



Roche Roche Group

# Annual Report 2022

Fiscal year ended December 31, 2022

## INNOVATION BEYOND IMAGINATION

CHUGAI PHARMACEUTICAL CO., LTD.

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## Editorial Policy

We have issued this integrated report (annual report) with the aim of communicating to stakeholders, such as our shareholders and investors, our efforts to increase our corporate value, both in financial and non-financial terms, and to create a catalyst for engagement with them. In light of their importance in terms of Chugai's short-, medium-, and long-term value creation and their impact on our stakeholders, in this booklet we have presented Chugai's value creation process for sustainable growth, the specific growth strategies of TOP I 2030 and our progress on them, as well as our initiatives and structures for sustainable value creation.

## Scope of This Report

Chugai Pharmaceutical Co., Ltd.  
and the Chugai Group

## Timeframe

January 1, 2022 to December 31, 2022

(The financial reporting period)

Note: In view of the importance of providing the latest information available, some information relating to activities that occurred in 2023 is included, mainly in research and clinical development data.

## Reference Guidelines:

- IFRS Foundation "International Integrated Reporting Framework"
- Ministry of Economy, Trade and Industry "Guidance for Integrated Corporate Disclosure and Company-Investor Dialogues for Collaborative Value Creation"

## Forward-Looking Statements

This report may include forward-looking statements pertaining to the business and prospects of Chugai Pharmaceutical Co., Ltd. (the "Company"). These statements reflect the Company's current analysis of existing information and trends. Actual results may differ from expectations based on risks and uncertainties that may affect the Company's businesses.

## Disclaimer

In this report, information on pharmaceutical products or drug candidates under development may be included, but such information is not intended for promotional or advertising purposes, or as medical advice, etc. The trademarks appearing in the report are protected by trademark rights, copyright, and other intellectual property (IP) rights.

# 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

## 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

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At Chugai, our Mission Statement is the basis of everything we do. It is Chugai's most enduring and important concept, and represents our adherence to the Company's founding spirit and our founder's vow to "create drugs that benefit the world" in response to a medicine shortage following a major natural disaster. Our Core Values are the values that employees share and embody. They represent our commitment to maintaining the highest standards in all we do to meet the expectations and requirements of society as we pursue innovation with a pioneering spirit for the benefit of patients. In our Envisioned Future, we have set the goal of becoming a top innovator in the healthcare industry by going beyond the conventional scope of the pharmaceutical business in anticipation of future changes in the healthcare landscape. Chugai's vision of value creation is to fulfill its Mission Statement by creating shared value.





# Introduction

Looking Ahead to 2030

## Envisioned Future

At Chugai, there is one thing we are driven to accomplish: the realization of advanced and sustainable patient-centric healthcare.

To achieve this, we defined a specific strategy aimed at becoming a top innovator in the healthcare industry in 2030. This move seeks to unite our workforce to deliver the energy to propel us to our goal.

## Top Innovator in the Healthcare Industry



### Expectation from Patients All over the World

With world-class drug discovery capabilities, patients around the world expect that “Chugai will surely create new treatments.”



### Attracting Talent and Players from around the World

Attract passionate talent from all over the world and inspire players globally to think they can create something new by partnering with Chugai.



### Role Model for the World

Recognized for its ESG initiatives through its business activities, Chugai will become a global role model as a leader in resolving social issues.

After extensive discussions among management, in 2021, Chugai announced “Top Innovator in the Healthcare Industry” as its explicit vision for value creation in the coming decade. This has naturally coalesced around the perspectives of patients, talent and players, and society, rooted in the management team’s fundamental policy of creating shared value.

For Chugai, the aim ultimately is the realization of advanced and sustainable patient-centric healthcare.

So many people around the world still suffer from diseases that have no cure, or have conditions that harbor many medical challenges. Through patient-centric innovation, and by drawing on its world-class drug discovery capabilities, Chugai is working to resolve one unmet medical need after another. By continuously delivering such results and value, Chugai seeks to be an attractive company for passionate players worldwide. We are also building advanced business models across the entire value chain and prioritizing the investment of the resources gained in Research and Early Development (RED)\* functions, thereby generating innovation that offers true value for patients. Additionally, as attention mounts regarding how companies respond to environmental, social and governance (ESG) concerns, Chugai strives to serve as a global role model by proactively meeting social expectations and demands, and leading the way in resolving social issues.

\* Includes the process of pharmaceutical technology functions related to early development

#### Column

#### Employee Survey

Sense of satisfaction with envisioned future and strategy is high, but room for improvement in ensuring employee enablement

	Employee engagement	Employee enablement
Deviation from average for global top companies	±0pts	-8pts

Note: Exceeded the average for Japanese companies for all questions

Chugai carries out regular employee surveys to identify organizational issues requiring reform and to support the formulation of strategy. Chugai employee surveys are designed around two axes — “Employee engagement” and “Employee enablement.” In the 2022 survey, “Employee engagement” remained at a level consistent with the average for global top companies (strong performers). Among other positives, employees are extremely proud to work at Chugai, and shared identification with both the envisioned future and strategy is gaining ground. On the other hand, while our score for “Employee enablement” was, as in the previous survey, in line with the global average, it was eight points lower than the average for global top companies, still leaving room for improvement. Particular issues that emerged included enhancing further optimization of companywide resources, promoting fundamental operational processes, and providing support for employee career formation. As we push ahead with reforms under “TOP I 2030,” we are committed to a thorough review of business processes and more robust human resource management without overreliance on previous frameworks or methodologies.



Looking Ahead to 2030

# Pathway

TOP I 2030, our growth strategy for meeting goals for 2030, has two pillars: realizing global first-class drug discovery and building a futuristic business model.

While Chugai today possesses industry-leading drug discovery capabilities and productivity, we have no intention of stopping there. Being the top innovator in the healthcare industry demands global first-class performance.

## Two Pillars of TOP I 2030

### Global First-Class Drug Discovery

**Concentrated investment  
Cash flow growth**

#### Key points for enabling global first-class drug discovery

- Expansion of platforms for small molecule/antibody/mid-size molecule drug discovery
- Development of new technological bases through a multi-modality strategy
- Creation of opportunities for innovation, including through external collaborations

#### Review of Status in 2022

- ✓ Breakthrough therapy designations: nine projects
- ✓ Progress on application of mid-size molecule and proprietary next-generation antibody engineering technologies
- ✓ Global development ongoing for six late-stage products developed from Chugai research

### Futuristic Business Model

**Improved profitability  
Investment resource planning**

#### Key points for building a futuristic business model

- Dramatic improvement in product/patient value by restructuring business model with digital utilization at its core
- Improved productivity of all value chains
- Commercialization of Insight Business with the aim of maximizing the value of pharmaceuticals and having a new business pillar

#### Review of Status in 2022

- ✓ Launch of new research center, and preparation of center for small and mid-size molecule production
- ✓ Progress on developing platforms for AI drug discovery, digital plants and next-generation IT

We are eyeing the road to becoming a top innovator in the healthcare industry by promoting initiatives targeting the two pillars of our “TOP I 2030” growth strategy: achieving global first-class drug discovery and building a futuristic business model. RED Shift, DX and Open Innovation are three key drivers for getting there.

To achieve global first-class drug discovery, we will concentrate management resource investment in RED, moving to bolster small molecule/antibody/mid-size molecule drug discovery and develop new modalities through partnerships with academia and high-tech companies. Additionally, we will cultivate sources of cash flow growth through steps to create even more innovative drugs with higher success rates.

To build a futuristic business model, we will leverage digital technologies to dramatically increase productivity across all value chains, using the investment resources secured to make greater investment in RED and deliver improved product/patient value.





Looking Ahead to 2030

# Vision for Growth

Under TOP I 2030, we will agilely review plans in response to environmental changes.

Holding to single-year plans, we will respond flexibly to changes in the business environment and maintain agility in management decision-making.

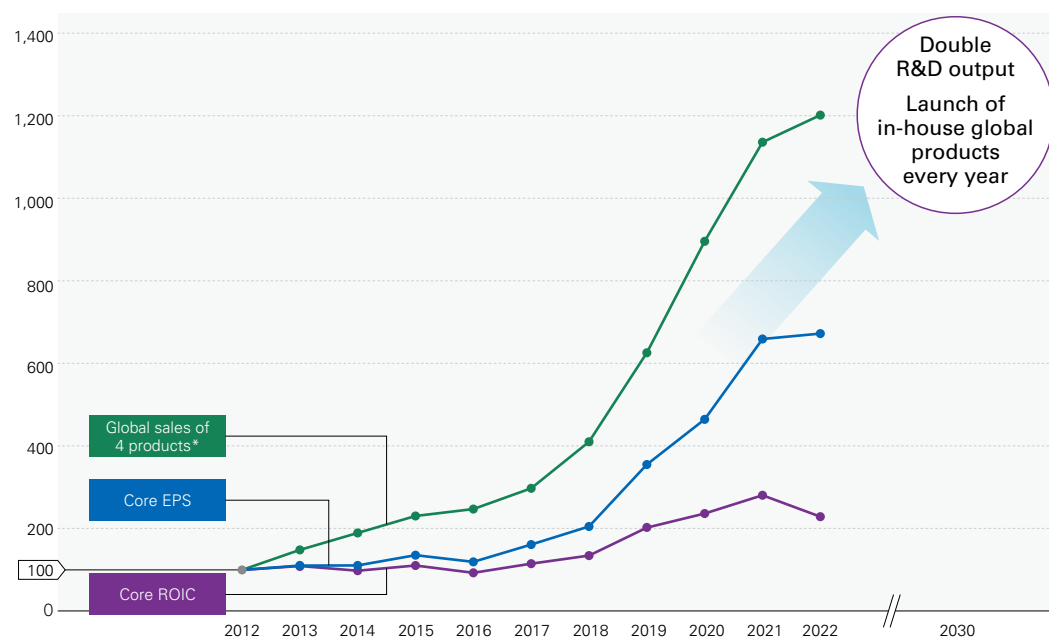
We have set ambitious targets of doubling R&D output and launching in-house global products every year in 2030.

In-house global products have typically led growth, and this trend remains unchanged. By achieving these dual goals, we aim to dramatically increase corporate value in 2030.



## Trends for the Past 10 Years

Changes in results (indexed to 100 in 2012)



\*Sum of domestic and overseas sales of Actemra, Alecensa, Hemlibra and Enspryng, and royalty income from initial shipments of Hemlibra

### Comparison of 2022 with 2012

Revenue	¥386.6 billion	→	¥1,168.0 billion (3.0 times)
Global sales of 4 products	¥42.7 billion	→	¥516.4 billion (12.1 times)
Core operating profit	¥75.6 billion	→	¥451.7 billion (6.0 times)
Core EPS	¥28.55	→	¥193.11 (6.8 times)
Core ROIC	15.7%	→	36.1% (+20.4%pts)
Market capitalization	¥898.5 billion	→	¥5,655.0 billion (6.3 times)
	2012		2022

Amid a rapidly changing business environment, rather than creating business plans built around periods of three years or so, we will instead move under TOP I 2030 to establish medium-term milestones by function, while flexibly reviewing strategy. To this end, rather than announcing financial guidance, we have set a goal of establishing a structure capable of achieving both “Double R&D output” and “Launch in-house global products every year” in 2030.

What these two goals indicate is that growth is driven by Chugai products. Looking at trends from the past decade, we see that growth of 12.1 times in domestic and overseas sales of in-house products has culminated in profit growth, with Core EPS up 6.8 times. In terms of capital efficiency as well, thanks to progress on selection and concentration with a focus on Chugai products, Core ROIC has risen by 20.4 percentage points. It is clear that the discovery of innovative pharmaceuticals is the leading pathway to increased corporate value. Under TOP I 2030, the entire organization will work together to double R&D output and launch in-house global products every year, with the aim of increasing corporate value.



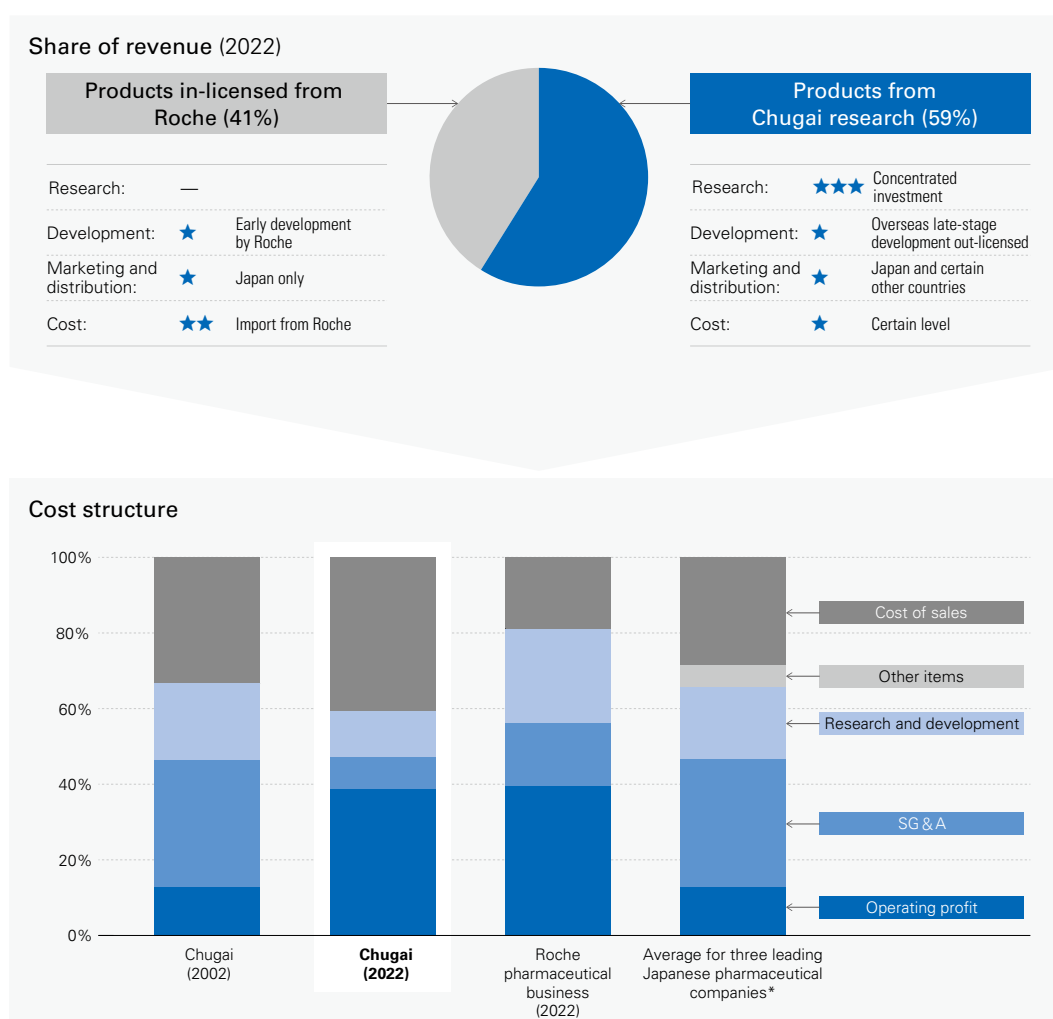
Looking Ahead to 2030

# Earnings Model

To enable this growth trajectory, we have a unique business model backed by our strategic alliance with Roche.

This business model includes division of roles and functions with Roche, which enables concentrated investment on in-house drug discovery. These special characteristics result in an extremely profitable earnings structure.

## Features of the Earnings Structure Apparent in Our Unique Business Model



\* Average of the top three listed pharmaceutical companies in Japan for ethical drugs (Takeda Pharmaceutical Company Limited, Astellas Pharma Inc., and Daiichi Sankyo Co., Ltd.); from each company's financial results materials for the fiscal year ended March 31, 2022

Under its unique business model based on its strategic alliance with Roche, Chugai has two revenue bases. For products from Chugai research, global late-stage development and sales activities are conducted using the platform of Roche or a third party through out-licensing, resulting in high profitability. Conversely, for products in-licensed from Roche, Chugai is primarily responsible for development and marketing activities in Japan. Since cost of sales includes margins paid to Roche and so forth, cost to sales ratio is high, but this is an important earnings base.

With the increase in revenue from products from Chugai research marketed globally, the characteristics outlined in this business model have also produced a unique cost structure and high operating profit ratio in our recent business results. This can be clearly seen by contrasting our cost structure today with that at the start of our alliance with Roche (2002) or with the average for the three leading Japanese pharmaceutical companies. Our cost to sales ratio reflects the higher ratio for products in-licensed from Roche compared to products from Chugai research. With regard to R&D expenses, we concentrate the allocation of our resources on research and early development in order to realize world-class drug discovery capabilities. On the other hand, we have been able to mitigate the burden of enormous operation costs needed for global late-stage development and marketing activities, thereby keeping overall expenses at a low level. As a result, we have realized extremely high profitability with an operating profit ratio of around 40%, which is comparable to that of pharma giant Roche.

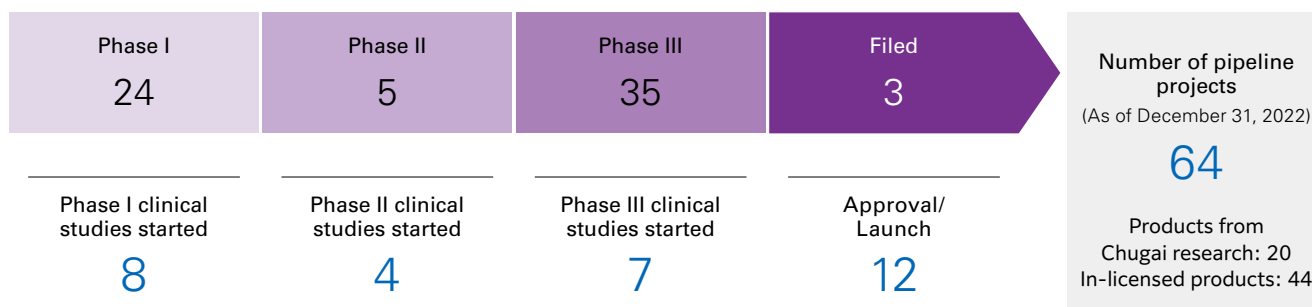
Features of the Strategic Alliance and Business Model "Alliance with Roche"  
<https://youtu.be/d7JSPJuZefw>



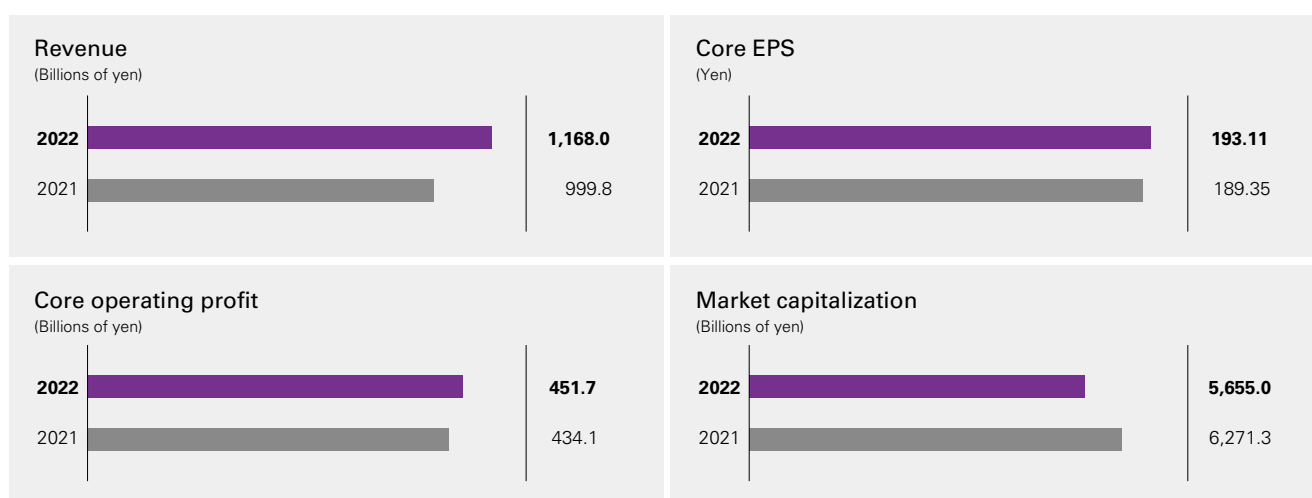
# Themes of the Year

## R&D Results (January 1, 2022 - December 31, 2022)

(Number of projects)



## Financial Performance



## Activity Themes

R&D	<ul style="list-style-type: none"> <li>Steady progress on clinical development of in-house projects such as the mid-size molecule project LUNA18</li> <li>Termination of development on six projects (five Roche projects and one in-house project)</li> <li>Full-scale entry into the ophthalmology field through approval and launch of Vabysmo. Expansion of indications for nine products, including Tecentriq and Hemlibra</li> <li>Construction of new R&amp;D site, Chugai Life Science Park Yokohama, was completed in October 2022</li> <li>Further progress in utilization of AI and digital technology in drug discovery process</li> </ul>
Pharmaceutical Technology and Solutions	<ul style="list-style-type: none"> <li>Completion of manufacturing building for small and mid-size molecule active pharmaceutical ingredients (APIs) at Fujieda Plant (FJ2)</li> <li>Start of digital plant initiatives at Ukima Plant and deployment at other plants</li> <li>Initiation and expansion of new value delivery channels combining in-person and digital formats</li> </ul>
Foundation for Growth	<ul style="list-style-type: none"> <li>Formulation of new HR management policy</li> <li>Acceleration of digital transformation (DX) activities, continuation of listing as a DX Stock in 2022, receipt of DX Grand Prix 2022 Award</li> <li>Continuation of listing in DJSI World, an index of top global companies for environmental, social, and governance (ESG) investment, first place globally in the Pharmaceutical Sector</li> </ul>



# Initiatives

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## Message from the CEO



**We will deliver innovation to patients worldwide and create shared value with society in “advanced and sustainable patient-centric healthcare”.**

**Dr. Osamu Okuda**

Representative Director, President and CEO

### **Ambitious Goals to Become a Top Innovator in the Healthcare Industry**

To help realize advanced and sustainable patient-centric healthcare, Chugai pursues policy goals in support of shared value with society.

To achieve this, our envisioned future for 2030 is to become a top innovator in the field of global healthcare. We built this image from three standpoints: “expectation from patients all over the world,” “attracting talent and players from around the world,” and “role model for the world”. Our ten-year growth strategy to achieve these goals is “TOP I 2030”.

TOP I 2030 promotes two primary targets: to “double R&D output” and “launch in-house global products every year”. There are many diseases and disorders in the world with no established treatment, giving us many important problems to address. As a top innovator, I want Chugai to deliver the kind of innovation only we can produce to patients around the world. One of the ways these goals have taken shape is our aim to be able to deliver one new global product to patients every year. Looking at our results from the past decade, in which we introduced just three new such products – Alecensa, Hemlibra and Enspryng – this is an extremely ambitious goal. We will have to triple our output of global products. To do this, we must increase the success rate of research and development while doubling our previous level of R&D output.

Innovation happens in seeking ways to achieve an ambitious goal. Each division and function is pursuing its own

transformative changes to become a top innovator based on two strategic pillars — “global first-class drug discovery” and “a futuristic business model”. With two years passed since the start of TOP I 2030, we are beginning to see that these goals are achievable, as well as a path that will lead us there.

### **Leveraging Our Original Business Model through Collaboration with Roche for Value Creation**

We believe our unique business model, in strategic alliance with Roche, is a springboard for creating new value. This business model allows us to deliver innovative products from Chugai research to patients worldwide through the Roche sales network, and revolutionary Roche products to patients in Japan, all while maintaining operational independence.

Over the 20 years in partnership with Roche, both our operating profit and total share value have increased roughly 17-fold (as of December 31, 2022), and every business function has evolved. A particular case in point is our drug discovery capabilities. Collaboration with Roche is a precondition for making our innovation available to patients worldwide, so we naturally work to produce world-class innovative drugs, resulting in substantial growth of our drug discovery capabilities. Also, the in-licensing of Roche products secures stable revenue for us, so Chugai researchers can be free to focus their research on their strengths in science and manufacturing. By confirming that a given drug is clinically exhibiting its projected mechanisms of efficacy and building data before moving to human trials for proof of concept,



we have achieved a 100% success rate in phase III clinical testing of products from Chugai research, significantly raising the value of our products in development.

This business model is now well-established at Chugai as it means a great deal to both Chugai and Roche. The global products we out-license are growth drivers for Roche, contributing to value creation for the entire Roche Group. Roche places high value on both our drug discovery and sales capabilities, which are evidenced by our first-place ranking among sales promotion companies<sup>1</sup> in domestic sales.

Chugai and Roche are linked together at multiple levels – committees, business divisions, and teams – and constant collaboration is the foundation for Chugai's growing corporate value. With Roche CEO Thomas Schinecker, who took office in March 2023, we have reconfirmed the effectiveness of our strategic alliance, and we maintain close dialogue on collaborations and strategies for the future.

1. IQVIA Pharmaceutical Market Data, calendar years 2021 and 2022

## 2022: A Year of Wide-Ranging Positive Results and a Sixth Consecutive Record for Profits

In 2022, we steadfastly implemented plans in R&D, products, and business infrastructure, and accomplished a great deal.

In R&D, we began clinical trials on DONQ52 (for celiac disease) and RAY121 (for autoimmune disorder) employing next-generation antibody engineering technology, applied for government approval of four new products, and obtained approval for sales or indication expansions of twelve products including Vabysmo, Polivy, Tecentriq, and Hemlibra. Our first mid-size molecule project, LUNA18, has been making steady progress in phase I clinical trials, as have the projects

that followed. We are also making progress in reforming our operation model through the introduction of various digital technologies, such as the application of real-world data (RWD), and research to increase our accuracy of projected results of human trials.

On the market front, National Health Insurance (NHI) drug price revisions and the impact of generic drugs have affected our business in Japan, but new and core products grew thanks to our entry into new fields and digitally enhanced information provision activities to address the pandemic. In overseas markets, exports of Hemlibra and Actemra to Roche have increased.

Reinforcing the infrastructure of our business, we enhanced our innovation centers and facilities by completing construction of Chugai Life Science Park Yokohama (full operation beginning in April 2023), and the new FJ2 building at the Fujieda Plant, which will produce active pharmaceutical ingredients for small and mid-size molecule drugs. Our DX initiatives are making steady progress through projects in various divisions, including AI-assisted drug discovery and digital plants. RPA, for example, has reduced labor by 150,000 hours in total. This and other DX initiatives were recognized by the industry when Chugai received the "DX Grand Prix 2022" Award<sup>3</sup>. Chugai was also selected for the third consecutive year as a constituent of the Dow Jones Sustainability World Index, the world's leading ESG investment index, and ranked number one in the pharmaceutical sector. I feel that this kind of recognition is wonderful because it did not come from a goal that we set to become number one, but instead comes as a result of the efforts of every Chugai employee, thinking independently about reform themes and embracing the challenge of making those changes happen. For me, this is a great example to illustrate how Chugai is evolving into an autonomous organization.

### "TOP I 2030" growth strategy

TOP INNOVATOR  
**TOPi 2030**

"Double R&D output" "Launch in-house global products every year"

#### Global First-Class Drug Discovery

- Expansion of existing technological bases and building a new technological foundation to materialize unique drug discovery ideas
- Launch in-house global products every year by doubling R&D output
- Acceleration of innovation opportunities by leveraging digital technologies and strengthening collaboration with leading global players

#### Futuristic Business Model

- Dramatic improvement in product/patient value by restructuring business model, having digital utilization as a core
- Improve productivity of entire value chain by leveraging digital technologies
- Commercialization of Insight Business with the aim of maximizing the value of pharmaceuticals and having a new business pillar

**Key Drivers** • DX • RED<sup>2</sup> SHIFT • Open Innovation

2. RED: "Research & Early Development". Research, early clinical development, and pharmaceutical technology functions related to early product development

In 2022, revenue exceeded 1 trillion yen for the first time, and it was our sixth consecutive record-breaking year, with all-time highs for both sales and profits. Our core business did well both in Japan and abroad, and COVID-related drugs Ronapreve and Actemra drove our positive earnings.

Of the challenges before us, what interests me most currently is the results of the recent employee awareness survey, which was last conducted in 2020. In our top-priority area, “employee engagement,” we maintained the average level for top global firms reporting positive results. We know that much remains to be improved, however, in “employee enablement,” where I think fundamental reform is needed. I will explain more about this later.

3. Leading the “Digital Transformation Stocks (DX Stocks) 2022” as selected jointly by the Ministry of Economy, Trade and Industry and the Tokyo Stock Exchange, Chugai won the Grand Prix Award for excellence in DX initiatives.

## Attention to Environmental Risks and Patient Access to Drugs

Looking forward at our prospective business environment, we expect the pressure to reduce healthcare and pharmaceutical costs will accelerate worldwide, while new modalities, such as gene therapy, cell therapy, and digital therapeutics, will continue to diversify. As more patients choose their preferred modes of healthcare and providers further emphasize economic awareness in how they select drugs for their patients, we expect that the trend to choose only those drugs and solutions with clear value will continue to grow.

In terms of current risks, we need to keep a close eye on pharmaceutical price trends not only in Japan, but in the US as well. We must better prepare for geopolitical risks, such as we have seen in US-China relations and the situation in Russia, as well as inflation, which can lead to steep rises in the cost of ingredients and other concerns. In the domestic market, many important issues are coming to the surface. Japan’s delay in developing COVID-19 treatments and vaccines is now seen as a national healthcare security risk. There are concerns about another wave of “drug lag,” with data showing that 72% of drugs approved in Europe and the US were not approved in Japan in the five years up to 2020. This is due to a complex web of factors, including the systems and practices for clinical trials and approvals. Above all else, however, we consider the leading cause to be Japan’s unattractiveness as a market for drug makers from abroad in terms of factors including market scale, growth potential, and government-set prices. This is a serious problem, depriving patients of access to drugs, so we at Chugai plan to actively work to build a drug-pricing system in which innovation is better valued.

## Three Key Drivers on the Road to Sustainable Growth

In TOP I 2030, we are committed to promoting three key drivers: “RED Shift,” a policy to invest heavily in

strengthening our value-creation engine of research and early development (RED); “DX,” for substantial expansion of our drug discovery capabilities and groupwide productivity; and “Open Innovation,” designed to combine our strengths with those of external partners in creating value.

In “RED Shift,” we are working to further evolve technologies for mid-size molecule drug discovery and the next generation of antibody engineering technology while also enhancing our technological base for multi-modality drug discovery. In development, we are striving to increase success rates and early verification of patient QoL measurements by employing digital technologies and organoid research. At the same time, to make this kind of resource investment possible, we are building a futuristic business model through resource generating initiatives such as work-process reforms and cost-structure reviews.

In “DX,” we are accelerating the application of artificial intelligence and the digitalization of pathological analysis in antibody and mid-size molecule drug discovery, starting with MALEXA® technology, which uses machine learning to identify antibody sequences with superior bonding and other optimal characteristics. Also on our drawing board are initiatives to build digital plants for higher productivity, and a new customer engagement model using digital technology. With this new foundation, we are promoting the ASPIRE<sup>4</sup> Program, a joint effort with Roche to develop the next generation of our core business infrastructure, which will enhance our work processes and raise the efficiency of our collaboration with Roche.

Finally, to realize transformation in these rapidly changing fields, we are putting increasing effort into “Open Innovation.” Our goal with multi-modality drug discovery is to combine our proprietary drug discovery technology with new modalities, technologies, and biology from external partners to offer new value to patients. We will accelerate alliances with other companies to help evolve our business infrastructure in DX, pharmaceutical technology, and environmental initiatives as well.

Although our profit growth will likely be affected by the maturing domestic and international markets for Actemra, NHI drug price revisions, and the advancement of generics, we expect our core business both in Japan and overseas will show steady growth. In the short to medium term, in addition to the stable growth of products in-licensed from Roche, we expect Hemlibra and Alecensa to further contribute to revenue while products from Chugai research, including Enspryng, crovalimab, and nemolizumab, will become global growth drivers. In the medium to long term, we are seeing promising drug candidates in the early development phases as well as mid-size molecules/next-generation antibodies in non-clinical testing that will be new growth drivers as they become marketed products and grow. By renovating our core businesses infrastructure and reviewing work processes, we expect to realize major improvements in productivity in the short to medium term.

Furthermore, in TOP I 2030, we will not disclose financial quantitative guidance in consideration of the possibility of erroneous projections caused by rapidly changing business conditions. As such, in order for our shareholders and investors to accurately analyze and evaluate our businesses, we will thoroughly disclose information including the progress of each strategy as three- to five-year medium-term milestones, as well as R&D and ESG initiatives which will have a significant impact on medium- to long-term corporate value.

4. A business and digital transformation program to implement cutting-edge, global standardization processes and the next generation of Enterprise Resource Planning across the Chugai Group.

## Generating Innovation from Diversity

The top priority in Chugai's value-creation effort remains the pursuit of innovation. The beating heart of that, as I have said many times, is our belief that "in the end, it's our people."

In TOP I 2030, we are promoting work-satisfaction reforms in "employee engagement" and "employee enablement" for our spontaneous and proactive employees to feel even more fulfilled at work. We are focusing on groupwide optimization of resources, fundamental work-process reforms, and career-building assistance for employees to address challenges in "employee enablement" revealed in the results of our 2022 employee awareness survey.

An important theme in promoting such innovation is diversity. Innovation is borne out of employees with diverse experiences, knowledge, and values contributing ideas and participating in healthy exchanges of opinion with respect to each other's differences. Chugai began addressing D&I as an important management theme in 2010 and has been working to nurture an inclusive corporate culture, in addition to promoting pro-D&I systems, workplace reforms, and employee awareness-raising. These efforts are showing progress – for example, women now account for 35% of our total workforce and 26% of career employees (Chugai and its affiliates in Japan). However, further acceleration is needed – we will increase diversity in all levels of the company, including directors, and prioritize dialogue and collaboration with external partners to actively absorb different senses of value. To increase gender diversity, we have set a goal to raise the percentage of women in all roles to equal the overall percentage of women in our workforce by the end of 2030. To achieve this, we are working to increase the visibility of all aspects of our employees and help them grow while improving their work environments.

The key to bringing out diversity and realizing innovation is a sense of ownership. Employees are able to design their own careers and boldly rise to whatever challenges may come their way when they can display leadership and work actively and with autonomy. I am proud of the aforementioned premier recognition that Chugai has received from external organizations for its achievements in ESG and digital transformation, and I want to spread our culture of evolution via ownership throughout the company.



## Chugai Contributes to Society and Patients in Ways that No one Else Can

Our top-priority core value is being "Patient Centric." We conduct various surveys and interviews to understand patient needs, and hold active dialogues with patient organizations. I participate in a dialogue every year as well to talk with patients in person. To address the challenges raised in our dialogues, we are implementing specific measures including "PHARMONY," a new initiative to include patient opinions from the early stages of drug discovery, and improving systems to make information on drugs and clinical trials more accessible to patients. However, Chugai cannot resolve such issues on its own – shared ownership and cooperation with government organizations, legal authorities, medical institutions, academia, and our peers in the pharmaceutical industry is essential. Shared intent among all stakeholders in collaboration is commonly needed to resolve any social issue, from public health to environmental preservation and the protection of human rights. Based on this kind of shared intent, all stakeholders must accept their respective share of responsibility and contribute to solutions. So how should Chugai contribute?

We should be ahead of others in making proposals and initiating collaboration, of course. I think it is important to lead by example, sharing specific examples through concrete measures. We can accomplish a great deal in innovative drug discovery and ESG initiatives, even if we are not on the same scale as a "mega pharma." Simply put, we want to continue generating innovative new drugs and provide value to society by stepping up efforts to address ESG initiatives in ways that make us a role model for the world at the level expected of a top innovator. This is our envisioned future for 2030 – a company in which employees, industry players, other companies, and patients all invest high hopes.



# History of Value Creation

From foundation to 2000

**1925**

Founded in response to shortages of medicine in Japan

**Since 1930s**

Import and sales of drugs

Manufacturing and sales of over-the-counter (OTC) drugs

**Since 1960s**

Shift to prescription pharmaceuticals

Developed research strengths

**Since 1980s**

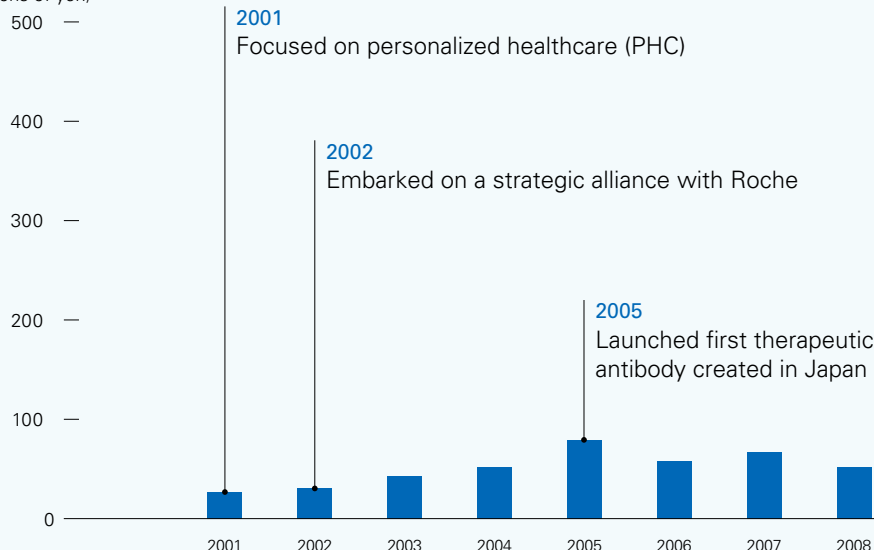
Stepped up development and marketing of drugs from Chugai research

Focused on research into biopharmaceuticals

2001

Operating profit between 2001 and 2022<sup>1</sup>

(Billions of yen)



Evolution of discovery technology

Mid-size molecules  
Antibody


Technologies to create best-in-class antibodies<sup>2</sup>

Effect of strategic alliance with Roche

Chugai was founded in 1925 in response to the shortage of medicine after the Great Kanto Earthquake. It has continued since then to change its business model in step with changes in the management environment. In 2002, Chugai decided to enter a strategic alliance with Roche, a world-leading pharmaceutical company, in order to focus on accelerating innovation and contributing to patients around the world. Under our unique business model, we have driven growth in Japan through products in-licensed from Roche, which provide stable revenue. Backed by this revenue source, we have also focused on drug discovery research for the creation of innovative new drugs. Chugai has also taken its research and development to world-class levels, refining antibody engineering technologies and other unique drug discovery

technologies and receiving breakthrough therapy designation for a total of nine projects. In the 20 years since the alliance was forged, the Company has achieved rapid global growth in sales, profits, and market capitalization by delivering these products from Chugai research via the Roche network to patients around the world. In its recent business plans, the Company has continued to achieve steady results, and in 2019, it declared that it would work toward advanced and sustainable patient-centric healthcare based on the creation of shared value. In 2021, the Company defined a specific strategy aimed at becoming a top innovator in the healthcare industry in 2030. Chugai is pursuing the TOP I 2030 growth strategy to achieve this goal.

1. The fiscal year ended December 31, 2003 is the financial results for a nine-month period. For 2012 and earlier years, the Company applied JGAAP, and from 2013 onward it has applied IFRS on a Core basis.

 For Core basis results, please refer to "Financial and Pre-Financial Highlights (IFRS)" on page 78.

2. With such attributes as improved stability and pharmacokinetics profile, or reduced immunogenicity

3. Such as bispecific antibodies, recycling antibodies, sweeping antibodies, or T-cell redirecting antibodies (TRABs)

4. Such as switch antibodies, next-generation TRABs, LINC-Ig, or PAC-Ig

2010

2022



Technologies to target intracellular tough targets

Technologies to create antibodies with unique mode of action<sup>3</sup>Technologies to confer diseased tissue or cell specificity<sup>4</sup>

Technologies to expand site of action

In-licensing Roche products in Japan (eliminate drug lag and ensure stable revenue source)

Utilization of Roche's network (global growth of in-house products)

Collaboration on various functions, such as utilization of research infrastructure

**20th anniversary of alliance**

〈Compared to before alliance〉

- Revenue: 7.1 times
- Operating profit: 16.9 times
- Market capitalization: 16.9 times

**Previous Mid-Term Business Plans**

From 2008 to 2012

**Sunrise 2012**

Formulation and launch of the "top pharmaceutical company" goal

**Results and issues**

- Established high profitability
- Continuous stream of in-house candidates into clinical development
- Developed and established proprietary antibody engineering technologies
- Promoted PHC

From 2013 to 2015

**ACCEL 15**

Prepare the foundation for achieving the "top pharmaceutical company" goal

**Results and issues**

- Product growth exceeding market average
- Global development of products from Chugai research
- Strengthened R&D structure
- Enhanced functions for providing solutions

From 2016 to 2018

**IBI 18**

Realization of the "top pharmaceutical company" goal

**Results and issues**

- Achieved record-high results
- Continuously created therapeutic antibody projects and enhanced the mid-size molecule drug creation technology platform
- New products approved, prepared to accelerate growth
- Created a structure for providing solutions by region

From 2019 to 2020

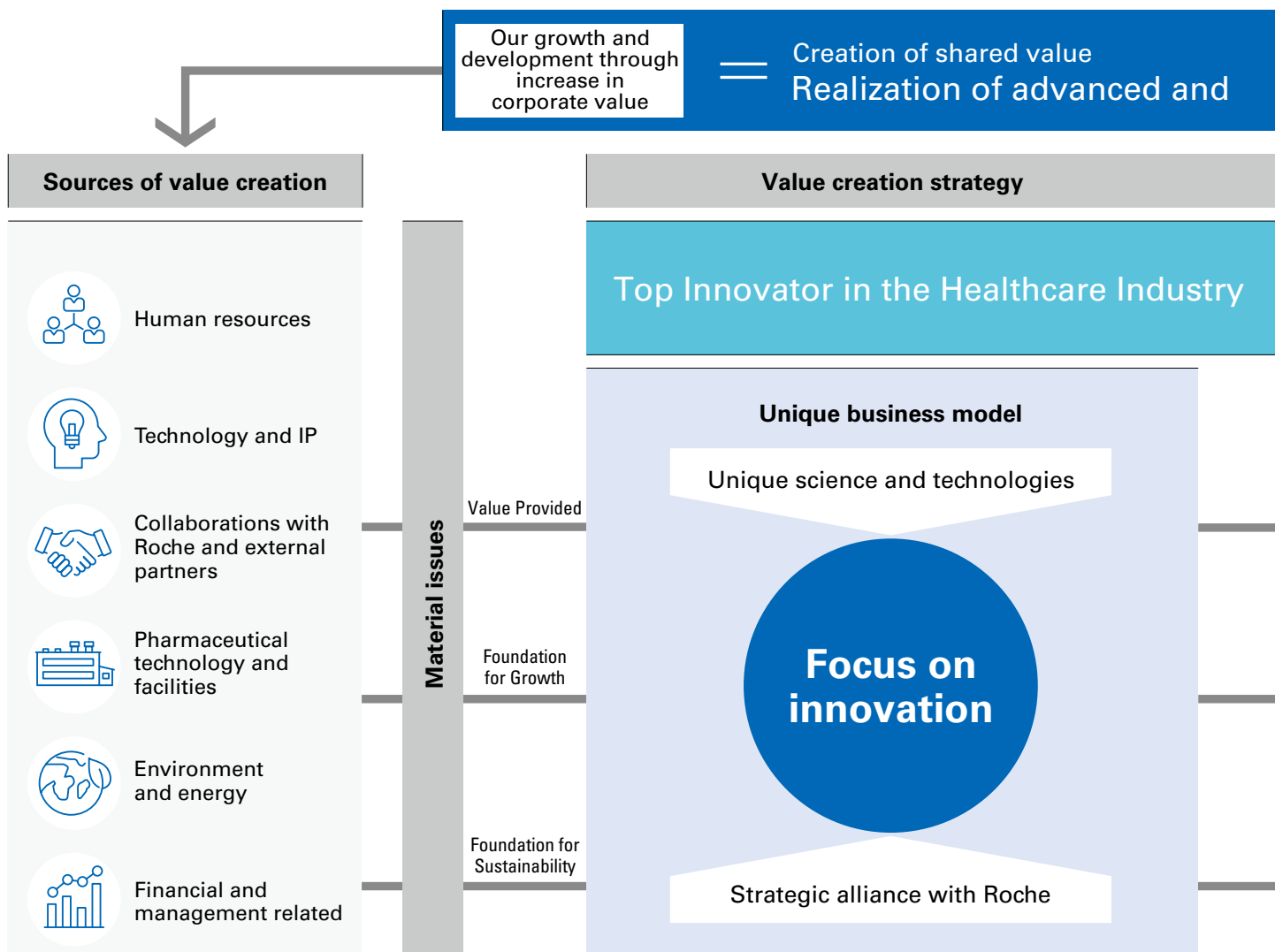
**IBI 21**

Creating shared value through innovation

**Results and issues**

- Reached targets in two years, completed plan one year ahead of schedule
- Global growth of products from Chugai research, domestic growth of new products
- Made steady progress with in-house drug discovery themes including mid-size molecules
- Further development of products from Chugai research
- Enhanced the foundation for growth, including human resources and digital infrastructure

# Value Creation Model



## Management Resources and Material Issues for Realization of Advanced and Sustainable Patient-Centric Healthcare

Chugai has adopted “creating shared value” as its basic management policy, in line with the philosophy of growing together with its various stakeholders by resolving social issues through business activities. The goal of this shared value, which is also part of our Envisioned Future, is to realize advanced and sustainable patient-centric healthcare. Now, we are realigning the flow of value creation and reviewing our value creation model in order to foster a deeper understanding of this position on value creation in and outside Chugai.

The external environment that we have envisaged is one where more sustainable healthcare systems are needed around the world due to global population growth and demographic aging, as well as the spread of COVID-19. Dramatic advances in life sciences and digital technology are expanding business opportunities, but governments are implementing more and more stringent policies to curb medical expenditures, including drug costs. Given the limited resources available, we expect the medical community to

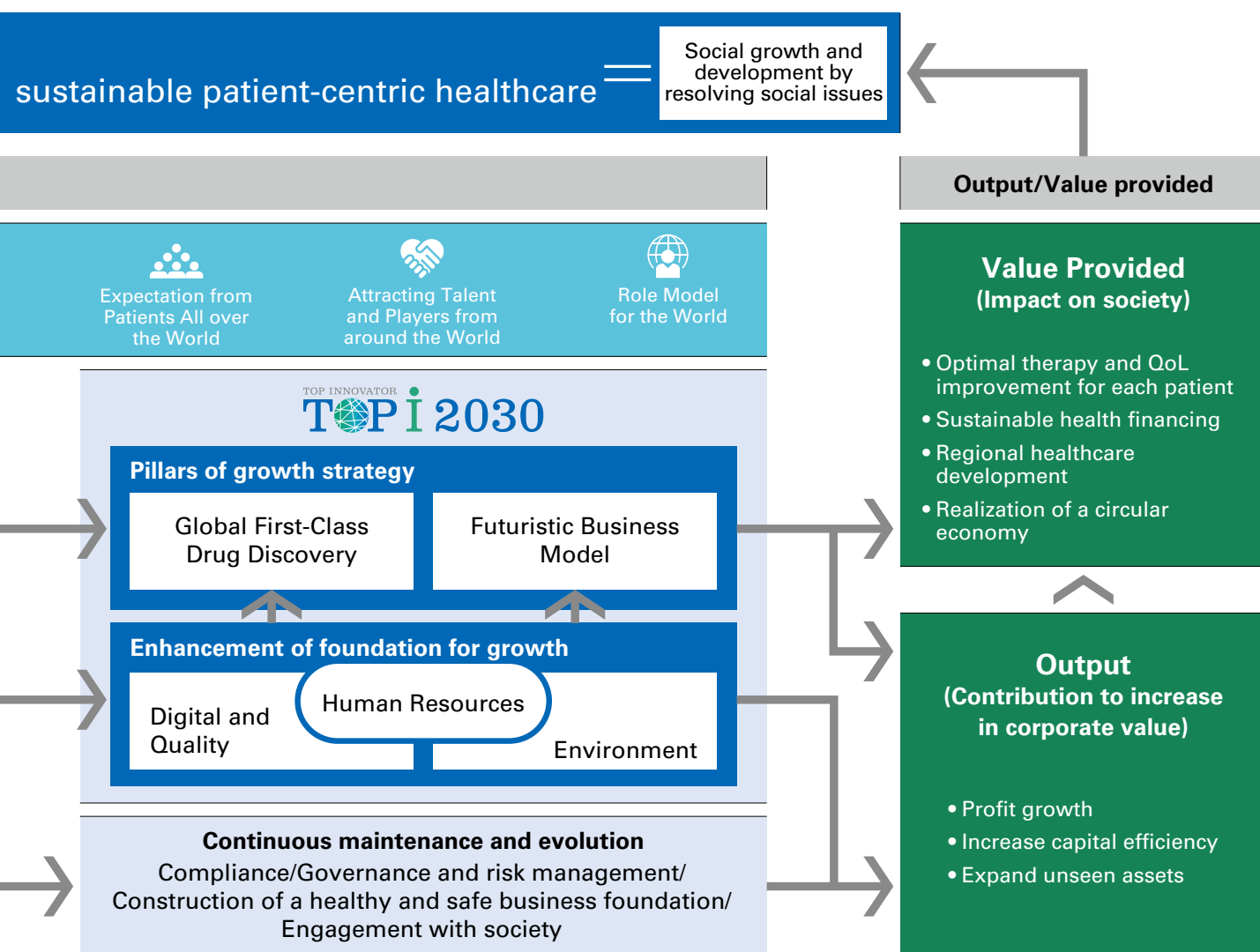
converge even faster on value-based healthcare (VBHC), where only those solutions that deliver true value are adopted. [See “Business Environment Recognition” on page 22.](#)

Based on this environmental outlook, Chugai has determined a policy for investing management resources such as human resources, technology and intellectual property, collaborations with Roche and external partners, pharmaceutical technology and facilities, environment and energy, and financial and management related. Guided by our material issues for creating shared value, we will promote initiatives for value creation (value creation strategy) taking a medium- to long-term view. We have organized our material issues into matters that should be focused on toward the realization of advanced and sustainable patient-centric healthcare, under our basic management policy of creating shared value. [See “Sources of Value Creation” on page 26 and “Material Issues” on page 27.](#)

## Be a Top Innovator in the Healthcare Industry to Create Shared Value

Focus on innovation will continue to be key to promoting our value creation strategy. To continuously create innovative





new drugs that satisfy unmet medical needs, we must explore new therapeutic targets, achieve further innovation in drug discovery technologies, and acquire a deeper understanding of biology. It is therefore important to make maximum use of our unique business model, which is based on our unique science and technology capabilities and our strategic alliance with Roche.

In designing our value creation strategy, we started by defining our vision of becoming a top innovator in the healthcare industry in 2030. Chugai needs to be a company that generates expectations from patients all over the world, attracts healthcare-related talent and players, and is a global role model that resolves social issues. TOP I 2030 is our roadmap for realizing this goal by enhancing our growth strategy and foundation for growth. To enhance the value we provide, we have formed a business structure that enables high productivity and reinvestment based on the two pillars of global first-class drug discovery and a futuristic business model. With this, we aim to double R&D output and launch in-house global products every year. To realize this, we will enhance our foundation for growth by implementing initiatives targeting key themes including human resources and organizations, digital and quality, and environmental

preservation. The areas of compliance, governance and risk management, construction of a healthy and safe business foundation, and engagement with society are not items for transformation under TOP I 2030. Rather, we will continuously maintain and evolve these throughout the Company and in each business division.

See "Overview of TOP I 2030" on page 24.

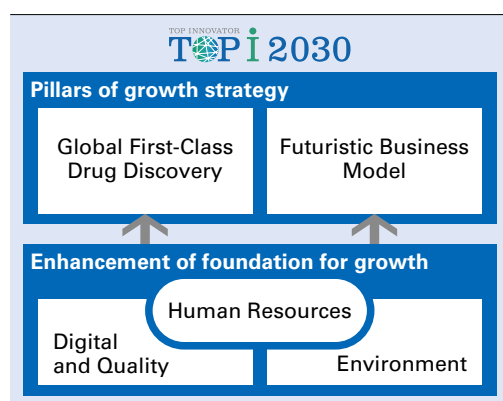
Through the promotion of this strategy, Chugai will create innovative drugs that deliver true value and continuously supply them to patients worldwide. With this, we aim to realize a healthcare system and society where each patient can receive optimal treatment, while also achieving financial growth for the Company. We will increase our capital efficiency by building a robust earning structure and reducing risk so that we can continue to deliver R&D results over the medium to long term. In addition, we will enhance the quality of our management foundation in order to contribute to the realization of a circular economy in response to climate change and resource and energy issues.

See "Creation of shared value" on page 23.

# Value Creation Indicators

We use a wide range of indicators to check on the progress and results of our strategies for value creation and share them inside and outside the company. Previously we had organized the relationships between financial indicators and business activity indicators (pre-financial indicators) for drivers of corporate value increase. With the revision of our value creation model, we have reorganized the key indicators for value creation. Here, we have categorized these as performance indicators in the value creation strategy of our value creation model, output indicators that contribute to financial corporate value increase, and outcome indicators that measure our impact on society.

## Performance Indicators



In our value creation strategy, we have set goals under TOP I 2030 of “doubling our R&D output” and “launching in-house global products every year,” as well as establishing medium-term milestones for each strategy and confirming our progress. Medium-term milestones include both quantitative and qualitative targets. Now, to show our progress toward our vision under TOP I 2030, we have organized our performance indicators as follows, according to their strategic perspectives.

For details of strategic targets and medium-term milestones, please refer to the “Progress” section on page 32. In particular, we have provided detailed information about human resources on page 48 and the environment on page 52.

	Indicator perspective	Indicators	2022 actual
Target	Increase R&D output	In-house projects that progressed to preclinical phase	0
		In-house projects that acquired PoC	0
		Projects that advanced to phase III clinical trials	7
		Applications filed for approval	4
		New products launched and new indications	12
	Launch in-house global products every year	In-house global products out-licensed	1
		In-house products launched globally	0
Global first-class drug discovery	(Foundation) Technology and research foundation	Academic papers and presentations on research findings at scientific conferences	82
		Patent applications filed (antibody/mid-size molecule)	16/16
		Projects from Chugai research	85 and above
Futuristic business model	(Quality) Productivity	Operating profit per employee (Core)	¥58.13 million
	(Quantity) Patient value and product value	Customer satisfaction evaluation <sup>1</sup>	No.1
	(Foundation) Investment	R&D expenses (Core)	¥143.7 billion
		Capital investment	¥61.8 billion
Human resources	Overall	Employee engagement indicator <sup>2</sup>	100
		Employee enablement indicator <sup>2</sup>	89
		Fill rate for highly competent specialists	68%
	Engagement & collaboration	Ratio of female managers/female managers with subordinates	17.8% / 15.9%
Digital and quality	Digital	In-house digital human resources <sup>3</sup>	367
	Quality	Pharmaceuticals/medical devices audits	176
		Regulatory inspections	17
Environment	Climate change countermeasures	Scope 1+2 CO <sub>2</sub> emissions reduction	62.2 thousand metric tons
		Scope 3 CO <sub>2</sub> emissions <sup>4</sup>	2,251.2 thousand metric tons

1. INTAGE Healthcare “Rep-i August 2022 Survey” (reprint prohibited); based on survey results for an overall company assessment targeting only physicians according to Chugai’s definition  
2. Chugai’s status where the score of companies with strong global performance is 100 (positive response)  
3. Number of resources who have acquired Chugai’s Digital Project Leader/Data Scientist certification  
4. Calculated based on the method certified by SBTi

## Output Indicators

### Output (Contribution to increase in corporate value)

- Profit growth
- Increase in capital efficiency
- Expansion of unseen assets

Our output indicators that have a direct impact on increasing corporate value take three perspectives. These are “profit growth” for maintaining and increasing top-line growth and profitability, “increase in capital efficiency” by increasing the efficiency of invested capital and reducing the cost of capital, and “enhancement of unseen assets” through human capital, intellectual capital, and ESG evaluation.

Moreover, while all of the indicators also place an emphasis on short-term financial results, they are basically for managing with a view to medium- to long-term growth.

	Indicator perspective		Indicator proposal	2022 result
Corporate value impact	Profit growth	<ul style="list-style-type: none"> <li>• Creating innovative new drugs</li> <li>• Provision and expansion of product value</li> </ul>	Total net sales of products from Chugai research (Japan + overseas exports)	¥555.8 billion
			Overseas revenue ratio	43.7%
			Global sales of products from Chugai research	¥1,183 billion
		<ul style="list-style-type: none"> <li>• Increase in added value / Securing of investment resources</li> </ul>	Core operating profit	¥451.7 billion
			Core EPS CAGR	2.0%
	Increase in capital efficiency	<ul style="list-style-type: none"> <li>• Increase in efficiency of invested capital</li> </ul>	Core ROIC	36.1%
			Ratio of Core operating profit to revenue	38.7%
	Expansion of unseen assets	<ul style="list-style-type: none"> <li>• Improvement of ESG evaluation</li> </ul>	Selection for DJSI World Index	Selection as global No. 1 in pharmaceutical sector
			Selection for GPIF's ESG Index for Japanese Equities	Selected for all five

## Outcome Indicators

### Value Provided (Impact on society)

- Optimal therapy and QoL improvement for each patient
- Sustainable health financing
- Regional healthcare development
- Realization of a circular economy

Outcome indicators are intended as indicators representing the value created toward the shared value creation goal of “realization of advanced and sustainable patient-centric healthcare.” Currently, in addition to indicators for in-house monitoring, we are continuing to examine outcome indicators based on expectations and demands from society. For example, we place importance not only on the effect of drugs measured with conventional endpoints such as treatment results by illness and treatment continuation rates, but also on QoL and healthcare economics. We will research various parameters and aim to clarify endpoints with the goal of establishing true endpoints that can measure effects that constitute true value for patients.



## Business Environment Recognition

Change in the Market	Change in Science & Technology	Change in Customers
<ul style="list-style-type: none"> <li>Increasing fiscal pressures around the world, acceleration of controls on drug costs, and continued shift to value-based healthcare (VBHC)</li> <li>United States is a market driver, with China becoming increasingly important</li> </ul>	<ul style="list-style-type: none"> <li>New modalities will not compete against pharmaceuticals but play a complementary role</li> <li>Digital technologies will become a key requirement for business model evolution and competitive advantage</li> </ul>	<ul style="list-style-type: none"> <li>Increased influence of informed patients and payers*</li> <li>Evolution of DX at customers</li> <li>Difficulties in transforming healthcare into an information-based industry</li> </ul>

At Chugai we have conducted medium- to long-term scenario analyses as a prerequisite to our value creation strategy, with changes anticipated in the market, science and technology, and customers through 2030, as well as business possibilities based on these changes, summarized in the diagram above.

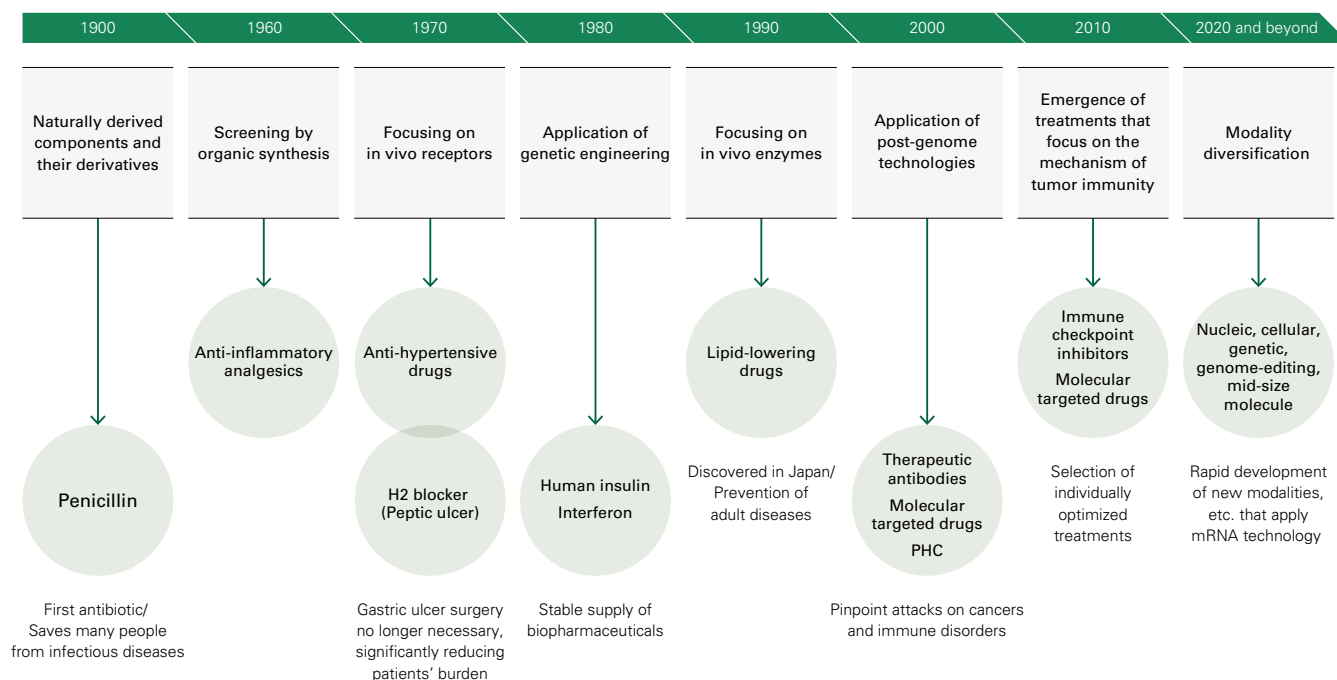
Until now, drug treatment worldwide has typically progressed in step with scientific progress itself. In particular, the explanation of disease mechanisms within the body and the development of recombinant technology and genomic analysis have sparked the discovery of a wave of innovative drugs, among them molecular targeted drugs and immune checkpoint inhibitors. Nevertheless, in the healthcare industry going forward, measures to contain drug costs are likely to accelerate around the world because of fiscal pressures from the impact of population growth, demographic aging, or COVID-19, for example. Consequently, we are entering an era when only products or solutions that offer true value will succeed. In addition, informed patients and payers will have

an increasingly important presence, as we are starting to see already through payers moving to merge and expand business scope. More than ever, it is critical that we demonstrate value to patients in terms of QoL and lifetime value. Cell therapies, nucleic acid drugs, and other new modalities need to be developed alongside existing pharmaceuticals in a mutually complementary fashion, and we need to embrace DX to evolve each value chain, including drug discovery, and restructure customer engagement models.

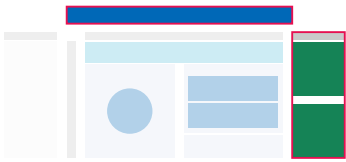
In light of this outlook, we believe that innovative drug discovery as our core business remains unchanged, and that Chugai must continue providing value across society and meeting the expectations of patients and other stakeholders through innovation that creates new treatments and the continued evolution of technologies and platforms.

\* Organizations that provide funds to cover healthcare costs based on fixed contracts and using revenue from insurance premiums

## Evolution of Drug Therapy



# Creation of Shared Value



Output (Contribution to increase in corporate value)	
<b>Profit growth</b>	<ul style="list-style-type: none"> <li>• Creation of innovative new drugs</li> <li>• Provision and expansion of product value</li> <li>• Increase in added value and securing of investment resources</li> </ul>
<b>Increase in capital efficiency</b>	<ul style="list-style-type: none"> <li>• Increase in efficiency in invested resources</li> <li>• Reduced cost of capital and reduced risk</li> </ul>
<b>Expansion of unseen assets</b>	<ul style="list-style-type: none"> <li>• Increase in human and intellectual capital</li> <li>• Improvement of ESG evaluation</li> </ul>

Value Provided (Impact on society)	
<b>Patient- and healthcare-related</b>	<ul style="list-style-type: none"> <li>• Improvement of drug efficacy and safety</li> <li>• Improvement of QoL</li> <li>• Treatment tailored to each individual patient</li> </ul>
<b>Countries, communities, and the environment</b>	<ul style="list-style-type: none"> <li>• Sustainable health financing</li> <li>• Local healthcare development</li> <li>• Global environmental protection</li> </ul>

Under its basic management policy of creating shared value with society, Chugai aims to increase its corporate value by resolving social issues. Chugai's goal is the "realization of advanced and sustainable patient-centric healthcare." By achieving global first-class drug discovery and a futuristic business model through our value creation strategy, and qualitatively strengthening our management infrastructure, we aim to contribute to patients as well as to the healthcare system and society that nurture them. In terms of stakeholders, we look seriously at the impacts of our activities on patients and healthcare, as well as on countries, communities, and the global environment.

Chugai's policy for increasing financial corporate value is to achieve profit growth, increase capital efficiency, and expand its unseen assets. By continuing to create innovative drugs

and deliver products to patients worldwide through Roche's network and other channels, we aim to achieve global growth while also maintaining and strengthening our earnings structure to secure investment resources and realizing powerful profit growth.

Moreover, the most important thing in terms of the value provided by Chugai (social impact) is achieving a better QoL for each patient by ensuring they can receive optimal treatment. Within value-based healthcare (VBHC), we will contribute to sustainable health financing and local healthcare development by providing products and services that offer true value. Meanwhile, we will also contribute to the realization of a circular economy through measures such as reducing our environmental impact and making efficient use of resources.

# Overview of TOP I 2030



“Double R&D output”  
“Launch in-house global products every year”



## Global First-Class Drug Discovery

- Expansion of existing technological bases and building a new technological foundation to materialize unique drug discovery ideas
- Launch in-house global products every year by doubling R&D output
- Accelerating innovation opportunities by strengthening collaboration with leading global players and leveraging digital technologies

## Futuristic Business Model

- Dramatic improvement in product/patient value by restructuring business model, having digital utilization as a core
- Improve productivity of entire value chain by leveraging digital technologies
- Commercialization of Insight Business with the aim of maximizing the value of pharmaceuticals and having a new business pillar

Key Drivers • DX • RED SHIFT • Open Innovation

## Summary of Strategy

Taking into account this business environmental outlook and the progress made with our strategies thus far, the new growth strategy, TOP I 2030,\* is based on two pillars—global first-class drug discovery and a futuristic business model—and includes three key drivers and five reforms to achieve this strategy. Our targets for 2030 are to double R&D output and to become a company that is able to launch innovative in-house global products every year.

\*TOP expresses our aspiration to become “the world’s top innovator, not just in Japan.” The “I” has two meanings: in addition to “innovator,” it also expresses that each and every member of the Chugai Group plays an important role in our efforts to realize TOP I 2030.

## Two Strategy Pillars

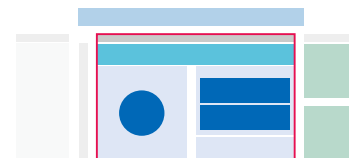
To achieve global first-class drug discovery, we will continue to expand our existing technological bases and establish new

ones, which should allow us to create even more innovative drugs with higher success rates, thereby achieving the quantitative targets described above. To build a futuristic business model, we will utilize digital technologies to fundamentally rebuild our business model in order to secure resources for investing in RED, with the goal of achieving a dramatic increase in productivity across the entire value chain and delivering greater value to patients.

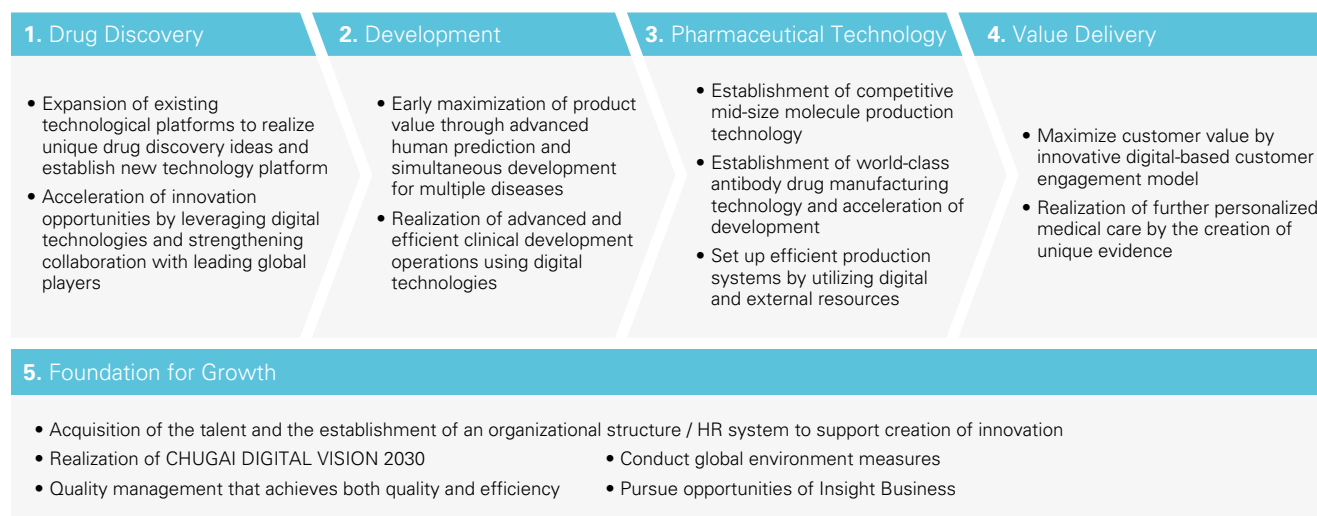
## Three Key Drivers and Reforms in Five Areas

As for the three key drivers, under RED Shift we will focus the resource investments in the processes involved from drug discovery through early development in order to create a continuous cycle of innovation in the future. Under DX, we will enhance our digital infrastructure and improve productivity across all value chains, with the goal of utilizing digital applications for innovative new drug discovery.

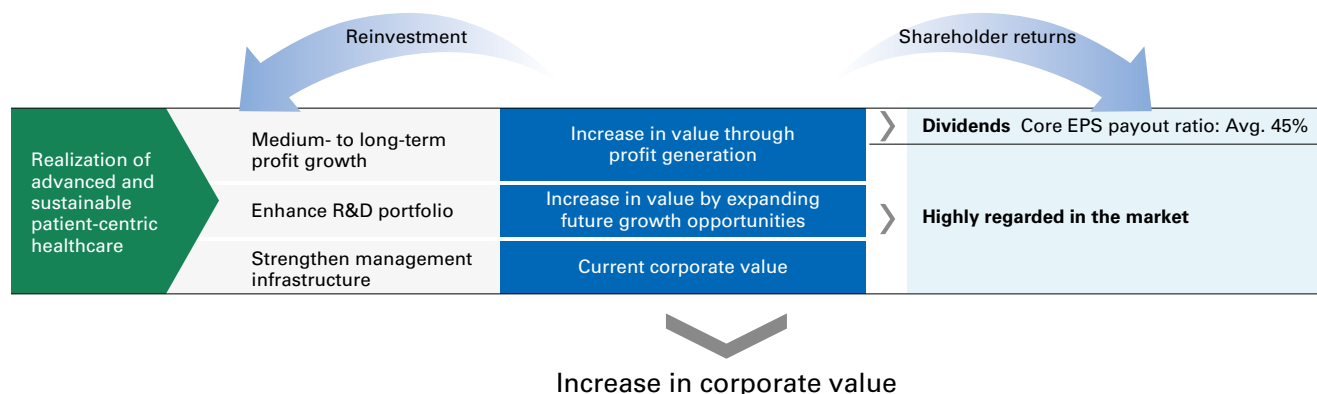




## Five Reforms



## Basic Principles of Increasing Corporate Value and Shareholder Returns



Under Open Innovation, we will step up collaborations with external partners, focus on the application of external technologies, take a flexible approach to the adoption of new advances in science and technology, and work to create new opportunities for innovation.

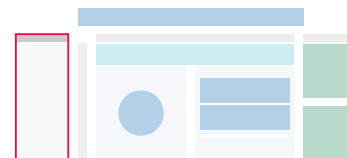
We have formulated plans and set medium-term milestones as medium-term targets for each of our five reforms—drug discovery, development, pharmaceutical technology, value delivery, and growth foundation. These medium-term milestones are targets for the next 3-5 years in accordance with strategy and will be changed and revised as necessary based on environmental changes and progress on strategies.

on Core EPS, taking into account the balance between shareholder returns and the internal reserves necessary for strategic investments aimed at increasing corporate value.

## Shareholder Returns Policy

For shareholder returns, we aim to provide stable dividends with a dividend payout ratio of 45 percent on average based




# Sources of Shared Value Creation



To realize advanced and sustainable patient-centric healthcare, Chugai has organized its key management resources (capitals) as well as the strategic direction for utilizing and investing them (inputs), its current resource shortfalls, and measures for addressing them, as follows.

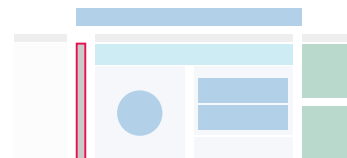
For example, the sources of our most important resource, human resources, are employees and a corporate culture

distinguished by diversity and global top level employee engagement. Important prerequisites include improving job satisfaction and a sense of fulfillment, as well as building capabilities and skills. To enable the future growth of our business results, we need to continuously acquire highly competent specialists and create an environment where each one of them can fully demonstrate their capabilities and play an active role.

Category	Key Theme	Sources of Shared Value Creation <sup>1</sup>	Recognition of Issues and Countermeasures
 Human resources (Human capital)	<ul style="list-style-type: none"> <li>• Increase employees' job satisfaction, improve sense of fulfillment</li> <li>• Acquire and develop human resources and foster a corporate culture that will contribute to continuous innovation</li> <li>• Continuously pursue diversity and inclusion (D&amp;I)</li> </ul>	<ul style="list-style-type: none"> <li>• Employees (overall: 7,771; men: 65%; women: 35%)</li> <li>• Organizational culture (employee awareness survey - employee engagement: top level in global terms; employee enablement: average in global terms)</li> </ul>	<ul style="list-style-type: none"> <li>• Continuous acquisition and development of highly specialized talent</li> <li>• Creation of an environment where each employee can exercise autonomy and be enabled</li> <li>• Maintenance and enhancement of a system and corporate culture that support continuous innovation</li> </ul>
 Technology and IP (Intellectual capital)	<ul style="list-style-type: none"> <li>• Advance multi-modality approach</li> <li>• Expand patents for world-leading, highly competitive drug discovery technology and platforms</li> <li>• Strengthen and expand drug discovery platforms using digital technology</li> <li>• Deepen our understanding of biology research</li> </ul>	<ul style="list-style-type: none"> <li>• Antibody engineering technology and small molecule and mid-size molecule drug discovery technology</li> <li>• Research process library</li> <li>• IP related to research and pharmaceutical technology (number of patents held: 6,578)</li> </ul>	<ul style="list-style-type: none"> <li>• Concentration on R&amp;D investment</li> <li>• External collaboration that complements multi-modality technology</li> <li>• Deepening of understanding of disease biology and external collaboration</li> </ul>
 Collaborations with Roche and external partners (Social capital)	<ul style="list-style-type: none"> <li>• Develop products from Chugai research globally and collaborate via the Roche Group and other networks</li> <li>• Collaborate with cutting-edge companies, academia, and start-ups on technology, science, and DX</li> <li>• Engage in dialogue with various stakeholders</li> </ul>	<ul style="list-style-type: none"> <li>• Exclusive sales rights to Roche products (number of products in-licensed from Roche in the pipeline<sup>2</sup>: 41), infrastructure</li> <li>• Networks with academia (IFReC, the University of Tokyo, National Cancer Center Japan, and overseas research institutions)</li> <li>• Dialogue with patient organizations, patients, investors, and others</li> </ul>	<ul style="list-style-type: none"> <li>• Ongoing substantial contribution to collaboration with Roche (new FIC/BIC drug discovery through Chugai's proprietary technologies, and so forth)</li> <li>• Evolution of systems for collaboration and co-creation with academia, start-ups, and others</li> </ul>
 Pharmaceutical technology and facilities (Manufacturing capital)	<ul style="list-style-type: none"> <li>• Advance research and production suited to continuous modalities, technologies, and digital technology</li> <li>• Develop systems for flexible and rapid development and next-generation production</li> <li>• Ensure stable supply and rigorous quality assurance including evolution of contract manufacturing organization (CMO) management</li> </ul>	<ul style="list-style-type: none"> <li>• Research sites (Yokohama, Ukima, and Singapore)</li> <li>• Production sites (Ukima, Fujieda, Utsunomiya)</li> <li>• Quality management system</li> </ul>	<ul style="list-style-type: none"> <li>• Establishment of systems to keep pace with increasing R&amp;D output</li> <li>• Continuous response to quality and supply risks, and risk reduction</li> </ul>
 Environment and energy (Natural capital)	<ul style="list-style-type: none"> <li>• Contribute to climate change countermeasures and protection of biodiversity</li> <li>• Recycle resources consistent with a circular economy</li> </ul>	<ul style="list-style-type: none"> <li>• CO<sub>2</sub> reduction</li> <li>• Environmental investment</li> <li>• Initiatives to abolish use of SVHC</li> <li>• Environmental management system</li> </ul>	<ul style="list-style-type: none"> <li>• Stable, steady introduction of sustainable electricity</li> <li>• Promotion of best mix of CO<sub>2</sub> emissions, energy, and cost</li> <li>• Development of low-EHS risk manufacturing processes</li> </ul>
 Financial and management related (Financial capital)	<ul style="list-style-type: none"> <li>• Continuously evolve revenue structures</li> <li>• Increase cash flows to ensure a growth trajectory and agile strategic investment</li> </ul>	<ul style="list-style-type: none"> <li>• Earnings structure (Core ROIC 36.1%, ratio of Core operating profit to revenue 38.7%)</li> <li>• Cash position (net cash ¥503.1 billion)</li> </ul>	<ul style="list-style-type: none"> <li>• Continuous reinvestment</li> <li>• Continuous build-up of reputation in capital markets</li> </ul>

1. Apart from certain exceptions, figures are as of December 31, 2022 2. As of February 2, 2023

# Material Issues



## 26 Material Issues across Eight Categories

■ Group classification ■ Category ● Material Issue

Value Provided		
Sustainable Healthcare		
<ul style="list-style-type: none"> <li>Creation of innovative drugs and services</li> <li>Quality assurance and stable supply of products</li> </ul>	<ul style="list-style-type: none"> <li>Provision of solutions for patients</li> <li>Fair marketing</li> </ul>	<ul style="list-style-type: none"> <li>Adverse event management</li> <li>Fair pricing</li> </ul>
Environment	Society	Governance
<b>Global Environment</b> <ul style="list-style-type: none"> <li>Climate change countermeasures (energy, etc.)</li> <li>Use of renewable/recycled resources (water, waste, etc.)</li> <li>Protection of biodiversity (environmental burden mitigation)</li> <li>Environmental management system</li> </ul>	<b>Human Rights</b> <ul style="list-style-type: none"> <li>Human rights</li> <li>Safety of clinical trial subjects</li> </ul> <b>Human Resources</b> <ul style="list-style-type: none"> <li>Employee job satisfaction</li> <li>Development of employee potential</li> <li>Diversity and inclusion (D&amp;I)</li> <li>Employee health and safety</li> </ul> <b>Social Contribution</b> <ul style="list-style-type: none"> <li>Social contribution activities</li> <li>Access to healthcare</li> </ul>	<b>Governance</b> <ul style="list-style-type: none"> <li>Corporate governance</li> <li>Risk management</li> <li>Disclosure and engagement</li> <li>Personal information protection and information security</li> </ul> <b>Ethics and Compliance</b> <ul style="list-style-type: none"> <li>Compliance</li> <li>Code of conduct</li> <li>Fair transactions</li> </ul> <b>Supply Chain Management</b> <ul style="list-style-type: none"> <li>Supply chain management</li> </ul>

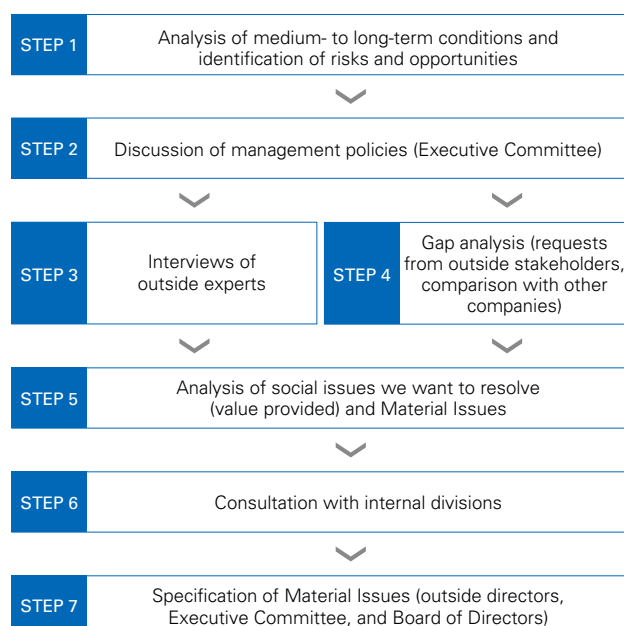
## Positioning of Material Issues

Under a basic policy of creating shared value with stakeholders, Chugai has identified Material Issues that should be given priority toward the realization of advanced and sustainable patient-centric healthcare. Chugai first identified its Material Issues in 2019, following the process shown on the right. We identified a comprehensive list of expectations and requirements of society, based on a future business environmental outlook and its analysis and by examining and referring to the SDGs, Global Reporting Initiative (GRI), and Sustainability Accounting Standards Board (SASB) reports. 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. Material Issues are an integral part of our management strategy. They provide a compass for appropriate and steady strategy development in all areas of Chugai's business activities. We will update them in the most appropriate manner from time to time in light of progress with our strategies and requirements from society.

## Verifying and Reassessing Material Issues

We periodically review and verify Material Issues against the business environment and external expectations and requirements, as well as the progress of our strategies and so forth. In 2022, we updated our Material Issues by changing "occupational health and safety" to "employee health and safety." This is to clarify our policy on maintaining

and increasing employee health, since each individual's health and safety is important given the extreme importance of individual employee contributions to realizing our ambitious strategy, TOP I 2030. We will continue to review the Material Issues periodically, focusing on external trends and feedback from external dialogue.



## Relationship between Management Resources, Material Issues, and Strategy

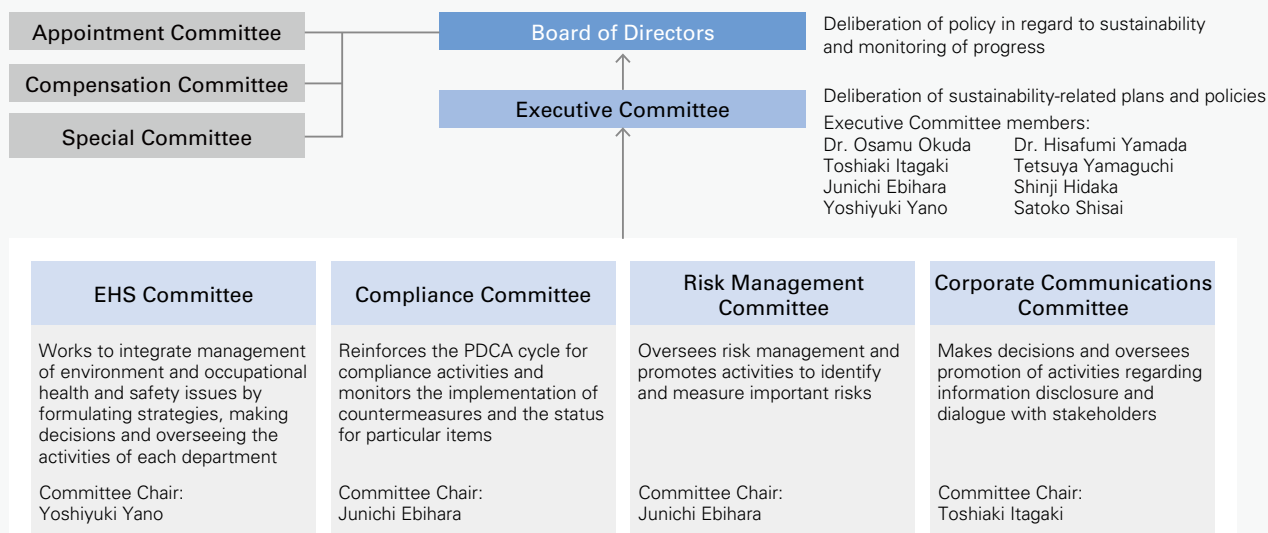
The table below arranges the 26 Material Issues for incorporation into management strategy and business activities based on our approach to utilizing management resources (capital) and to investing resources. The Material Issues can be categorized into six issues for increasing and

expanding “value provided,” along with eight issues for refining and enhancing the “foundation for growth” and 12 issues requiring continuous efforts to ensure sustainable business activities. Under TOP I 2030, we have focused on a “growth strategy” and “enhancement of the foundation for growth,” and are also working toward Material Issues for ongoing maintenance and evolution.



\*See the next section (page 29) for corresponding Material Issues

## Column Framework for Promoting Sustainability

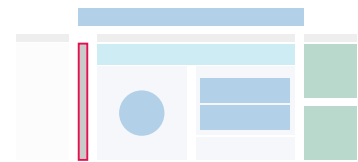


The Chugai Group views sustainability as the sustainable development of both our company and society. We consider it important to take a unified company-wide approach to promoting sustainability, and our strategies, progress, activities and so forth are deliberated and decided on by the Board of Directors, the Executive Committee, and the Corporate Management Committees.

Representative Director, President & CEO Dr. Osamu Okuda, who is the chair of the Board of Directors and the Executive Committee, is responsible for overall sustainability. Responsibility for execution is held by the eight members

of the Executive Committee. Four advisory bodies (the EHS Committee, Compliance Committee, Risk Management Committee, and Corporate Communications Committee) deliberate specific matters within their field of expertise, and then the Executive Committee deliberates and approves plans and policies. Executive Vice President Yoshiyuki Yano chairs the EHS Committee, and Executive Vice President Junichi Ebihara chairs both the Compliance Committee and the Risk Management Committee. Director, Executive Vice President and CFO Toshiaki Itagaki, who chairs the Corporate Communications Committee, has overall responsibility for ESG communications.





## Policy on Material Issues

Category	Material Issues	Policy	Main Initiatives in Value Creation Strategy
Sustainable Healthcare	① Creation of innovative drugs and services	Create innovative drugs	Acquisition and development of highly specialized human resources to support the creation of innovative drugs, expansion in the number of in-house projects, increase in success rates, initiatives for new modalities, increase of intellectual capital
	② Provision of solutions for patients	Realize patient-centric healthcare	Improvement of QoL, realization of healthcare offering selection of individually optimized treatment
	③ Adverse event management	Perform appropriate pharmacovigilance activities and promote proper drug use	Establishment of advanced safety evaluation/information provision system including use of biomarkers
	④ Quality assurance and stable supply of products	Ensure quality and stable supply of products and services	Pursuit of productivity and maintenance and advancement of global stable supply system
	⑤ Fair marketing	Marketing in compliance with national guidelines	Improvement of the marketing system and provision of solution according to the actual medical practice in each country
	⑥ Fair pricing	Pricing that reflects drug and service value	Obtaining fair consideration for innovation, acquisition of health insurance coverage
Global Environment	⑦ Climate change countermeasures (energy, etc.)	Minimize impact on global environment (Targets set in Mid-Term Environmental Goals 2030)	Coordination with external stakeholders, achievement of targets set in Mid-Term Environmental Goals 2030
	⑧ Use of renewable/recycled resources (water, waste, etc.)		
	⑨ Protection of biodiversity (environmental burden mitigation)		
	⑩ Environmental management system	Third-party assurance of performance data	Selection of appropriate third-party assurance indicators and acquisition of assurances
Human Rights	⑪ Human rights	Respect human rights of all persons involved in business	Rigorous observance of Chugai standards for suppliers and due diligence
	⑫ Safety of clinical trial subjects	Conduct clinical trials under high ethical and scientific standards with safety	Development of internal regulations in compliance with relevant laws, and cooperation with patient organizations
Human Resources	⑬ Employee job satisfaction	Improve employee engagement and create an environment for employee enhancement	Improvement of employee engagement and initiatives to maximize employee independence
	⑭ Development of employee potential	HR recruitment and training to realize strategic targets and accelerate innovation	Promotion of independent learning
	⑮ Diversity and inclusion (D&I)	Create new value through diverse talents	Promotion of diversity and inclusion (D&I)
	⑯ Employee health and safety	Maintain and enhance safe workplace environment and employee health	Promotion of EHS activities and health and productivity management
Social Contribution	⑰ Social contribution activities	Develop networks in key areas	Promotion of activities in five key areas
	⑱ Access to healthcare	Improve access to healthcare including drug development	Active cooperation in international joint funds and domestic and international NPOs and NGOs, increase of access to healthcare
Governance	⑲ Corporate governance	Realize sustained growth and increased corporate value	Introduction of various stakeholders' perspectives, securing the rights and equality of shareholders and improving the effectiveness of the Board of Directors
	⑳ Risk management	Perform risk assessment and evaluate responses	Integrated management of whole company-level risks, and execution of countermeasures according to risk appetite policies
	㉑ Disclosure and engagement	Earn market trust through appropriate information disclosure	Continuous selection for inclusion in major ESG indexes, appropriate communication with stakeholders such as investors
	㉒ Personal information protection and information security	Thorough risk management for all types of information held, including personal information	Construction of an information management system in cross-border transactions
Ethics and Compliance	㉓ Compliance	Appropriately manage compliance risks	Compliance monitoring and improvement of the effectiveness of countermeasures, continued implementation of quality awareness-building activities
	㉔ Code of conduct	Promote understanding and awareness of the Chugai Group Code of Conduct (CCC)	Promoting internal comprehension and awareness raising of standards
	㉕ Fair transactions	Ensure compliance with trading laws and regulations and build fair and transparent business relationships	Management of bribery risk and continuous evolution of procurement process
Supply Chain Management	㉖ Supply chain management	Perform comprehensive supplier evaluation	Construction of supplier management system covering the entire supply chain

# Executive Officers (As of April 1, 2023)

## Top Executives and Executive Officers in Their Area of Responsibility



**Dr. Osamu Okuda**

Representative Director,  
President & CEO  
Supervisory responsibility for Corporate Planning,  
Partnering, External Affairs, and Audit  
In charge of Partnering Dept., External Affairs  
Dept., and Audit Dept.



**Dr. Hisafumi Yamada**

Director, Executive Vice President  
Supervisory responsibility for Project & Lifecycle  
Management (R&D), Research, Translational  
Research, Clinical Development, Pharmaceutical  
Technology, and Manufacturing Technology



**Toshiaki Itagaki**

Director, Executive Vice President & CFO  
Supervisory responsibility for Finance &  
Accounting, Corporate Communications,  
and Procurement



**Tetsuya Yamaguchi**

Executive Vice President  
Supervisory responsibility for Project & Lifecycle  
Management (Marketing), Drug Safety, Medical  
Affairs, and Foundation Medicine  
Head of Project & Lifecycle Management Unit  
and Head of Foundation Medicine Unit



**Junichi Ebihara**

Executive Vice President  
Supervisory responsibility for Legal, Intellectual  
Property, General Affairs, Risk Management,  
Compliance, and Quality & Regulatory Compliance  
In charge of Legal Dept., Intellectual Property  
Dept., and General Affairs Dept.



**Shinji Hidaka**

Executive Vice President  
Supervisory responsibility for Marketing & Sales  
Head of Marketing & Sales Div.



**Yoshiyuki Yano**

Executive Vice President  
Supervisory responsibility for Human Resource  
Management and EHS  
In charge of Human Resources  
Management Dept.



**Satoko Shisai**

Executive Vice President  
Supervisory responsibility for  
Digital Transformation  
Head of Digital Transformation Unit

## Membership of Committees

Name	Committees ( ● Chair ■ Participating member)								
	Executive Committee	Enlarged Executive Committee	Corporate Management Committees				RDPM Committees		
			Corporate Communications Committee <sup>1</sup>	Risk Management Committee <sup>2</sup>	Compliance Committee <sup>3</sup>	EHS Committee <sup>4</sup>	Portfolio Management Committee <sup>5</sup>	Strategic Marketing Committee <sup>6</sup>	Digital Strategy Committee <sup>7</sup>
Dr. Osamu Okuda	●	●							
Dr. Hisafumi Yamada							●		
Toshiaki Itagaki			●						
Tetsuya Yamaguchi								●	
Junichi Ebihara				●	●				
Shinji Hidaka									
Yoshiyuki Yano						●			
Satoko Shisai									●
Tsukasa Kusano									
Dr. Kaori Ouchi									
Shinya Takuma									
Dr. Hitoshi Iikura									
Masayoshi Higuchi									
Dr. Tomoyuki Igawa									
Takanori Muto									
Kazuhiko Nishi									

1. Committee members also include the Head of Finance Supervisory Division and the general managers of the following departments: Corporate Communications, Corporate Planning, Finance & Accounting, Risk Management & Compliance, and General Affairs.

2. Committee members also include the general managers of the following departments: Finance & Accounting, Corporate Planning, Corporate Communications, Risk Management & Compliance, and Legal.

3. Committee members also include the general managers of the following departments: Corporate Planning, Legal, Finance & Accounting, Corporate Communications, IT Solution, Risk Management & Compliance, and Procurement.

4. Committee members also include the general managers of the following departments: Corporate Planning, General Affairs, Finance & Accounting, and Corporate Communications.

5. Committee members also include the general managers of the following departments: R&D Portfolio Management, Partnering, Regulatory Affairs, Corporate Planning, and External Affairs.

6. Committee members also include the general managers of the following departments: Regulatory Affairs, Partnering, Marketing & Sales Planning, Corporate Planning, and External Affairs.

7. Committee members also include the general managers of the following departments: Digital Strategy, IT Solution, Science & Technology Intelligence, and Corporate Planning.



**Tsukasa Kusano**

Vice President  
Head of Clinical Development Div.



**Dr. Kaori Ouchi**

Vice President  
Head of Drug Safety Div.



**Shinya Takuma**

Vice President  
Head of Manufacturing Technology Div.  
and Representative Director & President of  
Chugai Pharma Manufacturing Co., Ltd. (CPMC)



**Dr. Hitoshi Iikura**

Vice President  
Head of Research Div.



**Masayoshi Higuchi**

Vice President  
Head of Quality & Regulatory Compliance Unit  
In charge of Risk & Compliance Dept.



**Dr. Tomoyuki Igawa**

Associate Vice President  
Head of Translational Research Div.



**Takanori Muto**

Associate Vice President  
Head of Pharmaceutical Technology Div.



**Kazuhiko Nishi**

Head of Medical Affairs Div.

## Areas of Supervisory Responsibility and Areas in Charge of

Name	Areas of supervisory responsibility  and areas in charge of										
	Research	Development /TR	Pharmaceutical Technology	Marketing & Sales / MA / Safety	Cross-divisional functions						
					Human Resources	Digital	EHS	Quality & Regulatory Compliance	PLCM <sup>8</sup>	Partnering	Other Corporate Functions <sup>9</sup>
Dr. Osamu Okuda											
Dr. Hisafumi Yamada		<sup>10,11</sup>									
Toshiaki Itagaki											
Tetsuya Yamaguchi				<sup>13,14</sup>							
Junichi Ebihara											
Shinji Hidaka				<sup>12</sup>							
Yoshiyuki Yano											
Satoko Shisai											
Tsukasa Kusano		<sup>10</sup>									
Dr. Kaori Ouchi				<sup>14</sup>							
Shinya Takuma											
Dr. Hitoshi Iikura											
Masayoshi Higuchi											
Dr. Tomoyuki Igawa		<sup>11</sup>									
Takanori Muto											
Kazuhiko Nishi				<sup>13</sup>							

8. PLCM: Project & Lifecycle Management

9. Corporate Planning, General Affairs, Risk Management, Compliance, Audit, Intellectual Property, External Affairs, Finance & Accounting, Corporate Communications, Procurement, Foundation Medicine

10. Clinical Development

11. Translational Research

12. Marketing & Sales

13. MA: Medical Affairs

14. Drug Safety



# Progress

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- 56 Message from the CFO





# Executive Summary

## Review of Strategic Policies for 2022

Continuous creation of R&D output	<ul style="list-style-type: none"> <li>• Mid-size molecule projects: LUNA18 and subsequent mid-size molecule projects are on track</li> <li>• Progress of in-house projects is slightly behind the plan               <ul style="list-style-type: none"> <li>• Slight delay in the PC transition of new projects</li> <li>• Phase I study preparation/progress are on track</li> <li>• Global phase III studies are on track</li> </ul> </li> <li>• Partial change in plan for regulatory filings               <ul style="list-style-type: none"> <li>• Filed: four projects</li> <li>• Development discontinued/changed: seven projects</li> </ul> </li> <li>• Steady progress in approval/launch               <ul style="list-style-type: none"> <li>• Approved/launched: 12 projects</li> </ul> </li> </ul>
Maximizing value of growth drivers	<ul style="list-style-type: none"> <li>• Tecentriq: Early market penetration in expanded indications such as eNSCLC<sup>1</sup></li> <li>• Vabysmo: Successful entry into the ophthalmology field, and established product position</li> <li>• Hemlibra: Steady market penetration in Japan and overseas</li> <li>• Establishment of new distribution system: Established an efficient distribution system for specialty products</li> </ul>
Strengthening of business foundation	<ul style="list-style-type: none"> <li>• Chugai Life Science Park Yokohama: Completed in October 2022; transfer of research function started in November 2022</li> <li>• Steady progress in the drug discovery process using AI technology</li> <li>• Utilization and consideration of development and application strategies utilizing RWD</li> <li>• Initiation and expansion of new value delivery channels: Optimized mix of Real/Remote MRs, MSLs, SEs and Digital</li> <li>• Employee awareness survey: A high positive “employee engagement” response rate was maintained. Room for improvement in “employee enablement”</li> <li>• Implementation of human resource management reform as part of the transformation of affiliates, and establishment of an autonomous business management system</li> <li>• Digital plants: Initiate digital infrastructure to support new production operations at Ukima Plant</li> </ul>

## Strategic Policies for 2023

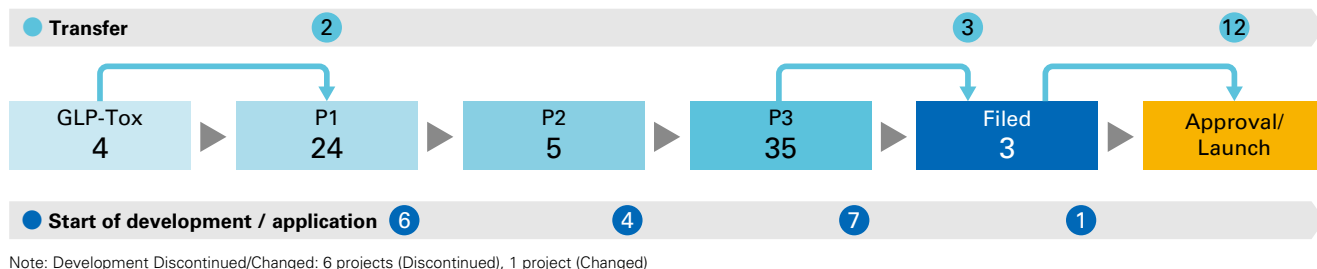
1. Strengthening of RED functions and delivering achievements Enhancement and development of in-house development portfolio	2. Maximization of the value of growth drivers Promotion of development/ value delivery and evolution of operations	3. Strengthening of business foundation Innovation, efficiency, and ESG
<ul style="list-style-type: none"> <li>• Promotion and expansion of development of mid-size molecule projects Acceleration of phase I study for LUNA18</li> <li>• Continuous creation of new projects and construction of technological bases Development of next-generation antibody engineering technologies</li> <li>• Proof of value of in-house pre-PoC projects and strengthening of foundation Accelerated development of in-house projects</li> <li>• Acceleration of open innovation Establishment of system for promotion</li> </ul>	<ul style="list-style-type: none"> <li>• Enhancement of value of post-PoC projects Achievement of approval/application plan</li> <li>• Maximization of value of new products and growth drivers Penetration of mainstay products in Japan and overseas (Hemlibra, Tecentriq, Enspryng, Vabysmo, Polivy, etc.)</li> <li>• Operation model evolution Increase in efficiency of production system and late-stage development operations</li> </ul>	<ul style="list-style-type: none"> <li>• Fostering of an organizational culture that continues to produce innovation Change in human resource behavior and promote D&amp;I</li> <li>• Resource creation by business process reform Promotion of ASPIRE program<sup>2</sup> and business transformation (Bx)</li> <li>• Increase in sophistication of risk management functions Improvement of risk compliance system</li> <li>• Promotion of autonomous management of affiliated companies Increase in sophistication of group management</li> <li>• Measures to address Medium-Term Environmental Goals Continuous initiatives for environmental protection</li> </ul>

1. Early non-small cell lung cancer

2. ASPIRE: The name of a business and digital transformation program that will deliver cutting-edge global standard processes and the next-generation ERP platforms across the Chugai Group.

# Progress in R&D

## Changes in the Number of R&D Projects (from January 1 to December 31, 2022)



	Number of projects	Main progress
Start of phase I studies	Products from Chugai research.....2 Products in-licensed from Roche.....6	Start studies of DONQ52, which uses next-generation antibody engineering technologies for celiac disease, and RAY121 for autoimmune disease.
Start of phase II studies	Products from Chugai research.....2 Products in-licensed from Roche.....2	Start studies of GYM329 for spinal muscular atrophy in combination with Evrysdi, and crovalimab for sickle cell disease.
Start of phase III studies	Products from Chugai research.....3 Products in-licensed from Roche.....4	Start studies for additional indications for Enspryng (MOGAD, AIE) and Alecensa.
Filed (including public knowledge-based applications)	Products from Chugai research.....2 Products in-licensed from Roche.....2	Submissions filed for RG6264 <sup>1</sup> (breast cancer/colorectal cancer), crovalimab (PNH in China), Gazyva (CLL) <sup>2</sup> and Actemra (SSc-ILD in EU).
Approval (additional indication) and launch (including public knowledge-based applications)	Products from Chugai research.....5 Products in-licensed from Roche.....7	Made full-scale entry into the ophthalmology field with approval and launch of Vabysmo. Additional indications for products including Tecentriq, Polivy, Hemlibra, and Actemra.
Termination	Products from Chugai research.....1 Products in-licensed from Roche.....5	Development terminated in a total of six projects, including Tecentriq, tiragolumab (small-cell lung cancer), gantenerumab, as they failed to achieve primary endpoints in phase III studies, as well as AMY109 (solid tumors).

1. Perjeta/Herceptin subcutaneous fixed-dose combination  
2. Application filed in March 2022, approved in December 2022

## Research Portfolio in Each Modality (As of February 2, 2023)

### Antibody Drug, Cellular and Gene Therapy Product: Research Portfolio

Note: Projects that utilize multiple technologies are displayed in each technology. As of February 2, 2023

Discovery	GLP-Tox	Clinical Trial	Launched
Recycling Antibody <sup>®</sup> Sweeping Antibody <sup>®</sup> , etc.		<ul style="list-style-type: none"> <li>AMY109 (endometriosis: P1)</li> <li>GYM329 (SMA: P2/3)</li> <li>RAY121 (autoimmune disease: P1)</li> </ul>	<ul style="list-style-type: none"> <li>Enspryng</li> <li>Crovalimab<sup>3</sup> (PNH: P3) 3. Filed in China</li> </ul>
Multispecific antibody (Non-Oncology)		<ul style="list-style-type: none"> <li>NXT007 (hemophilia A: P1/2)</li> <li>DONQ52 (celiac disease: P1)</li> </ul>	<ul style="list-style-type: none"> <li>Hemlibra</li> </ul>
Bispecific antibody (Oncology, Dual-Ig <sup>®</sup> , etc.)	<ul style="list-style-type: none"> <li>(cancer)</li> </ul>	<ul style="list-style-type: none"> <li>ERY974 (cancer: P1)</li> <li>ALPS12 (cancer: P1)</li> </ul>	
Switch Antibody <sup>™</sup>	<ul style="list-style-type: none"> <li>(cancer)</li> </ul>	<ul style="list-style-type: none"> <li>STA551 (cancer: P1)</li> </ul>	
PAC-Ig <sup>®</sup> , new technologies, etc.	<ul style="list-style-type: none"> <li>(infectious disease)</li> </ul>	<ul style="list-style-type: none"> <li>SOF10 (cancer: P1)</li> <li>GC33 (cancer: P1)</li> </ul>	<ul style="list-style-type: none"> <li>Actemra</li> <li>Mitchga (atopic dermatitis/JPN)</li> </ul>

## Introduction

Initiatives

## Progress:




Governance

## Performance Data

#### 4. Before obtaining PoC

# Accelerating Expansion of Innovative New Drugs— Progress of Multi-Modality Strategy

## Drug Discovery

Mid-Size Molecule Drugs	<ul style="list-style-type: none"> <li>✓ <b>Establishment of technological base</b></li> <li>✓ <b>Progress of research projects</b> <ul style="list-style-type: none"> <li>• Clinical candidate molecule optimization: more than ten projects</li> <li>• Clinical candidate molecules gained: two projects</li> </ul> </li> <li>✓ <b>Completion of AI drug discovery demonstration</b></li> </ul>	<ul style="list-style-type: none"> <li>✓ <b>Operation of new research center</b> (Chugai Life Science Park Yokohama)</li> </ul>  <p>Exterior view</p>
Antibody Drugs	<ul style="list-style-type: none"> <li>✓ <b>Development of new proprietary antibody technologies</b> (Switch antibody/next-generation bispecific antibody technologies, etc.)</li> <li>✓ <b>Implementation of AI for lead antibody acquisition/development candidate selection</b></li> <li>✓ <b>AI application to the immunogenicity reduction process</b></li> </ul>	 <p>"Spine" (corridor) connecting laboratory and office wings</p>
Small Molecule Drugs	<ul style="list-style-type: none"> <li>✓ <b>Progress of drug discovery for tough targets</b></li> </ul>	 <p>Laboratory space</p>
New Modality	<ul style="list-style-type: none"> <li>✓ <b>Adoption of CAR-T cell therapy "PRIME technology"</b></li> </ul>	

## Key Points of Multi-Modality Strategy

In its drive to address unmet medical needs, in addition to disease biology research and target molecule exploration, Chugai remains focused on the development of drug discovery technologies that make previously difficult targeted drug effects possible. With the aim of augmenting its lineup of in-house products, Chugai is moving under TOP I 2030 to roll out a multi-modality strategy that incorporates cellular and gene therapy products through external collaboration, while centering at its core the intensification of its own global top-class antibody engineering and mid-size molecule drug discovery technologies.

As it pursues RED Shift, DX and Open Innovation as key drivers of TOP I 2030, Chugai is working simultaneously to pursue medium-term initiatives linking the drug discovery, development and pharmaceutical technology phases. In anticipation of the ongoing creation of drug discovery projects applying new technologies, we are moving in advance to establish development processes that enhance success rates and speed, while preparing for the manufacture of investigational drugs and post-launch supply systems. Meanwhile, Chugai Life Science Park Yokohama is newly

operating as a center leveraging several attributes, including next-generation lab automation architecture and facility design that promotes researcher communication, to accelerate the pace of innovation.

## Initiatives by Modality

For mid-size molecule drugs, starting with library creation, the elemental technologies critical to the discovery of innovative new drugs are being put into practical use, and have begun functioning as platforms for enabling continuous drug discovery. Along with progress on the clinical development of first major project LUNA18, there has been progress at the optimization phases of over 10 projects at the research stage. In two of these projects, acquisition of clinical candidate molecules was completed. Greater research efficiency is emerging from results of structural analyses enabled by newly introduced cryo-electron microscopy equipment, coupled with recognition of important strides made in binding site prediction and multi-aspect optimization utilizing AI technology. Beyond development model evolution for mid-size molecule projects under clinical development, in pharmaceutical technology, capital investment has proceeded





✓ RED Shift

✓ Open Innovation

✓ DX

## Development

## Pharmaceutical Technology

✓ **Progress of phase I clinical trial**  
(LUNA18)

✓ **Establishment of development operation**

✓ **New development pipeline entries from proprietary antibody technology application projects**  
(DONQ52, RAY121, other)

✓ **Progress on out-licensing**  
(SOF10, NXT007, ALPS12)

✓ **Development project progress beyond the Rule of 5**  
(OWL833)

✓ **Adoption of newly developed products**  
(Gene therapy, nucleic acid drugs, etc.)

✓ **Establishment of structure for early development investigational drug manufacturing** (FJ2)

✓ **Construction of manufacturing structure for late-stage development/commercial production** (FJ3)



FJ2



FJ3

✓ **Construction of biopharmaceutical API manufacturing facility** (UK4)



UK4

✓ **Completion of next-generation biopharmaceutical production plant technology demonstration**

✓ **Establishment of structure for early/late-stage development and commercial production** (FJ2, FJ3)

apace at the Fujieda Plant since 2019. August 2022 saw the completion of construction for FJ2, which will spearhead investigational drug manufacturing for early development projects. Construction is proceeding on FJ3, scheduled for completion in 2024, which will head up late-stage development and initial commercial production.

In antibody drugs, in tandem with progress on drug discovery projects leveraging highly unique new antibody engineering technologies (Dual-Ig<sup>®</sup>, LINC-Ig<sup>®</sup>, PAC-Ig<sup>®</sup>, other), we were able to specify clinical candidate antibodies with high-level functionality beyond what in-house researchers proposed via MALEXA<sup>®1</sup>, an antibody drug discovery support technology that uses AI. In clinical development, new compounds (DONQ52, RAY121, ALPS12, other) enabled by proprietary antibody engineering technology have entered the development pipeline. Similarly, in pharmaceutical technology, construction is moving apace on UK4, a biopharmaceutical API manufacturing facility at the Ukima Plant, with sights set on the continuous development of biopharmaceuticals using new antibody engineering technology.

In small molecule drugs, Chugai has taken on the challenge of drug discovery for tough targets beyond the so-called

“Rule of 5” (RO5)<sup>2</sup>. Elsewhere, we have acquired a PoC<sup>3</sup> in clinical settings for OWL833, currently under development by licensee Eli Lilly and Company. The FJ2 and FJ3 facilities at the Fujieda Plant will also contribute to these expansions in small molecule research. With respect to new modalities, Chugai is flexibly incorporating cellular therapy, gene therapy and other new modality technologies, combining these with in-house technologies in striving to expand and enhance modality platforms. In August 2022, Chugai signed a licensing agreement regarding PRIME (proliferation inducing and migration enhancing) technology, a proprietary CAR-T cellular therapy owned by Noile-Immune Biotech Inc. We are also moving ahead with the adoption of gene therapy, regenerative medicine, nucleic acid drugs and other products developed from new modalities. Along with steady progress on these product developments, we are prepared to link these to technology development for in-house production.

1. Machine Learning x Antibody
2. A rule of thumb to determine whether a compound has properties suitable for oral drugs; the RO5 has contributed to improved success rates for previous small molecule drugs.
3. Proof of Concept: Confirmation that the therapeutic effect conceived of in the research stage is effective in humans

# Strategy Implementation 1



## Drug Discovery

Aiming to double output by strengthening digital capabilities, promoting external collaboration, and enhancing technological bases for drug discovery to realize original drug discovery ideas

In TOP I 2030, we aim to build on the strengths of our in-house capabilities accumulated over the years to realize original drug discovery ideas, as part of our goal to achieve global first-class drug discovery.

We will prioritize the investment of business resources into the third modality – mid-size molecule drugs – as they will be the core drug discovery platform that will drive growth over the medium and long term. While making steady progress on our first mid-size molecule project, LUNA18, which moved into the clinical phases in 2021, we will make effective use of the trial data – which includes information on safety, pharmacokinetics, and preliminary efficacy – in subsequent mid-size molecule projects. Currently, multiple mid-size molecule projects are progressing through the drug discovery and preclinical phases. We will accelerate research and development, including through collaboration with external partners.

We are working to further expand our technological bases for small molecule drugs and therapeutic antibodies. In 2022, several therapeutic antibodies that utilize our proprietary technologies moved into clinical trials, including DONQ52, RAY121, and ALPS12<sup>1</sup>, and we made steady

advances with continuous creation of products from Chugai research.

In addition, we are leveraging our expertise in protein engineering technologies – working to establish new modalities and flexibly incorporating technologies from Roche and other external parties in order to evolve our drug discovery efforts to a world-class level of multi-modality drug discovery. In 2022, we in-licensed the proprietary CAR-T cell therapy technology of Noile-Immune Biotech Inc. with the aim of realizing CAR-T cell therapy for solid tumors, which we aim to achieve by combining it with Chugai's drug discovery technology.

For drug discovery platforms, we are applying digital technologies, starting with AI, to advance drug discovery technology and transform the drug discovery process. With the full commencement of operations at Chugai Life Science Park Yokohama in April 2023, we are further accelerating processes, starting with the application of AI in antibody and mid-size molecule design, and other efforts such as utilizing digital technologies in pathology imaging analysis, and experiment automation.

1. ALPS12 entered clinical trials in January 2023

### Medium-Term Milestones and Progress

★ Internal quantitative target set ● Progressing to schedule

Milestone	Timing (year)	Progress
Acquisition of ePoC <sup>2</sup> for LUNA18	2024	●
Continuous creation of drug discovery projects utilizing mid-size molecule technology★	2023-2025	● (PC transition:0 (2022))
Establishment of new technologies that enhance competitive advantage (Acquisition of new MOA <sup>3</sup> )	2023-2025	●
Developing next-generation antibody technologies to solve drug-wants <sup>4</sup> <ul style="list-style-type: none"> <li>PC transition<sup>5</sup> of new antibody engineering technologies that work selectively with tissue and cells following Switch-Ig<sup>TM</sup></li> </ul>	2023	●
Establishment of a technological base and new modality research platform comprising multiple modalities with competitive advantages <ul style="list-style-type: none"> <li>PoC of new technologies through a combination of protein engineering technologies and new modalities</li> <li>Project creation and PC transition<sup>5</sup> by combining antibody engineering technologies and new modalities</li> </ul>	2023	●
	2025	●
Strengthening the drug discovery process by utilizing digital technology <ul style="list-style-type: none"> <li>Antibodies: Efficiency of the discovery process through machine learning technology</li> <li>Implementation of lab automation at Yokohama site</li> <li>Establishment of digital infrastructure to increase drug discovery productivity★</li> </ul>	2023	●
	2024	●
	2024	●
Creation and promotion of innovative drug discovery projects by strengthening biology <ul style="list-style-type: none"> <li>Speeding up<sup>6</sup> access to inaccessible human clinical samples as part of improving the accuracy of non-clinical research</li> <li>Creation of a platform for drug discovery approaches that target continuous innovation from a biological perspective</li> </ul>	2024	●
	2024	●
Capturing external innovation <ul style="list-style-type: none"> <li>Incorporation of new modalities, technologies, and molecules★</li> </ul>	2024	● (In-licensed: 2 (2022))

2. In addition to safety, signs of efficacy or pharmacological effect have been confirmed in a limited number of cases. 3. Mode of Action

4. Profiles and mechanisms of action wanted in drug discovery 5. Transition to GLP-Tox studies (non-clinical safety studies) 6. Changes to clarify targets from 2023 onward

## Pick Up Operation of the new research center, Chugai Life Science Park Yokohama

Chugai Life Science Park Yokohama (Chugai LSP Yokohama) was completed in October 2022 and started full operation in April 2023. As Chugai's only drug discovery research center in Japan, the facility integrates drug discovery research functions that had been split between Gotemba and Kamakura. Currently around 1,000 employees work here. The site has incorporated a large amount of greenery, aiming to harmonize with the local community and to reduce environmental impact by introducing the latest facilities and considering coexistence with the environment, sustainability, and safety.

A variety of design features were adopted to encourage innovation by enabling researchers from different fields to engage in active communication in various places, mainly a 300-meter corridor called the "Spine," which connects labs and office areas. In the area of DX, in addition to the implementation of AI in antibody and mid-size molecule drug discovery that we have promoted to date and the use of state-of-the-art technology such as cryo-electron microscopy, we are working on building next-generation laboratory automation to improve productivity and quality, including the introduction of interacting robots that connect between automated equipment.

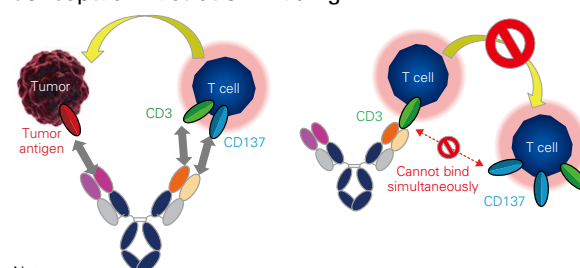
By making Chugai LSP Yokohama an attractive research center, we aim to attract high-performing talent and continue to evolve, including through utilization of business sites that have yet to be built upon.



Total floor area	119,500m <sup>2</sup>
Building structure	16 buildings in total
Total investment	Land: ¥43.0 billion Building and equipment: ¥128.8 billion

ALPS12, the first next-generation T-cell redirecting antibody applying Chugai's proprietary Dual-Ig<sup>®</sup> technology, started phase I trial in January 2023. Conventional T-cell redirecting antibodies are designed to guide T cells to the target cancer cells by activating and engaging T cells through their binding to CD3 on T cells. One of the challenges, however, is that they have limited antitumor killing ability against poorly T-cell infiltrated tumors. Dual-Ig<sup>®</sup> is a novel technology providing antibodies with the ability to induce CD137 signalling, a co-stimulating molecule, in addition to CD3 signalling. This property potentially results in more potent antitumor effect against poorly T-cell infiltrated tumors. ALPS12 was licensed to Roche at the preclinical stage, and we started a phase I clinical trial for solid tumors jointly with Roche.

### Conceptual illustration: Dual-Ig<sup>®</sup>



#### Notes:

1. Tumor antigen is not disclosed.
2. The actual molecular shape of ALPS12 is different from the molecular shape of Dual-Ig<sup>®</sup> used in this conceptual illustration.
3. Out-licensed to Roche

In antibodies and mid-size molecules, we are making advances in innovation of the drug discovery process using AI technology, and we are promoting the application of our proprietary antibody drug discovery support technology MALEXA<sup>®</sup> in multiple projects. Automation of experiments and introduction of robotics are also proceeding smoothly. We have started mobile robot operations, and we will be conducting various demonstration tests at Chugai Life Science Park Yokohama, including automation and upgrading of image analysis and structural analysis.

# Strategy Implementation 2



## Development

Realizing a world-class clinical development model that can maximize product value by improving productivity and the clinical trial success rate through the use of digital technologies

In early-stage clinical development through to PoC, our focus is on improving clinical study success rates and maximizing product value to build a world-class clinical development model. Specifically, we are developing an intricate and quantitative understanding of biological responses in the non-clinical and clinical stages. Through the application of innovative mathematical models and culture technologies, combined with the full use of real-world data (RWD) and a wealth of data on diseases and treatments that we have accumulated, we will improve the predictability of dosage and administration, efficacy, and safety, as well as increase the success rates of clinical trials. In addition to current initiatives, we are utilizing the most up-to-date technologies, such as modeling and simulation (M&S)<sup>1</sup> and human organoid construction,<sup>2</sup> to build a platform for clinical predictability. We are expanding its implementation. This platform will be applied to a wide range of clinical development projects.

Combined with an understanding and analysis of biological responses, we will focus on the steady development of digital biomarkers (dBM)s and digital devices for objective evaluation and quantification of pain or emotions while identifying healthcare issues for each disease, and linking the results to appropriate diagnosis and treatment. Furthermore, by combining the data we obtain with RWD, we will demonstrate the True Endpoints in early stages, thereby contributing to the improvement of patients' QoL.

In late-stage clinical development, we see patients as partners, and are implementing fundamental reforms to improve productivity, such as working to build a "patient-centric operational model" aimed at maximizing shared value

with patients. This will improve the efficiency of monitoring and management tasks through active application of digital technologies, while at the same time allowing us to reduce the size and duration of studies and make operations more efficient by incorporating RWD into study designs. We are aiming to double productivity in late-stage clinical development in 2030.

### Improving Predictability and Success Rates

We are working on M&S, an innovative technology to support optimal dosing and personalized healthcare by gathering a wide range of observed data and applying AI analysis to work out a formula (model) that indicates pharmacokinetics and biological response, as well as organoid research aimed at acquiring data to increase prediction accuracy. In organoid research, cutting-edge stem cell research technology is used to generate cells that can be cultured in vitro to help raise accuracy in the prediction of drug absorption and metabolism. This approach is already being applied in the analysis of drug action and toxicity mechanisms. In addition, we have successfully constructed an AI model that uses molecular structure data to predict the absorption rate of development candidates in the human digestive tract. Analysis and verification using this model is progressing in multiple projects.

1. Technology that integrates computer-based mathematical simulations with biological sciences. Supports key decision-making during pharmaceutical development.
2. Tissue structures designed to have similarities to organs in the human body

### Medium-Term Milestones and Progress

★Internal quantitative target set ●Progressing to schedule

Milestone	Timing (year)	Progress
Strengthening the clinical predictability platform and implementing M&S projects	2025	●
● Improving clinical predictability through M&S and implementing clinical trials based on M&S★		
● Implementation of patient segmentation based on pathological biomarkers	2025	●
Accelerating value expansion of in-house-developed products through simultaneous development of multiple diseases	2023	●
● Multiple projects for simultaneous development of multiple diseases based on science and commerciality		
Proof of value of in-house projects	2025	●
● Establishing general-purpose indicators that lead to True Endpoint assessment of patients		
Evolution of late-stage development operations★	2023	●
● Increase in workforce productivity		
● Implementation of clinical/regulatory applications utilizing RWD, control group data, disease registry data, etc.	2023	●



## Pick Up Late-stage clinical development: transforming the operation model

In late-stage clinical development, we are working to advance our business processes, management structure, and methods with a view to increasing speed, quality, and productivity. In our business processes, for example, we have shifted to a concentrated management system for follow-up studies<sup>3</sup>, which were previously conducted with one study leader managing one study. Specifically, currently over 10 studies are being conducted under the management of several study leaders, and by conducting integrated operation processes with Roche and CROs<sup>4</sup>, while also promoting standardization of study management processes, we have achieved a marked increase in productivity. We are looking at shifting human resources into the areas of new trial management and science, while also applying the standardization model established here to other trials. We are transitioning to a management structure in which Chugai Clinical Research Center, which has focused mainly on monitoring operations to date, will take on study management, and monitoring operations will be outsourced to CROs. Furthermore, to streamline management processes, we will examine and promote efficiency gains through the use of digital technology such as a content management system that integrates the generation of various types of request forms.

3. A trial that continues administration of the trial drug to subjects (patients) and observation after the data has been collected for a regulatory filing

4. Contract Research Organization



**Takahiro Mizui**

Head of Oncology Clinical Development Department  
Clinical Development Div.

## Orphan Drugs Brought to Market over the Past 10 Years

Year approved/ marketed <sup>5</sup>	Product name	Indication(s)
2012	<b>Pulmozyme</b>	Cystic fibrosis (improves lung function)
2013	<b>Avastin</b>	Malignant glioma
2014	<b>Alecensa</b>	Metastatic/unresectable <i>ALK</i> -positive NSC lung cancer
2015	<b>Zelboraf</b>	Malignant melanoma with <i>BRAF V600</i> gene mutation
2016	<b>Avastin</b>	Cervical cancer
2017	<b>Actemra</b>	Large-vessel vasculitis
2018	<b>Hemlibra</b>	Suppression of bleeding in hemophiliacs without factor VIII inhibitors
2019	<b>Tecentriq</b>	Small-cell lung cancer

Year approved/ marketed <sup>5</sup>	Product name	Indication(s)
2019	<b>Rozlytrek</b>	Locally advanced or metastatic <i>NTRK</i> gene fusion-positive solid tumors
2020	<b>Alecensa</b>	<i>ALK</i> -positive anaplastic large-cell lymphoma
2020	<b>Enspryng</b>	Neuromyelitis optica and related diseases
2021	<b>Evrysdi</b>	Spinal muscular atrophy (SMA)
2021	<b>Polivy</b>	Diffuse large B-cell lymphoma (DLBCL)
2022	<b>Rituxan</b>	Prevention of recurrent neuromyelitis optica spectrum disorder (including neuromyelitis optica)
2022	<b>Hemlibra</b>	Control of bleeding tendency in patients with acquired hemophilia A

5. Year in which the drug was approved and first marketed with an orphan drug designation (including expanded indications). For products not yet on the market when approved, the year indicated is the year the drug was first marketed.

Our in-house development project RAY121 started phase I clinical trials for autoimmune disease in October 2022. Our development policy for this project is predicated on simultaneous drug development for multiple diseases with a view to accelerating the expansion of value.

Several projects are advancing the use of dBMs to enable objective diagnosis and outcome evaluation by measuring patient biological data. For example, in the area of endometriosis, we have created a pain index to analyze biological data collected with a wearable device in order to measure the primary symptom, pain, objectively over time. We are strengthening our partnership with US digital therapeutics company Biofourmis with the aim of establishing this technology and developing software to support pain measurement and patient care.

# Strategy Implementation 3



## Pharmaceutical Technology

Realize pharmaceutical technology functions befitting a top innovator by combining high cost competitiveness with world-class technologies for turning drug discovery ideas into drugs

In the area of early-stage technology development for pharmaceutical technology – a component of the RED function – we are pursuing world-class pharmaceutical technologies in terms of both technological sophistication and development speed in order to ensure the commercialization of innovative pharmaceuticals, while responding to the significant expansion of R&D output. We will further strengthen collaboration with drug discovery and development and accelerate the establishment of organizations for investigational drug development and early-stage production. Our aim is to develop active pharmaceutical ingredient (API) manufacturing and formulation methods for drugs of high difficulty, starting with mid-size molecules and next-generation antibodies, which are tied directly to creating a competitive advantage. In the field of small and mid-size molecule synthesized drugs, we are working to develop a flexible and rapid API supply system. At the Fujieda Plant, we have completed construction of the FJ2 building, which will manufacture APIs for early development, and are proceeding with construction of the FJ3 building, which will manufacture APIs for late-stage development and commercial production. At the Ukima Plant, we are making progress on construction of the UK4 building, which will manufacture biopharmaceutical APIs for early-stage development.

In our production functions, we are establishing new systems that will balance enhanced functions with low-cost operations. We are making steady progress in the use of digital plants and robotics, starting with the installation of an IT infrastructure to improve efficiency. In the area of digital plants, we have started operations of our first initiative at the Ukima Plant, and we are now working to expand to other plants as well. In antibody API production, we are building next-generation antibody API plants that will aid efforts to reduce plant size as well as the amount of resources invested, and advancing with demonstration testing of technologies for cell cultivation and purification processes.

In commercial production, we are working to build a production system that can respond flexibly to fluctuations in demand and changes in procurement plans for materials and components. We are also working on our second-site strategy, which is to optimize the balance of internal and external production, making strategic use of contract manufacturing organizations (CMOs) and contract development and manufacturing organizations (CDMOs) for products that can be outsourced to external partners, in order to maintain world-class production technology capabilities and quality while pursuing cost competitiveness and cost reduction.

### Construction of API supply system

	Phase I to phase II		Phase III to initial commercial production	Full-scale commercial production
Small/mid-size molecules	FJ1 FJ2		Small molecules: Outsourcing to CMOs Mid-size molecules: FJ3	Outsourcing to CMOs
Antibodies	UK4	UK1 UK2	UK3	Utsunomiya Plant/ Outsourcing to CMOs

### Medium-Term Milestones and Progress

● Progressing to schedule

Milestone		Timing (year)	Progress
Establishment of manufacturing system and process for mid-size molecules	• Establishment of mid-size molecule CMC <sup>1</sup> technologies and production bases for APIs and formulations	2024	●
	• Shortening the time to PoC in collaboration with non-clinical functions	2024	●
Establishment of biopharmaceutical API development and manufacturing systems in response to doubling of R&D output	• Establish a manufacturing system through facilities dedicated to APIs (FIHs <sup>2</sup> ) (UK4)	2024	●
	• Establishment of cost reduction technologies for in-house production	2024	●
	• Develop antibody pharmaceutical technologies to become the world's forerunner	2027	●
	• Shortening the time to IND <sup>3</sup> in collaboration with non-clinical functions	2024	●
Establishment of an efficient manufacturing system for CPMC <sup>4</sup>	• Strengthen core manufacturing technologies, establish a cost-competitive CPMC system, and firmly establish operations	2023	●
	• Establishment of a CMO/CDMO management system for future product portfolio	2023	●
	• Launch of a new operational model at other sites through the development of digital and IT infrastructure	2023	●
	• Reflecting the use of robotics in the design of new facilities	2025	●

1. Chemistry, manufacturing, and controls data for API and drug product formulations needed for approval submissions

2. First-in-human (FIH) studies where the first doses are administered to humans

3. Investigational new drug (IND) application for clinical study 4. Chugai Pharma Manufacturing Co., Ltd.

## Pick Up Digital plant initiative: completion of WAVE 1

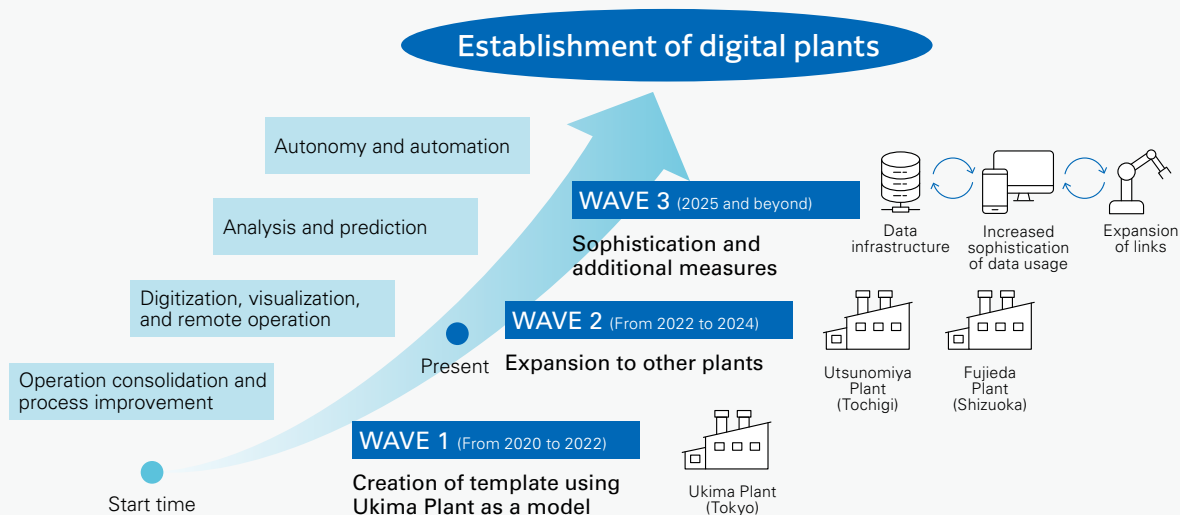
To respond to the acceleration of drug discovery and environmental changes, Chugai is promoting initiatives to build digital plants aimed at innovating production functions through linking and optimization of personnel and operation data. In October 2022, we completed WAVE 1 of this process, namely the creation of a template for a new production operation model and the construction of a supporting digital platform, and started operating them at the Ukima Plant.

The digital platform comprises three systems, – education, planning, and remote support –, based on a review of all business processes. It aims to achieve visualization and overall optimization of production planning and assignments, and flexible workstyles across the organization. It also aims to reduce risks to pharmaceutical laws and regulations, including data reliability.

Currently, under WAVE 2, we are expanding this model to other plants. We aim to have it operating at the Utsunomiya Plant in 2023 and at the Fujieda Plant in 2024. A unified approach to strengthening technology and compliance with pharmaceutical laws and regulations at the three plants is expected to produce a marked improvement in productivity and reliability. Moreover, from 2024 onward, based on these developments, we will also work on further increases in sophistication and additional measures, and establish digital plants.



Coordination with a remote assistant using a smartphone



We made progress on the development of technologies for APIs and formulations capable of large-volume supply for mid-size molecules with complex structures that are difficult to absorb orally. In terms of the manufacturing system, construction has proceeded steadily on three buildings: FJ2 for manufacturing APIs for early-stage development, FJ3 for manufacturing APIs for late-stage development through to initial commercial production, and E01 for developing formulations of high difficulty.



Building E01 for developing formulations

We renewed the CPMC organization structure and started its operation, while also formulating and developing our vision for the future looking at 2030 with the aim of autonomous business operation and functional enhancement. In addition, we took steps to increase the sophistication of our selection and operation management structure for CMOs/CDMOs, which will contribute to stable production.

# Strategy Implementation 4



## Value Delivery

Achieving sophisticated value delivery by generating evidence for personalized healthcare (PHC) and building an innovative customer engagement model

In light of the development of digital tools and the impact of COVID-19, we are building an innovative customer engagement model to reflect the dramatic change in how we engage with healthcare customers, such as physicians and pharmacists. Specifically, by optimizing the use of in-person, remote, and digital means and coordinating specialized sales, safety, and medical functions, we will build a solution system that accurately and promptly delivers information truly valuable to customers and patients while maintaining a high level of expertise. To achieve this, our sales, safety, and medical personnel are expanding flexible remote and digital activities tailored to their customers' circumstances, and we are also utilizing an integrated platform that combines customer databases with information on various solutions. This system uses an AI-based decision support engine to assist our representatives in their activities, and we are currently working to incorporate it into targeted activities and improve operational results.

Chugai aims to realize a new phase of PHC. By comprehensively analyzing and utilizing RWD and various databases accumulated

through drug discovery and clinical development, we will advance the creation of evidence to promote PHC. We are currently conducting research to visualize QoL and clinical symptoms in various diseases, starting with hemophilia, and we will also accelerate the development of biomarkers that accurately predict efficacy and safety for each patient. Furthermore, we are developing algorithms to support the identification of rare driver genes through AI-based histopathological image analysis to facilitate detection of gene mutations.

In line with future changes in our product portfolio, we will plan bold shifts in resource allocation to new and growth areas and focus on optimizing matters including personnel and sites. We will implement drastic reforms to our back-office operations, including digitalization, outsourcing, and consolidation of operations.

### Medium-Term Milestones and Progress

★ Internal quantitative target set ● Progressing to schedule

Milestone		Timing (year)	Progress
Building an engagement model to meet diversifying customer needs	• Implement a precise individual strategy that combines in-person, remote, and digital channels	2023	●
	Customer satisfaction (cancer): No. 1 in obtaining information other than MRs		No. 1 <sup>1</sup>
	Customer satisfaction (MA Priority Activity Disease Area Assessment): Top 3 in all areas		Ranked in the top 3 in all disease areas <sup>2</sup>
	Customer satisfaction (providing safety information): No. 1		No. 1 <sup>3</sup>
Creation of unique evidence contributing to personalized healthcare (PHC)	• Realization of integrated use of internal and external data for predicting effectiveness and safety	2024	●
Functional reforms through resource shifts and digital use, etc.	• Systematically withdraw from mature areas and invest resources in new areas★	2023	●
	• Establishment of a business execution system that does not interfere with remote work, and the realization of assignments of employees with specialized knowledge from all over the country, regardless of their location	2025	●
Contribute to further advancement of PHC by expanding new portfolio (monitoring the efficacy of therapies)	• Introduction of assays for monitoring the therapeutic effects of molecular target drugs	2024	Considering new goals/options

1. MCI DIGITAL, *Multimedia White Paper on Physicians* Summer 2022, based on a survey of oncologists, "owned media ranking (No. 1), non-pharma medical websites ranking (No. 1)"

2. Source: INTAGE Healthcare Inc., survey results

3. Source: INTAGE Healthcare Inc., 2022 questionnaire about safety information needs

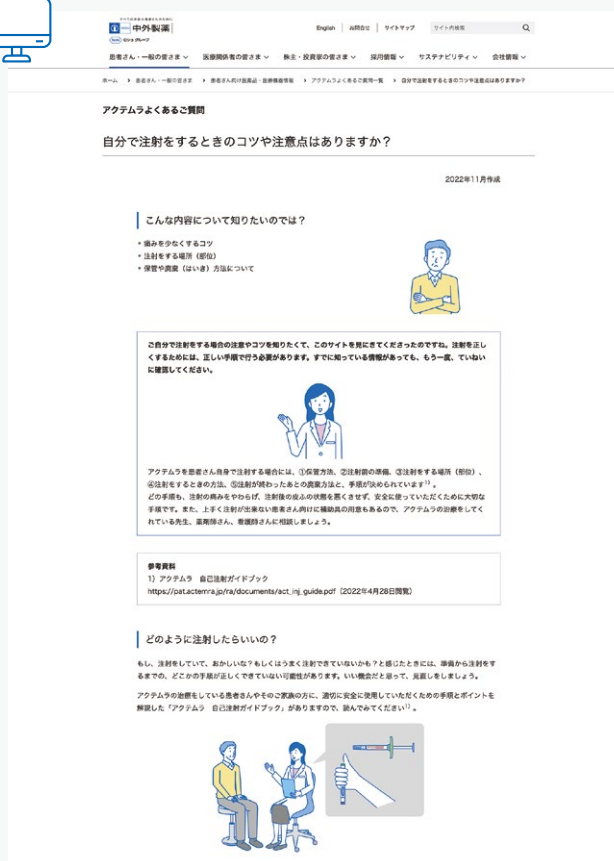


## Pick Up

## Enhancing information provision to help improve access for patients

The Medical Affairs (MA) Division is committed to the mission of contributing to patients and healthcare providers by focusing on creating evidence regarding innovative in-house drugs and providing appropriate solutions and information related to unmet medical needs.

One of the MA Division's patient-centric initiatives is "improving patient access to information." The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices states that "the general public must use pharmaceuticals, etc. in an appropriate manner, and make efforts to improve their own knowledge and understanding of the efficacy and safety thereof," but it is difficult for patients to obtain correct information, even if they want to. The MA Division has published its first FAQ section for patients on the Chugai website, featuring illustrations and easy-to-understand explanations. These can also be accessed from the cross-company information platform overseen by the RAD-AR Council of Japan. In addition, we will install dedicated operators for patients on the medicine consultation hotline in 2023 in order to provide a better response. Looking ahead, we at the MA Division will continue to think about the real issues of actual clinical settings and patients, making every effort to rapidly generate useful evidence and provide solutions.



Frequently asked questions published for patients (in Japanese only) (created in November 2022)

In 2022, our new products steadily penetrated the market. In Chugai's first full-scale entry in the ophthalmology field, the first bispecific antibody in the field, Vabysmo, successfully entered the market and established its position as a product. Hemlibra achieved steady market penetration in Japan and overseas, while Polivy was approved for an additional indication for the first time in 20 years as a new treatment option for previously untreated diffuse large B-cell lymphoma (DLBCL). Evrysdi reinforced its position as the only oral treatment available for spinal muscular atrophy (SMA).

To further advance PHC, Chugai is conducting research to add and expand various solutions under actual clinical conditions with the aim of not only ensuring efficacy and safety, but also enhancing value provided including patients' QoL and healthcare economics. For example, we conducted research on triple negative breast cancer subjects to look at the actual status of adverse events in the administration of Tecentriq under lifestyle conditions. We also conducted an endpoint study of Hemlibra administration to hemophilia A patients concerning their activity status and daily lifestyles (TSUBASA study), and made an interim report in 2022.

# Strategy Implementation 5



## Foundation for Growth

Enhancing the foundation for growth needed for innovation, and evolving all value chains

**People and organization** ▶ We will promote the assignment of the right person to the right position through further advances in position management and talent management, and enhance its corporate culture to encourage personnel to boldly take on challenges and engage in dialogue. We will also focus on the acquisition, development, and provision of the highly specialized human resources who will be key in implementing business strategies including science and digital technology, and will strive to foster a culture that creates innovation through promotion of Diversity & Inclusion (D&I).

**Digital** ▶ In CHUGAI DIGITAL VISION 2030, we will focus on innovative drug discovery applying digital technologies, while also promoting DX in all value chains to improve efficiency. We will establish a global-level IT infrastructure by building a digital platform for both software and hardware and collaborating with the Roche Group to integrate various in-house data and build an analysis platform.

**Environment** ▶ We will contribute to realizing a sustainable global environment by implementing advanced initiatives to achieve our “Mid-Term Environmental Goals 2030” for the three issues identified as material: climate change countermeasures, use of renewable/recycled resources, and

protection of biodiversity. Climate change countermeasures in particular will focus on long-term initiatives, such as our goal of achieving zero CO<sub>2</sub> emissions by 2050.

**Quality** ▶ In addition to ensuring product quality, we are also working to advance quality management in regulatory affairs and across all business processes. Furthermore, we will enhance our development and implementation of quality management methods that balance both quality and efficiency suited to changing business processes, including responding to regulatory matters that address challenges brought about by new modalities and diverse technological evolution, enhancing digital compliance, and developing a quality assurance system in anticipation of expanded collaboration with external parties.

**Insight Business** ▶ Working in partnership with other Roche Group companies, Chugai will collect external data, including RWD and data obtained at each stage (drug discovery, development, pharmaceutical technology, and value delivery), understand patient needs, and perform advanced analysis to extract and utilize various insights that contribute to in-house drug discovery and development and maximizing the value of pharmaceuticals.

### Medium-Term Milestones and Progress

★ Internal quantitative target set ● Progressing to schedule

	Milestone	Timing (year)	Progress
People and organization	Increase in active employees based on awareness survey results	● Percentage of active employees: Achieve the same level as companies with strong global performance	2024 Recognized a gap <sup>1</sup> between the goal and the current status
	Acceleration and penetration of D&I	● Positive response rate for employee awareness survey innovation questions★ ● Ratio of female managers / Ratio of female managers with subordinates: Achieve 17%/17%	2024 Recognized a gap <sup>1</sup> between the goal and the current status 2023 On schedule 17.8%/15.9%
	Employee's health	● Smoking rate: 9% ● Cancer reexamination rate: 80% ● Percentage of high-stress employees who request interviews (those who requested/those who were examined): 1.5%	2025 2025 2026 Added in 2023
Digital	Improvement in efficiency of all value chains	● Improve productivity of targeted operations based on the impact of digital investment projects★	2025 Reduce a total of 150,000 hours by RPA
Environment	Strengthening of the foundation for sustainability at the global level	● Continued selection for Dow Jones Sustainability World Index (DJSI World)	2025
		● Scope 1 + 2 CO <sub>2</sub> emissions: Achieve 40% reduction (compared to 2019)	2025
		● Use of CFCs: Achieve 25% reduction (compared to 2020)	2025
Quality	Next-generation quality management that balances quality and efficiency with an eye toward new modalities and new business processes	● Productivity improvement: Personnel and costs per product and development projects★	2024
		● Establishment of a Chugai quality system for total assurance of products in new domains	2024
Overseas sales	Strengthening of overseas business foundation to drive growth and maximize Chugai products' global value	● Launch of six global products from Chugai research (Actemra, Alecensa, Hemlibra, Enspryng, crovalimab, and nemolizumab)	2025 (Five products in 2022)
		● Establishment of early development and regulatory systems at U.S. and European subsidiaries in response to an increase in early-stage projects	2025
Insight Business	Search for commercialization of Insight Business	● Establishment of an Insight Business promotion system (infrastructure development, capabilities, and information aggregation as a hub)	2024
		● Start using data assets aggregated through in-house projects or use case related to the FMU business	2025

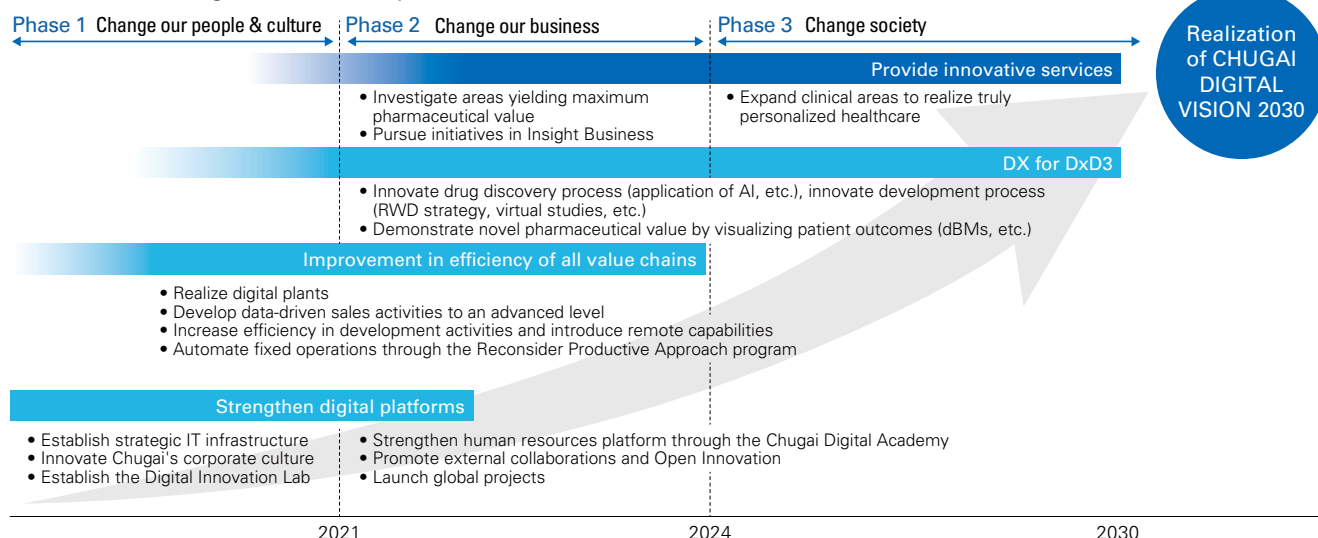
1. These items did not reach the targets in the employee awareness survey. We will accelerate our response to these issues and aim to meet the targets. (For information on the 2022 survey results and our response, see “Column: Employee Survey” on page 3 and “Message from the CEO” on pages 12-15.)

# Main Progress: Digital

## CHUGAI DIGITAL VISION 2030 CHUGAI DIGITAL

Transform our business by using digital technologies to make Chugai a top innovator in the provision of society-changing healthcare solutions

### Three Basic Strategies and Roadmap



Chugai is promoting three basic strategies under CHUGAI DIGITAL VISION 2030, its roadmap for 2030. Under the strategy of strengthening digital platforms, which includes reforming our corporate culture, strengthening our digital human resources, and building infrastructure for promoting data utilization, we are aiming to optimize all value chains through the use of various digital technologies. Then, to realize DX for Dx3<sup>2</sup>, we will build on the management resources generated by the above strategies, using AI, RWD, and digital biomarkers (dbMs) in a way unique to Chugai to create innovative drugs by applying digital technologies.

In 2022, we received the DX Grand Prix<sup>3</sup> 2022 award in the selection of the DX Stocks, in recognition of our initiatives covering drug discovery and production processes through to healthcare providers and patients. In 2023, our next-generation ERP implementation program, ASPIRE, started in collaboration with Roche, and we will aim to generate results by further accelerating digital and IT strategies.

- Digital Transformation for Drug Discovery and Development
- Selected as a DX Stock for the third consecutive year. Chugai was the only pharmaceutical company selected for a third consecutive year.



### Progress of Main Strategies

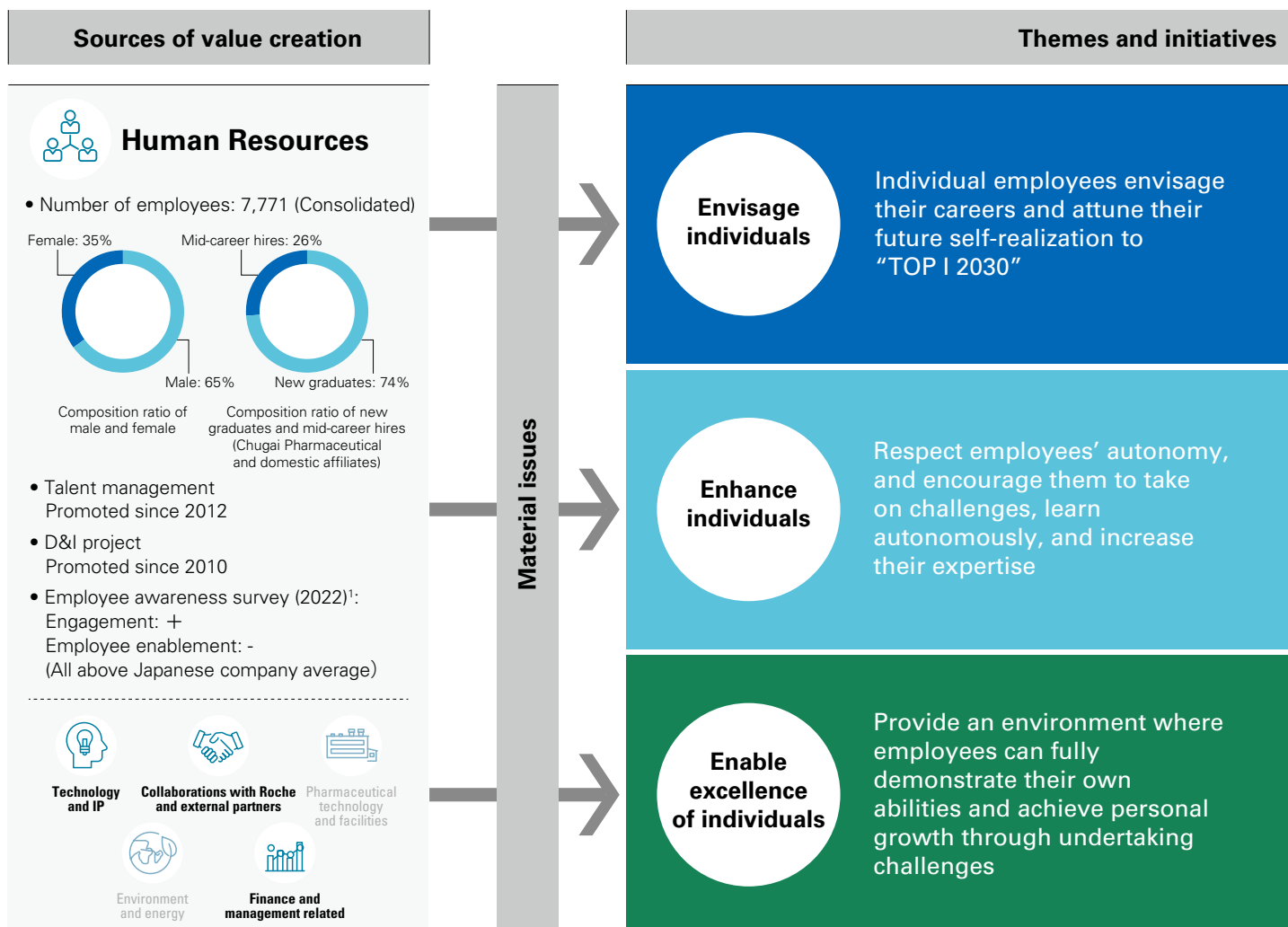
DX for Dx3	<ul style="list-style-type: none"> <li>Increased efficiency in the antibody drug discovery process using the proprietary AI tool MALEXA®, and advanced analytical technology for pathology images using AI</li> <li>Advanced technologies for predicting human pharmacokinetics using modeling and simulation</li> <li>Advanced dbM development and use of RWD to support internal decision-making and drug approval applications</li> </ul>
Optimize all value chains	<ul style="list-style-type: none"> <li>Started operation of WAVE 1 of digital plant construction at the Ukima Plant and started expansion to other plants as WAVE 2.</li> <li>Implemented clinical trials in which participants are not required to attend a medical institution (decentralized clinical trials)</li> <li>Rolled out a Company-wide digital marketing system and launched its full-scale operation</li> <li>Rolled out CHUGAI RPA (achieved a total reduction of 150,000 hours)</li> </ul>
Strengthen digital platforms	<ul style="list-style-type: none"> <li>Expanded operation of Chugai Scientific Infrastructure (CSI) for integrating the use of internal and external data (over 100 environments), and started application in non-science domains</li> <li>Held CHUGAI INNOVATION DAY to generate innovation (R&amp;D/Digital) in the healthcare field</li> <li>Full-scale development of Digital Innovation Lab (implementing over 450 ideas)</li> <li>Advanced personnel development through CHUGAI DIGITAL ACADEMY (approximately 170 participants in course for development of data scientists and digital project leaders)</li> </ul>

### Column ASPIRE Program for Implementation of Next-generation ERP

Chugai has decided to participate in Roche's ASPIRE program for implementing next-generation enterprise resource planning (ERP), as its mission-critical business process systems are due for replacement in the near future. With this project, we aim to significantly reduce implementation costs and labor hours, and strengthen our collaboration with Roche in areas such as supply chains, purchasing, sales, accounting, and IT. At the same time, we will accelerate our transformative shift to state-of-the-art business processes that can respond to a doubling of our R&D output going forward. Led by a dedicated department that was newly established in 2023, we will reform our business processes across the Company, replace and upgrade systems, and work on organizational reforms in conjunction with this.

# Main Progress: Human Resources

## Value Creation Process for Human Capital



Note: Those of the six sources that have particularly deep relationships to "themes and initiatives" related to human capital are boldfaced.

1. For details on the employee awareness survey, refer to the column on page 3.

Chugai believes that human resources are the key to achieving "TOP I 2030" and thereby realizing advanced and sustainable patient-centric healthcare. This is because it is human resources who generate innovation and individual employees who drive value creation. The current status of Chugai's human resources and organization reflects over 10 years of working on talent management and D&I initiatives, with our employee awareness survey results also indicating that engagement is one of our strengths. At the same time, the results also showed that there is room for improvement in our efforts to create an environment where employees can thrive and grow. Given this situation, we formulated a human resources management policy that focuses on the diverse individuality of employees, and on the personal growth and challenges of each individual. The new policy aims to realize the envisaging, enhancing, and enabling excellence of individuals as a way to change them, change the Company, and ultimately promote the growth of the entire Chugai Group. The driving force for value creation is individuals, in other words, human resources. This means that each of us

has a leading role to play in realizing "TOP I 2030."

In the first step, "Envisage individuals," individual employees envisage their careers and attune their future self-realization to "TOP I 2030." One of our most important tasks is to secure the next generation of management personnel who are able to maintain and develop our relationship with our strategic partner, Roche. We are systematically identifying and developing candidate personnel for key positions. Furthermore, to help realize "TOP I 2030," we are promoting the acquisition and appointment of the most suitable human resources for each position. This includes acquiring and developing highly competent specialists who will lead strategy execution in fields such as science and digital technology, and assigning them without regard to age or background.

The second step, "Enhance individuals," refers to respecting employees' autonomy, and encouraging them to take on challenges, learn independently, and increase their expertise. To generate innovation it is essential to have a system that

## Output

### Top Innovator in the Healthcare Industry

#### Achievement of "TOP I 2030"

TOP INNOVATOR  
**TOP i 2030**

- Global first-class drug discovery
- Futuristic business model

#### Change in individuals

(Personal transformation and growth)

#### Change in the Company

(Growth of the entire Chugai Group)

**Increase in effective employees (human resources who act autonomously to realize and achieve the Company's targets) and generation of innovation**

## Outcome

Creation of shared value

**Realization of advanced and sustainable patient-centric healthcare**



- Systematic nurturing of next-generation management personnel who can maintain and develop an equal relationship with Roche
- Identification, recruitment, and development of highly competent specialists, including digital talent
- Internal promotion and improvement of a job-oriented human resources system
- Implementation of measures to improve the coaching abilities of managers and to implement self-supporting management

- "Check-in" sessions between employees and their managers, and others as well, to support an awareness of personal growth
- Strengthening of mutual learning using "I Learning" and skill sets
- Personnel exchanges with Roche

- Cultivation of a culture that praises activities for challenges and personal growth instead of approving activities based on gratitude
- Promotion of job satisfaction reforms (engagement and enablement)
- Promotion of D&I
- Promotion of health and productivity management

encourages individuals to up-skill, take on challenges, and grow. To this end, Chugai is promoting dialogue between employees, regardless of their seniority to one another, and investing in individual career development and training programs. Furthermore, personnel exchanges with our strategic partner Roche provide a good opportunity for employees to acquire global knowledge and experience.

In the third step, "Enable individual excellence," we provide an environment that enables individuals to fully demonstrate their own abilities and achieve personal growth through undertaking challenges. To generate innovation, we believe it is of paramount importance to create an environment in which individuals can demonstrate their unique talents and participate. We are therefore working to foster an inclusive workplace culture that makes full use of diversity and an organizational culture that encourages challenges and personal growth, while also promoting job satisfaction reform, promoting "health and productivity management,"<sup>2</sup> and working to establish D&I.

Chugai defines human resources who work autonomously toward the Company's goals as "effective employees." We implement a variety of initiatives based on our new human resources management policy to increase effective employees who drive innovation. By realizing the three steps of envisaging, enhancing, and enabling excellence of individuals, we aim to increase effective employees (i.e., change individuals), to a level that is equal to or greater than that of companies with strong global performance by 2023.

Our human resources management policy aims to create a virtuous cycle in which individual growth generates innovation and increases corporate value, enabling Chugai to attract even better human resources and enhance these individuals to generate further innovation.

2. For details, please refer to the Company's sustainability website.  
Website: Sustainability > Health and Productivity Management  
<https://www.chugai-pharm.co.jp/english/sustainability/healthmanagement/>



# Main Progress: Human Resources

## Initiatives by Theme

### Envisage individuals

In human resources management, Chugai aims to realize management strategy and generate innovation by ensuring the assignment of the right person to the right position using position and talent management.

Talent management involves describing the expected requirements of a position then identifying and developing management personnel and highly competent specialists at an early stage, based on their competencies, performance, and potential. For the next generation of management personnel, we have a unique successor development program in place. Every year, the medium- to long-term successor development policy is discussed and determined by top management and division heads, then strategic assignments and appointments are made to promote systematic development. The successor preparation rate for important key positions in Japan and overseas is over 200%.

With regard to highly competent specialists, also, these individuals are identified each year by the Executive Committee based on strategy, and a company-wide effort is made to acquire and develop them. We have around 70% of the target number of personnel. In particular, we have prioritized efforts to acquire specialists in the fields of science, such as clinical scientists and MDs, and DX, such as data scientists, as the top skill sets, and have filled over 80% of the target positions.

The Chugai Group has promoted the assignment of the right person to the right position through further advances in talent management, introducing a job-oriented human resources system in April 2020 and establishing treatment based on the value of the position's professional duties. To actively encourage people to undertake challenges, around one-third of the employees newly posted in management positions have come through the "Challenge Assignment System" for supporting personal challenges or the in-house job posting system. The number of users and applicants of each system has been increasing year after year, as the corporate culture of autonomous career building regardless of age or attribution is gradually becoming established.

### Enhance individuals

To further enhance its independent drug discovery capabilities and technical capabilities and continuously generate new value and results, Chugai has been focusing on self-directed learning support and career development.

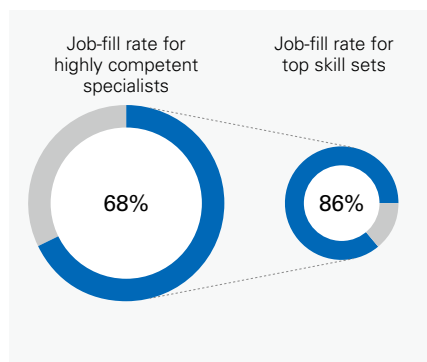
To support junior staff in their challenges and personal growth, we are promoting 1-on-1 "check-in" sessions with their managers as a company-wide practice. In 2022, the "check-in" rate was 78%, and we aim to continue increasing the quality of "check-in" sessions.

An online learning platform, "I Learning," was introduced in 2021, and has now been deployed throughout the Chugai Group. It has been used by around 70% of employees and is also used as a space for employee-led mutual learning opportunities. Furthermore, to enable individual employees to develop their careers autonomously, we make visible the expertise (skill sets) needed for each division and work type, as well as promoting the use of tools that match these with employees' own careers and expert skill training programs for each division.

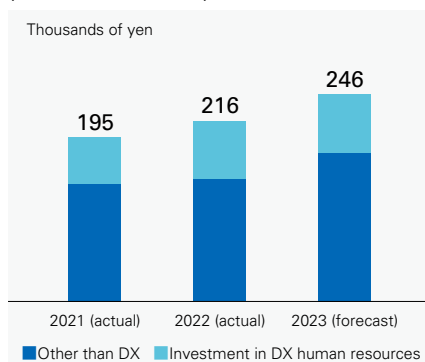
To help develop human resources with digital and global capabilities, we are increasing investment in human resource development each year. In 2022, the amount of investment in human resource development per person exceeded ¥200,000. Looking forward, we will promote investment in human resources, who are the greatest source of innovation.

The acquisition of global knowledge and experience through personnel exchanges with our strategic partner Roche is a unique strength of Chugai. Dispatches to the Roche Group have been continuing every year since 2004. Currently, 20 Chugai employees are assigned to Roche sites overseas, and nearly 250 employees in total have graduated from this program. Through these exchanges, Chugai's employees not only enhance their specialist expertise, but also cultivate a broad perspective that enables them to work in various areas.

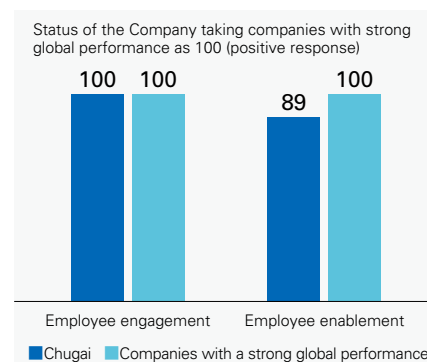
**Job-fill rate for highly competent specialists<sup>3</sup> and top skill sets<sup>4</sup> (2022, non-consolidated)**



**Amount of investment in human resource development per person (non-consolidated)**



**Employee engagement and employee enablement (2022)**



3. Highly competent specialists who are essential for realizing management strategy and generating innovation

4. Highly competent specialists that the Company should prioritize for acquisition and development, such as science and DX specialists.

## Enable individual excellence

As a foundation for generating innovation, we provide an environment that enables individuals to fully demonstrate their own abilities and achieve personal growth through undertaking challenges.

Based on the employee awareness survey conducted in 2022, we found that the Company offers a work environment with high psychological safety, with employees actively expressing mutual approval and gratitude. Therefore, to help realize "TOP I 2030," we aim to transform our culture into one where people can discuss matters freely and openly with each other, regardless of differences in department, role, and position. As part of this, we are creating systems to encourage employees to undertake challenges, such as introducing the "ChuLiP" recognition system for verbally praising people who have taken on a challenge.

We have been promoting workstyle reform since 2018, and have put in place an environment where people can select and practice their optimal workstyle based on the type and characteristics of their work, using a hybrid of working from home and working in the office. As work values diversify going forward, from 2022 our job satisfaction reform will involve promoting initiatives to increase employee engagement and create an enabling environment where diverse employees can participate with a view to increasing individual employees' job satisfaction. We will also aim to further increase effective employees to realize "TOP I 2030."

Moreover, we recognize that health and productivity management is the foundation of job satisfaction reform, and we are focused on promoting self-directed efforts by employees to maintain and improve their health. In 2022, a high proportion of around 90% of employees participated in cancer reexaminations. In addition, through the promotion of D&I, we will further accelerate efforts to promote the success of women (target for the end of 2030: a ratio of female managers that matches the overall ratio of female employees), as well as continuing to focus on creating an environment that enables diverse employees to play active

roles at work and achieve personal growth by tackling various issues such as balancing nursing care and childcare with work and issues faced by LGBTQ employees.

### Human Resource-related Indicators

	Indicators	2022 (actual)
Envisage individuals	Successor preparation rate for important key positions in Japan and overseas	224%
	Job-fill rate for highly competent specialists in fields such as science and digital technology (progress on target number)	68%
	Rate of people trying the challenge of management positions (ratio of new appointments through the Challenge Assignment System or in-house job posting system)	29%
Enhance individuals	Rate of regular "check-in" sessions conducted	78%
	Investment in human resource development per person	¥216 thousand
	Number of employees on assignment through the Roche Human Resource Exchange Program (cumulative)	245
Enable excellence of individuals	Employee engagement score (where score of companies with strong global performance is 100)	100
	Employee enablement score (where score of companies with strong global performance is 100)	89
	Ratio of female managers Ratio of female managers with subordinates <sup>5</sup>	17.8% 15.9%
	Percentage of male employees taking childcare leave	89.7%

5. Management positions with subordinates

### Column

## Personal Growth through the Experience of Free and Open Discussion with Researchers in Europe and the U.S. through Roche's Development of Global Formulation to Respond to Global Drug Regulations

Through dialogue with Roche leaders, I learned about the culture of leading global companies and R&D management. I learned that leadership that conducts field surveys and combines knowledge across organizations and fields becomes a source of open innovation. Ever since I realized that this was the key to further developing Chugai's strengths, I have been taking the initiative in conducting R&D that deepens the understanding of other fields and combines knowledge and experience.

It is also very helpful to have networks between dispatched employees across organizations in order to maintain a global culture of respect for individual opinions and questioning of one's own values, and a growth environment. After returning to Japan, I have drawn upon my dispatch experience to incorporate external technologies that have synergy potential with modalities that Chugai specializes in, aiming to provide value to society through swift R&D.



**Ryusuke Takano**

Group Manager  
Pre-Formulation 1 Group  
Formulation Development Dept.  
(At the time of dispatch in 2017:  
Production Engineering Dept.)

# Main Progress: Environment

## Initiatives for Mid-Term Environmental Goals 2030

Environmental preservation activities are an important platform to support all business activities. They are linked not only to reducing long-term environmental risks, but also to future cost reduction and the building of facility and equipment systems that generate innovation. In this way, environmental preservation activities have a significant impact on increasing corporate value.

Our Mid-Term Environmental Goals 2030 were formulated in 2020. Based on analysis of environmental issues, the goals identify three material issues and set out ambitious targets that are each also aligned with the environmental goals of the Roche Group. With regard to climate change countermeasures, a longer-term plan is needed, so we have set our goal of zero CO<sub>2</sub> emissions for the year by 2050 (Scope 1<sup>1</sup> and Scope 2<sup>1</sup>). We will work on measures such as renewing facilities and equipment and on converting to sustainable electricity, while also focusing on setting Scope 3<sup>2</sup> emissions reduction targets to reduce emissions across

the supply chain.

By promoting specific measures such as aggressively introducing sustainable electricity based on our roadmap for reducing CO<sub>2</sub> emissions, in 2022 we achieved a reduction of more than the 40% target for 2025. We are also making steady progress on our 2030 target of reducing emissions by 60-75%, with progress on electrification of equipment and optimization of the capacity utilization of co-generation systems. In 2020, we also conducted a scenario analysis in accordance with the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD), and have disclosed this on our website. In addition, we will continue to renew our scenario analysis following changes in business activities.

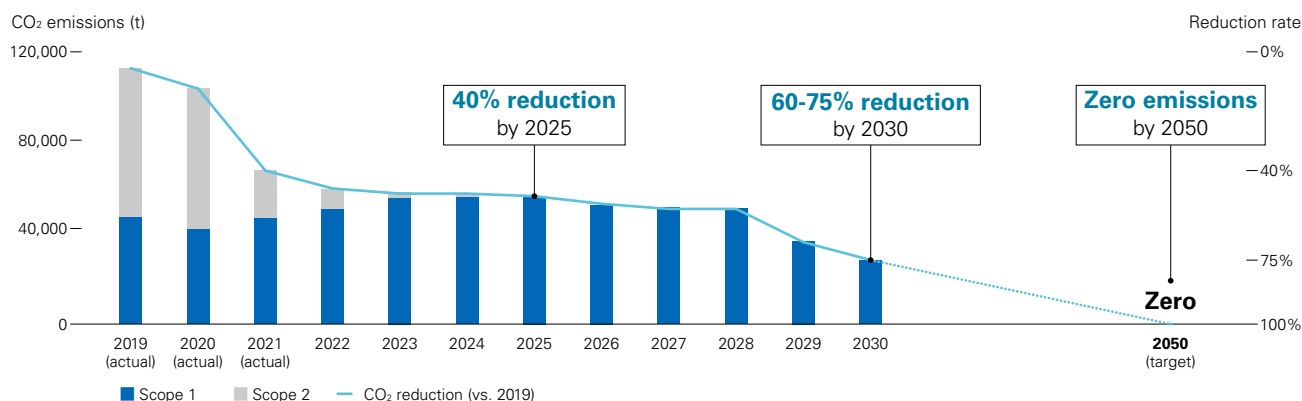
To promote the use of renewable and recycled resources, we are working toward zero waste emissions and reduced water consumption. For protection of biodiversity, meanwhile, we are introducing stricter management of hazardous chemical substances and designing improved manufacturing processes.

## Mid-Term Environmental Goals 2030

Material Issue	Item	KPI (Base year 2019)		
Climate change countermeasures (Prevention of global warming)	Scope 1+2 <sup>1</sup> CO <sub>2</sub> emissions reduction	40% reduction by 2025	60-75% reduction by 2030	Zero emissions by 2050
	Scope 1+2 <sup>1</sup> energy reduction	5% reduction <sup>3</sup> by 2025	15% reduction <sup>3</sup> by 2030	
	Sustainable electricity ratio	100% by 2025		
	Fuel consumption by MR vehicles	35% reduction by 2025	75% reduction by 2030	
	Fluorocarbons (Base year 2020)	25% reduction by 2025	100% reduction by 2030	
	Scope 3 <sup>2</sup> CO <sub>2</sub> emissions		30% reduction by 2030	
Use of renewable/recycled resources (Resource conservation, waste management)	Industrial waste reduction	5% reduction <sup>3</sup> by 2025	10% reduction <sup>3</sup> by 2030	
	Plastic waste reduction	5% reduction <sup>3</sup> by 2025	10% reduction <sup>3</sup> by 2030	
	Water resource conservation (water withdrawal)		15% reduction <sup>3</sup> by 2030	
Protection of biodiversity (environmental burden mitigation)	Chemical substance management (SVHCs <sup>4</sup> )	After 2021, manufacturing processes without using SVHC-listed chemicals are established for all Chugai original candidate molecules by commercial productions.		
	Hazardous waste reduction	5% reduction <sup>3</sup> by 2025	10% reduction <sup>3</sup> by 2030	

1. Scope 1: Direct emissions, Scope 2: Indirect emissions from the generation of purchased energy 2. Scope 3: Indirect emissions not included in Scope 1 and 2, target added in 2021  
3. Per total floor area (excluding leased properties) 4. Substances of Very High Concern

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




On the other hand, challenges to be addressed include new construction, equipment upgrades, and process improvements toward zero CO<sub>2</sub> emissions, including synchronization of production plans and the introduction of environmental equipment, in addition to the stable procurement of sustainable electricity at sites in Japan, its introduction at sites

overseas (Asia), and the development of equipment that uses natural refrigerants to help abolish the use of fluorocarbons. Currently, we are examining the technological issues for resolving these challenges one by one, and promoting a specific action plan across the entire Company.

Mid-Term Environmental Goals 2030 Categories	Action Steps	Main Progress and Initiatives
Scope 1+2 CO <sub>2</sub> emissions Energy consumption	<ul style="list-style-type: none"> <li>Build new facilities, update equipment, improve processes</li> <li>Measures to increase efficiency of existing facilities</li> <li>Electrification of Scope 1 facilities</li> <li>Identify next-generation energy sources</li> </ul>	<ul style="list-style-type: none"> <li>Achieved 2025 reduction target (40%) ahead of schedule</li> <li>Chugai Life Science Park Yokohama expected to obtain CASBEE<sup>5</sup> certification</li> <li>Introduced solar panels and non-distillation/membrane industrial water treatment facilities at new pharmaceutical manufacturing facilities</li> </ul>
Sustainable electricity ratio	<ul style="list-style-type: none"> <li>Stable procurement of sustainable electricity</li> <li>Introduction in Asia</li> </ul>	<ul style="list-style-type: none"> <li>100% introduction at four main business locations including Yokohama and Head Office planned from 2023</li> </ul>
Fluorocarbons usage	<ul style="list-style-type: none"> <li>Update and introduce production/HVAC equipment in line with facility characteristics</li> <li>Handling equipment without non-fluorocarbon technology</li> <li>Compatibility of production and facility renewal plans</li> </ul>	<ul style="list-style-type: none"> <li>Introduced new HCFO-1233zd(E) refrigerant in some existing equipment</li> <li>Planned to adopt centralized systems for some HVAC equipment</li> <li>Developed small-scale trial devices for use with natural refrigerant</li> </ul>

5. Comprehensive Assessment System for Built Environment Efficiency

 Please see the following for detailed environmental information.

Global Environment <https://www.chugai-pharm.co.jp/english/sustainability/environment/>

Sustainability Policy and Data <https://www.chugai-pharm.co.jp/english/sustainability/data/policy.html>

Activity Reports <https://www.chugai-pharm.co.jp/english/sustainability/activity/>

## Other Topics: Supply Chain Management

Chugai also evaluates suppliers from the perspectives of quality, supply, finance, agreements, and intellectual property/security, as well as environmental health and safety (EHS), human rights, and compliance, with a view to creating shared value. We hold information meetings to promote shared understanding and obtain statements of consent from suppliers regarding standards of behavior based on PSCI<sup>6</sup> principles. We also request improvements and provide advice based on the evaluation results in order to reduce risk. In addition, we are working to construct systems that can comprehensively evaluate and manage the results of the above evaluations.

In particular, with regard to evaluations from the perspectives of EHS and human rights and compliance, we have identified contract manufacturing organizations (CMOs) as important primary suppliers for evaluation, and we completed documentary evaluation and on-site inspections under the

PSCI framework by 2022 (based on the results, we did not terminate business with any companies), and at the same time, we have conducted periodic monitoring. Going forward, we will formulate methods for evaluating important secondary suppliers, and plan to conduct evaluations by 2030.

Looking ahead, we will focus on using external auditing organizations, developing internal auditors, and utilizing IT systems and digital technology to establish efficient evaluation and audit systems.

6. Pharmaceutical Supply Chain Initiative

### Comprehensive supplier evaluation goals

Subject	Item	Goal
Important new primary suppliers	Supplier evaluation completion	100% by 2030
Important existing secondary suppliers	Supplier evaluation completion	100% by 2030

## Other Topics: Intellectual Property Strategy

We consider our intellectual property strategy to be an important management issue. By integrating it with our management and R&D strategies, we will ensure the competitive advantage of our products globally and secure the freedom of our business. In particular, in addition to patents covering the substance and application of our products, to contribute to the maximization of product value, we also file strategic patent applications to provide long-term protection of products with respect to formulations, manufacturing methods, diagnostic methods, and personalized healthcare. We also strive to secure patents related to important drug discovery technologies, such

as the antibodies and mid-size molecules necessary for innovative drug discovery. Moreover, while we respect the effective intellectual property held by other companies, we deal rigorously with infringements on our own intellectual property, both in Japan and overseas. In April 2022, we published “Chugai’s position on Intellectual Property and Access to Health,” emphasizing the connection between intellectual property strategy and the resolution of social issues. We also report regularly to the Board of Directors regarding important issues related to intellectual property that are directly related to management.



# Dialogue with Stakeholders and External Evaluations

## Approach to Goals


To fulfill its basic management policy of creating shared value, Chugai believes that dialogue with shareholders, investors, and other stakeholders is essential. We strive to expand opportunities for dialogue and to analyze the opinions obtained through dialogue and incorporate them into

management. We also focus on providing timely, appropriate, and fair disclosure in accordance with relevant laws and regulations, and on actively disclosing information using various tools.

## Activity Performance

In 2022, we held meetings with institutional investors, securities analysts, and journalists to provide briefings on financial results, new products, and research and development addressing areas of high need, as well as an ESG Meeting, at which an independent outside director also gave a presentation. Furthermore, eight top executives including the CEO held an IR Day as an opportunity to speak and have discussions directly with institutional investors and securities analysts in small groups. For individual investors, we held online company presentations at which notable investors and economic analysts were invited for discussion. Moreover, we invited local residents and media for a tour of Chugai Life Science Park Yokohama, which was completed in October.

Meanwhile, with the aim of realizing advanced and sustainable patient-centric healthcare, we engage in proactive communication with patients, who are our key stakeholders, to facilitate mutual understanding. As for dialogue with patient organizations, in addition to dialogue held by each department as necessary, from 2020 onward, we have been holding a Company-wide dialogue once a year with participation by top management.

 For details, please refer to the Company's sustainability website.

Presentation materials

[https://www.chugai-pharm.co.jp/english/ir/reports\\_downloads/presentations.html](https://www.chugai-pharm.co.jp/english/ir/reports_downloads/presentations.html)

Collaboration with patient organizations (in Japanese only)

<https://www.chugai-pharm.co.jp/profile/overview/patientcentricity/collaboration/>



**IR Day (September)**  
Direct dialogue in small groups between eight top executives and institutional investors and securities analysts



**Company briefing for individual shareholders and investors (September)**  
A discussion between investor Mr. Toshiya Imura and CEO Dr. Osamu Okuda



**Company briefing for individual shareholders and investors (December)**  
A discussion between financial analyst Ms. Mariko Mabuchi and CFO Toshiaki Itagaki

## Main Initiatives and Progress (Last 3 years)

	2020	2021	2022
Number of media and IR information events	30	36	28
Total number of institutional investors and securities analysts attending meetings worldwide (Of which, number interviewed by executive team/executive officers at road shows overseas)	385 (33)	487 (94)	582 (99)
Number of briefings for individual investors and shareholders (Number of on-demand video views)	3 (1,604)	2 (1,818)	3 (4,670)
Attendance at the Annual General Meeting of Shareholders	46	68	86

## External Evaluations

Chugai ascertains expectations and demands from society and objectively examines its own initiatives based on analysis of the results of its selection for sustainability indices and the results of external evaluations of its ESG and IR activities, and uses its findings to improve its own activities. In a rapidly changing external environment, as a result of continuously working through this PDCA cycle, in 2022 we achieved high external evaluations for our ESG and IR activities, such as continued selection for major indices. In ESG especially, we were selected for the third consecutive year for DJSI World, which is composed of the top companies of each industry in the world, and we were also ranked No. 1 in the world in the pharmaceutical sector. In IR activities, we were ranked first among Japanese pharmaceutical companies in the CEO, CFO, and IR Team categories of the All Japan Executive Team ranking by US Institutional Investor magazine, as a

result of voting by 425 institutional investors and securities analysts worldwide.

Category	Material issue	External requirements	Industry standards	Progress on initiatives
Sustainable Healthcare	Creation of innovative drugs and services			
	Provision of solutions for patients			
	Adverse event management			
	Quality assurance and stable supply of products			
	Fair pricing			
Global Environment	Climate change countermeasures (energy, etc.)			
	Use of renewable/recycled resources (water, waste, etc.)			
	Prevention of substances from environmental burden (outgassing)			
	Environmental management system			
Human Rights	Human rights			
Human Resources	Safety of clinical trial subjects			
	Employee job satisfaction			
	Development of employee potential			
	Diversity and inclusion (D&I)			
Social Contribution	Occupational health and safety			
	Access to healthcare			
Governance	Corporate governance			
	Risk management			
	Disclosure and engagement			
	Personal information protection and information security			
Ethics and Compliance	Compliance			
	Code of conduct			
Supply Chain Management	Supply chain management			

### Materiality analysis based on index evaluation analysis

For details, please refer to the presentation material of Chugai ESG Meeting held in 2022

[https://www.chugai-pharm.co.jp/cont\\_file\\_dl.php?f=FILE\\_1\\_111.pdf&src=%0\],\[%1\]&rep=139,111](https://www.chugai-pharm.co.jp/cont_file_dl.php?f=FILE_1_111.pdf&src=%0],[%1]&rep=139,111)

## Main External Evaluations for ESG and IR Activities

ESG (DJSI, Pharmaceutical Sector)		2020	2021	2022
		3rd (Among 56 companies)	2nd (Among 53 companies)	1st (Among 47 companies)
	Global ranking			
	Asia Pacific ranking	1st (Among 16 companies)	1st (Among 18 companies)	1st (Among 15 companies)
IR (All Japan Executive Team, Biotechnology & Pharmaceuticals Sector)		2021	2022	2023
		2nd	6th	1st
		2nd	3rd	1st
		1st	3rd	1st

Selected for three consecutive years in the DJSI World, a global ESG investment index  
Received the world's highest rating in pharmaceutical sector in the DJSI 2022



Selected as a constituent in the FTSE4Good Index Series for the 20th consecutive year



Continued to be listed in all five ESG indices covering Japanese equities selected by GPIF\*



FTSE Blossom Japan



FTSE Blossom Japan Sector Relative Index



2022 CONSTITUENT MSCI JAPAN EMPOWERING WOMEN INDEX (WIN)

2022 CONSTITUENT MSCI JAPAN ESG SELECT LEADERS INDEX



\* Government Pension Investment Fund

As the result of a third-party audit, FTSE Russell (a registered trademark of FTSE International Limited and Frank Russell Company) hereby attests that Chugai satisfies the conditions of listing on the FTSE Blossom Japan Index and has been made a constituent stock of such index. The FTSE Blossom Japan Index was created by FTSE Russell, a global index provider, and has been designed to measure the performance of Japanese companies demonstrating excellent environmental, social, and governance (ESG) practices. The FTSE Blossom Japan Index is widely used in the creation and evaluation of sustainable investment funds and other financial products. As the result of a third-party audit, FTSE Russell (a registered trademark of FTSE International Limited and Frank Russell Company) hereby attests that Chugai satisfies the conditions of listing on the FTSE Blossom Japan Sector Relative Index and has been made a constituent stock of such index. The FTSE Blossom Japan Sector Relative Index is widely used in the creation and evaluation of sustainable investment funds and other financial products.

The inclusion of Chugai Pharmaceutical Co., Ltd. in any MSCI index, and the use of MSCI logos, trademarks, service marks or index names herein, do not constitute a sponsorship, endorsement or promotion of Chugai Pharmaceutical Co., Ltd. by MSCI or any of its affiliates. The MSCI indices are the exclusive property of MSCI. MSCI and the MSCI index names and logos are trademarks or service marks of MSCI or its affiliates.

## Message from the CFO



**We are focused on innovation — increasing strategic investment by taking full advantage of our unique business model, and boldly moving forward to make advanced medicines a reality. As a corporate member of society, we take our social responsibility seriously, providing social contribution and acting as a model corporate citizen.**

**Toshiaki Itagaki**

Director, Executive Vice President and CFO

### Facing Uncertainty and Fulfilling Our Commitment

We began 2022 with uncertainty. We announced our goal of sales and profit growth with revenue exceeding ¥1 trillion, but our contract with the government to supply Ronapreve was left unsigned, and there were concerns about decreasing exports of Actemra as the COVID-19 pandemic subsided. With 2022 behind us we are proud to say we were able to end the year with higher-than-projected results due to steady revenue growth from our core products both in Japan and abroad. Revenue was ¥1,168 billion (+16.8% year on year / +1.6% above projection), and our Core operating profit was ¥451.7 billion (+4.1% year on year / +2.7% above projection). 2022 was our sixth consecutive year of record-breaking financial results.

Based on a new contract forged in 2022, we successfully supplied Ronapreve to the government. Core products including Hemlibra and Kadcyla showed positive sales growth, and new products including Evrysdi, Polivy, Enspryng, and Vabysmo have been driving domestic sales. In overseas sales, exports of Actemra grew to address supply shortages in the market due to strong demand related to COVID-19, and exports of Hemlibra were steady, with strong ongoing demand.

On the other hand, royalties and other operating income decreased as predicted, as initial-stock royalties for Hemlibra ended. Our cost-to-sales ratio rose as planned with sales growth related to the government supply of Ronapreve, as did expenditures from increased investments in research

and development. As it was, 2022 brought us strong results despite the uncertainty in the business environment.

### A New Year and a Strong Trajectory

Considering the downside effects of pandemic-related demand coming full circle, I am projecting that some erosion of sales and profit is inevitable in 2023. I estimate a dip of ¥142.7 billion in revenue and ¥36.9 billion in Core operating profit for 2023 due to decreases in exports of Ronapreve and Actemra. Excluding these unique temporary factors, the upward trend in our sales and profit will remain intact. Our fundamental business is rock-solid.

In the domestic market, new products – Polivy, Vabysmo, Enspryng and Evrysdi – will contribute to growing sales. In overseas markets, we projected reduced sales of Hemlibra due to export restraints related to inventory optimization at Roche, but global demand for prescription drugs remains strong, so I expect that such restraints will be temporary. To endorse the strength of our overseas markets, we are projecting a 16.6% growth in other revenue, which includes royalties from Roche. We also project improvement in our cost-to-sales ratio with the decrease in sales of Ronapreve.

We plan to bring selling, general and administrative (SG&A) expenses below their 2022 levels by working to further raise efficiency and productivity, while enhancing our growth engine by increasing our R&D budget by ¥21.3 billion.

As a result, we are planning to achieve ¥1,070 billion in revenue (down 8.4% year on year), and ¥415 billion in Core operating profit (down 8.1% year on year). Although we are projecting a decline in both sales and profit, we are still expecting a second consecutive year of revenue over ¥1 trillion, Core operating profit exceeding ¥400 billion, and an operating profit ratio exceeding our 2022 figure at 38.8%.

For 2023, we are working to draw a clear trajectory to becoming a top innovator, giving up no momentum in R&D investment and responding flexibly to change.

## Another Year Unbridled by the Mid-Term Business Plan

Having freed ourselves from the constraint of the traditional three-year business plan, we have enjoyed two years of rolling out agile, event-driven planning. We have built a system to create optimal qualitative/quantitative balance and to reliably execute prioritized directions, without compromising essential strategy in favor of short-term profit and loss.

In compliance with the rules of the Tokyo Stock Exchange, we announce our projected performance figures for each year, but in 2021, we had to revise our projections mid-year due to the effects of the pandemic and issues related to the production of generic drugs. In 2022 there was no need to revise projections, as exchange-rate fluctuations, price increases, and shipping delays due to problems in the supply chain were balanced out by the positive effects of other factors. That said, our performance figures in real value

showed differences far greater than projected.

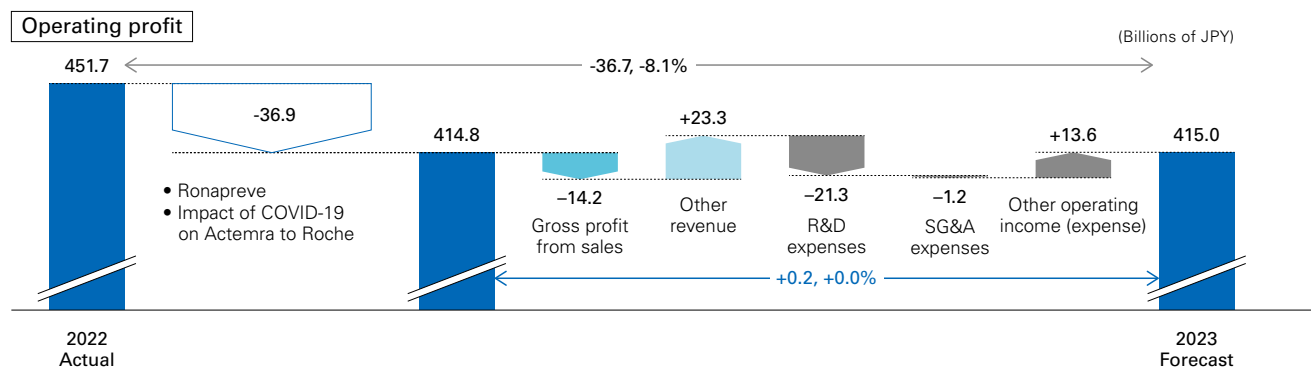
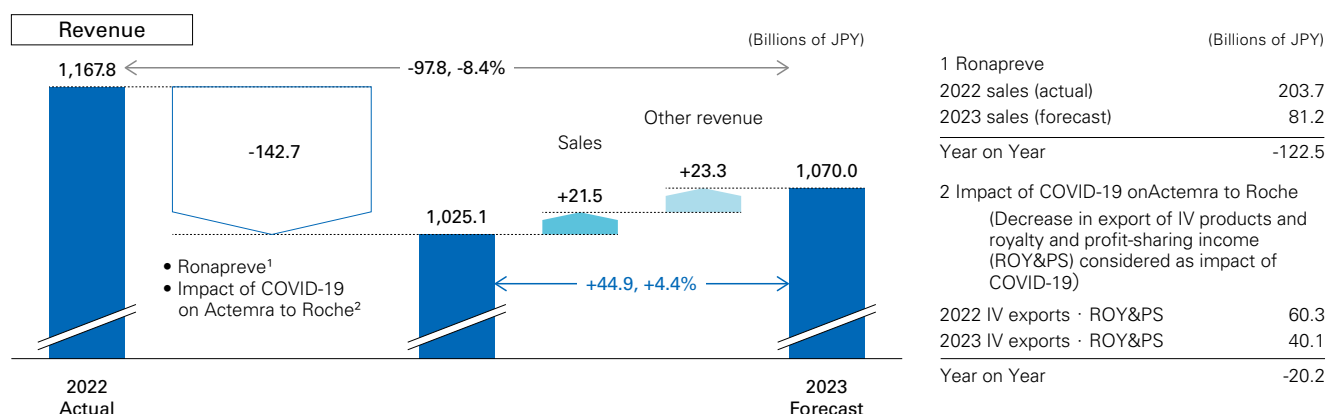
Our new projections for 2023, calculated to factor in changes in both the internal and external environments, are far different from our projections for 2023 in the three-year business plan drawn up in 2021. Had we continued operating under a fixed mid-term business plan and set financial goals to be achieved three years later, we would have wound up withdrawing and revising all those goals this year, in what would have been the final year of that plan.

Meanwhile our strategic challenges remain largely unaffected, as they were determined by back-casting from a long-term perspective. We need only make minor adjustments to the measures designated for each reform theme, depending on the progress toward preset milestones. We are working diligently to disclose more non-financial information, including progress related to our medium-term milestones and development pipelines, so we can maintain high-quality dialogue with our stakeholders.

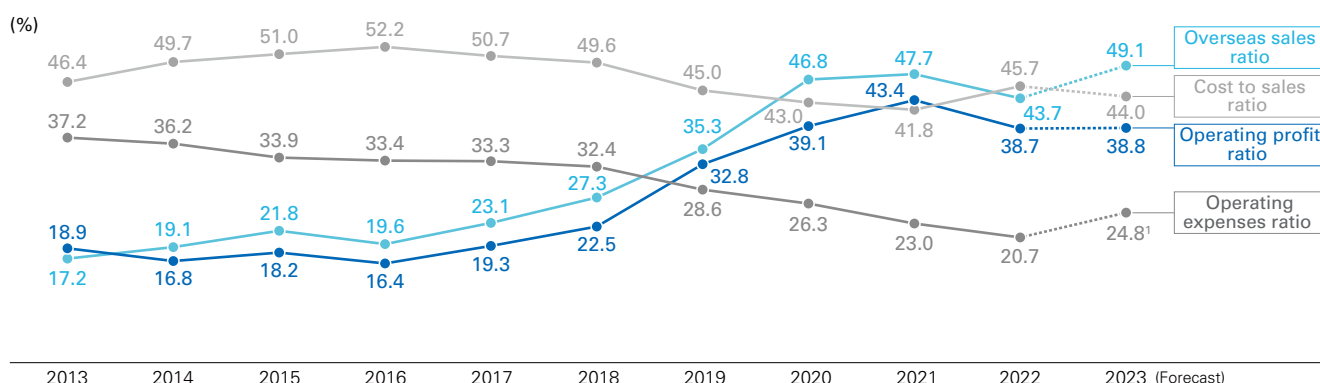
## Management Tools for a Unique Business Model

Our growth strategy spans ten years, back-casting medium-term milestones and implementing action plans to get there. Similarly, from a financial viewpoint, it is necessary to look at the ground under our feet (short-term), the flow of the river current (medium-term), and the bird's-eye view (long-term). We established financial KPIs based on these ideas, focusing on sales and Core operating profit in the short-term, growth rate of Core EPS in the medium term, and Core ROIC in the

### Impact of COVID-19-related Revenue



## Earnings Structure (Core Basis)



1. Expenses for 2023 forecast are calculated as R&D expenses + SG&A expenses

long term. Chugai has many products with a high market share, and so has a social responsibility to always maintain a certain level of safety stock, and – to ensure our autonomy – limit the holdings of Roche and remain listed on the stock markets for necessary liquidity of equity. This limits the firm in terms of total asset turnover and financial leverage control. This means that in order to improve ROE, we must raise our profit-to-sales ratio (margin). Based on this, we believe that the CAGR for Core EPS, which illustrates sustained margin growth, is the appropriate financial KPI for the medium term. The pharmaceuticals business necessarily operates in time frames of a decade and longer, so we must clearly quantify long-term investment efficiency. That is why we have chosen Core ROIC as our long-term KPI, even as many other firms instead choose ROE as their main indicator for capital efficiency.

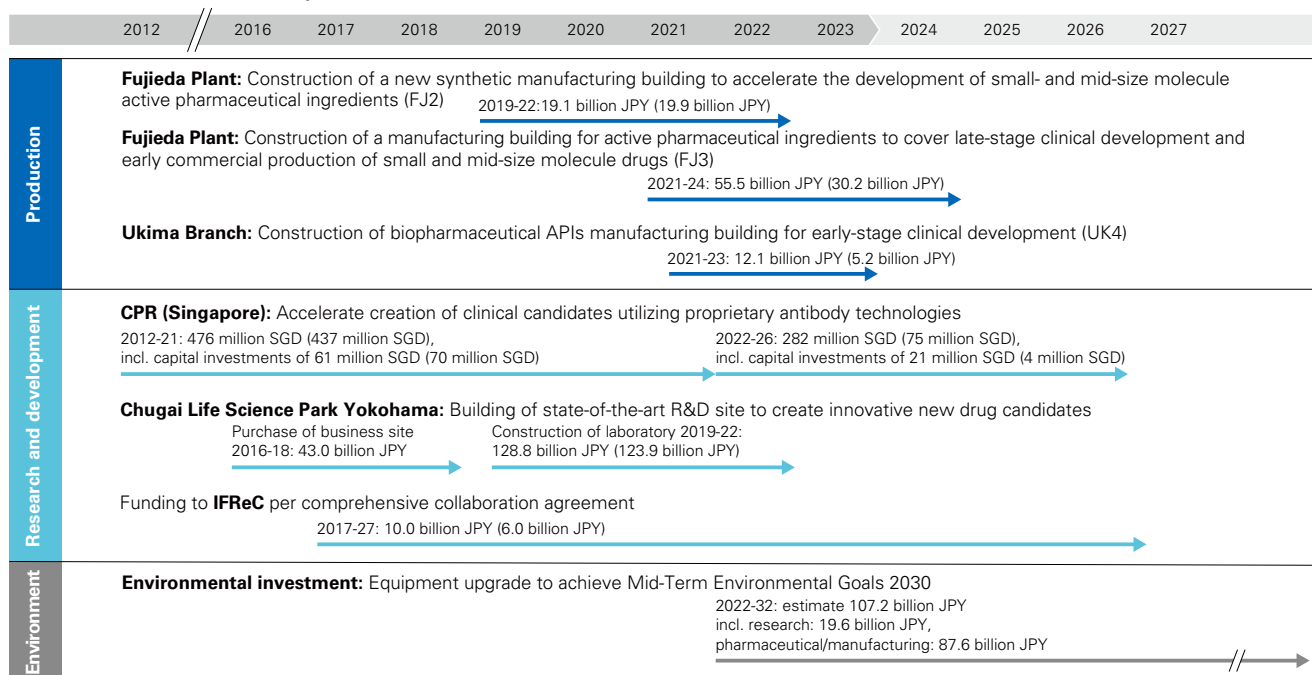
Our Core ROIC for 2022 was 36.1%, far above the return on investment/WACC that the capital markets expect, proving the efficiency of Chugai operations.

## Selection and Concentration for Cost Allocation

Our distribution of resources is unique, just like our financial viewpoint. You have probably noticed that Chugai's cost structure is significantly different from those of other companies in our line of work. Our cost-to-sales ratio is high, while the ratios of our sales management and R&D costs are low, and our operating profit ratio is very high. This profile comes from our unique business model. Our cost-to-sales ratio is high because we import Roche products for exclusive sales in Japan, which ensures stability in our earnings. Because we license Roche to develop and sell Chugai products abroad, our sales management and R&D costs are kept relatively low, but this also means that our revenue from them is low as well. However, the royalties we receive as the price of research on Chugai products keep our operating profit ratio high.

To keep this business model operating at a high level, two things are essential: strengthening our capability to produce

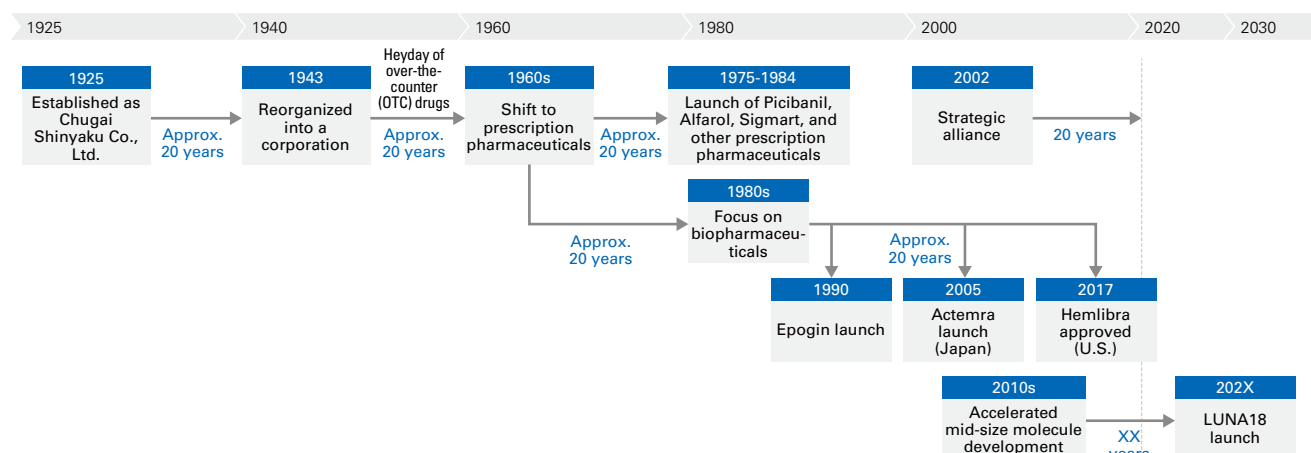
## Current Status / Plan for Major Investments



( ): Cumulative amount at the end of Mar, 2023



## 20-Year Cycle of Decisions and Outcomes



ground-breaking drug discovery, and continuously building productivity in sales, manufacturing, and other areas. This is why “RED Shift” is at the top of our strategic priorities in “TOP I 2030.” It focuses resources on our growth engine — drug discovery — and is designed to hone that strength through “Open Innovation” and optimize / raise the efficiency of operations through “DX.” We distribute our resources in accordance with this strategy. Our acceleration of R&D investment (+45% over three years, from ¥113.5 billion in 2020 to ¥165 billion projected for 2023) is proof of this. The goal of this strategic investment is to allow us to produce at least one new in-house global product every year, and to benefit patients around the world while building a high-revenue structure.

### Increasing Investment in the Source of Value Creation

This year we reviewed and restructured our value creation model (p.18). As it shows, the value we share with society “to realize advanced and sustainable patient-centric healthcare” is only possible with the creation and sustainable supply of innovative pharmaceutical products and services to society.

For this reason, we have created the TOP I 2030 value creation strategy, lighting the path to our target year, 2030. However, it takes more than ten years to discover innovative new drugs. So, we must move forward while looking even further into the future. In retrospect, we know it takes at least 20 years to accomplish anything meaningful. Looking beyond 2030, we must remain committed to innovation, and boldly move forward.

It has been more than a decade since we started research in mid-size molecule drug discovery, and the phase I results of our first mid-size molecule project, LUNA 18, will soon be announced. We are also honing our antibody-engineering technology. At the same time, we are making progress in cooperation with external partners in discovering innovative new drugs employing AI and digital technologies, as well as initiatives in process reformation. We will further increase investment in

human resources, drug discovery technologies, and networks, all of which are fundamental to the future of Chugai.

For shareholders, we plan to continue stable dividend payments without regard for short-term profit fluctuations, with a payout ratio averaging 45% of Core EPS as our benchmark.

See “Value Creation Model” on page 18.

### Moving Forward with Awareness of Our Responsibility to Society

From the standpoint of higher competitive value, we have designated social investment as an important theme, in addition to strategic investment as described above. ESG initiatives, for example, can be a profit-compressing factor in the short run, but they can help reduce the need for capital investment and capital cost in the future, so it is important to comprehensively manage and promote social investments while ascertaining their relative priority. Achieving our 2030 goal of being fluorocarbon<sup>2</sup>-free and reducing carbon dioxide emissions by 60-75% will require over ¥100 billion in environment-related investments. We believe that we will eventually recoup these investments as we are accepted by society as a corporate citizen who is a leader in addressing social challenges, with endorsement turning to empathy and returning to us as added corporate value. As a corporate member of society, we take our social responsibility seriously, working continuously to contribute and model responsible behavior.

We will continue working actively to make the most of virtual and in-person opportunities for dialogue with institutional and individual investors, as well as media representatives, through financial briefings and other theme-specific announcements on new products, ESGs and R&D. I hope you will share your honest opinions with us. Thank you very much for your support.

2. While making natural refrigerants the first choice, effectively select new refrigerants (green refrigerants)



# Governance

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# Message from the Chair of the Appointment Committee



**Dr. Fumio Tateishi**

Independent Outside Director  
Chair of the Appointment Committee

**Succession planning is extremely important for the sustainable increase of corporate value. Recognizing this, we are continually discussing the selection and development of a wide range of candidates.**

## Role and Composition of the Appointment Committee

The business environment going forward will be uncertain, volatile, and complex. To increase corporate value in such an environment, it is essential to select a management team in a manner that is objective, transparent and accountable, and to have a succession plan. To fulfill this role, the Appointment Committee functions as an advisory body to the Board of Directors, deliberating over the selection or dismissal of directors and plans for the development of successors for executive directors including the CEO.

The committee is to have one internal member, and at least three outside members, including at least one independent outside director. Moreover, with a view to ensuring diversity with regard to career background, expertise, culture, etc., the current committee comprises four members: Independent Outside Director Dr. Mariko Y Momoi, Non-Executive Director Teresa A. Graham, Representative Director, President & CEO Dr. Osamu Okuda, and myself. The committee is to be chaired by an outside director, and I was appointed to the role in March 2023.

## Focus Points and Aspirations Going Forward

In 2022, the Appointment Committee met twice, mainly to deliberate proposals for director candidates for the following fiscal year and the selection and development report on successor candidates to the CEO. Based on this deliberation, I was appointed director, and the committee also examined the optimal director composition for promoting TOP I 2030 and increasing corporate value. I have been told that these were extremely multifaceted discussions and deliberation.

With regard to succession plans for the executive team, including CEO successor candidates, we need a long-term and broad-ranging development plan. The Appointment Committee monitors the development plan for the execution side and analyzes the results of external assessments, as well as having discussions with the successor candidates. The target group mainly comprises executive officers, extending to a secondary group of potential candidates for the following generation.

Currently, the development plan for the executive team is focused on the experience and capabilities needed to continue and evolve the Company's unique business model, and on diversity. By incorporating fresh perspectives from newly appointed directors such as myself, we will engage in deeper discussion of this policy and methods for evaluating it. I will strive to enhance my conversations with candidates through various opportunities such as internal meetings and executive study sessions, and engage in continued discussion about the future vision for the Company's management and its management team, with a view to contributing to the enrichment of the Company's succession plans.



# Message from the Chair of the Compensation Committee



**Teresa A. Graham**

Non-Executive Director  
Chair of the Compensation Committee

**I will promote discussions to encourage continuous evolution based on rapidly changing industry trends, with a view to establishing an executive remuneration system linked to corporate value and management strategy.**

## **Role of the Compensation Committee and Approach to Executive Remuneration**

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My name is Teresa Graham, and I've been appointed chair of the Compensation Committee in March 2023. An important part of increasing corporate value is securing talented personnel who are able to implement the corporate philosophy and providing them appropriate incentives. The Compensation Committee plays a key role in our efforts to do this, and I will make every effort to uphold my responsibility as chair.

During the decision-making for executive remuneration and so forth, the Compensation Committee deliberates on the individual remuneration of each director, which is then finalized by resolution of the Board of Directors. The Compensation Committee is composed of four members, all of whom are non-executive or independent outside directors. The structure enables deliberations without any internal directors, which ensures that the process of deciding executive remuneration is transparent and objective. It is also important that we continue to evolve until we have a system design that is linked to corporate value increase and management strategy.

## **Activities of the Committee and Future Focus Points**

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The remuneration system has seen the strengthening of incentives for performance improvement with the introduction of restricted stock compensation in 2017 and has been revised to reflect not only financial results but also R&D results and achievement on ESG issues in the indicators for performance-linked remuneration in 2021. I think it is important that we continue to investigate these kinds of design.

In particular, since the Company's business environment and industry trends related to executive remuneration are changing rapidly, we must closely monitor recent cases. In 2023, the Compensation Committee will change its member composition, including the appointment of two new members. While firmly maintaining our existing policy, we must also respond to environmental changes and evolve further.

Last year, a third-party organization reviewed the Company's executive remuneration system and identified issues to be addressed. Looking ahead, we will analyze and examine these findings, and we will continue to strengthen our remuneration governance by improving the effectiveness of the Compensation Committee even further through continuous examination of system design and decision-making processes, while keeping an eye on the rapidly changing business environment and the latest industry trends related to executive remuneration.

# Message from the Chair of the Special Committee



**Hideo Teramoto**

Independent Outside Director  
Chair of the Special Committee

**To protect the interests of minority shareholders, we will deepen our discussion and deliberation in the Special Committee, looking to increase corporate value.**

## Establishment and Purpose of the Special Committee

In order to increase its corporate value, Chugai believes it is essential to have a governance structure to support its unique business model, backed by its strategic alliance with Roche. Therefore, we treat the protection of minority shareholders' interests as a critical issue. Before the establishment of the Special Committee, for important transactions with Roche, we undertook resolutions and reporting at the Board of Directors meetings, with directors belonging to Roche not participating in the deliberations due to their status as people with special interest relationships. In this way, we ensured transparency and objectivity.

However, with the revision of Japan's Corporate Governance Code, the Company decided to establish the Special Committee on March 29, 2022, with the intention of creating even stronger protection for the interests of minority shareholders as a company that has a controlling shareholder. By having the Special Committee deliberate and discuss transactions and actions that hold potential for a conflict of interest between Roche and minority shareholders, we can ensure fair transactions equivalent to third-party transactions. The Committee is to be made up of at least three members, all of whom must be independent outside directors or Audit & Supervisory Board members. From March 2023, I have been serving as the chair of the committee, and the other members have been Independent Outside Director Dr. Fumio Tateishi and Independent Outside Audit & Supervisory Board Member Kenichi Masuda.

## Activities to Date and Policy Going Forward

In addition to ensuring fairness for shareholders, the Special Committee's activities also help to support and evolve the Company's unique business model. In 2022, the Committee met four times, discussing and examining a revision of a basic agreement on a strategic alliance and proposals for in-licensing and out-licensing. The results were reported to the Board of Directors and the details of the discussions shared with the current committee members.

For agreements and licensing with Roche, there are a large number of extremely specialized matters, and each committee member needs to have sufficient understanding to be able to deliberate properly. We therefore intend to continue enhancing the provision of materials and individual dialogue with executive members prior to deliberation.

I myself will also deepen my understanding of industry trends and alliances, while concentrating my efforts as chair of the Special Committee on promoting deep and active discussion and consideration from multiple angles with a view to strengthening minority shareholders' interests.



# Directors / Audit & Supervisory Board Members (As of April 1, 2023)

## Executive Directors



**Dr. Osamu Okuda**

Representative Director, President & CEO

**Executive Director**

(Shares of the Company owned: 105 thousand shares)

1987 Joined the Company  
 2008 Department Manager of Lifecycle Management Dept. II  
 2009 Department Manager and Lifecycle Leader of Lifecycle Management Dept. II  
 2011 President of Roche Products (Ireland) Limited  
 2013 Head of Oncology Unit, Marketing & Sales Div. of the Company  
 2014 Executive Officer, Head of Oncology Unit, Marketing & Sales Div.  
 2015 Executive Officer, Head of Corporate Planning Dept.  
 2017 Executive Vice President, Head of Corporate Planning Dept.  
 2018 Executive Vice President, Co-Head of Project & Lifecycle Management Unit  
 2020 Representative Director, President & COO  
 2021 Representative Director, President & CEO (to present)



**Dr. Hisafumi Yamada**

Director, Executive Vice President

**Executive Director**

(Shares of the Company owned: 97 thousand shares)

1991 Joined Nippon Roche K.K. ("NR")  
 2002 Head of Cancer Drugs Research Dept. 1, Research Division of NR  
 Head of Pharmaceutical Research Dept. 4 of the Company  
 2006 Head of Research Planning & Coordination Dept.  
 2009 Vice President, Head of Research Div.  
 2016 Executive Vice President, Head of Research Div.  
 2018 Executive Vice President, Head of Translational Clinical Research Div.  
 2021 Executive Vice President  
 2022 Director, Executive Vice President (to present)



**Toshiaki Itagaki**

Director, Executive Vice President & CFO

**Executive Director**

(Shares of the Company owned: 20 thousand shares)

1983 Joined the Company  
 2007 Head of Finance & Accounting Dept.  
 2010 Head of Planning & Research Dept.  
 2012 Head of Marketing & Sales Planning Dept.  
 2015 Vice President, Head of Finance & Accounting Dept.  
 2018 Executive Vice President, CFO, Head of Finance Supervisory Div., Head of IT Supervisory Div., and Head of Finance & Accounting Dept.  
 2022 Director, Executive Vice President, CFO (to present)

## Non-Executive Directors



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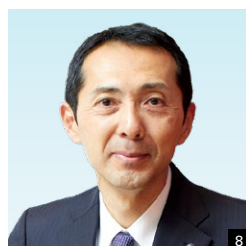


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## Audit & Supervisory Board Members



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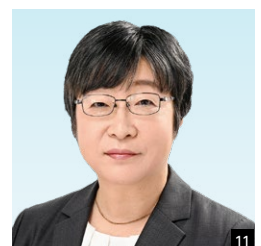
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## Non-Executive Directors

<b>1 Dr. Mariko Y Momoi</b> <span>Outside</span> <span>Independent</span> Professor Emeritus of Jichi Medical University Visiting Professor of School of Medicine, Shinshu University Regent of Tokyo Medical University (part-time)	1994	Head of Department of Pediatrics, Jichi Medical University	2014	Director of Japanese Medical Specialty Board
	2006	Director of Jichi Children's Medical Center Tochigi	2015	Vice President of International University of Health and Welfare and Head of IUHW Hospital
	2010	Dean of School of Medicine, Jichi Medical University	2017	Chief Medical Officer of Ryoumou Seishi Ryogoen, Kiryu Ryoiku Futabakai Social Welfare Corporation
	2012	Visiting Professor of School of Medicine, Shinshu University (to present)	2018	Regent of Tokyo Medical University (part-time) (to present)
	2013	Professor Emeritus of Jichi Medical University (to present) Vice President of International University of Health and Welfare	2020	Director of the Company (to present)
<b>2 Dr. Fumio Tateishi</b> <span>Outside</span> <span>Independent</span> Chairman of the Board of OMRON	1975	Joined Tateisi Electronics Co. (currently OMRON Corporation; "OMRON")	2003	Executive Officer and Executive Vice President of OMRON President, Industrial Automation Business Company of OMRON
	1997	Director of OMRON	2008	Director and Executive Vice Chairman of OMRON
	1999	Managing Executive Officer of OMRON	2013	Chairman of the Board of OMRON (to present)
	2001	Senior General Manager, Corporate Strategic Planning HQ of OMRON	2023	Director of the Company (to present)
<b>3 Hideo Teramoto</b> <span>Outside</span> <span>Independent</span> Representative Director, President of The Dai-ichi Life Research Institute Inc.	1983	Joined The Dai-ichi Mutual Life Insurance Company	2017	Director of DLH Representative Director and Vice Chairman of DLI
	2012	Director, Managing Executive Officer, Chief Deputy General Manager of Group Management Headquarters, and General Manager of Corporate Planning Dept. of The Dai-ichi Life Insurance Company, Limited ("DLI")	2020	Director, Vice Chairman, and General Manager of Innovation Strategy Unit of DLH
	2013	Director, Managing Executive Officer, and Deputy Chief General Manager of Group Management Headquarters of DLI	2021	Representative Director, Vice Chairman, and Executive Officer of DLH
	2015	Director, Senior Managing Executive Officer, Chief General Manager, Marketing Promotion of DLI	2022	Director of DLH Representative Director, President of The Dai-ichi Life Research Institute Inc. (to present)
	2016	Director, Senior Managing Executive Officer, and General Manager of Marketing Promotion of Dai-ichi Life Holdings, Inc. ("DLH")	2023	Director of the Company (to present)
		Director and Senior Managing Executive Officer of DLI		
<b>4 Dr. Christoph Franz</b> Vice-Chairman of the Board of Directors of Zurich Insurance Group Ltd. (Switzerland) Member of the Board of Directors of Stadler Rail Ltd. (Switzerland)	1990	Joined Deutsche Lufthansa AG	2011	Chairman of the Executive Board and CEO of Deutsche Lufthansa AG
	1994	Member of the Executive Board and CEO of Passenger Transport Division of Deutsche Bahn AG	2014	Chairman of the Board of Directors of Roche Holding Ltd.
	2004	CEO of Swiss International Air Lines AG	2017	Director of the Company (to present)
	2009	Deputy Chairman of the Executive Board of Deutsche Lufthansa AG		
<b>5 Dr. James H. Sabry</b> Global Head of Roche Pharma Partnering and Member of the Roche Enlarged Corporate Executive Committee	1997	Co-founder, President and CEO of Cytokinetics	2018	Global Head of Roche Pharma Partnering and Member of the Roche Enlarged Corporate Executive Committee (to present)
	2008	President and CEO of Arete Therapeutics	2019	Director of the Company (to present)
	2010	Global Head and Vice President of Genentech Partnering		
	2013	Global Head and Senior Vice President of Genentech Partnering		
<b>6 Teresa A. Graham</b> CEO of Roche Pharmaceuticals and Member of the Roche Corporate Executive Committee	2005	Joined Genentech as Product Manager	2017	Genentech Vice President Rheumatology/Nephrology
	2010	Genentech Sales Manager	2018	Genentech Vice President AATE & LGI Sales
	2011	Genentech Marketing Director, Rituxan Immunology	2019	Roche Pharma Head of Global Product Strategy
	2012	Genentech Marketing Director, Actemra	2023	CEO of Roche Pharmaceuticals and Member of the Roche Corporate Executive Committee (to present) Director of the Company (to present)
	2013	Genentech Sr. Director, Field Reimbursement Management		
	2015	Roche Lifecycle Leader, Actemra		

## Audit & Supervisory Board Members

<b>7 Dr. Yoshiaki Ohashi (Full-time)</b> (Shares of the Company owned: 42 thousand shares)	1988	Joined the Company	2018	Senior Vice President, Head of Quality & Regulatory Compliance Unit and Head of Drug Safety Div.
	2004	Department Manager, Quality & Regulatory Compliance Dept.	2021	Senior Vice President Full-Time Audit & Supervisory Board Member (to present)
	2009	Department Manager, Drug Safety Coordination Dept.		
	2013	Head of Drug Safety Div. and Department Manager of Drug Safety Coordination Dept.		
	2015	Vice President, Head of Drug Safety Div. Vice President, Head of Quality & Regulatory Compliance Unit, and Head of Drug Safety Div.		
<b>8 Dr. Shigehiro Yamada (Full-time)</b> (Shares of the Company owned: 1.9 thousand shares)	2005	Joined the Company	2019	Head of Corporate Social Responsibility Dept. of the Company Head of Sustainability Dept. of the Company
	2016	Head of Pharmaceutical Technology Planning Dept.	2023	Full-Time Audit & Supervisory Board Member (to present)
	2018	Head of Corporate Planning Dept. of Chugai Pharma Manufacturing Co., Ltd.		
<b>9 Takaaki Nimura</b> <span>Outside</span> <span>Independent</span> Representative of Nimura Certified Public Accountant Office	1974	Joined Arthur Young & Co., Tokyo Office	2008	Executive Board Member of Ernst & Young ShinNihon LLC
	1980	Seconded to Asahi & Co., Osaka Office	2010	Established Nimura Certified Public Accountant Office
	1983	Seconded to Arthur Young & Co., Los Angeles Office	2012	Outside Director of Sony Corporation
	1989	Partner, Asahi Shinwa & Co.	2016	Outside Audit & Supervisory Board Member of the Company (to present)
	1993	Joined Showa Ota & Co. (currently Ernst & Young ShinNihon LLC)		
	1997	Senior Partner of Showa Ota & Co. (currently Ernst & Young ShinNihon LLC)		
<b>10 Kenichi Masuda</b> <span>Outside</span> <span>Independent</span> Partner of Anderson Mōri & Tomotsune Outside Director of Bridgestone Corporation Outside Audit & Supervisory Board Member of Mercuria Holdings Co., Ltd.	1988	Registered as an attorney-at-law (Daini Tokyo Bar Association), joined Anderson Mōri & Tomotsune	2016	Outside Director of Bridgestone Corporation (to present) Outside Audit & Supervisory Board Member of Mercuria Investment Co., Ltd. (Currently Mercuria Holdings Co., Ltd.) (to present)
	1993	Registered as an attorney-at-law in the state of New York		
	1997	Partner of Anderson Mōri & Tomotsune (to present)		
	2007	Outside Corporate Auditor of LIFENET INSURANCE COMPANY	2019	Visiting Professor of School of Law, The University of Tokyo
	2010	Part-time Lecturer at School of Law, The University of Tokyo	2020	Outside Audit & Supervisory Board Member of the Company (to present)
	2011	Outside Corporate Auditor of Bridgestone Corporation		
<b>11 Yumiko Waseda</b> <span>Outside</span> <span>Independent</span> Partner Attorney-at-Law/Partner Patent Attorney, Tokyo Roppongi Law and Patent Office Outside Audit & Supervisory Board Member of IHI Corporation	1985	Joined Matsuda Masayuki Law and Patent Office (currently Mori Hamada & Matsumoto)	2015	Outside Audit & Supervisory Board Member of Asahi Group Holdings, Ltd.
	2004	Vice President of Daini Tokyo Bar Association	2016	President of Daini Tokyo Bar Association Vice President of Japan Federation of Bar Associations
	2005	Executive Governor of Japan Federation of Bar Associations	2021	Outside Audit & Supervisory Board Member of IHI Corporation (to present)
	2013	Joined Tokyo Roppongi Law & Patent Office	2023	Outside Audit & Supervisory Board Member of the Company (to present)
	2014	Outside Audit & Supervisory Board Member of KAO Corporation		

Independent Independent officer pursuant to Article 436-2 of the regulations of Tokyo Stock Exchange, Inc.  
Note: Outside Audit & Supervisory Board members do not own Company shares.

# Corporate Governance

## Towards Realizing Our Mission

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. Under this Mission, Chugai aims to achieve the advanced and sustainable patient-centric healthcare set forth in its Envisioned Future through the creation of shared value with its various stakeholders.

To create this value on an ongoing basis, Chugai believes that putting in place and evolving a unique corporate governance system is also important. Under its strategic alliance with Roche, while being a member of the Roche Group, Chugai maintains its managerial autonomy and independence as a publicly listed company. Chugai pursues management that fulfills the mandate of its many stakeholders appropriately and fairly. The composition of the Board of Directors and the associated monitoring mechanisms are also based on this approach, which is designed to generate innovation by leveraging the essential value of our unique business model with its emphasis on diversity.

In response to the June 2021 revision of the Corporate Governance Code of the Tokyo Stock Exchange, we

reconfirmed our compliance with each of its principles. In the case of non-compliance, the item and the reason are indicated below as well as in our Corporate Governance Report.

### [Reasons for Not Implementing the Respective Principles of the Corporate Governance Code] Supplementary Principle 4.10.1 Establishment of independent advisory committees

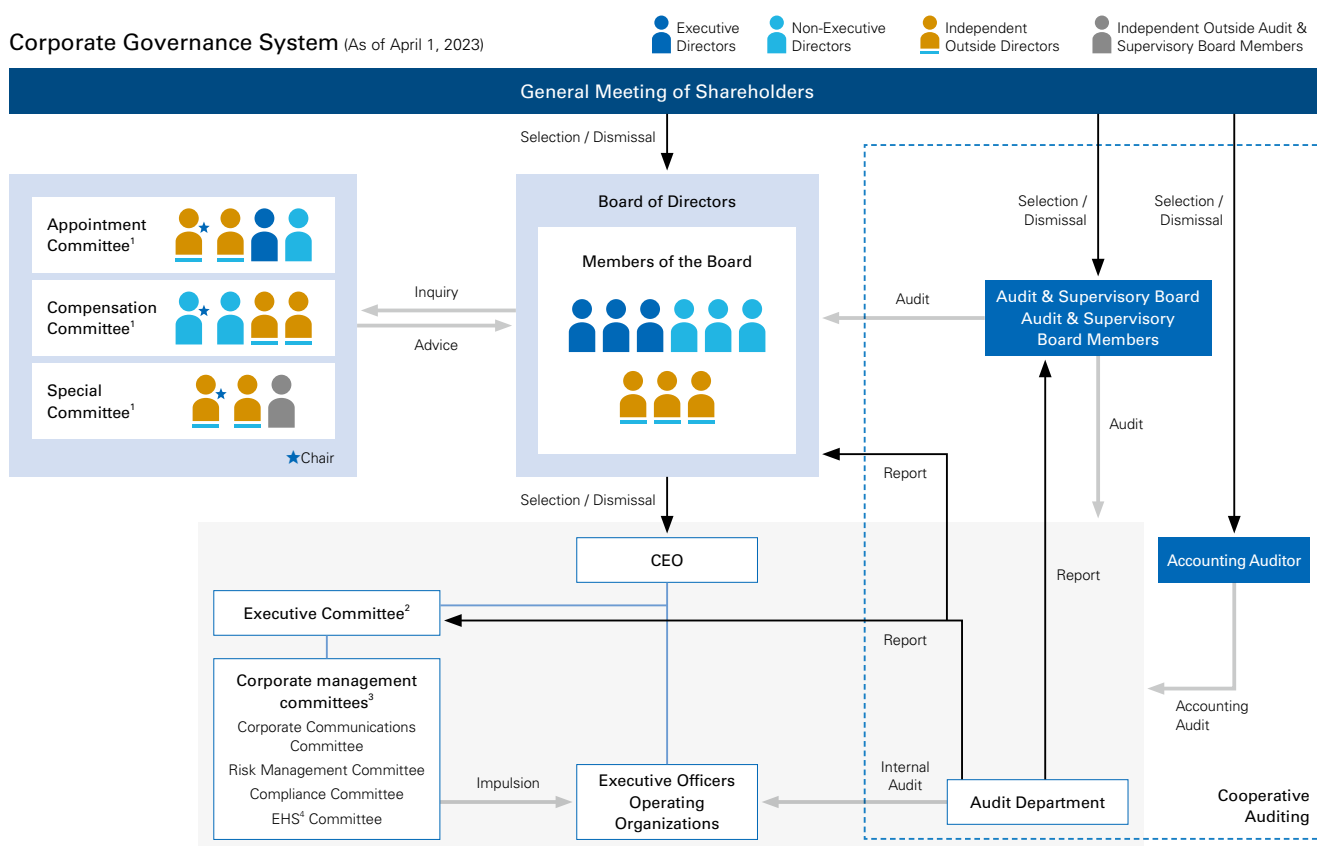
Although Chugai's Compensation Committee is not comprised of a majority of independent outside directors, all four of the Committee members are non-executive directors, including at least two independent outside directors.

In the deliberation by the Compensation Committee, if the deliberation by the Special Committee is considered appropriate by the member who also serves on the Special Committee, the Special Committee will deliberate and consider it, and report it to the Board of Directors. The Special Committee deliberates and reviews significant transactions and conducts, etc. that may generate a conflict of interests between the parent company Roche and minority shareholders. Therefore, in view of the purpose of the Corporate Governance Code, we believe that deliberations on remuneration are conducted with transparency and objectivity in the current structure.



Corporate Governance report and related materials  
<https://www.chugai-pharm.co.jp/english/ir/governance/report.html>

## Corporate Governance System (As of April 1, 2023)



1. Appointment Committee / Compensation Committee / Special Committee: Advisory bodies to the Board of Directors. The Appointment Committee deliberates on the selection of director candidates, succession plans for executive directors, and the dismissal of directors. The Compensation Committee deliberates on remuneration policy for directors and the remuneration of individual directors. The Special Committee, meanwhile, deliberates on and reviews including important transactions involving a potential conflict of interests between the parent company (Roche) and minority shareholders.
2. Executive Committee: Makes decisions on Company-wide management strategy and important matters concerning business execution.
3. Corporate management committees: Subcommittees of the Executive Committee. The Corporate Communications Committee makes decisions and oversees promotion of activities regarding information disclosure and dialogue with stakeholders; the Risk Management Committee oversees risk management and promotes activities to identify and measure major risks; the Compliance Committee reinforces the PDCA cycle for compliance activities and monitors the implementation of countermeasures and the status for particular items; and the EHS Committee works to integrate management of environment and occupational health and safety issues by making decisions, formulating strategies and overseeing the activities of each department.
4. Environment, Health and Safety (EHS)

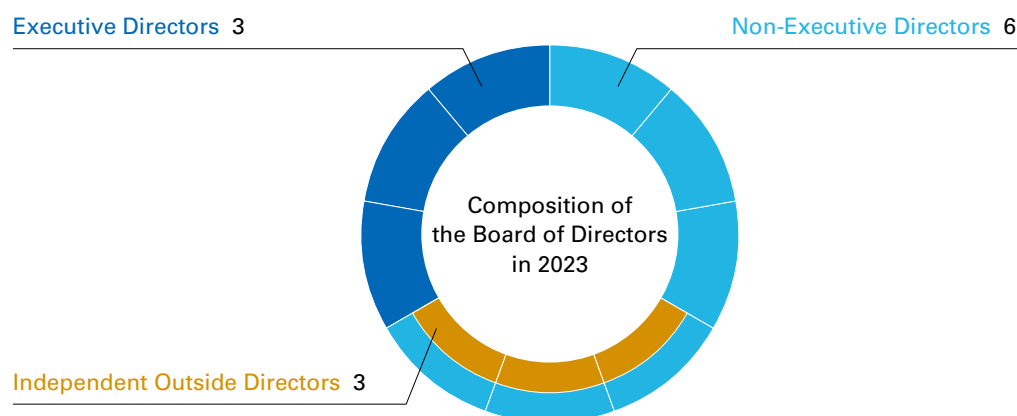
## A Governance Structure Supporting Chugai's Unique Business Model

In order to promote Chugai's unique business model while ensuring its effectiveness, we separate management decision-making (Board of Directors) and business execution (Executive Committee and others), thereby expediting business execution and clarifying executive responsibility.

To demonstrate the true value of its unique business model, the Board of Directors comprises three types of directors: executive directors, independent outside directors, and non-executive directors (excluding independent outside directors), each comprising one-third of the board, respectively. The composition of members preserves the diversity and scale of each type, which enables effective corporate governance that ensures management autonomy as an independent publicly listed company within the Roche Group, and helps to increase corporate value.

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.

Among the non-executive directors, independent outside directors are appointed based on their experience, 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 perspective. Other non-executive directors are 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. The terms of the office of five directors and two Audit & Supervisory Board members expired at the closing of the Annual General Meeting of Shareholders held on March 30, 2023. Two of the directors were reelected, in addition to which Dr. Fumio Tateishi, Mr. Hideo Teramoto, and Ms. Teresa A. Graham were newly elected and appointed as directors, and Dr. Shigehiro Yamada and Ms. Yumiko Waseda as Audit & Supervisory Board members.



### Column

#### Creation of Opportunities for Dialogue between Independent Outside Directors and Investors at ESG Meeting

Chugai's Board of Directors aims to ensure the rights and fair treatment of minority shareholders by conducting analysis of the status of exercise of voting rights at the Annual General Meeting of Shareholders to grasp and extract the opinion of minority shareholders, using this information as the basis for improvement activities. In the exercise of voting rights at the Annual General Meeting of Shareholders held in March 2022, the approval rate for CEO Dr. Okuda was a few percentage points lower than for other directors. We therefore identified the investors who voted against and analyzed their voting criteria. As a result, we determined that the reason was that we did not meet the criteria for voting in agreement of having a ratio of independent outside directors that constituted a majority of the overall Board of Directors (of a company with a controlling shareholder). We therefore set about fostering a deeper understanding of the Company's governance system and its current functional status. To this end, we judged it essential to provide new opportunities for dialogue with investors and set up an opportunity at our ESG Meeting held in November for then independent outside director Mr. Masayuki Oku to explain Chugai's governance from an independent perspective and its challenges going forward. At the Q&A session, there was a lively exchange of opinions. There is a high demand for opportunities for dialogue with independent outside directors and others, and we will strive to strengthen this kind of engagement going forward.



## Expertise and Experience of Directors and Audit & Supervisory Board Members (As of April 1, 2023)

	Positions, Responsibilities	Name	Roles	Expertise and experience expected of directors and Audit & Supervisory Board members						
				Corporate management	R&D	Sales, Marketing	Finance, Accounting, Tax affairs	Legal affairs, intellectual property, Risk management	Medical science, Pharmaceutical sciences	International experience
Executive Directors	Representative Director, President & CEO	Dr. Osamu Okuda	Chair of the Board of Directors Appointment Committee member	●	●	●			●	●
	Director Executive Vice President	Dr. Hisafumi Yamada		●	●				●	●
	Director Executive Vice President & CFO	Toshiaki Itagaki		●		●	●			●
Independent Outside Directors	Outside Director*	Dr. Mariko Y Momoi	Appointment Committee member						●	●
	Outside Director*	Dr. Fumio Tateishi	Chair of the Appointment Committee Compensation Committee member Special Committee member	●		●		●		●
	Outside Director*	Hideo Teramoto	Chair of the Special Committee Compensation Committee member	●		●	●	●		
Non-Executive Directors	Director	Dr. Christoph Franz	Compensation Committee member	●						●
	Director (Global Head of Roche Pharma Partnering and Member of the Roche Enlarged Corporate Executive Committee)	Dr. James H. Sabry		●	●				●	●
	Director (CEO Roche Pharmaceuticals and Member of the Roche Corporate Executive Committee)	Teresa A. Graham	Chair of the Compensation Committee Appointment Committee member	●	●	●				●
Audit & Supervisory Board Members	Full-Time Audit & Supervisory Board Member	Dr. Yoshiaki Ohashi			●			●	●	●
	Full-Time Audit & Supervisory Board Member	Dr. Shigehiro Yamada			●			●		●
	Outside Audit & Supervisory Board Member*	Takaaki Nimura					●			●
	Outside Audit & Supervisory Board Member*	Kenichi Masuda	Special Committee member					●		●
	Outside Audit & Supervisory Board Member*	Yumiko Waseda						●		

\* Designated as an independent officer pursuant to the regulations of Tokyo Stock Exchange, Inc., to which notification has been made.

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

In accordance with the strategic alliance between the two companies, Chugai's parent company Roche holds 59.89% of Chugai's outstanding shares. Chugai and Roche have further agreed to cooperate to maintain Chugai's common stock listing on the Prime Market of the Tokyo Stock Exchange (TSE). As an independently listed company, Chugai bases all decision-making 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 Prime Market of the TSE—such as its solid credit



rating, flexible fund procurement, name recognition, and social presence—are supported by the understanding of shareholders other than Roche, i.e., minority shareholders 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. Furthermore, the Special Committee was established in March 2022 to deliberate and review significant transactions and conducts, etc. that may generate a conflict of interests between the parent company Roche and minority shareholders. Chugai is working to gain the latter's trust by ensuring due consideration of their interests. In 2022, the Special Committee met four times: two ordinary meetings and two extraordinary meetings.

To ensure substantially equal treatment of shareholders, Chugai emphasizes the importance of giving due consideration to minority and foreign shareholders and maintaining an environment that allows them to exercise their rights. We therefore undertake timely, appropriate, and fair information disclosure activities in accordance with relevant laws and regulations.

#### 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

#### Column Message from Roche's CEO

*Our alliance has been a win-win relationship – for Chugai and Roche, and even more importantly for so many patients in Japan as well as around the world.*

#### Dr. Thomas Schinecker

Chief Executive Officer, Roche Group



As the new Roche Group CEO, I am delighted to continue our close collaboration with Chugai as part of our companies' strategic alliance. Our commitment to innovations and entrepreneurial spirit are the pillars of our joint success.

I have always considered the partnership between Roche and Chugai an outstanding success story: since the beginning of our strategic alliance more than 20 years ago, Chugai has made twenty Roche medicines available to patients in Japan, and four breakthrough medicines from Chugai have reached patients across the world through Roche. Our alliance has been a win-win relationship – for Chugai and Roche, and even more importantly for so many patients in Japan as well as around the world.

With Roche as a majority shareholder, Chugai has been able to maintain a high degree of independence. This enables Chugai to make the right decisions for its Japanese market, and it also supports Chugai's own approach to innovation.

Chugai has a unique culture and exceptional technological and scientific expertise. This has been the foundation of Chugai's leadership in Japan. I admire Chugai's innovation power and the persistence the company has demonstrated in discovering novel drugs and translating them into innovative medicines to patients. Chugai's research and development endeavors led to game-changing medicines such as Hemlibra and Enspryng.

While both companies have their own distinct cultures, the strong collaborative mindset between Chugai and Roche, based on mutual trust and our common pursuit to make a real difference for patients, has been and will remain at the core of our alliance. I very much look forward to continuing our highly successful collaboration.

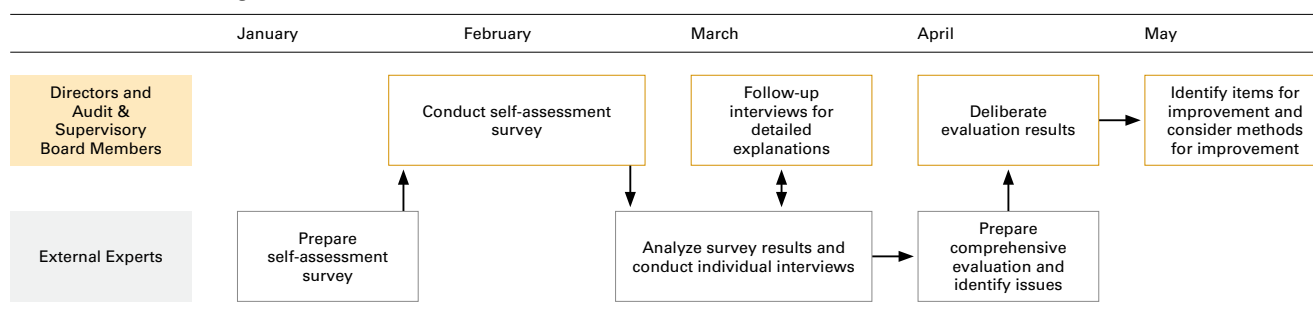
## Improving the Effectiveness of the Board of Directors

Chugai has focused on evaluation of the effectiveness of the Board of Directors and improvement activities based on evaluation results since 2015.

Effectiveness evaluation is carried out from February to March of every year through a self-assessment survey of currently serving directors and Audit & Supervisory Board members who were in office during the applicable period. The Board of Directors discusses the survey results after receiving a relevant report from the Secretariat. Starting with

the 2019 effectiveness evaluation, we made changes to further enhance outside perspectives and objectivity. Under the new system, external experts formulate the survey items and analyze the grounds for the respective self-assessments and the logical basis for reaching the self-assessment results, as well as other matters. Then, they make a comprehensive evaluation after conducting individual interviews if necessary, and report issues and propose effective countermeasures to the Board of Directors.

### Process for Evaluating the Effectiveness of the Board of Directors



### Status of Improvements Identified through Evaluation of the Effectiveness of the Board of Directors (Last 5 years)

Applicable year	Main items for improvement	Main new initiatives implemented after analysis and evaluation
2017	<ul style="list-style-type: none"> <li>Conduct prior and additional explanations on agenda items with complex content such as governance and legal matters</li> </ul>	<ul style="list-style-type: none"> <li>Issued the Chugai IR Activities Report to outside officers (every quarter)</li> <li>Provided a glossary of technical terms, abbreviations, and the like to outside officers</li> </ul>
2018	<ul style="list-style-type: none"> <li>Ensure greater diversity of the Board of Directors</li> <li>Provide more information to outside directors and outside Audit &amp; Supervisory Board members</li> </ul>	<ul style="list-style-type: none"> <li>Conducted deliberation by the Appointment Committee</li> <li>Convened a Board of Directors' meeting and conducted a tour at the Fujieda Plant</li> <li>Held briefings on departmental operations</li> </ul>
2019	<ul style="list-style-type: none"> <li>Oversight of transactions with the parent company</li> <li>Enhanced Group company oversight and Group internal control</li> </ul>	<ul style="list-style-type: none"> <li>Conducted briefings through liaison meetings for outside officers to enhance understanding of the content of the basic agreement with the parent company</li> <li>Presented regular and timely reports on the internal control status of overseas subsidiaries at Board of Directors' meetings</li> </ul>
2020	<ul style="list-style-type: none"> <li>Compliance with the revised Corporate Governance Code</li> </ul>	<ul style="list-style-type: none"> <li>Revised our Basic Corporate Governance Policy</li> </ul>
2021	<ul style="list-style-type: none"> <li>Reorganization of the framework and elements for consideration pertaining to determining the fairness of transaction conditions by the Special Committee, and deliberation on these by the Board of Directors on the basis of the report by the Special Committee</li> <li>Operation of the Board of Directors, information provision and information sharing during the COVID-19 pandemic</li> </ul>	<ul style="list-style-type: none"> <li>Established and operated the Special Committee</li> <li>Established the Special Committee, operated it appropriately, and made reports to the Board of Directors</li> <li>Conducted Board of Directors meetings at overseas research laboratories of the Chugai Group</li> </ul>

## Principal Matters Deliberated by the Board of Directors

<b>Matters Concerning the General Meeting of Shareholders</b>	<ul style="list-style-type: none"> <li>• Calling of the General Meeting of Shareholders and determination of the agenda items</li> <li>• Approval of the business report, financial statements, and other documents</li> <li>• Selection of director and Audit &amp; Supervisory Board member candidates</li> </ul>
<b>Matters Concerning Directors and Audit &amp; Supervisory Board Members</b>	<ul style="list-style-type: none"> <li>• Directors' remuneration</li> <li>• Selection and dismissal of executive officers and advisors</li> <li>• Selection of Appointment Committee, Compensation Committee, and Special Committee members</li> <li>• Selection and dismissal of representative directors and executive directors</li> </ul>
<b>Matters Concerning Stock</b>	<ul style="list-style-type: none"> <li>• Payment of interim dividends</li> <li>• Allocation of restricted stock</li> </ul>
<b>Matters Concerning Management in General</b>	<ul style="list-style-type: none"> <li>• Formulation of plans and policies and relevant progress reports (concerning TOP I 2030, the HR system, Mid-Term Environmental Goals 2030, etc.)</li> <li>• Discussion of new business plans, alliances, and related matters (e.g., research and development, DX, and other open innovation-related items)</li> <li>• Discussion of decision-making structure and organizations</li> <li>• Matters concerning finance and assets (construction plans for new production facilities, restructuring plans for research facilities, etc.)</li> </ul>
<b>Other Matters</b>	<ul style="list-style-type: none"> <li>• Approval and reporting of competing transactions</li> <li>• Approval and reporting of conflict of interest transactions</li> <li>• Reporting on internal control, internal audits, Risk Management Committee, Compliance Committee, EHS Committee, and investor relations (IR) activities</li> <li>• Implementation and reporting of evaluation of the effectiveness of the Board of Directors</li> <li>• Status of voting on proposals at the Annual General Meeting of Shareholders</li> <li>• Verification of cross shareholdings</li> </ul>

## Principal Matters Deliberated by the Executive Committee and Corporate Management Committees (2022)

<b>Executive Committee</b>	<ul style="list-style-type: none"> <li>• Management policy, medium- to long-term strategy, and other key policies</li> <li>• Medium- to long-term and annual business plans</li> <li>• Key policies relating to Company-wide business execution</li> <li>• Policy on issues of management strategy</li> <li>• Key matters in Company-wide control and coordination</li> <li>• Key policy matters relating to HR development, appointment, individual personnel matters, and allocation</li> <li>• Matters relating to organizational performance evaluation systems</li> <li>• Other key matters relating to general corporate management</li> </ul>
<b>Corporate Communications Committee</b>	<ul style="list-style-type: none"> <li>• Formulation of policy on corporate information disclosure (Company-wide communications) to internal and external stakeholders</li> <li>• Decision on corporate communications strategy and policy on risks impacting corporate value and reputation</li> </ul>
<b>Risk Management Committee</b>	<ul style="list-style-type: none"> <li>• Deliberation and proposal of risk management policy</li> <li>• Maintenance and monitoring of risk management system</li> <li>• Submission to Executive Committee of identification of important risk issues and selection of the responding departments</li> <li>• Deliberation and decision on the establishment of risk response subcommittees and the Emergency Headquarters</li> </ul>
<b>Compliance Committee*</b>	<ul style="list-style-type: none"> <li>• Formulation and evaluation of key measures relating to compliance promotion and monitoring of their progress</li> <li>• Assessment of compliance risk and formulation of countermeasures</li> <li>• Analysis of cause of compliance infringements or other compliance issues and exploration of measures to prevent recurrence (in cooperation with the Risk Management Committee)</li> <li>• Revision of compliance-related regulations</li> </ul>
<b>EHS Committee</b>	<ul style="list-style-type: none"> <li>• Key policies and measures relating to environmental protection and health and safety activities</li> </ul>

\* Made up of the Corporate Meeting, Healthcare Meeting, and GxP Meeting

## Officer Remuneration Emphasizing Linkage with Performance and Stock Price

Chugai has designed its remuneration plan for directors and Audit & Supervisory Board members to attract outstanding people and appropriately motivate them in order to continuously increase the Chugai Group's corporate value.

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, executive director remuneration consists of bonuses paid according to performance and other factors in each fiscal year as a short-term incentive and restricted stock compensation linked to medium- and long-term performance (tenure-based and performance-based) as a long-term incentive, in addition to fixed regular compensation. The guidelines for remuneration composition by type are as follows: for CEO remuneration it is 35 percent regular compensation, 30 percent bonuses, and 35 percent stock compensation; for other executive directors it is determined in consideration of duties and other factors (see table below).

Bonuses are determined by multiplying the standard amount set for each position by an evaluation coefficient reflecting an overall assessment based on Company and individual performance set with reference to the published forecasts for the relevant fiscal year. For restricted stock compensation, 50 percent is tenure-based restricted stock with a transfer restriction period of three to five years, and 50 percent is performance-based restricted stock.

Remuneration of non-executive directors, including outside directors, and Audit & Supervisory Board members consists solely of fixed regular compensation.

Individual remuneration is determined within the total amounts approved at the General Meeting of Shareholders via the following respective processes: Remuneration is decided for executive directors by the Board of Directors following deliberation by the Compensation Committee; for non-executive directors, including outside directors, by the CEO acting on request from the Board of Directors and based on a report by the Compensation Committee; and for Audit & Supervisory Board members through deliberation among the members themselves. So that the relevant deliberations take place with expert input on officer remuneration systems and with due consideration of other factors, including the wider changes affecting corporate executive remuneration, the Compensation Committee—which is appointed by the Board of Directors and consists of three or more external members, at least one of whom is an independent outside director—bases its discussion on the results of a survey by an external expert organization, thus ensuring the transparency and objectivity of the decision-making process so that it can uphold accountability to stakeholders.



Notice of Convocation of the 112th Annual General Meeting of Shareholders (Pages 51–54)  
[https://www.chugai-pharm.co.jp/english/ir/share/agm/files/230228eChugai\\_112thAGM\\_Convo.pdf#page=52](https://www.chugai-pharm.co.jp/english/ir/share/agm/files/230228eChugai_112thAGM_Convo.pdf#page=52)

### System for Remuneration of Directors and Audit & Supervisory Board Members

Type of remuneration			Eligible officers			Payment criteria	Payment method
			Executive directors	Non-executive directors (including outside directors)	Audit & Supervisory Board members		
Fixed Regular Compensation	Regular compensation		●	●	●	Position, duties, and other factors	Monthly (Cash)
	Bonuses		●	—	—	Performance in each fiscal year	Yearly (Cash)
Performance-Based Remuneration	Long-term incentive (Stock-based compensation)	Tenure-based restricted stock	●	—	—	Fixed length of service	Yearly (Common stock)
		Performance-based restricted stock	●	—	—	Performance over fixed period in addition to above	Yearly (Common stock)

### Reference Indicators for Performance-Based Remuneration of Executive Directors

Fixed	Performance-based	
Regular compensation (CEO: 35%)	Bonuses (CEO: 30%)	Restricted stock compensation (CEO: 35%)
	Indicators	Indicators
	<ul style="list-style-type: none"> <li>Core operating profit</li> <li>Revenue</li> <li>R&amp;D performance (Main R&amp;D output (pre/post-PoC), number of projects progressing to preclinical phase)</li> <li>Measures to meet performance targets in areas of operational responsibility</li> <li>Degree of achievement of ESG objectives (based on evaluation by expert organization, etc.)</li> </ul>	<ul style="list-style-type: none"> <li><b>[Continuous service-based] (50%)</b> <ul style="list-style-type: none"> <li>Continuous service during the transfer restriction period</li> </ul> </li> <li><b>[Performance-based] (50%)</b> <ul style="list-style-type: none"> <li>Total shareholder return (TSR) (Evaluation period: 3 fiscal years) (Number of shares applicable to the lifting of transfer restriction shall be determined within the range of 0% to 100%, based on the comparison of total shareholder return with other domestic pharmaceutical companies.)</li> </ul> </li> </ul>

## Results in 2022: Amount of Remuneration Paid to Directors and Audit & Supervisory Board Members

Position	Total remuneration, etc. (Millions of yen)	Total amount by type of remuneration, etc. (Millions of yen)				Number of eligible officers
		Regular compensation	Bonuses	Restricted stock compensation		
				Tenure-based	Performance-based	
Directors (Excluding Outside Directors)	486	195	159	65	68	5
Outside Directors	48	48	—	—	—	3
Total	534	401		133		8
Audit & Supervisory Board Members (Excluding Outside Audit & Supervisory Board Members)	63	63	—	—	—	2
Outside Audit & Supervisory Board Members	38	38	—	—	—	3
Total	101	101		—		5


Notes: 1. Amounts are rounded to the nearest million yen.  
 2. The above includes two directors who retired during the fiscal year under review.  
 3. The above bonus amount is the actual amount of executive bonuses for the fiscal year under review.  
 4. The amounts of restricted stock compensation (tenure-based and performance-based) shown in the table above are the amounts recorded as expenses for the fiscal year under review as each respective restricted stock compensation.


## Results in 2022: Amount of Remuneration Paid to Representative Director

Name	Consolidated remuneration total by type (Millions of yen)				Total consolidated remuneration (Millions of yen)
	Regular compensation	Bonuses	Restricted stock compensation		
			Tenure-based	Performance-based	
Dr. Osamu Okuda	108	110	35	45	299

Notes: 1. Amounts are rounded to the nearest million yen.  
 2. Figures show the total amount of remuneration, etc., for representative director.  
 3. Other than the representative director in the table above, no director or Audit & Supervisory Board member received total remuneration of ¥100 million or more.


For more information on Chugai's Corporate Governance, please refer to our website.


 Corporate Governance  
<https://www.chugai-pharm.co.jp/english/ir/governance/>

 Corporate Governance report and related materials  
<https://www.chugai-pharm.co.jp/english/ir/governance/report.html>

 Basic Approach  
<https://www.chugai-pharm.co.jp/english/ir/governance/concept.html>

- Corporate Governance Report
- Basic Corporate Governance Policy
- The Resolutions concerning the Internal Control System by the Board of Directors
- Evaluation Results of Effectiveness of the Board of Directors

 Introduction of Outside Perspectives  
<https://www.chugai-pharm.co.jp/english/ir/governance/perspective.html>

 Officer Remuneration  
<https://www.chugai-pharm.co.jp/english/ir/governance/remuneration.html>








 Communication with Stakeholders  
<https://www.chugai-pharm.co.jp/english/ir/governance/dialogue.html>




# Risk Management

## Main Risks and Countermeasures (Strategic Risk and Operational Risk)

This section presents the main risks and their countermeasures in the Group's business development as of the end of December 2022.

Main risks*		Specific risk scenarios	Impact on corporate value
Strategic Risk	Technology and Innovation	<ul style="list-style-type: none"> <li>• Delay or failure in in-house drug discovery or technology development</li> <li>• Failure in development of mid-size molecule drugs</li> <li>• Emergence of innovative products and solutions by competition</li> <li>• Emergence of disruptive new technologies and solutions</li> <li>• Infringement of IP rights</li> </ul>	<ul style="list-style-type: none"> <li>• Delays in creating in-house products, rise in R&amp;D expenditures</li> <li>• Revision of development and investment plans</li> <li>• Decline in value of in-house technologies and projects</li> <li>• Reduction in the value of in-house technology and products, decrease in revenue, lawsuits by other parties, suspension of manufacturing and marketing or of technology utilization, incurring of utilization fees</li> </ul>
	Systems, Regulations, and Policies	<ul style="list-style-type: none"> <li>• Changes in pharmaceutical regulations, systems, and policies in Japan and overseas</li> <li>• Further tightening of environmental regulations</li> </ul>	<ul style="list-style-type: none"> <li>• Decrease in revenue due to reduction in drug prices</li> <li>• Decrease in revenue due to government policy to promote BS products</li> <li>• Increase in investment for compliance with environmental regulations</li> </ul>
	Markets and Customers	<ul style="list-style-type: none"> <li>• Market changes and decrease in market presence</li> <li>• Restrictions on business due to increase in geopolitical risk</li> </ul>	<ul style="list-style-type: none"> <li>• Decrease in value of therapy and decline in number of target patients due to diversification of scope of therapeutic value, such as prevention</li> <li>• Restriction or withdrawal of business in related areas (loss of production, R&amp;D, and sales locations, decrease in profit, loss of future opportunities)</li> <li>• Impact on stable supply due to supply chain fragmentation</li> </ul>
	Business Platforms	<ul style="list-style-type: none"> <li>• Failure of development or market penetration for products in-licensed from Roche/out-licensed to Roche</li> <li>• Failure to attract, develop, and promote the active careers of human resources</li> <li>• Deterioration in earning conditions due to greater-than-anticipated cost increase</li> <li>• Impediment to DX promotion</li> </ul>	<ul style="list-style-type: none"> <li>• Decline in stable revenue source in Japan and deterioration in overseas revenue</li> <li>• Non-achievement of strategic targets due to failure to attract and develop strategic human resources</li> <li>• Mismatches, shortage, or surplus of human resources due to change in required operations and quality caused by environmental change</li> <li>• Inability to form challenge-oriented organizational culture, hindering innovation</li> <li>• Deterioration in earning conditions due to increase in R&amp;D expenses and costs due to excessive operation quality</li> <li>• Delays in strategies such as increasing human predictability and clinical study efficiency, due to lack of progress on digital technology</li> <li>• Stalling of DX and emergence of issues due to insufficient digital capability and understanding of digital compliance</li> </ul>
Operational Risk	Quality and Side Effects 	<ul style="list-style-type: none"> <li>• Emergence of product quality issue, emergence of serious side effects exceeding expectations</li> </ul>	<ul style="list-style-type: none"> <li>• Decrease in revenue due to product recall, sales suspension, etc., product liability litigation, compensation for damages, loss of public trust</li> </ul>
	IT Security and Information Control 	<ul style="list-style-type: none"> <li>• Operational impairment, suspension of external service delivery, interference with the content of information provided, the leakage of trade secrets relating to research and development or other areas, or of personal or other information, as a result of cyberattack or incident in-house or in supply chain</li> </ul>	<ul style="list-style-type: none"> <li>• Suspension or delay of business activities, revision of business plans, loss of competitive advantage, loss of public trust, compensation for damages, incurring of expenses for urgent response and related measures</li> </ul>
	Large-Scale Disasters 	<ul style="list-style-type: none"> <li>• Damage to business site or supplier from earthquake, typhoon, fire, or other large-scale disaster</li> </ul>	<ul style="list-style-type: none"> <li>• Suspension of drug supply, incurring of costs for facility repair, etc., restriction of business activities, decrease in revenue</li> </ul>
	Human Rights 	<ul style="list-style-type: none"> <li>• Delay in taking action on occupational health and safety, or other human rights issues</li> </ul>	<ul style="list-style-type: none"> <li>• Deterioration in employee physical or mental health or HR capabilities, loss of public trust due to harassment, or other human rights issues</li> </ul>
	Supply Chain 	<ul style="list-style-type: none"> <li>• Delay or slowing of delivery from suppliers, environment, health, and safety (EHS)-related risk at suppliers</li> </ul>	<ul style="list-style-type: none"> <li>• Decrease in revenue or market share, loss of public trust</li> </ul>
	Global Environmental Issues 	<ul style="list-style-type: none"> <li>• Delay in technology- and facility-related response to climate change</li> <li>• Unexpected environmental contamination or damage by harmful substances</li> <li>• Insufficient response to social expectations and requirements relating to environmental protection</li> <li>• Further strengthening of environment-related regulations</li> </ul>	<ul style="list-style-type: none"> <li>• Revision of capital investment plans, incurring of additional expenses</li> <li>• Incurring of expenditures for response measures or compensation for damage, loss of public trust</li> <li>• Reputational decline among customers and capital markets</li> <li>• Increase in expenditures for environmental measures, limitation of business activities</li> </ul>
	Pandemics 	<ul style="list-style-type: none"> <li>• National or global pandemic of new infectious disease</li> </ul>	<ul style="list-style-type: none"> <li>• Suspension of drug supply, restriction of business activities, decrease in revenue</li> </ul>

\* Operational risks are classified into the two following types:

 Risks whose probability of materializing and degree of impact have increased rapidly  Important long-standing risks

### Main countermeasures

- Seek access to latest science and technologies
- Diversify by strengthening external collaborations
- Strengthen alliances for drug discovery, development, and pharmaceutical technology
- Pursue a multi-modality strategy
- Further strengthen IP strategy, respond actively to biosimilars (BS)/generics and competitor products with IP measures

- Visualize and demonstrate patient value
- Enhance revenue structure, develop next-generation products, put in place IP measures
- Strengthen dialogue with experts and policy decision-makers
- Enhance overseas intelligence functions
- Timely understanding of environmental regulatory trends

- Strengthen customer engagement
- Diversify product range
- Build organizational structure able to respond flexibly to fluctuations in demand
- Rebuild safety management system
- Strengthen business continuity plans (BCPs) and supply back-up system

- Support formulation and execution of Roche's global development and marketing plan, and explore in-licensing from third parties
- Clear definition of strategic human resources and plan-based securing and development
- Increase investment in organization and human resources
- Build organizational structure and recruitment plans based on careful monitoring of trends in the business environment
- Minimize operational costs through DX and business model reform
- Strengthen capabilities of specialist departments and deploy external competent human resources

- Strengthen quality assurance activities and ensure comprehensive rollout
- Strengthen pharmacovigilance activities and ensure comprehensive rollout
- Strengthen safety information provision activities to promote proper use

- Strengthen security management system and system robustness and availability, strengthen functions to detect cyberattacks and viruses and upgrade monitoring systems, strengthen system for responding to information security incidents, enhance employee security training, monitor status of countermeasures

- Strengthen earthquake resilience strategy, safety stock, and related systems, and maintain operation of BCPs

- Continue implementation of in-house training, promote health and productivity management, provide internal reporting hotlines, conduct enhanced human rights due diligence on suppliers

- Maintain stable drug supply system, such as ensuring safety stock and alternative suppliers, and strengthen EHS activities

- Planned medium- to long-term environmental investment
- Strengthen access to latest environmental technology
- Enhance dialogue with external experts and evaluation organizations
- Ongoing monitoring and analysis of latest trends

- Ensure safety stock and maintain operation of BCPs
- Establishment of highly flexible "new work styles" such as telecommuting
- Stockpiling of masks and liquid sanitizer, in-house infection prevention measures.

The Chugai Group identifies Chugai Group risk issues that may have a material impact on management, taking into consideration the company-wide risk analysis and assessment, responses by each division, and trends in the industry and external environment, and gives priority to addressing these issues. Here we introduce some of the themes of our initiatives.

### Building a Third-Party Risk Management System

Under our growth strategy for 2030, TOP I 2030, we aim to create new value through even more active engagement in alliances with external business partners and open innovation, and by combining these with our own strengths.

However, if a situation were to arise causing a business partner's activities to become restricted, it could have a significant impact on the Group's business activities and operating results, such as delaying R&D and impeding the stable supply of drugs.

To counteract the increase in risk associated with the acceleration of such external alliances, the Group is building a system for conducting a series of third-party risk management processes in a centralized, efficient, and effective manner on an IT system. These processes include selection of business partners, risk assessment when making contracts, monitoring items for improvement after entering into contracts, and timely detection of incident information.

### Building a Geopolitical Risk-Related Impact Analysis and Response System

The impact of geopolitical risks on business activities are currently in focus. These include the invasion of Ukraine by Russia starting in February 2022 and the associated energy supply concerns in Europe, the increasing confrontation between the United States and China over issues such as human rights, high technology, and Taiwan, and the strengthening of economic security laws in every country sparked by these situations.

A rapid change in these international situations, or the outbreak of international conflict, could give rise to the risk of business restriction or withdrawal in related regions (loss of production, R&D, and sales locations, decline in profit, loss of future opportunities), or stalling of the supply chain or delayed supplies and so forth in the related regions.

In response to these geopolitical risks, the Chugai Group is setting up internal systems to gather external information and analyze the impacts on business. It is also rebuilding its safety management system in preparation for sudden events and strengthen its business continuity plans (BCPs) and back-up supply systems.

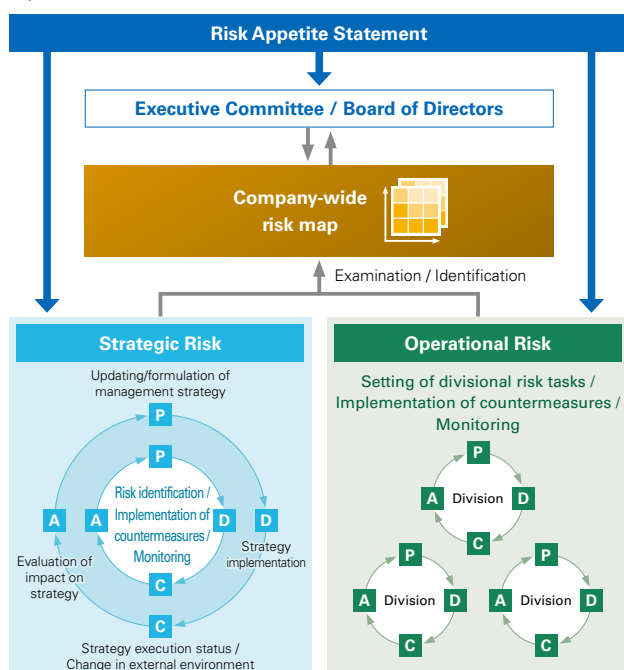
## Risk Management / Compliance Promotion System

Chugai has established the Risk Management Committee and the Compliance Committee under the Executive Committee to promote Group-wide risk management and compliance. In January 2023, the Risk & Compliance Department has been newly set up to integrate functions that were previously spread across multiple departments, such as risk management, compliance promotion, and company information management. The aim is to achieve centralized, efficient operation of second-line functions of the three lines of defense.

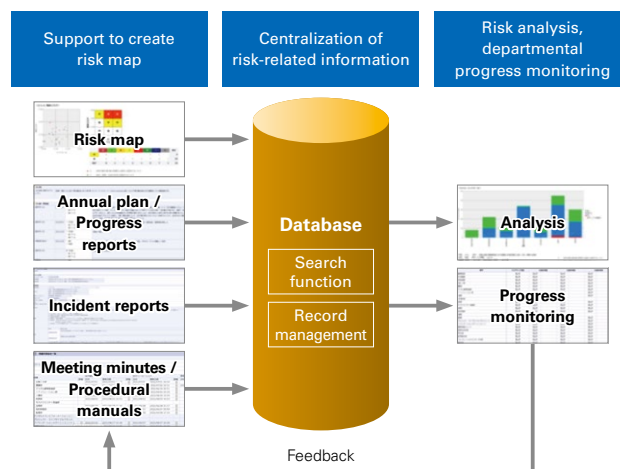
### Risk Management

To maximize corporate value, Chugai has implemented and operates a framework for enterprise risk management (ERM) based on visualization and integrated management of risk. We have set out our policy on risk preferences in a Risk Appetite Statement, divided the risks to be addressed into strategic risks and operational risks, and systematized these risks by identifying, classifying, and visualizing them in a centralized fashion. By sharing and discussing this system on a Company-wide basis, we will not only promote effective and efficient risk management but also further strengthen our accountability to external stakeholders. To drive efficient gathering, analysis, and feedback of risk information, we have developed and implemented a unique risk management system. Using a database for centralized management, divisions can record their risk maps, annual risk response plans, incident reports, business continuity plan (BCP) manuals, and other relevant information. This enables us to analyze risks for the Group as a whole, and monitor countermeasures at each division.

### Operational Outline of ERM



### Centralized Control of Risk Information Using IT Systems



### Compliance Promotion

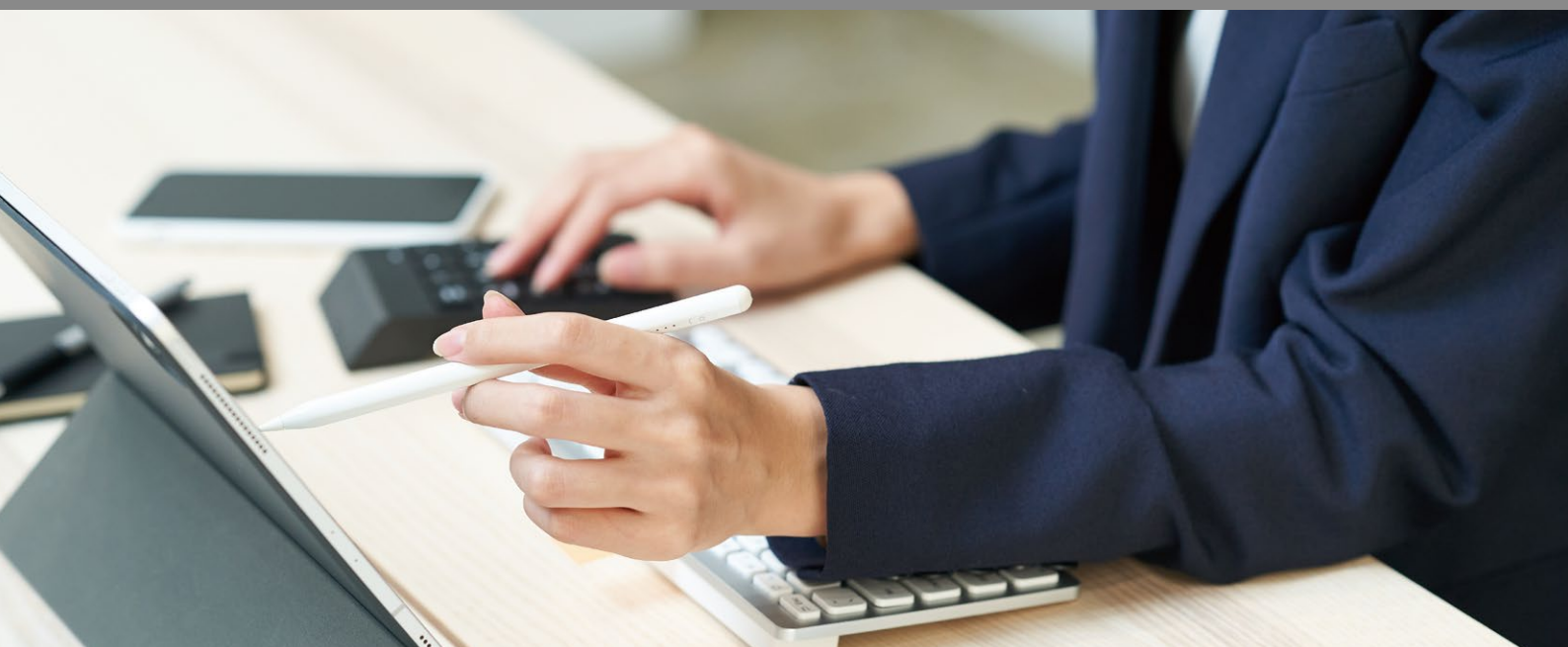
Rooted in its belief that corporate ethics take priority over profit, Chugai places paramount importance on respect for life, and strives for fair and transparent corporate activities based on high ethical standards, along with sincere scientific initiatives. Chugai strictly complies with laws, regulations, and voluntary industry standards and proactively takes part in the compliance activities of various associations and organizations. Chugai has also established its own guidelines for transparency with healthcare professionals in Japan and overseas, helping 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 a compliance system, we have concentrated all compliance supervision functions related to the Company in the Compliance Committee, which is a subcommittee of the Executive Committee, thereby building a system that is directly connected to management. At the same time, we established functions within the Quality & Regulatory Compliance Unit and the Risk & Compliance Department to monitor, lead, and support compliance across the Chugai Group, aiming to enhance compliance promotion activities through organization-wide monitoring and various types of training. In addition, each division appoints a Compliance Manager and a Compliance Officer who work to promote compliance in each workplace. Internal and external consultation desks have been established to receive inquiries and reports from Chugai Group employees concerning laws, Company rules, the Chugai Group Code of Conduct, and other related matters.





# Performance Data

78	Financial and Pre-Financial Highlights (IFRS)
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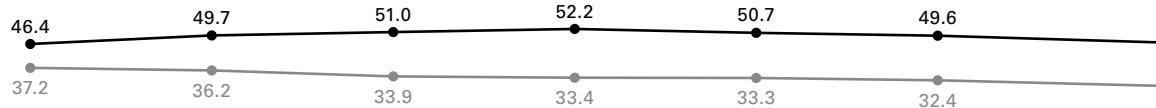
# Financial and Pre-Financial Highlights (IFRS)

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

## Financial Indicators [Core Basis]

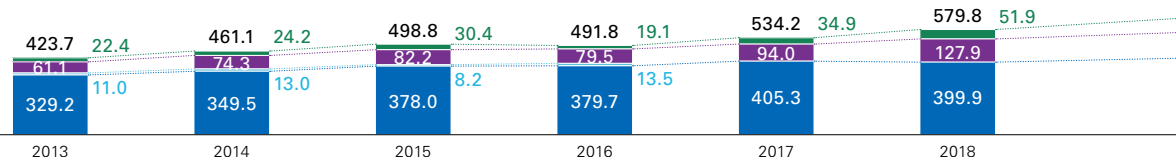
### Results

- Cost to sales ratio (%)
- Ratio of operating expenses to revenue (%)



### Revenue (Billions of yen)

- Royalties and other operating income
- Overseas sales
- Tamiflu
- Domestic sales (excluding Tamiflu)<sup>2</sup>



### Productivity improvement

#### Launch of main products in Japan

Perjeta ★ Actemra (subcutaneous injection) Bonviva	Kadcyla ★ Alecensa	Zelboraf	Alaglio	★ Hemlibra (with/without inhibitors) Tecentriq Gazyva
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#### Approval of main products overseas

★ Actemra (subcutaneous injection / U.S.)	★ Actemra (subcutaneous injection / EU)	★ Alecensa (U.S.)	★ Hemlibra (with inhibitors / U.S.) ★ Alecensa (EU)	★ Hemlibra (with inhibitors / EU) ★ Hemlibra (without inhibitors / U.S.)
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#### ★ Chugai product

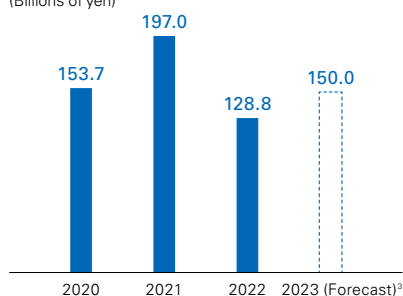
1. Calculated by (R&D expenses + SG&A expenses) ÷ Revenue
2. From 2017, domestic sales include Tamiflu.

#### 3. The Company has partially amended the financial statements from the fiscal year 2023 as follows.

- The item "Royalties and other operating income" previously reported under revenue has been changed to "other revenue," while income from disposal of product rights has been excluded therefrom.
- "Other operating income (expense)" has been established as a new category equivalent to R&D expenses, marketing and distribution expenses, and general and administration expenses. "Other operating income (expense)"

### Royalties and Other Operating Income (Other Revenue)

(Billions of yen)

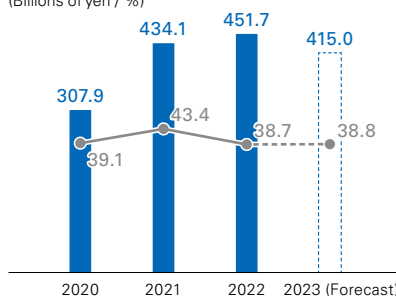


■ Royalties and other operating income

In 2022, royalty and profit-sharing income declined with the end of initial-stock royalties on Hemlibra. In 2023, other revenue is expected to increase due to an increase of Hemlibra-related royalty and profit-sharing income and an increase in one-time income.

### Core Operating Profit / Ratio of Core Operating Profit to Revenue

(Billions of yen / %)

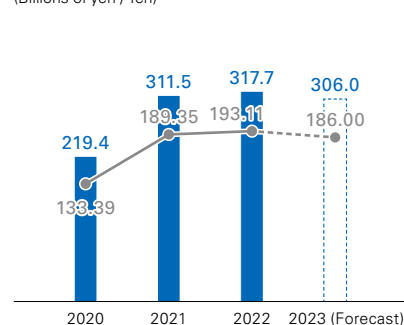


■ Core operating profit  
● Ratio of Core operating profit to revenue

In 2022, Core operating profit was the highest on record primarily due to significant growth in sales including supply of Ronapreve to the government. The ratio of Core operating profit to revenue decreased due to factors such as a change in the product mix, but was maintained in the top class in the industry. Despite the anticipated decline in profits in 2023, a slight increase is expected when excluding the temporary impact related to drugs for the treatment of COVID-19.

### Core Net Income / Core EPS<sup>4</sup>

(Billions of yen / Yen)



■ Core net income  
● Core EPS

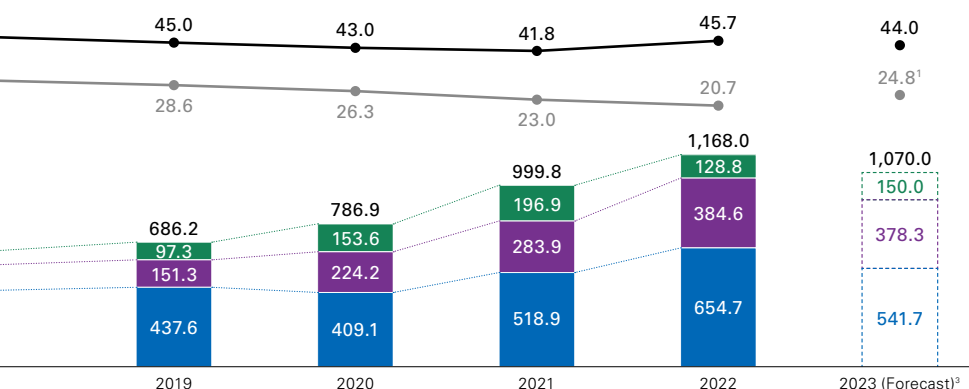
In 2022, the record-high profit level we achieved resulted in Core EPS rising by 2.0 percent from the previous year to ¥193.11. In 2023, net income, like operating profit, is forecast to decrease year on year, with Core EPS of ¥186.00 expected.

4. Effective July 1, 2020, Chugai has implemented a three-for-one stock split of its common stock. Calculated based on the assumption that the stock split was implemented at the beginning of 2020.

5. Return on invested capital: Indicates how efficiently a company uses capital invested for business activities (invested capital) to generate profit.

6. Core ROIC is calculated using average NOA.





#### Global sales of Chugai products

FoundationOne  
CDx  
Cancer Genomic  
Profile  
Rozlytrek

★ Enspryng

Polivy

Vabysmo

Evrysdi  
Ronapreve  
FoundationOne Liquid CDx  
Cancer Genomic Profile

★ Hemlibra (without  
inhibitors / EU)

★ Enspryng (U.S.)  
★ Ediol (China)

★ Enspryng (EU)

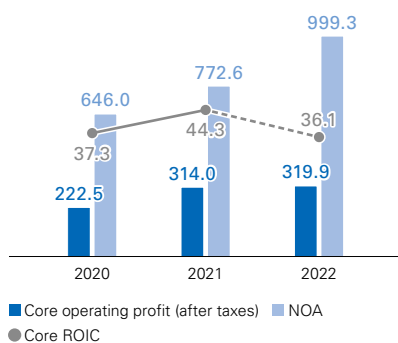
includes the income from disposal of product rights, which has been excluded from revenue as described above, and income and expenses associated with operating activities that were previously included in "General and administration" but could not be classified into functional expense categories, such as gain (loss) on sale of land and buildings, etc.

- Marketing and distribution expenses and general and administration expenses have been integrated and presented as "SG&A expenses."

Chugai has substantially improved its cost structure in view of the increase in the cost to sales ratio due to the increase in products in-licensed from Roche following the signing of the strategic alliance between the two companies. As a result, we have now secured high profitability by continuously achieving a profit margin of a level that compares favorably with the world's leading pharmaceutical companies. In addition, global products from Chugai research, which have a low cost to sales ratio, have performed solidly in recent years and become a revenue base driving growth. Results for 2022 showed record-high revenue for the sixth consecutive year. Domestic sales increased mainly due to the steady market penetration of the new products Evrysdi, Polivy, Enspryng and Vabysmo, the favorable sales of the mainstay products Hemlibra and Kadcyca, and the supply of Ronapreve to the government, despite the impact of NHI drug price revisions and market penetration of generics. Overseas, there was a major increase in the exports of Hemlibra and Actemra. In 2023, although decrease in revenue is forecast due to domestic sales decreasing as a result of a decline in sales of Ronapreve supplied to the government, and the effects of generics, drug price revisions, etc., and overseas sales decreasing caused by a decrease in Actemra and a decrease in Hemlibra due to the impact of optimization of inventory by Roche, strong performance is expected with revenue increasing when the COVID-19-related temporary impact of Ronapreve and Actemra are excluded.

#### Core Operating Profit after Taxes / NOA / Core ROIC

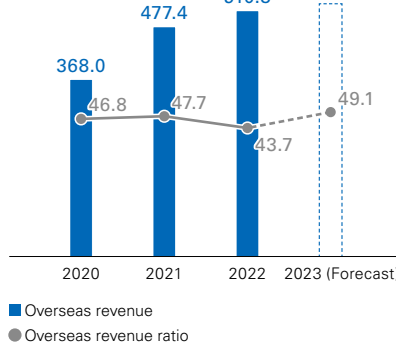
(Billions of yen / %)



Chugai has been using Core ROIC<sup>5</sup> as a financial KPI since 2019 to give greater consideration to long-term investment efficiency. Although Core operating profit (after taxes) (1) grew year on year in 2022, net operating assets (NOA)<sup>6</sup> (2) grew significantly with the increase in accounts receivable for Ronapreve, and Core ROIC (1)/(2) decreased to 36.1%, but a high level of capital efficiency is being maintained.

#### Overseas Revenue / Overseas Revenue Ratio

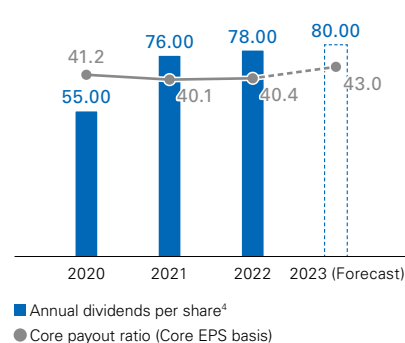
(Billions of yen / %)



Overseas revenue is projected to grow again in 2023. Although overseas sales are forecast to decrease slightly due to a decrease in the volume of Hemlibra exports resulting from optimization of inventory levels by Roche, increase of other revenue related to Hemlibra is expected to contribute. However, with the domestic market seeing a significant decrease in the supply of Ronapreve to the government, the overseas revenue ratio is expected to rise year on year.

#### Dividends per Share / Core Payout Ratio

(Yen / %)



Our shareholder return target reflects business results forecasts and the developing demand for strategic investment funds in light of evolving drug discovery technology and the advancing digitalization of the healthcare industry. Accordingly, with the aim of maintaining a stable dividend into the future, since 2020 we have adopted an approximate target payout ratio of 45 percent on average as a proportion of Core EPS.

#### About Core Basis Results

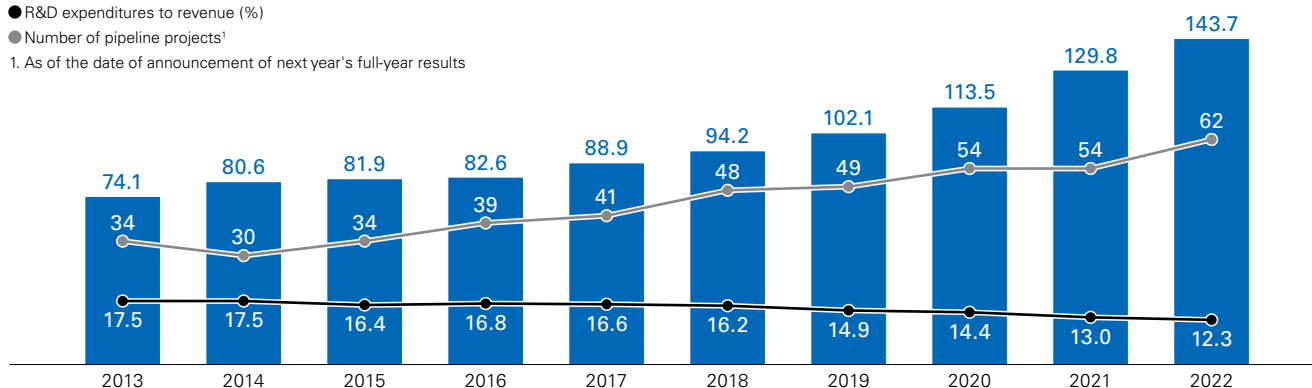
Chugai reports its results on a Core basis from 2013 in conjunction with its decision to adopt IFRS. Core basis results are the IFRS basis results adjusted by excluding non-Core items. The items regarded as non-Core by Chugai may differ from those considered as such by Roche due to differences in business scale and range as well as other factors. 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.

## R&D [Core Basis]

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

- R&D expenditures (Billions of yen)
- R&D expenditures to revenue (%)
- Number of pipeline projects<sup>1</sup>

1. As of the date of announcement of next year's full-year results



CPR establishment and business expansion, and development of next-generation antibody engineering technologies

Investment in facilities for multiple and simultaneous development projects

Comprehensive collaboration in immunology research activities with the IFReC

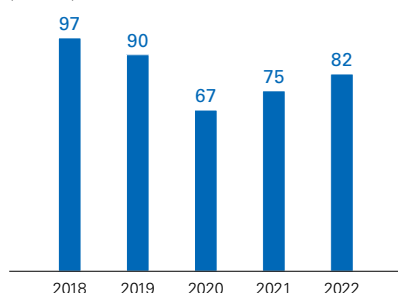
With growing sales revenue, Chugai has increased R&D investment, generating research findings that have created innovative drugs and contributed to the development of healthcare and the pharmaceutical industry worldwide. Moreover, we have been promoting efficient development of new drugs with high success rates under our strategic alliance with Roche, which enables us, for instance, to consider and decide on in-licensing Roche products on the basis of early-stage clinical trial results. A number of in-house projects based on next-generation antibody engineering technology and mid-size molecule technology have

progressed to the clinical phase in recent years, helping to maintain a robust pipeline in terms of both quality and quantity. Going forward, in addition to concentrating Company-wide management resources in Research & Early Development<sup>2</sup> (RED) as a source of value creation, we will also seek to rapidly expand our drug discovery output by applying AI-based drug discovery and other digital technologies and actively driving Open Innovation.

2. Includes the process of pharmaceutical technology functions related to early development

### Academic Papers and Presentations on Research Findings at Scientific Conferences<sup>3</sup>

(Number)

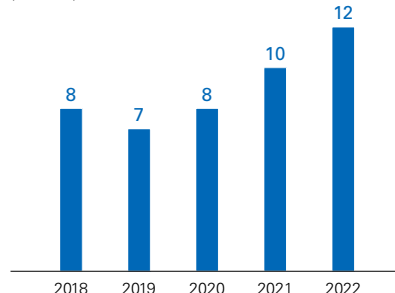


Chugai develops innovative medicines that allow it to differentiate itself from competitors by continuously establishing proprietary drug discovery technologies and applying them to development candidates while developing pharmaceutical technology for mid-size molecules, next-generation antibodies, and other drug types where there are strong challenges to overcome. We will continue to successively generate research findings that may contribute to the overall advancement of healthcare, presenting those findings at scientific conferences and publishing them in academic papers.

3. Total of drug discovery and pharmaceutical technology

### New Products Launched and New Indications

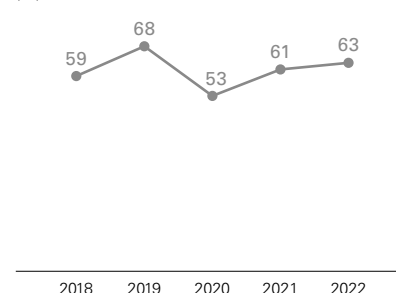
(Number)



In 2022, the number of new product launches and new indications remained at a high level due to the launch of the new product Vabysmo, the expansion of indications for Tecentriq to include adjuvant therapy in PD-L1-positive non-small cell lung cancer, and the expansion of indications for Polivy to previously untreated diffuse large B-cell lymphoma (DLBCL).

### Percentage of Product Sales Qualifying for Premium Pricing

(%)



The sales share of products qualifying for premium pricing was maintained at a high level due to the steady growth in mainstay products and new products.

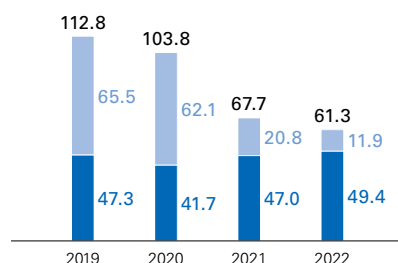
Note: Ronapreve was excluded from the calculation of sales share for 2021 and 2022 due to its not yet being listed in the NHI drug price standard (supply to government).

## Environment and Social

### Scope 1 and Scope 2 Emissions

(Thousands of tons)

■ Scope 1 ■ Scope 2

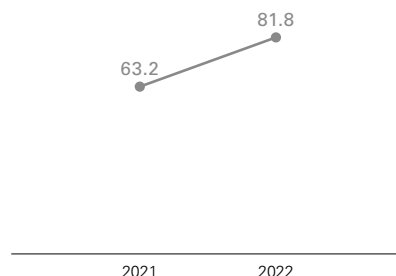


In 2022, Scope 1 and Scope 2<sup>1</sup> emissions according to the market-based method<sup>2</sup> were reduced 45.6 percent compared to the base year of 2019<sup>3</sup> due mainly to the introduction of sustainable power in major business locations. Going forward, operation of new facilities is expected, and it is anticipated that a 40 percent reduction in Scope 1 and Scope 2 emissions, which is the target for 2025, will be achieved. The target for Scope 1 and Scope 2 emissions is a 60 percent to 75 percent reduction in 2030 and zero emissions by 2050.

1. Calculation method based on the CO<sub>2</sub> emissions coefficient of the electric power supply specifically contracted by the Company
2. Scope 1: Direct emissions, Scope 2: Indirect emissions from the generation of purchased energy
3. From 2022, this includes the portion based on the renewable energy certificates and non-fossil certificates purchased.

### Sustainable Electricity Ratio

(%)

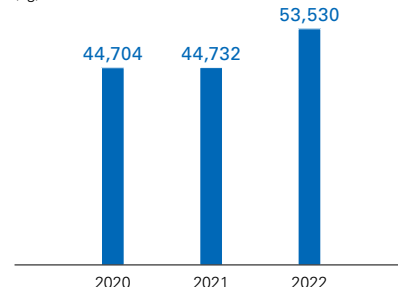


In addition to the Utsunomiya Plant (100 percent), the Ukima Branch (100 percent)<sup>4</sup>, and the Kamakura and Gotemba research laboratories (approx. 75 percent), implementation began in the head office and the Fujieda Plant in 2022, and the sustainable electricity ratio was 81.8 percent for the full year of 2022. Steady progress is being made toward the 100 percent sustainable electricity ratio in 2025 set in the Mid-Term Environmental Goals 2030. There are plans to introduce sustainable electricity in the Chugai Life Science Park Yokohama and domestic sales branches, etc. in 2023.

4. From 2022, this includes the portion based on the renewable energy certificates and non-fossil certificates purchased.

### Discontinuation of and Shift from Fluorocarbons<sup>5</sup> Usage

(kg)

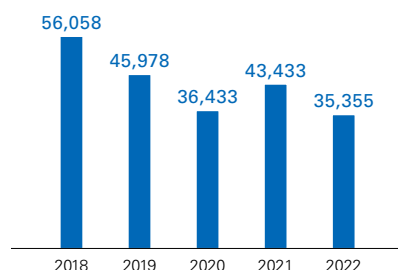


Usage increased by approximately 20 percent in 2022 with the increase of facilities resulting from the completion of new research laboratories, but a decrease is expected from 2023 due to the closure of old research laboratories. We will proceed to update production and air conditioning facilities according to characteristics and implement natural cooling facilities in new facilities, engage in the development of equipment using natural cooling through collaboration with manufacturers, and seek consistency between business plans and facility renewal plans as we aim to achieve 25 percent reductions in 2025 and 100% reductions in 2030 compared to 2020.

5. While making natural refrigerants the first choice, effectively select new refrigerants (green refrigerants)

### Number of Inquiries to Medical Information (Non-consolidated)

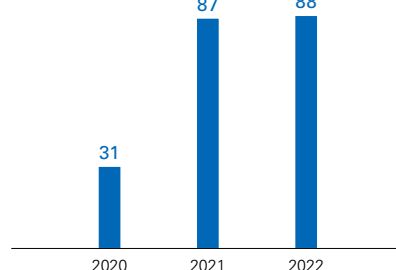
(Number)



The number of inquiries by telephone was 35,000 in 2022, down 8,000 from the previous year mainly due to a decrease in inquiries about drugs for the treatment of COVID-19. Around 70 percent of the inquiries were from pharmacists. By group of effect, there were many inquiries about humanized anti-human IL-6 receptor monoclonal antibody drugs, osteoporosis agents and anti-cancer agents.

### Number of Supplier Evaluations Conducted

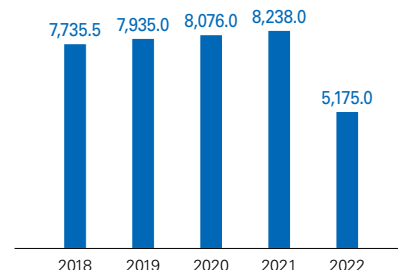
(Number)



Supplier evaluations were conducted based on the Principles for Responsible Supply Chain Management established by the PSCI (Pharmaceutical Supply Chain Initiative), a non-profit organization made up of global pharmaceutical companies, for the realization of sustainable transactions in the supply chain. All suppliers are required to respect and comply with ethics, labor, safety & health, environmental and other relevant management systems.

### Total Time of Implementation of CCC and Human Rights Training

(Hours)



Training is conducted for all employees to instill Chugai Group Code of Conduct (CCC) and raise awareness of human rights. In 2022, we conducted training on the themes of "business and human rights" and "prevention of harassment," and raised awareness for respect of human rights in the supply chain and employees' workplaces. This provided opportunities to think about efforts to address human rights issues including rights related to labor in stakeholders related to business activities and the entire supply chain.

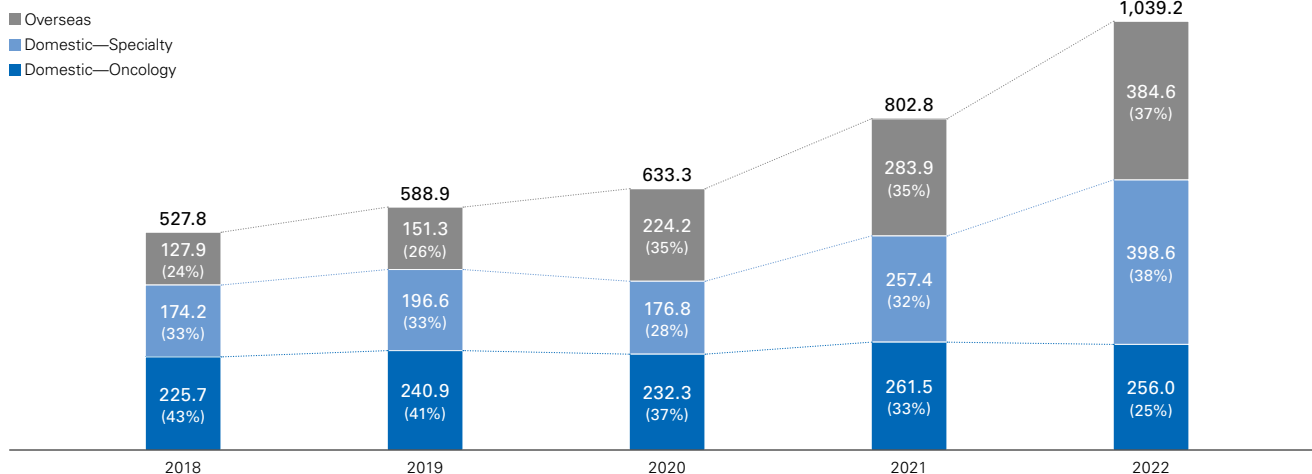
Note: Implemented 1.5 hours per year in 2018 to 2021, and 1.0 hour per year in 2022.

# Review by Product

## Sales

Although sales have been impacted in the domestic market by the NHI drug price revisions and the market penetration of generics, growth across all areas in both new and mainstay products, combined with a major increase in exports of Chugai products, has resulted in overall sales growth of approximately 60% over the last five years, even when the temporary factors caused by Ronapreve are excluded.

(Billions of yen)



## Review by Disease Area

### Domestic—Oncology

#### Opportunities

- Disease areas with a high level of UMN<sup>1</sup>
- Advances in personalized healthcare (PHC) based on analysis of gene alterations

#### Risks

- Intensified global competition in cancer immunotherapy
- Market entry of competitor drugs and biosimilars

#### Review of 2022 Performance

Sales in the Oncology area fell 2.1% year on year to ¥256.0 billion. Sales increased due to steady market penetration due to the additional indications of the new product Polivy, strong performance of the mainstay product Kadcyla and growth in the number of tests using the genomic mutation analysis program<sup>2</sup>. Meanwhile, sales of Avastin and Herceptin decreased due to the impact of NHI drug price revisions and market penetration of generics, and sales of Tecentriq also decreased mainly due to the impact of special market-expansion repricing in August 2021.

### Domestic specialty<sup>3</sup>

#### Opportunities

- There are still diseases with high UMN in ophthalmology
- There is a complex range of pathologies and syndromes with a high level of UMN in neurology and immunology

#### Risks

- Neurological and immunological treatments may have a small number of target patients

#### Review of 2022 Performance

In the Specialty area, sales increased 54.9% year on year to ¥398.6 billion. While sales of Ediol, Mircera and other products fell due to the NHI drug price revisions and the market penetration of generics, there were solid performances by the mainstay product Hemlibra. In terms of new products, in addition to the significant increase in sales from the supply of Ronapreve to the government, the steady market penetration of Evrysdi, Enspryng and Vabysmo also contributed. Furthermore, sales of the supply of products were also recorded for Mitchga, which was launched by Maruho in August 2022.

### Overseas

#### Opportunities

- Rollout of Actemra to other countries of indication for COVID-19
- There is room for expansion of share of non-inhibitors for hemophilia A

#### Risks

- Market entry of competitor drugs and biosimilars
- Off-label use and expanded indications of existing drugs

#### Review of 2022 Performance

Overseas sales totaled ¥384.6 billion, a major year-on-year increase of 35.5%. With regard to exports to Roche, although Alecensa decreased year on year due to optimization of inventory levels by Roche, Hemlibra increased significantly with full-scale export at the regular shipment price. In addition, although recording of Actemra, which received approval as a COVID-19 treatment in Europe and the United States, was partially delayed into 2023 due to supply chain delays, it increased from the previous year.

1. Unmet medical needs: Medical treatment needs that are not adequately met due to a lack of effective therapies

2. "FoundationOne Liquid CDx Cancer Genomic Profile" and "FoundationOne CDx Cancer Genomic Profile"

3. "Primary" used as the name of disease area is replaced with "Specialty" from July 2022

## Sales of Major Products

★Products from Chugai research	■ Domestic—Oncology ■ Domestic—Specialty ■ Overseas	(Billions of yen)
Ronapreve	2022 203.7 2021 77.4	+163.2%
★ Hemlibra (Overseas)	2022 193.7 2021 114.2	+69.6%
★ Actemra (Overseas)	2022 130.5 2021 102.8	+26.9%
Avastin	2022 67.5 2021 80.9	-16.6%
Tecentriq	2022 60.9 2021 62.2	-2.1%
★ Hemlibra (Domestic)	2022 49.3 2021 41.6	+18.5%
★ Actemra (Domestic)	2022 42.8 2021 43.2	-0.9%
★ Alecensa (Overseas)	2022 40.5 2021 50.1	-19.2%
Perjeta	2022 32.3 2021 32.2	+0.3%
★ Alecensa (Domestic)	2022 28.9 2021 27.7	+4.3%
Kadcyla	2022 18.1 2021 15.7	+15.3%
★ Enspryng (Domestic)	2022 16.7 2021 9.7	+72.2%
Polivy	2022 15.5 2021 6.8	+127.9%
Evrysdi	2022 11.5 2021 2.3	+400.0%
★ Ediol	2022 11.2 2021 22.3	-49.8%
Mircera	2022 10.8 2021 14.4	-25.0%
★ Neutrogen (Overseas)	2022 8.7 2021 9.1	-4.4%
CellCept	2022 7.9 2021 8.4	-6.0%
Herceptin	2022 7.1 2021 9.8	-27.6%
Foundation Medicine	2022 7.1 2021 5.1	+39.2%
Bonviva	2022 7.1 2021 8.2	-13.4%
Vabysmo	2022 6.4 2021 —	—
★ Oxarol	2022 5.5 2021 6.2	-11.3%
Rituxan	2022 4.4 2021 5.1	-13.7%
Gazyva	2022 4.0 2021 4.5	-11.1%

### Ronapreve

Ronapreve received Special Approval for Emergency for the treatment of moderate COVID-19 in July 2021 and supply to the government began. In November 2021, it also received approval for the additional indication of prevention of symptomatic COVID-19 infection. In 2022, the volume supplied to the government increased significantly year on year, reaching ¥203.7 billion.

### Hemlibra (Overseas)

Export sales posted a year-on-year increase of ¥79.5 billion or 69.6% to ¥193.7 billion. The two main factors in the major growth were the start of full-scale exports to Roche at the regular shipment price from the second quarter of 2021 and increasing market penetration in regions other than Europe and the United States, such as China.

### Actemra (Overseas)

Export sales in 2022 posted a year-on-year increase of ¥27.7 billion or 26.9% to ¥130.5 billion due to resolving the supply shortage associated with the increase in COVID-19 demand in 2021. However, the posting of some sales was delayed to 2023 due to the impact of supply chain delays (currently resolved), resulting in falling short of the initial plan by approximately ¥14.0 billion.

### Avastin

Although the solid sales for the indication of hepatocellular carcinoma contributed, sales fell significantly short of the previous year's level, decreasing ¥13.4 billion or 16.6% year on year to ¥67.5 billion due to the impact of the NHI drug price revisions and market penetration by biosimilars for some indications.

### Tecentriq

Although market penetration of the indication of hepatocellular carcinoma progressed, sales decreased by ¥1.3 billion or 2.1% year on year to ¥60.9 billion due to the impact of an NHI drug price revision in August 2021 based on special market-expansion repricing and restrictions on supply of concomitant drugs for some indications.

### Hemlibra (Domestic)

For congenital hemophilia A (cases without inhibitors), prescriptions steadily progressed for cases of difficulty establishing venous routes, overburdening caregivers and struggling to cope with control of bleeding. Approval for the additional indication of acquired hemophilia A was obtained in June 2022. Sales increased by ¥7.7 billion or 18.5% year on year to ¥49.3 billion.



# Development Pipeline

(As of February 2, 2023)

Disease Area	Development Code	Origin	Generic Name [Product Name]	Indication ♦Additional Indication / (Combination Drug)
Oncology	RG6264	Roche	trastuzumab / pertuzumab [Product name undetermined]	Breast cancer / Colorectal cancer
	AF802 / RG7853	In-house	alectinib [Alecensa]	Non-small cell lung cancer (NSCLC) [adjuvant]♦ Maintenance treatment of NSCLC (stage III) after chemoradiotherapy♦
	RG7446	Roche	atezolizumab [Tecentriq]	NSCLC [neoadjuvant]♦ Muscle-invasive bladder cancer [adjuvant]♦ Renal cell carcinoma [2nd line]♦ / (cabozantinib) Early breast cancer [adjuvant]♦ Early breast cancer [neoadjuvant]♦ Hepatocellular carcinoma (HCC) [adjuvant]♦ / (Avastin)♦ HCC [intermediate stage]♦ / (Avastin)♦ HCC [2nd line]♦ / (lenvatinib or sorafenib) Head and neck carcinoma [adjuvant]♦ Prostate cancer [2nd line]♦ / (cabozantinib)
	RG435	Roche	bevacizumab [Avastin]	Small cell lung cancer (SCLC) [1st line]♦ / (Tecentriq)
	RG7440	Array BioPharma	ipatasertib [Product name undetermined]	Prostate cancer [1st line] / (abiraterone) NSCLC [1st line] / (Tecentriq) NSCLC [Stage III] / (Tecentriq)♦
	RG6058	Roche	tiragolumab [Product name undetermined]	Non-squamous NSCLC [1st line] / (Tecentriq) Esophageal cancer / (Tecentriq)♦
	RG6171	Roche	giredestrant [Product name undetermined]	Breast cancer [adjuvant] Breast cancer [1st line] / (palbociclib + letrozole) Follicular lymphoma [2nd line] / (lenalidomide)
	RG7828	Roche	mosunetuzumab [Product name undetermined]	Relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma / (Polivy)♦ Follicular lymphoma [3rd line] NSCLC [1st line] / (pembrolizumab) NSCLC [2nd line]
	RG6396	Blueprint Medicines	pralsetinib [Product name undetermined]	Solid tumors
	LUNA18	In-house	—	Solid tumors
	GC33	In-house	codrituzumab [Product name undetermined]	HCC
	ERY974	In-house	—	Solid tumors
	STA551	In-house	—	Solid tumors
	SOF10 / RG6440	In-house	—	Solid tumors
	ALPS12 / RG6524	In-house	—	Solid tumors
	SPYK04	In-house	—	Solid tumors
	RG7421	Exelixis	cobimetinib [Product name undetermined]	Solid tumors
	RG7802	Roche	cibisatamab [Product name undetermined]	Solid tumors
	RG6026	Roche	glofitamab [Product name undetermined]	Hematologic tumors
	RG6194	Roche	runimotamab [Product name undetermined]	Solid tumors
	RG6160	Roche	cevostamab [Product name undetermined]	Relapsed or refractory multiple myeloma
	RG6330	Roche	—	Solid tumors
	RG6433	Relay Therapeutics	—	Solid tumors
Immunology	MRA / RG1569	In-house	tocilizumab [Actemra]	Systemic sclerosis with interstitial lung disease (SSc-ILD)♦
	RG7159	GlycArt Biotechnology	obinutuzumab [Gazyva]	Lupus nephritis♦
	DONQ52	In-house	—	Celiac disease
	RAY121	In-house	—	Autoimmune disease
Neuroscience	SA237 / RG6168	In-house	satralizumab [Enspryng]	Generalized myasthenia gravis (gMG)♦ Myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD)♦ Autoimmune encephalitis (AIE)♦
	RG6356 / SRP-9001	Sarepta Therapeutics	delandistrogene moxeparvec [Product name undetermined]	Duchenne muscular dystrophy (DMD)
	GYM329 / RG6237	In-house	—	Spinal muscular atrophy (SMA) / (Evrysdi) Neuromuscular disease
	RG6042	Ionis Pharmaceuticals	tominersen [Product name undetermined]	Huntington's disease
	RG7906	Roche	ralmitaront [Product name undetermined]	Schizophrenia
	RG7935	Prothena	prasinezumab [Product name undetermined]	Parkinson's disease
	RG6100	AC Immune	semorinemab [Product name undetermined]	Alzheimer's disease
	RG6102	MorphoSys	trontinemab [Product name undetermined]	Alzheimer's disease
Hematology	SKY59 / RG6107	In-house	crovalimab [Product name undetermined]	Paroxysmal nocturnal hemoglobinuria (PNH) Atypical hemolytic uremic syndrome (aHUS) Sickle cell disease (SCD)
	NXT007 / RG6512	In-house	—	Hemophilia A
Ophthalmology	RG7716	Roche	faricimab [Vabysmo]	Retinal vein occlusion♦
	RG6321	Roche	ranibizumab (Port delivery system) [Product name undetermined]	Neovascular age-related macular degeneration Diabetic macular edema
Other Diseases	AMY109	In-house	—	Endometriosis

Designates change in status since January 1, 2022

\* Sarepta Therapeutics manages the global clinical study, including Japan.

Status					Country / Region	Projected Submission	Partner	Mode of Action [Modality (Dosage Form)]
	Phase I	Phase II	Phase III	Filed				
					Japan	September 2022	Roche	Anti-HER2 humanized monoclonal antibody / HER2 dimerization inhibitory humanized monoclonal antibody [Antibody (fixed-dose combination, SC)]
					Global	2023	Roche	ALK inhibitor [Small molecule (Oral)]
					Global	2025 and beyond	Roche	Engineered anti-PD-L1 monoclonal antibody [Antibody (IV)]
					Japan	2024	Roche	
					Japan	2024	Roche	
					Japan	2023	Takeda	
					Japan	2024	Roche	
					Japan	2024	Roche	
					Japan	2023	Roche	
					Japan	2025 and beyond	Roche	
					Japan	2025 and beyond	Roche	
					Japan	2024	Roche	
					Japan	—	Takeda	
					Japan / China	2024	Roche (China)	Anti-VEGF (Vascular Endothelial Growth Factor) humanized monoclonal antibody [Antibody (IV)]
					Japan	—	Roche	AKT inhibitor [Small molecule (Oral)]
					Japan	2023	Roche	Anti-TIGIT human monoclonal antibody [Antibody (IV)]
					Japan	2024	Roche	
					Japan	2025 and beyond	Roche	
					Japan	2025 and beyond	Roche	
					Japan	2025 and beyond	Roche	
					Japan	2025 and beyond	Roche	SERD (Selective estrogen receptor degrader) [Small molecule (Oral)]
					Japan	2025 and beyond	Roche	Anti-CD20 / CD3 bispecific antibody [Antibody (IV)]
					Japan	2024	Roche	Anti-CD20 / CD3 bispecific antibody [Antibody (SC)]
					Japan	2024	—	Anti-CD20 / CD3 bispecific antibody [Antibody (IV)]
					Japan	2025 and beyond	Roche	RET inhibitor [Small molecule (Oral)]
					Japan	2024	Roche	
					Japan	—	Roche	
					Global	—	—	RAS inhibitor [Mid-size molecule (Oral)]
					Global	—	—	Anti-Glypican-3 humanized monoclonal antibody [Antibody (IV)]
					Global	—	—	Anti-Glypican-3 / CD3 bispecific antibody [Antibody (IV)]
					Global	—	—	Anti-CD137 agonistic switch antibody [Antibody (IV)]
					Global	—	Roche	Anti-latent TGF-β1 monoclonal antibody [Antibody (IV)]
					Global	—	Roche	—[Antibody (IV)]
					Global	—	—	—[Small molecule (Oral)]
					Japan	—	Roche	MEK inhibitor [Small molecule (Oral)]
					Japan	—	Roche	Anti-CEA / CD3 bispecific antibody [Antibody (IV)]
					Japan	—	Roche	Anti-CD20 / CD3 bispecific antibody [Antibody (IV)]
					Japan	—	Roche	Anti-HER2 / CD3 bispecific antibody [Antibody (IV)]
					Japan	—	Roche	Anti-FcRH5 / CD3 bispecific antibody [Antibody (IV)]
					Japan	—	Roche	KRAS G12C inhibitor [Small molecule (Oral)]
					Japan	—	Roche	SHP2 inhibitor [Small molecule (Oral)]
					EU	August 2022	Roche	Humanized anti-human IL-6 receptor monoclonal antibody [Antibody (SC)]
					Japan	2025 and beyond	Nippon Shinyaku	Glycoengineered type II anti-CD20 monoclonal antibody [Antibody (IV)]
					Global	—	—	Anti-HLA-DQ2.5 / gluten peptides multi-specific antibody [Antibody (SC)]
					Global	—	—	—[Antibody (—)]
					Global	2024	Roche	pH-dependent binding humanized anti-IL6 receptor monoclonal antibody [Antibody (SC)]
					Global	2025 and beyond	Roche	
					Global	2025 and beyond	Roche	
					Japan	2024	Sarepta*	Micro-dystrophin gene therapy [Gene therapy (IV)]
					Global	2025 and beyond	Roche	Anti-latent myostatin sweeping antibody [Antibody (SC)]
					Global	—	Roche	
					Japan	—	Roche	Antisense oligonucleotide targeting <i>HTT</i> mRNA [Nucleic acid (IV)]
					Japan	—	Roche	Partial TAAR1 agonist [Small molecule (Oral)]
					Japan	—	Roche	Anti-α-synuclein monoclonal antibody [Antibody (IV)]
					Japan	—	Roche	Anti-tau humanized monoclonal antibody [Antibody (IV)]
					Japan	—	Roche	Anti-amyloid beta / Tfr1 fusion protein [Antibody (IV)]
					China	August 2022	Roche	Anti-C5 recycling antibody [Antibody (SC)]
					Global	2023	Roche	
					Global	2024	Roche	
					US / EU	2025 and beyond	Roche	Anti-coagulation factor IXa / X humanized bispecific monoclonal antibody [Antibody (SC)]
					Global	—	Roche	
					Japan	2023	Roche	Anti-VEGF / anti-Ang-2 bispecific antibody [Antibody (Vitreous injection)]
					Japan	2024	Roche	Humanized anti-VEGF monoclonal antibody Fragment Fab [Antibody (Injection via implant)]
					Japan	2024	Roche	
					Global	—	—	Anti-IL8 recycling antibody [Antibody (SC)]

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

Introduction

Initiatives

Progress

Governance

Performance Data

# Consolidated Financial Indicators

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

	2022		2021		2020		2019	
International Financial Reporting Standards (IFRS)	IFRS	Core <sup>1</sup>	IFRS	Core <sup>1</sup>	IFRS	Core <sup>1</sup>	IFRS	Core <sup>1</sup>

## Results

Revenue <sup>2</sup>	1,259.9	1,168.0	999.8		786.9		686.2	
Sales	1,039.2		802.8		633.3		588.9	
Royalties and other operating income	128.8		196.9		153.6		97.3	
Cost of sales	(476.3)	(475.0)	(338.1)	(335.5)	(273.5)	(272.3)	(266.1)	(265.1)
Operating expenses	(250.4)	(241.3)	(239.7)	(230.2)	(212.3)	(206.7)	(209.5)	(196.2)
Marketing and distribution	(77.1)	(76.7)	(76.6)	(75.8)	(72.6)	(71.5)	(77.2)	(73.5)
Research and development	(149.6)	(143.7)	(137.3)	(129.8)	(117.9)	(113.5)	(107.9)	(102.1)
General and administration	(23.6)	(20.9)	(25.8)	(24.6)	(21.8)	(21.7)	(24.4)	(20.6)
Operating profit	533.3	451.7	421.9	434.1	301.2	307.9	210.6	224.9
Profit before taxes	531.2	449.5	419.4	431.6	298.2	304.9	207.9	222.2
Net income	374.4	317.7	303.0	311.5	214.7	219.4	157.6	167.6
Attributable to Chugai shareholders	374.4	317.7	303.0	311.5	214.7	219.4	157.6	167.6
Core EPS (Yen) <sup>3</sup>	—	193.11	—	189.35	—	133.39	—	101.93
Cash dividends per share (Yen) <sup>3</sup>	78.00		76.00		55.00		46.67	
Core payout ratio	—	40.4%	—	40.1%	—	41.2%	—	45.8%

## Financial Position

Net operating assets (NOA)	999.3		772.6		646.0		547.0	
Total assets	1,869.8		1,538.7		1,235.5		1,058.9	
Total liabilities	(445.4)		(350.7)		(255.5)		(204.9)	
Total net assets	1,424.4		1,188.0		980.0		854.0	
Investments in property, plant and equipment	61.8		72.0		75.2		54.0	
Depreciation	23.7		21.0		22.0		17.8	

## Main Indicators

Cost to sales ratio	45.8%	45.7%	42.1%	41.8%	43.2%	43.0%	45.2%	45.0%
Ratio of operating profit to revenue	42.3%	38.7%	42.2%	43.4%	38.3%	39.1%	30.7%	32.8%
Ratio of R&D expenditures to revenue	11.9%	12.3%	13.7%	13.0%	15.0%	14.4%	15.7%	14.9%
Core return on invested capital (Core ROIC) <sup>4,5</sup>	42.5%	36.1%	43.1%	44.3%	36.5%	37.3%	30.1%	31.9%
Ratio of net income to equity attributable to Chugai shareholders (ROE) <sup>6</sup>	28.7%	—	28.0%	—	23.4%	—	19.6%	—
Ratio of profit to total assets (ROA) <sup>7</sup>	22.0%	—	21.8%	—	18.7%	—	15.8%	—
Equity per share attributable to Chugai shareholders (BPS) (Yen) <sup>3</sup>	865.88	—	722.50	—	596.16	—	519.91	—
Ratio of equity attributable to Chugai shareholders	76.2%	—	77.2%	—	79.3%	—	80.6%	—
Number of employees	7,771		7,664		7,555		7,394	

1. Core basis results are the IFRS basis results adjusted for items recognized by Chugai as atypical-recurring.

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. Revenue does not include consumption tax.

3. Effective July 1, 2020, Chugai has implemented a three-for-one stock split of its common stock.

Calculated based on the assumption that the stock split was implemented at the beginning of 2013.

(Billions of yen)

2018		2017		2016		2015		2014		2013	
IFRS	Core <sup>1</sup>	IFRS	Core <sup>1</sup>	IFRS	Core <sup>1</sup>	IFRS	Core <sup>1</sup>	IFRS	Core <sup>1</sup>	IFRS	Core <sup>1</sup>
579.8		534.2		491.8		498.8		461.1		423.7	
527.8		499.3		472.7		468.4		436.9		401.3	
51.9		34.9		19.1		30.4		24.2		22.4	
(262.8)	(261.9)	(254.2)	(252.9)	(247.9)	(246.7)	(240.2)	(238.9)	(218.1)	(217.0)	(187.0)	(186.1)
(192.6)	(187.6)	(181.1)	(178.1)	(167.0)	(164.5)	(171.8)	(169.3)	(167.2)	(166.8)	(157.9)	(157.7)
(73.7)	(73.7)	(72.8)	(72.8)	(69.8)	(69.8)	(74.8)	(74.7)	(71.7)	(71.7)	(71.6)	(71.5)
(99.2)	(94.2)	(92.9)	(88.9)	(85.0)	(82.6)	(83.8)	(81.9)	(80.8)	(80.6)	(74.3)	(74.1)
(19.7)	(19.7)	(15.3)	(16.3)	(12.2)	(12.1)	(13.2)	(12.8)	(14.6)	(14.6)	(12.1)	(12.1)
124.3	130.3	98.9	103.2	76.9	80.6	86.8	90.7	75.9	77.3	78.7	79.9
121.4	127.5	97.0	101.3	74.4	78.1	87.3	91.2	76.2	77.6	76.9	78.1
93.1	97.3	73.5	76.7	54.4	56.8	62.4	64.9	52.1	53.0	51.9	52.6
92.5	96.7	72.7	75.9	53.6	56.1	61.1	63.7	51.0	51.9	50.9	51.6
—	58.81	—	46.23	—	34.17	—	38.81	—	31.68	—	31.56
28.67		20.67		17.33		19.33		16.00		15.00	
—	48.7%	—	44.7%	—	50.7%	—	49.8%	—	50.5%	—	47.5%

505.3		440.2		431.1		380.4		357.7		325.2	
919.5		852.5		806.3		787.4		739.5		697.2	
(163.0)		(159.6)		(159.8)		(160.1)		(141.8)		(124.0)	
756.5		692.9		646.5		627.3		597.8		573.2	
71.8		34.3		19.4		28.7		16.3		13.0	
14.6		14.5		14.8		14.0		13.7		13.5	

49.8%	49.6%	50.9%	50.7%	52.4%	52.2%	51.3%	51.0%	49.9%	49.7%	46.6%	46.4%
21.4%	22.5%	18.5%	19.3%	15.6%	16.4%	17.4%	18.2%	16.5%	16.8%	18.6%	18.9%
17.1%	16.2%	17.4%	16.6%	17.3%	16.8%	16.8%	16.4%	17.5%	17.5%	17.5%	17.5%
20.3%	21.2%	17.3%	18.1%	—	14.6%	—	—	—	—	—	—
12.8%	—	10.9%	—	8.4%	—	10.0%	—	8.7%	—	9.3%	—
10.5%	—	8.9%	—	6.8%	—	8.2%	—	7.3%	—	7.7%	—
460.42	—	421.82	—	393.89	—	382.06	—	364.30	—	349.82	—
82.2%	—	81.2%	—	80.1%	—	79.5%	—	80.6%	—	82.0%	—
7,432		7,372		7,245		7,169		7,023		6,872	

4. ROIC = Net operating profit after taxes / Average NOA balances

5. Core return on invested capital (Core ROIC) = Core net operating profit after taxes / Average NOA

6. 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)

7. Ratio of profit to total assets (ROA) = Net income / total assets

# Management's Discussion and Analysis

## Management Policy

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 based on its strategic alliance with Roche. 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.

Our TOP I 2030 growth strategy announced in 2021 gives concrete form to our vision of becoming a top innovator in the healthcare industry in 2030 and sets out a path to its realization.

In recent years, all aspects of our business environment, from the evolution of science and technology to government healthcare policy and market trends, have been drastically changing, which has made it all the more important to review and implement strategy in a more flexible manner. We have reflected this need in the structure of TOP I 2030; instead of being staged in three-year phases like a conventional business plan, it sets out provisional interim milestones for each strategy based on a three to five-year cycle as well as TOP I 2030 goals. This will result in a more agile response by enabling us to adjust the milestones in line with changes in

the business environment and the progress of the strategy. In parallel, we will formulate a series of single-year plans focused on the 2030 goals and the interim milestones. The growth strategy has two pillars: Realizing global first-class drug discovery and building a futuristic business model. To firmly implant these pillars, in addition to concentrating Company-wide management resources on research and early development, which is the source of our value creation, Chugai will utilize AI-based drug discovery and other digital technologies to energetically drive Open Innovation. Additionally, as specific initiatives within the growth strategy, we have announced five areas of reform: Drug discovery, development, pharmaceutical technology, value delivery through our various value chains, and foundation for growth supporting each of these areas.

The aim of our shareholder return policy is to provide shareholders with stable dividends on a continuous basis after taking into account financial forecasts and strategic funding requirements. For payout ratio, we have adopted an approximate target of 45% on average as a proportion of Core EPS. Internal reserves will be used to increase corporate value through investments for further growth in existing strategic areas and to explore future business opportunities.

## Overview of Results

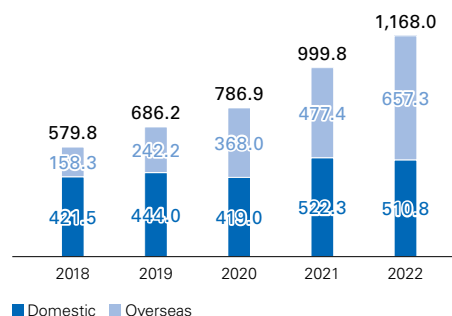
### Revenue [Core Basis]

	2020	2021	2022	(Billions of yen) 2021/2022 Change
Revenue	786.9	999.8	1,168.0	+16.8%
Sales	633.3	802.8	1,039.2	+29.4%
Royalties and other operating income (ROOI)	153.6	196.9	128.8	-34.6%

- Revenue in 2022 showed a significant year-on-year increase. This was the result of the solid performance of new and mainstay products in the Japanese market and an increase in supply of Ronapreve to the government, combined with expanding exports to Roche of in-house products Hemlibra and Actemra.
- Overseas revenue increased steadily with the growth of global products from Chugai research.

### Revenue

(Billions of yen)



### Domestic Sales by Area

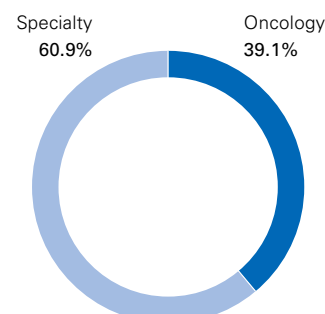
	2020	2021	2022	(Billions of yen) 2021/2022 Change
Domestic sales	409.1	518.9	654.7	+26.2%
Oncology	232.3	261.5	256.0	-2.1%
Specialty	176.8	257.4	398.6	+54.9%

- In 2022, domestic sales were impacted by the NHI drug price revisions of 2021 and 2022 and the market penetration of generics. Nevertheless, we posted growth of 26.2% in this area primarily due to the favorable market penetration by new products and mainstay products as well as the supply of Ronapreve to the government.
- In the Oncology area, although there was growth in the new product Polivy, the mainstay product Kadcyla and the number of tests provided by the Foundation Medicine\* genomic mutation analysis program, sales of Avastin, Herceptin and Tecentriq decreased due to the impact of NHI drug price revisions and the penetration of generics, resulting in sales decreasing by 2.1%.
- In the Specialty area, although sales were impacted by NHI drug price revisions and generics, strong performance of the mainstay product Hemlibra, supply of the new product Ronapreve to the government, and Evrysdi, Enspryng and Vabysmo made contributions, resulting in a significant increase in sales.

\* "FoundationOne Liquid CDx Cancer Genomic Profile" and "FoundationOne CDx Cancer Genomic Profile"

### Percentage of Domestic Sales

(2022)





## Overseas Sales

	(Billions of yen)			
	2020	2021	2022	2021/2022 Change
Overseas sales	224.2	283.9	384.6	+35.5%
Hemlibra (exports to Roche)	24.6	112.0	191.1	+70.6%
Actemra (exports to Roche)	132.0	100.1	126.2	+26.1%
Alecensa (exports to Roche)	43.0	48.2	38.0	-21.2%
Enspryng (exports to Roche)	5.6	1.5	2.8	+86.7%

- Overseas sales in 2022 were impacted by a year-on-year decrease in exports to Roche of Alecensa. However, Hemlibra sales grew significantly with the start of full-scale export at the regular shipment price. As Actemra also performed well, overseas sales showed a large increase overall.

## Cost of Sales [Core Basis]

	(Billions of yen)			
	2020	2021	2022	2021/2022 Change
Cost of sales	(272.3)	(335.5)	(475.0)	+41.6%
Cost to sales ratio	43.0%	41.8%	45.7%	+3.9%pts

- The cost to sales ratio for 2022 showed a year-on-year increase due to changes in the product mix and other factors.

## Operating Expenses (Marketing and Distribution Expenses, R&D expenses, and General and Administration Expenses) [Core Basis]

	(Billions of yen)			
	2020	2021	2022	2021/2022 Change
Total operating expenses	(206.7)	(230.2)	(241.3)	+4.8%
Marketing and distribution	(71.5)	(75.8)	(76.7)	+1.2%
Research and development	(113.5)	(129.8)	(143.7)	+10.7%
General and administration	(21.7)	(24.6)	(20.9)	-15.0%

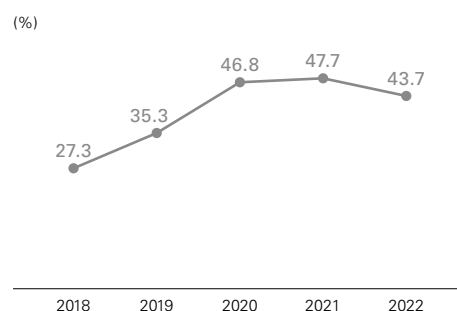
- Marketing and distribution expenses increased due to the impact of foreign exchange and other factors.
- R&D expenses increased year on year due to expenses increasing as development projects progressed and the impact of foreign exchange and other factors, and were the main factor in an overall increase in operating expenses.
- General and administration expenses decreased due to a decrease in various expenses and also gain on sale of property, plant and equipment.

## Operating Profit and Net Income [Core Basis]

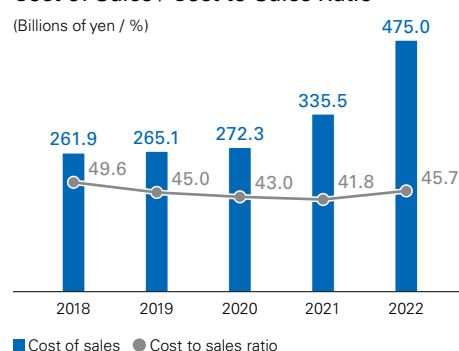
	(Billions of yen)			
	2020	2021	2022	2021/2022 Change
Operating profit	307.9	434.1	451.7	+4.1%
Ratio of operating profit to revenue	39.1%	43.4%	38.7%	-4.7%pts
Net income	219.4	311.5	317.7	+2.0%

- Although royalty income from initial shipments of Hemlibra decreased significantly, sales increased in both Japan and overseas, resulting in increases in both operating profit and net income.
- The ratio of operating profit to revenue decreased year on year due to an increase in the cost to sales ratio caused by factors such as a change in the product mix, and also an increase in R&D expenses due to the progress of development projects, the impact of foreign exchange and other factors.

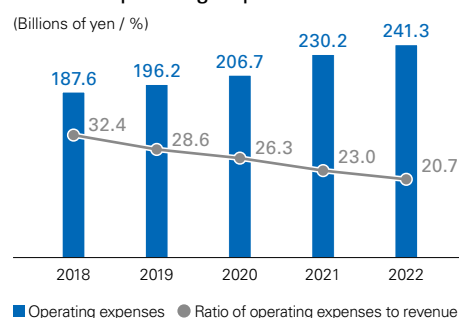
## Overseas revenue



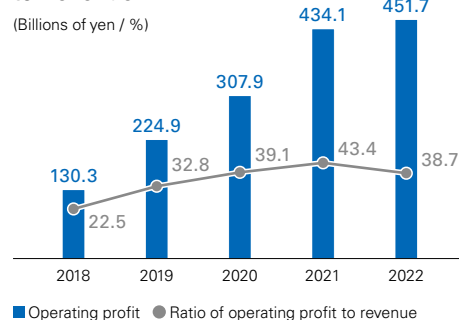
## Cost of Sales / Cost to Sales Ratio



## Operating Expenses / Ratio of Operating Expenses to Revenue



## Operating Profit / Ratio of Operating Profit to Revenue



## Profitability Indicators

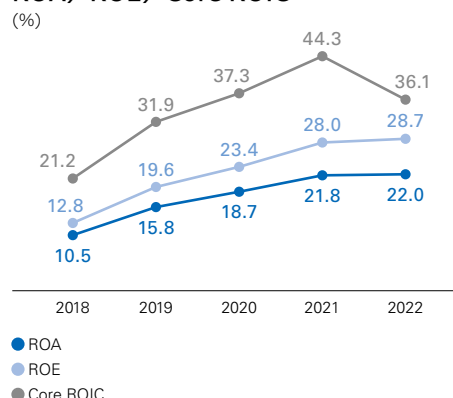
	2020	2021	2022	2021/2022 Change
Gross profit to revenue (%) (Core)	65.4	66.4	59.3	-7.1%pts
Operating profit to revenue (%) (Core)	39.1	43.4	38.7	-4.7%pts
ROA (%) (IFRS)	18.7	21.8	22.0	+0.2%pts
ROE (%) (IFRS)	23.4	28.0	28.7	+0.7%pts
Core ROIC (%)	37.3	44.3	36.1	-8.2%pts

Notes:

1. ROA = Net income attributable to Chugai shareholders / Total assets
2. ROE = Net income attributable to Chugai shareholders / Capital and reserves attributable to Chugai shareholders
3. Core ROIC = Core net operating profit after taxes / Net operating assets (Core ROIC is calculated by using Core income taxes.)

- Although Core net operating profit after taxes grew, net operating assets (NOA) increased significantly due to aggressive strategic investments such as Chugai Life Science Park Yokohama, in addition to a significant increase in net working capital associated with the delivery of Ronapreve to the government in 2022, resulting in a year-on-year decrease in Core ROIC.

## ROA/ROE/Core ROIC



## Financial Position

### Assets, Liabilities, and Net Assets

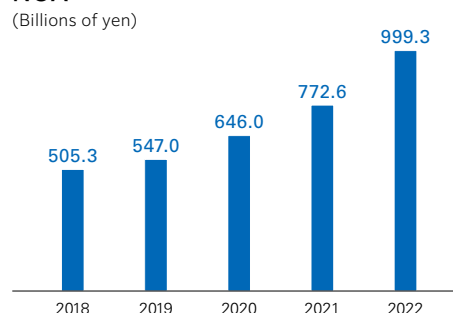
In conjunction with its decision to apply IFRS from 2013, Chugai has reorganized the consolidated balance sheets and discloses assets and liabilities including NOA for use as internal performance indicators (Roche discloses the same indicators). No items have been excluded from the balance sheets, as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

### NOA

	2020	2021	2022	2021/2022 Change
Net working capital	300.0	370.1	551.6	+49.0%
Long-term net operating assets	346.0	402.4	447.8	+11.3%
NOA	646.0	772.6	999.3	+29.3%

- Net working capital at the end of 2022 increased significantly from the end of the previous year due mainly to increase in accounts receivable such as Ronapreve. Long-term NOA grew, notably due to the increase in property, plant and equipment resulting from the investments in Chugai Life Science Park Yokohama and the manufacturing building for active pharmaceutical ingredients (APIs) for small and mid-size molecule drugs at the Fujieda Plant.

### NOA



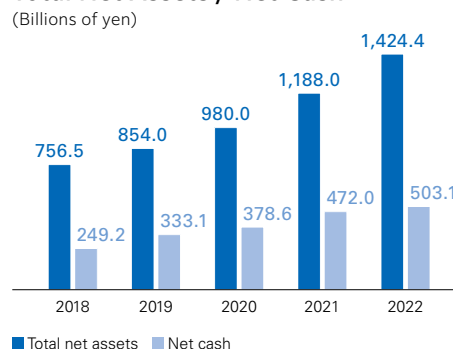
NOA are the total of net working capital and long-term NOA. Net working capital is composed of accounts receivable, inventories, accounts payable, and other payables and receivables. Long-term NOA are composed of property, plant and equipment, intangible assets, and other items.

### Total Net Assets

	2020	2021	2022	2021/2022 Change
NOA	646.0	772.6	999.3	+29.3%
Net cash	378.6	472.0	503.1	+6.6%
Other non-operating assets – net	(44.6)	(56.5)	(78.1)	+38.2%
Total net assets	980.0	1,188.0	1,424.4	+19.9%

- Total net assets at December 31, 2022 increased from a year earlier due to factors including an increase in accounts receivable such as Ronapreve, and an increase in property, plant and equipment resulting from investment in Chugai Life Science Park Yokohama and the manufacturing building for APIs for small and mid-size molecule drugs at the Fujieda Plant, and an increase in net cash.
- We will allocate these assets to strategic investments aimed at further increasing corporate value. Specifically, we will promote ongoing innovation while at the same time responding to changes in the business environment. These range from pressures on medical treatment funding to the evolution of drug discovery technology, the digitalization of the healthcare industry, and the need for ESG-related investment.

### Total Net Assets / Net Cash



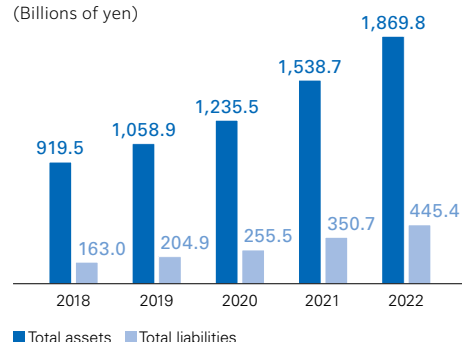
## Total Assets and Total Liabilities

	2020	2021	2022	2021/2022 Change
Total assets	1,235.5	1,538.7	1,869.8	+21.5%
Total liabilities	(255.5)	(350.7)	(445.4)	+27.0%

- Calculated under the headings of assets, liabilities, and net assets, there has been an increasing tendency in total assets, total liabilities, and total net assets.

## Total Assets / Total Liabilities

(Billions of yen)



## Financial Position Indicators

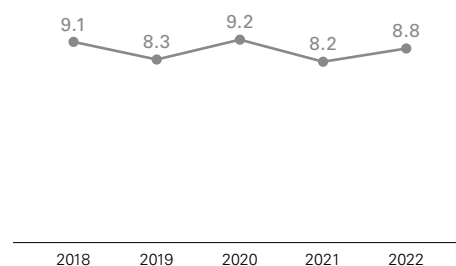
	2020	2021	2022	2021/2022 Change
Ratio of equity attributable to Chugai shareholders (%)	79.3	77.2	76.2	-1.0%pts
Cash conversion cycle (Months)	9.2	8.2	8.8	+0.6 months
Net cash turnover period (Months)	5.8	5.7	4.8	-0.9 months
Current ratio (%)	353.7	324.9	315.4	-9.5%pts
Debt-to-equity ratio (%)	0.0	0.0	0.0	—

Notes:

1. Ratio of equity attributable to Chugai shareholders = Capital and reserves attributable to Chugai shareholders (fiscal year-end) / Total assets (fiscal year-end)
2. Cash conversion cycle = [Trade accounts receivable / Sales + (Inventories – Trade accounts payable) / Cost of sales] x Months passed
3. Net cash turnover period = Net cash / Revenue x Months passed
4. Current ratio = Current assets (fiscal year-end) / Current liabilities (fiscal year-end)
5. Debt-to-equity ratio = Interest-bearing debt (fiscal year-end) / Capital and reserves attributable to Chugai shareholders (fiscal year-end)

## Cash Conversion Cycle

(Months)



## Cash Flows

In conjunction with its decision to apply IFRS from 2013, Chugai has reorganized the consolidated statement 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.

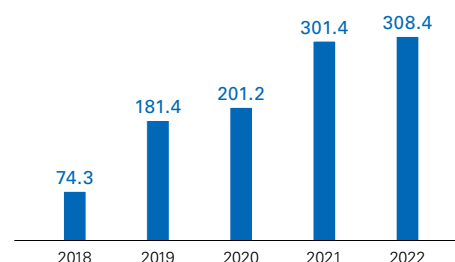
	2020	2021	2022	2021/2022 Change
<b>Movement of Free Cash Flow</b>				
Operating profit	301.2	421.9	533.3	+26.4%
Operating profit, net of operating cash adjustment	335.5	466.4	570.6	+22.3%
Operating free cash flow	201.2	301.4	308.4	+2.3%
Free cash flow	135.4	189.4	166.4	-12.1%
Net change in net cash	45.5	93.4	31.1	-66.7%
<b>Consolidated Statement of Cash Flows</b>				
Cash flows from operating activities	205.0	279.6	244.1	-12.7%
Cash flows from investing activities	(98.3)	(118.9)	(146.0)	+22.8%
Cash flows from financing activities	(99.5)	(107.4)	(145.6)	+35.6%
Net change in cash and cash equivalents	8.4	55.5	(45.6)	-%
Cash and cash equivalents at December 31	212.3	267.8	222.2	-17.0%

## Operating Free Cash Flow

- Operating profit, net of operating cash adjustment, is calculated by adjusting for depreciation and other items that are included in operating profit but are not accompanied by cash inflows or outflows and all inflows and outflows related to NOA that are not accompanied by profit or loss.
- Operating free cash flow for the fiscal year under review amounted to a net inflow of ¥308.4 billion due to an increase in operating profit, despite an increase in net working capital and other related items of ¥183.3 billion, as well as expenditures of ¥62.6 billion for the purchase of property, plant and equipment. The purchase of property, plant and equipment included investment and other expenditures for Chugai Life Science Park Yokohama and the construction of a manufacturing building at the Fujieda Plant for the development of small and mid-size molecule APIs.

## Operating Free Cash Flow

(Billions of yen)

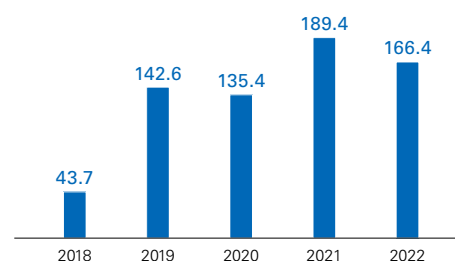


## Free Cash Flow

- Free cash flow was a net cash inflow of ¥166.4 billion due mainly to income taxes paid of ¥152.1 billion.
- Net cash as of December 31, 2022, after subtracting dividends paid of ¥138.2 billion and other expenditures, showed an increase of ¥31.1 billion from the previous year end to ¥503.1 billion.

## Free Cash Flow

(Billions of yen)



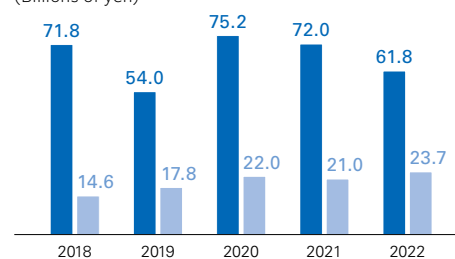
## Capital Investments

	(Billions of yen)			
	2020	2021	2022	2021/2022 Change
Investments in property, plant and equipment	75.2	72.0	61.8	-14.2%
Depreciation	22.0	21.0	23.7	+12.9%

- Capital investments in 2022 included investment in Chugai Life Science Park Yokohama and investments in manufacturing buildings at the Fujieda Plant and the Ukima Branch.
- Capital investment planned for 2023 amounts to ¥80 billion, including the major facility additions in the table below, with depreciation expenses of ¥24 billion.

## Capital Investments in Property, Plant and Equipment / Depreciation

(Billions of yen)



■ 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)		Fundraising method	Start of construction	Planned transfer/ completion date
		Total amount	Investment to date			
Ukima Branch (Kita-ku, Tokyo)	Manufacture of antibody APIs for early clinical trials (UK4)	12.1	3.3	Self-financing	November 2021	September 2023

### The Company and domestic subsidiary (Chugai Pharma Manufacturing Co., Ltd.)

Facilities (Location)	Description	Planned investment (Billions of yen)		Fundraising method	Start of construction	Planned transfer/ completion date
		Total amount	Investment to date			
Fujieda Plant (Fujieda City, Shizuoka)	Manufacture of APIs to cover late-stage clinical development and early commercial production of small and mid-size molecule drugs (FJ3)	55.5	23.2	Self-financing	September 2021	October 2024

## Outlook for 2023 [Core Basis]

Forecast assumptions: For 2023, Chugai assumes exchange rates of ¥138/CHF, ¥141/EUR, ¥131/USD, and ¥98/SGD.

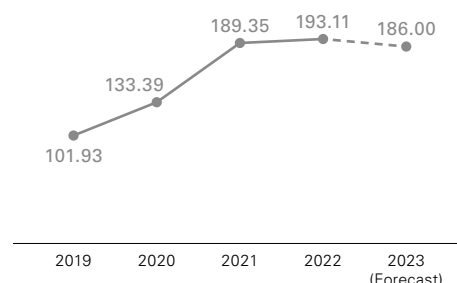
		(Billions of yen)	
	2022	2023 (Forecast)	2022/2023 Change
Core revenue	1,167.8	1,070.0	-8.4%
Sales	1,039.2	920.0	-11.5%
Domestic	654.7	541.7	-17.3%
Overseas	384.6	378.3	-1.6%
Other revenue	128.6	150.0	+16.6%
Core operating profit	451.7	415.0	-8.1%
Core EPS (Yen) <sup>1</sup>	193.11	186.00	-3.7%

Note: The Company has partially amended the financial statements from the fiscal year 2023 as follows;

- The item "Royalties and other operating income" previously reported under revenue has been changed to "other revenue," while income from disposal of product rights has been excluded therefrom.
- "Other operating income (expense)" has been established as a new category equivalent to R&D expenses, marketing and distribution expenses, and general and administration expenses. "Other operating income (expense)" includes the income from disposal of product rights, which has been excluded from revenue as described above, and income and expenses associated with operating activities that were previously included in "General and administration" but could not be classified into functional expense categories, such as gain (loss) on sale of land and buildings, etc.
- Marketing and distribution expenses and general and administration expenses have been integrated and presented as "SG&A expenses."

- With regard to domestic sales, although sales are forecast to grow for new products such as Polivy, Vabysmo and Enspryng and mainstay products such as Tecentrig and Hemlibra, domestic sales are forecast to decrease year on year due to a decrease in sales from supply of Ronapreve to the government, and a decrease in sales due to the impact of intensifying competition such as that associated with the launch of generics along with NHI drug price revisions.
- With regard to overseas sales, although Alecensa is forecast to experience growth, overseas sales are forecast to decrease year on year mainly due to a decrease in Actemra caused by a decrease in COVID-19 demand, and the impact of the decrease in Hemlibra sales caused by optimization of inventory levels by Roche.
- Other revenue is expected to increase due to the increases of royalty and profit-sharing income mainly from Hemlibra-related income, in addition to an increase in one-time income.
- The cost to sales ratio is expected to improve year on year, due notably to a change in the product mix.
- R&D expenses are expected to increase due to investments in drug discovery and early development, including the operation of Chugai Life Science Park Yokohama, and progress of development projects, etc. SG&A expenses are expected to increase slightly year on year. Furthermore, with regard to other operating income (expense), income from disposal of product rights is expected to significantly increase year on year.
- Core operating profit and Core EPS are expected to decrease in 2023 due to a decrease in supply of Ronapreve to the government and an increase in R&D expenses, etc., despite increases in other revenue and income from disposal of product rights, etc. Excluding the COVID-19-related temporary impact, Core revenue is expected to increase, and Core operating profit is expected to increase slightly.

## Core EPS<sup>1, 2</sup> (Yen)



1. Effective July 1, 2020, Chugai has implemented a three-for-one stock split of its common stock. Calculated based on the assumption that the stock split was implemented at the beginning of 2019.
2. Core EPS = Core net income attributable to Chugai shareholders / Diluted weighted average shares outstanding

## Fundamental Profit Distribution Policy and Dividends

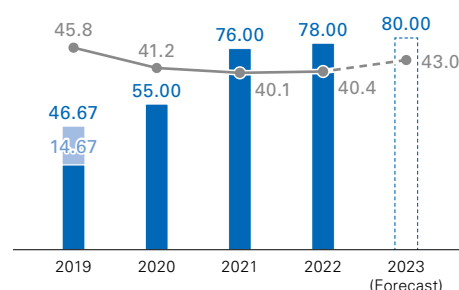
After taking into account projected business results and evolving needs in strategic investment funding, Chugai aims to offer shareholders a stable dividend, with a target payout ratio of 45% on average based on Core EPS. Internal reserves will be used to increase corporate value through investments for further growth in existing strategic areas and to explore future business opportunities.

	2020	2021	2022	2023 (Forecast)
Basic net income per share (EPS <sup>3</sup> )	130.66	184.29	227.64	—
Core EPS <sup>3</sup>	133.39	189.35	193.11	186.00
Equity per share attributable to Chugai shareholders (BPS <sup>3</sup> )	596.16	722.50	865.88	—
Cash dividends per share <sup>3</sup>	55.00	76.00	78.00	80.00
Core payout ratio	41.2%	40.1%	40.4%	43.0%
Core payout ratio (five-year average)	44.9%	42.9%	42.0%	41.8%

- Cash dividends per share for 2022 totaled ¥78, and the five-year average Core EPS payout ratio was 42.0 %.
- The dividend forecast for 2023 calls for an interim dividend of ¥40 and a year-end dividend of ¥40.

## Cash Dividends per Share<sup>3</sup> / Core Payout Ratio

(Yen / %)



- Annual dividends per share
- Special dividends
- Core payout ratio

3. Effective July 1, 2020, Chugai has implemented a three-for-one stock split of its common stock. Calculated based on the assumption that the stock split was implemented at the beginning of 2019.



# Shareholder Information

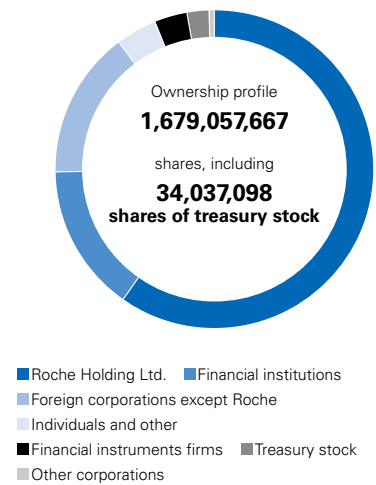
(As of December 31, 2022)

## Top 10 Largest Shareholders

Name	Number of Shares Held (Thousands)	Percentage of Voting Rights (%)
Roche Holding Ltd.	1,005,670	61.14%
The Master Trust Bank of Japan, Ltd. (Trust Account)	148,700	9.04%
Custody Bank of Japan, Ltd. (Trust Account)	61,476	3.73%
SMBC Nikko Securities Inc.	19,524	1.18%
JPMorgan Securities Japan Co., Ltd.	15,441	0.93%
STATE STREET BANK WEST CLIENT-TREATY 505234	14,445	0.87%
STATE STREET BANK AND TRUST COMPANY 505001	14,111	0.85%
NORTHERN TRUST CO. (AVFC) SUB A/C AMERICAN CLIENTS	11,266	0.68%
SUMITOMO LIFE INSURANCE COMPANY	9,000	0.54%
JP MORGAN CHASE BANK 385781	8,755	0.53%

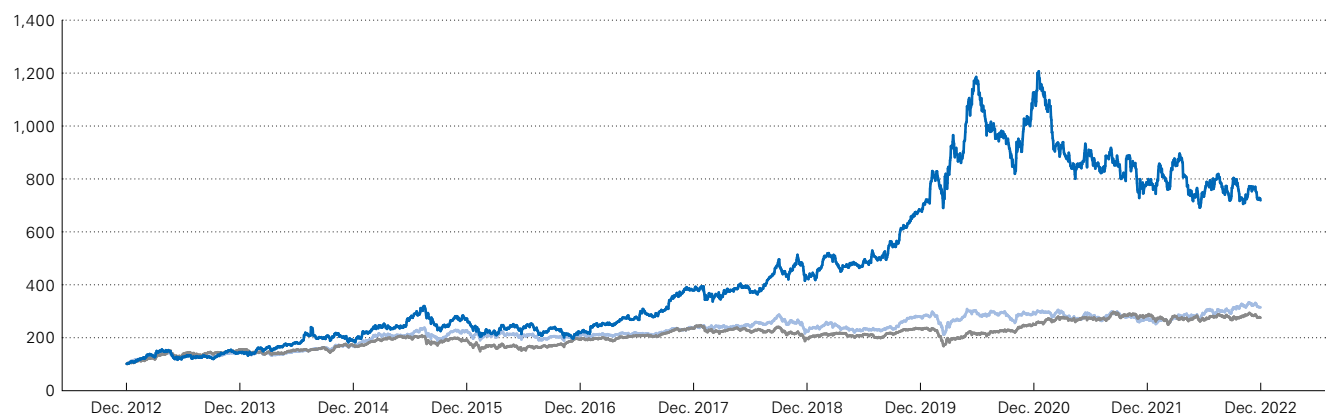
Note: The Company holds 34,037,098 shares of treasury stock, but is excluded from the ten major shareholders listed in the table above.

## Classification of Shareholders



## 10-Year Total Shareholder Return (TSR)

(Index)



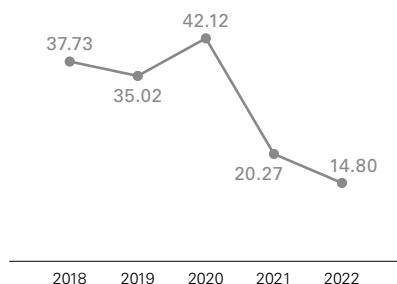
	Last 1 year	Last 3 years		Last 5 years		Last 10 years	
	TSR	TSR	Annualized TSR	TSR	Annualized TSR	TSR	Annualized TSR
Chugai	-7.8%	5.4%	8.9%	89.7%	19.9%	617.5%	27.2%
TOPIX	-2.5%	18.1%	5.9%	17.2%	4.0%	174.2%	11.9%
TOPIX-17 Pharmaceutical	16.8%	12.8%	4.6%	33.1%	6.6%	213.1%	13.3%

Note: In the above graphs and tables, the Chugai closing price and benchmark indexes as of December 31, 2012, are fixed at 100 and the figures for ROI assume re-investment of the dividends. The benchmark indexes used are the Tokyo Stock Price Index (TOPIX) and TOPIX-17 Pharmaceutical.

## Share Price Indicators

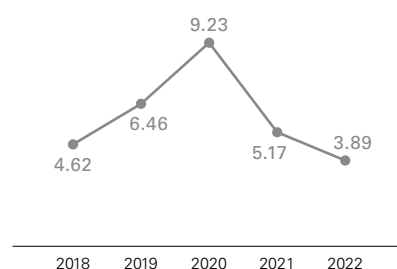
### Price / Earnings Ratio

Year-end share price / Basic net income per share (Times)



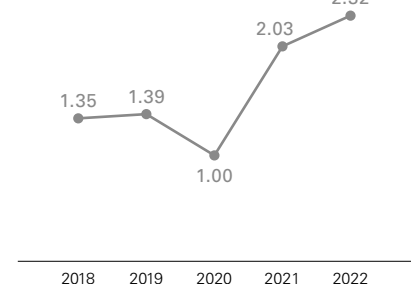
### Price / Book Ratio

Year-end share price / Equity per share attributable to Chugai shareholders (Times)



### Dividend Yield

Dividends per share / Year-end share price (%)



# Corporate Profile





(As of December 31, 2022)

## Corporate Overview

Company Name	Chugai Pharmaceutical Co., Ltd.
Date of Foundation	March 10, 1925
Date of Establishment	March 8, 1943
Head Office	2-1-1 Nihonbashi-Muromachi, Chuo-ku, Tokyo 103-8324, Japan Tel: +81-(0)3-3281-6611 (Main switchboard)
Stated Capital	¥73,202 million
Number of Employees	7,771 (Consolidated)

Number of Shares Issued of Common Stock	1,679,057,667 shares
Number of Shareholders	83,575
Stock Listing	Prime Market of Tokyo Stock Exchange
Fiscal Year-End	December 31
General Meeting of Shareholders	March
Transfer Agent	Mitsubishi UFJ Trust and Banking Corporation

## About the Information Shown

Printed publications	 <b>Annual Report (this publication)</b>	Aims to share information on the progress of our medium- to long-term value creation strategy Focus on information content of key importance, with stronger emphasis on effective presentation and reader-friendliness
Website	 <b>Sustainability</b> <a href="https://www.chugai-pharm.co.jp/english/sustainability/">https://www.chugai-pharm.co.jp/english/sustainability/</a>  <b>Investor Relations</b> <a href="https://www.chugai-pharm.co.jp/english/ir/">https://www.chugai-pharm.co.jp/english/ir/</a>  <b>About Chugai</b> <a href="https://www.chugai-pharm.co.jp/english/profile/">https://www.chugai-pharm.co.jp/english/profile/</a>	The printed publications and websites report Chugai Pharmaceutical's efforts utilizing their respective media characteristics. Please refer to the websites because they contain the information in the printed publications in addition to more detailed information.

## Column Production Process and Structure for this Report

August-September	October-November	December-January	February-March	April-May
<b>Secretariat Planning and Design</b> <ul style="list-style-type: none"> <li>Set up production systems</li> <li>Clarification of topics to be covered with main executive responsible (Itagaki)</li> <li>Create outline of planned structure</li> <li>Interview with investors</li> </ul>	<b>Draft Plan Review</b> <ul style="list-style-type: none"> <li>Review with <u>management team and review of material issues</u></li> <li>Interview with relevant parties</li> <li>Review of composition with relevant executives (Itagaki, Ebihara, Yano)</li> <li>Chugai ESG Meeting</li> <li>Review interviews</li> </ul>	<b>Content Production</b> <ul style="list-style-type: none"> <li>Review of value creation <u>model with management team</u></li> <li>Confirmation of content by relevant executives (Itagaki, Ebihara, Yano)</li> <li>Coordination with internal divisions</li> <li>Progress update on short-, medium-, and long-term plans</li> </ul>	<b>Specific Page Layout</b> <ul style="list-style-type: none"> <li>Develop messaging, structure composition, data</li> <li>Create messaging from <u>management team</u> (Okuda, Itagaki)</li> <li>Page layout verification by relevant executives</li> </ul>	<b>Finalization</b> <ul style="list-style-type: none"> <li>Final sign off by <u>management team</u> (Okuda, Itagaki)</li> <li>Overall checks, fine-tuning by production department</li> <li>Third-party review</li> </ul>

The underlined stages in the production processes listed above show the steps that involve the management team. In particular, as the main executive responsible, Director and CFO Toshiaki Itagaki engaged in discussions on its concept, structure, content, and design through a number of meetings and took responsibility up to its completion. In addition, the executive in charge of governance, Junichi Ebihara, and the executive in charge of environmental and social issues, Yoshiyuki Yano, also conducted regular discussions and verification of the composition and content. Interviews and confirmation of the content were conducted with Representative Director, President & CEO Dr. Osamu Okuda.


The production structure included the Corporate Communications Department as the secretariat, and CEO Dr. Okuda, CFO Itagaki, and the secretariat formed an integrated structure, just as with IR activities. In addition, the extended team included the executives in charge, Junichi Ebihara and Yoshiyuki Yano, as well as the Corporate Planning Department, Human Resources Management Department, General Affairs Department, and Risk & Compliance Department.



Innovation all for the patients



**CHUGAI PHARMACEUTICAL CO., LTD.**

 A member of the Roche group