CHUGAI

Roche Group

Annual Report 2018

Fiscal year ended December 31, 2018

CHUGAI PHARMACEUTICAL CO., LTD.

Contents

We Engage in Dialogue for Creating Shared Value.

To fulfill its Mission of benefitting the medical community and human health around the world, Chugai has emphasized achieving sustainable growth by sharing value with its various stakeholders. That fundamental commitment has not changed since the Company was founded in response to the shortage of medicine after the Great Kanto Earthquake of 1923.

To apply this stance in a more concrete strategic form, we now advocate "Creating shared value" as a basic tenet of our management and strategies. In addition to updating our Envisioned Future, we specified material issues that Chugai should work on over the medium to long term, and formulated a new mid-term business plan to achieve those objectives.

The plan emphasize active engagement in dialogue with stakeholders, and this report is structured to promote such dialogue with our shareholders, investors and other stakeholders. We hope it will be useful in sharing value with you.

Chugai's Sustainability and ESG

The material issues and strategies we have established form the basis of Chugai's approach to the sustainability of creating shared value with its stakeholders.

To facilitate deeper understanding among readers, we are working to enhance information on environmental, social and governance (ESG) metrics for assessing corporate value that does not appear in the financial statements.

Measures for Further Evolution

External initiatives such as the U.N. Sustainable Development Goals (SDGs) are increasingly being used as key metrics in recent corporate management. Chugai's mid- to long-term management policy shares common values with the SDGs, and our discussions on formulating the new mid-term business plan were based on the SDG targets. Meanwhile, to make clearer the value we share with our stakeholders and to contribute to development in cooperation with society, we have narrowed down the range of SDGs that Chugai will prioritize in order to apply these goals as more concrete strategic targets.

Composition of the Annual Report

Chugai emphasizes dialogue with its stakeholders for creating shared value. Accordingly, in this report we aim to provide information that gives readers a deeper understanding of how we create that value. The composition of this report refers to the Guidance for Integrated Corporate Disclosure and Company-Investor Dialogue for Collaborative Value Creation from the Ministry of Economy, Trade and Industry (METI) of Japan and follows its relevant guidance, as shown above.

Editorial Policy

Chugai Pharmaceutical Co., Ltd. ("Chugai" or the "Company") has adopted integrated reporting to communicate both the financial and pre-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 2018. However, in view of the importance of providing the latest information available, some information relating to activities that occurred in 2019 is included, mainly in research and clinical development data.

Information in This Report
This report presents 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.

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) and Guidance for Integrated Corporate Disclosure and Company-Investor Dialogue for Collaborative Value Creation compiled by the Ministry of Economy, Trade and Industry of Japan.

CSR information was prepared with reference to the Environmental Reporting Guidelines (Fiscal Year 2018 Edition) of the Ministry of the Environment of Japan, the G4 Sustainability Reporting Guidelines of the Global Reporting Initiative (GRI) (issued in 2013) and the Final Report on Recommendations of the Task Force on Climate-related Financial Disclosures (TFCD).

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.

Our Commitments

Comments from executives, employees in our workplaces, external parties and others for creating shared value are presented throughout this annual report. They present each commenter's respective intentions and approach in order to facilitate the reader's understanding of actual conditions at Chugai.

Information on Chugai's Sustainability Initiatives

Chugai discloses its initiatives in a variety of media, including this printed report and its website. Please refer to the website for further details on initiatives presented in this report.

https://www.chugai-pharm.co.jp/english/csr

External Evaluation of Chugai's ESG Initiatives

FTSE4Good

MEMBER OF Dow Jones Sustainability Indices
In Collaboration with RobecoSAM

MSCI 2018 Constituent MSCI ESG Leaders Indexes

Chugai is included in all three ESG indices selected in 2017 by the Government Pension Investment Fund of Japan

FTSE Blossom Japan

MSCI 2018 Constituent MSCI Japan ESG Select Leaders Index

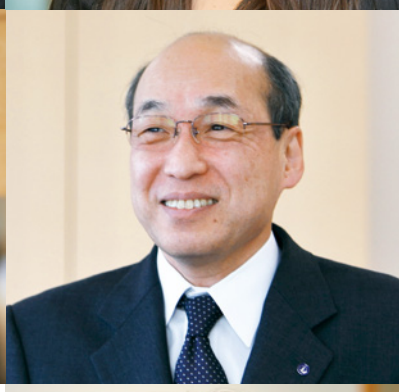
MSCI 2018 Constituent MSCI Japan Empowering Women Index (WIN)

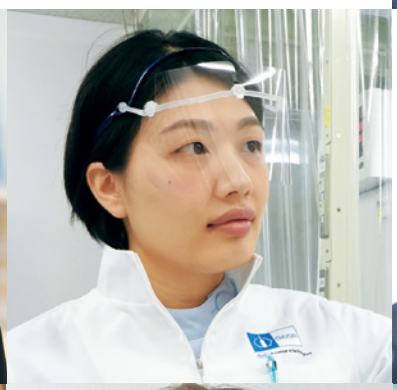







We pursue innovation for better healthcare.











Mission Statement

Mission

Dedicate ourselves to adding value by creating and delivering innovative products and services for the medical community and human health around the world

Core Values

1. Patient Centric
   Make each patient's wellbeing our highest priority
2. Pioneering Spirit
   Pursue innovation by improving ourselves and thinking differently
3. Integrity
   Maintain the highest standards in all we do to create shared value with society

About Our Mission Statement

To share value and grow together with its various stakeholders, Chugai has set forth a Mission Statement consisting of its Mission, Core Values and Envisioned Future. This Mission Statement forms the basis of all of Chugai's corporate activities.

We have established a new Envisioned Future, established material issues and formulated a new mid-term business plan and strategic agenda.

About Our Mission

Our Mission is the enduring, foremost concept behind Chugai's corporate activities. It is the idea that all we do is "for the benefit of the medical community and human health around the world," and is the continuation of our founding spirit, with which we sought to resolve medicine shortages following a natural disaster.

Envisioned Future

Become a top innovator for advanced and sustainable patient-centric healthcare, powered by our unique strengths in science and technology and the alliance with Roche

About Our Core Values

Formerly comprising seven items, our Core Values have been expressed in simpler terms reorganized for greater clarity. This has made them easier for employees to embody as shared values, and easier to understand. Contributing to the wellbeing of each patient, with their different disease conditions, circumstances and perspectives, underpins all our actions. It requires the ceaseless pursuit of innovation with a pioneering spirit. Moreover, the Core Values clearly state the importance of unwavering integrity to earn trust as a company that meets the expectations and requirements of society by working to solve social issues together with its stakeholders.

About Our Envisioned Future

Previously, we had set a goal of becoming a top pharmaceutical company by the latter half of the 2010s. Through continuous innovation, we have realized this goal, including the provision of value to patients and the establishment of our presence in the pharmaceutical industry. In light of the changing environment for medical treatment, we have committed ourselves to realizing an Envisioned Future as a "top innovator" that goes beyond the framework of the pharmaceutical business. Based on its alliance with Roche, Chugai will raise the quality of all its business activities by applying its unique strengths in science and technology as it works to solve social issues by achieving advanced and sustainable patient-centric healthcare.

Financial Performance

¥579.8 billion

Revenues (2018)

No. 6[1] among pharmaceutical companies in Japan

Due to exports of Chugai products and an increase in products in-licensed from Roche, among other factors, our revenues have grown substantially over the past 10 years, but we particularly emphasize profitability over the scale of sales. We are developing a business that specializes in the creation of innovative medicines, not blindly aiming for expansion.

21.4%

Ratio of operating profit to revenues (2018)

No. 2[1] among pharmaceutical companies in Japan

In working to increase Core EPS, the ratio of operating profit to revenues is an important indicator. We take pride in our very high ratio, with a ratio of operating expenses to revenues comparable to that of the world's leading pharmaceutical companies. This is the result of the pursuit of greater profitability from an increase in products created in-house and greater productivity from our collaborative relationship with Roche, as well as our cost structure reforms going back more than 10 years.

¥3.6 trillion

Market capitalization (as of December 31, 2018)

No. 1[1] among pharmaceutical companies in Japan

Chugai's market capitalization is about 10 times what it was prior to the strategic alliance with Roche and has roughly tripled over the past five years alone, ranking highest among Japanese pharmaceutical companies relative to sales (sixth in Japan). We will continue to emphasize dialogue with stakeholders as we accelerate value creation.

1. Financial results: Chugai: Fiscal year ended December 31, 2018; Other companies in the same industry: Fiscal year ended December 31, 2018 or March 31, 2018

Note: "Pharmaceutical companies" covers the top 10 Japanese domestic manufacturers of pharmaceuticals in terms of sales. (Takeda Pharmaceutical Company Limited, Astellas Pharma Inc., Otsuka Holdings Co., Ltd., Daiichi Sankyo Company, Limited, Eisai Co., Ltd., Chugai Pharmaceutical Co., Ltd., Sumitomo Dainippon Pharma Co., Ltd., Mitsubishi Tanabe Pharma Corporation, Kyowa Hakko Kirin Co., Ltd. and Shionogi & Co., Ltd.)

Chugai's Five Strengths

Continuous provision of innovative drugs

59%

Proportion of sales from products that qualify for premium pricing (2018)

48

Pipeline projects
(as of January 31, 2019)

With projects developed in-house and in-licensed from Roche, Chugai has one of the richest development pipelines in Japan as well as the technologies and systems for efficient and stable production of the resulting new drugs. This underpins our continuous provision of innovative medicines. As a result, in Japan we have held the top market share[2] in the oncology field for 11 consecutive years and have market-leading product lineups in the fields of bone and joint diseases and renal diseases.

Unique science and technology

24.5%[2]

Share of sales in the Japanese therapeutic antibody market (2018)

7

Breakthrough therapy designations[3]
(as of January 31, 2019)

Chugai has gained a reputation worldwide for its proprietary antibody engineering technologies as well as for its strong drug discovery capabilities backed by a research infrastructure in various modalities including small molecules. We also focus on technology research and genetic analysis for therapeutic antibodies as we strive for a deeper understanding of diseases and biology. We are the leading presence in the Japanese therapeutic antibody market.

Leader of next-generation personalized healthcare (PHC)

More than 50%

Proportion of development projects based on PHC
(as of January 31, 2019)

27

Number of development projects based on PHC
(as of January 31, 2019)

As a pioneer of PHC in Japan, Chugai has contributed to the progress of this approach to healthcare, in which treatment plans are prepared according to each patient's genetic profile and other factors. Today, our efforts include providing PHC that uses genomic analysis technology and contributing to the progress of cancer genomic medicine to usher in the next generation of PHC, which offers more advanced treatments optimized for each patient.

Provision of advanced patient-centric solutions

No. 1[4] in Japan

Satisfaction ranking based on healthcare providers' assessments (hospitals with 100 or more beds) (2018)

No. 1[5] in Japan

Adequacy ranking for provision of safety information based on healthcare providers' assessments (hospitals with 100 or more beds) (2018)

Chugai has established a system for providing solutions that can be precisely adapted to diverse needs in different regions, backed by industry-leading safety management and a high level of expertise in each disease area. Our efforts to promote multidisciplinary team care and regional healthcare coordination include providing various kinds of information, holding study sessions and cooperating with the government in activities to raise awareness. These initiatives receive strong support from healthcare providers.

Strategic alliance with Roche

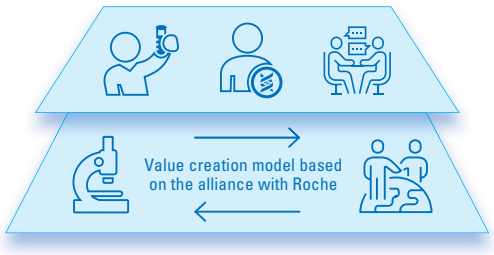
More than 110 countries

Number of countries in which Chugai products have been approved (as of January 31, 2019)

15

Number of products in-licensed from Roche
(2014-2018)

Chugai maintains its management independence under its strategic alliance with Roche, one of the world's leading pharmaceutical companies. In addition to efficiently in-licensing the Roche Group's pharmaceuticals for sale in Japan, we use the Roche Group's powerful research infrastructure and its global development and sales platform to offer significant value to the rest of the world.



Chugai has identified "five strengths" to help stakeholders recognize and understand the source of its unique value. These strengths were selected through evaluation and analysis from the perspective of patient value and competitive advantage, based on quantitative, comparable information and data. Previously, we had established "seven strengths," but due to factors including changes in the external environment and the evolution of Chugai's various functions, we reorganized our strengths into five. To create value going forward, we have also specified initiatives for further developing our strengths, and will continuously enhance the source of our value creation.

2. Copyright © 2019 IQVIA. Source: JPM 2018. Reprinted with permission. The scope of the market is defined by Chugai.
3. A system introduced in July 2012 by the U.S. Food and Drug Administration aimed at expediting the development and review of drugs for the treatment of severe or life-threatening diseases or symptoms
4. Copyright © 2019 anterio. Source: Rep-i 201808. Reprinted with permission. Based on a survey of overall assessments of companies by physicians, as defined by Chugai.
5. Based on an anterio market survey in 2018 for understanding safety information needs

The History of Chugai

Management

1925

❶ Founded in response to a post-earthquake medicine shortage

2002

❺ Strategic alliance with Roche

Transformation of business model and revenue bases

Science and

1980s

❸ Focus on biopharmaceuticals

2005

❻ Launch of the first therapeutic antibody created in Japan

Patient-Centric Solutions

1960s

❷ Shift to prescription pharmaceuticals

2001

❹ Focus on PHC

❶

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. This founding spirit has been passed down through the years. Since its foundation, Chugai has continued to innovate its business structure based on the changing needs of patients, while repeatedly facing challenges including rebuilding in the aftermath of the Second World War.

❷

In the 1960s, rapid change in the over-the-counter (OTC) drug market weakened Chugai's performance. Subsequently, in light of changing healthcare conditions that required more advanced treatment, the Company restored its business by shifting its focus from OTC to prescription drugs. Meanwhile, Nippon Roche reinforced its research and production functions to generate outcomes including a major product in the oncology field.

❸

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 launched a biopharmaceutical product created through genetic engineering, laying the foundation for what would become one of its core strengths.

❹

Factors including the launch in Japan of Herceptin, which Chugai in-licensed from Roche, led to a focus on the development of PHC. Recognizing that expanding the use of PHC was a priority issue in medical care, Chugai began providing support for relevant R&D as well as supplying healthcare providers with information and guidelines for its dissemination. In doing so, Chugai has made a substantial contribution as a pioneer of PHC.

Initiatives toward becoming a top pharmaceutical company

2019
Becoming a top innovator

New vision and mid-term business plan

Top Innovator

Having secured a clear presence as a top pharmaceutical company, Chugai has established a new Envisioned Future as the starting point for its mid- to long-term policy in consideration of factors such as changes in its operating environment and the expectations and requirements of society. Under the slogan "Creating shared value," we have proclaimed our determination to contribute to patient-centric healthcare overall as a healthcare industry innovator, and have launched a new mid-term business plan to realize this goal.

2009
⑦ Becoming a top pharmaceutical company

Technology

Development and enhancement of proprietary drug discovery technologies

2013
⑧ Received first breakthrough therapy designation from the U.S. FDA

Contribution to team healthcare and regional healthcare

Shift to provision of solutions in marketing, medical affairs and drug safety

⑤

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, in anticipation of an increase in the number of projects in-licensed from Roche, Chugai reorganized its research centers and manufacturing plants and transformed its earnings structure.

⑥

Building on its experience in manufacturing biopharmaceuticals since the 1980s, in 2005 Chugai launched Actemra, the first therapeutic antibody created in Japan. Chugai also captured the top domestic market share in the field of oncology with a powerful product lineup. Since then, Chugai has maintained the top share in oncology and in the therapeutic antibody market.*

* Copyright © 2019 IQVIA. Source: JPM 2018. Reprinted with permission. The scope of the market is defined by Chugai.

⑦

In 2009, to achieve even greater innovation, Chugai set the goal of becoming a top pharmaceutical company by the late 2010s. We also set targets for our position and presence in Japan and overseas as a trusted company that satisfies its stakeholders and lives up to their expectations. To achieve our goal and these targets, we continued to conduct business with a commitment to innovation.

⑧

Chugai has been committing management resources to the creation of innovative products in-house, backed in part by its strength in antibody engineering technologies and access to highly efficient research infrastructure through its strategic alliance with Roche. As a result, Chugai's products have received seven breakthrough therapy designations from the FDA, proof of the high level of the Company's drug discovery capabilities.

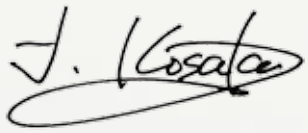
Message from the CEO

With an unwavering focus on innovation, Chugai has finally achieved its longstanding management goal of becoming a top pharmaceutical company.

Starting in 2019, we will work toward becoming a "top innovator" for advanced and sustainable patient-centric healthcare based on creation of shared value with stakeholders.

The key to achieving that will remain the pursuit of innovation.

Chugai will further enhance its corporate value through steady and continuous innovation for the benefit of patients and the medical community.



Tatsuro Kosaka
Representative Director,
President & CEO

Question 1

What kind of company is Chugai? Please summarize the Company's growth and progress to date.

We are a company that pursues innovation for the benefit of patients and the medical community. As a result, we have also achieved our goal of becoming a top pharmaceutical company.

The key word for us has always been, and still is, innovation.

Chugai was founded in response to the shortage of medicine in the aftermath of the Great Kanto Earthquake of 1923. Since then, the Company has consistently conducted its business for the benefit of patients and human health. Chugai's history is marked by ups and downs, but each time we have faced a significant change in the external environment or a management crisis, we have overcome it through innovation, and have continued to grow. The shift of our business from over-the-counter drugs to prescription drugs, our venture into and investment in biopharmaceutical research, and our strategic alliance with Roche, were all decisions Chugai made in order to continue to innovate for the benefit of patients and the medical community.

The "top pharmaceutical company" ideal we decided on in 2009 was a goal we sought to achieve by the late 2010s in order to position Chugai for further innovation. We set numerical and qualitative targets, and as a result of reforms in all our functions, we achieved our goal in 2018 (see page 12 for details). I view our position in the industry, successes in research and development, progress in globalization and other accomplishments as indicators of our evolution into a company that has earned the trust and confidence of stakeholders. In 2018, the final year of mid-term business plan IBI 18, accomplishments included the global growth of products from Chugai research, including Hemlibra, and the launch of Tecentriq in Japan, and we steadily advanced our priority agenda. Financially, we reported record profits, and as a result, our market capitalization was also in the top tier of Japanese pharmaceutical companies.

Question 2

Please explain the key factors that enabled Chugai to achieve the top pharmaceutical company goal, and the challenges that lie ahead.

Our drug discovery capabilities, our unique business model and the growth of our human resources were the key factors. Moving forward, we will need to think about ways to contribute more broadly in such areas as the lifestyles of patients and medicine itself.

The key factor behind that achievement is our drug discovery capabilities. Innovative products from Chugai's own research, including Actemra, Alecensa and Hemlibra, became growth drivers. Our development pipeline is also full of promising projects. Satralizumab (SA237), which has the potential to be our fourth global product, has received breakthrough therapy designation from the FDA, and is showing good results in clinical trials. Our unique business model based on our alliance with Roche enabled us to accelerate research and development and make it a foundation of our business. That model has led to significant achievements, as access to Roche's network has made it possible for us to develop and market our products globally while in-licensing Roche's major products, including Tecentriq, for sale in Japan. Above all, I am pleased that the growth of our human resources has become a driving force of our business growth. Our employees have continually taken on the challenge of meeting the rising expectations of patients and healthcare professionals. This in turn has made our employees more confident.

On the other hand, the healthcare and pharmaceutical industries foresee an environment of greater uncertainty and fierce competition. The problem of financing healthcare systems is becoming increasingly serious worldwide, while industry barriers are expected to disappear as a result of advances in life science and digital technologies, including artificial intelligence and IoT. Expectations for the healthcare and pharmaceutical industries will continue to rise, creating opportunities for Chugai, which has a leading presence in the industry, to contribute more broadly. While our core focus will continue to be pharmaceutical products for the benefit of patients ("the pill"), we also need to position Chugai for the future by expanding our field of vision to "around the pill" – i.e., initiatives to maximize the value of medicines – as well as services "beyond the pill" in medicine and healthcare, including the use of artificial intelligence and other disruptive innovations. An example is the genomic profiling tool of the FMI business,* which began in 2018. Use of this tool in diagnosis will promote the advancement of personalized healthcare, and by combining it with real-world data, we will further broaden the value we create.

* Development and commercialization of the products of Foundation Medicine Inc. in Japan

Question 3

What are your thoughts on Chugai's value creation going forward?

We aim to become a top innovator for advanced and sustainable patient-centric healthcare based on the creation of shared value with stakeholders.

To show the direction of our value creation going forward, we decided to aim for "creating shared value" with stakeholders. We have long believed that the value of our medicines and solutions must lead to value for society. Our thinking is the same as that behind the U.N. Sustainable Development Goals (SDGs). For instance, with Hemlibra we help people with hemophilia A and their families. This drug not only improves the symptoms of the disease and quality of life, but is expected to dramatically change people's lives. As we expand the scope of our contribution and our areas of value creation, I would like our employees to have a clear awareness of shared value. I think this could even be a driving force for innovation.

Based on this line of thinking, we have updated the Core Values and the Envisioned

Results of Quantitative and Qualitative Goals for Becoming a Top Pharmaceutical Company

Numerical target: Rank within the top 3 major Japanese pharmaceutical companies in the following categories

Domestic sales share	Ranked 5th[1]	△
Consolidated operating profit margin	2nd	○
Consolidated operating profit per employee	2nd	○
Domestic sales per MR	1st[2]	○

Numerical target: No.1 domestic presence in strategic disease areas

	Market share	Stakeholder satisfaction	
Oncology	1st[1]	1st[3]	○

Renal: 2nd[1]/2nd[3], Bone & Joint: 2nd[1]/2nd[3], RA (biologics): 2nd[1]/1st[3]

Numerical target: No.1 presence in hospital market based on medical care networks linking healthcare providers

	Market share	Stakeholder satisfaction	
Share of hospital sales (≥100 beds)	1st[1]	1st[3]	○

Numerical target: Expansion of global presence

Increase overseas sales ratio	2008: 10.4% 2018: 24.2%

○ = Achieved △ = Almost achieved

1. Copyright © 2019 IQVIA. Source: JPM 2018. Reprinted with permission. The scope of the market is defined by Chugai.
2. Calculated by Chugai, based on data from Fuji-Keizai Co., Ltd.
3. Copyright © 2019 anterio. Source: Rep-i 201808. Reprinted with permission. Based on a survey of physicians' overall evaluation of MRs. Scope of the survey is defined by Chugai.

Qualitative target: A company that satisfies all its stakeholders and receives their active support and trust

Patients and Healthcare Professionals: Play a part in increasing treatment satisfaction and the contribution of drugs in cancer treatment in our capacity as a leading oncology company	○
Shareholders and Investors: Realize growth strategies based on innovation (Market capitalization: 31st in Japan overall, 1st in domestic pharmaceutical industry) (as of December 28, 2018)	○
Roche: Contribute to growth of Roche Group by out-licensing Actemra, Alecensa, and Hemlibra and realize revenue and profit growth by fully leveraging our alliance with Roche.	○

Goal: 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	○

- 7 breakthrough therapy designations for 4 products (No. 1 in domestic pharm.)
- Establish world-class manufacturing base (completion of HEM/ALC global inspections)

Contribution to the Roche Group's results through product-appropriate fostering and sales	○

- Maximize product value through simultaneous global development and filing
- Achieve no. 1 customer satisfaction in strategic disease areas by establishing a system for providing new solutions

Leadership in pharmaceutical industry activities	○

- Promote personalized healthcare in Japan
- Raise employee awareness of being part of a top pharmaceutical company
- Lead the field of drug safety by establishing a system to provide value-added safety information

Activities in which all employees have an awareness, sense of responsibility and pride as part of a top pharmaceutical company	○

- Lead the industry as Japan's foremost company in biopharmaceuticals
- Become a world-class company in employee engagement
- Facilitate human resource development that also creates win-win relationships at the individual level through collaboration with Roche

Future in our Mission Statement to clarify the path Chugai will take (see pages 4-5 for details on our Core Values and Envisioned Future). Now that we have achieved our goal of becoming a top pharmaceutical company, our next goal is to be a top innovator in the healthcare industry. In our difficult business environment, there is only one way for us to realize advanced and sustainable patient-centric healthcare, and that is to continuously pursue innovation. Our image of a "top innovator" is that of a drug discovery startup that has the benefit of scale.

At the same time, through a wide-ranging assessment, we established the material issues we should work on in creating shared value. Sharing these issues both internally and externally will increase the momentum of our strategic initiatives and facilitate dialogue with stakeholders.

Question 4

What are you aiming for in the new mid-term business plan?

Based on the five strategies of our priority agenda, we will continue to promote innovation and sharing value with stakeholders, thereby increasing our corporate value.

We formulated the new mid-term business plan IBI 21 for the three years from 2019 based on our view of the external environment and approach to value creation, which I mentioned earlier. It consists of strategies for continuously promoting innovation and sharing value with stakeholders, thereby increasing our own corporate value. The "IBI" in the name of the plan expresses our intention to achieve sustained business growth through innovation by further strengthening Chugai's basic stance with regard to innovation: "Innovation Beyond Imagination."

The plan consists of a two-part priority agenda – "Create global growth drivers and maximize value" and "Strengthen HR and infrastructure that support Chugai's business" – and five strategies for accomplishing them. (See pages 38-51 for details on new mid-term business plan IBI 21.) We will focus even more on creating innovative drugs through advancement of new discovery technologies and modalities, and will enhance the value of solutions for addressing increasingly complex and diverse needs. We will also leverage the FMI business to promote the development of personalized healthcare.

To build a business foundation that will enable us to concentrate our resources on innovation, we will continue to strengthen talent development and improve our cost structure. At the same time, we will establish and strengthen platforms for the sustainability of both Chugai and society. There has been increasing emphasis on ESG issues recently, and I believe that bolstering initiatives for sustainability is what companies should aspire toward. We will concentrate on doing so while carefully examining issues.

Question 5

What will you need to do in order to carry out your strategies and enhance corporate value over the medium to long term?

The pursuit of innovation will continue to be the key. We will focus on three elements that give rise to innovation: science, technology and corporate culture.

The essential elements in carrying out our strategies – in other words, elements that give rise to innovation – are science, technology and corporate culture. While maintaining our uncompromising approach to science, which is the source of our value and the standard for determining our actions, we will accelerate open innovation with academia, startups, and companies in different industries. We plan to increase investment in this area. In addition, we will step up efforts for greater diversity and strengthen succession plans and talent management to shape our corporate culture for the continued pursuit of innovation.

Chugai has many employees who are mild-mannered yet passionately committed to improvement. The long-term perspective of Chugai's founder is embedded in our corporate culture. It may be part of the reason why our employees persevere even after repeated setbacks, which has led to numerous research breakthroughs and new, unprecedented projects. If our employees can embrace new challenges supported by this culture and guided by a strong belief in sharing value with society, I am confident that we can create even greater value.

I plan to focus even more on engaging our shareholders and other stakeholders in active dialogue for sharing value. We remain committed to meeting your expectations.

Message from the Deputy Chairman

Motoo Ueno
Representative Director & Deputy Chairman
In charge of Sustainability Dept., Audit Dept.

Chugai will pursue innovation to create shared value with stakeholders. Adopting that approach throughout our business, we will continue our own evolution as a company.

Stakeholders with a Common Purpose

Human health and wellbeing is a shared goal among all of our stakeholder groups: patients, healthcare providers, business partners, and employees; the governments, health insurers and regulators that support healthcare systems; university and other research institutions, and companies in other industries; and patients' families, communities, countries, industries and society as a whole. At Chugai, benefitting the medical community and human health around the world is the value we seek to deliver and subsequently expand through the pursuit of innovation.

That effort is focused on providing innovative pharmaceutical products, but it does not end there. We provide various kinds of information and promote coordination between healthcare facilities to enable the best treatment for each patient. We have also taken measures to improve screening rates and increase diagnostic accuracy, and cooperated with government entities and business partners in patient awareness campaigns. These and other activities, for which we have partnered with healthcare providers and local governments across Japan, have helped to eliminate regional disparities in standards of care, promote personalized healthcare and facilitate early detection and intervention in potential patients. As a result, the innovative Chugai products that play a part in patient-centric healthcare are widely used, and Chugai itself has grown.

However, maintaining sustainable growth in the current climate of uncertainty and rapid change will require us to further clarify our shared value with society and integrate it into concrete strategic activities. Accordingly, we have set our redefined Envisioned Future as the foundation of creating shared value. The strategy we have formulated to realize that Envisioned Future is the new mid-term business plan IBI 21. I mentioned in *Annual Report 2017* that we would draw up a value creation strategy that includes non-financial aspects by analyzing the social environment and identifying the value we can contribute. The strategy we developed from that process is synonymous with creating shared value, and I believe it will promote an even more active dialogue with stakeholders. In that regard, you can look forward to what comes next.

Strengthening the Principles and Platforms for Creating Shared Value

To move forward on creating shared value, we redefined the values shared by all our employees (Core Values) and updated the Chugai Business Conduct Guidelines as the Chugai Group Code of Conduct. These principles will guide us in precisely and quickly creating shared value based on changes in the external environment and stakeholder expectations. I will personally engage in dialogue with employees to ingrain the new code of conduct in our everyday operations as early as possible.

One of the strategies in IBI 21 is to strengthen sustainable platforms. For that, we analyzed and identified future issues for Chugai and defined priority areas for enhancement. We will take a more proactive approach to social issues such as climate change and environmental pollution. Moreover, we want to particularly emphasize human rights, health and productivity management, and compliance.

While respect for human rights was already part of our behavioral standards, and was emphasized in our operations, we felt doing more to ensure the protection of human rights throughout our supply chain was another key theme. Therefore, we recently issued a human rights declaration, and are working on a plan to steadily conduct due diligence in the supply chain.

In health and productivity management, a key theme is that the health of employees is connected to the health of the organization and improvement of productivity. This is an area where we believe Chugai should be in the forefront. We will raise the level of our health and productivity management by developing new metrics and accumulating case studies.

Compliance has always been important to Chugai, and that will not change. At Chugai, corporate ethics take priority over profit. Furthermore, we believe that in addition to abiding by laws and regulations, compliance is also about complying with the expectations and requests of stakeholders – in short, creating shared value. After restructuring our compliance system at the global level in 2017, we took further steps in 2018 that included the introduction of compliance planning and monitoring at each workplace. We will continue our rigorous efforts to ensure corporate, healthcare and regulatory compliance.

Innovation in Management

Having committed to a strategy of creating shared value, we will go beyond the innovation of products and services, and plan to focus more than ever on innovation and productivity improvement across the entire supply chain, as well as promoting the evolution of healthcare structures as a whole. Creating value by developing pharmaceuticals and providing solutions will remain our core business, but in the medium to long term, we can make a significant impact on healthcare overall by clarifying the value we deliver to patients and improving access to healthcare.

In the process of formulating our management strategy, we held discussions on the evolution of Chugai's management. One topic of those discussions was participation in the Sustainable Development Goals (SDGs) adopted by the U.N. We fully endorse the underlying purpose and principles of the SDGs, and I believe that advancing the strategy we have formulated will advance the SDGs. Among the goals, "3. Good health and well-being" is aligned with Chugai's Mission. Management is committed to fulfilling this goal, and will also actively work toward other objectives such as ensuring job satisfaction for employees, achieving technological innovation, and carrying out responsible manufacturing and marketing.

We will share value with our various stakeholders and grow together with them. To that end, Chugai will promote continuous innovation in management.

Chugai's SDG Focus

Among the 17 SDGs, Chugai prioritizes Goal 3, which directly links to its Mission. The next four SDGs shown help to achieve Goal 3, and the final six undergird its business activities.

Chugai Group Code of Conduct

The Mission set forth in the Mission Statement of the Chugai Group is to "Dedicate ourselves to adding value by creating and delivering innovative products and services for the medical community and human health around the world."

We set Core Values as the most important standards of value judgment in realizing the Mission and will operate our business in accordance with them. Chugai Group will contribute to the realization of a sustainable society by solving social issues through creating innovation and efforts toward the global environment, human rights and others.

By acting as an appropriate business guide for every employee within the Chugai Group, the Chugai Group Code of Conduct aims to ensure that these business operations are implemented. Every member of the Chugai Group must act and judge in accordance with this code.

1. Responsibility to Patients
   We will make each patient's wellbeing our highest priority, and provide innovative, high-quality products and services with superior safety and efficacy.
2. Pursuing Innovation
   With deep understanding and a broad perspective, we will focus our diverse talents on the continuous pursuit of innovation.
3. Acting with Integrity
   We will strictly adhere to all laws and regulations in every situation, and maintain the highest standards of integrity and ethicality.
4. Respect for Human Rights
   We will respect human rights in every aspect of our business activities.
5. Appropriate Partnerships
   We will maintain appropriate and transparent relations with all of our stakeholders through ongoing discussion. We will work together to realize mutual development and find solutions to social issues. We also expect our business partners to maintain the highest standards of integrity and ethicality.
6. Management of Corporate Assets
   We will achieve our management objectives through the optimal and appropriate management and use of corporate assets.
7. Disclosure of Information
   We will actively and fairly disclose corporate information.
8. Social Contribution
   As a good corporate citizen, we will actively promote our social contribution programs, and contribute to realizing a sustainable society.
9. Protection of the Global Environment
   We conduct our business activities in harmony with nature and the environment, and preserve our "one and only Earth" for future generations.

Our Approach to Value Creation

Mission Statement

—Innovation all for the patients—

Mission

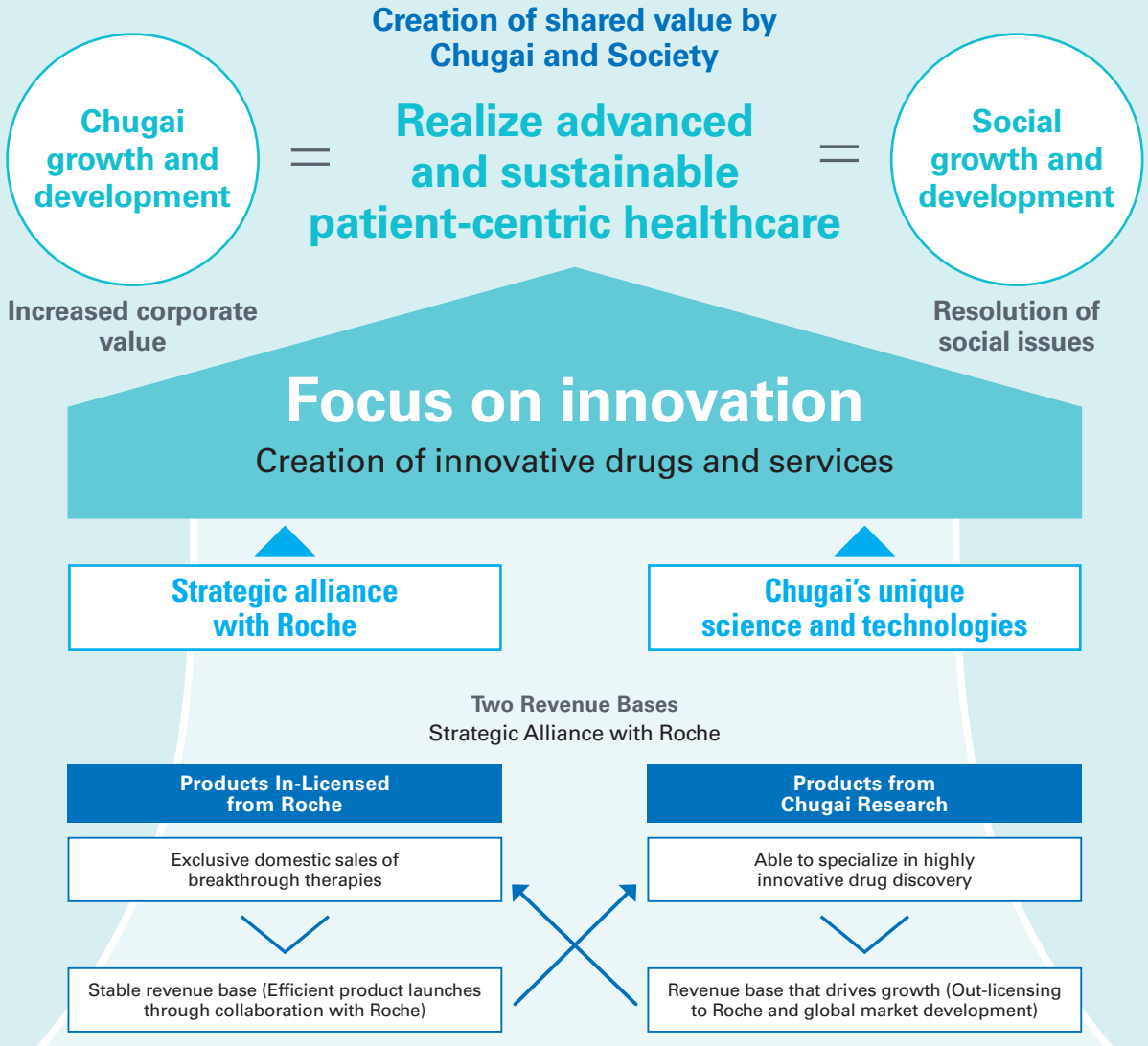
Dedicate ourselves to adding value by creating and delivering innovative products and services for the medical community and human health around the world

Core Values

Patient Centric/Pioneering Spirit/Integrity

Envisioned Future

Become a top innovator for advanced and sustainable patient-centric healthcare, powered by our unique strengths in science and technology and the alliance with Roche



Chugai business model adopted

Chugai has adopted creating shared value with stakeholders as its basic policy.

The goal of this shared value is to bring about the realization of advanced and sustainable patient-centric healthcare. This goal is set forth in our Envisioned Future. While sharing value with our various stakeholders, we will also increase our corporate value by contributing to patients and to the creation of a framework for the next generation of healthcare. That is our approach for value creation.

In the emerging healthcare landscape, rapid advances in life science and digital technology will drive dramatic changes in social structures. Likewise, the healthcare issues that require solutions are expected to become more sophisticated, diverse and complex. Measures to curb drug costs will be tightened further due to financial strains on healthcare systems caused by the growth and aging of populations worldwide, and only solutions that offer true value will be pursued. This situation will make it increasingly difficult for pharmaceutical companies to maintain a sound earnings structure. Rather than being content with its growth thus far, Chugai is shifting to a business structure for concentrating its resources on value creation while making the resolution of social issues the linchpin of its operations.

The key to creating shared value is to focus on innovation. We will continuously generate innovation by fully leveraging our unique business model, which is based on the strategic alliance with Roche and our unique strength in science and technology.

In working to create shared value, Chugai recently specified 25 material issues in eight categories that should be given priority. They were identified through a multifaceted analysis of material issues that incorporated objective views from outside experts. We also set in-house performance indicators to measure our progress in addressing each issue. These material issues may be adjusted in response to changes in the external environment or the evolution of Chugai's business activities, and we plan to update them periodically.

25 Material Issues in 8 Categories

Categories	Material Issues	
Sustainable healthcare	• Creation of innovative drugs and services • Provision of solutions for patients • Fair marketing • Fair pricing	• Adverse event management • Quality assurance and stable supply of products
Corporate governance	• Corporate governance • Risk management	• Disclosure and engagement
Ethics and compliance	• Compliance • Code of conduct	• Fair transactions
Supply chain management	• Supply chain management	
Human resources	• Employee job satisfaction • Development of employee potential	• Diversity and inclusion • Improvement of occupational health and safety
Human rights	• Human rights	• Safety of clinical trial subjects
Social contribution	• Social contribution activities	• Improvement of access to healthcare
Global environment	• Climate change countermeasures • Use of renewable/recycled resources	• Protection of biodiversity • Environmental management system

Value Shared with Stakeholders

In the context of patient-centric healthcare, we believe that Chugai should contribute to the actual structures and systems needed for realizing advanced, sustainable healthcare, while sharing value with its various stakeholder groups.

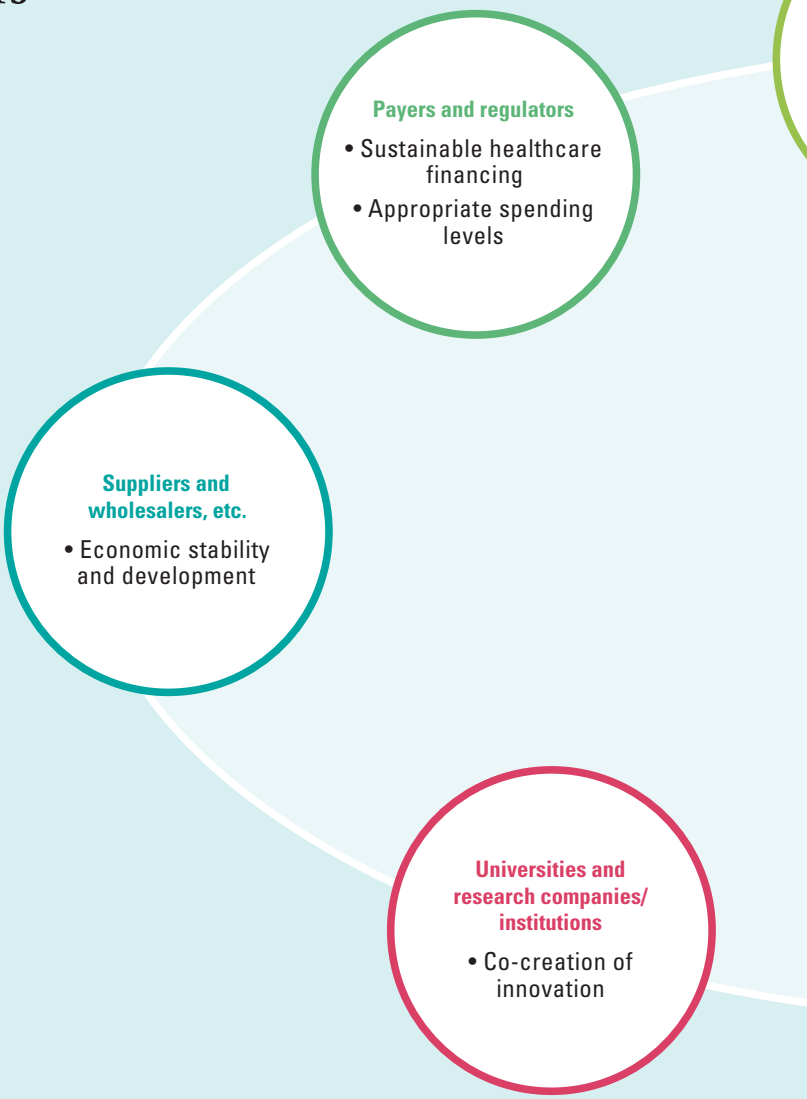
For patients, in addition to ensuring high drug efficacy and safety, we must enable them to receive care that matches their values and allows them to maintain their quality of life – in other words, to enable each individual patient to obtain true value. We also need to reduce the various burdens borne by patients' families in connection with treatment and caregiving. For healthcare providers, value includes enabling proper disease control and expanding treatment options. As for insurers and regulators that build the medical insurance and authorization systems, they need to achieve appropriate levels of spending and sustainable healthcare financing so that patients and society can enjoy true value.

For government, enhancing regional healthcare in accordance with the delivery systems in each community where patients live is important. For countries, in addition to improving healthcare finances, development of healthcare as a growth industry is sure to have significant value. For the universities and research companies and institutions that collaborate with Chugai, as well as its partner companies, suppliers, pharmaceutical wholesalers and others, significant value will result from jointly promoting innovation and increasing added value toward the establishment of a framework for the next generation of healthcare. This will lead to sustainable growth for all, and shareholders who invest in the healthcare industry will also be able to share in the benefits of that added value.

Moreover, employees whose work is directly tied to the issue that society expects us to address – realization of advanced and sustainable patient-centric healthcare – will gain job satisfaction, a sense of fulfillment and opportunities to enhance their own abilities.

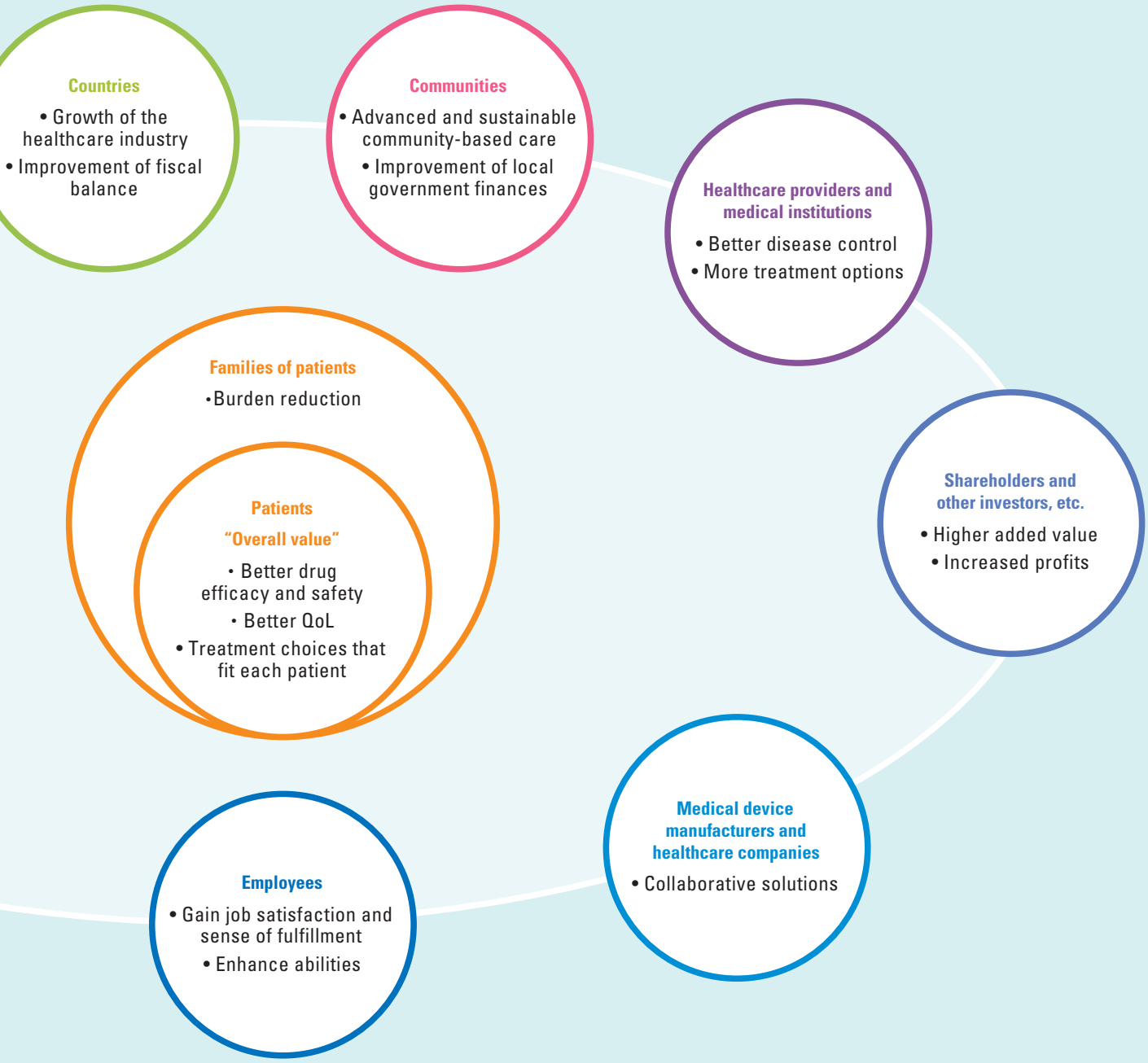
Chugai believes that sharing value with these various stakeholders beyond mere cooperation is the shortest path to realizing advanced, sustainable healthcare.

The chart to the right shows the material issues that we have identified as having particular importance in our creation of shared value with the stakeholders above.



Relationship between Stakeholders and Material Issues

- Patients and families of patients
  - Creation of innovative drugs and services
  - Provision of solutions for patients
  - Adverse event management
  - Quality assurance and stable supply of products
  - Safety of clinical trial subjects
  - Improvement of access to healthcare
- Healthcare providers and medical institutions
  - Creation of innovative drugs and services
  - Provision of solutions for patients
  - Fair marketing
  - Adverse event management
  - Quality assurance and stable supply of products



- **Shareholders and other investors, etc.**
  - Corporate governance
  - Risk management
  - Compliance
  - Code of conduct
  - Disclosure and dialogue
- **Employees**
  - Human rights
  - Employee job satisfaction
  - Development of employee potential
  - Diversity and inclusion
  - Improvement of occupational health and safety
- **Payers and regulators**
  - Fair pricing
  - Creation of innovative drugs and services
- **Suppliers and wholesalers, etc.**
  - Supply chain management
  - Fair transactions
- **Countries**
  - Creation of innovative drugs and services
  - Fair pricing
  - Improvement of access to health services
- **Communities**
  - Provision of solutions for patients
  - Fair pricing
  - Social contribution activities
  - Climate change countermeasures
  - Use of renewable/recycled resources
  - Protection of biodiversity
  - Environmental management system
- **Universities and research companies/ institutions**
  - Creation of innovative drugs and services
  - Provision of solutions for patients
- **Medical device manufacturers and healthcare companies**
  - Creation of innovative drugs and services
  - Provision of solutions for patients

Will

What We Will Do

Bring true value to patients

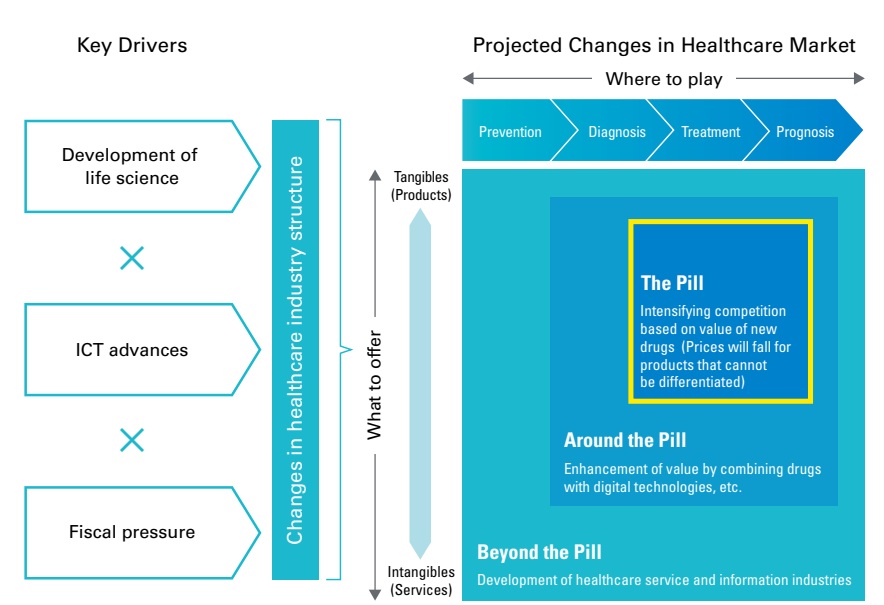
- Work toward treatment and disease control
- Contribute to the next generation of healthcare that delivers overall value to patients

Chugai has continuously created innovative drugs and delivered them to patients around the world. As creation and development of new drugs becomes increasingly challenging, we intend to create value and deliver it more broadly.

Our value creation has two aspects. One is disease control. We believe that with scientific excellence and the potential of medicines, it is possible to realize medical care in which healthcare providers can control diseases and minimize the suffering of patients, even if they cannot eliminate the disease entirely. This will require the creation of pharmaceuticals that offer both greater efficacy and a high level of safety, and giving healthcare providers the tools to accurately grasp medical conditions.

The other aspect is going beyond treatment with existing pharmaceuticals to provide solutions that offer true value to patients. We believe that the next generation of healthcare will involve delivering overall value to patients by providing treatments that fit their situation and values, and which consider factors such as quality of life after administration of drugs and the psychological, physical and financial burdens. The key here will be proof of value. If we can scientifically measure and assess value for patients, and provide solutions that enhance that value, we can make a significant contribution to improving patients' lives.

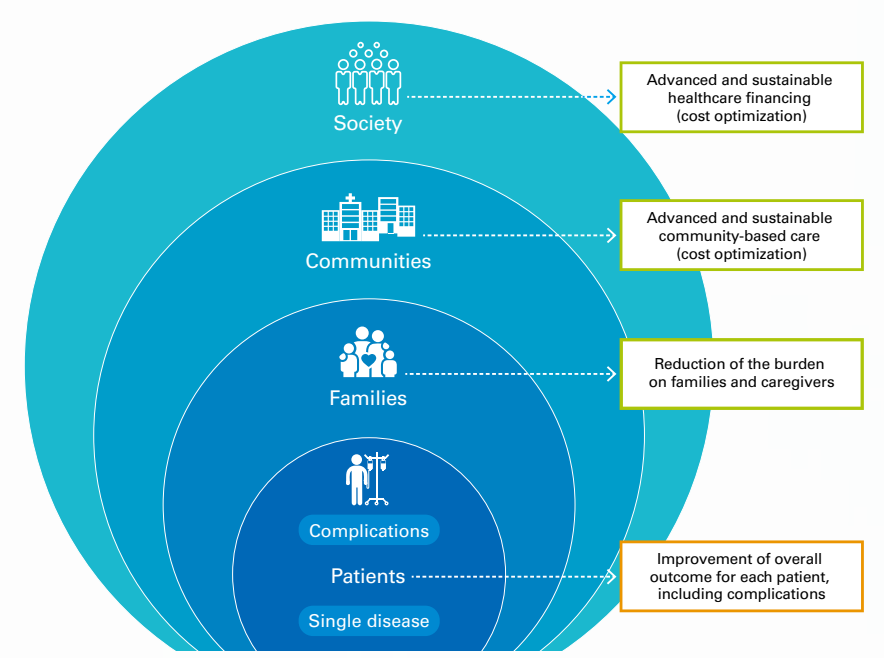
Expanding Our Field of View from the Pill to around and beyond the Pill



In the next generation of healthcare that Chugai envisions, value creation entails providing solutions beyond the scope of products, and encompasses not just treatment, but the entire process from prevention and diagnosis to post-treatment.

Solutions to increase the value of drug therapy ("around the pill") include diagnosis and post-treatment. Even now, diagnosis and treatment are seen as part of an integrated process in personalized healthcare, but with advances in genomic profiling and digital technology, preventive medicine will also play an important role. Furthermore, "beyond the pill" services may include providing solutions using different devices, and even information itself.

Enhancing Overall Value for a Broad Range of Stakeholders



When considering cost effectiveness in terms of healthcare financing, it is necessary to take into account not just the price of the medicine itself, but also the therapeutic effect and impact on the patient's lifestyle. The cost of a drug varies depending on the dosing frequency and dosing period, and other costs arise from managing adverse events after administration, traveling to and from the hospital, and so on. For instance, some drugs may cost less than others but require significant spending on adverse event management or limit the patient's ability to work after treatment commences. In such cases, a more expensive drug often provides better overall value because the post-treatment financial burden is smaller. Going forward, it will be important to measure and prove the overall value of a drug, including patients' ability to maintain employment and a normal lifestyle as well as quality of life.

Must

What We Must Do

Fulfill our obligations as a top pharmaceutical company

- Build a sustainable healthcare framework
- Tirelessly pursue quality in every function

The problem of financing healthcare systems is becoming increasingly serious in many countries. Given the ongoing growth of populations and a rising proportion of seniors, who have relatively greater need for healthcare, providing healthcare sustainably is a critical issue going forward. Moreover, drug discovery is becoming more difficult, and the cost of creating new drugs is enormous. To ensure sustainable healthcare given limited resources, investment will be focused only on solutions that are truly valuable for patients. A framework for such healthcare must be built.

At the same time, on a global scale and from the perspective of social systems as a whole, companies are expected to contribute more broadly and at a more sophisticated level, both in terms of the issues they address and the roles they play. The SDGs adopted by the U.N. are an example of one such international initiative. Chugai supports the aims and philosophy of the SDGs in their entirety, and is working proactively toward their realization.

As a company that has established a solid presence in the industry through its growth and development, Chugai recognizes that it has an obligation to take greater initiative in resolving social issues. While playing a part in realizing sustainable healthcare, we will continue to raise the quality of our activities across all functions by pursuing innovation from the standpoint of increasing shared value with stakeholders. In this way, we will fulfill the role expected of us by society at a higher level.

The Accelerating Increase in Time Requirements and Cost of New Drug Creations

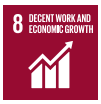
In the drug approval process in various countries, judgment of the novelty of new drugs is becoming increasingly strict. Moreover, while advances in areas such as genomic research and data analysis will contribute substantially to new drug development, the costs associated with these technological breakthroughs are soaring, and global development competition is fierce. According to one study, successfully developing and launching a new drug requires investment of as much as U.S.$2.5 billion, including the cost of projects that quietly fail. Pharmaceutical companies cannot deliver value to patients and grow without the financial strength to shoulder this cost.

Stepping Up Activities Based on SDGs to Create Shared Value

In defining material issues, Chugai verified each issue against the SDGs, and also examined such matters as what role Chugai should play and which goals should be given lower priority considering Chugai's business. The development goal we are focusing on the most is "3. Good health and well-being." However, there are also a number of other issues we should work on in partnership with stakeholders. Currently, our main efforts include those listed below. Going forward, we intend to define these development goals in more detail and concentrate on high-priority and high-profile initiatives.

We adopt a patient-centric approach to creating innovative drugs and providing solutions to cure and manage diseases. Through joint research and other initiatives, we are also working on treatments for neglected tropical diseases, including development of a new therapeutic antibody targeting the dengue virus.

Provision of innovative drugs and services/Provision of solutions for patients/Contribution to global health



In addition to recruiting talented and diverse people to support innovation, we provide rewarding environments where employees are able to develop their skills. We strive to optimize work environments and provide systems and conditions that promote job satisfaction and a sense of security among employees. We also expect our suppliers to consider EHS* issues in their business activities.

Improvement of occupational health and safety/Talent management/Promotion of work-life synergy (promotion of use of childcare leave system by male employees and telecommuting system, etc.)/Supply chain management

We support and promote innovation in the field of healthcare by investing aggressively in research and development and by building open innovation networks through collaborative research with academia.

Provision of innovative drugs and services/Initiatives for personalized healthcare/Establishment of open innovation networks with academia and other parties

In the healthcare industry, we are working to ensure a stable supply and quality at a high level, including the accuracy of product quality and information. We are also promoting the reuse and sustainability of natural resources through efforts including environmental management and targeting water use throughout the value chain.

Ensuring stable supply and stable inventories/Strengthening of quality assurance and stable supply/Use of renewable and recyclable resources/Environmental management

To help solve social issues, we are working in collaboration with research organizations, governments, non-governmental organizations and other specialized bodies. We also disclose information to our stakeholders and promote appropriate understanding of our corporate activities through dialogue.

Establishment of open innovation networks/Stakeholder engagement strategy/Participation in GHIT Fund and Access Accelerated

* Environment, health and safety

Can

What We Can Do

Focus on science-based innovation

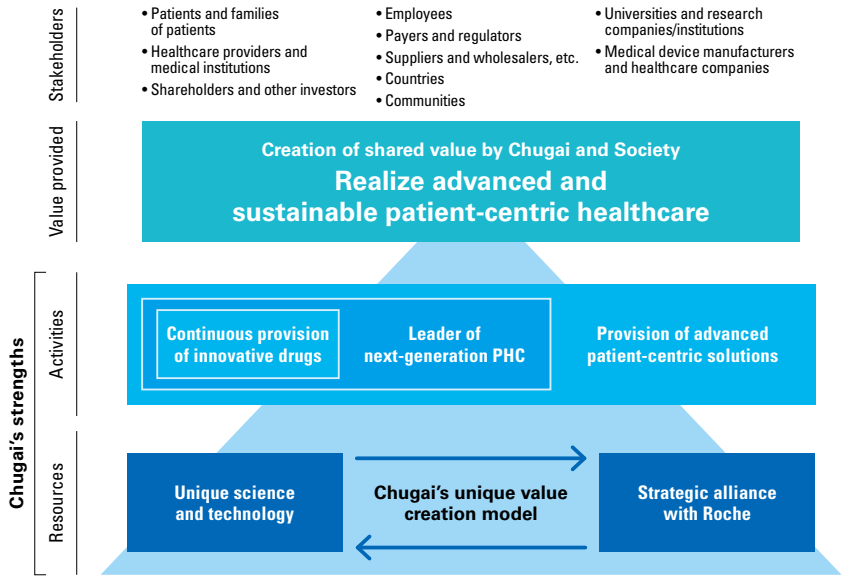
- Further innovate our unique strengths and technologies
- Take full advantage of cooperation with Roche

We have determined that the key to Chugai's creation of shared value is to concentrate on innovation. Innovation is an important theme at any company, but we are proud that Chugai has maintained a commitment to science-based innovation ever since it was founded. Innovation is essential to creating breakthrough medicines, but drug discovery is not the only area where we innovate. We have been focusing our efforts on innovation with a scientific approach in all aspects of our business, including development, production, marketing, medical affairs, safety and quality assurance. One example is our use of precise area marketing based on a diverse range of information including real-world data. This approach helps us understand the characteristics of regional healthcare delivery systems and promote cooperation among healthcare providers. Innovating in various fields has allowed Chugai to establish its unique strengths, which are the source of its growth and development. By refining and reinforcing these strengths, we aim to bring about the realization of advanced and sustainable patient-centric healthcare.

Chugai's concentration on innovation is enabled by its business model, which is based on partnership with Roche, and the efficient, resilient revenue bases that have been built through this model. We intend to make this business structure even stronger so that we can continue to steadily generate innovation.

Use of Chugai's Unique Strengths and Further Progress

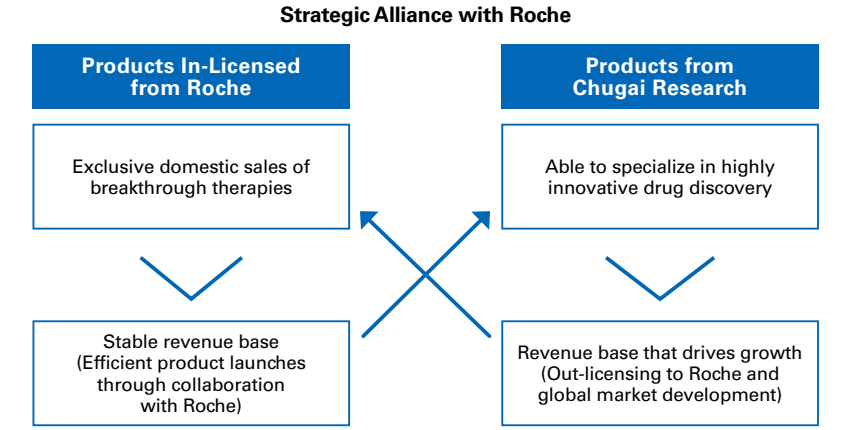
Structure of Chugai's Strengths



Chugai has unique strengths that give it a competitive advantage and have a considerable impact on the value it provides for patients. The diagram to the left shows how Chugai has redefined those strengths based on the direction of its value creation strategy, changes in the operating environment and other factors. Our business model, which combines scientific excellence with the strategic alliance with Roche, is the source of our value creation. Continuously providing innovative drugs that lead to further advancement of personalized healthcare, and providing healthcare services that maximize their value – these value creation activities are Chugai's core strengths. We will continue to evolve these strengths by putting our strategies into action.

Optimal Use of Two Revenue Bases Allows Us to Concentrate on Innovation

Two Revenue Bases



Under the strategic alliance with Roche, Chugai efficiently in-licenses Roche's innovative products and markets them on an exclusive basis in Japan. This stable revenue base allows us to concentrate investment on highly innovative proprietary technologies and drug discovery. In addition, out-licensing our in-house products to Roche gives us access to global markets, providing a revenue base that drives growth and generates profits that can be reinvested.

This business model also enables Roche to sell Chugai products – which have been created through highly innovative, specialized in-house research – in global markets. It is truly a win-win relationship. Based on this business model, we will further deepen our cooperation with Roche to drive continued innovation.

Process for Establishing Material Issues

STEP 1 — Analysis of mid- to long-term conditions and identification of risks and opportunities

- Healthcare industry outlook, and forecasts and assumptions of domains and participating companies
- Identification of future risks and opportunities, and our relevant strengths and weaknesses

STEP 2 — Discussion of management policies (Executive Committee)

- Decisions on management policies and business plan formulation process
- Discussion on Mission Statement to express both Chugai's growth and the development of society

STEP 3 — Interviews of outside experts

STEP 4 — Gap analysis (requests from outside stakeholders, comparison with other companies)

- Advice of Chugai International Council (CIC) on mid- to long-term environmental changes and risks, strategic direction, and contributions Chugai can make
- Advice from outside consultants on Chugai's sustainability activities
- Extraction of material issue categories based on expectations and requirements of society in accordance with the SDGs, GRI, SASB, etc.
- Conducted gap analysis of current measures in terms of DJSI, MSCI and FTSE survey items

STEP 5 — Analysis of social issues we want to solve (value) and material issues

- Drew up plan for solutions to social issues of stakeholders (value) and plan for material issues
- Scope of outcome: "Move toward realization of advanced and sustainable patient-centric healthcare"

STEP 6 — Consultation with internal divisions

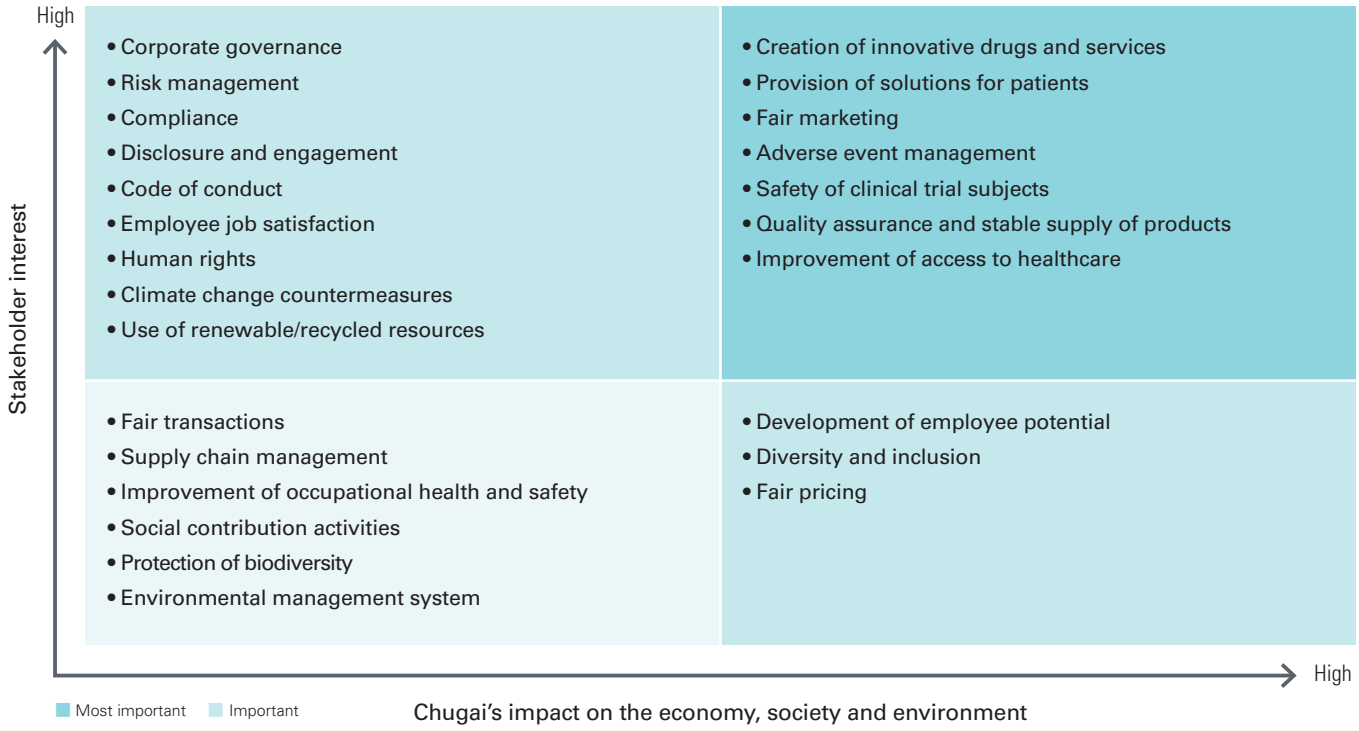
- Review of plan for solutions to social issues (value) and plan for material issues, and consultations on wishes and views of divisions and supervising officers (Global Health Policy, Corporate Social Responsibility, Human Resources Management)

STEP 7 — Specification of material issues (Outside directors, Executive Committee, Board of Directors)

- Based on the preceding steps, specified material issues on two axes: "stakeholder interest" and "Chugai's impact on the economy, society and the environment"
- Finalization after review by the Executive Committee, and approval by the Board of Directors

In establishing material issues, we analyzed the future market environment, referred to the SDGs, GRI, SASB and other frameworks, and comprehensively identified the issues that society expects Chugai to address. We also scrutinized items for which Chugai is not sufficiently meeting expectations. We conducted an objective analysis that incorporated outside views, and narrowed the list of issues to those for realizing Chugai's Envisioned Future. Based on that process, we specified 25 material issues in eight categories. (See table on page 17.)

Specification of Material Issues



Kuniko Muramatsu
Member, Chugai Sustainability Advisory Committee*
Representative Director, Wellness Systems Institute

* Name changed from CSR Advisory Committee as of April 1, 2019

Process for Establishing Material Issues

I think that Chugai's process for establishing material issues was accurate because in the interest of thoroughness it incorporated gap analyses against an array of indices and objective third-party opinions. Above all, however, my evaluation of the process is positive because decisions are based on historical review and analysis of the medium-to-long-term environment, beginning with the Mission Statement renewal, and took into account consultations with each division and discussions among Chugai's committees. As a result, the idea of sustainability has been embedded in the new mid-term business plan. As a member of the CSR Advisory Committee, I had the opportunity to offer opinions during the process. I believe that the interrelationships among issues have since been further clarified and made easier to understand.

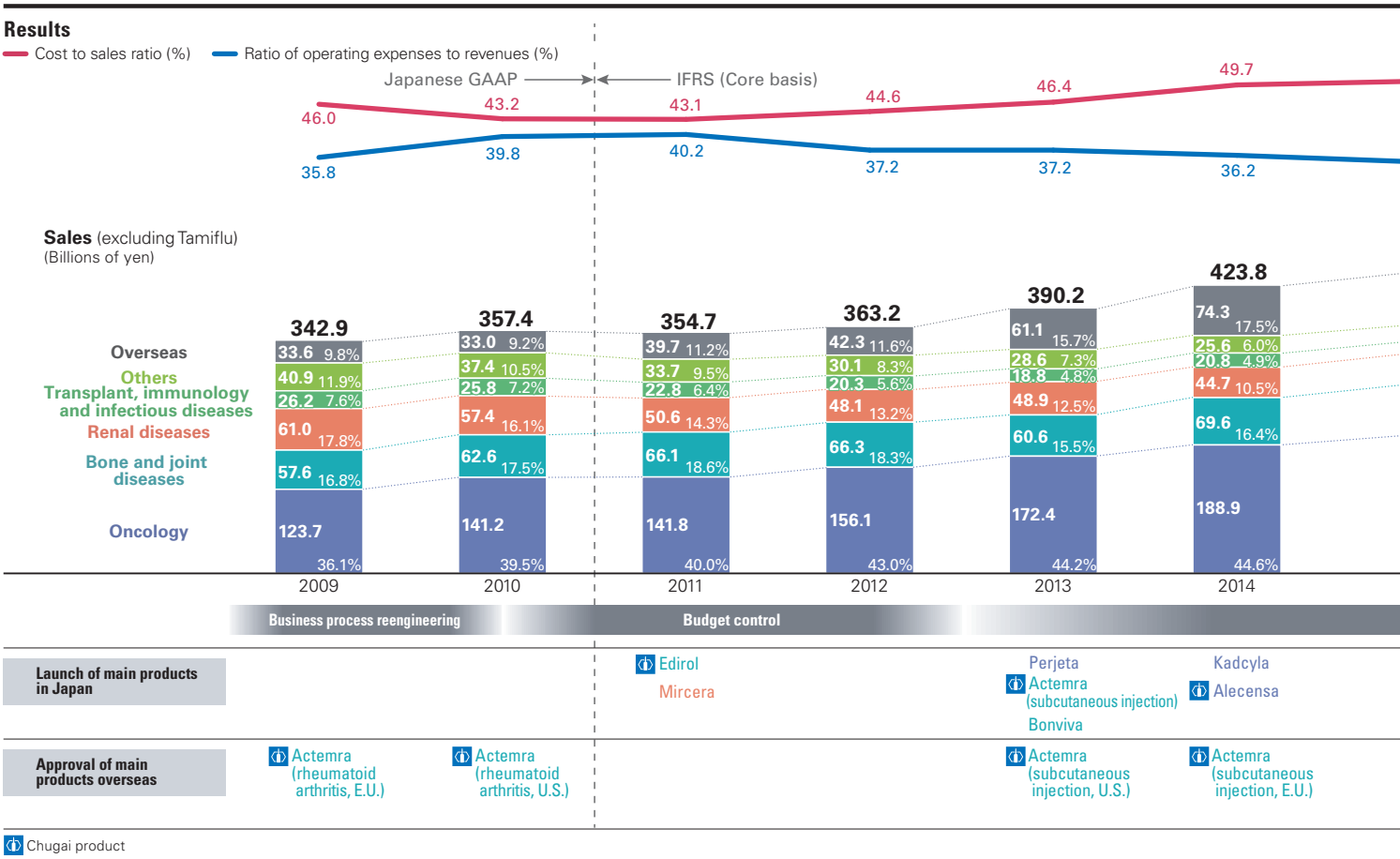
I am confident in the effectiveness of Chugai's material issues because in determing them Chugai has eschewed standard formulae and had the will to define issues, risks and opportunities in its own terms.

In the future, Chugai will of course have to take on issues based on its strategies, but dialogue with stakeholders remains important. By using annual reports based upon material issues as a common language in internal and external communications, these issues will become known throughout the Group. I have high expectations that Chugai will be able to craft its own unique approach to sustainability as a result.

Financial and Pre-Financial Highlights (IFRS)

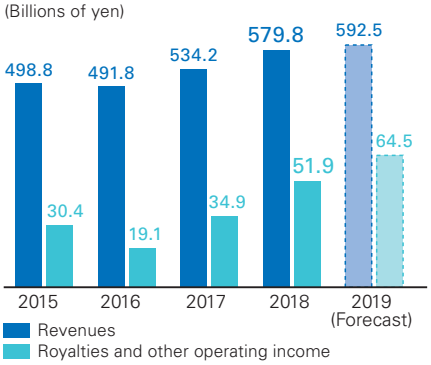
Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries/Years ended December 31

Financial Indicators (Core Basis)



Revenues/ Royalties and Other Operating Income

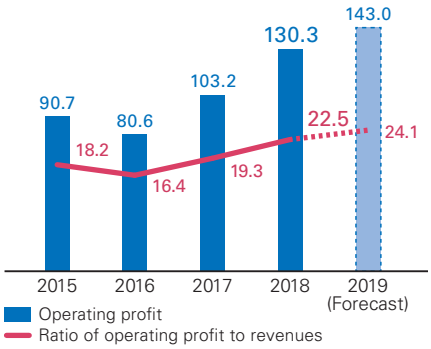
(Billions of yen)



Revenues expanded substantially in 2018 due to exports of Chugai products and non-recurring income from the transfer of long-listed products and others. Royalties and other operating income (ROOI) is composed of recurring income, which has been increasing in conjunction with overseas sales of Actemra and other products, and non-recurring income, which changes from year to year and is the principal factor in the fluctuations in ROOI.

Operating Profit/ Ratio of Operating Profit to Revenues

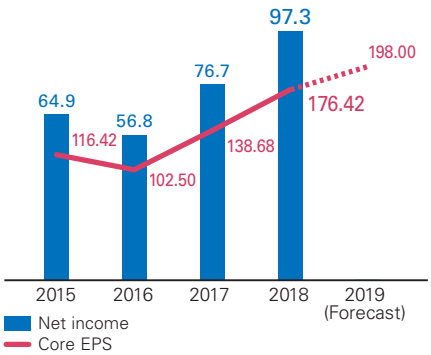
(Billions of yen/%)



The ratio of operating profit to revenues is consistently high due to the low ratio of operating expenses to revenues. In 2018, the increase in ROOI and the lower cost to sales ratio contributed to the increase in the ratio of operating profit to revenues. In 2019, we expect record profit due to factors including ROOI growth from royalty income for Chugai product Hemlibra.

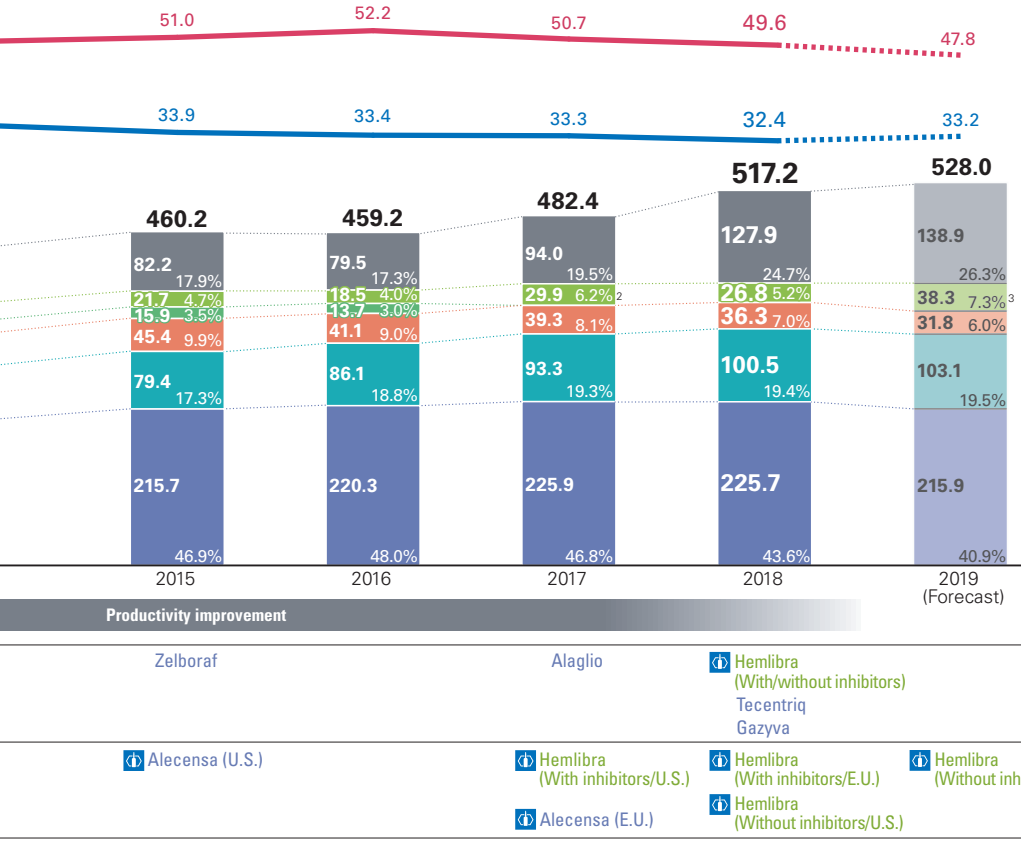
Net Income/Core EPS

(Billions of yen/Yen)



In new mid-term business plan IBI 21, we set a high single-digit[1] Core EPS compound annual growth rate (CAGR) as the quantitative outlook, and are using it as a key performance indicator shared both internally and externally.

1. Based on constant exchange rates for the three-year period



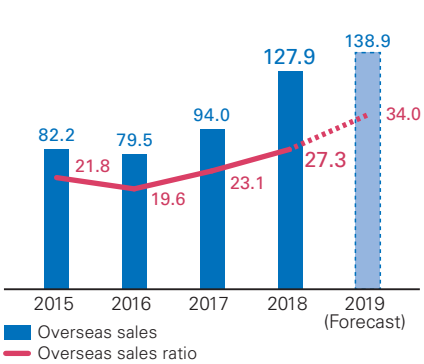
Chugai has substantially improved its cost structure in view of the rising cost to sales ratio resulting from the increase in products in-licensed from Roche under the strategic alliance between the two companies. We have now secured high profitability by continuously achieving a ratio of operating expenses to revenues at a level that compares favorably with the world's leading pharmaceutical companies.

Overseas sales were strong due to an increase in exports of Chugai products Actemra and Alecensa to Roche. In Japan, despite the impact of NHI drug price revisions and generic drugs on some mainstay products, Chugai products such as Alecensa and Actemra continued to drive growth.

2. Sales of the transplant, immunology and infectious diseases area, which were disclosed separately up until 2016, were included and disclosed in sales of the Others area from 2017.
3. From 2019, Tamiflu is included in Others.

Overseas Sales/Overseas Sales Ratio

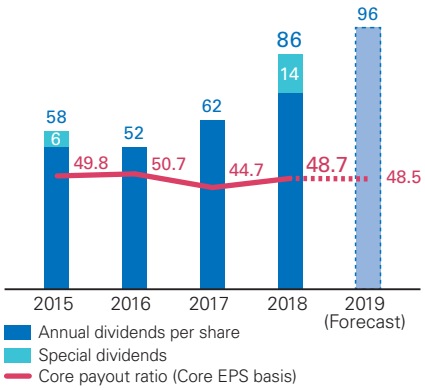
(Billions of yen/%)



Chugai was a growth driver for the Roche Group, with global sales of Actemra (including Japan) exceeding 2.0 billion Swiss francs in 2018 and strong sales of Alecensa in Europe and the United States. An additional indication for Hemlibra is also expected to contribute substantially to overseas revenues in 2019.

Dividends per Share/Core Payout Ratio

(Yen/%)



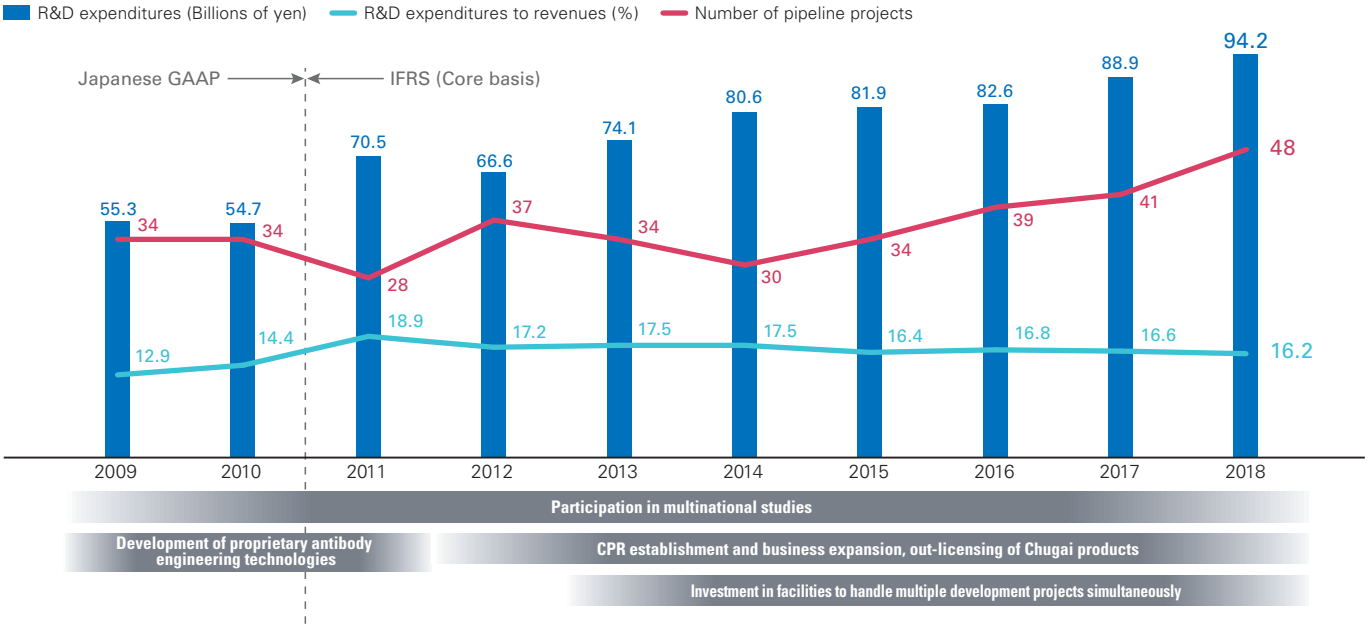
Regarding shareholder returns, we target stable dividends with a Core EPS payout ratio of 50 percent on average, based on an approach of dividing core net income equally between the Company and our shareholders. This policy will continue unchanged under IBI 21, our new mid-term business plan.

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 by excluding 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.

Research, Clinical Development, Pharmaceutical Technology and Production

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

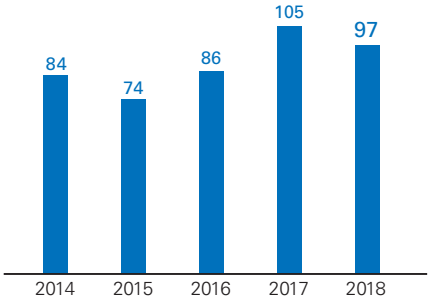


As revenues grow, Chugai increases investment in research and development. In addition to the steady creation of innovative drugs, this leads to research findings that may contribute to the advancement of healthcare and the pharmaceutical industry worldwide. Our policy is to proactively conduct speedy research and development in light of the competitive environment, as well as upfront investment to acquire and enhance future competitiveness, while keeping growth in overall operating expenses within the rate of revenue growth as a general principle.

Under our strategic alliance with Roche, we have been promoting new drug development with higher success rates and greater efficiency by collaborating with Roche in ways such as examining and deciding on which Roche products to in-license based on the results of early-stage clinical trials. In recent years, we have maintained a robust pipeline, with several products from Chugai research having moved into the clinical phase, including in-house products from Chugai Pharmabody Research (CPR),[1] which has expanded its operations to accelerate the creation of innovative therapeutic antibodies.

1. Established in Singapore in 2012

Publications in Academic Papers and Presentations at Scientific Conferences regarding Chugai Research Findings[2]

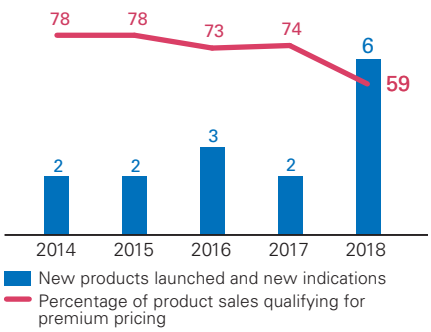


Chugai develops innovative medicines that allow it to differentiate itself from competitors by continuously establishing proprietary drug discovery technologies and applying them to development candidates while promoting research on commercialization for high quality and high added value. We will continue to generate research findings that may contribute to the overall advancement of healthcare, presenting those findings at scientific conferences and publishing them in academic papers.

2. Total of drug discovery and pharmaceutical technology

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

(Number/%)

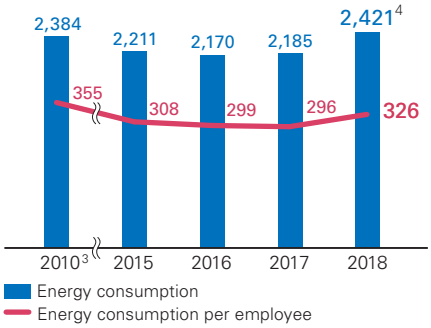


Although the percentage of product sales qualifying for premium pricing decreased substantially in 2018 due to the loss of premium pricing status for new drug creation and launches of generics, the number of new products and additional indications increased significantly. With our stable revenue base from the efficient in-licensing of Roche products for the Japanese market, we will continue to concentrate on the creation of innovative medicines.

Note: Products subject to special market-expansion repricing (2016, 2017: Avastin) are counted as products qualifying for premium pricing because they were assumed to meet the conditions for such pricing in the relevant fiscal years.

Energy Consumption/ Energy Consumption per Employee

(Thousands of GJ/GJ per employee)

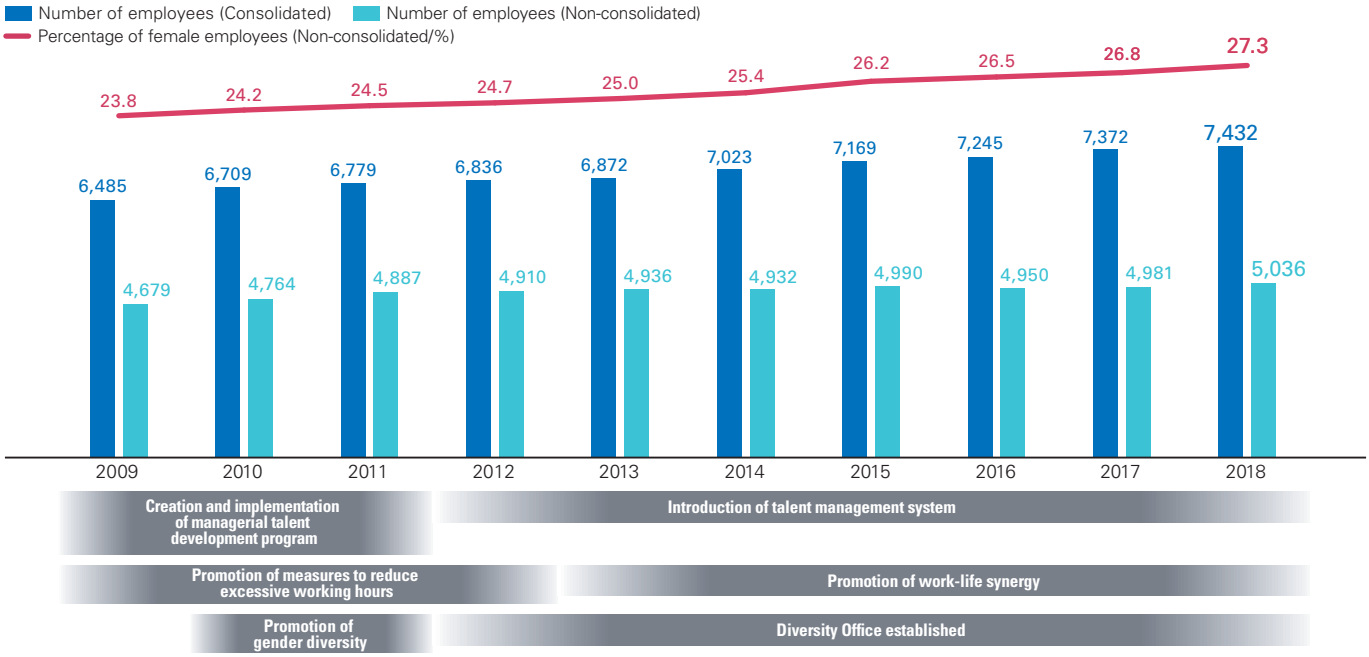


Energy consumption increased 10 percent year-on-year in 2018 due to the start of production at UK3.[5] As Chugai expands its production system for new drugs, it is also working to reduce energy consumption as one of its tasks, based on its Core Values, "We care about the global environment." (See pages 91-93 for details on environmental, health and safety initiatives.)

3. Benchmark year for mid-term environmental goals
4. Includes 40,000 GJ of overseas consumption
5. A new high-mix low-volume biological API manufacturing facility within the Ukima Plant (Kita-ku, Tokyo)

Human Resource Management

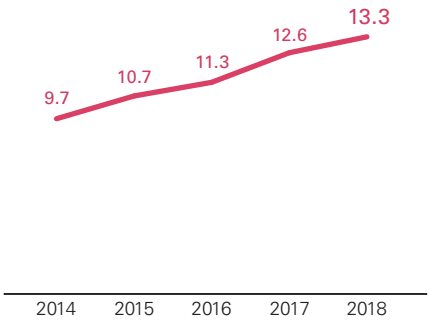
Employees/Ratio of Female Employees



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 implemented a talent management system to develop and retain leaders and core personnel, and also promote diversity and inclusion and work-life synergy so our diverse human resources can generate new value. The ratio of female employees is rising, and women have been steadily making inroads not only in our personnel systems but also in our initiatives.

Ratio of Female Managers

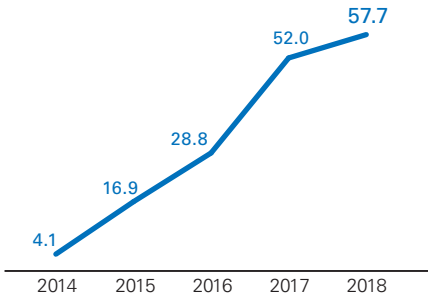
(Non-consolidated/%)



To promote the success of women in the workplace, we set a target ratio of female managers of 13 percent or higher by 2018, and focused on programs such as management candidate training to support the career development and professional growth of women. As a result, the percentage reached 13.3 percent as of December 31, 2018. However, this is still below global levels, so we plan to further accelerate our initiatives to develop female leaders.

Percentage of Male Employees Taking Childcare Leave[6]

(Non-consolidated/%)

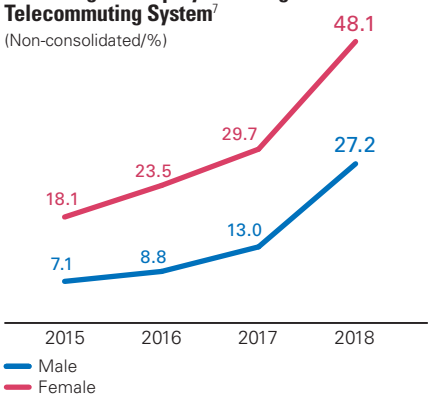


Chugai implements various measures to promote work-life synergy and work arrangements that fit employee lifestyles, and to improve productivity. The number of male employees taking childcare leave is increasing. In addition to sending e-mails about taking childcare leave to men with newborn children and their supervisors, we have created a handbook for supervisors that contains examples of employees taking leave and guidance on key management points.

6. Number of male employees taking childcare leave as a percentage of all male employees with newborn children

Percentage of Employees Using the Telecommuting System[7]

(Non-consolidated/%)



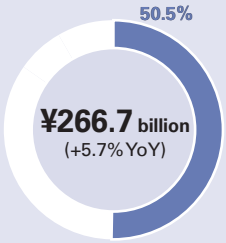
Since introducing the telecommuting system in 2012 for employees caring for young children and other family members, and for late-night teleconferencing with people overseas, we expanded the conditions for use of the system in 2015 to include productivity improvement, temporary injury and regular outpatient treatment. The number of users is on the rise. We will continue our efforts to raise awareness about the use of this system and continue to promote additional initiatives to achieve more flexible work styles.

7. Percentage of eligible employees

Review by Disease Area

Oncology

Sales and Percentage of Total Sales



Opportunities and Risks

Opportunities

- Cancer is the largest area of unmet medical need[1] (the leading cause of death in Japan).
- Personalized healthcare is expected to advance further due to factors including insurance coverage for cancer genomic profiling.
- Phase Three of the Basic Plan to Promote Cancer Control Programs is promoting delivery systems for cancer genomic medicine.

Risks

- Intensifying global competition for cancer immunotherapies including anti-PD-1/PD-L1 immune checkpoint inhibitors
- Return of premium for new drug creation for mainstay products
- Entry of large pharmaceutical companies into biosimilar[2] markets

Review of 2018 Performance

In Japan, market penetration by new product Tecentriq was steady and sales of Alecensa, a product from Chugai research, were firm. However, sales decreased 0.1 percent year on year to ¥225.7 billion due to factors including the effect of NHI drug price revisions and lower sales of mainstay products Herceptin and Rituxan.

Overall sales, including overseas sales, increased 5.7 percent to ¥266.7 billion supported by dramatic growth in Alecensa exports to Roche, which rose 107.9 percent to ¥28.9 billion, and other factors.

Bone and Joint Diseases/ Autoimmune Diseases

Sales and Percentage of Total Sales[3]

Opportunities and Risks

Opportunities

- The emergence of biologics has dramatically improved the effectiveness of rheumatoid arthritis (RA) treatment, and the treatment goal is shifting to remission (a symptom-free state).
- The number of osteoporosis patients is increasing yearly as populations age.
- There are many potential osteoporosis patients because the treatment rate and adherence to treatment remain low.

Risks

- Intensifying global competition in the RA market
- Slower growth due to the maturing of Actemra in the medium to long term
- The emergence of biosimilars that compete with biologics

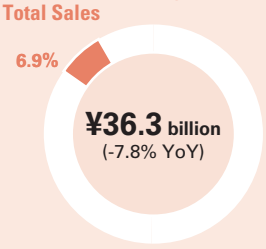
Review of 2018 Performance

In Japan, sales increased 7.7 percent year on year to ¥100.5 billion. The increase was driven by the solid performance of mainstay products Actemra, a product from Chugai research for treatment of RA and other diseases; Edirol, another product from Chugai research and the top brand in oral osteoporosis drugs; and Bonviva, which treats osteoporosis by inhibiting bone resorption.

Overall sales, including overseas sales such as exports of Actemra, which is approved in more than 110 countries and is distributed through Roche, increased 17.4 percent to ¥181.0 billion.

Renal Diseases

Sales and Percentage of Total Sales



Opportunities and Risks

Opportunities

- Screening rates are increasing among potential patients and people who have not been screened due to enhanced measures to address chronic kidney disease (CKD) by the Ministry of Health, Labour and Welfare.
- Early intervention in potential patients is improving the treatment rate of renal anemia.
- Renal anemia is divided into the dialysis stage and the pre-dialysis stage, and the number of patients treated in the pre-dialysis stage is trending upward every year.

Risks

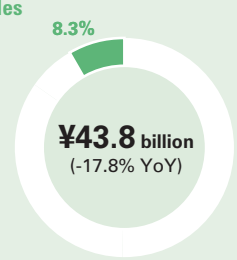
- Intensifying competition in the renal anemia market due to a reduction in fee points for dialysis as part of medical fee revisions

Review of 2018 Performance

In Japan, sales decreased 7.8 percent year on year to ¥36.3 billion. Sales of Oxarol, an agent for secondary hyperparathyroidism, and Mircera, a long-acting erythropoiesis stimulating agent, decreased in part because of the effect of NHI price revisions.

Other Diseases

Sales and Percentage of Total Sales



Opportunities and Risks

Opportunities

- The burden on people with hemophilia A and caregivers due to the development of inhibitors and frequent administration is an issue.
- Neurology is an area of very high unmet medical need, with many pathologies and syndromes.
- Medical fee points have been increased to promote more kidney transplants, and treatment needs for kidney transplants in Japan are rising.
- In addition to skin deterioration, itching associated with atopic dermatitis reduces patients' quality of life by disrupting sleep.

Risks

- Intensifying global competition due to the limited number of known molecular targets
- Possibility of few target patients despite high unmet medical need

Review of 2018 Performance

In Japan, market penetration was steady for Hemlibra, a treatment for hemophilia A launched in 2018, and CellCept, an immunosuppressant, maintained its share of the transplant segment and increased its share for lupus nephritis. However, sales decreased 10.4 percent year on year to ¥26.8 billion due to the transfer of long-listed products to Taiyo Pharma Co., Ltd. Sales of anti-influenza agent Tamiflu for ordinary use decreased 15.1 percent year on year to ¥10.1 billion, and sales for government stockpiles, etc. decreased 90.0 percent to ¥500 million.

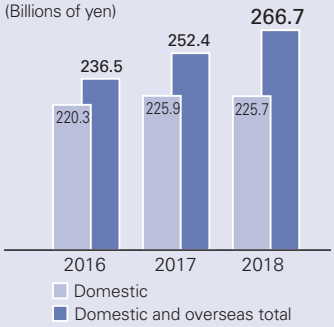
Overall sales in the other diseases category decreased 17.8 percent year on year to ¥43.8 billion.

1. Medical need that is not adequately met due to a lack of effective treatments
2. Successor products to biopharmaceuticals whose patent term has expired, made by manufacturers other than the manufacturer that developed the antecedent biopharmaceutical
3. Bone and joint diseases only

Sales

Domestic market share in oncology: No. 1[4]

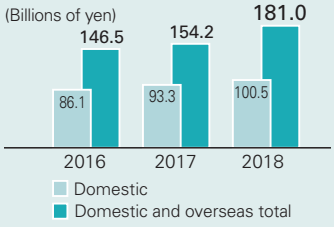
(Billions of yen)



Domestic market share in osteoporosis: No. 2[4]

Domestic market share in RA: No. 2[4]

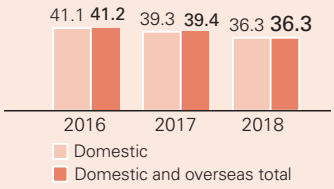
(Billions of yen)



Note: Graph shows sales for bone and joint diseases only.

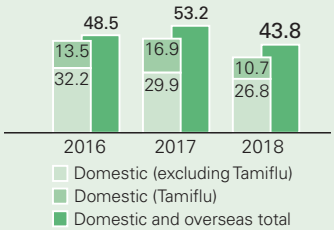
Domestic market share in renal diseases: No. 2[4]

(Billions of yen)



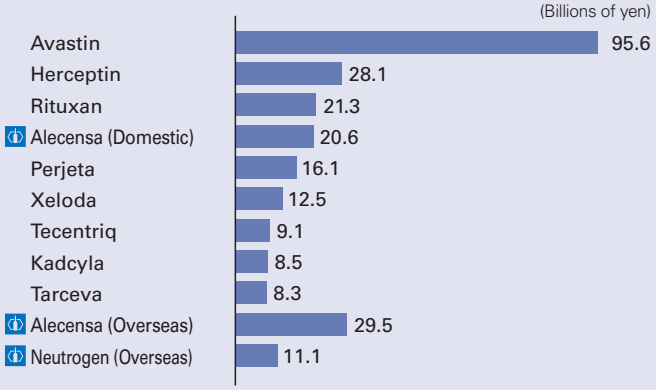
Other Diseases

(Billions of yen)

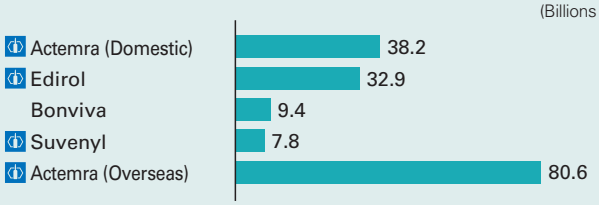


Sales of Major Products

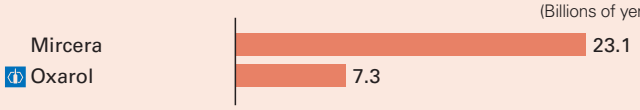
(Billions of yen)



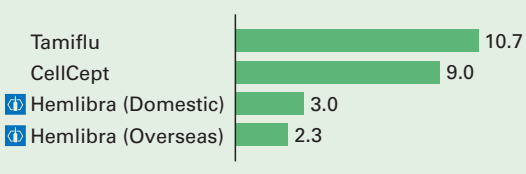
(Billions of yen)



(Billions of yen)



(Billions of yen)



Development Pipeline
(Including additional indications)

- AF802 (Alecensa)
- RG435 (Avastin)
- RG3502 (Kadcyla)
- RG7446 (Tecentriq)
- RG7440
- RG7596
- GC33
- CKI27
- ERY974
- RG7421
- RG6268
- RG6264
- RG7802
- RG7828
- ED-71 (Edirol)
- NRD101 (Suvenyl)
- MRA (Actemra)
- RG7845
- EOS789
- ACE910 (Hemlibra)
- RG1450
- RG7412
- RG6206
- RG7916
- CIM331
- SKY59
- PCO371
- RG7716
- GYM329
- RG7935
- SA237
- AMY109
- RG7906

Products from Chugai research

Development Pipeline (As of January 31, 2019)

Development Code (*Additional Indication)	Indication	Status: Phase Ⅰ / Phase Ⅱ / Phase Ⅲ / Filed / Approved	Approved/Filing Date [Planned Year of Filing]
Oncology			
RG7446	◆Non-small cell lung cancer (NSCLC) [2nd line]	Approved	Jan. 2018
	◆NSCLC [1st line]	Approved	Dec. 2018
	◆Small cell lung cancer	Filed	Dec. 2018
	◆Breast cancer	Filed	Dec. 2018
	◆NSCLC (adjuvant)	Phase Ⅲ (Multinational Study)	[2020]
	◆Urothelial carcinoma	Phase Ⅲ (Multinational Study)	[2021 or later]
	◆Muscle invasive urothelial carcinoma (adjuvant)	Phase Ⅲ (Multinational Study)	[2020]
	◆Renal cell carcinoma	Phase Ⅲ (Multinational Study)	[2020]
	◆Renal cell carcinoma (adjuvant)	Phase Ⅲ (Multinational Study)	[2021 or later]
	◆Early breast cancer	Phase Ⅲ (Multinational Study)	[2021 or later]
	◆Ovarian cancer	Phase Ⅲ (Multinational Study)	[2020]
	◆Prostate cancer	Phase Ⅲ (Multinational Study)	[2021 or later]
	◆Hepatocellular carcinoma	Phase Ⅲ (Multinational Study)	[2021 or later]
	◆Head and neck carcinoma (adjuvant)	Phase Ⅲ (Multinational Study)	[2021 or later]
GA101 (RG7159)	Follicular lymphoma	Approved	Jul. 2018
RG1273*	◆Breast cancer (adjuvant)	Approved	Oct. 2018
RG6268	◆Solid tumors [*NTRK* fusion-positive]	Filed	Dec. 2018
	◆NSCLC	Phase Ⅱ (Multinational Study)	[2019]
RG435*	Renal cell carcinoma	Phase Ⅲ (Multinational Study)	[2020]
	Hepatocellular carcinoma	Phase Ⅲ (Multinational Study)	[2021 or later]
RG3502*	◆Breast cancer (adjuvant)	Phase Ⅲ (Multinational Study)	[2020]
RG7440	◆Prostate cancer	Phase Ⅲ (Multinational Study)	[2021 or later]
	◆Breast cancer	Phase Ⅲ (Multinational Study)	[2020]
RG7596	Diffuse large B-cell lymphoma (DLBCL)	Phase Ⅲ (Multinational Study)	[2021 or later]
RG6264	◆Breast cancer (Fixed-dose combination, subcutaneous injection)	Phase Ⅲ (Multinational Study)	[2021 or later]
AF802 (RG7853)*	◆NSCLC (adjuvant)	Phase Ⅲ (Multinational Study)	[2021 or later]
GC33	◆Hepatocellular carcinoma	Phase Ⅰ (Multinational Study)[1]	
CKI27	◆Solid tumors	Phase Ⅰ	
ERY974	◆Solid tumors	Phase Ⅰ	
RG7421	Solid tumors	Phase Ⅰ	
RG7802	◆Solid tumors	Phase Ⅰ	
RG7828	Hematologic tumors	Phase Ⅰ	
Bone and Joint Diseases			
ED-71	Osteoporosis	Filed (China)	Feb. 2018
NRD101	Knee osteoarthritis/Shoulder periarthritis	Phase Ⅲ (China)	[2019]
Renal Diseases			
EOS789	Hyperphosphatemia	Phase Ⅰ	
Autoimmune Diseases			
MRA* (RG1569)	Systemic sclerosis	Phase Ⅲ (Multinational Study)	[2019]
RG7845	Rheumatoid arthritis	Phase Ⅰ	
Neurology			
RG1450	◆Alzheimer's disease	Phase Ⅲ (Multinational Study)	[2021 or later]
RG7412	◆Alzheimer's disease	Phase Ⅲ (Multinational Study)	[2021 or later]
SA237 (RG6168)	Neuromyelitis optica spectrum disorder (NMOSD)	Phase Ⅲ (Multinational Study)[1]	[2019]
RG6206	Duchenne muscular dystrophy (DMD)	Phase Ⅱ/Ⅲ (Multinational Study)	[2020]
RG7916	Spinal muscular atrophy (SMA)	Phase Ⅱ/Ⅲ (Multinational Study)	[2020]
RG7935	◆Parkinson's disease	Phase Ⅰ	
GYM329 (RG6237)	Neuromuscular disease	Phase Ⅰ	
RG7906	Psychiatric disorders	Phase Ⅰ	
Other Diseases			
ACE910 (RG6013)	Hemophilia A (Inhibitor)	Approved	(E.U.) Feb. 2018, (Japan) Mar. 2018, (Taiwan) Dec. 2018
	Hemophilia A (Non-inhibitor)	Approved	(U.S.) Oct. 2018, (Japan) Dec. 2018
		Filed	(Taiwan) Jan. 2019
		Filed	(E.U.) Apr. 2018
RG7716	Diabetic macular edema	Phase Ⅲ (Multinational Study)	[2021 or later]
	Wet age-related macular degeneration	Phase Ⅰ	
CIM331	Pruritus in dialysis patients[2]	Phase Ⅱ	[2021 or later]
SKY59 (RG6107)	Paroxysmal nocturnal hemoglobinuria (PNH)	Phase Ⅰ/Ⅱ (Multinational Study)	
PCO371	Hypoparathyroidism	Phase Ⅰ	
AMY109	◆Endometriosis	Phase Ⅰ	

○○○○○ Designates change in status in 2018 and thereafter ◆ PHC-based drug discovery

1. Multinational study managed by Chugai Pharmaceutical 2. Development of atopic dermatitis was out-licensed to Galderma S.A. (Overseas)/Maruho Co., Ltd. (Japan)

Generic Name/Product Name	Origin (Collaborator)	Mode of Action
atezolizumab/Tecentriq	Roche	Engineered anti-PDL1 monoclonal antibody (Injection)
obinutuzumab/Gazyva (Overseas name: Gazyva/Gazyvaro (E.U.))	Roche (Nippon Shinyaku)	GIycoengineered type II anti-CD20 monoclonal antibody (Injection)
pertuzumab/Perjeta	Roche	HER2 dimerization inhibitory humanized monoclonal antibody (Injection)
entrectinib/Product name undetermined	Roche/ Nerviano Medical Sciences	ROS1/TRK inhibitor (Oral)
bevacizumab/Avastin	Roche	Anti-VEGF (Vascular Endothelial Growth Factor) humanized monoclonal antibody (Injection)
trastuzumab emtansine/Kadcyla	Roche	Anti-HER2 antibody-tubulin polymerization inhibitor conjugate (Injection)
ipatasertib/Product name undetermined	Roche/Array BioPharma	AKT inhibitor (Oral)
polatuzumab vedotin/Product name undetermined	Roche	Anti-CD79b antibody-drug conjugate (Injection)
trastuzumab/pertuzumab, Herceptin/Perjeta	Roche	Anti-HER2 humanized monoclonal antibody/HER2 dimerization inhibitory humanized monoclonal antibody (Injection)
alectinib/Alecensa	In-house (Roche)	ALK inhibitor (Oral)
codrituzumab/Product name undetermined	In-house	Anti-Glypican-3 humanized monoclonal antibody (Injection)
Generic and product names undetermined	In-house	Raf and MEK dual inhibitor (Oral)
Generic and product names undetermined	In-house	Anti-Glypican-3/CD3 bispecific antibody (Injection)
cobimetinib/Product name undetermined (Overseas name: Cotellic)	Roche/Exelixis	MEK inhibitor (Oral)
cibisatamab/Product name undetermined	Roche	Anti-CEA/CD3 bispecific antibody (Injection)
mosunetuzumab/Product name undetermined	Roche	Anti-CD20/CD3 bispecific antibody (Injection)
eldecalcitol/Edirol	In-house	Activated vitamin D_3 agent (Oral)
purified sodium hyaluronate/Suvenyl	In-house	Sodium hyaluronate (Injection)
Generic and product names undetermined	In-house	— (Oral)
tocilizumab/Actemra (Overseas name: Actemra/RoActemra (E.U.))	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody (Injection)
fenebrutinib/Product name undetermined	Roche	BTK inhibitor (Oral)
gantenerumab/Product name undetermined	Roche/MorphoSys	Anti-amyloid-beta human monoclonal antibody (Injection)
crenezumab/Product name undetermined	Roche/AC Immune	Anti-amyloid-beta humanized monoclonal antibody (Injection)
satralizumab/Product name undetermined	In-house (Roche)	Anti-IL-6 receptor recycling antibody (Injection)
Generic and product names undetermined	Roche/Bristol-Myers Squibb	Anti-myostatin adnectin (Injection)
risdiplam/Product name undetermined	Roche/PTC Therapeutics	SMN2 splicing modifier (Oral)
prasinezumab/Product name undetermined	Roche/Prothena	Anti-α-synuclein monoclonal antibody (Injection)
Generic and product names undetermined	In-house (Roche)	— (Injection)
Generic and product names undetermined	Roche	— (Oral)
emicizumab/Hemlibra	In-house (Roche)	Anti-factor IXa/X bispecific antibody (Injection)
faricimab/Product name undetermined	Roche	Anti-VEGF/Ang2 bispecific antibody (Injection)
nemolizumab/Product name undetermined	In-house	Anti-IL-31 receptor A humanized monoclonal antibody (Injection)
Generic and product names undetermined	In-house (Roche)	Anti-C5 recycling antibody (Injection)
Generic and product names undetermined	In-house	PTH1 receptor agonist (Oral)
Generic and product names undetermined	In-house	— (Injection)

Note: In principle, completion of first dose is regarded as the start of clinical studies in each phase.

Through innovation, we create shared value that leads to corporate growth.

Chugai's Growth Strategies

Previous Mid-Term Business Plans

Sunrise 2012
(2008-2012)

Business environment

- Emphasis on unmet medical need
- Stronger pressure to contain healthcare costs

Formulation and launch of the "top pharmaceutical company" goal; sophistication of commercial activities to realize high growth and creation of new markets with innovative new drugs.

Strategies

- Strengthen portfolio management
- Exhibit strategic marketing functions
- Maximize Company-wide productivity

Quantitative guidance

2012 targets	Result
Revenues: ¥460 bn →	**¥391.2 bn**
Operating profit: ¥80 bn →	**¥76.4 bn**
Operating profit margin: 17.4% →	**19.5%**

ACCEL 15
(2013-2015)

Business environment

- Evolution of discovery technology
- Stricter drug approval requirements
- More severe impact from drug price revisions

Development and acquisition of strengths for early realization of the "top pharmaceutical company" goal and achievement of sustained growth through an emphasis on speed and innovation

Strategies

- Increase marketing productivity
- Accelerate global development
- Continuously generate innovative projects
- Further strengthen management infrastructure

Quantitative guidance

3-year target	Result
Core EPS[1] CAGR[2] (2012-2015): Mid to high single digit[3] →	**18.3%**[3]

IBI 18
(2016-2018)

Business environment

- Advances in life science
- Increasing difficulty of creating new drugs
- Fierce global competition

Transformation into a globally successful company through realization of the "top pharmaceutical company" goal

Strategies

- Acquisition and implementation of competitiveness at a top global level
- Selection and concentration strategy for acceleration of growth (Set 13 priority issues in 5 areas: Drug discovery, development, pharmaceutical technology, marketing & sales/ medical affairs/drug safety, and Company-wide)

Quantitative guidance

3-year target	Result
Core EPS CAGR (2016-2018): Low single digit[4] →	**17.1%**[3]

Chugai has established and implemented mid-term business plans with due consideration to changes in the external environment; the results of strategies, as well as the challenges encountered in their implementation; and the evolution of the Company's strengths. The strategies in each mid-term business plan were evolutionary and linked, and while we addressed higher-level issues, we achieved steady results on all of them and demonstrated strong execution.

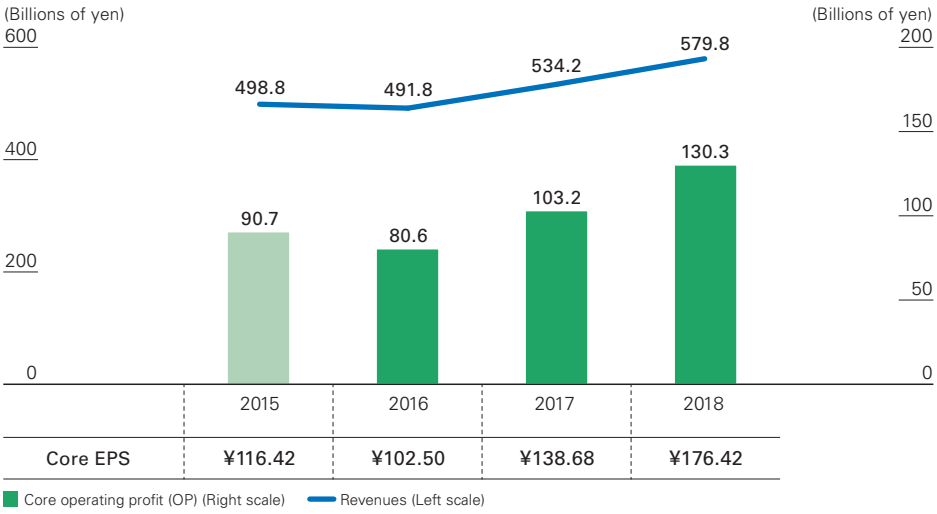
In the new mid-term business plan IBI 21, we will build on the value creation capabilities developed under our previous plans as we aim to create new value.

1. Diluted earnings per share attributable to Chugai shareholders on a core basis.
2. Compound annual growth rate
3. Based on average exchange rates for 2012
4. Based on average exchange rates for 2015

Context of the Formulation of IBI 21

Review of Previous Mid-Term Business Plan IBI 18

Business Performance during IBI 18



2015-2018 CAGR

Revenues +5.1%

Core OP +12.8%

Core EPS +14.9%

IBI 18 Target		Initial Target	Result	Status
	Core EPS CAGR (2015-2018)	Low single digit	17.1%	○

In IBI 18, the previous mid-term business plan, Chugai focused on two priority agenda objectives: acquiring and implementing competitiveness at a top global level and pursuing a selection and concentration strategy for acceleration of growth. We worked to evolve quickly in every function, and achieved overwhelming success as a result.

In drug discovery, we successively generated a number of antibody projects and strengthened our technology platforms, including for middle molecule drugs. Development operations produced a steady stream of launches and new indications. We also improved our structure for providing healthcare solutions.

Financially, we achieved strong growth in sales and profits, and surpassed our guidance for Core EPS CAGR by a wide margin. Key factors driving these results included a substantial increase in exports of Chugai products, including Alecensa, to the Roche Group, better-than-expected sales of Tecentriq in Japan, and an increase in one-time income partly from the transfer of long-listed products.

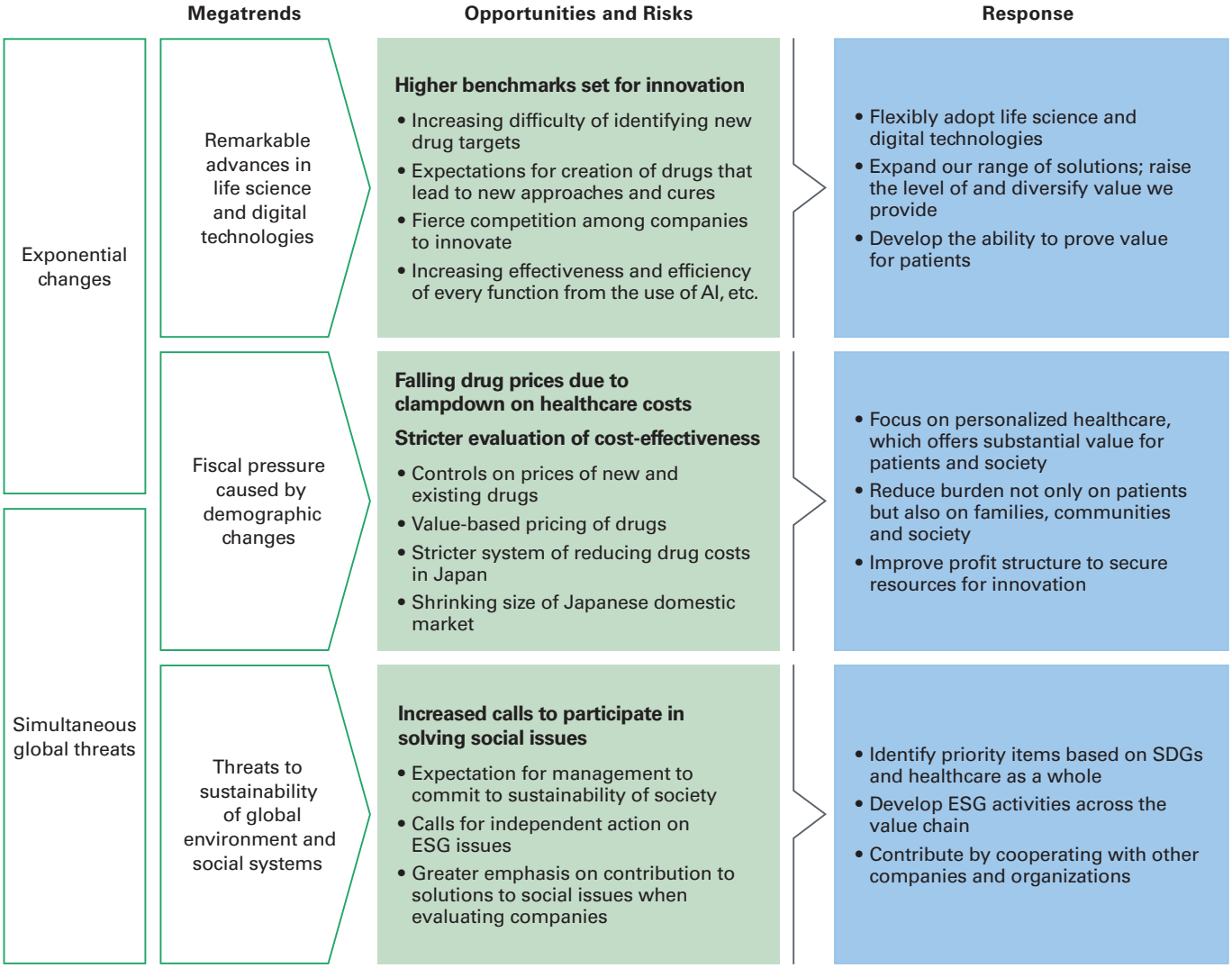
Summary of IBI 18

Achieving record high profit, Chugai is enriching its platforms for further growth

			Status
Financial targets		• Posted consecutive record revenues and operating profit • Achieved industry-leading market capitalization	○
Priority agenda	Acquisition and implementation of competitiveness at a top global level	• Continuously generated new antibody projects and enhanced drug discovery platform for middle molecules • Obtained early approval for Hemlibra • Obtained approval for Tecentriq and simultaneously developed drugs for 19 indications • Established system to manage FDA GMP* inspections • Established framework to execute regional strategy through collaboration of three Chugai divisions (Marketing & Sales/Medical Affairs/Drug Safety) • Made steady inroads towards accelerated growth based on Hemlibra and Tecentriq	○
	Selection and concentration strategy for accelerated growth		

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

Operating Environment



Chugai's operating environment is expected to change more rapidly than ever. Several megatrends will have a significant impact, including remarkable advances in life science and digital technologies, fiscal pressure caused by demographic changes due to population growth and aging populations worldwide, and threats to the sustainability of the global environment and social systems, including healthcare systems. In response to this changing landscape, Chugai has identified the most important opportunities and risks and determined the approaches it should take in response.

Advances in life science technologies and digital technologies are expected to lead to the discovery of new disease mechanisms and entirely new approaches to drug discovery. With competition among companies for innovation likely to intensify further, Chugai will have to flexibly adopt various technologies to achieve more diverse and sophisticated value creation.

Demographic changes are fueling growing pressure to rein in healthcare costs. In the future, only those products and services proven to have true value for patients will be selected, which will further raise the stakes for success or failure among pharmaceutical companies. Chugai will need to focus on initiatives that bring substantial benefits for both patients and the sustainability of healthcare, as exemplified by personalized healthcare. In addition to healthcare, the sustainability of the environment and social systems are also global challenges, and it is already accepted that companies should participate in addressing such issues, as indicated by the adoption of the U.N. SDGs. Chugai is taking a holistic view of healthcare and will actively work to solve social issues in collaboration with governments, the rest of our industry, and other parties.

Overview of New Mid-Term Business Plan IBI 21

IBI 21

INNOVATION BEYOND IMAGINATION

Quantitative Outlook

Core EPS CAGR
(2018-2021)

High single digit*

- We will make essential investment for future growth, while maintaining the momentum of growth achieved during IBI 18, and realize sustainable profit growth and expansion of corporate value.
- We will continue to target a Core EPS payout ratio of 50 percent on average.

* 3 years, based on constant exchange rate

New Mid-Term Business Plan: 5 Strategies

Create Global Growth Drivers and Maximize Value

Strategy 1: Value Creation
Realize innovative drug discovery to cure and manage diseases

Strategy 2: Value Delivery
Deliver patient-centric solution to maximize value of growth drivers

Strategy 3: Promote Advances in Personalized Healthcare (PHC)
Realize the further advancement of PHC and innovate R&D process by utilizing digital technology and data

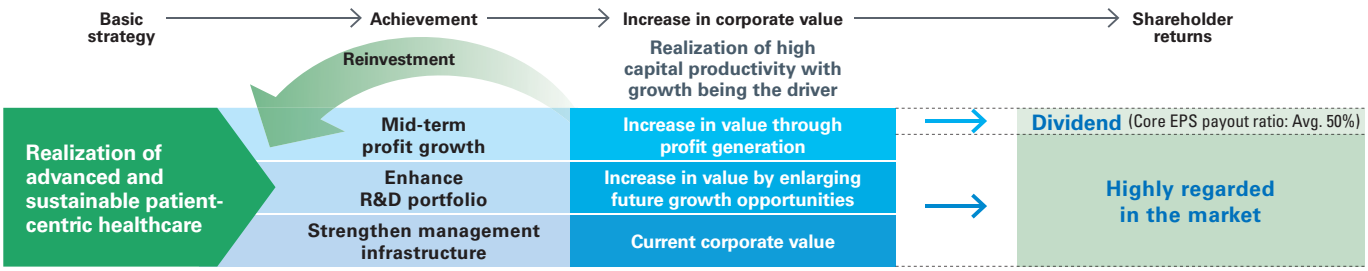
Strengthen HR and Infrastructure That Support Chugai's Business

Strategy 4: Strengthen Human Capital and Conduct Fundamental Structural Reform
Develop high-caliber HR talent that support innovation, and thoroughly reform costs, systems and processes

Strategy 5: Strengthen Sustainable Platforms
Simultaneously realize company growth and sustainable social development

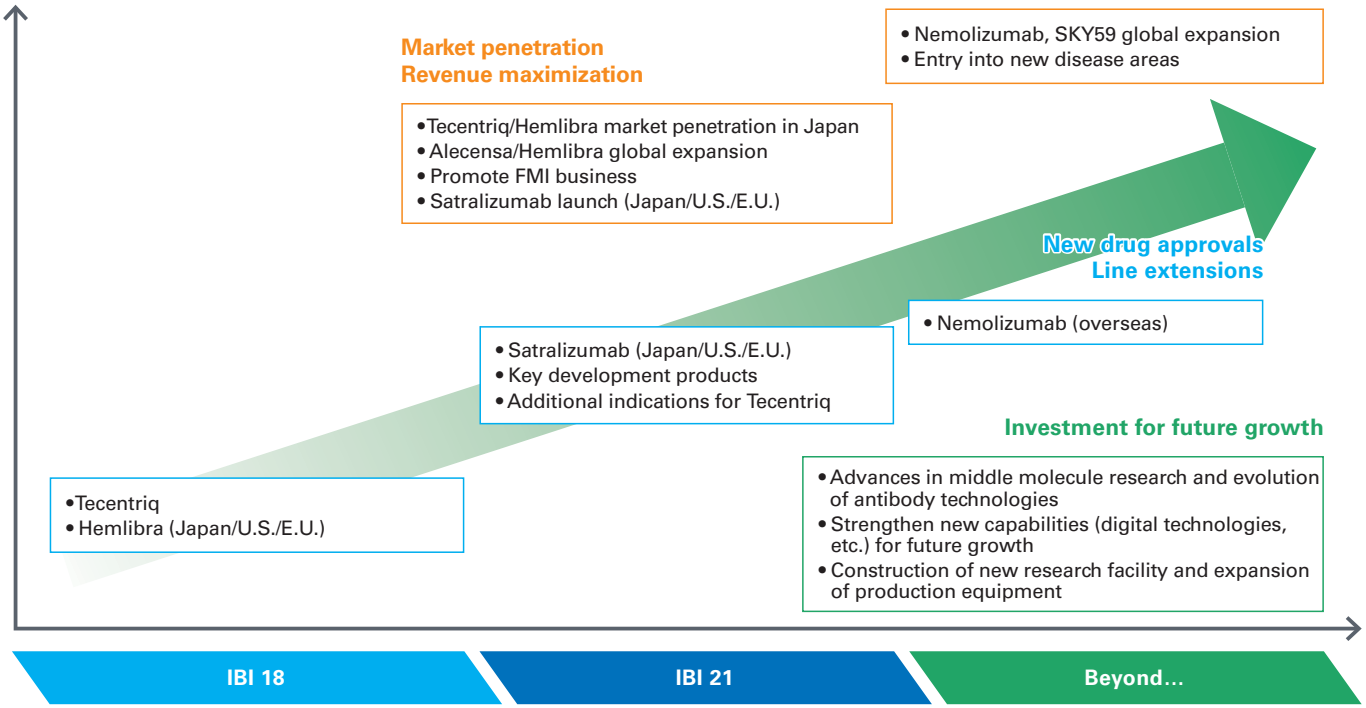
The name of the new mid-term business plan, IBI 21, expresses our commitment to pursuing continuous innovation based on "Innovation Beyond Imagination (IBI)," and the challenges we will take on at a new stage with "21." Based on five strategies, we aim to accelerate the advancement of society and Chugai by generating innovation focused on novel drugs. In quantitative terms, we are targeting a Core EPS CAGR in the high single-digit range (assuming constant exchange rates) for the three years of the plan, and will allocate resources and make management decisions with emphasis on profitability and capital productivity, including evaluation based on capital costs. Our policy on shareholder returns is to continue to aim for a dividend payout ratio of 50 percent of Core EPS on average to provide stable dividends, taking into account the balance between shareholder returns and the internal reserves necessary for increasing corporate value.

Basic Principles of Increasing Corporate Value and Shareholder Returns



IBI 21 Growth Outlook

In addition to market penetration of growth drivers in Japan and overseas, the approval and launch of satralizumab will support further growth.



Relationship of Strategies to Material Issues and SDGs

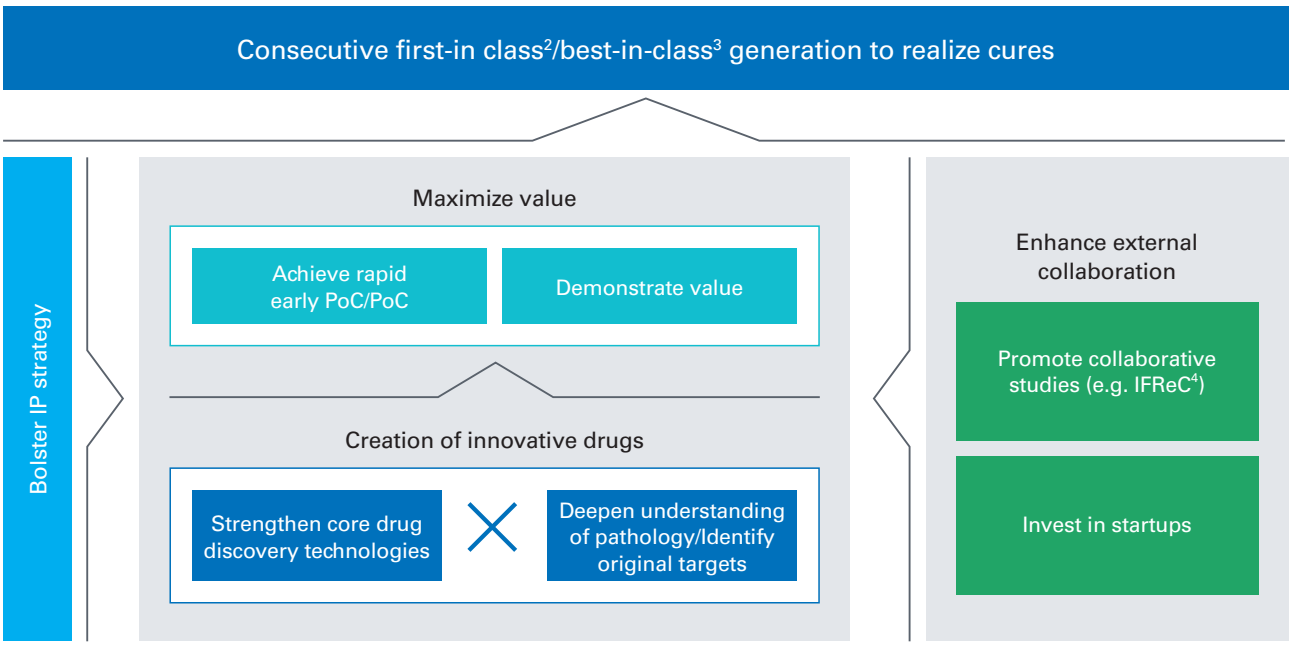
Five Strategies	Material Issues	SDGs
Strategy 1: Value Creation Strategy 2: Value Delivery Strategy 3: Promote Advances in PHC	• Creation of innovative drugs and services • Provision of solutions for patients • Fair marketing • Fair pricing • Adverse event management	
Strategy 4: Strengthen Human Capital and Conduct Fundamental Structural Reform	• Employee job satisfaction • Development of employee potential • Diversity and inclusion	
Strategy 5: Strengthen Sustainable Platforms	• Quality assurance and stable supply of products • Disclosure and dialogue • Improvement of healthcare access • Climate change countermeasures • Use of renewable/recycled resources • Protection of biodiversity • Environmental management system • Supply chain management • Human rights • Social contribution activities	

Strategy 1 ▶ Value Creation

Realize innovative drug discovery to cure and manage diseases by integrating our core drug discovery technologies and biology, and by achieving rapid proof of concept (PoC).

Strategic Points

- Strengthen core drug discovery technologies
- Deepen understanding of pathology/Identify unique targets
- Achieve rapid early PoC/PoC[1]
- Demonstrate value
- Bolster intellectual property (IP) strategy



1. PoC is confirmation 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.
2. An original drug that is highly novel and useful, and will significantly change the therapeutic system
3. A drug that offers clear advantages over other existing drugs in the same category, such as those with the same molecular target
4. Osaka University Immunology Frontier Research Center

Creation of Innovative Drugs

Continuous creation of innovative drugs is the core of Chugai's identity, and the driver of its growth. In our drug discovery operations, we have created a succession of new drugs by prioritizing investment in cutting-edge antibody engineering technologies. In addition to therapeutic antibodies and small molecule drugs, we have selected middle molecule drugs as the domain for our next-generation core drug discovery technology, and established the requisite technological infrastructure. In IBI 21, we will attempt drug discovery at a whole new level, with the theme, "Realize innovative drug discovery to cure and manage diseases."

At the same time, maintaining our technology-driven approach, we are aiming to achieve synergy by enhancing our understanding of biology. Our research thus far has shown the treatment limitations of drugs with only one mode of action, and that there are many diseases that have similar symptoms but completely different mechanisms. By gaining an even deeper understanding of biology, we can explore the potential for cure or full recovery from an earlier stage and identify original targets – it is here that Chugai's advanced technologies will play an even bigger role. According to Dr. Hisafumi Okabe, Executive Vice President in charge of Research and Translational Research, "We are setting the goal of curing and completely managing diseases that have been difficult to treat. To achieve that, we will conduct research to gain a deeper understanding of biology, advance our technologies, and bring about process innovations to build a stronger modality platform.[5]"

5. A drug discovery technology platform for small molecule, middle molecule, antibodies and other modalities

Maximizing Value

We will develop new drug candidates with world-class quality and speed. To that end, we will work to achieve PoC as quickly as possible by refining our development process, and will make full use of our translational research organization with bases in three regions – Japan, the United States and Europe – as well as Roche's network. By doing so, we will continuously create innovative drugs with the potential to become next-generation growth drivers. At the same time, it is predicted that only those products and services that offer true value for patients will be selected. Therefore, in IBI 21, we will place emphasis on proving the value of the drugs we develop. That effort will involve establishing a system for collecting, analyzing and managing various data from the development stage to prove the value of our products for patients, including in areas such as quality of life and healthcare economics.

To deliver such innovative new drugs to patients as quickly as possible, Chugai will enhance its systems for accelerated development and product supply, with emphasis on the further evolution of manufacturing technologies to handle R&D projects for drugs with highly complex formulations, such as middle molecule drugs. Chugai will also continue striving to enhance quality control, quality assurance and regulatory functions in accordance with global standards.

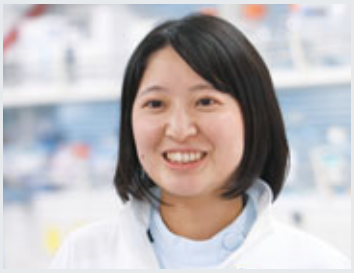
Strengthening Our IP Strategy and Accelerating Open Innovation

In conducting discovery research and clinical development, one of our competitive strategies is the application of intellectual property rights, including technology patents, and we will work to strengthen this process. We will also generate new opportunities from outside the Chugai Group through joint research with IFReC and other research organizations in Japan and overseas, and the establishment of external networks, including investment in startups.

By developing innovative drug discovery technologies and deepening our understanding of diseases, we are striving for healthcare that cures patients or allows them to not worry about their disease from day to day. We will improve our predictions of clinical efficacy, accelerate development speed and carry out development that generates evidence for improved patient quality of life.

Hisafumi Okabe
Executive Vice President
In charge of Research and Translational Research

I want to deliver innovative new drugs that help patients live fuller lives. To create next-generation medicines not possible with existing therapeutic antibodies or small molecules, we will further strengthen our core drug discovery technologies by harnessing our proprietary engineering technologies and ability to work as a team.



Miho Funaki
Discovery Biologics Group 3,
Discovery Biologics Dept.

Strategy 2 ▶ Value Delivery

Maximize value of growth drivers (innovative drugs and services) through patient-centric consulting and enhanced digital solutions.

Strategic Points

- Maximize value of growth drivers
- Work to realize patient-centric healthcare
- Provide effective and efficient solutions

Maximize value of growth drivers

Promote FMI business in Japan

Provide solutions through collaboration among a variety of specialists and integration of digital technology

Deepen three-division collaboration and deliver sophisticated consulting × Advancement of treatment support/ solutions utilizing digital technology

Additional value to realize personalization and differentiation

High-quality evidence including real-world evidence

Real-time safety information

Innovative drugs/services such as Hemlibra/Tecentriq

Maximizing Value for Patients

Making a contribution to patients involves more than simply supplying medicines. To ensure that those medicines are used appropriately, it is also essential to accurately inform healthcare providers about their value and provide comprehensive safety information so that doctors and patients can feel confident in using them. At Chugai, the divisions in charge of these functions – Marketing & Sales, Medical Affairs and Drug Safety – collaborate with each other to provide sophisticated and diverse solutions.

In Japan, Chugai has built a solid presence in the fields of oncology, renal diseases, bone and joint diseases, and rheumatoid arthritis, among others, and holds a leading share in the hospital market. In IBI 21, we will develop solutions in these fields at a higher level to realize advanced and sustainable patient-centric healthcare, taking into consideration Chugai's role and changes in society. "In the future, healthcare as a whole will be seen as an ecosystem in which various stakeholders converge as one community that shares the goal of maximizing value for patients," says Dr. Osamu Okuda, Executive Vice President and Co-Head of the Project & Lifecycle Management Unit. "The quality of the solutions Chugai provides as part of that ecosystem will also have to evolve to deliver true value to patients."

Acceleration of Growth Drivers

IBI 21, a plan designed to maximize the value of growth drivers by meeting the increasingly sophisticated and diverse needs of stakeholders in healthcare, includes measures for strengthening the incorporation of digital technology in response to technological advances. These efforts will focus specifically on new products and growth drivers including Tecentriq, Hemlibra and satralizumab (SA237). We are also looking to cooperate with Roche in the launch of Hemlibra and Edirol in China, which will further accelerate growth.

Advancing the Delivery of Effective and Efficient Solutions

Accordingly, in its value delivery strategy, Chugai will work to provide more sophisticated solutions through collaboration with various specialists and the integration of digital technology.

In medical affairs, in addition to continuing post-marketing clinical studies, we will generate high-quality evidence, including evidence derived from real-world data (RWD), to enhance the value of drugs for patients. In the field of drug safety, we will combine RWD from clinical settings with our existing post-marketing surveillance and safety information database tools to ensure the most up-to-date data and generate a visual image of safety evidence, enabling more effective solutions for healthcare providers. In marketing and sales, on the basis of these various forms of data, we have developed a database tool that is adaptable to local healthcare delivery systems, and we will use it to propose treatment plans optimized for each patient.

Along with these actions, we will develop the FMI business to promote cancer genomic medicine in Japan as an initiative for realizing advanced and sustainable patient-centric healthcare. See page 47 for details on the FMI business.

In the changing healthcare landscape, Chugai must create and deliver value at a higher level. We will grow by sharing value not only with patients, healthcare providers and medical institutions, but also with patients' families, local communities and governments.

Osamu Okuda
Executive Vice President
In charge of Project & Lifecycle Management (Marketing), Foundation Medicine, Corporate Planning and Co-Head of Project & Lifecycle Management Unit

Today, tomorrow and onward, I want to deliver innovative drugs to more and more patients! Giving top priority to the wellbeing of each patient, I will help to create patient-centric healthcare by providing high-value-added information.

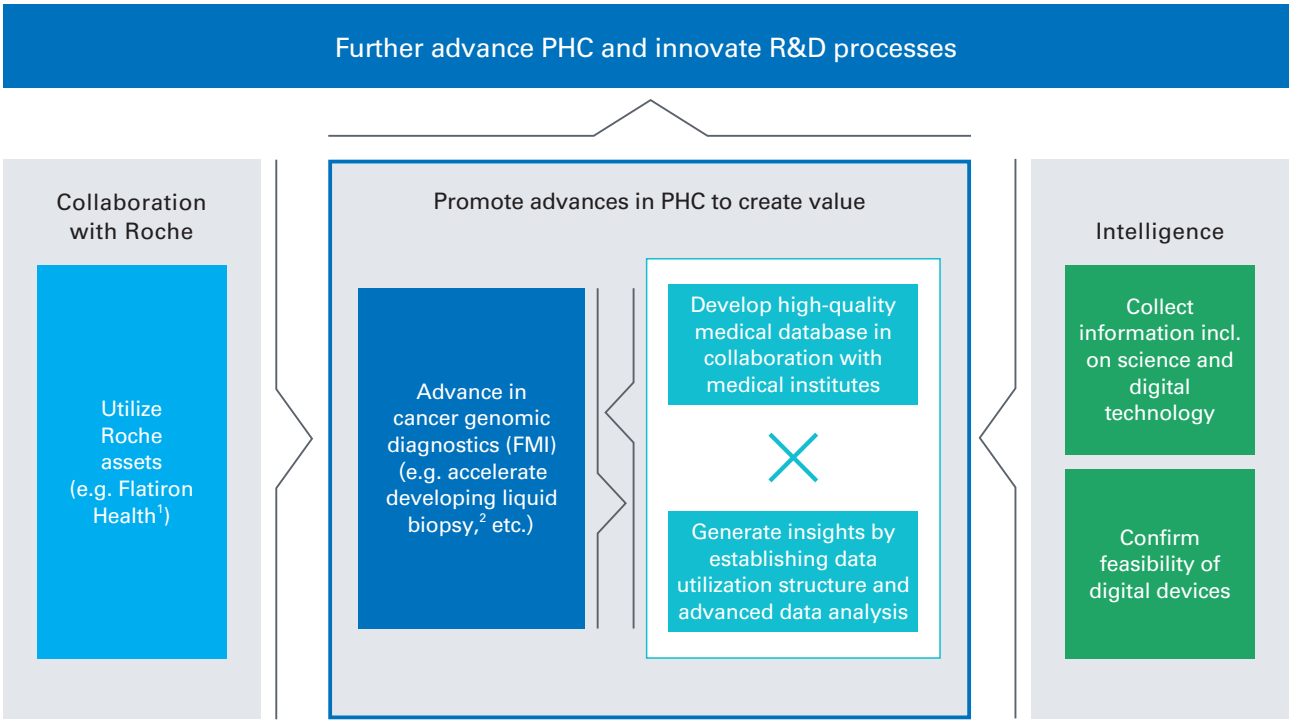
Maki Murata
Branch Manager, Atsugi Branch, Kanto-Minami Regional Management Office, Marketing & Sales Div.

Strategy 3 ▶ Promote Advances in PHC

Realize further advancements in personalized healthcare (PHC) and innovate R&D processes by utilizing digital technology and data.

Strategic Points

- Enable patient-centric PHC
- Establish a digital intelligence platform



1. A company that provides oncology-specific electronic health record systems and has a comprehensive database developed in collaboration with medical institutions. It became a member of the Roche Group in 2018.
2. Unlike a conventional biopsy, which uses an endoscope and needle to take a tissue sample, liquid biopsy is a technology that uses blood or other body fluid samples to make a diagnosis and a prediction of therapeutic response.

Enabling Patient-Centric Personalized Healthcare

Personalized healthcare (PHC) offers value for patients, healthcare finances and society because treatments are given only to patients who will benefit from them. PHC is the main approach for realizing advanced and sustainable patient-centric healthcare.

PHC has continued to advance in recent years, backed by dramatic progress in genomic medicine and data analysis technology. Chugai's FMI business is part of that progress. Moreover, the evolution of digital devices and other developments have made it possible to obtain an immense amount of patient information in a timely manner, and to rapidly quantify a wide range of benefits for patients, including aspects such as quality of life in addition to the conventional yardsticks of drug efficacy and safety.

In that context, as a member of the Roche Group, a global leader in PHC, and as a pioneer of PHC in Japan, Chugai will focus on promoting the next stage of PHC to provide the best treatment for each patient. In close cooperation with government and academia, and in collaboration with the Roche Group, including Flatiron Health, Chugai will help establish a comprehensive database for healthcare providers. Speaking about this initiative, Dr. Yasushi Ito, Executive Vice President and Co-Head of the Project & Lifecycle Management Unit, says, "Through the promotion of advances in PHC we want to enable patients to live better-quality lives."

Promoting Cancer Genomic Diagnostics (FMI Business)

To accelerate its contribution to PHC through cancer genomic medicine, in October 2018 Chugai established a specialized unit for FMI business that uses the technology of Roche Group member Foundation Medicine Inc. (FMI).

"FoundationOne® CDx Cancer Genomic Profile (F1CDx)," for which we obtained regulatory approval in December 2018, is a system for comprehensive cancer-related genomic profiling using next-generation sequencing. The system detects alterations in 324 cancer-related genes in a single operation using DNA obtained from a solid tumor, which enables the dual functionality of comprehensive genomic profiling and companion diagnostics for anticancer drugs. Chugai will work toward advancements in PHC (strategy 3) by expanding use of this product and accelerating its development for liquid biopsy.

Establishing an Intelligence Platform Based on Digital Technology

To make effective use of the vast information in the database, it will be necessary to create a data utilization structure in cooperation with medical institutions and other outside organizations, as well as to utilize AI and acquire sophisticated data analysis technology. Chugai will collaborate with Preferred Networks, Inc., with which it entered into a comprehensive partnership in 2018, and plans to rapidly acquire capabilities by hiring and developing specialists and investing resources in technology upgrades.

Through initiatives utilizing these digital technologies and data, we will also work actively on innovation in research and development processes, including more efficient identification of drug discovery targets and target molecules and use of RWD to streamline the clinical development process.

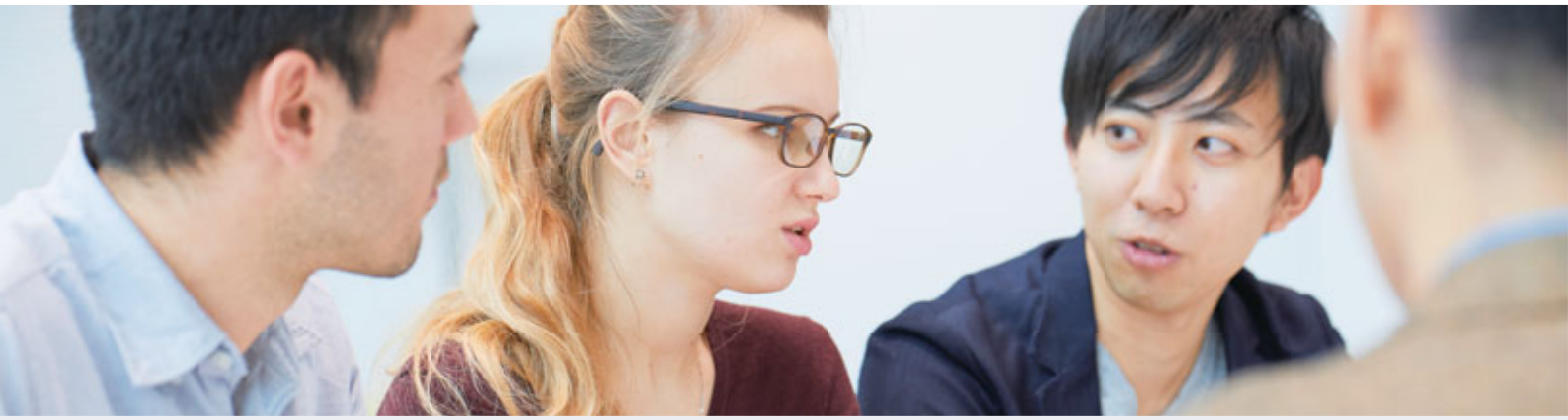
Based on our long-standing commitment to properly delivering effective medicines to patients, and by combining various types of data, we will be able to quantify and prove the value of those medicines, and share that value with society. We are working to build a structure for collecting, analyzing and managing data within the company for that purpose.

Yasushi Ito
Executive Vice President
In charge of Project & Lifecycle Management (R&D), Regulatory & Quality Management, Clinical Development, Drug Safety and Medical Affairs and Co-Head of Project & Lifecycle Management Unit

The FMI business provides cancer patients with access to appropriate treatments. By increasing the footprint of this service, we will be able to improve treatment outcomes, contribute to cancer genomic medicine, and bring about precision medicine.

Kosuke Iijima
Department Manager, Foundation Medicine Business Dept.

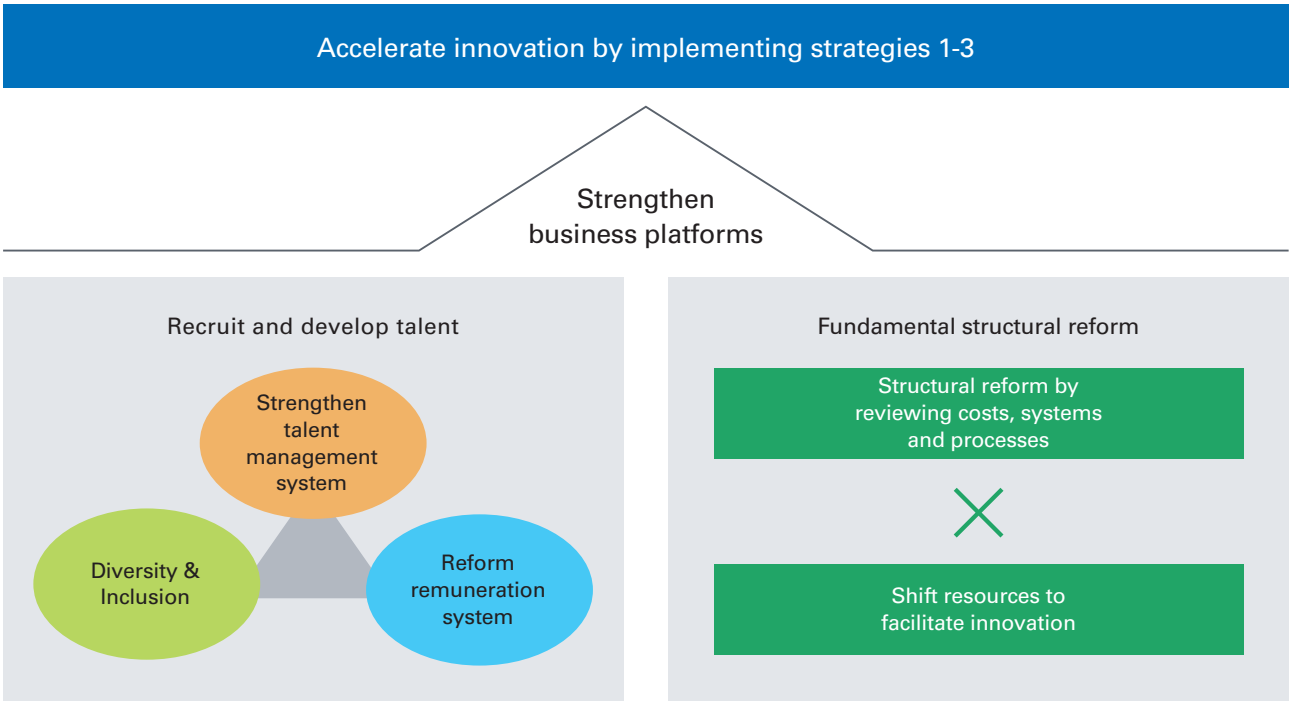
Strategy 4 ▶ Strengthen Human Capital and Conduct Fundamental Structural Reform



Recruit and develop diverse and high-caliber talent that supports innovation, and conduct fundamental structural reforms.

Strategic Points

- Develop and recruit talent from a mid- to long-term perspective
- Shift to a robust profit and cost structure



Developing and Recruiting Talent from a Mid- to Long-Term Perspective

At Chugai, our people are an invaluable asset that drives the company's growth and progress. Talent management is a key management theme for the pursuit of innovation.

In IBI 21, we are placing importance on recruiting, developing and assigning diverse, high-caliber human resources who will drive innovation and respond to the rapidly changing business environment as we implement strategies 1-3 described above. We will further strengthen human resource management with a medium- to long-term view. Shinya Unno, Executive Vice President in charge of Human Resources Management, explains Chugai's upcoming human resource strategy: "For Chugai, where innovation is the key to value creation, it is important to be a great place to work, a place where every employee can work in good health, gain a sense of satisfaction, and continue to produce results. Our strategy will revolve around strengthening talent management, transforming our organizational culture, and accelerating diversity and inclusion."

Specifically, we have revised human resource requirements, and will vigorously promote position management to assign the right leaders to the right positions, as well as talent management, including succession planning. In addition, we will recruit specialists who can play key roles in implementing strategies; shift to more flexible personnel and remuneration systems to support a corporate culture that embraces challenge; and further promote diversity and inclusion. Through these measures, we will foster an organizational culture that is conducive to innovation, and encourages the active participation of diverse employees.

In implementing the PDCA cycle in our human resource strategy, we will also change our approach to the employee surveys we have been conducting. In our formulation of IBI 21, we conducted a survey to identify human resource issues. The survey showed that our management system for implementing strategies and our level of employee engagement were at a high level compared to other global companies, but also that our work environments and organizational culture, though comparing favorably to our domestic competitors, still showed room for improvement at the global level. We will therefore focus on shifting to an organizational culture conducive to innovation throughout the company, and link that with implementation of IBI 21 to set detailed organizational reform tasks for each division and implement the PDCA cycle.

Transforming Our Profit Structure by Conducting Fundamental Structural Reform

Looking at carrying out the strategies of IBI 21 from a financial perspective, as financial pressure increasingly undermines the business environment for pharmaceutical companies, transforming cost structures will be critical to enable the concentration of resources on innovation. At Chugai, we have taken various measures that allow us to concentrate our finite resources on innovation, including productivity improvements aimed at reducing the expense ratio and the transfer of business rights of 13 long-term listed products in 2018, but we will make further improvements under IBI 21 to achieve greater profitability. We will reorganize systems, significantly reform our business processes and cost structures, and take firm steps to streamline operations, including the introduction of robotic process automation (RPA).* This will allow us to simultaneously achieve flexible investment in innovation and sustained profit growth. (See "Message from the CFO" on pages 52-55 for more details on Chugai's structural reforms.)

* Automation of routine office work

Our greatest resource in generating innovation for value creation is our people. Especially given the broadening scope of the value created by Chugai, we hope to produce many talented employees who can effectively collaborate with a wide range of outside organizations and companies in other industries.

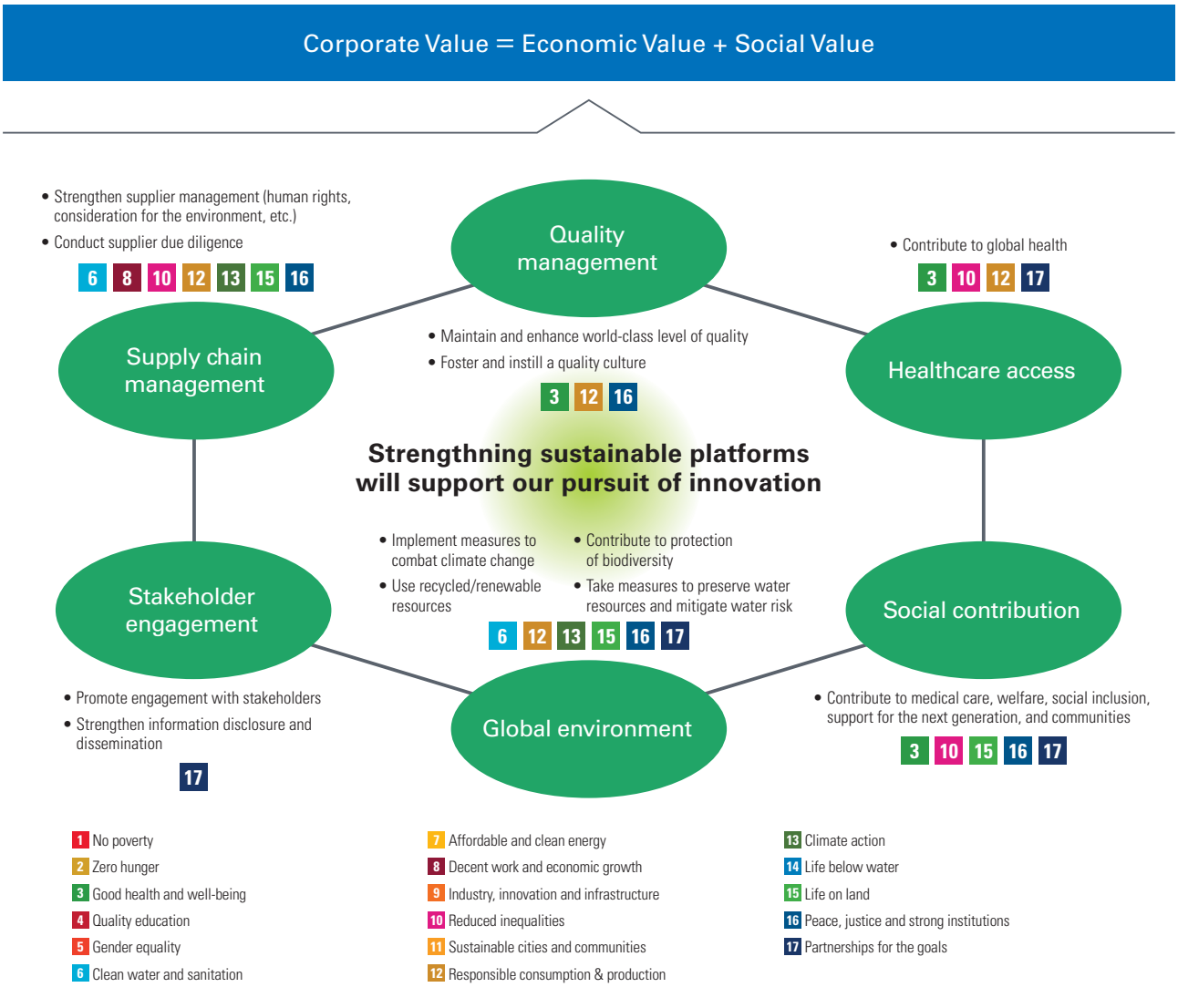
Shinya Unno
Executive Vice President
In charge of Human Resources Management, Human Capital Development, Legal, General Affairs and Secretarial and General Manager of Human Resources Supervisory Div., in charge of General Affairs Dept. and Secretarial Dept.

I have been devising and promoting a Company-wide digital strategy, and supporting structural and process reforms. This will help us to optimize efficient resource allocation across Chugai in our pursuit of innovation, while establishing the internal platforms for continuing to provide patient-centric, innovative healthcare.

Taro Sekizawa
Strategic Planning Group, Corporate Planning Dept.

Strategy 5 ▶ Strengthen Sustainable Platforms

With the aim of improving corporate value continuously, we have specified six priority areas that support our challenge toward innovation, based on expectations and requests from society, Chugai's impact on the economy, society and environment, and stakeholder interest.



Sustainable Platforms for Creating Shared Value

To achieve its Mission of benefiting the medical community and human health around the world, Chugai conducts its business in line with its Core Values[1] and the Chugai Group Code of Conduct.[1]

Today, however, companies are being asked to take a more active role in solving social issues because of threats to the global environment and the sustainability of social systems. Accordingly, Chugai has specified material issues for value creation with the goal of creating shared value with stakeholders. These are the key issues we need to address in order to simultaneously achieve company growth and the sustainable development of society. We have established them as sustainable platforms to support innovation. (See "Process for Establishing Material Issues" on page 26 for more information.)

Material Issues in Six Categories

In IBI 21, we will work in the following six areas to enhance sustainable platforms.

1) In **quality management**, we will maintain and enhance our world-class level of quality, a key factor in the value of our products and services. In addition, we will foster and champion an organizational culture that is dedicated to the "quality" of value in every function.

2) In **supply chain management**, in addition to our ongoing efforts to ensure stable supplies and quality management, we will focus on supplier management in the areas of human rights and the environment. As there is room for improvement among suppliers overall in terms of human rights, we will conduct supplier due diligence in line with the human rights policy we announced in 2019.

3) **Healthcare access** is an area of particular emphasis in IBI 21. Up to now, we have contributed to global health through the GHIT Fund[2] and Access Accelerated,[3] but we intend to expand our activities. As Keiji Kono, Senior Vice President in charge of Global Health Policy, explains, "Chugai's innovative products have made a broad contribution to patients around the world in more 90 countries. However, access to healthcare coverage is a serious issue, particularly in low- and middle-income countries. Specific issues vary by country and region, so we will leverage Roche's network and collaborate with international organizations, NGOs and other groups to develop activities that are precisely targeted to each issue."

4) In **social contribution**, we will clarify the areas in which Chugai is active, and focus on activities suited to Chugai in order to contribute to medical care, welfare, social inclusion, support for the next generation, and communities.

5) For the **global environment**, we will actively contribute to measures to combat climate change, an issue of serious global concern, as well as increase the use of renewable and recycled resources and protect biodiversity. In addition, we will work to mitigate water risk and preserve water resources, which are especially critical to the pharmaceutical industry.

6) In **stakeholder engagement**, we believe that engaging with individual stakeholders more actively is a central part of our drive to create shared value. Other priorities will include strengthening disclosure and information dissemination, two-way communication, and creating new dialogue opportunities.

1. Both were revised in 2019.
2. A public-private partnership to support research and development of pharmaceuticals, vaccines and diagnostics for serious infectious diseases in developing countries. It utilizes Japan's medical technology, innovation and knowledge more directly. (https://www.ghitfund.org/)
3. A global partnership launched by 22 major pharmaceutical companies that focuses on prevention and care of non-infectious diseases (http://www.accessaccelerated.org/)

The scope of Chugai's contributions to global health is expanding as the Company grows through a focus on innovation. We are working to conduct activities that will enable us to contribute to sustainable improvement of healthcare coverage centered on low- and middle-income countries by leveraging our capabilities (our strengths, technologies and expertise).

Keiji Kono
Senior Vice President
In charge of External Affairs Dept.
and Global Health Policy

The Sustainability Dept. will spearhead activities to build a more inclusive society. This will entail developing Company-wide systems for resolving social issues, including those relating to the environment and human rights, in order to create value shared by Chugai and society, as stated in our Basic Policy.

Shigehiro Yamada
General Manager,
Sustainability Dept.[4]

4. Name changed from Corporate Social Responsibility Department as of April 1, 2019

Message from the CFO

By pursuing a higher level of profitability and productivity, we will secure the financial resources for innovation and reinvest them in drug discovery that helps solve social issues.

Toshiaki Itagaki
Executive Vice President & CFO
In charge of Finance & Accounting, Corporate Communication, Information System and Purchasing

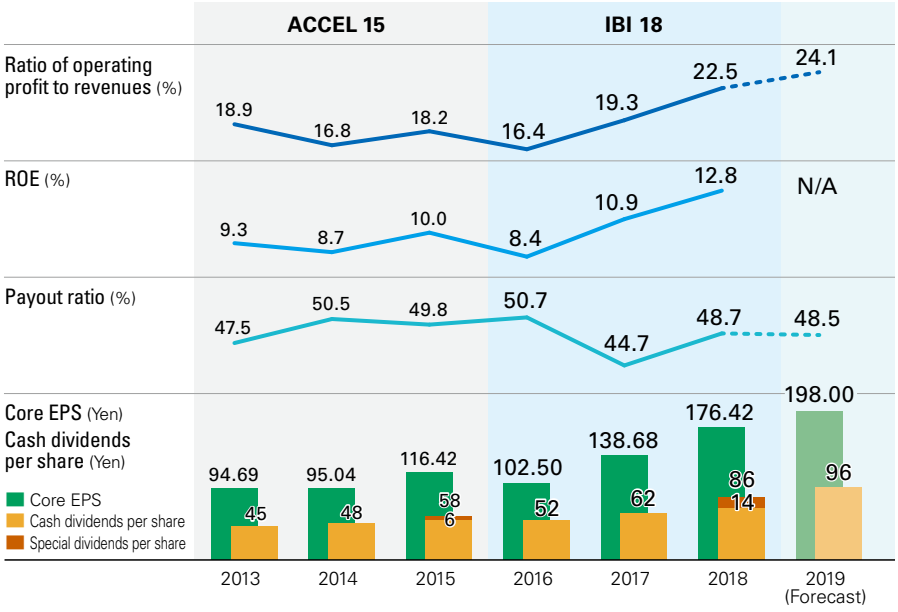
On a Strong Growth Track, But Level-Headed Analysis is Necessary

In the three years of our previous mid-term business plan IBI 18, Core EPS CAGR, our financial KPI, was 17.1 percent, well above our target of low single-digit growth (3 percent range based on constant exchange rates). Earnings were strong, with record-high revenues, operating profit and net income for two consecutive years. We saw steady increases in the ratio of operating profit to revenues (the operating margin) and return on equity (ROE), signifying substantial improvement in our profitability and capital productivity. This strong growth momentum also gave employee confidence a major boost.

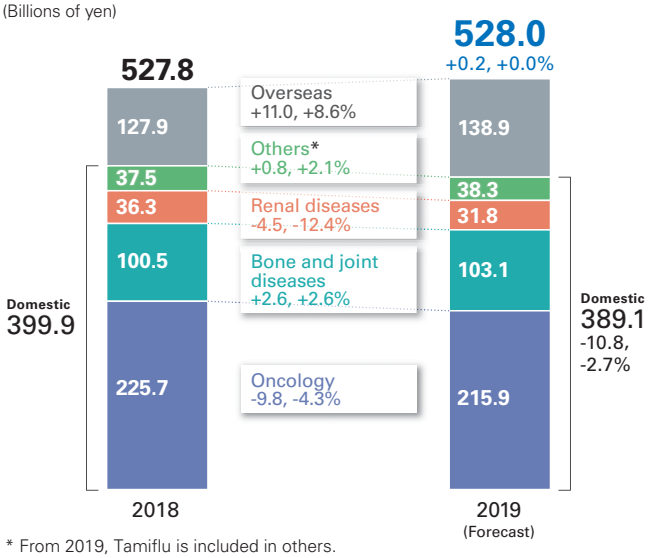
However, we cannot allow ourselves to become complacent. Level-headed analysis is needed. The primary reason we exceeded our financial targets is the growth of Chugai products Actemra, Alecensa and Hemlibra. These global products became growth drivers that expanded our export business. We expect them to continue to drive earnings. On the other hand, our domestic revenues outperformed the plan partly because of the delay of drug price revisions in connection with the increase in the consumption tax rate that had been scheduled for 2017, as well as one-time income from the transfer of long-term listed products. These non-recurring factors must be discounted.

In our domestic business, which faces an increasingly challenging market environment, several issues have become apparent. In 2018, the premiums for new drug creation for Herceptin and Rituxan had to be returned, and biosimilars entered the market. As a result, revenue growth in

Financial Indices



2019 Sales Forecast
(Billions of yen)



* From 2019, Tamiflu is included in others.

Sales Forecast **Year-on-Change**
(Billions of yen/%)

Overseas		
Alecensa	36.6	+7.1 (+24.1%)
Actemra	84.6	+4.0 (+5.0%)
Others		
Hemlibra	12.9	+9.9 (+330.0%)
Tamiflu (govt. stockpiles)	3.2	+2.7 (+540.0%)
Tamiflu (ordinary)	3.4	-6.7 (-66.3%)
Renal diseases		
Mircera	20.5	-2.6 (-11.3%)
Oncology		
Perjeta	21.2	+5.1 (+31.7%)
Alecensa	25.1	+4.5 (+21.8%)
Tecentriq	13.1	+4.0 (+44.0%)
Tarceva	5.6	-2.7 (-32.5%)
Xeloda	9.4	-3.1 (-24.8%)
Herceptin	24.0	-4.1 (-14.6%)
Avastin	89.4	-6.2 (-6.5%)
Rituxan	13.5	-7.8 (-36.6%)

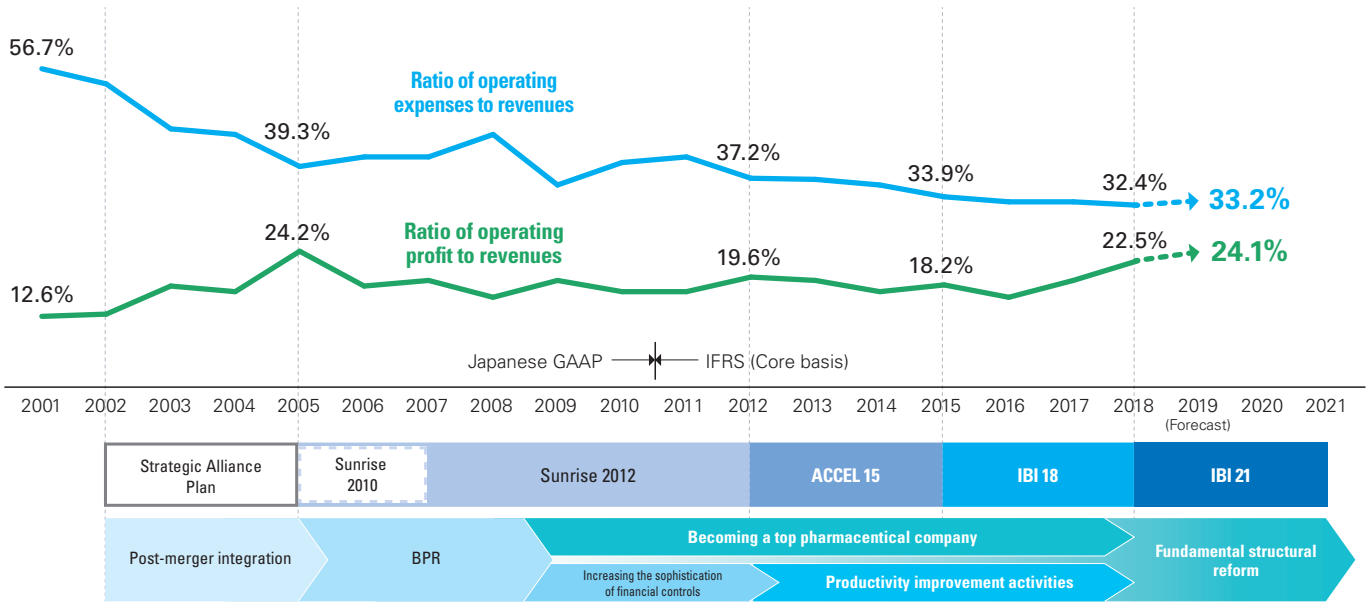
Japan was negative as increased sales volume did not fully offset the effects of drug price reductions and other factors, and we project that sales will decrease again in 2019. Other mainstay products that have contributed to growth up to now are also expected to face similar circumstances over the next few years. We will have to confront the increasing and intensifying severity of the domestic environment, and are nearing a crucial stage.

Structural Reform and Business Process Improvements Remain Essential

Chugai's business model based on the strategic alliance with Roche has two engines. One is the revenue base in which we supply breakthrough drugs discovered by Chugai to the world using the Roche Group's infrastructure. The other is the revenue base in which we sell Roche products on an exclusive basis in Japan, along with Chugai products. We have swiftly increased the horsepower of the first engine. We need to preserve the horsepower of both engines evenly to maintain their driving force, which enables us to push forward with innovation.

After the strategic alliance agreement, Chugai reduced the number of operating bases and divested non-pharmaceutical businesses. Since then, we have continued to implement cost optimization initiatives, including business process reengineering (BPR) and productivity improvement. The sales growth of Chugai products,

Performance and Efforts



particularly the expansion of exports to Roche, has boosted profitability, and Chugai's ratio of operating profit to revenues is now higher than the domestic industry average. Nevertheless, in order to continuously create innovative new drugs and services, we must achieve a higher level of profitability and productivity so that we can continue to generate cash for investing in innovation.

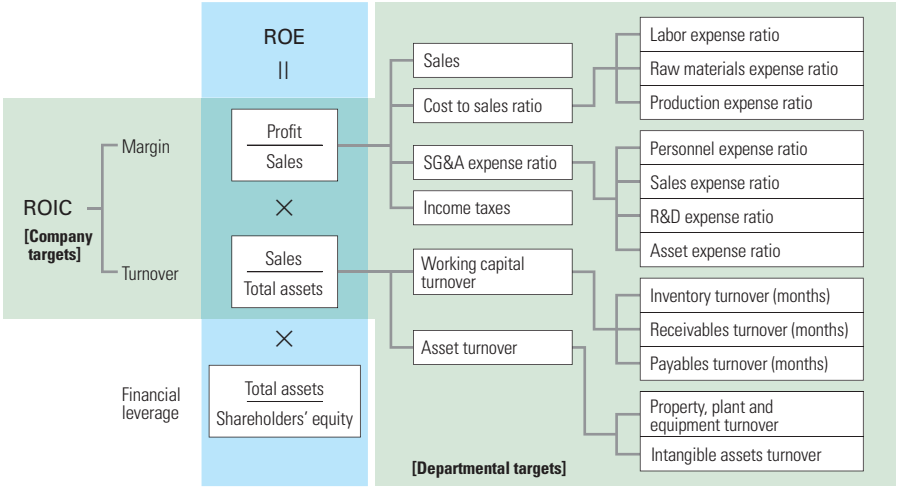
Accordingly, one of the strategies of IBI 21 is fundamental structural reform aimed at maintaining and improving the profitability and productivity of our domestic business. To that end, we will stay ahead of trends in the market environment, and conduct a complete review of systems, organizations, processes and resource allocation. In addition, we will work to improve productivity and increase liquidity costs with measures such as business automation using RPA and other ICT systems, as well as improvement of operational efficiency through shared services and business process outsourcing, and improvement of workflow utilizing AI and data.

A Financial KPI Based on Our Business Model

In recent times, ROE has been emphasized in Japan from the standpoint of governance, but Chugai does not use ROE as a target KPI. A large portion of our business is biopharmaceuticals, which have a relatively lengthy manufacturing process, and we are required to hold adequate safety stock to fulfill our duty of providing reliable supply. For these reasons, there are certain limitations on increasing turnover. In addition, to maintain our independent management in our alliance with Roche, we must keep Roche's equity share within a certain range, so it is difficult for us to reduce shareholders' equity with share buybacks and treasury share cancellation. Therefore, of the three components for raising ROE – profit margins, turnover and financial leverage – increasing margins in our core business is our main approach. The best indicator of sustained growth in absolute terms from the viewpoint of shareholders is Core EPS CAGR. We publicly disclose our target for Core EPS CAGR as our financial commitment.

Of course, we place priority on cost of capital. In developing mid- to long-term business plans, we set out our strategy by clarifying the gap between our targets and current conditions considering the capital spread. In assessing the business feasibility of investments and development projects, the concept of cost of capital is also built into our internal management decision-making processes and mechanisms in ways such as discounting present value at the WACC.[1] In addition, because of the need to consider both stock and flow, we began using ROIC[2] as an internal KPI in 2019. Goals cascade from Company-wide targets to division targets, and we are shifting to measurement management that gives greater consideration to investment efficiency and cost of capital.

Relationship between ROE and ROIC; ROIC Tree for Departmental Operations



Focusing Resources on Investment in Innovation

In the creation of innovative drugs and services, it will be increasingly essential to achieve world-class quality. We have to prioritize investment allocation to ensure that funds do not run out. We will increase our investments in artificial intelligence, ICT and acquisition of real-world data. Investment in open innovation – alliances with academia and startups – will also be needed. Projects already under way include R&D using deep learning technology with Preferred Networks, Inc., and a data utilization project. Data utilization requires a considerable investment to build the infrastructure for integrating and coordinating internal and external data, and to acquire data analysis technology. We are also expanding our research in collaboration with Osaka University Immunology Frontier Research Center (IFReC), and we have decided to invest an additional SGD 282 million over the next five years in Chugai Pharmabody Research (CPR), our Singapore subsidiary that specializes in antibody research.

During IBI 18, we focused investment mainly on manufacturing facilities, but during IBI 21, we will ramp up investment in the area of drug discovery. Besides the investments I have already mentioned, a new synthetic research building is under

1. Weighted average cost of capital; the most common method of calculating cost of capital. The weighted average of the cost of borrowing money and the cost of raising funds through equity.
2. Return on invested capital; indicates how efficiently a company uses capital invested for business activities (invested capital) to generate profit.

construction at the Ukima Research Laboratories. Moreover, in 2019 we will construct a new research laboratory on a 170,000 m² site in Yokohama, Kanagawa Prefecture that we acquired at the end of 2018.

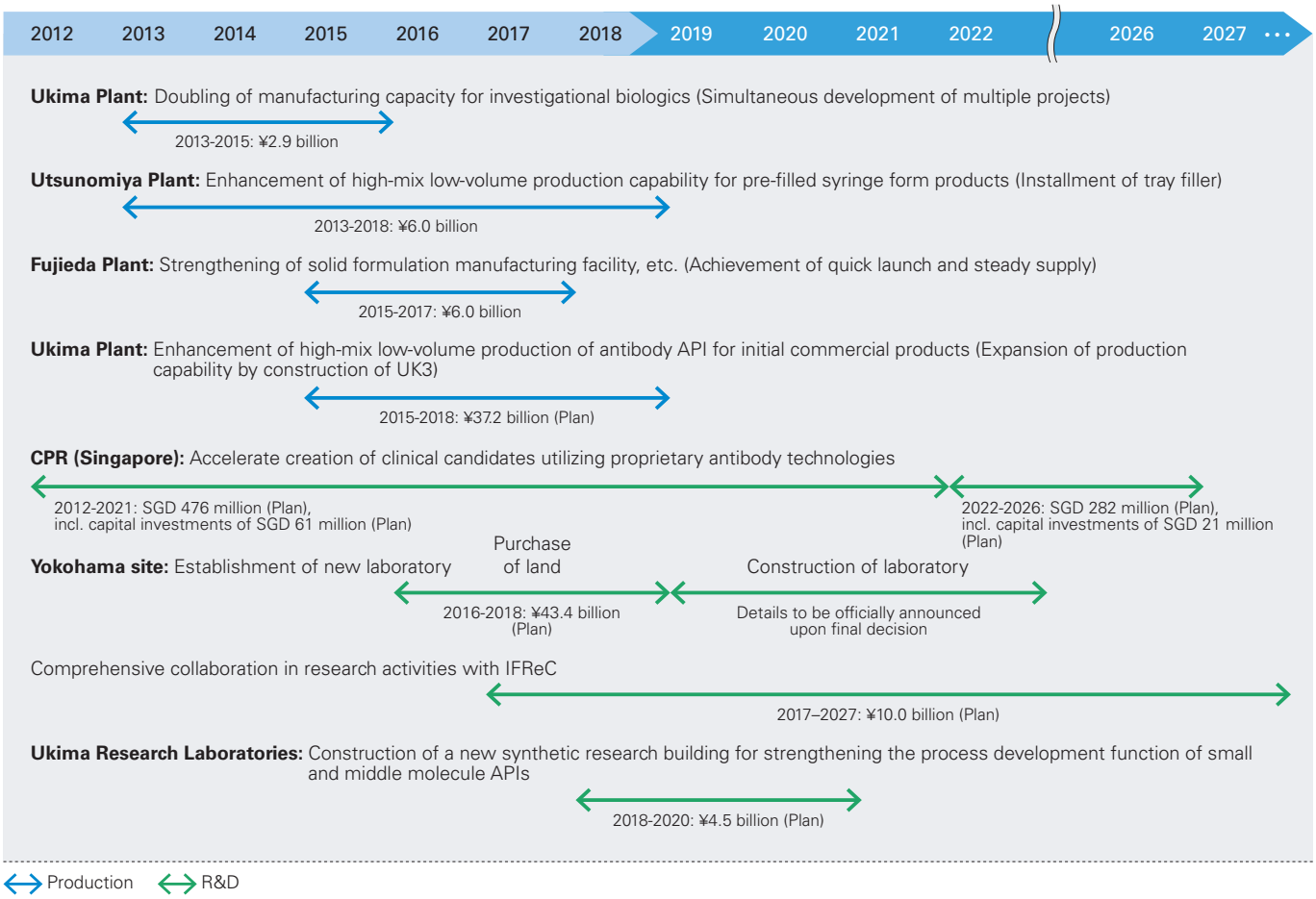
What makes these investments in intellectual capital for future value creation possible is the profit and cash inflow from our highly efficient and productive sales activities. In allocating that profit, we try to maintain a good balance between internal reserves that serve as investment resources and returns to shareholders. Our dividend policy is to deliver stable dividends with a target Core EPS payout ratio of 50 percent on average.

Deepening Dialogue with Society from the Perspective of Shared Value

Meeting the expectations of stakeholders by creating innovative pharmaceutical products and services is Chugai's Mission. Our thoughts and actions for fulfilling our Mission, and the results of those actions, are the only straightforward approach: when Chugai's financial value and social value rise, its corporate value – the sum of those two elements – increases. In that sense, the fact that Chugai's market capitalization at the end of December 2018 was the highest among the leaders in the Japanese pharmaceutical industry is proof that our shareholders and other stakeholders understand and have positively evaluated our actions. This evaluation has reinforced our confidence and belief in the goals we are striving to achieve.

We will continue to strive for timely, appropriate information disclosure through various media, and will work to promote dialogue with stakeholders. In IBI 21, as reflected in our new slogan, "Creating shared value," we will take a more active approach to providing information about the value we share with society, namely, the issues we plan to engage with and solve. To that end, we invite you to share your thoughts and comments with us. Thank you.

Current Status and Near-Term Plan of Major Investments



Message from the Chairman

At Chugai, our Mission is at the core of everything we do, and through our efforts to fulfill it, we will increase our corporate value.

Going forward, we will put more emphasis on ESG issues while evolving our governance system and taking steps to enhance our communication with stakeholders.

Osamu Nagayama
Representative Director & Chairman

Corporate Value and Governance

The importance of corporate governance has gained renewed attention in Japan in recent years. The Corporate Governance Code of the Tokyo Stock Exchange was revised, and among the issues currently being debated are the effectiveness of governance, the diversity of directors (including the percentage of outside directors on boards), clarification of criteria for CEO appointment and dismissal, and enhancement of succession plans.

In Chugai's governance, it is crucial that we evolve and properly operate the governance system we have established. Our guiding principle in doing this is Chugai's Mission, which defines the purpose of our business activities.

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." It is at the core of everything we do, and through our efforts to fulfill it we aim to increase our corporate value. That is Chugai's fundamental management objective. Corporate value ultimately must stand up to economic and quantitative evaluation. That's because, while corporate value incorporates various perspectives, since business activities are involved, providing returns to shareholders and other stakeholders is a critical responsibility.

Fulfilling Our Mission

Corporations exist side-by-side with various frameworks and relationships in society. In accomplishing their missions, they must abide by various regulations and fulfill responsibilities, and are required to follow certain rules while striving for economic efficiency in their business activities. Ensuring that they meet these requirements is the essence of governance. The Chugai Group Code of Conduct spells out the rules we must

follow, and is the evaluation standard for decisions in all our activities. Thorough compliance with the Code of Conduct supports Chugai.

So what is the key to fulfilling Chugai's Mission? The answer is innovation. Expectations and the need for pharmaceuticals are increasing due to advances in life science and technological innovation. Developing new drugs requires substantial investment in research and development, and pharmaceutical companies are facing the universal challenge of how to continuously generate the capital necessary for strategic investment. However, the trend of drug price reductions as part of measures to curb social security costs is expected to continue, and only medicines that offer truly innovative value will be successful in the market. Only companies that can contribute to society's development and meet medical and health needs through continuous innovation will be able to sustain growth.

Features of Chugai's Governance

To support continuous innovation, Chugai began a strategic alliance with Roche in 2002 and built its current business model. This alliance, in which Chugai is a member of the Roche Group while maintaining autonomy and management independence, also lends significant distinctive features to our governance.

As long as we maintain our stock listing, it is important that we ensure fair treatment of all our shareholders. Basing our decision-making on the interests of Roche, the controlling shareholder of Chugai, would negate the purpose of the business model. Chugai must always consider the interests of minority shareholders to the maximum extent possible and pursue business activities that do not harm those interests.

For this reason, Chugai's Board of Directors is divided equally into three types of directors: executive directors, non-executive directors from Roche, and independent outside directors. Each type consists of three people. I think this is a balanced composition that ensures fair treatment of minority shareholders while securing expertise and objectivity.

Another feature is that we have established the Chugai International Council (CIC), an advisory body composed of 10 experts and professionals from global business and the healthcare industry, to provide outside perspectives. The members of the CIC express their views and discuss matters such as Chugai's future direction. I believe we benefit immensely from being able to obtain advice from broad, fresh perspectives.

Focal Points of Discussion in the Board of Directors

The Board of Directors supervises business execution aimed at achieving Chugai's Mission through innovation. It deliberates and approves yearly plans and medium-to-long-term strategies, and monitors their progress. The board also receives timely reports in a number of important areas such as personnel systems and human resource development, and examines and discusses them. What we focus on here is whether activities in these areas have a scientific basis. We believe that it is Chugai's duty to conduct not just research and development but all of its business operations based on science.

In addition to supervising business execution, the Board of Directors also focuses on discussing future trends in healthcare as a whole and technological innovation. Healthcare five to ten years in the future will certainly be different from how it is now. As new methods of treatment, drug discovery modalities, and groundbreaking life science technologies emerge, it will be important for the board to assess Chugai's current technologies and consider the timeline for and extent to which it should prepare for future technological innovation.

Further Evolution of Governance

As I have already mentioned, there is no ideal form of governance. It must continuously evolve.

We have examined areas for improvement through evaluations of the effectiveness of the Board of Directors, and made improvements in the board's operation. The results of evaluations during the past three years show that a certain level of effectiveness has been secured, but we need to do more.

In particular, we will emphasize the ESG perspective, expanding the scope of our contributions and supervising execution and making decisions from the standpoint of contributing to society as a whole. In our social action programs, for instance, we intend to take a more proactive approach rather than simply doing what society asks us to do.

Evolution is also needed in stakeholder engagement. For example, our dialogue with shareholders and investors has largely focused on topics such as business plans and their progress, but recently we have been receiving more requests for dialogue on governance, including supervision by the Board of Directors. We will respond to such changes appropriately in our efforts to engage stakeholders in an active dialogue.

Through its constant pursuit of innovation, Chugai will work to further increase its corporate value to fulfill its Mission. Thank you for your continued support.

Messages from Directors

Yoichiro Ichimaru
Independent Outside Director
Senior Advisor of Aioi Nissay Dowa Insurance Co., Ltd.

A Virtuous Cycle That Drives Growth and Development

In 2018, Chugai was able to realize the goal it established in 2009 of becoming a top pharmaceutical company. Looking at each of the targets, Chugai's credibility and reputation in society have increased, including among healthcare providers and capital markets. Behind these successes is a business model based on the strategic alliance with Roche, and I believe that selection and concentration have been key to this alliance. Due to its collaboration with Roche, Chugai can select the regions and functions in which it concentrates management resources. This has led to a high level of results.

Another aspect where I feel Chugai excels is its use of diverse tools to effectively disseminate and share these results outside the Company. Chugai's special features and the orientation of its value creation are conveyed in a very understandable fashion not just in this report, but also on the Company website and via other media. Consequently, Chugai is able to attract capable people from outside the Company and improve motivation within the Company, leading to even better results. I believe that this virtuous circle drives Chugai's sustainable growth and development.

A Business Plan Imbued with Our Mission

The new mid-term business plan IBI 21 began in 2019. This plan reflects Chugai's intention to provide true value for patients. In corporate management, it is extremely important to draw up long-term strategies without obscuring the company's Mission, which expresses the purpose of its existence and what it intends to accomplish. It is likewise important to ensure that those strategies are adopted and implemented by everyone in the company. I worked for Toyota Motor Corporation for many years. To take an example from the automobile industry, which is at a turning point that only comes once every 100 years, a clear vision of wanting to provide freedom of movement for all is giving rise to innovative measures such as self-driving cars that will achieve new mobility for society. It is also bringing together diverse human resources and partner companies.

Without a doubt, the new mid-term business plan IBI 21 is imbued with Chugai's long-term thinking, and I expect the Company to reach the even higher levels of innovation and ability that will be required to execute its strategies.

Evolution of Governance

I feel that Chugai's governance system is a unique and effective framework from the viewpoint of fulfilling its Mission. Chugai has a large shareholder, Roche, whose long-term thinking is a perfect match. Consequently, Chugai can focus on sustainable growth without being limited by a short-term perspective. Moreover, by conducting independent management, Chugai can continue to produce results from its collaboration with Roche without losing its individuality. It is a win-win relationship that emphasizes diversity.

The Board of Directors consists of people from Chugai and Roche, as well as independent outside directors, such as me, with backgrounds in medicine, banking and manufacturing. I believe that lively discussions among directors with different experience and expertise are highly effective.

On the other hand, of course, there are also issues that still need to be addressed. I consider risk management particularly important. As society changes drastically and attention is focused on genomic medicine and other therapies, the risks Chugai faces will also change significantly. As it comes to grips with trends in other industries, the Company must envision and address new risks that affect the entire spectrum of the healthcare and pharmaceutical industries.

As an outside director, I still have much to learn about the pharmaceutical industry. In addition to gaining access to more substantive support so that I better understand the business, I will also study harder as I commit myself to Chugai's management. Thank you for your continued support.

Christoph Franz

Non-Executive Director
Chairman of the Board of Directors of Roche Holding Ltd.
Member of the Board of Directors of Stadler Rail AG (Switzerland)
Member of the Board of Directors of Zurich Insurance Group Ltd. (Switzerland)

Importance of Improving Corporate Value

The Chugai-Roche strategic alliance has been a tremendous success story over the past 16 years. Together we are making a significant difference to patients in Japan and all over the world. Since 2003, Chugai has launched 14 Roche Group-originated products into the Japanese market, becoming the market leader in oncology. During this time, Chugai has also licensed nine compounds to Roche. Two terrific recent examples are Alecensa (reducing the risk of disease worsening or death by almost 80 percent in Asian patients with a specific lung cancer), which in 2018 was one of the key global growth drivers of our Pharma business, and Hemlibra (transforming medical practice in the treatment of haemophilia A), which is already indicated for most people with haemophilia A in the U.S. Another testament to the innovation power of the alliance is the fact that over the last six years, the Roche Group has received 25 breakthrough therapy designations from the U.S. Food and Drug Administration (FDA), with seven of them originating from Chugai. This high number, amongst the most in the industry, demonstrates how we are capitalizing on cutting-edge science for difficult-to-treat diseases such as haemophilia A, lung and breast cancer, and achieving great medical advances for millions of patients.

Management System of Chugai

Just as important as our joint success today, is how we foster the collaboration going forward. Our achievements are rooted in a mutually beneficial business model. Although Roche is the majority shareholder, Chugai maintains its Japanese culture and identity and is managed autonomously, yet closely coordinated with Roche. It is our deep conviction that strong and self-reliant local management fosters an entrepreneurial spirit and drives innovation. On this basis our partnership has created a win-win situation. On the one hand, the Japanese management better understands business practices and the national environment, bringing Roche's medicines more quickly to Japanese patients. On the other hand, Chugai is able to expand opportunities for innovative medicines through R&D synergies within the Group and gain access to the global market through Roche's network, while still autonomously directing strategy and resources in drug discovery research. Thus, we mutually foster and benefit from our innovations.

Future Evolution of Chugai Management

Representing the interests of all shareholders, I and my colleagues of Chugai's Board of Directors will continue to focus on our responsibilities as required by Japanese law, including the approval of senior management appointments and budgets for operations, research, development and capital expenditure.

There is a huge medical need and a growing demand for specific diagnostics and effective, better-tolerated therapies not only in Japan, Europe and the U.S. (due to rising life expectancy), but also increasingly in Asia, Latin America and Africa. Consequently, for Roche and Chugai there is still much work to do.

The foundation of our success is and will remain a clear focus on scientific innovation. Importantly, we have made great strides in advancing personalised healthcare, increasingly supported by real-world data and advanced analytics. Our success depends not only on working together within the Roche Group, but also on our access to external innovation, or in other words, to good ideas from the outside to further complement our capabilities.

Thus, we need to further focus on our strengths. In particular, I encourage Chugai management to concentrate their efforts on what they can do better than Roche and foster the collaborative spirit where there are joint opportunities. I am convinced that the companies that will succeed in the future are those that can differentiate themselves through such a strategic approach to innovation.

Corporate Governance

Chugai's Corporate Governance

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.

To fulfill this mission, we have structured a unique business model, with a management emphasis on innovation. Under the strategic alliance with Roche, one of the world's largest pharmaceutical manufacturers, Chugai is a member of the Roche Group, but at the same time maintains managerial autonomy and independence as a separate listed company. Chugai pursues management that fulfills the mandate of many stakeholders appropriately and fairly. Director composition and monitoring mechanisms are also based on this mindset.

In addition, corporate governance is an integral part of management at Chugai. We believe that both raising the effectiveness of corporate governance and creating systems and mechanisms for increasing corporate value are important. In other words, we realize that constantly implementing the PDCA cycle to continuously examine and improve corporate governance is essential. Making consistent efforts toward that objective is a major responsibility of management.

To fulfill our accountability to shareholders and other investors, Chugai's corporate governance initiatives and policies are clearly stated in the Chugai Pharmaceutical Co., Ltd. Basic Corporate Governance Policy, which is disclosed on our website.[1]

1. https://www.chugai-pharm.co.jp/english/ir/policy/governance.html

Responding to the Corporate Governance Code

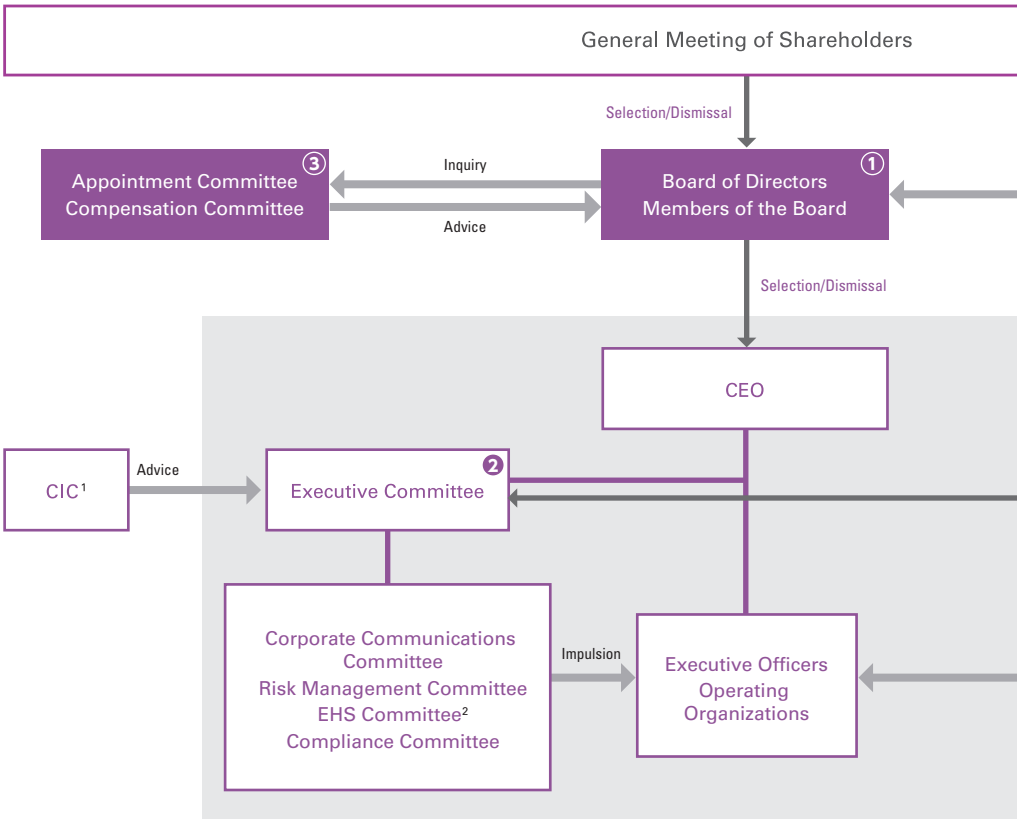
We have verified and reviewed the status of compliance with each principle of the Corporate Governance Code of the Tokyo Stock Exchange in accordance with the

❶ 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 nine directors including three independent outside directors.

❷ Executive Committee: The Executive Committee makes decisions on Company-wide management strategy and important matters concerning business execution. It consists of executive directors, including the CEO, and key executive officers. In addition, the Corporate Communications Committee, Risk Management Committee, EHS Committee and Compliance Committee have been established under the Executive Committee.

❸ Appointment Committee and Compensation Committee: As an advisory body to the Board of Directors, the Appointment Committee deliberates on the selection of director candidates and succession plans for or dismissal of executive directors, including the CEO. The Appointment Committee consists of one member from inside the Company and at least three outside members, including at least one independent outside director. The member from inside the Company is appointed by the Board of Directors from among the representative directors and persons with experience as representative directors. The outside committee members are appointed by the Board of Directors from among the non-executive directors and persons with experience as non-executive directors.

Chugai's Corporate Governance System (As of April 1, 2019)



1. Chugai International Council (CIC): Chugai established the CIC as an advisory body composed of Japanese, American and European industry leaders and professionals in various sectors to respond accurately to changes in the global business environment and conduct business in an appropriate manner, and to provide advice to further enhance decision-making.
2. Environment, Health and Safety Committee. Promotes EHS activities for the Chugai Group.

revision of June 2018. Specifically, we clarified and announced policies for issues including the election and dismissal of executive directors, planning for and development of successors to the CEO and other top executives, verifying the suitability of holding and reducing cross-shareholdings, and the roles of corporate pension funds as asset owners. We also revised the Chugai Pharmaceutical Co., Ltd. Basic Corporate Governance Policy. In addition, our operating environment and strategy will continue to change quickly, so we plan to regularly verify these policies to support sustainable growth in the future.

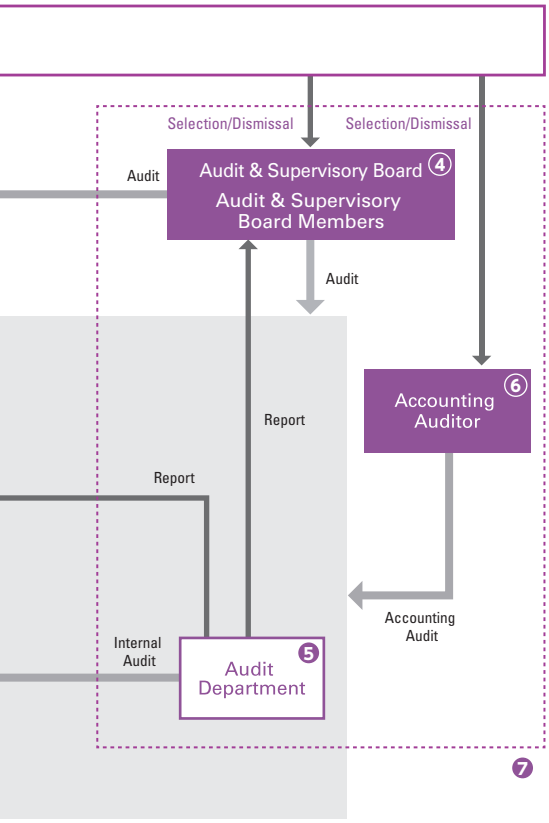
The following two items are aligned with the concepts of the Corporate Governance Code. However, they are not applied at present or in all cases due to differences in specific structures, roles and for other reasons.

Principle 4-1-3: Appropriate Oversight of a Succession Plan for the CEO and Other Top Executives

Chugai revised the Chugai Pharmaceutical Co., Ltd. Basic Corporate Governance Policy. The Appointment Committee now deliberates on the succession plan for the CEO and other executive directors. The Appointment Committee provides the Board of Directors with policy, summary and progress reports to enable the Board to supervise successor candidate development that is conducted systematically with sufficient time and resources.

Principle 4-10-1: Establishment of Independent Advisory Committees

Independent outside directors do not make up the majority of Chugai's Compensation Committee members. However, the committee comprises non-executive directors including one or more independent outside directors. Therefore, in consideration of the purpose of the Corporate Governance Code, Chugai believes that the current mechanism enables transparent and objective deliberation on compensation.



As an advisory body 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 outside director, appointed by the Board of Directors from among the nonexecutive directors including outside directors and persons with experience as non-executive directors.

❹ Audit & Supervisory Board Member Audits: Chugai has an Audit & Supervisory Board, and audits of management decision-making and business execution are conducted independently from business operations by five Audit & Supervisory Board members, including three outside members.

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

❺ Internal Audits: The Audit Department, with a staff that includes certified internal auditors and certified fraud examiners, conducts audits of the status of business execution of the Chugai Group, including subsidiaries, from various standpoints, such as the effectiveness, efficiency and compliance of business activities; reports and makes recommendations to the Executive Committee; and reports to the Audit & Supervisory Board. In addition, Audit Department staff serve as Audit & Supervisory Board members at subsidiaries.

In addition, the Audit Department assesses whether effective internal controls are established and being implemented in accordance with internal control standards generally accepted as fair and appropriate in Japan to ensure the reliability of financial reporting based on the Financial Instruments and Exchange Act.

❻ Accounting Audits: KPMG AZSA LLC handles accounting audits and internal control audits.

❼ Cooperative Auditing: Audit & Supervisory Board members, the Audit Department and the Accounting Auditor cooperate closely by regularly exchanging 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 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.

PDCA Cycle to Enhance Governance (Items Revised in 2018)

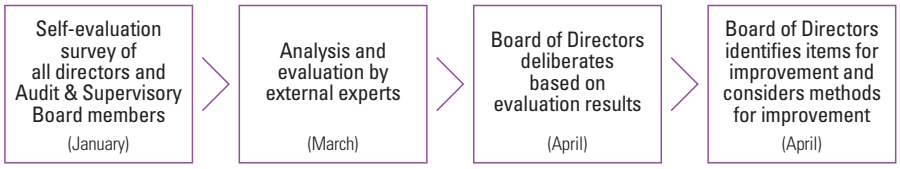
Based on the belief that constantly implementing the PDCA cycle to improve corporate governance is essential, Chugai emphasizes evaluation of the effectiveness of the Board of Directors and improvement activities based on evaluation results.

Chugai has been evaluating the effectiveness of the Board of Directors since 2015, and did so for the fourth time in 2018. We conduct a self-assessment survey in January every year for directors and Audit & Supervisory Board members who were in office during the applicable period, and discuss the results after receiving reports from the Secretariat for the Board of Directors. Based on the advice of external experts, the Secretariat for the Board of Directors prepares the survey, collects the directors' responses and reports the results to the Board of Directors after having them aggregated, analyzed and evaluated by the external experts. A large number of responses for each item of the self-evaluation survey indicate achievement, and the percentage of responses indicating achievement has increased, confirming the overall effectiveness of the Board of Directors.

An analysis of results in 2017 indicated items that needed improvement, including consultation prior to discussion and enhanced explanation of complex agenda items. In response, in 2018 we were assiduous about deadlines for the submission of materials by divisions responsible for agenda items. We also confirmed complex agenda items with relevant divisions including governance and legal matters, and set required responses including additional information and advance explanation.

In 2019, we plan further improvements to the mechanism for evaluating the effectiveness of the Board of Directors. Formerly, attorneys conducted third-party evaluation and analysis based on the self-evaluations. We will consider having third parties other than attorneys evaluate effectiveness to add weight to the third-party perspective and increase objectivity.

Process for Evaluating Effectiveness of Board of Directors



Status of Improvements Identified through Evaluation of the Effectiveness of the Board of Directors

	Main Items for Improvement	Main New Initiatives Implemented after Analysis and Evaluation
2016	• Review structure of self-evaluation survey and answer options • Assiduously provide materials for Board of Directors meetings at least four business days prior to the event • Enhance content of reports provided to Board of Directors and make materials easily understood	• Began providing information on industry environment trends and other information to outside directors in a Chairman's Message at the beginning of the Board of Directors meetings • Provided Board of Directors meeting schedule for the coming year at an early date • Implemented factory tours
2017	• Change the procedure for providing materials to outside officers • Enhance topics for reports to the Board of Directors	• Held lectures (information on trends of general shareholders meetings) by external experts (attorneys)
2018	• Conduct prior and additional explanations on agenda items with complex content such as governance and legal matters	• Issued the Chugai IR Activities Report to outside officers (every quarter) • Provided a glossary of technical terms, abbreviations and the like to outside officers

Chugai's Corporate Governance in 2018

Organizational form		Company with an Audit & Supervisory Board
Management and execution		Separated
Introduction of external perspectives		Implemented • 3 outside directors (of whom 3 are independent), 2 outside Audit & Supervisory Board members (of whom 2 are independent), and 3 other non-executive directors • Appointment Committee and Compensation Committee as advisory bodies • Chugai International Council (CIC)
Board of Directors	Composition	9 members (3 executive directors, 6 non-executive directors (of whom 3 are independent))
	Number of meetings in 2018	9
Executive Committee	Composition	12 members (2 directors, 10 executive officers (excluding directors))
	Number of meetings in 2018	35
Appointment Committee	Chairperson	Independent outside director
	Composition	4 members (1 director, 3 non-executive directors (of whom 2 are independent))
	Number of meetings in 2018	2
Compensation Committee	Chairperson	Non-executive director
	Composition	3 members (3 non-executive directors (of whom 1 is independent))
	Number of meetings in 2018	2
Audit & Supervisory Board	Composition	4 members (2 full-time Audit & Supervisory Board members and 2 outside Audit & Supervisory Board members including 2 who are independent)
	Number of meetings in 2018	11 (including 1 extraordinary meeting)
Internal committees		Established IR Committee, Risk Management Committee, Corporate Social Responsibility Committee and Compliance Committee

The Governance Structure That Supports Chugai's Business Model

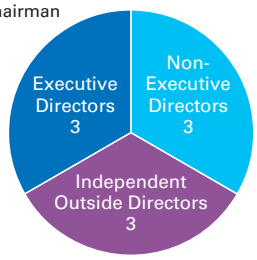
Separating management decision-making and business execution to expedite business execution and clarify executive responsibility is essential for promoting Chugai's unique business model while ensuring its effectiveness. To that end, the Board of Directors is responsible for making decisions on management issues of primary importance, while other decisions on business execution are made at organizations such as the Executive Committee. The Chief Executive Officer (CEO) has ultimate responsibility for making decisions on Company-wide management strategies and important matters concerning business execution.

Principal Matters Deliberated by the Board of Directors

Matters Concerning the General Meeting of Shareholders	• Calling of the General Meeting of Shareholders and determination of the agenda items • Approval of the Business Report, financial statements and other documents • Selection of director and Audit & Supervisory Board member candidates
Matters Concerning Directors and Audit & Supervisory Board Members	• Selection and dismissal of representative directors and executive directors • Directors' remuneration and bonuses • Selection and dismissal of executive officers and advisors
Matters Concerning Stock	• Payment of interim dividend
Matters Concerning Management in General	• Formulation of plans and policies, and reports on their progress • Discussion of new business plans, alliances and other matters • Discussion of decision-making structure and organizations • Matters concerning finance and assets
Other Matters	• Approval and reporting of competing transactions • Approval and reporting of conflict of interest transactions • Implementation and reporting of evaluation of the effectiveness of the Board of Directors • Status of voting on proposals at the General Meeting of Shareholders • Verification of cross-shareholdings

Composition of the Board of Directors

- Osamu Nagayama
  Representative Director, Chairman
- Motoo Ueno
  Representative Director, Deputy Chairman
- Tatsuro Kosaka
  Representative Director, President & CEO



- Dr. Christoph Franz
  Chairman of the Board of Directors of Roche Holding Ltd.
- William N. Anderson
  CEO of Roche Pharmaceuticals
- Dr. James H. Sabry
  Global Head of Roche Pharma Partnering

- Dr. Yasuo Ikeda
  Outside Director
  Vice-Chairman of the Board of Directors, Musashi Academy of the Nezu Foundation
  Specially Appointed Professor of Waseda University, Professor Emeritus of Keio University
- Masayuki Oku
  Outside Director
  Outside Director of Komatsu Ltd.
  Outside Director of Panasonic Corporation
  Outside Corporate Auditor of Nankai Electric Railway Co., Ltd.
  Non-Executive Director of The Bank of East Asia (China)
- Yoichiro Ichimaru
  Outside Director
  Senior Advisor of Aioi Nissay Dowa Insurance Co., Ltd.

Composition of the Board of Directors

Chugai's Board of Directors comprises three types of directors: executive directors, independent outside directors, and non-executive directors. The balance of experience among directors of each type enables effective corporate governance that ensures management autonomy as an independent publicly listed company within the Roche Group, and helps to increase corporate value.

Roles are as follows. Executive directors are responsible for business execution and supervision, report on and explain business execution matters and hold discussions on management. They execute the strategies decided in Board of Directors meetings. Currently, three executive directors are representative directors. Independent outside directors are appointed based on their knowledge and expertise as outside corporate executives or as medical, academic and other professionals. Their role is to provide advice concerning management, exercise supervisory functions and participate in discussions and decision-making at Board of Directors meetings from an objective, outside perspective. Other non-executive directors are principally appointed from the management team of the Roche Group. They provide an objective, expert perspective from a standpoint that is independent from business execution, offer recommendations and advice regarding strategies and management, and participate in discussions at Board of Directors meetings.

Chugai International Council (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)
  Former 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 Emeritus at the Institute for Advanced Study, Princeton University
  Discoverer of the p53 cancer suppressor protein
- Sonosuke Kadonaga (Japan)
  President, Intrinsics

Introduction of Outside Perspectives

To reflect diverse stakeholder viewpoints in business decisions, Chugai has actively taken measures to obtain outside perspectives, such as nominating outside directors and outside Audit & Supervisory Board members, enhancing support for outside officers, and establishing a council made up of domestic and overseas specialists.

Chugai International Council (CIC)

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 current 10 council members, including the CIC Chair, one is a woman and one is Japanese.

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 materials for board meetings in advance.

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. Chugai also provides additional information

Director Roles and Expertise in 2018

	Roles and Responsibilities	Name	Expertise	Board of Directors Meeting Attendance in 2018	Chugai Shares Owned
Executive Directors	Representative Director, Chairman	Osamu Nagayama	Corporate management Pharmaceuticals and healthcare	9 of 9	298,900 shares
	Representative Director, Deputy Chairman In charge of Corporate Social Responsibility Dept., Audit Dept.	Motoo Ueno	Corporate management Pharmaceuticals and healthcare	9 of 9	788,300 shares
	Representative Director, President & CEO	Tatsuro Kosaka	Corporate management Pharmaceuticals and healthcare	9 of 9	34,700 shares
Independent Outside Directors	Director	Dr. Yasuo Ikeda	Research Medical science and healthcare	9 of 9	0 shares
	Director	Masayuki Oku	Corporate management Global Group governance	9 of 9	0 shares
	Director	Yoichiro Ichimaru	Corporate management Global Group governance	9 of 9	0 shares
Non-Executive Directors	Director	Dr. Christoph Franz	Corporate management Global Group governance	8 of 9	0 shares
	Director	Daniel O'Day	Corporate management Pharmaceuticals and healthcare	9 of 9	0 shares
	Director	Dr. Sophie Kornowski-Bonnet	Corporate management Pharmaceuticals and healthcare	8 of 9	0 shares

required by outside directors and outside Audit & Supervisory Board members and takes advantage of opportunities to provide advance explanation.

The Relationship with Roche and Securing the Rights and Equality of Shareholders

Roche, the parent company of Chugai, holds 59.89 percent of Chugai's outstanding shares based on the strategic alliance agreement between the two companies. Roche and Chugai have agreed to cooperate in maintaining the listing of Chugai's common stock on the First Section of the Tokyo Stock Exchange.[2]

The aim of this alliance is to establish a new business model that differs from conventional corporate acquisitions and joint ventures. Although Roche Holding Ltd. includes Chugai in its consolidated accounts, Chugai functions as an independent listed company and makes all of its own management decisions based on the principle of self-governance. 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. Chugai recognizes that the various benefits from being listed on the First Section of the Tokyo Stock Exchange – such as its solid credit rating, flexible fund procurement, name recognition and social presence – are supported by the understanding of minority shareholders, Roche and investors who are potential shareholders. That is why in its business dealings with the Roche Group, Chugai conducts all transactions fairly using third-party prices to protect the interests of minority shareholders.

As of March 28, 2019, three of Chugai's nine 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.

Chugai believes 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.

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

Restrictions on Roche's Shareholding

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

Officer Remuneration That Emphasizes Linkage with Performance and Stock Price

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 align their interests with those of shareholders.

In order to further clarify the link between remuneration and the Company's business performance and shareholder value, and to raise directors' ambition and motivate them to improve performance, remuneration of executive directors consists of bonuses paid according to performance in each fiscal year and restricted stock compensation linked to mid- and long-term performance (tenure-based and performance-based) as a long-term incentive to continuously increase corporate value, in addition to fixed regular compensation. These three 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 Compensation 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 non-executive directors and Audit & Supervisory Board members (including outside members) consists solely of fixed regular compensation, and is paid by resolution of the Board of Directors for non-executive 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).

At the 106th Annual General Meeting of Shareholders held on March 23, 2017, a resolution was passed to newly introduce

System for Remuneration of Directors and Audit & Supervisory Board Members

Type of Remuneration			Eligible Officers: Executive Directors	Eligible Officers: Non-executive Directors (including Outside Directors)	Eligible Officers: Audit & Supervisory Board Members	Payment Criteria	Payment Method
Fixed Regular Compensation	Regular Compensation		●	●	●	Paid according to position and other factors	Monthly (Cash)
Performance-based Remuneration	Bonuses		●			Paid according to performance in each fiscal year	Yearly (Cash)
	Long-term Incentive (Stock-based Compensation)	Tenure-based Restricted Stock	●			Paid according to fixed length of service	Yearly (Common stock)
		Performance-based Restricted Stock	●			Paid according to performance over fixed period in addition to above	Yearly (Common stock)

Amount of Remuneration Paid to Directors and Audit & Supervisory Board Members (2018)

Position	Total Remuneration, etc. (Millions of yen)	Total Amount by Type of Remuneration, etc. (Millions of yen): Regular Remuneration	Bonuses	Restricted Stock Compensation: Tenure-based	Restricted Stock Compensation: Performance-based	Stock Options: Common	Stock Options: Stock-based Compensation	Number of Eligible Officers
Directors (Excluding Outside Directors)	533	261	123	57	72	21	—	5
Outside Directors	43	43	—	—	—	—	—	3
Total	576	427		129		21	—	8
Audit & Supervisory Board Members (Excluding Outside Audit & Supervisory Board Members)	63	63	—	—	—	—	—	2
Outside Audit & Supervisory Board Members	24	24	—	—	—	—	—	2
Total	87	87		—		—	—	4

1. The table above includes one director who retired during the fiscal year under review.
2. The amount of remuneration, etc. (regular remuneration and bonuses) paid to all directors was not more than ¥750 million per year as per the resolution passed in the 96th Annual General Meeting of Shareholders for the year ended December 31, 2006 held in March 2007.

   Apart from this, the maximum amount of compensation paid to directors (excluding non-executive directors and including outside directors) in the form of restricted stock compensation (tenure-based and performance-based) was not more than ¥345 million per year as per the resolution passed at the 106th Annual General Meeting of Shareholders for the year ended December 31, 2016 held in March 2017.
3. The amount of remuneration for all Audit & Supervisory Board members was not more than ¥100 million per year as per the resolution passed at the 95th Annual General Meeting of Shareholders for the year ended December 31, 2005 held in March 2006.
4. The amounts of "restricted stock compensation (tenure-based and performance-based)" shown in the table above are the amounts that were posted as expenses for the fiscal year as each respective restricted stock compensation.

   Accordingly, "number of eligible officers" includes one director who retired during the fiscal year under review and one director who retired during the previous fiscal year.
5. No new stock options have been granted in the fiscal year under review but the amount granted in the previous fiscal year that was posted as expenses in the current fiscal year is shown in Stock Options above.
6. A resolution was passed at the 98th Annual General Meeting of Shareholders for the year ended December 31, 2008 held in March 2009, to abolish the retirement benefits system for executive directors, and to pay retirement benefits corresponding to their residual term up to the abolishment of the system to each concerned director remaining in office after the closing of the 98th Annual General Meeting of Shareholders for the year ended December 31, 2008, at the respective time of their retirement.
7. Apart from the ¥234 million in provision for reserve for bonuses to directors noted in the Business Report for the previous fiscal year as bonuses for directors for the previous fiscal year, ¥136 million was paid to four directors (excluding non-executive directors and including outside directors) during the current fiscal year.

Amount of Remuneration Paid to Representative Directors (2018)

Name	Total Consolidated Remuneration, etc. by Type (Millions of yen): Regular Remuneration	Bonuses	Restricted Stock Compensation: Tenure-based	Restricted Stock Compensation: Performance-based	Stock Options: Common	Stock Options: Stock-based Compensation	Total Consolidated Remuneration, etc. (Millions of yen)
Osamu Nagayama	126	37	21	30	9	—	223
Motoo Ueno	58	26	14	17	4	—	118
Tatsuro Kosaka	68	60	19	24	4	—	174

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.

restricted stock in place of the current stock options for executive directors of the Company. The aggregate amount of such compensation shall not exceed ¥345 million on top of the aforementioned fixed regular compensation and bonuses. (For details of director remuneration, please refer to pages 43-44 of the "Notice of Convocation of the 108th Annual General Meeting of Shareholders for the Business Term Ended December 31, 2018.")

Internal Control System and Risk Management

On May 18, 2006, the Company approved the Board of Directors' resolutions concerning the Internal Control System as its basic policies in maintaining systems for ensuring appropriate business operations. On April 22, 2015, the Company revised the Board of Directors' resolutions concerning the Internal Control System in response to the main revisions of the Partial Amendment to the Companies Act and the amended Ordinance for Enforcement of the Companies Act, namely "enhancement of systems for groups of enterprises," "enhancement of audit systems," and "obligation to disclose status of operations," which came into effect in 2015. Since this revision, the status of implementation of the Internal Control System is regularly reported at Board of Directors meetings, and necessary revisions are made in a timely manner to maintain effective internal controls.

Chugai views risk management as a key issue pertaining to the Company's core operations. Chugai has established Risk Management Regulations based on its Risk Management Policy to prevent the materialization of 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 Division Risk Management Committees and a Risk Management Committee under the Executive Committee. Division Risk Management Committees summarize and create risk maps of all the risks facing their divisions, make proactive efforts to prevent the materialization of such risks, and submit reports on the progress of those efforts to the Risk Management Committee. The Risk Management Committee identifies Group-wide risk issues that may have a material impact on management and submits a progress report to the Executive Committee concerning preventive measures. (See "Business Risks" on page 120 for details.)

Chugai and 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 its 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.*)

* https://www.chugai-pharm.co.jp/english/csr/transparency/index.html

In light of increasing societal demands for greater compliance in the pharmaceutical industry, we have strengthened compliance measures Company-wide. In addition to working to enhance compliance education in each of our training programs, we conduct compliance risk management measures in each organizational unit. Moreover, every six months the Corporate Social Responsibility Department conducts monitoring surveys regarding compliance status. They are conducted for the entire organization, including subsidiaries and affiliated companies in Japan and overseas, and the results are reported to the Compliance Committee. Each organization appoints a Compliance Manager and Compliance Officer who work to ensure thorough legal compliance in the workplace and hold corporate ethics courses twice a year, among other programs.

The CCC Hotline and internal and external Harassment Hotlines have been established to receive employee inquiries and reports concerning laws, Company rules, the Chugai Group Code of Conduct and other related matters.

Enhancement of Global Compliance

In January 2017, the compliance oversight functions that were previously handled by multiple committees to comply with pharmaceutical regulations, general laws, industry standards, Company rules and healthcare compliance, were consolidated, and the Compliance Committee, a corporate management committee, was established to create an administrative system linked more directly to management.

The intention of this change is to facilitate proper and appropriate judgments and actions based on the societal norms and values required of pharmaceutical companies given the diversification of businesses and their employees due to the accelerating pace of globalization. It is also aimed at properly and appropriately responding to increasingly diverse and stringent regulatory regimes, including extraterritorial application of the laws of various countries, notably the antitrust and anti-bribery laws of the United States. Compliance oversight functions (Corporate Social Responsibility Department, Quality & Regulatory Compliance Unit) were established to monitor, lead and support the compliance of the Chugai Group as a whole, including overseas subsidiaries, creating a horizontal global compliance management framework.

Board of Directors, Audit & Supervisory Board and Executive Committee Members (As of April 1, 2019)

Representative Directors

Osamu Nagayama
Representative Director, Chairman
Outside Director and Chairman of the Board of Directors of Sony Corporation

Executive Director

1978 Joined the Company
1985 Director, Deputy General Manager of Development Planning Div.
1987 Director, Senior Vice President
1989 Representative Director, Deputy President
1992 Representative Director, President & CEO
2010 Outside Director of Sony Corporation (to present)
2012 Representative Director, Chairman & CEO
2013 Chairman of the Board of Directors of Sony Corporation (to present)
2018 Representative Director, Chairman (to present)

Motoo Ueno
Representative Director, Deputy Chairman
In charge of Sustainability Dept., Audit Dept.

Executive Director

1984 Joined the Company
1991 General Manager of London Representative Office
1993 Director
1994 Director, General Manager of Medical Information Div.
1995 Director, General Manager of Clinical Research & Development Division
1996 Director, 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 of Chugai Pharma Manufacturing Co., Ltd.
2012 Representative Director, Deputy Chairman (to present)

Tatsuro Kosaka
Representative Director, President & CEO
Outside Director of Asahi Group Holdings, Ltd.

Executive Director

1976 Joined 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
2012 Representative Director, President & COO
2016 Outside Director of Asahi Group Holdings, Ltd. (to present)
2018 Representative Director, President & CEO (to present)

Non-Executive Directors

Audit & Supervisory Board Members

Non-Executive Directors

1 Dr. Yasuo Ikeda

Vice-Chairman of the Board of Directors, Musashi Academy of the Nezu Foundation
Specially Appointed Professor of Waseda University
Professor Emeritus of Keio University

Outside **Independent**

1979 Director of Keio University Hospital Blood Center
1991 Professor of Internal Medicine, School of Medicine, Keio University
2001 Director of Center for Integrated Medical Research of Keio University
2005 Dean of School of Medicine, Keio University
2009 Professor Emeritus of Keio University (to present)
Professor of Department of Life Science and Medical Bioscience, Graduate School of Advanced Science and Engineering, Waseda University
2010 Director of the Company (to present)
2013 Vice-Chairman of the Board of Directors, Musashi Academy of the Nezu Foundation (to present)
2014 Specially Appointed Professor of Waseda University (to present)

2 Masayuki Oku

Outside Director of Komatsu Ltd.
Outside Director of Panasonic Corporation
Outside Corporate Auditor of Nankai Electric Railway Co., Ltd.
Non-Executive Director of The Bank of East Asia (China)

Outside **Independent**

1968 Joined The Sumitomo Bank, Ltd. ("SB")
1994 Director of SB
1998 Managing Director of SB
1999 Managing Director and Managing Executive Officer of SB
2001 Senior Managing Director and Senior Managing Executive Officer of 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 and Executive Officer of SMBC
2005 Chairman of SMFG
President and Chief Executive Officer of SMBC
2015 Director of the Company (to present)
2017 Director of SMFG
Honorary Advisor of SMFG (to present)

3 Yoichiro Ichimaru

Senior Advisor of Aioi Nissay Dowa Insurance Co., Ltd.

Outside **Independent**

1971 Joined Toyota Motor Sales Co., Ltd.
2001 Member of the Board of Directors of Toyota Motor Corporation ("TMC")
2003 Managing Executive Officer of TMC
2005 Senior Managing Director of TMC
2009 Representative Director, Executive Vice President of TMC
Corporate Auditor of Aioi Insurance Co., Ltd.
2010 Corporate Auditor of Aioi Nissay Dowa Insurance Co., Ltd.
2011 Senior Corporate Auditor of TMC
2015 Executive Advisor of TMC
Representative Director, Chairman of Aioi Nissay Dowa Insurance Co., Ltd.
2017 Director of the Company (to present)
Senior Advisor of Aioi Nissay Dowa Insurance Co., Ltd. (to present)

4 Dr. Christoph Franz

Chairman of the Board of Directors of Roche Holding Ltd.
Member of the Board of Directors of Stadler Rail (Switzerland)
Member of the Board of Directors of Zurich Insurance Group Ltd. (Switzerland)

1990 Joined Deutsche Lufthansa AG
1994 Member of the Executive Board and CEO of Passenger Transport Division of Deutsche Bahn AG
2004 CEO of Swiss International Air Lines AG
2009 Deputy Chairman of the Executive Board of Deutsche Lufthansa AG
2011 Chairman of the Executive Board and CEO of Deutsche Lufthansa AG
2014 Chairman of the Board of Directors of Roche Holding Ltd. (to present)
2017 Director of the Company (to present)

5 William N. Anderson

CEO of Roche Pharmaceuticals and Member of the Roche Corporate Executive Committee

1997 Joined Biogen Idec
1999 Managing Director, United Kingdom and Ireland of Biogen Idec
2001 Vice President of Finance, Business Planning of Biogen Idec
2004 Vice President and General Manager of Neurology Business Unit of Biogen Idec
2006 Senior Vice President of Immunology & Ophthalmology Business Unit of Genentech
2010 Senior Vice President of BioOncology Business Unit of Genentech
2013 Head of Global Product Strategy, Chief Marketing Officer of Roche
2017 CEO of Genentech
2019 CEO of Roche Pharmaceuticals and Member of the Roche Corporate Executive Committee (to present)
Director of the Company (to present)

6 Dr. James H. Sabry

Global Head of Roche Pharma Partnering and Member of the Roche Enlarged Corporate Executive Committee

1997 Co-founder, President and CEO of Cytokinetics
2008 President and CEO of Arete Therapeutics
2010 Global Head and Vice President of Genentech Partnering
2013 Global Head and Senior Vice President of Genentech Partnering
2018 Global Head of Roche Pharma Partnering and Member of the Roche Enlarged Corporate Executive Committee (to present)
2019 Director of the Company (to present)

Audit & Supervisory Board Members

7 Mamoru Togashi (Full-time)

1982 Joined the Company
2004 President, CBS Co., Ltd.
2006 General Manager of Corporate Communications Dept.
2009 General Manager of Human Resources Management Dept.
2010 Vice President, General Manager of Human Resources Supervisory Div. and General Manager of Human Resources Management Dept.
2017 Audit & Supervisory Board Member (to present)

8 Atsushi Sato (Full-time)

1981 Joined the Company
2009 General Manager of Risk Management & Compliance Dept.
2011 General Manager of Corporate Social Responsibility Dept.
2015 General Manager of Corporate Social Responsibility Dept. and General Affairs Dept.
General Manager of Corporate Social Responsibility Dept.
2016 Associate Vice President, General Manager of Corporate Social Responsibility Dept.
2019 Associate Vice President
Audit & Supervisory Board Member (to present)

9 Hisashi Hara

Advisor, The Law Office of Nagashima Ohno & Tsunematsu
Outside Director of the Board of Nippon Paint Holdings Co., Ltd.

Outside **Independent**

1975 Registered as an attorney-at-law (Dai-ichi Tokyo Bar Association)
Joined Nagashima & Ohno (currently, Nagashima Ohno & Tsunematsu)
1983 Partner, Nagashima & Ohno
1991 Managing Partner of Nagashima & Ohno
2006 Chairman, Nagashima Ohno & Tsunematsu
Administrative Council Member of the University of Tokyo
2008 Auditor, JPMorgan Securities Japan Co., Ltd.
2012 Outside Audit & Supervisory Board Member of the Company (to present)
2013 General Representative of the Asia-Pacific region, The Law Office of Nagashima Ohno & Tsunematsu
2018 Advisor, The Law Office of Nagashima Ohno & Tsunematsu (to present)
Outside Director of the Board of Nippon Paint Holdings Co., Ltd. (to present)

10 Takaaki Nimura

Representative of Nimura Certified Public Accountant Office

Outside **Independent**

1974 Joined Arthur Young & Co., Tokyo Office
1980 Seconded to Asahi & Co., Osaka Office
1983 Seconded to Arthur Young & Co., Los Angeles Office
1989 Partner, Asahi Shinwa & Co.
1993 Joined Showa Ota & Co.
1997 Senior Partner, Showa Ota & Co.
2008 Executive Board Member, Ernst & Young ShinNihon LLC
2010 Established Nimura Certified Public Accountant Office
2012 Outside Director, Sony Corporation
2016 Outside Audit & Supervisory Board Member of the Company (to present)

11 Dr. Yuko Maeda

Director of CellBank Corp.
Auditor (Part-time) for Japan Agency for Marine-Earth Science and Technology

Outside **Independent**

1984 Joined Bridgestone Corporation
1998 CFO of BTR Power Systems Japan
2001 (Concurrent) Vice President of Tokyo University of Agriculture and Technology TLO Co., Ltd.
2003 Director, Technology Transfer Center of Tokyo Medical and Dental University
2009 Project Coordinator of Innovation Initiative Network Japan
(Concurrent) Visiting Professor of Tokyo Medical and Dental University
2011 (Concurrent) Specially Appointed Professor of Kyoto Prefectural University of Medicine
2013 Executive Officer of Bridgestone Corporation
2014 (Concurrent) Auditor of Japan Agency for Marine-Earth Science and Technology (to present)
2017 Director of CellBank Corp. (to present)
2019 Outside Audit & Supervisory Board Member of the Company (to present)

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

Members of the Executive Committee and Enlarged Executive Committee Not on the Board of Directors (As of April 1, 2019)

1 Shinya Unno

Executive Vice President
In charge of Human Resources Management, Human Capital Development, Legal, General Affairs and Secretarial and General Manager of Human Resources Supervisory Div., in charge of General Affairs Dept. and Secretarial Dept.

EC * EEC **

1999 Joined the Company
2005 General Manager of Corporate Planning Dept.
2006 Vice President and General Manager of Corporate Planning Dept.
2007 Vice President and Deputy General Manager of Sales Div.
2010 Senior Vice President, General Manager of Corporate Planning Supervisory Div. and General Manager of Corporate Planning Dept.
2015 Senior Vice President, in charge of General Affairs and Secretarial Dept.
2017 Executive Vice President and General Manager of Human Resources Supervisory Div., in charge of General Affairs Dept. and Secretarial Dept. (to present)

2 Dr. Yasushi Ito

Executive Vice President
In charge of Project & Lifecycle Management (R&D), Regulatory & Quality Management, Clinical Development, Drug Safety and Medical Affairs and Co-Head of Project & Lifecycle Management Unit

EC EEC

2004 Joined the Company; Department Manager of Development Planning Dept.
2005 Department Manager of Targeted Disease Area Dept.
2007 Department Manager of Clinical Research Planning Dept.
2009 Department Manager of Medical Science Dept. and Clinical Research Planning Dept.
Vice President and Department Manager of Clinical Development Div.
2015 Vice President and Head of Project & Lifecycle Management Unit
2016 Senior Vice President and Head of Project & Lifecycle Management Unit
2018 Executive Vice President and Co-Head of Project & Lifecycle Management Unit (to present)

3 Dr. Osamu Okuda

Executive Vice President
In charge of Project & Lifecycle Management (Marketing), Foundation Medicine, Corporate Planning and Co-Head of Project & Lifecycle Management Unit

EC EEC

1987 Joined the Company
2009 Department Manager and Lifecycle Leader of Lifecycle Management Dept. 2
2011 President, Roche Products (Ireland) Limited
2013 Head of Oncology Unit of Marketing & Sales Div.
2014 Vice President and Head of Oncology Unit of Marketing & Sales Div.
2015 Vice President and General Manager of Corporate Planning Dept.
2017 Senior Vice President and General Manager of Corporate Planning Dept.
2018 Executive Vice President and Co-Head of Project & Lifecycle Management Unit (to present)

* Executive Committee
** Enlarged Executive Committee

4 Dr. Hisafumi Okabe

Executive Vice President
In charge of Research and Translational Research and General Manager of Translational Research Div.

EC EEC

1991 Joined Nippon Roche K.K.
2002 Joined the Company; Department Manager of Pharmaceutical Research Dept.
2007 Director, Forerunner Pharma Research Co., Ltd.
2009 Vice President and General Manager of Research Div. Head, C&C Research Laboratories (Korea) (to present)
2012 Director and COO, Chugai Pharmabody Research Pte. Ltd. (Singapore) (to present)
2016 Senior Vice President and General Manager of Research Div.
2018 Executive Vice President and General Manager of Translational Research Div. (to present)

5 Toshiaki Itagaki

Executive Vice President & CFO
In charge of Finance & Accounting, Corporate Communication, Information System and Purchasing and General Manager of Finance Supervisory Div., General Manager of IT Supervisory Div. and General Manager of Finance & Accounting Dept.

EC EEC

1983 Joined the Company
2007 General Manager of Finance & Accounting Dept.
2010 Department Manager of Planning & Research Dept.
2012 Department Manager of Marketing & Sales Planning Dept.
2015 Vice President, General Manager of Finance & Accounting Dept.
2017 Vice President, General Manager of IT Supervisory Div. and General Manager of Finance & Accounting Dept.
2018 Executive Vice President & CFO, General Manager of Finance Supervisory Div., General Manager of IT Supervisory Div. and General Manager of Finance & Accounting Dept. (to present)

6 Keiji Kono

Senior Vice President
In charge of External Affairs Dept. and Global Health Policy

EEC

2010 Joined the Company; Senior Advisor
Vice President and Deputy Head of Lifecycle Management Unit
Vice President, Deputy Head of Lifecycle Management & Marketing Unit and Department Manager of Lifecycle Management Dept. 2
2012 Vice President and Deputy General Manager of Marketing & Sales Div.
2013 Vice President and General Manager of IT Supervisory Div.
2015 Vice President in charge of Global Health Policy and General Manager of IT Supervisory Dept.
2017 Senior Vice President, in charge of External Affairs Dept. and Global Health Policy (to present)

7 Junichi Ebihara

Senior Vice President
General Manager of Legal Dept.

EEC

2014 Joined the Company; Senior Corporate Advisor
Vice President and General Manager of Legal Dept.
2017 Senior Vice President and General Manager of Legal Dept. (to present)

8 Dr. Yoshiaki Ohashi

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

EEC

1988 Joined the Company
2004 Department Manager, Quality & Regulatory Compliance Dept.
2009 Department Manager, Drug Safety Coordination Dept.
2011 Global PV Head (to present), Pharmacovigilance Manager
2013 General Manager of Drug Safety Div.
2015 Vice President, Head of Quality & Regulatory Compliance Unit, General Manager of Drug Safety Div. and General Marketing Compliance Officer (to present)
2018 Senior Vice President, Head of Quality & Regulatory Compliance Unit and General Manager of Drug Safety Div. (to present)

9 Dr. Hiroshi Murata

Vice President
General Manager of Pharmaceutical Technology Div.

EEC

1986 Joined the Company
2008 Department Manager of CMC Regulatory Affairs Dept.
2011 Department Manager of CMC Development Dept.
2012 Manager of Fujieda Plant, Chugai Pharma Manufacturing Co., Ltd.
2016 General Manager of Pharmaceutical Technology Div.
2018 Vice President and General Manager of Pharmaceutical Technology Div. (to present)

10 Tsunanori Sato

Vice President
General Manager of Marketing & Sales Div.

EEC

1982 Joined the Company
2005 Department Manager of Renal Disease Area Medical Business & Science Dept.
2009 Supervisory Branch Manager of Yokohama Branch
2011 Supervisory Branch Manager of Kyoto Branch
2013 Department Manager of Primary Sales Promotion Dept.
2015 Associate Vice President and Supervisory Branch Manager of Osaka Branch
2017 Associate Vice President and Head of Kansai Regional Management Office
2018 Vice President and General Manager of Marketing & Sales Div. (to present)

We are always innovating in every aspect of our business.

Chugai in Action

Overview of Activities in 2018

Category	Main initiatives	Connection with IBI 21 strategies* 1	2	3	4	5
Research	• Continuously generating first-in-class[1] and best-in-class[2] drugs	●				●
	• Creating molecular targeted drugs that contribute to personalized healthcare (PHC)	●	●	●		●
	• Strengthening innovative proprietary research technologies and creating innovative antibodies	●				●
	• Providing support and education for researchers from Asia				●	
	• Maintaining high animal welfare standards in accordance with international guidelines					●
Development	• Improving clinical development of drugs to address unmet medical need	●		●	●	●
	• Identifying latent medical need[3] and achieving early PoC[4]	●			●	
	• Increasing productivity and speed of global clinical development for early market launches	●		●	●	●
	• Conducting simultaneous development and regulatory filing of drug therapies and diagnostics that contribute to PHC	●		●	●	●
	• Strengthening lifecycle management to maximize product value	●		●	●	●
	• Obtaining early approval for projects in-licensed from Roche	●			●	
Pharmaceutical Technology and Production	• Providing a stable supply of high-quality drugs and investigational drugs	●	●			●
	• Enhancing the system for faster global launches and simultaneous development of multiple products	●	●			
	• Achieving early PoC by raising the level of CMC[5] development	●			●	
	• Raising the level of competitive advantages from late-stage development to initial commercial production (including investigation of next-generation industrial technologies)					●
	• Achieving world-class quality control, quality assurance and regulatory functions	●				●
Marketing	• Contributing to advances in medicine as Japan's leading therapeutic antibody company		●			
	• Promoting standards of care and proper use of medicines in oncology		●	●		
	• Promoting PHC for optimal treatment options		●	●		
	• Supporting the resolution of medical issues in mainstay product areas and regions		●			
	• Patient-centric consideration of therapeutic approach		●			
Medical Affairs	• Building a consistent global medical affairs promotion system with proper independence of roles		●			
	• Strengthening systems for healthcare compliance and governance of contract-based post-marketing studies		●			
	• Conducting area-based evidence creation and promoting scientific communication activities		●			
	• Introducing, expanding and upgrading global medical information functions		●			
Drug Safety	• Strengthening pharmacovigilance system to meet the world's strictest standards and most comprehensive global regulations					●
	• Providing solutions to patients and healthcare providers using drug safety information		●			
	• Preparing and implementing risk management plans (RMPs)		●			●
Quality and Regulatory Compliance	• Enhancing production system for Actemra, Alecensa and Hemlibra, which are innovative products from Chugai research	●			●	
	• Developing cross-organizational quality and regulatory compliance framework in order to strengthen quality control, quality assurance and regulatory intelligence functions					●
	• Strengthening compliance risk management throughout the product lifecycle and carrying out quality management that fosters a culture of quality					●
Intellectual Property	• Protecting and effectively using rights for broadly applicable innovative technologies		●	●	●	●
	• Filing high-quality patent applications and effectively allocating resources	●	●	●	●	●
	• Aggressively filing patent applications outside Japan with a view to global co-development	●	●	●	●	●

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

*1: Value Creation; 2: Value Delivery; 3: Promote Advances in PHC;
4: Strengthen Human Capital and Conduct Fundamental Structural Reform; 5: Strengthen Sustainable Platforms

Main performance indicators in 2018

- In-house products in development pipeline: 15 (as of January 31, 2019)
- Academic papers and presentations at scientific conferences regarding Chugai's innovative proprietary technologies: 53 (2014-2018)
- Published academic papers regarding Chugai's research findings: 90 (2014-2018)
- R&D expenditures to revenues: 16.2%

- Expanded business at Singapore subsidiary Chugai Pharmabody Research Pte. Ltd.
- Created development projects using Chugai's Recycling Antibody®, Sweeping Antibody®, bispecific antibody and other proprietary antibody technologies
- Started operation of a collaborative lab at IFReC based on an agreement with Osaka University and conducted full-scale assessment and introduction of candidate compounds
- Held "Chugai 3R Day" training on animal welfare for all research staff involved in laboratory work

- Pipeline projects: 48 (as of January 31, 2019)
- New products launched and new indications: 15 (2014-2018)
- PHC-based development projects: 27 (as of January 31, 2019)
- Projects in-licensed from Roche: 15 (2014-2018)

- Projects being co-developed with Roche Group: 37 (as of January 31, 2019)
- Projects in response to development requests for unapproved drugs/indications: 4 (2014-2018)

- Invested in facilities for faster launches and simultaneous development of multiple antibodies and small molecule drugs (established new biological API manufacturing facility at Ukima Plant (UK3), enlarged solid formulation manufacturing facility at Fujieda Plant, etc.)
- Received FDA pre-approval inspection and approval for Actemra (new manufacturing method)
- Received pre-approval inspection and approval for Hemlibra in countries around the world

- Strengthened global supply chain management
- Enhanced next-generation core technologies for API manufacture and formulation
- Strengthened development ability by reducing costs from the early stage onward and planning and implementing a dosage form strategy
- Established a system for quality control functions to enhance specialization and raise operational efficiency

- Share of sales in the Japanese therapeutic antibody market: 24.5%[6]
- Share of sales in the Japanese oncology market: 17.9%[6]
- Satisfaction ranking based on healthcare providers' assessments (hospitals with 100 or more beds)[7]: 1st
- Adequacy ranking for provision of safety information based on healthcare providers' assessments (hospitals with 100 or more beds): 1st[8]
- Education for MRs with a high level of expertise

- Enhanced communication of safety information through use of post-marketing surveillance and adverse reaction databases and cooperation with Safety Experts
- Enhanced marketing functions based on local area characteristics
- Patient-centric support activities for regional healthcare and multidisciplinary team care
- Promotion of proper use of medicines through trial service of an app that supports adherence to medication by facilitating smooth communication between patients and their healthcare providers
- Promoted disease awareness in cooperation with the government

- Contract-based post-marketing studies: 28
- Staff with GCP Passport (JSCTR certification): 154 (as of January 31, 2019)
- Number of joint preclinical studies: 11

- Published research papers on Chugai's preclinical studies: 11
  Presentations at scientific conferences: 5 overseas, 6 in Japan
- Inquiries to the Medical Information Department: 56,120 (including telephone, e-mail and fax inquiries)

- Cases for which drug safety information was collected from Japan and overseas according to global standards for clinical trials and post-marketing studies: 18,400
- Increased capacity for generating drug safety information using advanced technologies such as epidemiology and information technology, and enhanced the activities of Safety Experts, a new specialist position for handling drug safety information

- RMPs prepared and implemented for thorough risk management: 12 products
- Papers and conference presentations on drug safety based on the results of post-marketing surveillance: 9

- Developed quality and regulatory compliance framework for genomic mutation analysis program FoundationOne® CDx Cancer Genomic Profile and obtained regulatory approval
- Prepared for inspection and obtained approval from FDA for Actemra (new production method), and Alecensa and Hemlibra (additional production sites)

- Formulated and circulated a global policy on counterfeit drugs, and raised awareness through activities in cooperation with Roche and at scientific conferences in Japan and overseas
- Carried out awareness activities targeting all fundamental organizational units and introduced risk management methodologies at all companies in order to foster a "culture of quality" as recommended by the FDA

- Patents held (including pending applications): 4,647
- New patents granted worldwide: 213
- Market defense in lawsuits with manufacturers of similar products with the equivalent effect or developers and manufacturers of biosimilars

- Operated a system for monitoring other companies' patents
- Strengthened cooperation with the Research Division and Pharmaceutical Technology Division using IP liaisons as a hub

5. Chemistry, Manufacturing and Controls: A concept that integrates API process research and pharmaceutical development research with quality evaluation research
6. Copyright © 2019 IQVIA. Source: JPM 2018. Reprinted with permission. The scope of the market is defined by Chugai.
7. Copyright © 2019 anterio. Source: Rep-i 201808. Reprinted with permission. Based on a survey of overall assessments of companies by physicians, as defined by Chugai.
8. Based on an anterio market survey in 2018 for understanding safety information needs

E: Environmental Protection; S: Providing Value to Society; G: Human Resources

Category	Examples of ESG initiatives in each division	E	S	G
Research	• Fostered employee awareness of energy saving through energy visualization	●		
	• Continued joint cleanup activities with a local high school for the Shinkawa River, which flows through the Kamakura Research Laboratories site	●		
	• Conducted activities at Kamakura Research Laboratories to raise awareness of the importance of cancer screening		●	
	• As part of the Company's support for recovery from the Great East Japan Earthquake, held a charity sale at the Kamakura Research Laboratories of specialty products from the affected area		●	
Development	• Fostered a corporate culture where employees can participate actively after returning from childcare or other leave			●
	• Held cross-cultural training to cultivate leaders who can succeed globally			●
	• Held study sessions with instructors from other industries to promote global success			●
	• Held the Quality Forum to foster a corporate climate for becoming a top pharmaceutical company			●
Pharmaceutical Technology and Production	• Reduced greenhouse gas emissions with the scheduled introduction of high-efficiency air conditioning	●		
	• Promoted reduction of energy consumption through an energy visualization task force	●		
	• Conducted firefighting activities in cooperation with local fire departments		●	
	• Promoted "Techno" technology review activities to create new core competencies and strengthen basic technologies			●
	• Held U-MAST (at Utsunomiya Plant), UK-NEXT (at Ukima Plant) and F-OPEX (at Fujieda Plant) as initiatives to train young employees through proposal and improvement activities			●
	• Held interdivisional exchange meetings (Knowledge Cube for Marketing & Sales, Medical Affairs and Pharmaceutical Technology divisions and BRIDGE for Research, Clinical Development, Translational Clinical Research and Pharmaceutical Technology divisions)			●
Marketing	• Promoted proper use of medicines through support for improvements in the rate and accuracy of testing		●	
	• Participated in Lung Cancer Awareness and attended to patient requests regarding drugs		●	
	• Conducted support activities for working while undergoing breast cancer treatment		●	
	• Promoted disease awareness through cooperation with businesses in other industries		●	
	• Held the Bone and Joint Forum 14 times as a measure against locomotive syndrome		●	
	• Disseminated information on a new issue related to cancer treatment (cancer patient dementia) through the Chugai website		●	
Medical Affairs	• Conducted a training program from the standpoint of cultivating global medical human resources			●
	• Measures to evaluate the effect of drugs on improving conditions for working during outpatient treatment		●	
Drug Safety	• Promoted paperless operations for stored materials and meeting materials	●		
	• Provided the latest drug safety information through lectures and awareness-raising activities for the media		●	
	• Contributed to the enhancement of Japan's epidemiological database		●	
	• Contributed to regulatory reforms and strengthening of drug safety monitoring systems in Japan and overseas through industry activities		●	●
Quality and Regulatory Compliance	• Held information-exchange events for contract manufacturing organizations to share examples of Chugai best practices to ensure compliance with new regulations and regulatory trends		●	
	• Promoted reduction in paper consumption through the introduction of an electronic document archive system and digitalization of existing paper documents	●		
	• Provided direct advice on amendments to the Law for Ensuring the Quality, Efficacy and Safety of Drugs and Medical Devices through industry activities		●	
	• Promoted activities to foster a "culture of quality" as recommended by the FDA			●
Intellectual Property	• Created and operated a paperless process for applications for public disclosure approval	●		
	• Established a separate organization specializing in intellectual property disputes (IP Liaison Group)			●

Chugai's 2018 in Review

Products and Development Projects	
January	Tecentriq intravenous infusion 1200mg obtained approval (unresectable, advanced or recurrent non-small cell lung cancer; Japan)
February	Hemlibra obtained approval (hemophilia A with inhibitors; E.U.)
March	Hemlibra obtained approval (hemophilia A with inhibitors; Japan)
April	**Hemlibra received breakthrough therapy designation** (hemophilia A without inhibitors; U.S.)
April	**Tecentriq launched (Japan)**
May	Alecensa obtained approval for additional indication (first line therapy for ALK-positive non-small cell lung cancer; Taiwan)
May	**Hemlibra launched (Japan)**
June	**Hemlibra received priority review designation (hemophilia A without inhibitors; U.S)**
July	Gazyva intravenous infusion 1000 mg obtained approval (CD20-positive follicular lymphoma; Japan)
August	**Gazyva launched (Japan)**
September	**Chugai and Eli Lilly and Company entered into a license agreement for GLP-1 receptor agonist OWL833**
October	Hemlibra obtained approval for additional indication (hemophilia A without inhibitors; U.S.)
October	Perjeta obtained approval for additional indication (neoadjuvant and adjuvant therapy for HER2-positive early breast cancer; Japan)
December	Hemlibra obtained approval (hemophilia A with inhibitors; Taiwan)
December	**Satralizumab received breakthrough therapy designation** (neuromyelitis optica and neuromyelitis optica spectrum disorder; U.S.)
December	Hemlibra obtained approval for additional indication (hemophilia A without inhibitors; Japan)
December	Tecentriq obtained approval for additional indication (unresectable, advanced or recurrent non-small cell lung cancer; Japan)
December	Chugai obtained approval for genomic mutation analysis program FoundationOne® CDx Cancer Genomic Profile (Japan's first program with two functions of cancer genomic profiling and companion diagnostics, it enables oncology gene panel profiling)

Management	
January	Transferred 13 long-listed products from Chugai to Taiyo Pharma
March	Appointed new CEO
March	Entered a license agreement with Roche to begin activities toward commercialization of the products of FMI in Japan
July	FMI business unit established
July	Extended Chugai Pharmabody Research operations for five years and committed to investment totaling 282 million SGD from 2022 through 2026
July	Decided to construct a new building for synthetic research at Ukima Research Laboratories to enhance process development for small and middle molecule APIs
July	Entered into comprehensive partnership agreement with Preferred Networks, Inc.

Stakeholders	
March	Selected as a 2017 Tokyo Sports Promotion Model Company
March	Selected as a Nadeshiko Brand for the fourth consecutive year and recognized in the New Diversity Management Selection 100
August	Obtained Platinum Kurumin certification from the Minister of Health, Labour and Welfare as a company supporting childrearing; the number of male employees taking childcare leave increased sevenfold in two years
September	Selected for the fourth time for Dow Jones Sustainability Asia Pacific Index
September	Donated para-transit vehicles to welfare services
October	Expressed support for the Japan Climate Action Summit Declaration
October	First in the pharmaceutical industry to begin providing a treatment support app for immune checkpoint inhibitors using multidisciplinary SNS
October	Xeloda® adherence support app began contributing to improving communication between cancer patients and healthcare providers
December	Establishment of Gan with, an information website for cancer patients, their families and coworkers

Organizational Facts and Figures

(Non-consolidated; as of December 31, 2018)

Number of employees	5,037
Ratio of female employees	27.3%
Ratio of female managers[1]	13.3%
Number of female officers[2]	1
Average tenure	Male: 18.4 years Female: 13.0 years
Number of employees posted through the Roche Human Resource Exchange Program (2004-2018)	174
Percentage of employees using the telecommuting system[3]	34.5%
Percentage of employees taking childcare leave[4]	Male: 57.7% Female: 100.0%

1. Number of female managers as a percentage of the total number of managers
2. Officers as per the Companies Act
3. Percentage of eligible employees who used the system
4. Percentage of employees who have had children

Research

IBI 18 (2016–2018)

- Continuous new drug creation using proprietary antibody technologies
- Establishment of a technology platform for middle molecule drugs
- Strengthening of the research base for oncology/immunology using external network

IBI 21 (2019–2021)

- Construction of leading drug discovery technologies and continuous addition to pipeline
- Creation and promotion of innovative projects through the deepening of biological research into human diseases
- Expansion of opportunities to acquire new candidate compounds using external network

Continuation → Evolution

S (Strengths)

- Proprietary drug discovery technology, particularly in biotechnology (in-house products: 15[1], no. of academic papers and presentations at scientific conferences regarding Chugai's innovative proprietary technologies: 53[2])
- Efficient collaboration with the Roche Group, including infrastructure sharing (Ratio of research and development expenditures to revenues: 16.2%)

W (Weaknesses)

- Infrastructure for recruiting researchers is incomplete
- Lack of resources for biotechnology research

O (Opportunities)

- Progress in new modalities, including middle molecule drugs
- Mounting social expectations on drug discovery and healthcare as a growth industry

T (Threats)

- Increasing difficulty and escalating cost of new drug development worldwide, and intensifying competition
- Potential paradigm shift due to disruptive technologies, etc.

1. As of January 31, 2019 2. 2014-2018

Functions

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 gained experience through our own pioneering initiatives while also incorporating outside technologies. As a result, we have continuously evolved our capabilities, and have built a technology platform that we can flexibly and appropriately apply to drug discovery.

We are using this platform to generate a steady stream of innovative new drugs with first-in-class or best-in-class potential to address unmet medical need. In addition to developing antibody engineering technologies ahead of other companies, Chugai has industry-leading research and technological capabilities backed by small and middle molecule[1] technologies, the world-class research infrastructure of the Roche Group and a powerful external network with academia and other parties. Through presentations of research findings at scientific conferences and other means, these strengths lead to benefits for the medical community around the world as we leverage them in the creation of in-house projects.

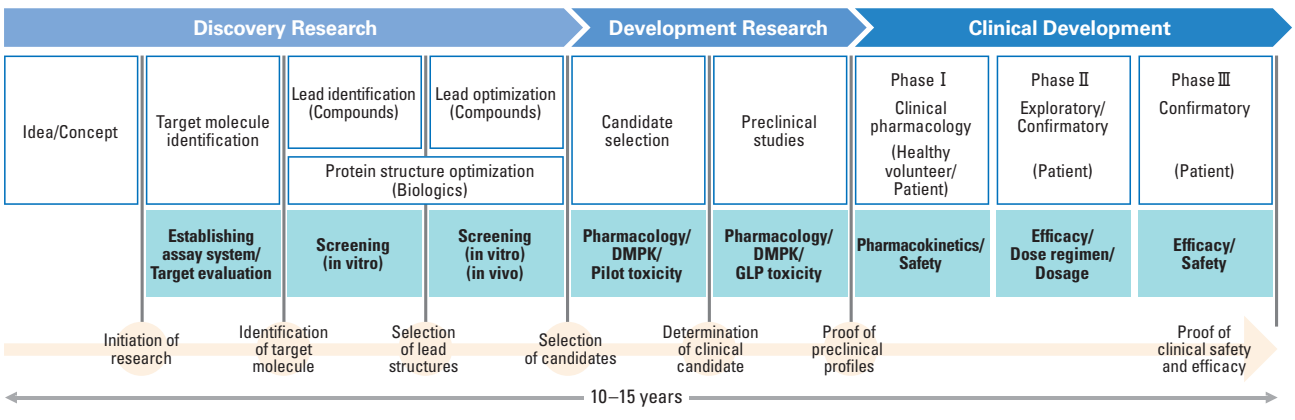
1. Middle molecules have significant potential because they are capable of inhibiting protein-protein interaction (PPI) in intercellular molecules, which is difficult to achieve with antibodies and small molecules.

Business Model

One of Chugai's strategic advantages that enables it to continuously create innovative drugs is its ability to concentrate resources on innovative research. Efficient development in Japan of projects in-licensed from Roche provides a stable revenue base while we conduct global development of projects from our own research in collaboration with Roche. This enables us to concentrate personnel and funds on groundbreaking in-house projects, leading to the creation of a steady stream of innovative drugs. Another powerful advantage is our access to Roche's global research infrastructure. The ability to share Roche's global research resources and infrastructure, including a rich compound library for use in high-throughput screening,[2] is a significant plus for Chugai in terms of cost, efficiency and other factors, and has dramatically increased our research productivity.

2. A technology that conducts evaluations at a high speed with 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

Process and Milestones of Drug Development



In addition, by concentrating on the creation of new therapeutic antibodies, Chugai Pharmabody Research (CPR), which we established in Singapore in 2012, is working to continuously create innovative therapeutic antibody drugs that apply our proprietary antibody engineering technologies and to accelerate the speed of drug discovery.

Allocation of Resources

In allocating research resources, we prioritize each project based on the following criteria:
(1) The project's potential for development as a novel medicine that can be clearly differentiated
(2) Whether it has a scientific basis for addressing unmet medical need
(3) Whether it will enable personalized healthcare (PHC)

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

Bioethics and Animal Welfare

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, 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 to minimize their pain, keeping in mind the scientific conditions.

In 2018, we also held the Chugai 3Rs Day as part of our promotion of the principles of the 3Rs (Replacement, Reduction and Refinement) and animal welfare. Through such activities, we strive to raise awareness of animal welfare among all employees working in our laboratories.

Main Initiatives and Progress

Creation of Innovative New Drugs

In 2018, PHC-based projects represented 56 percent of our total pipeline, including projects in-licensed from Roche. Hemlibra received approval as a treatment for hemophilia A in the United States in November 2017, and in Europe and Japan in 2018. It is the first project applying our proprietary antibody technologies to be approved.

Collaboration with Our External Network

In April 2017, a collaborative lab began operating under our comprehensive agreement with Osaka University Immunology Frontier Research Center (IFReC) to conduct ongoing assessment and introduction of new candidate compounds from its cutting-edge immunology research.

Immunity is involved not only in diseases of the immune system itself, but also in cancer and various other diseases, and immune-mediated therapies are now becoming mainstream cancer treatments. Combining the global top-class research in immunology at IFReC and Chugai's expertise in drug discovery research, accumulated through its proprietary technologies, is expected to result in the creation of innovative new drugs.

We are also looking to innovate the drug discovery process itself, including for next-generation personalized healthcare, by applying the highly advanced genomic analysis techniques and other capabilities of FMI, which joined the Roche Group in 2015.

Research at Satellite Labs

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 and the identification of new drug targets at Forerunner Pharma Research Co., Ltd. CPR is making steady progress in the discovery of new therapeutic antibodies, with GYM329 entering clinical development in 2018 after SKY59. In addition, C&C Research Laboratories in South Korea is conducting small molecule drug discovery research, mainly in the fields of oncology and immunology.

Evolution of Drug Discovery Modalities

In the pharmaceutical industry, modality refers to the material classification of drugs such as therapeutic antibodies or therapeutic nucleic acids. Until around 1990, small

Progress of Development Projects

(January 1, 2018 – January 31, 2019)

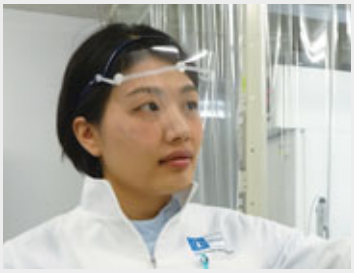
	Number of Projects	Breakdown		
		New Molecular Entities	Additional Indications	Additional Dosage and Administration/ Formulations
Approved	13	6	5	2
Filed	17	3	10	4
Started phase III	10	5	5	0
Started phase II	1	1	0	0
Started phase I	6	6	0	0
Development suspended	4	3	1	—

Comparison of Drug Discovery Modalities

	Small molecules	Middle molecules	Biologics
Molecular weight	Below 500	500 - 2,000	10,000 and above
Target specificity	Fair	High	High
Intracellular targets	Wide range	Numerous	Limited
PPI inhibition	Fair	Good	Good
Administration route	Oral/Injection	Oral/Injection	Injection
Manufacturing method	Organic synthesis	Organic synthesis	Cell culture

*PPI: Protein Protein Interaction

I am establishing a new assay system for selecting middle molecule candidates. By identifying the characteristics of distribution and metabolism within the body, including uptake through the cellular membrane, we will be able to select middle molecule candidates that are readily absorbed following oral administration. This will lead to greater convenience for patients and stable efficacy.



Hengmin Tang
Discovery DMPK Group 3,
Discovery ADMET Dept.

molecule drugs were virtually the only modality available, but modality options are now increasing. Chugai is currently focusing on establishing middle molecules as a third modality in addition to biologics and small molecules, in which it is already strong. Middle molecules are a valuable method for reaching intracellular targets that are difficult to approach using antibodies and small molecules, and we are proactively promoting the establishment of a hit/lead compound generation technology platform as we work toward the creation of development projects.

Enhancing our Intelligence Functions

Rapid scientific and technological advances, especially in life science and information and communications technology (ICT), are bringing dramatic changes to society and the pharmaceutical industry. Chugai's Science and Technology Intelligence (STI) Department was established in April 2017 as an intelligence unit to consider Chugai's response to emerging issues in the healthcare business.

Healthcare in the future is expected to center on PHC, which provides optimal solutions tailored to individual patients, and in addition to diagnosis and treatment, which are the focus of the current model, greater value will need to be provided in areas such as prevention and prognosis. Our goal is to contribute to higher-quality healthcare with solutions that lead to new value, and a critical part of that effort is formulating strategies for disruptive innovation,[3] which will be essential for realizing such solutions.

STI's mission is to find promising seeds for pursuing disruptive innovation, and to create strategies for bringing it about. In the three areas of life science, healthcare ICT, and data utilization, STI will perform radar, hub and intelligence functions in cooperation with internal cross-functional teams of experts. A number of projects have already begun.

In July 2018, Chugai entered into a comprehensive partnership agreement with Preferred Networks, Inc. (PFN), a global leader in AI technology. We aim to create innovative drugs and new value through the application of PFN's cutting-edge deep learning technology and Chugai's expertise, technologies and data.

3. Innovation that disrupts the order of existing business and causes drastic changes in the industry structure

Chugai's Proprietary Technologies

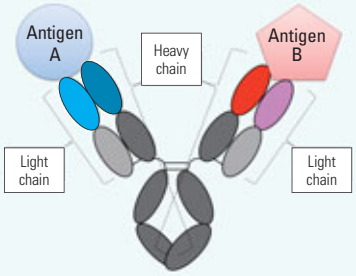
Drug discovery technologies, largely antibody engineering technologies, are Chugai's core competence. We are focused on development of proprietary technologies that are necessary for addressing areas of unmet medical need. Their application leads to the generation of innovative and competitive medicines.

Chugai's research and development operations have focused on the development of new antibody engineering technologies to create a series of technologies that overturned conventional wisdom about antibody engineering. Examples include the development of our Recycling Antibody®, Sweeping Antibody® and bispecific antibody technologies. In addition to antibody engineering and small molecules, we have selected drug discovery technologies for middle molecules as a candidate for our next-generation core technology. We intend to concentrate investments in this area to establish this new technology and quickly generate new projects.

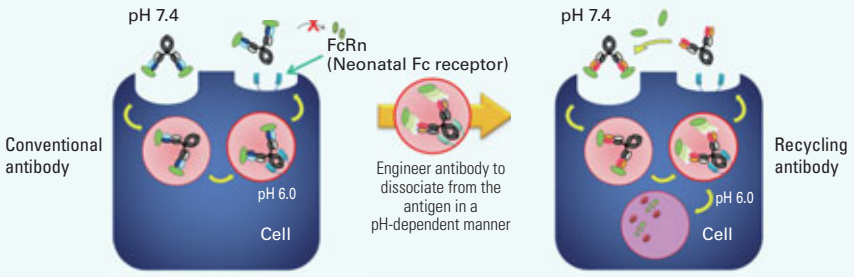
Eight Technologies

Antibody technology	Features
SMART-Ig®	Creates the Recycling Antibody®, which has a longer duration of action than conventional antibodies because it can bind to an antigen multiple times.
SMART-Fc®	Creates the Sweeping Antibody®, which eliminates disease-causing antigens from plasma.
ART-Ig®/FAST-Ig®	Enable large-scale production of bispecific antibodies. Unlike conventional antibodies that bind only to a single antigen, bispecific antibodies bind to two different antigens, and are therefore expected to exhibit efficacy in a variety of ways.
ART-Fc®	Enhances the antibody-dependent cellular cytotoxicity (ADCC) activity using ART-Ig®. Induces enhanced ADCC activity compared with existing technologies. Potential applications in the oncology field.
TwoB-Ig®	Increases binding selectivity of the Fc region to inhibitory Fcγ receptor IIb. Potential applications in autoimmune diseases and other areas.
TRAB®	Activates T cells in an antigen-dependent manner to specifically kill cancer cells.
ACT-Ig®	Reduces clearance from plasma.

Bispecific Antibody



Effect of Recycling Antibody® against Soluble Antigen in Plasma



- Antibody can bind to the antigen only once
- Antigen persists as an antibody bound form, accumulating in plasma

- Antibody can bind to the antigen multiple times
- Prevents antigen accumulation by discarding the antigen within the cell

Development

IBI 18 (2016–2018)

- Maximization of the value of Roche products through simultaneous global development and regulatory filing
- Global development and early acquisition of PoC for Chugai products
- Implementation of an IDCP[1] from the initial stage of development to maximize the value of each Chugai product

IBI 21 (2019–2021)

- Establishment of development methods for Chugai products with new modalities and mechanisms of action
- Further acceleration of development through use of data assets
- Maximization of product value based on VBHC[2]

Continuation Evolution

1. Integrated Development and Commercialization Plan 2. Value-based healthcare

S (Strengths)
- Comprehensive development track record (total no. of clinical trials: 104[1])
- High development success rate of innovative in-house products (FPI[2]: 3 projects; breakthrough therapy designation (BTD)[3]: 1)[1]
- Global collaboration with Roche (global studies: over 60%; joint development projects: 21)[4]

W (Weaknesses)
- Evolution of quality and speed at a top global level in early development
- Constant and cross-functional operation of the process for proof of value
- Infrastructure development and acquisition of human resources for utilization of real world data (RWD), data assets, and cutting-edge technologies

O (Opportunities)
- Increasing expectations for development of innovative drugs using proprietary technology
- Advances in development of personalized healthcare using large-scale data such as genetic information
- Greater flexibility and diversification in the application filing process

T (Threats)
- Intensified global competition in new drug development and escalating development costs
- Potential paradigm shift due to disruptive technologies, etc.
- Decline in competitive advantage of in-house products due to the emergence of new modalities

1. January-December 2018 2. First patient in 3. A system introduced in July 2012 by the U.S. Food and Drug Administration aimed at expediting the development and review of drugs for the treatment of severe or life-threatening diseases or symptoms 4. As of December 31, 2018

Functions

Chugai has established a lifecycle management[1] system for project-level integrated management of each of its functions, and cooperates with numerous medical institutions and clinical research centers. In this way, we work to implement clinical trials distinguished by exceptional speed, efficiency and scientific rigor.

Specifically, in clinical development, we draw up clinical development plans based on the latest scientific findings and invite medical institutions to conduct clinical trials. In pharmaceutical technology and production, we examine commercial production that will turn candidate compounds into pharmaceutical products and manufacture investigational drugs for clinical trials. In drug safety, we ensure a high level of safety in clinical trials by gaining an understanding and beginning assessments of each drug's safety profile from the early stages.

Through our alliance with the Roche Group, we are implementing multiple global development projects (multinational studies) and strengthening the process that enables simultaneous development of drugs and companion diagnostics intended for personalized healthcare (PHC). Through these initiatives, we are creating best practices in development and filing for approval in Japan, which we believe contribute to the advancement of the industry.

1. 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.

Enhancement of Functions and Organizational Change

In October 2018, Chugai partially reorganized its Translational Clinical Research (TCR) Division. The aim of the change was to promote the development of in-house products that have passed from research to the early clinical development stage. From this perspective, we changed the name to the Translational Research (TR) Division, which functions as a bridge between preclinical and early clinical development. For overseas development of projects from in-house research, U.S. subsidiary Chugai Pharma USA and U.K. subsidiary Chugai Pharma Europe conduct high-quality clinical trials in close cooperation with medical institutions in the United States and Europe.

We also accelerate global development by sharing knowledge and platforms for clinical development with the Roche Group. Moreover, we utilize Foundation Medicine Inc. (FMI)[2] and others to generate evidence that will lead to PHC from the clinical development stage.

In the Clinical Development Division, we have established the new Clinical Information & Intelligence Department to work as a hub for the collection, management, analysis and transmission of all clinical development data. The aim of the department is to strengthen data utilization and intelligence functions, which enable the planning of optimal clinical development strategies.

2. FMI was established in Massachusetts, U.S.A. in 2010. In 2015, Roche took a majority stake, and then acquired the remaining outstanding shares in 2018 to make FMI a wholly-owned subsidiary. Chugai established the FMI business as a specialized unit in October 2018 to carry out commercialization and product value maximization of FMI's "Comprehensive Genomic Profiling Service" in Japan.

Main Initiatives and Progress

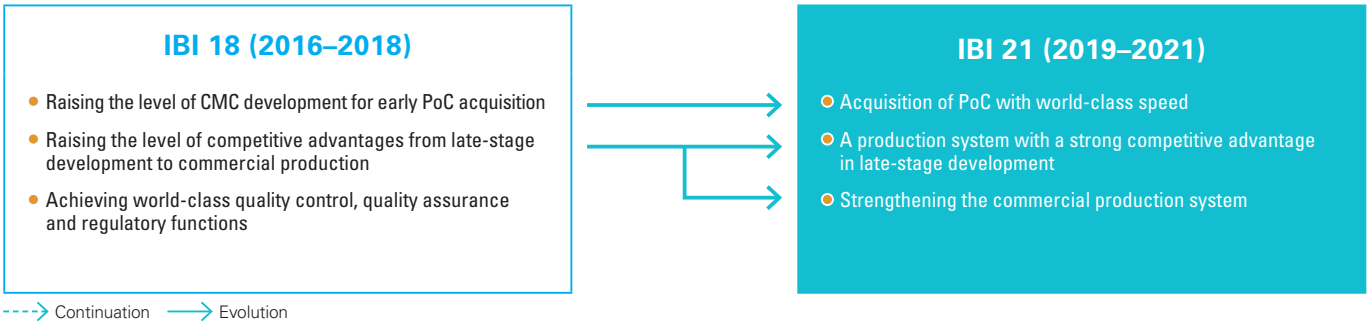
A Well-Stocked Pipeline

In 2018, all projects made steady progress. Chugai filed for regulatory approval for 5 projects, and obtained approval for 6 projects. Chugai's pipeline grew even richer, with 6 new projects in-house or in-licensed (from Roche) advancing to the clinical phase.

Speedy Global Development

Chugai has been working to speed up global development by following a development model with a high probability of success and by making efforts to prove the value of in-house projects from the early stages of development. As a result, Alecensa took just seven years from concept to launch in Japan, and Hemlibra, for which we filed for approval simultaneously in Japan, the United States and Europe, obtained approval in less than five years, far ahead of our initial plan. Hemlibra is dramatically transforming treatment strategies for hemophilia and achieving unprecedented results. Moreover, now that nemolizumab (CIM331) has acquired PoC and satralizumab (SA237) has obtained positive results in global studies under Chugai's management, we are taking on the new challenge of global filings for approval during 2019 in collaboration with Roche.

Pharmaceutical Technology and Production



S (Strengths)
- Advanced therapeutic antibody production technology and state-of-the-art equipment (cultivation capacity: approx. 130,000 L)
- Proven track record of global inspections and applications (New manufacturing processes of Hemlibra, Alecensa, and Actemra)

W (Weaknesses)
- Information collection and system development on the latest global regulations, including data integrity
- Efficient development of production system utilizing external resources

O (Opportunities)
- Fast-track review system to support early approval of innovative new drugs
- Initiation of a system for pharmaceutical quality management

T (Threats)
- Progress in global control over drug costs, the shrinking domestic market amid drastic reform of NHI drug prices
- Loss of premium pricing status for new drug creation on mainstay products and the emergence of generic drugs
- Potential paradigm shift due to disruptive technologies, etc.

Functions

Our pharmaceutical technology and production functions play a wide range of roles in the pharmaceutical value chain – from turning drug candidates into products to stably supplying them. These candidates may be compounds created in our laboratories or projects in-licensed from Roche or elsewhere.

Product creation includes research on production methods for active pharmaceutical ingredients (APIs), formulation and packaging design, production of investigational APIs, and collection and analysis of production data. Among these activities, we have most recently been taking positive steps to build and patent a new technology platform that will give us a distinct advantage in commercial production of innovative medicines such as next-generation antibodies and middle molecules.

Through stable supply of our products, we maintain the trust of patients and healthcare providers – a duty central to Chugai's existence as a pharmaceutical manufacturer. That is why we need to build and maintain a robust supply chain with production bases (including contract manufacturing organizations) in various regions around the world.

Chugai has competencies at Japan's top level, including bioproduction technology and the ability to accommodate inspections. We will leverage our strengths as a member of the Roche Group to become a top innovator in our pharmaceutical technology and production operations.

Main Initiatives and Progress

Improving Flexibility and Speed

In its pharmaceutical technology and production operations, Chugai is aiming for simultaneous development of multiple products for the quickest launches possible.

Specifically, at the Ukima Plant, we have achieved a significant increase in capacity utilization by employing plastic single-use bioreactors, and to prepare for development candidates that apply next-generation antibody technologies we have constructed UK3, a new antibody API facility capable of high-mix, low-volume production from late-stage development to initial commercial products. At the Utsunomiya Plant, we have increased production flexibility by installing tray fillers that can handle filling of liquid medicines without making line changes or modifications, regardless of the syringe type.

Evolving Supply Chain Management

To minimize risks related to the supply and price of raw materials, we promote the globalization of our suppliers of raw materials and intermediate products in tandem with the globalization and establishment of two production bases for each finished product.

Our subsidiary Chugai Distribution Co., Ltd. handles distribution of pharmaceuticals in Japan. The company's computerized inventory management and inspection ensure stable and safe distribution, and the staff conducts ongoing process innovation in packaging.

Thorough Quality Assurance

Quality assurance functions have diversified in recent years in response to the increasing complexity of supplying products and accelerated development with the introduction of the fast-track review system to support the early launch of innovative new drugs.

In view of these trends, Chugai is working to further strengthen GMP* management oversight to promote more rigorous and high-level quality assurance. As part of these efforts, Chugai has created and operates a world-class system for pharmaceutical quality management.

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

Biological API Production: Our Facility Portfolio

Plant	Target	Bioreactors	Features	Products
Utsunomiya	Commercial production (Large-scale)	10,000 L x 8 (UT1, UT2: Stainless steel tanks)	• Competitive low-cost production • Dedicated facilities	Actemra
Ukima	Commercial production/ Production of investigational APIs (Medium-scale)	6,000 L x 6 (UK3: Stainless steel tanks)	• Emphasis on flexibility • Can handle high-mix, low-volume production	Future development projects
Ukima	Commercial production/ Production of investigational APIs (Small-scale)	2,000 L x 4 (UK1, UK2: Single-use plastic bags)	• Improved capacity utilization through the application of single-use bioreactor technology	Future development projects

Marketing

IBI 18 (2016–2018)

- Realization of sales growth by concentrating on sales driver products and new products
- Providing advanced solutions through cross-functional collaboration with experts in different divisions
- Establishment of strategic and tactical system adapted to local area characteristics

IBI 21 (2019–2021)

- Maximization of the value of growth drivers (innovative drugs and services)
- Enhancement of consulting activities for innovative products to select the best treatment according to each patient's condition
- Provision of solutions through cooperation with diverse specialized human resources and incorporation of digital technology

Continuation → Evolution

S (Strengths)
- Leading presence in specialty areas, such as biopharmaceuticals and personalized healthcare (PHC)
- A system for providing advanced solutions based on regional and customer characteristics, multidisciplinary team care and drug safety activities utilizing a database of adverse events, etc.

W (Weaknesses)
- Response to an increase in competing products and an increase in new entrants
- Response to the emergence of biosimilars[1] and generic drugs[2]

O (Opportunities)
- Further increase in unmet medical needs as a result of the aging population as well as incurable diseases and orphan drug designations[3]
- Increase in therapeutic opportunities due to early detection and promotion of testing
- Progress in personalized and advanced healthcare, including genetic diagnosis

T (Threats)
- Progress in global control over drug costs, the shrinking domestic market amid drastic reform of NHI drug prices
- Loss of premium pricing status for new drug creation on mainstay products and the emergence of generic drugs
- Tighter regulations on promotional activities due to higher ethical and transparency standards

1. Successor products to biopharmaceuticals whose patent term has expired, made by manufacturers other than the manufacturer that developed the antecedent biopharmaceutical
2. Drugs approved after the expiry of the patents for original drugs with the same active ingredients and efficacy
3. Medical need that is not adequately met due to a lack of effective treatments

Functions

The need for new therapeutic agents to deal with cancers or rare or refractory diseases that lack effective treatments (unmet medical need) is high, and more sophisticated and individualized medical procedures such as cancer immunotherapy and genomic testing are attracting attention. Chugai is pursuing initiatives to meet unmet medical need based on its extensive lineup of first-in-class and best-in-class drugs and new diagnostic technologies.

As medicine becomes more sophisticated and individualized, healthcare providers will be expected to promptly provide high-quality information. Chugai takes three approaches to this process, which it refers to as "consulting."

For patients

We conduct patient-centric consulting that gives the highest priority to patients, including proposing the optimal drug treatment according to each patient's condition, providing relevant information on proper use and safety, and follow-up activities.

For regional healthcare

We aim to provide liaison services for regional healthcare with the aim of solving medical issues according to local area characteristics. We conduct consulting that improves patients' access to treatment by supporting regional healthcare coordination among healthcare providers and medical institutions as well as collaboration among local governments, public entities, and other industries.

For stakeholders

Multidisciplinary team care has advanced in recent years, with various specialist healthcare providers working in collaboration to carry out treatment according to each patient's condition. We conduct consulting to support our diverse stakeholders and multidisciplinary teams who follow up on treatment through proper management of adverse events.

Because consulting activities necessarily require extensive communication with relevant parties, our MRs play a key role. In addition to MRs, we also have a system for providing solutions that meet medical needs through participation in cross-functional teams by members of the Marketing & Sales, Medical Affairs and Drug Safety divisions, who have high-level expertise.

At the same time, we are innovating business processes using the latest digital technologies such as artificial intelligence and the Internet of Things to build a system that can provide more efficient and effective solutions based on higher-quality consulting.

As part of a multidisciplinary team, I am working toward treatments for bone diseases, which can be a factor causing a patient to require nursing care. Through collaboration with medical associations and local government, in 2019 we will create a framework that builds patient awareness and links it to examination and treatment. We then plan to expand this framework prefecture-wide to make Oita Prefecture a place where people have strong, resilient bones.

Yutaro Satake
Kumamoto and Oita Branch, Kyushu Regional Management Office, Marketing & Sales Div.

Main Initiatives and Progress

Oncology

In 2018, sales in the oncology area in Japan decreased 0.1 percent year on year to ¥225.7 billion. The contribution from new products included ¥9.1 billion from rapid market penetration of Tecentriq, an anti-PD-L1 monoclonal antibody launched in April 2018 as a second-line treatment for non-small cell lung cancer (NSCLC) and ¥0.6 billion from Gazyva, a treatment for CD20-positive follicular lymphoma launched in August 2018, including sales due to a switchover from Rituxan. In addition, market uptake substantially exceeded expectations for Perjeta for the additional indication of HER2-positive early breast cancer, and sales increased ¥2.5 billion (18.4 percent) to ¥16.1 billion, contributing significantly to results.

In addition, amid the emergence of various new drugs in each area and their changing position in treatment, we were able to minimize the impact of the decrease in NHI drug prices resulting from the loss of premium pricing status for new drug creation for Herceptin and Rituxan by maintaining sales volume for mainstay drug Avastin and growing sales of new and existing products

In 2019, we aim for further growth in the oncology area led by Tecentriq, which obtained approval for indication as a first-line treatment for NSCLC in December 2018, as well as from market uptake of Gazyva and from maintaining the position of our mainstay drug Avastin as a treatment for multiple types of cancer.

Bone and Joint Diseases

In 2018, sales in the bone and joint diseases area in Japan increased ¥7.2 billion, or 7.7 percent, year on year to ¥100.5 billion. In addition to growth from uptake of Actemra as a first-line biologic for the treatment of rheumatoid arthritis (RA), sales growth continued for Edirol, which has been recognized as a base treatment for osteoporosis, and for Bonviva, which was launched in an oral formulation in April 2016 in addition to the intravenous formulation. Sales of Actemra outside Japan including exports to Roche increased ¥19.7 billion, or 32.3 percent, to ¥80.6 billion as firm global sales by Roche compensated for the negative effect of exchange rates.

In 2019, we expect continued firm sales of treatments in the bone and joint diseases area in Japan. Outside Japan, we expect growth in sales of Actemra, mainly due to further uptake of the subcutaneous formulation for RA and sales for giant cell arteritis, which became an additional indication in 2017.

Renal Diseases

Sales in the renal diseases area in Japan in 2018 decreased ¥3.0 billion, or 7.6 percent, year on year to ¥36.3 billion. Mircera, which only needs to be administered once every four weeks, has established a reputation in the pre-dialysis segment for convenience and long duration of action, and prescriptions are increasing. However, sales decreased slightly due to competition from biosimilars and other therapeutic agents in the dialysis field, in addition to the NHI drug price revision in April 2018. Sales of Oxarol decreased partly due to the impact of generics.

In 2019, we aim to maintain and improve the market presence of Mircera and Oxarol in the pre-dialysis and dialysis stages through ongoing provision of information and patient-centric activities rooted in our high level of expertise in the area of renal diseases.

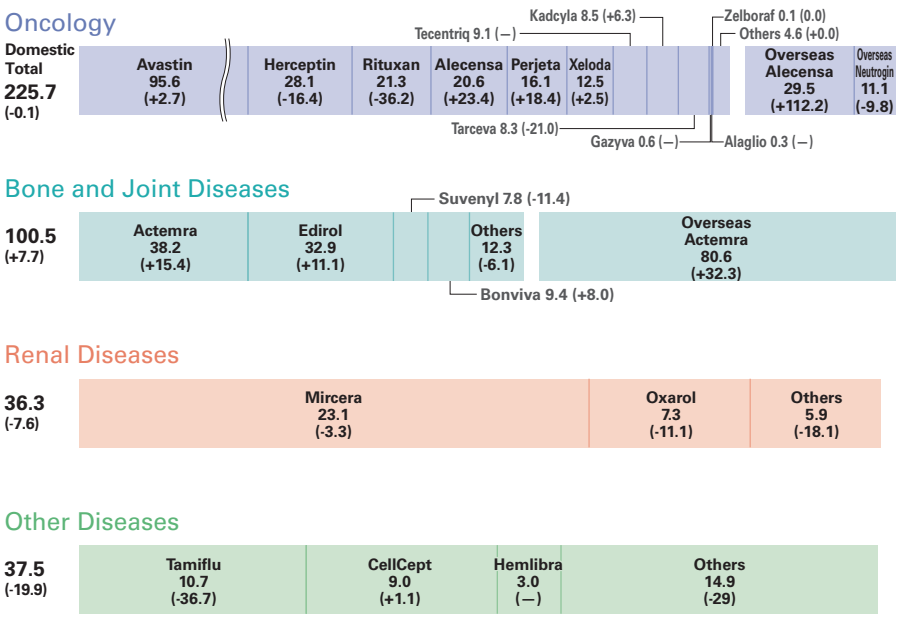
Other Diseases

Hemlibra is a bispecific antibody created using Chugai's innovative antibody engineering technologies. It obtained approval for routine prophylaxis in people with congenital hemophilia A with blood coagulation factor VIII inhibitors in March 2018, and received a drug price listing and was launched in May. Hemlibra's product characteristics are different from those of conventional coagulation factor agents. We focused on providing information on clinical results demonstrating its high level of efficacy in reducing the frequency of bleeding episodes, and sales in Japan were ¥3.0 billion in 2018. In December 2018, Hemlibra also obtained approval for an additional indication for people with hemophilia A without factor VIII inhibitors, enabling administration regardless of the presence of such inhibitors. The approval also allowed dosing intervals of two weeks or four weeks in addition to once-weekly administration, enabling treatment options according to the needs of people with hemophilia A and their healthcare providers. In 2019, by focusing on collecting and providing safety information on people with hemophilia A with factor VIII inhibitors who are already using Hemlibra as well as activities to promote its proper use among people with hemophilia A without factor VIII inhibitors, we anticipate further uptake of Hemlibra as a treatment for congenital hemophilia A.

In the influenza segment, where Chugai plays an important role as a provider of Tamiflu, we focus on providing information on the product's safety and effectiveness, including prevention of the disease, based on extensive clinical data accumulated over a long period. Sales of Tamiflu, including sales for government stockpiles, were ¥10.7 billion.

Sales of CellCept, an immunosuppressant, increased ¥0.1 billion, or 1.1 percent, to ¥9.0 billion in 2018 due to the effect of an increase in kidney transplants and an increase in use in treating lupus nephritis, a refractory disease for which it received approval in May 2016. We will continue to maintain a presence in the transplant segment in 2019 and expect further uptake for lupus nephritis.

2018 Product Sales by Therapeutic Area (Billions of yen)



Note: Figures in parentheses are year-on-year percentage changes.

Medical Affairs

IBI 18 (2016–2018)

- Acceleration of evidence creation
- Promotion of medical affairs in Japan and overseas

→ Evolution

IBI 21 (2019–2021)

- Contribution to healthcare through acceleration and advancement of evidence creation
- Promotion of innovative medical affairs through strengthening collaboration with all stakeholders and actively introducing new technologies

--→ Continuation

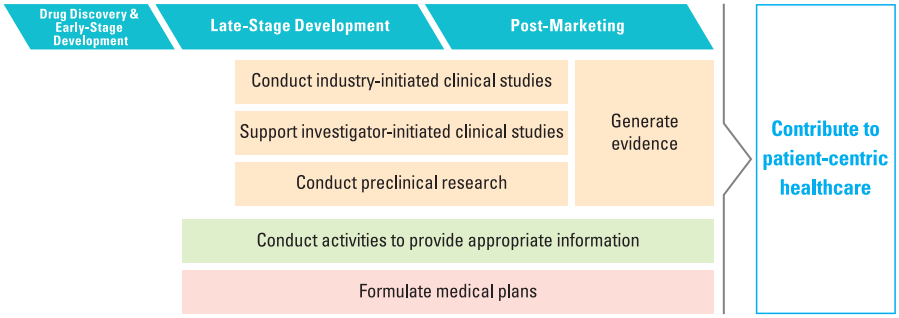
S (Strengths) • Extensive track record in evidence creation • Global collaboration with Roche and overseas subsidiaries	**W** (Weaknesses) • Systematic development of clinical research infrastructure
O (Opportunities) • Increase in opportunities to use internal and external databases following the promulgation of the Next Generation Medical Infrastructure Act • Unmet medical need appearing with the advancement of medical care	**T** (Threats) • Changes in the clinical research system in association with the promulgation of the Clinical Trials Act • Potential paradigm shift due to disruptive technologies or other factors

Functions

In addition to creating a steady flow of innovative drugs, Chugai recognizes the importance of ensuring that the value of its products is delivered accurately to patients, which will lead to better treatment. We have been focusing on creating evidence in support of this objective and supplying appropriate information to healthcare providers. We have also been working to establish a global support system for post-marketing studies. Our efforts have included being one of the first companies to operate a scheme for contract-based post-marketing studies to guarantee the independence and transparency of research, and establishing a research support structure that conforms to the GCP[1] guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) to raise the quality and reliability of research. In addition, we have been preparing an implementation and support system for post-marketing studies under the Clinical Trials Act that was promulgated in Japan in April 2018. We also started a new initiative in anticipation of the Next Generation Medical Infrastructure Act, which was promulgated in May 2018. In 2017, Chugai acquired third-party accreditation[2] for its medical science liaison (MSL) certification program from the Japanese Association of Pharmaceutical Medicine, and we maintain global-level compliance standards, including transparency in funding and appropriate separation of marketing and medical affairs.[3] At the same time, we are working to further enhance our internal systems to help raise the quality and scientific level of clinical and preclinical (basic) research and to deal with changes in our operating environment.

1. Good Clinical Practice: Standards for conducting pharmaceutical clinical trials
2. Composed of evaluation criteria (a total of 222 items in 42 categories) from the three perspectives of independence from promotional activities (compliance system), medical and scientific expertise, and the training system. In the accreditation examination, mail-in and on-site surveys of the evaluation criteria are conducted to evaluate whether the MSL certification program at the applicant company is being properly implemented.
3. Activities that contribute to healthcare from a scientific standpoint

Main Medical Affairs Activities



Main Initiatives and Progress

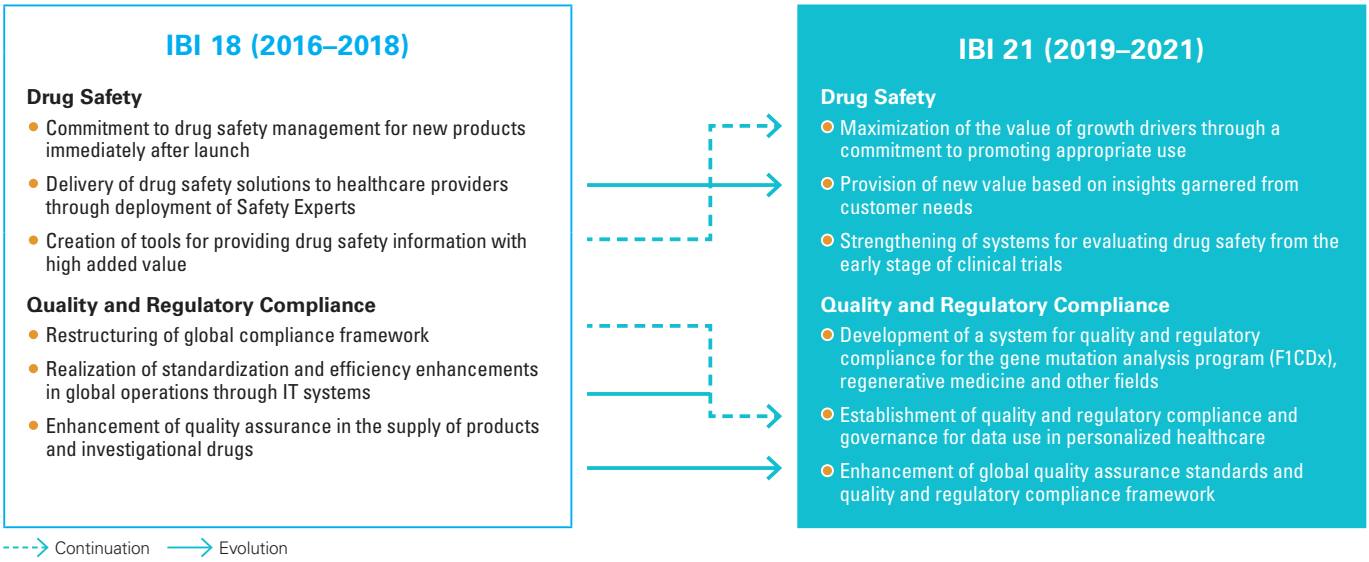
Activities to Generate Evidence

We conduct and support contract-based post-marketing studies to create, communicate and disseminate evidence on efficacy and safety in the clinical setting and non-clinical studies (basic research) to shed light on the modes of action of drugs. Conducted in cooperation with medical institutions and healthcare providers, these studies are based on complete transparency.

Enhancing Intelligence Functions and Measures for PHC

In the future of healthcare, along with elucidation of the causes of diseases and pathological conditions, progress is expected in establishing preventive and treatment methods based on individual genetic, environmental and lifestyle differences. We will respond promptly to this changing environment by enhancing our intelligence functions, such as using ICT and other means to obtain medical information and gain insights from its analysis. At the same time, we intend to provide more suitable treatment methods through the generation of new evidence with higher scientific value and other activities that provide solutions. Through these measures, we will contribute to the development of patient-centric medical research and advanced healthcare.

Drug Safety/Quality and Regulatory Compliance



S (Strengths)

Drug Safety
- Industry-leading achievements (introduction of the database tool and establishment of Safety Experts, etc.)
- Solid partnership with the Drug Safety Division of Roche Group
- A track record of industry activities in areas utilizing epidemiological and medical data

Quality and Regulatory Compliance
- Excellence in global inspections and quality assurance
- Corporate culture and organizational climate in pursuit of compliance and quality

W (Weaknesses)

Drug Safety
- Response to the constant shortage of high-quality human resources

Quality and Regulatory Compliance
- Response to expected cost performance demands and need for high-speed development
- Countermeasures against counterfeit pharmaceuticals

O (Opportunities)

Drug Safety
- Rising need for safety information from healthcare providers to effectively launch innovative new drugs
- Possible automation of some business operations and solutions due to disruptive technologies
- Deepening personalized healthcare through advancements in science

Quality and Regulatory Compliance
- Rising expectations on quality management through technology revolution
- Advancement of pharmaceutical regulations and compliance for global standardization

T (Threats)

Drug Safety
- Strengthening of global pharmacovigilance (PV) regulations in Europe, Asia and other regions
- Dramatically increasing safety information
- Fewer opportunities to convey drug safety information as a result of tighter regulations on visits to medical institutions

Quality and Regulatory Compliance
- Need for enhanced quality compliance in complex business partnerships
- Strict demands for quality data integrity and digital healthcare

Drug Safety Functions

In Japan and overseas, Chugai handles numerous biopharmaceuticals, molecular targeted therapies and other pharmaceuticals with innovative modes of action. To promote the appropriate use of these pharmaceuticals around the world and gain acceptance from patients and healthcare providers, Chugai establishes pharmacovigilance protocols with Roche and other partners and collects safety information on a global level. We consider expert safety evaluation and speedy decision-making to be essential for timely provision of safety information and implementation of measures to ensure safety. Consequently, Chugai has established an independent Drug Safety Division and a system directly linked to management. Through measures such as these, Chugai is building greater credibility, with the aim of providing truly valuable safety data and contributing to patients and healthcare worldwide.

Quality and Regulatory Compliance Functions

Protecting the rights of patients and clinical trial subjects and ensuring the reliability of data are serious responsibilities for the pharmaceutical industry. The Quality & Regulatory Compliance Unit is responsible for ascertaining trends in pharmaceutical regulations and ensuring the soundness of the quality management system spanning our business processes. It also ensures the reliability of data by confirming, improving and verifying the validity of these business processes through quality audits throughout the product lifecycle. In proactively leading cross-divisional activities for the purposes of introducing a global IT system and maintaining and improving quality, the unit aims to foster a self-sustaining quality mindset Company-wide and build a sturdier quality management system. Moreover, by engaging in dialogue with regulatory authorities through industry activities, it is also working to align regulations with society's demands, in ways including revisions to the Law for Ensuring the Quality, Efficacy and Safety of Drugs and Medical Devices.

Main Initiatives and Progress

Collecting and Managing Safety Information

Post-marketing surveillance, which includes all-case registration surveillance, is conducted in (real world) clinical settings to collect safety information unobtainable in clinical trials. In post-marketing surveillance, data on safety are collected from medical institutions through electronic systems. Information on the results obtained from analysis of this data is provided to medical institutions and announced via scientific conferences, papers and other means.

Numerous anticancer agents, innovative new biopharmaceuticals and other drugs require wider-ranging and more rigorous management, such as thorough management of distribution and confirmation of conditions of use, in addition to all-case registration, in which all patients administered a product are registered. With its extensive experience in all-case registration surveillance and other areas, Chugai leads the industry in drug safety evaluation and safety measures. In accordance with the revised Ministerial Ordinance on Good Post-marketing Study Practice (Revised GPSP Ordinance) that came into effect in April 2018, we are contributing to the implementation of epidemiological research, including a survey of post-marketing databases utilizing a network of domestic medical information databases.

Leading the Industry in Risk Management Plans

Chugai has been ahead of its competitors in drawing up and applying risk management plans (RMPs) to several of its products, and discloses them on its website. We consider RMPs to be part of our commitment to patients and healthcare providers. In applying RMPs, we believe we need to strengthen our ability to analyze data from an epidemiological standpoint. To achieve this, a specialized internal group in charge of epidemiology functions is cooperating with specialized companies and others to help upgrade Japan's epidemiological database. We are also driving the industry in ways such as proactively working to formulate industry-wide recommendations and guidance for database research.

Enhancing Drug Safety Evaluations

Chugai is committed to highly transparent and speedy reporting and release of drug safety information. We collect a large volume of safety information from countries around the world and evaluate it from a medical standpoint. Using advanced information technology, we have established a system for recording the information in a database and conducting signal detection of adverse events using that database. Under this system, we are able to promptly consult with regulatory authorities in each country regarding safety measures. In addition to managing this large volume of safety information, we have in-house doctors with abundant clinical experience who also conduct expert safety evaluations.

Communications on Safety

Communications with customers include providing information on noteworthy adverse events to medical institutions and academic societies. We also distribute information leaflets for patients, post information on our website and present a variety of lectures. In particular, our ability to rapidly provide information according to patient characteristics using the post-marketing surveillance database tool (PMS DB tool) and safety information database tool (SAFETY DB tool) that we developed in 2016 has won praise from healthcare providers.[1] With these tools, which include post-marketing surveillance and domestic post-marketing safety data, we can respond in a timely manner to urgent needs for safety information. In 2018, we broadened our contribution through the rollout of a clinical trial database tool for safety information on phase III multinational clinical trials so that healthcare providers can use new products with confidence immediately after their launch. Also, we have started using an app[2] that supports adherence to medication in conjunction with a multidisciplinary social networking service (SNS). The app helps to alleviate the anxiety of patients undergoing treatment by facilitating smooth communication between patients and their healthcare providers. In addition, we have assigned Safety Experts as professional staff in each region to support risk communication geared to local area characteristics, and are strengthening safety-related consultation according to needs and building networks with local doctors and pharmacists.

1. Source: Online article by Nikkei Medical Publishing, Inc. on AGING Web "Chugai's Ideal Information Prescription: 'PMS and SAFETY Database Tools' Providing Necessary Information to Those Who Need It, When They Need It" (Japanese only)
   Part 1 (November 10, 2017) http://www.nikkeibp.co.jp/aging/article/ innovator/2017111001/
   Part 2 (November 17, 2017) http://www.nikkeibp.co.jp/aging/article/ innovator/2017111701/
2. A service developed by Chugai to support multidisciplinary team care in cancer treatment. The app is linked with MedicalCareSTATION, a completely private SNS developed exclusively for healthcare providers and operated by Embrace Co., Ltd., and promotes drug adherence and adverse event management.

I am working with in-house epidemiological specialists and colleagues from other departments to plan post-marketing database surveillance and drug use-results surveys, so that we can provide patients with the information they truly need in a proper and timely manner, while responding to changes in the social environment.

Yuki Miyano
Real World Data Planning Group,
Real World Data Science Dept.

New Efforts for Quality and Regulatory Compliance

- Ensuring quality and regulatory compliance in innovation and digital healthcare
- Comprehensively improving quality to achieve patient-centric medical care
- Fostering a culture of quality

In addition to the creation of new drugs, Chugai's innovation will expand into medical devices, regenerative medicine and gene therapy. This innovation will include generating evidence in support of these areas, as well as to digital healthcare. Furthermore, as a leading innovator, we feel a heavy responsibility to create and champion related new quality assurance methods.

It is particularly important to realize patient-centric healthcare, and by refining our process for responding to patient requests we will improve our products and the quality and timeliness of the information we provide. It is our mission to comprehensively improve quality by proactively sharing experiences and knowledge regarding quality and regulatory compliance with stakeholders and affiliated companies involved in production, development and other processes, and thereby raise the competence of all parties.

To accomplish the above, fostering a culture of quality is essential. There are numerous procedures and rules in place at Chugai. However, given the successive appearance of new drug regulations, continuing to upgrade our systems for quality and regulatory compliance is vital. Particularly when we find faults in our rules, we must harness a Company-wide autonomous quality mindset that pushes forward with improvements and reforms. By infusing this attitude toward quality among employees, we will cultivate a culture of quality that further increases the trust we earn from all stakeholders.

Intellectual Property

IBI 18 (2016–2018)

- Realization of IP activities that help to acquire and demonstrate global top-class competitiveness
- Strengthening of rights formation functions globally
- Strengthening of strategic utilization of IP including in patent disputes

IBI 21 (2019–2021)

- Creation of a database of Chugai's competitors and use it to search out opportunities for utilizing the Company's rights
- Utilization of antibody engineering technology patents through licensing and other means
- Formulation and execution of a scenario for combating biosimilars and generics

Continuation → Evolution

S (Strengths)
- Expanded and upgraded portfolio of technological patent applications
- Progress in securing rights for products

W (Weaknesses)
- Negative impact on the development of technological patent rights due to early applications for "Freedom to Operate" (FTO)*
- Limited to capturing one-time opportunities for utilizing technological patents

O (Opportunities)
- Increasing importance of protecting intellectual property based on the establishment of drug discovery technology infrastructure
- Increase in opportunities to generate intellectual property due to progress in digital technology

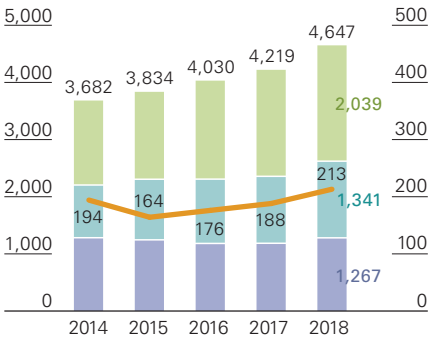
T (Threats)
- Ensuring FTO in the intense, competitive R&D environment.
- Market erosion due to increase in biosimilar products

* The ability to conduct business without the possibility of infringing the rights of others

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. Moreover, we are building our own database for patents related to antibody engineering technologies, which are becoming increasingly complex and sophisticated, and are using this database to plan IP strategies, including monitoring trends at other companies.

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



Patents held (including pending applications) (left scale)
- Oncology
- Bone and joint diseases
- Others

New patents granted (right scale)

Main Initiatives and Progress

Integration of IP and Research Strategies (Strategic Mix)

At Chugai, we view our antibody engineering technologies as a core drug discovery technology platform, and we are deploying research and development strategies both to cultivate basic technologies and to apply them to product development. Since 2018, we have been dispatching IP liaisons to the Fuji Gotemba Research Laboratories and Kamakura Research Laboratories to strengthen cooperation at the initial stage of research, and they are enhancing and promoting a strategic mix that builds a portfolio of our own technologies and development compounds in the white spaces (gaps) of technologies and rights. IP liaisons hold monthly meetings to review intellectual property with the Pharmaceutical Technology Division, which is also promoting the same strategic mix in manufacturing.

Current Patent Portfolio

Bone and joint diseases account for approximately 29% of patents by therapeutic area, oncology for approximately 27%, and other areas including chronic disorders, hematologic diseases, and drug discovery technology for approximately 44%. Supported by technological development, we have structured a well-balanced patent portfolio that reflects the diversity of products and development projects generated through Chugai's own R&D. In addition, in 2018 Chugai acquired 213 patents in Japan, the United States, and major European countries, as well as other countries worldwide.

Creating Opportunities to Use the Company's Rights and Establishing an IP Liaison Group

With the globalization of our product portfolio, the chance of conflicts arising over product-related IP is increasing. In addition, more sophisticated execution of strategies for utilizing lifecycle patents are required given the growing importance of generics, including biosimilars, in our IP strategy. Chugai will raise the sophistication of its strategies for using drug discovery technology patents by quickly identifying competitors that might use its proprietary drug discovery technologies and delineating drug discovery technology patent rights and their use. Moreover, we have established the IP Liaison Group as an implementation unit to resolve conflicts over IP rights, which are expected to increase in the future. Through these actions, we will continue to maximize the value of our business.

Human Resources

IBI 18 (2016–2018)

- Promotion of talent management to become a top pharmaceutical company.
- Structuring of a world-class platform shared across the Group.
- Productivity improvements through the promotion of diversity and inclusion and work-life synergy.

IBI 21 (2019–2021)

- Assignment of the right people to the right positions using position management and talent management and provision of growth opportunities.
- Promotion of talent management to quickly identify and develop leaders and highly competent specialists to accelerate strategy execution and innovation.
- Maintenance and deepening of employee engagement and fostering of an organizational culture for the pursuit of innovation.

Continuation Evolution

Talent That Spearheads Innovation

Our people are our greatest asset in realizing management strategies and generating innovation, and we therefore position human resource management as a key management theme. Our Envisioned Future is to become a top innovator in the healthcare industry. Chugai will pursue this objective by building understanding and connection with the Mission Statement (corporate philosophy) among all employees. Furthermore, we will encourage employees to embody the Mission Statement while fulfilling their potential in accordance with their role.

Establishing an Organizational Culture That Generates Innovation

Chugai provides career development support over many years so that employees can excel in roles that reflect their expertise, ability and aptitude. Since 2012, we have instituted various measures and systems, including introducing a talent management system, promoting diversity and revising our personnel systems. As a result of these initiatives, we have secured leaders capable of driving sustainable growth, assigned roles and growth opportunities according to each individual's ability and aptitude, and created an environment that supports the success of women.

At the same time, the speed of change in the business environment is escalating. Clarifying each employee's approach and responsibilities to improve quality, speed and success rates in strategy execution will be essential to realizing our management strategies and establishing a competitive advantage. In addition to these issues, an important theme is to support our employees in proactively taking on challenges to generate innovation and new added value.

We have determined the following human resource management priorities as measures for these objectives and themes. With these measures, we aim to establish an organizational culture in which employees support each other to continuously generate innovation.

Through the introduction of a new mid-career recruitment system focused on a thorough understanding of people, we will acquire excellent talent who can adopt the perspective of patients and contribute to fulfilling Chugai's Mission. By designing and implementing a leadership development program with an eye to 10 or 20 years down the line, we will develop the next generation of CEOs capable of achieving sustainable corporate growth.

Tom Mayes
Talent Management Group,
Human Resources Management Dept.

Changes to the All-Employee Survey

Chugai has regularly conducted its all-employee survey for instilling and promoting its identity as a top pharmaceutical company, initiatives to change organizational culture, and mid-term business plans. However, the high level of survey results in recent years made it difficult to set higher goals and to satisfactorily identify issues, and we were unable to use the results to compare Chugai with global companies and others. Therefore, in 2018 we transitioned to an employee survey that enables comparison against benchmarks.

Our objective for the new employee survey is to identify organizational change issues linked to the strategies of IBI 21. We will address the issues we identify with Group-wide and divisional PDCA cycles, while working to achieve our ideals.

Overview of Employee Survey (2018)

Participants and response rate	Participants: 6,994 (6,498 in Japan, 496 overseas) Respondents: 6,806 (6,321 in Japan, 485 overseas) Response rate: 97.3%
Question categories	Employee engagement, environment for utilizing employees, strategy and direction, leadership, quality and customer orientation, respect for individuals, opportunities for growth, compensation and benefits, performance indicators, authority and discretion, resources, education and training, framework for collaboration, business processes and organizational structure, and innovation
Benchmark data	Average results from global companies, leading companies, pharmaceutical companies and Japanese companies

Survey Results (Overall Trends)

- In all question categories, Chugai scored above the average for Japanese companies. In Japan, Chugai is a leader in terms of employee awareness.
- Chugai is on par with global companies. Employee engagement is on par with top global companies.
- Issues for further improvement are the environment for utilizing employees, as well as the resources, framework for collaboration, and business processes and organizational structure that underlie that environment.
- The percentage of employees who gave employee engagement and working environment high marks is at the level of global companies.

1. Assignment of the right people to the right positions using position management and talent management and provision of growth opportunities
2. Promotion of talent management to quickly identify and develop leaders and highly competent specialists to accelerate strategy execution and innovation.
3. Promotion of diversity and inclusion (D&I) to accelerate the success of women.

In addition, we switched to a new employee survey in 2018 to set more ambitious targets and identify issues more accurately. Based on the results of this survey, we will conduct organizational reforms linked to IBI 21.

Main Initiatives and Progress

Competency-Based Development

Upgrading Standards and Platforms to a Global Level

In competency-based human resource development, a prerequisite for implementing talent management, we clarified the mindset and behavior that Chugai requires and are standardizing Group-wide competencies on which employees are evaluated. Under IBI 18, we identified the type of global-level employees we are looking for and articulated these competencies in our decision-making standards and behavioral standards. As a basis for developing human resources, we conduct workshops and training for the managers of individual organizations to encourage dialogue between supervisors and their staff based on these competencies.

In addition, in 2017, we revamped our backbone system for human resource management. The new system, called "CAPTAIN" (Chugai All Persons Talent Information system), is a multilingual, cloud-based global personnel system. The use of a common personnel database throughout the Chugai Group will enable managers to conduct unified talent management and real-time monitoring and analysis of organizational conditions, leading to faster, more effective enhancement of our human resource capabilities.

In new mid-term business plan IBI 21, in addition to talent management, we will conduct position management to ensure the right people are assigned to the right positions throughout the Group, and provide growth opportunities for employees who actively take on challenges. In line with changes to the business environment, we also need to update our requirements for the type of people we seek. In position management, we will clearly define the roles and duties required for realizing our strategies and visualize the corresponding human resource requirements. This will facilitate operation in concert with talent management and accelerate the realization of our strategies.

Talent Management

Structuring Human Resource Development Plans with the Strong Commitment of Management

Since 2012, Chugai has been introducing and promoting a talent management system for developing individuals based on visualization of human resources and their capabilities. Each department held discussions on medium-to-long-term human resource development policies and formulated individual development plans. At the same time, we have created a talent pool of future management candidates. In addition, we clarified our succession plan by selecting successor candidates for a total of 94 general manager and department manager positions in Japan. The Company-wide plan, which includes medium-to-long-term career paths for each candidate, is being formulated and implemented through discussions by executive management and department managers to accelerate training of successor candidates.

Under IBI 18, we expanded talent management to a global scale, creating a new system that has enabled Chugai to systematically and continuously recruit, develop and promote people who can perform internationally. For key positions in strategy execution, in addition to internal candidates, we also consider hiring from outside the Company, whether in Japan or overseas, and candidate selection is under the direct supervision of the president. In IBI 21, we will review our training system to improve our ability to acquire, develop and deploy world-class human resources with the aim of identifying and training them more quickly.

Establishment and Enhancement of the Foundations of Human Resource Management

Promoting Diversity & Inclusion and Work-Life Synergy to Improve Productivity

Chugai has positioned D&I as a priority issue for the establishment and enhancement of the foundations of human resource management. We believe that D&I, which leads to the creation of a diverse workforce that works together with enthusiasm, is essential in order for employees to generate new value – in other words, diversity is necessary for generating innovation. As such, in 2010 we launched a working team led by the president, and in 2012 we established a dedicated organization that has since been conducting initiatives to promote diversity.

To promote gender diversity, we are actively providing opportunities for women to succeed. We set a target for 2018 of a 13 percent or higher female manager ratio, and have focused on career planning and development measures for women. With a female manager ratio of 13.3 percent as of December 31, 2018, we have achieved that target and are working for further advances. To promote the success of older employees and foreign employees in Japan, we are building awareness of their potential through training and other programs and creating environments including workplace systems to help them play active roles. Also, amid demands for more active participation by diverse human resources, managers play a key part in promoting D&I. We will aim to enhance their practical workplace skills through training in diversity management awareness, skills and behavior modification. Under IBI 18, we focused on leveraging D&I and presenting in-house case studies to encourage implementation by employees and vitalize the organization, thereby contributing to business success.

We also provide work arrangements and support systems so that all employees can benefit from work-life synergy that accommodates a variety of life events including but not limited to childbirth, child care

Chugai Diversity Promotion Forum: The Essence of Inclusion

and nursing care. With respect to "work style reform," which is currently a focal issue in Japan, studies and discussions between labor and management are under way with the goals of improving the work environment to enable employees to fully demonstrate their capabilities and promoting innovation by organically combining diverse knowledge.

Promoting D&I and work-life synergy is all about supporting the autonomy and growth of individuals to help realize an organization that generates innovation, which in turn contributes significantly to improving organizational productivity and increasing corporate value over the medium to long term.

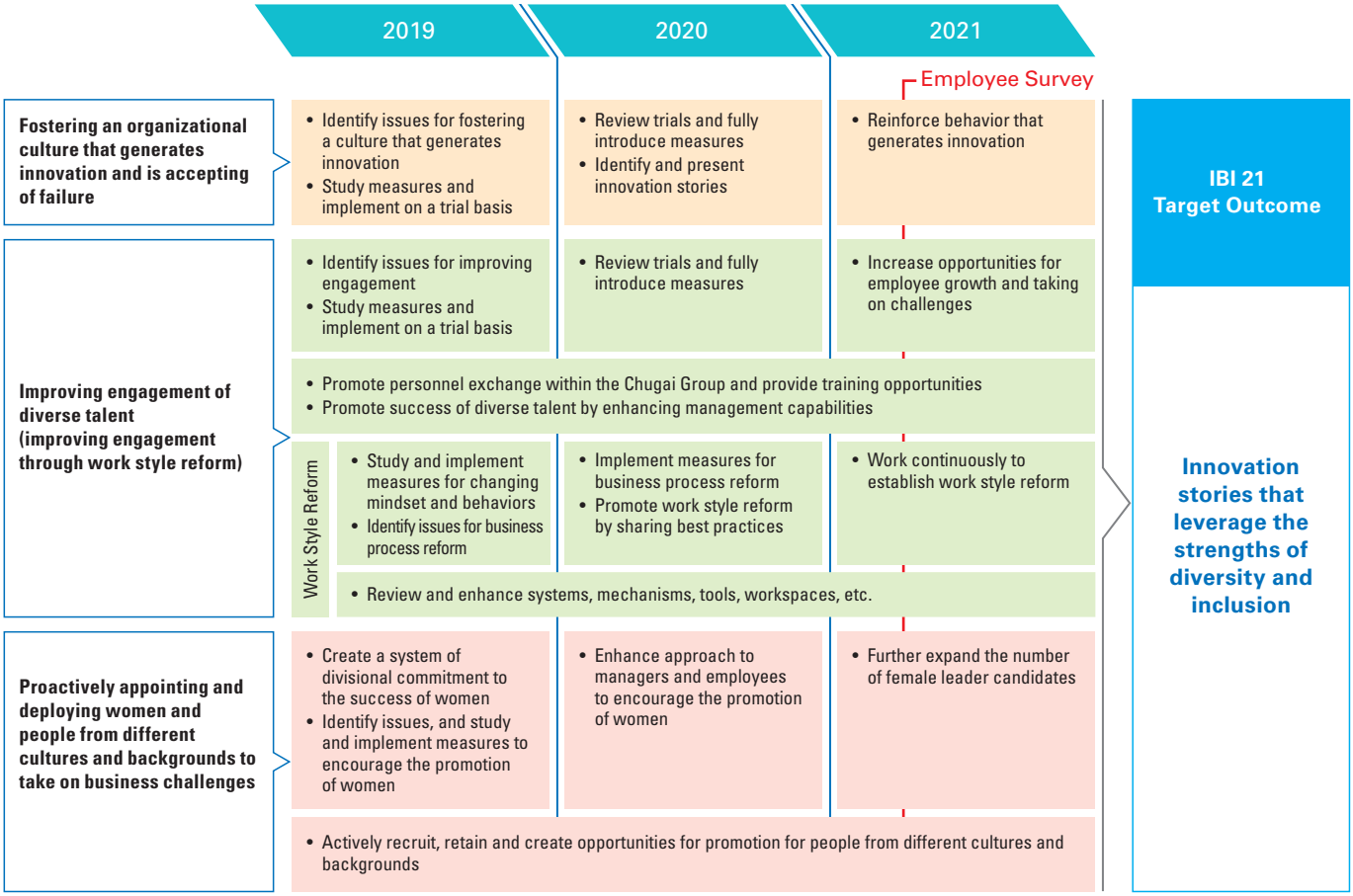
IBI 21 sets forth a target outcome of innovation stories generated by leveraging the strengths of D&I, and we have created a roadmap for expedited realization of our strategies. Based on respect for different values and ideas, we are working to address the following three issues in order to foster an inclusive organizational culture in which diverse human resources can succeed and pursue innovation.

1. Fostering an organizational culture that generates innovation and is accepting of failure
2. Improving engagement of diverse talent
3. Proactively appointing and deploying women and people from different cultures and backgrounds to take on business challenges

We are targeting a 16 percent or higher female manager ratio by the end of 2021, and will continue to focus on career planning and development measures for women.

For four years in a row since fiscal 2014, Chugai has been selected as a Nadeshiko Brand for its exceptional record in promoting the success of women.

D&I Roadmap for Promotion of IBI 21



Human Rights

IBI 18 (2016–2018)

- Conduct human rights awareness training
- Formulate a policy on respect for human rights
- Exchange opinions with third-party organizations

IBI 21 (2019–2021)

- Continue to conduct human rights awareness training
- Conduct human rights due diligence, including for suppliers
- Exchange opinions with third-party organizations to execute measures for resolving social issues

Continuation Evolution

Basic Approach

Chugai believes that a culture of respect for human rights is a cornerstone for a company to be recognized as a member of society and to earn trust. Therefore, we declare our respect for human rights in the Chugai Business Conduct Guidelines (Chugai BCG), which are based on our shared Core Values. In respecting human rights, we aim to realize workplaces that prize diversity, where each person values his or her own feelings and accepts the values of others – allowing everyone to fully demonstrate his or her abilities, based on an organizational climate of appreciation for oneself and others. People in such a workplace can work creatively with enthusiasm and engagement, thus increasing their achievements. Moreover, we believe that the actions of individuals who raise their sensitivity to human rights and show respect for others in such a workplace can also help to eliminate social discrimination and infringements of human rights in society in general through corporate activities and their private lives.

Today, companies are expected not only to conduct in-house initiatives regarding human rights, which have been increasing in importance as a social issue, but also to conduct business activities that respect human rights throughout the entire supply chain. With our deep involvement in people's lives and health as a member of the healthcare industry, we are promoting measures with a greater awareness of respect for human rights (see our website* for more details on our human rights policy).

* https://www.chugai-pharm.co.jp/english/csr/humanrights/

Issues and Initiatives

In previous initiatives toward respect of human rights, Chugai mainly focused on its employees in areas such as prohibition of workplace discrimination and harassment, respect for employee diversity, and safety and health. However, to conduct business activities in various regions of the world as a global company, we recognize that we need to address human rights issues throughout our entire supply chain, including labor-related rights at stakeholders involved in our business activities. Based on the United Nations' Guiding Principles on Business and Human Rights, we began preparations for drawing up a policy on respect for human rights and for conducting human rights due diligence.

In September 2018, Chugai participated in the 2018 Business and Human Rights Conference in Tokyo sponsored by Caux Round Table Japan, and engaged in dialogue with individual experts from overseas, receiving opinions and advice on putting the U.N.'s guiding principles into practice, including the formulation of a human rights policy. Through discussions of the Chugai Group's initiatives in the context of the principles, we received suggestions from these experts that will lead to more effective communication. They also expressed their expectations for us to incorporate and implement these principles in our business activities.

Dialogue with overseas experts

Based on these opinions, Chugai established its Policy on Respect for Human Rights in January 2019. In conducting human rights due diligence, we will also call on our business partners to comply with laws and social norms. In addition, we will work together with those partners in respecting human rights, with the expectation that efforts will take into account working conditions in ways including eliminating child labor and forced labor, prohibiting all forms of discrimination by race, gender or other attributes, respecting the dignity of individual employees and maintaining safety and health.

In addition, Chugai has established an Anti-Bribery Policy to help prevent bribery as part of the management of its corporate activities. In addition to setting standards for our own conduct, it prohibits our business partners from engaging in bribery of government officials, civil servants, corporate staff and other parties, whether corporations or individuals. We will continue our comprehensive efforts to prevent bribery.

We recognize Chugai's responsibility for respecting the human rights of all people involved in its business activities, and will work to fulfill it by ensuring that we do not infringe on the human rights of these people, and by responding appropriately with corrective action in the event of an infringement.

Initiatives to ensure respect for human rights must not be limited to employees, but should extend to all people affected by our business activities. We will convey the significance of such efforts through in-house training and foster understanding of their criticality among all links in our supply chain.

Emiko Mori
Senior Specialist, Business Ethics Group, Sustainability Dept.

Environment, Health and Safety

IBI 18 (2016–2018)

- Establishment of a promotion system for environment, health and safety (EHS)
- Formulation and execution of single-year goals to achieve mid-term environmental goals
- Formulation of priority items for health and productivity management, setting of targets and execution

IBI 21 (2019–2021)

- Establishment of a global EHS promotion system
- Achievement of mid-term environmental goals and formulation of new mid- and long-term environmental goals
- Execution of priority items for health and productivity management and reassessment of evaluation indicators

Continuation Evolution

Our Environmental, Health and Safety Functions

As a healthcare company, Chugai is engaged in many specialized scientific activities. One aspect of those activities involves handling antibodies and highly active pharmaceutical substances. Our responsibilities in environmental protection and health and safety are numerous, and we consider them an important foundation for all our business activities.

At the same time, the demands of society have grown more diverse and sophisticated. Integrated management of environment, health and safety is now required worldwide because of the close connection between "environmental protection" and "health and safety." Accordingly, Chugai has developed an integrated management system for EHS and implements the plan – do – check – act (PDCA) cycle based on a consistent policy Company-wide, from top management to each facility.

We consider EHS management to extend throughout the value chain, from the procurement of raw materials to the manufacture of products and their supply to patients and healthcare providers. Going forward, we intend to broaden our activities to cover the overall value chain in closer cooperation with customers and suppliers, partners and industry organizations.

To utilize the PDCA cycle effectively, we introduced health and safety risk assessment in 2014 and EHS risk assessment in 2017 to remove EHS risks in the workplace. Since 2008, we have implemented an assessment system throughout the Chugai Group to reduce the risk of occupational injuries from exposure to all substances handled, not only restricted substances.

Main Initiatives and Progress

Promotion and Progress of Environmental Protection Activities

Chugai's aims encompass not only its own sustainable development but also environmental protection in local communities and globally. We have set priority items to be addressed as well as medium-to-long-term targets.

Chugai designated climate change countermeasures, energy conservation,

Initiatives by Theme

Theme	Details of Initiatives
• Implementation of EHS risk assessment • Workplace safety measures	Create work environments that are free from unacceptable EHS risks.
• Climate change countermeasures • Energy conservation	Reduce greenhouse gas emissions by reducing energy consumption. Focus not only on reducing energy consumption at plants and laboratories, but also on promoting eco-friendly cars in the MR fleet and other Company-wide initiatives.
• Resource conservation • Waste management	Achieve zero emissions of waste by improving recycling ratio and further reducing landfill waste. Promote awareness of effective use of water resources by monitoring water consumption and wastewater discharge.
• Biodiversity protection • Prevention of environmental pollution	Curb destruction of the ozone layer by eliminating usage of specific CFCs. Prevent emissions of pollutants into the environment by observing laws, regulations, agreements and other rules for air, water quality and soil. In particular, focus on controlling emissions into water with whole effluent toxicity (WET) tests and other methods to protect the water environment.
• Improvement of environmental literacy	Circulate information on laws and regulations among related staff and raise awareness through ISO 14001 internal auditor training.
• Chemical substance management	Advance the establishment of a system for proper management of chemical substances, and promote safety and the prevention of environmental pollution. Continue risk assessments to prevent exposure to substances handled.
• Reduction of environmental risk	Ensure thorough compliance with environmental laws and regulations by conducting extensive environmental law checks through external consultants.
• Employee health management • Improvement of health literacy	Maintain a support system based on cooperation with the health management organization and related departments. Improve health literacy as the basis for all health and safety activities, and enhance awareness through various media and opportunities.
• Support for employees with cancer	Aim for early detection of cancer and provide enhanced support for continuing to work while undergoing cancer treatment.
• Measures to prevent and treat lifestyle diseases among employees	Recommend check-ups for high-risk individuals and provide health guidance to those diagnosed to reduce leaves of absence, job departures and accidents caused by lifestyle diseases.
• Measures for employees' mental health	Conduct a return-to-work program for employees on leave due to mental health issues and use the results of stress checks to improve working environments in cooperation with related departments.
• Measures to address employee presenteeism (working while sick)	Plan, implement and determine the effectiveness of measures based on health survey results.

resource conservation and waste management, biodiversity protection, prevention of environmental pollution and improvement of environmental literacy as its priority items. In 2010, we set four mid-term environmental goals focusing on management of energy consumption and waste from a medium-term perspective, with 2020 as the final year. We are implementing the PDCA cycle and conducting initiatives to meet these goals.

As measures to conserve energy, we are reducing energy consumption by introducing highly energy-efficient facilities, switching fuels, introducing eco-friendly cars, and conducting an energy conservation program in daily business activities while curbing greenhouse gas emissions,[1] which is the key to combating climate change. To prevent environmental pollution, we are also working to reduce the use of CFCs and HCFCs to halt the destruction of the ozone layer, and to prevent the leakage of environmental pollutants.

Water is an important raw material in pharmaceutical manufacturing, and it is also a crucial global resource. Chugai therefore considers risks related to procurement and water damage to be water-related risks. Although Chugai's procurement-related risks are low at present, it monitors the volume of water it uses and the wastewater it discharges each year, and is building awareness of the effective use of water resources. At the same time, Chugai conducts countermeasures for the risks to stable supply caused by water damage. In waste management, we aim to increase the waste recycling ratio and further reduce landfill waste to achieve zero emissions of waste, and our initiatives are yielding results.

Moreover, from the standpoint of protecting biodiversity, we began conducting WET tests[2] in 2013 to ascertain the ecological impact of wastewater discharged from our facilities. In 2018, we conducted WET tests once at all plants and research laboratories, and confirmed that there were no problems.

1. We received independent verification of our 2018 greenhouse gas emissions associated with energy consumption, leakage of CFCs and HCFCs, use of aircraft for business travel, and industrial waste generated.
2. Whole effluent toxicity test: 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

Mid-Term Environmental Goals	• Energy consumption per employee: 20 percent reduction compared with 2010 • Discontinuance of the use of chlorofluorocarbons (CFCs) and hydrochlorofluorocarbons (HCFCs) • Zero emissions of waste:[2] Three facilities • Average fuel efficiency of MR fleet: 16 km/L or higher
Environmental Goals for 2018	• Energy consumption and greenhouse gas (GHG) emissions: Reduction of 2 percent or more compared with the previous year • Ratio of eco-friendly cars:[3] 60 percent or higher; average fuel efficiency of MR fleet: 16 km/L or higher • A recycling ratio of 80 percent or higher and a final disposal ratio of 2 percent or lower • On-site verification of 100 percent of waste disposal contractor facilities over a three-year period • Plain paper copier (PPC) paper purchased: Less than the previous year; recycling ratio of 80 percent or higher
Mid-Term Health and Safety Goals	• Cancer screening participation rate[4]: 90 percent or higher • Percentage of employees at high risk for lifestyle diseases: 2 percent or lower by 2020 • Awareness of Company programs: 90 percent or higher • EHS risk assessment: Conduct at each site at least once every three years

2. A waste recycling ratio of 99 percent or higher
3. Includes hybrids and fuel-efficient vehicles
4. Screening rate for lung, breast, gastric, colon and cervical cancer

Promotion and Progress of Health and Safety Activities

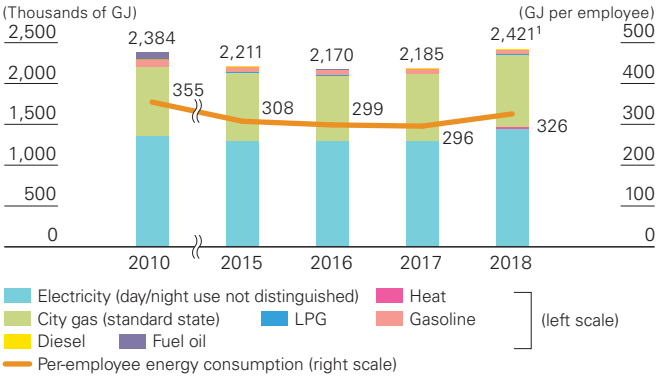
Chugai engages in health and safety activities as one aspect of its health and productivity management, in the belief that sound employee physical and mental health and a satisfying and rewarding work environment where all employees can do their jobs with enthusiasm are the foundation for growth.

Climate Change Countermeasures

(2010 is the base year for per-employee energy consumption and CO_2 emission mid-term environmental goals.)

Total and Per-Employee Energy Consumption

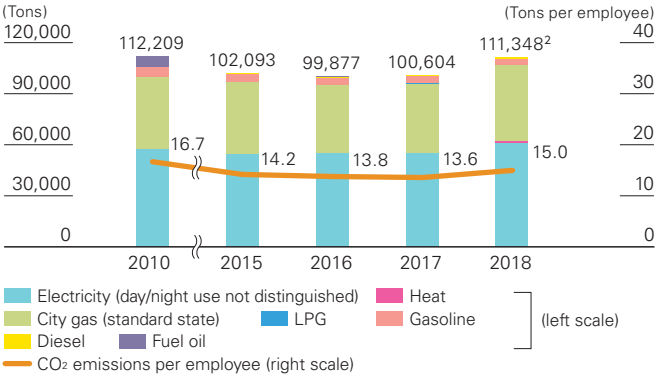
The Chugai Group's energy consumption in 2018 increased 10% over the previous year. The main reason was the newly constructed UK3 manufacturing plant for handling high-mix, low-volume biological API production within the Ukima Research Laboratories in Kita-ku, Tokyo.



1. Includes 40,000 GJ of overseas consumption (electricity, heat)

CO_2 Emissions and CO_2 Emissions per Employee

Total CO_2 emissions increased 11% from 2017 to 111,348 tons. CO_2 emissions per employee increased 1.4 tons. The main reason was the newly constructed UK3 manufacturing plant for handling high-mix, low-volume biological API production within the Ukima Research Laboratories in Kita-ku, Tokyo.



2. Includes 1,947 tons of overseas emissions (electricity, heat)

To create such an environment, we established a Company-wide health and safety promotion framework in 2017, based on a policy of cooperating with the health insurance society and the labor union in simultaneous pursuit of both individual and organizational health. We also established six priority items: support for employees with cancer, measures to prevent and treat lifestyle diseases among employees, measures for employees' mental health, measures to address employee presenteeism (working while sick), improvement of health literacy and workplace safety measures. We set mid-term health and safety goals for the underlined items and are conducting activities to achieve them. We are also working to improve organizational health using the results of an organizational analysis of stress checks in collaboration with relevant departments.

Of course, in addition to these preventive measures, we continue to conduct our existing programs to support employees during cancer treatment and after they return to work, as well as mental health awareness activities.

GHG Emissions

Scope 1: 49,486 tons

Direct emissions from fuel combustion: 49,240 tons

Plants: 31,017 tons
Research labs: 13,996 tons
Overseas: 0 tons

Branches: 4,203 tons

Head Office: 24 tons
Distribution: 0 tons

Fugitive emissions

Fluorocarbons, etc. from business activities

248 tons
Japan: 248 tons
Overseas: 0 tons

Scope 2: 62,108 tons

Indirect emissions from the generation of purchased energy (electricity), heat

Plants: 31,842 tons
Research labs: 26,030 tons
Overseas: 1,951 tons

Branches: 1,111 tons
Head Office: 558 tons
Distribution: 617 tons

Scope 3: 4,583 tons

Indirect emissions other than Scope 1 and 2

Category 5 (Waste materials)
Industrial waste generated by business activities
302 tons
Japan: 277 tons
Overseas: 25 tons

Category 6 (Business travel)
By aircraft
4,281 tons

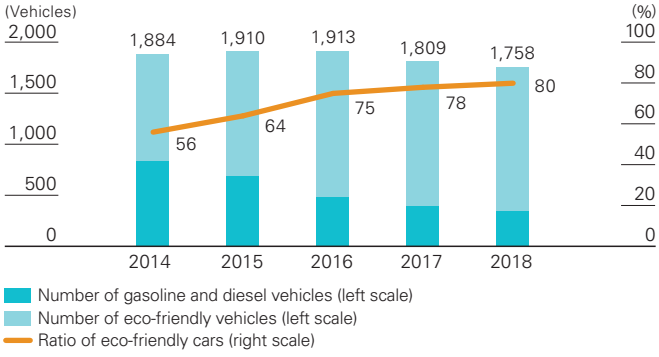
To achieve our 2020 environmental goals, we have introduced a system for visualizing energy use, conducted data analysis, and created an energy conservation plan. In 2019, we will implement energy-saving measures according to plan, bringing us closer to achieving our environmental goals for 2020.

Masatake Takei
Formulation Research Group 2,
Production Engineering Dept.

Resource Saving and Waste Reduction

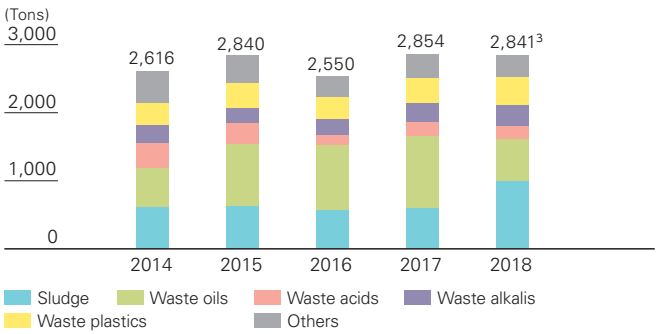
Ratio of Eco-Friendly Cars

As of December 31, 2018, Chugai had introduced a cumulative total of 1,415 hybrid and fuel-efficient vehicles in its MR fleet. The ratio of eco-friendly cars was 80 percent, remaining above the target of 60 percent.



Industrial Waste

The amount of industrial waste generated increased 13 tons from 2017 to 2,841 tons. Sludge increased due to higher production volume, but waste oil decreased substantially. The main reason for the decrease was that the Fujieda Plant, which had generated the largest amount of waste oil, was able to treat most of the waste oil as water by enhancing its wastewater treatment facilities.



3. Includes 9 tons of overseas waste

Social Contribution

IBI 18 (2016–2018)

- Cultivation of human resources to handle next-generation scientific technologies
- Contribution to health through disease awareness-raising activities
- Understanding of diversity through para-sports

IBI 21 (2019–2021)

- International contribution in the field of global health
- Contribution to health in local communities
- Promotion of understanding of diversity to achieve a society of co-existence

Continuation → Evolution

Chugai's Social Contribution Activities

As a responsible pharmaceutical company in healthcare, we work to raise awareness of diseases.

In the area of welfare, in conjunction with our business activities in the renal and bone and joint areas, we conduct ongoing donations of specially equipped para-transit vehicles as we understand the importance of transportation assistance services for people who require in-home nursing care. Regarding education, as a company that deals with leading-edge science we conduct activities to raise awareness of science and medicine among students, from elementary school children to university students, as well as among adults.

Moreover, we cooperate with local communities and engage in disaster preparedness education, mainly in areas where our research laboratories and plants are located. We also support para-sports to help create a society where everyone can participate in sports. Please see our website[1] for more details on Chugai's basic stance on social contribution.

1. https://www.chugai-pharm.co.jp/english/csr/community/

Main Initiatives

Disease Awareness

Chugai participates in a variety of activities to support cancer patients and their families. One such activity is 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 participate as relay teams, was held in 48 locations throughout Japan in 2018. Chugai employees have participated as volunteers in Relay For Life Japan since 2007. A total of 500 employees took part as "Team Chugai" at 27 locations in 2018.

This year, we conducted the awareness raising activity of screenings with the "Try! Scope," which uses a fiberscope, and participants in various locations enjoyed the experience. As Team Chugai members provided explanations, participants experienced a simulated endoscopy, gaining an understanding of the importance of screening and early detection and treatment. We also promoted understanding of the importance of screening by using "Try! Scope" in health events hosted by local governments.

Initiatives for Generation AYA

Chugai launched the website AYA Life[2] for young cancer patients in March 2017 and has been continuously updating the contents. The term "AYA" (an abbreviation of Adolescents and Young Adults) was relatively unknown in Japan at the time of the launch, but recognition has grown with the inclusion of "Generation AYA Cancer" in the Japanese government's Third-Term Basic Plan to Promote Cancer Control Programs in March 2018. However, as the AYA generation ages, it will be dealing with a wide range of issues including higher education, employment and marriage. As a leader in the area of oncology, Chugai cooperates with academic and patient organizations to spread knowledge of generation AYA cancer patients' individual concerns and social issues to create an environment where they can receive treatment with peace of mind.

2. https://aya-life.jp/ (Japanese only)

Promotion of Measures against Locomotive Syndrome

Locomotive syndrome is a condition in which muscles, bones, joints, cartilage, intervertebral discs and other parts of the musculoskeletal system become impaired and motor function declines. The progression of the syndrome is highly likely to impede daily life. The Japanese Orthopaedic Association proposed it as a concept in 2007 and has been working to prevent the syndrome, establish measures for coping with it, and improve awareness. In cooperation with the prefectural chapters of the Japanese Clinical Orthopaedic Association, Chugai holds the Musculoskeletal Disorder/Bone and Joint Forum 10 or more times a year to deliver the latest information to healthcare providers. We will continue helping to promote healthy life expectancy through this activity.

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." The main activities Chugai conducted in 2018 are as follows.

Dispatch of Volunteers to Competitive Sports Events

Chugai held the Chugai Pharmaceutical 2018 Wheelchair Softball Tournament in Tokyo as the title sponsor and provided support by sending 25 employee volunteers to assist with set-up, event management, English interpreting and other matters.

Raising Awareness of Para-Sports

- Co-sponsorship of a chair ski school for parents and children held by the Japan Chair Ski Association
- Support for a wheelchair tennis camp for children
- Operated a booth for experiencing wheelchair tennis and chair skiing at local community events and other venues
- Presentation of the para-sports-related webpages "Another Sport" and "ATHLETE MOTHERS" on the Chugai website (Japanese only)

Parent and child enjoying chair skiing class

Initiatives for Employees and Their Families

To deepen understanding of para-sports and people with disabilities, Chugai held a hands-on event for experiencing blind sports in cooperation with the Yokohama City Special Support School for the Visually Impaired. There were 18 participants from Chugai, including employees and their family members.

Disaster Relief

Support for Children in Stricken Areas

Chugai once again participated in the global charity event Roche Children's Walk conducted by Roche to support children in need. In this annual initiative, Chugai matches the total amount of funds raised by its employees, with half of the total amount donated to Malawi and other countries and the remainder donated to an organization in an earthquake-affected area in Japan. In 2018, the recipient organization was the non-profit organization Chobora, a cooperative facility for disabled children and adults in Iwaki City, Fukushima Prefecture.

Charity Sale

As part of its support for recovery from the 2011 Great East Japan Earthquake and heavy rain in Western Japan in July 2018, Chugai held a charity sale at its Head Office and Kamakura Research Laboratories. As employees at each location handled the goods and conversed with the sales staff, they renewed their hopes and prayers for the restoration and recovery of the affected areas.

Para-Transit Vehicle Donation Program

Chugai's program to donate specially equipped para-transit vehicles began in 1985 as part of activities to commemorate the Company's 60th anniversary. The program marked its 34th year in 2018. A total of 253 vehicles have been donated since the start of the program, including the five donated in 2018.

Securing the means for senior citizens and disabled people living at home to go to places such as hospitals, day service centers and day care centers and for staff from these facilities to visit homes to perform in-house care, is significant from the viewpoint of enhancing welfare services.

The para-transit 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.

Initiatives for Global Health

As international contributions in the area of global health, Chugai participates in the Global Health Innovative Technology Fund (GHIT Fund),[3] which aims to conquer infectious diseases in developing countries, and Access Accelerated,[4] which conducts measures for people in low and middle-income countries who are living with noncommunicable diseases (NCDs). Please see our website[5] for more details on Chugai's basic stance on global health initiatives.

3. For details, see the GHIT Fund website (http://www. ghtfund.org/en).
4. For details, see the Access Accelerated website (http://www.accessaccelerated.org/).
5. https://www.chugai-pharm.co.jp/english/csr/globalhealth/

GHIT Fund

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, the GHIT Fund is Japan's first public-private partnership to support and promote research and development of drugs, vaccines and diagnostics for infectious diseases in developing countries.

In December 2014, Chugai announced its participation in the GHIT Fund and contributed capital. It has also been promoting efforts using its innovative discovery technologies and research resources, including a program to develop drugs to prevent and treat dengue fever. As a partner in the GHIT Fund, Chugai expects that furthering the development of new medical technologies will go beyond fulfilling its basic social responsibility, leading to the promotion of health and sound economic growth in developing countries.

Access Accelerated

Access Accelerated was established in January 2017 by 22 global pharmaceutical companies including Chugai at the World Economic Forum Annual Meeting held in Davos, Switzerland. In partnership with the World Bank Group and the Union for International Cancer Control (UICC), Access Accelerated is working to achieve the U.N. Sustainable Development Goal 3 target of reducing premature deaths due to NCDs by one-third by 2030.

In addition to collaborative programs with other member companies, Chugai is conducting its own project to promote safer childbirth and maternity healthcare in Myanmar in partnership with AMDA-MINDS (AMDA-Multisectoral and Integrated Development Services). Through participation in Access Accelerated, Chugai will help to improve access to healthcare in low and middle-income countries.

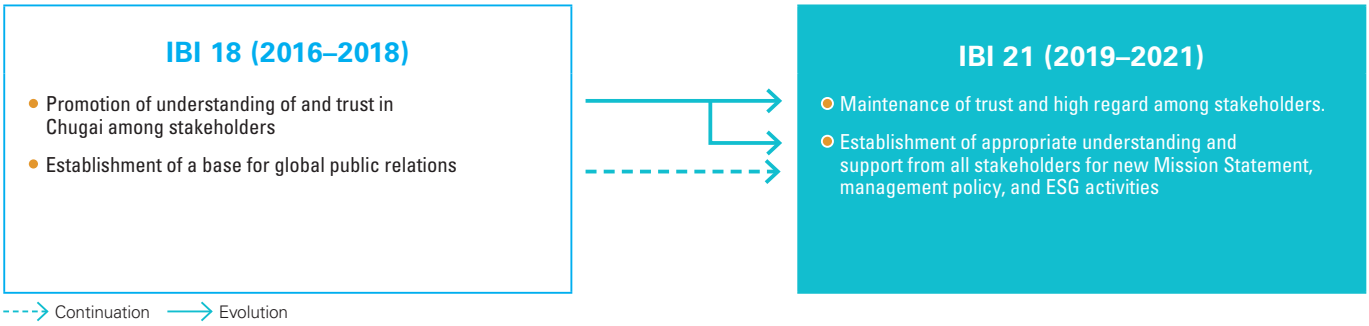
Main Initiatives and Progress

- Conducted awareness-raising and support activities for para-sports (served as title sponsor of a sporting event, provided training facilities, and operated a booth for experiencing para-sports)
- Donation of para-transit vehicles to provide transportation for home welfare services: Total of 253 vehicles over 34 years (1 vehicle each to 5 organizations in 2018)
- Number of locations in which Chugai employees participated in the 24-hour charity event Relay For Life Japan: 27
- Biology lab classes for children at the Japan Science Foundation's Science Museum: 130 participants in 12 labs
- Endowed courses at Waseda University: 2
- Number of employees who took volunteer leave: 45

We are supporting para-sports, healthcare, welfare and disaster relief efforts with the goal of creating a society in which everyone has the opportunity to flourish. We will continue to work on a broad range of issues based on social needs, contributing to the creation of a sustainable society in the process.

Megumi Sakai
Social Contribution Group,
Sustainability Dept.

Corporate Communications



Functions

Chugai is strengthening communication activities for internal and external stakeholders with the aim of securing their support and trust and sustainably increasing corporate value. In addition to clearly, fairly and continuously transmitting information on activities related to the creation of shared value with society, as well as our business activities, we emphasize two-way communication.

As a result, Chugai is well regarded externally. Chugai was chosen for inclusion in all four ESG indices selected by the Japanese Government Pension Investment Fund (GPIF), and has been selected as a component of DJSI Asia Pacific for the fourth time. (See page 2 for more details on external evaluation of our ESG initiatives.)

Disclosure Policy

Under new mid-term business plan IBI 21, we have identified "strengthen sustainable platforms" as a Group-wide strategy. Accordingly, we will strive to further develop communications as we believe that enhancing the platforms through dialogue with stakeholders will support our quest for innovation. To this end, in April 2019 the IR Committee was reorganized as the Corporate Communications Committee and shifted its focus from considering information disclosure policies for capital market participants to considering corporate communication strategies encompassing a wider array of stakeholders.

The Corporate Communications Committee is a corporate management committee composed of the CFO and general managers of the Corporate Communications Department, the Corporate Planning Department, the Finance & Accounting Department, the Sustainability Department and the General Affairs Department. The committee holds regular meetings and is responsible for the establishment, revision and internal dissemination of the Disclosure Policy, and for the management and promotion of information collection, disclosure and other related activities. Top management, including the CEO and key executive officers, has primary accountability for disclosure. In addition, the Corporate Communications Department takes the lead in coordinating with relevant departments, using various tools to communicate promptly and effectively.

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

Communication with Shareholders and Investors

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, as a means to ensure transparency, we disclose information simultaneously in Japanese and English in principle, to allow easy access to disclosed information.

The 108th Annual General Meeting of Shareholders was held on March 28, 2019, and all agenda items were approved and passed by a majority. Moreover, in addition to quarterly investor presentations and conference calls to explain operations, we also conducted "R&D conference calls" to present and answer questions about information of great interest to investors. Furthermore, to improve communication with individual shareholders and investors, we hold production site tours and conduct investor presentations at securities company branches and via the Internet. Senior management also hosts visits by overseas institutional investors, and each year the president holds informal discussions with investors and analysts as an opportunity to speak directly in small groups.

Due to the introduction of the Principles for Responsible Institutional Investors (Japan's Stewardship Code) and Japan's Corporate Governance Code, greater dialogue between companies and shareholders is required. Chugai has proactively established forums for ongoing discussions between investors and the management team to ensure a fuller exchange of opinions. We will continue measures to enhance face-to-face IR with management.

Communicating Information to a Wide Range of Stakeholders

We emphasize proactive communication of information that is easy to understand in order to gain the support and trust of a wide range of stakeholders. Chugai takes an active approach to media relations through methods including press releases, various types of information meetings and informal discussions with management. We also use our website and a variety of other tools to promote understanding among the general public of the broad range of activities through which our businesses contribute to healthcare, the environment, human rights, society, human resource development and other areas. We plan to strengthen communication activities because we believe they help to enhance corporate value.

Main Initiatives and Progress

- Media and IR information events: 15
- Security analysts and institutional investors worldwide with whom individual meetings were held: 407
- Briefings for individual investors and shareholders: 8
- Attendees at the General Meeting of Shareholders: 414
- Second Prize, Nikkei Annual Report Award 2018
- 3rd place, Pharmaceuticals Category, 2018 Awards for Excellence in Corporate Disclosure, The Securities Analysts Association of Japan
- 2nd place, The 2018 All-Japan Executive Team Rankings, *Institutional Investor* magazine
- ESG website newly created

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 fiscal 2017 (the year ended March 2018), national medical expenses[1] totaled ¥42.2 trillion, a ¥0.9 trillion or 2.3 percent increase from the previous year. The accelerating pace of aging of Japan's society presents serious challenges to efficiently managing the increase in medical expenses for the elderly.

1. Source: Trends of recent medical expenditure (FY 2017) by Ministry of Health, Labour and Welfare

Promotion of the Use of Generics

The Japanese government is promoting the use of generics 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 2017 set the new goal of raising the volume market share of generics, which was 72.6 percent[2] as of September 2018, to 80 percent by the end of September 2020. The government is also aiming to double the number of biosimilars by the end of March 2021.

2. Preliminary results of the Drug Price Survey

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 2018 (the year ending March 2019), drug reimbursement prices are set to decline by 1.65 percent overall on a medical expense basis and 7.48 percent on a reimbursement price basis (-6.17 percent from revision of actual market prices and -1.31 percent from fundamental reform of the drug pricing system).

A special revision of NHI drug reimbursement prices will be implemented in conjunction with the increase in the consumption tax rate in October 2019. In its fiscal 2019 budget, the Japanese government has decided to reduce reimbursement prices by 0.51 percent on a government spending basis (+0.42 percent to reflect the consumption tax and a -0.93 percent revision based on actual market prices and other factors).

NHI Drug Price Revision Rate (%)

	2008	2010	2012	2014*	2016	2018
Industry Average	(5.2)	(6.5)	(6.25)	(2.65)	(7.8)	(7.48)
Chugai	(7.2)	(6.8)	(6.0)	0.8	(5.5)	(6.7)

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

Repricing Based on Market Expansion

Under this repricing rule introduced in 1994, drugs priced by the cost calculation method with annual sales exceeding ¥10.0 billion and more than 10 times the original forecast at the time of price revision, or with annual sales exceeding ¥15.0 billion and more than two times the original forecast, are subject to a price reduction of up to 25.0 percent. Drugs priced by methods other than the cost calculation method (including the similar efficacy comparison method) with annual sales exceeding ¥15.0 billion and more than two times the original forecast at the time of the price revision are subject to a price reduction of up to 15.0 percent. In addition,

the prices of drugs that have pharmacological action similar to a drug subject to this repricing rule are reduced by the same rate. In the NHI drug pricing system fundamental reforms of fiscal 2018, the NHI listing of new drugs that takes place four times a year will be used as an opportunity for repricing of drugs with annual sales exceeding ¥35.0 billion. The purpose of this change is to respond more quickly when sales expand rapidly due to an additional indication or other reasons.

Special Market-Expansion Repricing

In the reforms to the drug pricing system in fiscal 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 the sustainability 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 a 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, including Avastin, were subject to the additional repricing rule. In fiscal 2018, two active ingredients and four products were subject to the rule. In the NHI drug pricing system fundamental reforms of fiscal 2018, it was decided to use the NHI listing of new drugs that takes place four times a year as an opportunity for repricing under this scheme.

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[3] problem. In this scheme, at the time of the NHI drug price revisions, prices are maintained on 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.

This premium pricing for new drugs was continued on a trial basis in subsequent NHI drug pricing system reforms. However, in the NHI drug pricing system fundamental reforms of fiscal 2018, the decision was made to revise the requirements for companies and products and list them in the drug repricing rules.

Companies that do not respond appropriately to development requests from MHLW will continue to be excluded from eligibility for premium pricing. In addition, indicators have been set for (A) creation of innovative drugs, (B) drug lag countermeasures, and (C) development of novel drugs ahead of other countries, and the pricing premiums may vary according to the level of achievement or fulfillment of these indicators. Healthcare-related ventures are expected to play an important role in the creation of innovative

Response to Requests from the MHLW Review Committee on Unapproved Drugs and Indications with High Medical Needs
(As of February 1, 2019)

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
	Avastin	Ovarian cancer	Approved in November 2013
Second development request	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	Approved in May 2016
Third development request	Tamiflu	Additional dosage for neonates and infants younger than 12 months	Approved in March 2017
	Xeloda	Adjuvant chemotherapy in rectal cancer	Approved in August 2016
	Avastin	Additional Q2W dosage and administration for ovarian cancer	Submitted company opinion and waiting for evaluation by committee
Fourth development request	Copegus	Improvement of viraemia associated with genotype 3 chronic hepatitis C or compensated cirrhosis related to hepatitis C when administered in combination with sofosbuvir	Approved in March 2017
	Xeloda	Neuroendocrine tumor	Submitted company opinion and waiting for evaluation by committee
	Avastin	Cerebral edema induced by radiation necrosis	Submitted company opinion and waiting for evaluation by committee
	Neutrogin	Combination therapy with chemotherapy including fludarabine for relapsed/refractory acute myeloid leukemia	Submitted company opinion and waiting for evaluation by committee

drugs, and will be evaluated accordingly, irrespective of the company indicators.

Regarding the product requirements, the percentage price difference requirement will be abolished, and the price premium will be limited to novel drugs during their patent period, and drugs that are truly innovative and useful. More specifically, it will be limited to orphan drugs, drugs for which development was publicly requested, drugs to which the premium was applied because of their usefulness at the time they were newly listed, and drugs with novel mechanisms of action that are innovative or useful (limited to the top three first-in-class drugs within three years from listing).

In fiscal 2018, 314 active ingredients and 560 products qualified for premium pricing (publicly announced).

Among new drugs subject to premium pricing, including those for which generics (including biosimilars) have been launched or 15 years have elapsed since their drug price listing, the cumulative amount of premium pricing is deducted from the NHI drug price in the subsequent initial drug price revision. Furthermore, a reduction or other adjustment due to the actual market price of the new drug during the fiscal year is made to the NHI drug price less the cumulative amount.

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

Solving the Drug Lag Problem

In January 2005, MHLW established the Investigational Committee for Usage of Unapproved Drugs as one means of helping solve the drug lag problem. The committee is charged with investigating the clinical necessity and the appropriateness of usage of drugs already approved in Europe and the United States, but not yet approved in Japan. The aim of these investigations is to promote the 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 fiscal 2017 was 11.8 months. For new drug applications filed in Japan during fiscal 2017, the median review time was 0.2 years longer than that of the United States, which was smaller than in the average year.

Annual Drug Price Survey and Annual NHI Drug Price Revision

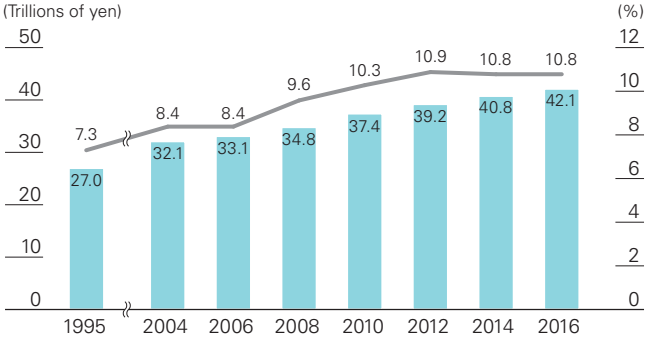
Due to the growing public financial burden of the current situation, in which drug prices are maintained for up to two years even if the market price declines, it was decided in the NHI drug pricing system fundamental reforms of fiscal 2018 that drug price surveys and drug price revisions will be carried out even in interim years when there would ordinarily be no price revisions. Fiscal 2018 and fiscal 2020 (the year ending March 2021) are price revision years even under the current system, and it is expected that a price revision will be implemented in conjunction with the consumption tax rate increase in October 2019. Therefore, the interim-year price revisions under the new rules will take place starting from fiscal 2021 (the year ending March 2022). The scope of items subject to interim-year price revisions will be deliberated by the Central Social Insurance Medical Council (Chuikyo) and other organizations.

Creation of a System for Cost-Effectiveness Assessments

A system of price adjustments based on cost-effectiveness assessments has been approved by Chuikyo, and will be implemented starting in April 2019. The system primarily applies to products that meet the requirements of the selection criteria at the time of their NHI price listing. Cost-effectiveness assessments will be conducted for a certain period after the listing, and the price will be adjusted according to the results. The extent of the price adjustment is the portion corresponding to the amount of the corrective premium for usefulness applied at the time of the drug's initial pricing (for products with a degree of disclosure under 50 percent, as calculated by the cost calculation method, the portion corresponding to operating profit is also subject to adjustment). Price adjustments will be made according to the incremental cost effectiveness ratio (ICER).[4] The corrective premium will be maintained if the ICER is less than ¥5 million (less than ¥7.5 million for anticancer agents), but will be reduced in stages by up to 90 percent if the ICER is ¥5 million or more. The price adjustment will be limited to 10-15 percent of the total drug price.

4. The ICER indicates the extent to which additional investment would be necessary to obtain the additional benefit from replacing existing drug (technology) B with new drug A.

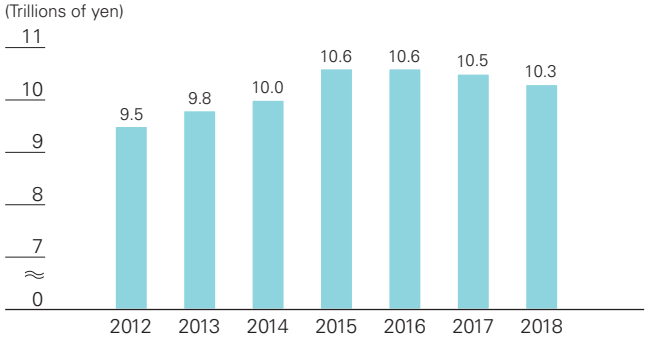
Trends of Medical Care Expenditure



Source: Overview of Estimates of National Medical Care Expenditure, FY2016 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



Oncology

Overview of Disease and Treatment Methods

Leading Cause of Death in Japan

Cancer has been the single most common cause of death in Japan since 1981. In 2017, 373,334 people[1] died of cancer, accounting for 27.9 percent[1] of all deaths in that year and the highest number since government surveys began in 1899.

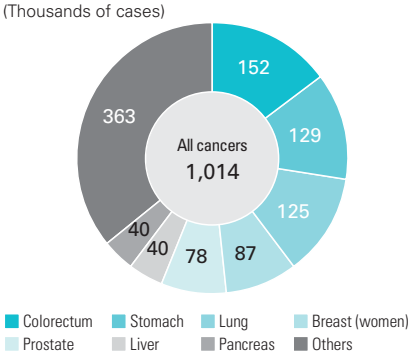
1. Source: Outline of Vital Statistics (2017) by Ministry of Health, Labour and Welfare

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

The Cancer Control Act was enacted in June 2006 to establish a system so that patients can receive appropriate treatment based on scientific knowledge regardless of the region in which they reside and with respect paid to their wishes, as well as to implement the Basic Plan to Promote Cancer Control Programs (the "Basic Plan"). Since the enactment of the Cancer Control Act, significant results have been obtained, including establishment of designated cancer hospitals and a reduction of the cancer mortality rate and improvement of the five-year survival rate owing to advances in cancer treatment. The goal of reducing the age-adjusted cancer mortality rate by 20 percent over the 10-year period from fiscal 2007 was judged difficult to achieve, and 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.

Projected Cancer Incidence (2018)

(Thousands of cases)



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

Note: Projections were performed with a model incorporating age, calendar year at diagnosis, and their interactions as independent variables, utilizing frequency of incidence of cancer by age bracket from Monitoring of Cancer Incidence in Japan (1975-2014 nationwide estimates) and cancer mortality figures from the Outline of Vital Statistics (1975-2016 estimates). The total may not add up because projections have been performed by cancer type and figures have been rounded.

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

In recent years, it has become apparent that new measures are necessary to fight rare cancers, difficult-to-treat cancers, childhood cancers, and cancers in adolescents and young adults (AYA); to promote new treatments such as genomic medicine; and to address societal problems including employment. The principles of the Cancer Control Act revised in 2016 require that the national and local governments make effective use of healthcare and welfare resources and implement cancer control measures from the viewpoint of serving the public in order to achieve the stated goal of creating a society in which cancer patients can live with peace of mind and dignity. In the 3rd Basic Plan to Promote Cancer Control Programs released in March 2018, measures are being implemented based on three pillars – cancer prevention, cancer medical care and research, and coexistence with cancer – to educate the public, including patients, about cancer and help them to overcome it.

Changes in Treatment Methods

Cancer treatment is increasingly being based on a multidisciplinary approach that combines surgery, radiation therapy and chemotherapy. 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 testing patients with companion diagnostics when administering molecular targeted drugs to identify patients who are likely to benefit 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 drugs 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 and gene panel testing using next-generation sequencing. Moreover, the MHLW and pharmaceutical industry organizations have been setting up a framework to promote the realization of genomic medicine, starting with the Council to Promote the Realization of Genomic Medicine, which was established by the Japanese government in January 2015. 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. Immune checkpoint inhibitors, one type of immunotherapy now in use, 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 rising for their high therapeutic efficacy and potential for treating a wide range of cancers. On the other hand, some patients do not respond to cancer immunotherapy, so screening to select patients for whom this therapy is likely to be effective and combination therapy with existing anticancer agents are also being examined.

Avastin (RG435)

Anti-VEGF humanized monoclonal antibody
(Generic name: bevacizumab)
Launch in Japan: June 2007

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 colorectal cancer. In 2009, Chugai obtained approval for a new dosage and administration for colorectal cancer and the additional indication of unresectable advanced or recurrent non-squamous non-small cell lung cancer (NSCLC), followed in 2011 by inoperable or recurrent

breast cancer. Chugai also obtained approval for the additional indications of malignant glioma and ovarian cancer in 2013, and advanced or recurrent cervical cancer in May 2016.

Review of 2018 Performance

Sales of Avastin increased ¥2.5 billion, or 2.7 percent, year on year to ¥95.6 billion. Avastin has built a solid position in the treatment of colorectal cancer and lung cancer, but the competitive environment in the field of lung cancer has been changing due to the introduction of immune checkpoint inhibitors and other products. On the other hand, the use of Avastin for other indications, including breast cancer, has increased steadily. Phase III multinational studies in combination with Tecentriq in renal cell carcinoma and hepatocellular carcinoma patients are under way.

Herceptin

Anti-HER2 humanized monoclonal antibody
(Generic name: trastuzumab)
Launch in Japan: June 2001

Basic Information

Herceptin is a humanized monoclonal antibody that targets human epidermal growth factor receptor type 2 (HER2),[2] which contributes to tumor cell growth. The earliest PHC-based anticancer agent, Herceptin has built a solid reputation as an essential treatment for HER2-positive breast cancer since its launch in 2001.

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 2018 Performance

Sales of Herceptin decreased ¥5.5 billion, or 16.4 percent, year on year to ¥28.1 billion. The decrease was mainly due to the substantial NHI drug price revision (-20.4 percent) that resulted from the return of the premium for new drug creation. Widely used in first-line treatment of HER2-positive advanced or recurrent breast cancer in combination with Perjeta, Herceptin is also used for more than 90 percent of lymph-node positive patients undergoing postoperative (adjuvant) chemotherapy for HER2-positive breast cancer. For gastric cancer, although Herceptin maintained its established position in first-line treatment, sales decreased slightly due to competition in second-line treatment.

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)
Launch in Japan: September 2013

Basic Information

Perjeta is a humanized monoclonal antibody and is the first molecular targeted therapy that inhibits the dimerization of HER2. The combination of Perjeta and Herceptin, which also targets HER2, provides a more comprehensive blockade of HER signaling pathways associated with the proliferation of tumor cells. Chugai launched Perjeta for the indication of HER2-positive inoperable or recurrent breast cancer in September 2013, after obtaining approval in June 2013. In 2018, Perjeta obtained approval for the additional indication of neoadjuvant and adjuvant therapy for HER2-positive breast cancer.

Review of 2018 Performance

Sales of Perjeta increased ¥2.5 billion, or 18.4 percent, year on year to ¥16.1 billion, exceeding projections. In the clinical practice guidelines for breast cancer, which were updated in July 2015, 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, and uptake as a first-line treatment was steady. In addition, a phase III multinational study is underway for RG6264 (subcutaneous injection), a fixed-dose combination of Herceptin and Perjeta, for the potential treatment of HER2-positive breast cancer.

Kadcyla (RG3502)

Anti-HER2 antibody-tubulin polymerization inhibitor conjugate
(Generic name: trastuzumab emtansine)
Launch in Japan: April 2014

Basic Information

Kadcyla is an antibody-drug conjugate of the anti-HER2 humanized monoclonal antibody trastuzumab (product name: 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 2018 Performance

Sales of Kadcyla increased ¥0.5 billion, or 6.3 percent, year on year to ¥8.5 billion. Kadcyla is used as a second-line treatment in patients whose cancer worsened in first-line treatment with Herceptin and Perjeta plus a chemotherapeutic agent. In development, a phase III multinational study for the potential treatment of HER2-positive breast cancer (adjuvant) is under way.

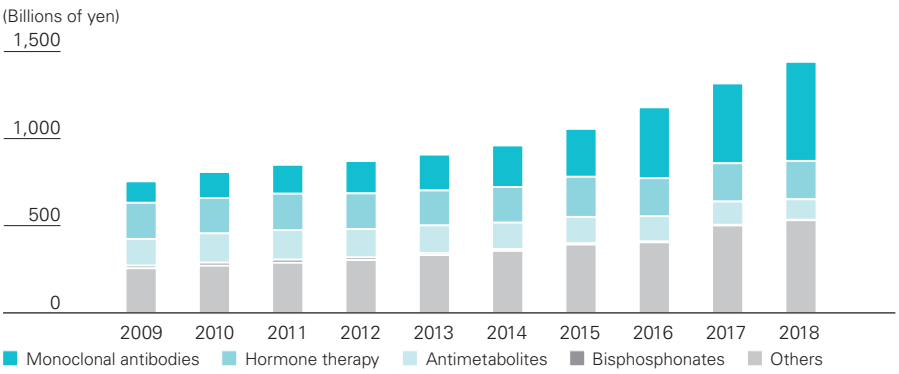
Rituxan

Anti-CD20 monoclonal antibody
(Generic name: rituximab)
Launch in Japan: September 2001

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,

Anticancer Agent Market in Japan



Source: JPM 2009-2018
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The scope of the market is defined by Chugai.

the usefulness of Rituxan has been recognized in treating CD20-positive, B-cell lymphoma in immunosuppressed patients, granulomatosis with polyangiitis (GPA) (formerly known as Wegener's granulomatosis) and microscopic polyangiitis (MPA), refractory nephrotic syndrome with frequent relapses or steroid dependence, suppression of antibody-mediated rejection in ABO-incompatible kidney and liver transplantation, and idiopathic thrombocytopenic purpura (ITP). It has also become a valuable treatment option for patients with autoimmune diseases and other conditions.

Review of 2018 Performance

Sales of Rituxan decreased ¥12.1 billion, or 36.2 percent, year on year to ¥21.3 billion. The decrease was due to more intense competition resulting from the launch of a generic product and the substantial NHI drug price revision (-26.2 percent) with the return of the premium for new drug creation.

Alecensa (AF802/RG7853)

ALK inhibitor
(Generic name: alectinib)
Launch in Japan: September 2014

Basic Information

Alecensa, an oral, small molecule-targeted molecular therapy created by Chugai, inhibits the activity of the tyrosine kinase anaplastic lymphoma kinase (ALK) with *EML4-ALK* fusion gene expressed in about 2 to 5 percent of NSCLC. It was designated as an orphan drug in Japan in September 2013 for the treatment of *ALK* fusion gene-positive unresectable, recurrent/advanced NSCLC. In October 2013, Chugai filed an application for approval. Following approval in July 2014, Alecensa was launched first in Japan in September 2014. In addition to being the first product from Chugai research to be granted breakthrough therapy designation by the U.S. Food and Drug Administration (FDA), Alecensa received its second such designation as a first-line treatment in 2016, and it is contributing to the treatment of patients around the world. Outside Japan, after obtaining approval in the United States in December 2015 and in Europe in February 2017 for the indication of ALK-positive metastatic (advanced) NSCLC in patients whose disease has progressed or who are intolerant to crizotinib, Alecensa obtained approval as a first-line treatment in the United States in November 2017 and Europe in December 2017.

Review of 2018 Performance

Market penetration proceeded further with the announcement of positive results that led to the early stopping for benefit of a study comparing the efficacy and safety of Alecensa and a competing product on patients in Japan (J-ALEX study). Sales of Alecensa in Japan increased ¥3.9 billion, or 23.4 percent, year on year to ¥20.6 billion, due to a high rate of continuation of treatment. Overseas sales of Alecensa (including exports to Roche) increased ¥15.6 billion, or 112.2 percent, year on year to ¥29.5 billion. In development, a phase III multinational study for the potential treatment of ALK-positive NSCLC (adjuvant) is under way.

Xeloda

Antimetabolite, 5-FU derivative
(Generic name: capecitabine)
Launch in Japan: June 2003

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. Xeloda has obtained approval for the treatment of inoperable or recurrent breast cancer, colorectal cancer and gastric cancer.

Review of 2018 Performance

Sales of Xeloda increased ¥0.3 billion, or 2.5 percent, year on year to ¥12.5 billion. Backed by Chugai's initiatives to promote adverse drug reaction management, Xeloda has established a top position in adjuvant therapy performed to inhibit recurrence after surgery for colon cancer. In gastric cancer, prescriptions have increased for adjuvant therapy, for which Xeloda obtained approval in November 2015.

Tarceva

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

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 NSCLC 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 15 percent of NSCLC patients in Europe and about 40 percent in 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 2018 Performance

Sales of Tarceva decreased ¥2.2 billion, or 21.0 percent, year on year to ¥8.3 billion. In NSCLC, sales decreased compared with the previous year due to competition from other products.

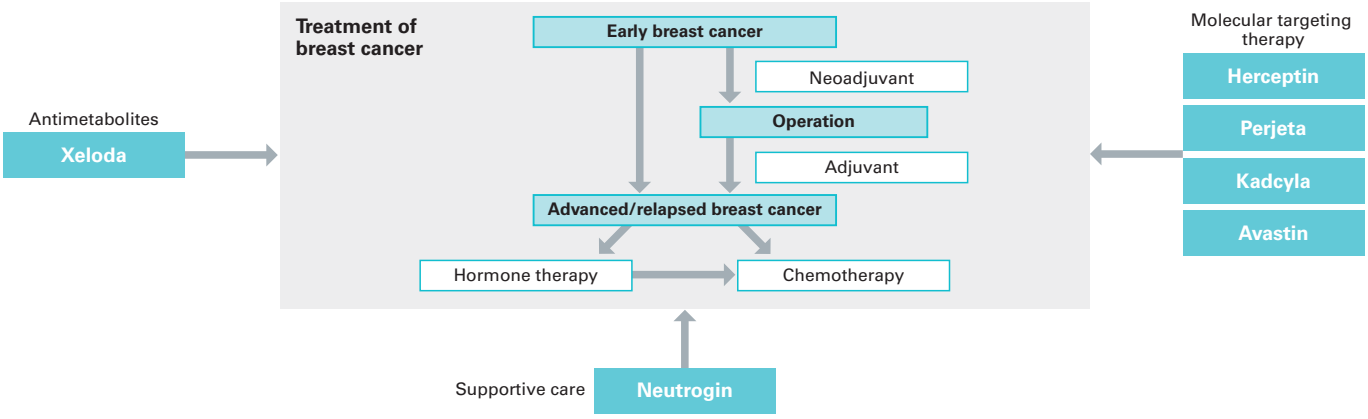
Neutrogin

Recombinant human granulocyte colony-stimulating factor (G-CSF)
(Generic name: lenograstim; overseas product name: Granocyte)
Launch in Japan: December 1991

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

Extensive Contribution to Cancer Treatment (Breast Cancer)



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 stem cell transplantation, which is performed for illnesses that affect production of normal blood cells, such as leukemia.

Review of 2018 Performance

Sales of Neutrogin decreased ¥1.2 billion, or 9.8 percent, year on year to ¥11.1 billion due to intensified competition.

Tecentriq (RG7446)

Engineered anti-PD-L1 monoclonal antibody
(Generic name: atezolizumab)
Launch in Japan: April 2018

Basic Information

Tecentriq is an engineered anti-PD-L1 monoclonal antibody in-licensed from Roche. One way that tumor cells evade the immune system is by expressing a protein called programmed death-ligand (PD-L1) on their surface, which is believed to shield them from immune system attacks by binding to T cells. Tecentriq restores and maintains the immune response of T cells by binding to PD-L1, and is expected to demonstrate efficacy against cancer cells. 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 various cancer types. Chugai obtained approval in January 2018 for the treatment of unresectable advanced or recurrent NSCLC, and obtained approval in December 2018 for the treatment of previously untreated unresectable advanced or recurrent non-squamous NSCLC in combination with Avastin and chemotherapy. In December 2018, Chugai also filed applications for approval of Tecentriq as a treatment for breast cancer and small cell lung cancer (SCLC). In addition, Chugai is participating in phase III multinational studies for the potential treatment of NSCLC (adjuvant), urothelial carcinoma, muscle invasive urothelial carcinoma (adjuvant), renal cell carcinoma, renal cell carcinoma (adjuvant), early breast cancer, ovarian cancer, prostate cancer, hepatocellular carcinoma, and head and neck carcinoma (adjuvant).

Review of 2018 Performance

Sales of Tecentriq were ¥9.1 billion, substantially higher than expected. Uptake was strong because in its position in second-line treatment and later for NSCLC, it can be prescribed regardless of PD-L1 expression.

Gazyva (GA101/RG7159)

Glycoengineered type II anti-CD20 monoclonal antibody
(Generic name: obinutuzumab)
Launch in Japan: August 2018

Basic Information

Gazyva is a glycoengineered type II monoclonal antibody in-licensed from Roche that, like Rituxan, targets CD20. A study that directly compared its efficacy and safety with Rituxan, currently the most widely used monoclonal antibody, in patients in Japan and overseas (the GALLIUM study) was stopped early for benefit after positive results were reported. Gazyva obtained approval for the treatment of CD20-positive B-cell follicular lymphoma in July 2018, and was launched in August 2018. In November 2012, Chugai entered into an agreement with Nippon Shinyaku Co., Ltd. to co-develop and co-market this agent in Japan.

Review of 2018 Performance

Sales of Gazyva after its launch in August 2018 were ¥0.6 billion.

GC33 (RG7686) Development project

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

GC33, a humanized monoclonal antibody created by Chugai, targets glypican-3 (GPC3), which is specifically expressed in hepatocellular carcinoma. GC33 did not meet the primary endpoint in a phase II multinational monotherapy study started in March 2012. A phase I clinical study for the potential treatment of hepatocellular carcinoma in combination with Tecentriq has been under way since August 2016, and the study results were presented at the European Society of Medical Oncology (ESMO) 2018 Congress.

ERY974 Development project

Anti-glypican-3/CD3 bispecific antibody

ERY974 is the first T-cell redirecting antibody (TRAB) developed by Chugai. TRAB is a bispecific antibody that creates a short bridge between CD3 on T cells and tumor antigen on tumor cells to activate T cells in a tumor antigen-dependent manner, and is expected to demonstrate strong cytotoxicity against tumor cells. GPC3, a tumor antigen targeted by ERY974, is reported to be expressed in multiple types of tumor cells including hepatocellular carcinoma, gastric cancer and esophageal cancer. A phase I clinical study started overseas in August 2016.

RG7596 Development project

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. In-licensed from Roche, the conjugate is designed to deliver MMAE directly into B cells via CD79b, which is expressed on B cells, so that the inhibitor can act. To demonstrate a cytostatic effect on tumor cells, a phase III multinational study for the treatment of previously untreated diffuse large B-cell lymphoma (DLBCL) started in November 2017, and a phase II clinical study for the treatment of relapsed or refractory DLBCL started in Japan in October 2018.

RG7440 Development project

AKT inhibitor
(Generic name: ipatasertib)

RG7440 is an AKT inhibitor in-licensed from Roche. Phase III multinational studies started in June 2017 for the treatment of prostate cancer and in January 2018 for the treatment of breast cancer.

CKI27 Development project

Raf/MEK inhibitor

CKI27 is a Raf and MEK dual inhibitor created by Chugai. Phase I clinical studies in Japan and overseas have been completed. Multiple investigator-initiated clinical studies (as monotherapy and in combination therapy) are ongoing in the United Kingdom and the United States, and study results were announced at the 2017 Annual Meeting of the American Society of Clinical Oncology (ASCO). A presentation of summary results is planned at the International Congress on Targeted Anticancer Therapies (TAT) in 2019.

RG7421 Development project

MEK inhibitor
(Generic name: cobimetinib)

RG7421 is an MEK inhibitor in-licensed from Roche. Chugai started a phase I clinical study for the treatment of solid tumors in Japan in July 2017.

CEA-TCB (RG7802) Development project

Anti-CEA/CD3 bispecific antibody
(Generic name: cibisatamab)

CEA-TCB, a bispecific antibody in-licensed from Roche, is expected to activate T-cells and attack tumor cells by cross-linking CD3 on T-cells to carcinoembryonic antigen (CEA) on tumor cells. With a novel structure engineered to bind simultaneously with one arm to CD3 on T-cells and two arms to CEA on tumor cells, it exhibits higher tumor selectivity and stronger binding to CEA. CEA is reported to be overexpressed in a variety of cancers, including colorectal cancer.

CEA-TCB-mediated intra-tumor T-cell proliferation may yield efficacy in tumor types that are not responsive to current cancer immunotherapies because there are few T-cells in the tumor. In addition, combination immunotherapy of CEA-TCB with Tecentriq is expected to yield a potent antitumor effect

in various CEA-positive cancers by inducing further T-cell activation. Chugai started a phase I clinical study of CEA-TCB for the treatment of solid tumors in Japan in January 2018.

CD20-TDB (RG7828) Development project

Anti-CD20/CD3 bispecific antibody
(Generic name: mosunetuzumab)

CD20-TDB is a bispecific antibody in-licensed from Roche. Similar to CEA-TCB, it is expected to activate T cells and attack tumor cells by cross-linking CD3 on T cells to CD20 on B cells. Chugai started a phase I clinical study for the treatment of hematologic tumors in Japan in March 2018.

RG6268 Development project

ROS1/TRK inhibitor
(Generic name: entrectinib)

RG6268, in-licensed from Roche, is an orally bioavailable CNS-active tyrosine kinase inhibitor that potently and selectively inhibits the ROS1 and TRK family, and also acts on brain metastases. Targeting *NTRK* fusion gene-positive solid tumors, RG6268 has been granted breakthrough therapy designation in the United States, PRIorityMEdicines (PRIME) designation in the EU, and Sakigake designation in Japan. Chugai filed an application for approval for the treatment of *NTRK* fusion gene-positive solid tumors in December 2018.

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 daily activities. Among these, compression fractures of the spine and femoral neck fractures can decrease quality of life by leaving patients bedridden and can also increase mortality risk. About 13 million people in Japan suffer from osteoporosis. However, the treatment rate stands at around only 20 percent of the estimated number of sufferers because there are usually no 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.

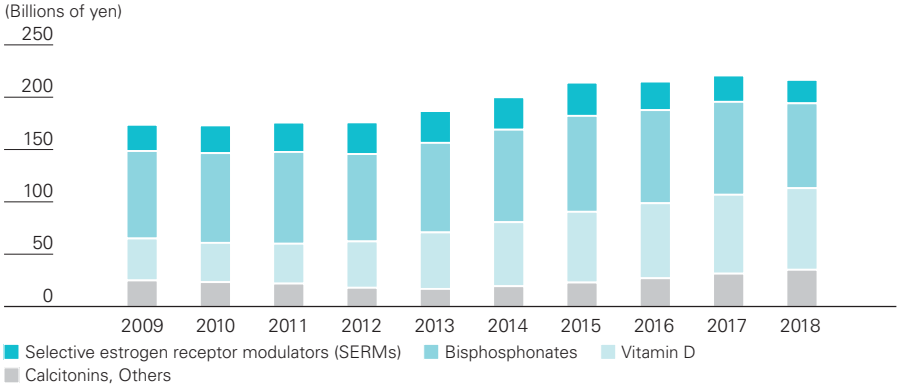
Treatment Methods

Osteoporosis drug therapies include active vitamin D_3 derivatives, which improve bone metabolism, bisphosphonates, which are bone resorption inhibitors, an anti-RANKL antibody, selective estrogen receptor modulators (SERMs), and human parathyroid hormone (PTH), which is a bone formation agent.

Regulatory Trends

National prevention and treatment guidelines for osteoporosis 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 the interim, Edirol and other medicines have 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 management and treatment guidelines for steroid-induced osteoporosis have been adopted. Bonviva IV Injection and other medicines have been launched and covered by insurance, and revised guidelines were issued in July 2015.

Osteoporosis Market in Japan



Source: JPM 2009-2018
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The scope of the market is defined by Chugai.

Recently, an osteoporosis liaison service (OLS) initiated by the Japan Osteoporosis Society was introduced for the purpose of preventing osteoporosis and inhibiting bone fractures by coordinating the efforts of various healthcare professionals, including doctors, nurses, pharmacists and physical therapists. Medical staff involved in liaison and possessing extensive knowledge related to osteoporosis are called osteoporosis managers. This education program has been ongoing since 2012, and more than 2,400 osteoporosis managers were active as of April 2018.

Edirol

Active vitamin D_3 derivative
(Generic name: eldecalcitol)
Launch in Japan: April 2011

Basic Information

Edirol, a vitamin D_3 preparation born out of Chugai's many years of research in vitamin D, is an agent that improves bone metabolism in addition to calcium metabolism. Chugai started sales of Edirol in April 2011 as the successor drug to Alfarol for the indication of osteoporosis. Under an agreement signed in May 2008, Edirol has been co-developed and is currently co-marketed with Taisho Pharmaceutical Co., Ltd. Clinical trials have confirmed that Edirol has a similar safety profile to alfacalcidol with a statistically significant greater effect in preventing fractures. In the 2015 osteoporosis prevention and treatment guidelines, Edirol received a Grade A recommendation, the only one for an active vitamin D_3 preparation, for its effectiveness in increasing bone density and preventing vertebral fractures.

Review of 2018 Performance

Sales of Edirol increased ¥3.3 billion, or 11.1 percent, to ¥32.9 billion. It has become the most widely used active vitamin D_3 preparation because of its superior efficacy in increasing bone mass and preventing fractures compared with existing products. Recognition and understanding of Edirol as a

base treatment has broadened. As a result, its use in combination with other drugs is expanding, as are prescriptions, primarily for new cases. In China, an application has been filed for approval of Edirol as a treatment for osteoporosis.

Bonviva

Bisphosphonate anti-resorptive agent
(Generic name: ibandronate)
Launch in Japan: August 2013

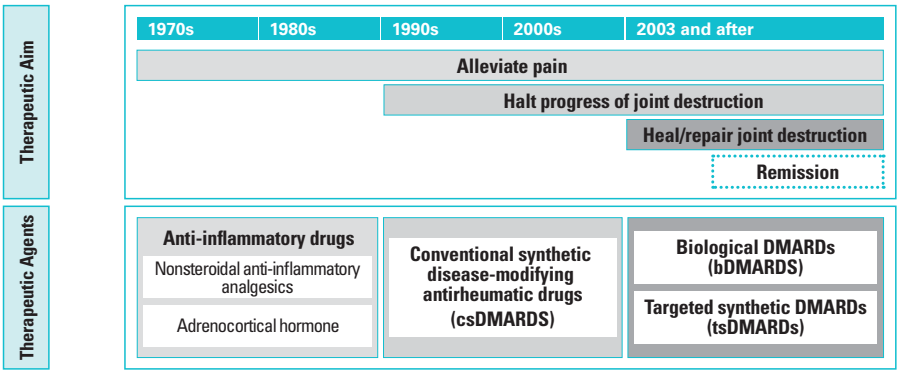
Basic Information

Bonviva is a bisphosphonate in-licensed from Roche. Bonviva IV Injection 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. Bonviva IV Injection can be given as a rapid intravenous injection once a month, and thus may significantly reduce the burden on patients. It is also expected to benefit patients who have difficulty taking oral formulations or who tend to forget to take their medication. In addition, Bonviva Tablet, a once–monthly oral formulation, demonstrated non-inferiority to Bonviva IV Injection in a phase III clinical trial, and Chugai began sales in April 2016. By enabling drug selection according to patient lifestyle, monthly Bonviva IV Injection and Bonviva Tablet are expected to help improve patient adherence, convenience for healthcare providers and the rate of continuation of treatment.

Review of 2018 Performance

Sales of Bonviva increased ¥0.7 billion, or 8.0 percent, to ¥9.4 billion. The intravenous injection and oral formulations have the same high level of efficacy, and the ability to select the formulation according to the patient's condition has helped to differentiate Bonviva from other bisphosphonates.

Changes in Rheumatoid Arthritis Drug Therapy



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

Rheumatoid Arthritis

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. There are currently an estimated 700,000 to 800,000 patients in Japan suffering from RA, of whom some 330,000 are currently receiving drug treatment. The aging of the patient population has also become a problem in recent years. On the other hand, there are only about 8,000 patients in Japan with juvenile idiopathic arthritis (JIA), a form of RA suffered by children under 16 years of age.

Treatment Methods and Market Conditions

In drug therapy for RA, the introduction of biologics has made high remission rates a realistic treatment goal. 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 $56.7 billion* by 2024. The market continues to change, and the range of treatment options for RA is expanding. In 2013, biological DMARDs, a new class of oral drugs, were launched in the United States and Japan, and in 2014, a biosimilar was launched in Japan after previously being launched in Europe.

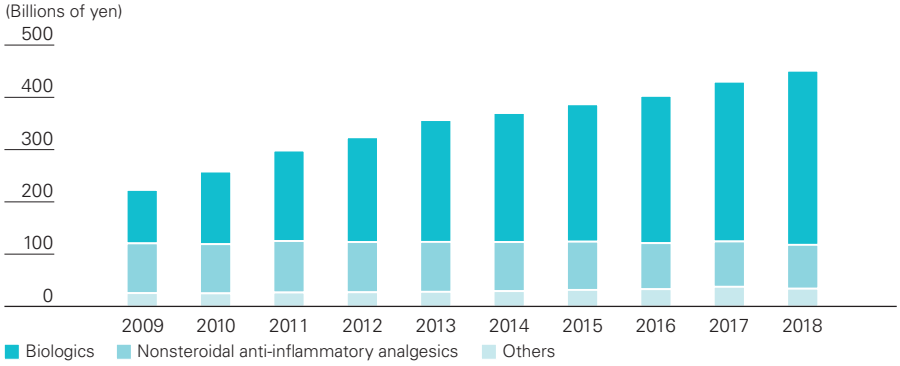
Systemic juvenile idiopathic arthritis (sJIA) accounts for 30 to 40 percent of all JIA cases, but steroids, the main treatment for sJIA, can cause growth impairment and other adverse reactions. Consequently, the approval and launch of Actemra in April 2008 provided a significant advance in therapy.

* Source: Evaluate Pharma®

Regulatory Trends

In November 2018, MHLW released an update of the Report of the Rheumatism and Allergy Countermeasure Committee, which was previously issued in 2005 and 2011. To maximize long-term quality of life of RA patients through appropriate treatment that controls disease activity, and to provide comprehensive support in daily life at workplaces and schools, and for life events such as pregnancy and childbirth, the report calls for (1) enhancement of medical service systems; (2) improvement of the patient environment, including consultation opportunities and access to information, and (3) promotion of research and development and other activities. In Europe, revised treatment recommendations in 2013 added Actemra and Abatacept to the biologic drugs recommended in first-line therapy, which were 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. Moreover, the updated European League Against Rheumatism (EULAR) recommendations that were

Rheumatoid Arthritis Market in Japan



Source: JPM 2009-2018
Reprinted with permission.
The scope of the market is defined by Chugai.

announced in June 2016 state the superiority of biologics in interleukin-6 (IL-6) inhibitor therapy in cases where MTX and other therapies cannot be used.

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 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 arteritis and giant cell arteritis (temporal arteritis).

Takayasu 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 are reduced head and cerebral blood flow-related conditions, primarily 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)
Launch in Japan: June 2005

Basic Information

Actemra, created by Chugai and the first therapeutic antibody originating in Japan, blocks the activity of 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 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.

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. Actemra also received breakthrough therapy designation from the U.S. FDA in 2016 as a treatment for giant cell arteritis. In Japan, it became possible in June 2017 to reduce the dose interval of Actemra from two weeks to one week in patients with an inadequate response to use of the subcutaneous formulation for RA. Actemra obtained approval in Japan for the additional indications of Takayasu arteritis and giant cell arteritis in August 2017.

Review of 2018 Performance

Sales of Actemra in Japan increased ¥5.1 billion, or 15.4 percent, to ¥38.2 billion. The increase continued to be driven by the strong growth of the subcutaneous formulation after Chugai obtained approval for an additional dosage and administration with a shorter dose interval of the subcutaneous formulation for RA, and for the additional indications of Takayasu arteritis and giant cell arteritis. Sales of the subcutaneous formulation accounted for more than 50 percent of the total.

Sales of Actemra outside Japan (including exports to Roche) increased ¥19.3 billion, or 32.5 percent, to ¥78.7 billion. Roche's global sales increased 12.0 percent year on year with steady market penetration, including solid uptake of the subcutaneous formulation in all regions.

In development, Actemra obtained approval for the additional indication of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome in Europe in August 2018. In the United States, an autoinjector obtained approval as an additional formulation for the treatment of RA, giant cell arteritis, and sJIA and pJIA in November 2018.

RG7845 Development project

BTK Inhibitor
(Generic name: fenebrutinib)

RG7845 is an oral, small molecule Bruton's tyrosine kinase (BTK) inhibitor in-licensed from Roche. BTK, a non-receptor tyrosine kinase expressed in B cells and bone marrow, is involved in arteritis and joint destruction associated with RA. RG7845 is expected to improve RA symptoms because it selectively and reversibly binds to the BTK molecule, thereby having an inhibiting effect on its activity. A phase I clinical trial started in June 2017.

Osteoarthritis

The most common joint disease is osteoarthritis. It leads to degeneration of the cartilage in the joints and surrounding areas, causing joint pain and reduced mobility. The prevalence of this disease increases with age. Knee osteoarthritis is particularly common among women, and is reported to affect an estimated 30 percent of women in their fifties, 57 percent in their sixties, and 80 percent at 80 years of age or older.

Academic societies 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.

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 periarthritis of the shoulder and knee joint pain associated with rheumatoid arthritis.

Suvenyl

Agent for joint function improvement
(Generic name: sodium hyaluronate)
Launch in Japan: August 2000

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 2018 Performance

Sales of Suvenyl decreased ¥1.0 billion, or 11.4 percent, to ¥7.8 billion, due to the impact from NHI drug price revisions and from competing products. In China, phase III clinical studies are under way for the potential treatment of knee osteoarthritis and shoulder periarthritis.

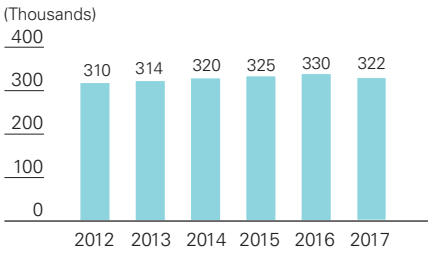
Renal Diseases

Renal Anemia

Complications of Renal Dysfunction

In dialysis patients and end-stage chronic kidney disease (CKD) patients, a key issue is treating the various complications of advanced renal dysfunction, such as renal anemia, secondary hyperparathyroidism, and abnormal calcium and phosphorus metabolism. 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 CKD patients. Renal anemia is associated with reduced quality of life, and is also a factor in the progress of organ damage, including decreased cardiac function.

Number of Dialysis Patients in Japan



Source: Overview of Regular Dialysis Treatment in Japan (as of December 31, 2017) by Statistical Survey Committee, The Japanese Society for Dialysis Therapy

The importance of treating renal anemia and chronic kidney disease - mineral and bone disorder (CKD-MBD) was indicated in the Guideline for Renal Anemia in Chronic Kidney Disease (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 (2018) issued by the Japanese Society of Nephrology.

Erythropoiesis-Stimulating Agent (ESA)

Erythropoietin (EPO) is a hemopoietic factor produced mainly in the kidneys. It speeds up erythrocyte production using erythroid progenitor cells found in bone marrow. An erythropoiesis-stimulating agent (ESA) is effective in treating renal anemia caused primarily by the decline in EPO production due to CKD, and is thought to help improve quality of life. ESAs are currently used by approximately 80 percent of dialysis patients as well as by some pre-dialysis CKD patients with renal anemia. ESAs are thus an essential drug for the treatment of renal anemia.

Flat-Sum Reimbursement System for ESAs

Since the 2006 revisions of medical fees, ESAs have been included in medical fee points for hemodialysis (artificial kidney). The integrated fee points are reviewed with each revision of medical fees, and were reduced in 2018, which has led to intensified price competition for ESAs in the dialysis market.

Mircera

Long-acting erythropoiesis-stimulating agent
(Generic name: epoetin beta pegol)
Launch in Japan: July 2011

Basic Information

Mircera is a drug that raises the stability of epoetin beta in the bloodstream through pegylation. It is a new type of renal anemia treatment with the longest serum half-life among ESAs, enabling stable and sustained control of hemoglobin. It stimulates erythropoiesis through a different interaction with the EPO receptor on burst-forming unit erythroid (BFU-E) 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 efficacy in relieving the symptoms of anemia when administered at four-week intervals during the maintenance period. Consequently, it is expected to reduce the burden of hospital visits on patients with pre-dialysis CKD and to contribute to better treatment adherence. Furthermore, as a dialysis-related treatment, Mircera is expected to reduce the burden on medical staff and improve medical safety 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 2018 Performance

Sales of Mircera decreased ¥0.8 billion, or 3.3 percent, to ¥23.1 billion. While the use of Mircera in pre-dialysis CKD patients expanded, sales decreased because of an NHI drug price revision as well as intensified price competition in the dialysis market after integrated fee points for artificial kidney (hemodialysis) were reduced due to the revision of medical fees.

Others

Oxarol

Agent for secondary hyperparathyroidism
(Generic name: maxacalcitol)
Launch in Japan: September 2000

Basic Information

Synthesized by Chugai, Oxarol is the first intravenous active vitamin D_3 derivative agent in Japan. It treats secondary hyperparathyroidism, a result of conditions such as impaired vitamin D activation associated with renal dysfunction, by acting directly with high concentration on the parathyroid gland to control parathyroid hormone synthesis and secretion, and by acting to improve bone metabolism. With its short serum half-life, Oxarol shows efficacy and enables treatment in patients who previously could not be treated adequately with oral vitamin D_3 derivatives due to the onset of hypercalcemia.

Review of 2018 Performance

Sales of Oxarol decreased ¥0.9 billion, or 11.1 percent, to ¥7.3 billion due to the impact of the NHI drug price revision, despite slower uptake of a generic product.

EOS789 Development project

EOS789 is an oral drug created by Chugai with a molecular weight of over 500 g/mol. Following the completion of a phase I clinical trial as a potential treatment for hyperphosphatemia in Japan, a phase I clinical trial for the same indication started overseas in February 2017.

Neurology

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 Development project

Anti-amyloid-beta human monoclonal antibody
(Generic name: gantenerumab)

RG1450 is an anti-amyloid-beta human monoclonal antibody in-licensed from Roche. The drug targets aggregate amyloid beta, with a high binding affinity to plaques in particular. It is expected to reduce cognitive deterioration by removing amyloid beta in the brain. Phase III multinational studies of RG1450 as a potential treatment for AD began in June and July 2018.

RG7412 Development project

Anti-amyloid-beta humanized monoclonal antibody
(Generic name: crenezumab)

RG7412 is an anti-amyloid-beta humanized monoclonal antibody in-licensed from Roche. The drug targets all types of amyloid beta, with a high binding affinity to oligomers. It is expected to reduce cognitive deterioration by removing amyloid beta in the brain. A phase III multinational study of RG7412 as a potential treatment for AD is under way.

Neuromyelitis Optica Spectrum Disorder

Neuromyelitis optica spectrum disorder (NMOSD) is a neurological autoimmune disorder 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 (in some cases progressing to blindness) and impairment of motor function and sensation. In some cases, the disease results in death. However, as there are no approved treatments available, NMOSD 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. Formerly, the diagnostic criteria of neuromyelitis optica (NMO) accompanied by optic neuritis and myelitis, and NMOSD accompanied by either optic neuritis or myelitis were proposed. Recently, however, it was proposed to reorganize and unify the definitions of both disorders under the term NMOSD. This term is now widely used to refer to a broader spectrum of disease.

SA237 Development project

Anti-IL-6 receptor humanized monoclonal antibody
(Generic name: satralizumab)

SA237, created by Chugai, is a next-generation therapeutic antibody that has shown success in blocking IL-6 receptors with a longer duration of action. Chugai created SA237 by applying its novel antibody technology (Recycling Antibody technology) that enables a single antibody molecule to block the target antigen repeatedly. As a result, a prolonged serum half-life has been demonstrated in clinical trials, and it is expected that a lower dosing frequency will be possible. Because IL-6 promotes the production of the anti-AQP4 antibodies that cause NMOSD, this drug is expected to improve (reduce recurrence of) the symptoms of these diseases as it inhibits the production of those antibodies by blocking the IL-6 signal. Two Chugai-sponsored phase III multinational studies in NMO and NMOSD patients achieved their primary endpoints. In addition to its designation as an orphan drug by the U.S. FDA, SA237 was also granted

orphan drug designation in Europe in 2016. Furthermore, in June 2016, Chugai concluded a license agreement that grants Roche exclusive rights for the development and marketing of SA237 worldwide, with the exception of Japan, South Korea and Taiwan. SA237 was granted breakthrough therapy designation by the FDA in December 2018 for the treatment of NMO and NMOSD.

Duchenne Muscular Dystrophy

Duchenne muscular dystrophy (DMD) is a fatal hereditary disease primarily characterized by degeneration, necrosis and regeneration of the skeletal muscles, with progressive muscle weakness as the clinical symptom. It is caused by a mutation of the dystrophin gene located on the X chromosome. It affects one in 3,000 to 4,000 males at birth, and the estimated number of patients in Japan is between 4,000 and 5,000. Currently, steroids are the only approved treatment available in Japan, but it has been recognized that life expectancy and quality of life have improved due to progress in breathing control methods such as noninvasive positive-pressure ventilation.

RG6206 Development project

Anti-myostatin-inhibiting adnectin fusion protein

RG6206 is a recombinant protein with two anti-myostatin adnectin molecules binding to the human IgG1 Fc fragment. Myostatin is a cell growth inhibitor that negatively regulates skeletal muscle mass. By lowering the level of active, free serum myostatin, RG6206 is expected to have therapeutic effects including maintenance of muscular strength associated with an increase in skeletal muscle mass. A phase II/III multinational study is under way.

Spinal Muscular Atrophy

Spinal muscular atrophy (SMA) is a lower motor neuron disease characterized by amyotrophy and progressive muscle weakness caused by degeneration of anterior horn cells in the spinal cord. The estimated number of patients in Japan is reported to be around 1,000. The disease is caused by a defect in the *SMN1* gene, and onset usually occurs in childhood. In severe cases it is fatal.

RG7916 Development project

SMN2 splicing modifier
(Generic name: risdiplam)

RG7916 is an SMN2 splicing modifier that increases generation of a protein derived from the *SMN2* gene. This protein is nearly identical to the protein made from the *SMN1* gene, which is not functional in SMA patients. RG7916 shows promise in improving neural and muscular function. A phase II/III multinational study is under way. RG7916 was granted PRIME designation by the European Medicines Agency (EMA) in December 2018.

Parkinson's Disease

Parkinson's disease is a progressive neurodegenerative disease characterized by aggregation of α-synuclein in the central nervous system and peripheral nervous system. A wide range of motor symptoms (tremor, muscle rigidity, akinesia, impairment of postural reflexes, etc.) and non-motor symptoms (sleep disorders, autonomic dysfunction, cognitive and mental disorders, etc.) occur. The estimated number of patients in Japan is 150,000. A progressive disease seen mainly in people age 50 or older, it can lead to becoming bedridden as the condition worsens.

RG7935 Development project

Anti-α-synuclein monoclonal antibody
(Generic name: prasinezumab)

RG7935 inhibits the spread of synuclein and the expansion of nerve cell death by removing neurotoxic α-synuclein aggregations with an antibody, and is expected to reduce and delay progression of the disease. A phase I clinical trial began in February 2018.

Others

GYM329/RG6237 Development project

GYM329, created by Chugai, is a next-generation antibody that applies Chugai's proprietary antibody technologies, including its recycling antibody and sweeping antibody technologies. A phase I clinical trial of GYM329 for the potential treatment of neuromuscular disease began in October 2018. Chugai out-licensed GYM329 to Roche at an early stage before the start of clinical testing in order to accelerate global development by taking advantage of Roche's experience and expertise.

RG7906 Development project

RG7906 is a small molecule drug in development for the potential treatment of psychiatric disorders. A phase I clinical trial began in January 2019.

Other Diseases

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 of hemophilia A is centered on replacement therapy to supplement factor VIII. However, since it involves intravenous injections two to 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.

Hemlibra (ACE910/RG6013)

Anti-factor IXa/X bispecific antibody
(Generic name: emicizumab)
Launch in Japan: May 2018

Hemlibra is an anti-factor IXa/X bispecific antibody that employs Chugai's innovative antibody engineering technologies. Like factor VIII, which is low or missing in hemophilia A, Hemlibra simultaneously binds to factor IXa and factor X, stimulating the activation of factor X by activated factor IX and promoting normal blood coagulation for hemostasis. Unaffected by inhibitors, Hemlibra can prevent

bleeding with once weekly (or less-frequent) subcutaneous injections, and is promising as a drug that can potentially change the existing system of treatment. Another key feature is that Chugai's proprietary technology ART-Ig can be applied to Hemlibra, enabling industrial production of bispecific antibodies.

Chugai concluded an out-licensing agreement with Roche in July 2014 and in May 2017 entered into a license agreement with JW Pharmaceutical Corporation for the exclusive marketing rights in South Korea. The drug received breakthrough therapy designation from the U.S. FDA in September 2015 for its potential to prevent bleeding in hemophilia patients with inhibitors, and in April 2018 for its potential to prevent bleeding in patients without inhibitors. Applications for approval for the treatment of hemophilia A (with inhibitors) were filed in the United States and Europe in June 2017 and in Japan in July 2017. In the United States, Hemlibra received priority review designation in August 2017, and in November 2017 obtained approval for routine prophylaxis with once-weekly subcutaneous administration in adult and pediatric patients with hemophilia A with factor VIII inhibitors. Hemlibra was also granted accelerated assessment in Europe, and received regulatory approval from the European Commission in February 2018. In Japan, it obtained approval in March 2018 and was launched in May 2018. It also obtained approval in Taiwan in December 2018.

Applications were filed in the United States, Europe and Japan in April 2018, and in Taiwan in January 2019, for routine prophylaxis of bleeding episodes, as well as for additional dosage and administration as a biweekly or four-weekly treatment, for people with hemophilia A without inhibitors. In the United States, Hemlibra was granted priority review status in June 2018, and in October 2018, it obtained approval for prophylactic treatment by subcutaneous administration once weekly, every two weeks, or every four weeks in adults or children with hemophilia A without inhibitors, as well as additional dosing options of every two weeks or every four weeks in adults and children with hemophilia A with inhibitors. Hemlibra also obtained approval in Japan in December 2018, and received an approval recommendation from the EU Committee for Medicinal Products for Human Use (CHMP) in February 2019.

Review of 2018 Performance

Hemlibra was launched in Japan for treatment of patients with inhibitors in May 2018, and sales were ¥3.0 billion. With more cases than expected in which people struggled to control bleeding, the launch was smooth as switches to Hemlibra took place early on, mainly in pediatric patients.

Influenza

Influenza is an acute infectious disease characterized by the rapid onset of high fever (38 degrees centigrade or higher) and severe systemic symptoms. It is highly infectious, and epidemics can develop quickly. In some cases, secondary infections can lead to very serious illness and death. 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.

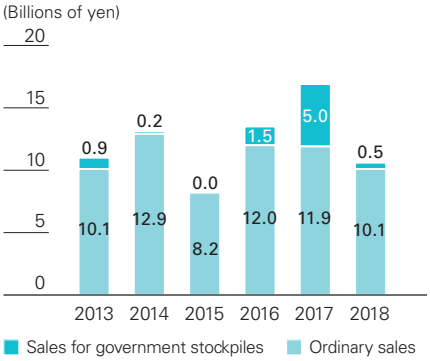
Tamiflu

Anti-influenza agent
(Generic name: oseltamivir phosphate)
Launch in Japan: February 2001

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. From March 2007, restrictions on the use of Tamiflu in teenage patients with seasonal influenza were 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. In May 2018, the Subcommittee on Drug Safety of the Ministry of Health, Labour and Welfare confirmed that abnormal behavior occurs regardless of whether anti-influenza drugs have been given, and in July 2018, the same subcommittee decided that the restrictions should be removed. Accordingly, the package insert was revised and restrictions on the use of Tamiflu in teenage patients were removed in August 2018. 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 10 years starting with the portion shipped in 2015. In March 2017, Chugai obtained approval for additional dosage and administration of Tamiflu Dry Syrup for neonates and infants younger than 12 months.

Tamiflu Sales



Review of 2018 Performance

Sales of Tamiflu decreased ¥6.2 billion, or 36.7 percent, to ¥10.7 billion. Ordinary sales were ¥10.1 billion, while sales for government stockpiles were ¥0.5 billion. Chugai continued to highlight the drug's efficacy and the benefits of its unique dry syrup formulation.

Others

CellCept

Immunosuppressant
(Generic name: mycophenolate mofetil)
Launch in Japan: November 1999

Sales of CellCept increased ¥0.1 billion, or 1.1 percent, to ¥9.0 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 medication has been rising in Japan, driven by advances in transplantation therapy. In May 2016, CellCept received approval for the indication of lupus nephritis, a refractory disease associated with the autoimmune disease systemic lupus erythematosus.

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 is drug therapy using topical steroid preparations and/or 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 Development project

Anti-IL-31 receptor A humanized monoclonal antibody
(Generic name: nemolizumab)

Nemolizumab (CIM331) is an anti-IL-31 receptor A humanized monoclonal antibody originating from Chugai. The drug is expected to suppress itching and skin inflammation in atopic dermatitis by blocking IL-31, a proinflammatory cytokine, from binding to its receptor.

A phase II clinical study of CIM331 as a potential treatment for pruritus in dialysis patients has been completed.

In July 2016, Chugai entered into a global license agreement granting Galderma S.A. of Switzerland exclusive rights for the development and marketing of nemolizumab worldwide, with the exception of Japan and Taiwan. In September 2016, Chugai entered into a license agreement granting Maruho Co., Ltd. the rights for the development and marketing of nemolizumab in the skin disease area for the Japanese market. Clinical trials by both companies are currently under way.

Paroxysmal Nocturnal Hemoglobinuria

Paroxysmal nocturnal hemoglobinuria (PNH) is a disorder that leads to complications such as thrombosis and CKD, in addition to anemia and dark brown urine caused by hemolysis as well as infections and bleeding tendency associated with a decrease in white blood cells and platelets. It is a progressive and life-threatening disease in which acquired genetic mutation affecting hematopoietic stem cells causes the creation of red blood cells that have no complement resistance, and hemolysis occurs when complements are activated in vivo. An estimated 430 patients suffer from PNH in Japan, and the disease reportedly affects approximately 5,000 people globally. Although this number is small, PNH is a progressive disease with a high risk of mortality. The drug approved in Japan to suppress hemolysis in patients who need blood transfusions must be administered once every two weeks, requiring regular hospital visits due to the seriousness of the disease.

SKY59/RG6107 Development project

Anti-C5 recycling antibody

SKY59 is a recycling antibody discovered by Chugai that inhibits the C5 complement component. By blocking cleavage of C5 to C5a and C5b, it is expected to inhibit complement activation, which is the cause of a number of diseases. In PNH, SKY59 may have a suppressive effect on hemolysis by preventing the destruction of red blood cells. Application of multiple Chugai proprietary antibody engineering technologies resulted in a prolonged half-life (in preclinical trials), and the antibody is being developed as a subcutaneous self-injection. Chugai is co-developing SKY59 with Roche, and a phase I/II multinational study began in November 2016. In September 2017, SKY59 received orphan drug designation in the United States as a potential treatment for PNH.

wAMD/DME

Wet age-related macular degeneration (wAMD) is a disease in which abnormal blood vessel growth (choroidal neovascularization) caused by age-related accumulation of waste products extends into the space under the retinal pigment epithelium (RPE) or between the retina and the RPE, leading to retinal tissue injury. If the choroidal neovascularization and the associated effusion progress into the fovea centralis, which governs vision, it may lead to deterioration of visual acuity along with the symptoms of image distortion, vision loss and central scotoma. Left untreated, wAMD may lead to irreversible visual impairment.

Diabetic macular edema (DME) is a retinal disease associated with diabetic retinopathy. In diabetes, consistently high blood sugar causes blockage of retinal capillaries, ischemic change, and edema induced by vascular hyperpermeability. Blurred vision occurs when swelling extends to the central part of the macula, which governs vision. Left untreated, DME may lead to irreversible visual impairment.

RG7716 Development project

Anti-VEGF/Ang-2 bispecific antibody
(Generic name: faricimab)

RG7716, which Chugai in-licensed from Roche, is the first bispecific antibody for ophthalmology diseases. It selectively binds to vascular endothelial growth factor (VEGF-A), a key mediator of angiogenesis and vascular permeability, and angiopoietin-2 (Ang-2, an antagonist of Ang-1, which contributes to the stability of mature vessels), a destabilizer of chorioretinal vessels and inducer of vascular permeability. By simultaneously neutralizing intraocular VEGF-A and Ang-2 in wAMD and DME patients, RG7716 is expected to demonstrate better treatment outcomes and a more sustained effect than the anti-VEGF drugs that are the current standard of care. A phase I clinical trial began in 2017, and a phase III multinational study for the potential treatment of DME began in September 2018.

Endometriosis

Affecting one out of 10 women in their twenties to forties, endometriosis is the repeated proliferation and shedding of endometrial tissue outside the uterus, accompanied by dysmenorrhea and chronic lower abdominal pain, and is a cause of infertility. The disease can interfere with daily life, including absences from work or school, as sufferers find it difficult to do more than lie still when symptoms are severe. The only existing medications are hormonal agents. Moreover, if the pain cannot be controlled by drugs, the only treatment is surgical removal, and many patients experience a recurrence years after surgery, making this a disease with a high level of unmet medical need.

AMY109 Development project

AMY109 is the third therapeutic antibody to apply the recycling antibody technology created by Chugai. Its approach differs from hormone therapy, which is the standard treatment for endometriosis, and its anti-inflammatory action is expected to provide new value to patients. A phase I clinical study started in February 2018.

9-Year Financial Summary

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

International Financial Reporting Standards (IFRS)	2018		2017		2016		2015	
	IFRS	Core[1]	IFRS	Core	IFRS	Core	IFRS	Core
Results								
Revenues[2]	579.8		534.2		491.8		498.8	
Sales	527.8		499.3		472.7		468.4	
Royalties and other operating income	51.9		34.9		19.1		30.4	
Cost of sales	(262.8)	(261.9)	(254.2)	(252.9)	(247.9)	(246.7)	(240.2)	(238.9)
Operating expenses	(192.6)	(187.6)	(181.1)	(178.1)	(167.0)	(164.5)	(171.8)	(169.3)
Marketing and distribution	(73.7)	(73.7)	(72.8)	(72.8)	(69.8)	(69.8)	(74.8)	(74.7)
Research and development	(99.2)	(94.2)	(92.9)	(88.9)	(85.0)	(82.6)	(83.8)	(81.9)
General and administration	(19.7)	(19.7)	(15.3)	(16.3)	(12.2)	(12.1)	(13.2)	(12.8)
Operating profit	124.3	130.3	98.9	103.2	76.9	80.6	86.8	90.7
Profit before taxes	121.4	127.5	97.0	101.3	74.4	78.1	87.3	91.2
Net income	93.1	97.3	73.5	76.7	54.4	56.8	62.4	64.9
Attributable to Chugai shareholders	92.5	96.7	72.7	75.9	53.6	56.1	61.1	63.7
Core EPS (Yen)	—	176.42	—	138.68	—	102.50	—	116.42
Cash dividends per share (Yen)	86		62		52		58	
Core payout ratio	—	48.7%	—	44.7%	—	50.7%	—	49.8%
Financial Position								
Net operating assets	505.3		440.2		431.1		380.4	
Total assets	919.5		852.5		806.3		787.4	
Total liabilities	(163.0)		(159.6)		(159.8)		(160.1)	
Total net assets	756.5		692.9		646.5		627.3	
Investments in property, plant and equipment	71.8		34.3		19.4		28.7	
Depreciation	14.6		14.5		14.8		14.0	
Main Indicators								
Cost to sales ratio	49.8%	49.6%	50.9%	50.7%	52.4%	52.2%	51.3%	51.0%
Ratio of operating profit to revenues	21.4%	22.5%	18.5%	19.3%	15.6%	16.4%	17.4%	18.2%
Ratio of research and development expenditures to revenues	17.1%	16.2%	17.4%	16.6%	17.3%	16.8%	16.8%	16.4%
Ratio of net income to equity attributable to Chugai shareholders (ROE)[3]	12.8%	—	10.9%	—	8.4%	—	10.0%	—
Ratio of profit before taxes to total assets (ROA)[4]	13.7%	—	11.7%	—	9.3%	—	11.4%	—
Equity per share attributable to Chugai shareholders (BPS) (Yen)	1,381.26	—	1,265.46	—	1,181.67	—	1,146.17	—
Ratio of equity attributable to Chugai shareholders	82.2%	—	81.2%	—	80.1%	—	79.5%	—
Number of employees	7,432		7,372		7,245		7,169	

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)

2014		2013		2012	
IFRS	Core	IFRS	Core	IFRS	Core
461.1		423.7		386.6	
436.9		401.3		375.2	
24.2		22.4		11.3	
(218.1)	(217.0)	(187.0)	(186.1)	(168.2)	(167.3)
(167.2)	(166.8)	(157.9)	(157.7)	(143.7)	(143.7)
(71.7)	(71.7)	(71.6)	(71.5)	(67.9)	(67.9)
(80.8)	(80.6)	(74.3)	(74.1)	(66.6)	(66.6)
(14.6)	(14.6)	(12.1)	(12.1)	(9.2)	(9.2)
75.9	77.3	78.7	79.9	74.7	75.6
76.2	77.6	76.9	78.1	72.7	73.6
52.1	53.0	51.9	52.6	46.8	47.4
51.0	51.9	50.9	51.6	46.1	46.6
—	95.04	—	94.69	—	85.64
48		45		40	
—	50.5%	—	47.5%	—	46.7%
357.7		325.2		307.9	
739.5		697.2		645.3	
(141.8)		(124.0)		(116.2)	
597.8		573.2		529.2	
16.3		13.0		14.2	
13.7		13.5		13.3	
49.9%	49.7%	46.6%	46.4%	44.8%	44.6%
16.5%	16.8%	18.6%	18.9%	19.3%	19.6%
17.5%	17.5%	17.5%	17.5%	17.2%	17.2%
8.7%	—	9.3%	—	9.0%	—
10.6%	—	11.5%	—	11.8%	—
1,092.90	—	1,049.47	—	970.08	—
80.6%	—	82.0%	—	81.8%	—
7,023		6,872		6,836	

(Billions of yen)

Japanese GAAP	2012	2011
Results		
Revenues[1]	391.2	373.5
Sales	375.2	363.6
Other operating revenues	16.0	9.9
Cost of sales	167.7	157.5
Selling, general and administrative expenses	147.1	153.6
Marketing and distribution expenses	92.0	97.7
Research and development expenditures	55.1	55.9
Operating income	76.4	62.4
Net income (loss)	48.2	35.2
Net income per share (basic) (Yen)	88.58	64.75
Net income per share (diluted) (Yen)	88.54	64.72
Cash dividends per share (Yen)	40	40
Payout ratio	45.2%	61.8%
Financial Position		
Total assets	587.7	533.5
Total net assets[2]	490.1	459.1
Capital investments	14.2	11.9
Depreciation and amortization	15.3	15.9
Main Indicators		
Cost to sales ratio	44.7%	43.3%
Ratio of operating income to revenues	19.5%	16.7%
Ratio of research and development expenditures to revenues	14.1%	15.0%
Return on equity[3]	10.2%	7.8%
Return on assets[4]	8.6%	6.8%
Net assets per share (Yen)	896.02	839.50
Shareholders' equity to total assets	83.0%	85.6%
Number of employees	6,836	6,779

1. Revenues do not include consumption tax.
2. Net assets include minority interests.
3. Return on equity = Net income / Shareholders' equity (average of beginning and end of fiscal year)
4. Return on assets = Net income / Total assets (average of beginning and end of fiscal year)

Management's Discussion and Analysis

Management Policy

Based on its strategic alliance with Roche, Chugai's Mission is to dedicate itself to adding value by creating and delivering innovative products and services for the medical community and human health around the world. Aiming at becoming a top innovator for advanced and sustainable patient-centric healthcare, we set up our fundamental management policy of growing together with society. To achieve our goal, we have leveraged our close relationship with Roche and built systems capable of efficiently and continuously developing and launching new drugs. Refining our strengths has also contributed to achieving innovation that has enabled us to create state-of-the-art drug discovery technology and maintain the top share of the domestic oncology area.

In the previous mid-term business plan, IBI 18, we generated record revenues and operating profit in each of the three years from 2016 through 2018, and focused on the core strategy of acquiring and implementing competitiveness at a top global level. In the new mid-term business plan, IBI 21, we aim to accelerate the growth of society and the Company through innovation focusing on the creation of innovative new drugs. The numerical outlook through the final year of the plan is a compound annual growth rate for Core EPS in the high single digits, based on a fixed exchange rate. Chugai is also aiming for a consolidated dividend payout ratio that averages 50 percent of Core EPS to provide a stable allocation of profit to all shareholders.

Overview of Results

Revenues

(Billions of yen)

	2016	2017	2018	2017/2018 Change
Revenues	491.8	534.2	**579.8**	+8.5%
Sales	472.7	499.3	**527.8**	+5.7%
Royalties and other operating income (ROOI)	19.1	34.9	**51.9**	+48.7%

- In 2018, revenues exceeded the level of the previous year despite the impact of NHI drug price revisions because of strong sales of mainstay products in Japan and of new products Tecentriq and Hemlibra, and an increase in exports to Roche and ROOI.
- ROOI increased year on year due to an increase in one-time income from the transfer of long-term listed products and the out-licensing of a developed product for diabetes.

Domestic Sales by Area

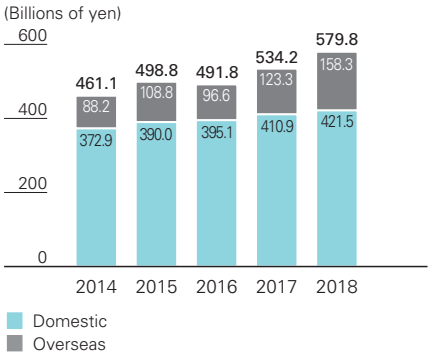
(Billions of yen)

	2016	2017	2018	2017/2018 Change
Domestic sales (excluding Tamiflu)	379.7	388.4	**389.2**	+0.2%
Oncology	220.3	225.9	**225.7**	-0.1%
Bone and joint diseases	86.1	93.3	**100.5**	+7.7%
Renal diseases	41.1	39.3	**36.3**	-7.6%
Others	32.2	29.9	**26.8**	-10.4%
Tamiflu sales	13.5	16.9	**10.7**	-36.7%
Ordinary sales	12.0	11.9	**10.1**	-15.1%
Sales for government stockpiles	1.5	5.0	**0.5**	-90.0%

Note: Sales of the transplant, immunology and infectious diseases area, which were disclosed separately up until 2016, were disclosed in Others from 2017. Figures for 2016 have been restated accordingly.

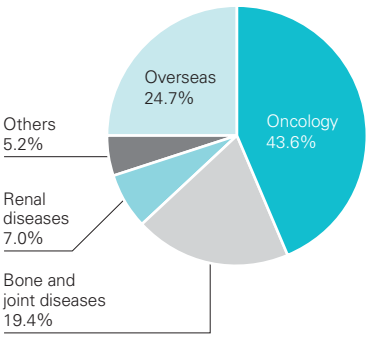
- In 2018, domestic sales (excluding Tamiflu) increased year on year despite the impact of the NHI drug price revisions in April 2018, led by new products in the oncology area and firm sales in the mainstay bone and joint diseases area.
- During 2018, we maintained our number-one share of the domestic oncology market (17.9 percent)*. Strong sales of Tecentriq, launched in April 2018, and steady increases in sales of mainstay products such as Alecensa offset lower sales of Herceptin and Rituxan due to the NHI drug price revisions in 2018.
- In the bone and joint diseases area, sales of mainstay products increased strongly, including Actemra, Edirol, which has been recognized as a standard therapy for osteoporosis, and Bonviva, which is available in both oral and intravenous formulations and has equivalent effect.

Revenues



Percentage of Total Sales (Excluding Tamiflu)

(2018)



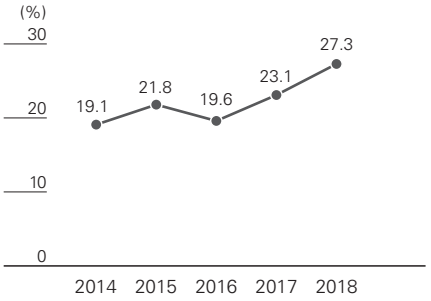
Overseas Sales

(Billions of yen)

	2016	2017	2018	2017/2018 Change
Overseas sales	79.5	94.0	**127.9**	+36.1%
Actemra (exports to Roche)	59.1	59.4	**78.7**	+32.5%
Alecensa (exports to Roche)	3.7	13.9	**28.9**	+107.9%

- Overseas sales increased year on year in 2018. Contributing factors included solid sales of Actemra centered on the subcutaneous formulation and exports of Alecensa to Roche that exceeded forecasts at the beginning of the year due to its significant penetration of the U.S. and European markets.

Overseas Sales Ratio



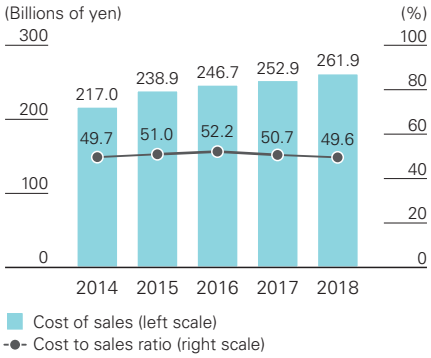
Cost of Sales (Core basis)

(Billions of yen)

	2016	2017	2018	2017/2018 Change
Cost of sales	(246.7)	(252.9)	**(261.9)**	+3.6%
Cost to sales ratio	52.2%	50.7%	**49.6%**	-1.1% pts

- The cost to sales ratio decreased year on year in 2018, mainly because Chugai products, which have a lower cost to sales ratio than products in-licensed from Roche, accounted for a higher percentage of the sales mix.

Cost of Sales/Cost to Sales Ratio



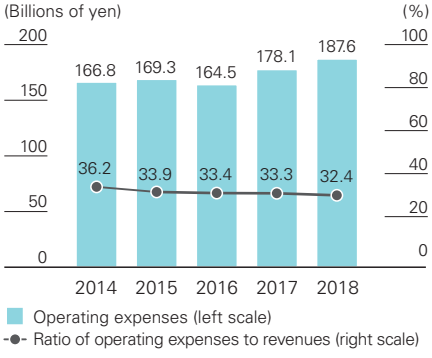
Operating Expenses (Marketing and Distribution Expenses, R&D Expenditures and General and Administration Expenses) (Core Basis)

(Billions of yen)

	2016	2017	2018	2017/2018 Change
Total operating expenses	(164.5)	(178.1)	**(187.6)**	+5.3%
Marketing and distribution expenses	(69.8)	(72.8)	**(73.7)**	+1.2%
R&D expenditures	(82.6)	(88.9)	**(94.2)**	+6.0%
General and administration expenses	(12.1)	(16.3)	**(19.7)**	+20.9%

- Marketing and distribution expenses increased slightly year on year in 2018 because of an increase in promotional activities centered on new products and other factors.
- R&D expenditures increased year on year due to factors including the progress of development projects.
- General and administration expenses increased year on year due to an increase in expenses including legal fees and the enterprise tax.

Operating Expenses/ Ratio of Operating Expenses to Revenues



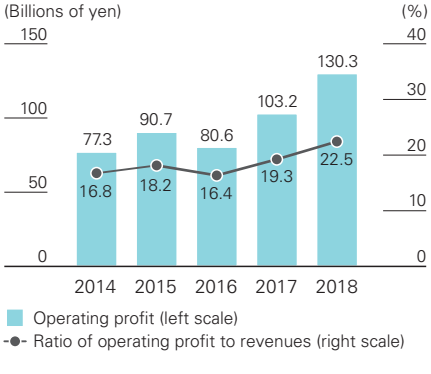
Operating Profit and Net Income (Core Basis)

(Billions of yen)

	2016	2017	2018	2017/2018 Change
Operating profit	80.6	103.2	**130.3**	+26.3%
Ratio of operating profit to revenues	16.4%	19.3%	**22.5%**	+3.2% pts
Net income	56.8	76.7	**97.3**	+26.9%
Net income attributable to Chugai shareholders	56.1	75.9	**96.7**	+27.4%

- Operating profit and net income increased year on year in 2018. Factors included an increase in ROOI. In addition, the ratio of operating profit to revenues increased because of a lower cost to sales ratio due to the higher percentage of Chugai products in the sales mix.

Operating Profit/ Ratio of Operating Profit to Revenues

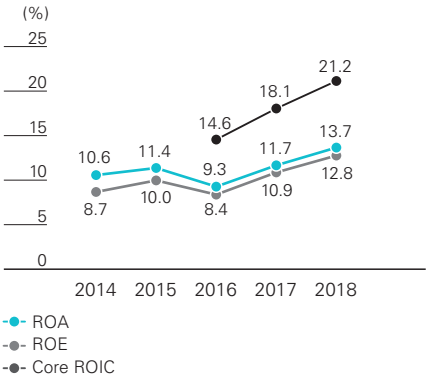


Profitability Indicators (Consolidated)

	2016	2017	2018	2016/2017 Change
Gross profit to revenues (%) (Core)	49.8	52.7	**54.8**	+2.1% pts
Operating profit to revenues (%) (Core)	16.4	19.3	**22.5**	+3.2% pts
Ratio of profit before taxes to total assets (ROA[1]) (%) (IFRS)	9.3	11.7	**13.7**	+2.0% pts
Ratio of net income attributable to Chugai shareholders (ROE[2]) (%) (IFRS)	8.4	10.9	**12.8**	+1.9% pts
Core return on invested capital (Core ROIC[3]) (%)	14.6	18.1	**21.2**	+3.1% pts

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)
3. Core ROIC = Core net operating profit after taxes / Net operating assets (Core ROIC is calculated by using Core income taxes)

ROA/ROE/Core ROIC



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.

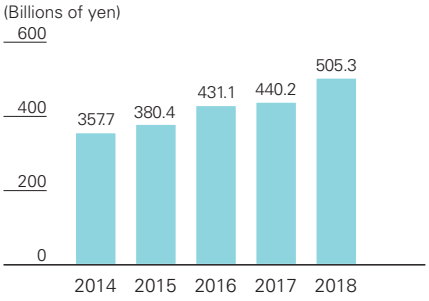
Net Operating Assets (NOA)

(Billions of yen)

	2016	2017	2018	2017/2018 Change
Net working capital	258.5	250.7	**235.1**	-6.2%
Long-term net operating assets	172.7	189.5	**270.1**	+42.5%
Net operating assets (NOA)	431.1	440.2	**505.3**	+14.8%

- Net working capital at December 31, 2018 decreased from a year earlier, largely because inventories decreased due to the absence of front-loaded purchases centered on global products in the previous year and the effect of the transfer of long-term listed products.
- Long-term net operating assets increased from a year earlier because of an increase in investments in property, plant and equipment, primarily due to the purchase of land in Yokohama for a new laboratory.
- As a result, NOA increased from a year earlier due to factors including investments for the future.

Net Operating Assets



NOA 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.

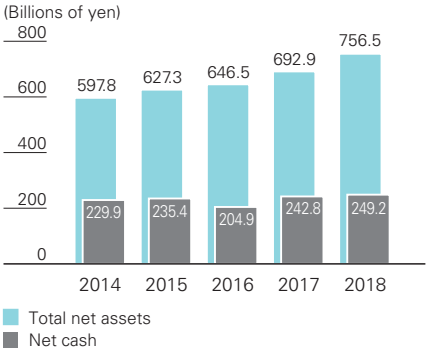
Total Net Assets

(Billions of yen)

	2016	2017	2018	2017/2018 Change
Net operating assets (NOA)	431.1	440.2	**505.3**	+14.8%
Net cash	204.9	242.8	**249.2**	+2.6%
Other non-operating assets – net	10.5	9.9	**2.1**	-78.8%
Total net assets	646.5	692.9	**756.5**	+9.2%

- Total net assets at December 31, 2018 increased from a year earlier due to the purchase of land in Yokohama for a new laboratory.
- Despite aggressive investments for future growth, net cash has stayed above ¥200.0 billion for the past six years as Chugai's ability to generate cash has remained high.

Total Net Assets/Net Cash



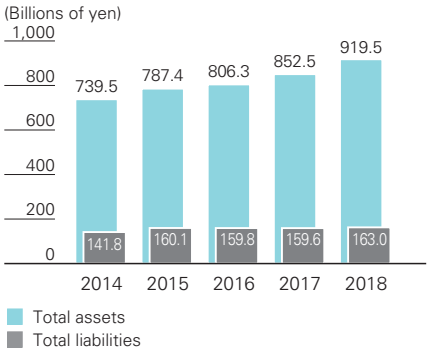
Total Assets and Total Liabilities

(Billions of yen)

	2016	2017	2018	2017/2018 Change
Total assets	806.3	852.5	**919.5**	+7.9%
Total liabilities	(159.8)	(159.6)	**(163.0)**	+2.1%

- Looking at the components of total assets, total liabilities and total net assets, total liabilities at December 31, 2018 did not change significantly from a year earlier, and total assets and total net assets increased from a year earlier.

Total Assets/Total Liabilities

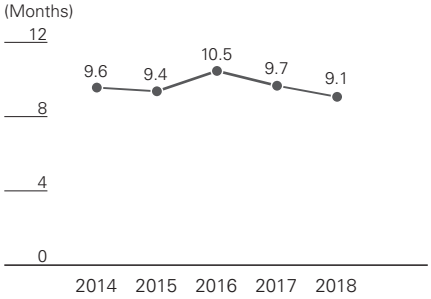


Financial Position Indicators

	2016	2017	2018	2017/2018 Change
Ratio of equity attributable to Chugai shareholders (%)	80.1	81.2	**82.2**	+1.0% pts
Core return on net operating assets (Core RONOA) (%)	14.0	17.6	**20.6**	+3.0% pts
Cash conversion cycle (months)	10.5	9.7	**9.1**	-0.6 months
Net cash turnover period (months)	5.0	5.5	**5.2**	-0.3 months
Current ratio (%)	468.0	487.5	**443.8**	-43.7% pts
Debt-to-equity ratio (%)	0.1	0.0	**0.0**	—

Notes: 1. Ratio of equity attributable to Chugai shareholders = Capital and reserves attributable to Chugai shareholders (fiscal year-end) / Total assets (fiscal year-end)
2. Core RONOA = 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)

Cash Conversion Cycle



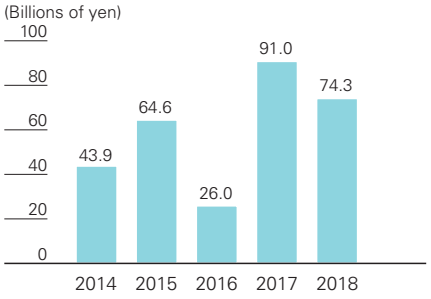
Cash Flows

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 internal performance indicators (Roche discloses the same indicators). No items have been excluded from cash flows, as the Core basis results concept only applies to the income statement.

(Billions of yen)

	2016	2017	2018	2017/2018 Change
Movement of Free Cash Flows				
Operating profit	76.9	98.9	**124.3**	+25.7%
Operating profit, net of operating cash adjustment	98.5	121.0	**147.4**	+21.8%
Operating free cash flow	26.0	91.0	**74.3**	-18.4%
Free cash flow	4.3	64.7	**43.7**	-32.5%
Net increase/decrease in cash	(30.5)	37.9	**6.4**	-83.1%
Consolidated Statement of Cash Flows				
Cash flows from operating activities	38.8	107.6	**119.1**	+10.7%
Cash flows from investing activities	(10.1)	(36.7)	**(74.1)**	+101.9%
Cash flows from financing activities	(33.4)	(29.6)	**(35.0)**	+18.2%
Net increase in cash and cash equivalents	(6.3)	43.7	**7.8**	-82.2%
Cash and cash equivalents at end of year	95.4	139.1	**146.9**	+5.6%

Operating Free Cash Flow



Operating free cash flow

- Operating profit, net of operating cash adjustment, totaled ¥147.4 billion after adjustment for items including ¥14.6 billion for depreciation of property, plant and equipment and impairment.

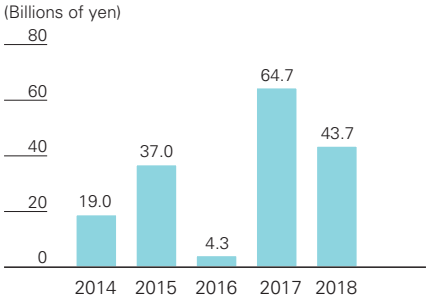
- Operating free cash flow was ¥74.3 billion. It is calculated by adjusting operating profit, net of operating cash adjustment, by subtracting the decrease in net working capital of ¥4.5 billion and subtracting expenditures of ¥77.7 billion for the purchase of property, plant and equipment and intangible assets. Purchases of property, plant and equipment mainly involved the purchase of land in Yokohama for a new laboratory and investments in research and plant equipment.

Free cash flow (FCF)

- Free cash flow for 2018 was ¥43.7 billion after items including income taxes paid of ¥31.6 billion and settlement for transfer pricing taxation of ¥3.2 billion.
- Net cash as of December 31, 2018, after dividends paid and foreign currency translation adjustments, increased ¥6.4 billion compared with the end of the previous fiscal year to ¥249.2 billion.

Note: Chugai formerly stated free cash flow net of dividends paid, but began stating free cash flow before dividends paid from the second quarter of 2016. Chugai changed its presentation of free cash flow to a generally accepted calculation that conforms to the change in the way that Roche defines free cash flow. Free cash flow from 2014 has been restated accordingly. The change has had no effect on operating free cash flow.

Free Cash Flow



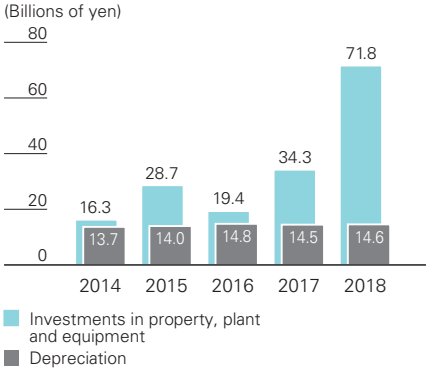
Capital Investments

(Billions of yen)

	2016	2017	2018	2017/2018 Change
Investments in property, plant and equipment	19.4	34.3	71.8	+109.3%
Depreciation	14.8	14.5	14.6	+0.7%

- The increase in capital investments in 2018 was largely the result of expenditures to purchase land in Yokohama for a new laboratory and to acquire research and plant equipment.
- Chugai plans to make capital investments of ¥56.0 billion during 2019, consisting primarily of new investment in the main facilities below, and expects depreciation to total ¥15.0 billion.

Capital Investments in Property, Plant and Equipment/Depreciation



Major Capital Investments – Current and Planned

(Chugai Pharmaceutical Co., Ltd.)

Facilities (Location)	Description	Planned investment (Billions of yen) Total amount	Planned investment (Billions of yen) Investment to date	Fund-raising method	Start of construction	Planned transfer/ completion date
—	Purchase of land for business in Totsuka-ku, Yokohama	43.4	43.0	Self-financing	March 2016	December 2018
—	Comprehensive collaboration in research activities with IFReC	10.0	—	Self-financing	April 2017	March 2027
Ukima Research Laboratories (Kita-ku, Tokyo)	Construction of a new synthetic research building for strengthening the process development function of small and middle molecule APIs	4.5	1.3	Self-financing	May 2018	January 2020

(Chugai Pharma Manufacturing Co., Ltd.)

Facilities (Location)	Description	Planned investment (Billions of yen) Total amount	Planned investment (Billions of yen) Investment to date	Fund-raising method	Start of construction	Planned transfer/ completion date
Utsunomiya Plant (Utsunomiya City, Tochigi)	Enhancement of high-mix, low-volume production capability for pre-filled syringe form products (Installation of tray filler)	6.0	6.0	Self-financing	September 2013	October 2018
Ukima Plant (Kita-ku, Tokyo)	Enhancement of high-mix, low-volume production of antibody APIs for initial commercial products (Expansion of production capability with construction of UK3 facility)	37.2	36.7	Self-financing	November 2015	December 2018

Outlook for 2019

Forecast Assumptions

For 2019, Chugai assumes exchange rates of ¥114/CHF, ¥128/EUR, ¥111/USD and ¥82/SGD.

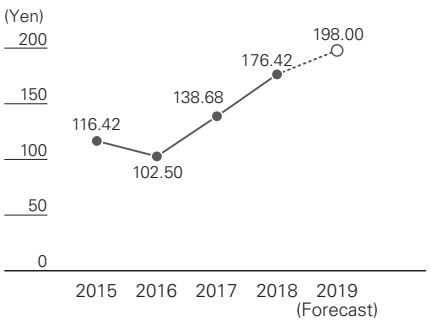
Results Forecast (Core Basis)

(Billions of yen)

	2017	2018	2019 Forecast	2018/2019 Change
Sales	499.3	527.8	528.0	0.0%
Domestic	405.3	399.9	389.1	-2.7%
Overseas	94.0	127.9	138.9	+8.6%
Royalties and other operating income (ROOI)	34.9	51.9	64.5	+24.3%
Royalty and profit-sharing income	17.2	24.1	53.5	+122.0%
Other operating income	17.7	27.9	11.0	-60.6%
Core operating profit	103.2	130.3	143.0	+9.7%
Core EPS (Yen)	138.68	176.42	198.00	+12.2%

- Domestic sales are forecast to decrease compared with 2018 despite expected sales growth from new products including Hemlibra and Tecentriq due to competing products including generics and the effect of NHI drug price revisions.
- Overseas sales are forecast to increase in exports to Roche compared with 2018 because of favorable growth of Alecensa and sustained growth in Actemra sales volume.
- ROOI is forecast to increase substantially because component royalties and profit-sharing income are expected to increase, primarily from Roche in connection with Hemlibra. At the same time, other operating income is expected to decrease due to factors including the absence of one-time income from transfer of long-term listed products recognized in 2018.
- Regarding cost of sales and operating expenses, we expect the cost to sales ratio to decrease compared with the previous year due to changes in the composition of sales by product, but we expect overall operating expenses to increase, mainly due to an increase in R&D expenditures as a result of the progress of development projects.
- We forecast that Core operating profit and Core EPS will increase despite the expected slight decrease in domestic sales, mainly as a result of growth in exports to Roche, additional royalty income from Roche for Hemlibra, and the lower cost to sales ratio.

Core EPS*



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

Fundamental Profit Distribution Policy and Dividends

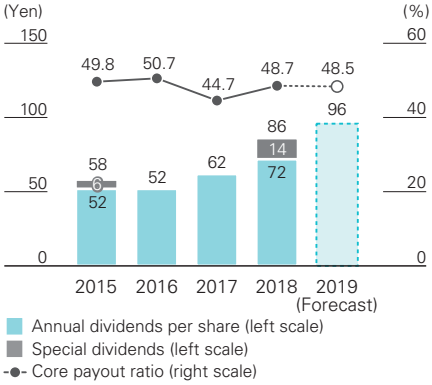
After taking strategic funding needs and the results forecast into account, Chugai aims for a consolidated payout ratio of 50 percent of Core EPS on average to provide for stable allocation of profit to all shareholders. Internal reserves will be used to increase corporate value through investments for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

(Yen)

	2016	2017	2018	2019 Forecast
Basic net income per share (EPS)	98.12	133.04	169.08	—
Core EPS	102.50	138.68	176.42	198.00
Equity per share attributable to Chugai shareholders (BPS)	1,181.67	1,265.46	1,381.26	—
Cash dividends per share	52	62	86	96
Core payout ratio	50.7%	44.7%	48.7%	48.5%

- Cash dividends per share for 2018 totaled ¥86.
- The five-year average Core EPS payout ratio for 2018 was 48.6 percent. (We expect the five-year average Core EPS payout ratio for 2019 to be 48.4 percent.)
- The forecast for cash dividends per share for 2019 includes an interim dividend of ¥48.

Dividends per Share/Core Payout Ratio



Business Risks

Chugai's corporate performance is subject to material impact from a range of possible future events. Below, we list what we consider the principal sources of risk to the development of our business. We recognize the possibility of these risk events actually occurring, and have prepared policies to forestall such events and take appropriate measures when they do occur.

The categories of risk identified in this section are based on assessments made by Chugai Pharmaceutical as of December 31, 2018.

New Product Research and Development

With the aim of becoming a top innovator for advanced and sustainable patient-centric healthcare, powered by its unique strength in science and technology, 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, including revisions to the system of reimbursement of medical fees, and NHI drug price reforms. 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	
	2018	2017
Revenues	**579,787**	**534,199**
Sales (Notes 2 and 3)	527,844	499,308
Royalties and other operating income (Notes 2 and 3)	51,943	34,891
Cost of sales	(262,847)	(254,171)
Gross profit	**316,940**	**280,028**
Marketing and distribution	(73,706)	(72,800)
Research and development	(99,202)	(92,947)
General and administration	(19,710)	(15,347)
Operating profit	**124,323**	**98,934**
Financing costs (Note 4)	(111)	(110)
Other financial income (expense) (Note 4)	449	(87)
Other expense (Note 5)	(3,212)	(1,706)
Profit before taxes	**121,449**	**97,031**
Income taxes (Note 6)	(28,370)	(23,490)
Net income	**93,079**	**73,541**
Attributable to:		
Chugai shareholders (Note 21)	92,488	72,713
Non-controlling interests (Note 22)	591	827
Earnings per share (Note 26)		
Basic (yen)	169.08	133.04
Diluted (yen)	168.80	132.83

(2) Consolidated statement of comprehensive income in millions of yen

	Year ended December 31	
	2018	2017
Net income recognized in income statement	**93,079**	**73,541**
Other comprehensive income		
Remeasurements of defined benefit plans (Notes 6 and 21)	(2,472)	916
Financial assets measured at fair value through OCI (Notes 6 and 21)	363	-
Items that will never be reclassified to the income statement	**(2,109)**	**916**
Available-for-sale financial assets (Notes 6 and 21)	-	1,204
Financial assets measured at fair value through OCI (Notes 6 and 21)	0	-
Cash flow hedges (Notes 6 and 21)	(225)	(3,293)
Currency translation of foreign operations (Notes 6 and 21)	(3,158)	3,713
Items that are or may be reclassified to the income statement	**(3,383)**	**1,624**
Other comprehensive income, net of tax (Note 6)	**(5,492)**	**2,540**
Total comprehensive income	**87,587**	**76,081**
Attributable to:		
Chugai shareholders (Note 21)	87,078	75,154
Non-controlling interests (Note 22)	509	927

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

	December 31, 2018	December 31, 2017
Assets		
Non-current assets:		
Property, plant and equipment (Note 7)	222,388	171,569
Intangible assets (Note 8)	22,699	21,078
Financial non-current assets (Note 9)	9,723	11,350
Deferred tax assets (Note 6)	35,568	34,501
Other non-current assets (Note 10)	29,077	14,836
Total non-current assets	**319,455**	**253,333**
Current assets:		
Inventories (Note 11)	159,360	169,056
Accounts receivable (Note 12)	179,556	174,284
Current income tax assets (Note 6)	3	717
Marketable securities (Note 13)	102,533	104,018
Cash and cash equivalents (Note 14)	146,860	139,074
Other current assets (Note 15)	11,781	11,990
Total current assets	**600,093**	**599,141**
Total assets	**919,548**	**852,473**
Liabilities		
Non-current liabilities:		
Long-term debt (Note 16)	(82)	(207)
Deferred tax liabilities (Note 6)	(9,031)	(9,211)
Defined benefit plan liabilities (Note 24)	(14,671)	(9,292)
Long-term provisions (Note 17)	(2,072)	(2,041)
Other non-current liabilities (Note 18)	(1,946)	(15,923)
Total non-current liabilities	**(27,802)**	**(36,674)**
Current liabilities:		
Short-term debt (Note 16)	(133)	(129)
Current income tax liabilities (Note 6)	(19,567)	(18,541)
Short-term provisions (Note 17)	(1)	(79)
Accounts payable (Note 19)	(71,706)	(63,518)
Other current liabilities (Note 20)	(43,810)	(40,635)
Total current liabilities	**(135,218)**	**(122,902)**
Total liabilities	**(163,019)**	**(159,576)**
Total net assets	**756,529**	**692,897**
Equity:		
Capital and reserves attributable to Chugai shareholders (Note 21)	755,864	691,924
Equity attributable to non-controlling interests (Note 22)	664	973
Total equity	**756,529**	**692,897**

3. **Consolidated statement of cash flows** in millions of yen

	Year ended December 31	
	2018	2017
Cash flows from operating activities		
Cash generated from operations (Note 27)	151,857	124,776
(Increase) decrease in working capital	4,486	14,465
Payments made for defined benefit plans	(2,652)	(2,483)
Utilization of provisions (Note 17)	(29)	(34)
Other operating cash flows	(3,022)	(6,447)
Cash flows from operating activities, before income taxes paid	**150,639**	**130,278**
Income taxes paid	(31,565)	(22,655)
Total cash flows from operating activities	**119,074**	**107,623**
Cash flows from investing activities		
Purchase of property, plant and equipment	(71,785)	(32,881)
Purchase of intangible assets	(5,886)	(11,645)
Disposal of property, plant and equipment	49	64
Disposal of intangible assets	-	452
Interest and dividends received (Note 27)	200	271
Purchases of marketable securities	(263,503)	(208,480)
Sales of marketable securities	264,711	215,510
Purchases of investment securities	(709)	-
Sales of investment securities	2,863	-
Other investing cash flows	(0)	(8)
Total cash flows from investing activities	**(74,060)**	**(36,718)**
Cash flows from financing activities		
Interest paid	(5)	(5)
Dividends paid to Chugai shareholders	(35,010)	(30,054)
Dividends paid to non-controlling shareholders	(791)	(944)
Exercises as part of equity compensation plans (Note 25)	996	922
(Increase) decrease in own equity instruments	(19)	(20)
Other financing cash flows	(187)	538
Total cash flows from financing activities	**(35,014)**	**(29,563)**
Net effect of currency translation on cash and cash equivalents	(2,215)	2,363
Increase (decrease) in cash and cash equivalents	**7,785**	**43,706**
Cash and cash equivalents at January 1	139,074	95,368
Cash and cash equivalents at December 31 (Note 14)	**146,860**	**139,074**

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

	Attributable to Chugai shareholders						
	Share capital	Capital surplus	Retained earnings	Other reserves	Subtotal	Non-controlling interests	Total equity
Year ended December 31, 2017							
At January 1, 2017	**72,967**	**63,500**	**507,399**	**1,642**	**645,508**	**989**	**646,497**
Net income	-	-	72,713	-	72,713	827	73,541
Available-for-sale financial assets (Notes 6 and 21)	-	-	-	1,204	1,204	-	1,204
Cash flow hedges (Notes 6 and 21)	-	-	-	(3,293)	(3,293)	-	(3,293)
Currency translation of foreign operations (Notes 6, 21 and 22)	-	-	-	3,613	3,613	100	3,713
Remeasurements of defined benefit plans (Notes 6 and 21)	-	-	916	-	916	-	916
Total comprehensive income	-	-	**73,630**	**1,524**	**75,154**	**927**	**76,081**
Dividends (Notes 21 and 22)	-	-	(30,055)	-	(30,055)	(944)	(30,998)
Equity compensation plans (Note 21)	3	102	-	-	105	-	105
Own equity instruments (Note 21)	-	1,213	-	-	1,213	-	1,213
At December 31, 2017	**72,970**	**64,815**	**550,974**	**3,166**	**691,924**	**973**	**692,897**
Year ended December 31, 2018							
At January 1, 2018	**72,970**	**64,815**	**550,974**	**3,166**	**691,924**	**973**	**692,897**
Impact of changes in accounting policies	**-**	**-**	**10,606**	**-**	**10,606**	**-**	**10,606**
At January 1, 2018 (revised)	**72,970**	**64,815**	**561,580**	**3,166**	**702,530**	**973**	**703,503**
Net income	-	-	92,488	-	92,488	591	93,079
Financial assets measured at fair value through OCI (Notes 6 and 21)	-	-	-	363	363	-	363
Cash flow hedges (Notes 6 and 21)	-	-	-	(225)	(225)	-	(225)
Currency translation of foreign operations (Notes 6, 21 and 22)	-	-	-	(3,077)	(3,077)	(82)	(3,158)
Remeasurements of defined benefit plans (Notes 6 and 21)	-	-	(2,472)	-	(2,472)	-	(2,472)
Total comprehensive income	**-**	**-**	**90,016**	**(2,938)**	**87,078**	**509**	**87,587**
Dividends (Notes 21 and 22)	-	-	(35,003)	-	(35,003)	(817)	(35,820)
Equity compensation plans (Note 21)	31	(97)	-	-	(66)	-	(66)
Own equity instruments (Note 21)	-	1,325	-	-	1,325	-	1,325
Transfer from other reserves to retained earnings	-	-	1,498	(1,498)	-	-	-
At December 31, 2018	**73,000**	**66,043**	**618,091**	**(1,270)**	**755,864**	**664**	**756,529**

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 Tatsuro Kosaka, President & CEO, and Toshiaki Itagaki, Executive Vice President & CFO on March 28, 2019.

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% (61.25% of the total number of shares issued excluding own equity instruments). The Group became a principal 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 under Designated International Financial Reporting Standards" 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). 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.
Policy applicable from 1 January 2018
Sales are recorded net of allowances for estimated rebates, cash discounts and estimates of product returns, all of which are established at the time of sale. The estimated rebates, chargebacks, cash discounts and estimates of product returns are recorded as current liabilities. 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.

Out-licensing agreements may be entered into with no further obligation or may include commitments to conduct research, late-stage development, regulatory approval, co-marketing or manufacturing. These may be settled by a combination of upfront payments, milestone payments, and reimbursements for services provided. Whether to consider these commitments as a single performance obligation or separate ones, or even being in scope of IFRS 15 'Revenues from Contracts with Customers', is not straightforward and requires some judgement. Depending on the conclusion, this may result in all revenue being calculated at inception and either being recognized at once or spread over the term of a longer performance obligation.

As a practical expedient, the Group does not adjust the promised amount of consideration for the effects of a significant financing component, if the group expects, at contract inception, that the period between when the group transfers a promised good or service to a customer and when the customer pays for that good or service will be one year or less.

Policy applicable before 1 January 2018
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.

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 a number of defined benefit plans and the fair values 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 defined benefit plan 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 reliably estimated. Where no reliable estimate can be made, no provision is recorded and contingent liabilities are disclosed where material. The status of significant legal cases is disclosed in Additional Information. 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.

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. Where tax positions are uncertain, accruals are recorded within income tax liabilities for management's best estimate of the ultimate liability that is expected to arise based on the specific circumstances and the Group's historical experience. Factors that may have an 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) 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 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

Policy applicable from 1 January 2018

Sales. Revenue from the sale of goods supplied is recorded as 'Sales'.

Sales are recognized when a promise in a customer contract (performance obligation) has been satisfied by transferring control over the promised goods to the customer. Control over a promised good refers to the ability to direct the use of, and obtain substantially all of the remaining benefits from, those goods. Control is usually transferred upon shipment or delivery to or upon receipt of goods by the customer, in accordance with the delivery and acceptance terms agreed with the customers.

The amount of sales to be recognized (transaction price) is based on the consideration the Group expects to receive in exchange for its goods, excluding amounts collected on behalf of third parties such as consumption tax or other taxes directly linked to sales. The Group recognises a deferred income (contract liability) if consideration has been received (or has become receivable) before the Group transfers the promised goods to the customer.

Royalty and other operating income. 'Royalty and other operating income' includes royalty income, income from out-licensing agreements and income from disposal of products and other items.

Revenue for a sales-based or usage-based royalty promised in exchange for a license of intellectual property is recognized when the subsequent sale or usage occurs.

Income from out-licensing agreements typically arises from the receipt of upfront, milestone and other similar payments from third parties for granting a license to product or technology related intellectual property (IP). Out-licensing agreements may be entered into with no further obligation or may include commitments to conduct research, late-stage development, regulatory approval, co-marketing or manufacturing. Licenses granted are usually rights to use IP and generally unique. Therefore the basis of allocating revenue to performance obligations makes use of the residual approach. Upfront payments and other licensing fees are usually recognized upon granting the license unless some of the income shall be deferred for other performance obligations using the residual approach. Such deferred income is released and recognized as revenue when other performance obligations are satisfied. Milestone income is recognized at the point in time when it is highly probable that the respective milestone event criteria is achieved, and the risk of revenue reversal is considered remote.

Payments received for the disposal of product and similar rights are recognized as revenue upon transfer of control over such rights. To the extent that some of these payments relate to other performance obligations, a portion is deferred using the residual approach and recognized as revenue when performance obligations are satisfied.

Income from profit-sharing arrangements with collaboration partners is recognized as underlying sales and cost of sales are recorded by the collaboration partners.

Policy applicable before 1 January 2018
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.

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.

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.

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, including restricted stocks, 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 are transferred to the Group. Finance leases 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 exist 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: 10–17 years
- Marketing intangibles in use: 5 years
- Technology intangibles in use: 7–9 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 realisable value. The cost of finished goods, work in process and intermediates includes raw materials, direct labour and other directly attributable costs and overheads based upon the normal capacity of production facilities. Cost is determined using the weighted average method. Net realisable value is the estimated selling price less cost to completion and selling expenses.

Accounts receivable
Policy applicable from 1 January 2018
Accounts receivable are carried at the original invoice amount less allowances made for doubtful accounts, trade discounts, cash discounts, volume rebates and similar allowances. A receivable represents a right to consideration that is unconditional and excludes contract assets. The Group always measures an allowance for doubtful accounts that result from transactions that are within the scope of IFRS 15 equal to the credit losses expected over the lifetime of the trade receivables. These estimates are based on specific indicators, such as the ageing of customer balances, specific credit circumstances and the Group's historical loss rates for each category of customers, and adjusted for forward looking macroeconomic data. While the Group measures an allowance for doubtful accounts that result from transactions that are not within the scope of IFRS 15 equal to 12-months expected credit losses, when the credit risk for these accounts has not increased significantly since initial recognition.

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. Accounts receivable are written off (either partially or in full) when there is no reasonable expectation of recovery. Where receivables have been written off, the Group continues to engage in enforcement activities to attempt to recover the receivable due. Where recoveries are made, these are recognized in profit or loss.

Policy applicable before 1 January 2018
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
Policy applicable from 1 January 2018
The Group classifies its financial assets, with the exception of derivatives, in the following measurement categories: amortized cost; fair value through OCI; fair value through profit or loss.

The classification depends on the Group's business model for managing the financial assets and the contractual terms of the cash flows. The Group reclassifies debt securities and financial assets measured at amortized cost when and only when its business model for managing those assets changes.

At initial recognition, the Group measures a financial asset at its fair value excluding trade receivables at transaction price if it does not contain a significant financing component. In the case of a financial asset not at fair value through profit or loss, transaction costs that are directly attributable to the acquisition of the financial asset are added to the fair value.

Financial assets measured at amortized cost: Assets that are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest are measured at amortized cost. A gain or loss on a debt security that is subsequently measured at amortized cost and is not part of a hedging relationship is recognized in profit or loss when the asset is derecognized or impaired. Interest income from these financial assets is included in other financial income using the effective interest rate method. Financial assets measured at amortized cost are mainly comprised of accounts receivable, cash and cash equivalents and time accounts over three months.

Financial assets measured at fair value through other comprehensive income (fair value through OCI): These are financial assets that are held for collection of contractual cash flows and for selling the financial assets, where the assets' cash flows represent solely payments of principal and interest. These assets are initially recorded and subsequently carried at fair value. Changes in the fair value are recorded in other comprehensive income, except for the recognition of impairment gains or losses, interest revenue and foreign exchange gains and losses which are recognized in profit and loss. When the financial asset is derecognized, the cumulative gain or loss previously recognized in OCI is reclassified from equity to profit or loss. Interest income from these financial assets is included in other financial income using the effective interest rate method. Financial assets measured at fair value through other comprehensive income are mainly comprised of money market instruments.

Equity instruments measured at fair value through other comprehensive income (fair value through OCI): These are equity instruments measured at fair value through OCI for which an irrevocable election at initial recognition has been made, to present subsequent changes in fair value in other comprehensive income. Dividends are recognized as other financial income in profit or loss. Other net gains and losses are recognized in OCI and are never reclassified to profit or loss. When the instruments are derecognized, the cumulative amount of other comprehensive income is transferred to retained earnings.

The Group classifies its financial liabilities as measured at amortized cost, except for derivatives. Financial liabilities are initially recorded at fair value, less transaction costs and subsequently carried at amortized cost using the effective interest rate method. Financial liabilities are mainly comprised of trade payables.

Derivative financial instruments that are used to manage the exposures to foreign currency exchange rate fluctuations 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).

Policy applicable before 1 January 2018
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 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
Policy applicable from 1 January 2018
A financial asset is derecognized when the contractual rights to the 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.

Policy applicable before 1 January 2018
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
Policy applicable from 1 January 2018
The Group recognises loss allowances for expected credit losses ('ECL') for financial assets measured at amortized cost and debt securities measured at fair value through OCI.

The Group always measures loss allowance that result from transactions that are within the scope of IFRS 15 equal to the credit losses expected over the lifetime of the trade receivables.

The Group measures loss allowances at an amount equal to 12-month expected credit losses for its debt securities carried at fair value through OCI and at amortized cost when the credit risk for these accounts has not increased significantly since initial recognition at the reporting date. The Group considers a debt investment to have low credit risk when their credit risk rating is equivalent to the globally understood definition of 'investment grade'. The Group considers this to be at least Baa3 from Moody's and BBB-from S&P.

The Group measures the allowances for doubtful account at an amount equal to lifetime ECL for its debt investments at fair value through OCI and at amortized cost on which credit risk has increased significantly since their initial recognition. The Group assumes that the credit risk on a financial asset has increased significantly if it is more than 30 days past due.

The Group considers a financial asset to be in default when the counterparty is unlikely to pay its obligations to the Group in full. In assessing whether a counterparty is in default, the Group considers both qualitative and quantitative indicators that are based on data developed internally and for certain financial assets also obtained from external sources.

Financial assets are written off (either partially or in full) when there is no realistic prospect of recovery. This is generally the case when the Group determines that the customer does not have assets or sources of income that could generate sufficient cash flows to repay the amounts subject to the write-off. However, financial assets that are written off are still subject to enforcement activities in order to comply with the Group's policy for recovery of amounts due.

Policy applicable before 1 January 2018
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. 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 transaction, when that transaction 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, otherwise included in profit or loss when the hedged transaction affects net income.

For other hedged forecasted cash flows, 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.

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. Where the amount of tax liabilities is uncertain, accruals are recorded within income tax liabilities for management's best estimate of the ultimate liability that is expected to arise based on the specific circumstances and the Group's historical experience.

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) Significant accounting policies
The Group applies the same significant accounting policies that are used for the previous fiscal year to the Consolidated Financial Statements, except for those stated in (5) Changes in accounting policies below.

(5) Changes in accounting policies
In 2018 the Group implemented the following new standards, including any consequential amendments to other standards, with a date of initial application of January 1, 2018.
- IFRS 9 'Financial Instruments'
- IFRS 15 'Revenue from Contracts with Customers'

The nature and the effects of the changes most relevant to the Group's Consolidated Financial Statements are given below.

IFRS 9 'Financial Instruments'
Effective January 1, 2018 the Group has implemented IFRS 9 'Financial Instruments.' The new standard replaces IAS 39 'Financial Instruments: Recognition and Measurement.' The standard deals with the classification, recognition and measurement (including impairment) of financial instruments and also introduces a new hedge accounting model.

There is no material impact on the Group's performance or financial position from the application of this standard.

Classification and measurement of financial instruments.
In accordance with the transitional provisions of IFRS 9, financial instruments are classified, on the basis of the facts and circumstances that exist at the date of initial application, as follows: Items such as equity securities and debt securities which were previously classified as available-for-sale under IAS 39, with the exception of time accounts over three months, are classified as financial assets measured at fair value through other comprehensive income (OCI), and time accounts over three months as amortized cost. Though the Group takes advantage of the exemption allowing it not to restate comparative information for prior periods with respect to classification and measurement changes, since there were no changes in the carrying amounts, no adjustments were made to retained earnings as of January 1, 2018.

Changes in the fair value of equity instruments designated as financial assets measured at fair value through other comprehensive income are recognized in other comprehensive income, and the cumulative amount of other comprehensive income is transferred to retained earnings when the instruments are derecognized.

Impairment of financial assets.
On January 1, 2018 the Group changed the methodology of assessing impairment of its financial assets from the incurred loss model (used in IAS 39) to the expected credit loss model (used in IFRS 9). The new impairment model is applied to financial assets measured at amortized cost and debt securities measured at fair value through OCI, but not equity securities. In accordance with the transitional provisions of IFRS 9, the Group has not restated prior periods but it has reassessed the impairment allowances under the expected credit loss model as of January 1, 2018.

Hedge accounting.
As the Group may continue to apply the hedge accounting requirements of IAS 39 instead of those in IFRS 9 at the initial application of IFRS 9, the Group has chosen to continue to apply the hedge accounting requirements of IAS 39.

IFRS 15 'Revenue from Contracts with Customers'
Effective January 1, 2018 the Group has implemented IFRS 15 'Revenue from contracts with customers.' The new standard replaces IAS 18 'Revenue' and IAS 11 'Construction Contracts.' IFRS 15 establishes a comprehensive framework for determining whether, how much and when revenue is recognized, and also contains new requirements related to presentation. The core principle in that framework is that revenue should be recognized dependent on the transfer of promised goods or services to the customer for an amount that reflects the consideration which should be received in exchange for those goods or services. The objective of the standard is to provide a five-step approach to revenue recognition that includes identifying contracts with customers, identifying performance obligations, determining transaction prices, allocating transaction prices to performance obligations, and recognizing revenue when or as performance obligations are satisfied. Judgement will need to be applied, including making estimates and assumptions, for multiple-element contracts in identifying performance obligations, in constraining estimates of variable consideration and in allocating the transaction price to each performance obligation. The new standard results in an increased volume of disclosure information in the Annual Financial Statements.

Changes introduced by the standard relevant to the Group.
The new standard provides new requirements and additional guidance that are relevant to the Group, notably on the following areas:

- Revenues from licenses of intellectual property, including sales-based royalties, on constraining estimates of variable consideration such as e.g. development milestones that may be regarded as a separate performance obligation involving variable consideration. There is no material impact from these changes.
- The new standard also clarifies how to allocate sales, including the treatment of discounts, to each element in multiple-elements contracts and when to recognize sales for each of those elements. It requires the use of estimates and assumptions and some judgement to apply this guidance in practice. There is no material impact from this guidance.
- Out-licensing contracts may be entered into with no further obligation or may include commitments to research, late-stage development, regulatory approval, co-marketing or manufacturing. These may be settled by a combination of up-front payments, milestone payments, and reimbursements for services provided. Whether to consider these commitments as a single performance obligation or separate ones is not straight-forward and requires some judgement. Depending on the conclusion, this may result in all revenue being calculated at inception and either being recognized at once or spread over the term of a longer performance obligation. With the application of this standard, upfront payment received, which was formerly recognized over time as deferred income, is recognized as one-time income on out-licensing.

Transition approach.
The Group recognizes the cumulative effect of applying the new standard at the date of initial application, with no restatement of the comparative periods presented. It records the cumulative effect, the amount of ¥10,606 million after tax effect, as an adjustment to the opening balance of retained earnings at the date of initial application. Except for this adjustment, there is no material impact on the Group's performance or financial position from the application of this standard.

(6) Future new and revised standards
Of the new and revised standards that have been issued by the International Accounting Standards Board (IASB) by the date of approval of the Consolidated Financial Statements, the Group will implement the following from 2019.

Although there were other new establishments, minor revisions, etc. to the standards, the Group believes there is no material impact on the Group's performance or financial position.

1) Standards that will be effective from January 1, 2019
IFRS 16 Leases
The main impact of the new standard will be to bring operating leases (lessee) on-balance sheet. In applying this standard, the Group will adopt a method that recognizes the cumulative effect at the date of initial application, which is permitted as a transitional measure.

The Group is assessing the potential impact, but currently anticipates that the new standard will result in the carrying value of leased assets being increased by approximately ¥15.0 billion, with lease liabilities increased by a similar amount at the date of implementation. The application of the new standard will result in part of what are currently reported as operating lease costs being recorded as interest expenses. Given the leases involved and the current low interest rate

environment, the Group does not currently expect this effect to be material. The new standard will also result in an increased volume of disclosure information in the Annual Financial Statements.

2) Standards that will be effective from January 1, 2020 and beyond

The Group is currently assessing the potential impacts of new standards and interpretations that will be effective from January 1, 2020 and beyond.

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

	2018		2017	
	Sales	Royalties and other operating income	Sales	Royalties and other operating income
Japan	399,906	21,569	405,280	5,635
Overseas	127,939	30,374	94,028	29,256
of which Switzerland	109,938	24,250	76,359	28,957
Total	**527,844**	**51,943**	**499,308**	**34,891**

Information on revenues by major customers in millions of yen

	2018	2017
	Revenues	Revenues
F. Hoffmann-La Roche Ltd.	134,188	105,262
Alfresa Corporation	103,959	104,952
Mediceo Corporation	76,004	80,390

3. Revenue

Disaggregated revenue information in millions of yen

	2018		
	Revenue from contracts with customers	Revenue from other sources	**Total**
Sales	525,643	2,202	**527,844**
Japan	399,906	-	**399,906**
Overseas	125,737	2,202	**127,939**
Royalties and other operating income	40,803	11,140	**51,943**
Royalty and profit-sharing income	12,942	11,140	**24,082**
Other operating income	27,861	-	**27,861**

For an explanation of the effects for the revenue from contracts with customers from the application of IFRS 15, please refer to "Changes in accounting policies" on Note1 (4). The Group does not restate the information for the comparative periods, when IFRS 15 is first applied. The revenue from other sources primarily relates to collaboration income for which the counterparty is not considered a customer, such as income from profit-sharing arrangements and the gains or losses from hedge.

Contract balances in millions of yen

	December 31, 2018	January 1, 2018
Receivables-contracts from customers	162,879	155,951
Accounts receivable	150,804	148,495
Other current receivable	12,075	7,456
Contract assets	-	-
Contract liabilities	206	-

In 2018 there was revenue recognized of ¥17,364 million relating to performance obligations that were satisfied in previous periods, mainly due to royalty and milestone revenue.

Transaction price allocated to the remaining performance obligations

There is no material impact for transaction price allocated to the remaining obligations which has an original expected duration of more than one year as of December 31, 2018. As a practical expedient, the Group does not disclose the information for the remaining performance obligations. The performance obligation is part of a contract that has an original expected duration of one year or less.

There is no material amounts which do not include the transaction price in the consideration from the contracts with customers.

4. Financing costs and other financial income (expense)

Financing costs in millions of yen

	2018	2017
Interest expense	(5)	(5)
Net interest cost of defined benefit plans	(53)	(48)
Net other financing costs	(53)	(56)
Total financing costs	(111)	**(110)**

Other financial income (expense) in millions of yen

	2018	2017
Dividend income from available-for-sale financial assets	-	183
Dividend income from equity instruments measured at fair value through OCI	115	-
Write-downs and impairments of equity instruments	-	(97)
Net income from equity securities	**115**	**86**
Interest income from available-for-sale financial assets	-	93
Interest income from debt securities measured at fair value through OCI	9	-
Interest income from financial assets measured at amortized cost	74	-
Net interest income and income from debt securities	**83**	**93**
Foreign exchange gains (losses)	680	140
Gains (losses) on foreign currency derivatives	(429)	(406)
Net foreign exchange gains (losses)	**251**	**(266)**
Total other financial income (expense)	**449**	**(87)**

5. Other expense

Chugai filed an Advance Pricing Arrangement covering certain transactions with F. Hoffmann-La Roche Ltd., to the Japanese and Swiss tax authorities. In the year ended December 31, 2017, Chugai received a notice of agreement from both tax authorities which includes the instruction that the taxable income of Chugai shall be decreased by a certain amount and that of Roche shall be increased by the same amount in each fiscal year from 2016 to 2020, and if necessary, additional adjustments to the accounts shall be made in 2021.

As a result of this agreement, Chugai will transfer a part of the deducted amount of corporate tax etc, to Roche as the estimated tax payable for Roche, in accordance with the license agreement between Chugai and Roche. In addition, it has posted ¥3,212 million of adjustment from transfer pricing taxation.

6. Income taxes

Income tax expenses in millions of yen

	2018	2017
Current income taxes	(32,646)	(29,884)
Deferred taxes	4,276	6,394
Total income tax (expense)	**(28,370)**	**(23,490)**

Reconciliation of the Group's effective tax rate

	2018	2017
Weighted average expected tax rate	30.3%	30.3%
Tax effect of		
- Non-taxable income/non-deductible expenses	0.4%	0.5%
- Effect of changes in applicable tax rates on deferred tax balances	0.0%	-%
- Research and development tax credits	(5.4)%	(5.9)%
- Transfer pricing taxation related	(2.2)%	(4.7)%
- Other differences	0.4%	4.0%
Group's effective tax rate	**23.4%**	**24.2%**

Tax effects of other comprehensive income in millions of yen

	2018			2017		
	Pre-tax amount	Tax benefit	After-tax amount	Pre-tax amount	Tax benefit	After-tax Amount
Remeasurements of defined benefit plans	(3,566)	1,094	(2,472)	1,313	(396)	916
Available-for-sale financial assets	-	-	-	1,734	(530)	1,204
Financial assets measured at fair value through OCI	529	(166)	363	-	-	-
Cash flow hedges	(320)	95	(225)	(4,756)	1,463	(3,293)
Currency translation of foreign operations	(3,158)	-	(3,158)	3,713	-	3,713
Other comprehensive income	**(6,516)**	**1,024**	**(5,492)**	**2,004**	**537**	**2,540**

Income tax assets (liabilities) in millions of yen

	December 31, 2018	December 31, 2017
Current income taxes		
- Assets	3	717
- Liabilities	(19,567)	(18,541)
Net current income tax assets (liabilities)	**(19,564)**	**(17,824)**
Deferred taxes		
- Assets	35,568	34,501
- Liabilities	(9,031)	(9,211)
Net deferred tax assets (liabilities)	**26,537**	**25,290**

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

	2018	2017
Net current income tax assets (liabilities) at January 1	(17,824)	(10,532)
Income taxes paid	31,565	22,655
(Charged) credited to the income statement	(32,646)	(29,884)
Currency translation effects and other	(659)	(62)
Net current income tax assets (liabilities) at December 31	**(19,564)**	**(17,824)**

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

	Property, plant and equipment	Intangible assets	Provisions	Employee benefits	Other temporary differences	Total
Year ended December 31, 2017						
At January 1, 2017	(18,689)	(2,411)	69	5,568	33,790	18,328
(Charged) credited to the income statement	(306)	(745)	(31)	168	7,308	6,394
(Charged) credited to other comprehensive income	-	-	-	(396)	933	537
Currency translation effects and other	(7)	2	4	6	27	31
At December 31, 2017	**(19,002)**	**(3,155)**	**43**	**5,346**	**42,058**	**25,290**
Year ended December 31, 2018						
At January 1, 2018	(19,002)	(3,155)	43	5,346	42,058	25,290
(Charged) credited to the income statement	(1,227)	32	2	253	5,216	4,276
(Charged) credited to other comprehensive income	-	-	-	1,094	595	1,690
(Charged) credited to Equity	-	-	-	-	(4,677)	(4,677)
Currency translation effects and other	9	(1)	(3)	(4)	(42)	(41)
At December 31, 2018	**(20,219)**	**(3,124)**	**42**	**6,689**	**43,149**	**26,537**

Other temporary differences mainly relate to prepaid expenses, amortization of deferred assets and accrued expenses.

Deferred tax assets are not recognized for deductible temporary differences of ¥1,749 million (2017: ¥1,601 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

	2018	2017
Less than one year	-	-
Over one year and less than five years	242	117
Over five years	0	-
Tax losses not recognized in deferred tax assets	**242**	**117**

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

	2018	2017
Less than one year	-	-
Over one year and less than five years	-	29
Over five years	111	114
Unused tax credits not recognized in deferred tax assets	**111**	**143**

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 ¥2,107 million (2017: ¥2,042 million).

7. 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, 2017					
Cost	9,141	117,163	175,949	19,459	321,712
Accumulated depreciation and impairment	(28)	(58,470)	(106,133)	-	(164,631)
Net book value	**9,112**	**58,693**	**69,817**	**19,459**	**157,081**
Year ended December 31, 2017					
At January 1, 2017	9,112	58,693	69,817	19,459	157,081
Additions	-	1	368	33,916	34,285
Disposals	-	(115)	(230)	-	(345)
Transfers	-	3,523	17,761	(21,284)	-
Depreciation charge	-	(4,164)	(10,385)	-	(14,549)
Impairment charge	-	1	(5)	-	(4)
Other	-	-	(5,034)	-	(5,034)
Currency translation effects	-	(2)	112	25	136
At December 31, 2017	**9,112**	**57,937**	**72,404**	**32,116**	**171,569**
Cost	9,141	119,981	186,617	32,116	347,854
Accumulated depreciation and impairment	(28)	(62,044)	(114,212)	-	(176,285)
Net book value	**9,112**	**57,937**	**72,404**	**32,116**	**171,569**
Year ended December 31, 2018					
At January 1, 2018	9,112	57,937	72,404	32,116	171,569
Additions	-	13	633	71,197	71,843
Disposals	-	(94)	(299)	-	(394)
Transfers	43,040	16,506	38,938	(98,484)	-
Depreciation charge	-	(4,232)	(10,358)	-	(14,590)
Impairment charge	-	-	(59)	-	(59)
Other	-	-	(5,791)	-	(5,791)
Currency translation effects	-	(45)	(120)	(24)	(189)
At December 31, 2018	**52,152**	**70,085**	**95,347**	**4,804**	**222,388**
Cost	52,169	135,620	211,362	4,804	403,955
Accumulated depreciation and impairment	(16)	(65,535)	(116,015)	-	(181,566)
Net book value	**52,152**	**70,085**	**95,347**	**4,804**	**222,388**

In 2018, no borrowing costs were capitalized as property, plant and equipment (2017: none).

Impairment charge

The carrying value was reduced to the recoverable amount in use as the recoverable amount of certain assets was less than the carrying value.

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

	2018	2017
Cost of sales	59	4
Marketing and distribution	-	-
Research and development	-	-
General and administration	-	-
Total impairment charge	**59**	**4**

Finance leases

The capitalized cost of property, plant and equipment under finance leases was ¥701 million (2017: ¥759 million) and the net book value of these assets was ¥198 million (2017: ¥311 million). The carrying value of the leasing obligation was ¥214 million (2017: ¥336 million), which is reported as part of Debt (see Note 16).

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 ¥7,184 million (2017: ¥7,013 million).

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

	December 31, 2018	December 31, 2017
Within one year	5,177	4,656
Between one and five years	9,143	9,378
More than five years	91	46
Total minimum payments	**14,411**	**14,081**

Capital commitments

The Group has non-cancellable capital commitments for the purchase or construction of property, plant and equipment totaling ¥6,362 million (2017: ¥13,995 million).

8. 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, 2017					
Cost	18,479	15,992	3,035	103	37,608
Accumulated amortization and impairment	(13,074)	(4,492)	(691)	(52)	(18,309)
Net book value	**5,405**	**11,500**	**2,344**	**51**	**19,299**
Year ended December 31, 2017					
At January 1, 2017	5,405	11,500	2,344	51	19,299
Additions	25	6,581	1,348	-	7,953
Disposals	-	(452)	-	-	(452)
Transfers	1,100	(1,100)	-	-	-
Amortization charge	(1,243)	-	(525)	(17)	(1,785)
Impairment charge	-	(3,992)	(44)	-	(4,035)
Currency translation effects	25	72	-	-	97
At December 31, 2017	**5,312**	**12,609**	**3,123**	**33**	**21,078**
Cost	19,916	21,241	4,382	103	45,641
Accumulated amortization and impairment	(14,604)	(8,631)	(1,259)	(69)	(24,564)
Net book value	**5,312**	**12,609**	**3,123**	**33**	**21,078**
Year ended December 31, 2018					
At January 1, 2018	5,312	12,609	3,123	33	21,078
Additions	148	5,178	2,577	564	8,468
Disposals	-	-	-	-	-
Transfers	1,562	(1,562)	-	-	-
Amortization charge	(916)	-	(818)	(254)	(1,988)
Impairment charge	(78)	(4,765)	-	-	(4,844)
Currency translation effects	(13)	(2)	-	-	(15)
At December 31, 2018	**6,015**	**11,457**	**4,883**	**344**	**22,699**
Cost	21,409	20,662	6,887	667	49,625
Accumulated amortization and impairment	(15,394)	(9,205)	(2,004)	(323)	(26,927)
Net book value	**6,015**	**11,457**	**4,883**	**344**	**22,699**

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 3 to 16 years.

Impairment charge

Impairment charge in each year was mainly related to the cessation of R&D projects and the uncertainty regarding expected profits.

Classification of amortization and impairment expenses in millions of yen

	2018		2017	
	Amortization	Impairment	Amortization	Impairment
Cost of sales	1,014	-	1,327	-
Marketing and distribution	133	-	133	-
Research and development	428	4,844	93	4,035
General and administration	413	-	232	-
Total	**1,988**	**4,844**	**1,785**	**4,035**

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, 2018 in millions of yen

	Third party	Related party	Total
Within one year	581	1,864	2,445
Between one and two years	221	3,031	3,251
Between two and three years	593	7,355	7,948
Total	**1,395**	**12,250**	**13,645**

9. Financial non-current assets

Financial non-current assets in millions of yen

	December 31, 2018	December 31, 2017
Available-for-sale financial assets	-	11,350
Financial assets measured at fair value through OCI	9,723	-
Total financial non-current assets	**9,723**	**11,350**

Financial non-current assets are equity instruments held not for pure investment purposes, but for the Group's business purposes to maintain and strengthen the relationship with business partners. Therefore, the Group has designated all equity instruments as measured at fair value through OCI (classified as available-for-sale in 2017).

10. Other non-current assets

Other non-current assets in millions of yen

	December 31, 2018	December 31, 2017
Long-term prepaid expenses	23,654	10,064
Other assets	5,422	4,772
Total other non-current assets	**29,077**	**14,836**

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.

11. Inventories

Inventories in millions of yen

	December 31, 2018	December 31, 2017
Raw materials and supplies	42,199	55,239
Work in process	118	30
Intermediates	53,682	42,963
Finished goods	65,037	72,904
Provision for slow-moving and obsolete inventory	(1,676)	(2,080)
Total inventories	**159,360**	**169,056**

Inventories expensed through cost of sales totalled ¥245,919 million (2017: ¥241,487 million). Inventory write-downs during the year resulted in an expense of ¥1,051 million (2017: ¥630 million).

12. Accounts receivable

Accounts receivable in millions of yen

	December 31, 2018	December 31, 2017
Trade receivables – third party	125,478	128,884
Trade receivables – related party	25,307	19,593
Notes receivables	19	18
Other receivables – third party (Contracts with customers)	1,105	-
Other receivables – related party (Contracts with customers)	10,970	-
Other receivables – third party	6,717	5,320
Other receivables – related party	9,967	20,475
Allowances for doubtful accounts	(7)	(6)
Total accounts receivable	**179,556**	**174,284**

13. Marketable securities

Marketable securities in millions of yen

	December 31, 2018	December 31, 2017
Available-for-sale financial assets		
Money market instruments and time accounts over three months	-	99,018
Debt securities	-	5,000
Financial assets measured at fair value through OCI		
Money market instruments	94,000	-
Debt securities	8,001	-
Financial assets measured at amortized cost		
Time accounts over three months	532	-
Total marketable securities	**102,533**	**104,018**

Marketable securities are held for fund management purposes. Money market instruments are mainly certificates of deposit, cash in trust and commercial papers. Debt securities are mainly corporate bonds.

14. Cash and cash equivalents

Cash and cash equivalents in millions of yen

	December 31, 2018	December 31, 2017
Cash - cash in hand and in current or call accounts	140,912	136,219
Cash equivalents - time accounts with a maturity of three months or less	5,948	2,855
Total cash and cash equivalents	**146,860**	**139,074**

15. Other current assets

Other current assets in millions of yen

	December 31, 2018	December 31, 2017
Derivative financial instruments	2,204	2,107
Total financial current assets	**2,204**	**2,107**
Prepaid expenses	9,577	9,883
Total non-financial current assets	**9,577**	**9,883**
Total other current assets	**11,781**	**11,990**

16. Debt

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

	2018	2017
At January 1	336	645
Increase in debt	12	1
Decrease in debt	(134)	(310)
At December 31	**214**	**336**
Finance lease obligations	214	336
Total debt	**214**	**336**
Long-term debt	82	207
Short-term debt	133	129
Total debt	**214**	**336**

17. Provisions and contingent liabilities

Provisions: movements in recognized liabilities in millions of yen

	Environmental provisions	Other provisions	Total
Year ended December 31, 2017			
At January 1, 2017	356	1,859	2,216
Additional provisions created	22	23	45
Unused amounts reversed	(33)	(77)	(110)
Utilized	(34)	-	(34)
Other	-	3	3
At December 31, 2017	**311**	**1,808**	**2,120**
Long-term provisions	283	1,758	2,041
Short-term provisions	29	51	79
At December 31, 2017	**311**	**1,808**	**2,120**
Year ended December 31, 2018			
At January 1, 2018	311	1,808	2,120
Additional provisions created	-	36	36
Unused amounts reversed	-	-	-
Utilized	(29)	(51)	(80)
Other	-	(3)	(3)
At December 31, 2018	**282**	**1,791**	**2,073**
Long-term provisions	281	1,791	2,072
Short-term provisions	1	-	1
At December 31, 2018	**282**	**1,791**	**2,073**
Expected outflow of resources			
Within one year	1	-	1
Between one to two years	-	235	235
Between two to three years	-	-	-
More than three years	281	1,556	1,837
At December 31, 2018	**282**	**1,791**	**2,073**

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.

Other provisions

Other provisions arise mainly from asset retirement obligations. 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 8.

18. Other non-current liabilities

Other non-current liabilities in millions of yen

	December 31, 2018	December 31, 2017
Deferred income	727	14,127
Other long-term liabilities	1,219	1,796
Total other non-current liabilities	**1,946**	**15,923**

19. Accounts payable

Accounts payable in millions of yen

	December 31, 2018	December 31, 2017
Trade payables – third party	5,991	9,761
Trade payables – related party	29,943	28,673
Other taxes payable	6,600	4,438
Accounts payable - purchase of property, plant and equipment	5,637	5,642
Other payables – third party	4,909	2,967
Other payables – related party	18,626	12,037
Total accounts payable	**71,706**	**63,518**

20. Other current liabilities

Other current liabilities in millions of yen

	December 31, 2018	December 31, 2017
Deferred income	239	1,598
Accrued bonus and related items	14,024	12,480
Derivative financial instruments	2,096	1,652
Other accrued liabilities	27,451	24,905
Total other current liabilities	**43,810**	**40,635**

21. Equity attributable to Chugai shareholders

Changes in equity attributable to Chugai shareholders in millions of yen

	Share capital	Capital surplus	Retained earnings	Other reserves			Total
				Fair value reserve	Hedging reserve	Translation reserve	
Year ended December 31, 2017							
At January 1, 2017	72,967	63,500	507,399	4,864	3,574	(6,796)	645,508
Net income attributable to Chugai shareholders	-	-	72,713	-	-	-	72,713
Available-for-sale financial assets							
- Fair value gains (losses) taken to equity	-	-	-	1,639	-	-	1,639
- Transferred to income statement on sale or impairment	-	-	-	95	-	-	95
- Income taxes	-	-	-	(530)	-	-	(530)
Cash flow hedges							
- Effective portion of fair value gains (losses) taken to equity	-	-	-	-	(1,415)	-	(1,415)
- Transferred to income statement	-	-	-	-	(114)	-	(114)
- Transferred to initial carrying amount of hedged items	-	-	-	-	(3,228)	-	(3,228)
- Income taxes	-	-	-	-	1,463	-	1,463
Currency translation of foreign Operations							
- Exchange differences	-	-	-	-	-	3,713	3,713
- Non-controlling interests	-	-	-	-	-	(100)	(100)
Defined benefit plans							
- Remeasurement gains (losses)	-	-	1,313	-	-	-	1,313
- Income taxes	-	-	(396)	-	-	-	(396)
Other comprehensive income, net of tax	**-**	**-**	**916**	**1,204**	**(3,293)**	**3,613**	**2,440**
Total comprehensive income	**-**	**-**	**73,630**	**1,204**	**(3,293)**	**3,613**	**75,154**
Dividends	-	-	(30,055)	-	-	-	(30,055)
Equity compensation plans	3	102	-	-	-	-	105
Own equity instruments	-	1,213	-	-	-	-	1,213
At December 31, 2017	**72,970**	**64,815**	**550,974**	**6,068**	**281**	**(3,183)**	**691,924**

Changes in equity attributable to Chugai shareholders in millions of yen

	Share capital	Capital surplus	Retained earnings	Other reserves			Total
				Fair value reserve	Hedging reserve	Translation reserve	
Year ended December 31, 2018							
At January 1, 2018	72,970	64,815	550,974	6,068	281	(3,183)	691,924
Impact of changes in accounting policies	-	-	10,606	-	-	-	10,606
At January 1, 2018 (revised)	72,970	64,815	561,580	6,068	281	(3,183)	702,530
Net income attributable to Chugai shareholders	-	-	92,488	-	-	-	92,488
Financial assets measured at fair value through OCI							
- Equity instruments measured at fair value through OCI	-	-	-	528	-	-	528
- Debt securities at fair value through OCI	-	-	-	1	-	-	1
- Income taxes	-	-	-	(166)	-	-	(166)
Cash flow hedges							
- Effective portion of fair value gains (losses) taken to equity	-	-	-	-	(441)	-	(441)
- Transferred to income statement	-	-	-	-	42	-	42
- Transferred to initial carrying amount of hedged items	-	-	-	-	79	-	79
- Income taxes	-	-	-	-	95	-	95
Currency translation of foreign Operations							
- Exchange differences	-	-	-	-	-	(3,158)	(3,158)
- Non-controlling interests	-	-	-	-	-	82	82
Defined benefit plans							
- Remeasurement gains (losses)	-	-	(3,566)	-	-	-	(3,566)
- Income taxes	-	-	1,094	-	-	-	1,094
Other comprehensive income, net of tax	**-**	**-**	**(2,472)**	**363**	**(225)**	**(3,077)**	**(5,410)**
Total comprehensive income	-	-	**90,016**	**363**	**(225)**	**(3,077)**	**87,078**
Dividends	-	-	(35,003)	-	-	-	(35,003)
Equity compensation plans	31	(97)	-	-	-	-	(66)
Own equity instruments	-	1,325	-	-	-	-	1,325
Transfer from other reserves to retained earnings	-	-	1,498	(1,498)	-	-	-
At December 31, 2018	**73,000**	**66,043**	**618,091**	**4,933**	**57**	**(6,260)**	**755,864**

Share capital (Number of shares)

	December 31, 2018	December 31, 2017
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 23, 2017 (Resolution of the Annual General Meeting of shareholders)	Common stock	14,203	26	December 31, 2016	March 24, 2017
July 27, 2017 (Board resolution)	Common stock	15,852	29	June 30, 2017	September 1, 2017
March 22, 2018 (Resolution of the Annual General Meeting of shareholders)	Common stock	18,044	33	December 31, 2017	March 23, 2018
July 26, 2018 (Board resolution)	Common stock	16,960	31	June 30, 2018	August 31, 2018
March 28, 2019 (Resolution of the Annual General Meeting of shareholders)	Common stock	30,097	55	December 31, 2018	March 29, 2019

Own equity instruments

	Number of shares	
	2018	2017
At January 1	12,909,947	13,417,953
Issue of common stocks	-	-
Exercises of equity compensation plans	(393,800)	(389,600)
Purchase/Disposal of own equity instruments	3,566	4,594
Retirement of own equity instruments	-	(123,000)
Grant of restricted stock	(60,300)	-
At December 31	**12,459,413**	**12,909,947**
Book value (millions of yen)	**29,190**	**30,233**

Other reserves

Fair value reserve: The fair value reserve represents the cumulative net change in the fair value of financial assets measured at fair value through OCI (previously 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.

22. Non-controlling interests

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

	2018	2017
At January 1	973	989
Net income attributable to non-controlling interests	591	827
Currency translation of foreign operations	(82)	100
Other comprehensive income, net of tax	**(82)**	**100**
Total comprehensive income	**509**	**927**
Dividends to non-controlling shareholders	(817)	(944)
At December 31	**664**	**973**

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

23. Employee benefits

Employee benefits expense in millions of yen

	2018	2017
Wages and salaries	74,551	70,595
Social security costs	9,064	9,046
Defined contribution plans	973	1,029
Operating expenses for defined benefit plans	4,427	4,231
Equity compensation plans	286	415
Other employee benefits	4,235	4,143
Employee benefits expense included in operating results	**93,535**	**89,459**
Net interest cost of defined benefit plans	53	48
Total employee benefits expense	**93,588**	**89,507**

Other employee benefits consist mainly of welfare costs.

24. Post-employment benefits plans

Post-employment benefits 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 ¥973 million (2017: ¥1,029 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.

A pension asset management strategy is developed to optimize expected returns and to manage risks through adopting investment strategies from a long-term perspective. For this purpose, the Group focusses on long-term objectives which are not influenced by fluctuations in short-term yields, and maintains a well-diversified portfolio.

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

	2018	2017
Current service cost	4,427	4,231
Total operating expenses	**4,427**	**4,231**
Net interest cost of defined benefit plans	53	48
Total expense recognized in income statement	**4,479**	**4,279**

Defined benefit plans: funding status in millions of yen

	December 31, 2018	December 31, 2017
Fair value of plan assets	76,157	78,516
Defined benefit obligation	(90,829)	(87,809)
Over (under) funding	**(14,671)**	**(9,292)**
Defined benefit plan assets	-	-
Defined benefit plan liabilities	(14,671)	(9,292)
Net recognized asset (liability)	**(14,671)**	**(9,292)**

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

	2018	2017
At January 1	78,516	76,551
Interest income on plan assets	545	538
Remeasurements on plan assets	(2,227)	2,336
Currency translation effects	(8)	10
Employer contributions	2,442	2,243
Benefits paid – funded plans	(3,112)	(3,162)
At December 31	**76,157**	**78,516**
Composition of plan assets		
- Equity securities	10,640	13,426
- Debt securities	49,035	47,112
- Cash and cash equivalents	7,114	7,685
- Other investments	9,368	10,293
Total plan assets	**76,157**	**78,516**

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

	2018	2017
At January 1	87,809	85,341
Current service cost	4,427	4,231
Interest cost	597	586
Remeasurements – demographic assumption	991	513
Remeasurements – financial assumptions	153	76
Remeasurements – experience adjustments	197	434
Currency translation effects	(23)	30
Benefits paid – funded plans	(3,322)	(3,403)
At December 31	**90,829**	**87,809**
Duration in years	15	15.2

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, 2018	December 31, 2017
Discount rates (%)	0.69	0.70

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.

	2018
Discount rates	
- 0.25% increase	(3,385)
- 0.25% decrease	3,607
Life expectancy	
- 1 year increase	1,614

Future cash flows

Based on the most recent actuarial valuations, the Group expects that employer contributions for defined benefit plans in 2019 will be approximately ¥2,443 million.

25. 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. Effective since 2017, for the purpose of further promoting shared value with shareholders and providing an incentive to sustainably increase the Group’s corporate value, strengthening linkage between their compensation and mid- to long-term business performance, a restricted stock compensation plan (the “Compensation Plan”) was introduced in place of the existing stock option compensation plans.

Expenses for equity compensation plans in millions of yen

	2018	2017
Cost of sales	1	3
Marketing and distribution	29	42
Research and development	60	70
General and administration	192	300
Total	**282**	**415**
Equity-settled plans		
- Chugai common stock options	52	212
- Chugai stock options as stock-based compensation	-	34
- Tenure-based restricted stock	158	134
- Performance-based restricted stock	72	35

Cash inflow from equity compensation plans in millions of yen

	2018	2017
Equity-settled plans		
- Exercises of Chugai common stock options	996	922
- Exercises of Chugai stock options as stock-based compensation	0	0

(1) Stock options

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

	2018		2017	
	Number of rights	Weighted average exercise price (yen)	Number of rights	Weighted average exercise price (yen)
Outstanding at January 1	11,727	288,337	15,966	278,016
Granted	-	-	-	-
Forfeited	-	-	(40)	381,125
Exercised	(3,736)	266,623	(3,803)	242,506
Expired	-	-	(396)	302,978
Outstanding at December 31	**7,991**	**298,489**	**11,727**	**288,337**
- of which exercisable	7,991	298,489	9,013	262,362

Chugai common stock options – terms of rights outstanding at December 31, 2018

Year of grant	Rights outstanding			Rights exercisable	
	Number outstanding	Weighted average years remaining contractual life	Weighted average exercise price (yen)	Number exercisable	Weighted average exercise price (yen)
2009	20	0.23	169,600	20	169,600
2010	290	1.31	188,100	290	188,100
2011	213	2.40	139,700	213	139,700
2012	1,251	3.31	152,800	1,251	152,800
2013	1,108	4.32	250,000	1,108	250,000
2014	1,293	5.31	267,400	1,293	267,400
2015	2,075	6.31	400,700	2,075	400,700
2016	1,741	7.31	374,600	1,741	374,600
Total	**7,991**	**5.32**	**298,489**	**7,991**	**298,489**

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

	2018		2017	
	Number of rights	Weighted average exercise price (yen)	Number of rights	Weighted average exercise price (yen)
Outstanding at January 1	3,985	100	4,078	100
Granted	-	-	-	-
Forfeited	-	-	-	-
Exercised	(202)	100	(93)	100
Expired	-	-	-	-
Outstanding at December 31	**3,783**	**100**	**3,985**	**100**
- of which exercisable	-	-	-	-

Chugai stock options as stock-based compensation – terms of rights outstanding at December 31, 2018

Year of grant	Rights outstanding			Rights exercisable	
	Number outstanding	Weighted average years remaining contractual life	Weighted average exercise price (yen)	Number exercisable	Weighted average exercise price (yen)
2009	519	20.31	100	-	-
2010	579	21.31	100	-	-
2011	672	22.40	100	-	-
2012	659	23.31	100	-	-
2013	414	24.32	100	-	-
2014	383	25.31	100	-	-
2015	261	26.31	100	-	-
2016	296	27.31	100	-	-
Total	**3,783**	**23.27**	**100**	**-**	**-**

Exercise of stock acquisition rights

	2018		2017	
	Number of rights	Weighted average share price (yen)	Number of rights	Weighted average share price (yen)
Chugai common stock options	3,736	6,158	3,803	4,512
Chugai stock options as stock-based compensation	202	5,380	93	3,950

(2) Restricted stock compensation plan

Under the Compensation Plan, the restricted stocks to be provided consist of "tenure-based restricted stock" for Eligible Directors, as well as certain employees, which requires continuous service for a certain period for Chugai, and "performance-based restricted stock" for only Eligible Directors which requires the attainment of Chugai's mid- to long-term business performance target in addition to the aforementioned continuous service. The Eligible Directors and employees, shall make in-kind contribution of all monetary compensation claims or monetary claims to be provided by Chugai according to the Compensation Plan, and shall, in return, receive shares of common stock of Chugai that will be issued or disposed of by Chugai.

For the disposal of shares of common stocks of Chugai under the Compensation Plan, Chugai and each Eligible Directors and employees, shall make an agreement on allotment of restricted stocks including that (1) The Eligible Directors and employees, shall not transfer, create a security interest on, or otherwise dispose of the allotted shares during a certain restriction period, and (2) Chugai shall take back all or part of the allotted shares without cost in case where certain events happen.

Number of shares allotted and fair value at the grant date by year

Year		Tenure-based restricted stock	Performance-based restricted stock
2017	Number of shares allotted	74,900 shares	48,100 shares
	Fair value at the grant date	3,820 yen	2,910 yen
2018	Number of shares allotted	40,600 shares	19,700 shares
	Fair value at the grant date	5,400 yen	5,788 yen

Overview of the Compensation Plan

	Tenure-based restricted stock	Performance-based restricted stock
Evaluation method	Market price	Monte Carlo simulation
Allottees	Directors of Chugai Employees of Chugai Directors of Chugai's subsidiaries Employees of Chugai's subsidiaries	Directors of Chugai
Settlement method	Equity settlement	
Transfer restriction period	3 years	
Conditions for releasing transfer restriction	On the condition that the Eligible Directors, Vice presidents and Employees maintain their positions continuously during the transfer restriction period, Chugai shall release the transfer restriction for all of the allotted shares at the expiration of the transfer restriction period.	On the condition that the Eligible Directors maintain their positions continuously during the transfer restriction period, Chugai shall release the transfer restriction for the number of allotted shares, which is calculated by multiplying the number of shares that the Eligible Directors obtain at the expiration of the transfer restriction period by the release rate that is determined by the growth rate on the three-year (the "Evaluation Period") Total Shareholders Return (TSR) for a peer group as a performance goal decided by the Board of Directors in advance. The release rate is applied against the number of shares that is provided at the beginning of the restriction period by multiplying the maximum coefficient of 150%, ranging from 0% to 150% separately set by Chugai's Board, and is set from 0% to 100%.

The TSR calculation formula is as follows:

TSR=(Increase in the stock price during the Evaluation Period (B-A) + Dividends during the Evaluation Period) ÷ Initial stock price (A)

A: Initial stock price (Average closing price for the three months prior to the start of the Evaluation Period)
B: Final stock price (Average closing price for the three months prior to the end of the Evaluation Period)

26. Earnings per share

Basic earnings per share

	2018	2017
Net income attributable to Chugai shareholders (millions of yen)	**92,488**	**72,713**
Weighted average number of common stock	559,685,889	559,685,889
Weighted average number of own equity instruments	(12,662,197)	(13,147,406)
Weighted average number of shares in issue	**547,023,692**	**546,538,483**
Basic earnings per share (yen)	**169.08**	**133.04**

Diluted earnings per share

	2018	2017
Net income attributable to Chugai shareholders (millions of yen)	**92,488**	**72,713**
Weighted average number of shares in issue	547,023,692	546,538,483
Adjustment for assumed exercise of equity compensation plans, where dilutive	892,227	886,414
Weighted average number of shares in issue used to calculate diluted earnings per share	**547,915,919**	**547,424,897**
Diluted earnings per share (yen)	**168.80**	**132.83**

There were no rights in equity compensation plans, which are anti-dilutive, and therefore excluded from the calculation of diluted earnings per share (2017: none).

27. 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

	2018	2017
Net income	93,079	73,541
Financing costs	111	110
Other financial income (expense)	(449)	87
Other expense	3,212	1,706
Income taxes	28,370	23,490
Operating profit	**124,323**	**98,934**
Depreciation of property, plant and equipment	14,590	14,549
Amortization of intangible assets	1,988	1,785
Impairment of property, plant and equipment	59	4
Impairment of intangible assets	4,844	4,035
Operating expense for defined benefit plans	4,427	4,231
Operating expense for equity-settled equity compensation plans	282	415
Net (income) expense for provisions	-	(11)
Inventories write-down	1,051	630
Other adjustments	294	205
Cash generated from operations	**151,857**	**124,776**

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

	2018	2017
Interest received	85	88
Dividends received	115	183
Total	**200**	**271**

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 (2017: none).

28. 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. 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.

1) 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 material collateral was held for trade receivables (2017: 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, 2018.

Trade receivables: major customers in millions of yen

	December 31, 2018	December 31, 2017
Alfresa Corporation	32,483	31,492
Mediceo Corporation	22,585	24,656
Suzuken Co., Ltd.	19,998	22,192
Toho Pharmaceutical Co., Ltd.	13,171	13,592
Total	**88,237**	**91,932**

Customer credit risk exposure based on accounts receivable days overdue that are within the scope of IFRS15 in millions of yen

	Current	Overdue 1-3 months	Overdue 4-12 months	Overdue more than 1 year	Credit Impaired	Total
At December 31, 2018						
Gross carrying amount	162,742	137	-	0	-	162,879
- Expected credit loss rate (%)	0	0	-	100	-	0
Allowance for doubtful accounts	(7)	(0)	-	(0)	-	(7)

The expected credit loss ('ECL') rate is based on the Group's historical experience and the Group's expectation of economic conditions over the period until receivables are expected to be paid.

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

	December 31, 2017
Neither overdue nor impaired	174,215
Overdue less than 1 month	64
Overdue 1-3 months	4
Overdue 4-6 months	1
Overdue 7-12 months	-
Overdue more than 1 year	-
Total	**174,284**

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.

Financial assets with credit risks (excluding accounts receivables that result from transactions that are within the scope of IFRS 15)
Cash and cash equivalents are held with banks and financial institutions, which are predominantly rated investment grade, based on Moody's and S&P Ratings. Cash and short-term time deposits are subject to rules which limit the Group's exposure to individual financial institutions.

Investments in marketable securities (excluding equity securities) are entered into on the basis of guidelines with regard to liquidity, quality and maximum amount. As a general rule, the Group invests only in high-quality securities with adequate liquidity and with counterparties that have a credit rating of at least Baa3 from Moody's and BBB- from S&P.

Credit risk on accounts receivables that result from transactions that are not within the scope of IFRS 15, are managed based on data obtained from external sources and historical experience.

The credit risk of the counterparties with external ratings below investment grade or non-rated is closely monitored and reviewed on an individual basis.

Rating analysis (excluding accounts receivables that result from transactions that are within the scope of IFRS 15) in millions of yen

	2018		
	Total	Fair value through OCI (12-month ECL)	Amortized costs (12-month ECL)
AAA~BBB- range	263,010	102,001	161,009
Total investment grade	**263,010**	**102,001**	**161,009**
Below BBB- range (below investment grade)	-	-	-
Unrated	3,067	-	3,067
Total gross carrying amounts	**266,076**	**102,001**	**164,076**
Loss allowance	**-**	**-**	**-**

Financial assets measured at amortized cost and those at fair value through OCI (excluding equity securities) are investment grade and therefore considered to be low risk, and thus the impairment allowance is determined at 12 months expected credit losses ('ECL') with a reference to external credit ratings of the counterparties. There were no financial assets for which the Group observed a significant increase in the credit risk which would require the application of the lifetime expected credit losses impairment model. There was no material impact resulting from the revised impairment approach under IFRS 9. In addition, there were no material movements in the loss allowance in 2018.

Impairment losses by asset class
The Group's impairment loss on available-for-sale financial assets was ¥97million in 2017.

2) 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 (2017: ¥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
At December 31, 2018					
Accounts payable	71,706	68,178	3,340	28	160
Other current liabilities					
- Derivative financial instruments*	2,096	531	302	890	372
Total financial liabilities	**73,802**	**68,709**	**3,642**	**919**	**532**
At December 31, 2017					
Accounts payable	63,518	61,447	2,029	43	-
Other current liabilities					
- Derivative financial instruments*	1,652	625	324	478	225
Total financial liabilities	**65,170**	**62,072**	**2,353**	**521**	**225**

*Derivative financial instruments are held for risk management purposes and will not be canceled before the maturity date.

3) 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 to reduce the risk of foreign currency exchange fluctuations related to both 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

	2018	2017
Average exchange rate (yen per each currency)		
CHF	112.92	113.90
EUR	130.36	126.39
USD	110.45	112.17
Profit before taxes (millions of yen)		
CHF	12	(256)
EUR	32	9
USD	(289)	(187)

(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.

	2018			2017		
	Exposure (m CHF)	Exposure (m YEN)	Impact (m YEN)	Exposure (m CHF)	Exposure (m YEN)	Impact (m YEN)
CHF						
Accounts receivable	324	36,278	(363)	227	26,165	(262)
Accounts payable	(344)	(38,513)	385	(279)	(32,224)	322
Financial non-current assets	-	-	-	-	-	-
Cash and cash equivalents	15	1,667	(17)	40	4,629	(46)
Notional amounts of derivative financial instruments						
- Effective portion of hedge	(5)	(637)	6	230	27,007	(270)
- Other than above	-	-	-	-	-	-
Total	**(10)**	**(1,204)**	**12**	**218**	**25,576**	**(256)**
	Exposure (m EUR)	Exposure (m YEN)	Impact (m YEN)	Exposure (m EUR)	Exposure (m YEN)	Impact (m YEN)
EUR						
Accounts receivable	2	265	(3)	10	1,385	(14)
Accounts payable	(27)	(3,435)	34	(17)	(2,250)	23
Financial non-current assets	-	-	-	-	-	-
Cash and cash equivalents	-	-	-	-	-	-
Notional amounts of derivative financial instruments						
- Effective portion of hedge	-	-	-	-	-	-
- Other than above	-	-	-	-	-	-
Total	**(25)**	**(3,170)**	**32**	**(6)**	**(865)**	**9**
	Exposure (m USD)	Exposure (m YEN)	Impact (m YEN)	Exposure (m USD)	Exposure (m YEN)	Impact (m YEN)
USD						
Accounts receivable	35	3,850	(38)	32	3,636	(36)
Accounts payable	(100)	(11,034)	110	(98)	(11,043)	110
Financial non-current assets	-	-	-	-	-	-
Cash and cash equivalents	-	-	-	-	-	-
Notional amounts of derivative financial instruments						
- Effective portion of hedge	333	36,061	(361)	240	26,139	(261)
- Other than above	-	-	-	-	-	-
Total	**267**	**28,877**	**(289)**	**174**	**18,732**	**(187)**

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

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.

Accounting classifications and fair values in millions of yen

	Financial assets measured at fair value through OCI	Fair value -hedging instruments	Fair value through profit or loss (mandatorily)-other	Financial assets at amortized cost	Financial liabilities at amortized cost	Total
At December 31, 2018						
Non-current financial assets						
- Equity instrument	9,723	-	-	-	-	9,723
Accounts receivable	-	-	-	179,556	-	179,556
Marketable securities						
- Debt instrument	8,001	-	-	-	-	8,001
- Money market instruments	94,000	-	-	-	-	94,000
- Time accounts over 3 months	-	-	-	532	-	532
Cash and cash equivalents	-	-	-	146,860	-	146,860
Other current assets						
- Derivative financial instruments	-	2,204	-	-	-	2,204
Total financial assets	**111,724**	**2,204**	**-**	**326,948**	**-**	**440,876**
Accounts payable	-	-	-	-	71,706	71,706
Other current liabilities						
- Derivative financial instruments	-	2,096	-	-	-	2,096
Total financial liabilities	**-**	**2,096**	**-**	**-**	**71,706**	**73,801**

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 directly or indirectly 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
At December 31, 2018				
Marketable securities:				
- Money market instruments	-	94,000	-	94,000
- Debt securities	8,001	-	-	8,001
Other current assets				
- Derivative financial instruments	-	2,204	-	2,204
Financial non-current assets				
- Equity instruments measured at fair value through OCI	7,330	-	2,394	9,723
Financial assets recognized at fair value	**15,331**	**96,204**	**2,394**	**113,928**
Other current liabilities				
- Derivative financial instruments	-	(2,096)	-	(2,096)
Financial liabilities recognized at fair value	**-**	**(2,096)**	**-**	**(2,096)**

	Level 1	Level 2	Level 3	Total
At December 31, 2017				
Marketable securities:				
- Money market instruments and time accounts over 3 months	-	99,018	-	99,018
- Debt securities	5,000	-	-	5,000
Other current assets				
- Derivative financial instruments	-	2,107	-	2,107
Financial non-current assets				
- Available-for-sale financial assets	9,734	-	1,616	11,350
Financial assets recognized at fair value	**14,735**	**101,125**	**1,616**	**117,476**
Other current liabilities				
- Derivative financial instruments	-	(1,652)	-	(1,652)
Financial liabilities recognized at fair value	**-**	**(1,652)**	**-**	**(1,652)**

The fair value hierarchy has been adjusted to reflect the presentational changes required as a result from implementing IFRS 9 'Financial Instruments. Time accounts over three months are accounted for at amortized cost under IFRS 9 and as a result are no longer included in the fair value hierarchy analysis for 2018 (they were accounted for as available-for-sale under IAS 39 and therefore were included in the fair value hierarchy in 2017).

Level 1 financial assets consist of corporate bonds and quoted shares. Level 2 financial assets consist primarily of certificates of deposit, cash in trust, commercial paper and derivative financial instruments.

Fair values Level 2 financial assets are determined 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.

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. Valuation is based on valuation method which includes unobservable inputs.

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, 2017	1,552	-	1,552
Gains or losses	64	-	64
Purchases	-	-	-
Disposals	-	-	-
Transfers	-	-	-
Currency translation effects	(1)	-	(1)
At December 31, 2017	**1,616**	**-**	**1,616**
At January 1, 2018	1,616	-	1,616
Gains or losses	72	-	72
Purchases	706	-	706
Disposals	-	-	-
Transfers	-	-	-
Currency translation effects	(1)	-	(1)
At December 31, 2018	**2,394**	**-**	**2,394**

(3) Derivative financial instruments

Derivative financial instruments in millions of yen

Assets	December 31, 2018	December 31, 2017
Forward exchange contracts	2,204	2,107
Total	**2,204**	**2,107**

Liabilities	December 31, 2018	December 31, 2017
Forward exchange contracts	(2,096)	(1,652)
Total	**(2,096)**	**(1,652)**

Hedge accounting

Hedge effectiveness is determined at the inception of the hedge relationship, and through periodic prospective effectiveness assessments at each reporting date to ensure that an economic relationship exists between the hedged item and hedging instrument. The Group performs a qualitative assessment of the hedge effectiveness, and the Group concludes that risks being hedged for the hedged items and the hedging instruments are sufficiently aligned.

The Group manages foreign exchange rate fluctuation risks by applying cash flow hedge, and an ineffective portion may occur when the volume of hedged items is lower than the hedged amount. The ineffective portion of the hedge accounting is recognized in the income statement and included in other financial income (expense). It is measured using the hypothetical derivative method for cash flow hedges. In 2018 there were no actual ineffectiveness being reported for any hedge accounting relationships, or hedging relationships for which hedge accounting is no longer applied (2017: None).

The table below shows fair values and nominal amounts of derivative financial instruments, including a range of the timing of the nominal amounts of the hedging instruments, which are designated as hedging instruments in a cash flow hedge. At 31 December 2018 the Group has the following cash flow hedges which are designated in a qualifying hedge relationship.

Cash flow hedges

	Nominal amount	Fair value in million Yen		Maturity range
		Asset	Liability	
Risk hedged:				
Foreign exchange rate fluctuations				
- Forward exchange contracts	CHF 2,108 million	1,893	(1,863)	2019-2020
	USD 333 million	311	(233)	2019-2020
Total		**2,204**	**(2,096)**	

The Group is exposed to foreign exchange risk from transactions for inventories and others in foreign currencies with foreign related parties. The Group has entered into foreign exchange forward contracts to hedge a part of foreign exchange risk. Such instruments are recorded as fair value assets of ¥109 million (2017: fair value assets of ¥456 million).

Reconciliation of hedging reserves in equity in millions of yen

	Forward exchange contracts
At January 1, 2018	281
Effective portion of fair value gains (losses) taken to equity	(441)
Transferred to income statement	42
Transferred to initial carrying amount of hedged items	79
Income taxes	95
At December 31, 2018	**57**

The present value of expected cash flows from qualifying cash flow hedges is shown in the table below.

Present value of expected cash flows of qualifying cash flow hedges in millions of yen

	Total	0-6 months	7-12 months	Over 1 Year
Year ended December 31, 2018				
Cash inflows	275,004	102,316	119,583	53,105
Cash outflows	(274,895)	(102,221)	(119,610)	(53,065)
Total cash inflow (outflow)	**109**	**95**	**(27)**	**41**
Year ended December 31, 2017				
Cash inflows	242,308	107,794	96,290	38,224
Cash outflows	(241,852)	(107,570)	(96,042)	(38,239)
Total cash inflow (outflow)	**456**	**223**	**248**	**(15)**

(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, 2018	December 31, 2017
Capital and reserves attributable to Chugai shareholders	755,864	691,924
Equity attributable to non-controlling interests	664	973
Total equity	756,529	692,897
Total debt	214	336
Capitalization	**756,743**	**693,233**

29. 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 etc. 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 totalled ¥21,454 million (2017: ¥18,437 million).

(2) Material transactions and balances with related parties

Transactions with F. Hoffmann-La Roche in millions of yen

	2018	2017
Sales	109,938	76,359
Purchases of inventory and other materials	125,657	124,792

Balances with F. Hoffmann-La Roche in millions of yen

	December 31, 2018	December 31, 2017
Trade accounts receivable	25,307	19,593
Trade accounts payable	(29,567)	(24,805)

(3) Remuneration of key management personnel

Remuneration of members of the board and audit & supervisory board members in millions of yen

	2018	2017
Board of Directors		
- Regular remuneration	304	333
- Bonuses	120	234
- Tenure-based restricted stock compensation plan	57	92
- Performance-based restricted stock compensation plan	72	35
- Chugai common stock options	21	83
- Chugai stock options as stock-based compensation	-	34
Total	**573**	**811**
Audit & supervisory board members		
- Regular remuneration	87	85
Total	**87**	**85**

Effective from the previous fiscal year, for the purpose of further promoting shared value with shareholders and providing an incentive to sustainably increase the Group's corporate value, strengthening linkage between their compensation and mid- to long-term business performance, a restricted stock compensation plan was introduced in place of the existing stock option compensation plans.

30. Subsidiaries

Subsidiaries	Country of incorporation	Equity interest %	
		2018	2017
Consolidated subsidiaries			
Chugai Research Institute for Medical Science, Inc.	Japan	100	100 %
Chugai Clinical Research Center Co., Ltd.	Japan	100	100 %
Chugai Business Support Co., Ltd.	Japan	100	100 %
Medical Culture, Inc.	Japan	100	100 %
Chugai Distribution Co., Ltd.	Japan	100	100 %
Chugai Pharma Manufacturing Co., Ltd.	Japan	100	100 %
Forerunner Pharma Research Co., Ltd.	Japan	100	100 %
Chugai 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 France S.A.S.	France	100	100 %
Chugai sanofi-aventis S.N.C.	France	55	55 %
Chugai Pharma Taiwan Ltd.	Taiwan	100	100 %
Chugai Pharma Science (Beijing) Co., Ltd.	China	100	100 %
Chugai Pharma China Co., Ltd.	China	100	100 %
Chugai Pharma Technology Taizhou Co., Ltd.	China	100	100 %
Chugai Pharmabody Research Pte. Ltd.	Singapore	100	100 %

(Note) Chugai sanofi-aventis S.N.C. became a wholly-owned subsidiary of Chugai Pharma Europe Ltd., through the additional acquisition of its shares in January 2019, and changed its name to Chugai Pharma Europe Logistics S.A.S. In addition, Chugai Pharma Germany GmbH was established as a subsidiary of Chugai Pharma Europe Ltd. in February 2019.

31. Subsequent events

There were no material subsequent events.

Additional information

This Additional information is provided for the information of readers and does not form part of the consolidated financial statements.

1. Significant legal cases

At December 31, 2018, the Group is involved in the following significant legal cases for which the outcome cannot be determined at this time, but for which the Group assesses that the possibility of any settlement to be remote:

(1) Arbitration in United Kingdom regarding Actemra
In May 2017 Medical Research Council and LifeArc (formerly Medical Research Council Technology) ('Claimants') requested arbitration against Chugai Pharmaceutical Co., Ltd. with an arbitrator being appointed on 9 August 2017. In April 2018 United Kingdom Research and Innovation ('UKRI') was established and became the successor in title to the Medical Research Council, and the current claimants in the arbitration are LifeArc and UKRI. Sums are sought from Chugai for alleged breach of obligations under a collaboration agreement dated 15 August 1990 in connection with the development of the humanized anti-human IL-6 receptor monoclonal antibody, Actemra. It is claimed that Chugai is obliged to pay royalties to the Claimants pursuant to the collaboration agreement.

(2) Patent infringement lawsuit regarding emicizumab in Japan
Baxalta (Baxalta Incorporated and Baxalta GmbH) filed a lawsuit against Chugai at the Tokyo District Court on 6 May 2016 requesting an injunction against the manufacture, usage, transfer, exportation and offer of any transfer regarding emicizumab alleging emicizumab is infringing its Japanese patent (patent number 4313531). With regard to this action, Tokyo District Court rendered a decision in favor of Chugai's claim. Given this ruling, Baxalta appealed to the Intellectual Property High Court on 29 June 2018.

(3) Patent infringement lawsuit regarding emicizumab in the United States
Baxalta (Baxalta Incorporated and Baxalta GmbH) filed a lawsuit against Chugai and Genentech Inc., at the United States District Court for the District of Delaware on 4 May 2017 requesting relief including an injunction against manufacturing, using, offering to sell, or selling of emicizumab within the United States, or importing emicizumab into the United States. Baxalta filed a stipulation of dismissal with prejudice regarding Baxalta's claims against Chugai with the Court on 13 September 2018, and the Court issued an Order Dismissing Chugai from this lawsuit on 19 September 2018.

(4) Patent infringement lawsuit against Alexion in the United States
Chugai alleges that the anti-C5 antibody ALXN1210 (ravulizumab) product, an investigational drug developed by Alexion Pharmaceuticals, Inc., infringes one of its U.S. patents (U.S. Patent No. 9,890,377) relating to its proprietary antibody engineering technology. Thus, Chugai filed a patent infringement lawsuit against Alexion at the United States District Court for the District of Delaware on 15 November 2018 requesting a judgment that the ALXN1210 product infringes Chugai's U.S. patent and injunctive relief precluding manufacturing and selling of the ALXN1210 product within the United States.

(5) Patent infringement lawsuit against Alexion in Japan
Chugai alleges that the anti-C5 antibody ALXN1210 (ravulizumab) product, an investigational drug developed by Alexion Pharma Godo Kaisha (Japan Regional Headquarters), infringes some of its Japan patents (Patent No. 4954326 and No. 6417431) relating to its proprietary antibody engineering technology. Thus, Chugai filed a patent infringement lawsuit against Alexion at the Tokyo District Court on 5 December 2018 requesting a judgment that the ALXN1210 product infringes Chugai's Japan patent and injunctive relief precluding manufacturing and selling of the ALXN1210 product in Japan.

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 Pharamaceutical Co., Ltd. and its consolidated subsidiaries, which comprise the consolidated balance sheet as at December 31, 2018, 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, 2018, and their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards.

KPMG AZSA LLC

March 28, 2019
Tokyo, Japan

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.

Proof of Concept (PoC)/Early PoC
Proof of concept (PoC) is confirmation 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 the purpose of filing an application for approval are called clinical trials.

Phase I: Performed on a small number of healthy volunteers (or, for certain disease areas 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 verify 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 drug's safety and efficacy for its approved indication(s).

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 Minister 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.

Additional indication
A new indication for a previously approved 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.

Terms Related to Drug Discovery

Personalized Healthcare
Even when a particular disease is treated with the same drug, there may be differences in the efficacy and side effects of that drug depending on the patient. One of the causes is thought to be that the genetic information related to the disease is different in each patient. Personalized healthcare (PHC) is an approach that focuses on these genetic-level differences to provide treatment tailored to the characteristics of each patient's disease. It therefore brings significant benefits in term of efficiency, safety and cost effectiveness.

Cancer Genomic Medicine
One example of personalized healthcare. Medical treatment that measures multiple cancer-related genes in a single operation using gene panel examination and performs optimal treatment according to each patient's genomic profile.

Biopharmaceuticals
Drugs created by applying biotechnology such as genetic recombination. In the 1980s, when rapid advances were made in genetic engineering, Chugai decided to shift to research and development of biopharmaceuticals and made related large-scale capital investments.

Therapeutic antibody
A type of biopharmaceutical, it is an artificially created antibody used as a medicine to prevent or treat diseases. Therapeutic antibodies are designed to act only on the specific molecule (antigen) that causes the disease, and therefore can be expected to provide high therapeutic efficacy and reduce side effects. Chugai launched the first therapeutic antibody created in Japan in 2005, and is leading the world with its proprietary antibody engineering technologies.

Modality
In the pharmaceutical industry, refers to the material classification of a medicine. Until the 1990s, small molecule drugs were virtually the only modality, but the options are now increasing. New modalities enable new approaches to diseases that have no effective treatment methods. Chugai is focusing on establishing middle molecules as a third modality, in addition to its biologics and small molecules.

Open innovation
Generating innovative value by utilizing the technologies and development capabilities of external research networks such as with universities, research institutions and other organizations.

Translational Research
Research that builds a bridge between the findings of basic research by academia and the development of new medicines by pharmaceutical companies.

Terms Related to Human Resources

Work-life synergy (Work-life balance)
Chugai's work-life synergy aims to generate a synergistic effect that brings forth motivation, vitality and innovation by enhancing both work and the lives of individuals. Work-life synergy, an advancement of the concept of work-life balance, is necessary for a fulfilling personal life, as well as for becoming the top innovator in the healthcare industry.

Diversity and Inclusion
At Chugai, diversity refers to a diversity of attributes such as gender, age and nationality, as well as ways of thinking, values and experience. Inclusion refers to the state of respecting each other's differences and the ability of everyone to contribute and perform at his or her full potential. When people with various backgrounds work together, they become aware of diverse perspectives and ideas. Companies promote diversity to create new value, which leads to innovation. Using this awareness for business innovation, companies promote diversity to create better-quality products and services. Also called "diversity and inclusion (D&I)," which 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
Talent management is the human resource strategy by which we identify and develop leaders and highly skilled specialists at an early stage. It is also the means by which we improve the skills and enhance the motivation of employees throughout the Company, with the aim of realizing our corporate strategy and catalyzing the creation of innovation. Each organization at Chugai has formulated a long-term human resource development plan and is building a talent pool of leaders.

Terms Related to the Roche Group

Roche
A pharmaceutical company established in 1896 and headquartered in Basel, Switzerland. With business operations in more than 100 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 2018 were 56.8 billion Swiss francs.

Roche Diagnostics K.K.
The Japanese subsidiary of the Roche Group's diagnostics division. Established in 1998, Roche Diagnostics K.K. provides a wide range of innovative diagnostic solutions, including in-vitro diagnostics and diagnostic equipment and research reagents and related equipment.

Genentech Inc.
A leading biotechnology company headquartered in South San Francisco, California. Genentech has been a member of the Roche Group since 1990.

Foundation Medicine Inc. (FMI)
FMI was established in Massachusetts, U.S.A. in 2010. In 2015, Roche took a majority stake, and then acquired the remaining outstanding shares in 2018 to make FMI a wholly-owned subsidiary. Chugai established the FMI business as a specialized unit in October 2018 to carry out commercialization and product value maximization of FMI's "Comprehensive Genomic Profiling Service" in Japan.

Network (As of April 1, 2019)

Chugai Pharmaceutical

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URL: https://www.chugai-pharm.co.jp/english/

Research Laboratories

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Kamakura Research Laboratories
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Kanagawa Pref. 247-8530 Japan
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Ukima Research Laboratories
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Tokyo 115-8543 Japan
Tel +81-(0)3-3968-6111

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Discovery Research Center
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Clinical Research Center
#903 E&C Venture Dream Tower 3, 38-21,
Digital-ro 31-gil, Guro-gu,
Seoul 08376 Korea
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Shareholder Information (As of December 31, 2018)

Major Shareholders

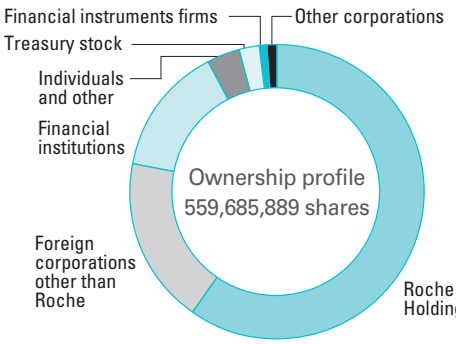
Name	Number of Shares Held (Thousands)	Percentage of Voting Rights (%)
Roche Holding Ltd	335,223	61.27
The Master Trust Bank of Japan, Ltd. (Trust Account)	29,342	5.36
Japan Trustee Services Bank, Ltd. (Trust Account)	16,320	2.98
STATE STREET BANK AND TRUST COMPANY 505001	15,614	2.85
JP MORGAN CHASE BANK 380055	13,924	2.54
STATE STREET BANK WEST CLIENT - TREATY 505234	4,231	0.77
Japan Trustee Services Bank, Ltd. (Trust Account 5)	4,091	0.74
Trust & Custody Services Bank, Ltd. (Securities Investment Trust Account)	3,829	0.70
Japan Trustee Services Bank, Ltd. (Trust Account 7)	3,748	0.68
SSBTC CLIENT OMNIBUS ACCOUNT	3,651	0.66

Note: 12,459,413 shares of treasury stock held by the Company are not included in the above breakdown of major shareholders.

Stock Price Information (From January 1, 2018 to December 31, 2018)

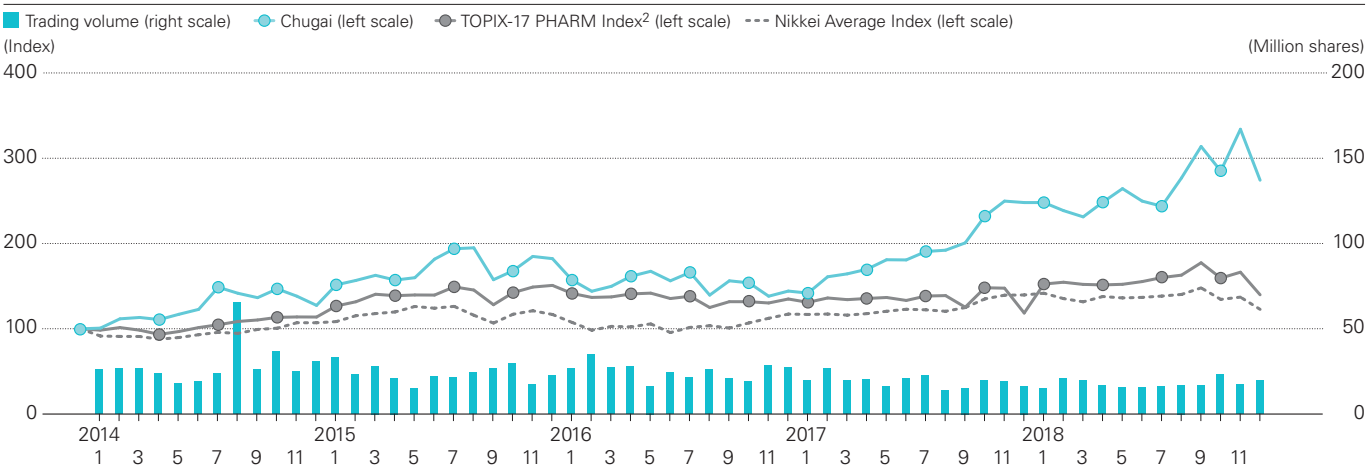
	Stock Price	
	Low	High
First Quarter	¥5,080	¥6,080
Second Quarter	5,310	6,210
Third Quarter	5,430	7,370
Fourth Quarter	6,230	7,850

Classification of Shareholders



- Roche Holding Ltd. — Shares: 335,223,645 — 59.89% — (Shareholder: 1)
- Foreign corporations other than Roche — Shares: 101,646,649 — 18.16% — (Shareholders: 751)
- Financial institutions — Shares: 79,685,192 — 14.23% — (Shareholders: 64)
- Individuals and other — Shares: 19,865,429 — 3.54% — (Shareholders: 18,941)
- Treasury stock — Shares: 12,459,413 — 2.22% — (Shareholder: 1)
- Financial instruments firms — Shares: 5,751,170 — 1.02% — (Shareholders: 39)
- Other corporations — Shares: 5,054,391 — 0.90% — (Shareholders: 150)

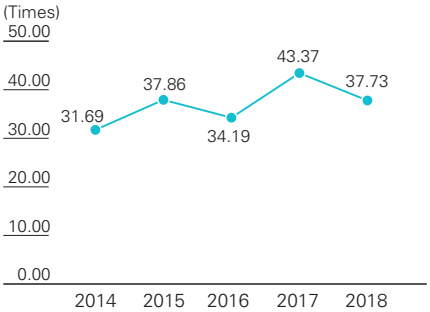
Share Performance[1] with Stock Indices



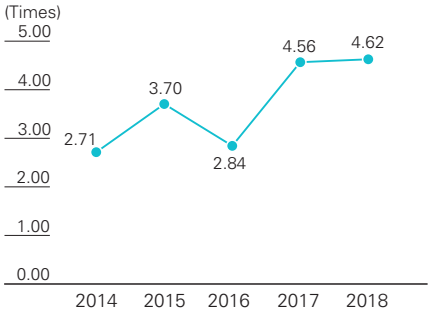
1. Closing price on December 30, 2013 = 100
2. A capitalization-weighted index that consists of pharmaceutical companies on the Tokyo Stock Exchange, First Section.

Share Price Indicators

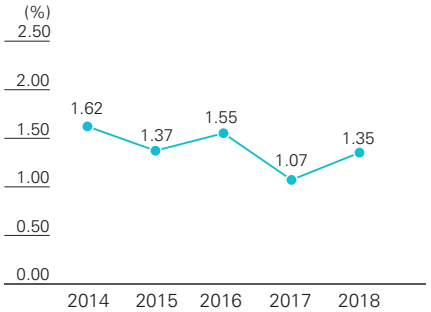
Price/Earnings Ratio
Year-end share price / Basic net income per share



Price/Book Ratio
Year-end share price / Equity per share attributable to Chugai shareholders



Dividend Yield
Dividends per share / Year-end share price



Corporate Overview (As of December 31, 2018)

Company Name
Chugai Pharmaceutical Co., Ltd.

Year of Foundation
1925

Year of Establishment
1943

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

Stated Capital
¥73,202 million

Number of Employees
7,432 (Consolidated)

Number of Shares Issued of Common Stock
559,685,889

Number of Shareholders
19,947

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 (https://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*.

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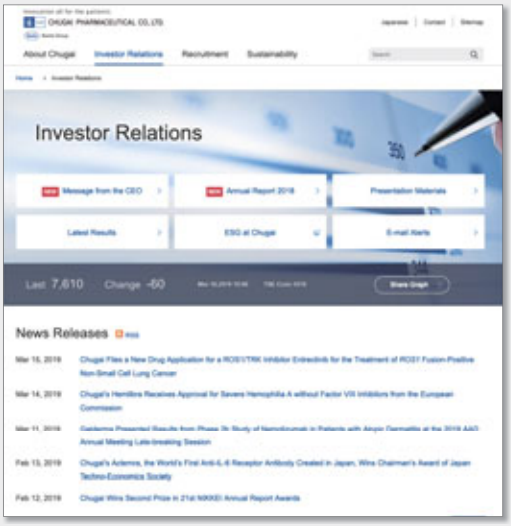
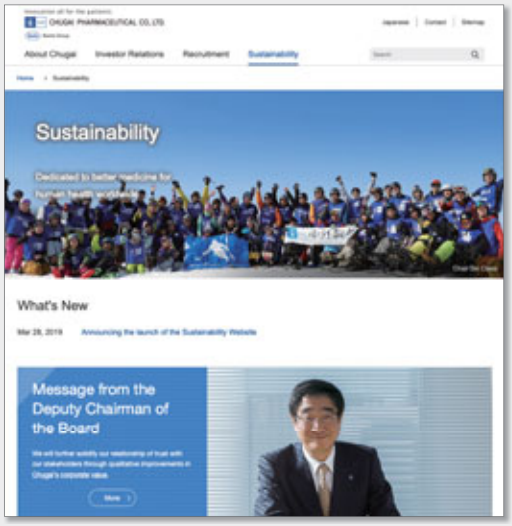


Sustainability website
https://www.chugai-pharm.co.jp/english/csr/



Innovation all for the patients

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A member of the Roche group

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