



CHUGAI

Roche Roche Group

# Annual Report 2015

Fiscal year ended December 31, 2015



## INNOVATION BEYOND IMAGINATION

Innovation all for the patients

CHUGAI PHARMACEUTICAL CO., LTD.



We want to help patients who are suffering from disease.

That commitment has driven us to  
innovate ever since our foundation.

We remain dedicated to exceeding the hopes and  
expectations of people around the world by challenging  
conventional wisdom and frameworks.

Our slogan, "INNOVATION BEYOND IMAGINATION,"  
encapsulates this attitude and passion, and expresses  
our approach to value creation.

We will continue to innovate for patients as we work  
to create value globally.



A large, curved globe is composed of a mosaic of numerous small, square photographs. The photos depict a wide variety of subjects: people of different ages, ethnicities, and genders smiling or interacting; natural landscapes like oceans, forests, and sunsets; and various activities such as playing sports, gardening, and family time. The globe is set against a light blue background with soft, white, cloud-like patterns.

Value that will benefit people  
around the world



The background of the page is a photograph of a modern building's exterior. It features a wide, multi-level staircase with glass railings and a yellow escalator. The architecture is contemporary, with clean lines and a light-colored facade. The image is slightly blurred, giving it a sense of depth and movement.

## PROFILE

Chugai Pharmaceutical Co., Ltd. and its consolidated subsidiaries (“Chugai”) believe that achieving the Mission stated below will result in the creation and improvement of corporate value, and continue to take on new challenges based on the business philosophy of “Innovation all for the patients.”

The healthcare delivery environment is changing rapidly, and the needs of patients and healthcare providers are becoming more diverse and sophisticated, but Chugai will strive to be a company that delivers a high level of satisfaction to all of its stakeholders and receives their active support and trust.

### **Mission**

The mission of 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



There are still many areas of unmet medical need due to a lack of effective treatments. At Chugai, we believe that we have a duty as an industry leader to constantly innovate to deliver value to patients worldwide who are suffering from disease.



# Message from the CEO



## Using Innovation as a Driving Force to Benefit Patients Worldwide

We will take on unprecedented challenges to achieve innovation for patients as we work toward our goal of becoming a “top pharmaceutical company.”

### Steady Growth despite a Rapidly Changing Environment

Chugai's goal is to become a “top pharmaceutical company” in the second half of this decade. Mid-term business plan ACCEL 15, which was implemented for the three years from 2013, was designed to accelerate our achievement of that goal. I am pleased to report that we met virtually all of our targets in ACCEL 15 and achieved steady growth.

However, the operating environment of the pharmaceutical industry has been changing significantly. Safety and quality regulations have been tightened while various countries have implemented measures to contain healthcare expenses. In research and development, declining success rates coupled with sharply rising costs have fueled fierce competition globally. Creating innovative drugs has become increasingly expensive in recent years; according to one study,<sup>1</sup> it now costs \$2.5 billion (about ¥300 billion), including the cost of unsuccessful projects, to develop a single new drug.

In Japan, expectations for healthcare-related fields are increasing, partly due to the inclusion of “innovation for the development of new drugs that will contribute to Japan's national growth strategy” as an objective in the government's Basic Policy on Economic and Fiscal Management Reform introduced in June 2015. On the other hand, that policy also included the new goal of increasing the market share of generic drugs to 80 percent. As for drug prices, in April 2016 an additional repricing rule was introduced for drugs with sales over ¥100 billion, and drug price revisions for three consecutive years are expected, instead of the typical schedule of every two years. These factors will make the operating environment extremely challenging for Chugai.

### Strengths Established through Our Initiatives

The alliance with Roche in 2002 was a strategy we undertook after foreseeing to a certain extent such a series of changes in the healthcare market. In discussions with Roche's management, we concluded that Roche, Genentech and Chugai would need to take a collaborative approach in order to create innovative drugs while dealing with the changes in the operating environment. As a result, the Roche Group as a whole now spends ¥1 trillion a year on research and development, one of the largest R&D investments in the global pharma industry, and the three major Roche Group companies are able to focus on activities that make the most of their respective strengths.

In this context, by concentrating investments on the areas where we have a competitive advantage, we have developed world-leading antibody engineering technologies and are among the top companies in the world in the number of patents for antibody optimization technologies. Chugai has also established powerful new discovery technologies for small molecules. In the last several years, these efforts have yielded a string of innovative new projects, with three compounds – Actemra, Alecensa and ACE910 – receiving breakthrough therapy designation from the U.S. Food and Drug Administration (FDA) from 2014 through 2015.

We have also established a new development model and created a structure for seamless production of investigational drugs to expedite development of multiple compounds amid intensifying global competition in development. As a result of such initiatives, we have also significantly increased the sophistication of our development and production systems. To achieve even faster global development, we amended our licensing agreement with Roche in 2014 to enable decisions at an earlier stage of the development process called early proof of concept (PoC).<sup>2</sup> And in 2015, we established the Translational Clinical Research Division for the purpose of improving early development functions. With these initiatives, we have reformed and upgraded our global development system.

In marketing, our efforts to promote the expansion of personalized healthcare<sup>3</sup> and contribute to regional healthcare are highly regarded and have further increased our domestic presence. Our area marketing innovations have been successful, and marketing productivity has increased about 22 percent since the start of ACCEL 15. In addition, overseas sales have increased about 11 percent, driven by growth in exports of Actemra to Roche. We have also established a leading position in Japan in the areas of medical affairs and drug safety.

### Taking on Unprecedented Challenges for the Benefit of Patients Worldwide

As I have explained, Chugai is now among the industry leaders in Japan in various functions. But we cannot be complacent if we want to continue to deliver new value to patients around the world. Advances such as innovations in information and communication technology and genome profiling technology, as well as understanding of pathological mechanisms, may well change the paradigm of research and development, so it is vital that

we continue to pursue innovation through the evolution of our current strengths.

IBI 18, the mid-term business plan that started in 2016, is not simply an extension of our efforts up to now. It is aimed at bringing all of our functions to a world-class level of competitiveness. The plan contains an agenda with five priority objectives. For each of them, rather than following the lead of other companies, we will embark on a voyage into uncharted waters.

Chugai has a history of effecting unparalleled changes and carving its own path. Examples include initiating biopharmaceutical research ahead of other Japanese companies, making large investments in antibody discovery research and production, and the alliance with Roche. I am confident that we have the ability to turn unprecedented challenges into growth.

The source of this innovation and value creation is ultimately our people. We have accelerated our diversity promotion initiatives, established an organizational culture that encourages autonomous innovation, and formulated a new talent management strategy to speed up development of world-class talent.

Chugai's idea of a "top pharmaceutical company" is being a very reliable company that provides a high level of satisfaction to its stakeholders and receives their active support. There are still many diseases in the world with no effective treatments, and people are suffering from them. Addressing unmet medical need<sup>4</sup> by continuing to innovate for the benefit of patients is how we will realize our goal of becoming a top pharmaceutical company and raise our corporate value.

As expressed in our slogan, "INNOVATION BEYOND IMAGINATION," and the name of our new mid-term business plan, we will use innovation as a driving force to benefit patients worldwide.

### Osamu Nagayama

Representative Director,  
Chairman and CEO



1. Study by the Tufts Center for the Study of Drug Development
2. A demonstration that the therapeutic effect conceived in the research stage is effective in humans. Early PoC means that in addition to safety, signs of efficacy or pharmacological effect have been confirmed in a limited number of cases.
3. A treatment approach designed and implemented according to each patient's unique molecular and genetic profile
4. Medical need that is not adequately met due to a lack of effective treatments

# CONTENTS

## 4 Message from the CEO/ Introduction

Message from the CEO.....	4
Understanding Chugai .....	7
Chugai's Value Creation Model .....	20
Financial and Non-Financial Highlights.....	22



## 28 Management Section



Overview of New Mid-Term Business Plan IBI 18.....	30
Message from the President .....	32
Opportunities and Risks .....	36
A Conversation between the Deputy Chairman and the Outside Directors Creating New Value beyond Our 90th Year.....	37

Board of Directors/ Audit & Supervisory Board .....	40
Executive Committee Members .....	42
Corporate Governance Policies .....	44
Human Resource Management.....	47



## 50 Feature: Value Creation Driven by Our Strengths

Evolution of Chugai's Seven Strengths in New Mid-Term Business Plan IBI 18 .....	52
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Examples of Outcomes from Chugai's Strengths: Breakthrough Therapy Designation from the U.S. FDA.....	55
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## 58 Chugai's Activities



The CFO Answers Frequently Asked Questions from Investors.....	60
Overview of Activities in 2015.....	64
Marketing .....	68
Development .....	72
Production and Procurement.....	74
Research.....	76
Medical Affairs.....	79
Drug Safety .....	80
Intellectual Property .....	82
Environmental Protection, Safety and Health.....	83
Social Contribution Activities.....	86
Corporate Communication.....	88

## 90 Detailed Performance Report

Basic Information.....	92
Environmental Data.....	108
Corporate Governance.....	110
Organization.....	115
Glossary.....	116



## 117 Financial Section

12-Year Financial Summary.....	118
Management's Discussion and Analysis .....	120
Consolidated Financial Statements .....	128
Independent Auditor's Report ....	173
Network .....	174
Shareholder Information.....	176
Corporate Data.....	177





# Understanding Chugai

## Annual Report 2015 Digest

Over the years, Chugai has made continuous innovations for the benefit of patients. These successful efforts have led to the Company's growth and development. With the launch of a new mid-term business plan in 2016, Chugai is taking on new challenges for further value creation.

To provide a better understanding of Chugai, this section outlines our history, characteristics, current position and strategy for the future. We hope you find it informative.

# Throughout our 90 years, we probably haven't relaxed for a single day.

Chugai celebrated its 90th anniversary in 2015. The founding of the Company was driven by the anxiety about medicine shortages brought on by the Great Kanto Earthquake. In the years that followed, management faced some difficulties, but the Company's founding spirit of "creating drugs that benefit the world" has remained unchanged.



## The History of Chugai

### 1920s – 1950s

In 1925, concerned by the acute shortage of medicines following the Great Kanto Earthquake, Chugai's founder Juzo Ueno established Chugai Shinyaku Shokai, Chugai's predecessor. Later, the Company rebuilt in the aftermath of the Second World War. Although it faced hurdles including a steep drop in demand for its mainstay products, Chugai had broadened its value in ways such as bringing its global product Guronsan to patients in 31 countries.

1925: Chugai's predecessor Chugai Shinyaku Shokai established

1932: Nippon Roche established

### 1960s – 1970s

Rapid change in the over-the-counter (OTC) drug market weakened Chugai's performance, so the company restructured, shifting its business focus from OTC to prescription drugs, leading to a successful recovery. Meanwhile, Nippon Roche moved to reinforce its business foundation in the 1960s, and created a major product in the oncology field. It was the first foreign-affiliated pharmaceutical company to establish full-scale laboratories and manufacturing plants in Japan.

1966: Business operations restructured to focus on prescription drugs (Chugai)

1967: "Three Corporate Principles" (Economic Performance, Social Awareness and Human Development) for stable growth announced (Chugai)

1972: Nippon Roche Research Center established (Nippon Roche)

### 1980s – 1990s

Chugai decided that establishing biotechnology was essential to its future, and began investing resources in research and development of biopharmaceuticals in the 1980s. The Company also worked to establish technology for the mass production of biopharmaceuticals, and in the early 1990s it successfully launched a biopharmaceutical product created through genetic engineering, laying the foundation for what would become one of its core strengths.

1983: Began collaborative research and development with a U.S. biotech venture, which led to the launch of the first biopharmaceutical in 1990 (Chugai)

1984: World's first successful purification of G-CSF\* which led to the launch of Neutrogen in 1991 (Chugai)

\*Granulocyte colony-stimulating factor





## 2000 – 2004

Chugai's strategic alliance with Roche, one of the world's leading pharmaceutical companies, started in 2002. With this alliance, Chugai made a fresh start and created a unique business model in which each company benefited from the other's strengths. Later, as the number of projects in-licensed from Roche increased, Chugai reorganized its research centers and manufacturing plants and transformed its earnings structure.

2002: Chugai merges with Nippon Roche K.K. and becomes a member of the Roche Group

## 2005 – 2009

Building on its experience in manufacturing biopharmaceuticals since the 1980s, Chugai discovered, developed and in 2005 began manufacturing Japan's first therapeutic antibody. Chugai also has captured the top domestic market share in the field of oncology with a powerful lineup of anticancer agents and supportive treatments. In 2009, to achieve even greater innovation for patients, Chugai set the goal of becoming a "top pharmaceutical company" by the late 2010s.

2005: Launch of Actemra, the first therapeutic antibody created in Japan  
2008: Chugai captures the top share in the domestic oncology market  
2009: Chugai sets its goal of becoming a "top pharmaceutical company"

## 2010s

In 2013, Chugai launched mid-term business plan ACCEL 15, which has produced substantial results in terms of providing value to patients and reinforcing the Company's strengths. In addition to steadily generating innovative medicines and leading the world with its antibody engineering technologies, Chugai has also become an industry leader in areas such as promoting personalized healthcare and initiatives to improve drug safety.

2010: Innovative antibody engineering technology announced  
2013: Start of mid-term business plan ACCEL 15  
2016: Start of new mid-term business plan IBI 18

# Constant innovation has readied us to become a top pharmaceutical company.

After the alliance with Roche, one of the world's largest biopharmaceutical companies, Chugai built a unique business model that has two revenue bases. With a firm belief in patient-oriented value creation, Chugai resolved to become a top pharmaceutical company.



## Definition of a “Top Pharmaceutical Company” (The company Chugai aims to become by the late 2010s)

### Corporate Vision

Company that focuses on first-in-class<sup>1</sup> and best-in-class<sup>2</sup> products and services, and continuously provides new solutions to patients and medical communities around the world

– Innovation all for the patients –

1. An original drug that is highly novel and useful, and will significantly change the therapeutic system
2. A drug that offers clear advantages over other existing drugs in the same category, such as those with the same molecular target

### Quantitative Aspects

#### 1. Among the top three Japanese pharmaceutical companies in the following:

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

#### 2. No. 1 presence in strategic disease areas

- Oncology/Renal/Bone & Joint/RA: Top-class sales share and stakeholder satisfaction

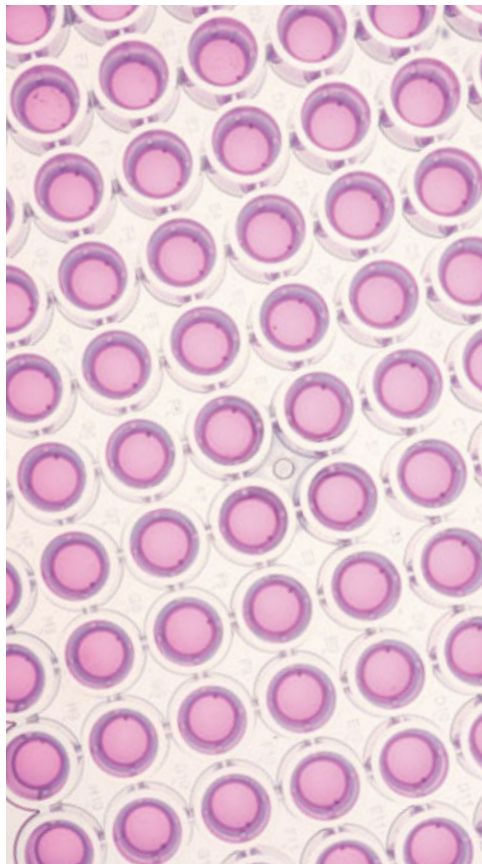
- Establishment of top brand in hospital market by supporting medical liaison networks between medical professionals

#### 3. Expansion of global presence

- Higher overseas sales ratio
- Number of large global products in lineup
- Number of global projects in late-stage development
- Continuous addition of first-in-class and best-in-class in-house projects to the portfolio

Underlined text indicates additions and revisions from previous targets (announced in January 2016).





## Two Revenue Bases

### Qualitative Aspects

1. A company that satisfies all its stakeholders and receives their active support and trust
2. A company that works proactively on a global level
  - Continuous creation, development, and domestic and overseas launches of products with a competitive advantage in clinical results
  - Contribution to the Roche Group's results through product-appropriate fostering and sales
  - Leadership in pharmaceutical industry activities
  - Activities in which all employees have an awareness, sense of responsibility and pride as part of a top pharmaceutical company

### Products In-Licensed from Roche

Stable revenue base  
(Efficient product launches through collaboration with Roche)

### Products from Chugai Research

Revenue base that drives growth  
(Out-licensing to Roche and global market development)

The strategic alliance with Roche allows Chugai to in-license and sell Roche's groundbreaking therapies on an exclusive basis in Japan. This stable earnings foundation allows us to concentrate investment on highly innovative proprietary technologies and drug discovery. Moreover, out-licensing our in-house products to Roche gives us access to global markets, which provides a revenue base that drives growth. Meanwhile, the alliance enables Roche to sell our products – which we create through highly innovative, specialized research – in global markets. It is a win-win relationship.

Note: See "Chugai's Value Creation Model" on page 20 for details.

# Chugai has seven strengths it can be proud of.

Chugai has many products, development projects and functions at or near the top level in Japan. We distilled them down to seven strengths that clearly contribute to patients and represent unique competitive advantages. These strengths will serve as sources of growth going forward, so Chugai must continue to refine and develop them further.

## Chugai's Seven Strengths

We have identified the following seven strengths as the source of our value to help stakeholders recognize and understand Chugai as it works to realize its goal becoming a top pharmaceutical company.

④

Cutting-edge drug discovery technologies, especially biotechnology

With more than three decades of experience in biopharmaceutical research and development, Chugai has developed a series of innovative antibody engineering technologies. We have also established a discovery research platform that allows us to continually create drugs in-house.

①

High product potential that addresses unmet medical need

In Japan, Chugai maintains the number-one market share\* in the oncology field and in the therapeutic antibody market, and has market-leading products for bone and joint and renal diseases. We also lead our industry peers in participation in multinational clinical studies.

②

One of the richest pipelines in Japan

Chugai's oncology pipeline is one of the richest in Japan, and includes a large number of clinical candidates targeting diseases with significant unmet medical need.

⑤

Knowledge and experience as a pioneer in personalized healthcare (PHC)

Chugai develops many projects based on PHC, which tailors treatment to each individual patient. We also focus on the simultaneous development and approval of drugs and companion diagnostics.

⑥

Commitment to safety management

Chugai has conducted all-case registration surveillance and managed safety for over 20,000 cases. From this experience, we have established a global-standard, industry-leading system for collection, assessment and analysis of safety information.

\*Copyright 2016 IMS Health  
Source: JPM 2015. Reprinted with permission.  
The scope of the market is defined by Chugai.





## The Process of Identifying Our Seven Strengths

### ③ Strategic alliance with the Roche Group

Chugai has established a powerful network with Roche and Genentech, two of the world's leading pharmaceutical companies. We also efficiently in-license many products and development projects from Roche for the Japanese market.

### ⑦ Support for healthcare delivery

With a high level of expertise in oncology and other therapeutic fields, Chugai provides full support for multidisciplinary team care and promotes regional healthcare coordination.

### Visualization


In our project to become a top pharmaceutical company, which started in 2009, we visualized the intangible strengths that Chugai has built, and shared 96 examples of those strengths within the Company.

### Analysis of Value and Advantage

Based on those 96 examples, in 2013 we evaluated and analyzed Chugai's strengths from the standpoints of value to patients and competitive advantage, resulting in 25 categories.

### Distillation Down to Seven Strengths

We organized these 25 categories through outside analysis and other means and distilled them down to seven strengths, establishing a basic message for communications.



# 2015 was another year of significant advances. We are pleased with the rising levels of employee talent.

In 2015, Chugai achieved substantial progress not only in financial performance but also in terms of the quality and speed of business activities. This was driven in part by our unique strengths, but we also see it as a result of the employee talent underlying those strengths.

## Chugai in 2015

### No. 1<sup>1</sup>

Share of therapeutic antibody market

Share of domestic sales in 2015

### No. 1<sup>1</sup>

Share of oncology market

Share of domestic sales in 2015

### 34

Number of pipeline projects

As of January 28, 2016

### +8.2%

Growth in revenues

YoY

### +17.3%

Growth in Core operating profit<sup>3</sup>

YoY

### +22.5%

Growth in Core EPS<sup>3</sup>

YoY

1. Copyright 2016 IMS Health  
Source: JPM 2015. Reprinted with permission.  
The scope of the market is defined by Chugai.

2. Percentage of all managers

3. Excluding items that Chugai defines as non-Core





**10.7%**

Percentage of female managers<sup>2</sup>

As of December 31, 2015

**49.8%**

Core EPS<sup>3</sup> payout ratio

Year ended December 31, 2015

## Highlights

<b>February:</b>	Launched anticancer agent/BRAF inhibitor Zelboraf
<b>March:</b>	Selected as a "Nadeshiko Brand" for exceptional efforts in promoting the success of women
<b>April:</b>	Established the Translational Clinical Research Division specializing in early clinical development
<b>May:</b>	Revised the working support program for employees undergoing cancer treatment to enable them to continue working while receiving treatment
<b>June:</b>	Announced the integration and reorganization of overseas subsidiaries
<b>September:</b>	Selected as a constituent of the Dow Jones Sustainability Asia Pacific Index for the second straight year
<b>September:</b>	Hemophilia A treatment ACE910 received breakthrough therapy designation from the U.S. Food and Drug Administration
<b>October:</b>	Decided to construct an antibody API manufacturing plant to handle high-mix, low-volume production
<b>December:</b>	Obtained approval for ALK inhibitor Alecensa in the United States

And in 2016, we launched our new mid-term business plan, IBI 18. We are confident it will be effective.

In previous mid-term business plans, we made steady progress in solving the issues that were raised. IBI 18, which started in 2016, will significantly advance our transformation into a top pharmaceutical company. We will continue forward on the path of innovation with the aim of increasing value globally.



#### Results of ACCEL 15 (Mid-Term Business Plan for 2013-2015)

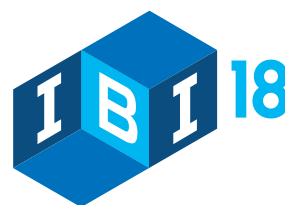
✓	Core EPS CAGR <sup>1</sup> (2012-2015)	<b>+18.3%</b> <sup>2</sup>
✓	Core EPS payout ratio	Five-year average <sup>3</sup> <b>50.3%</b>
✓	Increase of marketing productivity	
✓	Acceleration of global development	
✓	Continuous generation of innovative projects	
✓	Further strengthening of management infrastructure	

1. Compound annual growth rate

2. Quantitative guidance: Mid-to-high single-digit growth (%), based on average exchange rates for 2012

3. Quantitative guidance: Approx. 50 percent on average

#### New Mid-Term Business Plan IBI 18



INNOVATION BEYOND IMAGINATION

In IBI 18, we will work to create value for patients around the world by further developing our strengths and tirelessly pursuing innovation to become a top pharmaceutical company.

Note: See page 30 for the results of ACCEL 15 and details of IBI 18.





## Priority Agenda

Acquisition and implementation of competitiveness at a top global level

Selection and concentration strategy for acceleration of growth

## Quantitative Outlook

Core EPS CAGR  
(2015-2018)

Low single digit<sup>4</sup>

4. Growth less than 4%, based on average exchange rates for 2015

Drug Discovery	Continuous creation of first-in-class and best-in-class projects based on innovative technologies
Development	Promotion of early launch and quick market penetration based on global top-class translational clinical research (TCR) <sup>5</sup> and development activities
Pharmaceutical Technology	Strengthening of pharmaceutical technology system for multiple and simultaneous global development, fast global launch and cost reduction
Marketing/ Medical Affairs/ Safety	Provision of advanced and diverse solutions through independent roles and cross-functional cooperation
Company-wide	Accelerate acquisition, development and assignment of talent who are key for innovation and responding to environmental change

5. Clinical research during preclinical stage to proof-of-concept (PoC) that verifies the scientific concept developed through drug discovery operations in the clinical setting. PoC is a demonstration that the therapeutic effect conceived in the research stage is effective in humans.



# INNOVATION BEYOND IMAGINATION





## 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.

### 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 2015. However, in view of the importance of providing the latest information available, some information relating to activities that occurred in 2016 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 important 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

The content of this report is focused on value creation, using as reference The International Integrated Reporting Framework issued by the International Integrated Reporting Council (IIRC).<sup>\*</sup> 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).

<sup>\*</sup> 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.

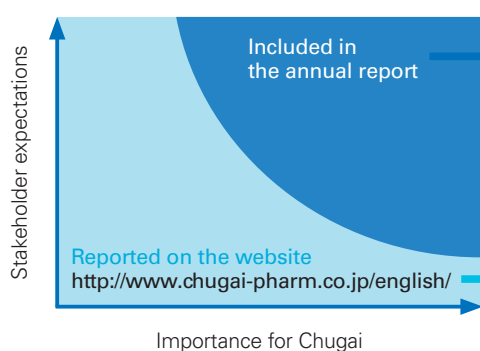
### Forward-Looking Statements

This annual report includes forward-looking statements pertaining to the business and prospects of Chugai. 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.

## Chugai CSR Information



### Annual Report

[http://www.chugai-pharm.co.jp/english/ir/reports\\_downloads/annual\\_reports.html](http://www.chugai-pharm.co.jp/english/ir/reports_downloads/annual_reports.html)

### CSR Website

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

Topics include:

- Chugai's Approach to CSR
- Chugai's Transparency Guidelines
- Initiatives for Stakeholders
- Environment and Safety
- Performance Data
- Diversity Initiatives

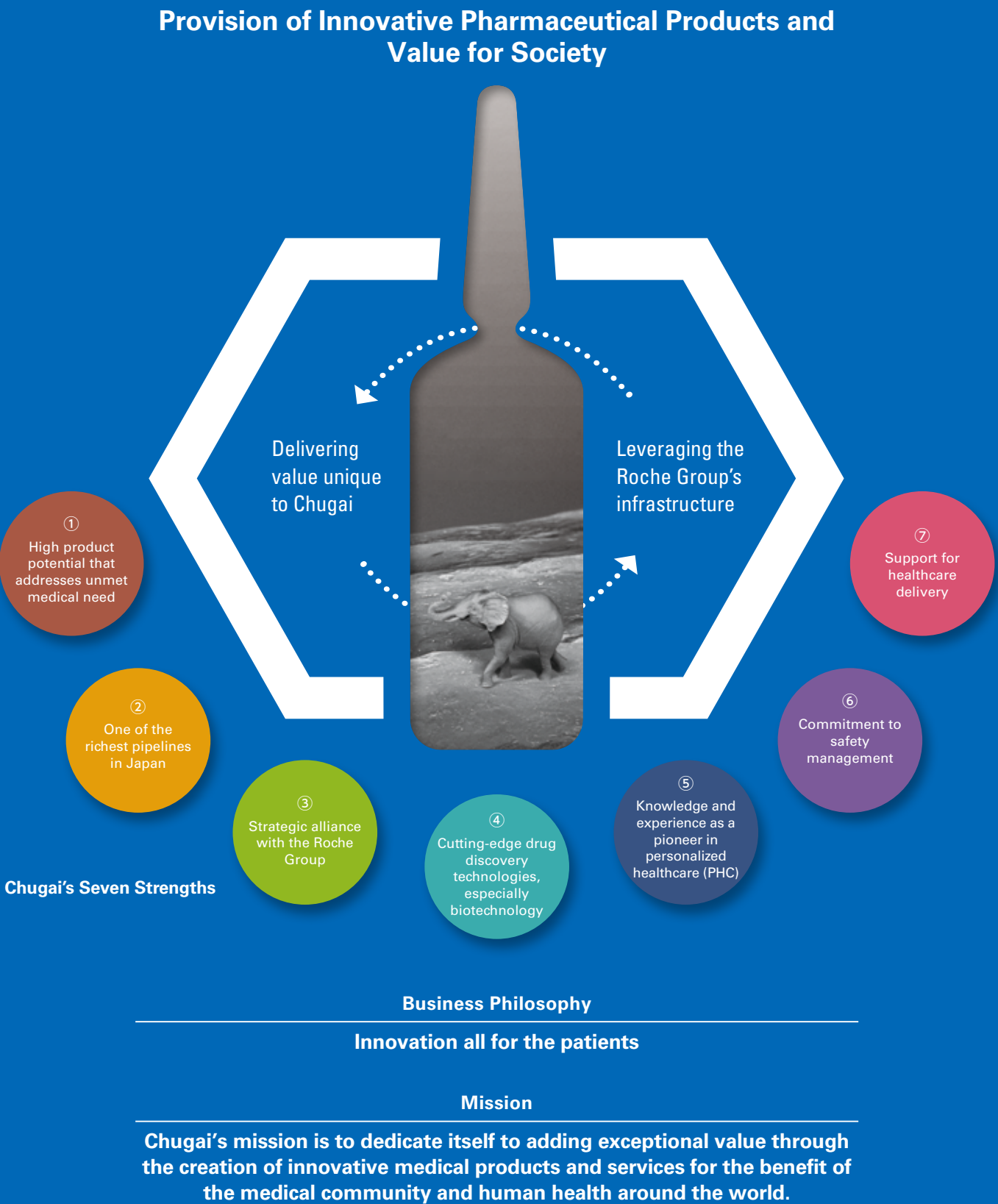
### About CSR Information

Chugai reports its social responsibility activities in a printed report and on its website, taking advantage of the characteristics of each media type. The printed report covers Chugai's main initiatives in 2015, while the website includes more detailed information in addition to the information in the printed report.



Chugai's CSR website can be accessed by scanning the QR code above.

# Chugai's Value Creation Model



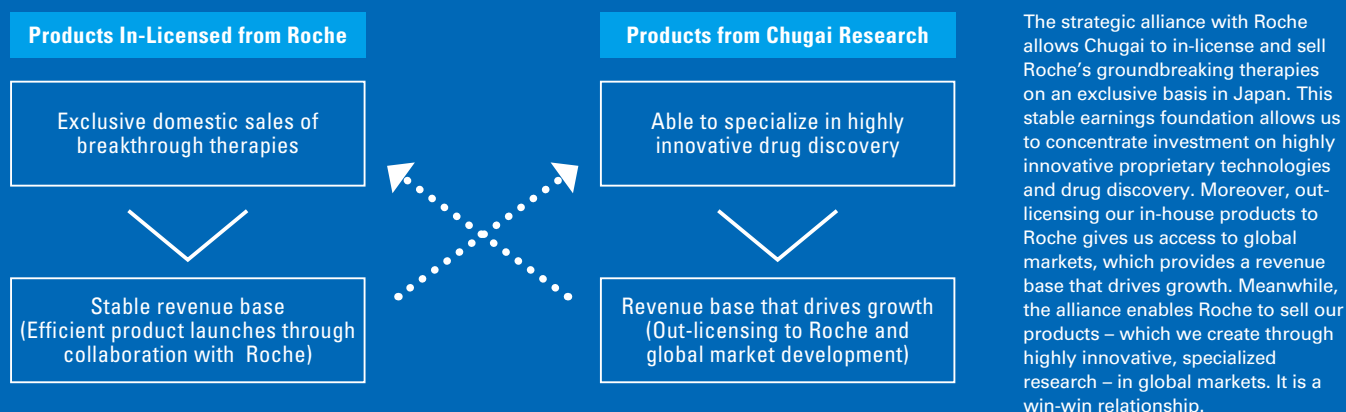


Based on its mission and business philosophy, Chugai contributes to the benefit of patients and healthcare professionals worldwide by delivering value unique to Chugai and leveraging the Roche Group's infrastructure. We will work to create value for patients and increase our corporate value through the continuous evolution of Chugai's seven strengths.

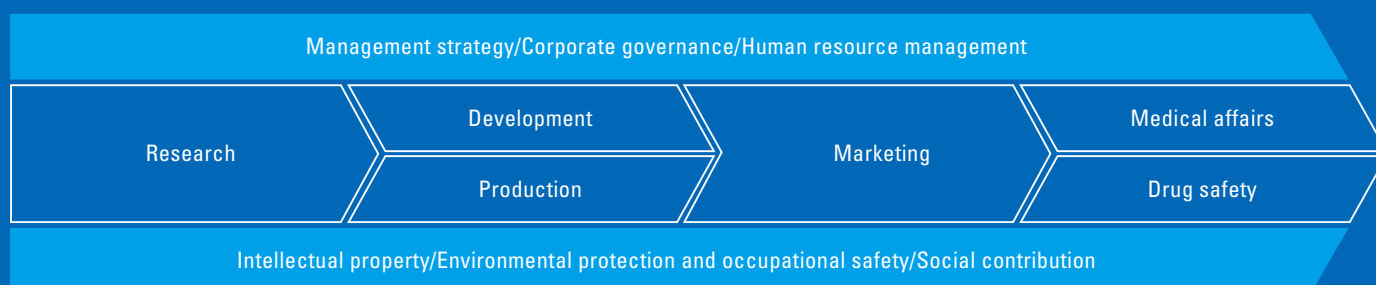
## Additional Value for Society



## Two Revenue Bases



## Business Processes



The "Invisible Art: Elephant" series of corporate advertisements, which was based on Chugai's slogan, "INNOVATION BEYOND IMAGINATION," was placed in the center of the value creation model to symbolize innovation. See page 88 for details.

# Financial and Non-Financial Highlights

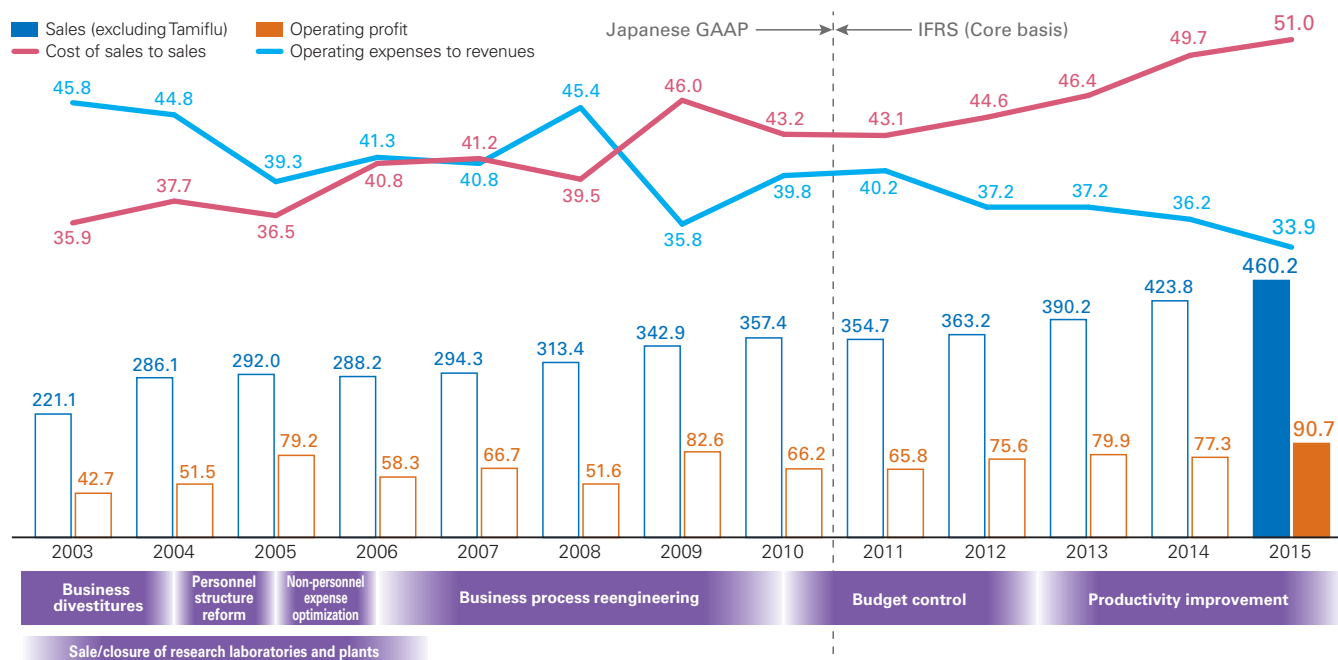
Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries/Years ended December 31

(Figures for 2003 are for the nine months ended December 31, 2003)

## Financial Indicators (Core Basis)

### Results

(Billions of yen/%)

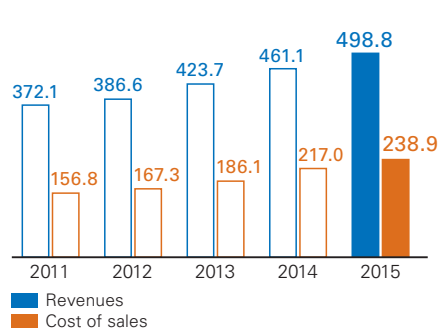


Since the alliance with Roche, Chugai has transformed its earnings structure while expanding sales. Given the higher cost of sales to sales ratio resulting from the increase in products in-licensed from Roche, we have continuously implemented business structure reforms, business process reengineering, cost reduction measures and other improvements, which has dramatically improved

our cost structure. As a result, we have reduced the ratio of operating expenses to revenues to a level comparable with the world's leading pharmaceutical companies and secured high profitability.

### Revenues/Cost of Sales

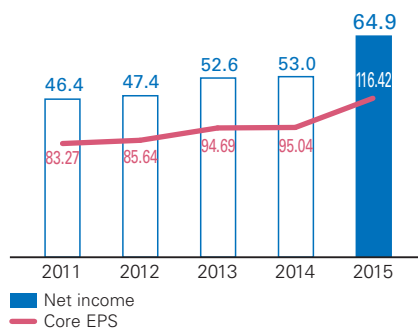
(Billions of yen)



We have maintained consistent profit growth with solid top-line expansion that exceeds increases in cost of sales.

### Net Income/Core EPS

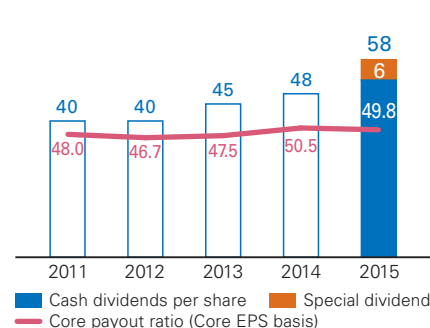
(Billions of yen/Yen)



In the new mid-term business plan, IBI 18, we set Core EPS CAGR as the quantitative outlook, and will use it as a uniform key performance indicator both internally and externally. (See page 25 for an explanation of Core basis results.)

### Cash Dividends/Core Payout Ratio

(Yen/%)



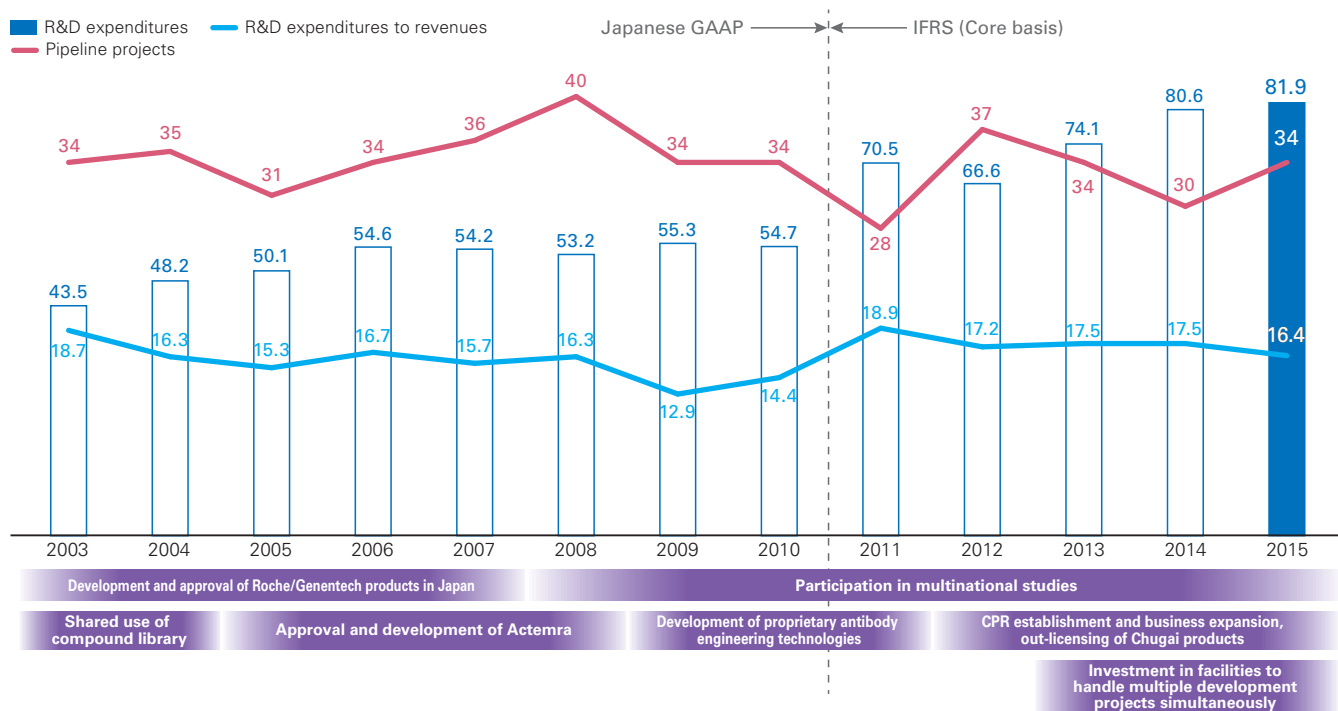
In IBI 18, we continue to target a Core EPS payout ratio of 50 percent on average while maintaining stable dividends.



## Research, Clinical Development and Production

### R&D Expenditures/R&D Expenditures to Revenues/Pipeline Projects

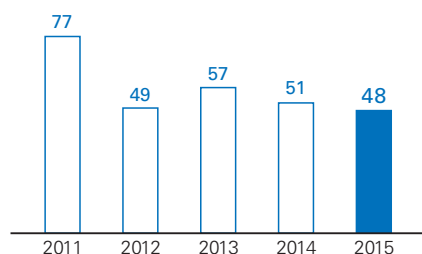
(Billions of yen/%/Projects)



As revenues grow, Chugai increases investment in research and development to steadily create innovative drugs. These investments have also led to the creation of research technologies and findings that may contribute to the advancement of healthcare and the pharmaceutical industry worldwide. Development of Roche Group products in Japan has proceeded smoothly since

our alliance began, and we currently have a development system capable of simultaneous filings in Japan, the United States and Europe. In addition, we enhance our drug discovery capabilities to maintain a robust pipeline, with numerous products from Chugai research having moved into the clinical phase.

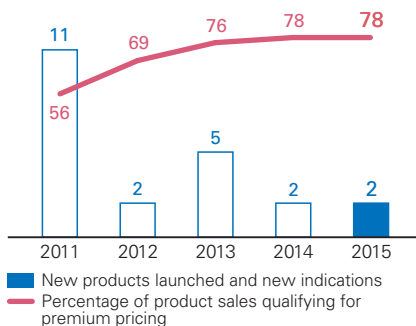
### Publications in Academic Papers and Presentations at Scientific Conferences regarding Chugai Research Findings



With its unique strengths, including the antibody engineering technologies it has pioneered, Chugai contributes to healthcare overall in ways such as creation of in-house projects, presentations on research findings at scientific conferences and publications in academic papers.

### New Products Launched and New Indications/Percentage of Product Sales Qualifying for Premium Pricing

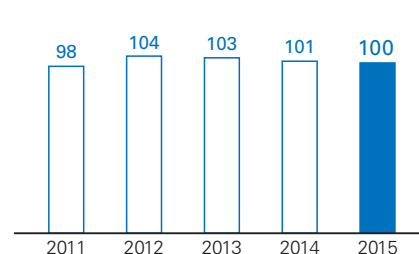
(Number/%)



Chugai makes many innovative drugs and valuable treatments available to patients by steadily launching new products and adding new indications.

### CO<sub>2</sub> Emissions

(Thousand tons)

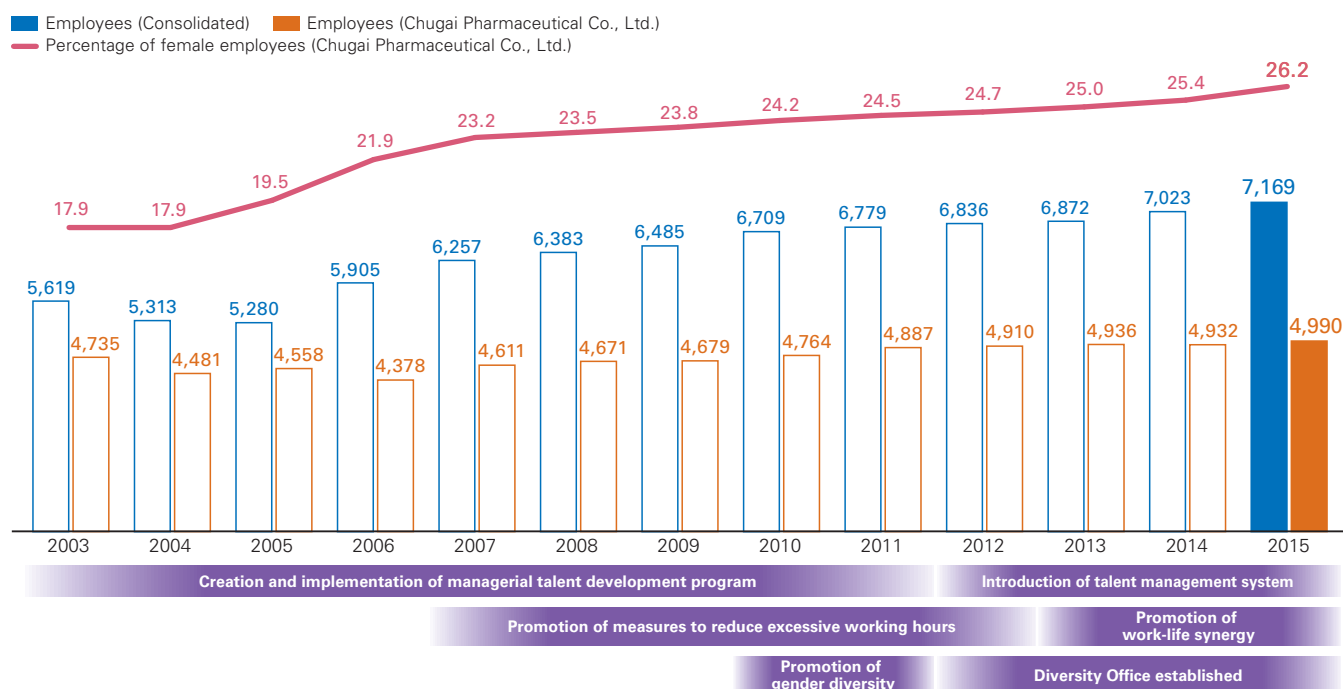


While continuing to make capital investments for simultaneous development of multiple drugs, we are emphasizing care for the global environment as one of our Core Values, and take steps to avoid a significant increase in our CO<sub>2</sub> emissions.

## Human Resource Management

### Employees/Percentage of Female Employees

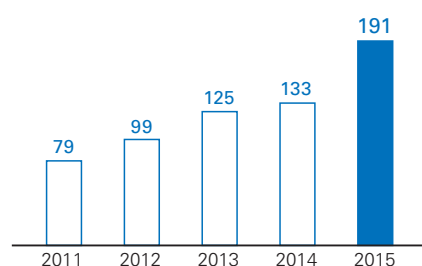
(Number of employees/%)



Chugai is working to enhance its management of human resources based on the belief that its people are the source of its contribution to patients in terms of providing greater value. We have introduced and implement a talent management system to develop and retain leaders and core personnel, and

also focus on diversity management and promotion of work-life synergy so our diverse human resources can generate new value. The rising percentage of female employees is indicative of the steady progress of systems and measures to foster an inclusive organizational culture.

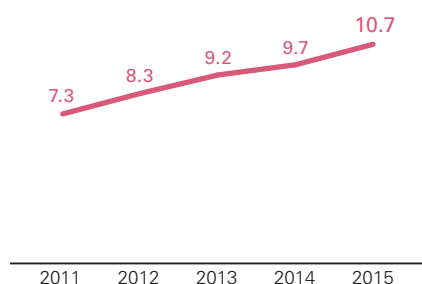
### Employees Taking Childcare Leave



Chugai implements various measures to promote work-life synergy so that employees can choose work arrangements that fit their lifestyles.

### Percentage of Female Managers (Non-Consolidated)

(%)

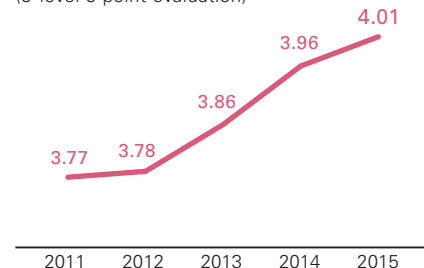


The percentage of female managers is increasing, but compared to global levels there is still room for improvement. We therefore plan to further accelerate our initiatives to develop female leaders.

### Awareness of the "Top Pharmaceutical Company" Strategy

(Based on Results of Chugai Employee Survey)\*

(5-level 5-point evaluation)



Note: Survey results of overseas subsidiaries and affiliates are reflected from 2013.

The increase in awareness of the top pharmaceutical company strategy is directly linked to a growing sense of autonomy among employees and higher productivity, and helps to raise corporate value. Awareness of activities aimed at becoming a top pharmaceutical company has already reached a high level, but we will continue efforts for further improvement.

\* 2013-2015 Employee Survey  
Copyright Recruit Management Solutions Co., Ltd.



## 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 <sup>1</sup> (Except as otherwise specified)
	2015	2014	2013	2014/2015	2015
<b>Results for the year:</b>					
Revenues .....	¥ 498.8	¥ 461.1	¥ 423.7	+8.2%	\$4,122
Operating profit .....	90.7	77.3	79.9	+17.3	750
Net income .....	64.9	53.0	52.6	+22.5	536
R&D expenditures .....	(81.9)	(80.6)	(74.1)	+1.6	(677)
Sales .....	¥ 468.4	¥ 436.9	¥ 401.3	+7.2%	\$3,871
Oncology .....	215.7	188.9	172.4	+14.2	1,783
Bone and joint diseases .....	79.4	69.6	60.6	+14.1	656
Renal diseases .....	45.4	44.7	48.9	+1.6	375
Transplant, immunology and infectious diseases ...	15.9	20.8	18.8	-23.6	131
Others .....	21.7	25.6	28.6	-15.2	179
Tamiflu .....	8.2	13.0	11.0	-36.9	68
Overseas .....	82.2	74.3	61.1	+10.6	679
Royalties and other operating income .....	30.4	24.2	22.4	+25.6	251
<b>Financial position at year-end:</b>					
Total assets .....	¥ 787.4	¥ 739.5	¥ 697.2	+6.5%	\$6,507
Interest-bearing debt .....	(0.7)	(0.2)	(0.2)	+250.0	(6)
Total net assets .....	627.3	597.8	573.2	+4.9	5,184
<b>Cash flows during the year:</b>					
Cash flows from operating activities .....	¥ 62.9	¥ 37.0	¥ 53.5	+70.0%	\$ 520
Operating free cash flows .....	64.6	43.9	63.0	+47.2	534
<b>Amounts per share (Yen and U.S. dollars):</b>					
Core EPS .....	¥ 116.42	¥ 95.04	¥ 94.69	+22.5%	\$0.962
Equity per share attributable to Chugai shareholders (BPS) .....	1,146.17	1,092.90	1,049.47	+4.9	9.472
Dividends .....	58	48	45	—	0.479
<b>Number of shares outstanding</b> .....	<b>559,685,889</b>	<b>559,685,889</b>	<b>559,685,889</b>		
<b>Number of employees</b> .....	<b>7,169</b>	<b>7,023</b>	<b>6,872</b>		
<b>Ratios:</b>					
Operating profit to revenues (%) .....	18.2	16.8	18.9		
Ratio of net income to equity attributable to Chugai shareholders (ROE) (%) <sup>2</sup> .....	10.0	8.7	9.3		
Ratio of equity attributable to Chugai shareholders (%) .....	79.5	80.6	82.0		
R&D expenditures to revenues (%) .....	16.4	17.5	17.5		
Payout ratio (%) <sup>3</sup> .....	49.8	50.5	47.5		

Notes: 1. The U.S. dollar amounts have been converted from Japanese yen amounts at the rate of ¥121 to U.S.\$1.00, the approximate exchange rate prevailing on December 31, 2015.

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.

### 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 establishing profit distributions such as returns to shareholders. No items have been excluded from the IFRS balance sheet and cash flows, as the Core basis results concept only applies to the income statement.

## Development Pipeline (As of January 28, 2016)

Development Code (*Additional Indication)	Indication	Status (Date)				
		Phase I	Phase II	Phase III	Filed	Approved
Oncology						
RG340*	Gastric cancer (adjuvant)					Nov. 2015
AF802 (RG7853)	◆ Non-small cell lung cancer [post-crizotinib]					Dec. 2015 (U.S.)
	◆ NSCLC [1st line]				(Europe)	
RG435*	Cervical cancer					
	Renal cell carcinoma			(Multinational study)		
RG1273*	◆ Breast cancer (adjuvant)			(Multinational study)		
	◆ Gastric cancer			(Multinational study)		
RG3502*	◆ Breast cancer (adjuvant)			(Multinational study)		
GA101 (RG7159)	Aggressive non-Hodgkin's lymphoma			(Multinational study)		
	Indolent non-Hodgkin's lymphoma			(Multinational study)		
RG7446	◆ Non-small cell lung cancer			(Multinational study)		
	◆ Non-small cell lung cancer (adjuvant)			(Multinational study)		
	◆ Bladder cancer			(Multinational study)		
	◆ Muscle invasive bladder cancer (adjuvant)			(Multinational study)		
	◆ Renal cell carcinoma			(Multinational study)		
GC33 (RG7686)	◆ Hepatocellular carcinoma			(Multinational study)		
CKI27 (RG7304)	◆ Solid tumors					
		(Overseas)				
RG7596	Non-Hodgkin's lymphoma					
RG7604	◆ Solid tumors					
RG7440	◆ Solid tumors					
Bone and Joint Diseases						
RG484	Osteoporosis					Jan. 2016
ED-71	Osteoporosis			(China)		
Autoimmune Diseases						
MRA* (RG1569)	Large-vessel vasculitis					
	Giant cell arteritis			(Overseas)		
	Systemic sclerosis			(Multinational study)		
SA237	Neuromyelitis optica			(Multinational study)*		
Renal Diseases						
EOS789	Hyperphosphatemia					
Central Nervous System						
RG1450	◆ Alzheimer's disease			(Multinational study)		
RG1662	Improvement of intellectual ability in individuals with Down syndrome					
Others						
RG3637	◆ Asthma			(Multinational study)		
	◆ Idiopathic pulmonary fibrosis			(Multinational study)		
ACE910 (RG6013)	Hemophilia A			(Multinational study)		
CIM331	Atopic dermatitis			(Multinational study)*		
	Pruritus in dialysis patients					
URC102	Gout			(Overseas)		
PCO371	Hypoparathyroidism		(Overseas)			

●●●●● Designates change in status in 2015 and thereafter ◆ PHC-based drug discovery

\* Multinational study managed by Chugai Pharmaceutical



Generic Name/Product Name	Origin (Collaborator)	Mode of Action
capecitabine/Xeloda (Overseas name: Xeloda)	Roche (Yakult Honsha)	Antimetabolite, 5-FU derivative (Oral)
alectinib/Alecensa (Overseas name: Alecensa)	In-house (Roche)	ALK inhibitor (Oral)
bevacizumab/Avastin (Overseas name: Avastin)	Roche	Anti-VEGF (vascular endothelial growth factor) humanized monoclonal antibody (Injection)
pertuzumab/Perjeta (Overseas name: Perjeta)	Roche	HER2 dimerization inhibitory humanized monoclonal antibody (Injection)
trastuzumab emtansine/Kadcyla (Overseas name: Kadcyla)	Roche	Anti-HER2 antibody-tubulin polymerization inhibitor conjugate (Injection)
obinutuzumab/Product name undetermined (Overseas name: Gazyva/Gazyvaro (E.U.))	Roche (Nippon Shinyaku)	Glycoengineered type II anti-CD20 monoclonal antibody (Injection)
atezolizumab/Product name undetermined	Roche	Engineered anti-PDL1 monoclonal antibody (Injection)
codrituzumab/Product name undetermined	In-house (Roche)	Anti-glypican-3 humanized monoclonal antibody (Injection)
Generic and product names undetermined	In-house (Roche)	Raf and MEK dual inhibitor (Oral)
polatuzumab vedotin/Product name undetermined	Roche	Anti-CD79b antibody-drug conjugate (Injection)
taselisib/Product name undetermined	Roche	PI3K inhibitor (Oral)
ipatasertib/Product name undetermined	Roche/Array BioPharma	AKT inhibitor (Oral)
ibandronic acid/Bonviva (Overseas name: Bonviva/Boniva (U.S.))	Roche (Taisho Pharmaceutical)	Bisphosphonate (Oral)
eldecalcitol/Edirol	In-house	Activated vitamin D <sub>3</sub> agent (Oral)
tocilizumab/Actemra (Overseas name: Actemra/RoActemra (E.U.))	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody (Injection)
Generic and product names undetermined	In-house	Anti-IL-6 receptor humanized monoclonal antibody (Injection)
Generic and product names undetermined	In-house	— (Oral)
gantenerumab/Product name undetermined	Roche/MorphoSys	Anti-amyloid-beta human monoclonal antibody (Injection)
basmisaniil/Product name undetermined	Roche	GABAA $\alpha$ 5 receptor antagonist (Oral)
lebrikizumab/Product name undetermined	Roche	Anti-IL-13 humanized monoclonal antibody (Injection)
emicizumab/Product name undetermined	In-house (Roche)	Anti-factor IXa/X bispecific antibody (Injection)
nemolizumab/Product name undetermined	In-house	Anti-IL-31 receptor humanized monoclonal antibody (Injection)
Generic and product names undetermined	In-house/JW Pharmaceutical	URAT1 inhibitor (Oral)
Generic and product names undetermined	In-house	PTH1 receptor agonist (Oral)

# Management Section

Overview of New Mid-Term Business Plan IBI 18 .....	30
Message from the President .....	32
Opportunities and Risks .....	36
A Conversation between the Deputy Chairman and the Outside Directors Creating New Value beyond Our 90th Year.....	37
Board of Directors/ Audit & Supervisory Board .....	40
Executive Committee Members .....	42
Corporate Governance Policies .....	44
Human Resource Management.....	47

## 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.

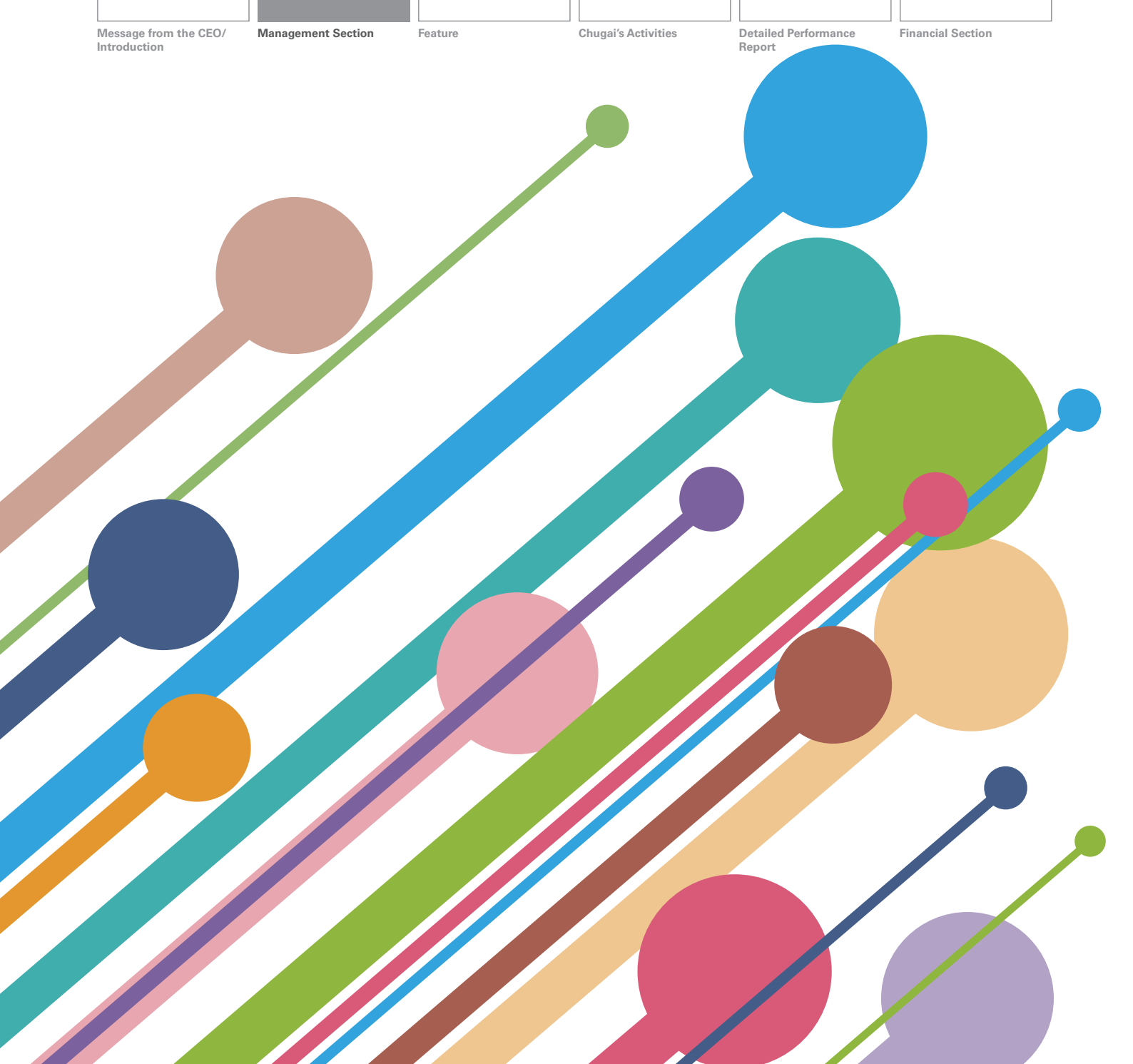
## Core Values

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, customers and other business partners.

### • 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.

# Overview of New Mid-Term Business Plan IBI 18



INNOVATION **B**EYOND IMAGINATION

Chugai's new mid-term business plan IBI 18 (2016-2018) is aimed at transforming Chugai into a globally successful company through its competitive advantage that leverages the strategic alliance with Roche, and through the realization of its "top pharmaceutical company" goal. The name IBI 18 was chosen to express Chugai's relentless pursuit of "INNOVATION BEYOND IMAGINATION."

## Priority Agenda

- Acquisition and implementation of competitiveness at a top global level
- Selection and concentration strategy for acceleration of growth

Drug Discovery	Development	Pharmaceutical Technology	Marketing/Medical Affairs/Safety	Company-wide
<ul style="list-style-type: none"> <li>Continuous creation of engineered antibody projects</li> <li>Establishment of drug discovery technologies for middle molecules</li> <li>Research base for oncology/immunology</li> </ul>	<ul style="list-style-type: none"> <li>ACE910 (emicizumab), atezolizumab</li> <li>Realization of early PoC with TCR</li> <li>Proof process for medical/economic value</li> </ul>	<ul style="list-style-type: none"> <li>Enhancement of CMC<sup>1</sup> development infrastructure for early PoC acquisition</li> <li>Strengthening competitive advantages from late development to initial commercial production</li> <li>QA, QC and regulatory functions</li> </ul>	<ul style="list-style-type: none"> <li>Growth driver products, emicizumab, atezolizumab</li> <li>Providing advanced solutions through a cross-functional system</li> <li>Establishment of system adapted to local characteristics</li> </ul>	<ul style="list-style-type: none"> <li>Acquisition, development and assignment of global top-class talent to lead value creation activities through innovation</li> </ul>

● Expansion of achievements through selection and concentration utilizing competitive advantage

● Strengthening competitive foundation for global top-class level

1. Chemistry, Manufacturing and Controls: a concept that integrates API process research and pharmaceutical development research with quality evaluation research

## ACCEL 15 Achievements

	Initial Objective	Result	Status		Initial Objective	Result	Status		
<b>Core EPS CAGR<sup>2</sup></b> (2012-2015)	Mid-to-high single-digit growth <sup>3</sup>	<b>+18.3%<sup>3</sup></b>		<b>Core EPS payout ratio</b>	Approximately 50% on average	<b>Five-year average 50.3%</b>			
<b>Main Results</b>				<b>Main Results</b>					
<b>Increase of marketing productivity</b>	<ul style="list-style-type: none"><li>Achieved above average market growth (domestic, Actemra overseas)</li><li>Domestic MR sales productivity up 22%, reached top-class level</li></ul>				<b>Continuous generation of innovative projects</b>	<ul style="list-style-type: none"><li>PC0371 and EOS789 (phase I started), URC102 (entered phase II)</li><li>atezolizumab: In-licensed from Roche, phase III started</li><li>In-licensed 15 new projects domestically and globally</li><li>Pursuing 20 engineered antibody projects at CPR<sup>4</sup></li></ul>			
<b>Acceleration of global development</b>	<ul style="list-style-type: none"><li>Alecensa: Out-licensed to Roche, approved in the U.S., filed in Europe</li><li>emicizumab: Achieved PoC, out-licensed to Roche, phase III started</li><li>3 breakthrough therapy designations in the U.S.</li><li>Developing 11 original global projects</li></ul>				<b>Further strengthening of management infrastructure</b>	<ul style="list-style-type: none"><li>Established new global development scheme with Roche</li><li>Enhancing global R&amp;D functions with expanded CPR and establishment of TCR Division, strengthening supply system for clinical trial materials</li><li>Strengthening medical affairs and drug safety information functions</li><li>Non-Japanese staff up 49%, female managers up 35%</li></ul>			

2. CAGR: Compound annual growth rate (%)

3. Core EPS growth rate: Based on average exchange rates for 2012

4. Chugai Pharmaceutical Research (Singapore)

2. CAGR: Compound annual growth rate (%)

3. Core EPS growth rate: Based on average exchange rates for 2012

4. Chugai Pharmabody Research (Singapore)



## Quantitative Outlook

**Core EPS CAGR**  
(2015-18)

**Low single digit<sup>5</sup>**

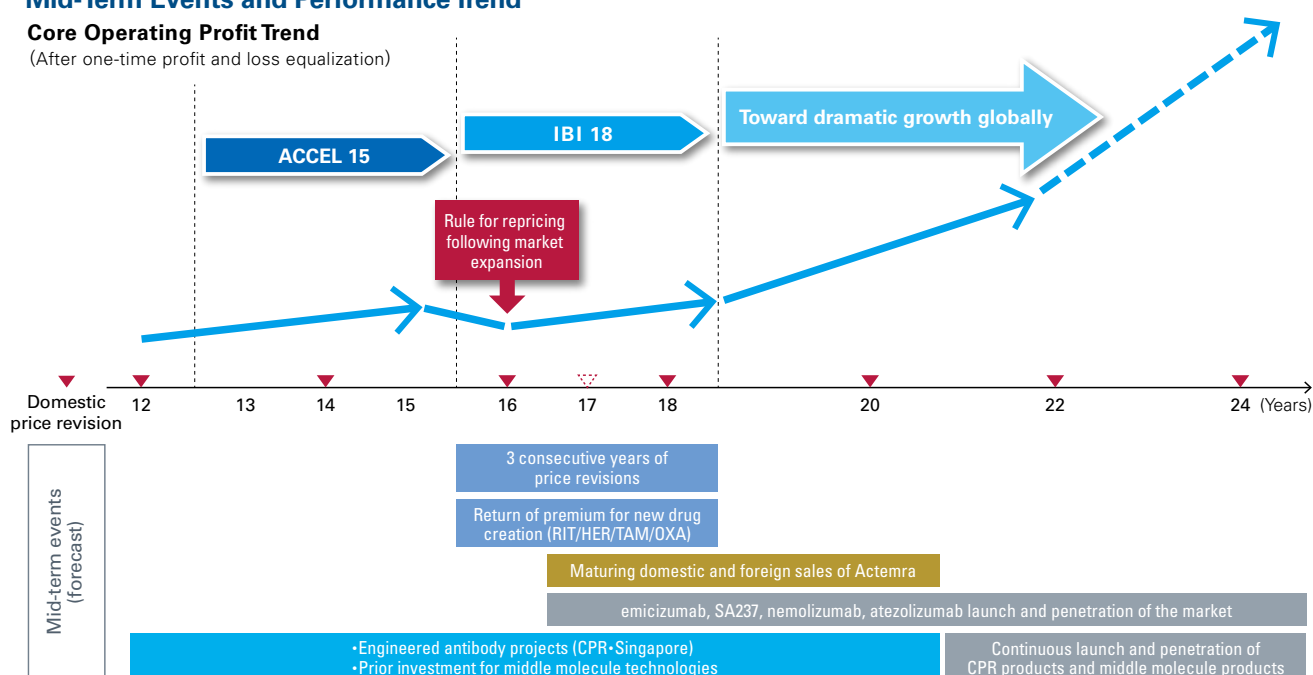
- In the three years of IBI 18, we will establish a solid foundation for dramatic growth in the 2020s.
- We will continue to target a Core EPS payout ratio of 50 percent on average.

5. Growth less than 4%, based on average exchange rates for 2015

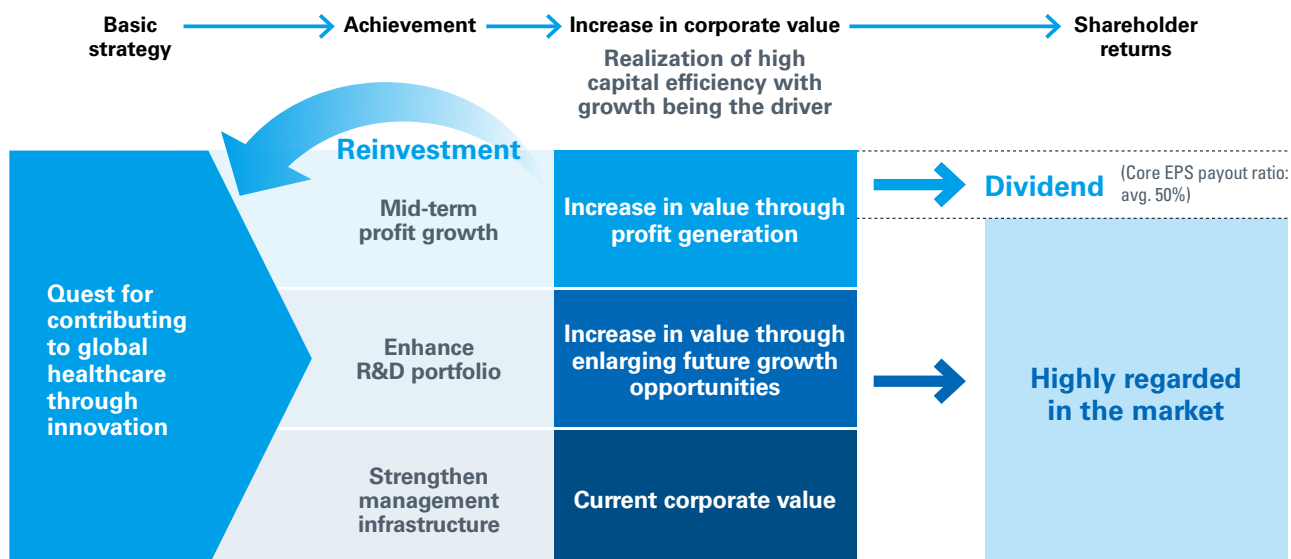
## Mid-Term Events and Performance Trend

### Core Operating Profit Trend

(After one-time profit and loss equalization)



## Basic Principles of Increasing Corporate Value and Shareholder Returns



# Message from the President

## Tatsuro Kosaka

Representative Director,  
President and COO

We will acquire and maintain competitiveness at a top global level through further innovation as we work to increase our corporate value by contributing to medical care and human health around the world.

1. Fully diluted net income per share attributable to shareholders of Chugai after deducting items that Chugai defines as non-Core items
2. A designation program of the U.S. Food and Drug Administration (FDA) aimed at expediting the development and review of drugs for the treatment of severe or life-threatening diseases or symptoms. To receive the designation, preliminary clinical evidence is required demonstrating that the drug may provide substantial improvement over existing therapies on at least one clinically significant endpoint.

## Review of ACCEL 15

### Solid Results and a Strong Foundation for Growth Built under ACCEL 15

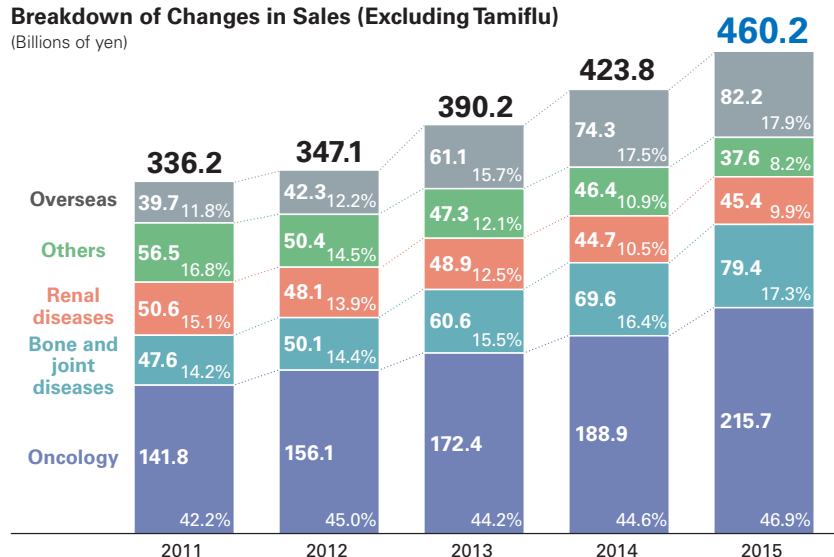
In explaining our strategies going forward, I want to first review the previous mid-term business plan, ACCEL 15 (2013-2015). The changes we made during ACCEL 15 to take full advantage of our strengths under our philosophy, "Innovation all for the patients," yielded results that were even better than our original expectations. Core EPS<sup>1</sup> compound annual growth (based on average exchange rates for 2012), the quantitative guidance in

the plan, was projected to be in the mid-to-high single digits, but the actual result was well above that at 18.3 percent. Sales and profits reached record highs in 2015. We also steadily delivered returns to shareholders at an average Core EPS payout ratio of 49.3 percent over the three years of the plan, in line with our initial outlook.

Qualitatively, we made smooth progress in all four of our strategic policies. The increase in marketing productivity exceeded market growth, and reached a top-class level in Japan. Acceleration of global development was steady. Alecensa obtained approval in the United States and an application for marketing approval was filed in Europe; a phase III multinational study of ACE910 (emicizumab) started; and three products from Chugai research, including Alecensa and ACE910, received breakthrough therapy<sup>2</sup> designation, proof of Chugai's drug discovery capabilities. In continuous generation of innovative projects, three Chugai projects advanced to the clinical phase, and we joined eight phase III multinational studies with atezolizumab, an immune checkpoint inhibitor with blockbuster potential. Chugai Pharmabody Research (CPR), which we established in Singapore in 2012, also made steady progress in antibody discovery. To further strengthen our management infrastructure, we amended our global development arrangement with Roche in 2014, allowing us to concentrate more resources on early-stage development. As a result, we established the Translational Clinical Research Division to strengthen early-stage development functions and reinforced our clinical trial supply chain. We also significantly

## 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.



## Potential of Projects after PoC

(Outlook as of December 31, 2015)

★★★
<ul style="list-style-type: none"> <li>• <a href="#">emicizumab (ACE910)</a></li> <li>• <a href="#">nemolizumab (CIM331)</a></li> <li>• <a href="#">atezolizumab (RG7446)</a></li> <li>• <a href="#">obinutuzumab (GA101)</a></li> <li>• <a href="#">gantenerumab (RG1450)</a></li> </ul>
★★
<ul style="list-style-type: none"> <li>• <a href="#">Alecensa</a></li> <li>• <a href="#">lebrikizumab (RG3637)</a></li> <li>• <a href="#">peretinoin (NIK333)</a></li> </ul>
★
<ul style="list-style-type: none"> <li>• <a href="#">SA237</a></li> </ul>

Chugai original products

In-licensed products

Underline: Therapeutic antibody

Peak sales scale

★★★ 【Chugai】Global (local) over  
¥200 billion

【Introduction】Domestic over  
¥20 billion

★★ 【Chugai】Global (local) over  
¥100 billion

【Introduction】Domestic over  
¥10 billion

★ 【Chugai】Global (local) below  
¥100 billion

Note: See page 26 for details on  
development projects.

enhanced infrastructure in other functions including discovery, medical affairs and drug safety information.

## Medium-to-Long-Term Outlook

### Challenging Conditions in Japan and Globally

The steps we took under ACCEL 15 created a solid foundation for steady growth. Now we must focus on new innovations to meet the challenges ahead.

The global pharmaceutical market is likely to continue to grow as aging populations worldwide heighten the importance of medicines that support people's lives. Advances in science and technology will lead to a more detailed understanding of disease mechanisms, exemplified by the use of information and communication technology (ICT) for genetic information analysis, and to more opportunities for innovating new treatment options such as next-generation antibodies and regenerative medicine. On the other hand, drug companies are facing intensifying competition, including from other industries, to increase the speed of research and development.

In Japan, the rapid aging of the population and government budget constraints are placing even stronger downward pressure on drug costs. Market growth is therefore projected to remain at a low level. A new rule for repricing following market expansion that was introduced in the drug price revisions of April 2016 will have a significant impact on Avastin, one of our core products. Furthermore, if another round of price cuts takes place with the consumption tax increase in April 2017, prices will have been reduced for three consecutive years, creating very difficult conditions in the Japanese market. As for Chugai products, we must return the premium for new drug creation for Oxarol and Tamiflu in 2016, and for Herceptin and Rituxan in 2017, a year ahead of schedule, if the third round of price revisions takes place.

### Adding to Our Definition of "Top Pharmaceutical Company" for Global Success

Under these circumstances, Chugai must further evolve its strengths and transform into a globally successful company in order to continue to deliver value to patients worldwide. To that end, we amended the quantitative

targets for the "top pharmaceutical company" we are aiming to become by the late 2010s. In addition to our existing sales and profit targets, we set new targets from the perspective of increasing our domestic and overseas presence. (For details on the quantitative targets, see pages 10 and 35.)

## Overview of New Mid-Term Business Plan IBI 18

### Acquiring and Maintaining Competitiveness at a Top Global Level

The name of the new mid-term business plan we launched in 2016 is IBI 18. It was taken from the initials of our slogan, "INNOVATION BEYOND IMAGINATION," to express our commitment to achieving even greater transformation and raising our corporate value to become a top pharmaceutical company.

The priority agenda objectives in IBI 18 are "acquisition and implementation of competitiveness at a top global level" and "selection and concentration strategy for acceleration of growth." We believe that the key to successfully meeting these objectives is to capitalize fully on Chugai's unique business model through the alliance with Roche. In the discovery and early clinical development phases, where uniqueness and diversity are important, we will invest resources in discovery utilizing Chugai's innovative proprietary technologies, and will focus on proving the medical and economic value of drug candidates at an earlier stage. In late-stage development and after launch, global economies of scale and operations tailored to the conditions in each region are essential. Therefore, we will focus on rapid late-stage development and market expansion globally in collaboration with Roche and other licensees while working to maximize the value of our in-house products and those in-licensed from Roche in Japan and our other marketing territories.

### Priority Agenda Objectives by Function in Order to Transform into a Globally Successful Company

Each of our core business functions will be transformed in accordance with the two priority agenda objectives of IBI 18.

In drug discovery, we will aim for continuous creation of first-in-class and best-in-class projects utilizing innovative technologies while



3. Clinical research ranging from preclinical research to PoC that clinically verifies the scientific concept that was developed through drug discovery operations
4. Chugai established the Translational Clinical Research Division in 2015 to specialize and solidify its functions in early clinical development to rapidly achieve PoC for development projects from in-house research, and quickly move them into global development.
5. A demonstration that the therapeutic effect conceived in the research stage is effective in humans.
6. A plan from development to launch that establishes a story showing the value of a clinical candidate. An IDCP is typically prepared by the PoC stage, and is created through cross-functional cooperation from the discovery stage.

prioritizing investment in CPR to accelerate research projects and establish new innovative technologies. In addition, we have selected drug discovery technologies for middle molecules as a candidate for our next-generation core technology in addition to antibody engineering and small-molecule technologies, and will make concentrated investments to establish this new candidate and quickly generate projects. We will also strengthen our research foundation in oncology and immunology by using genetic information analysis and other technologies through collaboration with our external network.

Our objective in development is to promote faster launches and quick market penetration based on global top-class translational clinical research (TCR)<sup>3</sup> and development activities. Development of potential future growth drivers emicizumab and atezolizumab will be a top priority. Based on the global TCR structure<sup>4</sup> we established in 2015, we will concentrate resources on early-stage development to quickly achieve proof-of-concept (PoC).<sup>5</sup> We will also begin creating integrated development and commercialization plans (IDCP)<sup>6</sup> at an earlier stage by coordinating various functions and focus on establishing evidence to demonstrate medical and economic potential at the PoC stage, in addition to accelerating late-stage development and market penetration.

In pharmaceutical technology (PT), which plays an important role in both late-stage development and after launch, we will focus on strengthening the PT system for multiple and simultaneous global development projects, fast global launches and cost

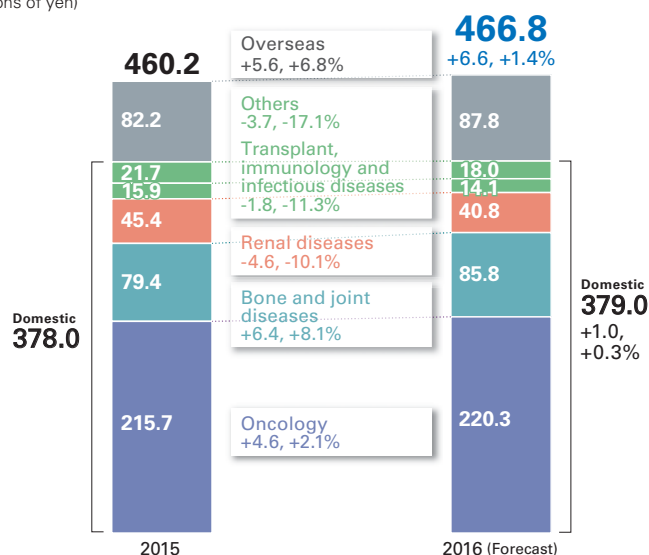
reductions. We intend to establish a flexible facility and personnel structure to enable timely supply of investigational drugs and investigational antibodies for clinical trials to achieve early PoC, and upgrade production technology to handle projects for middle molecules and other difficult-to-formulate compounds. In addition, capital investments will be made in the Ukima plant and other facilities to build a speedy and cost-competitive production system for seamless supply from late-stage development to initial commercial production. At the same time, we intend to improve our responsiveness to regulatory trends in major global markets.

In sales, medical affairs and safety, we will provide advanced and diverse solutions through both independent roles and cross-functional cooperation to address the dramatic changes expected in the healthcare delivery environment and need. We will concentrate on growth drivers such as Avastin and Actemra and new products such as emicizumab and atezolizumab. We must enhance our ability to help solve medical issues by breaking divisional silos through cooperation between sales, medical affairs, safety and other functions to provide more sophisticated information and healthcare coordination support. To respond more accurately to diverse healthcare needs in different areas, we intend to organize cross-functional teams based on local characteristics to enable each area to formulate and implement its own strategies.

To achieve these priority objectives, our human resources will unquestionably be the source of value. In IBI 18, we are placing even greater emphasis on successively developing the talent necessary for driving innovation and responding to the rapid changes in our operating environment. We will identify critical positions, establish their talent profiles, and carry out systematic and speedy acquisition, development and assignment of people appropriate for those positions.

## 2016 Sales Forecast (Excluding Tamiflu)

(Billions of yen)



## Quantitative Outlook of IBI 18

### Plotting a Steady Course to Rapid Growth in the 2020s

In addition to the challenging outlook I described, Actemra, a growth driver that has maintained double-digit growth up to now, is expected to continue growing through this decade, but is likely approaching the maturity stage of its product lifecycle.



## Progress toward Quantitative Targets for Becoming a Top Pharmaceutical Company (2015)

### 1. Gain a position among the top three major Japanese pharmaceutical companies<sup>1</sup>

Domestic sales share	Ranked 4th <sup>2</sup>	△
Consolidated operating profit to revenue	Ranked 2nd	○
Consolidated operating profit to revenue per employee	Ranked 1st	○
Domestic sales per MR <sup>3</sup>	Ranked 2nd	○

### 2. Gain the top share in our strategic therapeutic fields in Japan

Oncology	Ranked 1st <sup>2</sup>	○
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#### Other main fields in 2015:

Renal (ESA): 2nd<sup>2</sup>  
Osteoporosis: 3rd<sup>2</sup>  
Rheumatoid arthritis: 3rd<sup>2</sup>

### 3. Increase overseas sales ratio

Overseas sales ratio	21.8%	○
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○ = Achieved △ = Almost achieved

1. Financial results: Chugai: 2015, other companies: Years ended December 31, 2014 or March 31, 2015

2. Copyright 2016 IMS Health  
Source: JPM 2015. Reprinted with permission. The scope of the market is defined by Chugai.

3. Calculated by Chugai, based on data from Fuji-Keizai Co., Ltd.

On the other hand, our post-PoC pipeline contains many highly promising projects. We have five compounds, including two from in-house research, with sales potential of ¥20.0 billion in Japan and ¥200.0 billion globally, and three with sales potential of ¥10.0 billion in Japan and ¥100.0 billion globally. Accelerating the development and market penetration of these projects will be a primary mission for the next three years.

In 2016, we expect the sales volume of core products in oncology and bone and joint diseases to expand steadily. However, the drug price revisions I discussed earlier will have a major impact, and with a decrease in royalties and other operating income due to a decrease in one-time income in comparison with 2015 and lower prices for Actemra exports to Roche, we are projecting a 0.8 percent year-on-year decrease in revenues, a 21.7 percent decrease in Core operating profit and a 20.5 percent decrease in Core EPS.

While results will drop temporarily in 2016, we will generate solid profit growth over the next three years and lay the foundation for rapid growth in the future by steadily executing our strategies.

Based on this outlook, in IBI 18, we project a Core EPS compound annual growth rate in the low single digits (less than 4 percent), based on average exchange rates for 2015. Our aim will be to begin a period of rapid growth in the 2020s by launching a succession of new products from our innovative research and robust pipeline that includes future key growth drivers emicizumab and atezolizumab.

dividends per share totaled ¥58, including a ¥6 special dividend.) We remain committed to generating steady profit growth while maintaining appropriate returns to shareholders to realize our goal of becoming a top pharmaceutical company.

## Value Creation Going Forward

### Speeding up Innovation to Contribute to Global Healthcare

I believe that Chugai's growth to this point stems from its commitment to innovation solely for the benefit of patients. The strengths we have now, including drug discovery capabilities on par with the world's leading pharmaceutical companies, are the result of continuous patient-oriented improvements and evolution.

As for competitiveness at a top global level, of course I do not think it will be easy to attain, but it is certainly achievable if we fully leverage our advantages through selection and concentration and increase the speed of innovation. I am confident we have the ability to do so.

Chugai's commitment to contributing to patients and healthcare worldwide will continue. I would like to thank all our stakeholders for their ongoing support.

### Tatsuro Kosaka

Representative Director,  
President and COO



## Capital Strategy and Shareholder Returns

### Returns for Shareholders from Higher Corporate Value

Chugai's basic strategy is to continuously generate profits and increase its corporate value by focusing on innovation. The results will then be returned to shareholders through higher valuation in capital markets and stable dividends.

In IBI 18, we will continue to target a Core EPS payout ratio of 50 percent on average while maintaining stable dividends. Based on that policy, we plan to pay cash dividends of ¥52 per share for 2016, with a projected Core payout ratio of 56.2 percent. (For 2015, cash

# Opportunities and Risks

Chugai identifies global and domestic opportunities and risks, and uses them as assumptions in strategic planning. We also identify risks to business continuity from the perspective of risk management, and are working on proactive and reactive countermeasures.

## Main Opportunities and Risks in the Pharmaceutical Industry (Background for Formulation of Mid-Term Business Plan IBI 18)

Opportunities	Risks
<b>Global</b> <ul style="list-style-type: none"> <li>Increasing importance of pharmaceuticals due to growth and aging of the global population</li> <li>Increase in opportunities to innovate due to advances in life science and ICT</li> </ul> <b>Japan</b> <ul style="list-style-type: none"> <li>Increasing expectations for healthcare-related fields, including the emphasis on extending healthy life expectancy in the Japan Revitalization Strategy</li> <li>Initiatives to promote development of breakthrough therapies, including establishment of the <i>Sakigake</i> (forerunner) designation system (fast-track review system) and the inauguration of the Japan Agency for Medical Research and Development</li> </ul>	<b>Global</b> <ul style="list-style-type: none"> <li>Accelerating pace of competition in innovation in order to grow</li> <li>Progress of measures to curb healthcare costs in various countries</li> <li>Declining success rates and rising costs in research and development</li> <li>Tightening of regulations for safety, quality assurance, marketing and other areas</li> </ul> <b>Japan</b> <ul style="list-style-type: none"> <li>Strong pressure to curb drug expenses with the rapidly aging population and financial difficulties</li> <li>April 2016 introduction of a special repricing rule for market expansion</li> <li>Possibility of drug price cuts for a third consecutive year because of the consumption tax increase in April 2017</li> </ul>

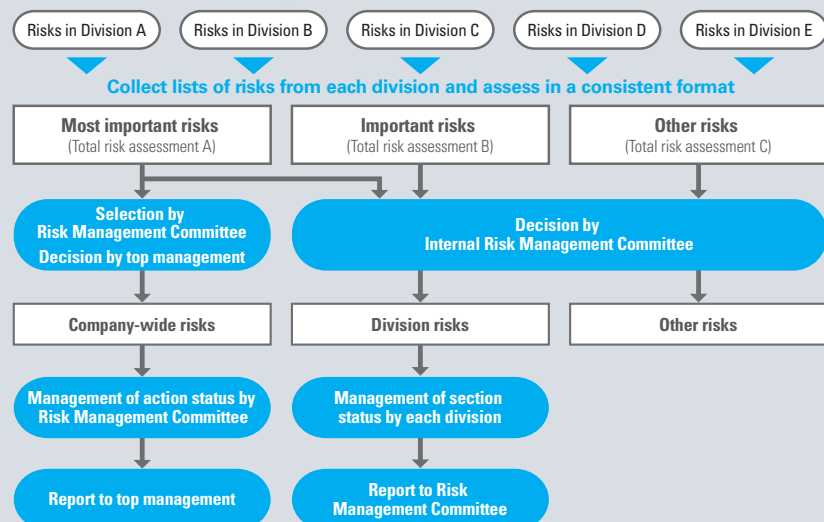
Note: Underlined risks are the background for formulation of IBI 18.

## Company-Wide Risk Priorities

Company-wide risk priorities (Rebuilding of system to prevent employment injuries and promoting action plans for compliance risks)  
Division risk priorities (86), Other priorities (1,114)

Note: Figures in parentheses are the number of risk priorities set in 2015.

### Method for Determining Company-Wide Risks



### Risk Management at Normal Times

We use the following method to prevent and preclude risk.

#### Development of Risk Map

- The Division Risk Management Committee identifies risks in each division during the fourth quarter of every year, develops a risk map, and reports to the Risk Management Committee.

#### Determining and Responding to Division Risks

- Division risks are the risks identified in the risk map for which each division prioritizes countermeasures throughout the year. The divisions dealing with the risks plan and implement countermeasures and report action status to the Risk Management Committee every three months.

#### Determining and Responding to Company-Wide Risks

- The Risk Management Committee designates the risks identified on the risk map that have a particularly strong impact on management as Company-wide risks, selects the divisions that will deal with these risks, and decides which to place on the agenda of the Executive Committee.
- The divisions that deal with the risks plan and implement countermeasures and report action status to the Risk Management Committee every three months.
- The Risk Management Committee assesses the content of action status reports and reports to the Executive Committee as needed.

### Historical Overview of Company-Wide Risks

#### 2010

- Promotion of countermeasures against large-scale earthquakes
- Promotion of countermeasures against new influenza strain
- Change to high-level information management

#### 2011

- Enhancement of countermeasures against mental health diseases
- Establishment of compliance system for Chugai overseas affiliates

#### 2012

- Promotion of countermeasures against large-scale earthquakes

#### 2013

- Promotion of countermeasures against large-scale earthquakes

#### 2014

- Promotion of countermeasures against large-scale earthquakes
- Rebuilding system to prevent employment injuries
- Promotion of action plans for compliance risks

## A Conversation between the Deputy Chairman and the Outside Directors

# Creating New Value beyond Our 90th Year



From left

### Yasuo Ikeda

Director, Chugai Pharmaceutical Co., Ltd.  
Vice-Chairman of the Board of Directors,  
Musashi Academy of the Nezu Foundation,  
University Professor of Waseda University,  
Professor Emeritus of Keio University

Mr. Ikeda became a Chugai director in 2010 after serving as Director of the Keio University Hospital Blood Center, professor in the Keio University Department of Medicine, and Director of that department.

### Masayuki Oku

Director, Chugai Pharmaceutical Co., Ltd.  
Chairman of Sumitomo Mitsui Financial Group, Inc.

Mr. Oku joined Sumitomo Bank, Ltd. in 1968. In 2005, he was appointed President and Chief Executive Officer of Sumitomo Mitsui Banking Corporation and Chairman of Sumitomo Mitsui Financial Group, his current position. He became a Chugai director in 2015.

### Motoo Ueno

Representative Director, Deputy Chairman  
Corporate Social Responsibility, Audit  
Chugai Pharmaceutical Co., Ltd.

After joining Chugai in 1984, Mr. Ueno served in positions including General Manager of London Representative Office, Director and General Manager of Medical Information Division, Director and General Manager of Clinical Research & Development Division, and Director and General Manager of Research Division. He has been Representative Director and Deputy Chairman since 2012.

Chugai celebrated 90 years in business in 2015. This inspired Representative Director & Deputy Chairman Motoo Ueno to discuss the creation of new value with outside directors Yasuo Ikeda and Masayuki Oku. Their conversation ranges from the value Chugai has built over 90 years to the global value it expects to create in the future.

## The Value Chugai Has Built over 90 Years

**Ueno** Chugai was founded two years after the Great Kanto Earthquake and celebrated its 90th anniversary in 2015. Then, as now, we have worked with various stakeholders to resolve numerous social issues ranging from the stable supply of essential drugs to helping people understand and use standards of care. What are your opinions about the value Chugai has created over the past 90 years?

**Ikeda** I was the Director of Keio University Hospital Blood Center when Chugai began developing biopharmaceuticals and changing significantly during the 1980s. I was deeply impressed by Epogin and Neutrogen as pioneering biopharmaceuticals in Japan that became essential to healthcare. I subsequently paid more attention to Chugai, which focuses on biotechnology, creating a series of new, wonderfully original concepts that demonstrate its capabilities as a drug discovery company.

**Ueno** We certainly dealt with setbacks at first. Some questioned whether biotechnology was an effective way to

create drugs. In the context of the times, our decision to develop biopharmaceuticals was among the most momentous in our history.

**Oku** I would say that speed in making management decisions has been part of Chugai's DNA since the beginning. The strategic alliance with Roche in 2002 is a typical example. My impression from that time was that Chugai is a company that actively engages in major transformations, and when I became an outside director in 2015 I realized that Chugai is a company that is always moving forward.

**Ueno** Chugai's management and employees were both motivated by their sense of mission to address unmet medical need, which enabled major transformations such as the development of biopharmaceuticals and the alliance with Roche. We have worked consistently to innovate our capabilities in core areas and functions to bring out the best of our competencies and fulfill our desire to address unmet medical need.

**Ikeda** Chugai really has developed a series of first-in-class drugs to address unmet medical need. The U.S. Food and Drug Administration has designated

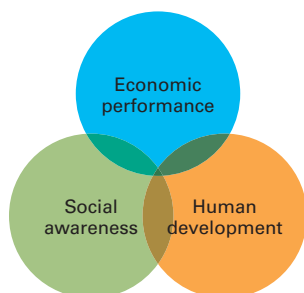




ACE910 and other drugs as breakthrough therapies, which exemplifies growing international recognition for drugs from Chugai research. I sometimes visit laboratories to speak with Chugai scientists, and I am impressed by the willingness to take on challenges, the tenacity and the passion that backs their ability to create new drugs. Their collective efforts are making a real contribution to healthcare.

**Ueno** Thank you. We believe that we have an obligation to leverage our strengths to support patients and healthcare. For example, we have contributed to reducing the drug lag by introducing numerous Roche products in Japan. Chugai has also earned recognition as an industry leader because of its commitment to promoting personalized healthcare and to better regional healthcare.

#### Chugai's Concept of Corporate Value



#### Corporate Value Created from Shared Values and Clear Direction

**Ueno** Chugai needs to leverage the strengths we have mentioned to further enhance corporate value. Economic performance, social awareness and human development are all elements of the comprehensive assessment that determines corporate value. Therefore, earnings growth alone does not define corporate growth – it is also defined by its processes and quality. We need to fuse these three elements on a higher plane to seek value.

**Oku** I agree completely. We need to create an organization for the future that is able to share the value of economic performance, social awareness and human development. That means we need to share information and knowledge, and to transform information into knowledge. Otherwise, the organization cannot grow. We can then share the profits we derive from them in a cycle of value creation.

**Ikeda** Within Chugai, sharing involves inculcating the company's philosophy and strategic concepts. When I attend management meetings of heads of Chugai business functions, I get a clear sense that everyone is looking beyond the boundaries

of their particular departments to have a shared basis for discussion. This is very encouraging. The Japanese government is now emphasizing translational research, which bridges basic research and clinical development. Chugai has already taken the initiative to quickly build an organization that can conduct translational research driven by this interdisciplinary collaboration. The healthcare world increasingly requires a combination of specialization, technological skill and humanity – fusion of the arts and sciences. People who can achieve this will be an important strength in contexts such as interdisciplinary cooperation and collaboration with academia.

**Oku** Yes indeed. Bringing together technology and the liberal arts, fusing the arts and sciences, is the source of innovation. I see Chugai's growth and development as closely linked to Chugai's commitment to using the alliance with Roche to focus intently on being the best rather than on just getting bigger. The alliance with Roche is unique and a rare example of a truly mutually beneficial relationship. It allows Chugai to formulate clear management strategies and focus on its strengths, which accelerates operations.

**Ikeda** Certainly, Chugai's targeted direction is readily apparent. Chugai has identified oncology, renal diseases, bone and joint diseases, and rheumatoid arthritis as strategic therapeutic fields and is concentrating resources in these areas with the goal of being a global leader in each. A leader in Japan in oncology and antibody technologies, Chugai is clearly devoting its core strengths to benefit society.

**Ueno** Friendly competition has made the alliance with Roche outstanding. Initially, the alliance involved extensive discussion of our mutual direction and respective roles, and sometimes required a bit of persuasion. The alliance today is a result of these experiences. In place for 10 years, the alliance has clearly defined roles and responsibilities, and has transitioned to a cooperative framework that enables focused investment of resources in areas of strength. It is a win-win relationship that has evolved to help patients worldwide.

## Chugai Rapidly Creates Global Value to Contribute to Society

**Ueno** Chugai is a leader in addressing unmet medical need, and our stakeholders expect much of us. Going forward, we must deliver value globally, not just in Japan. What advice do you have on creating global value?

**Oku** The alliance with Roche has been remarkably effective, but both companies need to take the dialogue to a higher level. Also, while Chugai and Roche may recognize one another's independence, the two entities do not regard each other as something different in nature. Front-line operations need to embrace differences between the two companies in this way to raise global competitiveness. Symbiosis, not assimilation, is the key. Similarly, we need to accelerate the promotion of diversity in terms of gender, age, nationality and ethnicity.



**Ueno** Diversity is essential for our innovation. A full-scale program begun in 2010 has roughly doubled the number of female managers and the number of organizations with non-Japanese employees in five years, but we aim to make further increases. Also, we will complement diversity in gender, age, nationality and the like by focusing on giving employees with diverse experience and values the opportunity to excel. Improving front-line management skills will be a key priority in addition to system and plan execution.

**Oku** Speed is part of Chugai's DNA, and I would like to reiterate that Chugai must become even faster to compete effectively against global companies. Speed is added value in and of itself.

**Ueno** As you suggest, we need swift decision-making and faster day-to-day operations. A good example is the extremely intense competition in global development. At the same time, stronger corporate governance is essential for sustained growth while maintaining speed. We are committed to prioritizing corporate ethics over profit and will continuously enhance compliance and risk management. Every year we implement increasingly

sophisticated initiatives to identify and map Company-wide risks and implement suitable countermeasures.

**Ikeda** Chugai will have a major role in the future, even from the perspective of the healthcare and pharmaceutical industries as a whole. In Japan, medical expenses have become an issue with the rapid aging of the population and a low birthrate, and matters such as frameworks for collaboration among healthcare facilities and doctors are under discussion. The emphasis in drug discovery must be on efficiency. Efficiency is not defined solely by efficacy, nor by effectiveness in contributing to patient treatment. We also need to consider overall societal efficiency in judging whether a drug is useful for treating patients. Chugai has proprietary technologies such as its breakthrough antibody technology, SMART-Ig. We can leverage these technologies to significantly increase efficiency and lower costs, and we expect them to replace many therapies worldwide. I would certainly like to see Chugai lead the industry in pursuing drug discovery that is meaningful for society.

People all around the world are suffering from illnesses. Chugai needs to focus on domains in which it is strong. We also need to decide if Chugai should expand or maintain its current focus. I expect Chugai to define its domains, grow with a sense of urgency and help patients worldwide.

**Ueno** The three factors that drive growth and value creation for Chugai will not change: economic performance, social awareness and human development. I want Chugai to fulfill its mission by emphasizing core technology strengths and continuity to help resolve social issues including unmet medical need with the spirit of continuous innovation and challenge we have had since Chugai's founding.

**Ikeda** **Oku** Thank you.

# Board of Directors/Audit & Supervisory Board

(As of April 1, 2016)

## Representative Directors



**Osamu Nagayama**  
Executive Director



**Motoo Ueno**  
Executive Director



**Tatsuro Kosaka**  
Executive Director

## Directors



**Yoshio Itaya**  
Executive Director



**Yutaka Tanaka**  
Executive Director



**Yasuo Ikeda**  
Vice-Chairman of the Board of Directors,  
Musashi Academy of the Nezu Foundation,  
University Professor of Waseda University,  
Professor Emeritus of Keio University  
Outside Independent



**Masayuki Oku**  
Chairman of Sumitomo Mitsui Financial  
Group, Inc.  
Outside Independent



**Franz B. Humer**  
Non-executive Chairman of Diageo Plc. (U.K.)  
Outside



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



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

## Audit & Supervisory Board Members



**Kunitoshi Watanabe**  
(full-time)



**Shunji Yokoyama**  
(full-time)



**Hisashi Hara**  
General Representative of the Asia-Pacific  
region, The Law Office of Nagashima Ohno &  
Tsunematsu  
Outside



**Takaaki Nimura**  
Representative of Nimura Certified Public  
Accountant Office, Outside Director and  
Chairman of Audit Committee of Sony Corporation  
Outside Independent

**Independent** Independent officer pursuant to Article 436-2 of the regulations of Tokyo Stock Exchange, Inc.



**Board of Directors** (As of April 1, 2016)**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 Outside 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, Vice 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. (U.K.)  
 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, Head of Lifecycle Management & Marketing Unit  
 2011 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. (to present) and Finance & Accounting Dept.  
 2012 Director, Executive Vice President & CFO (to present)

**Yutaka Tanaka**

1984 Entered Nippon Roche K.K. (NR)  
 2001 Department Manager of Product Research Dept. of Nippon Roche Research Center  
 2002 Senior Specialist of Product Research Dept. of the Company  
 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 (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 Outside Director of the Company (to present)  
 2013 Vice-Chairman of the Board of Directors, Musashi Academy of the Nezu Foundation (to present)  
 2014 Specially Appointed Professor of Waseda University (to present)

**Masayuki Oku**

1968 Entered The Sumitomo Bank, Ltd. (SB)  
 1994 Director, SB  
 1998 Managing Director, SB  
 1999 Managing Director and Managing Executive Officer, SB  
 2001 Senior Managing Director and Senior Managing Executive Officer, SB  
 Senior Managing Director and Senior Managing Executive Officer of Sumitomo Mitsui Banking Corporation (SMBC)  
 2002 Senior Managing Director of Sumitomo Mitsui Financial Group, Inc. (SMFG)  
 2003 Deputy President, SMBC  
 2005 Chairman, SMFG (to present)  
 President and Chief Executive Officer, SMBC  
 2015 Outside Director of the Company (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 Outside Director of the Company  
 2008 Chairman of the Board of Directors of RH  
 Non-executive Chairman of Diageo Plc (U.K.) (to present)  
 2009 Retired as Director of the Company  
 2014 Outside Director of the Company (to present)  
 2015 Director of Bial-Portela & Ca., S.A. (Portugal) (to present)

**Daniel O'Day**

1987 Entered Roche Pharma USA  
 1995 Director Human Resources, Roche Pharma U.S.A.  
 1996 Director Product Marketing, Roche Pharma U.S.A.  
 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, U.S.A.  
 Marketing Research Analyst  
 1990 Abbott Pharmaceutical Products – New York, U.S.A.  
 Neuroscience Sales Representative  
 1991 Sanofi Winthrop – New York, U.S.A.  
 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. U.S.A.  
 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 Committee Members

(As of April 1, 2016)



① **Osamu Nagayama**  
Chairman & CEO

② **Motoo Ueno**  
Deputy Chairman  
Corporate Social Responsibility,  
Audit

③ **Tatsuro Kosaka**  
President & COO

④ **Yoshio Itaya**  
Director, Executive Vice President  
CFO, General Manager of Finance  
Supervisory Div.

⑤ **Yutaka Tanaka**  
Director, Executive Vice President

⑥ **Kunitoshi Watanabe**  
Audit & Supervisory Board Member  
(full-time)

⑦ **Shunji Yokoyama**  
Audit & Supervisory Board Member  
(full-time)

⑧ **Yasushi Ito**  
Vice President  
Head of Project & Lifecycle  
Management Unit

⑨ **Hisafumi Okabe**  
Senior Vice President  
General Manager of Research Div.

⑩ **Susumu Kato**  
Senior Vice President  
General Manager of Marketing &  
Sales Div.



⑪ Hitoshi Kuboniwa  
Senior Vice President

⑫ Shinya Unno  
Senior Vice President  
General Affairs and Secretarial

⑬ Mitsuru Kikuchi  
Senior Vice President  
External Affairs

⑭ Yoshiaki Ohhashi  
Vice President  
Head of Regulatory & Quality  
Management Unit and General  
Manager of Drug Safety Div.





# Corporate Governance Policies

## Message from the Board of Directors

Chugai's mission is to dedicate itself to adding exceptional value through the creation of innovative medical products and services for the benefit of the medical community and human health around the world. Chugai's basic management objective is to become a top pharmaceutical company. Even though it is a member of the Roche Group, Chugai maintains its managerial autonomy and independence as an independent listed company and will constantly strive to perfect its corporate governance to fulfill the mandate of its many stakeholders appropriately and fairly.

Chugai quickly adopted an executive officer system for swifter executive decision-making. In addition, Chugai has actively created advisory boards such as the Appointment Committee and the Compensation Committee to secure management transparency. Moreover, the Board of Directors is appropriately sized; features multifaceted knowledge, experience, skills and expertise; and has an exceptionally diverse composition in terms of nationality, gender, age and other characteristics.

To clarify our corporate governance initiatives and policies and fulfill our obligation to explain them to shareholders and investors, in November 2015 the Board of Directors approved and instituted the Chugai Pharmaceutical Co., Ltd. Basic Corporate Governance Policy.

In accordance with this policy, we will continue to fulfill our responsibilities to all stakeholders including patients, consumers, healthcare providers, business partners, society, employees and shareholders, while sustaining growth and increasing our corporate value. We request the support of our stakeholders in these efforts.

### Detailed Performance Report ..... p. 110

- Basic Approach
- Management Decision-Making, Execution and Oversight of Business Operations
- Reasons for Election of Outside Directors and Outside Audit & Supervisory Board Members
- Independence Standards
- Introduction of Outside Perspectives
- Support System for Outside Directors and Outside Audit & Supervisory Board Members
- Auditing System
- Officer Remuneration
- Maintenance and Management of Internal Controls
- Addressing the Corporate Governance Code

## Addressing the Corporate Governance Code

Based on the Chugai Pharmaceutical Co., Ltd. Basic Corporate Governance Policy, we intend to implement all of the principles of the Corporate Governance Code of the Tokyo Stock Exchange. As of March 31, 2016, we had not completely addressed the following principle, but plan to do so in 2016.

### Supplementary Principle 4.11.3: Summary of the Analysis and Evaluation of the Overall Effectiveness of the Board of Directors

Chugai has not yet analyzed or evaluated the overall effectiveness of its Board of Directors. In 2016 we will analyze and evaluate the status of the activities of the Board of Directors carried out during 2015 and disclose a summary of the results. We plan to do this every year from now on.

## Effectiveness of Corporate Governance

Chugai is focusing on perfecting corporate governance. In keeping with our goal of increasing corporate value, we believe that raising effectiveness is important because simply creating systems and mechanisms is

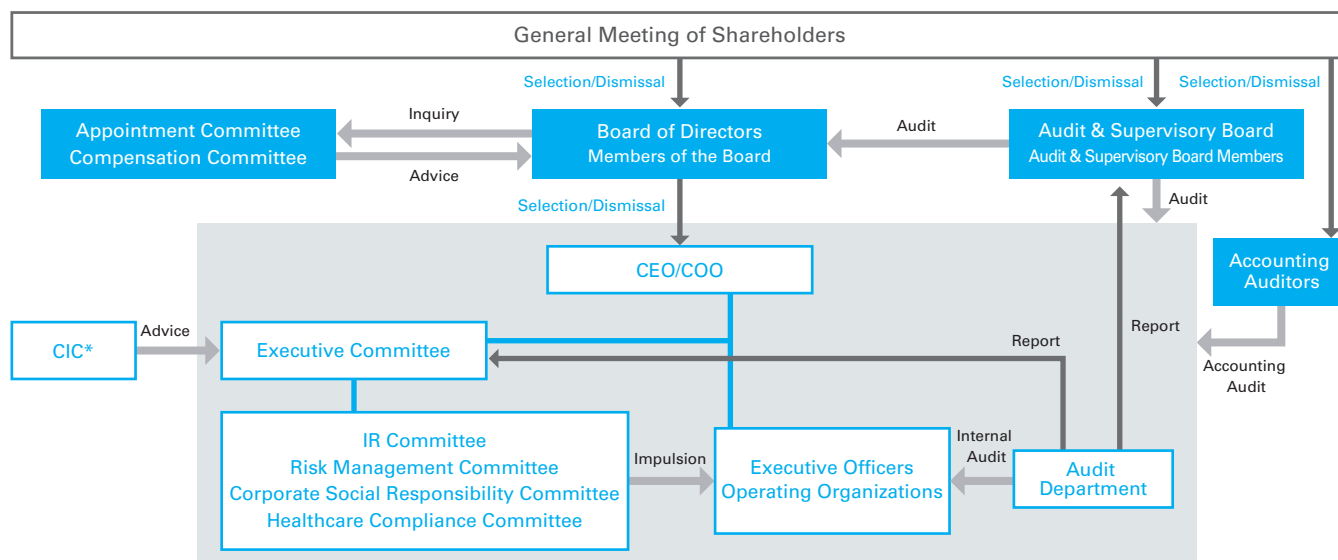
insufficient. While we believe that our current corporate governance is effective to a certain extent, we will constantly endeavor to strengthen it.

Our approach to effectiveness and initiatives for enhancement follow below.

Chugai has an Audit & Supervisory Board to ensure highly effective monitoring of directors from an independent and objective perspective. Management decision-making and monitoring are separated from business execution, and we have introduced an executive officer system. While the Board of Directors is in charge of decision-making with respect to the most important managerial matters, other decisions on business operations are made at organizations such as the Executive Committee, which we believe ensures swift decision-making.

Chugai appoints at least two independent outside directors to introduce outside perspectives, and in November 2015 formulated and disclosed 12 Independence Standards for outside officers. We have also ensured management transparency by establishing boards to advise the Board of Directors. The Appointment Committee, established in March 2007, and the Compensation Committee, established in November 2010, each have at least three

## Chugai's Corporate Governance System



\* To respond accurately to changes in the global business environment and conduct business in an appropriate manner, Chugai established the Chugai International Council (CIC) as an advisory body composed of Japanese, American and European industry leaders and professionals in various sectors to provide it with advice to further enhance decision-making.



Chugai International Council (CIC)

outside members including one independent outside director. Moreover, we believe that outside directors and outside Audit & Supervisory Board members must acquire the knowledge needed for them to fulfill their particular roles and responsibilities. We therefore provide opportunities for and cover the cost of training upon their appointment and throughout their tenure.

We appropriately determine the yearly schedule for the Board of Directors as well as the agenda items and meeting frequency to promote active deliberations of the Board of Directors and to ensure sufficient time for deliberation. We also distribute materials relevant to agenda items well in advance of meetings and provide explanation as necessary to support understanding of the materials. In addition, we have established an environment that gives Board members access to the advice of outside experts such as lawyers, certified public accountants, consultants and academics.

We have also decided to analyze and evaluate the effectiveness of Board decision-making and supervision, and disclose summaries of the results.

agreement between the two companies. Roche and Chugai have agreed to cooperate in maintaining the listing of Chugai's common stock on the First Section of the Tokyo Stock Exchange.\*

The aim of this alliance is to establish a new business model that differs from conventional corporate acquisitions and joint ventures. Although ROCHE HOLDING LTD includes Chugai in its consolidated accounts, Chugai functions as an independent listed company and makes all of its own management decisions based on the principle of self-governance. Chugai believes that autonomy and diversity are key to generating innovation, that maintaining its independent management brings diversity to the Roche Group, and that the pharmaceuticals it creates as a result contribute to all stakeholders, including patients and minority shareholders. 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.

## Relationship with Roche

Roche, the parent company of Chugai, owns 59.89 percent of Chugai's outstanding shares based on the strategic alliance

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

### External Recognition

In 2015, Chugai was selected as a constituent of the Dow Jones Sustainability Asia Pacific Index for the second consecutive year. A total of 600 leading companies in Asia applied for inclusion and 145 were selected, including 62 Japanese companies.

In addition, since 2003 Chugai has been continuously selected as a constituent of the FTSE4Good Index Series, an index for socially responsible investment (SRI). As of January 31, 2016, 803 companies were listed, of which Chugai was one of 176 Japanese companies.

Chugai has been selected as a component of these global SRI indices in recognition of its proactive initiatives from the standpoint of corporate sustainability in areas including the environment, society and governance. Chugai will continue to fulfill its social responsibility as a healthcare company.

MEMBER OF

**Dow Jones  
Sustainability Indices**

In Collaboration with RobecoSAM



## Ensuring the Rights and Equal Treatment of and Dialogue with Shareholders

Chugai is a member of the Roche Group. We believe that securing substantially equal treatment of shareholders is very important. We therefore emphasize giving due consideration to minority and foreign shareholders and to maintaining an environment that allows them to exercise their rights.

Therefore, recognizing that business plans are a commitment to shareholders, Chugai promotes the disclosure of a variety of information and constructive dialogue with shareholders and investors. Directors and executive officers make every reasonable effort to meet requests for interviews from shareholders and investors.

### Restrictions on Roche's Shareholding

Period	Maximum Shareholding
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

### Chugai's Corporate Governance in 2015

Organizational form		Company with an Audit & Supervisory Board
Management and execution		Separated
Introduction of external perspectives		Implemented 5 outside directors <sup>1</sup> (2 of whom are independent directors) and 2 outside Audit & Supervisory Board members (1 of whom is independent) CIC (Chugai International Council) established
Board of Directors	Composition	10 members (5 directors from Chugai, 5 outside directors of whom 2 are independent)
	Number of meetings in 2015	8
Executive Committee	Composition	Management Strategy Committee <sup>2</sup> : 14 members (5 directors, 7 executive officers (excluding directors) and 2 Audit & Supervisory Board members) Business Operation Committee <sup>3</sup> : 12 members (3 directors, 7 executive officers (excluding directors) and 2 Audit & Supervisory Board members)
	Number of meetings in 2015	Management Strategy Committee: 29 Business Operation Committee: 19
Appointment Committee	Chairperson	Outside director
	Composition	5 members (1 director, 3 outside directors and 1 person with experience sitting on an appointment committee)
	Number of meetings in 2015	3
Compensation Committee	Chairperson	Outside director
	Composition	3 members (2 outside directors, and 1 person with experience as an outside director of Chugai)
	Number of meetings in 2015	1
Audit & Supervisory Board	Composition	4 members (2 full-time Audit & Supervisory Board members and 2 outside Audit & Supervisory Board members including one independent Audit & Supervisory Board member)
	Number of meetings in 2015	10 (including 1 extraordinary meeting)
Internal committees		Established IR Committee, Risk Management Committee, Corporate Social Responsibility Committee and Healthcare Compliance Committee

Notes: 1. In 2015, directors from Roche were also regarded as outside directors.

2. Management Strategy Committee agenda items: largely fundamental strategies and policies relevant to overall management

3. Business Operation Committee agenda items: Specific policies and other items that are important for business execution



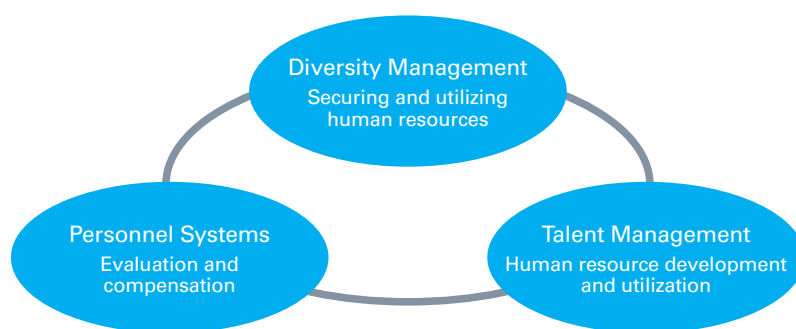
# Human Resource Management

## Human Resource Strategy



In November 2015, a forum was held for persons in charge of diversity promotion from each department on the theme of "Diversity That Leads to Further Development at the Global Level."

People are an invaluable asset in generating a company's growth and development. In line with that fundamental principle, Chugai's human resource management is based on the three pillars of diversity management, talent management and personnel systems. We are fostering an organizational culture of respect for diverse values, not only in attitudes but also through further measures in areas such as personnel systems, mechanisms and work styles to make diversity in human resources a value of our organization. In this way, we will generate innovation and become a top pharmaceutical company.



## Diversity Management

Chugai has placed priority on diversity management to enable a rich variety of employees to work enthusiastically and create new value. To begin addressing this issue, we launched a management working team in 2010 to deal with gender issues and established the Diversity Office in 2012 to promote measures dealing with nationality and age in addition to gender. Besides distributing educational guidebooks to all employees and conducting diversity management training for all managers, we have conducted activities to promote the concept in every department. Through these initiatives, we have deepened understanding and moved to create workplace environments in which diverse employees can make full use of their talents.

In promoting gender diversity, we are taking active steps to provide opportunities for women to succeed. We set a target of 60 female managers in 2015, about twice the number in 2010, and have implemented career planning and development measures. For example, we have organized career forums for women, held gatherings and awareness-raising sessions for employees

## Human Resource Evaluation and Vision

Chugai has grown steadily in recent years, and I believe much of that growth is attributable to the continuously rising quality of our human resources.

In our human resource strategy for becoming a top pharmaceutical company, for example, we are accelerating progress in diversity management and talent management. Indicators such as the percentage of female managers, the number of departments with non-Japanese employees and the number of training programs geared to career development plans, have each roughly doubled in the last five years. Moreover, the number of training programs geared to career development plans is about four times higher than it was 10 years ago. Even when I listen to conversations at various meetings and training sessions, most people are discussing efforts to be more global-minded, and I get a sense that there has been significant change in employees' views.

During the past 10 years, Chugai has aggressively hired new university graduates and mid-career professionals. Employees who joined the Company after the alliance with Roche now make up over 40 percent of our total workforce. Even with this rapid change, the business philosophy we have held since our founding, "Innovation all for the patients," has remained firmly embedded. I think this is

one of our strengths, along with our corporate culture that emphasizes human resource development.

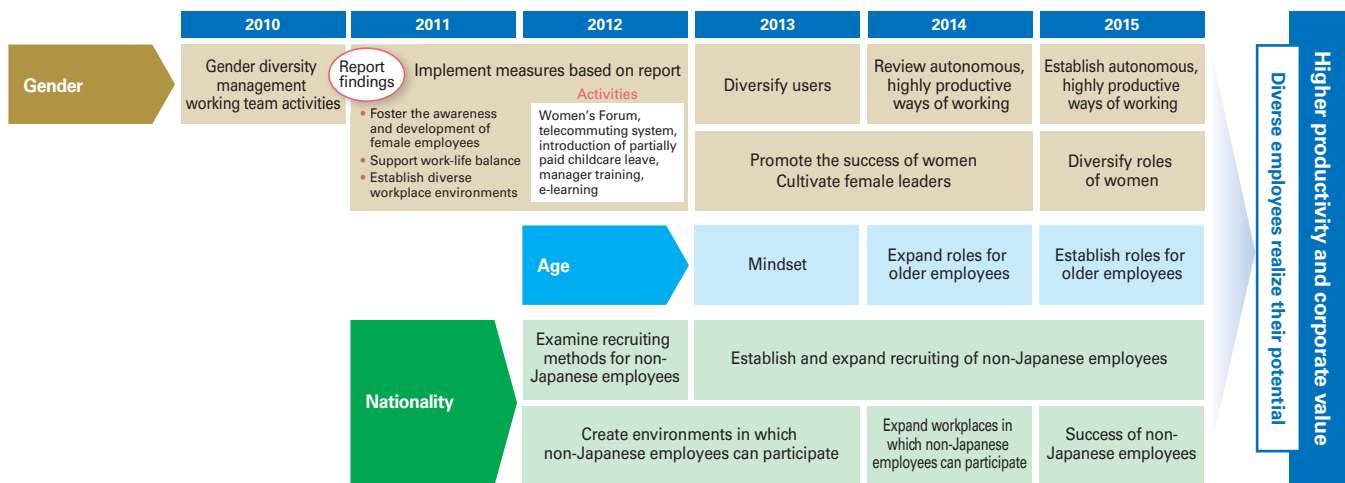
However, our efforts to raise the level of our human resources will never stop. We intend to enhance diversity management and talent management even more quickly, and increasing the value that every employee contributes (i.e., their productivity) will remain an important objective. In addition to strategic initiatives, our future efforts will include fundamentally changing ways of working. I want to foster a global mindset in as many of our employees as possible.

### Mamoru Togashi

Vice President  
General Manager of Human  
Resources Supervisory Div.



## Diversity Promotion Roadmap



## External Recognition



At the awards ceremony of the Commendation of Companies Promoting Gender Equality and Work-Life Balance for 2014, sponsored by the Ministry of Health, Labour and Welfare, Chugai received the Minister's Prize for Excellence (Companies promoting gender equality) and the Tokyo Prefectural Labor Bureau Chief's Prize for Excellence (Family-friendly companies) in recognition of its diversity initiatives.



For two years in a row, Chugai has been selected as a "Nadeshiko Brand" for its exceptional record in promoting the success of women.



"Kurumin" mark

who are caring for children, and introduced a female leader program to develop upper-level leaders. As of December 2015, Chugai Pharmaceutical had 62 women in management positions, and women accounted for 10.7 percent of all managers. Our goal for 2018 is to raise that percentage to 13 percent. To achieve this goal, we will cultivate future candidates among female employees to ensure the steady development of female managers to expand the ranks of the next generation of leaders.

To promote the success of older employees, we are building awareness of career training and other programs, as well as engaging every employee by establishing working systems and providing opportunities to play important roles. The number of non-Japanese people we employ in Japan is also increasing. We provide information and support for non-Japanese employees, organize gatherings and take other steps to create a better environment for working together with Japanese colleagues. In addition to attributes such as gender and age, we are diversifying in terms of employees' work styles, including telecommuting. We will continue our efforts to foster an inclusive organizational culture so that all employees can make the most of their abilities regardless of gender, nationality or age.

## 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. In 2008, 2011 and 2015, Japan's Ministry of Health, Labour and Welfare certified Chugai under the Act on Advancement of Measures to Support Raising Next-Generation Children, and the Company is currently conducting its Phase 4 Action Plan.

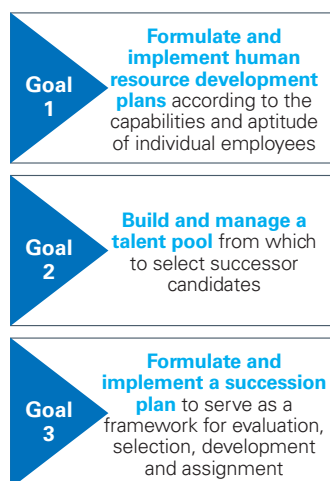
Moreover, beginning from 2007, the labor union and management have been promoting the reduction of excessive working hours. Since summarizing our approach to work-life balance as "the pursuit of work-life synergy" in 2013, we have been working to make the concept understood and adopted by employees. Under this concept, when individuals and workplaces come up with original ways to work and live, and pursue synergy between the two, it helps to expand the potential of individuals and raise the productivity of the organization, thus becoming a win-win relationship for the Company and each employee.

## 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 2015 each organization continued its efforts from the previous year, holding discussions on medium-to-long-term human resource development policy, drafting a human resource development plan and creating a talent pool.\* Based on the development

\* A group of candidates for the next generation of leaders

### Three Goals of the Talent Management System



plans, the organizations carried out strategic employee assignment 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 92 general managers and department managers in Japan. We are currently implementing development plans for these candidates to help them strengthen 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.

### Career Development Framework

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 filing 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 manager to facilitate self-directed career development. We also supplement the basic cycle with various measures to promote further autonomy and mutual growth.

The Career Consultation Office, established in 2007, supports the use of the various career-related systems available within the Company

by providing employees with information for planning their careers and tips on skill development. As of December 31, 2015, a total of 600 people had come to the office for consultation.

### BCG and Human Rights Training

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

The theme for the first half of 2015 was "The gap between awareness and action in practicing the Chugai BCG." Even if people consciously want to make the right decisions and do the right thing, they may be unable to do so because of influences such as the pressures of time and target achievement, and relationships with others. To close this gap between awareness and actions, employees learned how to act before, during and after various situations.

In the second half, the theme was "Personal relations in the workplace: Moving from a single-point to a multi-point perspective." This training shared the idea that people can understand each other's different perspectives by moving a step closer to each other in their interactions, and that applying such an approach in the workplace can lead to new discoveries and a stronger organization.

### Equal Opportunity and Fairness in Recruiting

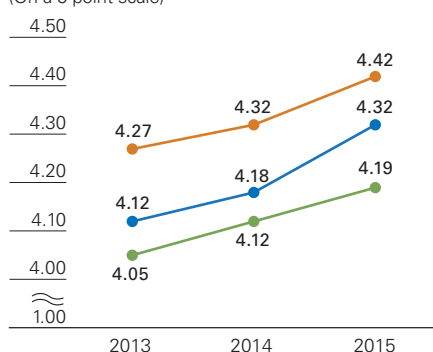
Based on its equal opportunity policy, Chugai treats and compensates its employees equally regardless of gender, age, nationality or disability. In accordance with this policy, we actively seek to hire disabled people in addition to hiring new university graduates, mid-career professionals and non-Japanese. As of December 31, 2015, the ratio of employees with disabilities in the Company was 2.02 percent.

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

### Degree of Penetration of Chugai BCG

(Based on Results of Chugai Employee Survey)\*

(On a 5-point scale)



#### Evaluation Items

- The Chugai Group is practicing CSR appropriate for a top pharmaceutical company through decisions and actions based on the Chugai BCG
- In doing your job, you make judgments based on the Chugai BCG, laws, regulations and other rules
- In your workplace, human rights are respected and there is no discrimination or harassment

\* 2013-2015 Employee Survey  
Copyright Recruit Management Solutions Co., Ltd.



# Feature: Value Creation Driven by Our Strengths

Evolution of Chugai's Seven Strengths in  
New Mid-Term Business Plan IBI 18 ..... 52

Examples of Outcomes from Chugai's  
Strengths: Breakthrough Therapy  
Designation from the U.S. FDA ..... 55





# Evolution of Chugai's Seven Strengths in New Mid-Term Business Plan IBI 18



Chugai has identified its seven core strengths to help stakeholders recognize and understand the sources of its unique value. These strengths were determined through evaluation and analysis from the standpoints of value for patients and competitive advantage for Chugai based on quantitative and comparable information and data.

These strengths were identified as the source of our current value creation. With dramatic changes likely to occur in the external environment, however, simply maintaining our current strengths will not be enough. To create value in the future, we must evolve and refine these strengths.

In new mid-term business plan IBI 18, Chugai aims to raise its corporate value over the medium to long term through innovation of its unique strengths.

## 1 Evolution of Strengths in Marketing

### Solving Problems by Understanding the Patient Flow

Chugai has many outstanding medicines, but those medicines do not necessarily reach all the patients who need them. Our marketing activities as a manufacturer that creates innovative drugs should help to ensure that our medicines are used appropriately by all patients who can benefit from them.

Based on this thinking, during the three years of ACCEL 15, we shifted to a strategy of strengthening area marketing based on an understanding of the patient flow at the local level. We produced visualization tools to provide a clear picture of the situation in order to understand the patient flow from the viewpoint of "disease" flow, from testing and diagnosis to standard of care and continuation of treatment, and the "functional" flow, from primary care physician to acute care hospital, rehabilitation hospital and home care. Information based on real-world data such as disease rates, screening rates, diagnosis rates, availability of testing equipment, sales of each drug and rates of adherence to medication was put into a database. We then pinpointed the junctures of these various elements that formed bottlenecks to delivering effective treatment to patients, and applied that information in concrete activities and disease-specific strategies in each local area to resolve those bottlenecks.

As a result, timely decision-making was implemented by our MRs and we were able to uncover latent demand and promote appropriate drug use, which led to a dramatic increase in marketing productivity. But the most noticeable effect was the improvement in the motivation of our MRs. They experienced first-hand how their activities were directly



**Susumu Kato**  
Senior Vice President  
General Manager of Marketing & Sales Division

connected to the resolution of healthcare issues, and their own analyses and judgments have led to continuous innovation in clinical practice.

### Creating Added Value with Pride and a Sense of Mission

Based on these results, we plan to carry out more sophisticated area marketing. If we broadly divide our marketing activities into consulting and liaison activities, our consulting activities are at a high level compared with other companies. We will make structural changes to further enhance our expertise in oncology, and will focus on collaborative initiatives among the Marketing & Sales Division, Drug Safety Division and Medical Affairs Division to prepare for new regulations on MR activities. On the other hand, we plan to put greater emphasis on strengthening

our liaison activities to help enhance cooperation among healthcare facilities and among healthcare providers, particularly collaboration between specialists and primary care physicians to improve screening rates, testing rates and adherence rates. By demonstrating leadership in our therapeutic areas through such initiatives, we will achieve further growth.

We create appropriate paths so that our medicines, which can benefit patients, will be selected by healthcare providers. This simple effort inspires our employees to generate added value with pride and a sense of mission in their work. We are confident that the results will lead to a higher level of satisfaction among healthcare providers.



## Strengths That We Will Evolve (Marketing, Medical Affairs and Drug Safety)

- 
- Strong product portfolio in oncology, where Chugai has the top domestic market share ①
  - Innovative drugs that address unmet medical need
  - MRs with a high level of expertise
  - Support for the coordination of regional healthcare ⑦
  - Ability to collect and analyze safety data and plan safety measures ⑥
  - Global-level safety evaluation and analysis system
  - Provision of evidence-based safety information ⑥
  - Strong support from medical staff ⑦
  - Further expansion of Chugai's market presence by focusing on growth drivers and ACE910 (emicizumab) and atezolizumab
  - Enhancement of consulting functions and of liaison functions through verification of the patient flow
  - Convey easy-to-use safety information by strengthening communication globally, and strengthen epidemiology functions
  - Area-based structure in which marketing, medical affairs and drug safety operations collaborate to provide their respective expertise

Note: Circled numbers indicate connection with one of the seven strengths.

## 2 Evolution of Strengths in Safety

### The Importance of Sharing Safety Information

Chugai's Drug Safety Division has gained solid recognition for its advanced initiatives such as collection of safety information on more than 180,000 cases annually, and monitoring and evaluation of those cases. In the last three years, we have made additional innovations, including the establishment of departments focusing on communication and epidemiology, and established a presence as a domestic industry leader in drug safety initiatives.

The Drug Safety Division strengthened its functions after the introduction of risk management plan (RMP) requirements in 2013. Moreover, providing and sharing information on medicine has become critically important in addition to the product itself, as per the requirement in the revised Pharmaceutical Affairs Law (the Pharmaceuticals and Medical Devices Act) of 2014 stipulating that people must make efforts to inform themselves about drug efficacy and safety. In these circumstances, Chugai is strongly committed to ensuring that easy-to-understand, scientifically verified safety information is communicated to patients.

### Our Responsibility to Lead the Industry in Raising the Level of Drug Safety Information

Since becoming mandatory in Japan, RMPs have not been sufficiently utilized in clinical settings due to a lack of awareness and understanding of RMPs among healthcare providers. Even as a sincere commitment by the pharmaceutical company, an RMP is meaningless if it is not used. At Chugai, we compiled RMPs, which can be dozens of pages long, into easy-to-understand summary versions based on examples implemented at advanced medical institutions, and formatted them for tablets and other devices for the convenience of busy healthcare



Yoshiaki Ohhashi

Vice President, Head of Regulatory & Quality Management Unit and General Manager of Drug Safety Division

providers. Chugai proposed this approach to the Japan Pharmaceutical Manufacturers Association, and is cooperating with the Japan Society of Hospital Pharmacists to promote the use of RMPs and the summary versions nationwide. Chugai plans to expand its efforts beyond RMPs to include other information needed in clinical practice in collaboration with pharmacists, who frequently deal with safety information. In 2015, Chugai gave 10 lectures at seminars for hospital pharmacists, a first in the pharmaceutical industry. Encouraged by solid recognition of these activities, Chugai will develop new methods of providing and using information.

On the other hand, we believe more innovation is needed in epidemiology. Currently in Japan, data obtained in post-marketing surveillance is centered on patients who were given drug treatments.

However, scientific comparative analysis cannot be done without data on people who did not receive those drugs. In other countries, insurance companies have huge epidemiology databases, but Japan is behind in that area. Although building an epidemiology database takes time, Chugai is focusing on raising the level of epidemiology in Japan through cross-departmental research projects and other initiatives, in addition to the efforts of an internal group specializing in epidemiology.

Drug safety is critical for contributing to patients and the medical community, and therefore to a company's valuation and long-term growth. With our proven track record of leadership in the Japanese pharmaceutical industry, we now have a responsibility to accumulate results through grassroots-level activities while building safety information into a source of added value by working to influence regulatory authorities, various associations and the industry.

Chugai is committed to evolving its strengths in drug safety, and linking those strengths to sustainable growth.

## Strengths That We Will Evolve

(Research, Clinical Development and Production)

- Products under development for unmet medical need ②
- Abundant experience in advancing biopharmaceuticals to approval ④

- Proprietary antibody engineering technologies
- Drug discovery technologies for middle molecules ④
- Top-level biotechnology capabilities in Japan
- Biomarker measurement technologies and system for simultaneous development with drugs ⑤

- Strengthening of early PoC achievement aimed at speeding up global development
- Stronger competitiveness and centralized management of global development under the Translational Clinical Research Division

- Establishment of discovery technologies for cyclic peptides and other middle molecules and production technologies for middle molecules, etc., in addition to the platform of antibody engineering and small molecule drug discovery technologies

- Enhancement of biomarker discovery and application of genetic analysis information in discovery research and clinical development, in collaboration with Roche and others

Note: Circled numbers indicate connection with one of the seven strengths

## 3

## Evolution of Strengths in Research, Development and Production

### Linking the Successes of ACCEL 15 to Further Innovations

For Chugai, which places primary emphasis on the creation of innovative drugs, the three years of ACCEL 15 were a period of significant progress. Whether in creation and in-licensing of innovative projects, advancement of late-stage development projects, or the number of product approvals and launches, we demonstrated world-class drug discovery capabilities. We also greatly increased our competitiveness in global development with the establishment of a system for simultaneous development of multiple projects and faster launches. Contributing to these successes was the establishment of capabilities for continuously creating in-house products, including the development of proprietary antibody technologies, the establishment of a development model with a high success rate, and the creation of a seamless production system for investigational drugs. Another factor was the improvement in quality and speed across every function to deliver those products to patients.

However, research and development conditions around the world are constantly changing due to technological innovations, including advances in information and communication technology (ICT). Chugai's strengths will inevitably become obsolete unless they evolve. In IBI 18, our strategy is to continuously work on the next innovations while building on the success of ACCEL 15.

### Promoting Continuous Innovation and Evolution of Our Technologies

Chugai's drug discovery is based on unique technologies. While we will focus on further developing proprietary antibody engineering technologies, we have selected technologies for discovery of middle



**Yutaka Tanaka**  
Director and Executive Vice President

molecules as our next-generation core technology candidate. Middle molecules have significant potential because they are capable of blocking protein-protein interaction in intercellular molecules, which is difficult to achieve with antibodies and small molecules. Chugai will continue to concentrate investment of resources on this area to quickly create projects. Oncology and immunology will be our focal therapeutic fields, and we will strengthen our research foundation by collaborating with external networks and utilizing genetic analysis information.

In development, we will focus resources on accelerating achievement of early PoC with the global development structure we established in 2015 that coordinates preclinical and clinical development. While our pipeline is expected to remain full, we will work to further increase development speed by establishing a model to raise prediction accuracy in translational research and identifying new parameters.

To realize faster development, in production we will establish facilities capable of handling high-mix, low-volume production, which will facilitate simultaneous development of multiple products and early product launches. We will also raise the sophistication of our formulation technology, already considered among the most advanced in the industry, to handle middle molecules and other difficult-to-formulate compounds.

In areas of high unmet medical need, which we focus on, it has become difficult to bring a product to market unless it is a groundbreaking drug with the potential to be designated as a breakthrough therapy. We will continue to move forward and evolve to help patients around the world who are suffering due to a lack of effective treatments.

# Examples of Outcomes from Chugai's Strengths: Breakthrough Therapy Designation from the U.S. FDA

## The Significance of Breakthrough Therapy Designation Proof Positive of Drug Discovery Capabilities

Breakthrough therapy designation (BTD)<sup>1</sup> was introduced by the U.S. Food and Drug Administration (FDA) in July 2012. Its purpose is to expedite the development and review of medicines to treat serious or life-threatening diseases or conditions.

BTD can be seen as an assessment by the FDA that a therapy may provide a significant improvement over existing therapies in filling an unmet medical need, and that the company has the capability to create breakthrough therapies.

In recent years, Chugai has obtained BTD in quick succession for Alecensa, ACE910 (emicizumab) and Actemra (for systemic sclerosis).

This is an outstanding accomplishment for Chugai, which primarily creates novel drugs with first-in-class or best-in-class potential.

It also represents the outcome of our search for the points where our proprietary antibody technologies merge with areas of unmet medical need, and of our rapid drug discovery process using Roche's cutting-edge discovery infrastructure.

1. In breakthrough therapy designation, preliminary clinical evidence is required demonstrating that the drug may provide substantial improvement over existing therapies on at least one clinically significant endpoint.

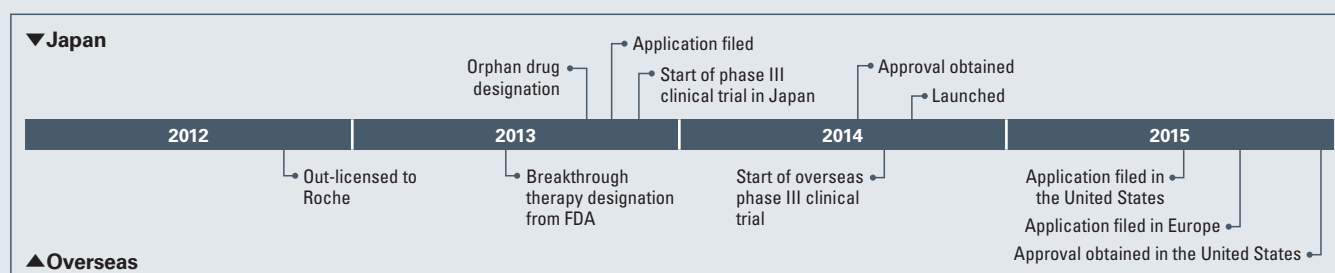
## 1 Significance and Expansion of Alecensa

In 2007, the *ALK* fusion gene was discovered by a team led by Dr. Hiroyuki Mano of Jichi Medical University (now at University of Tokyo), and was reported to be a strong causative gene in lung cancer. Soon after that, Chugai began developing an *ALK* inhibitor. Through repeated trial and error, we successfully created Alecensa, an *ALK* inhibitor with high selectivity, powerful inhibitory activity, and a potential effect on brain metastasis. A phase I/II clinical trial (the AF-001JP study), in which the agent was first administered to humans, started in 2010, and the results confirmed excellent efficacy (a response rate of 93.5 percent) and tolerability. Normally, the results of phase III clinical trials are necessary to file for approval of a drug, but given the outstanding results, including the AF-001JP study, we were able to file for approval without waiting for the phase III results, a world first. Approval was obtained in 2014, just seven years after the start of discovery research, which is an exceptionally short time. In developing Alecensa, we applied our accumulated experience and research platform for kinase. Based on a PHC-oriented development strategy, we designed and executed a development plan aimed at an early filing. These and other factors contributed to the successful development of this innovative medicine in such a short period of time.

Onset of *ALK* fusion gene-positive lung cancer is most common among adults in their 40s and 50s, people in the prime of their life. In the year since Alecensa's approval, we received thanks from healthcare providers and from patients for whom Alecensa improved their condition enough for them to do housework or return to work.



As of December 31, 2015, Alecensa had only been launched in Japan and the United States, but amid calls for early approval in other countries, in 2015 we filed for approval in Europe. We will continue working to deliver Alecensa to all patients who need it.





## What Breakthrough Therapy Designation Allows Us to Do

### Bringing Medicines to Patients Sooner

Products with BTB that show potential to significantly address an unmet medical need obtain the full cooperation of the FDA from the early stages of development. They can also receive the benefits of other FDA programs for expedited development and review, such as fast track designation.<sup>2</sup> BTB can thus be expected to shorten time to market.

By enabling an innovative therapy to be launched sooner, BTB also increases the value of the therapy throughout its lifecycle.

In addition, because the therapy's degree of innovation has been officially evaluated, expectations from healthcare providers rise, which facilitates faster market penetration once the product is launched.

Alecensa and ACE910 were recognized as being highly innovative based on the results of phase I/II clinical trials.

Confirmation of superior efficacy and safety compared with existing treatments in patients from the first clinical trial led to early BTB.

To take full advantage of the benefits of BTB, it is important to have a structure in place for rapid development once the designation is granted.

Chugai aims to make its innovative medicines available to patients as quickly as possible by taking advantage of the Roche Group's global development network, knowledge of pharmaceutical regulations and extensive experience in dealing with the FDA to shorten development time.

2. A program to promote early commercialization by expediting development and review of new drugs that have the potential to provide a meaningful therapeutic benefit for a disease that is difficult to treat

## 2

## Significance and Progress of ACE910

### A New Approach to Treating Hemophilia A

Hemophilia A is a bleeding disorder caused by a deficiency or dysfunction of blood coagulation factor VIII. In recent years, regular replacement therapy to supplement factor VIII has spread as a way to control bleeding tendency, and has helped to improve the quality of life for patients and their families. However, subcutaneous absorption of factor VIII is low, and its blood half-life is only about half a day. Consequently, intravenous administration is necessary two to three times a week during regular replacement therapy. Administration at home places a particularly heavy burden on patients and their families. Moreover, therapy with a factor VIII preparation may lead to the appearance of neutralizing antibodies called inhibitors, which would render the preparation ineffective.

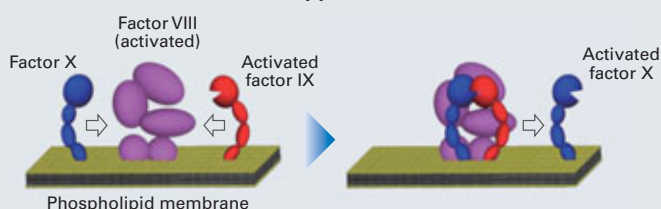
When factor VIII is activated and converted into factor VIIIa, it cross-links factor IXa and factor X, and stimulates the activation of factor X by factor IXa. At Chugai, the first company in Japan to focus on therapeutic antibodies, researchers devised an approach in which an asymmetrical bispecific antibody mimics the function of factor VIIIa on factor IXa and factor X. Since antibodies generally have a long blood half-life and can be administered subcutaneously, the problems associated with intravenous administration can be avoided. Antibodies also have a molecular structure completely different from that of factor VIII, and are therefore not expected to induce or be affected by factor VIII inhibitors.

To reproduce the function of factor VIIIa, the positions and angles of factor IXa and factor X had to be carefully aligned. Our researchers produced tens of thousands of bispecific antibody variations, from which they selected a prototype antibody. They then designed thousands of modified antibodies and developed an antibody engineering technology for manufacturing bispecific antibodies, which culminated in the creation of ACE910 (emicizumab). In preclinical studies, emicizumab improved coagulation in hemophilia A plasma irrespective of the presence of factor VIII inhibitors, and exhibited hemostatic activity in a hemophilia A animal model.

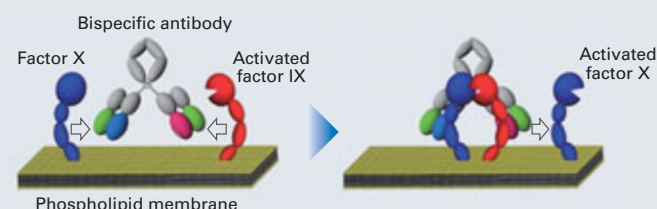
In the results of a Japanese phase I clinical trial presented at the American Society of Hematology Annual Meeting in December 2014 and a Japanese phase I/II clinical trial presented at the International Society on Thrombosis and Haemostasis Congress in June 2015, once-weekly subcutaneous administration of ACE910 demonstrated a hemostatic effect and a favorable tolerability profile whether or not factor VIII inhibitors were present.

Based on the Japanese phase I/II clinical trial, in September 2015 ACE910 was granted breakthrough therapy designation by the FDA for the prophylactic treatment of people who are 12 years or older with hemophilia A with factor VIII inhibitors.

### Mode of Action of Current Therapy



### Mode of Action of Emicizumab



## Value Creation in the Future

### Investment for Simultaneous Development of Multiple Drugs

The Japanese government is also encouraging the development of breakthrough therapies. The *Sakigake* (forerunner) designation system was rolled out on a trial basis in April 2015, and the Japan Agency for Medical Research and Development (AMED) was established to consolidate management of research and development expenses. If a project is innovative, these initiatives will enable groundbreaking therapies to be made available to patients at a high rate of success.

On the other hand, even if the FDA or Japanese regulators grant designation as a breakthrough therapy, the designation may be revoked if another therapy that fills the same unmet medical need obtains approval first.

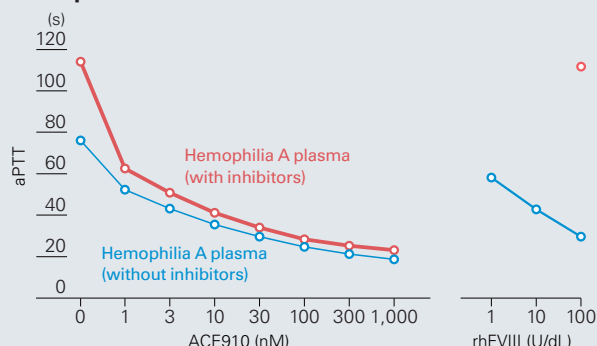
With the use of designation programs in various countries becoming an important option, strategic and flexible development operations will be required.

Chugai will prioritize investment in Chugai Pharmabody Research (CPR) to continuously create projects that apply its proprietary antibody engineering technologies. At the same time, we will focus on more innovative research projects, including establishing discovery technologies for middle molecules to fill unmet medical need that cannot be resolved with antibodies or small molecules.

In development, we will focus on accelerating achievement of early PoC for our own products based on the global development system that we reformed and established up to 2015. In manufacturing, we are making investments to enhance our development infrastructure and further increase the value of our products globally.

Chugai and Roche are currently carrying out a phase III multinational study in patients with inhibitors, and are planning to file for approval in 2017. A phase III multinational study in patients without inhibitors and a trial in pediatric patients are scheduled to start in 2016.

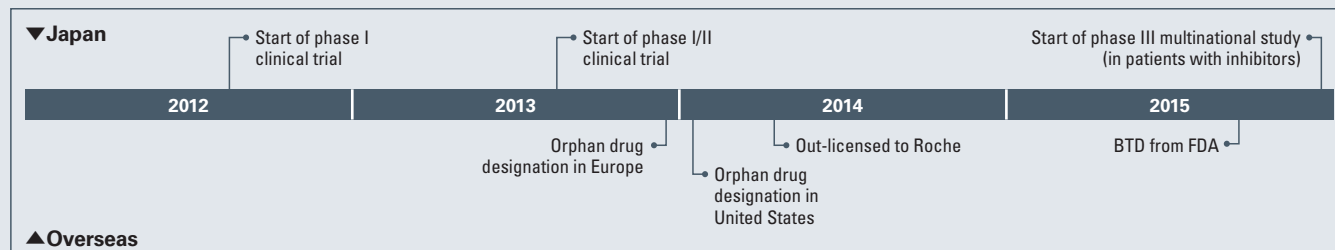
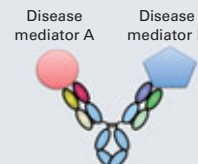
### Evaluation of Procoagulant Activity of Emicizumab in Hemophilia A Plasma



Source: Muto A., et al. *J Thromb Haemost.* 2014; 12: 206

### Use of Bispecific Antibody Technology

Normal antibodies bind with only one type of target molecule. In contrast, a bispecific antibody can bind simultaneously to two different target molecules. However, the complicated structure of bispecific antibodies makes it extremely difficult to manufacture them with a high level of productivity and purity. At Chugai, we overcame this challenge by establishing a proprietary technology called ART-Ig. Bispecific antibodies not only provide the effect of two agents in one, but are also expected to display functions unachievable by conventional antibodies, such as exerting a stronger antitumor effect by cross-linking tumor cells and immune cells, inducing intracellular signals through cross-linkage of different sites on the same cell and eliciting a therapeutic effect by facilitating access between two different molecules (for example, an enzyme and substrate).



# Chugai's Activities

The CFO Answers Frequently Asked Questions from Investors.....	60
Overview of Activities in 2015.....	64
Marketing .....	68
Development.....	72
Production and Procurement.....	74
Research .....	76
Medical Affairs .....	79
Drug Safety .....	80
Intellectual Property.....	82
Environmental Protection, Safety and Health .....	83
Social Contribution Activities .....	86
Corporate Communication .....	88



①

High product  
potential that  
addresses unmet  
medical need

②

One of the richest  
pipelines in  
Japan

③

Strategic alliance  
with the Roche  
Group

④

Cutting-edge  
drug discovery  
technologies,  
especially  
biotechnology

⑤

Knowledge and  
experience as  
a pioneer in  
personalized  
healthcare (PHC)

⑥

Commitment  
to safety  
management

⑦

Support for  
healthcare  
delivery

## Chugai's Seven Strengths

# The CFO Answers Frequently Asked Questions from Investors

**Yoshio Itaya**

Director, Executive Vice President & CFO



## 1. Review of ACCEL 15

### Q What is your assessment of the results of ACCEL 15?

We produced significant results under the initial strategic policies of ACCEL 15, and achieved our quantitative targets as well. In terms of financial strategy, we have established a highly efficient cost structure even by global standards, maintaining a ratio of operating expenses to revenues of around 35 percent. I feel that Chugai's ability to successfully execute its stated strategies and objectives has grown. This is a structural result of our efforts over many years.

After the alliance with Roche, we anticipated that the cost of sales would rise with the expansion of in-licensed products from Roche. To offset that rise, we took various measures to reduce costs, including business divestitures and the sale and integration of research laboratories and production facilities. In ACCEL 15, we improved efficiency across our operations and overhauled our IT systems. As a result, while the ratio of cost of sales to sales is 18 percentage points higher than it was before the alliance with Roche (the year ended March 2003), the ratio of operating expenses to revenues has improved by around 20 percentage points, so we have achieved structural improvements.

### Q Based on the results of ACCEL 15, what would you say is the source of Chugai's value creation?

Through the innovations we have made up to now, each function in the value chain – research, development, production and

marketing – has become much stronger. Chugai has defined and established its "seven strengths" based on these strong points. We did so by taking the 96 examples of Chugai's strengths visualized in the project to become a top pharmaceutical company, which was started in 2009, and distilling them down to seven core elements through evaluations from the standpoints of value for patients and competitive advantage for Chugai, and through outside assessments. Essentially, these seven strengths constitute Chugai's unique growth platform. Refining and further developing these seven strengths will be a must for future growth. In corporate departments, we began to reform and strengthen our intellectual property operations in 2014 in response to the continuous creation of new projects from in-house research and the smooth startup of Chugai Pharmabody Research (CPR) in Singapore. Among our various achievements in patent application strategy and patent litigation was the promotion of an intellectual property strategy with both offensive and defensive measures.

While we have established these organizational and functional foundations, the real source of the value creation underpinning those foundations is our talented people. Since the alliance, we have followed Roche's example, and I feel that in friendly competition with Roche we are well on our way to raising our employee talent to a global top-class level.

## 2. New Mid-Term Business Plan IBI 18

### Q Please talk about the outlook for implementation of IBI 18.

The success we achieved in ACCEL 15 is an indication of our ability to instill and execute our strategies throughout the Company, and I believe we can build on those results through the various initiatives under the priority agenda of IBI 18.

At Chugai, we have extensive discussions through workshops and communication in various Company media. The high degree of penetration of strategies among employees throughout our organization is one of the hallmarks of Chugai. The results of in-house surveys have confirmed the high degree of "understanding" of the strategies and the increases in "action" and "realization" over the past three years. The integral philosophy that Chugai has embraced since its foundation, "Innovation all for the patients," has been instilled in our employees, and that makes us very proud.

That degree of penetration contributed to solid results under ACCEL 15, but from an overall perspective of medium-to-long-term growth, I believe we must complete another stage of transformation. In IBI 18, we have begun to transform the mentality in the Company to one of "autonomy" through constant innovation on our own to deal with rapid changes in the operating environment, including future technological innovations and changes in the industry structure. In other words, we will carry out this transformation during IBI 18 in order to achieve strong growth in 2019 and beyond.

### Q Please explain the financial strategy of IBI 18.

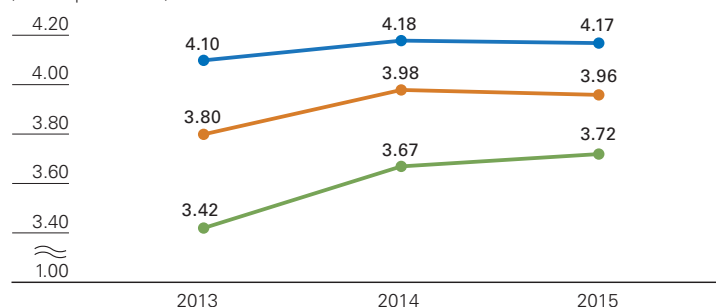
In Japan, there are changes in the operating environment that will put pressure on earnings, such as repricing following market expansion, and the impact of those changes on profit margins cannot be ignored. Nevertheless, we intend to maintain our highly efficient cost structure over the medium to long term. To manage operating expenses, we will continue our basic policy of keeping their growth within the rate of revenue growth as a general principle.

Chugai has ample net cash (cash and cash equivalents plus marketable securities less interest-bearing debt), which amounts to roughly half of annual revenues. Effectively managing this net cash and the cash flow generated by steady earnings will be a key issue. In the financial strategy of IBI 18, we will use funds to invest in future business opportunities and to provide appropriate returns to shareholders.

Under ACCEL 15, we steadily made investments based on a consistent approach that considered the Company's current strengths and expectations for medium-to-long-term growth. Of particular note, we more than tripled investment in CPR compared with the initial plan in order to accelerate discovery of development candidates using antibody engineering technologies. In addition, we doubled manufacturing capacity for investigational biologics to enable simultaneous development of multiple drugs in response to the successive creation of development candidates by CPR.

#### Awareness of ACCEL 15 Strategies (Based on Results of Chugai Employee Survey)\*

(On a 5-point scale)



#### Evaluation Items

- I understand why it is necessary to try to achieve the goals of ACCEL15 (understanding)
- I am doing my part to achieve the goals of ACCEL 15 (action)
- Positive changes are beginning to appear in my workplace due to activities for ACCEL 15 (realization)

\* 2013-2015 Employee Survey  
Copyright Recruit Management Solutions Co., Ltd.



Given the success of these efforts in drug discovery, clinical development and production of investigational biologics, in IBI 18 we have decided to invest in expansion of production capacity and the construction of a new antibody active pharmaceutical ingredient (API) plant at the Ukima plant to strengthen our capabilities in the next phase from late-stage development to early commercial production. We plan to continue making investments that will contribute to future growth, including successive creation of in-house products and establishment of drug discovery technologies for middle molecules, a candidate for our next-generation core technology.

the efficiency of resource inputs while using our strengths to raise both the quality and quantity of outputs. Using the Company intranet to visualize the efforts of each unit and division enables them to compare their progress. One of the strategic policies of ACCEL 15 was to increase marketing productivity. The productivity of domestic marketing operations (sales per MR) has improved by more than 20 percent, putting us in the top tier of the domestic industry. In production, we shortened throughput time and raised efficiency in indirect operations. We are also transforming into an organization that voluntarily and continuously seeks ways to improve productivity.

Q

### What are the key measures planned for transformation and growth?

We have five priority objectives in our agenda for IBI 18. All of them are important, of course, but one of the measures for transforming the mentality in the Company to promote constant innovation on our own, which I explained earlier, is the evolution of the Productivity Improvement Project.

The Productivity Improvement Project is something we have been working on since 2013. If we divide productivity into inputs as the denominator and outputs as the numerator, the basic concept is to continue to increase

Next we will focus on raising corporate value by organically linking these productivity gains with diversity and inclusion (D&I) and work-life synergy. These elements tend to be seen as conflicting, but that is not the case by any means. We believe that by promoting D&I and work-life synergy to establish an environment in which everyone can maximize their potential, we can improve Chugai's organizational productivity and thus increase corporate value over the medium to long term.

While advancing these interconnected efforts, we also want to rationally test and analyze the relationship between each productivity measure and D&I and work-life synergy.

### Major Capital Investments in ACCEL 15 and IBI 18

Time Frame	Planned Investment	Site	Details
2012-2021	SGD 476 million (about ¥40.0 billion*)	CPR (Singapore)	Business expansion (Accelerate creation of clinical candidates utilizing proprietary antibody technologies) (Initial plan: ¥12.5 billion)
2013-2015	¥2.9 billion	Ukima plant	Renovation of investigational drug building No. 2 for biologics (Doubling of manufacturing capacity for investigational biologics to enable simultaneous development of multiple drugs)
2013-2015	¥4.6 billion	Utsunomiya plant	Renovation of manufacturing building No. 1 for biological APIs (UT1) (Improving production yield for Actemra subcutaneous formulation and stabilizing supply by having two manufacturing sites, one in Japan and another in the United States)
2013-2017	¥6.0 billion	Utsunomiya plant	Enhancement of high mix, low-volume production capability for pre-filled syringe form products (Installment of tray filler)
2015-2019	¥37.2 billion	Ukima plant	Enhancement of high-mix, low-volume production of antibody APIs for initial commercial products (Expansion of production capacity)
2015-2018	¥6.0 billion	Fujieda plant	Strengthening of solid formulation manufacturing facility, etc. (Handle quick launch and steady supply)

\* Converted at ¥90.0/SGD

### 3. Dialogue with Investors and Increasing Corporate Value

#### Q What is your view of corporate value?

In general, corporate value is thought to be synonymous with market capitalization. But I think of it as a company's overall qualitative and quantitative value, which includes intangible value such as the company's reputation and trust among stakeholders including customers, suppliers and employees. From a long-term perspective, I think we should humbly face and address our qualitative and non-financial value directly.

We will work diligently to ensure that our corporate value is reflected in shareholder value (market capitalization) to ensure an accurate valuation, including non-financial information. In that sense, the seven strengths I talked about earlier are the visualization of Chugai's non-financial value. We will therefore focus on promoting understanding and recognition of those strengths.

To that end, dialogue with shareholders and other investors will be increasingly important. I personally meet face-to-face with about 200 shareholders and investors every year. I plan to continue doing so, and will try to enrich the content of our dialogue.

1. Core basis results are the results after adjusting non-Core items to IFRS basis results. Core basis results are used by Chugai as an internal performance indicator, for representing recurring profit trends both internally and externally, and as indices for establishing profit distributions such as returns to shareholders.

2. Growth rate based on average exchange rates for 2012

#### Q What are your thoughts on the Company's common objectives with shareholders?

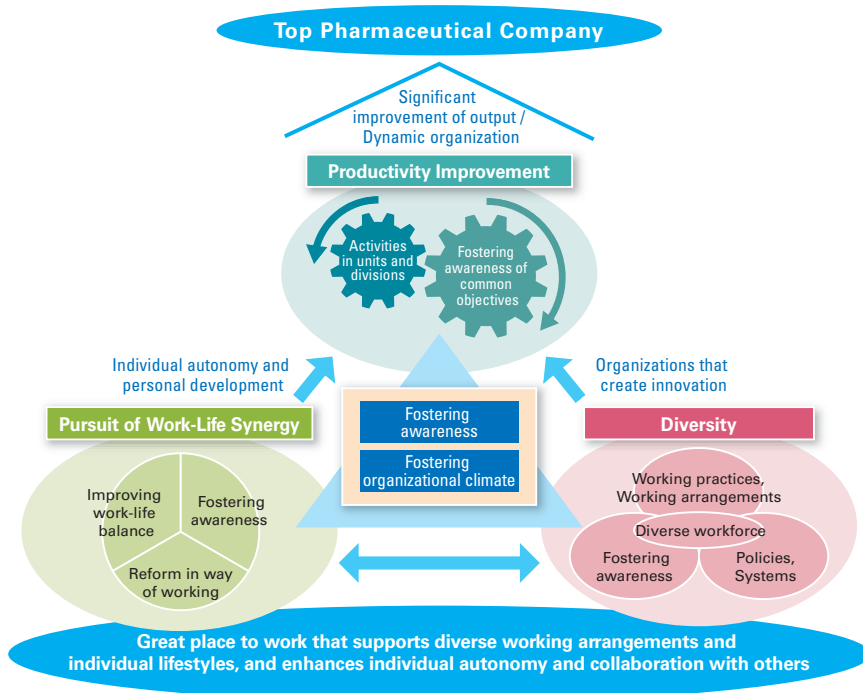
One of management's roles is to provide returns to shareholders through dividends while increasing shareholder value over the medium to long term.

Therefore, we held extensive internal discussions on how to define common objectives with shareholders in 2013 when we formulated ACCEL 15 and adopted IFRS. As a result, we decided to disclose Core basis<sup>1</sup> projections and results aligned with internal performance indicators to provide a shared framework for dialogue with shareholders and investors. These changes facilitate more accurate analysis by shareholders and investors around the world. Based on the idea that Core basis net income should be divided evenly between the Company and its shareholders, we set the target for the payout ratio at 50 percent of Core earnings per share (EPS) on average.

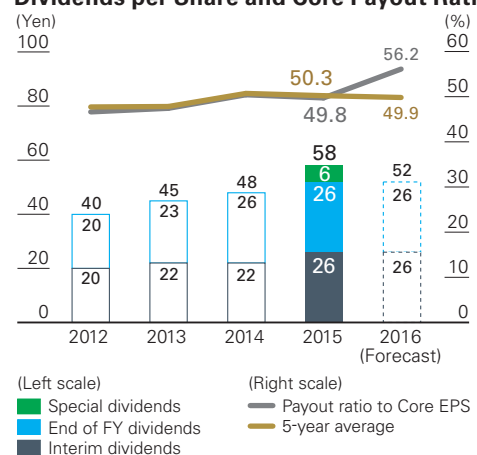
Simply stated, Chugai's common objective with shareholders is growth on a Core basis.

In the last three years, Core EPS CAGR<sup>2</sup> was 18.3 percent and market capitalization has risen 157 percent. So while I can say we have achieved results to a certain extent, we aim to meet the expectations for medium-to-long-term growth and increases in shareholder value through further innovation.

### Productivity Improvement, Work-Life Synergy and Diversity



#### Dividends per Share and Core Payout Ratio



# Overview of Activities in 2015

Items	Main initiatives	Main performance indicators in 2015
Marketing	<ul style="list-style-type: none"> <li>Contributing to advances in medicine as Japan's leading oncology drug and therapeutic antibody company</li> <li>Promoting standards of care, regional healthcare and personalized healthcare (PHC)<sup>1</sup></li> <li>Contributing to care through consulting and liaison functions</li> <li>Enhancing area promotion strategy to increase marketing productivity</li> <li>Conducting disease awareness and patient support activities in mainstay product areas</li> </ul>	<ul style="list-style-type: none"> <li>Share of sales in the Japanese therapeutic antibody market: 35.3%<sup>2</sup></li> <li>Share of sales in the Japanese oncology market: 22.6%<sup>2</sup></li> <li>Education for MRs with a high level of expertise</li> <li>Enhancement of marketing functions based on local characteristics</li> <li>Customer inquiries answered by Chugai's Drug Information Center: 59,161 (includes telephone, e-mail and fax inquiries)</li> </ul>
Development	<ul style="list-style-type: none"> <li>Improving clinical development of drugs to address unmet medical need<sup>3</sup></li> <li>Increasing productivity and speed of global clinical development for early market launches</li> <li>Conducting simultaneous development and regulatory filing of drug therapies and diagnostics that contribute to PHC</li> <li>Strengthening lifecycle management to maximize product value</li> </ul>	<ul style="list-style-type: none"> <li>Pipeline projects: 34 (as of January 28, 2016)</li> <li>New products launched/new indications: 9 (2013-2015)</li> <li>PHC-based development projects: 17 (as of January 28, 2016)</li> <li>Projects in-licensed from Roche: 10 (2013-2015)</li> </ul>
Production and Procurement	<ul style="list-style-type: none"> <li>Providing a continuous stable supply of pharmaceuticals, raw materials and packaging materials</li> <li>Strengthening global supply chain management</li> <li>Strengthening consistent quality assurance throughout product lifecycles with a global pharmaceutical quality management system</li> <li>Continuously standardizing and optimizing purchasing processes to build fair, transparent relationships</li> <li>Promoting purchasing that balances compliance, operational efficiency and cost reduction</li> </ul>	<ul style="list-style-type: none"> <li>Invested in facilities to handle multiple antibody development projects simultaneously</li> <li>Established and started operation of a world-class system for pharmaceutical quality management</li> <li>Promoted fairness and transparency that includes cataloging of indirect materials in the electronic purchasing system</li> </ul>
Research	<ul style="list-style-type: none"> <li>Continuously generating first-in-class<sup>4</sup> and best-in-class<sup>5</sup> drugs</li> <li>Creating molecular targeted therapies<sup>6</sup> that contribute to PHC</li> <li>Strengthening innovative proprietary research technologies and creating innovative antibodies</li> <li>Providing support and education for researchers from Asia</li> <li>Maintaining high animal welfare standards in accordance with international guidelines</li> </ul>	<ul style="list-style-type: none"> <li>In-house products in pipeline research: 11 (as of January 28, 2016)</li> <li>Expanded business at Singapore subsidiary Chugai Pharmabody Research Pte. Ltd.</li> <li>Publications in academic papers and presentations at scientific conferences regarding Chugai's innovative proprietary technologies: 40 (2013-2015)</li> <li>Published academic papers regarding Chugai's research findings: 60 (2013-2015)</li> </ul>
Medical Affairs	<ul style="list-style-type: none"> <li>Building a system for consistent management of medical affairs throughout Chugai</li> <li>Strengthening systems for healthcare compliance<sup>7</sup> and governance of contract-based post-marketing studies</li> <li>Promoting medical plans by area</li> <li>Conducting contract-based post-marketing studies that conform to GCP and ethics guidelines</li> </ul>	<ul style="list-style-type: none"> <li>Contract-based post-marketing studies: 21 (as of December 31, 2015)</li> <li>Staff handling regional medical affairs: 213 (as of December 31, 2015)</li> <li>Staff with GCP Passport (JSCTR certification): 157 (as of January 31, 2016)</li> </ul>
Drug Safety	<ul style="list-style-type: none"> <li>Strengthening pharmacovigilance system to meet the world's strictest standards and most comprehensive global regulations</li> <li>Providing solutions to patients and healthcare professionals using drug safety information</li> <li>Preparing and implementing risk management plans (RMPs)</li> </ul>	<ul style="list-style-type: none"> <li>Cases for which safety information was collected from Japan and overseas according to global standards for clinical trials and post-marketing studies: Approximately 186,000 adverse drug reaction reports (January-December 2015)</li> </ul>

1. A treatment approach designed and implemented according to each patient's unique molecular and genetic profile

2. Copyright 2016 IMS Health Source: JPM 2015. Reprinted with permission. The scope of the market is defined by Chugai.

3. Medical need that is not adequately met due to a lack of effective treatments

4. An original drug that is highly novel and useful, and will significantly change the therapeutic system



	Page reference	Items described in detail on website (As of March 24, 2016)
	68-71	Drug Information Center
<ul style="list-style-type: none"> <li>Projects being co-developed with Roche Group: 27 (as of January 28, 2016)</li> <li>Projects in response to development requests for unapproved drugs/indications: 11 (2011-2015)</li> </ul>	72-73	Development Pipeline/Co-Development and Joint Promotion with Roche/Conduct of Clinical Trials
<ul style="list-style-type: none"> <li>Published research papers from the Pharmaceutical Technology Division: 76 (2010-2015)</li> <li>Formulated procurement strategies for key materials and exchange of opinions with users</li> <li>Issues of in-house newsletter <i>Purchasing News</i>: 3</li> <li>Internal e-learning held (for new employees and mid-career hires): 14 times</li> </ul>	74-75	A Global-Standard Regulatory Compliance and Quality Assurance System/Policy for Regulatory Compliance and Quality Assurance/Initiatives for Building Fair, Transparent Relationships/Chugai Ethical Purchasing Standards
<ul style="list-style-type: none"> <li>R&amp;D expenditures to revenues: 16.4%</li> <li>Created new antibodies using Chugai's recycling antibody, sweeping antibody, bispecific antibody and other proprietary antibody technologies</li> <li>In-house education and training for people who handle laboratory animals: 1 session attended by 578 people</li> <li>In-house education for people who handle human-derived test materials: 1 session attended by 617 people</li> </ul>	76-78	Drug Discovery/R&D Infrastructure/R&D Structure/Chugai's View of Animal Welfare/Bioethics Initiatives in R&D/Chugai Academy for Advanced Oncology Holds International Forum/Supporting Researchers from Asia
<ul style="list-style-type: none"> <li>Product Research Department: Published research papers: 124 (2010-2015) Academic conference awards: 8 (2010-2015)</li> </ul>	79	Future Post-Marketing Studies/Clinical Research Policy (Both information for healthcare providers in Japanese only)
<ul style="list-style-type: none"> <li>New RMPs prepared and carried out: 9 products (as of February 2016)</li> <li>Papers and conference presentations on safety based on the results of post-marketing surveillance: 27 (2015)</li> </ul>	80-81	Post-Marketing All-Case Surveillance

5. A drug that offers clear advantages over other existing drugs in the same category, such as those with the same molecular target

6. A drug designed to specifically inhibit the action of a molecular target that is implicated in a disease process. Molecular targeted therapies play a central role in PHC, which uses advance testing for biomarkers.

7. Chugai defines healthcare compliance as compliance in general business operations related to conducting clinical testing, clinical research and non-clinical research, support operations, collecting medical information and providing drug information.

Items	Main initiatives	Main performance indicators in 2015
Intellectual Property	<ul style="list-style-type: none"> <li>Protecting and effectively using rights for broadly applicable innovative technologies</li> <li>Filing of high-quality patent applications and effectively allocating resources</li> <li>Aggressive filing of patent applications outside Japan with a view to global co-development</li> </ul>	<ul style="list-style-type: none"> <li>Patents held (including pending applications): 3,834</li> <li>New patents granted worldwide: 164</li> <li>Applications to register a patent term extension filed in Japan: 3</li> <li>Created a system for monitoring other companies' patents</li> </ul>
Environmental Protection, Safety and Health	<ul style="list-style-type: none"> <li>Promoting global warming countermeasures, resource conservation and waste reduction</li> <li>Thoroughly managing chemical substances</li> <li>Disclosing environmental information</li> <li>Enhancing environmental awareness and making environment-related contributions to local communities</li> <li>Creating safe, comfortable workplaces</li> </ul>	<ul style="list-style-type: none"> <li>Energy consumption per employee compared with 2010: Down 13% (Chugai Group in Japan)</li> <li>Amount of waste generated compared with 2014: Up 9% (Chugai Group in Japan)</li> <li>Amount of landfill waste compared with 2014: Down 36% (Chugai Group in Japan)</li> <li>Ratio of fuel-efficient sales vehicles: 55%</li> </ul>
Social Contribution	<ul style="list-style-type: none"> <li>Creating an inclusive society through support for para-sports</li> <li>Nurturing the next generation who will carry science and technology forward</li> <li>Supporting employee volunteer activities</li> <li>Contributing to communities where Chugai Group facilities and sites are located</li> </ul>	<ul style="list-style-type: none"> <li>Conducted awareness-raising and support activities for para-sports (prepared an educational pamphlet on para-sports, and held an event for trying wheelchair basketball, a photograph exhibition and a talk show with para-athletes)</li> <li>Donation of welfare vehicles to provide transportation for home welfare services: Total of 238 vehicles over 31 years (total of 35 vehicles to 35 organizations in 2015)</li> <li>Cumulative number of countries receiving free therapeutic drugs for treating lymphangiomas: 83 (program in its 25th year)</li> <li>Number of locations in which Chugai employees participated in the 24-hour charity event Relay For Life: 27 nationwide</li> </ul>
Human Resources	<ul style="list-style-type: none"> <li>Fostering human resources who are competent in the global arena</li> <li>Building work environments in which diverse people can succeed</li> <li>Building sound labor-management relations</li> <li>Fostering high ethical standards through training on the BCG; making continuous efforts to build human rights awareness</li> </ul>	<ul style="list-style-type: none"> <li>Implemented leader development program, all-employee program, division programs and Self-Innovation Program (SIP)</li> <li>Employees posted through the Roche Human Resource Exchange Program: 125 (2004-2015)</li> <li>Percentage of female managers<sup>8</sup>: 10.7%</li> <li>Employees approved for telecommuting: 412</li> <li>Employees taking childcare leave: 191</li> </ul>
Corporate Governance	<ul style="list-style-type: none"> <li>Prompt decision-making, clarification of executive responsibilities and management transparency</li> <li>Enhancing decision-making by introducing outside perspectives</li> <li>Maintaining an internal control system</li> <li>Promoting compliance with the Pharmaceutical Affairs Law, fair competition codes, promotion codes, and other laws and regulations</li> </ul>	<ul style="list-style-type: none"> <li>Board of Directors meetings: 8 (average attendance rate of outside directors 85.0%)</li> <li>Auditing system: 4 Audit &amp; Supervisory Board Members (including 2 outside members)</li> <li>Chugai International Council (CIC) meetings: 1</li> <li>Established the Healthcare Compliance Committee</li> </ul>
Corporate Communication	<ul style="list-style-type: none"> <li>Proactive disclosure of information to and promotion of IR activities for institutional investors, security analysts, individual investors and other stakeholders in Japan and overseas</li> <li>Building good relationships with media outlets and disseminating information appropriately and in a timely manner (media relations)</li> <li>Building and establishing the corporate brand</li> </ul>	<ul style="list-style-type: none"> <li>Information events for the media and institutional investors: 16</li> <li>Security analysts and institutional investors in Japan with whom individual meetings/conference calls were held: 466</li> <li>Information meetings for individual investors and shareholders: 4</li> <li>Plant tours for shareholders and media: 2</li> <li>Attendees at General Meeting of Shareholders: 601</li> <li>Branding campaign (TV commercials and newspaper advertisements)</li> <li>Website ranked 2nd in the pharmaceutical industry by Nikko Investor Relations Co., Ltd.</li> </ul>

8. Percentage of all managers (non-consolidated)

	Page reference	Items described in detail on website (As of March 24, 2016)
<ul style="list-style-type: none"> <li>Improved efficiency by using electronic documents and visualizing workflows</li> </ul>	82	
<ul style="list-style-type: none"> <li>Occupational incidence rate: 1.78 (No. of occupational injuries and deaths / No. of hours actually worked x 1,000,000)</li> <li>Accidents accompanied by lost worktime: 5 (Chugai Group in Japan)</li> <li>Lost workdays resulting from occupational accidents: 88 (Chugai Group in Japan)</li> </ul>	83-85 108-109	Chugai's Approach to CSR/Creating Supportive Work Environments/ Environmental and Safety Initiatives/Environmental Action Plans and Performance/Safety and Health Activities/Preventing Global Warming/Chemical Substance Management/Resource Conservation and Waste Management/Prevention of Air, Water and Soil Pollution/Education, Communication and Environmental Accounting/Strengthening Training for the Environmental Management System Designed for Internal Auditors/Performance Data/ Response to Programs for Reporting on Measures against Global Warming (Tokyo Metropolitan Government)
<ul style="list-style-type: none"> <li>Video presentations given at Dr. Kitanomaru's Bio Pharmaceutical Laboratory exhibit: 40,352 (January - December 2015)</li> <li>Biology lab classes for children at the Japan Science Foundation's Science Museum: 169 participants in 15 labs</li> <li>Endowed courses at Waseda University: Total of 15 lectures</li> <li>Number of employees who took volunteer leave: 22</li> </ul>	86-87	Relay for Life/NPO Shuhei Ogita Fund Supporting Patients with Lymphatic Malformations/Chugai's Social Contribution Activities/ Support for Para-Sports (Japanese only)
<ul style="list-style-type: none"> <li>Percentage of employees with disabilities: 2.02%</li> <li>BCG and human rights training attendees: 13,840 (includes repeat attendees; Chugai Group in Japan)</li> <li>Conducted ethical and legal compliance survey within the Sales Division and Medical Affairs Division: 2,413 participants</li> <li>Selected as a "Nadeshiko Brand" in March 2016 by the Ministry of Economy, Trade and Industry and the Tokyo Stock Exchange</li> </ul>	47-49	Business Conduct Guidelines/Promotion of the Active Participation of Women/Our Commitment to Corporate Ethics/Creating Workplaces Free from Harassment/Human Resource Strategy to Become a Top Japanese Pharmaceutical Company/Talent Management According to Each Person's Capabilities and Aptitude/ Personnel Systems That Help Our Diverse People to Succeed/ Diversity Initiatives/Diversity Promotion System/Initiatives to Promote the Success of Diverse Employees/Facilitating Work-Life Balance/Performance Data Related to Diversity
	44-46 110-115	Basic Corporate Governance Policy/Corporate Governance Report/ The Resolutions concerning the Internal Control System by the Board of Directors/Relationship with Roche/Chugai's Transparency Guidelines/Emergency Response
<ul style="list-style-type: none"> <li>Won 2015 Internet IR Excellence Award from Daiwa Investor Relations</li> <li>Won Grand Prize at 18th Nikkei Annual Report Awards</li> <li>Won Prize for Best Work at the 83rd Mainichi Advertisement Design Competition held by the Mainichi Newspapers Co., Ltd.</li> <li>Won Excellence Award in 35th Newspaper Advertisement Awards sponsored by the Japan Newspaper Publishers and Editors Association</li> <li>Won Best Lifestyle Award in Nikkei BP Advertising Awards and Excellence Prize in Yomiuri Advertising Awards in "Writing" category</li> </ul>	88-89	Shareholder Information/Shareholder Meetings/Shareholder Returns/ Financial Results/Message to Individual Investors (Japanese only)/ Chugai Brand Story/Videos & Advertisements

# Marketing

## Initiatives and Performance in 2015

**35.3%<sup>1</sup>**

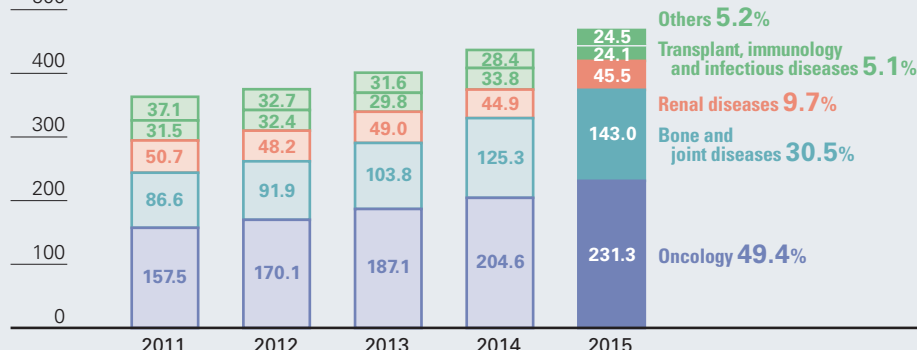
Share of sales in the Japanese therapeutic antibody market (2015)

**22.6%<sup>1</sup>**

Share of sales in the Japanese oncology market (2015)

## Sales and Percentage of Total Sales

(Billions of yen)



## Marketing Policies

For Chugai, which aims to continuously create and provide innovative medical products, delivering these valuable products to all patients and ensuring their proper use are major responsibilities. However, not all patients with diseases receive medical examinations, adequate testing and diagnosis, or continuity of treatment in line with standards of care and therapeutic purposes.

Consequently, based on extensive data, Chugai accurately visualizes the flow of patients' treatment in each area and coordination among organizations providing healthcare, then uses that information to help patients by deploying its consulting and liaison functions. Consulting focuses on proposing treatment options and side-effect management plans tailored to each patient based on a high level of expertise. To enhance its liaison functions, Chugai makes various efforts to disseminate information and holds

study sessions and workshops to act as an intermediary among healthcare providers and organizations providing healthcare in each area.

We believe the steady sales we achieved during ACCEL 15 were the result of increased sales productivity based on the aforementioned approach of visualizing the actual conditions of healthcare delivery to strengthen marketing in each area.

Considering these results, our policy under the new mid-term business plan, IBI 18, will be to broaden our contribution to healthcare in each region by strengthening cooperation among the Sales Division, Medical Affairs Division and Drug Safety Division to fully promote a higher level of expertise and to provide information tailored to regional characteristics.

## Relationship to Our Strengths



- ① High product potential that addresses unmet medical need
- ⑤ Knowledge and experience as a pioneer in personalized healthcare (PHC)
- ⑥ Commitment to safety management
- ⑦ Support for healthcare delivery

## Oncology

Cancer is the leading cause of death in Japan, with over 360,000 patients dying every year.<sup>2</sup> Chugai is the leading provider of anticancer agents in Japan, primarily for gastrointestinal, lung, breast and hematological cancer. We are committed to working for the benefit of patients by delivering cancer treatments that allow them to stand up against their disease with hope.

Avastin is a major product that has been approved for five indications including colorectal, lung and breast cancer. Our HER2 franchise of three products – Herceptin and its combination therapy Perjeta, which target the protein HER2, and the antibody-drug conjugate Kadcyla – are contributing to the treatment of HER2-positive breast cancer.



### ① Avastin (bevacizumab)

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

### ② Herceptin (trastuzumab)

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

### ③ Rituxan (rituximab)

Anti-CD20 monoclonal antibody  
Launch in Japan: September 2001

### ④ Tarceva (erlotinib)

Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor  
Launch in Japan: December 2007

### ⑤ Xeloda (capecitabine)

Fluoropyrimidine anti-tumor agent  
Launch in Japan: June 2003

### ⑥ Perjeta (pertuzumab)

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

### ⑦ Kadcyla (trastuzumab emtansine)

Anti-HER2 antibody-tubulin polymerization inhibitor conjugate  
Launch in Japan: April 2014

### ⑧ ⑫ Alecensa (alectinib)

ALK inhibitor  
Launch in Japan: September 2014

### ⑨ ⑪ Neutrogin (lenograstim)

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

### ⑩ Zelboraf (vemurafenib)

BRAF inhibitor  
Launch in Japan: February 2015

### ⑬ Aloxi (palonosetron)

5-HT3 receptor antagonist  
Launch in U.K.: January 2015

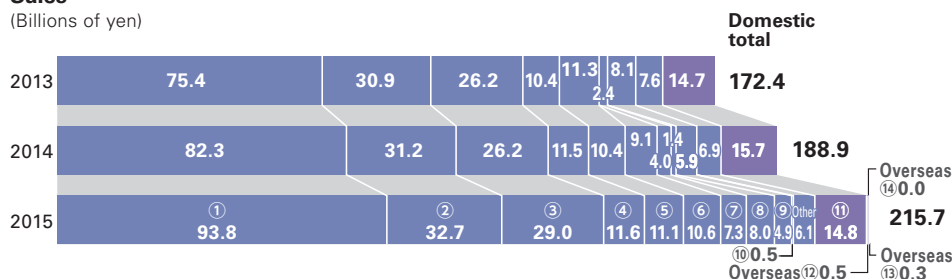
### ⑭ Akynzeo (oral combination of netupitant and palonosetron)

Oral antiemetic agent  
Launch in U.K.: September 2015  
Launch in Ireland: December 2015



## Sales

(Billions of yen)



## Review of 2015 Performance

In 2015, sales in the oncology field in Japan grew steadily, increasing ¥26.8 billion, or 14.2 percent, year on year to ¥215.7 billion. Major product Avastin and each product in the HER2 franchise contributed substantially to growth. New products Alecensa, which was launched in September 2014, and Zelboraf, which was launched in February 2015, got off to a smooth start as a result of efforts to promote their appropriate use, earning a positive response among healthcare providers for their high level of efficacy.

With these results, we increased our lead in the Japanese oncology market to a 22.6 percent<sup>1</sup> share, up 0.6 percentage points from 2014, maintaining our leading position in the field for the eighth consecutive year.

## Strategies of New Mid-Term Business Plan IBI 18

Chugai will continue to promote the creation of conditions that allow patients to deal positively with treatment by providing products that can be used for various cancer types in multiple lines of therapy.

We currently handle 11 products for nine types of cancer, and expect this to increase to 15 products for 13 types of cancer. On this basis, we introduced an organization of oncology specialists in five urban areas in October 2015, in addition to enhancing education and training of MRs. By having two specialized offices – one for gastrointestinal and breast cancers and another for lung, hematological, gynecological and other types of cancer – we will acquire more advanced expertise to meet the needs of urban healthcare practitioners.

To further strengthen area marketing, a topic of focus for the entire company, we will particularly concentrate on improving the rate and accuracy of testing and the continuity

of appropriate treatment in the course of patients' therapy in each area. In personalized healthcare, where Chugai is an industry leader, testing to select treatments that can be expected to have strong therapeutic effects and reduced side effects is highly meaningful, but there is still room for improvement in the rate and accuracy of testing in actual practice. We will help to promote the selection of the appropriate treatment for each patient by collaborating with the Japanese Society of Pathology, conducting detailed verification with pathologists at each facility and holding study sessions based on test data from each region and other sources. To improve the continuity of appropriate treatments, we will hold workshops on multidisciplinary team care and provide a variety of information to propose side-effect management so that effective treatments are not abandoned.

As for specific strategies by disease field, we will continue to promote our major product Avastin for colorectal cancer and work to expand combination therapy with Xeloda. For lung cancer, we will capitalize on our advantage of having multiple treatments with Avastin, Tarceva and Alecensa, and prepare for the launch of the engineered anti-PD-L1 antibody (generic name: atezolizumab). PD-L1 has been attracting attention as a new type of anticancer agent and we plan to file an application for approval in 2017. For HER2-positive inoperable or recurrent breast cancer, we will establish the positioning of Herceptin, Perjeta and chemotherapy as a first-time treatment together with Kadcyla as a second-line treatment, which received a Grade A recommendation in the revised clinical practice guidelines for breast cancer published in July 2015.

**①⑥ 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)

**② Edirol** (eldecalcitol)

Active vitamin D<sub>3</sub> derivative  
Launch in Japan: April 2011

**③ Suvenyl** (sodium hyaluronate)

Agent for joint function improvement  
Launch in Japan: August 2000

**④ Bonviva** (ibandronate sodium hydrate)

Bisphosphonate  
Launch in Japan: August 2013

**⑤ Alfarol** (alfacalcidol)

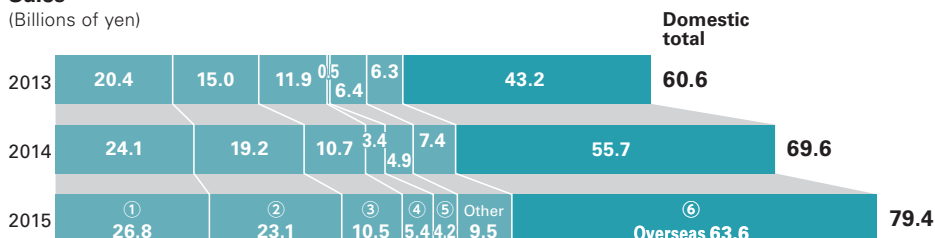
Active vitamin D<sub>3</sub> derivative (1 $\alpha$ (OH) D<sub>3</sub>) for improving bone metabolism  
Launch in Japan: January 1981



## Bone and Joint Diseases

### Sales

(Billions of yen)



Actemra, the first therapeutic antibody created in Japan, is the result of more than 20 years of Chugai biopharmaceutical research. It is sold in more than 90 countries as a treatment for rheumatoid arthritis (RA) and other diseases related to interleukin-6 (IL-6). Now, ten years after its launch, Actemra has become a global product, with worldwide Roche Group sales exceeding 1 billion Swiss francs. We are working at a global level to expand treatment options, including the launch of subcutaneous formulations in 2013.

In the osteoporosis segment, "locomotive syndrome," which refers to the loss of mobility of the legs and back due to advanced age or lifestyle factors, has received growing attention in Japan due to its impact on quality of life. This has boosted awareness of the importance of treatment. We have been working to meet the therapeutic needs of osteoporosis patients by adding Edirol to our product lineup in 2011 and Bonviva IV Injection in 2013.

### Review of 2015 Performance

In 2015, sales in the bone and joint diseases field in Japan increased ¥9.8 billion, or 14.1 percent, year on year to ¥79.4 billion. Actemra drove growth, and in the osteoporosis segment, Edirol continued to grow, backed by its evaluation as a base treatment, and sales of Bonviva IV Injection expanded steadily due to promotion focused on its demonstrated effectiveness with a once-monthly intravenous injection.

Sales of Actemra outside Japan increased ¥7.9 billion, or 14.2 percent, to ¥63.6 billion, driven by sales of the subcutaneous formulations in the United States and major European countries, in addition to the effect on exports to Roche due to the depreciation of the yen against the Swiss franc.

### Strategies of New Mid-Term Business Plan IBI 18

In the RA segment, we will continue to contribute to the medical community around the world through the spread of Actemra, with its high and sustained remission rate (decrease in or disappearance of symptoms). In Japan, we will focus on proposals for therapeutic systems that promote Actemra's characteristic ability to be used as a monotherapy, and raise awareness about the early-stage use of biologics. Outside Japan, we will strengthen cooperation with the Roche Group, working in particular to expand the use of Actemra in first-line treatment by fostering recognition of its high efficacy as a biologic monotherapy. We supply Actemra to Roche based on estimates of future local demand and will revise growth projections for shipments based on a detailed export plan.

In the osteoporosis segment, only about 20 percent of the total number of estimated sufferers are believed to be receiving treatment due to the few noticeable symptoms and other factors. Consequently, we will focus on promoting early detection and treatment through measures such as raising public awareness of the importance of measuring bone density. In particular, we will promote cooperation between specialists and primary care physicians so that patients can undergo check-ups at medical facilities equipped to measure bone density. Thereafter, we will provide information and coordinate treatment to improve continuity of treatment and adherence.<sup>3</sup> As for product strategy, we will propose treatment with Edirol as the base drug in combination with Bonviva or other products.

Chugai has numerous products that can contribute to the treatment of RA, osteoporosis and osteoarthritis, which are the primary underlying diseases that cause locomotive syndrome. We will also focus on making treatment proposals that lead to improved patient quality of life.

3. A patient's active participation in deciding a treatment plan and receipt of treatment in accordance with that decision

**①Mircera** (epoetin beta pegol)

Continuous erythropoietin receptor activator  
Launch in Japan: July 2011

**②Oxarol** (maxacalcitol)

Agent for secondary hyperparathyroidism  
Launch in Japan: September 2000

**③Epogin** (epoetin beta)

Recombinant human erythropoietin  
Launch in Japan: April 1990



## Renal Diseases

### Sales

(Billions of yen)

					Domestic total
2013	22.5	12.2	10.5	3.7	48.9
2014	22.6	12.2	6.6	3.4	44.7
2015	① 23.8	② 12.9	③ 5.9	Other 2.8	45.4

Since the 1990 launch of Epogin, Chugai has led the industry in promoting awareness of the importance of early treatment of renal anemia. Our ongoing contributions to chronic kidney disease (CKD) patients in Japan include the 2011 launch of Mircera, which has a significantly lower dosing frequency than existing medicines, as well as the launches of Oxarol in 2000 and Renagel in 2003.

In the market for renal anemia treatment, attention is focused on the pre-dialysis segment, with public awareness campaigns to promote early diagnosis and treatment, and an increase in the number of patients. In the dialysis segment, however, market conditions are severe due to downward pressure on medical costs and the aging of patients.

Under these conditions, sales in the renal diseases field in Japan in 2015 increased ¥0.7 billion, or 1.6 percent, to ¥45.4 billion. Uptake of Mircera increased in the pre-dialysis segment as it established a reputation for convenience and long duration of action, but in the dialysis segment, uptake was limited by intensifying competition with biosimilars and other competitor products.

In addition to continuing our emphasis on raising awareness of early treatment, we will propose treatments that make full use of the characteristics of Mircera from new perspectives.

**①Tamiflu** (oseltamivir phosphate)

Anti-influenza agent  
Launch in Japan: February 2001

**②CellCept** (mycophenolate mofetil)

Immunosuppressant  
Launch in Japan: November 1999

**③Pegasys** (peginterferon alfa-2a)

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

**④Copegus** (ribavirin)

Anti-viral agent  
Launch in Japan: March 2007

**⑤Sigmart** (nicorandil)

Anti-anginal agent  
Launch in Japan: April 1984



## Transplant, Immunology and Infectious Diseases, and Others

### Sales

(Billions of yen)

Sales (Billions of yen)										Domestic total
2013	11.0	7.2	5.5	1.3	4.8	8.6	20.0		3.1	Incl. 18.8 Transplant, immunology and infectious diseases, and 28.6 Others
2014	13.0	6.5	7.0	3.1	4.2	6.4	19.2		2.9	Incl. 20.8 Transplant, immunology and infectious diseases, and 25.6 Others
2015	① 8.2	② 7.0	③ 1.9	④ 2.9	Other 4.0	⑤ 5.2	Other 16.6	Other and Overseas 3.0	Incl. 15.9 Transplant, immunology and infectious diseases, and 21.7 Others	

In the influenza area, where Chugai plays an important role as a provider of Tamiflu, we focus on providing information on the product's safety and effectiveness, including for prevention of the disease, based on extensive clinical data accumulated over a long period. In the area of chronic hepatitis, we work to raise awareness of the importance of early detection and treatment of chronic hepatitis C.

Under these conditions, sales in the transplant, immunology and infectious diseases field in Japan in 2015 decreased ¥4.9 billion, or 23.6 percent, year on year to ¥15.9 billion. Sales in the Others field in Japan

decreased ¥3.9 billion, or 15.2 percent, to ¥21.7 billion.

Under new mid-term business plan IBI 18, we intend to proactively provide information to a wide range of facilities by advancing e-promotion and cooperation with wholesalers, based on obtaining proper understanding of Tamiflu-resistant viruses. To prepare for the launches of products for hemophilia A, bronchial asthma and central nervous system diseases, which are expected later this decade, we will take steps such as training MRs and establishing the necessary marketing organization.

# Development

## Initiatives and Performance in 2015

### 34

Pipeline projects  
(As of January 28, 2016)

### 9

New products launched and new indications  
(2013-2015)

### 17

PHC-based development projects  
(As of January 28, 2016)

### 10

Products in-licensed from Roche  
(2013-2015)

1. Proof-of-concept (PoC) is a demonstration that the therapeutic effect conceived in the research stage is effective in humans. Early PoC means that in addition to safety, signs of efficacy or pharmacological effect have been confirmed in a limited number of cases.

## Chugai's Development System

Guided by its business philosophy, "Innovation all for the patients," Chugai has established a lifecycle management system that coordinates multiple operations, including preclinical and clinical studies, manufacturing, drug safety and regulatory affairs, to bring innovative pharmaceuticals to patients as quickly as possible. Function leaders are assigned from different departments for each development project, and lifecycle leaders, who have been given authority over certain personnel matters, provide strong leadership for cross-divisional lifecycle teams to expedite the progress of each project and the filing of applications for approval.

## Acceleration of Global Development

We are making various changes aimed at speeding up global development to maximize the value of our in-house products.

For example, Alecensa (development code: AF802) was launched in September 2014, a mere seven years after the project was conceived. In the United States, Alecensa received breakthrough therapy designation

from the FDA, and obtained approval in December 2015, just three months after it was designated for priority review. Another product, ACE 910, was out-licensed to Roche less than two years after the start of clinical development. These successes are the result of following a development model with a higher probability of success and efforts to maximize the value of in-house projects from the early stages of development by enrolling patients and selecting appropriate endpoints in phase I clinical trials. In addition, for SA237 and CIM331, Chugai has taken a new approach by managing multinational studies.

In August 2014, we amended our business agreement with Roche regarding out-licensing. Among the changes, we now offer Roche first refusal rights for overseas development of all products upon achievement of early PoC.<sup>1</sup> This enables Chugai to prioritize the allocation of resources to accelerate early clinical development, and to design global development plans and negotiate with partners earlier to facilitate a smooth transition to phase III multinational studies. Moreover, as part of our drive to speed up the development process for in-house projects, we established the Translational Clinical Research (TCR) Division in April 2015 and are shifting to unified management in our three key regions of Japan, the United States and Europe by

## Relationship to Our Strengths



- ① High product potential that addresses unmet medical need
- ② One of the richest pipelines in Japan
- ③ Strategic alliance with the Roche Group
- ⑤ Knowledge and experience as a pioneer in personalized healthcare (PHC)
- ⑥ Commitment to safety management

## Reinforcement of Global Development Functions

I was appointed Chief Medical Officer of Chugai Pharma USA in March 2014. Over the last two years, I have witnessed Chugai's impressive discovery technologies and the enthusiasm of its employees. I felt that Chugai needed to leverage those strengths to increase its presence globally. Now, Chugai is working hard Group-wide to strengthen global development, including the establishment of the TCR Division and expansion of development operations in the United States. I believe these are significant steps toward reducing the time to achieve early PoC or PoC through stronger early clinical development. Going forward, we want to meet the expectations of patients by making innovative products available to them faster. To do so, we will further speed up global development by adapting to the healthcare needs, drug regulations, commercial value and other aspects in each country from the early development stage.

### Athos Gianella-Borradori, M.D.

Chief Medical Officer (CMO), Chugai Pharma USA, Inc.  
Department Manager, TCR Science & Strategy Department,  
Translational Clinical Research Division,  
Chugai Pharmaceutical Co., Ltd.





integrating and reorganizing our overseas subsidiaries. This new operating structure will allow us to carry out a faster, more competitive global development strategy.

steady progress. Chugai filed for regulatory approval for two projects, and obtained approval for three others. Chugai's pipeline grew even richer, with three projects from Chugai research and four new projects in-licensed from Roche advancing to the clinical phase.

## Results and Overview of Development Activities

Of the 34 projects currently in Chugai's pipeline, 15 originated from Chugai research, and half are based on PHC (as of January 28, 2016). In 2015, all projects continued to make

### Development Pipeline (As of January 28, 2016)

	Phase I	Phase II	Phase III	Filed
Oncology	<p>❖ CKI27 (RG7304) (Japan/Overseas)</p> <p>◆ Solid tumors</p> <p>RG7596 NHL</p> <p>RG7604</p> <p>◆ Solid tumors</p> <p><b>RG7440</b></p> <p>◆ Solid tumors</p>	<p>❖ GC33 (RG7686)</p> <p>◆ Hepatocellular carcinoma</p>	<p>❖ <b>AF802 (RG7853) (Alecensa)</b> (Overseas)</p> <p>◆ Non-small cell lung cancer (NSCLC) [1st line]</p> <p>RG1273 (Perjeta)</p> <p>◆ Breast cancer (adjuvant)</p> <p>◆ Gastric cancer</p> <p>RG3502 (Kadcyla)</p> <p>◆ Breast cancer (adjuvant)</p> <p>GA101 (RG7159) Aggressive non-Hodgkin's lymphoma (NHL) Indolent NHL</p> <p><b>RG7446</b></p> <p>◆ NSCLC</p> <p>◆ NSCLC (adjuvant)</p> <p>◆ Bladder cancer</p> <p>◆ Muscle invasive bladder cancer (adjuvant)</p> <p>◆ Renal cell carcinoma</p> <p><b>RG435 (Avastin)</b> Renal cell carcinoma</p>	<p><b>RG435 (Avastin)</b> Cervical cancer</p> <p>❖ <b>AF802 (RG7853)</b> (Alecensa) (Europe)</p> <p>◆ NSCLC [post-crizotinib]</p>
Bone and Joint Diseases			<p>❖ <b>ED-71 (Edirol) (China)</b> Osteoporosis</p>	
Autoimmune Diseases			<p>❖ <b>MRA (RG1569) (Actemra)</b> Large-vessel vasculitis Giant cell arteritis (Overseas) Systemic sclerosis</p> <p>❖ SA237 Neuromyelitis optica (NMO)*</p>	
Renal Diseases	<p>❖ <b>EOS789</b> Hyperphosphatemia</p>			
Central Nervous System	<p>RG1662 Improvement of intellectual ability in individuals with Down syndrome</p>		<p>RG1450</p> <p>◆ Alzheimer's disease</p>	
Others	<p>❖ <b>PCO371 (Overseas)</b> Hypoparathyroidism</p>	<p>RG3637</p> <p>◆ Idiopathic pulmonary fibrosis</p> <p>❖ <b>CIM331</b> Atopic dermatitis* Pruritus in dialysis patients</p> <p>❖ URC102 Gout (Overseas)</p>	<p>RG3637</p> <p>◆ Asthma</p> <p>❖ <b>ACE910 (RG6013)</b> Hemophilia A</p>	

❖ Originated in-house Colored letters indicate change in status in 2015 or thereafter. ◆ PHC-based drug discovery

\* Multinational study managed by Chugai Pharmaceutical

# Production and Procurement

## Initiatives and Performance in 2015

Invested in facilities to handle multiple antibody development projects simultaneously

Created and started operation of a world-class system for pharmaceutical quality management

# 76

Published research papers from the Pharmaceutical Technology Division (2010-2015)

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

## Relationship to Our Strengths



- ① High product potential that addresses unmet medical need
- ③ Strategic alliance with the Roche Group
- ④ Cutting-edge drug discovery technologies, especially biotechnology
- ⑥ Commitment to safety management

## Features of Chugai's Production Functions

Chugai is enhancing its production technologies and working toward a more robust production system based on the belief that its production functions create value through stable supply to patients and healthcare providers and product creation that allows the Company to deliver innovative pharmaceuticals to patients as early as possible.

Chugai has been accumulating new knowledge and experience backed by continuous innovation, particularly in the manufacture of therapeutic antibodies, where our technologies are at the top level in Japan. For example, we have achieved commercial-scale production of a series of pharmaceuticals developed using our new antibody technologies.

Our production bases are located in various regions around the world, with three domestic plants in Utsunomiya, Ukima and Fujieda. We have also created a rigorous quality control system in line with global standards, including compliance with GMP.\*

## Measures to Enhance Production Functions

Chugai focuses on enhancing its production functions for accelerated market launches and simultaneous development based on continuous generation of development projects that are more innovative.

One measure is the establishment of a seamless integrated production system. Formerly, investigational new drug production and post-marketing production each had their own exclusive facilities and staff. However, raising the level of GMP and sharing technologies for flexible use of both lines immediately reduced the time required for development while accommodating a staged increase in scale from clinical development to post-marketing production. The extremely rapid acquisition of approval for Alecensa and other products exemplifies the success of this measure. To expedite multiple development projects, we employ single-use bioreactors at the Ukima plant. This makes washing and inspection after cultivation unnecessary, allowing cultivation of the next batch without interruption and thus dramatically raising capacity utilization (currently four such 2,000-liter units are in operation, including two units installed in 2015).

Future development of drugs using recycling antibody, sweeping antibody and other technologies will require an active pharmaceutical ingredient (API) production system that can handle simultaneous development of multiple projects. For this purpose, Chugai decided in 2015 to build a new antibody API plant at the Ukima plant capable of high-mix, low volume production of late-stage investigational biologics and initial commercial products. At the Utsunomiya plant, we are upgrading production systems, and have already installed tray fillers to handle various types of syringes on the same production line during the filling process for injectable formulations.

## Overview of Production Bases

Plant	Features	Products Manufactured
<b>Utsunomiya plant (Tochigi Prefecture)</b>	One of Japan's largest facilities for cultivating biological active pharmaceutical ingredients (APIs) and a state-of-the-art production line for injectable formulations	Biological APIs: Actemra APIs Injectable formulations: Actemra, Avastin, Epogin and others
<b>Ukima plant (Tokyo)</b>	Manufactures and packages solid and injectable formulations and biological APIs. Started manufacturing investigational new drugs in 2013.	Biological APIs: Epogin APIs and others Injectable formulations: Oxarol and others Solid formulations: Alecensa and others
<b>Fujieda plant (Shizuoka Prefecture)</b>	Integrated production system from API synthesis to formulation and packaging. Also supplies its APIs overseas.	API synthesis: Ediol API and others Solid formulations: Ediol, Tarceva, Xeloda and others



2,000-liter single-use bioreactors

## Reliable Distribution of Pharmaceuticals

In addition to ensuring a stable and continuous supply of safe, high-quality pharmaceuticals, Chugai is strengthening its supply chain management. As part of that effort, we share information and collaborate with Roche to meet global demand, drawing on our experience as the supplier of Japan's first original therapeutic antibody to overseas markets.

With the globalization of our suppliers of raw materials and intermediates and our production bases for finished products, we are ensuring shipping quality between bases and 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.



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



Cell separation: Cells are eliminated from the culture medium.



Tray fillers

## 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.

## Quality Assurance

Placing top priority on patients, Chugai seeks to provide high-quality products and services that offer outstanding efficacy and safety. From this perspective, Chugai's Quality Assurance Department is working closely with manufacturing sites, including Roche's production facilities, to improve product quality.

Quality assurance functions have diversified in recent years in response to the increasing complexity of the product supply process and the acceleration of development with the introduction of the fast-track review system to support the early launch of innovative new drugs. Quality requirements are becoming increasingly stringent with Japan's accession to the Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) in July 2014 and the start of implementation of the international Pharmaceutical Quality System guideline.

In view of these trends, Chugai conducts consistent GMP throughout the product lifecycle from development to manufacturing, and is strengthening oversight of GMP management to promote more rigorous and high-level quality assurance. As part of its efforts to strengthen oversight, Chugai has created a world-class system for pharmaceutical quality management that began operation in April 2014.

# Research

## Initiatives and Performance in 2015

11

In-house projects in pipeline  
(As of January 28, 2016)

40

Academic papers and presentations at scientific conferences regarding Chugai's innovative proprietary technologies  
(2013-2015)

60

Articles regarding Chugai research findings  
(2013-2015)

1. Generating innovative, new value by utilizing the technologies and development capabilities of external research networks in addition to in-house capabilities

## Relationship to Our Strengths



- ③ Strategic alliance with the Roche Group
- ④ Cutting-edge drug discovery technologies, especially biotechnology
- ⑤ Knowledge and experience as a pioneer in personalized healthcare (PHC)

## Basic Policy and Allocation of Resources

Chugai's mission 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. In allocating research resources, we prioritize projects based on the following criteria:

- The 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
- Whether it is a project that will enable personalized healthcare (PHC)

At various decision points during research, we focus first and foremost on patient need, reflecting our belief that creating medicines truly needed by patients and healthcare providers will lead to Chugai's medium-to-long-term growth.

## Advantages of Chugai's Research Operations

**Strategic:** One of Chugai's strategic advantages is its ability to concentrate resources on innovative research. With a development pipeline that includes projects in-licensed from Roche and projects from our own research, we are able to maintain a robust R&D portfolio. Moreover, conducting global development of our projects in

collaboration with Roche enables us to focus personnel and funds on groundbreaking projects and create a steady succession of innovative drugs. In the early conceptual and research stages, including basic research, in addition to making in-house efforts we acquire new candidate compounds by making use of our external network. To continuously generate our own projects as part of the Roche Group, we need to create products that have value equal to or higher than the projects originating at Roche and Genentech. This is also a driving force behind our innovation.

**Technological:** Drug discovery technologies, largely antibody engineering technologies, are Chugai's core competence. We are focused on development of competitive proprietary technologies that are necessary to fill areas of unmet medical need. This leads to the generation of innovative medicines.

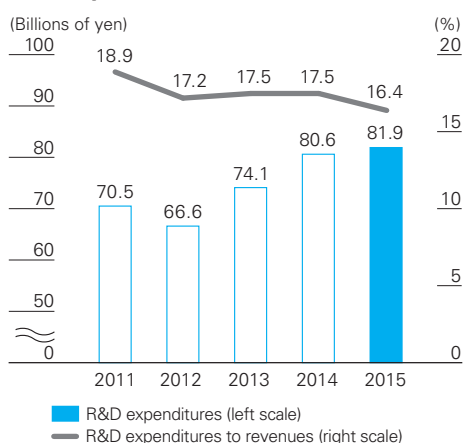
Chugai began conducting research and development of biopharmaceuticals more than 30 years ago, and the former Nippon Roche had also established world-class technology for the discovery of chemically synthesized agents. Over the years, we have cultivated knowledge and experience through our own pioneering initiatives while also incorporating outside technologies. As a result, we have continuously evolved our technologies, and have built a technology platform that we can flexibly and appropriately apply to drug discovery.

This disciplined approach to research and technology has become Chugai's identity. In the relationships we are building with our research and development partners, including Roche and academia, we recognize each other's technological strengths and expertise, which leads to valuable discussions.

In the new mid-term business plan, we have selected middle molecules as a next-generation core candidate technology in addition to antibody engineering technologies and small molecules. We intend to invest heavily in this area to establish technologies and quickly generate new projects.

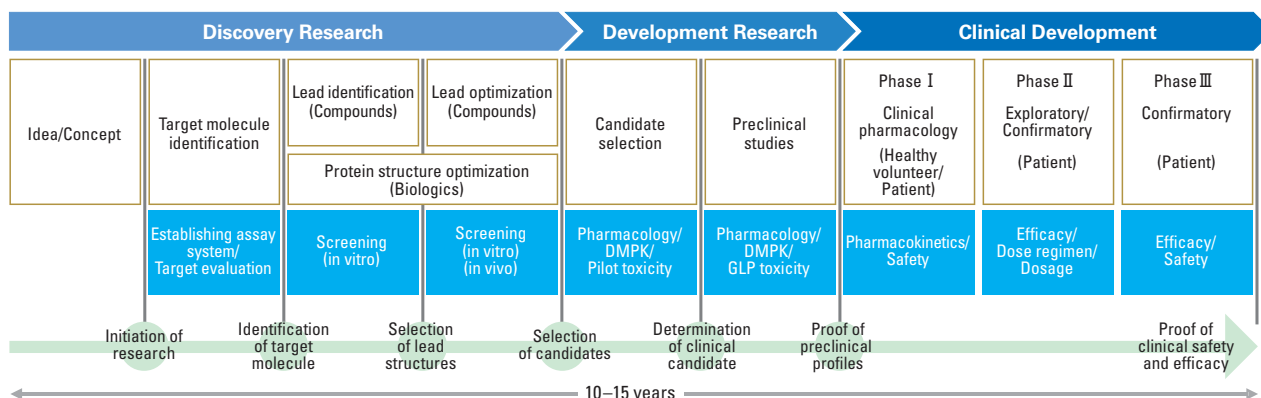
**Structural:** Backed by our competitive technological strengths, we have established our research structure in an open innovation<sup>1</sup> environment. We are building a productive external network by steadily pursuing joint research with academic institutions in which we provide our highly useful drug discovery technologies and expertise while they share their new discoveries with us. In addition, we

## R&D Expenditures (Core Basis)





## Process and Milestones of Drug Development



have established and operate satellite labs (research subsidiaries) whose mission is to conduct exploratory research, which does not typically produce short-term results but is important for the medium and long term.

Another key advantage is our 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,<sup>2</sup> is a significant advantage for Chugai in terms of cost and efficiency, and has dramatically increased our research productivity.

our total pipeline, including projects in-licensed from Roche.

We have also achieved significant results in development of proprietary antibody engineering technologies.<sup>3</sup> In May 2014, we licensed these technologies to Roche, including the recycling antibody, which extends a therapeutic antibody's duration of efficacy, the sweeping antibody, which eliminates disease-causing antigens from plasma, and the bispecific antibody.

Research at satellite labs has also yielded solid results, leading to the 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, has advanced into clinical development, and new drug targets have also been identified at Forerunner Pharma Research Co., Ltd. Moreover, Chugai Pharmabody Research Pte. Ltd. (CPR), which we established in Singapore in 2012, is making steady progress in research focusing on discovery of new therapeutic antibodies. Several of its projects are scheduled to enter clinical development in 2016.

## 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 three new compounds in our pipeline in 2015, two were developed in-house. PHC-related projects represented 50 percent of

### Progress of Development Projects

(January 1, 2015 – January 28, 2016)

	Number of Projects	Breakdown		
		New Molecular Entities	Additional Indications	Additional Dosage and Administration/ Formulations
Approved	7	1	2	4
Filed	6	2	2	2
Started phase III	8	6	2	0
Started phase II	2	1	1	0
Started phase I	3	3	0	0
Development suspended	4	—	—	—

2. A technology that conducts evaluations at a high speed with automated robots or other means to select chemical compounds having activities for drug creation targets from a library consisting of a vast number of compound types with various structures

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

## Bioethics in R&D

To ensure that research using human-derived test material is carried out appropriately, Chugai has established Ethical Guidelines for Research That Uses Human-Derived Test Material and a Research Ethics Committee. More than half of the members of this committee are from outside the Company, enabling fair evaluations from a pluralistic frame of reference. Moreover, we strive to ensure that research is conducted with respect for human rights by offering guidance to our researchers on the necessary ethical knowledge and standards required when conducting research on human-derived test material, including the Declaration of Helsinki and protection of personal information.

## Chugai's View of Animal Welfare

When handling laboratory animals used in research, Chugai acts in accordance with the Guidelines for the Care and Use of Laboratory Animals it has established to respect their lives from the standpoint of animal welfare and act so as to minimize their pain, keeping in mind the scientific conditions.

The Institutional Animal Care and Use Committee has added an examiner from outside the Company to assess the validity of research using laboratory animals from a more objective viewpoint and make appropriate improvements to reflect changes in the social environment and scientific progress. At the same time, an institutional qualification program was adopted for researchers and animal handlers to cultivate concern for animal welfare through education and training. These measures were positively evaluated by AAALAC International,<sup>4</sup> a global independent evaluation organization, and Chugai has maintained full accreditation since 2007.

## Academic Support Activities

Chugai actively promotes exchanges with researchers and healthcare providers around the world and particularly the fostering of young researchers in Asia.

The Chugai Academy for Advanced Oncology (CHAAO)<sup>5</sup> held its largest event, the International Academy for Advanced Oncology (IAAO) 2015 in Tokyo in July 2015. The main topic of this sixth annual forum was "Forefront of Oncology Care: Discovery, Development and HTA." Thirteen influential oncologists working at the forefront of their field gave lectures on cutting-edge cancer therapy. As in the previous two years, the event included discussion of cancer immunotherapy, which has shown increasing promise, as well as cancer epigenetics, the importance of which has been recognized in recent years.

Chugai conducts an international joint research fellowship program through the Tokyo Biochemical Research Foundation (TBRF).<sup>6</sup> 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 84 researchers from 17 Asian countries and regions. At a meeting in March 2015, 13 researchers from India, Indonesia, South Korea, China, Bangladesh and Myanmar made presentations.

4. 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.

5. 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.

6. For details on the foundation, see the TBRF website (<http://www.tokyobrf.or.jp/english/>)

# Medical Affairs

## Initiatives and Performance in 2015

21

Contract-based post-marketing studies (including 15 in accordance with ICH-GCP guidelines)

(As of December 31, 2015)

213

Staff handling regional medical affairs

(As of December 31, 2015)

157

Staff with the GCP Passport certification of the Japan Society of Clinical Trials and Research

(As of January 31, 2016)

1. Activities to contribute to healthcare from a scientific standpoint
2. Good Clinical Practice: Standards for conducting pharmaceutical clinical trials

## Relationship to Our Strengths



- ① High product potential that addresses unmet medical need
- ③ Strategic alliance with the Roche Group
- ⑥ Commitment to safety management
- ⑦ Support for healthcare delivery

## Organization of the Medical Affairs Division

In addition to creating a steady flow of innovative drugs, Chugai recognizes the importance of ensuring that the value of its products is delivered appropriately to patients, which will lead to better treatment. We believe that disseminating scientific data is important for promoting the safe and appropriate use of new products based on verification of their efficacy in treatment and other matters. At the same time, healthcare compliance requirements for pharmaceutical companies are being tightened worldwide. In Japan, separation of marketing and medical affairs<sup>1</sup> and enhancement of transparency and fairness in post-marketing clinical studies have become pressing issues.

In 2012, Chugai shifted all functions related to medical science to establish the independent Medical Affairs Division and unified functions for medical affairs and promotion of non-clinical studies. In 2013, we dispatched medical staff to each branch in addition to the Head Office to set up a system for consistent promotion of medical affairs throughout the Company. In 2014, we overhauled our organization and restructured the Medical Affairs Division to strengthen organizational governance and compliance in these unified activities. This division helps to promote the appropriate use of products by supporting post-marketing clinical studies, promoting safety measures for post-marketing surveillance and other areas, and training MRs.

## Strengthening Medical Affairs Functions and Initiatives

Chugai's Medical Affairs Division plans science-based medical activities to provide useful solutions to patients, and supports or performs post-marketing clinical studies, non-clinical studies (basic research) and other activities. Industry-academia collaboration with medical institutions and healthcare professionals is indispensable for these activities, and improving the transparency of payment of researcher compensation and dealing with conflicts of interest have become major issues in recent years. Since 2012, Chugai has developed its own post-marketing clinical study scheme under the name "contract-based post-marketing studies"

to guarantee the independence and transparency of research. In addition, we quickly set up a structure for responding to Ethical Guidelines on Medical Research Involving Human Subjects, which were enforced from April 2015. We have also established a research support structure that conforms to the GCP<sup>2</sup> guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Moreover, we are building an organization to support global post-marketing clinical research based on these structures.

At the same time, we are focusing on developing highly qualified medical affairs staff. We have established training programs for acquisition of clinical research support associate certification and scientific training for medical representatives (MRs), and we are working to improve learning tools and e-learning programs.

Recognizing the importance of conducting healthcare compliance throughout Japan, in 2015 we dispatched Area Compliance Leaders to each branch, and plan to further strengthen our Company-wide healthcare compliance organization with training for MRs and Medical Affairs Division staff. Moreover, along with our reorganization of subsidiaries outside Japan in 2015, we built infrastructure for integrated control of medical functions on a global level. We plan to establish a worldwide structure for medical information in 2016.

We will continue working to generate new clinical data and disseminate more appropriate information solutions to healthcare providers as we contribute to medical research in Japan.

# Drug Safety

## Initiatives and Performance in 2015

Approx. **186,000**

Cases for which safety information was collected in clinical trials and post-marketing studies (January-December 2015)

**9** products

New RMPs prepared and carried out (As of February 2016)

**27**

Papers and conference presentations on safety (2015)

## Relationship to Our Strengths



- ① High product potential that addresses unmet medical need
- ③ Strategic alliance with the Roche Group
- ⑥ Commitment to safety management
- ⑦ Support for healthcare delivery

## 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 a safety system directly linked to management. With measures such as these, Chugai builds greater credibility.

## Measures to Enhance Drug Safety

### Promoting Safety Evaluation and Appropriate Use

The Drug Safety Division is at the core of measures to collect and evaluate information on drug safety and efficacy. One such measure, post-marketing surveillance, which includes the all-case registration surveillance discussed below, is conducted on new drugs under actual treatment conditions, mainly to collect safety information that is unobtainable in a clinical trial. Post-marketing surveillance is conducted according to fixed protocols. Data forms are collected from medical institutions through electronic systems, and the accumulated data are analyzed as quickly as possible. The results obtained are shared with medical institutions and officially announced inside and outside the Company via scientific conferences, papers and other means.

Numerous innovative new drugs such as anticancer drugs or biopharmaceuticals require wider-ranging and more rigorous management, such as thorough management of distribution, including wholesalers and dispensing pharmacies, and confirmation of conditions of use, in addition to surveillance in which all patients to whom a product is being administered are registered (all-case registration surveillance). Ahead of other companies, Chugai conducted large-scale all-case registration surveillance, particularly for Avastin, Tarceva and Actemra. In the last two years, Alecensa and Zelboraf have been

launched, and we began all-case registration surveillance together with rigorous safety measures. 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 Evaluation and Communication

Chugai is committed to highly transparent, speedy and timely reporting and release of drug safety information. In 2015, we collected safety information on more than 180,000 cases and evaluated it from a medical standpoint. We have established a system for recording the collected information in a global database and conducting signal detection of adverse drug reactions using that database. With this system, we promptly disclose information to regulatory authorities in Japan, the United States, Europe and Asia. In addition to a large volume of safety information, we have in-house medical doctors with abundant clinical experience who conduct expert safety evaluations.

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. In addition, we have established a group that specializes in safety communications. It provides accurate information in a timely manner and proactively conducts activities for more robust communication with customers. Specifically, we provide extensive information to patients as well as pharmacists, doctors and other healthcare professionals, give presentations at workshops for pharmacists in various regions of Japan, and conduct seminars for the media. In the next few years, we plan to enrich our website content and enhance delivery of specialized information through smartphones to help healthcare professionals better navigate patient treatments. These activities will help to reduce the incidence and aggravation of



adverse drug reactions by creating an environment for treatment that takes high-risk patients into consideration.

## Leading the Industry through Risk Management Plans

Amid increasing pharmacovigilance activities and discussions worldwide in recent years, Chugai has established a world-class safety management system that can accommodate the pharmaceutical regulatory systems and review procedures of regulatory agencies in Japan, the United States and Europe. Moreover, to establish a plan – do – check cycle in our post-marketing pharmacovigilance activities, we collect and analyze information consistently from the preclinical and clinical stages, and have drawn up and applied risk management plans (RMPs) to nine of our products since 2012, ahead of our competitors. RMPs became mandatory in Japan in 2013, but we implemented them early because we consider RMPs to be part of our commitment to patients and medical institutions, not just a legal obligation. Consequently, we have also come to view them 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.

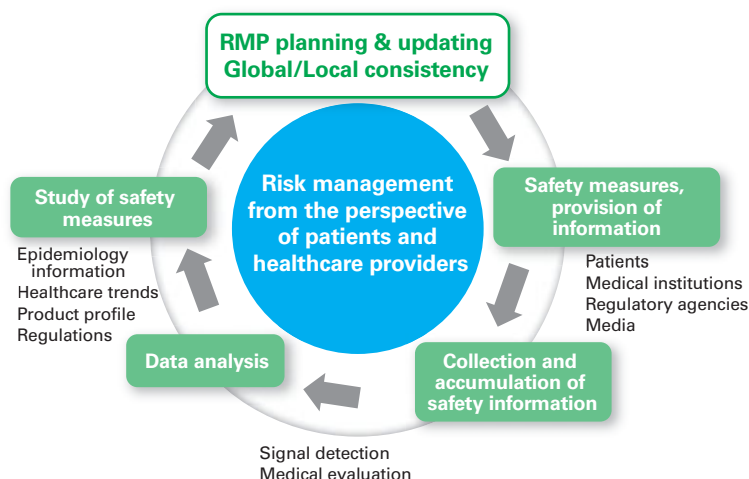
In applying RMPs, we were particularly aware of the need to strengthen our ability to

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 measures such as establishing signal detection and assessment tools for adverse events to assess potential risks and conduct more precise safety evaluations. In addition, based on the strong track record we have compiled ahead of our competitors, we are driving the industry in ways such as proactively working to formulate industrywide recommendations and guidance related to RMPs and database research.

## 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 cooperation in these ways, Chugai aims to provide patients and medical institutions with truly valuable safety data and contribute to healthcare worldwide.

### Organization Oriented to Risk Management



# Intellectual Property

## Initiatives and Performance in 2015

**3,834**

Number of patents held  
(including pending applications)  
(As of December 31, 2015)

**164**

New patents granted worldwide  
(2015)

**3**

Applications to register a patent  
term extension filed in Japan  
(2015)

**Improved efficiency by using  
electronic documents and  
visualizing workflows**

## Implementation of Our IP Strategy

Chugai views its global intellectual property (IP) strategy as the foundation for creating innovative new drugs. By integrating it with our business and R&D strategies, we protect the competitive advantage of our products and ensure operational flexibility. 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 substance and use. We also work to establish rights globally for significant drug discovery technologies such as innovative antibody technologies, and use those rights in planning and executing our IP strategy. In addition, we are building our own database for patents related to antibody engineering technologies, which are becoming increasingly complex and sophisticated, and are using it to plan IP strategies, including monitoring trends at other companies.

overseas such as application strategies for individual products, selection of countries where applications will be filed, and strategies for acquisition of rights. In addition, we endeavor to choose our best options globally by coordinating closely within the Roche Group, including Genentech, at all times.

Another feature is our strategic use of antibody-related technology patents. Antibody engineering technologies are an important part of our R&D strategy, and we actively conduct research and development both to cultivate our basic technologies and to apply them to product development. In our IP strategy, we make use of patents for antibody-related technologies to strategically secure a competitive advantage in the market.

## Current Patent Portfolio

By therapeutic area, oncology accounts for the largest share of our patent portfolio with approximately 32 percent of the total, a proportion that reflects our product portfolio. In 2015, Chugai acquired 164 patents in Japan, the United States and major European countries, as well as other countries worldwide. These include patents protecting CIM331, which was developed from Chugai research, and SMART-Ig, our innovative antibody technology.

## Relationship to Our Strengths

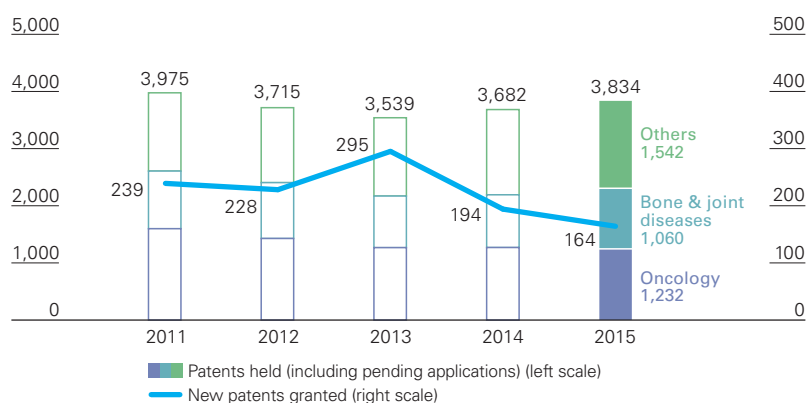


- ① High product potential that addresses unmet medical need
- ③ Strategic alliance with the Roche Group
- ④ Cutting-edge drug discovery technologies, especially biotechnology
- ⑤ Knowledge and experience as a pioneer in personalized healthcare (PHC)

## Features of Our IP Strategy

One feature of our IP strategy is that we take full advantage of our benefits as a member of the Roche Group. For inventions originating at Chugai, we take responsibility for planning and execution of matters in Japan and

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



# Environmental Protection, Safety and Health

## Initiatives and Performance in 2015

**-13%**

Energy consumption per employee compared with 2010  
(Chugai Group in Japan)  
(2015)

**+9%**

Amount of waste generated compared with 2014  
(Chugai Group in Japan)  
(2015)

**-36%**

Amount of landfill waste compared with 2014  
(Chugai Group in Japan)  
(2015)

**1.78**

Occupational incidence rate  
(No. of occupational injuries and deaths /  
No. of hours actually worked × 1,000,000)  
(As of December 31, 2015)

## Basic Stance

Based on its recognition of the importance of promoting occupational safety and health and environmental protection in order to continue to do business, the Chugai Group conducts activities in line with its Guidelines for Environmental Protection and Guidelines for Health and Safety. We continuously promote environmental, safety and health activities by going through the PDCA cycle for such activities at each facility.

## Framework for Promoting Environmental Protection, Safety and Health Activities



## Environmental Protection Activities

### Basic Approach

At Chugai, we conduct activities to minimize our impact on the environment in accordance with environmental laws and regulations, with the aim of contributing to the protection of the global environment as set forth in the Chugai Business Conduct Guidelines, based on one of our core values – “We care about the global environment” – and the Chugai Environmental Policy.

### Chugai Environmental Policy

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

#### Regulatory Compliance

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

#### System to Facilitate Action

Each year Chugai sets an environmental action plan and goals and establishes environmental management systems to continuously work to protect the environment.

#### Environmental Protection Activities

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

#### Education and Training

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

#### Information Disclosure

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

(Effective January 1, 2012)

### Mid-Term Environmental Goals

In 2014, the Chugai Group set the following four mid-term environmental goals, with 2020 as the final year, to promote environmental protection activities from a medium-to-long-term perspective.

- Energy consumption per employee: 20 percent reduction compared with 2010
- Discontinuance of the use of specified chlorofluorocarbons (CFCs) and hydrochlorofluorocarbons (HCFCs)
- Zero emissions of waste<sup>1</sup>: Three facilities
- Average fuel efficiency of MR fleet: 16 km/l or higher

Toward the achievement of these goals, we set the following goals for 2015. Although we did not set numerical targets for energy consumption per employee and discontinuance of the use of specified CFCs, we worked for continuous reductions.

- A recycling ratio of 80 percent or higher, a final disposal ratio of 2 percent or lower and on-site verification of 70 percent or more of waste disposal contractor facilities
- Plain paper copier (PPC) paper purchased: Less than the previous year; recycling ratio of 80 percent or higher
- Ratio of fuel-efficient vehicles<sup>2</sup>: 50 percent or higher; average fuel efficiency of MR fleet: 16 km/l or higher

### Climate Change Countermeasures

The Chugai Group works to reduce its volume of greenhouse gas emissions through measures including reducing energy consumption, introducing fuel-efficient vehicles and reducing the use of specified CFCs and HCFCs toward discontinuance. Progress in 2015 was as follows.

- Energy consumption per employee was 304 gigajoules, a 13 percent reduction compared with 2010.
- The ratio of fuel-efficient vehicles remained above 50 percent at 55 percent. Average fuel efficiency of the MR fleet was 14.2 km/l.
- The total amount of CFCs and HCFCs used was 5,690 kg, a decrease of 56 kg from 2014.

### Waste and Recycling

#### Industrial Waste in 2015

To achieve zero emissions of waste, the Chugai Group aims to increase its recycling ratio and further reduce its amount of landfill waste. In 2015, the amount of industrial waste generated was 2,840 tons (an increase of 224 tons, or 9 percent, compared with 2014), the amount of landfill waste was 25 tons (a decrease of 14 tons, or 36 percent),

the final disposal ratio<sup>3</sup> was 0.9 percent, and the recycling ratio was 79 percent (an increase of 5 percentage points). The recycling ratio fell slightly short of the target due to an increase in waste generated as a result of increased production activities and other factors, but we achieved the target for the final disposal ratio.

### Water Resources

Water is an important raw material for pharmaceutical manufacturing, and is also a crucial global resource. The Chugai Group has been building awareness of the effective use of water resources by monitoring the volume used and discharged each year. Moreover, from the standpoint of protecting biodiversity, we began conducting WET<sup>4</sup> tests in 2013 to ascertain the ecological impact of wastewater discharged from our facilities. In 2015, we conducted WET tests four times over the year at all plants and research laboratories, and confirmed that there were no problems.

### Environmental Accounting

Environmental accounting data compiled in 2015 are shown below. Investments in 2015 totaled ¥540 million, while costs were ¥1,378 million. Major investments included heat source equipment. The economic benefit was ¥54 million.

#### 2015 Investments and Costs for Environmental Protection (Millions of yen)

Breakdown of costs	Investments	Costs
(1) Business area costs	524	1,041
(2) Upstream and downstream costs	—	44
(3) Administration costs	16	279
(4) R&D costs	—	2
(5) Social activity costs	—	10
(6) Environmental remediation costs	—	3
<b>Total</b>	<b>540</b>	<b>1,378</b>

### Training Internal Environmental Auditors for Global ISO14001 Standards

To deal with environmental problems on a worldwide scale, the Chugai Group trains internal environmental auditors who can offer advice for continuous improvement of environmental management systems (EMSs) based on their global knowledge. Through a contract with the International Register of Certificated Auditors (IRCA) of the U.K. for its Organisations Employing Auditors (OEA) scheme, we have increased the number of IRCA-certified internal environmental auditors to 19. These auditors lead Group EMSs from a viewpoint of contributing to environment-oriented management.

1. A waste recycling ratio of 99 percent or more

2. Includes hybrids and class 3 fuel-efficient vehicles

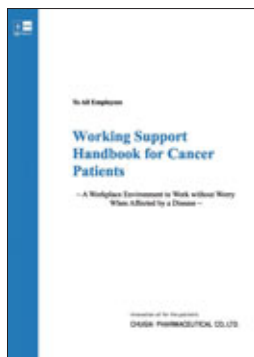
3. Amount of landfill waste / Amount of industrial waste generated

4. Whole Effluent Toxicity: A method for comprehensive evaluation of the safety of wastewater and the aquatic environment by determining the impact on crustaceans (*Daphnia*), algae and fish (*Oryzias latipes* and others) immersed in diluted wastewater





In recognition of its efforts to establish working conditions for employees undergoing cancer treatment, Chugai received the Excellence Award for 2015 from the Tokyo Metropolitan Government as a "company providing support to employees with cancer to keep a good balance between treatment and work."



Working Support Handbook for Cancer Patients

## Safety and Health Activities

### Basic Approach

Health and safety measures are based on our policy of placing priority on ensuring employee safety in all business operations, pursuant to our Guidelines for Health and Safety. We are taking proactive measures to upgrade our safety and health systems throughout the Company, ensure safety, prevent occupational injuries, promote health maintenance and create pleasant working environments. In addition, we work to uniformly conduct various measures at all facilities, including safety and health management and measures for mental health.

### Safety and Health Risk Assessment

The Chugai Group introduced safety and health risk assessment as a Company-wide activity in 2014 to effectively prevent workplace injuries and health hazards. In addition to ongoing activities at each workplace including those in tandem with safety and health patrols, in 2015 we established an assessment team system and an implementation plan for accurately and efficiently evaluating risks in divisions that research and manufacture pharmaceutical preparations, which have workplaces that are complex and varied.

### Health Management

Chugai has occupational physicians, nurses, psychologists, health officers and other occupational health staff to provide necessary support not only for employees who are unwell or on leave due to illness or injury, but for all employees who need consideration for their health condition at work, including those with abnormalities found in health checkups, those who work long hours, pregnant women, and employees with disabilities. Health staff, human resource managers and workplace supervisors cooperate as shown in the chart below.

### Support for Return to Work after Mental Health Leave

Support for employees returning to work after mental health leave is conducted within a framework similar to that for health management. Due to a program that provides individualized support for returning to work, the number of employees with problems that recur within a year of their return has fallen substantially. In addition, Chugai also conducts ongoing awareness activities including training for managers on promoting understanding of mental health problems and dealing with them appropriately.

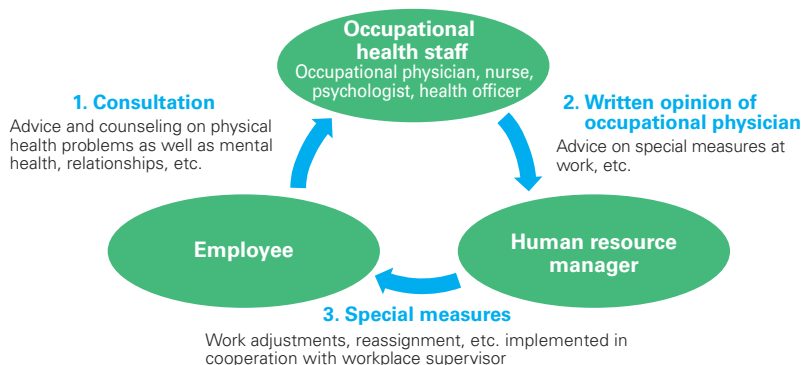
### Work Support Measures for Employees with Cancer

The Chugai Group has enhanced its support for employees who are working while undergoing cancer treatment so that they can do both without anxiety. In addition to establishing a consultation system for carrying out measures in accordance with treatment conditions and a support system for working during outpatient treatments such as chemotherapy, hormone therapy or radiation therapy, we created the *Working Support Handbook for Cancer Patients* to introduce the program to all employees.

### Creating Healthy, Energetic Workplaces

To prevent problems such as poor mental health or harassment, Chugai conducts measures to vitalize workplaces and improve the working climate to create highly productive environments where employees can work energetically. Since 2013, our health management and human capital development organizations have collaboratively conducted team coaching training for a cumulative total of 941 participants at 58 organizations as of December 31, 2015. Post-training surveys have shown improvement in work engagement, workplace identification and other items.

### Basic Health Management Structure



# Social Contribution Activities

## Initiatives and Performance in 2015

### Promoted awareness of para-sports

Donated 1 vehicle each to  
**35** organizations  
(Total of 238 vehicles  
donated over 31 years)

Donation of welfare vehicles to provide transportation for home welfare services  
(2015)

**83** (total over 25 years)

Cumulative number of countries receiving free therapeutic drugs for lymphangiomas  
(2015)

**27**

Number of locations in which Chugai employees participated in the 24-hour charity event Relay For Life Japan  
(2015)

## 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 Japan, 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 47 locations throughout Japan in 2015. Chugai employees have participated as volunteers in Relay For Life Japan since 2007. A total of 648 employees took part as "Team Chugai" at 27 locations in 2015. This year, Chugai produced and offered a new "Interactive 3D Adventure (Breast Cancer Edition)," in which 2,261 people participated at 22 locations while Team Chugai members provided explanations. Participants enjoyed learning about examinations for early detection of breast cancer and the importance of early treatment.



Chugai employees participate as volunteers in Relay For Life Japan.

## Support for Para-Sports

Chugai co-sponsors the Japanese Para-Sports Association (JPSA) as an official partner, and cooperates in activities to help realize the JPSA's philosophy of "creating a vital and inclusive society." Below are the main activities Chugai conducted in 2015.

- **Co-sponsorship of GOAL!, a pamphlet about para-sports**  
Chugai co-sponsored a pamphlet designed to show more people the appeal of para-sports. (Issued by the Japan Para-Sports Association)



- **Activities to support para-sports**

Events including a photo panel display on para-sports, a specialized equipment exhibition and an opportunity for visitors to try their hand at para-sports were held in Hokkaido, Aomori, Miyagi, Gunma, Tokyo, Fukui and Osaka prefectures.

- **Employees and their families try their hand at para-sports**

Chugai held a hands-on event for experiencing para-sports in cooperation with the Yokohama City Special Support School for the Visually Impaired. A total of 25 employees and their family members participated.



Para-sports experience event

## Disaster Relief Activities

### Support for Children in Stricken Areas

Chugai participated in the global charity event Roche Children's Walk 2015 conducted by Roche to support children in need. Of the total funds raised by Chugai employees and the matching amount from Chugai, ¥1.37 million was donated to Network Orange, an NPO in Kesennuma, Miyagi Prefecture that supports children and people with disabilities in the area affected by the Great East Japan Earthquake of March 2011.



Donation ceremony at Network Orange



Charity sale at the Kamakura plant

## Charity Sale to Support Recovery from the Great East Japan Earthquake

As part of its support for recovery from the Great East Japan Earthquake, Chugai held a charity sale at the Kamakura plant in cooperation with Kesennuma Fisheries Cooperative Association and the Association for Aid and Relief, Japan (AAR Japan), an authorized NGO. The event featured products from the disaster area, including specialties of Kesennuma, confectioneries made at a vocational training center in the disaster area and original charity goods from AAR Japan. Sales totaled more than ¥330,000.

## 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 60th anniversary. In 2015, the 31st year of the program, Chugai commemorated its ninetieth anniversary by donating a total of 30 four-wheel-drive welfare vehicles to six prefectures in the Tohoku region, mainly those impacted by the Great East Japan Earthquake, aside from its ongoing donation program. Those 30 vehicles, in addition to the five donated every year, brought to 238 the cumulative number of vehicles donated since the start of the program.

In Japan's super-aging society, the number of senior citizens and disabled people requiring nursing care is increasing year by year. Given these circumstances, securing the means for those living at home to go to places such as hospitals, day service centers and day care centers and to receive in-home care by staff from these facilities, is also significant from the viewpoint of enhancing welfare services.

The welfare vehicle donation 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.

## Participation in a Public-Private Partnership for Global Health

In December 2014, Chugai joined the Global Health Innovative Technology Fund (GHIT Fund) to promote Japan's international contributions in the area of global health (<https://www.ghitfund.org/en>).

### GHIT Fund Efforts and the Significance of Chugai's Participation

The GHIT Fund is a public-private partnership initiated in Japan that makes more direct use of Japan's medical technologies, scientific innovations and knowledge to support the development of new drugs to fight serious diseases such as malaria, tuberculosis and other infectious diseases in developing countries. Jointly established in April 2013 with funding from Japanese pharmaceutical companies, the Japanese government (the Ministry of Foreign Affairs and the Ministry of Health, Labour and Welfare), the Bill & Melinda Gates Foundation and the United Nations Development Programme, it supports and promotes new drug development for global health.

In line with its mission of working for the benefit of the medical community and human health around the world, Chugai contributed capital to the GHIT Fund, and at the same time decided to undertake a specific drug development program using its innovative discovery technologies and research resources. As a partner in the GHIT Fund, Chugai expects that promoting the development of new medical technologies will go beyond basic social responsibility, leading to the promotion of health and sound economic growth in developing countries. In addition, Chugai is participating in this public-private partnership in the belief that it is a necessary long-term investment in Japan's future growth.

**GHIT Fund**

Global Health Innovative Technology Fund

# Corporate Communication

## Initiatives and Performance in 2015

16

Information events for the media and institutional investors (2015)

466 (cumulative total)

Security analysts and institutional investors worldwide with whom individual meetings/conference calls were held (2015)

4

Briefings for individual investors and shareholders (2015)

2

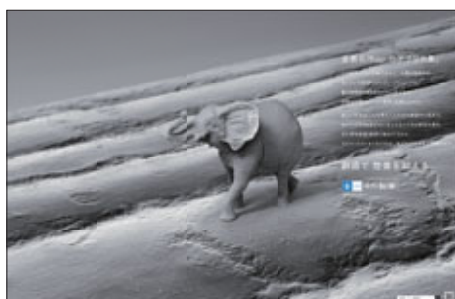
Plant tours for shareholders and media (2015)

## Communication with Society

Chugai emphasizes communication with stakeholders to increase its corporate value. As such, we are working to enhance communication not only with our shareholders and investors, but with the general public.

Since 2013, we have been conducting a project to develop our public relations strategy with the aim of establishing our corporate brand. By sharing Chugai's unique strengths with our stakeholders outside the Company, we aim to gain their recognition and understanding. Chugai's strengths have been identified and shared inside the Company as part of our project to become a top pharmaceutical company, which started in 2009. Using these strengths as a basis, through interviews inside and outside the Company, outside evaluations and analysis and other measures, we established Chugai's seven unique strengths. (For details on the seven strengths, see "Chugai's Seven Strengths" on pages 12-13.)

In December 2014, we adopted a new slogan, "INNOVATION BEYOND IMAGINATION."



The "Invisible Art: Elephant" series of Chugai branding advertisements, featuring "nano sculptures" by South African sculptor Jonty Hurwitz, has won the Prize for the Best Work at the 83rd Mainichi Advertisement Design Competition held by the Mainichi Newspapers Co., Ltd. and sponsored by the Ministry of Economy, Trade and Industry.

The slogan conveys the commitment of the Company and the strong desire of its employees to make Chugai a top pharmaceutical company that continuously creates not only the products anxiously awaited by people around the world but also unprecedented medicines that exceed all expectations.

## Media Relations Initiatives

Chugai conducts media relations activities on a daily basis to proactively disseminate information through methods including press releases, assistance with information gathering, various types of information meetings, observation tours and informal discussions with management. Recognizing the important role played by the media in conveying corporate information to all its stakeholders, Chugai works to build and maintain good relationships with media outlets while disclosing information appropriately and in a timely manner.

## 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 the same day as other companies. Convocation notices for the general meeting of shareholders are normally sent out more than four weeks prior to the meeting date.

## Chugai Receives Grand Prize at 18th Nikkei Annual Report Awards



The Nikkei Annual Report Awards have been held each year since 1998 for the further enhancement and diffusion of annual reports issued by Japanese companies, and 71 companies participated in 2015. Conveying the high quality of Chugai's management and clearly presenting its long-term management strategy, Chugai's report was recognized for its high degree of completeness as an integrated report comprehensive enough to function as an analyst's report.





Director, Executive Vice President & CFO Yoshio Itaya was selected as both the sell-side (securities companies) and buy-side (institutional investors) "All-Japan Executive Team Best CFO" in the healthcare and pharmaceuticals sector.\* This was his third consecutive year of selection by the sell side in recognition of his stance of increasing convenience for and enhancing communication with shareholders, investors and analysts in Japan and overseas.

\* 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.

The 105th annual general meeting of shareholders was held on March 24, 2016. 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

Coinciding with financial results announcements, Chugai holds information meetings and conference calls for investors, analysts and the media. In 2015, we held an information meeting for Zelboraf, an anticancer agent and BRAF inhibitor that we launched in February 2015. In response to strong demand from institutional investors, we also conducted tours of the Ukima plant and Kamakura research laboratories to introduce Chugai's advanced biopharmaceutical manufacturing technologies and small-molecule drug discovery research system. In addition, we have conducted tours of the Utsunomiya plant each year since 2013 to increase communication with individual shareholders. Moreover, in addition to participating in domestic and overseas conferences hosted by securities companies, Chugai is enhancing its outreach to individual investors by holding information meetings for them at branches of securities companies throughout Japan.

Senior management also holds overseas roadshows and in 2015 visited institutional investors in Europe, the United States and Asia. To deepen mutual understanding by providing an opportunity for direct discussion between the President and market participants in small groups, we held a series of four informal discussions between the President and a total of 45 institutional investors and securities analysts. We will continue measures to enhance "face-to-face IR with management" to promote understanding of Chugai's corporate value.

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, information meeting materials, annual reports and an IR event calendar. We work to provide comprehensive information to our stakeholders through measures such as 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.

## 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 a corporate management committee. The IR Committee holds regular meetings and is responsible for the establishment, revision and internal dissemination of the information disclosure policy, and for the management and promotion of information collection, disclosure and other related activities.

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

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

# Detailed Performance Report

Basic Information.....	92
Environmental Data.....	108
Corporate Governance .....	110
Organization.....	115
Glossary.....	116



# Basic Information

## 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 2 to 4 percent going forward. In the year ended March 2014, national medical expenses<sup>1</sup> totaled ¥40,061.0 billion, an ¥849.3 billion or 2.2 percent increase from the previous year. The rapid aging of Japan's society presents serious challenges to efficiently managing the increase in medical expenses for the elderly.

1. Source: Overview of National Medical Expense (2013) by Ministry of Health, Labour and Welfare

#### Promotion of the Use of Generics

The Japanese government is promoting the use of generics<sup>2</sup> 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. A Cabinet decision in June 2015 set the new goal of raising the volume market share of generics, which was 58.2 percent as of February 2015, to more than 80 percent by the end of March 2020.

2. Drugs 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 official 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 fiscal 2016, drug reimbursement prices declined by 1.22 percent overall on a medical expense basis, or 5.75 percent on a reimbursement price basis.

In addition, including the additional repricing based on market expansion, the estimated decline in prices was approximately 1.7 percent on a medical expense basis and approximately 7.8 percent on a reimbursement price basis.

#### NHI Drug Price Revision Rate (%)

	2008	2010	2012	2014*	2016
Industry Average	(5.2)	(6.5)	(6.25)	(2.65)	(7.8)
Chugai	(7.2)	(6.8)	(6.0)	0.8	(5.5)

Source: Chugai data

\* Includes provision for increase in consumption tax

#### Repricing based on Market Expansion

Under this repricing rule, which was introduced in 1994, drugs priced by the cost calculation method that have annual sales at the time of the price revisions exceeding ¥15.0 billion and more than two times the original forecast are subject to a price reduction of up to 25.0 percent or if the drug's annual sales exceeded ¥10.0 billion and were more than 10 times the original forecast. Drugs priced by methods other than the cost calculation method (including the similar efficacy

comparison method) that have annual sales at the time of the price revisions exceeding ¥15.0 billion and more than two times the original forecast are subject to a price reduction of up to 15.0 percent. In addition, the prices of drugs that have pharmacological action similar to the drug subject to this repricing rule are reduced by the same rate.

#### Additional Repricing based on Market Expansion

In the reforms to the drug pricing system in 2016, an additional repricing rule for drugs with very high annual sales was introduced as a special measure from the standpoint of balancing reward for innovation with maintenance of the National Health Insurance system. This rule lowers prices by up to 25.0 percent for drugs with annual sales of ¥100.0-¥150.0 billion and more than 1.5 times the original forecast, and lowers prices by up to 50.0 percent for drugs with annual sales exceeding ¥150.0 billion and more than 1.3 times the original forecast. In addition, the prices of drugs that have pharmacological action similar to the drug subject to the special repricing rule and were comparator drugs at the time of the NHI price listing are reduced by the same rate.

In 2016, four active ingredients and six products were subject to the additional repricing rule. The Central Social Insurance Medical Council (Chuikyo) plans to continue examining this rule further.

#### 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<sup>3</sup> problem. In this scheme, at the time of the NHI drug price revisions a premium (equal to the estimated value based on the market price multiplied by 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.<sup>4</sup>

This premium pricing for new drugs was continued on a trial basis in the NHI drug pricing system reforms of fiscal 2012, fiscal 2014 and fiscal 2016. The fiscal 2014 reforms 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 for creating new drugs will be eligible to receive premium pricing for their products.

In fiscal 2016, 416 active ingredients and 823 products received premium pricing (publicly announced).

3. The inability of Japanese patients to gain access to global standard or most advanced treatments because the drugs are not developed in Japan

4. 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.

#### Solving the Drug Lag Problem

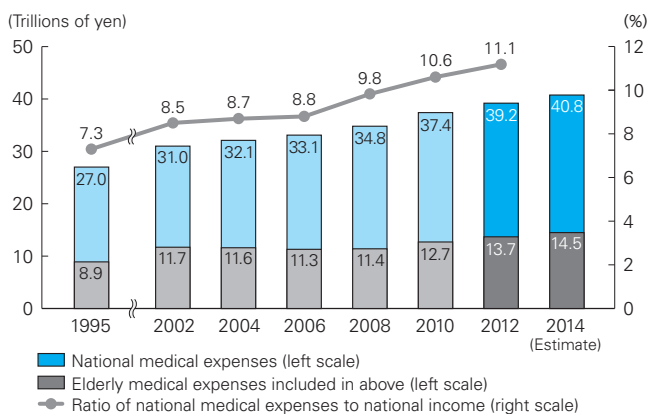
In January 2005, MHLW established the Investigational Committee for Usage of Unapproved Drugs as one means of helping solve the drug lag problem. The committee is charged with investigating the clinical necessity and the appropriateness of usage of drugs already approved in Europe and the United States, 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. As a result of continuous

efforts to strengthen the review function of the Pharmaceutical and Medical Devices Agency, an independent administrative institution responsible for reviewing drugs and medical devices for approval, the median total review time for new drugs in the year ended March 2015 was 11.9 months.

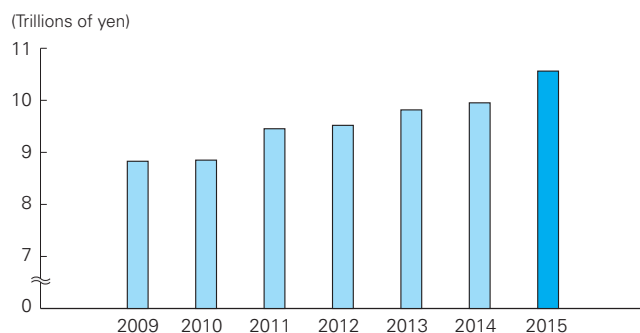
### Trends in National and Elderly Medical Expenses



Source: Overview of National Medical Expense (2012) by Ministry of Health, Labour and Welfare

Note: National income is based on the actual results of the System of National Accounts announced by the Cabinet office.

### Prescription Drug Market



Copyright 2016 IMS Health Source: JPM 2009-2015. Reprinted with permission. The scope of the market is defined by Chugai.

### Response to Requests from the MHLW Review Committee on Unapproved Drugs and Indications with High Medical Needs (As of January 28, 2016)

Development request	Product	Indication	Development status
First development request	Xeloda	Advanced or recurrent gastric cancer	Approved in February 2011
	Tarceva	Advanced or recurrent pancreatic cancer	Approved in July 2011
	Avastin	Advanced or recurrent breast cancer	Approved in September 2011
	CellCept	Pediatric renal transplant	Approved in September 2011
	Herceptin	Q3W dosage metastatic breast cancer overexpressing HER2	Approved in November 2011
		Neoadjuvant breast cancer overexpressing HER2	
	Kytril	Gastrointestinal symptoms associated with radiotherapy	Approved in December 2011
	Pulmozyme	Improvement of pulmonary function in patients with cystic fibrosis	Approved in March 2012
	Bactramin	Treatment and prevention of pneumocystis pneumonia	Approved in August 2012
Second development request	Avastin	Ovarian cancer	Approved in November 2013
	Avastin	Recurrent glioblastoma	Approved in June 2013 (Malignant glioma)
	Herceptin	Q1W dosage postoperative adjuvant breast cancer overexpressing HER2	Approved in June 2013
	CellCept	Lupus nephritis	Public knowledge-based application filed in August 2015
Third development request	Tamiflu	Additional dosage for neonates and infants younger than 12 months	Awaiting evaluation by study panel regarding Chugai's view with respect to development request
	Xeloda	Adjuvant chemotherapy in rectal cancer	Public knowledge-based application filed in March 2016

## Oncology

### Overview of Diseases and Treatment Methods

#### Leading Cause of Death in Japan

Cancer has been the leading cause of death in Japan since 1981. In 2014, 368,103 people<sup>1</sup> died of cancer, accounting for 28.9<sup>1</sup> percent of all deaths in that year and the highest figure since government surveys began in 1899.

1. Source: Outline of Vital Statistics (2013) by Ministry of Health, Labour and Welfare

#### 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 the optimal therapy based on scientific knowledge and in accordance with their wishes ("the availability of standard therapy" 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. Furthermore, it is projected that achieving the overall goal of reducing the age-adjusted cancer mortality rate by 20 percent over 10 years from 2007 in the Basic Plan to Promote Cancer Control

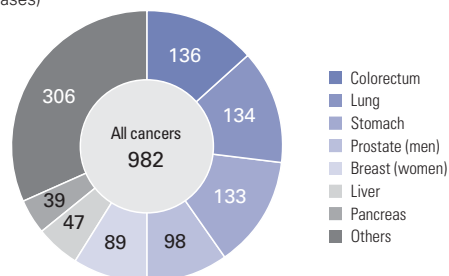
Programs (approved by the Cabinet in June 2012), will be difficult. Therefore, in December 2015, the Plan for Acceleration of Cancer Control Programs was formulated. This plan specified concrete measures that should be implemented intensively in a short period of time.

#### 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 medicines such as molecular targeted drugs have been introduced. This has brought a dramatic improvement in treatment outcomes in colorectal, lung and breast cancer, gynecological cancers, kidney cancer, brain tumors, malignant melanoma, hematological malignancy and other forms of cancer. Advances are being made in personalized healthcare, which involves

#### Projected Cancer Incidence (2015)

(Thousands of cases)



Source: National Cancer Center Cancer Information Service, "Cancer Registries/Statistics"

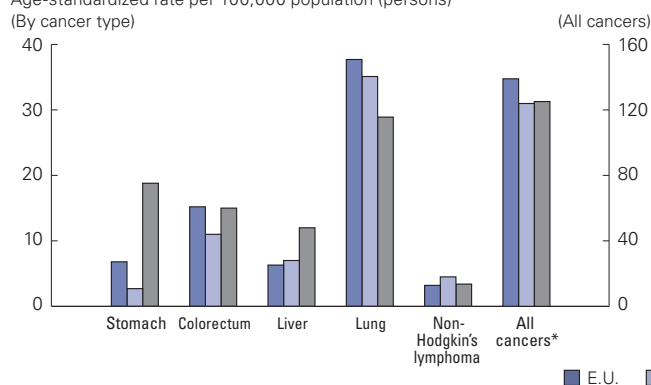
Note: Projections were performed by a model using age, calendar year at diagnosis, and their interactions as independent variables, utilizing the number of incidences of cancer by age bracket from Monitoring of Cancer Incidence in Japan (1975-2011 nationwide estimates) and mortality figures from Vital Statistics of Japan (1975-2013 estimates). The total may not add up due to projections performed by cancer type and rounding.

Reference material: Japanese Journal of Clinical Oncology 2014, 44: 36-41

#### International Comparison of Cancer Mortality Rates (2012)

##### Male

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

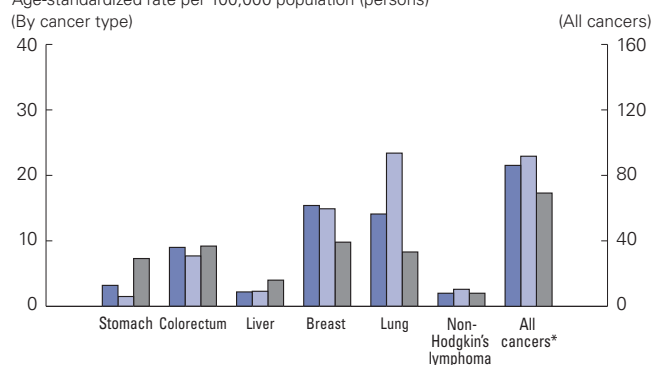


\* Excluding non-melanoma skin cancer

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 28/02/2015.

##### Female

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



testing patients with diagnostic agents when administering molecular target therapies to identify patients in whom the drug is likely to have the desired effect with minimal strain on the body and few side effects. In addition to enabling physicians to propose the optimal treatment tailored to each patient, this approach offers a number of other benefits. For example, it can reduce national healthcare expenditures by reducing the administration of drugs when their effect cannot be determined. When performing a diagnosis, there may be a number of different molecular targeted therapies available for the same disease, and there are some cases in which looking at the molecules expressed in the target tissues is insufficient for diagnosis; therefore, it is also becoming important to conduct exhaustive biomarker measurements such as multiplex testing. Moreover, the Council to Promote the Realization of Genomic Medicine established by the Japanese government in January 2015, the Ministry of Health, Labour and Welfare and pharmaceutical industry organizations have launched studies for the realization of genomic medicine. The provision of optimal treatments based on each patient's genetic profile is thus becoming a reality.

In addition, cancer immunotherapy, which takes advantage of the body's own immune cells to fight cancer is another important emerging field of treatment. Immunotherapies such as immune checkpoint inhibitors are a promising new direction in cancer treatment. Cancer has the ability to suppress immune functions to avoid attack from the immune system. By blocking the immune "brakes" (the binding of PD-1 to PD-L1) known as the immune checkpoint, immune cells can be awakened to attack cancer cells. In clinical trial results, immune checkpoint inhibitors have shown promise for long-term survival and cure, even in advanced cancer. Expectations are focused on their high therapeutic effect and potential for treating a wide range of cancers. On the other hand, some patients do not respond to immunotherapy, so screening to select patients for whom this therapy is effective and combination therapy with existing anti-cancer and other drugs are also being examined.

## Avastin (RG435)

Anti-VEGF humanized monoclonal antibody  
(Generic name: bevacizumab)

### Basic Information

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 cancer microenvironment. In Japan, Avastin was launched in 2007 for the treatment of unresectable, advanced or recurrent colon and rectal cancer. Chugai obtained approval for the additional indications of unresectable advanced or recurrent non-squamous non-small cell lung cancer (NSCLC) 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 2013 and 2014, respectively.

### Review of 2015 Performance

Sales of Avastin increased ¥11.5 billion, or 14.0 percent, year on year to ¥93.8 billion. It maintains a high market share and solid position in the treatment of colorectal cancer as an established standard of care at many medical institutions for advanced or recurrent cancer. Uptake has been steady for five cancer types, including lung and breast cancer. In January 2015, administration of Avastin began in a phase II clinical trial in Japan for the potential treatment of advanced or recurrent cervical cancer, and an application for approval was filed in September 2015. In addition, a phase III multinational study of

Avastin in combination with atezolizumab for the treatment of renal cell carcinoma started in June 2015.

## Rituxan

Anti-CD20 monoclonal antibody (Generic name: rituximab)

### Basic Information

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. In recent years, the usefulness of Rituxan in treating vasculitis and childhood-onset nephrotic syndrome has been recognized, and it has also become a valuable treatment option for patients with autoimmune diseases.

### Review of 2015 Performance

Sales of Rituxan increased ¥2.8 billion, or 10.7 percent, year on year to ¥29.0 billion. In addition to an increase in market share reflecting the approval for additional dosage and administration for non-Hodgkin's lymphoma maintenance therapy, approval based on a public knowledge-based application for the additional indication of refractory nephrotic syndrome also contributed to sales growth.

## Herceptin

Anti-HER2 humanized monoclonal antibody  
(Generic name: trastuzumab)

### Basic Information

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. Such cancer is diagnosed as HER2-positive. HER2-positive breast cancer progresses rapidly, and has been associated with a poor prognosis. However, treatment outcomes have improved significantly with the emergence of Herceptin and other medicines that target HER2. In 2011, Herceptin obtained 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.

### Review of 2015 Performance

Sales of Herceptin increased ¥1.5 billion, or 4.8 percent, year on year to ¥32.7 billion. As a pioneering product in personalized healthcare, Herceptin is valued as a mainstay in the treatment of HER2-positive breast cancer. The launches of Perjeta and Kadcyla stimulated activity in the treatment of HER2-positive breast cancer, and the use of Herceptin has continued across multiple lines of treatment. At the same time, increased awareness among physicians has helped to raise the rate of HER2 testing<sup>2</sup> for gastric cancer, further increasing the number of patients who can be treated with Herceptin.

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

## Perjeta (RG1273)

HER2 dimerization inhibitory humanized monoclonal antibody (Generic name: pertuzumab)

### Basic Information

Perjeta is a humanized monoclonal antibody and is the first molecular targeted therapy that inhibits the dimerization of HER2.

## Basic Information

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 launched Perjeta for the additional indication of HER2-positive inoperable or recurrent breast cancer in September 2013, after obtaining approval in June 2013.

### Review of 2015 Performance

Sales of Perjeta increased ¥1.5 billion, or 16.5 percent, year on year to ¥10.6 billion, significantly exceeding projections. Its use increased particularly in first-line treatment, backed by evidence that combination therapy with Herceptin improves overall survival (the length of time from diagnosis or start of treatment until death) in patients with HER2-positive inoperable or recurrent breast cancer. In the July 2015 update of clinical practice guidelines for breast cancer, the combination therapy of Herceptin and Perjeta with docetaxel was the only therapy to receive a Grade A recommendation as a first-line therapy for HER2-positive metastatic or recurrent breast cancer.

In development, phase III multinational studies are in progress for the potential treatment of HER2-positive breast cancer (adjuvant) and advanced or recurrent gastric cancer.

## Kadcyla (RG3502)

Anti-HER2 antibody-tubulin polymerization inhibitor conjugate (Generic name: trastuzumab emtansine)

### Basic Information

Kadcyla is an antibody-drug conjugate of the anti-HER2 humanized monoclonal antibody trastuzumab (the active ingredient of Herceptin) and the potent chemotherapeutic agent DM1, joined together with a stable linker. Chugai filed an application for approval for the treatment of HER2-positive inoperable or recurrent breast cancer in January 2013, obtained approval in September 2013 after priority review, and launched the product in April 2014.

### Review of 2015 Performance

Sales of Kadcyla were ¥7.3 billion. The drug's innovative mode of action has been highly evaluated since its launch in April 2014. In the July 2015 update of clinical practice guidelines for breast cancer, Kadcyla was the only drug to be given a Grade A recommendation for second-line treatment of HER2-positive metastatic or recurrent breast cancer.

In development, Chugai was participating in a phase III multinational study for the potential treatment of HER2-positive breast cancer

(adjuvant) (the GATSBY trial), but it failed to meet primary endpoints, and development was discontinued.

## Xeloda

Antimetabolite, 5-FU derivative (Generic name: capecitabine)

### Basic Information

Xeloda is a 5-fluorouracil (5-FU) anticancer agent developed at the research laboratories of the former Nippon Roche. Orally administered Xeloda is absorbed by the body, then gradually metabolized by certain highly active enzymes in liver and tumor tissue, 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 approval for treating patients with advanced or recurrent colon, colorectal and gastric cancer not amenable to curative resection.

### Review of 2015 Performance

Sales of Xeloda increased ¥0.7 billion, or 6.7 percent, year on year to ¥11.1 billion. By promoting side effect management, Xeloda has established a top position in postoperative adjuvant chemotherapy performed to inhibit recurrence after surgery for colon cancer. In gastric cancer, prescriptions have increased in cases of recurrence following postoperative adjuvant chemotherapy with other agents.

In development, Chugai filed an application for approval for the additional indication of gastric cancer (adjuvant) in December 2014, and obtained approval in November 2015.

## Tarceva

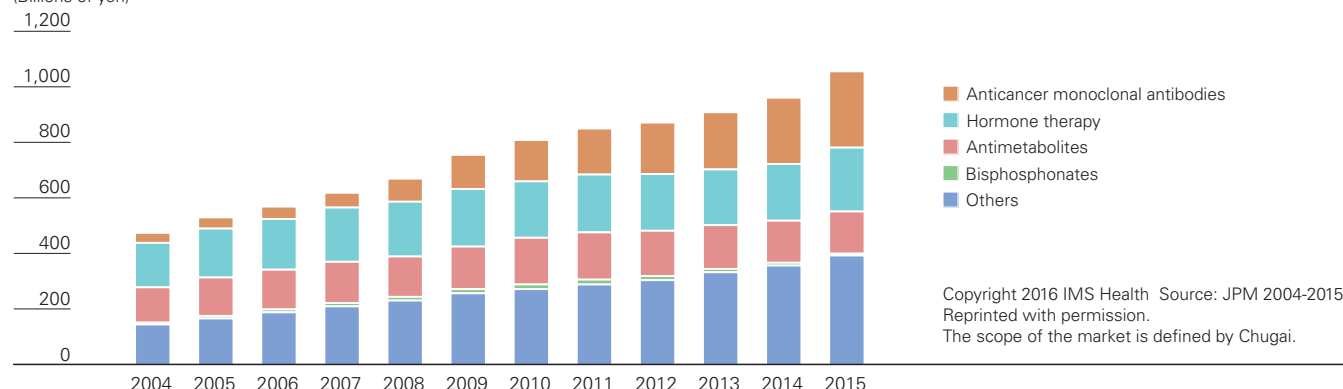
Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (Generic name: erlotinib)

### Basic Information

Tarceva is an oral targeted small-molecule drug that inhibits the activation of 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

## Anticancer Market in Japan

(Billions of yen)





Asia diagnose positive for *EGFR* mutations. In 2011, Tarceva obtained approval for the additional indication of pancreatic cancer not amenable to curative resection.

### Review of 2015 Performance

Sales of Tarceva increased ¥0.1 billion, or 0.9 percent, year on year to ¥11.6 billion. In non-small cell lung cancer, the use of Tarceva in first-line treatment in patients with *EGFR* mutations, an indication that obtained approval in 2013, continues to increase as planned, but replacement with competing products is increasing in the second-line setting.

## Neutrogin

Recombinant human granulocyte colony-stimulating factor (G-CSF) (Generic name: lenograstim)

### Basic Information

Neutrogin is a recombinant human granulocyte colony-stimulating factor (G-CSF) created 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, enabling the safer use of chemotherapy, thus helping to improve treatment outcomes. Neutrogin is also essential in hematopoietic cell transplantation, which is performed for illnesses that affect production of normal blood cells, such as leukemia.

### Review of 2015 Performance

Sales of Neutrogin in Japan decreased ¥1.0 billion, or 16.9 percent, year on year to ¥4.9 billion due to competition from other products, including biosimilars.<sup>3</sup> Overseas sales decreased ¥0.9 billion, or 5.7 percent, to ¥14.8 billion, due to the impact of exchange rates (high yen relative to the euro).

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

## Alecensa (AF802/RG7853)

ALK inhibitor (Generic name: alectinib)

### Basic Information

Alecensa, an oral, small-molecule targeted molecular therapy created by Chugai, inhibits the activity of ALK kinase with *EML4-ALK* fusion gene expressed in about 2 to 5 percent of non-small cell lung cancers. It was designated as an orphan drug in Japan in September

2013 for the treatment of *ALK* fusion gene-positive unresectable, recurrent/advanced non-small cell lung cancer. In October 2013, Chugai filed an application for approval. Following approval in July 2014, Alecensa was launched first in Japan in September 2014. As the first product from Chugai research to be granted breakthrough therapy designation by the U.S. Food and Drug Administration (FDA), it is expected to contribute to the treatment of patients around the world.

### Review of 2015 Performance

Clinical trials in Japan and other countries have suggested that Alecensa has a high degree of efficacy, and it is penetrating markets at a steady pace. Sales in 2015 were ¥8.0 billion. All-case registration surveillance is currently being conducted for Alecensa, and Chugai is promoting appropriate use and gathering safety information. To improve convenience for patients, Chugai launched a high-content 150 mg preparation in December 2015, in addition to the 20 mg and 40 mg preparations already available.

Outside Japan, applications were filed in the United States in July 2015 and in Europe in September 2015. In December 2015, Alecensa obtained conditional approval in the United States for the indication of *ALK*-positive, metastatic non-small cell lung cancer in patients whose disease has progressed on or who are intolerant to crizotinib based on evidence of its clinical benefits.

## Zelboraf

BRAF inhibitor (Generic name: vemurafenib)

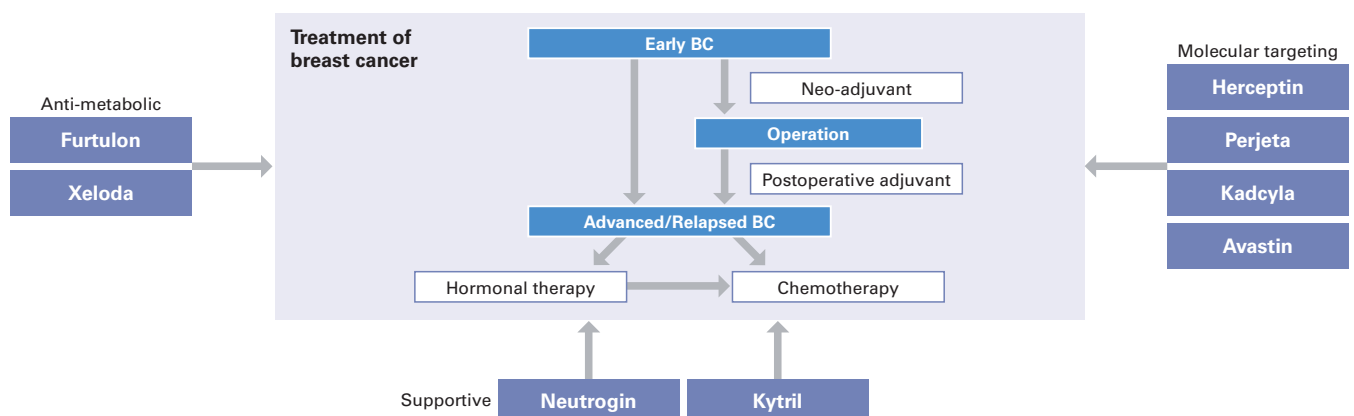
### Basic Information

Zelboraf, in-licensed from Roche, is an oral, small-molecule drug that selectively inhibits a mutated form of the BRAF protein found in 30 to 40 percent of all malignant melanoma cases. Chugai filed an application for approval of Zelboraf for the treatment of unresectable melanoma with *BRAF* mutation in April 2014, obtained approval in December 2014 and launched the product in February 2015.

### Review of 2015 Performance

Since its launch in February 2015, uptake has increased steadily, with sales of ¥0.5 billion in 2015. In addition, Roche Diagnostics K.K. filed an application for approval of a companion diagnostic to detect the *BRAF* mutation, and obtained approval in December 2014.

## Extensive Contribution to Cancer Treatment (Breast Cancer)



### Aloxi

5-HT<sub>3</sub> receptor antagonist (Generic name: palonosetron)

### Akynzeo

NEPA (Generic name: oral combination of netupitant and palonosetron)

#### Basic Information

These products are small molecules for the prevention of chemotherapy-induced nausea and vomiting. Chugai has been granted exclusive marketing rights by the Helsinn Group of Switzerland for Aloxi in the U.K. and Akynzeo in the U.K. and Ireland. Aloxi is a best-in-class 5-HT<sub>3</sub> receptor antagonist, and Akynzeo is an oral capsule that combines this receptor antagonist with netupitant, a novel NK1 receptor antagonist. Aloxi was launched in the U.K. in January 2015. Akynzeo was launched in the U.K. in September 2015 and in Ireland in December 2015.

#### Review of 2015 Performance

Sales in the U.K. for Aloxi and Akynzeo totaled ¥0.3 billion. All MRs in charge of promoting these products also handle Granocyte, which is creating synergy.

### GA101 (RG7159)

Type II glycoengineered humanized monoclonal antibody (Generic name: obinutuzumab; overseas product name: Gazyva/Gazyvaro (E.U.))

GA101 is a type II glycoengineered humanized monoclonal antibody in-licensed from Roche. Like Rituxan, GA101 targets CD20. Phase III multinational studies for the potential treatment of indolent non-Hodgkin's lymphoma and for aggressive 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.

### RG7446

Engineered anti-PDL1 monoclonal antibody (Generic name: atezolizumab)

RG7446 is an engineered anti-PDL1 monoclonal antibody in-licensed from Roche. 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 restores and maintains the immune response of T cells by binding to PD-L1, and is expected to demonstrate efficacy against cancer. Its mode of action differs from conventional treatments that attack cancer cells directly. Since it takes advantage of the patient's own immune response, it is also promising for use in combination with existing drugs and for a wide range of cancer types. Phase III multinational studies for the potential treatment of non-small cell lung cancer started in February 2014. In 2015, Chugai began participating from Japan in phase III multinational studies for the potential treatment of bladder cancer in January, renal cell carcinoma (in combination with Avastin) in June, bladder cancer (adjuvant) in November and non-small cell lung cancer (adjuvant) in December.

### GC33 (RG7686)

Anti-glypican-3 humanized monoclonal antibody (Generic name: codrituzumab)

GC33, a humanized monoclonal antibody created by Chugai, targets glypican-3, which is specifically expressed in hepatocellular carcinoma. 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. GC33 did not meet the primary endpoint in a phase II multinational monotherapy study started in March 2012. Future clinical trial plans, including combination therapy with other agents, are now under consideration.

### CKI27 (RG7304)

Raf/MEK inhibitor

CKI27 is a Raf and MEK dual inhibitor created by Chugai and out-licensed to Roche overseas. The two companies are co-developing CKI27, and phase I clinical trials in Japan and overseas have been completed. An investigator-initiated clinical trial is ongoing overseas, and interim results were announced at the 2015 annual meeting of the American Society of Clinical Oncology (ASCO).

### RG7596

Anti-CD79b antibody-drug conjugate (Generic name: polatuzumab vedotin)

RG7596 is an antibody-drug conjugate of an anti-CD79b monoclonal antibody and the microtubule inhibitor MMAE, joined together with a linker. A phase I clinical trial started in Japan in July 2014 for the potential treatment of non-Hodgkin's lymphoma. The conjugate is designed to deliver MMAE directly into B cells via CD79b, which is expressed in non-Hodgkin's lymphoma, so that the inhibitor can act. RG7596 is expected to demonstrate a cytostatic effect on tumor cells while limiting impact on normal cells.

### RG7604

PI3K inhibitor (Generic name: taselisib)

RG7604 is a PI3K inhibitor in-licensed from Roche. A phase I clinical trial started in Japan in September 2014 for the potential treatment of solid tumors. This drug is a small-molecule anticancer agent that selectively inhibits PI3K. It has been shown to exhibit stronger inhibitory activity against PI3Kα mutations compared with RG7321, development of which was discontinued in 2015.

### RG7440

AKT inhibitor (Generic name: ipatasertib)

RG7440 is an AKT inhibitor in-licensed from Roche. Chugai started a phase I clinical trial for the treatment of solid tumors in Japan in June 2015.

## 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 risk. About 13 million people in Japan suffer from osteoporosis, including one in every two women age 65 and older. However, the treatment rate stands at around only 20 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

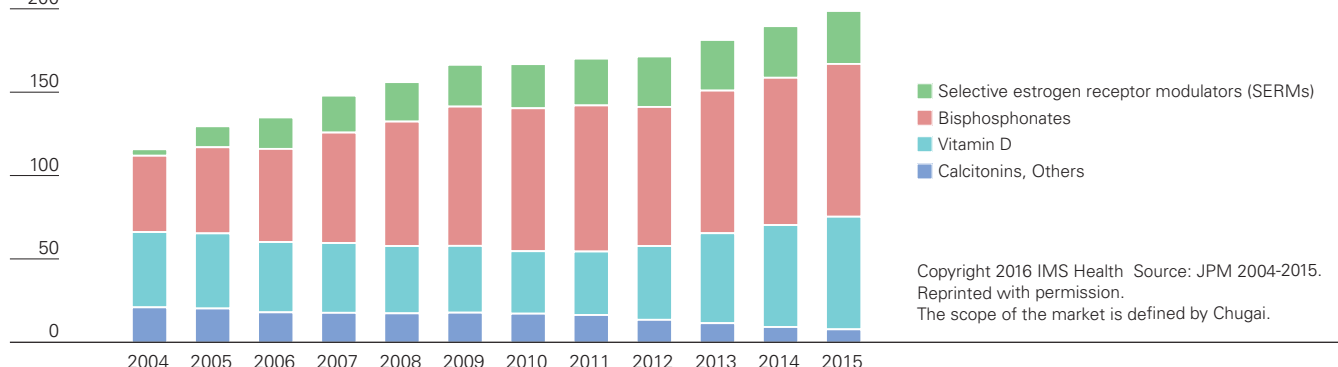
Osteoporosis has primarily been treated using bisphosphonates, calcitonin preparations and selective estrogen receptor modulators (SERMs), which are bone resorption inhibitors, and active vitamin D<sub>3</sub> derivatives, which improve bone metabolism, but treatments such as human parathyroid hormone (PTH) therapy and a humanized anti-RANKL antibody have also been approved.

#### Regulatory Trends

National guidelines for osteoporosis treatment were revised in October 2006. Subsequently, 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, Ediol and other medicines have recently been approved for insurance coverage. Revisions issued in December 2011 added preventive and diagnostic items in light of the importance of early prevention to broaden the overall scope of osteoporosis treatment. Since then, the 2012 revised diagnostic criteria for primary osteoporosis and revised management and treatment guidelines for steroid-induced osteoporosis have been adopted, Bonviva and other medicines have been launched and covered by insurance, and revised guidelines were issued in June 2015.

### Osteoporosis Market in Japan

(Billions of yen)  
200



### Alfarol

Active vitamin D<sub>3</sub> derivative (1 $\alpha$  (OH) D<sub>3</sub>) for improving bone metabolism (Generic name: alfacalcidol)

#### Basic Information

Alfarol is an active vitamin D<sub>3</sub> derivative approved in 1981. It maintains bone mass by adjusting calcium and bone metabolism, and therefore is effective in preventing vertebral fractures. The drug has been shown to be particularly effective in preventing falls, and attention has focused on this feature that sets Alfarol apart from other osteoporosis treatments.

#### Review of 2015 Performance

Sales of Alfarol decreased ¥0.7 billion, or 14.3 percent, to ¥4.2 billion due to the switch to Ediol and the market penetration of generics.

### Ediol

Active vitamin D<sub>3</sub> derivative (Generic name: eldecalcitol)

#### Basic Information

Ediol is a new vitamin D<sub>3</sub> preparation born out of Chugai's many years of research in vitamin D. Chugai started sales of Ediol in April 2011 as the successor drug to Alfarol for the indication of osteoporosis. Under an agreement signed in May 2008, Ediol has been co-developed and is currently co-marketed with Taisho Pharmaceutical Co., Ltd. Clinical trials have confirmed that Ediol has a similar safety profile to alfacalcidol with a statistically significant greater effect in preventing fractures. In the 2015 osteoporosis prevention and treatment guidelines (published in June 2015), Ediol received a Grade A recommendation, the only one for an active vitamin D<sub>3</sub> preparation, for its effectiveness in increasing bone density and preventing vertebral fractures.

#### Review of 2015 Performance

Sales of Ediol increased ¥3.9 billion, or 20.3 percent, to ¥23.1 billion. It has become the most widely used active vitamin D<sub>3</sub> preparation because of its superior efficacy in increasing bone mass and preventing fractures compared with existing products. Recognition and understanding of Ediol as a base treatment has also broadened. As a result, its use by medical institutions is increasing, as are prescriptions, primarily for new cases.

In China, a phase III clinical trial for the treatment of osteoporosis began in August 2015.

## Bonviva

Bisphosphonate anti-resorptive agent  
(Generic name: ibandronate)

### Basic Information

Bonviva is a bisphosphonate in-licensed from Roche. The injectable formulation was launched in August 2013. Under an agreement signed in September 2006, Bonviva is being co-developed and co-marketed with Taisho Pharmaceutical Co., Ltd. Bisphosphonates in Japan had previously been administered in drip infusions that took 30 minutes or longer, but Bonviva IV Injection is given in a rapid intravenous injection once a month. This is expected to significantly reduce the burden on patients at the time of administration. In a phase III clinical trial (the MOVEST study), the oral formulation demonstrated non-inferiority to Bonviva IV Injection. Chugai filed an application for approval in Japan in February 2015, and obtained approval in January 2016.

### Review of 2015 Performance

Sales of Bonviva IV Injection increased ¥2.0 billion, or 58.8 percent, to ¥5.4 billion. As this drug is particularly convenient for patients who have difficulty taking existing oral formulations, Chugai has actively promoted it to healthcare providers as a product that can be expected to improve adherence to treatment. This has helped to substantially increase recognition of the drug's usefulness.

## 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, there are only several hundred patients in Japan with systemic juvenile idiopathic arthritis (sJIA), the form of RA suffered by children below 16 years of age, but sJIA is considered even more difficult to treat than adult forms of the disease.

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, with knee osteoarthritis in particular affecting at least 80 percent of people 60 years of age or older, primarily women.

### Treatment Methods and Market Conditions

In drug therapy for RA, methotrexate, an anti-rheumatic drug, is mainly used in treatment, but with the introduction of biologics, the goal of treatment has now been extended to remission. 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 is forecast to reach ¥26.5 billion\* by 2020. 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 2014, a biosimilar was also launched in Japan.

In addition to drip infusions, which were the only formulations previously available, subcutaneous formulations have been added, and new formulations that improve convenience, such as a dosage form that can be injected simply by pushing a button, are increasing. In Japan, Europe and the United States, the subcutaneous market is estimated to be larger than the intravenous market.

Steroid drugs, which had been the only treatment available for sJIA, can cause growth impairment and other adverse reactions. Accordingly, the approval and launch of Actemra in April 2008 provided a significant advance in therapy.

The main drug therapies for osteoarthritis include non-steroidal anti-inflammatory analgesics, steroids and hyaluronic acid preparations, with intraarticular administration of hyaluronic acid preparations used as a treatment in the early and middle stages. Intraarticular administration of hyaluronic acid preparations has also demonstrated effectiveness in improving periartitis of the shoulder and knee joint pain associated with rheumatoid arthritis.

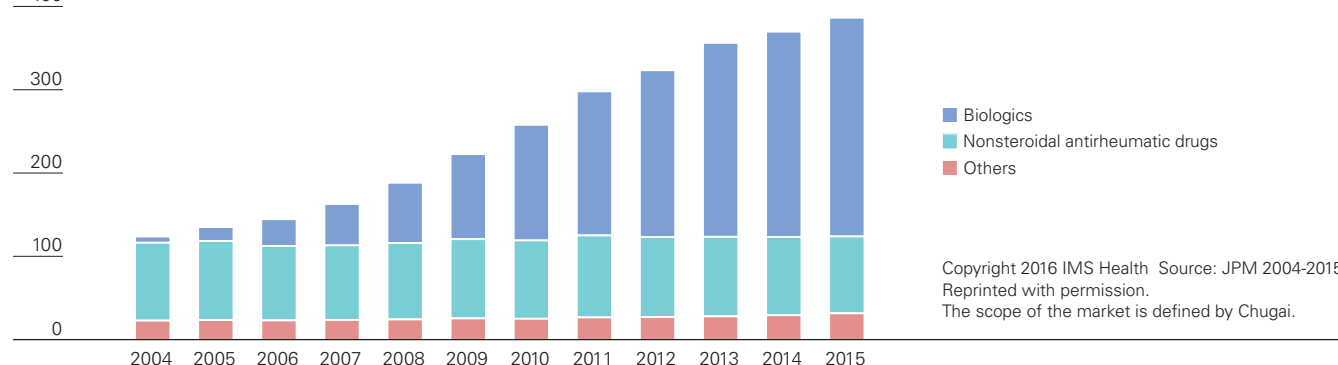
\* Source: EvaluatePharma

### Regulatory Trends

In October 2005, MHLW released a report of the Rheumatism and Allergy Countermeasure Committee. The report calls for the following measures to prevent rheumatoid arthritis from becoming severe: (1) promotion of early diagnosis and the development of

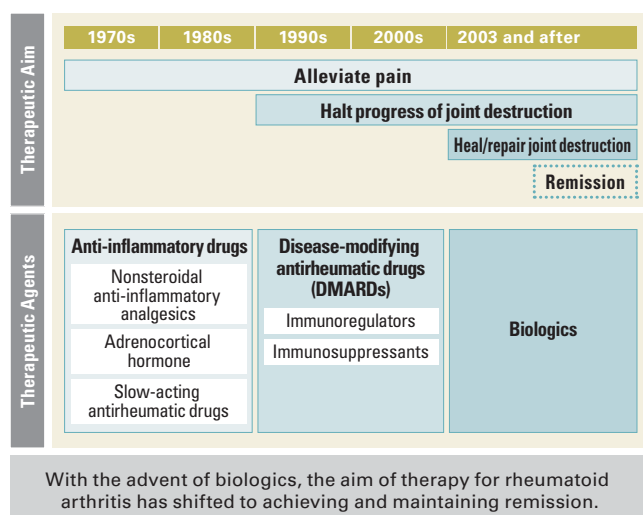
## Rheumatoid Arthritis Market in Japan

(Billions of yen)  
400





## Changes in Rheumatoid Arthritis Drug Therapy



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 Europe, revised treatment recommendations in 2013 added Actemra and Abatacept to the biologic drugs recommended in first-line therapy, which was previously limited to anti-TNF agents. In 2015, a proposed update of clinical practice guidelines was announced at the American College of Rheumatology, with biologics including Actemra added as first-line therapy along with anti-TNF agents.

In recent years, academic societies and other players have been aggressively promoting research, diagnosis and treatment of osteoarthritis as an underlying cause of "locomotive syndrome," a term proposed in the field of orthopedics to designate the condition of individuals at high risk of suffering loss of motor function due to advanced age that leaves them requiring nursing care and bedridden.

## 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 cytokines that causes inflammation. Castleman's disease is very rare, affecting approximately 1,500 people in Japan.

## Large-Vessel Vasculitis

Large-vessel vasculitis belongs to a group of autoimmune diseases called vasculitis syndromes. It refers to vasculitis in the aorta and the major aortic branches to the limbs and head and neck, and includes Takayasu's arteritis and giant cell arteritis (temporal arteritis).

Takayasu's arteritis leads to inflammation of the aortic arch and its branch vessels. It affects women more than men, at a ratio of 9:1, and age of onset is between 20 and 50 years. It occurs most commonly in Asia, including Japan, and the Middle East. Initial symptoms include reduced head and cerebral blood flow-related conditions such as dizziness, lightheadedness and headaches, as well as neck pain, chest pain and vascular pain along the limb arteries.

Giant cell arteritis is a granulomatous vasculitis occurring primarily in the aorta and aortic branches, mainly the temporal arteries. It also affects women more than men, at a ratio of 1.6:1, and the age of onset is 55 years or older. It occurs most commonly in Western countries and is rare in Japan. Common initial symptoms include headache, systemic conditions such as fever, and loss of vision.

## Systemic Sclerosis

Systemic sclerosis (SSc) is a rare, chronic disorder characterized by blood vessel abnormalities, as well as degenerative changes and scarring in the skin, joints and internal organs. The incidence rate of SSc is difficult to measure, but it is estimated to affect approximately 2.5 million people worldwide, and has the highest fatality rate of any rheumatic disease.

## Actemra (MRA/RG1569)

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

### Basic Information

Actemra, created by Chugai and the first therapeutic antibody originating in Japan, blocks the activity of interleukin-6 (IL-6), a type of cytokine. It was launched in Japan in June 2005 as a treatment for Castleman's disease. In April 2008, Chugai obtained approval in Japan for the additional indications of RA, polyarticular juvenile idiopathic arthritis (pJIA) and systemic juvenile idiopathic arthritis (sJIA). In May 2013, Chugai launched a new subcutaneous formulation that improves convenience for patients in addition to the existing drip infusion formulation. This subcutaneous formulation includes the first auto-injector in the Japanese RA market. In June 2014, the two-week limit on prescriptions was lifted, allowing Actemra to be prescribed for one month or longer.

Actemra is marketed globally through Roche. In Europe, where the medicine is known as RoACTEMRA, sales for the treatment of RA started in 2009. Chugai's marketing subsidiary co-promotes RoACTEMRA with Roche in the United Kingdom, France and Germany. In the United States, Actemra obtained approval in January 2010 for the treatment of adult patients with moderate to severe 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 obtained approval in the United States in October 2013 and in Europe in April 2014, and has been launched in both markets. RoACTEMRA was also approved for early RA in Europe in September 2014.

Furthermore, Actemra obtained approval for the additional indication of treatment of sJIA in the United States in April 2011 and in Europe in August 2011. In June 2015, Actemra received breakthrough therapy designation from the FDA as a potential treatment for systemic sclerosis. A phase III multinational study for this indication started in November 2015.

### Review of 2015 Performance

In 2015, sales of Actemra in Japan increased ¥2.7 billion, or 11.2 percent, to ¥26.8 billion, due to steady uptake of both the drip infusion and subcutaneous formulations. Sales of the subcutaneous formulation accounted for more than 30 percent of the total.

Sales of Actemra outside Japan (exports to Roche for sale in regions other than Japan, South Korea and Taiwan) increased ¥7.9 billion, or 14.2 percent, to ¥63.6 billion. Roche's global sales increased 13.6 percent year on year with steady market penetration. In particular, the subcutaneous formulation drove growth in the United States and key countries of Europe. Since Chugai has prepared an aggressive plan for Actemra's export to Roche, which is based on an outlook for local demand prepared over one year in advance, despite the effect of a weak yen, sales failed to reach the target.

In development, Actemra was designated as an orphan drug in Japan in June 2014, and a phase III clinical trial for Takayasu's arteritis, a type of large-vessel vasculitis, started in Japan in October 2014. Takayasu's arteritis and giant cell arteritis, for which Roche is currently conducting a phase III clinical trial, are both types of large-vessel arteritis and are pathologically similar. However, clinical differential diagnosis is required because there are differences in the age of onset and affected sites.

## Suvenyl

Agent for joint function improvement  
(Generic name: sodium hyaluronate)

### Basic Information

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. With physical and chemical properties close to that of hyaluronic acid found in the body, Suvenyl has been recognized for its superior performance, including its anti-inflammatory and analgesic effects.

### Review of 2015 Performance

Sales decreased ¥0.2 billion, or 1.9 percent, to ¥10.5 billion, due to the impact from competing products and generics.

## Neuromyelitis Optica

Neuromyelitis optica (NMO), also known as Devic's disease, is an autoimmune disease of the central nervous system characterized by severe optic neuritis and transverse myelitis. The disease affects 0.3 to 4.4 in 100,000 people, and there are about 4,000 patients in Japan. It is an incurable disease that typically appears around the age of 40 years and affects women more than men, at a ratio of 9:1. Symptoms include loss of vision (blindness) and impairment of motor function and sensation. In some cases, the disease results in death. However, as there are no approved treatments available, NMO is an orphan disease with high unmet medical need. It is believed to occur when aquaporin-4 (AQP4) in the central nervous system is attacked by autoantibodies called anti-AQP4 antibodies.

## SA237

Anti-IL-6 receptor humanized monoclonal antibody

### Basic Information

SA237, created by 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, and an extension of serum half-life has been demonstrated in clinical trials. Because IL-6 promotes the production of the anti-AQP4 antibodies that cause NMO, this drug is expected to improve (reduce recurrence of) the symptoms of this disease as it inhibits the production of those antibodies by blocking the IL-6 signal.

### Review of 2015 Performance

In February 2014, Chugai began a phase III multinational study for the potential treatment of NMO. In June 2014, SA237 was designated as an orphan drug in the United States.

## Renal Diseases

### Renal Anemia

#### Complications of Renal Dysfunction

For dialysis patients and end-stage renal disease 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 renal disease patients undergoing dialysis but also in pre-dialysis renal disease patients. Renal anemia, in turn, is thought to be responsible for a wide range of further complications suffered by renal disease patients, including deterioration in heart functions.

The importance of treating renal anemia and CKD - mineral and bone disorder (CKD-MBD) was indicated in the Guideline for Renal Anemia in Chronic Kidney Disease (2015) and the Clinical Practice Guidelines for the Management of CKD-MBD (2012) issued by The Japanese 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

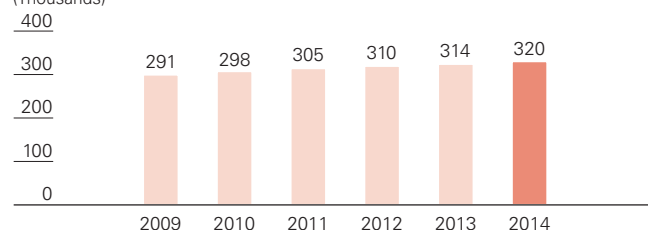
Erythropoietin (EPO) is a hemopoietic factor produced mainly in the kidneys. It speeds up erythrocyte production using erythropoietin progenitor cells found in bone marrow. EPO preparations are effective in treating renal anemia caused primarily by the decline in erythropoietin production due to CKD. In addition to improving quality of life, the drug is also thought to help improve complications by correcting and controlling anemia. It is estimated that EPO preparations are currently used by approximately 80 percent of dialysis patients and the majority of predialysis renal disease patients with renal anemia. Chugai's Epogin is thus an essential drug for the treatment of renal anemia.

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

In its 2006 revisions of medical fees, the Japanese 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. The integrated fee points are reviewed with each revision of medical fees.

#### Number of Dialysis Patients in Japan

(Thousands)



Source: Overview of Regular Dialysis Treatment in Japan (as of December 31, 2014) by Statistical Survey Committee, The Japanese Society for Dialysis Therapy

### Mircera

Long-acting erythropoietin-stimulating agent  
(Generic name: epoetin beta pegol)

#### Basic Information

Mircera is a new type of renal anemia treatment with a very long serum 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 renal anemia. Outside Japan, Mircera obtained approval in Europe in 2007 and is currently sold in more than 100 countries, including the United States.

The serum 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 burden of hospital visits on patients with pre-dialysis renal disease 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.

#### Review of 2015 Performance

Sales of Mircera increased ¥1.2 billion, or 5.3 percent, to ¥23.8 billion. Its use is steadily increasing in the renal anemia market, primarily in the pre-dialysis stage, where definite effects can be obtained with administration tailored to the frequency of patients' hospital visits, but also in the dialysis stage.

### Epogin

Recombinant human erythropoietin agent  
(Generic name: epoetin beta)

#### Basic Information

Epogin is a human erythropoietin agent 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 CKD. 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, anemia of prematurity and autologous blood transfusion of patients scheduled for surgery.

#### Review of 2015 Performance

Sales of Epogin decreased ¥0.7 billion, or 10.6 percent, to ¥5.9 billion due to the switch to Mircera and competing products, including biosimilars.

### Oxarol

Agent for secondary hyperparathyroidism  
(Generic name: maxacalcitol)

#### Basic Information

Synthesized by Chugai, Oxarol is the first intravenous active vitamin D<sub>3</sub> derivative agent in Japan. It treats secondary hyperparathyroidism,

a result of prolonged dialysis, by acting directly on the parathyroid gland with high concentration to control parathyroid hormone synthesis and secretion, and by acting to improve bone metabolism. With its short serum half-life, Oxarol is showing efficacy in patients who could not be treated sufficiently with oral vitamin D<sub>3</sub> derivatives due to the onset of hypercalcemia.

### Review of 2015 Performance

Sales of Oxarol increased ¥0.7 billion, or 5.7 percent, to ¥12.9 billion. Oxarol maintained its leading market position, supported by substantial clinical data showing that treatment with an active vitamin D derivative can extend survival.

## EOS789

A phase I clinical trial of EOS789 as a potential treatment for hyperphosphatemia started in September 2015.

## Central Nervous System Diseases

### 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 a treatment for the underlying cause does not yet exist. Consequently, unmet medical need is high, and there is strong demand for a more effective drug.

#### RG1450

**Anti-amyloid-beta human monoclonal antibody**  
(Generic name: gantenerumab)

RG1450 is an anti-amyloid-beta human monoclonal antibody in-licensed from Roche. A phase III multinational study of RG1450 as a potential treatment for AD began in May 2014.

RG1450 is intended for use before the onset of symptoms and in the early stages of Alzheimer's disease, and expectations are rising for this drug in early intervention therapy. The study targets patients most likely to respond to the treatment based on levels of amyloid deposition, as the compound is also seen as a possible disease-modifying drug (a drug that inhibits recurrence and slows progression of the disease).

regarded as the most common chromosome anomaly, present in 1 of every 650 to 1,000 newborns. Because of improvements in dealing with complications, average life expectancy has been prolonged in recent years, and the number of individuals with Down syndrome who play an active role in society is growing. The current lack of a drug therapy in Japan or overseas that improves the intellectual ability of individuals with Down syndrome is an obstacle to independent living.

#### RG1662

**GABAA $\alpha$ 5 receptor antagonist (Generic name: basmisanil)**

RG1662 is an oral GABAA $\alpha$ 5 receptor antagonist in-licensed from Roche as a potential treatment for improvement of intellectual ability in individuals with Down syndrome. Inhibitory neurotransmitters via GABA are dominant in Down syndrome. This is believed to hinder effective learning and memory. By selectively binding to the GABAA $\alpha$ 5 subunit, RG1662 weakens the binding activity between the subunit and GABA and inhibits excessive activity of GABA. It is therefore expected to increase cognitive and memory ability.

Overseas, Roche is conducting two phase II clinical trials on individuals with Down syndrome, one for those aged 12 to 30 and the other for those aged 6 to 11. In Japan, Chugai began a non-drug study of individuals with Down syndrome aged 6 to 30 in June 2015 to assess the suitability of assessment scales for use in future clinical trials.

### Down Syndrome

Down syndrome typically occurs as a result of the presence of an extra copy of chromosome 21 due to mutation. In addition to characteristic physical traits such as low muscle tone, most people with Down syndrome have delayed intellectual development. However, Down syndrome is viewed as an inborn characteristic (like personality and body type) rather than a disease. The syndrome is



## Other Diseases

### CellCept

Immunosuppressant  
(Generic name: mycophenolate mofetil)

Sales of CellCept, an immunosuppressant, increased ¥0.5 billion, or 7.7 percent, to ¥7.0 billion. CellCept is used to treat refractory rejection after kidney transplants and to prevent rejection after kidney, heart, liver, lung and pancreas transplants. The need for transplantation medicines has been rising in Japan, driven by advances in transplantation therapy.

### 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 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

Since 2001, the introduction of interferon-ribavirin combination therapy and of peginterferon<sup>1</sup> has significantly improved treatment outcomes for chronic 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. In 2014, the approval of an interferon-free treatment for patients who have not responded sufficiently to conventional therapies expanded the treatment options for chronic hepatitis C.

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.

### Pegasys

Peginterferon alfa-2a agent  
(Generic name: peginterferon alfa-2a)

### Copegus

Anti-viral agent (Generic name: ribavirin)

#### Basic Information

Pegasys is a pegylated interferon-based drug that was improved to achieve a sustained antiviral effect with once-weekly<sup>2</sup> 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 approval for Copegus in January 2007 and launched it in March as a combination therapy with Pegasys for the treatment of patients with chronic hepatitis C serogroup 1 infection<sup>3</sup> and high viral load, or those who have either not responded to, or have relapsed after 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

#### Review of 2015 Performance

Sales of Pegasys decreased ¥5.1 billion, or 72.9 percent, to ¥1.9 billion, and sales of Copegus decreased ¥0.2 billion, or 6.5 percent, to ¥2.9 billion. Sales of both products fell significantly due to the launch of competing products that are interferon-free.

### 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.

### Tamiflu

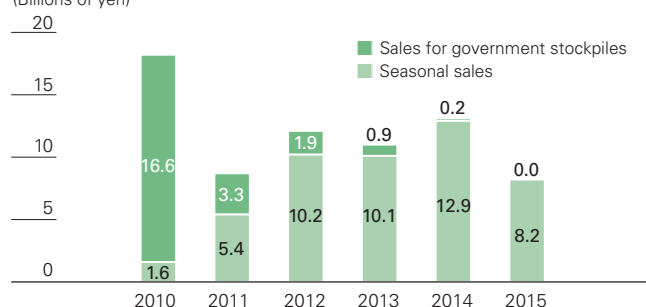
Anti-influenza agent (Generic name: oseltamivir phosphate)

#### Basic Information

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.

### Tamiflu Sales

(Billions of yen)



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 report of an epidemiological survey with 10,000 flu patients conducted 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. New research investigating the relationship between abnormal behavior and the use of Tamiflu is expected to begin in 2016. The shelf life of Tamiflu capsules was extended to 10 years from seven years for capsules manufactured after July 2013, and the shelf life of dry syrup was extended to seven years starting with the portion manufactured in the year ended March 2014.

### Review of 2015 Performance

Sales of Tamiflu decreased ¥4.8 billion, or 36.9 percent, to ¥8.2 billion. Seasonal sales decreased ¥4.7 billion, or 36.4 percent, to ¥8.2 billion, while sales for government stockpiles fell ¥0.2 billion, or 100.0 percent, to ¥0.0 billion. In 2015, Chugai highlighted the drug's efficacy and the benefits of its unique dry syrup formulation.

### 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. Vasodilators, such as nitric acid, that enlarge the coronary artery are used to control attacks. 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.

### Acute Heart Failure

Heart failure refers to the general condition that results from insufficient heart activity. When heart failure occurs suddenly in people with no previous history of heart disease, or when heart failure rapidly worsens in patients that had been stable, it is called acute heart failure. Treatments for acute heart failure include diuretics, vasodilators and inotropic drugs.

### Sigmar

Anti-anginal agent (Generic name: nicorandil)

Anti-anginal agent Sigmar is a drug that overcomes the flaws of nitrates 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 was granted for treatment of unstable angina pectoris in 1993 and for acute heart failure in 2007.

### 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 approximately 4 million people, and about 10 percent of patients have symptoms that are not adequately controlled with existing treatments.

### Idiopathic Pulmonary Fibrosis

Idiopathic pulmonary fibrosis (IPF) is a chronic and progressive lung disease of unknown cause and poor prognosis in which extensive fibrosis results in irreversible honeycomb lung. It is a fatal disease, with a five-year survival rate of around 50 percent. The goal of treatment is to slow the progression of the disease. Currently, only two drugs, pirfenidone and nintedanib, are approved for the treatment of this disease, but considering their side effects and efficacy, IPF remains a disease with high unmet medical need.

### RG3637

Anti-IL-13 humanized monoclonal antibody (Generic name: lebrikizumab)

In-licensed from Roche, RG3637 is an anti-IL-13 humanized monoclonal antibody in 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 levels of the periostin protein induced by IL-13. Chugai joined Roche's phase III multinational study in July 2013, and also joined a phase III multinational study on adolescent subjects in December 2015. In addition, Chugai started a phase II multinational study of RG3637 as a potential treatment for IPF in October 2014.

## Atopic Dermatitis

A type of allergic disorder, atopic dermatitis is a chronic skin disease characterized by an itchy rash that alternately improves and worsens. 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.

## Pruritus in Dialysis Patients

Pruritus is a complication found in more than 40 percent of dialysis patients. Various factors are thought to play complex roles in development of the condition, including skin dryness, accumulation of uremic toxins, secondary hyperparathyroidism, complement activation by dialysis membranes, the effect of heparin, and itch mediators. It is systemic and refractory, and the degree, site and timing of itching vary by patient. The itching not only reduces quality of life due to discomfort and sleeplessness, but is also reported to be involved in life expectancy.

### CIM331

Anti-IL-31 receptor humanized monoclonal antibody  
(Generic name: nemolizumab)

CIM331 is an anti-IL-31 receptor humanized monoclonal antibody originating from Chugai. A Chugai-managed phase II multinational study of this drug as a potential treatment for atopic dermatitis has been under way in Japan, the United States and Europe since December 2013, and is proceeding smoothly. CIM331 is expected to suppress itching by blocking IL-31, which is responsible for the itching in atopic dermatitis, from binding to its receptor. It is also expected to improve skin inflammation by cutting off the itch-scratch cycle.

A phase II clinical trial of CIM331 as a potential treatment for pruritus in dialysis patients began in August 2015.

## 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, since it involves intravenous injections three times a week, treatment is a significant burden, particularly on children. Moreover, patients must be monitored for the development of autoantibodies, called inhibitors, to the supplemented factor. Patients with inhibitors are treated by means such as bypass therapy or immune tolerance therapy, but these therapies are limited in terms of convenience and the stability of their effects. A more useful treatment method is therefore needed.

### ACE910

Anti-factor IXa/X bispecific antibody  
(Generic name: emicizumab)

ACE910 is an anti-factor IXa/X bispecific antibody that employs Chugai's innovative antibody engineering technologies. Like factor VIII, ACE910 simultaneously binds to factor IXa and factor X, stimulating the activation of factor X by activated factor IX and promoting the blood coagulation that occurs as a result. Unaffected by inhibitors, ACE910 is expected to prevent bleeding with once-weekly (or less-frequent) subcutaneous injections.

A phase I clinical trial for the potential treatment of hemophilia A started in August 2012. ACE910 was granted orphan drug designation in Europe in December 2013 and the United States in January 2014. Chugai concluded an out-licensing agreement with Roche in July 2014, and the drug received breakthrough therapy designation from the FDA in September 2015. In November 2015, a multinational phase III study began on patients with inhibitors. In data from phase I/II clinical trials announced in June 2015, ACE910 was shown to reduce bleeding frequency in both inhibitor and non-inhibitor patients, and is expected to change the existing therapeutic system. Another key feature of this drug is that Chugai's proprietary ART-Ig technology can be applied to enable commercial-scale production of bispecific antibodies.

## 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.

### URC102

URAT1 inhibitor

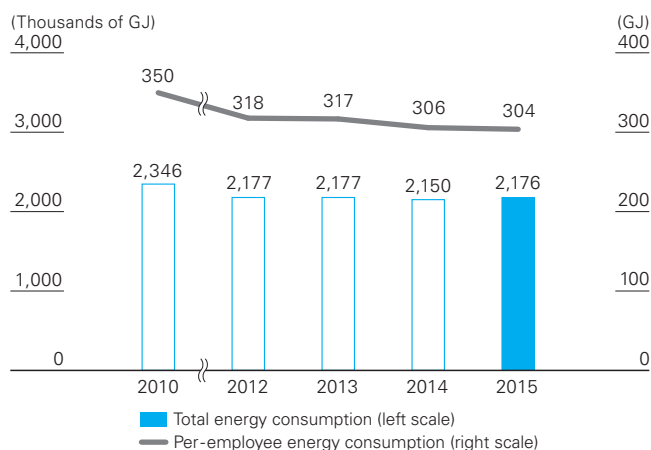
URC102 is a URAT1 inhibitor discovered at C&C Research Laboratories, a joint venture between Chugai and JW Pharmaceutical Corporation of South Korea. It is an oral small-molecule uricosuric agent expected to be effective against gout. This compound is expected to reduce the level of serum uric acid by promoting its excretion through inhibition of URAT1. URC102 is being co-developed with JW Pharmaceutical, and a phase II clinical trial started in South Korea in July 2014.

# Environmental Data

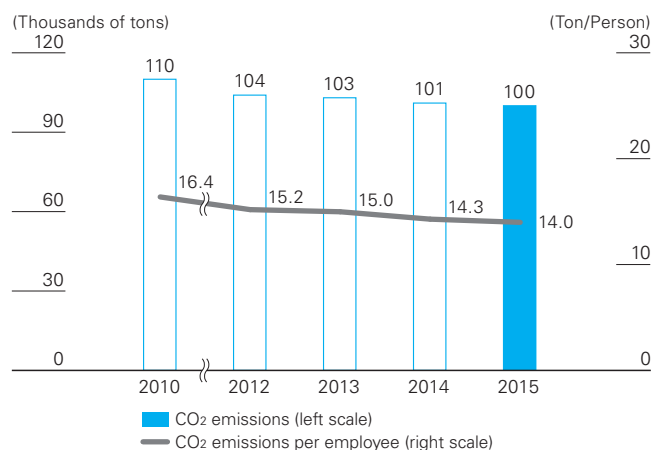
## Climate Change Measures

(2010 is the base year for per-employee energy consumption and CO<sub>2</sub> emission mid-term environmental goals.)

### Total and Per-Employee Energy Consumption

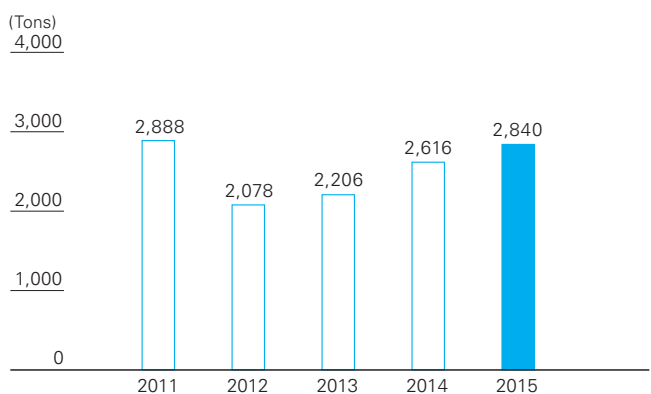


### CO<sub>2</sub> Emissions and CO<sub>2</sub> Emissions Per Employee

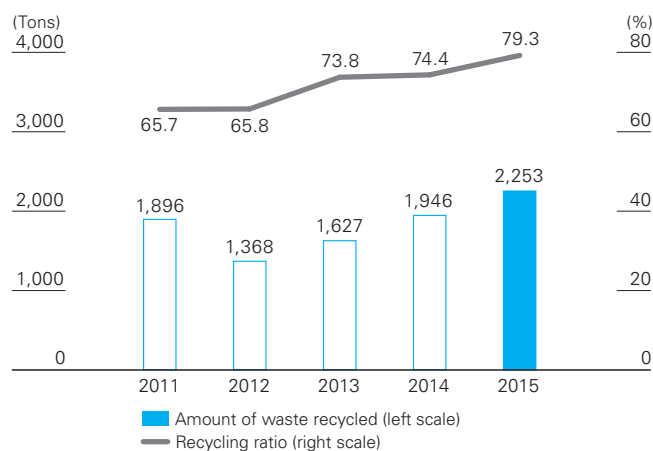


## Waste Reduction

### Industrial Waste Generation



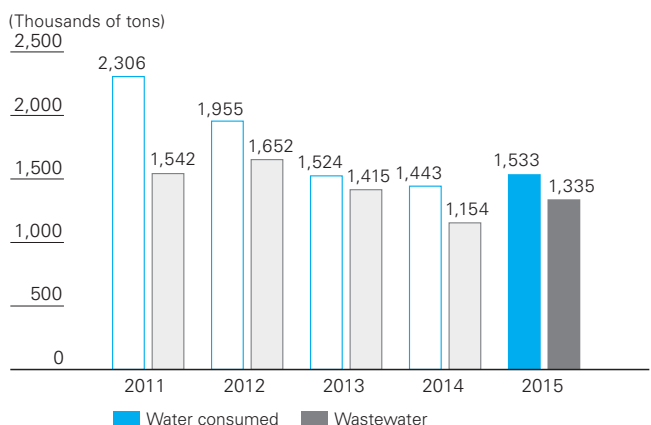
### Waste Recycled and Recycling Ratio<sup>1</sup>



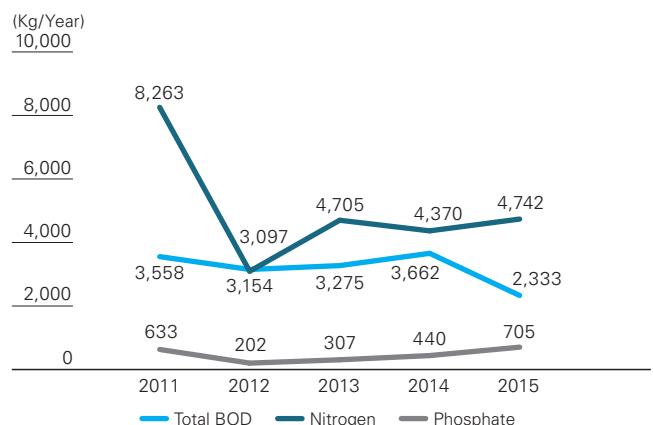
1. Amount of waste recycled / (Amount of waste disposed + Amount of waste recycled)

## Water and Air Pollution Countermeasures

### Water Consumed and Wastewater



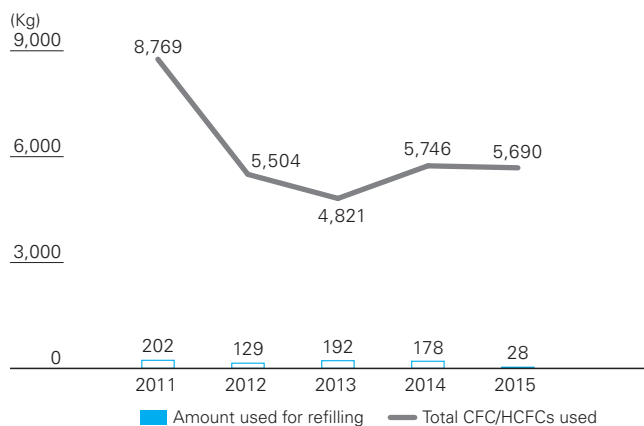
### Total BOD, Nitrogen and Phosphate



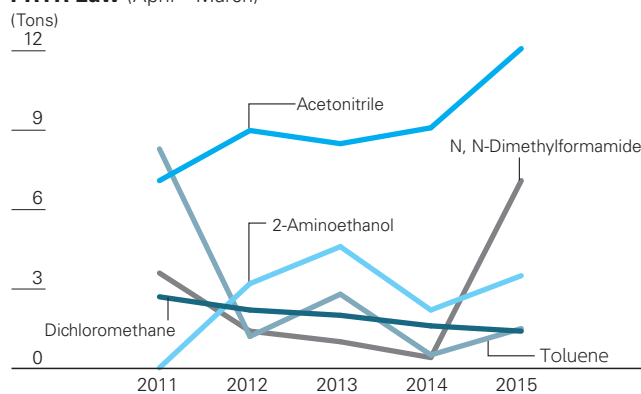


## Chemical Substance Management

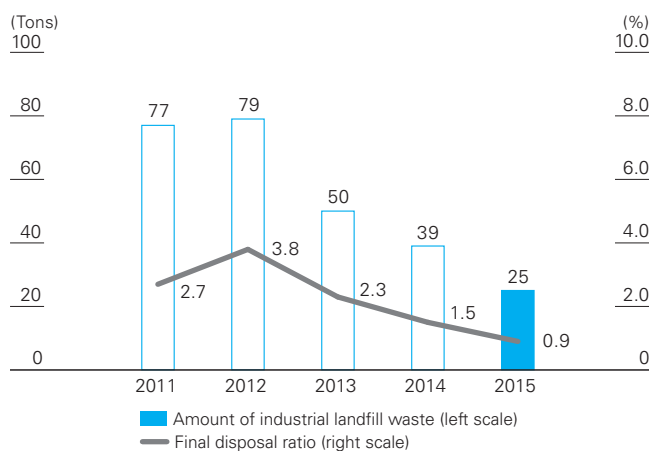
### CFCs and HCFCs Used to Fill Equipment



### Handled Amounts of Chemical Substances Covered by PRTR Law (April – March)

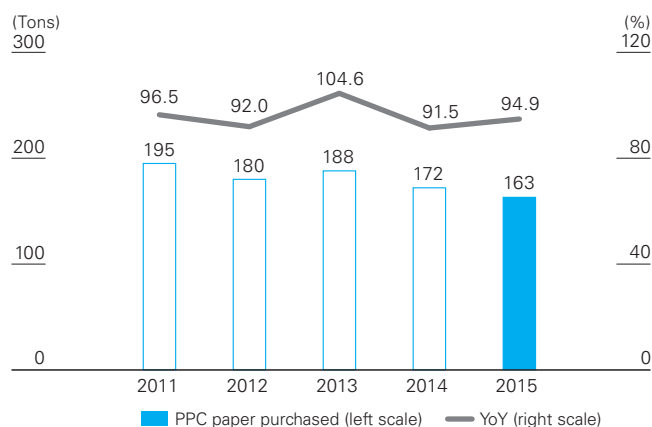


### Industrial Landfill Waste and Final Disposal Ratio<sup>2</sup>

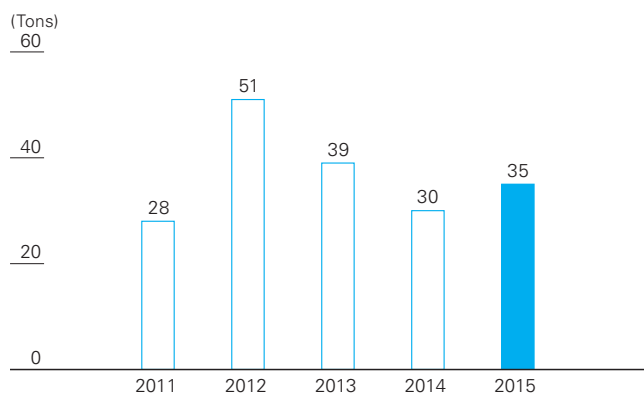


2. Amount of industrial landfill waste / Amount of waste generated

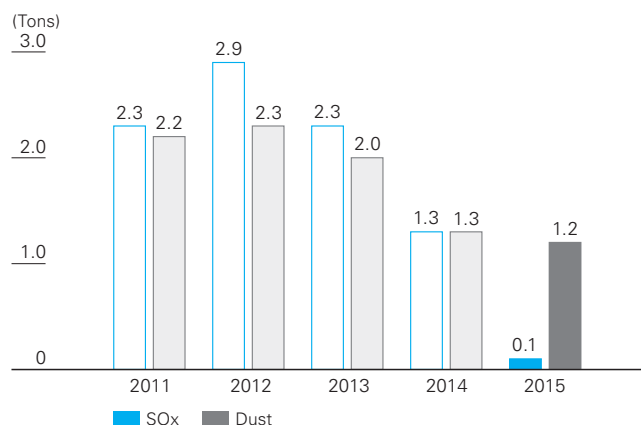
### PPC Paper Purchased



### NOx Emissions



### SOx and Dust Emissions



# Corporate Governance

## Basic Approach

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," and the company defines its basic management objective as to "become a top Japanese pharmaceutical company by providing a continuous flow of innovative new medicines domestically and internationally."

While being a member of the Roche Group, Chugai maintains its managerial autonomy and independence as a publicly listed company and will constantly strive to perfect its corporate governance as established in "Chugai Pharmaceutical Co., Ltd. Basic Corporate Governance Policy," in order to fulfil the mandate of its many stakeholders appropriately and fairly for the achievement of its basic management objective.

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

To expedite business operations and clarify executive responsibilities, Chugai has adopted an executive officer system to keep decision-making on management issues of primary importance separate from business execution. The Board of Directors is in charge of the former, while executive officers are entrusted by the board with the authority to conduct the latter. While the Board of Directors is in charge of decision-making with respect to the most important managerial matters, other decisions on business operations are made at organizations such as the Executive Committee. In execution of

business, since March 2012 the chief executive officer (CEO) has ultimate responsibility for decisions on Companywide 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 at the Executive Committee. It is also responsible for oversight of the execution of business operations. The board consists of 10 directors including three outside directors.

In 2015, the Board of Directors convened eight times.

Of note, the two directors appointed by Roche no longer met the requirements for outside director under the amended Companies Act as of the end of the General Meeting of Shareholders held on March 24, 2016.

## Executive Committee

Decisions concerning important matters related to business execution are made at organizations such as the Executive Committee. 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, Corporate Social Responsibility Committee and Healthcare Compliance Committee have been established under the Executive Committee.

## Appointment Committee and Compensation Committee

As an advisory board to the Board of Directors, the Appointment Committee deliberates on the selection of director candidates and candidates to succeed the executive directors, including the CEO. The Appointment Committee consists of the CEO and at least three

## Reasons for Election of Outside Directors and Outside Audit & Supervisory Board Members

	Name	Outside Position	Reason for Election
Outside Directors	Yasuo Ikeda	Vice-Chairman of the Board of Directors, Musashi Academy of the Nezu Foundation, Chairman of Japanese Medical Specialty Board, University Professor of Waseda University, Professor Emeritus of Keio University	Recommended or appointed based on the Company's judgment that as an outside director he can provide 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. In addition, he meets Chugai's Independence Standards for an outside officer and the requirements for an independent director set by Tokyo Stock Exchange, Inc., to which notification has been submitted.
	Masayuki Oku	Chairman of the Board, Sumitomo Mitsui Financial Group, Inc., Outside Director of Kao Corporation, Outside Director of Komatsu Ltd., Outside Director of Panasonic Corporation, Outside Corporate Auditor of Nankai Electric Railway Co., Ltd., Non-executive Director of Bank of East Asia (China)	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 and can properly execute duties of an outside director. In addition, he meets Chugai's Independence Standards for an outside officer and the requirements for an independent director set by Tokyo Stock Exchange, Inc., to which notification has been submitted.
	Franz B. Humer	Non-Executive Chairman of Diageo plc (U.K.) Former Chairman, ROCHE HOLDING LTD	Recommended or appointed based on the Company's judgment that as an outside director he can provide advice and monitoring with respect to the Company's management and business based on his abundant experience and knowledge as a manager of global pharmaceutical companies and can properly execute the duties of an outside director.
Outside Members of the Audit & Supervisory Board	Hisashi Hara	General Representative of the Asia-Pacific region, The Law Office of Nagashima Ohno & Tsunematsu	Recommended or appointed based on the Company's judgment that he can properly execute the duties of an outside member of the Audit & Supervisory Board because he has abundant experience and knowledge as an expert in corporate legal affairs (attorney at law).
	Takaaki Nimura	Representative of Nimura Certified Public Accounting Office, Outside Director and Chairman of Audit Committee of Sony Corporation	Recommended or appointed based on the Company's judgment that he can properly execute the duties of an outside member of the Audit & Supervisory Board because he has abundant experience and knowledge as an expert in corporate accounting (certified public accountant). In addition, he has been designated as an independent member of the Audit & Supervisory Board based on the regulations of Tokyo Stock Exchange, Inc., to which notification has been submitted.

## Independence Standards

Chugai will judge outside officers (outside directors and outside Audit & Supervisory Board members) that do not fall under any of the following to be independent officers (independent outside directors and independent outside Audit & Supervisory Board members) with no risk of a conflict of interests with Chugai's general shareholders:

- (1) a person who is currently or has been in the past ten years an executive<sup>1</sup> of Chugai or any of its subsidiaries (collectively, the "Chugai Group");
- (2) a person who is currently or has been in the past five years an executive of the parent company or any sister company of Chugai;
- (3) a person for whom the Chugai Group is a major business partner<sup>2</sup> or an executive of that person;
- (4) a major business partner<sup>2</sup> of the Chugai Group or an executive of that business partner;
- (5) a major lender<sup>3</sup> of the Chugai Group or an executive of that lender;
- (6) a consultant, accounting professional, or legal professional who receives a large amount of money or other such assets<sup>4</sup> other than officer remuneration from the Chugai Group (including any person belonging to a corporation, partnership, or other such organization that receives such assets);
- (7) a major shareholder<sup>5</sup> of Chugai or an executive of that shareholder;
- (8) an executive of a company for which the Chugai Group is a major shareholder
- (9) an executive of a company that engages a director or Audit & Supervisory Board member (regardless of whether full or part time) from the Chugai Group or an executive of the parent company or any subsidiary of such company;

- (10) a director or other executive of a corporation, partnership, or other such organization that receives contributions or aid exceeding a certain amount<sup>6</sup> from the Chugai Group;
  - (11) an accounting auditor of the Chugai Group or any person belonging to an auditing corporation that is an accounting auditor of the Chugai Group; and
  - (12) a close relative<sup>7</sup> of any person (limited to those in material positions<sup>8</sup>) who falls under any of (1) through (11) above.
1. An executive director, executive officer, corporate officer, or other such employee or the like.
  2. A business partner whose transactions with the Chugai Group in any business year within the past five years total 2 percent or more of the consolidated sales of that business partner or the Chugai Group.
  3. A lender from whom the Chugai Group's borrowings at the end of the business year exceed 2 percent of the Chugai Group's consolidated total assets at the end of that business year.
  4. In any business year within the past five years, money or other such assets in excess of the greater of (a) ¥10 million annually or (b) 2 percent of the total annual income of the person receiving the money or other such assets.
  5. A shareholder directly or indirectly holding 10 percent or more of total voting rights in any business year within the past five years.
  6. In any business year within the past five years, contributions or aid exceeding the greater of (a) ¥10 million annually or (b) 2 percent of the total annual income of the person receiving the contributions or aid.
  7. A spouse or a relative within the second degree of kinship.
  8. Directors (excluding outside directors), corporate officers, and executive officers, or any person with authority equivalent to any of these.

outside committee members, including at least one independent outside director, appointed by the Board of Directors from among the outside directors and persons with experience sitting on an appointment committee.

As an advisory board to the Board of Directors, the Compensation Committee deliberates on remuneration policy and the remuneration of individual directors. It consists of at least three outside committee members, including at least one independent outside director, appointed by the Board of Directors from among the outside directors and persons with experience as outside directors.

## 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 a council made up of domestic and overseas specialists.

### Chugai International Council

To respond accurately to changes in the global business environment and conduct international business in an appropriate manner, Chugai works to further enhance decision-making by operating the Chugai International Council (CIC), which is composed of Japanese and international professionals in various sectors. Of the 11 council members, one is a woman.

### 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 from their abundant experience and knowledge as corporate executives, physicians or university professors.

## CIC Composition

### CIC Chair

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

### CIC Members

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

The rate of attendance by outside directors at the eight board meetings in 2015 was 85.0 percent on average, the highest being 100 percent and the lowest 50.0 percent.\*

Of note, the two directors appointed by Roche no longer met the requirements for outside director under the amended Companies Act as of the end of the General Meeting of Shareholders held on March 24, 2016.

\* In 2015, directors from Roche were also regarded as outside directors.

## Support System for Outside Directors and Outside Audit & Supervisory Board Members

Chugai appoints staff in the Secretarial Department to support the activities of outside directors. Managers including the General Manager of the Corporate Planning Department provide as needed reports on major changes in the operating environment and advance explanation of particular items to further enhance decision-making.

The Office of Audit & Supervisory Board Members is responsible for supporting the activities of Audit & Supervisory Board members in ways such as conveying internal information and providing advance Audit & Supervisory Board materials.

In addition, Chugai invigorates the deliberations of the Board of Directors by preparing materials containing adequate information relevant to agenda items and distributing them to outside directors and outside Audit & Supervisory Board members well in advance of meetings. We also provide additional information required by outside directors and outside Audit & Supervisory Board members and take advantage of opportunities to provide advance explanation.

## 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 and certified fraud examiners, 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 addition, the Audit Department conducts internal control assessments based on the Financial Instruments and Exchange Act, J-SOX, and other criteria to help maintain sound operations. Chugai also dispatches its auditing staff as Audit & Supervisory Board members to subsidiaries in Japan.

### Accounting Auditors

KPMG AZSA LLC handles accounting audits and internal control audits.

### Cooperative Auditing

Audit & Supervisory Board members, the Audit Department and the Accounting Auditor cooperate closely by regularly exchanging

## Amount of Remuneration Paid to Directors and Audit & Supervisory Board Members (2015)

	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)	772	302	238	117	115	6
Outside Directors	53	53	—	—	—	4
<b>Total</b>	<b>825</b>	<b>593</b>		<b>117</b>	<b>115</b>	<b>10</b>
Audit & Supervisory Board Members (excluding outside members)	63	63	—	—	—	3
Audit & Supervisory Board Members (outside members)	22	22	—	—	—	2
<b>Total</b>	<b>85</b>	<b>85</b>		<b>—</b>	<b>—</b>	<b>5</b>

1. Amounts are rounded to the nearest million yen.

2. The table above includes one director and one Audit & Supervisory Board member who resigned during 2015.

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 2015.

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 2015 and the number of officers in 2015, respectively.

7. In addition to the total remuneration, etc. shown in the table above, the following amounts were paid as retirement benefits corresponding to the period from the time each officer assumed office to the abolishment of the retirement benefits system for directors and Audit & Supervisory Board members.

One retired outside director: ¥2 million

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 power, and to pay retirement benefits corresponding to the residual term up to the abolishment of the system to each concerned director remaining in office after the closing of the 98th Annual General Meeting of Shareholders, at the respective time of their retirement.

Also, a resolution was passed in the 95th Annual General Meeting of Shareholders held in March 2006 to abolish the retirement benefits system for directors and Audit & Supervisory Board members with no executive power, and to pay retirement benefits corresponding to the residual term up to the abolishment of the system to each concerned director and Audit & Supervisory Board member remaining in office after the closing of the 95th Annual General Meeting of Shareholders, at the respective time of their retirement.

8. In 2015, the amount of remuneration received by outside director Daniel O'Day as an officer from the parent company of the Company or subsidiaries of the said parent company totaled ¥1,161 million (converted into yen at the average exchange rate in 2015).

9. In addition to the bonuses in 2015 shown in the table above, and apart from the ¥220 million in provision of reserve for bonuses to directors presented in the Business Report for 2014, ¥6 million has been paid to five directors as bonuses for 2014.

10. In 2015, directors from Roche were also regarded as outside directors.



## 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	125	148	52	56	382
Motoo Ueno	55	24	20	18	117
Tatsuro Kosaka	55	30	20	21	126

1. Amounts are rounded to the nearest million yen.

2. Other than the representative directors in the table above, no director or Audit & Supervisory Board member received total remuneration of more than ¥100 million.

information to improve the effectiveness of their respective audits. Audit & Supervisory Board members and the Accounting Auditor confirm each other's audit plans and hold regular meetings to exchange opinions on matters including the results of quarterly audit reports. In addition, they work to strengthen governance at Group companies by coordinating with Audit & Supervisory Board members at subsidiaries in Japan on quarterly reports, fiscal year-end reports and other matters. 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 attract outstanding people and appropriately motivate them in order to continuously increase the Chugai Group's corporate value. At the same time, 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: fixed regular compensation, 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 sets policies and deliberates details concerning remuneration of 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. 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).

### Maintenance and Management of Internal Controls

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 effectiveness assessments for internal controls. 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. (For details of business risks, see page 127.)

### Compliance

Rooted in its belief that corporate ethics take priority 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.

As well as strictly complying with laws and regulations such as the Law for Ensuring the Quality, Efficacy and Safety of Drugs and Medical Devices and the voluntary Code of Practice for the industry established by the Japan Pharmaceutical Manufacturers Association (JPMA), Chugai proactively takes part in the activities of the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry, the JPMA Code Compliance Committee and other organizations. In addition, by establishing our own two guidelines for transparency, Chugai works to ensure a high level of ethics, morality and transparency in its various business activities including collaboration with medical institutions and other parties and cooperation with patient groups (For details about these transparency guidelines, see the Chugai website). To further promote compliance in healthcare, Chugai has also established internal organizations such as the Healthcare Compliance Committee and the Medical Affairs Division to promote internal consistency.

## Chugai Risk Management System



Chugai has put in place Compliance Regulations for its compliance system. These regulations are promoted by the Corporate Social Responsibility Committee and the Corporate Social Responsibility Department. In light of increasing societal demands for greater compliance in the pharmaceutical industry, in 2015 we strengthened compliance measures Company-wide. In addition to working to enhance compliance education in each of our training programs, we conducted compliance risk management measures in each organizational unit. Moreover, every six months the Corporate Social Responsibility Department conducted monitoring surveys regarding compliance status. Surveys were conducted internally, as well as for subsidiaries in Japan and overseas affiliated companies, and results were reported to the Corporate Social Responsibility Committee. Each organization works to ensure thorough legal compliance in the workplace through BCG promotion managers and assistants and holds corporate ethics courses twice a year, among other programs.

## Addressing the Corporate Governance Code

Chugai's policy is to implement all of the principles of the Corporate Governance Code of the Tokyo Stock Exchange. Based on these principles, we enacted the Chugai Pharmaceutical Co., Ltd. Basic Corporate Governance Policy on November 25, 2015 to institute our basic approach to corporate governance, and announced it on our website.

## Reasons for Not Implementing All Principles of the Corporate Governance Code

## Supplementary Principle 4.11.3: Summary of the Results of Analysis and Evaluation of the Overall Effectiveness of the Board of Directors

Chugai has not yet analyzed or evaluated the overall effectiveness of its Board of Directors. In 2016, we will analyze and evaluate the status of the activities of the Board of Directors carried out during 2015 and disclose a summary of the results. We plan to do this every year from now on.

## Addressing the General Principles of the Corporate Governance Code

## General Principle 1: Securing the Rights and Equal Treatment of Shareholders

The Company properly complies with laws and regulations to substantively secure shareholder rights, and ensures substantively

equal treatment of shareholders by giving due consideration to minority and foreign shareholders and by maintaining an environment in which shareholders can properly exercise their rights.

## General Principle 2: Appropriate Cooperation with Stakeholders Other Than Shareholders

Chugai's Board of Directors and executive directors respect the rights and positions of stakeholders, and are committed to compliance with laws and regulations and to exercising leadership in fostering a corporate culture based on high ethical and moral standards as a healthcare company. They also build good relationships with stakeholders and appropriately cooperate with them.

## General Principle 3: Ensuring Appropriate Information Disclosure and Transparency

Chugai makes information related to its business activities available in a transparent, fair and consistent manner to deepen mutual understanding and build relationships of trust with its stakeholders. Chugai provides timely, appropriate and fair disclosure of information to shareholders and other investors 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.

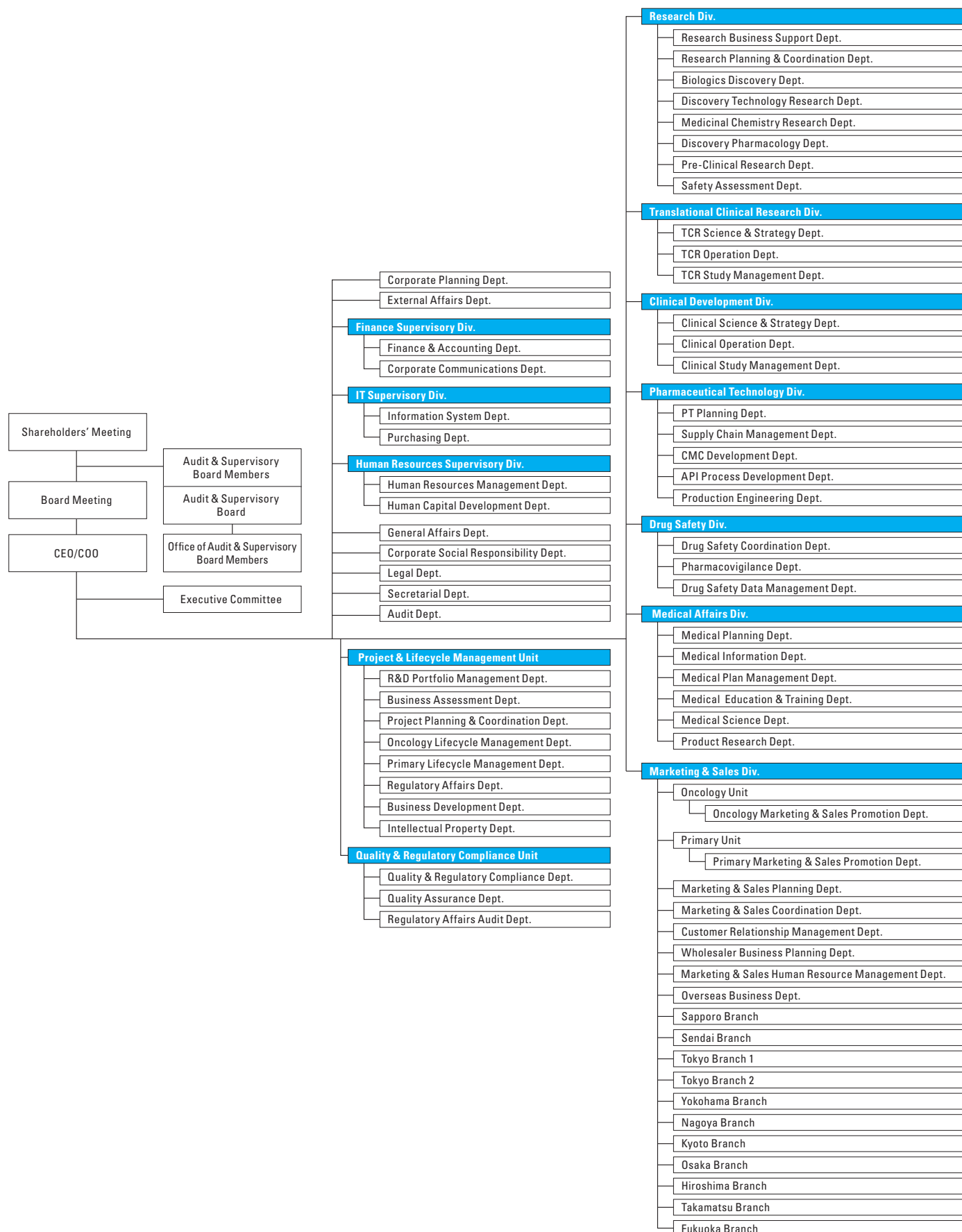
## General Principle 4: Responsibilities of the Board of Directors

Given its fiduciary responsibility and accountability to shareholders, in order to promote sustainable corporate growth, increase corporate value over the mid- to long-term, and enhance earnings and capital efficiency, the Board of Directors supervises business execution, makes key management decisions including business strategy and management plans, and maintains an environment that facilitates appropriate risk-taking by executive directors.

## General Principle 5: Dialogue with Shareholders

Chugai contributes to sustainable growth and increased corporate value over the medium to long term by engaging in constructive dialogue with shareholders and investors through the various investor relations activities of directors and executive officers.

# Organization (As of April 1, 2016)



# Glossary

## Terms Related to Chugai's Business

### Unmet medical need

Medical need that is not adequately met due to a lack of effective treatments.

### First in class

An original drug that is highly novel and useful, and will significantly change the therapeutic system.

### Best in class

A drug that offers clear advantages over other existing drugs in the same category, such as those with the same molecular target.

### Development pipeline

At pharmaceutical companies, refers to drug candidates that are being developed as potential new drugs. It is important to have a well-stocked pipeline that has a high success rate and is expected to lead to differentiation from other companies' products.

### Proof-of-Concept (PoC)/Early PoC

Proof-of-concept (PoC) is a demonstration that the therapeutic effect conceived in the research stage is effective in humans. Early PoC means that in addition to safety, signs of efficacy or pharmacological effect have been confirmed in a limited number of cases.

### Clinical trial

A study to verify the safety, efficacy and other characteristics of a drug in human subjects. Studies conducted for new drug development are called clinical trials. Clinical trials consist of phase I to phase III studies, which are conducted before filing for approval, and phase IV studies, which are conducted after obtaining approval.

**Phase I:** Performed on a small number of healthy volunteers (or, for certain therapeutic fields and diseases, on patients) to assess the drug's safety and the process by which it is absorbed, distributed, metabolized and eliminated by the body.

**Phase II:** Performed on a small number of consenting patients to determine the safest and most effective dosage and the dosing regimen.

**Phase III:** Performed on a large number of consenting patients to confirm the efficacy and safety of the new drug in comparison with existing drugs or placebo.

**Phase IV:** Post-marketing clinical surveillance. Performed on a larger number of consenting patients than in phase III studies to verify the efficacy of a new drug and gather information on any side effects or adverse reactions not identified in phase III.

### Application for approval

An application submitted by a pharmaceutical company to a regulatory agency to obtain approval for manufacturing and marketing of a new drug after its efficacy and safety have been verified in clinical trials. In Japan, the Ministry of Health, Labour and Welfare (MHLW) grants manufacturing and marketing approval to substances deemed appropriate as pharmaceuticals based on reviews by the Pharmaceutical Affairs and Medical Devices Agency as well as academic and other experts in the Pharmaceutical Affairs and Food Sanitation Council.

### NHI drug price

In Japan, the price paid by the National Health Insurance (NHI) system to hospitals and insurance pharmacies for the drugs they use for insured medical treatments. Drug prices are determined by the MHLW, and are revised based on prevailing market prices once every two years in principle.

### All-case registration surveillance

A survey conducted on all patients using a particular drug to verify the efficacy and safety of the drug in actual use and to gather and analyze information on the occurrence of side effects and appropriate use. Required as a condition of approval for certain drugs.

### Additional indication

A new indication added to the indication(s) already approved for a drug.

### Lifecycle management

The various measures taken to maximize the potential value of a drug, including shortening development time, expanding sales, extending the product's life, and conducting appropriate cost control. Competitiveness can be strengthened further by using earnings from sales of established drugs to strategically reinvest in new drug development, marketing or other areas.

### Drug lag

The time difference between the approval of drugs overseas and their approval in Japan. Progress has been made in eliminating the drug lag in recent years as the Japanese government and the pharmaceutical industry have taken various measures to make drugs available to patients in Japan as early as possible.

### Multidisciplinary team care

A collaborative approach in which a team of healthcare professionals is formed according to the patient's medical condition. As medicine has become more specialized with advances in medical technology, this approach brings together doctors with different medical specialties as well as pharmacists, nurses, therapists, nutritionists, medical social workers and other professionals to provide patient-centered care as one team.

## Terms Related to Drug Discovery

### Molecular targeted therapy

A drug developed to treat illnesses more safely and effectively by targeting specific molecules in the body and suppressing their activity. Since these drugs target only specific molecules, they do less damage to normal cells, and are therefore expected to ease the burden on patients in comparison with conventional therapies.

### Biopharmaceuticals

Drugs created by applying biotechnology such as genetic recombination and cell fusion. Chugai built its expertise in biopharmaceuticals through research and development of Epogin and Neutrogin.

### Antibody

A molecule that selectively binds to a specific antigen (target) on a foreign substance and helps to remove the foreign substance from the body. When a foreign substance enters the body, it stimulates the production of antibodies that selectively bind to the antigen on the foreign substance and act to remove the substance.

### Therapeutic antibody

A drug that is used to prevent or treat illness by creating an antibody against the substance that causes the illness. Therapeutic antibodies precisely target only specific antigens on the surface of cancer cells or other cells, and therefore can be expected to provide high therapeutic efficacy and reduce side effects.

### Open innovation

Generating innovative, new value by utilizing the technologies and development capabilities of external research networks such as with universities, research institutions and other organizations, in addition to in-house capabilities.

## Terms Related to the Roche Group

### Roche

A pharmaceutical company established in 1896 and headquartered in Basel, Switzerland. With business operations in more than 150 countries, the Roche Group contributes to medicine in a wide range of fields through its two business segments: pharmaceuticals and diagnostics. Central to the Roche Group's strategy is personalized healthcare, the approach of selecting the most appropriate treatment by using biomarkers and diagnostic tests to identify patients most likely to show a significant response to a particular drug. The Roche Group's sales in 2015 were 48.1 billion Swiss francs.

### Roche Diagnostics K.K.

The Japanese subsidiary of the Roche Group's diagnostics and equipment division. Established in 1998, Roche Diagnostics K.K. provides a wide range of innovative diagnostic solutions, from in-vitro diagnostics and diagnostic equipment and research reagents and related equipment to blood glucose meters for people with diabetes.

### Genentech

A leading biotechnology company headquartered in South San Francisco, California. Genentech has been a member of the Roche Group since 1990.

## Terms Related to Human Resources

### Work-life balance/Work-life synergy

Work-life balance is the concept of creating harmony between work and personal life (family, hobbies, recreation and community activities) and achieving satisfaction in both realms.

The aim of work-life synergy is to generate synergy between each employee's job and lifestyle while improving the quality of both, as well as raising Chugai's productivity as an organization to become a top pharmaceutical company.

### Diversity

At Chugai, diversity refers to a diversity of traits such as gender, age and nationality as well as ways of thinking and values. When people with various backgrounds work together, they become aware of diverse perspectives and ideas. Using this awareness for business innovation, companies promote diversity to create better-quality products and services. Also called "diversity and inclusion," this term refers to receptivity to diversity and incorporating diverse opinions and ideas rather than the simple pursuit of variety, and also encompasses the concept of raising organizational value.

### Talent management

A human resource strategy to support the development of the next generation of leaders and core human resources and to improve the skills and enhance the motivation of employees throughout the Company, with the aim of realizing our goal of becoming a top pharmaceutical company. Each organization at Chugai has formulated a long-term human resource development plan and is building a talent pool of next-generation leader candidates.



# Financial Section

12-Year Financial Summary.....	118
Management's Discussion and Analysis...	120
Consolidated Financial Statements.....	128
Independent Auditor's Report .....	173
Network .....	174
Shareholder Information.....	176
Corporate Data.....	177

# 12-Year Financial Summary

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

(Billions of yen)

International Financial Reporting Standards (IFRS)	2015		2014		2013		2012	
	IFRS	Core <sup>1</sup>	IFRS	Core <sup>1</sup>	IFRS	Core <sup>1</sup>	IFRS	Core <sup>1</sup>
<b>Results</b>								
Revenues <sup>2</sup>	498.8		461.1		423.7		386.6	
Sales	468.4		436.9		401.3		375.2	
Royalties and other operating income	30.4		24.2		22.4		11.3	
Cost of sales	(240.2)	(238.9)	(218.1)	(217.0)	(187.0)	(186.1)	(168.2)	(167.3)
Operating expenses	(171.8)	(169.3)	(167.2)	(166.8)	(157.9)	(157.7)	(143.7)	(143.7)
Marketing and distribution	(74.8)	(74.7)	(71.7)	(71.7)	(71.6)	(71.5)	(67.9)	(67.9)
Research and development	(83.8)	(81.9)	(80.8)	(80.6)	(74.3)	(74.1)	(66.6)	(66.6)
General and administration	(13.2)	(12.8)	(14.6)	(14.6)	(12.1)	(12.1)	(9.2)	(9.2)
Operating profit	86.8	90.7	75.9	77.3	78.7	79.9	74.7	75.6
Profit before taxes	87.3	91.2	76.2	77.6	76.9	78.1	72.7	73.6
Net income	62.4	64.9	52.1	53.0	51.9	52.6	46.8	47.4
Attributable to Chugai shareholders	61.1	63.7	51.0	51.9	50.9	51.6	46.1	46.6
Core EPS (Yen)	—	116.42	—	95.04	—	94.69	—	85.64
Cash dividends per share (Yen)	58		48		45		40	
Core payout ratio	—	49.8%	—	50.5%	—	47.5%	—	46.7%
<b>Financial Position</b>								
Net operating assets	380.4		357.7		325.2		307.9	
Total assets	787.4		739.5		697.2		645.3	
Total liabilities	(160.1)		(141.8)		(124.0)		(116.2)	
Total net assets	627.3		597.8		573.2		529.2	
Investment on property, plant and equipment	28.7		16.3		13.0		14.2	
Depreciation	14.0		13.7		13.5		13.3	
<b>Main Indicators</b>								
Cost of sales to sales	51.3%	51.0%	49.9%	49.7%	46.6%	46.4%	44.8%	44.6%
Operating profit to revenues	17.4%	18.2%	16.5%	16.8%	18.6%	18.9%	19.3%	19.6%
Research and development expenditures to revenues	16.8%	16.4%	17.5%	17.5%	17.5%	17.5%	17.2%	17.2%
Ratio of net income to equity attributable to Chugai shareholders (ROE) <sup>3</sup>	10.0%	—	8.7%	—	9.3%	—	9.0%	—
Ratio of profit before taxes to total assets (ROA) <sup>4</sup>	11.4%	—	10.6%	—	11.5%	—	11.8%	—
Equity per share attributable to Chugai shareholders (BPS) (Yen)	1,146.17	—	1,092.90	—	1,049.47	—	970.08	—
Ratio of equity attributable to Chugai shareholders	79.5%	—	80.6%	—	82.0%	—	81.8%	—
Number of employees	7,169		7,023		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, for representing 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)

(Billions of yen)

Japanese GAAP	2012	2011	2010	2009	2008	2007	2006	2005	2004
<b>Results</b>									
Revenues <sup>1</sup>	391.2	373.5	379.5	428.9	326.9	344.8	326.1	327.2	294.7
Sales	375.2	363.6	375.6	419.1	321.8	332.9	—	—	—
Other operating revenues	16.0	9.9	3.9	9.8	5.1	11.9	—	—	—
Cost of sales	167.7	157.5	162.4	192.9	127.0	137.3	133.1	119.4	111.1
Selling, general and administrative expenses	147.1	153.6	150.9	153.5	148.3	140.8	134.7	128.6	132.1
Marketing and distribution expenses	92.0	97.7	96.2	98.2	95.1	86.6	80.1	78.5	83.9
Research and development expenditures	55.1	55.9	54.7	55.3	53.2	54.2	54.6	50.1	48.2
Operating income	76.4	62.4	66.2	82.6	51.6	66.7	58.3	79.2	51.5
Net income (loss)	48.2	35.2	41.4	56.6	39.3	40.1	38.4	53.6	34.1
Net income per share (basic) (Yen)	88.58	64.75	76.14	104.00	72.07	73.23	69.35	97.00	62.27
Net income per share (diluted) (Yen)	88.54	64.72	76.12	103.98	72.04	73.16	69.26	96.33	61.34
Cash dividends per share (Yen) <sup>2</sup>	40	40	40	40	34	30	30	34	18
Payout ratio	45.2%	61.8%	52.5%	38.5%	47.2%	41.0%	43.3%	35.1%	28.9%
<b>Financial Position</b>									
Total assets	587.7	533.5	508.0	540.5	478.5	458.9	462.1	456.4	411.4
Total net assets <sup>3</sup>	490.1	459.1	449.4	434.7	397.1	385.8	391.6	368.3	320.8
Capital investments	14.2	11.9	12.7	14.6	26.6	19.6	16.3	16.1	9.9
Depreciation and amortization	15.3	15.9	18.0	19.5	20.1	14.9	13.8	17.0	14.4
<b>Main Indicators</b>									
Cost of sales to revenues	44.7%	43.3%	43.2%	46.0%	39.5%	41.2%	40.8%	36.5%	37.7%
Operating income to revenues	19.5%	16.7%	17.4%	19.3%	15.8%	19.3%	17.9%	24.2%	17.5%
Research and development expenditures to revenues	14.1%	15.0%	14.4%	12.9%	16.3%	15.7%	16.7%	15.3%	16.4%
Return on equity <sup>4</sup>	10.2%	7.8%	9.4%	13.7%	10.1%	10.4%	10.1%	15.6%	11.0%
Return on assets <sup>5</sup>	8.6%	6.8%	7.9%	11.1%	8.4%	17.4%	8.4%	12.4%	8.4%
Net assets per share (Yen)	896.02	839.50	821.87	794.51	725.18	703.80	703.08	665.29	583.61
Shareholders' equity to total assets	83.0%	85.6%	88.0%	80.0%	82.6%	83.5%	84.3%	80.7%	78.0%
Number of employees	6,836	6,779	6,709	6,485	6,383	6,257	5,905	5,280	5,313

1. Revenues do not include consumption tax.

2. Cash dividends per share for 2009 include a special year-end dividend of ¥6 per share. Cash dividends per share for 2005 include a special year-end dividend of ¥10 per share.

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

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

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

# Management's Discussion and Analysis

## Operating Environment

The pharmaceutical industry continued to face numerous issues and intense competition in 2015. In addition to an emphasis on cost-containment measures in healthcare and Health Technology Assessment (HTA)<sup>1</sup> stemming from the worsening of government finances in various countries, other factors included declining

R&D productivity, stricter regulations on safety and quality, and changes in marketing activities. On the other hand, continued expansion is forecast in biopharmaceuticals and oncology drugs, with expectations for ongoing growth of pharmaceutical markets that address unmet medical need.

1. A multidisciplinary process of transparently summarizing information on the clinical efficacy, cost effectiveness, social impact and other issues related to new health technologies. HTA provides information to assist in the formulation of safe and effective healthcare policies centered on patients.

## 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 as a leading member of the Roche Group. We have been working to fulfill this mission and achieve our goal by leveraging our close relationship with Roche and building systems capable of efficiently and continuously developing and marketing new drugs. We have also innovated by refining our strengths to attain leading-edge drug discovery technology and maintain the top share of the domestic oncology field.

Under our previous mid-term business plan, ACCEL 15, we generated top-class growth in Japan underpinned by several innovative new drugs and expanded our leading share

of the domestic oncology field. Other significant outcomes we achieved included world-class drug discovery capabilities exemplified by our antibody engineering technologies, and the creation of a robust pipeline that draws on Roche's rich portfolio of clinical candidates. This pipeline contains numerous convincing new drug candidates, which we see as major opportunities that will drive growth. At the same time, as these candidates come into their own as new growth drivers over the next several years, we expect that factors including significant price decreases for existing major products and lower prices for exports to Roche will slow the pace of sales growth.

Amid such a mixture of opportunities and threats, Chugai formulated its new medium-term business plan, IBI 18, which covers the period from 2016 through 2018, and commenced new initiatives with the aim of transforming into a company that continues making progress globally through demonstration of its competitive advantages

that leverage its strategic alliance with Roche. Chugai will work to resolve issues under the two main themes of IBI 18: "acquisition and implementation of competitiveness at a top global level" and "selection and concentration strategy for acceleration of growth." The quantitative outlook through the final year of the plan is a compound annual growth rate for Core EPS<sup>2</sup> in the low single digits (less than 4 percent) based on average exchange rates for 2015. Chugai aims for a consolidated dividend payout ratio of 50 percent on average of Core EPS to provide a stable allocation of profit to all shareholders.

Chugai will unceasingly pursue innovation based on its business philosophy of "Innovation all for the patients" and its slogan "INNOVATION BEYOND IMAGINATION."

2. Diluted net income per share attributable to Chugai shareholders after deducting items that Chugai defines as non-Core items

## Overview of Results

Chugai discloses its results on a Core basis from 2013 in conjunction with its decision to apply IFRS. Core results are the results after adjusting non-recurring items recognized by Chugai to IFRS results, and are consistent with the Core concept disclosed by Roche. Core results are used by Chugai as an internal performance indicator, for explaining the status of recurring profits both internally and externally, and as indices for establishing profit distributions such as returns to shareholders.

### General Overview

(Billions of yen)								
	2013		2014		2015		2014/2015 Change	
	IFRS	Core	IFRS	Core	IFRS	Core	IFRS	Core
Revenues	423.7		461.1		498.8		+8.2%	
Operating profit	78.7	79.9	75.9	77.3	86.8	90.7	+14.4%	+17.3%
Net income	51.9	52.6	52.1	53.0	62.4	64.9	+19.8%	+22.5%

Note: IFRS basis results for 2015 include amortization of intangible assets of ¥1.6 billion, impairment of intangible assets of ¥1.9 billion, environmental expenses of ¥0.5 billion and other items excluded from the Core basis results.

- In 2015, Core basis revenues and earnings increased because of steady growth for new products and major products and continued high profitability.



## Revenues

	2013	2014	2015	(Billions of yen) 2014/2015 Change
Revenues	423.7	461.1	498.8	+8.2%
Sales (including Tamiflu)	401.3	436.9	468.4	+7.2%
Sales (excluding Tamiflu)	390.2	423.8	460.2	+8.6%
Royalties and other operating income	22.4	24.2	30.4	+25.6%

- Sales increased because domestic sales and sales outside Japan remained strong in 2015. Revenues increased steadily because sales increased and royalties and other operating income expanded.
- Royalties and other operating income increased year on year due to factors including higher milestone revenues.

## Domestic Sales by Field

	2013	2014	2015	(Billions of yen) 2014/2015 Change
Domestic sales (excluding Tamiflu)	329.2	349.5	378.0	+8.2%
Oncology	172.4	188.9	215.7	+14.2%
Bone and joint diseases	60.6	69.6	79.4	+14.1%
Renal diseases	48.9	44.7	45.4	+1.6%
Transplant, immunology and infectious diseases	18.8	20.8	15.9	-23.6%
Others	28.6	25.6	21.7	-15.2%
Tamiflu sales	11.0	13.0	8.2	-36.9%
Seasonal sales	10.1	12.9	8.2	-36.4%
Sales for government stockpiles	0.9	0.2	0.0	-100.0%

- During 2015, we maintained our number-one share of the domestic oncology market (22.6 percent<sup>3</sup>). Two new products launched in 2014 contributed: Kadcyla, a treatment for HER2-positive breast cancer, and Alecensa, an ALK inhibitor for treating *ALK* fusion gene-positive non-small cell lung cancer. In addition, sales of major products including Perjeta and Avastin increased steadily. Launched in February 2015, Zelboraf generated sales of ¥0.5 billion.
- In the bone and joint diseases field, Edrol, which has become a top brand in the domestic market for oral therapeutic agents for osteoporosis, drove solid growth, along with other major products including Actemra and Bonviva.
- In the renal diseases field, sales increased year on year due to firm sales of Mircera, although sales of Epogin decreased due to factors including the impact of NHI drug price revisions in April 2014.
- In the transplant, immunology and infectious diseases field (excluding Tamiflu), sales of Pegasys decreased substantially because of the widespread adoption of a new therapy for chronic hepatitis C and the launch of new competitor products.
- Tamiflu sales decreased, including seasonal sales and sales for government stockpiles.

3. Copyright 2016 IMS Health

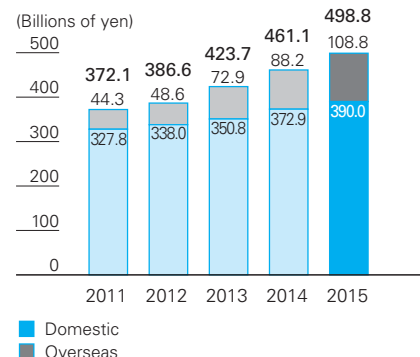
Source: JPM 2015. Reprinted with permission. The scope of the market is defined by Chugai.

## Overseas Sales

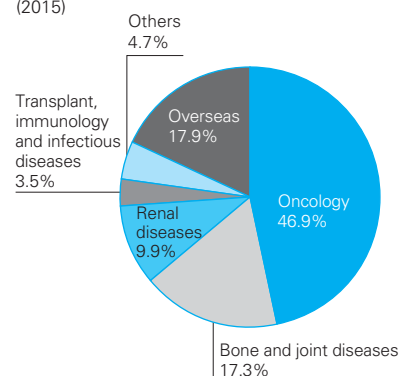
	2013	2014	2015	(Billions of yen) 2014/2015 Change
Overseas sales	61.1	74.3	82.2	+10.6%
Actemra (exports to Roche)	42.9	55.1	62.6	+13.6%

- Overseas sales increased substantially in 2015 because of the impact of the weaker yen and increased exports of Actemra to Roche on a volume basis.

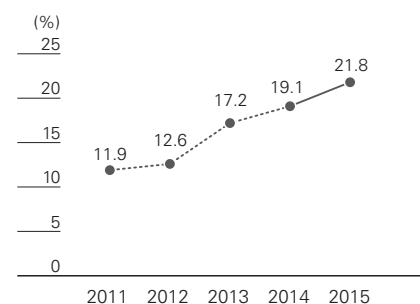
## Revenues



## Percentage of Total Sales (Excluding Tamiflu) (2015)



## Overseas Sales Ratio

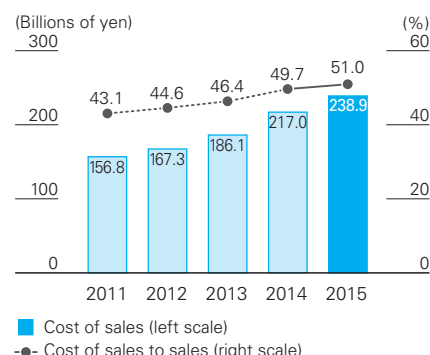


## Cost of Sales and Gross Profit (Core Basis)

	2013	2014	2015	(Billions of yen) 2014/2015 Change
Cost of sales	(186.1)	(217.0)	(238.9)	+10.1%
Ratio of cost of sales to sales	46.4%	49.7%	51.0%	+1.3% pts
Gross profit	237.6	244.2	260.0	+6.5%

- Cost of sales increased substantially year on year in 2015 because of increased sales volume and the impact of the weaker yen. The ratio of cost of sales to sales was higher primarily because of the weaker yen.
- On the other hand, gross profit increased year on year because solid revenue growth compensated for the increase in the ratio of cost of sales to sales.

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

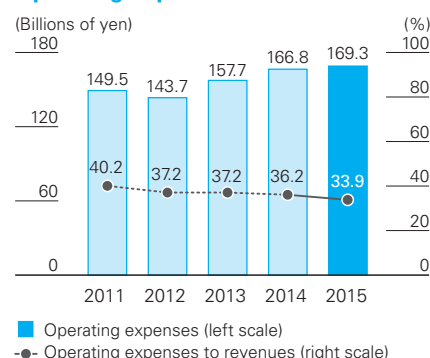


## Operating Expenses (Marketing and Distribution Expenses, R&D Expenditures and General and Administrative Expenses) (Core Basis)

	2013	2014	2015	(Billions of yen) 2014/2015 Change
Total operating expenses	(155.7)	(166.8)	(169.3)	+1.5%
Marketing and distribution expenses	(71.5)	(71.7)	(74.7)	+4.2%
R&D expenditures	(74.1)	(80.6)	(81.9)	+1.6%
General and administrative expenses	(12.1)	(14.6)	(12.8)	-12.3%

- Marketing and distribution expenses increased year on year in 2015 due to factors including increased marketing activities and revised donation expense classifications.
- R&D expenditures increased year on year due to factors including increased R&D activities as a result of the progress of development projects and the impact of the weaker yen.
- General and administrative expenses decreased year on year due to the absence of expenditures associated with removal of buildings and other nonrecurring expenses recorded in 2014.

### Operating Expenses/ Operating Expenses to Revenues

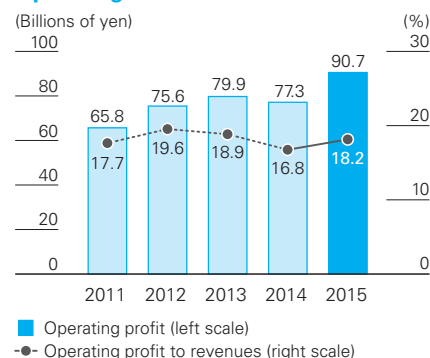


## Operating Profit and Net Income (Core Basis)

	2013	2014	2015	(Billions of yen) 2014/2015 Change
Operating profit	79.9	77.3	90.7	+17.3%
Ratio of operating profit to revenues	18.9%	16.8%	18.2%	+1.4% pts
Net income	52.6	53.0	64.9	+22.5%
Net income attributable to Chugai shareholders	51.6	51.9	63.7	+22.7%

- Mainly due to an increase in revenues, operating profit increased year on year in 2015, and the ratio of operating profit to revenues also increased.
- Net income in 2015 increased year on year because financing costs and other financial income (expense) did not change significantly, and the tax rate decreased due to changes in the taxation system.

### Operating Profit/ Operating Profit to Revenues

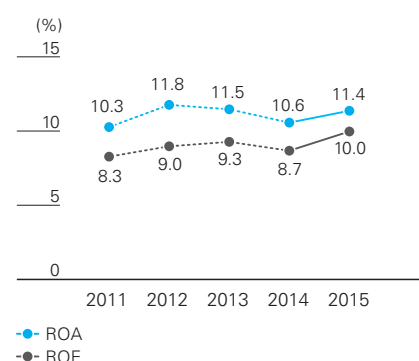


**Profitability Indicators (Consolidated)**

	2013	2014	2015	2014/2015 Change
Gross profit to revenues (%) (Core)	56.1	53.0	52.1	-0.9% pts
Operating profit to revenues (%) (Core)	18.9	16.8	18.2	+1.4% pts
Ratio of profit before taxes to total assets (ROA <sup>1</sup> ) (%) (IFRS)	11.5	10.6	11.4	+0.8% pts
Ratio of net income attributable to Chugai shareholders (ROE <sup>2</sup> ) (%) (IFRS)	9.3	8.7	10.0	+1.3% pts

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)

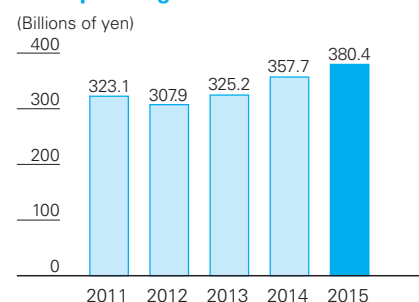
**ROA/ROE****Financial Position****Assets, Liabilities and Net Assets**

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 sheet, as the Core basis results concept only applies to the income statement.

**Net Operating Assets (NOA)**

	2013	2014	2015	(Billions of yen) 2014/2015 Change
Net working capital	177.1	209.4	214.6	+2.5%
Long-term net operating assets	148.1	148.4	165.8	+11.7%
Net operating assets (NOA)	325.2	357.7	380.4	+6.3%

- Net working capital at December 31, 2015 increased from a year earlier because the increase in inventories associated with the depreciation of the yen and the difference in the timing of imports exceeded the sum of the decrease in accounts receivable-trade and the increase in accounts payable-trade related to raw materials imported from Roche.
- Long-term net operating assets increased from a year earlier due mainly to the increase in construction in progress, equipment and intangible assets.
- As a result, net operating assets (NOA) increased from a year earlier.

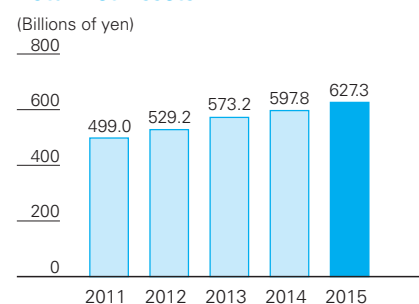
**Net Operating Assets**

Net operating assets are the total of net working capital and long-term net operating assets. Net working capital is composed of accounts receivable, inventories, accounts payable and other payables and receivables. Long-term net operating assets are composed of property, plant and equipment, intangible assets, and other items.

**Total Net Assets**

	2013	2014	2015	(Billions of yen) 2014/2015 Change
Net operating assets (NOA)	325.2	357.7	380.4	+6.3%
Net cash	234.4	229.9	235.4	+2.4%
Other non-operating assets – net	13.6	10.2	11.5	+12.7%
Total net assets	573.2	597.8	627.3	+4.9%

- Net cash, including marketable securities and interest-bearing debt, increased from a year earlier because of a net inflow from free cash flow.
- Other non-operating assets – net as of December 31, 2015 increased from a year earlier largely because a decrease in current income tax liabilities offset the increase in forward exchange contract liabilities.
- As a result, total net assets as of December 31, 2015, consisting of net operating assets (NOA), net cash, and other non-operating assets – net, increased from a year earlier.

**Total Net Assets**

## Total Assets and Total Liabilities

	2013	2014	2015	(Billions of yen) 2014/2015 Change
Total assets	697.2	739.5	787.4	+6.5%
Total liabilities	(124.0)	(141.8)	(160.1)	+12.9%

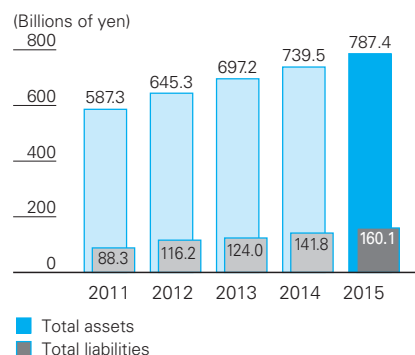
- Looking at the components of total assets, total liabilities and total net assets, total assets as of December 31, 2015 increased from a year earlier largely because property, plant and equipment, inventories, and marketable securities increased.
- Total liabilities increased from a year earlier largely because accounts payable and other liabilities increased.

## Financial Position Indicators

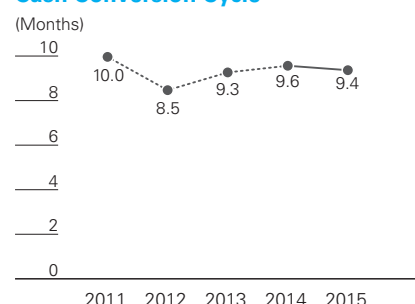
	2013	2014	2015	(Billions of yen) 2014/2015 Change
Ratio of equity attributable to Chugai shareholders (%)	82.0	80.6	79.5	-1.1% pts
Core return on net operating assets (%)	16.2	14.8	17.1	+2.3% pts
Cash conversion cycle (months)	9.3	9.6	9.4	-0.2 months
Net cash turnover period (months)	6.6	6.0	5.7	-0.3 months
Current ratio (%)	516.3	471.3	426.7	-44.6% pts
Debt-to-equity ratio (%)	0.0	0.0	0.1	+0.1% pts

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

## Total Assets/Total Liabilities



## Cash Conversion Cycle\*



## Cash Flows

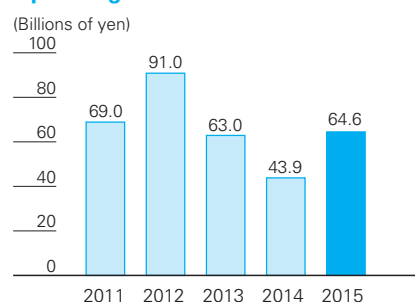
In conjunction with its decision to apply IFRS from 2013, Chugai has reorganized the consolidated statements of cash flows and uses free cash flows as an internal performance indicator (Roche discloses the same indicator). No items have been excluded from cash flows, as the Core basis results concept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

	2013	2014	2015	(Billions of yen) 2014/2015 Change
<b>Movements of Free Cash Flows</b>				
Operating profit	78.7	75.9	86.8	+14.4%
Operating profit, net of operating cash adjustment	97.3	96.4	105.4	+9.3%
Operating free cash flow	63.0	43.9	64.6	+47.2%
Free cash flow	15.0	(6.5)	7.6	—
Net increase in net cash	22.7	(4.5)	5.5	—
<b>Consolidated Statement of Cash Flows</b>				
Cash flows from operating activities	53.5	37.0	62.9	+70.0%
Cash flows from investing activities	(13.2)	(14.4)	(45.3)	+214.6%
Cash flows from financing activities	(23.2)	(24.4)	(28.5)	+16.8%
Net increase in cash and cash equivalents	19.6	(1.0)	(12.3)	12.3 times
Cash and cash equivalents at end of year	115.1	114.0	101.7	-10.8%

## Operating free cash flow

- Operating profit, net of operating cash adjustment totaled ¥105.4 billion after adjustment for items including ¥14.0 billion for depreciation of property, plant and equipment.
- Operating free cash flow, which is calculated by subtracting the increase in net working capital of ¥15.9 billion and expenditures of ¥24.8 billion for the purchase of property, plant and equipment and intangible assets from operating profit, net of operating cash adjustments, amounted to a net inflow of ¥64.6 billion (net inflow of ¥43.9 billion for 2014). Purchases of property, plant and equipment were mainly expenditures to acquire buildings and equipment for research laboratories and plants.

## Operating Free Cash Flow

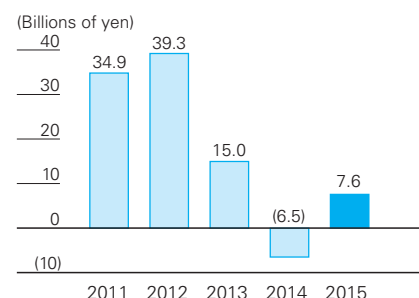




### Free cash flow (FCF)

- Free cash flow, which is calculated by subtracting the total of ¥57.0 billion of non-operating cash outflows from financial asset management, income taxes paid and dividends paid from operating free cash flow, was a net inflow of ¥7.6 billion (net outflow of ¥6.5 billion in the previous fiscal year).
- The net change in net cash, after foreign currency translation adjustments, was an increase of ¥5.5 billion compared with the end of the previous fiscal year. The net change in cash and cash equivalents, excluding changes in marketable securities and interest-bearing debt, was a net outflow of ¥12.3 billion.

### Free Cash Flow

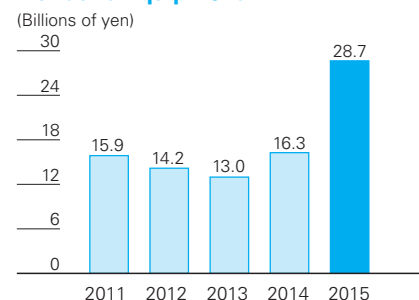


## Capital Investments

	(Billions of yen)			
	2013	2014	2015	2014/2015 Change
Investments in property, plant and equipment	13.0	16.3	28.7	+76.1%
Depreciation	13.5	13.7	14.0	+2.2%

- The increase in capital investments in 2015 was largely the result of expenditures to acquire research and plant equipment.
- Chugai plans to make capital investments of ¥19.0 billion during 2016 consisting primarily of new investment in the main facilities below, and expects depreciation to total ¥14.5 billion.

### Capital Investments on Property, Plant and Equipment



### Major Capital Investments Planned (Chugai Pharma Manufacturing Co., Ltd.)

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)	Enhancement of high-mix, low-volume production capability for pre-filled syringe form products (Installment of tray filler)	6.0	3.3	Self-financing	September 2013	July 2017
Ukima plant (Kita-ku, Tokyo)	Enhancement of high-mix low-volume production of antibody API for initial commercial products (Construction of new antibody API plant)	37.2	10.0	Self-financing	November 2015	May 2019
Fujieda Plant (Fujieda City, Shizuoka Prefecture)	Strengthening of solid formulation manufacturing facility, etc. (Handle quick launch and steady supply)	6.0	0.9	Self-financing	November 2015	December 2018

Note: Responsibility for installment of tray filler (enhancement of high-mix, low volume production capability for pre-filled syringe form products) was transferred to Chugai Pharma Manufacturing Co., Ltd. in 2015.

### Major Capital Investments Decided after December 31, 2015

Chugai decided to purchase, for its business purpose, properties in Yokohama-shi, Kanagawa Prefecture, owned by Hitachi, Ltd. and has concluded a real estate purchase agreement with Hitachi Ltd. as of March 7, 2016. The provisional purchase price is ¥41.7 billion, and the provisional date of property transfer is December 2018.

In order to achieve the key objectives of the new mid-term business plan "IBI 18" and to further grow in the global arena in future, it is essential for Chugai to continuously create and develop innovative pharmaceutical products, which requires further enhancement of research and production processes, a seamless transfer to clinical development, and accelerated proof-of-concept\*. Chugai has recognized the need for competent human resources and a core base facilitated with state-of-the-art research and development functions to create its own innovative new drug candidates, and accordingly, decided to purchase land for its business purpose so as to further ensure the success that has been achieved by the efficient implementation of its innovative business model, and to maximize the value of this business model.

\* A demonstration that the therapeutic effect conceived in the research stage is effective in humans.

## Outlook for 2016

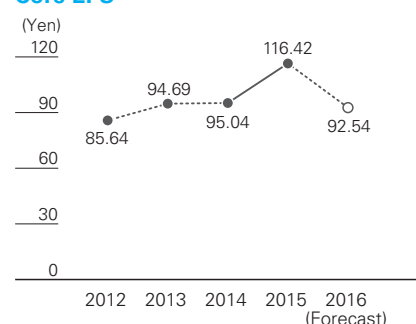
### Forecast Assumptions

For 2016, Chugai assumes exchange rates of ¥127/CHF, ¥134/EUR, ¥120/USD and ¥87/SGD, and that the scale of seasonal influenza will be about the same as the average since 2007, excluding the influenza pandemic in the 2009/2010 season.

### Results Forecast (Core Basis)

	2014	2015	2016 (Forecast)	2015/2016 Change
Domestic sales (excluding Tamiflu)	349.5	378.0	379.0	+0.3%
Tamiflu sales	13.0	8.2	8.6	+4.9%
Overseas sales	74.3	82.2	87.8	+6.8%
Exports to Roche	55.1	63.1	70.5	+11.7%
Royalties and other operating income	24.2	30.4	19.6	-35.5%
Gross profit	244.2	260.0	241.0	-7.3%
Core operating profit	77.3	90.7	71.0	-21.7 %
Core EPS (¥)	95.04	116.42	92.54	-20.5%

#### Core EPS\*



\* Core EPS = Core net income attributable to Chugai shareholders / Diluted weighted average shares outstanding

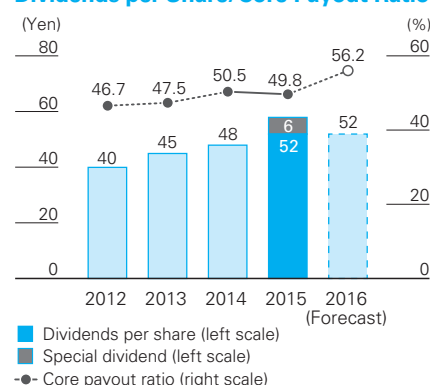
- Despite the expected impact of NHI price revisions, domestic sales excluding Tamiflu are forecast to be on par with 2015, with growth in sales of new oncology products led by our HER2 franchise including Kadcyla and Alecensa and growth driven by Actemra, Edrol and Bonviva in the bone and joint diseases field.
- Despite lower export prices, exports to Roche are expected to increase because of sustained growth in sales of Actemra outside Japan and growth in exports of Alecensa, which we initiated in 2015. On the other hand, sales outside Japan of other products are forecast to decrease due to a decline in sales of Neutrogen caused by competition from biosimilars.
- Royalties and other operating income are forecast to decrease despite higher revenues from Roche for co-promotion and royalties for Actemra because we do not expect to receive lump-sum payments in 2016.
- Gross profit is forecast to decrease mainly as a result of lower royalties and other operating income and a higher ratio of cost of sales to sales due to factors such as downward NHI price revisions and lower unit prices for Actemra exports.
- We expect overall operating expenses to remain essentially unchanged year on year, even though we will continue to invest in our primary operating activities as we did in 2015.
- As a result of the above, we forecast that Core operating profit and Core EPS will decrease.

### 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 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.

	2013	2014	2015	2016 (Forecast)
Basic net income per share (EPS)	93.47	93.53	112.00	—
Core EPS	94.69	95.04	116.42	92.54
Equity per share attributable to Chugai shareholders (BPS)	1,049.47	1,092.90	1,146.17	—
Cash dividends per share	45	48	58	52
Core payout ratio	47.5%	50.5%	49.8%	56.2%

#### Dividends per Share/Core Payout Ratio



- Cash dividends per share for 2015 totaled ¥58, including a special dividend of ¥6.
- The five-year average Core EPS payout ratio for 2015 was 50.3 percent. We expect the five-year average Core EPS payout ratio for 2016 to be 49.9 percent.
- The forecast for cash dividends per share for 2016 includes an interim dividend of ¥26.

## 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, 2015.

### 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 by regulatory authorities in each country 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.

### Medical System Reform

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. Overseas, pressure to reduce drug costs is increasing, especially in advanced countries. Future measures to curb drug costs in these countries could materially affect Chugai's business performance and financial position.

### 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 granted Roche first refusal rights with respect to its products in global markets outside Japan, excluding South Korea and Taiwan. Consequently, Chugai has in-licensed and out-licensed many products and projects from and to 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. Compliance and other problems arising from these issues could have a material impact on Chugai's business performance and financial position.

### Information Technology Security and Information Control

Chugai makes full use of a wide range of information technology systems in its business activities. Consequently, it is subject to the risk of its operations being disrupted due to system malfunctions, computer viruses or other external factors. In addition, an accident or other incident resulting in the leakage of confidential information 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.

### Litigation

There is a possibility that litigation may be brought against Chugai over side effects of pharmaceuticals, product liability, labor issues, fair trade or other issues associated with its business activities, which could have a material impact on Chugai's business performance and financial position.

### Environmental Issues

In addition to complying with laws and regulations related to environmental issues, Chugai has established a set of even higher voluntary standards and has been making efforts to achieve them. In the course of Chugai's business activities, violations of relevant laws or regulations may occur as a result of an accident or other incident. Any related expenses could 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	
	2015	2014
<b>Revenues</b>	<b>498,839</b>	<b>461,109</b>
Sales (Note 2)	468,427	436,883
Royalties and other operating income (Note 2)	30,413	24,226
Cost of sales	(240,238)	(218,076)
<b>Gross profit</b>	<b>258,601</b>	<b>243,033</b>
Marketing and distribution	(74,811)	(71,742)
Research and development	(83,799)	(80,800)
General and administration	(13,207)	(14,632)
<b>Operating profit</b>	<b>86,784</b>	<b>75,859</b>
Financing costs (Note 3)	(67)	(11)
Other financial income (expense) (Note 3)	559	315
<b>Profit before taxes</b>	<b>87,276</b>	<b>76,164</b>
Income taxes (Note 4)	(24,923)	(24,087)
<b>Net income</b>	<b>62,353</b>	<b>52,077</b>
Attributable to :		
Chugai shareholders (Note 19)	61,125	50,980
Non-controlling interests (Note 20)	1,228	1,097
Earnings per share (Note 24)		
Basic (yen)	112.00	93.53
Diluted (yen)	111.79	93.38



**2) Consolidated statement of comprehensive income** in millions of yen

	Year ended December 31	
	2015	2014
<b>Net income recognized in income statement</b>	<b>62,353</b>	<b>52,077</b>
Other comprehensive income		
Remeasurements of defined benefit plans (Notes 4 and 19)	(1,519)	(1,452)
<b>Items that will not be reclassified to the income statement</b>	<b>(1,519)</b>	<b>(1,452)</b>
Available-for-sale investments (Notes 4 and 19)	1,844	1,050
Cash flow hedges (Notes 4 and 19)	(1,741)	(4,052)
Currency translation of foreign operations (Notes 4 and 19)	(3,461)	862
<b>Items that may be reclassified subsequently to the income statement</b>	<b>(3,358)</b>	<b>(2,140)</b>
<b>Other comprehensive income, net of tax</b> (Note 4)	<b>(4,877)</b>	<b>(3,592)</b>
<b>Total comprehensive income</b>	<b>57,476</b>	<b>48,485</b>
Attributable to:		
Chugai shareholders (Note 19)	56,380	47,379
Non-controlling interests (Note 20)	1,096	1,107

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

	December 31, 2015	December 31, 2014
Assets		
Non-current assets:		
Property, plant and equipment (Note 5)	153,545	140,245
Intangible assets (Note 6)	13,511	11,286
Financial non-current assets (Note 7)	13,715	10,755
Deferred tax assets (Note 4)	26,025	25,673
Defined benefit plan assets (Note 22)	-	1,946
Other non-current assets (Note 8)	12,832	10,728
<b>Total non-current assets</b>	<b>219,628</b>	<b>200,635</b>
Current assets:		
Inventories (Note 9)	161,135	139,571
Accounts receivable (Note 10)	158,668	159,773
Current income tax assets (Note 4)	49	114
Marketable securities (Note 11)	134,419	116,030
Cash and cash equivalents (Note 12)	101,707	114,037
Other current assets (Note 13)	11,796	9,379
<b>Total current assets</b>	<b>567,773</b>	<b>538,904</b>
<b>Total assets</b>	<b>787,401</b>	<b>739,538</b>
Liabilities		
Non-current liabilities:		
Long-term debt (Note 14)	(604)	(185)
Deferred tax liabilities (Note 4)	(10,028)	(10,722)
Defined benefit plan liabilities (Note 22)	(2,358)	(2,616)
Long-term provisions (Note 15)	(1,974)	(2,110)
Other non-current liabilities (Note 16)	(12,108)	(11,799)
<b>Total non-current liabilities</b>	<b>(27,071)</b>	<b>(27,432)</b>
Current liabilities:		
Short-term debt (Note 14)	(131)	(29)
Current income tax liabilities (Note 4)	(13,133)	(16,619)
Short-term provisions (Note 15)	(180)	(987)
Accounts payable (Note 17)	(78,353)	(62,694)
Other current liabilities (Note 18)	(41,260)	(34,021)
<b>Total current liabilities</b>	<b>(133,058)</b>	<b>(114,350)</b>
<b>Total liabilities</b>	<b>(160,130)</b>	<b>(141,782)</b>
<b>Total net assets</b>	<b>627,271</b>	<b>597,756</b>
Equity:		
Capital and reserves attributable to Chugai shareholders (Note 19)	625,857	596,099
Equity attributable to non-controlling interests (Note 20)	1,414	1,657
<b>Total equity</b>	<b>627,271</b>	<b>597,756</b>

### 3. Consolidated statement of cash flows in millions of yen

	Year ended December 31	
	2015	2014
Cash flows from operating activities		
Cash generated from operations (Note 25)	110,159	99,050
(Increase) decrease in working capital	(15,945)	(33,302)
Payments made for defined benefit plans	(3,883)	(2,254)
Utilization of provisions (Note 15)	(510)	(122)
Other operating cash flows	2,239	(1,115)
<b>Cash flows from operating activities, before income taxes paid</b>	<b>92,059</b>	<b>62,256</b>
Income taxes paid	(29,141)	(25,222)
<b>Total cash flows from operating activities</b>	<b>62,918</b>	<b>37,034</b>
Cash flows from investing activities		
Purchase of property, plant and equipment	(18,367)	(16,232)
Purchase of intangible assets	(6,472)	(2,935)
Disposal of property, plant and equipment	(424)	794
Interest and dividends received (Note 25)	355	490
Purchases of marketable securities	(241,432)	(228,292)
Sales of marketable securities	221,679	231,873
Other investing cash flows	(607)	(49)
<b>Total cash flows from investing activities</b>	<b>(45,269)</b>	<b>(14,351)</b>
Cash flows from financing activities		
Interest paid	(7)	(6)
Dividends paid to Chugai shareholders	(28,375)	(24,520)
Dividends paid to non-controlling shareholders	(1,064)	(962)
Exercise of equity compensation plans (Note 23)	1,391	1,226
(Increase) decrease in own equity instruments	15	(19)
Other financing cash flows	(425)	(109)
<b>Total cash flows from financing activities</b>	<b>(28,467)</b>	<b>(24,388)</b>
Net effect of currency translation on cash and cash equivalents	(1,513)	673
<b>Increase (decrease) in cash and cash equivalents</b>	<b>(12,331)</b>	<b>(1,032)</b>
Cash and cash equivalents at January 1	114,037	115,070
<b>Cash and cash equivalents at December 31 (Note 12)</b>	<b>101,707</b>	<b>114,037</b>

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

	Attributable to Chugai shareholders					Non-controlling interests	Total equity
	Share capital	Capital surplus	Retained earnings	Other reserves	Subtotal		
<b>Year ended December 31, 2014</b>							
<b>At January 1, 2014</b>	<b>72,967</b>	<b>59,268</b>	<b>432,713</b>	<b>6,744</b>	<b>571,692</b>	<b>1,512</b>	<b>573,204</b>
Net income recognized in income statement	-	-	50,980	-	50,980	1,097	52,077
Available-for-sale investments (Notes 4 and 19)	-	-	-	1,050	1,050	-	1,050
Cash flow hedges (Notes 4 and 19)	-	-	-	(4,052)	(4,052)	-	(4,052)
Currency translation of foreign operations (Notes 4,19 and 20)	-	-	-	851	851	10	862
Remeasurements of defined benefit plans (Notes 4,19 and 20)	-	-	(1,451)	-	(1,451)	(1)	(1,452)
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>49,529</b>	<b>(2,150)</b>	<b>47,379</b>	<b>1,107</b>	<b>48,485</b>
Dividends (Notes 19 and 20)	-	-	(24,521)	-	(24,521)	(962)	(25,483)
Equity compensation plans (Note 19)	-	(73)	-	-	(73)	-	(73)
Own equity instruments (Note 19)	-	1,623	-	-	1,623	-	1,623
<b>At December 31, 2014</b>	<b>72,967</b>	<b>60,817</b>	<b>457,720</b>	<b>4,594</b>	<b>596,099</b>	<b>1,657</b>	<b>597,756</b>
<b>Year ended December 31, 2015</b>							
<b>At January 1, 2015</b>	<b>72,967</b>	<b>60,817</b>	<b>457,720</b>	<b>4,594</b>	<b>596,099</b>	<b>1,657</b>	<b>597,756</b>
Net income recognized in income statement	-	-	61,125	-	61,125	1,228	62,353
Available-for-sale investments (Notes 4 and 19)	-	-	-	1,844	1,844	-	1,844
Cash flow hedges (Notes 4 and 19)	-	-	-	(1,741)	(1,741)	-	(1,741)
Currency translation of foreign operations (Notes 4,19 and 20)	-	-	-	(3,329)	(3,329)	(132)	(3,461)
Remeasurements of defined benefit plans (Notes 4,19 and 20)	-	-	(1,519)	-	(1,519)	-	(1,519)
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>59,605</b>	<b>(3,225)</b>	<b>56,380</b>	<b>1,096</b>	<b>57,476</b>
Dividends (Notes 19 and 20)	-	-	(28,372)	-	(28,372)	(1,064)	(29,436)
Equity compensation plans (Note 19)	-	(44)	-	-	(44)	-	(44)
Own equity instruments (Note 19)	-	1,801	-	-	1,801	-	1,801
Changes in non-controlling Interests (Note 19 and 20)	-	(8)	-	-	(8)	(275)	(283)
<b>At December 31, 2015</b>	<b>72,967</b>	<b>62,567</b>	<b>488,954</b>	<b>1,369</b>	<b>625,857</b>	<b>1,414</b>	<b>627,271</b>



# 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., ("Chugai") 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 24, 2016.

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% (61.39% of the total number of shares issued excluding treasury stock). The Group became a member 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 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 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 ongoing 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 are 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 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: 5-16 years
- Marketing intangibles in use: 2-5 years
- Technology intangibles in use: 3-8 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 aging 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) Changes in accounting policies**

The accounting policies applied by the Group for the consolidated financial statements for the year ended December 31, 2015 are the same as for the previous year.

There were minor amendments to some the existing standards and interpretations, which do not materially impact the Group's overall results and financial position.



### 5) Future new and revised standards

The Group is currently assessing the potential impacts of new and revised standards and interpretations that will be effective from January 1, 2016 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 in 2016.

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

	IFRS	Mandatory adoption (from the year beginning)	To be adopted by the Group	Description of new and revised standards
IFRS 15	Revenue from Contracts with Customers	January 1, 2018	To be determined	Revision of accounting relating to revenue recognition
IFRS 9	Financial Instruments	January 1, 2018	To be determined	Classification, measurement and recognition of financial instruments, and revision of hedge accounting
IFRS 16	Leases	January 1, 2019	To be determined	Revision of accounting relating to recognition of leases

## 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

	2015		2014	
	Sales	Royalties and other operating income	Sales	Royalties and other operating income
Japan	386,241	3,770	362,574	10,300
Overseas	82,185	26,643	74,309	13,926
of which Switzerland	63,084	26,555	55,051	13,884
<b>Total</b>	<b>468,427</b>	<b>30,413</b>	<b>436,883</b>	<b>24,226</b>

### Information on revenues by major customers in millions of yen

	2015		2014	
	Revenues	%	Revenues	%
Alfresa Corporation	100,181	20.1	94,483	20.5
F. Hoffmann-La Roche Ltd	89,639	18.0	68,784	14.9
Mediceo Corporation	78,489	15.7	72,767	15.8
Suzuken Co., Ltd.	49,457	9.9	47,658	10.3

## 3. Financing costs and other financial income (expense)

### Financing costs in millions of yen

	2015	2014
Interest expense	(7)	(6)
Net interest cost of defined benefit plans	8	63
Net other financing costs	(68)	(68)
<b>Total financing costs</b>	<b>(67)</b>	<b>(11)</b>

### Other financial income (expense) in millions of yen

	2015	2014
Dividend income	208	287
Gains on sale of equity securities	2	-
Losses on sale of equity securities	-	-
Write-downs and impairments of equity securities	(64)	(0)
<b>Net income from equity securities</b>	<b>146</b>	<b>287</b>
Interest income	148	205
Gains on sale of debt securities	-	-
Losses on sale of debt securities	-	-
<b>Net interest income and income from debt securities</b>	<b>148</b>	<b>205</b>
Foreign exchange gains (losses)	(585)	(672)
Gains (losses) on foreign currency derivatives	849	495
<b>Net foreign exchange gains (losses)</b>	<b>265</b>	<b>(177)</b>
<b>Total other financial income (expense)</b>	<b>559</b>	<b>315</b>

## 4. Income taxes

### Income tax expenses in millions of yen

	2015	2014
Current income taxes	(25,471)	(29,244)
Deferred taxes	548	5,158
<b>Total income tax (expense)</b>	<b>(24,923)</b>	<b>(24,087)</b>

### Reconciliation of the Group's effective tax rate

	2015	2014
Expected tax rate	35.4%	38.0 %
Tax effect of		
- Non-taxable income/non-deductible expenses	+0.6%	+1.1 %
- Effect of changes in applicable tax rates on deferred tax balances	+1.6%	+2.4 %
- Research and development tax credits	(7.8)%	(7.7) %
- Other differences	(1.2)%	(2.2) %
<b>Group's effective tax rate</b>	<b>28.6%</b>	<b>31.6 %</b>

### Tax effects of other comprehensive income in millions of yen

	2015			2014		
	Pre-tax amount	Tax benefit	After-tax amount	Pre-tax amount	Tax benefit	After-tax Amount
Remeasurements of defined benefit plans	(1,782)	263	(1,519)	(2,256)	804	(1,452)
Available-for-sale investments	2,415	(571)	1,844	1,632	(582)	1,050
Cash flow hedges	(2,598)	857	(1,741)	(6,543)	2,491	(4,052)
Currency translation of foreign operations	(3,461)	-	(3,461)	862	-	862
<b>Other comprehensive income</b>	<b>(5,425)</b>	<b>548</b>	<b>(4,877)</b>	<b>(6,305)</b>	<b>2,713</b>	<b>(3,592)</b>

### Income tax assets (liabilities) in millions of yen

	December 31, 2015	December 31, 2014
Current income taxes		
- Assets	49	114
- Liabilities	(13,133)	(16,619)
<b>Net current income tax assets (liabilities)</b>	<b>(13,084)</b>	<b>(16,505)</b>
Deferred taxes		
- Assets	26,025	25,673
- Liabilities	(10,028)	(10,722)
<b>Net deferred tax assets (liabilities)</b>	<b>15,997</b>	<b>14,950</b>

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

	2015	2014
Net current income tax assets (liabilities) at January 1	(16,505)	(12,468)
Income taxes paid	29,141	25,222
(Charged) credited to the income statement	(25,471)	(29,244)
Currency translation effects and other	(248)	(15)
<b>Net current income tax assets (liabilities) at December 31</b>	<b>(13,084)</b>	<b>(16,505)</b>

**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
<b>Year ended December 31, 2014</b>						
At January 1, 2014	(20,142)	(709)	324	2,862	24,698	7,033
(Charged) credited to the income statement	1,334	(232)	304	(52)	3,804	5,158
(Charged) credited to other comprehensive income	-	-	-	804	1,909	2,713
(Charged) credited to equity	-	-	-	-	-	-
Currency translation effects and other	-	-	-	-	46	46
<b>At December 31, 2014</b>	<b>(18,808)</b>	<b>(940)</b>	<b>628</b>	<b>3,613</b>	<b>30,457</b>	<b>14,950</b>

**Year ended December 31, 2015**

At January 1, 2015	(18,808)	(940)	628	3,613	30,457	14,950
(Charged) credited to the income statement	(496)	(291)	(370)	262	1,444	548
(Charged) credited to other comprehensive income	-	-	-	263	286	548
(Charged) credited to equity	-	-	-	-	-	-
Currency translation effects and other	9	(3)	(5)	(2)	(48)	(50)
<b>At December 31, 2015</b>	<b>(19,295)</b>	<b>(1,235)</b>	<b>252</b>	<b>4,136</b>	<b>32,139</b>	<b>15,997</b>

Other temporary differences mainly relate to prepaid expenses, supplies and amortization of deferred assets.

Deferred tax assets are not recognized for deductible temporary differences of ¥1,586 million (2014: ¥1,530 million).

Deferred tax assets are recognized for tax losses carried forward only to the extent that realization of the related tax benefit is probable.

**Unrecognized tax losses: expiry in millions of yen**

	2015	2014
Less than one year	-	-
Over one year and less than five years	-	-
Over five years	410	2,617
<b>Tax losses not recognized in deferred tax assets</b>	<b>410</b>	<b>2,617</b>

Deferred tax assets for unused tax credits are recognized only to the extent that realization of the related tax benefit is probable.

**Unrecognized unused tax credits: expiry in millions of yen**

	2015	2014
Less than one year	-	-
Over one year and less than five years	-	-
Over five years	122	121
<b>Unused tax credits not recognized in deferred tax assets</b>	<b>122</b>	<b>121</b>

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 ¥1,746 million (2014: ¥1,857 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, 2014					
Cost	10,388	114,000	158,239	3,019	285,646
Accumulated depreciation and impairment	(275)	(54,003)	(90,924)	-	(145,201)
<b>Net book value</b>	<b>10,114</b>	<b>59,998</b>	<b>67,315</b>	<b>3,019</b>	<b>140,445</b>

#### Year ended December 31, 2014

At January 1, 2014	10,114	59,998	67,315	3,019	140,445
Additions	-	338	391	15,689	16,418
Disposals	(169)	(756)	(438)	-	(1,362)
Transfers	-	5,283	9,188	(14,471)	-
Depreciation charge	-	(3,777)	(9,911)	-	(13,688)
Impairment charge	(580)	(813)	(382)	-	(1,775)
Other	-	0	1	-	1
Currency translation effects	-	47	135	26	207
<b>At December 31, 2014</b>	<b>9,365</b>	<b>60,320</b>	<b>66,298</b>	<b>4,262</b>	<b>140,245</b>

Cost	9,973	117,796	160,610	4,262	292,642
Accumulated depreciation and impairment	(608)	(57,476)	(94,312)	-	(152,396)
<b>Net book value</b>	<b>9,365</b>	<b>60,320</b>	<b>66,298</b>	<b>4,262</b>	<b>140,245</b>

#### Year ended December 31, 2015

At January 1, 2015	9,365	60,320	66,298	4,262	140,245
Additions	-	63	1,261	27,409	28,733
Disposals	(253)	(340)	(556)	(3)	(1,153)
Transfers	-	3,780	15,722	(19,503)	-
Depreciation charge	-	(3,928)	(10,036)	-	(13,964)
Impairment charge	-	(114)	(88)	-	(202)
Currency translation effects	-	(6)	(107)	(2)	(115)
<b>At December 31, 2015</b>	<b>9,112</b>	<b>59,775</b>	<b>72,494</b>	<b>12,164</b>	<b>153,545</b>

Cost	9,141	115,036	171,457	12,164	307,798
Accumulated depreciation and impairment	(28)	(55,261)	(98,964)	-	(154,253)
<b>Net book value</b>	<b>9,112</b>	<b>59,775</b>	<b>72,494</b>	<b>12,164</b>	<b>153,545</b>

In 2015, no borrowing costs were capitalized as property, plant and equipment (2014: none).

### Impairment charge

During 2014 the impairment charge was mainly related to unused buildings at Ukima plant. The carrying value was reduced to the value in use as the recoverable amount of the assets was less than the carrying value.

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

	2015	2014
Cost of sales	139	1,116
Marketing and distribution	-	-
Research and development	63	4
General and administration	-	656
<b>Total impairment charge</b>	<b>202</b>	<b>1,775</b>



**Finance leases**

The capitalized cost of property, plant and equipment under finance leases was ¥741 million (2014: ¥191 million) and the net book value of these assets was ¥527 million (2014: ¥50 million). The carrying value of the leasing obligation was ¥570 million (2014: ¥53 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 ¥7,123 million (2014: ¥6,763 million).

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

	December 31, 2015	December 31, 2014
Within one year	4,732	4,400
Between one and five years	6,755	6,541
More than five years	350	598
<b>Total minimum payments</b>	<b>11,837</b>	<b>11,539</b>

**Capital commitments**

The Group has non-cancellable capital commitments for the purchase or construction of property, plant and equipment totaling ¥29,918 million (2014: ¥6,272 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, 2014					
Cost	14,055	5,174	225	75	19,529
Accumulated amortization and impairment	(9,870)	(89)	(49)	(7)	(10,014)
<b>Net book value</b>	<b>4,185</b>	<b>5,085</b>	<b>175</b>	<b>68</b>	<b>9,514</b>

#### Year ended December 31, 2014

At January 1, 2014	4,185	5,085	175	68	9,514
Additions	38	2,576	492	28	3,134
Disposals	-	-	-	-	-
Transfers	2,479	(2,479)	-	-	-
Amortization charge	(1,123)	-	(58)	(11)	(1,192)
Impairment charge	-	(171)	-	-	(171)
Currency translation effects	-	0	-	-	0
<b>At December 31, 2014</b>	<b>5,580</b>	<b>5,012</b>	<b>609</b>	<b>85</b>	<b>11,286</b>
Cost	16,577	5,271	717	103	22,668
Accumulated amortization and impairment	(10,997)	(259)	(107)	(17)	(11,381)
<b>Net book value</b>	<b>5,580</b>	<b>5,012</b>	<b>609</b>	<b>85</b>	<b>11,286</b>

#### Year ended December 31, 2015

At January 1, 2015	5,580	5,012	609	85	11,286
Additions	616	4,466	744	-	5,826
Disposals	-	-	-	-	-
Transfers	1,136	(1,136)	-	-	-
Amortization charge	(1,386)	-	(200)	(17)	(1,603)
Impairment charge	-	(1,852)	-	-	(1,852)
Currency translation effects	20	(166)	-	-	(146)
<b>At December 31, 2015</b>	<b>5,966</b>	<b>6,324</b>	<b>1,153</b>	<b>68</b>	<b>13,511</b>
Cost	18,027	8,435	1,460	103	28,026
Accumulated amortization and impairment	(12,061)	(2,112)	(307)	(35)	(14,515)
<b>Net book value</b>	<b>5,966</b>	<b>6,324</b>	<b>1,153</b>	<b>68</b>	<b>13,511</b>

### 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 16 years.

### Impairment charge

In 2015, impairment charge was mainly related to the cessation of R&D projects.

### Classification of amortization and impairment expenses in millions of yen

	2015		2014	
	Amortization	Impairment	Amortization	Impairment
Cost of sales	1,386	-	1,123	-
Marketing and distribution	154	-	58	-
Research and development	63	1,852	11	171
General and administration	-	-	-	-
<b>Total</b>	<b>1,603</b>	<b>1,852</b>	<b>1,192</b>	<b>171</b>

**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, 2015** in millions of yen

	Third party	Related party	Total
Within one year	2,527	917	3,444
Between one and two years	3,664	3,684	7,348
Between two and three years	719	1,509	2,228
<b>Total</b>	<b>6,910</b>	<b>6,110</b>	<b>13,020</b>

**7. Financial non-current assets****Financial non-current assets** in millions of yen

	December 31, 2015	December 31, 2014
Available-for-sale investments	13,715	10,755
Other financial non-current assets	-	-
<b>Total financial non-current assets</b>	<b>13,715</b>	<b>10,755</b>

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 securities in Japanese listed companies.

## 8. Other non-current assets

**Other non-current assets** in millions of yen

	December 31, 2015	December 31, 2014
Long-term prepaid expenses	8,240	6,177
Other assets	4,591	4,552
<b>Total other non-current assets</b>	<b>12,832</b>	<b>10,728</b>

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, 2015	December 31, 2014
Raw materials and supplies	59,146	34,668
Work in process	32	145
Intermediates	34,336	33,023
Finished goods	69,009	72,228
Less: Provision for slow-moving and obsolete inventory	(1,388)	(493)
<b>Total inventories</b>	<b>161,135</b>	<b>139,571</b>

Inventories expensed through cost of sales totaled ¥225,144 million (2014: ¥204,275 million). Expenses relating to inventory write-down totaled ¥1,481 million (2014: ¥1,182 million).

## 10. Accounts receivable

**Accounts receivable** in millions of yen

	December 31, 2015	December 31, 2014
Trade receivables – third party	120,926	124,697
Trade receivables – related party	13,529	16,630
Notes receivables	22	17
Other receivables – third party	4,986	6,818
Other receivables – related party	19,210	11,616
Allowances for doubtful accounts	(6)	(5)
<b>Total accounts receivable</b>	<b>158,668</b>	<b>159,773</b>

## 11. Marketable securities

**Marketable securities** in millions of yen

	December 31, 2015	December 31, 2014
Available-for-sale financial assets		
Money market instruments and time accounts over three months	134,419	116,030
<b>Total marketable securities</b>	<b>134,419</b>	<b>116,030</b>

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

## 12. Cash and cash equivalents

**Cash and cash equivalents** in millions of yen

	December 31, 2015	December 31, 2014
Cash - cash in hand and in current or call accounts	97,902	105,435
Cash equivalents - time accounts with a maturity of three months or less	3,805	8,602
<b>Total cash and cash equivalents</b>	<b>101,707</b>	<b>114,037</b>

## 13. Other current assets

**Other current assets** in millions of yen

	December 31, 2015	December 31, 2014
Derivative financial instruments	3,409	1,911
<b>Total financial current assets</b>	<b>3,409</b>	<b>1,911</b>
Prepaid expenses	8,387	7,468
<b>Total non-financial current assets</b>	<b>8,387</b>	<b>7,468</b>
<b>Total other current assets</b>	<b>11,796</b>	<b>9,379</b>

## 14. Debt

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

	2015	2014
At January 1	214	233
Increase in debt	606	27
Decrease in debt	(85)	(46)
<b>At December 31</b>	<b>735</b>	<b>214</b>
Finance lease obligations	570	53
Other debt	165	161
<b>Total debt</b>	<b>735</b>	<b>214</b>
Long-term debt	604	185
Short-term debt	131	29
<b>Total debt</b>	<b>735</b>	<b>214</b>



## 15. Provisions and contingent liabilities

### Provisions: movements in recognized liabilities in millions of yen

	Environmental provisions	Restructuring provisions	Other provisions	Total
<b>Year ended December 31, 2014</b>				
At January 1, 2014	444	69	1,674	2,187
Additional provisions created	83	63	1,070	1,215
Unused amounts reversed	(47)	-	(55)	(102)
Utilized	(28)	(95)	(89)	(212)
Other	-	5	3	8
<b>At December 31, 2014</b>	<b>453</b>	<b>42</b>	<b>2,602</b>	<b>3,097</b>
Long-term provisions	235	7	1,868	2,110
Short-term provisions	218	35	734	987
<b>At December 31, 2014</b>	<b>453</b>	<b>42</b>	<b>2,602</b>	<b>3,097</b>

<b>Year ended December 31, 2015</b>				
At January 1, 2015	453	42	2,602	3,097
Additional provisions created	458	-	107	565
Unused amounts reversed	(1)	(22)	(163)	(185)
Utilized	(488)	(21)	(808)	(1,317)
Other	-	1	(5)	(5)
<b>At December 31, 2015</b>	<b>421</b>	<b>-</b>	<b>1,733</b>	<b>2,154</b>
Long-term provisions	345	-	1,629	1,974
Short-term provisions	77	-	104	180
<b>At December 31, 2015</b>	<b>421</b>	<b>-</b>	<b>1,733</b>	<b>2,154</b>
<b>Expected outflow of resources</b>				
Within one year	77	-	104	180
Between one to two years	-	-	322	322
Between two to three years	-	-	-	-
More than three years	345	-	1,307	1,652
<b>At December 31, 2015</b>	<b>421</b>	<b>-</b>	<b>1,733</b>	<b>2,154</b>

### 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 asset retirement obligation. 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 industries 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 estimates for future commitment payments are given in Note 6.

**16. Other non-current liabilities**

**Other non-current liabilities** in millions of yen

	December 31, 2015	December 31, 2014
Deferred income	11,004	10,755
Other long-term liabilities	1,104	1,044
<b>Total other non-current liabilities</b>	<b>12,108</b>	<b>11,799</b>

**17. Accounts payable**

**Accounts payable** in millions of yen

	December 31, 2015	December 31, 2014
Trade payables – third party	7,194	7,267
Trade payables – related party	33,979	28,119
Other taxes payable	3,920	4,621
Accounts payable – purchase of property, plant and equipment	15,309	6,560
Other payables – third party	3,770	3,429
Other payables – related party	14,180	12,697
<b>Total accounts payable</b>	<b>78,353</b>	<b>62,694</b>

**18. Other current liabilities**

**Other current liabilities** in millions of yen

	December 31, 2015	December 31, 2014
Deferred income	1,095	701
Accrued bonus and related items	11,300	9,985
Derivative financial instruments	6,180	199
Other accrued liabilities	22,685	23,135
<b>Total other current liabilities</b>	<b>41,260</b>	<b>34,021</b>

## 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	
<b>Year ended December 31, 2014</b>							
At January 1, 2014	72,967	59,268	432,713	3,704	4,163	(1,123)	571,692
Net income attributable to Chugai shareholders	-	-	50,980	-	-	-	50,980
Available-for-sale investments							
- Fair value gains (losses) taken to equity	-	-	-	1,632	-	-	1,632
- Transferred to income statement on sale or impairment	-	-	-	0	-	-	0
- Income taxes	-	-	-	(582)	-	-	(582)
Cash flow hedges							
- Effective portion of fair value gains (losses) taken to equity	-	-	-	-	(803)	-	(803)
- Transferred to income statement	-	-	-	-	(337)	-	(337)
- Transferred to initial carrying amount of hedged items	-	-	-	-	(5,403)	-	(5,403)
- Income taxes	-	-	-	-	2,491	-	2,491
Currency translation of foreign operations							
- Exchange differences	-	-	-	-	-	862	862
- Non-controlling interests	-	-	-	-	-	(10)	(10)
Defined benefit plans							
- Remeasurement gains (losses)	-	-	(2,256)	-	-	-	(2,256)
- Income taxes	-	-	804	-	-	-	804
- Non-controlling interests	-	-	1	-	-	-	1
<b>Other comprehensive income, net of tax</b>	<b>-</b>	<b>-</b>	<b>(1,451)</b>	<b>1,050</b>	<b>(4,052)</b>	<b>851</b>	<b>(3,601)</b>
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>49,529</b>	<b>1,050</b>	<b>(4,052)</b>	<b>851</b>	<b>47,379</b>
Dividends	-	-	(24,521)	-	-	-	(24,521)
Equity compensation plans	-	(73)	-	-	-	-	(73)
Own equity instruments	-	1,623	-	-	-	-	1,623
At December 31, 2014	<b>72,967</b>	<b>60,817</b>	<b>457,720</b>	<b>4,755</b>	<b>111</b>	<b>(271)</b>	<b>596,099</b>

**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	
<b>Year ended December 31, 2015</b>							
At January 1, 2015	72,967	60,817	457,720	4,755	111	(271)	596,099
Net income attributable to Chugai shareholders	-	-	61,125	-	-	-	61,125
Available-for-sale investments							
- Fair value gains (losses) taken to equity	-	-	-	2,353	-	-	2,353
- Transferred to income statement on sale or impairment	-	-	-	62	-	-	62
- Income taxes	-	-	-	(571)	-	-	(571)
Cash flow hedges							
- Effective portion of fair value gains (losses) taken to equity	-	-	-	-	(4,207)	-	(4,207)
- Transferred to income statement	-	-	-	-	335	-	335
- Transferred to initial carrying amount of hedged items	-	-	-	-	1,274	-	1,274
- Income taxes	-	-	-	-	857	-	857
Currency translation of foreign operations							
- Exchange differences	-	-	-	-	-	(3,461)	(3,461)
- Non-controlling interests	-	-	-	-	-	132	132
Defined benefit plans							
- Remeasurement gains (losses)	-	-	(1,782)	-	-	-	(1,782)
- Income taxes	-	-	263	-	-	-	263
- Non-controlling interests	-	-	-	-	-	-	-
<b>Other comprehensive income, net of tax</b>	<b>-</b>	<b>-</b>	<b>(1,519)</b>	<b>1,844</b>	<b>(1,741)</b>	<b>(3,329)</b>	<b>(4,745)</b>
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>59,605</b>	<b>1,844</b>	<b>(1,741)</b>	<b>(3,329)</b>	<b>56,380</b>
Dividends	-	-	(28,372)	-	-	-	(28,372)
Equity compensation plans	-	(44)	-	-	-	-	(44)
Own equity instruments	-	1,801	-	-	-	-	1,801
Changes in non-controlling interests	-	(8)	-	-	-	-	(8)
At December 31, 2015	<b>72,967</b>	<b>62,567</b>	<b>488,954</b>	<b>6,599</b>	<b>(1,630)</b>	<b>(3,600)</b>	<b>625,857</b>

**Share capital (Number of shares)**

	December 31, 2015	December 31, 2014
Authorized shares	799,805,050	799,805,050
Issued shares (Non-par value common stock)	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 27, 2014 (Resolution of the Annual General Meeting of shareholders)	Common stock	12,529	23	December 31, 2013	March 28, 2014
July 24, 2014 (Board resolution)	Common stock	11,992	22	June 30, 2014	September 1, 2014
March 26, 2015 (Resolution of the Annual General Meeting of shareholders)	Common stock	14,181	26	December 31, 2014	March 27, 2015
July 23, 2015 (Board resolution)	Common stock	14,190	26	June 30, 2015	September 1, 2015
March 24, 2016 (Resolution of the Annual General Meeting of shareholders)	Common stock	17,473	32	December 31, 2015	March 25, 2016

**Own equity instruments**

	Number of shares	
	2015	2014
At January 1	14,258,437	14,944,320
Issue of common stocks	-	-
Exercises of equity compensation plans	(621,900)	(692,100)
Increase/decrease in own equity instruments	5,206	6,217
<b>At December 31</b>	<b>13,641,743</b>	<b>14,258,437</b>
<b>Book value (millions of yen)</b>	<b>31,935</b>	<b>33,370</b>

**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

	2015	2014
At January 1	1,657	1,512
Net income attributable to non-controlling interests	1,228	1,097
Currency translation of foreign operations	(132)	10
Remeasurements of defined benefit plans	-	(1)
<b>Other comprehensive income, net of tax</b>	<b>(132)</b>	<b>10</b>
<b>Total comprehensive income</b>	<b>1,096</b>	<b>1,107</b>
Dividends to non-controlling shareholders	(1,064)	(962)
Changes in non-controlling interests	(275)	-
<b>At December 31</b>	<b>1,414</b>	<b>1,657</b>

Non-controlling interests are attributable to the minority shareholders of Chugai sanofi-aventis S.N.C. and Chugai Pharma Taiwan Ltd. Since the group obtained the stocks of Chugai Pharma Taiwan Ltd. held by minority shareholders in May 2015, the non-controlling interests at December 31, 2015 are only attributable to the minority shareholders of Chugai sanofi-aventis S.N.C.

## 21. Employee benefits

### Employee benefits expense in millions of yen

	2015	2014
Wages and salaries	68,227	64,928
Social security costs	8,292	7,949
Defined contribution plans	1,020	912
Operating expenses for defined benefit plans	3,806	3,316
Equity compensation plans	387	342
Other employee benefits	4,373	3,386
<b>Employee benefits expense included in operating results</b>	<b>86,106</b>	<b>80,834</b>
Net interest cost of defined benefit plans	(8)	(63)
<b>Total employee benefits expense</b>	<b>86,097</b>	<b>80,771</b>

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 ¥1,020 million (2014: ¥912 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 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.

The defined benefit obligation is calculated using the projected unit credit method. If potential assets arise since defined benefit plans are over-funded, the recognition of pension assets is limited to the present value of any economic benefits available from refunds from the plans or reductions in future contributions to the plan.

### Defined benefit plans: income statement in millions of yen

	2015	2014
Current service cost	3,806	3,316
Past service (income) cost	-	-
Settlement (gain) loss	-	-
<b>Total operating expenses</b>	<b>3,806</b>	<b>3,316</b>
Net interest cost of defined benefit plans	(8)	(63)
<b>Total expense recognized in income statement</b>	<b>3,797</b>	<b>3,253</b>

### Defined benefit plans: funding status in millions of yen

	December 31, 2015	December 31, 2014
Fair value of plan assets	76,543	74,897
Defined benefit obligation	(78,901)	(75,567)
<b>Over (under) funding</b>	<b>(2,358)</b>	<b>(670)</b>
Defined benefit plan assets	-	1,946
Defined benefit plan liabilities	(2,358)	(2,616)
<b>Net recognized asset (liability)</b>	<b>(2,358)</b>	<b>(670)</b>

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

	2015	2014
At January 1	74,897	71,029
Interest income on plan assets	805	1,083
Remeasurements on plan assets	298	3,340
Currency translation effects	(11)	105
Employer contributions	3,665	1,992
Benefits paid – funded plans	(3,110)	(2,652)
<b>At December 31</b>	<b>76,543</b>	<b>74,897</b>
Composition of plan assets		
- Equity securities	11,421	16,437
- Debt securities	44,880	42,237
- Cash and cash equivalents	9,886	9,517
- Other investments	10,356	6,706
<b>Total plan assets</b>	<b>76,543</b>	<b>74,897</b>

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

	2015	2014
At January 1	75,567	68,436
Current service cost	3,806	3,316
Interest cost	796	1,021
Remeasurements – demographic assumption	1,206	683
Remeasurements – financial assumptions	144	4,865
Remeasurements – experience adjustments	731	48
Currency translation effects	(20)	113
Benefits paid – funded plans	(3,328)	(2,914)
<b>At December 31</b>	<b>78,901</b>	<b>75,567</b>
Duration in years	15.2	15.1

**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.

**Demographic assumptions:** Demographic assumptions relate to mortality and employee turnover rates. Mortality rates are based on the standard mortality rate stated in the Ordinance for Enforcement of the Defined-Benefit Corporate Pension Act. Rates of employee turnover are based on historical behavior within the Group companies.

**Financial assumptions:** Discount rates are determined mainly with reference to interest rates on high-quality corporate bonds and reflect the period over which the obligations are to be settled.

	December 31, 2015	December 31, 2014
Discount rates (%)	1.07	1.08
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.

	2015
Discount rates	
- 0.25% increase	(2,886)
- 0.25% decrease	3,071
Expected inflation rates	
- 0.25% increase	-
- 0.25% decrease	-
Life expectancy	
- 1 year increase	1,310

**Future cash flows**

Based on the most recent actuarial valuations, the Group expects that employer contributions for defined benefit plans in 2016 will be approximately ¥2,175 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

	2015	2014
Cost of sales	3	2
Marketing and distribution	41	36
Research and development	58	43
General and administration	285	260
<b>Total</b>	<b>387</b>	<b>342</b>
Equity-settled plans		
- Chugai common stock options	273	225
- Chugai stock options as stock-based compensation	115	117

### Cash inflow from equity compensation plans in millions of yen

	2015	2014
Equity-settled plans		
- Exercises of Chugai common stock options	1,391	1,226
- 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 since 2003. 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 approximately two years of continuous service of the holder after the grant date.

### Chugai common stock options – movement in number of rights outstanding

	2015		2014	
	Number of rights	Weighted average exercise price (yen)	Number of rights	Weighted average exercise price (yen)
Outstanding at January 1	19,201	221,330	23,025	204,917
Granted	2,814	400,700	3,100	267,400
Forfeited	(0)	-	-	-
Exercised	(6,219)	223,596	(6,511)	188,325
Expired	(98)	164,900	(413)	172,418
<b>Outstanding at December 31</b>	<b>15,698</b>	<b>252,938</b>	<b>19,201</b>	<b>221,330</b>
- of which exercisable	9,784	205,858	12,851	202,966



**Chugai common stock options – terms of rights outstanding at December 31, 2015**

Year of grant	Rights outstanding			Rights exercisable	
	Number outstanding	Weighted average years remaining	Weighted average exercise price	Number exercisable	Weighted average exercise price
		contractual life	(yen)		(yen)
2006	679	0.23	224,500	679	224,500
2007	1,534	1.23	303,900	1,534	303,900
2008 – no awards	-	-	-	-	-
2009	1,007	3.23	169,600	1,007	169,600
2010	1,162	4.31	188,100	1,162	188,100
2011	1,171	5.40	139,700	1,171	139,700
2012	2,214	6.31	152,800	2,214	152,800
2013	2,017	7.32	250,000	2,017	250,000
2014	3,100	8.31	267,400	-	-
2015	2,814	9.31	400,700	-	-
<b>Total</b>	<b>15,698</b>	<b>6.20</b>	<b>252,938</b>	<b>9,784</b>	<b>205,858</b>

**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**

	2015		2014	
	Number of rights	Weighted average exercise price (yen)	Number of rights	Weighted average exercise price (yen)
Outstanding at January 1	3,411	100	3,360	100
Granted	313	100	461	100
Forfeited	-	-	-	-
Exercised	-	-	(410)	100
Expired	-	-	-	-
<b>Outstanding at December 31</b>	<b>3,724</b>	<b>100</b>	<b>3,411</b>	<b>100</b>
- of which exercisable	-	-	-	-

**Chugai stock options as stock-based compensation – terms of rights outstanding at December 31, 2015**

Year of grant	Rights outstanding			Rights exercisable	
	Number outstanding	Weighted average years remaining	Weighted average exercise price	Number exercisable	Weighted average exercise price
		contractual life	(yen)		(yen)
2009	519	23.31	100	-	-
2010	579	24.31	100	-	-
2011	672	25.40	100	-	-
2012	723	26.31	100	-	-
2013	457	27.32	100	-	-
2014	461	28.31	100	-	-
2015	313	29.31	100	-	-
<b>Total</b>	<b>3,724</b>	<b>26.04</b>	<b>100</b>	<b>-</b>	<b>-</b>

**Fair value measurement**

The inputs used in the measurement of the fair values at grant date of the stock acquisition rights in 2015 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 2015**

Number of rights granted	2,814
Granted common stocks per right	100
Date of grant	May 11, 2015
Vesting period	May 11, 2015 – April 23, 2017
Contractual life(*)	May 11, 2015 – April 22, 2025
Fair value of rights at grant date	¥1,172
Model used	Binomial
Inputs to option pricing model	
- Share price at grant date	¥375,000
- Exercise price	¥400,700
- Expected volatility	31.79%
- Expected dividend yield	1.28%
- Risk-free rate	0.41%

(\*)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 2015**

Number of rights granted	313
Granted common stocks per a right	100
Date of grant	May 11, 2015
Vesting period	-
Contractual life(*)	May 11, 2015 – April 22, 2045
Fair value of rights at grant date	¥3,650
Model used	Binomial
Inputs to option pricing model	
- Share price at grant date	¥375,000
- Exercise price	¥100
- Expected volatility	33.63%
- Expected dividend yield	1.28%
- Risk-free rate	0.00%

(\*) 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**

	2015		2014	
	Number of rights	Weighted average share price (yen)	Number of rights	Weighted average share price (yen)
Chugai common stock options	6,219	3,990	6,511	2,951
Chugai stock options as stock-based compensation	-	-	410	2,577

## 24. Earnings per share

### Basic earnings per share

	2015	2014
<b>Net income attributable to Chugai shareholders (millions of yen)</b>	<b>61,125</b>	<b>50,980</b>
Weighted average number of common stock	559,685,889	559,685,889
Weighted average number of treasury stock	(13,912,427)	(14,630,702)
<b>Weighted average number of shares in issue</b>	<b>545,773,462</b>	<b>545,055,187</b>
<b>Basic earnings per share (yen)</b>	<b>112.00</b>	<b>93.53</b>

### Diluted earnings per share

	2015	2014
<b>Net income attributable to Chugai shareholders (millions of yen)</b>	<b>61,125</b>	<b>50,980</b>
Weighted average number of shares in issue	545,773,462	545,055,187
Adjustment for assumed exercise of equity compensation plans, where dilutive	1,028,628	892,848
<b>Weighted average number of shares in issue used to calculate diluted earnings per share</b>	<b>546,802,090</b>	<b>545,948,035</b>
<b>Diluted earnings per share (yen)</b>	<b>111.79</b>	<b>93.38</b>

There were 2,814 rights of equity compensation plans, which are anti-dilutive, and therefore excluded from the calculation of diluted earnings per share. (2014: 5,941 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

	2015	2014
Net income	62,353	52,077
Financing costs	67	11
Other financial income (expense)	(559)	(315)
Income taxes	24,923	24,087
<b>Operating profit</b>	<b>86,784</b>	<b>75,859</b>
Depreciation of property, plant and equipment	13,964	13,688
Amortization of intangible assets	1,603	1,192
Impairment of property, plant and equipment	202	1,775
Impairment of intangible assets	1,852	171
Operating expense for defined benefit plans	3,806	3,316
Operating expense for equity-settled equity compensation plans	387	342
Net (income) expense for provisions	436	99
Inventories write-down	1,481	1,182
Other adjustments	(358)	1,426
<b>Cash generated from operations</b>	<b>110,159</b>	<b>99,050</b>

### 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

	2015	2014
Interest received	147	203
Dividends received	208	287
<b>Total</b>	<b>355</b>	<b>490</b>

### 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 (2014: 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 approved 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 (2014: none).

Of the Group's accounts receivable, trade receivables from third parties are mainly to Japanese customers, of which major customers account for 70 % as of December 31, 2015.

#### Trade receivables: major customers in millions of yen

	December 31, 2015	December 31, 2014
Alfresa Corporation	29,866	29,876
Mediceo Corporation	24,065	28,875
Suzuken Co., Ltd.	18,942	19,513
Toho Pharmaceutical Co., Ltd.	11,876	11,280
<b>Total</b>	<b>84,748</b>	<b>89,545</b>

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

	December 31, 2015	December 31, 2014
Neither overdue nor impaired	158,472	159,698
Overdue less than 1 month	187	49
Overdue 1-3 months	7	12
Overdue 4-6 months	1	4
Overdue 7-12 months	-	-
Overdue more than 1 year	-	9
<b>Total</b>	<b>158,668</b>	<b>159,773</b>

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 class

The Group's impairment loss on available-for-sale investments was ¥64 million. (2014: Immaterial).



**(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 (2014: ¥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
<b>At December 31, 2015</b>					
Accounts payable	78,353	72,223	6,129	1	-
Other current liabilities					
- Derivative financial instruments	6,180	6,180	-	-	-
<b>Total financial liabilities</b>	<b>84,533</b>	<b>78,403</b>	<b>6,129</b>	<b>1</b>	<b>-</b>
<b>At December 31, 2014</b>					
Accounts payable	62,694	60,520	2,173	-	0
Other current liabilities					
- Derivative financial instruments	199	199	-	-	-
<b>Total financial liabilities</b>	<b>62,893</b>	<b>60,720</b>	<b>2,173</b>	<b>-</b>	<b>0</b>

**(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 denominated 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 denominated 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

	2015	2014
Average exchange rate (yen per each currency)		
CHF	125.74	115.69
EUR	134.36	140.49
USD	121.03	105.84
Profit before taxes (millions of yen)		
CHF	(567)	(39)
EUR	10	15
USD	(327)	33

(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.

	2015			2014		
	Exposure (m CHF)	Exposure (m YEN)	Impact (m YEN)	Exposure (m CHF)	Exposure (m YEN)	Impact (m YEN)
<b>CHF</b>						
Accounts receivable	217	26,462	(265)	184	22,189	(222)
Accounts payable	(357)	(43,535)	435	(306)	(36,947)	369
Financial non-current assets	-	-	-	-	-	-
Cash and cash equivalents	54	6,622	(66)	69	8,336	(83)
Notional amounts of derivative financial instruments						
- Effective portion of hedge	464	56,580	(566)	(100)	(12,214)	-
- Other than above	87	10,601	(106)	85	10,362	(104)
<b>Total</b>	<b>465</b>	<b>56,730</b>	<b>(567)</b>	<b>(68)</b>	<b>(8,274)</b>	<b>(39)</b>
	Exposure (m EUR)	Exposure (m YEN)	Impact (m YEN)	Exposure (m EUR)	Exposure (m YEN)	Impact (m YEN)
<b>EUR</b>						
Accounts receivable	10	1,364	(14)	4	645	(6)
Accounts payable	(18)	(2,364)	24	(15)	(2,154)	22
Financial non-current assets	-	-	-	-	-	-
Cash and cash equivalents	-	-	-	-	-	-
Notional amounts of derivative financial instruments						
- Effective portion of hedge	-	-	-	-	-	-
- Other than above	-	-	-	-	-	-
<b>Total</b>	<b>(8)</b>	<b>(1,000)</b>	<b>10</b>	<b>(10)</b>	<b>(1,509)</b>	<b>15</b>
	Exposure (m USD)	Exposure (m YEN)	Impact (m YEN)	Exposure (m USD)	Exposure (m YEN)	Impact (m YEN)
<b>USD</b>						
Accounts receivable	20	2,379	(24)	6	683	(7)
Accounts payable	(39)	(4,645)	46	(33)	(3,953)	40
Financial non-current assets	-	-	-	-	-	-
Cash and cash equivalents	-	-	-	-	-	-
Notional amounts of derivative financial instruments						
- Effective portion of hedge	262	31,345	(313)	110	13,231	-
- Other than above	30	3,594	(36)	-	-	-
<b>Total</b>	<b>273</b>	<b>32,672</b>	<b>(327)</b>	<b>83</b>	<b>9,961</b>	<b>33</b>

**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 reasonably approximate 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 – fair value determined using valuation method which includes unobservable inputs.

### Fair value hierarchy of financial instruments in millions of yen

	Level 1	Level 2	Level 3	Total
<b>At December 31, 2015</b>				
Marketable securities:				
- Money market instruments and time accounts over 3 months	-	134,419	-	134,419
- Debt securities	-	-	-	-
Other current assets				
- Derivative financial instruments	-	3,409	-	3,409
Financial non-current assets				
- Available-for-sale investments	12,262	-	1,453	13,715
<b>Financial assets recognized at fair value</b>	<b>12,262</b>	<b>137,828</b>	<b>1,453</b>	<b>151,543</b>
Other current liabilities				
- Derivative financial instruments	-	(6,180)	-	(6,180)
<b>Financial liabilities recognized at fair value</b>	<b>-</b>	<b>(6,180)</b>	<b>-</b>	<b>(6,180)</b>
<b>At December 31, 2014</b>				
Marketable securities:				
- Money market instruments and time accounts over 3 months	-	116,030	-	116,030
- Debt securities	-	-	-	-
Other current assets				
- Derivative financial instruments	-	1,911	-	1,911
Financial non-current assets				
- Available-for-sale investments	9,318	-	1,438	10,755
<b>Financial assets recognized at fair value</b>	<b>9,318</b>	<b>117,941</b>	<b>1,438</b>	<b>128,696</b>
Other current liabilities				
- Derivative financial instruments	-	(199)	-	(199)
<b>Financial liabilities recognized at fair value</b>	<b>-</b>	<b>(199)</b>	<b>-</b>	<b>(199)</b>

Level 1 financial assets consist of government bonds, corporate bonds and quoted shares. Level 2 financial assets consist primarily of certificates of deposit, cash in trust, commercial paper and derivative financial instruments.

Record of fair value of Level 2 financial assets is implemented as follows.

- 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.
- Available-for-sale financial assets are based on valuation methods with reference to the latest financial data.

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.

### Reconciliation of financial instruments classified into level 3 in millions of yen

	Fair value through other comprehensive income	Fair value through income statement	Total
At January 1, 2014	461	-	461
Gains or losses	826	-	826
Purchases	152	-	152
Disposals	(1)	-	(1)
Transfers	-	-	-
Currency translation effects	1	-	1
<b>At December 31, 2014</b>	<b>1,438</b>	<b>-</b>	<b>1,438</b>
At January 1, 2015	1,438	-	1,438
Gains or losses	(87)	-	(87)
Purchases	104	-	104
Disposals	(1)	-	(1)
Transfers	-	-	-
Currency translation effects	(0)	-	(0)
<b>At December 31, 2015</b>	<b>1,453</b>	<b>-</b>	<b>1,453</b>

### 3) Derivative financial instruments

#### Derivative financial instruments in millions of yen

Assets	December 31, 2015	December 31, 2014
Forward exchange contracts	3,409	1,911
Currency options	-	-
<b>Total derivative financial instruments</b>	<b>3,409</b>	<b>1,911</b>
Liabilities	December 31, 2015	December 31, 2014
Forward exchange contracts	(6,180)	(199)
Currency options	-	-
<b>Total derivative financial instruments</b>	<b>(6,180)</b>	<b>(199)</b>

#### 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 liabilities of ¥2,425 million (2014: fair value assets of ¥172 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
<b>Year ended December 31, 2015</b>				
Cash inflows	193,497	58,845	102,470	32,182
Cash outflows	(195,922)	(59,655)	(103,722)	(32,545)
<b>Total cash inflow (outflow)</b>	<b>(2,425)</b>	<b>(810)</b>	<b>(1,252)</b>	<b>(362)</b>
<b>Year ended December 31, 2014</b>				
Cash inflows	25,483	10,298	15,185	-
Cash outflows	(25,310)	(10,215)	(15,095)	-
<b>Total cash inflow (outflow)</b>	<b>172</b>	<b>82</b>	<b>90</b>	<b>-</b>

#### 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, 2015	December 31, 2014
Capital and reserves attributable to Chugai shareholders	625,857	596,099
Equity attributable to non-controlling interests	1,414	1,657
Total equity	627,271	597,756
Total debt	735	214
<b>Capitalization</b>	<b>628,006</b>	<b>597,970</b>

## 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 became a 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.

The Rest of the World Umbrella Rights Agreement (excluding Japan and South Korea) signed in May 2002 was revised and the Amended and Restated Rest of the World Umbrella Rights Agreement (excluding Japan, South Korea and Taiwan) was signed in August 2014. Under this Agreement, Roche has the right of first refusal on the development and marketing of Chugai's development compounds in markets outside Japan, excluding South Korea and Taiwan.



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 ¥17,432 million (2014: ¥15,085 million).

## 2) Material transactions and balances with related parties

### Transactions with F. Hoffmann-La Roche in millions of yen

	2015	2014
Sales	63,084	55,051
Purchases of inventory and other materials	131,025	122,189

### Balances with F. Hoffmann-La Roche in millions of yen

	December 31, 2015	December 31, 2014
Accounts receivable	32,489	28,201
Accounts payable	(43,560)	(37,447)

## 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

	2015	2014
Board of Directors		
- Regular remuneration	355	349
- Bonuses	238	220
- Chugai common stock options	117	104
- Chugai stock options as stock-based compensation	115	117
<b>Total</b>	<b>825</b>	<b>790</b>
Audit & supervisory board members		
- Regular remuneration	85	85
<b>Total</b>	<b>85</b>	<b>85</b>

## 28. Subsidiaries

Subsidiaries	Country of Incorporation	Equity interest %	
		2015	2014
<b>Consolidated subsidiaries</b>			
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 Pharma USA, Inc.	United States	100 %	100 %
Chugai Pharma Europe Ltd.	United Kingdom	100 %	100 %
Chugai Pharma U.K. Ltd.	United Kingdom	100 %	100 %
Chugai Pharma Development Ltd.	United Kingdom	100 %	100 %
Chugai Pharma France SAS	France	100 %	100 %
Chugai sanofi-aventis S.N.C.	France	55 %	55 %
Chugai Pharma Taiwan Ltd.	Taiwan	100 %	70 %
Chugai Pharma (Shanghai) Consulting Co., Ltd.	China	100 %	100 %
Chugai Pharma Science (Beijing) Co., Ltd.	China	100 %	100 %
Chugai Pharma China Co., Ltd.	China	100 %	100 %
Chugai Pharmabody Research Pte. Ltd.	Singapore	100 %	100 %

## 29. Subsequent events

Chugai decided to purchase, for its business purpose, properties in Yokohama-shi, Kanagawa Prefecture, owned by Hitachi, Ltd. and has concluded a real estate purchase agreement with Hitachi Ltd. as of March 7, 2016. The provisional purchase price is ¥41.7 billion, and the provisional date of property transfer is December 2018.

In order to achieve the key objectives of the new mid-term business plan "IBI 18" and to further grow in the global arena in future, it is essential for Chugai to continuously create and develop innovative pharmaceutical products, which requires further enhancement of research and production processes, a seamless transfer to clinical development, and accelerated Proof-of-Concept<sup>(\*)</sup>. Chugai has recognized the need for competent human resources and a core base facilitated with state-of-the-art research and development functions to create its own innovative new drug candidates, and accordingly, decided to purchase land for business purpose so as to further ensure the success that has been achieved by the efficient implementation of its innovative business model, and to maximize the value of this business model.

(\*)Proof-of-Concept (PoC) is a demonstration that the therapeutic effect conceived in the research stage is effective in humans.

# Independent Auditor's Report

## **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, 2015, 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 misstatement, 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, 2015, and their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards.

*KPMG AZSA LLC*

March 24, 2016  
Tokyo, Japan

# Network (As of April 1, 2016)

## Chugai Pharmaceutical

### Head Office

1-1 Nihonbashi-Muromachi 2-chome,  
Nihonbashi Mitsui Tower (Reception 15F)  
Chuo-ku, Tokyo 103-8324 Japan  
Tel +81-(0)3-3281-6611 (main switchboard)  
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

#### (Chugai Pharma Manufacturing Co., Ltd.)

##### Ukima Plant

5-5-1 Ukima, Kita-ku, Tokyo 115-8543 Japan  
Tel +81-(0)3-3968-6200

##### 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

8F 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

3F Sankyo Sendai Bldg., 1-12-7 Honcho,  
Aoba-ku, Sendai City,  
Miyagi Pref. 980-0014 Japan  
Tel +81-(0)22-225-8551

##### Tokyo Branch 1

17F Osaki Bright Core Bldg., 5-5-15  
Kitashinagawa, Shinagawa-ku,  
Tokyo 141-0001 Japan  
Tel +81-(0)5449-6760

##### Tokyo Branch 2

8F Omiya Center Bldg., 1-9-6 Sakuragicho,  
Omiya-ku, Saitama City,  
Saitama Pref. 330-0854 Japan  
Tel +81-(0)48-642-4771

##### Yokohama Branch

3F Yokohama East Square, 1-4 Kinkoucho,  
Kanagawa-ku, Yokohama City,  
Kanagawa Pref. 221-0056 Japan  
Tel +81-(0)45-450-7670

##### Nagoya Branch

7F KDX Sakuradori Bldg., 3-20-17  
Marunouchi, Naka-ku,  
Nagoya City, Aichi Pref. 460-0002 Japan  
Tel +81-(0)52-961-8511

##### Kyoto Branch

7F 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

13F Uemura Nissei Bldg., 3-3-31 Miyahara,  
Yodogawa-ku, Osaka City,  
Osaka 532-0003 Japan  
Tel +81-(0)6-6350-6355

##### Hiroshima Branch

6F Nissei Hiroshima Bldg., 7-32  
Nakamachi, Naka-ku, Hiroshima City,  
Hiroshima Pref. 730-0037 Japan  
Tel +81-(0)82-543-6100

##### Takamatsu Branch

7F Ichigo Takamatsu Bldg.,  
2-2-7 Kotobuki-cho, Takamatsu City,  
Kagawa Pref. 760-0023 Japan  
Tel +81-(0)87-811-6988

##### Fukuoka Branch

8F 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.

1-6 Suehiro-cho, Tsurumi-ku, Yokohama City,  
Kanagawa Pref. 230-0045 Japan  
Tel +81-(0)45-500-4110

## Overseas Subsidiaries, Affiliates and R&D Partners

#### Chugai Pharma U.K. Ltd.

Mulliner House, Flanders Road,  
Turnham Green, London W4 1 NN U.K.  
Tel +44-(0)20-8987-5680

#### Chugai Pharma Europe Ltd.

Mulliner House, Flanders Road,  
Turnham Green, London W4 1NN U.K.  
Tel +44-(0)20-8987-5600

#### Germany Branch

Lyoner Strasse 15 60528  
Frankfurt am Main, Germany  
Tel +49-(0)69-663000-0

#### Chugai Pharma France SAS

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.

82, avenue Raspail 94255  
Gentilly Cedex, France  
Tel +33-(0)1-41-24-66-69

#### Chugai Pharma USA, Inc.

300 Connell Drive, Suite 3100  
Berkeley Heights, NJ 07922 U.S.A.  
Tel +1-908-516-1350

#### Chugai Pharma China Co., Ltd.

Building G31, No. 801 Jiankang Dadao,  
Medical City, Taizhou, Jiangsu 225300 China  
Tel +86-(0)523-8681-9823

### Shanghai Branch

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 1508, Pearl River Tower, No. 15,  
Zhujiang West Road,  
Guangzhou 510623 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.

3F., No. 260, Dunhua N. Rd., Songshan  
District, Taipei 10548 Taiwan, R.O.C.  
Tel +886-(0)2-2715-2000

### Chugai Pharmabody Research Pte. Ltd.

3 Biopolis Drive, #07-11 to 16 Synapse,  
Singapore 138623  
Tel +65-(0)6933-4888

### C&C Research Laboratories

DRC, Sungkyunkwan University, 2066,  
Seobu-ro, Jangan-gu, Suwon-si, Gyeonggi-do  
16419 Korea  
Tel +82-(0)31-8014-6606

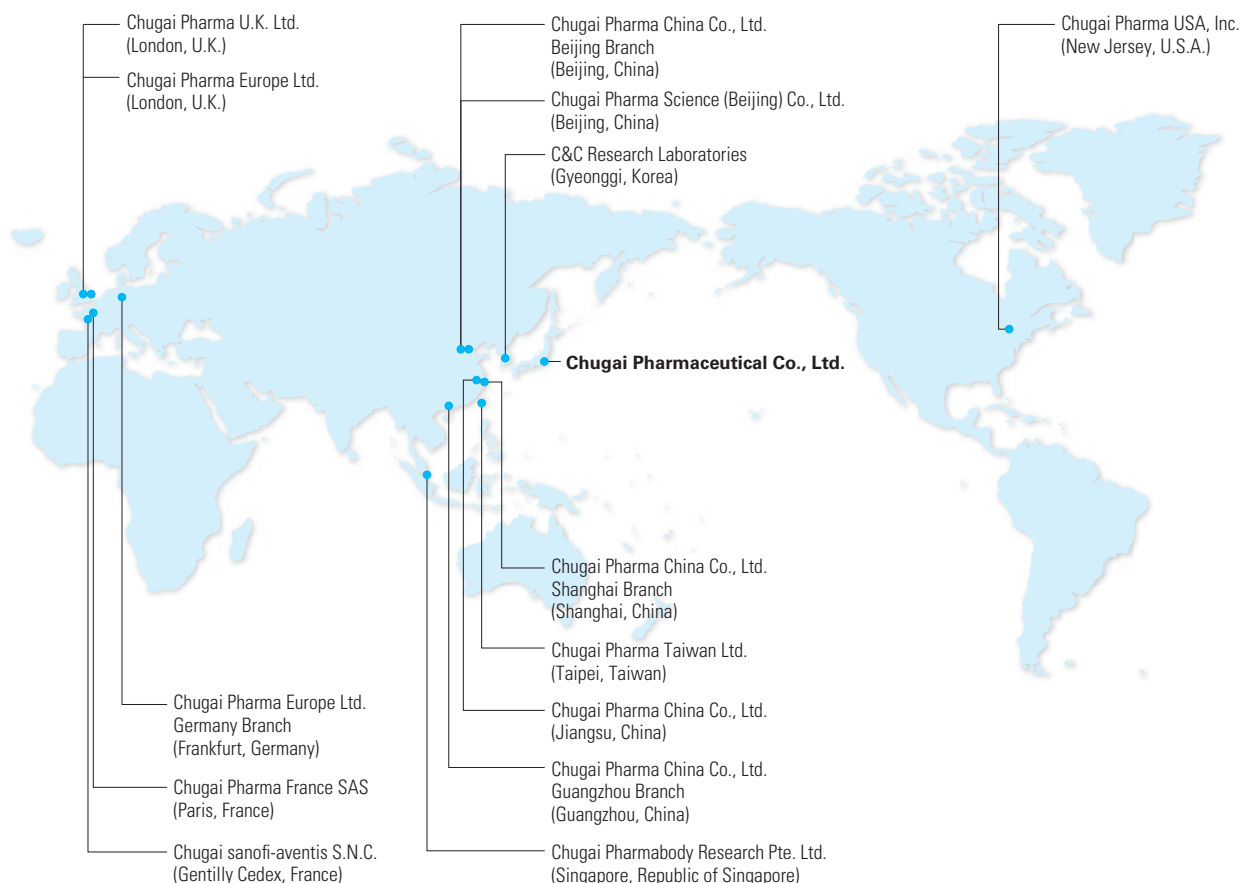
### Discovery Research Center

DRC, Sungkyunkwan University, 2066,  
Seobu-ro, Jangan-gu, Suwon-si,  
Gyeonggi-do 16419 Korea  
Tel +82-(0)31-8014-6606

### Clinical Research Center

#903 E&C Venture Dream Tower 3, 38-21,  
Digital-ro 31-gil, Guro-gu,  
Seoul 08376 Korea  
Tel +82-(0)2-858-6226

## Chugai's Global Network





# Shareholder Information (As of December 31, 2015)

## Major Shareholders\*

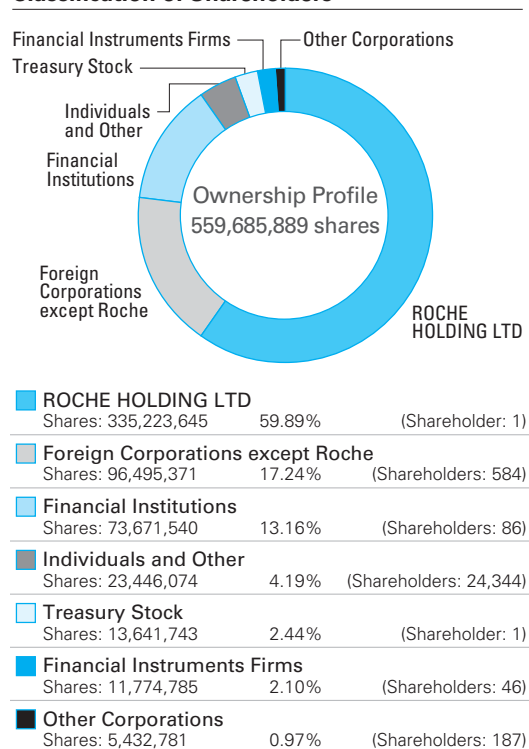
Name	Number of Shares Held (Thousands)	Percentage of Voting Rights (%)
ROCHE HOLDING LTD	335,223	61.41
The Master Trust Bank of Japan, Ltd. (Trust Account)	19,857	3.63
Japan Trustee Services Bank, Ltd. (Trust Account)	17,244	3.15
JP MORGAN CHASE BANK 385147	8,495	1.55
JP MORGAN CHASE BANK 380055	6,374	1.16
Goldman Sachs and Company Regular Account	3,660	0.67
STATE STREET BANK WEST CLIENT -TREATY 505234	3,644	0.66
Trust & Custody Services Bank, Ltd. (Trust Collateral Account)	3,594	0.65
Tokio Marine & Nichido Fire Insurance Co., Ltd.	3,282	0.60
THE BANK OF NEWYORK MELLON SA/NV 10	3,232	0.59

\* 13,641,743 shares of treasury stock held by the Company are not included in the above breakdown of major shareholders.

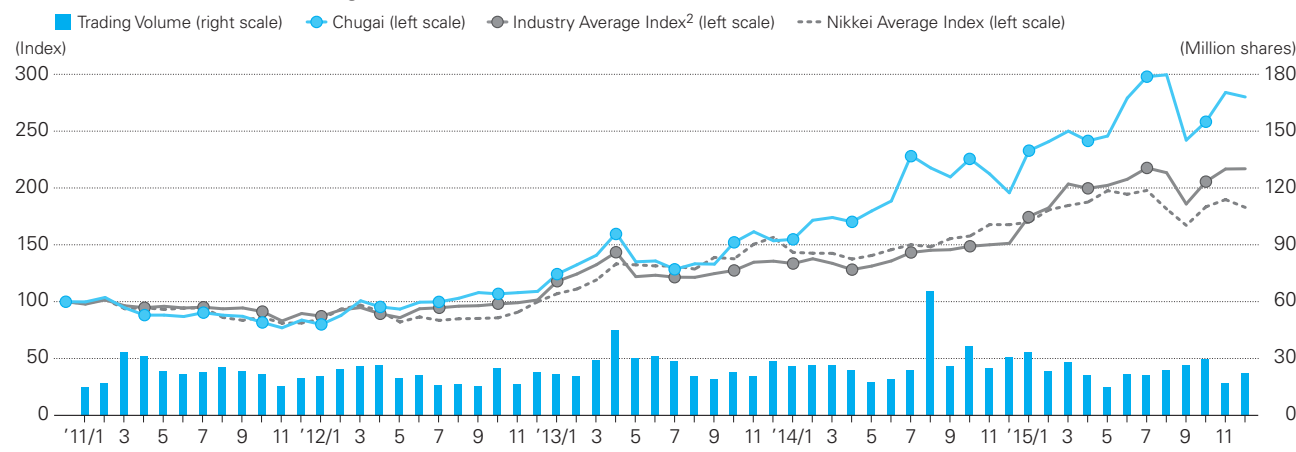
## Stock Price Information

	Stock Price	
	Low	High
From January 1, 2015 to December 31, 2015		
First Quarter	¥2,862	¥3,945
Second Quarter	3,620	4,330
Third Quarter	3,580	5,090
Fourth Quarter	3,525	4,685

## Classification of Shareholders



## Share Performance<sup>1</sup> and Trading Volume



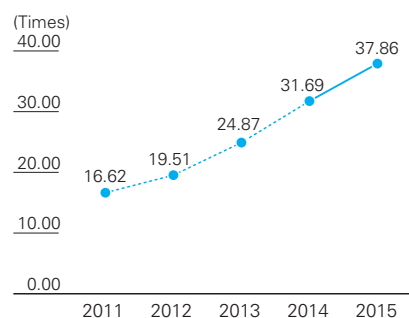
1. Closing price on January 4, 2011 = 100

2. Calculated from the share price of the following eight companies: Takeda, Daiichi-Sankyo, Astellas, Shionogi, Eisai, Mitsubishi-Tanabe, Dainippon-Sumitomo, and Chugai

## Share Price Indicators

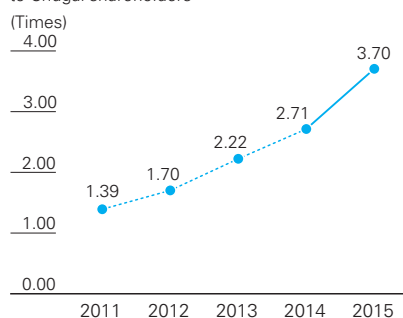
### Price/Earnings Ratio

Year-end share price/Basic net income per share



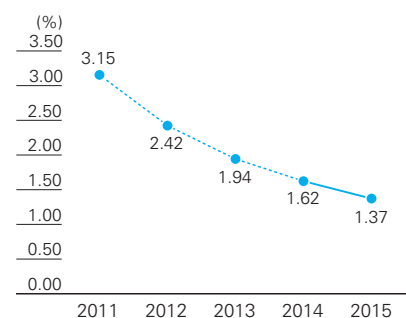
### Price/Book Ratio

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, 2015)

## 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

¥72,967 million

## Number of Employees

7,169 (Consolidated)

## Number of Shares Issued of Common Stock

559,685,889

## Number of Shareholders

25,249

## 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/ir/>) in Japanese. In case electronic communications are unavailable, public notices will be made in the newspaper *Nihon Keizai Shimbun*.

## For further information, please contact:

Corporate Communications Dept.

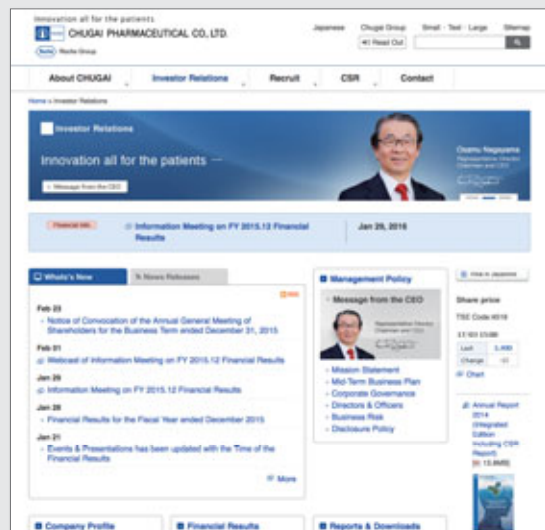
Tel: +81-(0)3-3273-3313

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

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

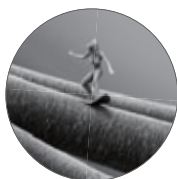
## IR website

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



## CSR website

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



## Did you notice the surfer?

Somewhere in this report is a surfer, one of the "nano-sculptures" created by Jonti Hurwitz that are featured in the "Invisible Art" series of Chugai branding advertisements. See if you can find her!

## Our Corporate Branding Activities


Chugai has renewed its corporate branding and is conducting activities to share its envisioned future and distinctive features and approaches with its stakeholders inside and outside the Company. Our brand website can be viewed using the QR code on the right.



Innovation all for the patients



**CHUGAI PHARMACEUTICAL CO., LTD.**

 A member of the Roche group