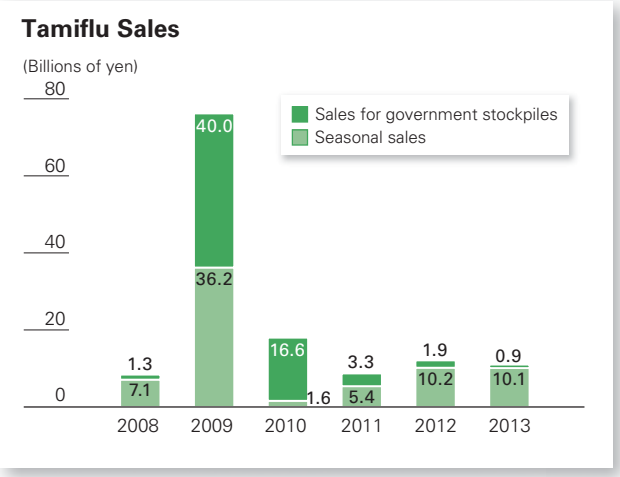
Review of 2013 Performance

In 2013, sales in transplant, immunology and infectious diseases decreased ¥1.5 billion, or 7.4 percent, year on year to ¥18.8 billion. Sales in the Others field decreased ¥1.5 billion, or 5.0 percent, to ¥28.6 billion.

Tamiflu sales decreased ¥1.0 billion, or 8.3 percent, to ¥11.0 billion. Seasonal sales were ¥10.1 billion, or ¥0.1 billion (1.0 percent) lower than the previous year, and pandemic sales were ¥0.9 billion, or ¥1.0 billion (52.6 percent) lower. Sales of Tamiflu proved resilient to competition due to efforts to provide information on the drug's effectiveness and the benefits of its unique dry syrup formulation. The shelf life of Tamiflu has been extended from seven to ten years for the capsule formulation and from six to seven years for the dry syrup formulation.

Sales of CellCept, an immunosuppressant, increased ¥0.7 billion, or 10.8 percent, to ¥7.2 billion. CellCept is used to treat refractory rejection after kidney transplants and to help prevent rejection after kidney, heart, liver, lung and pancreas transplants. The use of CellCept has increased with rising demand for organ transplants in Japan, which has been driven by advances in transplantation therapy.

Sales of Pegasys decreased ¥1.4 billion, or 20.3 percent, to ¥5.5 billion. The number of patients with chronic hepatitis C is decreasing in Japan, reflecting the aging population, and in 2013, more patients refrained from interferon therapy in anticipation of the upcoming launch of a formulation not administered in combination with interferon. Pegasys sales remained stable, however, in combination therapy with Copegus for compensated liver cirrhosis caused by hepatitis C, which is backed by extensive data on its high efficacy. Pegasys also contributes to the treatment of hepatitis as the only peginterferon indicated for chronic hepatitis B, which is commonly treated with nucleic acid analogues.



2014 Strategy and Outlook

In the area of anti-influenza agents, we expect competitive pressure in 2014, but we will continue to steadily provide information based on extensive safety and efficacy data.

In chronic hepatitis C, we expect a further increase in patients refraining from treatment with existing drugs, but will continue working to contribute to treatment by disseminating the accumulated data on the safety and efficacy of Pegasys/Copegus combination therapy. We will also work to establish the use of these products to treat compensated liver cirrhosis caused by hepatitis C, and chronic hepatitis B.

To prepare for the launch of products in severe asthma and neuroscience, which are expected in the late 2010s, we will provide education and training to MRs and work to establish the necessary marketing organization and other functions.

Patient Support Activities and Contribution to Healthcare

Disease Awareness Activities

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

One such activity is the Relay For Life, an awareness support campaign that forges ties in the fight against cancer. This event, a 24-hour walk-a-thon in which cancer patients, their families and supporters compete as relay teams, was held in 41 locations throughout Japan in 2013. Chugai employees have participated as volunteers in the Relay For Life since 2007. A total of 536 employees took part as "Team Chugai" at 21 locations in 2013. From this year, Chugai used iPads to offer an educational quiz on lung cancer, which 1,174 people took at 16 locations. As participants answered questions on the iPad, Team Chugai members provided explanations to deepen their understanding of lung cancer.

Chugai employees participate as volunteers in the Relay For Life.

Measures to Support Healthcare

Based on its business philosophy of "Innovation all for the patients," Chugai contributes to improving the level of healthcare with support that goes beyond simply providing pharmaceuticals.

Chugai has been at the forefront of promoting multidisciplinary team care, an increasingly important approach in recent years as treatments become more diverse and sophisticated. In 2013 we continued holding workshops and follow-up lectures, primarily at hub cancer hospitals in each region of Japan, and were active in presenting study sessions and other events at individual hospitals, which helped promote the spread of standards of care. Also during the year we held lectures in four prefectures on the Diagnosis Procedure Combination (DPC) system, featuring specialists and upper management of local flagship hospitals. These lectures provided a forum to discuss the use of DPC data for medical management and coordinating efforts among hospitals as a means of stimulating local activity, an important issue for healthcare in Japan.

To raise the efficiency of healthcare, Chugai proactively conducts e-promotion linked to various media. For example, in response to the diversifying channels and devices healthcare providers use to obtain information, we began providing information accessible by tablet computers and smartphones, and we improved the accessibility of product information such as package inserts and product news releases. Moreover, within our website for healthcare providers we established a new site to address the needs of pharmacists by providing patient guidance on how to take medicines and the pharmacist's role in multidisciplinary team care. We also held a web seminar for approximately 2,000 healthcare providers on the division of functions among medical institutions. The seminar was highly appreciated by participants who had not previously had an opportunity to learn in detail about Japan's future healthcare delivery policy.

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 global charity event Roche Children's Walk 2013, collecting donations between June 10 and 14, 2013. The Children's Walk raises funds each year 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. Approximately 3,000 Chugai employees helped raise funds, which were matched by the Company. As in 2012, half of the funds were donated to pay for the construction and operation of 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 other half was donated through Roche to assist orphaned children in Malawi.

For 20 years Chugai has worked with the nonprofit organization Shuhei Ogita Fund (http://www.fund-ogita.org/) to provide OK-432, an anticancer agent and agent for treating lymphangiomas,[1] free of charge to children worldwide suffering from incurable lymphatic malformations. 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.

The main activities of the fund in 2013 included providing full support for a Spanish patient with intractable lymphangioma who traveled to Japan for treatment and the establishment of Fundación Shuhei Ogita in Mexico.

Chugai companies and sites throughout Japan conduct fundraising activities

Roche Children's Walk 2013 near Chugai's head office

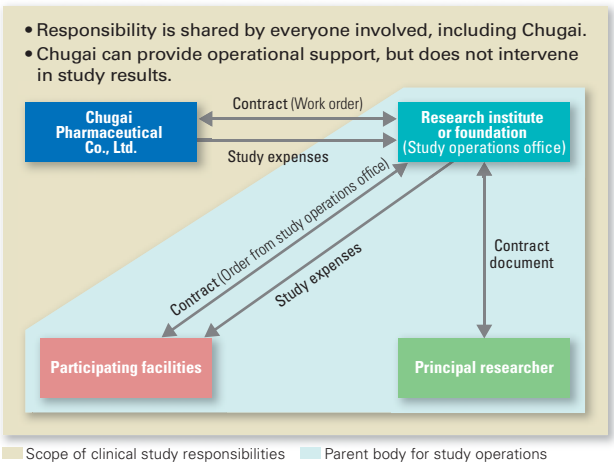
1. A rare disease in which lymphatic fluid abnormally pools in the lymphatic vessels to form cysts in parts of the body. In many cases, it is found at birth. Unlike cancer, lymphatic malformations are benign, but can retard children's development, and occasionally the cysts compress the respiratory tract 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

Ensuring Compliance in Contract-Based Post-Marketing Studies

Unlike clinical trials, which are conducted to determine the appropriate indication and dosage administration for the purpose of obtaining regulatory approval and launching a drug, post-marketing studies aim for further drug development after launch by collecting medical data that can lead to improved treatment. In recent years, increasing demand from society for proper use and further development of newly launched drugs based on data presents a critical opportunity to further improve the scientific validity, independence and transparency of post-marketing studies. Recognizing the importance of creating a clinical study system based on highly transparent contracts that expressly ensure the independence of post-marketing studies, Chugai established the Medical Affairs Division in April 2012. Under the name "contract-based post-marketing studies," we have started post-marketing studies with thoroughgoing efforts such as making clear the flow of funds and disclosing relationships and conflicts of interest to guarantee the independence and transparency of research. Chugai's post-marketing studies have been highly praised by an expert in the field of clinical research as the most transparent in Japan's regulatory environment.

We will continue contributing to the evolution of post-marketing studies to generate new data and to disseminate and spread more appropriate information to healthcare providers.

Contract-Based Post-Marketing Study Framework



Development

Chugai's Development System

Chugai coordinates multiple operations in its development. Our clinical development function draws up plans based on the latest scientific findings and invites medical institutions to conduct clinical trials to offer patients more satisfactory treatments as soon as possible. In addition to examining commercial production to turn candidate compounds into pharmaceutical products, our manufacturing function produces the investigational drugs used in clinical trials. Our drug safety function ensures a high level of safety in clinical trials by understanding and assessing the safety profile of each investigational drug from the early clinical trial stage, even before it obtains regulatory approval. Dealing with regulatory authorities, including applications for manufacturing and marketing approval, is handled mainly by our regulatory affairs function. As development involves multiple operations, Chugai's product lifecycle management system works cross-functionally to expedite the progress of each project and application for regulatory approval. Under this system, lifecycle leaders direct cross-divisional lifecycle teams together with leaders from each operation.

Based on its business philosophy, "Innovation all for the patients," Chugai continuously creates innovative pharmaceuticals that address unmet medical need for the benefit of the medical community and human health around the world. Therefore, we will continue to upgrade our systems for added speed and flexibility in providing investigational drugs by enhancing coordination among our various operations. In addition, we will further accelerate global development, including multinational studies of projects developed in-house.

Oncology

New Compounds

Chugai is developing new compounds with a focus on molecular targeted therapies. In our pipeline, six projects from Chugai and seven in-licensed from Roche are currently under way, and an application for regulatory approval has been filed for one project. Eleven of these projects are based on Personalized Healthcare (PHC).

Among compounds originating from Chugai research, we have filed an application for regulatory approval for one compound, and phase I or phase II clinical trials are under way for the other five projects.

Oncology Development Pipeline (As of January 30, 2014)

Development Code	Indication	Status	Generic Name	Dosage Form	Origin (Collaborator)
RG1273	Breast cancer	Approved	pertuzumab	Injection	Roche
	Breast cancer (adjuvant)	(Multinational study)			
	Gastric cancer	(Multinational study)			
RG1415	Non-small cell lung cancer (1st line)	Approved	erlotinib	Oral	Roche / OSI
RG435	Malignant glioma	Approved	bevacizumab	Injection	Roche
	Ovarian cancer	Approved			
	Breast cancer (adjuvant)	(Multinational study)			
RG3502	Breast cancer	Approved	trastuzumab emtansine	Injection	Roche
	Gastric cancer	(II / III) (Multinational study)			
RG3638	Non-small cell lung cancer	(Multinational study)	onartuzumab	Injection	Roche
GA101 (RG7159)	Indolent non-Hodgkin's lymphoma	(Multinational study)	obinutuzumab	Injection	Roche (Nippon Shinyaku)
	Aggressive non-Hodgkin's lymphoma	(Multinational study)			
GC33 (RG7686)	Liver cancer	(Multinational study)	—	Injection	In-house (Roche)
RG340	Gastric cancer (adjuvant)	Phase II	capecitabine	Oral	Roche (Yakult Honsha)
AF802 (RG7853)	Non-small cell lung cancer	Filed	alectinib	Oral	In-house (Roche)
		(I / II) (Overseas)			
RG7204	Melanoma	(I / II)	vemurafenib	Oral	Roche
CIF (RG7167)	Solid tumors	Phase I	—	Oral	In-house (Roche)
		(Overseas)			
CKI27 (RG7304)	Solid tumors	Phase I	—	Oral	In-house (Roche)
		(Overseas)			
PA799	Solid tumors	(Overseas)	—	Oral	In-house
RG7414	Solid tumors	Phase I	parsatuzumab	Injection	Roche
RG7321	Solid tumors	Phase I	pictilisib	Oral	Roche
RG7446	Solid tumors	Phase I	—	Injection	Roche

● Designates change in status in 2013 and thereafter

In October 2013, Chugai filed an application in Japan for regulatory approval of AF802 (generic name: alectinib) for the treatment of anaplastic lymphoma kinase (ALK)-positive unresectable, recurrent/advanced non-small cell lung cancer. AF802 was designated as an orphan drug by MHLW, and Chugai filed the application based on the results of a phase I/II clinical trial in Japan, before the phase III clinical trial results were available. The compound demonstrates its anti-tumor effect by selectively inhibiting the activity of the ALK tyrosine kinase. The efficacy of AF802 was confirmed in an extremely high 93.5 percent (43 out of 46) of patients who were tested positive for the ALK fusion gene, which is reported to occur in 2 to 5 percent of non-small cell lung cancer patients. Due to the favorable efficacy of AF802 and the high level of unmet medical need, the regulatory authority in Japan is reviewing it as a priority product. Overseas, it was Chugai's first in-house project to be designated as a Breakthrough Therapy by the U.S. Food and Drug Administration (FDA). AF802 is expected to make a major contribution to medicine worldwide.

Among the compounds in-licensed from Roche, Perjeta, a monoclonal antibody that inhibits HER2 dimerization, obtained approval in June 2013 for the indication of HER2-positive inoperable or recurrent breast cancer, and Chugai began sales in September. It has been shown to extend overall survival in patients with HER2-positive metastatic breast cancer. In July 2013, we started a phase III multinational study of Perjeta for gastric cancer, and it is proceeding smoothly along with a phase III multinational study for adjuvant therapy in HER2-positive breast cancer. For Kadcyla, an anti-HER2 humanized monoclonal antibody drug conjugate, we filed for regulatory approval in January 2013 and obtained approval in September 2013 for the indication of HER2-positive inoperable or recurrent breast cancer. Although we decided not to obtain an NHI price listing for the drug in November, we are conducting an additional clinical trial to make it available to patients and accumulate clinical data toward its eventual launch. A phase II/III multinational study for the expected indication of gastric cancer that started in 2012 is proceeding smoothly, and filing for regulatory approval is expected in 2015. Kadcyla is a combination of a powerful chemotherapeutic agent and trastuzumab, the active ingredient of Herceptin. It displays a strong anti-tumor effect while preventing impact on normal cells because the chemotherapeutic agent is delivered by trastuzumab directly to HER2-positive cancer cells, which internalize the conjugate. The trastuzumab component also has an anti-tumor effect of its own, making Kadcyla a molecular targeted therapy for cancer that achieves greater efficacy and a better safety profile as a single agent than standard combination treatments with chemotherapy.

Among projects that entered a new phase of clinical trials, the PI3K inhibitor RG7321 started phase I clinical trials in Japan in June 2013 as a potential treatment for solid tumors. Like PA799, which was developed in-house, RG7321 is a small-molecule anti-tumor agent that selectively inhibits PI3K. RG7414, an anti-EGFL7 humanized monoclonal antibody, started phase I clinical trials in Japan in March 2013 for the potential treatment of solid tumors, but Roche removed this project from its pipeline in October 2013. Further development in Japan is currently under consideration. Another project with the same expected indication, the engineered anti-PDL1 monoclonal antibody RG7446, started phase I clinical trials in Japan in September 2013. By expressing a protein called programmed death-ligand 1 (PD-L1) on their surface, tumor cells can evade attack by T cells due to immune tolerance induced via a PD-1 receptor/PD-L1 pathway signal. RG7446 binds to PD-L1 and inhibits the PD-1/PD-L1 pathway to restore the normal immune activity of the T cells for a stronger anti-tumor effect, and has gained attention as a new type of anticancer agent. A phase III multinational study for non-small lung cancer is scheduled to start in the first half of 2014.

Additional Indications

For existing products, Chugai has been making steady progress toward obtaining additional indications that maximize their value to make a greater contribution to patients. During 2013, we obtained regulatory approval for three major additional indications of two of our products. On April 6, 2012 we received a request from MHLW to develop Avastin for the treatment of recurrent glioblastoma as the result of an evaluation by the 11th Review Committee on Unapproved Drugs and Indications with High Medical Needs, which was held on March 23, 2012. Chugai filed an application for regulatory approval in September 2012, and in June 2013 Avastin obtained approval for the additional indication of malignant glioma. The approval was based on two phase II clinical studies in patients with recurrent glioblastoma in Japan and overseas and a phase III multinational study in patients with newly diagnosed glioblastoma (the AVAglio study). Japan is thus the first country in the world to approve Avastin for this indication, including for patients with newly diagnosed glioblastoma. Chugai also received a request from MHLW to develop Avastin for the treatment of ovarian cancer, and obtained regulatory approval for this additional indication in November 2013. Tarceva, which was approved in October 2007 for unresectable recurrent/advanced non-small cell lung cancer (NSCLC) that has become aggravated following chemotherapy, also obtained regulatory approval for the additional indication of chemotherapy-naïve,

unresectable, recurrent/advanced NSCLC with EGFR mutations in June 2013, thus providing patients a new option in first-line therapies.

Bone and Joint Diseases/ Autoimmune Diseases

In the field of rheumatoid arthritis (RA), we obtained regulatory approval in Japan in March 2013 for a new subcutaneous formulation (pre-filled syringe and auto-injector) of Actemra, which was developed in-house as the first IL-6 receptor inhibitor for the subcutaneous injection market, and launched it in May. The addition of this new formulation of Actemra to the existing intravenous infusion will increase treatment options that suit patients' lifestyles and meet the needs of healthcare providers, contributing to the improved convenience of Actemra therapy. The administration time of the subcutaneous formulation is substantially shorter and will reduce the burden on patients of visits to medical institutions, as it can also be administered at home by self-injection. An additional benefit for medical facilities is that it does not require preparation procedures prior to injection. Moreover, the auto-injector is the first such device for RA treatment in Japan that enables users to inject with the push of a button. In addition to reducing patient burden at the time of injection, its design is expected to reduce the risk of infection from needle-stick accidents after injection. The subcutaneous formulation (pre-filled syringe) was approved in the United States in October 2013 and is expected to obtain approval in the European Union in 2014. Overseas, Roche started a phase III study of Actemra in July 2013 for the expected indication of giant cell arteritis.

In addition, SA237 is a next-generation therapeutic antibody developed by applying recycling antibody technology, one of Chugai's innovative proprietary antibody engineering technologies. In the first half of 2014, a Chugai-managed phase III multinational study in Japan, the United States and Europe is scheduled to start for neuromyelitis opticas, a disease with high unmet medical need that has a suggested relationship to interleukin-6 (IL-6). A phase I clinical trial of SA237 involving repeated administration confirmed drug tolerance during the main evaluation period and improved pharmacokinetics, confirming the concept of extending serum half-life through the recycling effect. As a result, the drug is expected to improve convenience for patients in terms of administration dosage and frequency by enabling smaller, less frequent doses.

In the osteoporosis field, Bonviva IV Injection, a bisphosphonate antiresorptive agent in-licensed from Roche, obtained regulatory approval in June 2013 and co-marketing with Taisho Toyama Pharmaceutical Co., Ltd. started in August 2013 in Japan. Phase III clinical trials of an oral formulation as a co-development project with Taisho Pharmaceutical Co., Ltd. are also under way, with filing for regulatory approval planned in 2015 in Japan. Until now, bisphosphonates have generally been taken orally once a week, but Bonviva IV Injection can help improve convenience with a once-monthly single intravenous injection, as slowly as possible, enabling a new option for administration in line with the patient's lifestyle.

Central Nervous System/ Other Diseases

In the central nervous system (CNS) field, Chugai is developing projects for the expected indications of schizophrenia, major depressive disorder and

Bone and Joint Diseases/Autoimmune Diseases Development Pipeline (As of January 30, 2014)

Development Code	Indication	Status	Generic Name	Dosage Form	Origin (Collaborator)
Bone and Joint Diseases					
RG484	Osteoporosis	Approved	ibandronate sodium hydrate	Injection	Roche
		Phase III		Oral	(Taisho Pharmaceutical)
NRD101	Enthesopathy (Lateral epicondylitis, Patellar tendinitis, Achilles tendinopathy, Plantar fasciitis)	Phase III	sodium hyaluronate	Injection	In-house
Autoimmune Diseases					
MRA	Rheumatoid arthritis (new formulation: subcutaneous injection)	Approved (US)	tocilizumab	Injection	In-house (Roche)
		Filed (EU)			
	Giant Cell Arteritis	Phase III (Overseas)			
	Systemic Sclerosis	Phase II (Overseas)			
SA237	Rheumatoid arthritis	Phase I	—	Injection	In-house
RG7415	Systemic lupus erythematosus (SLE)	Phase I	rontalizumab	Injection	Roche

● Designates change in status in 2013 and thereafter

Alzheimer's disease. In May 2013, Chugai started phase I clinical trials in Japan for RG1577, a new monoamine-oxidase-B (MAO-B) inhibitor, for the expected indication of Alzheimer's disease. RG1450, an anti-amyloid-beta human monoclonal antibody currently in phase I clinical trials, is also under development for Alzheimer's. While RG1450 is intended for use before the onset of symptoms, RG1577 is expected to be effective in improving symptoms of Alzheimer's disease by raising cognitive function through selective inhibition of the activity of the enzyme MAO-B, which has been shown to be overexpressed in the brains of Alzheimer's patients. Both RG1577 and RG1450 have been in-licensed from Roche.

Originated from Chugai, CSG452 (tofogliflozin) is a selective SGLT2 inhibitor for the expected indication of type 2 diabetes. In October 2012, Chugai entered into licensing agreements with Kowa Company, Ltd. and Sanofi K.K., and in April 2013 the two companies filed applications for regulatory approval under their respective brand names. In March 2014, Kowa and Sanofi obtained MHLW approval under those brand names for the indication of type 2 diabetes. Chugai receives milestone payments from them as designated in the agreements and will supply the product to both companies after the launch.

In the respiratory diseases field, a phase III multinational study started in July 2013 for RG3637, an anti-IL-13 humanized monoclonal antibody for asthma. In-licensed from Roche, this compound has the potential to become a PHC treatment. RG3637 has demonstrated particular efficacy in patients with a high serum concentration of the protein periostin, which is induced by IL-13. The compound is expected to improve the symptoms of asthma and prevent asthmatic attacks in patients with moderate to severe asthma who are unable to control their symptoms with existing treatments.

In other fields, ACE910, a humanized bispecific antibody to factors IXa and X that employs Chugai's proprietary antibody engineering technologies, entered phase I clinical trials in Japan in August 2012 for the expected indication of hemophilia A and started phase I/II clinical trials in August 2013. Currently, the main treatment for hemophilia A is replacement therapy to supplement blood coagulation factor VIII. However, patients who develop autoantibodies that attack the replaced blood coagulation factor, also known as inhibitors, become unable to use this therapy. ACE910 shows promise as a therapeutic antibody that can prevent bleeding with once-weekly subcutaneous administration regardless of the presence of inhibitors. This compound applies Chugai's proprietary ART-Ig technology for commercially producing bispecific antibodies.

CIM331, an anti-IL-31 receptor humanized monoclonal antibody that originated from Chugai, blocks the binding of IL-31 with its receptors. As IL-31 is related to the itchiness of atopic dermatitis, CIM331 has potential to prevent itching and improve dermatitis by cutting off the itch-scratch cycle. A Chugai-managed phase II multinational study started in December 2013 in Japan, the United States and Europe.

Chugai started a phase I study in South Korea for the URAT1 inhibitor URC102 for the new expected indication of gout in June 2013. URC102 is a small-molecule compound originating from C&C Research Laboratories in South Korea, one of our satellite labs, and is being co-developed with JW Pharmaceutical Corporation of South Korea. The compound is expected to reduce the level of serum uric acid by promoting its excretion through inhibition of URAT1.

Central Nervous System/Other Diseases Development Pipeline (As of January 30, 2014)

Development Code	Indication	Status	Generic Name	Dosage Form	Origin (Collaborator)
Central Nervous System					
RG1678	Schizophrenia	(Multinational study)	bitopertin	Oral	Roche
RG7090	Major depressive disorder	(Multinational study)	—	Oral	Roche
RG1450	Alzheimer's disease		gantenerumab	Injection	Roche / MorphoSys
RG1577	Alzheimer's disease		—	Oral	Roche
Other Diseases					
RG3637	Asthma	(Multinational study)	lebrikizumab	Injection	Roche
CIM331	Atopic dermatitis	(Multinational study)*	—	Injection	In-house
ACE910	Hemophilia A	(I / II)	—	Injection	In-house
RG7652	Hyperlipidemia	(Overseas)	—	Injection	Roche
URC102	Gout	(Overseas)	—	Oral	In-house / JW Pharmaceutical

Designates change in status in 2013 and thereafter

* Multinational study managed by Chugai

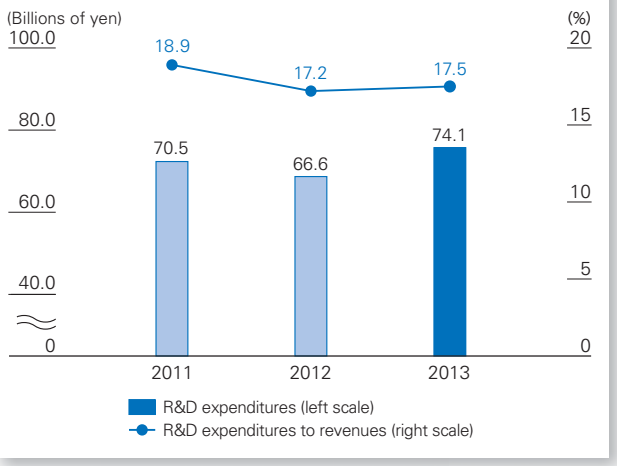
Research

Basic Policy and Allocation of Resources

Chugai's raison d'etre is to generate a steady stream of innovative products to address unmet medical need and benefit the medical community and human health around the world. Based on this principle, our key priority is to create new drugs with first-in-class or best-in-class potential. We are also a major player in Personalized Healthcare (PHC), where treatment is fitted to individual patient molecular and genetic profiles. Accordingly, we are focusing on the creation of molecular targeted therapies that are suitable for PHC; and we are also partnering with the Roche Group's Diagnostics Division for simultaneous development of companion diagnostics.

In allocating research resources, we prioritize projects based on criteria such as a compound's potential for development as a novel medicine that can be clearly differentiated; whether it has a scientific basis for addressing unmet medical need; and whether it is a project that will enable PHC. At various decision points during research, we focus first and foremost on patient needs, reflecting our belief that creating medicines that patients and healthcare providers truly need, will lead to Chugai's medium-to-long-term growth.

R&D Expenditures (Core Basis)



Strengths of Chugai's Research Organization

Chugai has three core strengths in its research operations.

The first is our years of accumulated knowledge and the benefits of the merger with Nippon Roche. Before the merger, Chugai had been engaged in research and development of biopharmaceuticals for more than 30 years and had a top-class 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 in 2002 created an industry-leading technology platform excelling in both biopharmaceuticals and small molecule drugs.

The second strength is access to Roche's global research infrastructure. The ability to share Roche's research resources and infrastructure, which include a rich compound library for use in high throughput screening[1] and a database of information on compounds, represents a significant advantage for Chugai in terms of cost and efficiency, and has dramatically increased our research productivity. While we enjoy the benefits of these assets of the Roche Group, our own discovery research system has ensured our independence.

The third strength is our research system's environment of open innovation. Chugai cooperates and collaborates with cutting-edge research institutions, and has steadily engaged in joint research, while contributing its own technology and know-how. Combined with recognition of our proprietary technologies, this has helped us to build strong external networks. Chugai also conducts research at satellite labs (research subsidiaries) with the aim of further reducing lead time in drug discovery and development, as well as continuously creating innovative R&D projects.

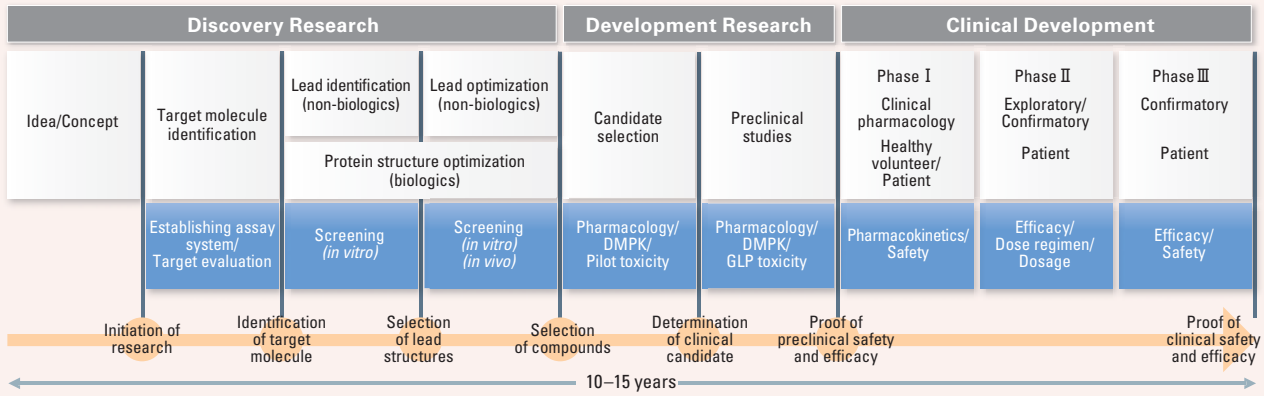
1. A technology that uses automated robots or other means to select active chemical compounds for drug creation targets from a library consisting of a vast number of compound types

Recent Outcomes of Research Activities and Continuous Creation of Innovative Products

In recent years, many projects from Chugai's research have entered clinical development. Of the 25 new compounds in our development pipeline in 2013, about 40 percent were developed in-house. PHC-related projects represented approximately 60 percent of our total pipeline (including projects in-licensed from Roche).

In addition to identifying new drug targets, developing technologies for drug discovery is critically important for continuously creating compounds with first-in-class or best-in-class potential. Many

Process and Milestones of Drug Development



pharmaceutical companies have begun developing molecular targeted therapies, but creating innovative medicines requires not only finding good targets, but also superior technologies. Chugai has announced a series of innovative, proprietary research technologies in recent years. We announced our recycling antibody technology in a scientific journal in 2010, and evolved it to develop our sweeping antibody technology in 2011. In October 2012, Chugai announced its development of ART-Ig, a technology for producing bispecific antibodies. (For details on these antibody technologies, see the column below). Therapeutic antibodies created by applying these technologies (SA237 and ACE910) are already in clinical development, and have gone through phase I clinical trials. Other technologies we have announced include ART-Fc, which enhances the potency of ADCC (antibody-dependent cell cytotoxicity); TRAB, T cell recruiting antibody; TwoB-Ig, which enhances selective binding to inhibitory Fcγ receptors; and ACT-Ig, which extends the serum half-life of antibodies. By incorporating the most advanced scientific knowledge and developing innovative technologies while confirming their essential properties, Chugai will continue to create new medicines from its own research that contribute to healthcare around the world.

Moreover, Chugai has expanded drug discovery research by operating satellite labs as part of its open innovation initiatives. Research findings at PharmaLogicals Research Pte. Ltd. in Singapore led

Chugai's Proprietary Technologies SMART-Ig and ART-Ig

SMART-Ig is the collective name for the innovative technologies behind Chugai's recycling antibody, which extends an antibody's duration of action, and sweeping antibody, which removes disease-causing antigens from plasma. The recycling antibody was engineered at the molecular level to dissociate from an antigen in acidic conditions so that when an antibody is taken on by a cell with the antigen, it can dissociate from that antigen. As a result, only the antigen is degraded in the cell, and the antibody returns to the plasma where it can bind to another antigen. This process is repeated multiple times. The sweeping antibody is a recycling antibody that has been further engineered so that the antigen bound to the antibody in plasma is actively taken up by the cell, allowing more target antigens to be degraded. Conventional antibodies cannot eliminate the disease-causing antigen from plasma, but the sweeping antibody can, which is expected to lead to improved treatment of illnesses.

ART-Ig is a technology that enables large-scale manufacturing of bispecific antibodies (BiAbs), which are capable of binding to two different types of antigen. Applying three technologies facilitates the expression of the target BiAb with production volume and purity similar to conventional antibodies. The development of this technology is expected to lead to the creation 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.

to the world's first successful establishment of stable cell lines of colon cancer stem cells in October 2012. In addition, URC102, a small-molecule compound discovered at C&C Research Laboratories in South Korea, a joint venture between Chugai and the JW Pharmaceutical Corporation of South Korea, has already entered clinical development. New drug targets have also been identified from research conducted at the University of Tokyo Research Center for Advanced Science and Technology and Forerunner Pharma Research Co., Ltd., a multidisciplinary research institution adjacent to the RIKEN Yokohama Institute. Chugai will effectively incorporate the findings at these research laboratories into drug discovery research to further enhance its development pipeline. Moreover, to accelerate new antibody creation driven by the proprietary antibody technologies described above, we established Chugai Pharmabody Research Pte. Ltd. (CPR) in Singapore in 2012. CPR specializes in antibody discovery, and aims to create 10 therapeutic antibody candidates in five years.

Note: For details on Chugai's innovative proprietary antibody technologies, see our website (http://www.chugai-pharm.co.jp/hc/ss/english/profile/rd/index.html).

Progress of Development Projects
January 1, 2013 – January 30, 2014

	Number of Projects	Breakdown		
		New Molecular Entities	Additional Indications	Additional Dosage and Administration/ Formulations
Approved	10	3	4[1]	3[2]
Filed	3	3[3]	—	—
Started phase Ⅲ	3	1	2	—
Started phase Ⅱ	2	2	—	—
Started phase Ⅰ	5	5	—	—
Development suspended	0	—	—	—

1. Includes Actemra for the indication of polyarticular juvenile idiopathic arthritis, which was approved overseas
2. Includes Herceptin for "once a week administration for postoperative adjuvant chemotherapy in breast cancer that overexpresses HER2," which was not in Chugai's pipeline, but 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
3. Includes CSG452, for which Kowa Company, Ltd. and Sanofi K.K. filed an application for the indication of type 2 diabetes

Academic Support Activities

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

The Chugai Academy for Advanced Oncology (CHAAO)[2] 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) 2013, the largest CHAAO event, took place over two days in Tokyo in July 2013. The main topic of this fourth annual forum was "Frontiers in Oncology Therapy." Thirteen influential oncologists working at the forefront of their field gave lectures on cutting-edge cancer therapy. A lecture on cancer immunotherapy, which has drawn considerable attention recently, generated especially lively discussion that provided a hint of the breakthroughs to come in this new area of oncology.

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 70 researchers from 14 Asian countries and regions. At a meeting in March 2013, six researchers from India, Egypt, Thailand, Nepal and Bangladesh presented their findings. For details on the program, see the TBRF website (http://www.tokyobrf.or.jp/english/).

2. Founded 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 2013, a CHAAO event

Intellectual Property

Basic Approach

Consistent with its business philosophy of "Innovation all for the patients," Chugai seeks to continually provide useful medicines to patients. We view our intellectual property (IP) strategy as the foundation for creating innovative new drugs, and have integrated it with our business and R&D strategies to protect the competitive advantage of our products and ensure operational flexibility. Under our basic policy, which emphasizes high-quality patent applications and effective allocation of resources, we have established a strong framework for cooperation within the Company. Our aim is to maximize the value of our products and technologies with IP rights and utilize them as a source of earnings through patent out-licensing.

How Our IP Strategy Creates Value

The Intellectual Property Department and the Research Division cooperate closely from the early stages of research and development to move R&D projects forward and secure a competitive advantage by conducting multifaceted analyses from an IP standpoint. In line with our basic policy, we focus resources on and secure IP rights for high-priority R&D projects. At the same time, we actively work to secure rights outside Japan with a view to global co-development with the Roche Group.

When we apply for patents for products, we include filings for our inventions related to formulation, production method, diagnostic method and Personalized Healthcare in addition to those for the basic substance and use. For significant drug discovery technologies such as innovative antibody technologies, we take advantage of accelerated examination programs and the Patent Prosecution Highway* to quickly establish rights globally. By viewing these product and technology patents in a matrix, we can strategically deploy them to optimize product protection and secure a technological advantage over our competitors. In addition, we are actively engaged in open innovation, and aggressively file patent applications for the research findings that emerge from our research networks with universities and research institutions.

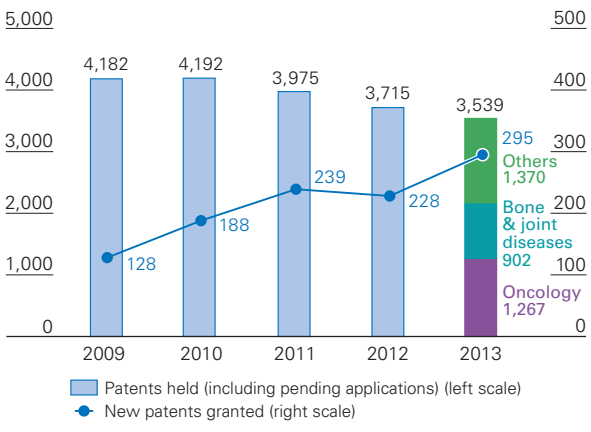
Investigating and analyzing the patents of other companies is also an important component of our IP strategy. We are therefore enhancing our patent search and analysis functions and promoting the use of patent information. In particular, the rights in antibody engineering technology are becoming more complex every year, so we are building our own related patent database and using it to plan IP strategies, including monitoring trends at other companies.

* Under the Patent Prosecution Highway, applicants whose patent applications are determined to satisfy the conditions for patentability in the country where the application was first filed (for example, Japan) can request an accelerated examination of the corresponding application filed in a second country (for example, the United States).

Current Patent Portfolio

Chugai currently holds about 3,500 patents worldwide, including patents pending. By therapeutic area, oncology accounts for the largest share of patents with approximately 35 percent of the total, a proportion that reflects Chugai's product portfolio. In 2013, Chugai acquired about 295 patents worldwide, primarily in its main markets of Japan, the United States and the European Union. These include patents protecting ACE910 and CIM331, which were developed from Chugai research, and SMART-Ig, our innovative antibody technology. On the other hand, we abandon patent applications that are no longer needed in order to reduce costs. In 2013, we abandoned 450 applications. With this approach, we are seeking to increase the overall value of our patent portfolio not only by securing high-value patents but also by conducting periodic reviews to determine whether or not patents should be maintained. In addition, we promote the efficient use of IP information by centralizing it in a patent management system so that it can be shared Company-wide.

Number of Patents Held (Including Pending Applications) and New Patents Granted



Drug Safety

Drug Safety Approach and System

In Japan and overseas, Chugai handles numerous biopharmaceuticals, molecular targeted therapies and other pharmaceuticals with innovative modes of action. Expert safety evaluation is essential for promoting the appropriate use of these pharmaceuticals around the world and gaining acceptance from patients and healthcare providers, while speedy decision-making is crucial for timely collection and provision of safety information and ensuring safety. Consequently, Chugai has established the Drug Safety Division and built a safety system directly linked to management. Based on this system, Chugai works with Roche to enhance its world-class operations. By carefully evaluating and disclosing the risk/benefit balance to healthcare providers and patients, Chugai increases its credibility.

Measures to Enhance Drug Safety

Promoting Safety Evaluation and Appropriate Use

Among measures to collect and evaluate information on the safety and efficacy of drugs after their market launch, our safety operations focus on conducting post-marketing, registration and specific registration surveillance. These types of surveillance are all based on the regulations of the relevant authorities. Post-marketing surveillance is conducted on new drugs under actual treatment conditions, mainly to collect safety information that is unobtainable in a clinical trial. 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. Post-marketing surveillance is conducted according to fixed protocols. The data forms are collected from medical institutions through electronic systems, and the accumulated data are analyzed as quickly as possible. This evaluated safety information is shared with medical institutions and officially announced inside and outside the Company via scientific conferences, papers and other means.

All-case registration surveillance is often imposed as a condition when marketing approval is obtained for innovative new drugs such as anticancer drugs or biopharmaceuticals. Begun immediately after a new drug is launched, this surveillance covers all medical institutions and cases where the relevant drug is used. As such, it requires a wider range and more rigorous management, such as thorough management of distribution, including wholesalers and dispensing pharmacies, and confirmation of conditions of use. Ahead of other companies, Chugai conducted large-scale all-case registration surveillance, particularly for Avastin, Tarceva and Actemra. With this extensive experience, we lead the industry in drug safety evaluation and safety measures. Now, even when we launch drugs that do not have all-case registration surveillance as a condition of approval, our MRs first explain the drug information, after which we check the facilities and organizational requirements of medical institutions to ensure that physicians are obtaining adequate information on the relevant drug. In this way, we have implemented a rigorous process for ensuring the appropriate use of our pharmaceuticals.

Safety Analysis and Adverse Drug Reaction Reports

Chugai is committed to highly transparent, speedy and timely reporting and release of drug safety information. We collect safety information on approximately 140,000 cases each year, the most for any pharmaceutical manufacturer in Japan, and evaluate it from a medical standpoint. We have established a system for recording evaluations in a global database and conducting signal detection of adverse drug reactions. With this system, we promptly disclose information on phenomena that may have a causal relationship, and on frequent or serious reactions, to regulatory authorities in Japan, the United States, Europe and Asia as well as to medical institutions. Aside from our large volume of safety information, our Drug Safety Division is staffed with medical doctors with abundant clinical experience. As full-time division employees, they conduct safety evaluations with a high level of expertise.

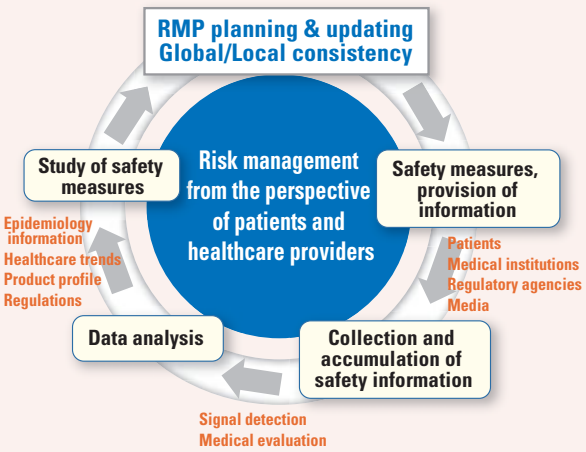
Moreover, we compile information on and typical examples of potential risk factors for the inherent adverse drug reactions of each product. We distribute patient information leaflets on adverse drug reactions to medical institutions and academic societies, in addition to posting information on the Company website, while MRs respond to inquiries from medical institutions individually. These activities help to reduce the incidence and aggravation of adverse drug reactions by creating an environment for treatment that takes high-risk patients into consideration.

Introduction of the Risk Management Plan (RMP)

A sweeping revision of pharmaceutical jurisprudence in Europe has energized pharmacovigilance worldwide in recent years. Demands include an expanded scope of safety information collection, globally standardized safety management systems, and an increase in transparency by ensuring the quality of information from collection to provision and promoting direct communication with medical institutions, patients and other parties. There is a growing consensus that companies should collect and analyze information consistently from the preclinical and clinical stages and should conduct evaluations that consider the risk/benefit profile, rather than taking the conventional approach of focusing mainly on post-marketing studies. The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) are also placing greater emphasis on pharmacovigilance in the drug approval process. Under these conditions, Chugai has set up a world-class safety management system that can accommodate the pharmaceutical jurisprudence and review procedures of regulatory agencies in Japan, the United States and Europe. In addition, to establish a plan – do – check cycle in our pharmacovigilance activities, we began drawing up and applying RMP measures to five of our products in 2012, ahead of our competitors. RMP became mandatory in Japan in April 2013, but we implemented it early because we consider RMP to be part of Chugai's commitment to patients and medical institutions, not just a legal obligation. Consequently, we have also come to view it as an opportunity to enhance our pharmacovigilance system and align it with global standards. Our efforts to date have included establishing a signal detection system, conducting evaluations with a high level of expertise, and making speedy decisions on measures to ensure safety.

In applying RMP, we were particularly aware of the need to strengthen our ability to analyze safety information data from an epidemiological standpoint. As a result, we are working to improve the precision of analysis through a specialized internal group in charge of epidemiology functions and proactively cooperating with specialist companies and others to help upgrade Japan's epidemiological database. We are also conducting new initiatives such as establishing signal detection and assessment tools for adverse events to assess potential risks and conduct more precise safety evaluations.

Organization Oriented to Risk Management



Globalization of Safety Information

To standardize safety information worldwide and conform to global safety standards, Chugai is establishing specific pharmacovigilance-related interactive communication protocols with Roche and other partner companies, and making arrangements for their smooth operation. In addition to standardizing safety evaluations for each product and sharing information on adverse drug reactions, we have already established a worldwide framework for speedy decision-making on safety measures and methods of response in coordination with Roche. By enhancing cooperative measures in these ways, Chugai aims to provide patients and medical institutions with truly valuable safety data and contribute to healthcare worldwide.

Production and Procurement

Chugai's Production System

Chugai is enhancing its production technologies and concentrating resources with two objectives: stable production that continues to earn the trust of patients and healthcare providers; and product creation that allows the Company to deliver previously unavailable pharmaceuticals to patients as soon as possible. The production function is responsible for a wide range of roles spanning from the development stage to post-marketing. These include studies on the manufacture and commercial production of biopharmaceuticals and small-molecule active pharmaceutical ingredients (APIs), the manufacture of investigational new drugs, and the design and manufacture of formulations and packaging.

Chugai's relevant production bases are spread around the globe, with three plants in Japan. As a world-class production base for biopharmaceuticals, the Utsunomiya plant conducts integrated manufacturing of Actemra and other biopharmaceuticals with one of Japan's largest facilities for cultivating biological APIs and a state-of-the-art production line for injectable formulations. The Ukima plant's diverse production menu includes solid and injectable formulations and packaging as well as biological APIs, to which the plant added the manufacture of investigational new drugs for development in 2013. The Fujieda plant has an integrated production line from API synthesis to formulation and packaging, and APIs produced at the plant are also supplied overseas. We have created a rigorous quality control system for these production operations in line with global standards, including compliance with GMP,* and they are an essential foundation supporting our growth.

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

Antibody production cell culture: Cells are transplanted in a 10,000-liter bioreactor for cultivation.

Cell separation: Cells are eliminated from the culture medium.

Purification: Impurities are removed with column chromatography to yield high-purity antibodies.

Reliable Distribution of Pharmaceuticals

To ensure a stable and continuous supply of safe, high-quality pharmaceuticals, Chugai is strengthening its supply chain management to optimize all activities, from raw material procurement to production and distribution. 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 global demand information with Roche and jointly developed a Global Demand & Supply Control System for optimal supply planning and management.

Also, in step with the globalization of purchasers, our suppliers of raw materials and intermediates, and our production bases for finished products are becoming globalized as well. Moreover, we are ensuring shipping quality through temperature control for transport between bases and by developing risk countermeasures, such as increasing the locations that produce essential products, based on our experience from the Great East Japan Earthquake. In ways such as these, we are working to maintain and improve the reliability of distribution in Japan and overseas by strengthening our

measures for supply chain management as it becomes increasingly complex and global.

Chugai Distribution Co., Ltd. handles distribution of pharmaceuticals in Japan. For stable and safe distribution, the company uses a computer system for inventory management and inspection, and the staff employs original methods for the careful packaging of products to enable easy sorting and prevent damage when recipients open the cartons.

Measures for Stable Procurement

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.

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 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 management.

Chugai's products are provided to patients worldwide, and we have affiliated manufacturing 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 manufacturing sites to ensure that we continue to deliver high-quality medicines to patients everywhere.

Building Fair, Transparent Relationships with Business Partners

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.

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

Environmental Protection and Occupational Safety

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.

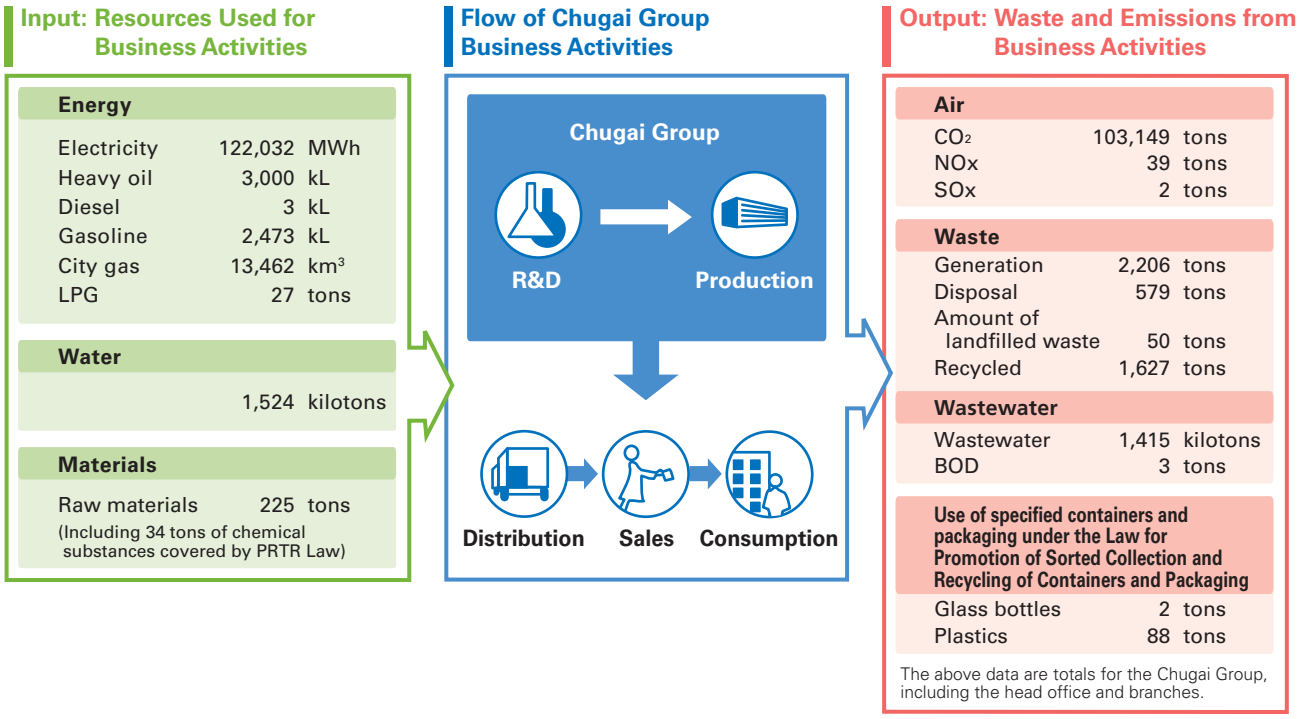
2013 Environmental Action Plan and Performance

Evaluation: ○ Goal achieved △ Goal 75% or more achieved × Goal less than 75% achieved

Item		2013 Goal or Mid-Term Plan	2013 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 7%	△
		Achieve average fuel efficiency of 16 km/l for MR fleet	Average fuel efficiency of MR fleet was 14 km/l	△
Waste reduction	Reduction in the amount of waste generated	Limit the amount of waste generated in 2013 to 2,000 tons or less	Amount of waste generated was 2,206 tons	△
	Reduction in the amount of landfill waste	Limit the amount of landfill waste in 2013 to 70 tons or less	Landfill waste in 2013 was 50 tons	○
	Promotion of recycling	Achieve a recycling ratio of 70% or higher	Recycling ratio was 74%	○
Resource conservation	Reduction in the amount of PPC paper purchased	Reduce the amount of PPC paper purchased in 2013 by 3% from the 2012 level	Increased by 5% from the 2012 level	×
	Improvement in the recycling ratio of PPC paper	Maintain a recycling ratio of 80% or higher for PPC paper in 2013	Achieved a recycling ratio of 95% in 2013	○

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

Material Flow



Measures to Prevent Global Warming

Reducing Energy Consumption

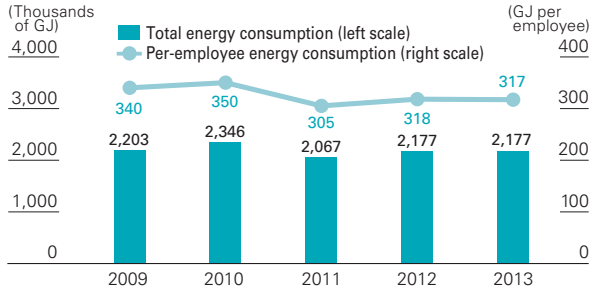
Chugai has set the goal of reducing energy consumption in 2014 by 10 percent from the 2009 level of 340 gigajoules (GJ) per employee.

Energy use in 2013 was 317 GJ per employee, or 93 percent of the base-year level.

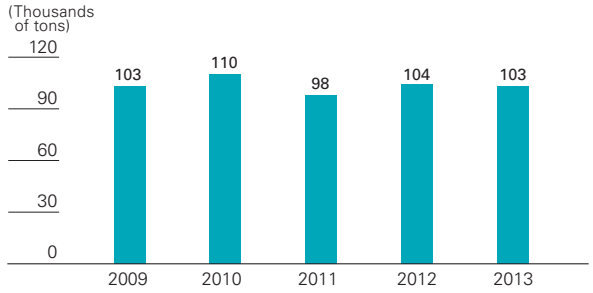
The trend of total CO_2 emissions is similar to that of total energy consumption.

As in 2012, Chugai did not install any solar power generation equipment with capacity of 100 kW or higher in 2013, and does not plan to do so in 2014.

Total and Per-Employee Energy Consumption



Total CO_2 Emissions

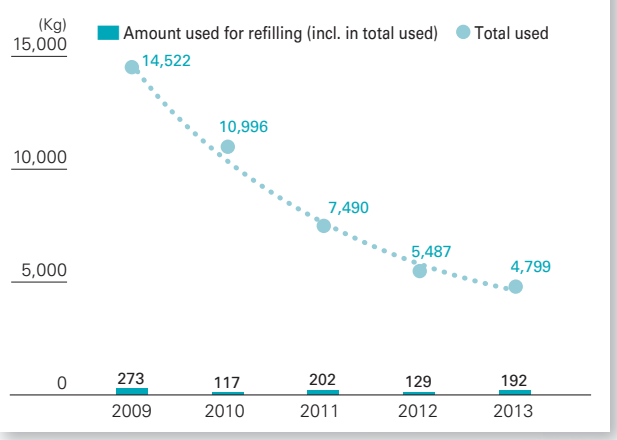


Discontinuation of Use of Halogenated Hydrocarbons

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 2013, the total amount of CFCs and HCFCs used was 4,799 kg.

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 2013, we had a total of 1,057 hybrid vehicles and conventional vehicles with similar fuel efficiency, which accounts for 54 percent of our fleet.

Reducing CO_2 Emissions with the Introduction of a Turbo Refrigerator

The Utsunomiya plant changed the fuel it uses for refrigeration from city gas to electricity by replacing its steam absorption refrigeration unit with an inverter turbo refrigerator. In addition, the refrigerator was improved with the introduction of an optimal controller for regulating the temperature and flow of chilled water. These measures reduced annual consumption of gas by approximately 320,000 m^3 and electricity by approximately 317,000 kWh (800 tons-CO_2) in 2013.

Note: Carbon dioxide emission coefficients are as follows:
Electricity: 0.000423 (per kWh)
City gas: 2.079660 (per 1,000 m^3)

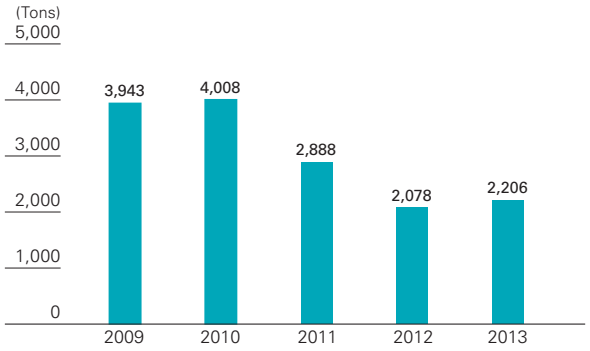
Inverter turbo refrigerator

Waste Reduction

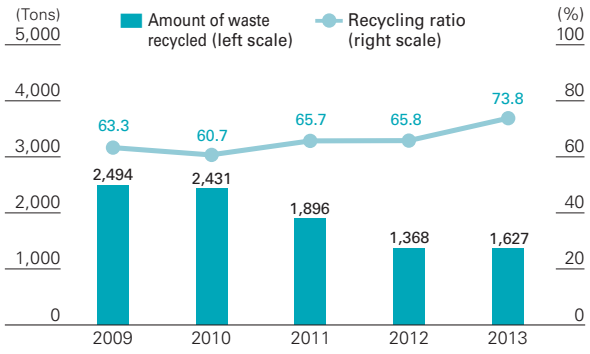
Results in 2013

In 2013, the amount of waste generated was 2,206 tons, an increase of 128 tons compared with 2012, the amount of waste recycled was 1,627 tons, an increase of 259 tons, and the amount of landfill waste was 50 tons, a decrease of 29 tons. As a result, the recycling ratio was 73.8 percent, an increase of 8 percentage points from 2012.

Industrial Waste Generation

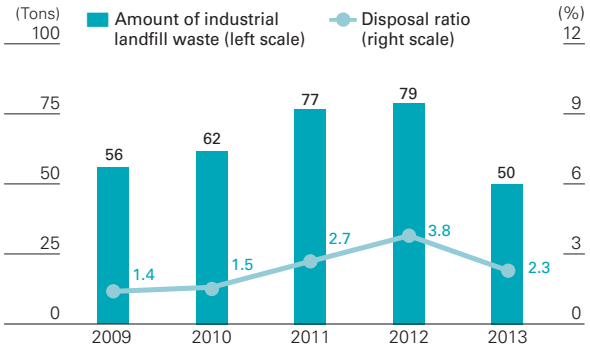


Waste Recycled and Recycling Ratio[1]



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

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



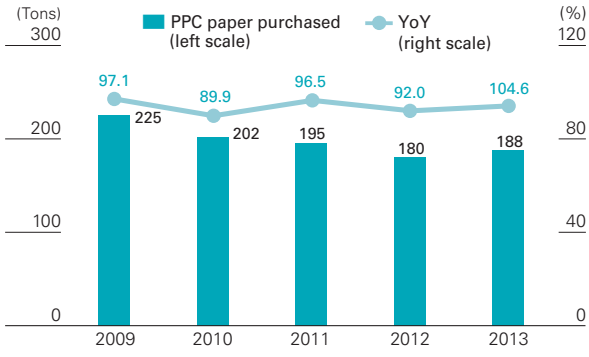
2. Amount of landfill waste/Amount of waste generated

Reduction in PPC Paper Used

The amount of PPC paper purchased increased by 5 percent compared with 2012 despite efforts including reduction of handouts at meetings, multi-page printing and duplex printing.

We continued to promote the purchase of PPC paper that meets green purchasing criteria (100% recycled paper, FSC certification, etc.).

PPC Paper Purchased

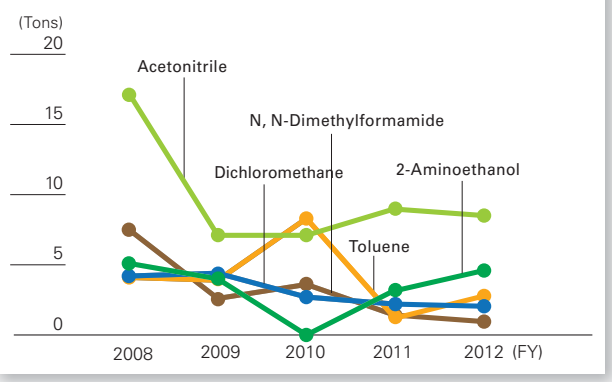


Chemical Substance Management

In the one-year period from April 2012 to March 2013 (fiscal 2012), Chugai handled more than one ton each of five chemical substances covered by the PRTR Law.* 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 Toluene and 2-Aminoethanol increased, but the amount of Acetonitrile, Dichloromethane and N,N-Dimethylformamide decreased slightly. As a result, the total amount of these five substances handled increased by 11 percent.

* 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

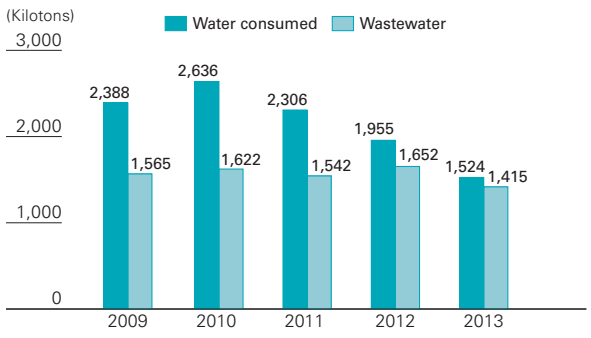


Prevention of Water and Air Pollution

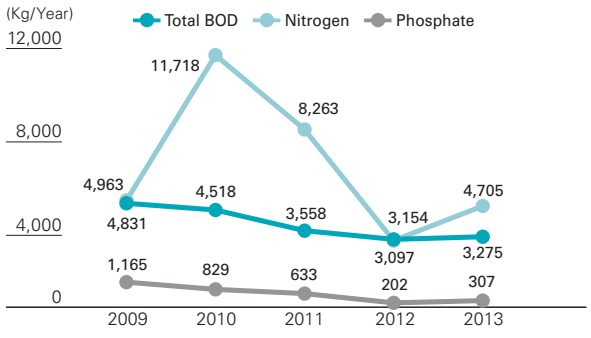
Water Consumed, Wastewater, Etc.

The amount of water consumed decreased by 431 kilotons compared with 2012. Nominal wastewater discharge at all Chugai plants and research laboratories was significantly below the prescribed environmental limits. Total biochemical oxygen demand (BOD) has increased by 121 kg compared with 2012.

Water Consumed and Wastewater



Total BOD, Nitrogen and Phosphate

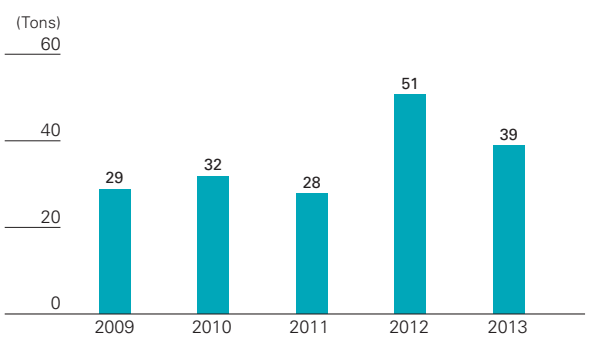


Air Pollutants Emitted

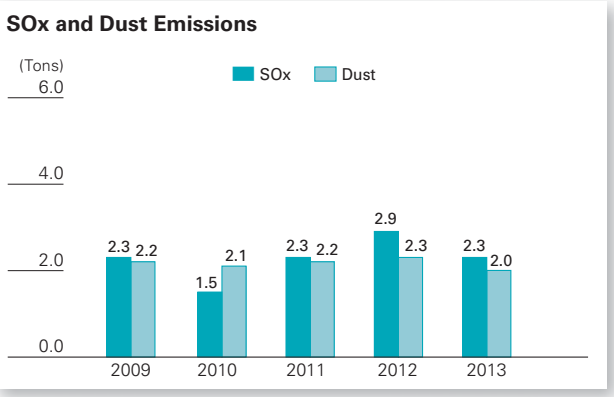
Air pollutants emitted by Chugai sites were significantly below the prescribed environmental limits at each site.

NOx emissions decreased by 12 tons compared with 2012.

NOx Emissions



SOx and Dust Emissions



Environmental Accounting

Environmental accounting data compiled in 2013 are shown below. Investments in 2013 totaled ¥475 million, while costs were ¥1,742 million.

Major investments included refrigeration- and boiler-related equipment.

The economic benefit was ¥29 million.

2013 Investments and Costs for Environmental Protection

(Millions of yen)

Breakdown of costs	Investments	Costs
(1) Business area costs	463	1,415
(1)-1 Pollution prevention costs	234	853
(1)-2 Global environmental protection costs	226	392
(1)-3 Resource recycling costs	2	170
(2) Upstream and downstream costs	—	33
(3) Administration costs	12	284
(4) R&D costs	—	1
(5) Social activity costs	—	11
(6) Environmental remediation costs	—	—
Total	**475**	**1,742**

Occupational Safety

The number of occupational accidents in the Chugai Group in 2013 is shown below. In 2013, there was one accident accompanied by lost worktime. Accidents that did not result in lost worktime increased by 3 cases compared with 2012.

Results of Occupational Accidents in 2013

	Number of accidents	Incidence rate
Lost worktime	1	0.08
No lost worktime	25	2.08
Total	**26**	**2.16**

Total number of lost workdays: 78*
* Including workdays lost as a result of accidents that occurred in the previous year

Social Contribution Activities

Support for the Japan Paralympic Committee as an Official Partner

In September 2013, Chugai became an official partner of the Japan Paralympic Committee (JPC), an organization of the Japan Sports Association for the Disabled, as part of its social contribution activities. Chugai has declared, "We recognize our responsibility as a good corporate citizen and actively continue with our social action programs." Chugai decided to support JPC as an official partner so that all its employees would feel motivated and encouraged through their support of athletes who are competing to be the best in their sport. At the same time, we wanted to provide opportunities to the athletes' many supporters to think about health, the importance of life and diversity.

Japan Paralympics track event

Welfare Vehicle Donation Program

Chugai's program to donate specially equipped welfare vehicles began in 1985 as part of activities to commemorate the Company's sixtieth anniversary. Five vehicles were donated in 2013, bringing the cumulative total over the 29 years of the program to 198.

The number of seniors and persons with disabilities in Japan who need nursing care continues to increase as the population ages. The welfare vehicles donated by Chugai are used to transport elderly people and people with disabilities who receive nursing care at home.

The five groups that received vehicles in 2013 were the social welfare councils of Nasushiobara City, Tochigi Prefecture; Nagahama City, Shiga Prefecture; Mihamacho, Fukui Prefecture; Wakasacho, Tottori Prefecture; and Aritacho, Saga Prefecture.

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.

Donation ceremony in Aritacho, Saga Prefecture

Donated vehicle

Endowed Courses on Medical Treatment

As a way of contributing to society, Chugai has established endowed courses at universities to raise interest in health and medical treatment among the next generation.

One such course was held for the second year at Keio University Global Security Research Institute from April to July 2013. In addition to general lectures on both local and global health from such diverse perspectives as government healthcare policy and health management, the course included practical lectures from the standpoint of pharmaceutical companies, hospital management and sports promotion. Students from various fields of study deepened their understanding of the current situation regarding "health" and engaged in small group discussions about ways to solve social issues.

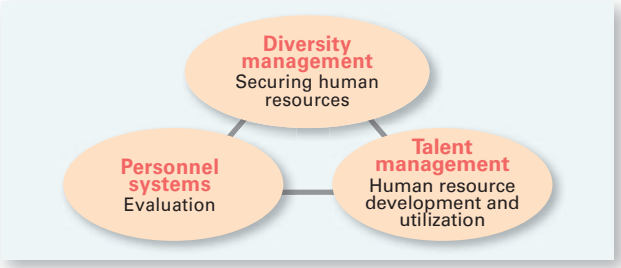
Another course, now in its third year at Waseda University, was held from October 2013 to January 2014. The theme was medical treatment, particularly cancer treatment. Some of Japan's leading clinical physicians and researchers as well as securities analysts gave lectures on the current state, challenges and future prospects for 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.

Lecture at Waseda University

Human Resources

Human Resource Strategy to Become a Top 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 pharmaceutical company, as expressed in its Mission Statement.



Diversity Management

Chugai has placed priority on diversity management to enable a rich variety of employees to work enthusiastically and create new value. We began addressing this issue with the launch of a management working team in 2010 to promote gender diversity. We established the Diversity Office in 2012 to spread awareness and improve the working environment. Since then, in addition to measures such as e-learning and manager training, forums have been held in every division to give women opportunities to think about their careers. To deepen consideration of women's careers and diversity from a global standpoint, we have held meetings where participants can exchange opinions with a female company director and work to nurture female leaders for broader discussion in various situations.

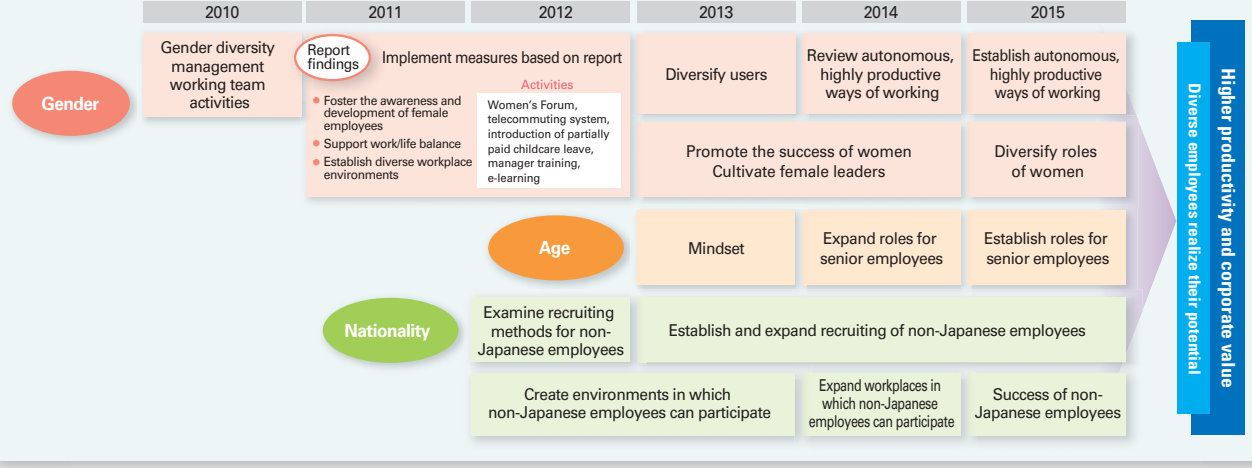
Female employees exchange opinions with Member of the Roche Enlarged Corporate Executive Committee Dr. Sophie Kornowski-Bonnet.

To help employees balance work and life events such as childcare or nursing care, we have instituted a telecommuting system. In light of the aging of Japan's society, we also held a seminar for a wide range of employees, irrespective of gender or age, regarding nursing care for the elderly. Moreover, we have launched a website that provides company and daily living information to help create a better working environment for non-Japanese employees, and we have started training to promote long-term career development for employees over 50. To conduct business at a global level, we will promote the activities of non-Japanese and senior employees in addition to promoting gender diversity to accelerate the active participation of a wider range of employees.

Talent Management System

Chugai conducts talent management to secure and nurture the leaders and core human resources who will carry out its management strategies to become a top pharmaceutical company. Specifically, in April 2013 each organization continued its efforts from the previous year by holding discussions on medium-to-long-term human resource development policy, drafting a human resource development plan and

Diversity Promotion Roadmap



creating a talent pool.* Based on the development plans, the organizations carried out strategic employee placement and training designed to strengthen leadership from a Company-wide perspective.

In addition, we clarified our succession plan by selecting successor candidates for a total of 88 general manager and department managers in Japan. We are currently implementing development plans for these candidates to help them hone a variety of skills and cultivate a wide-ranging perspective to ensure that they can display leadership on a global level.

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

Career Development Framework

Having already revised its personnel system and introduced diversity management and a talent management system, 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.

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

The Chugai Diversity Promotion Forum

In November 2013, we held the Chugai Diversity Promotion Forum to share and accelerate initiatives to promote diversity in each division. The approximately 120 participants included the Chairman, executive officers, division general managers, unit heads and other members in charge of diversity promotion from each division.

Initially, each division's activities related to women, but with the wider range of members promoting diversity in terms of gender, age, nationality and other attributes, each division is now making efforts in line with its own characteristics and issues, resulting in reports on a wide variety of plans and events with unique characteristics. The forum shared anew the awareness of how diversity is essential for growth, given rapid changes in the business environment and the increasing speed of technological innovation; it also renewed the participants' determination to further promote diversity.

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 disability. 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, 2013, the ratio of employees with disabilities in the Company was 2.01 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 to improve working conditions such as introducing a program to support employees who return to work after childcare leave. In recognition of these measures, in 2008 and 2011 Japan's Ministry of Health, Labour and Welfare certified Chugai as a company that actively supports the balance between work and family life under the terms of the act. In its Phase 3 Action Plan (April 1, 2011 – December 31, 2014), Chugai introduced a telecommuting system in 2012 and reduced the core working hours of its flextime system in 2013 to help employees fully utilize their abilities while raising children or providing nursing care.

In addition, we are making ongoing efforts to promote appropriate working hours. Measures to reduce overtime include labor-management sharing of information on overtime hours worked and the institution of "no overtime" days in each workplace. Other measures include encouraging the use of at least three paid vacation days and granting anniversary holidays every year.

Maintaining the Work Environment

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 each employee's issues, we have set up physical and mental health counseling services in which specialists including occupational health physicians, nurses and psychologists cooperate with human resource managers and workplace 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 two themes for the first half of 2013 were "The right attitude for using social media" and "Learning from the harmful effects of medicines." The first theme considered the scope of the social impact of information disseminated through social media, the disseminator's responsibilities, and the importance of employees acting with an awareness of their role in disseminating information to help the company meet the expectations and earn the trust of society. The second theme covered case studies of harmful effects from medicines and systems to prevent recurrence. This review helped to reconfirm that preventing such events, rather than studying them after they occur, and giving patient safety the highest priority are vital for a front-runner in the evolving field of healthcare. Moreover, based on our common commitment to patients, the training was an opportunity to share anew our awareness that each employee should work with a sense of urgency while ensuring that memories of past tragedies will not fade with the passing of the generations.

Training in the second half dealt with "Communication that empowers individuals" to allow each employee to display his or her abilities in a workplace with diverse values. Through active discussion, members of each workplace considered working styles that link individual achievements to organizational results and ways to turn this workplace attitude into "Chugai culture" to achieve the mission shared by all employees.

Corporate Ethics and Bioethics

Stance on Corporate Ethics

Based on its approach of prioritizing corporate ethics over profit, 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 programs including corporate ethics courses conducted during employee group training twice each year, 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 Chugai Business Conduct Guidelines (Chugai BCG).

Bioethics in R&D and Clinical Trials

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. Moreover, we strive for research that prioritizes ethics by offering our researchers courses and guidance on research ethics to give them the knowledge they need in their work, including information on the ethics of research using human-derived test material.

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,* a global independent evaluation organization. Chugai obtained full accreditation, which was renewed in 2010 and 2013.

* 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 900 facilities in 37 countries have been accredited.

Highly 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 takes steps to ensure that all of its corporate activities are highly ethical. We actively support the efforts of the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry and the Japan Pharmaceutical Manufacturers Association's Promotion Code Committee, which administer the self-regulatory industry rules. In addition, we have voluntarily established our own code of practice that extends beyond pharmaceutical promotion to cover the interactions of all directors and employees with researchers, healthcare workers, patient groups and other parties.

Corporate Governance

Management Decision-Making, Execution and Oversight of Business Operations

To expedite business operations and clarify executive responsibilities, Chugai Pharmaceutical Co., Ltd. ("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, since 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. Two of the outside directors are from the Roche Group.[1]

In 2013, 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.

1. Franz B. Humer, an outside director, retired from his position as a Member of the Board of Directors of the Roche Group in March 2014.

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)

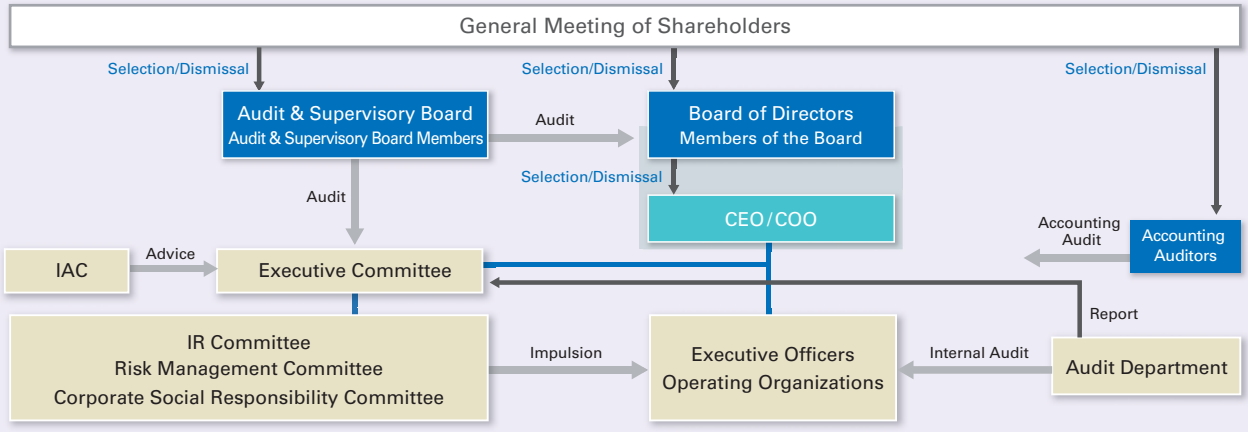
Chugai has established the International Advisory Council (IAC), an advisory board composed of industry leaders and other professionals from around the world. The IAC works to enhance decision-making by providing valuable advice on how to deal with changes in the global business environment and appropriate 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 point out issues and give advice concerning Chugai's management at their discretion. Those from Roche do so from a global perspective while the others do so from their abundant experience and knowledge as corporate executives, physicians or university professors.

Chugai's Corporate Governance System



The rate of attendance by outside directors at the seven board meetings in 2013 was 97.1 percent on average, the highest being 100 percent and the lowest 85.71 percent.

Members of the IAC

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)**
  Former 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

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.

Internal Audits

The Audit Department, with a staff that includes certified internal auditors, conducts audits of the status of the Chugai Group's business execution from various standpoints such as the effectiveness, efficiency and compliance of business activities, including those of subsidiaries in Japan and overseas; 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 and the Audit Department is working to maintain its quality. Please note that the independent evaluation by a third-party institution

Reasons for Election of Outside Directors

Name	Outside Position	Reason for Election
Mitsuo Ohashi	Supreme Counselor, 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, University Professor of Waseda University, Vice-Chairman of the Board of Directors, Musashi Academy of the Nezu Foundation	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.
Franz B. Humer	Former Chairman of the Board of Directors of ROCHE HOLDING LTD	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 based on his abundant experience and knowledge as a manager of global pharmaceutical companies.
Daniel O'Day	Chief Operating Officer of Roche Pharmaceuticals Division, Member of the Roche Corporate Executive Committee, Member of the Genentech Board of Directors	Managerial 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, Member of the Roche Enlarged 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.

does not provide representation, certification or other guarantee of the auditor's opinion and does not constitute a guarantee of the sufficiency of the internal audit process in the event that the accounting auditors need to use or evaluate it in the future.

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.

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. 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. In addition, the Office of Audit & Supervisory Board Members ensures the independence and enhances the auditing functions of Audit & Supervisory Board Members.

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

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

	Total Remuneration, etc. (Millions of yen)	Total Remuneration, etc. by Type (Millions of yen)				Number of eligible officers
		Regular Compensation	Bonuses	Common Stock Options	Stock Options as Stock-based Compensation	
Directors (excluding outside directors)	686	303	185	78	119	6
Outside Directors	31	31	—	—	—	3
Total	718	520		78	119	9
Audit & Supervisory Board Members (excluding outside members)	62	62	—	—	—	3
Audit & Supervisory Board Members (outside members)	21	21	—	—	—	2
Total	84	84		—	—	5

1. Amounts are rounded down to the nearest million yen.
2. The table above includes one Audit & Supervisory Board member who resigned during 2013.
3. The amount of remuneration (regular compensation and bonuses) paid to all directors is no more than ¥750 million per year as per the resolution passed in the 96th Annual General Meeting of Shareholders 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 98th Annual General Meeting of Shareholders held in March 2009.
4. 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 95th Annual General Meeting of Shareholders held in March 2006.
5. The amount of bonuses shown in the table above is the amount of the provision of reserve for bonuses to directors during 2013.
6. The amounts of common stock options and stock options as stock-based compensation and the number of eligible officers shown in the table above are the amounts that were posted as expenses for 2013 and the number of officers in 2013, respectively (including expenses of ¥1 million for one officer who retired in 2012).
7. In 2013, the amount of remuneration received by two outside directors, namely William M. Burns and Daniel O'Day, as officers from the parent company of the Company or subsidiaries of the said parent company totaled ¥690 million (converted into yen at the average exchange rate in 2013).

Amount of Remuneration Paid to Each Representative Director

	Total Consolidated Remuneration, etc. by Type (Millions of yen)				Total Consolidated Remuneration (Millions of yen)
	Regular Compensation	Bonuses	Common Stock Options	Stock Options as Stock-Based Compensation	
Osamu Nagayama (Representative Director)	124	142	32	58	357
Motoo Ueno (Representative Director)	51	19	12	16	100
Tatsuro Kosaka (Representative Director)	51	23	11	19	105

1. Amounts are rounded down to the nearest million yen.
2. The table above shows the total remuneration, etc. of representative directors.
3. No officers other than the representative directors listed above had total remuneration of ¥100 million or more.

directors with specific titles to ensure the objectivity and transparency of the remuneration-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 with executive powers. 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.[2]

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.

Two of Chugai's ten directors are from the Roche 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.

2. The Tokyo Stock Exchange requires delisting if the ratio of tradable shares to listed shares is less than 5 percent.

Restrictions on Roche's Shareholding

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

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 117 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 2013, the Corporate Social Responsibility Department

Chugai Risk Management System

conducted internal monitoring surveys regarding compliance status every quarter, and every half-year for overseas affiliated companies, and reported the results to the Corporate Social Responsibility Committee. Each organization worked to ensure thorough legal compliance in the workplace through BCG promotion managers and assistants.

The BCG Hotline and the internal and external Harassment Hotlines have been established to receive employee inquiries and reports concerning compliance with laws, Company rules and the Chugai BCG.

Disclosure Policy

Chugai conducts interactive corporate communication activities to deepen mutual understanding and build relationships of trust with its stakeholders, such as patients, healthcare providers, shareholders, investors and employees. In order to achieve these objectives, 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, appropriate 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

External Recognition

Chugai Wins Award for Excellence in 16th Nikkei Annual Report Awards

Beginning with *Annual Report 2012*, Chugai has integrated its annual report and corporate social responsibility (CSR) report. In the 2012 integrated report, Chugai's business philosophy, business model and business strategies were presented in easy-to-understand terms, and senior managers explained the measures in ACCEL 15 to link Chugai's unique strengths to creating and enhancing corporate value. These points contributed to the high evaluation of the report.

The awards ceremony (Right: Deputy Chairman Motoo Ueno)

Chugai Listed on FTSE4Good Index Series

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, 2013, 749 companies were listed, including 180 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.

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 well in advance. We sent the notice for the 103rd annual meeting more than four weeks prior to the meeting date.

The 103rd annual general meeting of shareholders was held on March 27, 2014. 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 August 2013, we held an information meeting jointly with Taisho Toyama Pharmaceutical Co., Ltd. on the new launch of Bonviva, an agent for osteoporosis, and explained the agent's features and its expected contribution to medical treatment. In addition, we conducted a factory tour for shareholders in October as a new initiative to enhance communication. Shareholders were able to see inside the Utsunomiya plant, where our flagship product Actemra is produced. By directly viewing our state-of-the-art biopharmaceutical manufacturing plant, they were able to deepen their understanding of our strength. In December, we also conducted a tour for investors and analysts at Chugai Pharmabody Research Pte. Ltd., established in Singapore as a base for antibody technology research, and explained the current status of activities there.

Director, Executive Vice President & CFO Yoshio Itaya was selected by the sell-side (securities companies) as "All-Japan Executive Team Best CFO" in the health care and pharmaceuticals sector* in recognition of his active communication with shareholders, investors and analysts in Japan and overseas.

Senior management also holds overseas roadshows and in 2013 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 enhancing its outreach to individual investors by holding information meetings for them at branches of securities companies throughout Japan.

In addition, Chugai has integrated reporting to communicate its corporate value, which includes both financial and non-financial aspects. We have combined the traditional annual report with the corporate social responsibility (CSR) report.

The Chugai website is another tool we use to 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, annual reports and an IR event calendar. We work to provide comprehensive information to our stakeholders. 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 our website, and other initiatives include posting webcasts of IR events on 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.

* Initiated by Institutional Investors LLC in 2013, this competition ranks candidates based on a survey of securities analysts and institutional investors around the world, including Japan.

Board of Directors/Audit & Supervisory Board

(As of April 1, 2014)

Representative Directors

Osamu Nagayama

Motoo Ueno

Tatsuro Kosaka

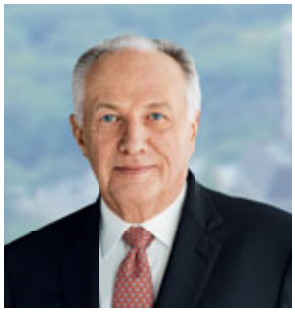
Directors

Yoshio Itaya

Yutaka Tanaka

Mitsuo Ohashi
Supreme Counselor,
SHOWA DENKO K.K.

Yasuo Ikeda
University Professor of
Waseda University



Franz B. Humer
Former Chairman of the Board of Directors of 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 April 1, 2014)

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
2010 Director, Sony Corporation (to present)
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
2012 Representative Director, President & COO (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.
2011 Senior Vice President, CFO, General Manager of Finance Supervisory Div. and Finance & Accounting Dept. (to present)
2012 Director, Executive Vice President & CFO (to present)

Yutaka Tanaka

1984 Entered Nippon Roche K.K. (NR)
2001 General Manager of Product Research Division of the Laboratory of NR
2002 General Manager of Product Research Dept. of the Company
2004 General Manager of Product Strategy Dept.
2005 General Manager of Renal Disease Area Dept.
2007 Vice President, General Manager of Clinical Research & Development Div.
2009 Senior Vice President, General Manager of Clinical Research & Development Div.
Senior Vice President, Head of Portfolio Management Unit
2011 Senior Vice President, Head of Lifecycle Management & Marketing Unit
2012 Senior Vice President, Head of Project & Lifecycle Management Unit
2014 Director, Executive Vice President, Head of Project & Lifecycle Management Unit (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
2014 Supreme Counselor, 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
2010 Director of the Company (to present)
2013 Vice-Chairman of the Board of Directors, Musashi Academy of the Nezu Foundation (to present)
2014 University Professor of Waseda University (to present)

Franz B. Humer

1971 Entered ICME Zurich
1973 Entered Schering Plough Corporation
1981 Entered Glaxo Holdings plc
1995 Member of the Board of Directors, Head of the Pharmaceuticals Division of F. Hoffmann-La Roche Ltd (FHLR)
1996 COO of FHLR
1998 CEO of ROCHE HOLDING LTD (RH)
2001 Chairman of the Board of Directors and CEO of RH
2002 Director of the Company
2008 Chairman of the Board of Directors of RH
Non-executive Chairman of Diageo Plc (U.K.) (to present)
2014 Director of the Company (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 Roche 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, Member of the Roche Enlarged Corporate Executive Committee (to present)
Director of the Company (to present)

Executive Officers (As of April 1, 2014)

Executive Committee Members

① Osamu Nagayama
Representative Director, Chairman
CEO

② Motoo Ueno
Representative Director, Deputy Chairman
Corporate Social Responsibility, Audit

③ Tatsuro Kosaka
Representative Director, President
COO

④ Yoshio Itaya
Director, Executive Vice President
CFO, General Manager of Finance Supervisory Div. and
General Manager of Finance & Accounting Dept.

⑤ Yutaka Tanaka
Executive Vice President
Head of Project & Lifecycle Management Unit

⑥ Kunitoshi Watanabe
Audit & Supervisory Board Member

⑦ Kotaro Miwa
Audit & Supervisory Board Member

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

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

Hitoshi Kuboniwa
Senior Vice President
General Manager of Pharmaceutical Technology Div.

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

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

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.

Yasushi Ito
Vice President
General Manager of Clinical Development Div.

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

Shinji Hidaka
Vice President
Head of Primary Unit

Osamu Okuda
Vice President
Head of Oncology 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.

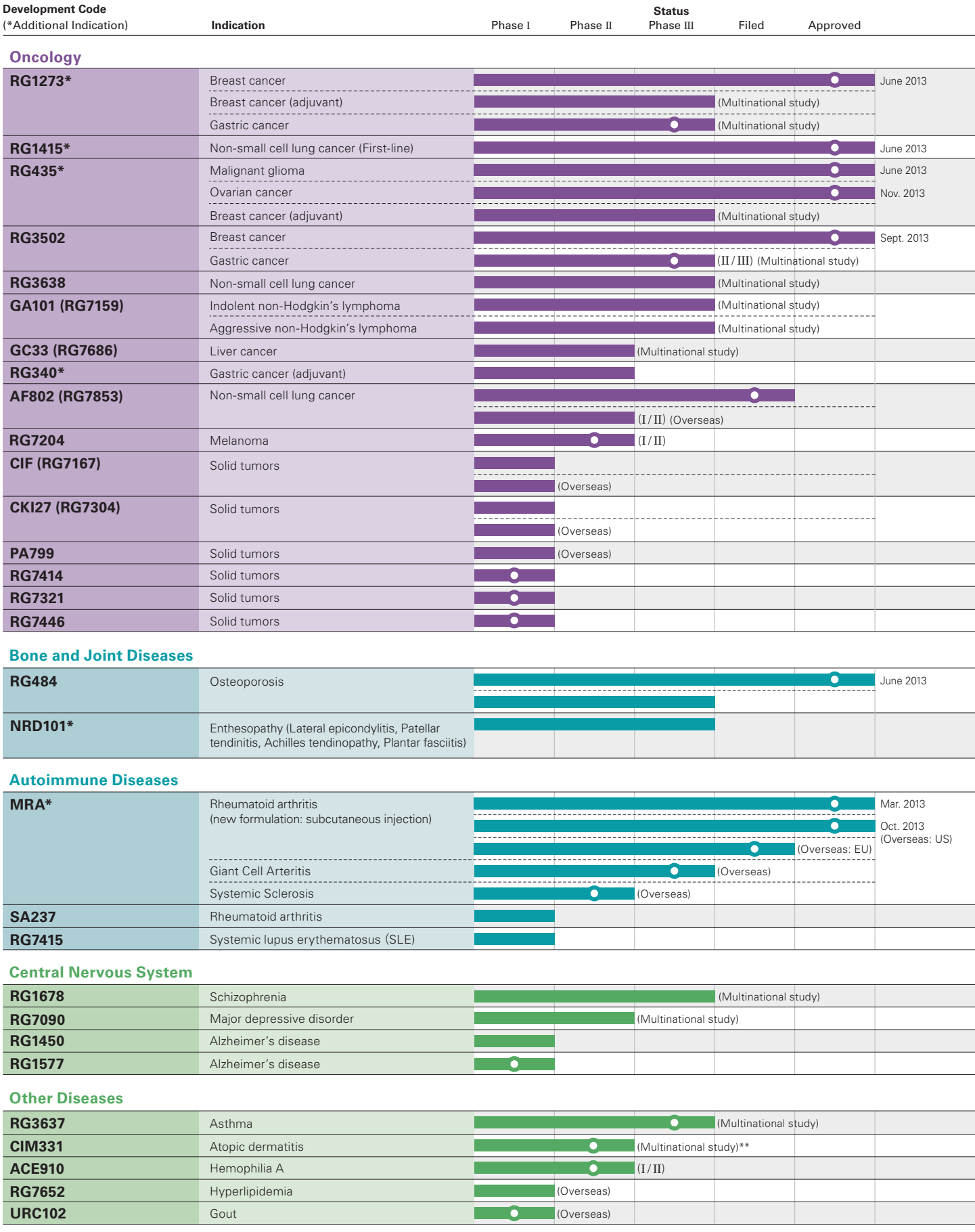
Toshihiko Tsuchiya
Vice President
General Manager of General Affairs Dept. and
General Manager of Secretarial Dept.

Junichi Ebihara
Vice President
General Manager of Legal Dept.

Data Section

This section is intended to give readers a deeper understanding of Chugai's innovations and the value we want to create. In addition to an overview of Chugai's development pipeline and basic information, this section includes general information on topics such as pharmaceutical industry and healthcare trends and the newest treatments.

Development Pipeline (As of January 30, 2014)



Designates change in status in 2013 and thereafter

** Multinational study managed by Chugai Pharmaceutical

Generic Name / Product Name	Origin (Collaborator)	Mode of Action
pertuzumab / Perjeta (Overseas name: Perjeta)	Roche	HER dimerization inhibitory humanized monoclonal antibody (Injection)
erlotinib / 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 / Kadcyla (Overseas name: Kadcyla)	Roche	Anti-HER2 antibody-drug conjugate (T-DM1) (Injection)
onartuzumab / Product name undetermined	Roche	Anti-MET humanized monoclonal antibody (MetMAb) (Injection)
obinutuzumab / Product name undetermined (Overseas name: Gazyva)	Roche (Nippon Shinyaku)	Glycoengineered type II anti-CD20 monoclonal antibody (Injection)
—	In-house (Roche)	Anti-Glypican-3 humanized monoclonal antibody (Injection)
capecitabine / Xeloda (Overseas name: Xeloda)	Roche (Yakult Honsha)	Antimetabolite, 5-FU derivative (Oral)
alectinib / Product name undetermined	In-house (Roche)	ALK inhibitor (Oral)
vemurafenib / Product name undetermined (Overseas name: Zelboraf)	Roche	BRAF inhibitor (Oral)
—	In-house (Roche)	MEK inhibitor (Oral)
—	In-house (Roche)	Raf and MEK dual inhibitor (Oral)
—	In-house	PI3K class I inhibitor (Oral)
parsatuzumab / Product name undetermined	Roche	Anti-EGFL7 humanized monoclonal antibody (Injection)
pictilisib / Product name undetermined	Roche	PI3K inhibitor (Oral)
—	Roche	Engineered anti-PDL1 monoclonal antibody (Injection)
ibandronate sodium hydrate / Bonviva (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)	Anti-human IL-6 receptor humanized monoclonal antibody (Injection)
—	In-house	Anti-IL-6 receptor humanized monoclonal antibody (Injection)
rontalizumab / Product name undetermined	Roche	Anti-interferon alpha humanized monoclonal antibody (Injection)
bitopertin / Product name undetermined	Roche	Glycine reuptake inhibitor (Oral)
—	Roche	mGluR5 antagonist (Oral)
gantenerumab / Product name undetermined	Roche / MorphoSys	Anti-amyloid-beta human monoclonal antibody (Injection)
—	Roche	MAO-B inhibitor (Oral)
lebrikizumab / Product name undetermined	Roche	Anti-IL-13 humanized monoclonal antibody (Injection)
—	In-house	Anti-IL-31 receptor humanized monoclonal antibody (Injection)
—	In-house	Anti-factor IXa x anti-factor X humanized bispecific antibody (Injection)
—	Roche	Anti-PCSK9 human monoclonal antibody (Injection)
—	In-house / JW Pharmaceutical	URAT1 inhibitor (Oral)

Basic Information on the Pharmaceutical Industry

Overview of Domestic Pharmaceutical Market and NHI Drug Prices

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 2012, national medical expenses totaled ¥38,585.0 billion, a ¥1,164.8 billion or 3.1 percent increase from the previous year. The rapid aging of Japan's society presents the serious challenge of efficiently managing the increase in medical expenses for the elderly.

Promotion of the Use of Generics

The Japanese government is promoting the use of generics[1] with the primary objective of reducing the cost burden on patients and improving the finances of the health insurance system. Various measures have been carried out under the action program announced in October 2007 to promote the worry-free use of generics. In April 2013, the new "Roadmap to Further Promote the Use of Generics" was formulated. The roadmap sets the goal of raising the volume market share of generics from 46.9 percent as of September 2013 to more than 60 percent by the end of March 2018.

1. Generic drugs, which are approved after the expiry of the patents for original drugs with the same active ingredients and efficacy

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 new standard prices (reimbursement prices) so that the prices of pharmaceuticals prescribed under the health insurance system approximate their actual market price. MHLW does this by investigating the prices and volumes of all prescription drug transactions during a given period. In the year ended March 2014, drug reimbursement prices declined by 0.58 percent overall on a medical expense basis, or 2.65 percent on a reimbursement price basis.

NHI Drug Price Revision Rate (%)

	2008	2010	2012	2014*
Industry Average	(5.2)	(6.5)	(6.25)	(2.65)
Chugai	(7.2)	(6.8)	(6.0)	0.8

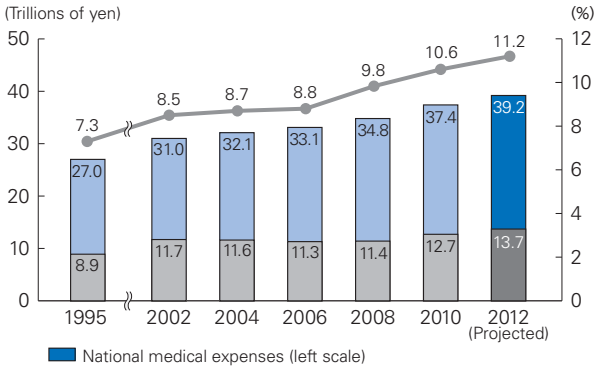
Source: Chugai data
* Includes provision for increase in consumption tax

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

As part of the NHI drug pricing system reforms of fiscal 2010 (the year ended March 2011), a new pricing scheme was implemented on a trial basis to promote the creation of innovative medical products and solve the drug lag[2] 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 are available (provided that they have been in the NHI price list for no more than 15 years), and which satisfy certain conditions.[3]

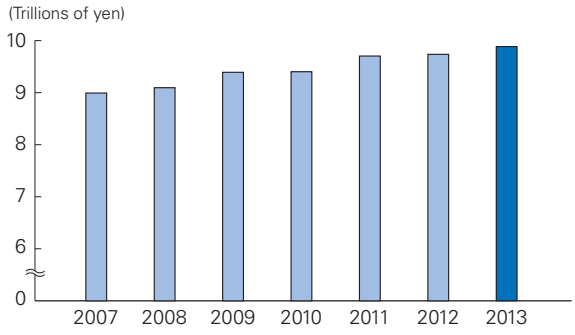
This premium pricing for new drugs was continued on a trial basis in the NHI drug pricing

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 2012 by the Cabinet office).

Prescription Drug Market



system reforms of fiscal 2012 and fiscal 2014. The fiscal 2014 reforms, however, added the condition that only companies that 1) conduct research and development of unapproved or off-label drugs as requested by a panel of MHLW, or 2) conduct research and development of drugs that clearly contribute to improving treatment quality[4] will be eligible to receive premium pricing for their products. In the year ended March 2014, 397 compounds and 758 products received premium pricing.

2. The inability of Japanese patients to gain access to global standard or most advanced treatments because the drugs are not developed in Japan
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.
4. Drugs for pediatric use, orphan drugs and drugs for diseases for which no currently available treatments are adequate (e.g., drugs for intractable diseases or unmet medical need)

Solving the Drug Lag Problem

In January 2005, MHLW established the Investigational Committee for Usage of Unapproved Drugs as one means of helping solve the drug lag problem. The committee is charged with investigating the clinical necessity and the appropriateness of usage of drugs already approved in Europe and the United States, but not yet approved in Japan. The aim of these investigations is to promote the development of those drugs in Japan. In February 2010, MHLW established the Review Committee on Unapproved Drugs and Indications with High Medical Needs. This committee evaluates the medical necessity of drugs and indications that are not yet approved in Japan and investigates matters such as the applicability of filings for approval based on evidence in the public domain. 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 have included 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. As a result, the median total review time for new drugs in the year ended March 2013 was 10.3 months.

Response to Requests from the MHLW Review Committee on Unapproved Drugs and Indications with High Medical Needs (As of January 30, 2014)

Development 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 metastatic breast cancer overexpressing HER2	Approved in Nov. 2011
		Neoadjuvant breast cancer overexpressing HER2	
	CellCept	Pediatric renal transplant	Approved in Sep. 2011
	Kytril	Gastrointestinal symptoms associated with radiotherapy	Approved in Dec. 2011
	Avastin	Ovarian cancer	Approved in Nov. 2013
	Pulmozyme	Improvement of pulmonary function in patients with cystic fibrosis	Approved in Mar. 2012
	Bactramin	Treatment and prevention of pneumocystis pneumonia	Approved in Aug. 2012
Second development request	Avastin	Recurrent glioblastoma	Approved in Jun. 2013 (Malignant glioma)
	Herceptin	Q1W dosage postoperative adjuvant breast cancer overexpressing HER2	Approved in Jun. 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 2012, 360,963 people died of cancer, accounting for 28.7 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 Improvement 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 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. As a result of the enactment of this law, progress has been made in the training of oncologists and medical staff such as nurses and pharmacists. Other advances include greater efforts to establish networks among local medical institutions by designating interregional hub cancer centers. Moreover, an increasing percentage of medical institutions are adopting multidisciplinary team care in which oncologists, nurses, pharmacists and nutritionists work together to provide care tailored to the condition of each individual patient. In December 2013, the Cancer Registration Law was enacted requiring hospitals nationwide to provide information on each cancer patient. The law is aimed at shedding light on the current state of cancer treatment by centralizing patient information in a single database and using that resource to improve early detection and treatment.

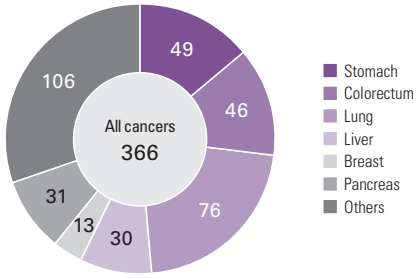
Changes in Treatment Methods

Cancer treatment is increasingly being based on a multimodal 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, hematological malignancy and other forms of cancer.

It is recognized that the safety profiles of these drugs differ from those of conventional anticancer agents. Consequently, there is a need for cancer drug therapy specialists with a thorough knowledge of drug modes of action, pharmacokinetics and drug interactions. Furthermore, whereas many earlier drug therapies were administered in an inpatient setting, there has been an increase in drug therapies that can be administered on an outpatient basis, which allows patients to maintain normal lifestyles as much as possible during treatment. To ensure the medical safety of drug therapy for these patients, various medical staff in addition to oncologists must contribute their respective expertise. As a result, multidisciplinary team care is becoming increasingly important.

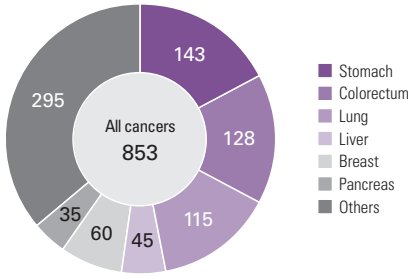
Cancer Mortality (Estimates for 2015)

(Thousands of cases)



Cancer Incidence (Estimates for 2015)

(Thousands of cases)

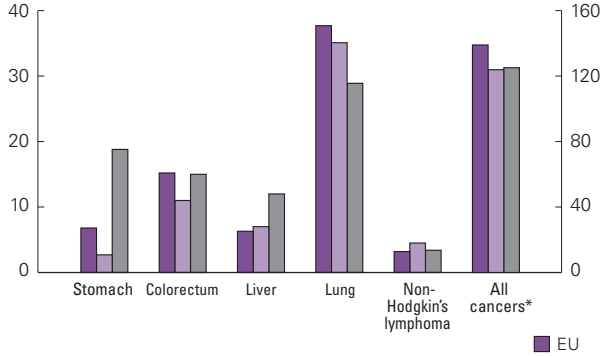


Source: Cancer White Paper-Incidence/Death/Prognosis-2012 (Shinoharashinsha Publishers Inc.)

International Comparison of Cancer Mortality Rates (2012)

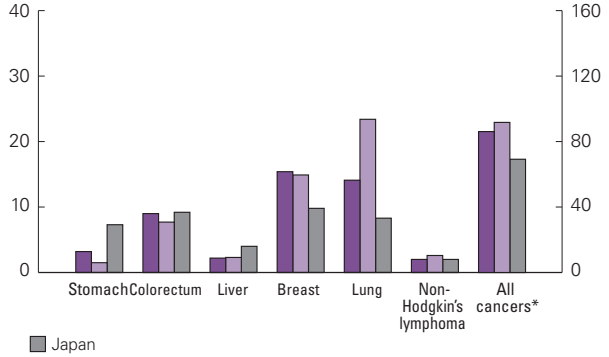
Male

Age-standardized rate per 100,000 population (persons)
(By cancer type) (All cancers)



Female

Age-standardized rate per 100,000 population (persons)
(By cancer type) (All cancers)



* Excluding non-melanoma skin cancer

Source: Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available from: http://globocan.iarc.fr, accessed on 28/02/2014.

Overview of Products and Development Projects

Avastin

Avastin is a humanized monoclonal antibody targeting vascular endothelial growth factor (VEGF). It is the first therapeutic agent in the world that inhibits angiogenesis (the growth of the network of blood vessels that supply nutrients and oxygen to the cancer).

Unlike conventional anticancer agents that act directly on cancer cells, Avastin acts on the microenvironment in the cancer cells. Its primary modes of action are thought to be regression of tumor vessels, inhibition of tumor angiogenesis and improvement of VEGF-induced vascular permeability. In Japan, Avastin was launched in 2007 for the treatment of unresectable, advanced or recurrent colon and rectal cancer. Chugai obtained regulatory approval for the additional indications of advanced or recurrent non-squamous non-small cell lung cancer in 2009, and inoperable or recurrent breast cancer in 2011. Chugai also obtained approval for the additional indications of malignant glioma and ovarian cancer in June and November 2013, respectively.

Rituxan

Rituxan is a monoclonal antibody targeting the CD20 antigen found on the surface of lymphocytes. As a standard therapy for CD20-positive, B-cell non-Hodgkin's lymphoma (hematological cancer), it has substantially improved clinical outcomes in combination with chemotherapy or in monotherapy. In Japan, Rituxan is marketed jointly by Chugai and Zenyaku Kogyo Co., Ltd. Outside Japan, Rituxan is sold under the brand name MabThera/Rituxan by the Roche Group.

Herceptin

Herceptin is a humanized monoclonal antibody that targets human epidermal growth factor receptor type 2 (HER2), which contributes to tumor cell growth. Overexpression of HER2 is found in about 20 percent of breast cancers, which are diagnosed as HER2-positive. HER2-positive breast cancer progresses rapidly, and has historically been associated with a poor prognosis. However, treatment outcomes have improved significantly with the emergence of Herceptin and other medicines targeting HER2. In 2011, Herceptin obtained regulatory approval for the additional indication of advanced or recurrent gastric cancer overexpressing HER2, not amenable to curative resection, bringing Personalized Healthcare to the field of gastric cancer.

Perjeta

Perjeta is a humanized monoclonal antibody and is the first molecular targeted therapy that inhibits the dimerization of HER2. The combination of Perjeta and Herceptin, which also targets HER2, provides a more comprehensive blockade of HER signaling pathways associated with the proliferation of tumor cells. Chugai obtained regulatory approval of Perjeta for the additional indication of HER2-positive inoperable or recurrent breast cancer in June 2013, and launched it in September 2013. Phase III multinational studies began in April 2012 for the indication of postoperative adjuvant chemotherapy in HER2-positive breast cancer and in July 2013 for the indication of HER2-positive gastric cancer.

Kadcyla

Kadcyla is an antibody-drug conjugate combining the anti-HER2 humanized monoclonal antibody trastuzumab (active ingredient of Herceptin) with the potent chemotherapeutic agent DM1. Chugai filed an application for regulatory approval for the treatment of HER2-positive inoperable or recurrent breast cancer in January 2013 and obtained approval in September 2013 after priority review. In addition, a phase II/III multinational study for this drug as a potential treatment for HER2-positive metastatic gastric cancer started in September 2012.

Xeloda

Xeloda is a 5-fluorouracil (5-FU) anticancer agent developed at the Kamakura Research Laboratories of the former Nippon Roche. Orally administered Xeloda is absorbed by the body, then gradually metabolized by certain highly active enzymes in the liver and tumor cells, and is eventually converted into active 5-FU within tumor tissue.

In Japan, Xeloda is currently used to treat inoperable or recurrent breast cancer and as a postoperative adjuvant chemotherapy for colon cancer. In addition, Xeloda has obtained regulatory approval for treating patients with advanced or recurrent colorectal cancer and for advanced or recurrent gastric cancer not amenable to curative resection. 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 an oral targeted small-molecule drug that inhibits the activation of human epidermal growth factor receptor (EGFR) tyrosine kinase, which is associated with the growth, progression and metastasis of cancer. In Japan, Tarceva had been used for second-line or later treatment of non-small cell lung cancer since its launch in 2007, but the approval of an additional indication in June 2013

allowed its use in first-line treatment of patients with EGFR mutations, in whom high efficacy is expected. About 10 percent of non-small cell lung cancer patients in Europe and about 30 percent in Asia test positive for EGFR mutations. In July 2011, Tarceva obtained regulatory approval for the additional indication of pancreatic cancer not amenable to curative resection.

Neutrogin

Neutrogin is a recombinant human granulocyte colony-stimulating factor (G-CSF) developed by Chugai. One common side effect of anticancer drugs is neutropenia, a decrease in the white blood cell count that heightens the risk of developing serious infections. Neutrogin stimulates the differentiation and growth of neutrophils, which allows the use of more potent chemotherapy, thus helping to improve outcomes. Neutrogin is also essential in hematopoietic cell transplantation, which is performed for illnesses that affect production of normal blood cells, such as leukemia. Overseas, Neutrogin is sold under the name Granocyte.

RG3638

RG3638 (onartuzumab), a humanized antibody in-licensed from Roche, targets MET, a hepatocyte growth factor (HGF) receptor. A phase III multinational study of RG3638 as a potential treatment for inoperable advanced or recurrent non-small cell lung cancer with high MET expression started in November 2012. Roche announced in March 2014 that an independent data monitoring committee has recommended that this phase III study be stopped due to a lack of clinically meaningful efficacy.

GA101 (RG7159) (overseas product name: Gazyva)

GA101 (obinutuzumab) is a type II glycoengineered humanized monoclonal antibody in-licensed from Roche. Like Rituxan, GA101 targets CD20. Phase III multinational studies as a potential treatment for aggressive non-Hodgkin's lymphoma and indolent non-Hodgkin's lymphoma are currently under way. 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, which is 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 former subsidiary of Chugai. A phase II multinational study started in March 2012.

AF802

AF802 (alectinib) is an oral targeted molecular therapy created by Chugai that is being developed for the treatment of anaplastic lymphoma kinase (ALK)-positive unresectable, recurrent/advanced non-small cell lung cancer. It inhibits the activity of EML4-ALK, a recombinant kinase expressed in about 2-5 percent of non-small cell lung cancers. AF802 was designated as an orphan drug in September 2013, and Chugai filed an application for regulatory approval in Japan in October 2013 based on the results of a phase I/II clinical trial in Japan, before phase III clinical trial results were available. Chugai has out-licensed the rights to this compound to Roche in Europe, North America and other markets outside Japan, and is co-developing it with Roche. Phase I/II clinical trials are under way overseas. In June 2013, AF802 was designated as a breakthrough therapy by the U.S. Food and Drug Administration (FDA).

RG7204 (overseas product name: Zelboraf)

RG7204 (vemurafenib), in-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.

CIF (RG7167)

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

CKI27 (RG7304)

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

PA799

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

RG7414

RG7414 (parsatuzumab) is an injectable anti-EGFL7 humanized monoclonal antibody in-licensed from Roche. Phase I clinical trials started in Japan in March 2013 for the potential treatment of solid tumors, but Roche discontinued development in October 2013. Development in Japan is currently under consideration.

RG7321

RG732 (pictilisib) is an oral PI3K inhibitor in-licensed from Roche. Phase I clinical trials started in Japan in June 2013 for the potential treatment of solid tumors.

RG7446

RG7446 is an engineered anti-PDL1 monoclonal antibody in-licensed from Roche, and is expected to become a treatment for various cancers. One way that tumor cells evade the immune system is by expressing a protein called programmed death-ligand 1 (PD-L1) on their surface, which is believed to shield them from immune system attacks. RG7446 maintains the immune response of T cells by binding to PD-L1, and is expected to demonstrate efficacy against cancer. Phase I clinical trials started in Japan in September 2013 for the potential treatment of solid tumors.

Bone and Joint Diseases/Autoimmune Diseases

Osteoporosis

Osteoporosis is a disease in which the bones become weak due to advanced age or other factors, increasing the risk of fractures. Osteoporosis patients may incur fractures through normal everyday activities. Among these, compression fractures of the spine and femoral neck fractures can decrease quality of life by leaving patients bed-ridden and can also increase mortality risks. It is estimated that over 12 million people suffer from osteoporosis in Japan, including one in every two women age 65 and older. However, the treatment rate stands at around only 30 percent of the estimated number of sufferers because there are virtually no noticeable symptoms until a fracture occurs. The availability of superior new drugs that have higher efficacy, safety and convenience has brought promise for improvement in the quality of life of patients.

Treatment Methods

Bone resorption inhibitors, bone formation stimulants and active vitamin D_3 derivatives are mainly used in the treatment of osteoporosis. Conventionally, bisphosphonates, calcitonin preparations and selective estrogen receptor modulators (SERMs), which are bone resorption inhibitors, and active vitamin D3 derivatives, which improve bone metabolism, have been the primary drug treatments used. More recently, treatments such as human parathyroid hormone (PTH) therapy and a humanized anti-RANKL antibody have also been approved and are being used.

Regulatory Trends

National guidelines for osteoporosis treatment were revised in October 2006. Subsequently, 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 now covered by insurance. Revised guidelines issued in December 2011 added preventative and diagnostic items from the standpoint of the importance of early treatment to broaden the overall scope of osteoporosis treatment. Since then, Bonviva and other medicines have been launched and covered by insurance, and updates to the guidelines are under discussion. Revision of management and treatment guidelines for steroid-induced osteoporosis is also under way.

Overview of Products and Development Projects

Alfarol

Alfarol, an active vitamin D_3 derivative that stimulates calcium/bone metabolism, 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 new 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. Under an agreement signed in May 2008, Edirol has been co-developed and is currently co-marketed with Taisho Pharmaceutical Co., Ltd. Clinical trials have confirmed that Edirol has a similar safety profile to the existing D_3 derivatives with a statistically significant greater effect in preventing fractures. Edirol received a grade A recommendation in the osteoporosis prevention and treatment guidelines in December 2011, the first for an active vitamin D_3 preparation.

Bonviva

Bonviva is a bisphosphonate in-licensed from Roche that was launched in August 2013. Under the agreement signed in September 2006, Bonviva is being co-developed and co-marketed with Taisho Pharmaceutical Co., Ltd. Bisphosphonates in Japan until then had been drip infusions, but Bonviva is given in a single intravenous injection, as slowly as possible, once a month, which is expected to significantly reduce the burden on patients at the time of administration. 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 painful inflammation and deformation of joints leading to dysfunction. Without appropriate treatment, the patient's condition deteriorates over time. It is estimated that there are about 700,000 patients in Japan suffering from RA, of whom some 330,000 are currently receiving drug treatment. The number of patients is increasing as the average age of the population rises. On the other hand, juvenile idiopathic arthritis (JIA), the form of RA suffered by children below 16 years of age, is associated with growth disorders, and is considered even more difficult to treat than adult forms of the disease, as few treatment options are available.

The most common joint disease is osteoarthritis. Degeneration of the cartilage in the joints and surrounding areas causes joint pain and reduced mobility in daily life. The prevalence of this disease increases with age, and it is thought to occur in 80 percent or more of people 60 years of age or older.

Treatment Methods and Market Conditions

Conventional RA treatment has been mainly symptomatic, using antirheumatic drugs, anti-inflammatory analgesics and steroids, but biologics (anti-tumor necrosis factor (TNF) agents) targeting 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 reached US$2.78 billion* in 2012, and continues to grow. The market is also changing; in 2013, a new oral formulation was launched in the United States and Japan, and a biosimilar was launched in Europe. In addition to drip infusions, which were the only formulations previously available, subcutaneous formulations have also been added, and formulations that improve convenience, such as a dosage form that can be injected simply by pushing a button, are increasing. The intravenous and subcutaneous markets each comprise about half of their respective total markets in Japan, while in Europe and the United States, the subcutaneous market is estimated to be larger by a 7:3 ratio.

JIA is a serious and potentially fatal disease. While it is rare in Japan, with only a few hundred patients, effective treatments were limited. Steroid drugs, which had been the only treatment available, 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, as the joint fluid in osteoarthritis patients is known to have reduced hyaluronic acid content (density and molecular weight), intraarticular administration of hyaluronic acid preparations is used as a treatment in the early and middle-stages.

Regulatory Trends

In October 2005, 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. In the European Union, revised treatment recommendations in 2013 added Actemra and Orencia to the biologic drugs recommended in first-line therapy, which was previously limited to anti-TNF agents.

The 2000-2010 period was designated as the Global 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 2005 as a treatment for Castleman's disease. In April 2008, we obtained regulatory approval in Japan for the additional indications of RA, polyarticular-course juvenile idiopathic arthritis (pJIA) and systemic-onset juvenile idiopathic arthritis (sJIA). 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, making Actemra an important option in treatment as a biological product. In May 2013, Chugai launched a new subcutaneous formulation that is expected to improve convenience for patients in addition to the existing drip infusion formulation. This subcutaneous formulation includes the first auto-injector in the Japanese RA market.

Actemra is marketed globally through Roche. In the European Union, where it is known as RoActemra, sales of the drug started for the treatment of RA in 2009. Chugai's marketing subsidiary co-promotes RoActemra with Roche in the UK, France and Germany. In the United States, Actemra obtained regulatory 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 biologic treatment. In Taiwan and South Korea, where Chugai has marketing rights, Actemra obtained approval in July 2011 and April 2012, respectively. Following its launch in Japan, the subcutaneous formulation was launched in the United States in November 2013 and is scheduled for approval and launch in the European Union in 2014.

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.

Suvenyl

Suvenyl, a drug that improves joint function through injection into the joint cavity, is a high molecular weight sodium hyaluronate drug that alleviates knee osteoarthritis, shoulder periarthritis and knee joint pain caused by RA. Because its physical and chemical properties are close to that of hyaluronic acid found in the body, the superior performance of Suvenyl over low molecular weight hyaluronic acid has been recognized. Phase III clinical trials are currently under way 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. Chugai created SA237 by applying its novel antibody technology (Recycling Antibody Technology) that enables a single antibody molecule to block the target antigen repeatedly. Preclinical studies have verified that this extends the duration of the blocking action on 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 under way in Japan.

Systemic Lupus Erythematosus

Systemic lupus erythematosus (SLE) is an autoimmune disorder in which the immune system attacks its own body due to an immune abnormality, causing various types of inflammation throughout the body. In Japan, 60,122 people had received certificates issued for specific disease treatment as of 2012. The actual number of patients is estimated to be even higher, with a 9:1 female-to-male ratio. Generalized symptoms include fever and fatigue, as well as skin and joint conditions and organ dysfunction. Steroids and immunosuppressants are used in current therapies.

Overview of Development Project

RG7415

RG7415 (rontalizumab) is an anti-interferon alpha humanized monoclonal antibody in-licensed from Roche. It binds to and neutralizes the 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 the Evidence-based Practice Guidelines for the Treatment of CKD in 2009, which were revised in 2012 and 2013, respectively. 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 chronic kidney disease - mineral and bone disorder (CKD-MBD) was indicated in the Guideline for Renal Anemia in Chronic Kidney Disease (2008) and the Clinical Practice Guidelines for the Management of CKD-MBD (2012) issued by the Japan Society for Dialysis Therapy and in the Evidence-based Practice Guidelines for the Treatment of CKD (2013) 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 310,000 people as of December 2012, 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, 2012 and 2014.

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 regulatory 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 intravenous injection or subcutaneous administration, 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 regulatory 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 with high concentration to control parathyroid hormone synthesis and secretion, and by acting to improve osteitis fibrosa and excess remodeling. With its short serum half-life, Oxarol is proving to be effective in cases that could not be treated sufficiently with oral vitamin D_3 derivatives due to the onset of hypercalcemia.

Central Nervous System Diseases

Schizophrenia

Schizophrenia is a severe mental disorder that affects approximately 26 million people worldwide and is a leading cause of disability. Typically diagnosed between the ages of 16 and 25, schizophrenia is broadly characterized by three types of symptoms: positive symptoms including hallucination and delusions, negative symptoms including lack of motivation and social withdrawal, and cognitive deficits including difficulty concentrating and disordered thinking.

Overview of Development Project

RG1678

RG1678 (bitopertin), a glycine reuptake inhibitor in-licensed from Roche, is an oral small-molecule compound that 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 Projects

RG1450

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

RG1577

RG1577, a monoamine-oxidase-B (MAO-B) inhibitor in-licensed from Roche, is an oral small-molecule compound that is expected to be effective in treating Alzheimer's disease. Phase I clinical trials started in Japan in May 2013.

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. Depression characterized by the presence of specific symptoms 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 metabotropic glutamate receptor subtype 5 (mGluR5) antagonist in-licensed from Roche. Since September 2012, Chugai has been participating in Roche's phase II multinational study for the treatment of major depressive disorder.

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 an estimated 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 efficacy was limited until about 2000, which led to an increase in the use of liver-support therapy in Japan. 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

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 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 2011, pegylated interferon monotherapy for hepatitis B and three-drug combination therapy for hepatitis C were among the treatments that became eligible for medical expense subsidies.

Overview of Products and Development Projects

Pegasys/Copegus

Pegasys is a pegylated interferon-based drug that was improved to achieve a sustained antiviral effect with once-weekly[2] administration. 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 regulatory 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.

2. Conventional interferon must be injected three or more times per week.
3. Genotypes I (1a) and II (1b), with which more than 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 an oral anti-influenza agent that is effective against both type A and type B infections. It inhibits viral replication by blocking the action of neuraminidase, an enzyme essential for the multiplication of the influenza virus. Launched in capsule form in February 2001 and dry syrup form in July 2002, dosages are available for patients one year of age and older.

Since March 2007, restrictions on the use of Tamiflu in teenage patients with seasonal influenza have been in force in Japan. The measure was introduced as a safety precaution following several reports of abnormal behavior in influenza patients who had taken Tamiflu. The interim report of an epidemiological survey published by a working group

of MHLW suggested that there are no findings to date that point to a causal association between Tamiflu and the abnormal behavior of patients taking the drug. MHLW has concluded that it is appropriate to continue to take precautions and other measures, and is thus 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 to treat exertional angina pectoris, a symptom that appears during physical activity such as climbing stairs, 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. Both oral and injectable forms are approved. Approval of the injectable formulation for acute heart failure was obtained in October 2007.

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, an anti-human IL-6 receptor humanized monoclonal antibody produced using genetic recombination technology, is the first therapeutic antibody created in Japan. With a mode 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.

Asthma

Asthma is a disease in which airways that have become sensitive due to inflammation narrow when exposed to irritants such as allergens, chemical substances or stress, 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

In-licensed from Roche, RG3637 (lebrikizumab) is an anti-IL-13 humanized monoclonal antibody under development for the treatment of asthma. It is expected to improve symptoms and prevent 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. Chugai joined Roche's phase III multinational study in July 2013.

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. Scratching the affected area exacerbates the skin symptoms and makes the itching worse, leading to an itch-scratch cycle. 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 anti-IL-31 receptor humanized monoclonal antibody originating from Chugai that is being developed as a potential treatment for atopic dermatitis. It is expected to suppress itching and improve skin inflammation. A phase II multinational study led by Chugai started in December 2013.

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 bispecific antibody to factor IXa and factor X that employs Chugai's innovative antibody engineering technologies. Factor VIII simultaneously binds to factor IXa and factor X, stimulating the activation of factor X by active factor IX and promoting the blood coagulation that occurs as a result. 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 even in patients lacking factor VIII. Unaffected by inhibitors, ACE910 is expected to prevent bleeding with once-weekly subcutaneous injections. Phase I/II clinical trials started in Japan in August 2013.

Dyslipidemia

Dyslipidemia (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. Although hyperlipidemia has no subjective symptoms, it is estimated that there are 22 million potential patients in Japan.

Overview of Development Project

RG7652

RG7652 is an anti-PCSK9 human monoclonal antibody in-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.

Gout

Gout occurs when uric acid crystals are deposited in the joints due to prolonged high levels of serum uric acid (hyperuricemia), causing inflammation. The peak age of onset is becoming younger, and has shifted from the 50s to the 30s. Hyperuricemia, the underlying cause of gout, has been increasing annually, and as many as 5 million people are estimated to be at risk for gout in Japan.

Overview of Development Project

URC102

URC102 is a URAT1 inhibitor discovered at C&C Research Laboratories, a joint venture between Chugai and JW Pharmaceutical Corporation of South Korea. It is an oral small-molecule agent expected to be effective against gout. This compound is being co-developed with JW Pharmaceutical, and phase I clinical trials started in South Korea in June 2013.

Financial Section

Message from the CFO

Chugai achieved substantial earnings in 2013. Going forward, we will invest for future growth and enhance shareholder returns while constantly innovating our cash management.

In 2013, successful efforts to link and evolve Chugai's unique strengths in each field led to smooth progress in the first year of ACCEL 15. We also made steady progress from a financial perspective, and are further strengthening our earnings structure, which has given us one of the highest operating profit margins in the industry. Some of the factors assumed when we drew up ACCEL 15, such as exchange rates, have since changed significantly, and cost of sales and expenses are both on an upward trend. However, we are focusing on efficiently managing expenses and appropriately controlling fixed costs. Some benefits have already materialized through various initiatives, particularly construction of IT systems to boost marketing and R&D productivity and the global purchasing strategy we are implementing together with Roche. In financial reporting, Chugai began applying International Financial Reporting Standards (IFRS) in 2013. We are also disclosing figures such as Core basis results and net operating assets (NOA) as performance indicators both internally and externally, and have incorporated Core basis results in the payout ratio to align it with internal management performance indicators. These and other changes are improving convenience for shareholders and investors and facilitating accurate analysis of Chugai's performance.

With our ample net cash flow, a key issue now for Chugai is effective cash management. Increasing capital efficiency is also important for maximizing shareholder value, and we plan to make aggressive investments in order to explore future growth opportunities while maintaining appropriate returns to shareholders. Our investment targets include plant and equipment and in-licensing opportunities to meet the future needs of patients as well as timely measures to deal with upcoming patent expirations on existing products. We will also focus on incorporating external research results and exploring business opportunities in areas such as cutting-edge medical treatment to lay the groundwork for future growth. The projects we in-licensed in Europe and the development of our own sales channels in China, both in 2013, are part of this investment strategy. However, we believe that speed will become even more critical, and will work to further accelerate strategic investments.

Chugai is also taking steps to enhance shareholder returns. Until 2012, our policy was to maintain a payout ratio of 40 percent or more on average. In 2013, we raised the Core earnings per share (EPS) basis payout ratio to 50 percent on average in order to increase the level of returns while maintaining stable dividends.

Beginning with *Annual Report 2012*, we integrated reporting. In doing so, we did not simply integrate the CSR report and the former annual report, but used our creativity throughout to further enrich the new report's content while making sure that we explained Chugai's corporate value to stakeholders concisely, clearly and accurately.

The backdrop to the solid progress we made in 2013, and the driving force of our future growth, is our unwavering business philosophy of "Innovation all for the patients." Chugai will continue to accelerate all of its activities in pursuit of constant innovation.

Yoshio Itaya
Director, Executive Vice President & CFO

11-Year Financial Summary

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

(Billions of yen)

International Financial Reporting Standards (IFRS)	2013		2012	
	IFRS	Core[1]	IFRS	Core[1]
Results				
Revenues[2]	423.7		386.6	
Sales	401.3		375.2	
Royalties and other operating income	22.4		11.3	
Cost of sales	(187.0)	(186.1)	(168.2)	(167.3)
Operating expenses	(157.9)	(157.7)	(143.7)	(143.7)
Marketing and distribution	(71.6)	(71.5)	(67.9)	(67.9)
Research and development	(74.3)	(74.1)	(66.6)	(66.6)
General and administration	(12.1)	(12.1)	(9.2)	(9.2)
Operating profit	78.7	79.9	74.7	75.6
Profit before taxes	76.9	78.1	72.7	73.6
Net income	51.9	52.6	46.8	47.4
Attributable to Chugai shareholders	50.9	51.6	46.1	46.6
Core EPS (Yen)	—	94.69	—	85.64
Cash dividends per share (Yen)	45		40	
Core payout ratio	—	47.5%	—	46.7%
Financial Position				
Net operating assets	325.2		307.9	
Total assets	697.2		645.3	
Total liabilities	(124.0)		(116.2)	
Total net assets	573.2		529.2	
Investment on property, plant and equipment	13.0		14.2	
Depreciation	13.5		13.3	
Main Indicators				
Cost of sales to revenues	44.1%	43.9%	43.5%	43.3%
Operating profit to revenues	18.6%	18.9%	19.3%	19.6%
Research and development expenditures to revenues	17.5%	17.5%	17.2%	17.2%
Ratio of net income to equity attributable to Chugai shareholders (ROE)[3]	9.3%	—	9.0%	—
Ratio of profit before taxes to total assets (ROA)[4]	11.5%	—	11.8%	—
Equity per share attributable to Chugai shareholders (BPS) (Yen)	1,049.47	—	970.08	—
Ratio of equity attributable to Chugai shareholders	82.0%	—	81.8%	—
Number of employees	6,872		6,836	

1. Core basis results are the results after adjusting non-Core items to IFRS basis results. Core basis results are used by Chugai as internal performance indicators to represent recurring profit trends both internally and externally, and as indices for establishing profit distributions such as returns to shareholders.
2. Revenues do not include consumption tax.
3. Ratio of net income to equity attributable to Chugai shareholders (ROE) = Net income attributable to Chugai shareholders/Capital and reserves attributable to Chugai shareholders (average of beginning and end of fiscal year)
4. Ratio of profit before taxes to total assets (ROA) = Profit before taxes/Total assets (average of beginning and end of fiscal year)

Japanese GAAP
Results
Revenues[2]
Sales
Other operating revenues
Cost of sales
Selling, general and administrative expenses
Research and development expenses
Operating income
Net income (loss)
Net income per share (basic) (Yen)
Net income per share (diluted) (Yen)
Cash dividends per share (Yen)[3]
Payout ratio
Financial Position
Total assets
Total net assets[4]
Capital investments
Depreciation and amortization
Main Indicators
Cost of sales to revenues
Operating income to revenues
Research and development expenditures to revenues
Return on equity[5]
Return on assets[6]
Net assets per share (Yen)
Shareholders' equity to total assets
Number of employees

(Billions of yen)

2012	2011	2010	2009	2008	2007	2006	2005	2004	2003[1]	2003/3
391.2	373.5	379.5	428.9	326.9	344.8	326.1	327.2	294.7	232.7	237.4
375.2	363.6	375.6	419.1	321.8	332.9	—	—	—	—	—
16.0	9.9	3.9	9.8	5.1	11.9	—	—	—	—	—
167.7	157.5	162.4	192.9	127.0	137.3	133.1	119.4	115.4	83.8	79.0
92.0	97.7	96.2	98.2	95.1	86.6	80.1	78.5	83.9	63.0	79.2
55.1	55.9	54.7	55.3	53.2	54.2	54.6	50.1	48.2	43.5	48.5
76.4	62.4	66.2	82.6	51.6	66.7	58.3	79.2	51.5	42.7	30.3
48.2	35.2	41.4	56.6	39.3	40.1	38.4	53.6	34.1	28.4	(20.1)
88.58	64.75	76.14	104.00	72.07	73.23	69.35	97.00	62.27	51.73	(51.75)
88.54	64.72	76.12	103.98	72.04	73.16	69.26	96.33	61.34	50.94	—
40.00	40.00	40.00	40.00	34.00	30.00	30.00	34.00	18.00	13.00	16.00
45.2%	61.8%	52.5%	38.5%	47.2%	41.0%	43.3%	35.1%	28.9%	25.1%	—
587.7	533.5	508.0	540.5	478.5	458.9	462.1	456.4	411.4	405.2	425.3
490.1	459.1	449.4	434.7	397.1	385.8	391.6	368.3	320.8	296.7	277.3
14.2	11.9	12.7	14.6	26.6	19.6	16.3	16.1	9.9	11.8	17.8
15.3	15.9	18.0	19.5	20.1	14.9	13.8	17.0	14.4	10.5	14.9
42.9%	42.2%	42.8%	45.0%	38.8%	39.8%	40.8%	36.5%	39.2%	36.0%	33.3%
19.5%	16.7%	17.4%	19.3%	15.8%	19.3%	17.9%	24.2%	17.5%	18.3%	12.8%
14.1%	15.0%	14.4%	12.9%	16.3%	15.7%	16.7%	15.3%	16.4%	18.7%	20.4%
10.2%	7.8%	9.4%	13.7%	10.1%	10.4%	10.1%	15.6%	11.0%	9.9%	—
8.6%	6.8%	7.9%	11.1%	8.4%	17.4%	8.4%	12.4%	8.4%	6.9%	—
896.02	839.50	821.87	794.51	725.18	703.80	703.08	665.29	583.61	542.96	503.41
83.0%	85.6%	88.0%	80.0%	82.6%	83.5%	84.3%	80.7%	78.0%	73.2%	65.2%
6,836	6,779	6,709	6,485	6,383	6,257	5,905	5,280	5,313	5,619	5,743

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. Revenues do not include consumption tax.
3. 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
4. Net assets include minority interests from 2006 in accordance with a revision to regulations for consolidated financial statements in Japan.
5. Return on equity = Net income/Shareholders' equity (average of beginning and end of fiscal year)
6. Return on assets = Net income/Total assets (average of beginning and end of fiscal year)

Operating Environment

The pharmaceutical industry continued to face a challenging operating environment in 2013. In addition to ongoing government policies to reduce healthcare costs in Japan, global factors included 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 need, with expectations for ongoing growth of biopharmaceuticals and oncology drugs.

Management Policies

Based on its 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 primary management goal is to become a top pharmaceutical company capable of continuously delivering innovative drugs 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 and promote global development and sales and by advancing Personalized Healthcare (PHC) and undertaking 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.

ACCEL 15, our mid-term business plan for the years 2013 to 2015, positions this period as a turning point for accelerating our progress toward becoming a top pharmaceutical company. To further augment the competitive advantages we have established and to promote sustained growth in corporate 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. As quantitative guidance, Chugai will aim for a Core EPS[1] compound annual growth rate in the mid to high single digits based on constant exchange rates (average for 2012), and will work to deliver shareholder returns with a target Core EPS payout ratio of 50 percent on average.

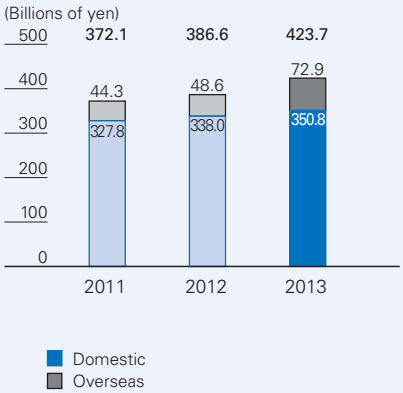
1. Core EPS is fully diluted net income per share attributable to shareholders of Chugai after deducting items that Chugai defines as non-Core items.

Overview of Results

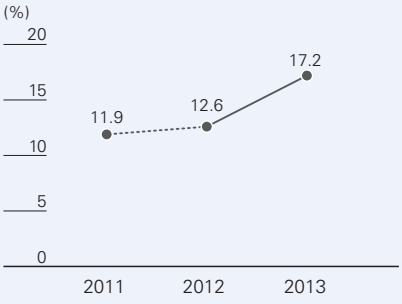
Chugai reports its results on a Core basis from 2013 in conjunction with its decision to apply IFRS. Core basis results are IFRS basis results adjusted to exclude non-Core items, and are consistent with the Core basis results disclosed by Roche. Chugai uses Core basis results as internal performance indicators to represent recurring profit trends both internally and externally, and as indices for establishing profit distributions such as returns to shareholders.

Core basis results for 2013 were revenues of ¥423.7 billion, a 9.6 percent increase from the previous year, operating profit of ¥79.9 billion, a 5.7 percent increase, and net income of ¥52.6 billion, an 11.0 percent increase, driven mainly by solid growth in sales of major products. IFRS basis results, before

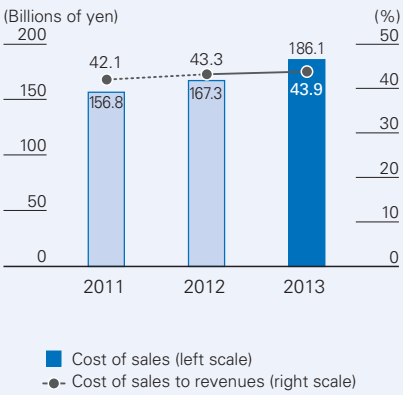
Revenues



Overseas Sales Ratio



Cost of Sales/ Cost of Sales to Revenues



adjustment to Core basis results, were operating profit of ¥78.7 billion, a 5.4 percent increase, and net income of ¥51.9 billion, a 10.9 percent increase. These results include amortization of intangible assets of ¥1.0 billion, restructuring costs of ¥0.2 billion and other items excluded from the Core basis results managed by Chugai.

Revenues

In 2013, revenues increased 9.6 percent compared with the previous year to ¥423.7 billion, with growth in sales, royalties and other operating revenues. Excluding sales of Tamiflu, which are seasonal, sales increased 7.4 percent to ¥390.2 billion.

Domestic Sales by Field

Domestic sales excluding Tamiflu increased 2.6 percent compared with the previous year to ¥329.2 billion. Sales in the oncology field continued to grow, rising 10.4 percent to ¥172.4 billion as Chugai maintained its number-one share (20.4 percent)[2] in the domestic oncology market. The main factors driving sales growth were the contribution of Perjeta, a humanized anti-HER2 monoclonal antibody launched in September 2013 for the treatment of HER2-positive metastatic breast cancer, as well as steady growth in sales of major anticancer agents such as Avastin, an anti-vascular endothelial growth factor (VEGF) humanized monoclonal antibody, and Tarceva, an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor. First-year sales of Perjeta were ¥2.4 billion.

In the bone and joint diseases field, sales decreased 8.6 percent compared with the previous year to ¥60.6 billion due to the expiration of the co-marketing agreement for Evista, which contributed sales of ¥16.1 billion in the previous year. Excluding Evista, sales grew more than 20 percent year on year, led by strong sales of Edirol, an active vitamin D_3 derivative that has become a top brand in the domestic market for oral osteoporosis treatments. A subcutaneous formulation of Actemra newly launched in May 2013 and Bonviva (ibandronate sodium hydrate), an osteoporosis treatment launched in August 2013, also contributed to sales growth. First-year sales of Bonviva were ¥0.5 billion.

Sales in the renal diseases field increased 1.7 percent compared with the previous year to ¥48.9 billion. Sales in this field had been declining due to the decrease in sales of Epogin, a recombinant human erythropoietin, but began to increase from the second half of 2013 as the growth of Mircera, a long-acting erythropoietin-stimulating agent (ESA), primarily in the pre-dialysis market, made up for this decline.

In the transplant, immunology and infectious diseases field, sales excluding Tamiflu decreased 7.4 percent compared with the previous year to ¥18.8 billion due to lower sales of peginterferon alfa-2a agent Pegasys and anti-viral agent Copegus, reflecting the shrinking market for interferon.

Sales of anti-influenza agent Tamiflu decreased 8.3 percent to ¥11.0 billion. Seasonal sales were ¥10.1 billion and sales to the government for pandemic stockpiles totaled ¥0.9 billion.

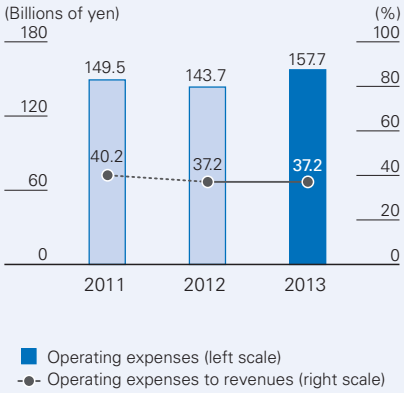
2. Copyright 2014 IMS Japan K.K. Source: JPM 2013. Reprinted with permission. The scope of the market is defined by Chugai.

Overseas Product Sales, Royalties and Other Operating Revenues

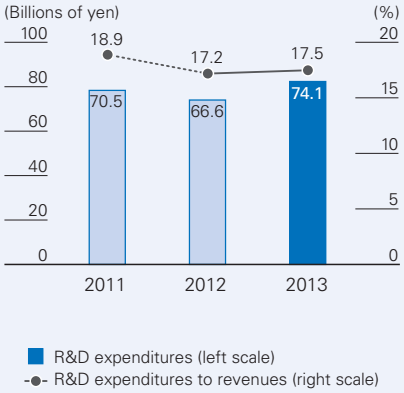
Overseas sales increased a substantial 44.4 percent compared with the previous year to ¥61.1 billion. Sales growth was driven by increased exports to Roche on a volume basis in addition to the impact of the weaker yen.

Royalties and other operating revenues increased 98.2 percent to ¥22.4 billion, reflecting an increase in milestone revenues and an increase in royalties and profit-sharing payments received from the Roche Group in connection with the overseas sales growth of Actemra, an anti-IL-6 humanized monoclonal antibody.

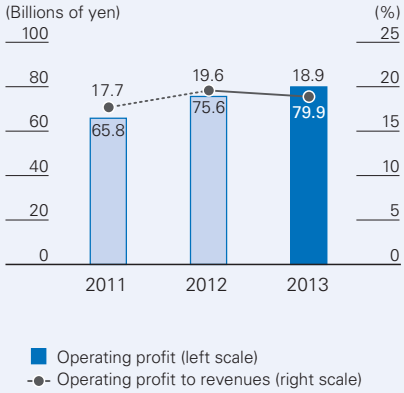
Operating Expenses/ Operating Expenses to Revenues



R&D Expenditures/ R&D Expenditures to Revenues



Operating Profit/ Operating Profit to Revenues



Cost of Sales and Gross Profit (Core Basis)

Cost of sales increased 11.2 percent to ¥186.1 billion compared with the previous year due to the increase in revenues, despite a higher cost-to-sales ratio reflecting the impact of the yen's depreciation. The cost-to-sales ratio increased 1.8 percentage points to 46.4 percent. Chugai partially revised its method of allocating cost variances in the third quarter of 2013 to more accurately reflect the purchase price variance associated with the substantial depreciation of the yen.

As a result of the above, gross profit increased 8.3 percent compared with the previous year to ¥237.6 billion.

Operating Expenses (Marketing and Distribution Expenses, R&D Expenditures and General and Administrative Expenses) and Operating Profit (Core Basis)

Operating expenses increased 9.7 percent to ¥157.7 billion. A breakdown of these expenses follows below.

Marketing and distribution expenses increased 5.3 percent to ¥71.5 billion, mainly due to an increase in expenses of overseas marketing subsidiaries as a result of the weaker yen and an increase in promotional activities with the launch of new products. R&D expenditures increased 11.3 percent to ¥74.1 billion due to the impact of the weaker yen, expenses arising from the start of full operations at Chugai Pharmabody Research Pte. Ltd. and the renewal of buildings and equipment. General and administrative expenses increased 31.5 percent to ¥12.1 billion as a result of higher overhead costs.

As a result of the above, operating profit increased 5.7 percent compared with the previous year to ¥79.9 billion, and the ratio of operating profit to revenues decreased 0.7 percentage points to 18.9 percent.

Net Income (Core Basis)

Financing costs were ¥0.0 billion, essentially unchanged from the previous year, and other financial expense decreased 5.3 percent to net expenditures of ¥1.8 billion. Profit before taxes increased 6.1 percent to ¥78.1 billion. Income taxes decreased 2.7 percent to ¥25.5 billion, resulting in net income of ¥52.6 billion, an 11.0 percent increase. Net income attributable to Chugai shareholders was ¥51.6 billion.

Profitability Indicators (Consolidated)

	2013	2012	2011
Gross profit to revenues (%) (Core)	56.1	56.7	57.9
Operating profit to revenues (%) (Core)	18.9	19.6	17.7
Ratio of profit before taxes to total assets (ROA) (%) (IFRS)	11.5	11.8	10.3
Ratio of net income attributable to Chugai shareholders (ROE) (%) (IFRS)	9.3	9.0	8.3

Notes:
1. ROA = Profit before taxes/Total assets (average of beginning and end of fiscal year)
2. ROE = Net income attributable to Chugai shareholders/Capital and reserves attributable to Chugai shareholders (average of beginning and end of fiscal year)

Financial Position

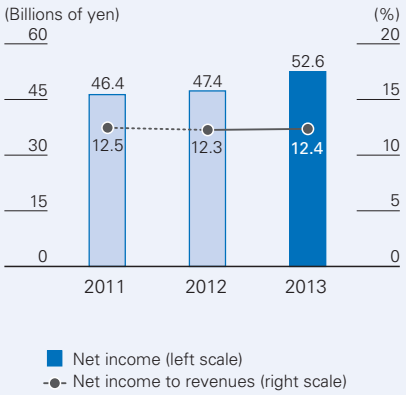
Asset, Liabilities and Net Assets

In conjunction with its decision to apply IFRS from 2013, Chugai has reorganized the consolidated balance sheets and discloses assets and liabilities including net operating assets for use as internal performance indicators (Roche discloses the same indicators). No items have been excluded from the IFRS balance sheets, as the Core basis results concept only applies to the income statement.

Net Operating Assets

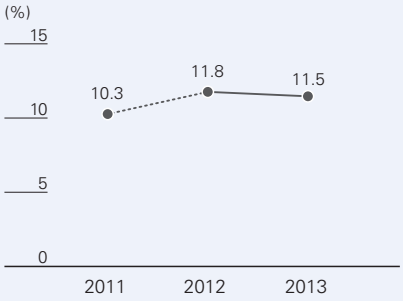
Net working capital, which is composed of accounts receivable, inventories, accounts payable and other payables and receivables, was ¥177.1 billion as of December 31, 2013, an increase of ¥19.2

Net Income/Net Income to Revenues

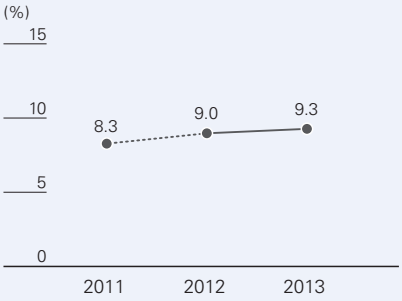


Net income (left scale)
Net income to revenues (right scale)

ROA



ROE



billion, or 12.2 percent, from a year earlier. The increase was mainly due to a ¥20.1 billion increase in inventories reflecting risk-response measures to ensure stable supplies, initial inventories of new products, and the impact of the yen's depreciation.

Long-term net operating assets, consisting of property, plant and equipment, intangible assets and other items, decreased ¥1.9 billion, or 1.3 percent, from the end of the previous year to ¥148.1 billion. Intangible assets increased ¥3.0 billion due to product in-licensing lump-sum payments, while property, plant and equipment decreased ¥2.7 billion as a result of depreciation and amortization. Other long-term net operating assets decreased ¥2.2 billion due to deferral of income related to product out-licensing.

As a result, net operating assets – the total of net working capital and long-term net operating assets – increased ¥17.3 billion, or 5.6 percent, to ¥325.2 billion.

Total Net Assets

Net cash, including marketable securities and interest-bearing debt, increased ¥22.7 billion, or 10.7 percent, to ¥234.4 billion. "Other non-operating assets – net" increased ¥4.0 billion, or 41.7 percent, from the end of the previous year to ¥13.6 billion due to factors including an increase in foreign exchange forward contracts.

As a result, total net assets, which is the total of net operating assets, net cash and "other non-operating assets – net," increased ¥44.0 billion, or 8.3 percent, to ¥573.2 billion.

The ratio of equity attributable to Chugai shareholders was 82.0 percent, up 0.2 percentage points from a year earlier.

Total Assets and Total Liabilities

Total assets on the consolidated balance sheet increased ¥51.9 billion, or 8.0 percent, from the end of the previous year to ¥697.2 billion, while total liabilities increased ¥7.8 billion, or 6.7 percent, to ¥124.0 billion.

Current assets minus current liabilities totaled ¥406.6 billion, and the current ratio was 516.1 percent, as Chugai maintained a highly sound financial position.

Financial Position (Billions of yen)

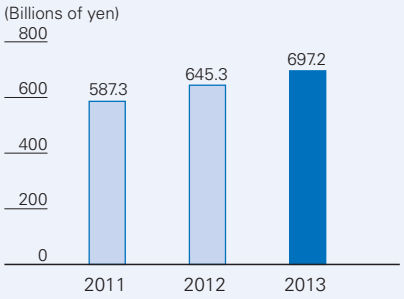
	2013	2012	2011
Movements of assets and liabilities			
Net working capital	177.1	157.9	168.5
Long-term net operating assets	148.1	150.0	154.6
Net operating assets	325.2	307.9	323.1
Net cash	234.4	211.7	169.5
Other non-operating assets – net	13.6	9.6	6.4
Total net assets	573.2	529.2	499.0
Consolidated Balance Sheets (IFRS)			
Total assets	697.2	645.3	587.3
Total liabilities	(124.0)	(116.2)	(88.3)
Total net assets	573.2	529.2	499.0

Financial Position Indicators

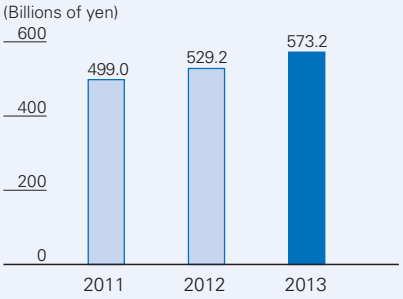
	2013	2012	2011
Ratio of equity attributable to Chugai shareholders (%)	82.0	81.8	84.8
Ratio of equity attributable to Chugai shareholders on a market basis (%)	181.7	139.2	117.6
Core return on net operating assets (%)	16.2	15.4	14.4
Cash conversion cycle (months)	9.3	8.5	10.0
Net cash turnover period (months)	6.6	6.6	5.5
Current ratio (%)	516.1	480.6	552.4
Debt-to-equity ratio (%)	0.0	0.0	0.0

Notes:
1. Ratio of equity attributable to Chugai shareholders = Capital and reserves attributable to Chugai shareholders (fiscal year-end)/Total assets (fiscal year-end)
2. Ratio of equity attributable to Chugai shareholders on a market basis = Total market capitalization/Total assets (fiscal year-end)
3. Core return on net operating assets = Core net income/net operating assets
4. Cash conversion cycle = [Trade accounts receivable/Sales + (Inventories – Trade accounts payable)/Cost of sales] x Months passed
5. Net cash turnover period = Net cash/Revenues x Months passed
6. Current ratio = Current assets (fiscal year-end)/Current liabilities (fiscal year-end)
7. Debt-to-equity ratio = Interest-bearing debt (fiscal year-end)/Capital and reserves attributable to Chugai shareholders (fiscal year-end)

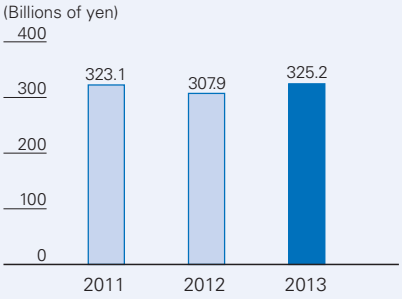
Total Assets



Total Net Assets



Net Operating Assets



Cash Flows

In conjunction with its decision to apply IFRS from 2013, Chugai has reorganized the consolidated statements of cash flows and uses free cash flows as an internal performance indicator (Roche discloses the same indicator). No items are excluded from cash flows, as the Core basis results concept only applies to the income statement.

Operating Free Cash Flows

Operating profit, net of operating cash adjustments (calculated by adjusting operating profit for depreciation and all other non-cash items included in operating profit and all cash inflows and outflows related to net operating assets that are not accompanied by profit and loss), amounted to a net cash inflow of ¥97.3 billion, compared with ¥88.2 billion for the previous year. The main adjustments were depreciation and impairment of property, plant and equipment totaling ¥15.2 billion.

Cash Flows (Billions of yen)

	2013	2012	2011
Movements of free cash flows			
Operating profit	78.7	74.7	59.4
Operating profit, net of operating cash adjustment	97.3	88.2	78.8
Operating free cash flow	63.0	91.0	69.0
Free cash flow	15.0	39.3	34.9
Net increase in net cash	22.7	42.2	32.2
Consolidated Statements of Cash Flows (IFRS Basis)			
Cash flows from operating activities	53.5	77.5	73.2
Cash flows from investing activities	(13.2)	(54.9)	(18.7)
Cash flows from financing activities	(23.2)	(22.8)	(24.6)
Net increase in cash and cash equivalents	19.6	1.0	29.3
Cash and cash equivalents at end of year	115.1	95.4	94.5

Operating free cash flows, which are calculated by deducting the increase in net working capital of ¥19.7 billion and expenditures of ¥14.7 billion for the purchase of property, plant and equipment and intangible assets from operating profit, net of operating cash adjustments, amounted to ¥63.0 billion (compared with ¥91.0 billion for the previous year). Purchases of property, plant and equipment mainly consisted of purchases of research and plant equipment.

Free Cash Flows (FCF)

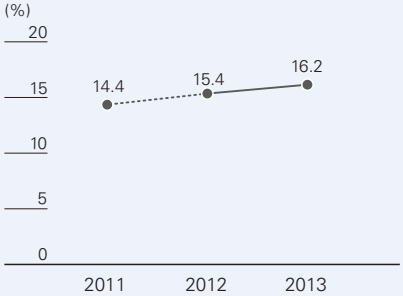
Free cash flows, calculated by deducting the total of ¥47.9 billion comprising cash flows from financial asset management, income taxes paid and cash dividends paid from operating free cash flow, amounted to ¥15.0 billion, compared with ¥39.3 billion for the previous year.

The result was a net increase of ¥22.7 billion in net cash after foreign currency translation adjustments. Cash and cash equivalents, excluding changes in marketable securities and interest-bearing debt, increased ¥19.6 billion. As a result, the balance of cash and cash equivalents at the end of the year was ¥115.1 billion.

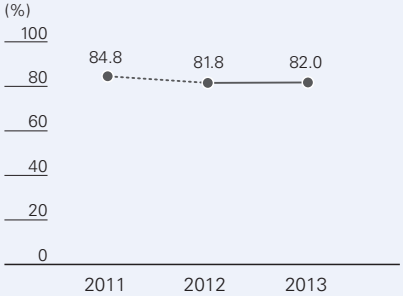
Cash Flows

Cash flows in the consolidated statements of cash flows were net cash provided by operating activities of ¥53.5 billion, net cash used in investing activities of ¥13.2 billion and net cash used in financing activities of ¥23.2 billion.

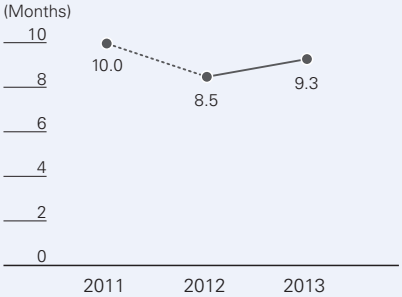
Core Return on Net Operating Assets



Ratio of Equity Attributable to Chugai Shareholders



Cash Conversion Cycle*



* Cash conversion cycle = [Trade accounts receivable/ Sales + (Inventories – Trade accounts payable)/ Cost of sales] x Months passed

Capital Investments

Capital investments decreased 8.5 percent compared with the previous year to ¥13.0 billion. Significant capital investments included routine expenditures for research and plant equipment. Depreciation and amortization increased 1.5 percent to ¥13.5 billion.

In 2014, Chugai is planning capital investments of ¥18.0 billion, including renovation of a biologic active pharmaceutical ingredients (API) production facility for investigational drugs at the Ukima site and renovation of biologic API production facilities at the Utsunomiya site. Depreciation is projected to be ¥14.0 billion.

Plans for New Construction and Renovation of Facilities

(Chugai Pharmaceutical Co., Ltd.)

Site name (Location)	Description	Planned investment (Billions of yen)		Funding method	Start of construction	Planned completion
		Total amount	Investment to date			
Ukima site (Kita-ku, Tokyo)	Renovation of investigational drug building No. 2 for biologics	2.9	0.9	Self-financing	June 2013	August 2015
Utsunomiya site (Utsunomiya City, Tochigi Prefecture)	Installment of tray filler	4.8	0.5	Self-financing	September 2013	March 2017

(Domestic subsidiary: Chugai Pharma Manufacturing Co., Ltd.)

(Billions of yen)

Site name (Location)	Description	Planned investment (Billions of yen)		Funding method	Start of construction	Planned completion
		Total amount	Investment to date			
Utsunomiya plant (Utsunomiya City, Tochigi Prefecture)	Renovation of manufacturing building No. 1 for biological APIs (UT1)	4.6	0.9	Self-financing	July 2013	September 2015

Per Share Data

Net income per share (basic) for 2013 increased ¥8.85 compared with the previous year to ¥93.47, and Core EPS was ¥94.69. Equity per share attributable to Chugai shareholders (BPS) as of December 31, 2013 increased ¥79.39 compared with a year earlier to ¥1,049.47.

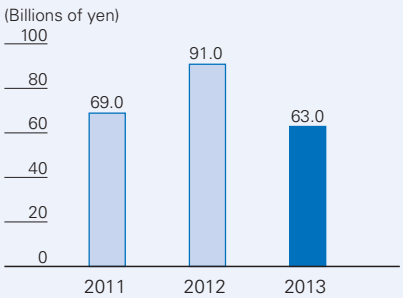
Per Share Data (Consolidated)

(Yen)

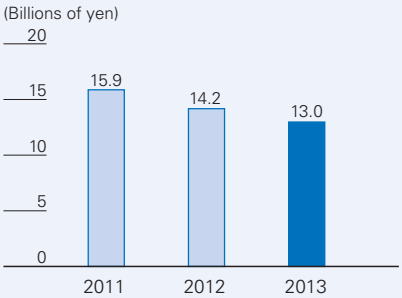
	2013	2012	2011
Net income per share (basic)	93.47	84.62	76.37
Core EPS	94.69	85.64	83.27
Equity per share attributable to Chugai shareholders (BPS)	1,049.47	970.08	914.72
Dividends per share	45.00	40.00	40.00
Core payout ratio (%)	47.5	46.7	48.0

Note: Core EPS = Core net income attributable to Chugai shareholders/Diluted weighted average shares outstanding

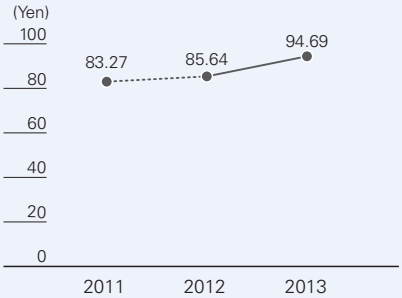
Operating Free Cash Flows



Capital Investments on Property, Plant and Equipment



Core EPS



Outlook for 2014

Forecast Assumptions

For 2014, Chugai assumes exchange rates of ¥116/CHF, ¥142/EUR and ¥104/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.

Results Forecast

Chugai forecasts revenues of ¥451.0 billion, an increase of 6.4 percent compared with 2013.

Domestic sales excluding Tamiflu are forecast to rise steadily to ¥335.7 billion, an increase of 2.0 percent year on year. While the scheduled drug price revision is forecast to have an impact on sales, Chugai expects continued growth in sales of Avastin and other drugs in the oncology field as well as Edirol, Actemra and Mircera. New products Perjeta and Bonviva are also expected to contribute to sales growth. Chugai plans to launch a number of new products in 2014, and has factored sales from these products into the forecast based on certain assumptions.

Exports to Roche are expected to increase steadily to ¥64.6 billion, a 50.6 percent increase year on year, reflecting the positive impact of the weaker yen and growth in sales of Actemra outside Japan. On the other hand, sales outside Japan of other products are forecast to be flat as a decrease in sales of Neutrogin due to competition from follow-on biologics is expected to be offset by the impact of the weaker yen. Royalties and other operating revenues are forecast to increase 7.1 percent year on year to ¥24.0 billion as a result of higher revenues from out-licensing and from Roche for co-promotion and royalties for Actemra.

Despite the growth in revenues, gross profit is forecast to be on par with the previous year because of an increase in cost of sales primarily due to the depreciation of the yen. In expenses, budgeted costs have been increased to reflect the impact of the weaker yen as well as higher expenses for an advancement of in-house development projects and the increase in activities at Chugai Pharmabody Research Pte. Ltd. As a result, Chugai forecasts Core operating profit of ¥71.0 billion, a decrease of 11.1 percent year on year. Core EPS is forecast to be ¥82.62, a decrease of 12.7 percent.

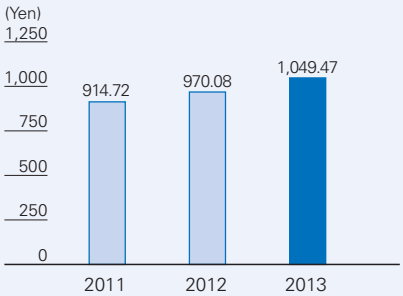
Fundamental Profit Distribution Policy and Dividends

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.

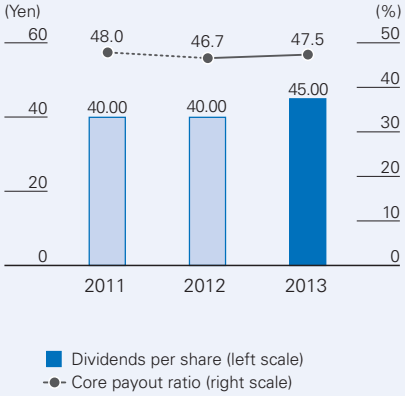
Total dividends for 2013 were ¥45.00 per share, and the Core payout ratio was 47.5 percent, with an average of 47.9 percent over the past five years.

Taking into account the new dividend policy and the performance forecast for the year, Chugai forecasts total dividends for 2014 of ¥45.00 per share, including an interim dividend of ¥22.00 per share. This estimate assumes a forecast for the payout ratio of 54.5 percent of Core EPS in 2014, which will bring the five-year average Core payout ratio to 51.6 percent.

Equity per Share Attributable to Chugai Shareholders



Dividends per Share/ Core Payout Ratio



Business Risks

Chugai's corporate performance is subject to material 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, 2013.

New Product Research and Development

With the goal of becoming a top 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 material 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 materially 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 material 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 materially 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 material 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 in-licensed many products and projects from Roche. Changes in Chugai's strategic alliance with Roche for any reason could have a material 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 material 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 material impact on Chugai's business performance and financial position.

Consolidated Financial Statements

1. Consolidated income statement and consolidated statement of comprehensive income

1) Consolidated income statement in millions of yen

	Year ended December 31	
	2013	2012
Revenues	**423,652**	**386,552**
Sales (Note 2)	401,298	375,234
Royalties and other operating income (Note 2)	22,354	11,318
Cost of sales	(186,977)	(168,152)
Gross profit	**236,675**	**218,400**
Marketing and distribution	(71,588)	(67,873)
Research and development	(74,280)	(66,639)
General and administration	(12,069)	(9,225)
Operating profit	**78,738**	**74,663**
Financing costs (Note 3)	(12)	(40)
Other financial income (expense) (Note 3)	(1,782)	(1,945)
Profit before taxes	**76,944**	**72,678**
Income taxes (Note 4)	(25,058)	(25,837)
Net income	**51,886**	**46,841**
Attributable to :		
Chugai shareholders (Note 19)	50,895	46,052
Non-controlling interests (Note 20)	991	789
Earnings per share (Note 24)		
Basic (yen)	93.47	84.62
Diluted (yen)	93.35	84.58

2) Consolidated statement of comprehensive income in millions of yen

	Year ended December 31	
	2013	2012
Net income recognized in income statement	**51,886**	**46,841**
Other comprehensive income		
Remeasurements of defined benefit plans (Notes 4 and 19)	964	1,275
Items that will not be reclassified to the income statement	**964**	**1,275**
Available-for-sale investments (Notes 4 and 19)	1,834	930
Cash flow hedges (Notes 4 and 19)	4,090	73
Currency translation of foreign operations (Notes 4 and 19)	8,019	3,369
Items that may be reclassified subsequently to the income statement	**13,942**	**4,372**
Other comprehensive income, net of tax (Note 4)	**14,907**	**5,647**
Total comprehensive income	**66,793**	**52,488**
Attributable to:		
Chugai shareholders (Note 19)	65,497	51,564
Non-controlling interests (Note 20)	1,296	924

2. **Consolidated balance sheet** in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Assets			
Non-current assets:			
Property, plant and equipment (Note 5)	140,445	143,056	143,356
Intangible assets (Note 6)	9,514	6,500	6,548
Financial non-current assets (Note 7)	9,066	6,332	4,946
Deferred tax assets (Note 4)	19,244	20,735	24,042
Defined benefit plan assets (Note 22)	3,862	2,680	993
Other non-current assets (Note 8)	10,846	10,921	11,316
Total non-current assets	**192,977**	**190,224**	**191,202**
Current assets:			
Inventories (Note 9)	128,536	108,413	102,834
Accounts receivable (Note 10)	128,182	128,306	119,506
Current income tax assets (Note 4)	205	344	27
Marketable securities (Note 11)	119,573	116,484	75,177
Cash and cash equivalents (Note 12)	115,070	95,445	94,474
Other current assets (Note 13)	12,669	6,108	4,035
Total current assets	**504,235**	**455,100**	**396,054**
Total assets	**697,212**	**645,325**	**587,255**
Liabilities			
Non-current liabilities:			
Long-term debt (Note 14)	(195)	(213)	(170)
Deferred tax liabilities (Note 4)	(12,211)	(9,963)	(9,342)
Defined benefit plan liabilities (Note 22)	(1,269)	(747)	(655)
Long-term provisions (Note 15)	(2,082)	(1,893)	(1,907)
Other non-current liabilities (Note 16)	(10,584)	(8,630)	(4,531)
Total non-current liabilities	**(26,341)**	**(21,446)**	**(16,606)**
Current liabilities:			
Short-term debt (Note 14)	(38)	(44)	(22)
Current income tax liabilities (Note 4)	(12,673)	(11,437)	(13,731)
Short-term provisions (Note 15)	(105)	(5)	(273)
Accounts payable (Note 17)	(59,544)	(60,096)	(35,895)
Other current liabilities (Note 18)	(25,307)	(23,135)	(21,740)
Total current liabilities	**(97,667)**	**(94,718)**	**(71,661)**
Total liabilities	**(124,008)**	**(116,164)**	**(88,266)**
Total net assets	**573,204**	**529,161**	**498,989**
Equity:			
Capital and reserves attributable to Chugai shareholders (Note 19)	571,692	527,961	497,782
Equity attributable to non-controlling interests (Note20)	1,512	1,200	1,207
Total equity	**573,204**	**529,161**	**498,989**

3. Consolidated statement of cash flows in millions of yen

	Year ended December 31	
	2013	2012
Cash flows from operating activities		
Cash generated from operations (Note 25)	100,959	91,553
(Increase) decrease in working capital	(19,660)	16,335
Payments made for defined benefit plans	(2,327)	(2,642)
Utilization of provisions (Note 15)	(163)	(288)
Other operating cash flows	(1,461)	(1,915)
Cash flows from operating activities, before income taxes paid	**77,348**	**103,043**
Income taxes paid	(23,827)	(25,501)
Total cash flows from operating activities	**53,521**	**77,542**
Cash flows from investing activities		
Purchase of property, plant and equipment	(11,287)	(14,849)
Purchase of intangible assets	(3,377)	(790)
Disposal of property, plant and equipment	(300)	30
Interest and dividends received (Note 25)	419	441
Purchases of marketable securities	(240,860)	(197,493)
Sales of marketable securities	242,198	157,985
Other investing cash flows	(6)	(224)
Total cash flows from investing activities	**(13,213)**	**(54,901)**
Cash flows from financing activities		
Interest paid	(11)	(9)
Dividends paid to Chugai shareholders	(22,874)	(21,778)
Dividends paid to non-controlling shareholders	(983)	(930)
Exercise of equity compensation plans (Note 23)	820	45
(Increase) decrease in own equity instruments	(12)	(4)
Other financing cash flows	(109)	(115)
Total cash flows from financing activities	**(23,169)**	**(22,792)**
Net effect of currency translation on cash and cash equivalents	2,486	1,121
Increase in cash and cash equivalents	**19,625**	**971**
Cash and cash equivalents at January 1	95,445	94,474
Cash and cash equivalents at December 31 (Note 12)	**115,070**	**95,445**

4. Consolidated statement of changes in equity in millions of yen

	Attributable to Chugai shareholders						
	Share capital	Capital surplus	Retained earnings	Other reserves	Subtotal	Non-controlling interests	Total equity
Year ended December 31, 2012							
At January 1, 2012	**72,967**	**64,385**	**371,560**	**(11,129)**	**497,782**	**1,207**	**498,989**
Net income recognized in income statement	–	–	46,052	–	46,052	789	46,841
Available-for-sale investments (Notes 4 and 19)	–	–	–	930	930	–	930
Cash flow hedges (Notes 4 and 19)	–	–	–	73	73	–	73
Currency translation of foreign operations (Notes 4,19 and 20)	–	–	–	3,231	3,231	138	3,369
Remeasurements of defined benefit plans (Notes 4,19 and 20)	–	–	1,278	–	1,278	(3)	1,275
Total comprehensive income	**–**	**–**	**47,330**	**4,234**	**51,564**	**924**	**52,488**
Dividends (Notes 19 and 20)	–	–	(21,768)	–	(21,768)	(930)	(22,698)
Equity compensation plans (Note 19)	–	206	–	–	206	–	206
Own equity instruments (Note 19)	–	77	–	–	77	–	77
Other movements	–	–	99	–	99	–	99
At December 31, 2012	**72,967**	**64,668**	**397,221**	**(6,895)**	**527,961**	**1,200**	**529,161**
Year ended December 31, 2013							
At January 1, 2013	**72,967**	**64,668**	**397,221**	**(6,895)**	**527,961**	**1,200**	**529,161**
Net income recognized in income statement	–	–	50,895	–	50,895	991	51,886
Available-for-sale investments (Notes 4 and 19)	–	–	–	1,834	1,834	–	1,834
Cash flow hedges (Notes 4 and 19)	–	–	–	4,090	4,090	–	4,090
Currency translation of foreign operations (Notes 4,19 and 20)	–	–	–	7,716	7,716	303	8,019
Remeasurements of defined benefit plans (Notes 4,19 and 20)	–	–	963	–	963	2	964
Total comprehensive income	**–**	**–**	**51,858**	**13,639**	**65,497**	**1,296**	**66,793**
Dividends (Notes 19 and 20)	–	–	(22,866)	–	(22,866)	(983)	(23,850)
Equity compensation plans (Note 19)	–	138	–	–	138	–	138
Own equity instruments (Note 19)	–	962	–	–	962	–	962
Other movements	–	–	–	–	–	–	–
At December 31, 2013	**72,967**	**65,768**	**426,213**	**6,744**	**571,692**	**1,512**	**573,204**

Notes to Consolidated Financial Statements

1. General accounting principles and significant accounting policies

1) Basis of preparation of the consolidated financial statements

These financial statements are the annual consolidated financial statements of Chugai Pharmaceutical Co., Ltd., a company registered in Japan, and its subsidiaries ("the Group"). The common stock of Chugai is publicly traded and is listed on the Tokyo Stock Exchange under the stock code "TSE: 4519". The consolidated financial statements were approved by Osamu Nagayama representative director, chairman of the Board & CEO, and Yoshio Itaya Board director & CFO on March 27, 2014.

Roche Holding Ltd. is a public company registered in Switzerland and the parent company of the Roche Group, which discloses its results in accordance with International Financial Reporting Standards ("IFRS"). The shareholding percentage of Roche Holding Ltd. in Chugai is 59.89% and the percentage ownership interest is 61.5%. Chugai and its subsidiaries became principal members of the Roche Group after entering into a strategic alliance in October 2002.

The Group meets all of the requirements for a "Specified Company" as stipulated under Article 1-2 of the "Regulations Concerning Terminology, Forms, and Preparation Methods of Consolidated Financial Statements" (Ministry of Finance of Japan Regulation No. 28, 1976, "the regulation"). Hence, in accordance with Article 93 of the regulation, the consolidated financial statements have been prepared in accordance with IFRS.

The consolidated financial statements are the first annual financial statements for the Group prepared in accordance with IFRS. Previously, the consolidated financial statements were prepared in conformity with accounting principles generally accepted in Japan ("JGAAP"). The last consolidated financial statements prepared under JGAAP were for the fiscal year ended December 31, 2012.

The date of transition to IFRS for the Group is January 1, 2012. Included in Note 30 of these consolidated financial statements are reconciliations of equity under JGAAP as compared to under IFRS as of January 1, 2012 and December 31, 2012. Note 30 also includes a reconciliation of the net income and comprehensive income reported for the year ended December 31, 2012 between JGAAP and IFRS.

The consolidated financial statements are presented in Japanese yen, which is Chugai's functional currency and amounts are rounded to the nearest ¥1 million. As a result, the totals shown in the accompanying consolidated financial statements do not necessarily agree with the sum of the individual amounts. They have been prepared using the historical cost convention except for items that are required to be accounted for at fair value.

2) Key accounting judgments, estimates and assumptions

The preparation of the consolidated financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities and contingent amounts. Actual outcomes could differ from those management estimates. The estimates and underlying assumptions are reviewed on an on-going basis and are based on historical experience and various other factors. Revisions to estimates are recognized in the period in which the estimate is revised. The following are considered to be the key accounting judgments, estimates and assumptions made and believed to be appropriate based upon currently available information.

Revenues. Revenues are only recognized when, in management's judgment, the significant risks and rewards of ownership have been transferred and when the Group does not retain continuing managerial involvement or effective control over the goods sold or when the obligation has been fulfilled. The Group is party to out-licensing agreements which involve upfront and milestone payments occurring over several years and which may also involve certain future obligations. Therefore, for some transactions this can result in cash receipts being initially recognized as deferred income and then released to income over subsequent periods on the basis of the performance of the conditions specified in the agreement.

Sales allowances. The Group makes accruals for expected sales rebates, which are estimated based on analyses of existing contractual or legislatively-mandated obligations, historical trends and the Group's experience. As these deductions are based on management estimates, they may be subject to change as better information becomes available. Such changes that arise could impact the accruals recognized in the balance sheet in future periods and consequently the level of sales recognized in the income statement in future periods.

Impairment. Intangible assets not yet available for use are reviewed annually for impairment. Property, plant and equipment and intangible assets in use are assessed for impairment when there is a triggering event that provides evidence that an asset may be impaired. To assess whether any impairment exists estimates of expected future cash flows are used. Actual outcomes could vary significantly from such estimates of discounted future cash flows. Factors such as changes in discount rates, the planned use of buildings, machinery or equipment, closure of facilities, the presence or absence of competition, technical obsolescence and lower than anticipated product sales could lead to shorter useful lives or impairment.

Post-employment benefits. The Group operates defined benefit plans and the fair value of the recognized plan assets and liabilities are based upon statistical and actuarial calculations. The measurement of the net defined benefit obligation is particularly sensitive to changes in the discount rate and expected mortality. The actuarial assumptions used may differ materially from actual results due to changes in market and economic conditions, longer or shorter life spans of participants, and other changes in the factors being assessed. These differences could impact on the assets or liabilities recognized in the balance sheet in future periods.

Legal. The Group provides for anticipated legal settlement costs when there is a probable outflow of resources that can be reasonably estimated. These estimates consider the specific circumstances of each legal case and relevant legal advice, and are inherently judgmental due to the highly complex nature of legal cases. The estimates could change substantially over time as new facts emerge and each legal case progresses. Where no reliable estimate can be made, no provision is recorded and contingent liabilities are disclosed where material.

Environmental. The Group provides for anticipated environmental remediation costs when there is a probable outflow of resources that can be reasonably estimated. Environmental provisions consist primarily of costs to fully clean and refurbish contaminated sites, including landfills, and to treat and contain contamination at certain other sites. These estimates are inherently judgmental due to uncertainties related to the detection of previously unknown contaminated sites, the method and extent of remediation, the percentage of the problematic materials attributable to the Group at the remediation sites, and the financial capabilities of the other potentially responsible parties. The estimates could change substantially over time as new facts emerge and each environmental remediation progresses.

Income taxes. Significant estimates are required to determine the current and deferred tax assets and liabilities. Some of these estimates are based on interpretations of existing tax laws or regulations. Factors that may impact on current and deferred taxes include changes in tax laws, regulations or rates, changing interpretations of existing tax laws or regulations, future levels of research and development spending and changes in pre-tax earnings.

Leases. The treatment of leasing transactions is mainly determined by whether the lease is considered to be an operating or finance lease. In making this assessment, management looks at the substance of the lease, as well as the legal form, and makes a judgment about whether substantially all of the risks and rewards of ownership are transferred. Arrangements which do not take the legal form of a lease but that nevertheless convey the right to use an asset are also covered by such assessments.

3) Significant accounting policies

Consolidation policy

Subsidiaries are all companies over which the Group has control. Chugai controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Companies acquired during the year are consolidated from the date on which control is transferred to the Group, and subsidiaries to be divested are included up to the date on which control passes from the Group. Inter-company balances, transactions and resulting unrealized income are eliminated in full. Changes in ownership interests in subsidiaries are accounted for as equity transactions if they occur after control has already been obtained and if they do not result in a loss of control. Associates are companies over which the Group exercises, or has the power to exercise, significant influence, but which it does not control and they are accounted for using the equity method.

Foreign currency translation

Most foreign subsidiaries of the Group use their local currency as their functional currency. Certain foreign subsidiaries use other currencies (such as the euro) as their functional currency where this is the currency of the primary economic environment in which the entity operates. Local transactions in other currencies are initially reported using the exchange rate at the date of the transaction. Gains and losses from the settlement of such transactions and gains and losses on translation of monetary assets and liabilities denominated in other currencies are included in income, except when they are qualifying cash flow hedges. In such cases the gains and losses are deferred into other comprehensive income.

Upon consolidation, assets and liabilities of foreign subsidiaries using functional currencies other than the Japanese yen are translated into Japanese yen using year-end rates of exchange. The income statement and statement of cash flows are translated at the average rates of exchange for the year. Translation differences due to the changes in exchange rates between the beginning and the end of the year and the difference between net income translated at the average and year-end exchange rates are taken directly to other comprehensive income.

Revenue recognition

Sales represent amounts received and receivable for goods supplied to customers after deducting trade discounts, cash discounts and volume rebates, and exclude consumption taxes and other taxes directly linked to sales. Revenues from the sale of products are recognized upon transfer to the customer of significant risks and rewards. Trade discounts, cash discounts and volume rebates are recorded on an accrual basis consistent with the recognition of the related sales. Sales returns, charge-backs and other rebates are also deducted from sales and recorded as accrued liabilities or as a deduction from accounts receivable.

Royalties and other operating income are recorded as earned or as the services are performed. Single transactions are split into separately identifiable components to reflect the substance of the transaction, where necessary. Conversely, two or more transactions may be considered together for revenue recognition purposes, where the commercial effect cannot be understood without reference to the series of transactions as a whole.

Cost of sales

Cost of sales includes the corresponding direct production costs and related production overheads of goods sold and services rendered. Royalties, alliance and collaboration expenses, including all collaboration profit-sharing arrangements are also reported as part of cost of sales. Start-up costs between validation and the achievement of normal production capacity are expensed as incurred.

Research and development
Internal research and development activities are expensed as incurred for the following:

- Internal research costs incurred for the purpose of gaining new scientific or technical knowledge and understanding.
- Internal development costs incurred for the application of research findings or other knowledge to plan and develop new products for commercial production. The development projects undertaken by the Group are subject to technical, regulatory and other uncertainties, such that, in the opinion of management, the criteria for capitalization as intangible assets are not met prior to obtaining marketing approval by the regulatory authorities in major markets.
- Post-marketing studies after regulatory approval, such as phase IV costs in the pharmaceuticals business, generally involve safety surveillance and on-going technical support of a drug after it receives marketing approval to be sold. They may be required by regulatory authorities or may be undertaken for safety or commercial reasons. The costs of such post-marketing studies are not capitalized as intangible assets, as in the opinion of management, they do not generate separately identifiable incremental future economic benefits that can be reliably measured.

Acquired in-process research and development resources obtained through in-licensing arrangements, business combinations or separate asset purchases are capitalized as intangible assets. The acquired asset must be controlled by the Group, be separately identifiable and expected to generate future economic benefits, even if uncertainty exists as to whether the research and development will ultimately result in a marketable product. Consequently, upfront and milestone payments to third parties for pharmaceutical products or compounds before regulatory marketing approval are recognized as intangible assets. Assets acquired through such arrangements are measured on the basis set out in the “Intangible assets” policy. Subsequent internal research and development costs incurred post-acquisition are treated in the same way as other internal research and development costs. If research and development are embedded in contracts for strategic alliances, the Group carefully assesses whether upfront or milestone payments constitute funding of research and development work or acquisition of an asset.

Licensing, milestone, and other upfront receipts
Royalty income is recognized on an accrual basis in accordance with the substance of the respective licensing agreements. If the collectability of a royalty amount is not reasonably assured, those royalties are recognized as revenues when the cash is received. The Group receives upfront, milestone and other similar payments from third parties relating to the sale or licensing of products or technology. Revenues associated with performance milestones are recognized based on achievement of the deliverables as defined in the respective agreements. Upfront payments and license fees for which there are subsequent deliverables are initially reported as deferred income and are recognized in income as earned over the period of the development collaboration or the manufacturing obligation.

Employee benefits
Short-term employee benefits include wages, salaries, social security contributions, paid annual leave and sick leave, profit sharing and bonuses, and non-monetary benefits for current employees. The costs are recognized within the operating results when the employee has rendered the associated service. The Group recognizes a liability for profit sharing and bonuses where contractually obliged or where there is a past practice that has created a constructive obligation.

Termination benefits are payable when employment is terminated by the Group before the normal retirement date, or whenever an employee accepts voluntary redundancy in exchange for these benefits. Termination costs are recognized at the earlier of when the Group can no longer withdraw the offer of the benefits or when the Group recognizes any related restructuring costs.

Post-employment benefits
For defined contribution plans, the Group contributions are recognized within the operating results when the employee has rendered the associated service.

For defined benefit plans the liability or asset recognized in the balance sheet is net amount of the present value of the defined benefit obligation and the fair value of the plan assets. All changes in the net defined benefit liability (asset) are recognized as they occur as follows:

Recognized in the income statement:
- Current service costs are charged to the appropriate income statement heading within the operating results.
- Past service costs, including curtailment gains or losses, are recognized immediately in general and administration within the operating results.
- Settlement gains or losses are recognized in general and administration within the operating results.
- Net interest on the net defined benefit liability (asset) is recognized in financing costs.

Recognized in other comprehensive income:
- Actuarial gains and losses arising from experience adjustments (the difference between previous assumptions and what has actually occurred) and changes in actuarial assumptions.
- The return on plan assets, excluding amounts included in net interest on the net defined benefit liability (asset).

Net interest on the net defined benefit liability (asset) comprises of interest income on plan assets and interest costs on the defined benefit obligation. The net interest is calculated using the same discount rate that is used in calculating the defined benefit obligation, applied to the net defined benefit liability (asset) at the start of the period, taking account of any changes from contribution or benefit payments.

Pension assets and liabilities in different defined benefit plans are not offset unless the Group has a legally enforceable right to use the surplus in one plan to settle obligations in the other plan.

Equity compensation plans
The fair value of all equity compensation awards granted to directors and certain employees is estimated at the grant date and recorded as an expense over the vesting period. The expense is charged to the appropriate income statement heading within the operating results. For equity-settled plans, an increase in equity is recorded for this expense and any subsequent cash flows from exercises of vested awards are recorded as changes in equity.

Property, plant and equipment
Property, plant and equipment are initially recorded at cost of purchase or construction, and include all costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management. These include items such as costs of site preparation, installation and assembly costs and professional fees. The net costs of testing whether the asset is functioning properly, including validation costs, are also included in the initially recorded cost of construction. Property, plant and equipment are depreciated on a straight-line basis, except for land, which is not depreciated. The estimated useful lives of major classes of depreciable assets are as follows:
- Land improvements 40 years
- Buildings 10-50 years
- Machinery and equipment 3-15 years

Where parts of an item of property, plant and equipment have different useful lives, they are accounted for as separate components. The estimated useful lives of the assets are regularly reviewed, and, if necessary, the future depreciation charges are accelerated. Repairs and maintenance costs are expensed as incurred.

Leases
Where the Group is the lessee, finance leases exist when substantially all of the risks and rewards of ownership of leased assets are transferred to the Group. Finance lease assets are capitalized at the start of the lease at fair value, or the present value of the minimum lease payments, if lower. The rental obligation, net of finance charges, is reported within debt. Finance lease assets are depreciated over the shorter of the lease term and its useful life. The interest element of the lease payment is charged against income over the lease term based on the effective interest rate method. Operating leases are when substantially all of the risks and rewards of ownership are not transferred to the Group. Payments made under operating leases are charged against income on a straight-line basis over the period of the lease.

Intangible assets
Purchased patents, trademarks, licenses and other intangible assets are initially recorded at cost. Assets that have been acquired through a business combination are initially recorded at fair value. Once available for use, intangible assets are amortized on a straight-line basis over their useful lives. The estimated useful life is the lower of the legal duration and the economic useful life. The estimated useful lives of intangible assets are regularly reviewed. Estimated useful lives of major classes of amortizable intangible assets are as follows:

- Product intangibles in use 4-20 years
- Marketing intangibles in use 2-5 years
- Technology intangibles in use 7-14 years

Impairment of property, plant and equipment and intangible assets
An impairment assessment is carried out at each reporting date when there is evidence that an item of property, plant and equipment or intangible asset in use may be impaired. In addition intangible assets that are not yet available for use are tested for impairment annually. When the recoverable amount of an asset, being the higher of its fair value less costs to sell and its value in use, is less than its carrying value, then the carrying value is reduced to its recoverable amount. This reduction is reported in the income statement as an impairment loss. Value in use is calculated using estimated cash flows. These are discounted using an appropriate long-term interest rate. When an impairment loss arises, the useful life of the asset is reviewed and, if necessary, the future depreciation/amortization charge is accelerated. If the amount of impairment loss subsequently decreases and the decrease can be related objectively to an event occurring after the impairment was recognized, then the previously recognized impairment loss is reversed through the income statement as an impairment reversal.

Inventories
Inventories are stated at the lower of cost and net realizable value. The cost of finished goods and work in process includes raw materials, direct labor and other directly attributable costs and overheads based upon the normal capacity of production facilities. Cost is determined using the weighted average method. Net realizable value is the estimated selling price less cost to completion and selling expenses.

Accounts receivable
Accounts receivable are carried at the original invoice amount less allowances made for doubtful accounts, trade discounts, cash discounts, volume rebates and similar allowances. An allowance for doubtful accounts is recorded where there is objective evidence that the Group will not be able to collect all amounts due. These estimates are based on specific indicators, such as the ageing of customer balances, specific credit circumstances and the Group's historical experience, taking also into account economic conditions. Expenses for doubtful trade receivables are recognized within marketing and distribution expenses. Trade discounts, cash discounts, volume rebates and similar allowances are recorded on an accrual basis consistent with the recognition of the related sales, using estimates based on existing contractual obligations, historical trends and the Group's experience.

Cash and cash equivalents
Cash and cash equivalents include cash on hand and time, call and current balances with banks and similar institutions. Such balances are only reported as cash equivalents if they are readily convertible to known amounts of cash, are subject to insignificant risk of changes in their fair value and have a maturity of three months or less from the date of acquisition.

Provisions and contingencies
Provisions are recognized where a legal or constructive obligation has been incurred which will probably lead to an outflow of resources that can be reliably estimated. In particular, restructuring provisions are recognized when the Group has a detailed formal plan that has either commenced implementation or has been announced. Provisions are recorded for the estimated ultimate liability that is expected to arise and are discounted when the time value of money is material. A contingent liability is disclosed where the existence of the obligation will only be confirmed by future events or where the amount of the obligation cannot be measured with reasonable reliability. Contingent assets are not recognized, but are disclosed where an inflow of economic benefits is probable.

Fair values
Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. It is determined by reference to quoted market prices or by the use of established valuation techniques such as option pricing models and the discounted cash flow method if quoted prices in an active market are not available.

Financial instruments
Financial instruments are classified into the following categories:

Available-for-sale. These are non-derivative financial assets that are either designated as such or are not classified in any other financial asset category. Available-for-sale financial assets are initially recorded and subsequently carried at fair value. Changes in fair value are recorded in other comprehensive income, except for impairments, interest and foreign exchange components. When an investment is derecognized the cumulative gains and losses in equity are reclassified to other financial income (expense). Available-for-sale assets are mainly comprised of marketable securities and most of financial non-current assets.

Fair value – hedging instruments. These are derivative financial instruments that are used to manage the exposures to foreign currency risk. Derivative financial instruments are initially recorded and subsequently carried at fair value. Apart from those derivatives designated as qualifying cash flow hedging instruments, all changes in fair value are recorded as other financial income (expense).

Fair value – designated. These are non-derivative financial instruments that are designated as fair value through profit or loss on initial recognition. Designated fair value instruments are initially recorded and subsequently carried at fair value. Changes in fair value are recorded in the income statement. Designated fair value instruments mainly comprise of financial assets held for trading.

Loans and receivables. These are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. Loans and receivables are initially recorded at fair value and subsequently carried at amortized cost using the effective interest rate method, less any impairment losses. Loans and receivables are mainly comprised of accounts receivable, cash and cash equivalents and a part of financial non-current assets.

Other financial liabilities. These are non-derivative financial liabilities. Other financial liabilities are initially recorded at fair value and subsequently carried at amortized cost using the effective interest rate method. Other financial liabilities are mainly comprised of accounts payable and debt.

Derecognition of financial instruments
A financial asset is derecognized when the contractual cash flows from the asset expire or when the Group transfers the rights to receive the contractual cash flows from the financial assets in a transaction in which substantially all the risks and rewards of ownership of the financial asset are transferred. A financial liability is derecognized when the contractual obligations are discharged, cancelled or expire.

Impairment of financial assets
Financial assets are individually assessed for possible impairment at each reporting date. An impairment charge is recorded where there is objective evidence of impairment, such as where the issuer is in bankruptcy, default or other significant financial difficulty. Available-for-sale equity securities that have a market value of more than 25% below their original cost, or have a market value below their original cost for a sustained six-month period will be considered as impaired.

For financial assets carried at amortized cost, any impairment charge is the difference between the carrying value and the recoverable amount, calculated using estimated future cash flows discounted using the original effective interest rate. For available-for-sale financial assets, any impairment charge is the amount currently carried in other comprehensive income for the difference between the original cost, net of any previous impairment, and the fair value.

An impairment loss is reversed if the reversal can be related objectively to an event occurring after the impairment loss was recognized. For equity securities held as available-for-sale, the reversal is recognized directly in other comprehensive income. For debt securities measured at amortized cost or available-for-sale, the reversal is recognized in other financial income (expense).

Hedge accounting
The Group uses derivatives to manage its exposures to foreign currency risk. The instruments used may include forwards contracts and options. The Group generally limits the use of hedge accounting to certain significant transactions. To qualify for hedge accounting the hedging relationship must meet several strict conditions on documentation, probability of occurrence, hedge effectiveness and reliability of measurement. While many of these transactions can be considered as hedges in economic terms, if the required conditions are not met, then the relationship does not qualify for hedge accounting. In this case the hedging instrument and the hedged item are reported independently as if there were no hedging relationship, which means that any derivatives are reported at fair value, with changes in fair value included in other financial income (expense).

Cash flow hedge. Is a hedge of the exposure to variability in cash flows that is attributable to a particular risk associated with a recognized asset or liability or a highly probable forecast transaction and could affect profit or loss. The hedging instrument is recorded at fair value. The effective portion of the hedge is included in other comprehensive income and any ineffective portion is reported in other financial income (expense). If the hedging relationship is the hedge of the foreign currency risk of a firm commitment or highly probable forecasted transaction that results in the recognition of a non-financial item, the cumulative changes in the fair value of the hedging instrument that have been recorded in other comprehensive income are included in the initial carrying value of the non-financial item at the date of recognition. For all other cash flow hedges, the cumulative changes in the fair value of the hedging instrument that have been recorded in other comprehensive income are included in other financial income (expense) when the forecasted transaction affects net income.

Fair value hedge. Is a hedge of the exposure to changes in fair value of a recognized asset or liability, or an unrecognized firm commitment, or an identified portion of such an asset, liability or firm commitment, that is attributable to a particular risk and could affect profit or loss. The hedging instrument is recorded at fair value and the hedged item is recorded at its previous carrying value, adjusted for any changes in fair value that are attributable to the hedged risk. Changes in the fair values are reported in other financial income (expense).

Taxation
Income taxes include all taxes based upon the taxable profits of the Group. Other taxes not based on income, such as property and capital taxes, are included in the appropriate heading within the operating results.

Liabilities for income taxes, which could arise on the remittance of retained earnings, principally relating to subsidiaries, are only recognized where it is probable that such earnings will be remitted in the foreseeable future.

Deferred tax assets and liabilities are recognized on temporary differences between the tax bases of assets and liabilities and their carrying values. Deferred tax assets are recognized to the extent that it is probable that future taxable profit will be available against which the unused tax losses can be utilized.

Current and deferred tax assets and liabilities are offset when the income taxes are levied by the same taxation authority and when there is a legally enforceable right to offset them. Deferred taxes are determined based on the currently enacted tax rates applicable in each tax jurisdiction where the Group operates.

Own equity instruments
The Group's holdings in its own equity instruments are recorded as a deduction from equity. The original purchase cost, consideration received for subsequent resale of these equity instruments and other movements are reported as changes in equity. The exercise of stock acquisition rights granted to directors and certain employees will result in the allotment from own equity instruments.

4) Future new and revised standards
The Group is currently assessing the potential impacts of new standards and interpretations that will be effective from January 1, 2014 and beyond. Based on the analysis to date, the Group does not anticipate that these will have a material impact on the Group's overall results and financial position.

By the date of approval of the consolidated financial statements, the following new and revised standard has been issued by the International Accounting Standards Board (IASB) and has not been implemented by the Group yet.

	IFRS	Mandatory adoption (from the year beginning)	To be adopted by the Group	Description of new and revised standards
IFRS 9	Financial Instruments	-	-	Classification, measurement and recognition of financial instruments

2. Operating segment information

The Group has a single business of pharmaceuticals and does not have multiple operating segments. The Group's pharmaceuticals business consists of the research and development of new prescription medicines and the subsequent manufacturing, marketing and distribution activities. These functional activities are integrated and managed effectively.

Information on revenues by geographical area in millions of yen

	2013		2012	
	Sales	Royalties and other operating income	Sales	Royalties and other operating income
Japan	340,241	10,512	332,942	5,040
Overseas	61,057	11,842	42,292	6,277
of which Switzerland	42,909	11,729	25,557	6,274
Total	**401,298**	**22,354**	**375,234**	**11,318**

Information on revenues by major customers in millions of yen

	2013		2012	
	Revenues	%	Revenues	%
Alfresa Corporation	94,288	22.3	89,954	23.3
Mediceo Corporation	75,240	17.8	75,378	19.5
F. Hoffmann-La Roche Ltd	54,638	12.9	31,531	8.2
Suzuken Co., Ltd.	49,728	11.7	46,295	12.0
Toho Pharmaceutical Co., Ltd.	40,869	9.6	40,343	10.4

3. Financing costs and other financial income (expense)

Financing costs in millions of yen

	2013	2012
Interest expense	(11)	(9)
Net interest cost of defined benefit plans	66	37
Net other financing costs	(68)	(68)
Total financing costs	**(12)**	**(40)**

Other financial income (expense) in millions of yen

	2013	2012
Dividend income	148	122
Gains on sale of equity securities	-	-
Losses on sale of equity securities	-	(4)
Write-downs and impairments of equity securities	(3)	(135)
Net income from equity securities	**145**	**(18)**
Interest income	243	358
Gains on sale of debt securities	-	-
Losses on sale of debt securities	-	-
Net interest income and income from debt securities	**243**	**358**
Foreign exchange gains (losses)	(5,730)	(3,787)
Gains (losses) on foreign currency derivatives	3,560	1,502
Net foreign exchange gains (losses)	**(2,170)**	**(2,285)**
Total other financial income (expense)	**(1,782)**	**(1,945)**

4. Income taxes

Income tax expenses in millions of yen

	2013	2012
Current income taxes	(25,260)	(22,929)
Deferred taxes	202	(2,907)
Total income tax (expense)	**(25,058)**	**(25,837)**

Reconciliation of the Group's effective tax rate

	2013	2012
Expected tax rate	38.0 %	40.4 %
Tax effect of		
- Non-taxable income/non-deductible expenses	+1.2 %	+1.3 %
- Effect of changes in applicable tax rates on deferred tax balances	+0.1 %	+2.2 %
- Research and development tax credits	(4.9) %	(8.1) %
- Other differences	(1.9) %	(0.1) %
Group's effective tax rate	**32.5 %**	**35.6 %**

The expected tax rate is based on the approximate statutory tax rate of Chugai. It was 38.0% for the year ended December 31, 2013 and will be 35.6% from 2016 onwards due to changes in applicable tax rate in Japan.

The effective tax rate was 32.5% compared to 35.6% in the previous fiscal year, decreased by 3.1 percentage points compared to prior fiscal year. This was due to the reduction of applicable tax rate in the fiscal year ended December 31, 2013, which more than offset the impact from reduction in tax allowances for research and development expenditure, and the impact of remeasurements of deferred tax assets conducted in the previous fiscal year as a result of the change of applicable tax rate.

Tax effects of other comprehensive income in millions of yen

	2013			2012		
	Pre-tax amount	Tax benefit	After-tax amount	Pre-tax amount	Tax benefit	After-tax Amount
Remeasurements of defined benefit plans	1,496	(532)	964	1,984	(710)	1,275
Available-for-sale investments	2,760	(926)	1,834	1,250	(320)	930
Cash flow hedges	6,597	(2,508)	4,090	118	(45)	73
Currency translation of foreign operations	8,019	-	8,019	3,369	-	3,369
Other comprehensive income	**18,873**	**(3,966)**	**14,907**	**6,721**	**(1,074)**	**5,647**

Income tax assets (liabilities) in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Current income taxes			
- Assets	205	344	27
- Liabilities	(12,673)	(11,437)	(13,731)
Net current income tax assets (liabilities)	**(12,468)**	**(11,093)**	**(13,703)**
Deferred taxes			
- Assets	19,244	20,735	24,042
- Liabilities	(12,211)	(9,963)	(9,342)
Net deferred tax assets (liabilities)	**7,033**	**10,772**	**14,700**

Current income taxes: movements in recognized net assets (liabilities) in millions of yen

	2013	2012
Net current income tax assets (liabilities) at January 1	(11,093)	(13,703)
Income taxes paid	23,827	25,501
(Charged) credited to the income statement	(25,260)	(22,929)
Currency translation effects and other	58	38
Net current income tax assets (liabilities) at December 31	**(12,468)**	**(11,093)**

Deferred taxes: movements in recognized net assets (liabilities) in millions of yen

	Property, plant and equipment	Intangible assets	Provisions	Employee benefits	Other temporary differences	Total
Year ended December 31, 2012						
At January 1, 2012	(20,729)	3,024	301	3,752	28,352	14,700
(Charged) credited to the income statement	(209)	(2,496)	(116)	112	(199)	(2,907)
(Charged) credited to other comprehensive income	-	-	-	(710)	(364)	(1,074)
(Charged) credited to equity	-	-	-	37	72	109
Currency translation effects and other	-	-	-	-	(56)	(56)
At December 31, 2012	**(20,938)**	**528**	**185**	**3,192**	**27,805**	**10,772**
Year ended December 31, 2013						
At January 1, 2013	(20,938)	528	185	3,192	27,805	10,772
(Charged) credited to the income statement	797	(1,237)	139	202	302	202
(Charged) credited to other comprehensive income	-	-	-	(532)	(3,434)	(3,966)
(Charged) credited to equity	-	-	-	-	-	-
Currency translation effects and other	-	-	-	-	25	25
At December 31, 2013	**(20,142)**	**(709)**	**324**	**2,862**	**24,698**	**7,033**

Other temporary differences mainly relate to R&D expenditures and amortization of deferred assets.

Deferred tax assets are not recognized for deductible temporary differences of ¥1,882 million at December 31, 2013 (2012: ¥4,070 million).
Deferred tax assets are recognized for tax losses carried forward only to the extent that realization of the related tax benefit is certain.

Unrecognised tax losses: expiry in millions of yen

	2013	2012
Less than one year	-	-
Over one year and less than five years	-	-
Over five years	3,212	2,589
Tax losses not recognized in deferred tax assets	**3,212**	**2,589**

Deferred tax assets on unused tax credit are recognized only to the extent that realization of the related tax benefit is certain.

Unrecognised unused tax credit: expiry in millions of yen

	2013	2012
Less than one year	-	-
Over one year and less than five years	2,358	186
Over five years	106	96
Tax losses not recognized in deferred tax assets	**2,464**	**282**

Deferred tax liabilities have not been established for the withholding tax and other taxes that would be payable on the unremitted earnings of wholly-owned foreign subsidiaries of the Group, where such amounts are currently regarded as permanently reinvested. The temporary differences relating to the unremitted earnings were ¥1,690 million (2012: ¥1,241 million, Date of the transition to IFRS: ¥1,021 million).

5. Property, plant and equipment

Property, plant and equipment: movements in carrying value of assets in millions of yen

	Land	Buildings and land improvements	Machinery and equipment	Construction in progress	Total
At January 1, 2012					
Cost	10,388	106,783	149,811	2,717	269,700
Accumulated depreciation and impairment	(246)	(48,140)	(77,958)	-	(126,344)
Net book value	**10,142**	**58,643**	**71,853**	**2,717**	**143,356**
Year ended December 31, 2012					
At January 1, 2012	10,142	58,643	71,853	2,717	143,356
Additions	-	1	1,544	12,591	14,136
Disposals	-	(181)	(226)	-	(408)
Transfers	-	5,528	9,265	(14,793)	-
Depreciation charge	-	(3,677)	(9,609)	-	(13,286)
Impairment charge	(28)	(1)	(194)	(44)	(267)
Other	-	17	(653)	-	(636)
Currency translation effects	-	11	151	-	162
At December 31, 2012	**10,114**	**60,340**	**72,129**	**472**	**143,056**
Cost	10,388	110,947	156,452	516	278,304
Accumulated depreciation and impairment	(274)	(50,607)	(84,323)	(44)	(135,248)
Net book value	**10,114**	**60,340**	**72,129**	**472**	**143,056**
Year ended December 31, 2013					
At January 1, 2013	10,114	60,340	72,129	472	143,056
Additions	-	4	304	12,691	12,999
Disposals	-	(209)	(416)	(51)	(675)
Transfers	-	4,267	5,788	(10,055)	-
Depreciation charge	-	(3,621)	(9,899)	-	(13,520)
Impairment charge	(1)	(771)	(882)	(44)	(1,697)
Other	-	(28)	0	-	(28)
Currency translation effects	-	16	290	4	310
At December 31, 2013	**10,114**	**59,998**	**67,315**	**3,019**	**140,445**
Cost	10,388	114,000	158,239	3,019	285,646
Accumulated depreciation and impairment	(275)	(54,003)	(90,924)	-	(145,201)
Net book value	**10,114**	**59,998**	**67,315**	**3,019**	**140,445**

No borrowing costs were capitalized as property, plant and equipment (2012: none).

Impairment charge

During 2013 impairment charge mainly related to unused buildings at Kamakura Research laboratories.

Classification of impairment of property, plant and equipment in millions of yen

	2013	2012
Cost of sales	188	168
Marketing and distribution	24	-
Research and development	1,485	57
General and administration	1	42
Total	**1,697**	**267**

Finance leases
The capitalized cost of property, plant and equipment under finance leases was ¥202 million (2012: ¥190 million) and the net book value of these assets was ¥67 million (2012: ¥97 million, Date of transition to IFRS: ¥36 million). The carrying value of the leasing obligation was ¥71 million (2012: ¥102 million, Date of transition to IFRS: ¥38 million), which is reported as part of Debt (see Note 14).

Operating leases
Group companies are party to a number of operating leases, mainly for machinery and equipment, motor vehicles and property rentals. The arrangements do not impose any significant restrictions on the Group. Total operating lease rental expense was ¥6,819 million (2012: ¥6,877 million).

Operating leases: future minimum lease payments under non-cancellable leases in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Within one year	4,632	4.327	4,031
Between one and five years	9,530	12,067	11,986
More than five years	749	938	1,467
Total minimum payments	**14,912**	**17,332**	**17,485**

Capital commitments
The Group has non-cancellable capital commitments for the purchase or construction of property, plant and equipment totaling ¥3,446 million (2012: ¥1,741 million, Date of transition to IFRS: ¥4,287 million).

6. Intangible assets

Intangible assets: movements in carrying value of assets in millions of yen

	Product Intangibles: in use	Product Intangibles: not available for use	Marketing Intangibles: in use	Technology Intangibles: in use	Total
At January 1, 2012					
Cost	12,048	1,591	-	-	13,639
Accumulated amortization and impairment	(7,091)	-	-	-	(7,091)
Net book value	**4,957**	**1,591**	**-**	**-**	**6,548**
Year ended December 31, 2012					
At January 1, 2012	4,957	1,591	-	-	6,548
Additions	34	590	169	45	838
Disposals	-	-	-	-	-
Transfers	-	-	-	-	-
Amortization charge	(875)	-	(10)	(0)	(886)
Impairment charge	-	-	-	-	-
Currency translation effects					
At December 31, 2012	**4,116**	**2,181**	**159**	**45**	**6,500**
Cost	12,369	2,181	169	45	14,765
Accumulated amortization and impairment	(8,254)	-	(10)	(0)	(8,265)
Net book value	**4,116**	**2,181**	**159**	**45**	**6,500**
Year ended December 31, 2013					
At January 1, 2013	4,116	2,181	159	45	6,500
Additions	-	3,909	56	30	3,995
Disposals	-	-	-	-	-
Transfers	994	(994)	-	-	-
Amortization charge	(924)	-	(39)	(6)	(970)
Impairment charge	-	(89)	-	-	(89)
Currency translation effects	-	78	-	-	78
At December 31, 2013	**4,185**	**5,085**	**175**	**68**	**9,514**
Cost	14,055	5,174	225	75	19,529
Accumulated amortization and impairment	(9,870)	(89)	(49)	(7)	(10,014)
Net book value	**4,185**	**5,085**	**175**	**68**	**9,514**

Significant intangible assets

The product intangibles in use and not available for use are mainly acquired through in-licensing agreements of products with related parties. The remaining amortization periods for product intangibles in use are from 1 to 11 years.

Classification of amortization and impairment expenses in millions of yen

	2013		2012	
	Amortization	Impairment	Amortization	Impairment
Cost of sales	924	-	875	-
Marketing and distribution	39	-	10	-
Research and development	6	89	0	-
General and administration	-	-	-	-
Total	**970**	**89**	**886**	**-**

Internally generated intangible assets
The Group currently has no internally generated intangible assets from development as the criteria for the recognition as an asset are not met.

Intangible assets with indefinite useful lives
The Group currently has no intangible assets with indefinite useful lives.

Product intangibles not available for use
These mostly represent in-process research and development assets acquired either through in-licensing arrangements or separate purchases. Due to the inherent uncertainties in the research and development processes, intangible assets not available for use are particularly at risk of impairment if the project is not expected to result in a commercialized product.

Impairment of intangible assets
Impairment charges arise from changes in the estimates of the future cash flows expected to result from the use of the asset and its eventual disposal. Factors such as the presence or absence of competition, technical obsolescence or lower than anticipated sales for products with capitalized rights could result in shortened useful lives or impairment.

Potential commitments from alliance collaborations
The Group is party to in-licensing and similar arrangements with its alliance partners. These arrangements may require the Group to make certain milestone or other similar payments dependent upon the achievement of agreed objectives or performance targets as defined in the collaboration agreements.

The Group's current estimate of future commitments for such payments is set out in the table below. These figures are undiscounted and are not risk adjusted, meaning that they include all such potential payments that can arise assuming all projects currently in development are successful. The timing is based on the Group's current best estimate.

Potential future collaboration payments at December 31, 2013 in millions of yen

	Third party	Related party	Total
Within one year	-	1,014	1,014
Between one and two years	1,044	1,961	3,004
Between two and three years	2,597	3,964	6,561
Total	**3,640**	**6,939**	**10,579**

7. Financial non-current assets

Financial non-current assets in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Available-for-sale investments	8,966	6,203	4,939
Other financial non-current assets	100	129	7
Total financial non-current assets	**9,066**	**6,332**	**4,946**

Financial non-current assets are held for the Group's business purposes to strengthen and maintain the relationship with business partners. The available-for-sale investments are mainly equity investments in Japanese listed companies.

8. Other non-current assets

Other non-current assets in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Long-term prepaid expenses	5,823	5,935	6,409
Other assets	5,023	4,986	4,907
Total other non-current assets	**10,846**	**10,921**	**11,316**

Long-term prepaid expenses are mainly payments to related parties for start-up and validation costs at plants used for outsourcing to the related parties.

9. Inventories

Inventories in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Raw materials and supplies	36,054	29,441	16,985
Work in process	101	347	24
Intermediates	34,770	28,166	27,400
Finished goods	58,249	51,082	59,535
Less: Provision for slow-moving and obsolete inventory	(639)	(623)	(1,109)
Total inventories	**128,536**	**108,413**	**102,834**

Inventories expensed through cost of sales totaled ¥179,077 million (2012: ¥164,163 million). Expenses relating to inventory write-down totaled ¥1,013 million (2012: ¥790 million).

10. Accounts receivable

Accounts receivable in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Trade receivables – third party	99,076	108,174	104,776
Trade receivables – related party	12,017	7,825	4,293
Notes receivables	15	14	11
Other receivables – third party	6,640	3,936	2,837
Other receivables – related party	10,442	8,363	7,592
Allowances for doubtful accounts	(7)	(7)	(3)
Total accounts receivable	**128,182**	**128,306**	**119,506**

11. Marketable securities

Marketable securities in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Available-for-sale financial assets			
Money market instruments and time accounts over three months	119,573	115,485	68,683
Debt securities	-	1,000	6,494
Total marketable securities	**119,573**	**116,484**	**75,177**

Marketable securities are held for fund management purposes. The money market instruments are mainly certificates of deposit and commercial papers.

Debt securities – contracted maturity in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Within one year	-	1,000	5,002
More than one year	-	-	1,492
Total debt securities	**-**	**1,000**	**6,494**

12. Cash and cash equivalents

Cash and cash equivalents in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Cash - cash in hand and in current or call accounts	110,810	92,101	92,277
Cash equivalents - time accounts with a maturity of three months or less	4,259	3,344	2,197
Total cash and cash equivalents	**115,070**	**95,445**	**94,474**

13. Other current assets

Other current assets in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Derivative financial instruments	7,367	1,701	17
Total financial current assets	**7,367**	**1,701**	**17**
Prepaid expenses	5,302	4,407	4,018
Total non-financial current assets	**5,302**	**4,407**	**4,018**
Total other current assets	**12,669**	**6,108**	**4,035**

14. Debt

Debt: movements in carrying value of recognized liabilities in millions of yen

	2013	2012
At January 1	257	192
Increase in debt	22	114
Decrease in debt	(47)	(49)
At December 31	**233**	**257**
Finance lease obligations	71	102
Other debt	162	155
Total debt	**233**	**257**
Long-term debt	195	213
Short-term debt	38	44
Total debt	**233**	**257**

15. Provisions and contingent liabilities

Provisions: movements in recognized liabilities in millions of yen

	Environmental provisions	Restructuring provisions	Other provisions	Total
Year ended December 31, 2012				
At January 1, 2012	553	256	1,370	2,179
Additional provisions created	-	5	-	5
Unused amounts reversed	-	-	-	-
Utilized	(39)	(249)	-	(288)
Other	-	1	0	2
At December 31, 2012	**515**	**13**	**1,370**	**1,898**
Long-term provisions	515	8	1,370	1,893
Short-term provisions	-	5	-	5
At December 31, 2012	**515**	**13**	**1,370**	**1,898**
Year ended December 31, 2013				
At January 1, 2013	515	13	1,370	1,898
Additional provisions created	1	211	390	601
Unused amounts reversed	(70)	-	(10)	(80)
Utilized	(1)	(161)	(76)	(239)
Other	-	7	-	7
At December 31, 2013	**444**	**69**	**1,674**	**2,187**
Long-term provisions	444	36	1,601	2,082
Short-term provisions	-	33	72	105
At December 31, 2013	**444**	**69**	**1,674**	**2,187**
Expected outflow of resources				
Within one year	-	33	72	105
Between one to two years	-	30	-	30
Between two to three years	-	6	-	6
More than three years	444	-	1,601	2,046
At December 31, 2013	**444**	**69**	**1,674**	**2,187**

Environmental provisions

Provisions for environmental matters include various separate environmental issues. By their nature the amounts and timings of any outflows are difficult to predict. Significant provisions are discounted where the time value of money is material.

Restructuring provisions

These arise from planned programs that materially change the scope of business undertaken by the Group or the manner in which business is conducted. Such provisions include only the costs necessarily entailed by the restructuring which are not associated with the recurring activities of the Group. The timings of these cash outflows are reasonably certain. These provisions are not discounted as the time value of money is not material in these matters.

Other provisions

Other provisions arise mainly from expected decommissioning and removal costs with respect to property, plant and equipment. The timings of cash outflows are by their nature uncertain. Significant provisions are discounted where the time value of money is material.

Contingent liabilities
The operations and earnings of the Group continue, from time to time and in varying degrees, to be affected by political, legislative, fiscal and regulatory developments, including those relating to environmental protection. The industry in which the Group operates are also subject to other risks of various kinds. The nature and frequency of these developments and events, not all of which are covered by insurance, as well as their effect on future operations and earnings, are not predictable.

The Group has entered into strategic alliances with various companies in order to gain access to potential new products or to utilize other companies to help develop the Group's own potential new products. Potential future payments may become due to certain collaboration partners achieving certain milestones as defined in the collaboration agreements. The Group's best estimate for future commitment payments are given in Note 6.

16. Other non-current liabilities

Other non-current liabilities in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Deferred income	9,462	7,576	3,384
Other long-term liabilities	1,122	1,054	1,147
Total other non-current liabilities	**10,584**	**8,630**	**4,531**

17. Accounts payable

Accounts payable in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Trade payables – third party	7,128	7,394	7,466
Trade payables – related party	28,811	34,403	9,914
Other taxes payable	2,420	3,959	2,490
Accounts payable - purchase of property, plant and equipment	6,459	4,753	7,442
Other payables – third party	3,008	2,335	2,758
Other payables – related party	11,719	7,252	5,824
Total accounts payable	**59,544**	**60,096**	**35,895**

18. Other current liabilities

Other current liabilities in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Deferred income	555	297	-
Accrued bonus and related items	9,595	9,361	8,818
Derivative financial instruments	-	-	-
Other accrued liabilities	15,158	13,478	12,922
Total other current liabilities	**25,307**	**23,135**	**21,740**

19. Equity attributable to Chugai shareholders

Changes in equity attributable to Chugai shareholders in millions of yen

	Share capital	Capital surplus	Retained earnings	Other reserves			Total
				Fair value reserve	Hedging reserve	Translation reserve	
Year ended December 31, 2012							
At January 1, 2012	72,967	64,385	371,560	940	-	(12,070)	497,782
Net income attributable to Chugai shareholders	-	-	46,052	-	-	-	46,052
Available-for-sale investments							
- Fair value gains (losses) taken to equity	-	-	-	1,114	-	-	1,114
- Transferred to income statement on sale or impairment	-	-	-	135	-	-	135
- Income taxes	-	-	-	(320)	-	-	(320)
Cash flow hedges							
- Effective portion of fair value gains (losses) taken to equity	-	-	-	-	118	-	118
- Transferred to income statement	-	-	-	-	-	-	-
- Transferred to initial carrying amount of hedged items	-	-	-	-	-	-	-
- Income taxes	-	-	-	-	(45)	-	(45)
Currency translation of foreign operations							
- Exchange differences	-	-	-	-	-	3,369	3,369
- Non-controlling interests	-	-	-	-	-	(138)	(138)
Defined benefit plans							
- Remeasurement gains (losses)	-	-	1,984	-	-	-	1,984
- Income taxes	-	-	(710)	-	-	-	(710)
- Non-controlling interests	-	-	3	-	-	-	3
Other comprehensive income, net of tax	**-**	**-**	**1,278**	**930**	**73**	**3,231**	**5,512**
Total comprehensive income	**-**	**-**	**47,330**	**930**	**73**	**3,231**	**51,564**
Dividends	-	-	(21,768)	-	-	-	(21,768)
Equity compensation plans	-	206	-	-	-	-	206
Own equity instruments	-	77	-	-	-	-	77
Other movements	-	-	99	-	-	-	99
At December 31, 2012	**72,967**	**64,668**	**397,221**	**1,871**	**73**	**(8,839)**	**527,961**

Changes in equity attributable to Chugai shareholders in millions of yen

	Share capital	Capital surplus	Retained earnings	Other reserves			Total
				Fair value reserve	Hedging reserve	Translation reserve	
Year ended December 31, 2013							
At January 1, 2013	72,967	64,668	397,221	1,871	73	(8,839)	527,961
Net income attributable to Chugai shareholders	-	-	50,895	-	-	-	50,895
Available-for-sale investments							
- Fair value gains (losses) taken to equity	-	-	-	2,757	-	-	2,757
- Transferred to income statement on sale or impairment	-	-	-	3	-	-	3
- Income taxes	-	-	-	(926)	-	-	(926)
Cash flow hedges							
- Effective portion of fair value gains (losses) taken to equity	-	-	-	-	7,327	-	7,327
- Transferred to income statement	-	-	-	-	(72)	-	(72)
- Transferred to initial carrying amount of hedged items	-	-	-	-	(657)	-	(657)
- Income taxes	-	-	-	-	(2,508)	-	(2,508)
Currency translation of foreign operations							
- Exchange differences	-	-	-	-	-	8,019	8,019
- Non-controlling interests	-	-	-	-	-	(303)	(303)
Defined benefit plans							
- Remeasurement gains (losses)	-	-	1,496	-	-	-	1,496
- Income taxes	-	-	(532)	-	-	-	(532)
- Non-controlling interests	-	-	(2)	-	-	-	(2)
Other comprehensive income, net of tax	**-**	**-**	**963**	**1,834**	**4,090**	**7,716**	**14,602**
Total comprehensive income	**-**	**-**	**51,858**	**1,834**	**4,090**	**7,716**	**65,497**
Dividends	-	-	(22,866)	-	-	-	(22,866)
Equity compensation plans	-	138	-	-	-	-	138
Own equity instruments	-	962	-	-	-	-	962
Other movements	-	-	-	-	-	-	-
At December 31, 2013	**72,967**	**65,768**	**426,213**	**3,704**	**4,163**	**(1,123)**	**571,692**

Share capital (Number of shares)

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Authorized shares	799,805,050	799,805,050	799,805,050
Issued shares (Non-par value common stock)	559,685,889	559,685,889	559,685,889

Dividends

Date of resolution	Type of shares	Total dividends (millions of yen)	Dividend per share (yen)	Record date	Effective date
March 28, 2012 (Resolution of the Annual General Meeting of shareholders)	Common stock	10,884	20	December 31, 2011	March 29, 2012
July 26, 2012 (Board resolution)	Common stock	10,884	20	June 30, 2012	August 31, 2012
March 27, 2013 (Resolution of the Annual General Meeting of shareholders)	Common stock	10,885	20	December 31, 2012	March 28, 2013
July 25, 2013 (Board resolution)	Common stock	11,981	22	June 30, 2013	August 30, 2013
March 27, 2014 (Resolution of the Annual General Meeting of shareholders)	Common stock	12,529	23	December 31, 2013	March 28, 2014

Own equity instruments

	Number of shares	
	2013	2012
At January 1	15,440,438	15,494,118
Issue of common stocks	-	-
Exercises of equity compensation plans	(501,600)	(56,500)
Increase/decrease in own equity instruments	5,482	2,820
At December 31	**14,944,320**	**15,440,438**
Book value (millions of yen)	34,970	36,132

Other reserves

Fair value reserve: The fair value reserve represents the cumulative net change in the fair value of available-for-sale financial assets until the asset is sold, impaired or otherwise disposed of.

Hedging reserve: The hedging reserve represents the effective portion of the cumulative net change in the fair value of cash flow hedging instruments related to hedged transactions that have not yet occurred.

Translation reserve: The translation reserve represents the cumulative currency translation differences relating to the consolidation of foreign subsidiaries of the Group that use functional currencies other than the Japanese yen.

20. Non-controlling interests

Changes in equity attributable to non-controlling interests in millions of yen

	2013	2012
At January 1	1,200	1,207
Net income attributable to non-controlling interests	991	789
Currency translation of foreign operations	303	138
Remeasurements of defined benefit plans	2	(3)
Other comprehensive income, net of tax	**305**	**134**
Total comprehensive income	**1,296**	**924**
Dividends to non-controlling shareholders	(983)	(930)
Changes in non-controlling interests	-	-
At December 31	**1,512**	**1,200**

Non-controlling interests are attributable to the minority shareholders of Chugai sanofi-aventis S.N.C. and Chugai Pharma Taiwan Ltd.

21. Employee benefits

Employee benefits expense in millions of yen

	2013	2012
Wages and salaries	62,652	60,162
Social security costs	7,725	7,448
Defined contribution plans	867	851
Operating expenses for defined benefit plans	3,214	3,060
Equity compensation plans	292	242
Other employee benefits	3,201	3,151
Employee benefits expense included in operating results	**77,951**	**74,915**
Net interest cost of defined benefit plans	(66)	(37)
Total employee benefits expense	**77,885**	**74,878**

Other employee benefits consist mainly of welfare costs.

22. Post-employment benefits plans

Post-employment benefit plans are classified as “defined contribution plans” if the Group pays fixed contributions into third-party financial institutions and will have no further legal or constructive obligation to pay further contributions. All other plans are classified as “defined benefit plans”, even if Chugai’s potential obligation is relatively minor or has a relatively remote possibility of arising.

Employees are covered by defined contribution and defined benefit plans sponsored by Group companies, most of which are classified as defined benefit plans.

A resolution was passed in the 98th Annual General Meeting of shareholders held in March 2009 to abolish the retirement benefits system for directors. In addition, 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 audit & supervisory board members).

Defined contribution plans
Defined contribution plans are funded through payments by the Group to funds administered by third parties. The Group’s expenses for these plans were ¥867 million (2012: ¥851 million).

Defined benefit plans
The Group has defined benefit plans mainly comprising a corporate pension fund and a lump-sum retirement benefit plan. Under the corporate pension fund, employees can receive a lump-sum payment based on the number of accumulated points received during their years of service. Employees with over a certain period of service can receive part of or all of the payment as certain annuity or life annuity. Under the lump-sum retirement benefit plan, employees can receive a lump-sum payment based on the number of accumulated points received during their years of service. A retirement benefit trust has been established for the lump-sum retirement benefit plan. Certain employees may be entitled to additional special retirement benefits apart from the defined benefit plans based on the conditions under which termination occurs.

The corporate pension fund and a retirement benefit plan trust are independent of the Group and are funded only by payments from the Group. These plan assets are invested in various financial instruments while taking into consideration long-term performance over the duration of the plan liabilities. The funding status is closely monitored at the corporate level and valuations at the balance sheet date are carried out annually.

Defined benefit plans: income statement in millions of yen

	2013	2012
Current service cost	3,214	3,060
Past service (income) cost	-	-
Settlement (gain) loss	-	-
Total operating expenses	**3,214**	**3,060**
Net interest cost of defined benefit plans	(66)	(37)
Total expense recognized in income statement	**3,148**	**3,024**

Defined benefit plans: funding status in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Fair value of plan assets	71,029	66,267	61,929
Defined benefit obligation	(68,436)	(64,334)	(61,591)
Over (under) funding	**2,593**	**1,933**	**338**
Defined benefit plan assets	3,862	2,680	993
Defined benefit plan liabilities	(1,269)	(747)	(655)
Net recognized asset (liability)	**2,593**	**1,933**	**338**

Defined benefit plans: fair value of plan assets in millions of yen

	2013	2012
At January 1	66,267	61,929
Interest income on plan assets	1,165	1,114
Remeasurements on plan assets	3,883	3,131
Currency translation effects	14	11
Employer contributions	1,949	2,013
Benefits paid – funded plans	(2,250)	(1,931)
At December 31	**71,029**	**66,267**
Composition of plan assets		
- Equity securities	15,272	11,258
- Debt securities	39,088	40,341
- Cash and cash equivalents	10,182	8,450
- Other investments	6,486	6,218
Total plan assets	**71,029**	**66,267**

Equity securities and debt securities have quoted market prices (Level 1 of fair value hierarchy).

Defined benefit plans: present value of defined benefit obligation in millions of yen

	2013	2012
At January 1	64,334	61,591
Current service cost	3,214	3,060
Interest cost	1,099	1,078
Remeasurements – demographic assumption	1	663
Remeasurements – financial assumptions	2,239	381
Remeasurements – experience adjustments	147	103
Currency translation effects	27	16
Benefits paid – funded plans	(2,625)	(2,558)
At December 31	**68,436**	**64,334**
Duration in years	14.8	14.5

Actuarial assumptions

Actuarial assumptions are unbiased and mutually compatible estimates of variables that determine the ultimate cost of providing post-employment benefits. They are set on an annual basis by the responsible departments of the Group based on advice from actuaries. Actuarial assumptions consist of demographic assumptions on matters such as mortality and employee turnover, and financial assumptions on matters such as interest rates, investment returns, and salary and benefit levels.

Demographic assumptions: The most significant demographic assumptions relate to mortality rates. Chugai's actuaries use the "Twentieth mortality table issued by Ministry of Health, Labour and Welfare" which takes into account historic patterns and expected changes, such as further increases in longevity. Rates of employee turnover, disability and early retirement are based on historical behavior within the Group companies.

Financial assumptions: These are based on market expectations for the period over which the obligations are to be settled. Discount rates are determined mainly with reference to interest rates on high-quality corporate bonds.

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Discount rates (%)	1.53	1.76	1.80
Expected inflation rates (%)	-	-	-

Defined benefit plans: sensitivity of defined benefit obligation to actuarial assumption in millions of yen
The impact resulting from changes of actuarial assumption on the defined benefit obligation is shown in the table below. It is based on the assumption that variables other than the stated assumption used for the calculation are held constant.

	2013
Discount rates	
- 0.25% increase	(2,507)
- 0.25% decrease	2,560
Expected inflation rates	
- 0.25% increase	-
- 0.25% decrease	-
Life expectancy	
- 1 year increase	984

Future cash flows
Based on the most recent actuarial valuations, the Group expects that employer contributions for defined benefit plans in 2014 will be approximately ¥2,031 million.

23. Equity compensation plans

The Group operates equity-settled equity compensation plans for directors and certain employees. IFRS 2 "Share-based Payment" requires that the value be estimated by fair value at grant date and recorded as an expense over the vesting period.

Expenses for equity compensation plans in millions of yen

	2013	2012
Cost of sales	2	0
Marketing and distribution	30	26
Research and development	32	23
General and administration	228	194
Total operating expenses	292	242
Equity-settled plans		
- Chugai common stock options	173	130
- Chugai stock options as stock-based compensation	119	112

Cash inflow from equity compensation plans in millions of yen

	2013	2012
Equity-settled plans		
- Exercises of Chugai common stock options	820	45
- Exercises of Chugai stock options as stock-based compensation	-	0

Chugai common stock options

The Group has issued stock acquisition rights to directors and certain employees as common stock options. Each right entitles the holder to purchase 100 Chugai shares at a specified exercise price. The rights are non-tradable and have an exercise period of around ten years after receiving the rights under the condition of two years of continuous service of the holder after the grant date.

Chugai common stock options – movement in number of rights outstanding

	2013		2012	
	Number of rights	Weighted average exercise price (yen)	Number of rights	Weighted average exercise price (yen)
Outstanding at January 1	25,113	190,214	22,135	195,229
Granted	3,270	250,000	3,340	152,800
Forfeited	40	201,400	-	-
Exercised	5,016	163,517	312	145,400
Expired	302	158,516	50	190,820
Outstanding at December 31	**23,025**	**204,917**	**25,113**	**190,214**
- of which exercisable	16,465	206,495	18,543	205,759

Chugai common stock options – terms of rights outstanding at December 31, 2013

Year of grant	Rights outstanding			Rights exercisable	
	Number outstanding	Weighted average years remaining contractual life	Weighted average exercise price (yen)	Number exercisable	Weighted average exercise price (yen)
2004	666	0.23	167,500	666	167,500
2005	1,154	1.22	164,900	1,154	164,900
2006	3,227	2.23	224,500	3,227	224,500
2007	3,420	3.23	303,900	3,420	303,900
2008 – no awards	-	-	-	-	-
2009	2,551	5.23	169,600	2,551	169,600
2010	2,907	6.31	188,100	2,907	188,100
2011	2,540	7.40	139,700	2,540	139,700
2012	3,310	8.31	152,800	-	-
2013	3,250	9.32	250,000	-	-
Total	**23,025**	**5.56**	**204,917**	**16,465**	**206,495**

Chugai stock options as stock-based compensation

The Group has issued stock acquisition rights to directors as stock options as stock-based compensation since 2009 in lieu of the retirement benefit system for directors which was abolished. Each right entitles the holder to purchase 100 Chugai shares at an exercise price of ¥100. The rights are non-tradable and have an exercise period of 30 years after receiving the rights, which may be vested upon the holder's retirement as a director of Chugai.

Chugai stock options as stock-based compensation – movement in number of rights outstanding

	2013		2012	
	Number of rights	Weighted average exercise price (yen)	Number of rights	Weighted average exercise price (yen)
Outstanding at January 1	2,838	100	2,274	100
Granted	522	100	817	100
Forfeited	-	-	-	-
Exercised	-	-	253	100
Expired	-	-	-	-
Outstanding at December 31	**3,360**	**100**	**2,838**	**100**
- of which exercisable	-	-	-	-

Chugai stock options as stock-based compensation – terms of rights outstanding at December 31, 2013

Year of grant	Rights outstanding			Rights exercisable	
	Number outstanding	Weighted average years remaining contractual life	Weighted average exercise price (yen)	Number exercisable	Weighted average exercise price (yen)
2009	594	25.31	100	-	-
2010	647	26.31	100	-	-
2011	780	27.40	100	-	-
2012	817	28.31	100	-	-
2013	522	29.32	100	-	-
Total	**3,360**	**27.34**	**100**	**-**	**-**

Fair value measurement

The inputs used in the measurement of the fair values at grant date of the stock acquisition rights in 2013 are set out below. Expected volatility was determined primarily based on historically observed prices of the underlying equity (same as exercise period).

Chugai common stock option in 2013

Number of rights granted	3,270
Granted common stocks per right	100
Date of grant	May 13, 2013
Vesting period	May 13.2013 – April 26, 2015
Contractual life(*)	May 13.2013 – April 25, 2023
Fair value of rights at grant date	¥740
Model used	Binomial
Inputs to option pricing model	
- Share price at grant date	¥244,900
- Exercise price	¥250,000
- Expected volatility	30.35 %
- Expected dividend yield	1.63 %
- Risk-free rate	0.69 %

(*)A person granted the stock acquisition rights cannot exercise the rights during the first two years after the date of approval for issuance.

Chugai stock option as stock-based compensation in 2013

Number of rights granted	522
Granted common stocks per a right	100
Date of grant	May 13, 2013
Vesting period	-
Contractual life(*)	May 13.2013 – April 25, 2043
Fair value of rights at grant date	¥2,342
Model used	Binomial
Inputs to option pricing model	
- Share price at grant date	¥244,900
- Exercise price	¥100
- Expected volatility	24.37 %
- Expected dividend yield	1.63 %
- Risk-free rate	0.15 %

(*) A person granted the stock acquisition rights can exercise all stock acquisition rights at one time within ten days from the day following the date on which he/she loses the position as a director.

Exercises of stock acquisition rights in 2013

	2013		2012	
	Number of rights	Weighted average share price (yen)	Number of rights	Weighted average share price (yen)
Chugai common stock options	5,016	2,128	312	1,602
Chugai stock options as stock-based compensation	-	-	253	1,444

24. Earnings per share

Basic earnings per share

	2013	2012
Net income attributable to Chugai shareholders (millions of yen)	**50,895**	**46,052**
Weighted average number of common stock	559,685,889	559,685,889
Weighted average number of treasury stock	(15,161,596)	(15,472,523)
Weighted average number of shares in issue	**544,524,293**	**544,213,366**
Basic earnings per share (yen)	**93.47**	**84.62**

Diluted earnings per share

	2013	2012
Net income attributable to Chugai shareholders (millions of yen)	**50,895**	**46,052**
Weighted average number of shares in issue	544,524,293	544,213,366
Adjustment for assumed exercise of equity compensation plans, where dilutive	659,346	260,206
Weighted average number of shares in issue used to calculate diluted earnings per share	**545,183,639**	**544,473,572**
Diluted earnings per share (yen)	**93.35**	**84.58**

There were 9,897 rights of equity compensation plans, where anti-dilutive, excluded from the calculation of diluted earnings per share. (2012: 21,121 rights)

25. Statement of cash flows

Cash flows from operating activities

Cash flows from operating activities arise from the Group's primary activities including research and development, manufacturing and sales in the Pharmaceuticals business. These are calculated by the indirect method by adjusting the Group's operating profit for any operating income and expenses that are not cash flows (for example depreciation, amortization and impairment) in order to derive the cash generated from operations. Operating cash flows also include income taxes paid on all activities.

Cash generated from operations in millions of yen

	2013	2012
Net income	51,886	46,841
Financing costs	12	40
Other financial income (expense)	1,782	1,945
Income taxes	25,058	25,837
Operating profit	**78,738**	**74,663**
Depreciation of property, plant and equipment	13,520	13,286
Amortization of intangible assets	970	886
Impairment of property, plant and equipment	1,697	267
Impairment of intangible assets	89	-
Operating expense for defined benefit plans	3,214	3,060
Operating expense for equity-settled equity compensation plans	292	242
Net (income) expense for provisions	142	5
Inventories write-down	1,013	790
Other adjustments	1,283	(1,646)
Cash generated from operations	**100,959**	**91,553**

Cash flows from investing activities

Cash flows from investing activities are principally those arising from the Group's investments in property, plant and equipment and intangible assets. Cash flows connected with the Group's portfolio of marketable securities and other investments are also included, as are any interest and dividend payments received in respect of these securities and investments.

Interest and dividends received in millions of yen

	2013	2012
Interest received	271	319
Dividends received	148	122
Total	**419**	**441**

Cash flows from financing activities

Cash flows from financing activities are primarily dividend payments to Chugai shareholders.

Significant non-cash transactions

There were no significant non-cash transactions (2012: none).

26. Risk management

1) Financial risk management

The Group is exposed to various financial risks arising from its underlying operations and corporate finance activities. The Group's financial risk exposures are predominantly related to changes in foreign exchange rates, interest rates and equity prices as well as the creditworthiness and the solvency of the Group's counterparties.

Financial risk management within the Group is governed by policies reviewed by the board of directors of Chugai. These policies cover credit risk, liquidity risk and market risk. The policies provide guidance on risk limits, type of authorized financial instruments and monitoring procedures. The policies prohibit the use of derivative financial instruments for speculative trading purposes. Policy implementation and day-to-day risk management are carried out by the relevant functions and regular reporting on these risks is performed by the relevant finance & accounting and controlling functions within Chugai.

(i) Credit risk

Accounts receivable are exposed to customer credit risk. The main accounts receivable are trade receivables. The management of trade receivables is focused on the assessment of country risk, setting of credit limits, ongoing credit evaluation and account monitoring procedures. As part of the credit risk management, sales administration departments regularly monitor the financial position of major customers by checking payment term and balances of trade receivables for each customer according to the accounting manuals to ensure early identification and mitigation of overdue balances and potential bad debts associated with the deterioration of customers' financial position.

The objective of the management of trade receivables is to sustain the growth and profitability of the Group by optimizing asset utilization while maintaining risks at an acceptable level. The Group obtains credit insurance and similar enhancements when appropriate to protect the collection of trade receivables. No collateral was held for trade receivables (2012: none, Date of transition to IFRS: none).

Of the Group's accounts receivable, trade receivables from third parties are mainly to Japanese customers, of which major customers account for 73 % as of December 31, 2013.

Trade receivables: major customers in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Alfresa Corporation	26,185	24,611	23,934
Mediceo Corporation	20,575	25,446	25,587
Suzuken Co., Ltd.	14,075	13,043	12,390
Toho Pharmaceutical Co., Ltd.	11,719	11,414	10,747
Total	**72,554**	**74,513**	**72,658**

Aging of accounts receivable that are not impaired in millions of yen

	2013	2012
Neither overdue nor impaired	128,043	128,159
Overdue under 1 month	131	102
Overdue 1-3 months	0	32
Overdue 4-6 months	8	13
Overdue 7-12 months	-	-
Overdue more than 1 year	-	-
Total	**128,182**	**128,306**

Derivative transactions and money market instruments are restricted to financial institutions with high credit ratings in an effort to mitigate the counterparty risks.

The maximum exposure to credit risk resulting from financial activities, without taking into account any collateral held or other credit enhancements, is equal to the carrying value of the Group's financial assets.

Impairment losses by asset classes

The Group's impairment loss on available-for-sale investments was ¥ 3 million (2012: ¥135 million).

(ii) Liquidity risk

Liquidity risk arises through a surplus of financial obligations over available financial assets due at any point in time. The Group's approach to liquidity risk is to maintain sufficient readily available reserves in order to meet its liquidity requirements at any point in time. The Group manages liquidity risks based on a cash management plan prepared and updated as appropriate by finance and accounting departments based on the reporting from each department.

Chugai is rated as highly creditable by more than one major credit rating agency. The ratings will permit efficient access to the international capital markets in the event of major financing requirements. Chugai has unused committed credit lines with various financial institutions totaling ¥40,000 million (2012: ¥40,000 million, Date of transition to IFRS: ¥40,000 million).

Contractual maturities of financial liabilities in millions of yen

	Total	0-3 months	4-6 months	7-12 months	Over 1 year
Year ended December 31, 2013					
Accounts payable	59,544	55,680	3,864	-	-
Other current liabilities					
- Derivative financial instruments	-	-	-	-	-
Total financial liabilities	59,544	55,680	3,864	-	-
Year ended December 31, 2012					
Accounts payable	60,096	58,008	2,089	-	-
Other current liabilities					
- Derivative financial instruments	-	-	-	-	-
Total financial liabilities	60,096	58,008	2,089	-	-

(iii) Market risk

Market risk arises from changing market prices, mainly due to foreign exchange rates and interest rates, of the Group's financial assets or financial liabilities which affect the Group's net income and equity.

Foreign exchange risk: Accounts receivable and accounts payable denominated in foreign currencies are exposed to foreign exchange risk. The objective of the Group's foreign exchange risk management activities is to preserve the economic value of its current and future assets and to minimize the volatility of the Group's financial result. The Group enters into derivative transactions such as foreign exchange forward contracts and currency options to reduce the risk of foreign currency exchange fluctuations related to assets and liabilities dominated in foreign currencies. Some of these transactions qualify as cash flow hedges at the point that the forecast transaction is expected.

When making use of derivatives for hedging foreign exchange risk on assets and liabilities dominated in foreign currencies, Chugai conducts such operations in accordance with its internal regulations and monthly reports are prepared on the balance of such transactions, valuation gains and losses, and other related matters at fair value. Consolidated subsidiaries do not utilize derivative transactions.

Sensitivity analysis: Chugai has financial instruments denominated in currencies other than its functional currency. The table below shows the impact to profit before taxes resulting from a 1% decrease of the Swiss franc, euro and US dollar against the Japanese yen, which is Chugai's functional currency. The effective portion of derivative financial instruments for which hedge accounting is applied is excluded from the calculation. All calculations are based on the assumption that exchange rates for other currencies are constant and there are no changes in other variables such as interest rates.

Foreign currency sensitivity analysis

	2013	2012
Average exchange rate (yen per each currency)		
CHF	105.24	85.12
EUR	129.51	102.59
USD	97.54	79.81
Profit before taxes (millions of yen)		
CHF	39	101
EUR	(2)	(3)
USD	14	2

(Note) Positive numbers are the amount of positive impact on profit before taxes resulting from a 1% decrease of each currency against the Japanese yen. The amounts above do not reflect the impact on Chugai's cash flows or forecast result.

The impact resulting from a 1% decrease of each currency against the Japanese yen on the financial instruments denominated in foreign currency is shown in the tables below.

	2013			2012		
	Exposure (m CHF)	Exposure (m YEN)	Impact (m YEN)	Exposure (m CHF)	Exposure (m YEN)	Impact (m YEN)
CHF						
Accounts receivable	140	16,635	(166)	112	10,552	(106)
Accounts payable	(333)	(39,417)	394	(413)	(38,927)	389
Financial non-current assets	-	-	-	-	-	-
Cash and cash equivalents	69	8,196	(82)	-	-	-
Notional amounts of derivative financial instruments						
- Effective portion of hedge	426	50,405	-	50	4,755	-
- Other than above	90	10,645	(106)	192	18,252	(183)
Total	**393**	**46,464**	**39**	**(59)**	**(5,368)**	**101**

	Exposure (m EUR)	Exposure (m YEN)	Impact (m YEN)	Exposure (m EUR)	Exposure (m YEN)	Impact (m YEN)
EUR						
Accounts receivable	3	377	(4)	6	691	(7)
Accounts payable	(1)	(192)	2	(3)	(354)	4
Financial non-current assets	-	-	-	-	-	-
Cash and cash equivalents	-	-	-	-	-	-
Notional amounts of derivative financial instruments					-	-
- Effective portion of hedge	-	-	-	-	-	-
- Other than above	-	-	-	-	-	-
Total	**1**	**185**	**(2)**	**3**	**338**	**(3)**

	Exposure (m USD)	Exposure (m YEN)	Impact (m YEN)	Exposure (m USD)	Exposure (m YEN)	Impact (m YEN)
USD						
Accounts receivable	3	342	(3)	2	153	(2)
Accounts payable	(16)	(1,714)	17	(32)	(2,784)	28
Financial non-current assets	-	-	-	-	-	-
Cash and cash equivalents	-	-	-	-	-	-
Notional amounts of derivative financial instruments						
- Effective portion of hedge	90	9,472	-	5	432	-
- Other than above	-	-	-	28	2,435	(24)
Total	**77**	**8,100**	**14**	**3**	**236**	**2**

Interest rate risk: The amounts of debt and loans were insignificant and therefore the Group is not exposed to material interest rate risk.

2) Financial instruments fair value

Carrying value and fair value of financial instruments

The Group's financial instruments are mainly comprised of financial non-current assets, accounts receivable, marketable securities, cash and cash equivalents, derivative financial instruments included in other current assets, accounts payable, derivative financial instruments included in other current liabilities and debt. The carrying values of these financial instruments are equal to or reasonable approximates of fair values.

Fair value hierarchy

The table below analyses financial instruments carried at fair value, by valuation method. The different levels have been defined as follows:

- Level 1 – quoted prices (unadjusted) in active markets for identical assets and liabilities.
- Level 2 – observable inputs other than quoted prices in active markets for identical assets and liabilities.
- Level 3 – unobservable inputs.

Fair value hierarchy of financial instruments in millions of yen

	Level 1	Level 2	Level 3	Total
At December 31, 2013				
Marketable securities:				
- Money market instruments and time accounts over 3 months	-	119,573	-	119,573
- Debt securities	-	-	-	-
Other current assets				
- Derivative financial instruments	-	7,367	-	7,367
Financial non-current assets				
- Available-for-sale investments	8,506	-	461	8,966
Financial assets recognized at fair value	**8,506**	**126,940**	**461**	**135,906**
Other current liabilities				
- Derivative financial instruments	-	-	-	-
Financial liabilities recognized at fair value	**-**	**-**	**-**	**-**
At December 31, 2012				
Marketable securities:				
- Money market instruments and time accounts over 3 months	-	115,485	-	115,485
- Debt securities	1,000	-	-	1,000
Other current assets				
- Derivative financial instruments	-	1,701	-	1,701
Financial non-current assets				
- Available-for-sale investments	5,741	-	462	6,203
Financial assets recognized at fair value	**6,741**	**117,186**	**462**	**124,388**
Other current liabilities				
- Derivative financial instruments	-	-	-	-
Financial liabilities recognized at fair value	**-**	**-**	**-**	**-**
At January 1, 2012				
Marketable securities:				
- Money market instruments and time accounts over 3 months	-	68,683	-	68,683
- Debt securities	6,494	-	-	6,494
Other current assets				
- Derivative financial instruments	-	17	-	17
Financial non-current assets				
- Available-for-sale investments	4,627	-	312	4,939
Financial assets recognized at fair value	**11,121**	**68,700**	**312**	**80,133**
Other current liabilities				
- Derivative financial instruments	-	-	-	-
Financial liabilities recognized at fair value	**-**	**-**	**-**	**-**

Level 1 financial assets consist of government bonds, corporate bonds and quoted shares. Level 2 financial assets consist primarily of commercial paper, certificates of deposit and derivative financial instruments.

Level 2 fair value for marketable securities and derivative financial instruments are based on valuation models that use observable market data for interest rates, yield curves, foreign exchange rates and implied volatilities for similar instruments at the measurement date.

The Group recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period during which the transfer has occurred. There were no significant transfers between Level 1 and Level 2 and vice versa.

Level 3 financial assets consist of unquoted shares. There were no significant movements in the amount of Level 3 financial assets.

3) Derivative financial instruments

Derivative financial instruments in millions of yen

Assets	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Forward exchange contracts	7,367	1,701	17
Currency options	-	-	-
Total derivative financial instruments	**7,367**	**1,701**	**17**

Liabilities	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Forward exchange contracts	-	-	-
Currency options	-	-	-
Total derivative financial instruments	**-**	**-**	**-**

Hedge accounting

The Group has the following cash flow hedges which are designated in a qualifying hedge relationship.

Cash flow hedges

The Group is exposed to foreign exchange risk from transactions for inventories and other materials in foreign currencies with foreign related parties. The Group has entered into foreign exchange forward contracts and currency options to hedge a part of foreign exchange risk. Such instruments are recorded as fair value assets of ¥6,715 million (2012: ¥118 million). There was no ineffective portion.

The present value of expected cash flows from qualifying cash flow hedges are shown in the table below.

Present value of expected cash flows of qualifying cash flow hedges in millions of yen

	Total	0-6 months	7-12 months	Over 1 year
Year ended December 31, 2013				
Cash inflows	59,877	18,802	31,015	10,059
Cash outflows	(53,162)	(16,872)	(27,467)	(8,823)
Total cash inflow (outflow)	**6,715**	**1,930**	**3,548**	**1,236**
Year ended December 31, 2012				
Cash inflows	5,187	4,755	432	-
Cash outflows	(5,069)	(4,645)	(424)	-
Total cash inflow (outflow)	**118**	**109**	**8**	**-**
At January1, 2012				
Cash inflows	-	-	-	-
Cash outflows	-	-	-	-
Total cash inflow (outflow)	**-**	**-**	**-**	**-**

4) Capital management

The Group defines the capital that it manages as the Group's total capitalization, being the sum of debt plus equity including non-controlling interests. The Group's objectives when managing capital are:

- To safeguard the Group's ability to continue as a going concern, so that it can continue to provide benefits for patients and returns to investors.
- To provide an adequate return to investors based on the level of risk undertaken.
- To have available the necessary financial resources to allow the Group to invest in areas that may deliver future benefits for patients and returns to investors.
- To maintain sufficient financial resources to mitigate against risks and unforeseen events.

Capitalization is monitored and reported to the Chief Financial Officer as part of the Group's regular internal management reporting.

The Group is not subject to regulatory capital adequacy requirements.

Capital in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Capital and reserves attributable to Chugai shareholders	571,692	527,961	497,782
Equity attributable to non-controlling interests	1,512	1,200	1,207
Total equity	**573,204**	**529,161**	**498,989**
Total debt	233	257	192
Capitalization	**573,437**	**529,419**	**499,181**

27. Related parties

1) Controlling shareholder

Effective October 1, 2002, Roche and Chugai completed an alliance to create a leading research-driven Japanese pharmaceutical company, which was formed by the merger of Chugai and Roche's Japanese pharmaceuticals subsidiary, Nippon Roche. Through the merger, Chugai become a principal member of the Roche Group as the surviving company.

Chugai has entered into certain agreements with Roche, which are discussed below:

Basic Alliance Agreement: As part of the Basic Alliance Agreement signed in December 2001, Roche and Chugai entered into certain arrangements covering the future operation and governance of Chugai. Amongst other matters these cover the following areas:

- The structuring of the alliance.
- Roche's rights as a shareholder.
- Roche's rights to nominate members of Chugai's Board of Directors.
- Certain limitations to Roche's ability to buy or sell Chugai's common stock.

Chugai issues additional shares of common stock in connection with its convertible debt and equity compensation plans, and may issue additional shares for other purposes, which affects Roche's percentage ownership interest. The Basic Alliance Agreement provides, amongst other matters, that Chugai will guarantee Roche's right to maintain its shareholding percentage in Chugai at not less than 50.1%.

Licensing Agreements: Under the Japan Umbrella Rights Agreement signed in December 2001, Chugai has exclusive rights to market Roche's pharmaceutical products in Japan. Chugai also has right of first refusal on the development and marketing in Japan of all development compounds advanced by Roche.

Under the Rest of the World Umbrella Rights Agreement signed in May 2002, Roche has the right of first refusal on the development and marketing of Chugai's development compounds in markets outside Japan, excluding South Korea, if Chugai decides that it requires a partner for such activities.

Further to these agreements, Roche and Chugai have signed a series of separate agreements for certain specific products. Depending on the specific circumstances and the terms of the agreement, this may result in payments on an arm's length basis between Roche and Chugai, for any or all of the following matters:

- Upfront payments, if a right of first refusal to license a product is exercised.
- Milestone payments, dependent upon the achievement of agreed performance targets.
- Royalties on future product sales.

These specific product agreements may also cover the manufacture and supply of the respective products to meet the other party's clinical and/or commercial requirements on an arm's length basis.

Research Collaboration Agreements: Roche and Chugai have entered into research collaboration agreements in the areas of small-molecule synthetic drug research and biotechnology-based drug discovery.

Dividends: The dividends distributed to Roche by Chugai in respect to its holdings of Chugai shares totaled ¥14,079 million (2012: ¥13,409 million).

2) Material transactions and balances with related parties

Transactions with F. Hoffmann-La Roche in millions of yen

	2013	2012
Sales	42,909	25,557
Purchases of inventory and other materials	112,799	84,272

Balances with F. Hoffmann-La Roche in millions of yen

	December 31, 2013	December 31, 2012	January 1, 2012 (Date of transition to IFRS)
Accounts receivable	22,245	16,136	11,704
Accounts payable	(39,417)	(38,948)	(15,595)

3) Key management personnel

The operating functions of Chugai are retained by the members of the Board of Directors who act as the chief operating decision-maker. The term of office for directors expires at the conclusion of the Annual General Meeting of shareholders held with respect to the last business year ending within two years after election. The term of office for audit & supervisory board members expires at the conclusion of the Annual General Meeting of shareholders held with respect to the last business year ending within four years after election.

Remuneration of members of the board and audit & supervisory board members in millions of yen

	2013	2012
Board of directors		
- Regular remuneration	335	354
- Bonuses	186	199
- Chugai common stock options	78	56
- Chugai stock options as stock-based compensation	119	112
Total	**718**	**722**
Audit & supervisory board members		
- Regular remuneration	85	85
Total	**85**	**85**

28. Subsidiaries

Subsidiaries	Country of Incorporation	Equity interest %	
		2013	2012
Consolidated subsidiaries			
Chugai Research Institute for Medical Science, Inc.	Japan	100 %	100 %
Chugai Clinical Research Center Co., Ltd.	Japan	100 %	100 %
Chugai Business Support Co., Ltd.	Japan	100 %	100 %
Medical Culture, Inc.	Japan	100 %	100 %
Chugai Distribution Co., Ltd.	Japan	100 %	100 %
Chugai Pharma Manufacturing Co., Ltd.	Japan	100 %	100 %
Forerunner Pharma Research Co., Ltd.	Japan	100 %	100 %
Chugai U.S.A. Inc.	United States	100 %	100 %
Chugai Pharma U.S.A., LLC	United States	100 %	100 %
Chugai Pharma Europe Ltd.	United Kingdom	100 %	100 %
Chugai Pharma UK Ltd.	United Kingdom	100 %	100 %
Chugai Pharma Marketing Ltd.	United Kingdom	100 %	100 %
Chugai Pharma France S.A.S.	France	100 %	100 %
Chugai sanofi-aventis S.N.C.	France	55 %	55 %
Chugai Pharma Taiwan Ltd.	Taiwan	70 %	70 %
Chugai Pharma R&D Taiwan Ltd.	Taiwan	100 %	-
Chugai Pharma (Shanghai) Consulting Co, Ltd.	China	100 %	100 %
Chugai Pharma Science (Beijing) Co, Ltd.	China	100 %	100 %
Chugai Pharmabody Research Pte.Ltd.	Singapore	100 %	100 %

29. Subsequent events

There were no material subsequent events (2012: none).

30. Transition to International Financial Reporting Standards

The financial statements are the first annual consolidated financial statements for the Group prepared in accordance with IFRS. The date of transition to IFRS is January 1, 2012. Previously, the Group prepared its financial statements in conformity with JGAAP. The last consolidated financial statements under JGAAP were for the year ended December 31, 2012.

Roche has issued consolidated financial statements in accordance with IFRS since 1990. Since entering into the strategic alliance, as a member of Roche Group, the Group has prepared financial reports in accordance with IFRS for inclusion in Roche's consolidated financial statements.

The Group voluntary adopted Paragraph D16, Item (a) of IFRS 1 "First-time Adoption of International Financial Reporting Standards" for first-time IFRS adoption, and has measured book value of assets and liabilities, based on the book value included in Roche's consolidated financial statements (excluding the impact of business combination accounting for the Group by Roche).

Reconciliation of equity in millions of yen

		December 31, 2012	January 1, 2012 (Date of transition to IFRS)
	Total net assets in previously published JGAAP financial statements	**490,075**	**459,073**
(a)	Property, plant and equipment	60,784	60,420
(b)	Intangible assets	4,865	4,714
(c)	Post-employment benefits	4,652	2,608
(d)	Long-term prepaid expense	2,060	2,534
(e)	Inventories	(481)	(2,149)
(f)	Deferred income	(7,521)	(3,027)
(g)	Accrued vacation	(2,946)	(2,995)
	Other differences	(179)	(217)
(h)	Deferred tax assets and liabilities	(22,148)	(21,972)
	Total adjustments to total net assets	**39,086**	**39,916**
	Equity in these IFRS financial statements	**529,161**	**498,989**

Reconciliation of net income in millions of yen

		2012
	Income before minority interests in previously published JGAAP financial statements	**48,992**
(a)	Property, plant and equipment	1,060
(b)	Intangible assets	369
(c)	Post-employment benefits	208
(d)	Long-term prepaid expense	(474)
(e)	Inventories	1,393
(f)	Deferred income	(4,640)
(g)	Accrued vacation	49
	Other differences	(610)
(h)	Deferred tax assets and liabilities	494
	Total adjustments to net income	**(2,151)**
	Net income in these IFRS consolidated financial statements	**46,841**

Reconciliation of comprehensive income in millions of yen

		2012
	Comprehensive income in previously published JGAAP consolidated financial statements	**53,318**
	Total adjustments to net income (from previous table)	(2,151)
(c)	Post-employment benefits	1,275
	Other differences	46
	Total adjustments to comprehensive income	**(830)**
	Comprehensive income in these IFRS consolidated financial statements	**52,488**

Notes to the reconciliations

(a) Under IFRS, the straight-line method is applied to depreciation of property, plant and equipment excluding leased assets, whereas the declining-balance method is used in JGAAP. The period of useful lives is different as well. Start-up and validation costs are expensed as incurred under JGAAP, whereas they are included in the acquisition cost of machinery and equipment under IFRS.

(b) In-licensing agreement payments are recognized as intangible assets under IFRS, while they are expensed under JGAAP.

(c) Some of the calculations for defined benefit assets and liabilities are different, such as the allocation method and discount rate. Actuarial gain and loss are amortized by the declining-balance method over the period of average remaining service years of employees at the time of occurrence from the following year of occurrence under JGAAP. Under IFRS, actuarial gain and loss are recognized as incurred in other comprehensive income in the consolidated statement of comprehensive income.

(d) Start-up and validation costs at outsourced plants are expensed as incurred under JGAAP, whereas they are treated as long-term prepaid expenses under IFRS.

(e) The difference in production costs caused by the difference in depreciation and other costs.

(f) Up-front income from out-licensing agreements is recognized as one-time income under JGAAP, whereas it is treated as deferred income under IFRS.

(g) Unused paid annual leave is not recognized under JGAAP, but it is accrued under IFRS.

(h) The matters described above in (a)–(g) result in change in temporary differences. In addition, there is a difference in the tax rate used for the calculation of the tax effect to eliminate unrealized gains.

Explanation of material adjustments to the cash flow statement for the year ended December 31, 2012

There are no significant differences between the consolidated cash flow statements disclosed in conformity with JGAAP and IFRS.

Independent Auditor's 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 sheet as at December 31, 2013, and the consolidated income statement, statement of comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, and notes, comprising 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 International Financial Reporting Standards, 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 audit. We conducted our audit 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.

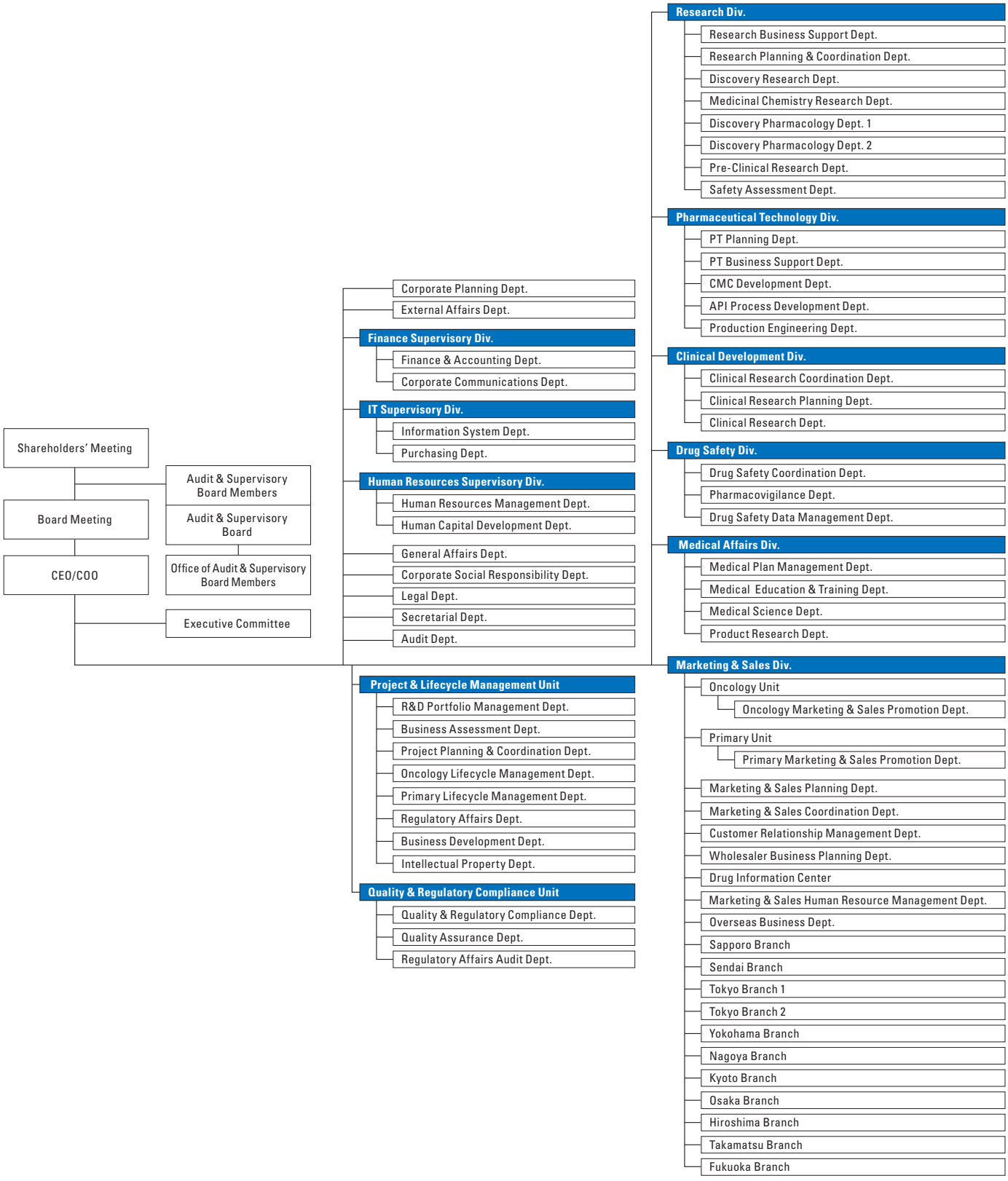
Opinion

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, 2013, and their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards.

KPMG AZSA LLC

March 27, 2014
Tokyo, Japan

Organization (As of March 27, 2014)



Network (As of March 27, 2014)

Chugai Pharmaceutical

Head Office

1-1 Nihonbashi-Muromachi 2-chome,
Chuo-ku, Tokyo 103-8324 Japan
Tel +81-(0)3-3281-6611
URL: http://www.chugai-pharm.co.jp/english

Research Laboratories

Fuji Gotemba Research Laboratories
1-135 Komakado, Gotemba City, Shizuoka Pref.
412-8513 Japan
Tel +81-(0)550-87-3411

Kamakura Research Laboratories
200 Kajiwara, Kamakura City, Kanagawa Pref.
247-8530 Japan
Tel +81-(0)467-47-2260

Ukima Research Laboratories
5-5-1 Ukima, Kita-ku, Tokyo 115-8543 Japan
Tel +81-(0)3-3968-6111

Plants

Ukima Plant
5-5-1 Ukima, Kita-ku, Tokyo 115-8543 Japan
Tel +81-(0)3-3968-6111

Fujieda Plant
2500 Takayanagi, Fujieda City, Shizuoka Pref.
426-0041 Japan
Tel +81-(0)54-635-2311

Utsunomiya Plant
16-3 Kiyohara-Kogyodanchi, Utsunomiya City,
Tochigi Pref. 321-3231 Japan
Tel +81-(0)28-667-7611

Branches

Domestic

Sapporo Branch
Nihon Seimei Sapporo Bldg., 4-1-1
Kita-sanjo-Nishi, Chuo-ku, Sapporo City,
Hokkaido 060-0003 Japan
Tel +81-(0)11-271-5311

Sendai Branch
Honcho Plaza Bldg., 1-12-7 Honcho,
Aoba-ku, Sendai City, Miyagi Pref.
980-0014 Japan
Tel +81-(0)22-225-8551

Tokyo Branch 1
Shinjuku NS Bldg., 2-4-1 Nishi-Shinjuku,
Shinjuku-ku, Tokyo 163-0807 Japan
Tel +81-(0)3-3346-0211

Tokyo Branch 2
Omiya Center Bldg., 1-9-6 Sakuragicho,
Omiya-ku, Saitama City, Saitama Pref.
330-0854 Japan
Tel +81-(0)48-642-4771

Yokohama Branch
Yokohama East Square, 1-4 Kinkoucho,
Kanagawa-ku, Yokohama City,
Kanagawa Pref. 221-0056 Japan
Tel +81-(0)45-450-7670

Nagoya Branch
Chugai Tokyo Kaijo Bldg., 3-20-17
Marunouchi, Naka-ku,
Nagoya City, Aichi Pref. 460-0002 Japan
Tel +81-(0)52-961-8511

Kyoto Branch
Karasuma Chuo Bldg., 659 Tearaimizu-cho,
Nishikikoji-agaru, Karasuma-dori,
Nakagyo-ku, Kyoto City, Kyoto
604-8152 Japan
Tel +81-(0)75-212-6090

Osaka Branch
Uemura Nissei Bldg., 3-3-31 Miyahara,
Yodogawa-ku, Osaka City, Osaka
532-0003 Japan
Tel +81-(0)6-6350-6355

Hiroshima Branch
Nissei Hiroshima Bldg., 7-32
Nakamachi, Naka-ku, Hiroshima City,
Hiroshima Pref. 730-0037 Japan
Tel +81-(0)82-543-6100

Takamatsu Branch
COI Bldg., 2-2-7 Kotobuki-cho, Takamatsu City,
Kagawa Pref. 760-0023 Japan
Tel +81-(0)87-811-6988

Fukuoka Branch
Echo Bldg., 2-13-34 Hakataeki-higashi,
Hakata-ku, Fukuoka City, Fukuoka Pref.
812-0013 Japan
Tel +81-(0)92-451-8181

Domestic Subsidiaries

Chugai Clinical Research Center Co., Ltd.
1-1 Nihonbashi-Muromachi 2-chome,
Chuo-ku, Tokyo 103-8324 Japan
(within the Chugai Pharmaceutical Head Office)
Tel+81-(0)3-3273-1173

Chugai Research Institute for Medical Science, Inc.
1-135 Komakado, Gotemba City,
Shizuoka Pref. 412-8513 Japan
(within the Fuji Gotemba Research Laboratories)
Tel +81-(0)550-87-5425

Chugai Business Support Co., Ltd.
5-5-1 Ukima, Kita-ku, Tokyo
115-8543 Japan
(within the Ukima Representative Office)
Tel +81-(0)3-3968-8760

Medical Culture Inc.
Muromachi CS Bldg., 4-6-5
Nihonbashi-Muromachi,
Chuo-ku, Tokyo 103-0022 Japan
Tel +81-(0)3-5202-8270

Chugai Distribution Co., Ltd.
1-20, Okuwa, Kazo City, Saitama Pref.
347-0010 Japan
(within the Kazo Distribution Center)
Tel +81-(0)480-76-0381

Chugai Pharma Manufacturing Co., Ltd.
5-5-1 Ukima, Kita-ku, Tokyo
115-8543 Japan
(within the Ukima Representative Office)
Tel +81-(0)3-3968-6200

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

Overseas Subsidiaries, Affiliates and R&D Partners

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

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

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

Germany Branch
Lyoner Strasse 15, Atricom 7 OG 60528
Frankfurt am Main, Germany
Tel +49-(0)69-663000-0

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

CHUGAI sanofi-aventis S.N.C.
9 rue du Président Allendé
94256 Gentilly Cedex, France
Tel +33-(0)1-41-24-65-29

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

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

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

Chugai Pharma (Shanghai) Consulting Co., Ltd.
Unit 2901, Central Plaza, No. 381
Central Huaihai Road,
Shanghai 200020 China
Tel +86-(0)21-6319-0388

Beijing Branch
2101 Beijing Fortune Bldg.
No. 5, Dong San Huan Bei Lu,
Chao Yang District,
Beijing 100004 China
Tel +86-(0)10-6590-8066

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

Chugai Pharma Science (Beijing) Co., Ltd.
2103 Beijing Fortune Bldg. No. 5,
Dong San Huan Bei Lu,
Chao Yang District, Beijing 100004 China
Tel +86-(0)10-6590-9556

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

Chugai Pharma R&D Taiwan Ltd.
8Fl-2, No. 73, ZhouZi Street, Neihu District,
Taipei 11493, Taiwan
Tel +886-(0)2-2659-8030

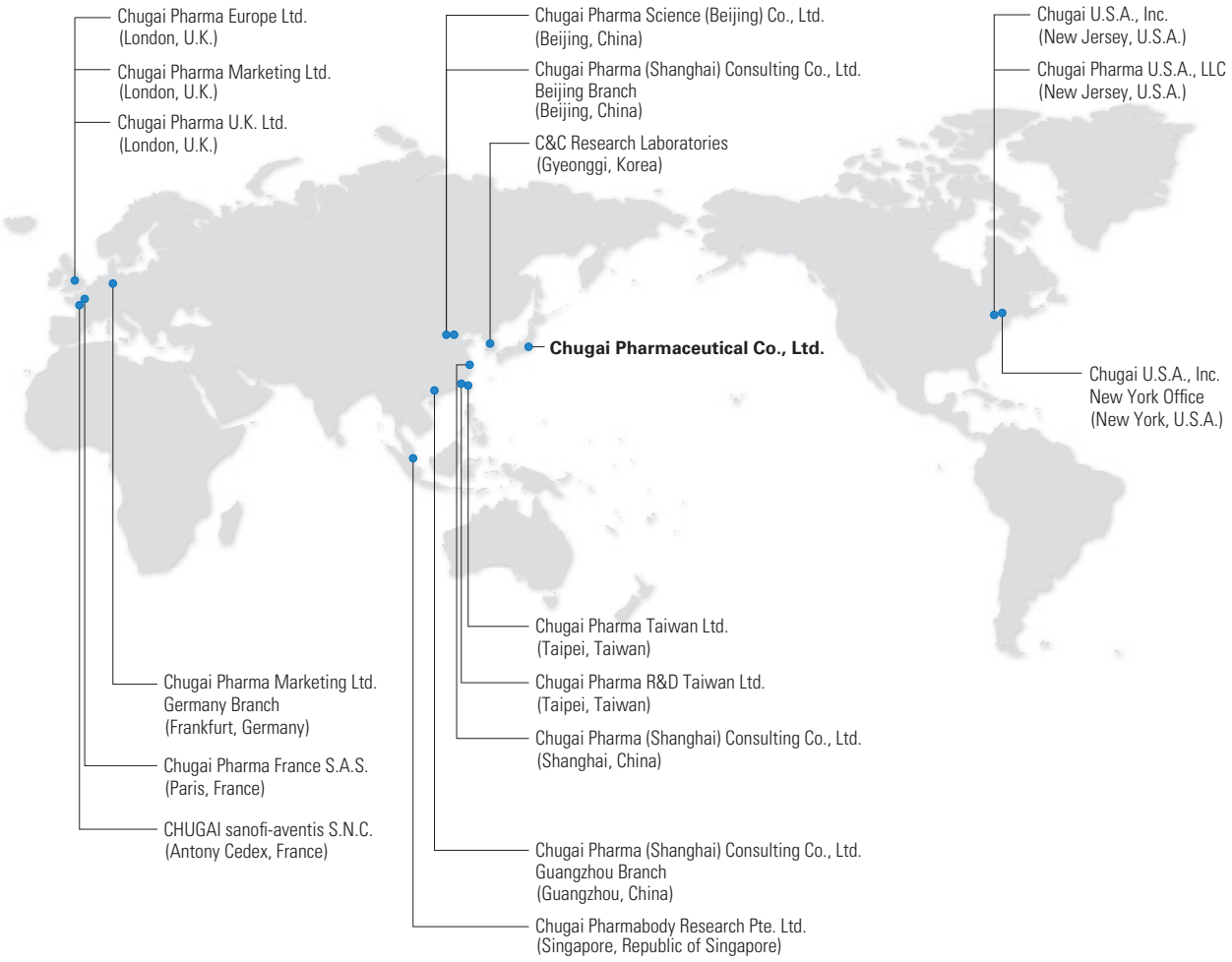
Chugai Pharmabody Research Pte. Ltd.
3 Biopolis Drive, #04-11 to 17 Synapse,
Singapore 138623
Tel +65-(0)6933-4888

C&C Research Laboratories

Discovery Research Center
DRC Natural Sciences Campus,
Sungkyunkwan University,
Cheoncheon-dong, Jangan-gu,
Suwon-si, Gyeonggi-do 440-746 Korea
Tel +82-(0)31-8014-6603

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



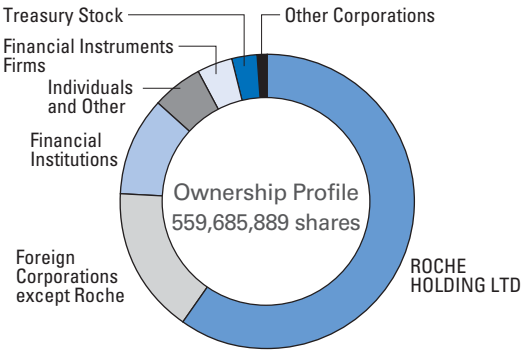
Shareholder Information (As of December 31, 2013)

Major Shareholders*

Name	Number of Shares Held (Thousands)	Percentage of Voting Rights (%)
ROCHE HOLDING LTD	335,223	61.56
The Master Trust Bank of Japan, Ltd. (Trust Account)	16,095	2.95
Japan Trustee Services Bank, Ltd. (Trust Account)	12,499	2.29
Nomura Securities Co., Ltd.	4,422	0.81
Tokio Marine & Nichido Fire Insurance Co., Ltd.	3,787	0.69
Chugai Pharmaceutical Employee Shareholders' Association	3,594	0.66
BNP Paribas Securities (Japan) Limited	3,516	0.64
Deutsche Securities Inc.	3,367	0.61
Sumitomo Life Insurance Company	3,000	0.55
BNP Paribas Sec Services Luxembourg/Jasdec/Aberdeen Global Client Assets	2,991	0.54

* 14,944,320 shares of treasury stock held by the Company are not included in the above breakdown of major shareholders.

Classification of Shareholders

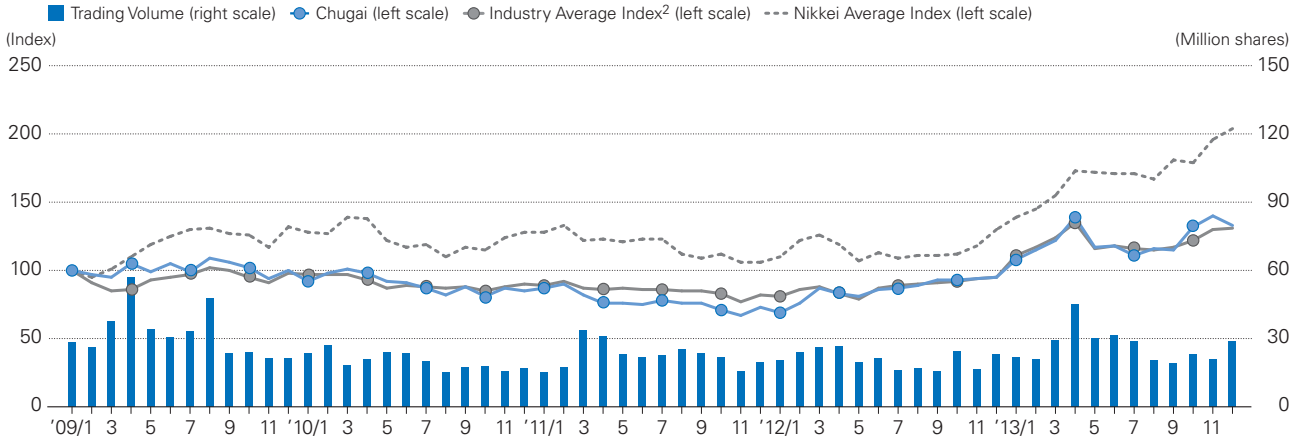


- ROCHE HOLDING LTD — Shares: 335,223,645 — 59.89% — (Shareholder: 1)
- Foreign Corporations except Roche — Shares: 90,100,479 — 16.09% — (Shareholders: 481)
- Financial Institutions — Shares: 61,169,486 — 10.92% — (Shareholders: 78)
- Individuals and Other — Shares: 30,986,166 — 5.53% — (Shareholders: 33,407)
- Financial Instruments Firms — Shares: 21,458,360 — 3.83% — (Shareholders: 49)
- Treasury Stock — Shares: 14,944,320 — 2.67% — (Shareholder: 1)
- Other Corporations — Shares: 5,803,433 — 1.03% — (Shareholders: 224)

Stock Price Information

	Stock Price	
	Low	High
From January 1, 2013 to December 31, 2013		
First Quarter	¥1,655	¥2,279
Second Quarter	1,900	2,550
Third Quarter	1,905	2,187
Fourth Quarter	1,910	2,504

Share Performance[1]

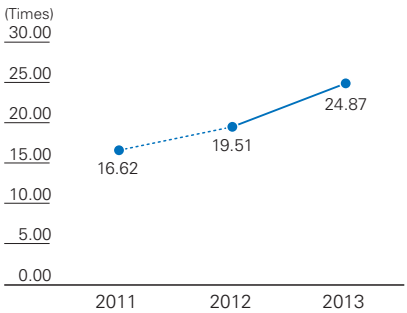


1. Share price on January 5, 2009 (¥1,727) = 100
2. Average of eight pharmaceutical companies (Takeda, Daiichi Sankyo, Astellas, Shionogi, Eisai, Mitsubishi Tanabe, Dainippon Sumitomo and Chugai)

Share Price Indicators

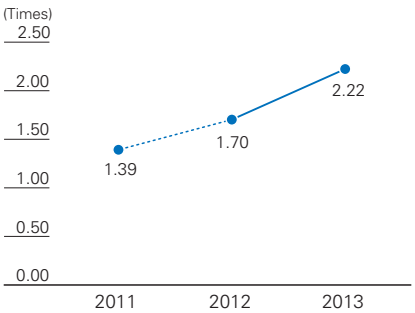
Price/Earnings Ratio

Year-end share price ÷ Basic net income per share



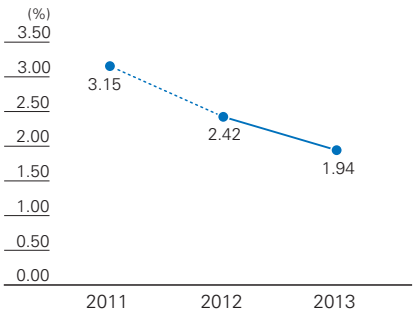
Price/Book Ratio

Year-end share price ÷ Equity per share attributable to Chugai shareholders



Dividend Yield

Dividends per share ÷ Year-end share price



Corporate Data (As of December 31, 2013)

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
¥72,966,825,723

Number of Employees
6,872 (Consolidated)

Number of Shares Issued of Common Stock
559,685,889

Number of Shareholders
34,241

Stock Listing
Tokyo Stock Exchange, First Section

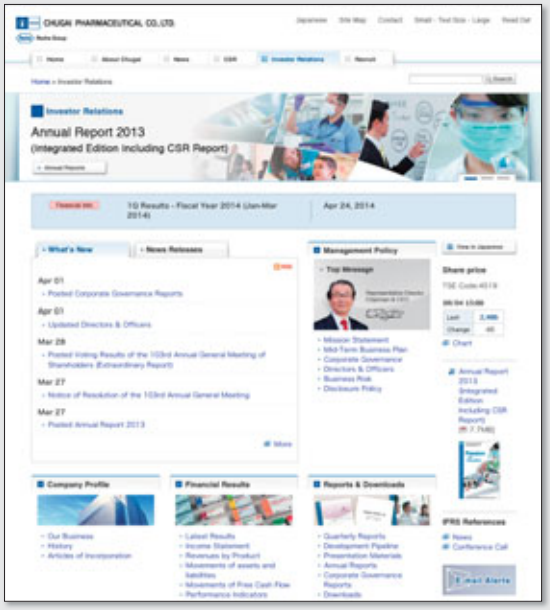
Fiscal Year-End
December 31

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/hc/ir) in Japanese. 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



For further information, please contact:

Corporate Communications Dept.
Tel: +81-(0)3-3273-3313
Fax: +81-(0)3-3281-6607
E-mail: ir@chugai-pharm.co.jp

Corporate Social Responsibility Dept.
Fax: +81-(0)3-3273-4909
E-mail: csr@chugai-pharm.co.jp