

Year Ended March 31, 2022

# Multi-Modality Innovator





## Basic Philosophy

Corporate philosophy of JCR Pharmaceuticals Co., Ltd. is “Contributing towards people’s healthcare through pharmaceutical products.” Under this philosophy, we aim to contribute to health improvements with better treatment options as a pioneer company engaged in research, development, manufacturing and marketing of biopharmaceuticals and regenerative medicine.

### Reliability

We strive to establish a reliable company for all stakeholders by actions with high sense of duty in addition to compliance.

### Confidence

We continue our research and development from our own point of view and provide high-quality products and information with confidence in the aim of providing pharmaceuticals that are accepted worldwide.

### Belief

We aim for further corporate growth in the belief of “Think by oneself, act by oneself” under the basic philosophy.



**In accordance with its corporate philosophy, JCR is boldly advancing to the next stage. With this in mind, we explain JCR's growth strategy and business activities in a comprehensive manner.**

JCR Pharmaceuticals Co., Ltd. (JCR) has the important missions of tackling rare and intractable diseases with its advanced biotechnologies, and researching, developing, and creating innovative medicines in the areas of cell therapy, regenerative medicine, and gene therapy. Mindful of those missions, JCR is implementing its Midterm Business Plan for

FY2020-FY2022 "REVOLUTION." Guided by this plan, JCR is working as one "Team JCR" to continuously meet the challenge of staying one step ahead of its competitors. In editing "JCR Report 2022," we have prepared an integrated report that outlines progress on JCR's growth strategy and overall image of business activities for realizing its Mid-

Long-Term Management Vision, with a focus on business management and financial information, and covers non-financial information including sustainability initiatives. Through this report, we seek to foster a full understanding of all of JCR's business activities among a wide range of stakeholders.

1	Corporate Philosophy/Editorial Policy
2	Top Message
6	Messages from the Management Team
8	JCR's Business Creation Model

## Growth Strategy

12	Mid- to Long-Term Management Vision "Toward 2030"
14	Midterm Business Plan for FY2020-FY2022 "REVOLUTION"
16	Feature 1: Challenge of Multiple Modalities
24	Feature 2: Global Business Strategy
30	Sustainability Basic Approach Contributing in the Rare Disease Arena Environmental Awareness Contributing to Unmet Medical Needs Human Resource Management Quality Assurance and Stable Supply Corporate Governance

50	Board of Directors, Audit & Supervisory Board Members, and Corporate Officers
53	Messages from Outside Directors

## Business Activities


56	History of Growth/Key Topics for FY2021
58	Consolidated Financial and Non-Financial Highlights
60	Research and Development
64	Production System
66	Quality Assurance
68	Marketing
70	Intellectual Property
72	Human Resources
73	Information Systems
74	Core Products
76	Financial Highlights
78	11-Year Financial Data
80	Consolidated Financial Statements
85	Corporate Information

- **Period covered**  
FY2021 (From April 1, 2021 to March 31, 2022)  
\* This report also contains some information from FY2022.
- **Organizations covered**  
JCR Group (JCR Pharmaceuticals Co., Ltd. and six consolidated subsidiaries)  
\* See explanatory notes for exceptions.
- **Presentation of currency units**  
Numerical values are rounded down to the nearest whole number in the specific unit, in principle.  
However, numerical values presented in units of hundred millions of yen are rounded up or down to the nearest hundred million yen.

### Forward-Looking Statements

"JCR Report 2022" contains forward-looking statements that are subject to known and unknown risks and uncertainties, many of which are outside our control and are based on our judgments derived from the information available to us at this time. Our actual results could be materially different from those expressed in our forward-looking statements, due to factors and events that include, but are not limited to, the following: a deterioration of economic conditions, a change in the legal or governmental system, a delay in launching a new product, impact on competitors' pricing and product strategies, a decline in marketing capabilities relating to our products, production difficulties or delays, an infringement of our intellectual property rights, an adverse court decision in a significant lawsuit and regulatory actions.



A man with dark hair and glasses, wearing a dark blue suit, a light blue shirt, and a patterned blue tie, stands with his hands clasped in front of him. He is positioned on the left side of the frame. The background is a modern interior space with a high ceiling, large windows, and architectural details like a dark pillar and a glass railing. The lighting is warm and ambient.

**Fueled by the remarkable results of  
“REVOLUTION,” accelerating  
challenges for the future.**



FY2021 was a year to significantly accelerate toward realization of Midterm Business Plan for FY2020-FY2022 “REVOLUTION,” achieving growth for the 10th consecutive year, with net sales and each profit item reaching record highs for the second year in a row.

We succeeded in commercializing the world’s first “technology delivering active ingredients to the brain,” our proprietary blood-brain barrier (BBB) penetration technology, J-Brain Cargo®. IZCARGO® I.V. infusion 10mg, a recombinant treatment for mucopolysaccharidosis II (MPS II), was launched in Japan in May 2021 and we were able to deliver it as planned to patients and their families, who had been waiting for such a groundbreaking drug.

Under strategic partnerships, JCR will maximize the value of J-Brain Cargo® by accelerating development of more than 15 items in the arena of lysosomal storage disorders (LSDs), a rare disease, and boldly take on the challenge or research into various types of modalities. JCR is also contributing to development of a sustainable society by proactively engaging in sustainability initiatives centered around contributions to rare diseases.

To achieve the management vision of being a global specialty pharma in the rare disease arena, JCR is engaged in a “REVOLUTION” to open the door to the future by marshalling all capabilities of “Team JCR.”

October 2022

**Shin Ashida**

Representative Director, Chairman,  
President, CEO and COO

A handwritten signature in black ink, appearing to read 'Shin Ashida', with a long horizontal stroke extending to the right.

### FY2021 Business Overview

#### Achieved growth for the 10th consecutive year and record-high net sales and profits for the 2nd year in a row.

In FY2021, JCR's net sales amounted to 51,082 million yen (69.8% increase year on year), recording a 10th consecutive year of growth. Operating income was 19,933 million yen (141.1% increase year on year) and profit attributable to owners of parent was 14,507 million yen (110.5% increase year on year).

Net sales increased sharply, although sales of the mainstay recombinant human growth hormone product GROWJECT® and treatment for renal anemia were affected by an NHI price revision, but there was a contribution from IZCARGO®, a recombinant treatment for MPS II, launched in May 2021, and other factors including from contractual payments and domestic production of AZD1222 bulk solution for the AstraZeneca K.K. (AstraZeneca) COVID-19 vaccine. Even excluding the consideration for the AZD1222 bulk solution, net sales and profits each achieved record highs for the second consecutive year.

Related page

[Financial Highlights](#)  P.76

### R&D Progress/Vaccine Bulk Solution Manufacturing Business

#### Main projects made steady progress, including the global development of JR-141

JCR is currently leveraging our proprietary blood-brain barrier (BBB) penetration technology J-Brain Cargo® to work on more than 15 types of new drug developments in the arena of lysosomal storage disorders (LSDs), a rare disease. Since starting research on BBB penetration technology in 2005, JCR has continued to boldly take on challenges, and as a result, in May 2021, JR-141, an enzyme treatment for MPS II (Product name: IZCARGO®), was for sale in Japan. In February 2022, JCR was presented with the New Treatment Award for JR-141 by an international research conference dedicated to LSDs for succeeding in commercializing the world's first "technology delivering active ingredients to the brain." JCR concluded a joint development and commercialization agreement with Takeda Pharmaceutical Company Limited (Takeda) in September 2021 to deliver the groundbreaking new drug to people around the world as soon as possible. In February 2022, dosing started on the first patients in Phase III global clinical trials for JR-141 in the U.S., Brazil, and Europe (German, France, UK, etc.)

Regarding JR-171, a therapeutic enzyme for MPS I, JCR has been conducting Phase I/II clinical trials of JR-171 in Japan, Brazil, and the U.S., and completed registration of all planned cases by March 2022.

Global clinical trials for JR-441, a therapeutic enzyme for MPS IIIA, are scheduled to start in early FY2023, and efforts are accelerating to enable the earliest possible implementation of global trials therapeutic enzymes for JR-443 for MPS VII and JR-446 for MPS IIIB, and JR-162 for Pompe disease.

In March 2022, JCR initiated development of JR-479 for the treatment of patients with GM2 gangliosidosis. Within the arena of LSDs, which are diseases where severe symptoms are expressed in the central nervous system, J-Brain Cargo® is expected to be particularly effective.

In fields such as cell therapy, regenerative medicine and for human growth hormone products, JCR is leveraging advanced biotechnologies it has cultivated since its founding to advance R&D that responds to the various wishes of patients and their families, such as JR-031HIE for the expanded indication of TEMCELL® HS Inj. and JR-142, a long-acting growth hormone.

To fulfill our mission as a biopharmaceutical pioneer, we completed all planned manufacturing within FY2021 of the AZD1222 bulk solution for AstraZeneca's COVID-19 vaccine, which AstraZeneca commissioned us to produce from December 2020. JCR completed the entire process while achieving high quality production without a rejected lot, and this verified our strength in the production field that we have cultivated since our foundation. Now, JCR is moving forward on the construction of a new plant in the Kobe Science Park in Nishi-ku, Kobe, which is due for completion in the fall of 2022, as part of the Ministry of Health, Labour and Welfare's 2020 Emergency Vaccine Production System Improvement Project.

JCR is focused on R&D and Manufacturing driven by a dedicated small group of specialists par excellence, and will continue to take on further challenges.

Related pages

[Feature 2: Global Business Strategy](#)  P.24

[Research and Development](#)  P.60

[Production System](#)  P.64



## Taking on the Challenges of New Product Creation

### Leveraging our original technology platforms to pursue application possibilities for various modalities.

J-Brain Cargo® is a new drug platform technology that enables flexible customization, so its uses are not limited only to the field of LSDs, but for a wide range of central nervous system diseases such as Alzheimer's disease, Parkinson's disease, neuro-oncology and neuro-inflammation. Furthermore, it has the potential for application as a therapeutic agent for systemic diseases such as neuromuscular and muscular diseases.

JCR has improved and modified J-Brain Cargo® based on the knowledge and know-how it has cultivated through R&D on treatments for LSDs to create an evolved form of the drug, including BBB-type VHH antibodies applicable to various modalities. Currently, we are moving forward on various initiatives with a view on the five areas of enzyme and protein delivery, oligonucleotide delivery, LNP, gene and cell therapy and antibody delivery.

In addition, regarding oligonucleotide delivery, LNP, gene and cell therapy, and other modalities, JCR will collaborate with partners possessing advanced technologies that JCR cannot use and work to pursue potential applications. As a part of these efforts, in March 2022, we entered into a research and development collaboration and exclusive license agreement with Takeda to develop gene therapies that apply J-Brain Cargo®. Under the agreement, LSDs are identified as priority diseases, but targets include other rare and non-rare diseases.

Related page

[Feature 1: Challenge of Multiple Modalities](#) 

## Sustainability

### JCR contributes to development of a sustainable society through business activities based on its corporate philosophy.

JCR has been promoting measures to realize a sustainable society in the core areas of Rare Diseases (RD), Environment (E), Society (S), and Corporate Governance (G).


JCR recognizes that rare diseases are the arena that we can make our greatest contribution from a CSV standpoint. To deliver JCR's technological value to patients around the world as soon as possible, we will continue to proactively invest in R&D.

From the environment aspect, we conducted a scenario analysis based on the recommendations of the Task Force on Climate-Related Financial Disclosures (TCFD). Going forward, we will aim to augment our measures addressing climate change based on the results, as well as strive to disclose appropriate information.

Regarding corporate governance, we have newly appointed two independent Outside Directors, which we believe will further enhance the effectiveness of management supervision.

In July 2022, the Board of Directors resolved to newly establish the Sustainability Advisory Committee, Sustainability Committee and Environmental Committee to enable in-depth discussions and formulating strategies in close alignment with management in response to the ever-changing social and business environment and challenges. Under the new promotion structure, JCR will continue to work as one team, driven by a sense of purpose in the rare disease field, to pursue sustainability in the manner unique to JCR.

Related pages

[Sustainability](#) 

[Corporate Governance](#) 

## Return to Shareholders

### We will provide continuous and stable dividends to shareholders.

Returning profits to shareholders is an important management policy for JCR. In FY2021, JCR achieved record-high operating results. Therefore, we decided to pay a term-end dividend of 12 yen per share (including a special dividend of 2 yen). On October 1, 2020, JCR conducted a 4-for-1 stock split of its common shares. Assuming that this stock split had been conducted at the start of FY2020, the annual dividend for FY2020 would be 12 yen per share, and for FY2021 would be 22 yen per share (an interim dividend of 10 yen and year-end dividend of 12 yen), which is an increase of 10 yen per share from the previous fiscal year.

## Messages from the Management Team



JCR transitioned to the Tokyo Stock Exchange Prime Market in April 2022. To meet the expectations of our many stakeholders, JCR will build an even higher-level corporate governance structure and strengthen initiatives to realize a sustainable society, including by addressing environmental issues such as climate change. In FY2022, as the final stage for Midterm Business Plan for FY2020-FY2022 “REVOLUTION,” JCR will continue to accelerate corporate activities to contribute to as many patients as possible, including continuing to work for those with lysosomal storage disorders (LSDs) and others in the rare disease arena, and make further progress toward the goal of becoming a “research-oriented specialty pharma with global exposure.”

**Toru Ashida**  
Senior Vice President  
Sales and Administration  
Executive Director, Sales Division

A handwritten signature in black ink that reads "T. ashida".



The approval of IZCARGO® and the partnership with Takeda have catalyzed JCR's transition from a domestic to an international biopharmaceutical company. JCR has metamorphosed from a contributor to a driver of biopharmaceutical innovation. International presence is a pre-requisite to successfully develop and commercialize drugs for orphan diseases. To this end, we will further enhance our clinical development capabilities and presence in key markets like the U.S. and Europe to make JCR's assets in rare diseases available to patients across the globe. Partnerships will be equally important to internal development to progress our extensive portfolio of assets based on the J-Brain Cargo® Technology.

**Mathias Schmidt, PD, Ph.D.**

Vice President  
Clinical Development, Global Business Strategy  
and Business Development  
ArmaGen, Inc. CEO  
JCR USA, Inc. President and CEO

A handwritten signature in black ink that reads "M. Schmidt".





FY2021 has been a fruitful year for JCR, starting from the launch of “IZCARGO®,” the protein therapeutic for MPS II, as the first product using J-Brain Cargo® technology. We also reached a license agreement with Takeda to commercialize IZCARGO® in global markets. These are significant milestones for JCR to become a global specialty pharma in the rare disease arena. Today, further research on various modalities is in progress, which will open new possibilities to apply J-Brain Cargo® technology also to diseases other than LSDs. A collaboration agreement with Takeda in gene therapy field is the first achievement on this journey. We will continue to invest in R&D and pursue developing life-changing drugs for patients through our unique technology.

**Hiroyuki Sonoda, Ph.D.**

Vice President  
Research and Corporate Strategy  
Executive Director, Research Division



JCR is strengthening its quality assurance and production system to supply our products globally. We are improving the reliability, transparency and robustness of all aspects of our operations including compliance with regulatory affairs, safety management and quality assurance to ensure JCR products can be used safely and effectively. In addition, for several J-Brain Cargo® developments currently underway, we are expanding manufacturing platforms to specialize in small-lot, multi-item production for stable supply after approval has been obtained. Our corporate activities have a foundation in compliance with laws and regulations, and we provide detailed training and education for all employees. Our employees will work as one to protect the future.

**Yoshio Hiyama, Ph.D.**

Senior Executive Director  
Production and Quality Assurance  
Executive Director, Production Division

Creating Value and Realizing Sustainability by Embodying the Corporate Philosophy

**Contributing towards people's healthcare through pharmaceutical products**

Our Goal "Toward 2030"

**Research-oriented specialty pharma with global exposure**

Business Model

Business activities propelled by both in-house drug discovery based on original platform technologies and open innovation

**Global Specialty Pharma**  
in the Rare Disease Arena



**Multi-Modality Innovator**  
Contributing to Various Disease Arenas

[JCR's Strengths]

R&D

**Creativity**  
**Breakthrough Capabilities**

Advancing "R&D" that challenges for creation and application of proprietary new drug platforms

Manufacturing

**Experience-Based Knowledge**  
**Perseverance**

Conducting "Manufacturing" leveraging a rich track record related to biopharmaceuticals production

Business Investment

**Foresight**  
**Decisiveness**

Implementing speedy business investment foreseeing the future and creating growth opportunities

Source of Our Value

**"Team JCR"**

Always act "from the standpoint of patients and their families," and marshal all capabilities of each and every one of our highly diverse employees



# JCR will achieve sustained value creation by working to develop proprietary technologies and innovative products in anticipation of the needs of the times.

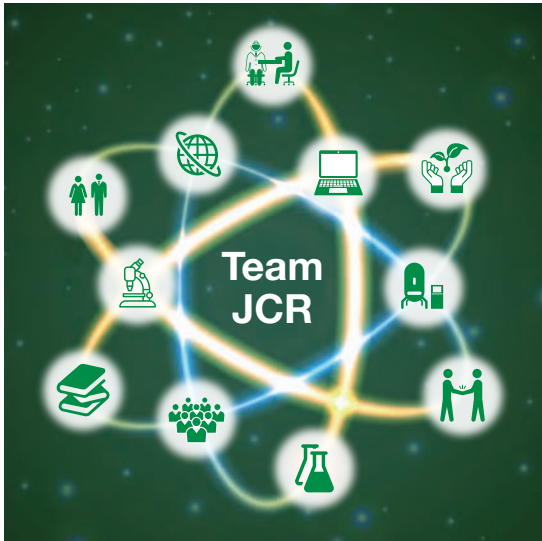
Since founding in 1975, JCR has grown through R&D with originality in fields where other companies have not been involved. JCR's proprietary blood-brain barrier (BBB) penetration technology, J-Brain Cargo®, one of the significant milestones of that R&D, has potential for application in various modalities, not just as a pharmaceutical development in the rare diseases arena, but targeting various patients and expected to develop pharmaceuticals jointly together with other companies.

A shift in drug development from common diseases to rare diseases that are more difficult to develop, an increasingly competitive environment and uncertainty regarding the NHI drug price system in Japan make the business environment increasingly harsher, and it is becoming ever difficult for pharmaceutical companies that cannot develop unique fundamental technologies and drugs to continue their business.

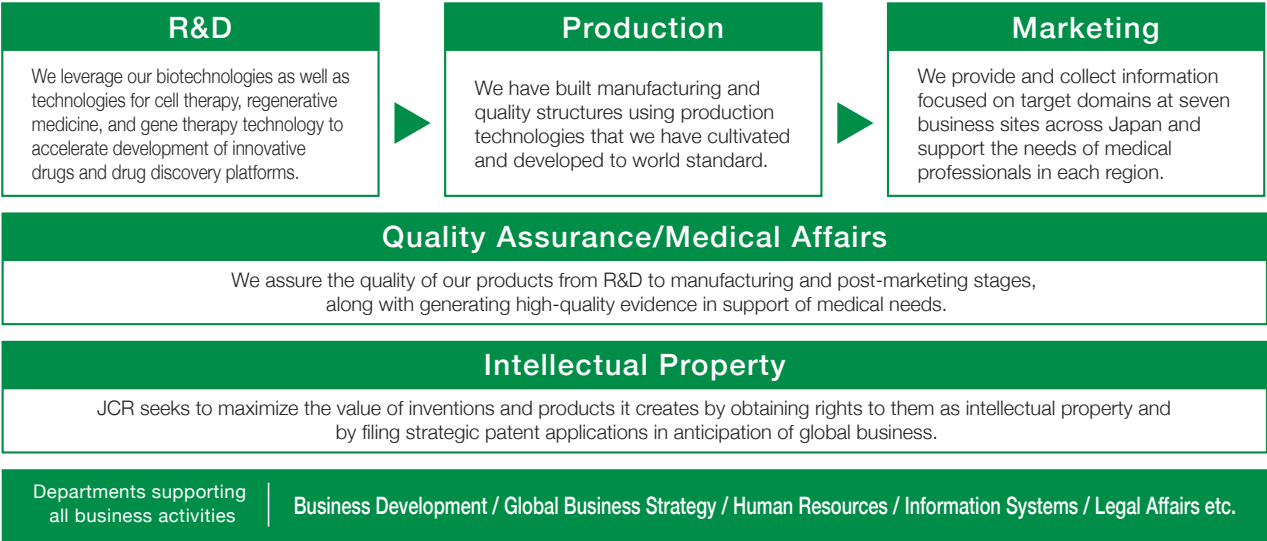
Through J-Brain Cargo®, JCR has paved the way for a

solution to the longstanding issue in drug development of brain barrier penetration. However, it will take a long time to be able to deliver this groundbreaking drug to patients living with diseases of the central nervous system and their families. JCR is heading toward the 50th anniversary of its founding and looking ahead at the 50 years beyond that, "Team JCR" will work as one to maximize its own strengths and continue to take on challenges to bring about a further "REVOLUTION" to be able to contribute at the earliest possible stage.

Related page  
[Growth Strategy](#) P.10



## [Business Process]



Related page  
[Business Activities](#) P.54

A vertical bar graphic consisting of two segments: a light green segment on top and a darker green segment on the bottom.

# Growth Strategy

JCR is accelerating business development globally based on the Mid- to Long-Term Management Vision “Toward 2030” and Midterm Business Plan for FY2020-FY2022 “REVOLUTION.” Based on the entrepreneurial spirit that has run in JCR since foundation and with the conviction that the source of our value, “Team JCR,” which shares the corporate culture, we will marshal all capabilities of each and every one of our diverse employees as we aim to become a “research-oriented specialty pharma with global exposure.”



The image features a stylized illustration of two hands, one on the left and one on the right, reaching towards each other. The hands are rendered in a dark, almost black silhouette. The interior of the hands and the space between them is filled with a dense collection of colorful bokeh lights in shades of orange, yellow, green, and red. A bright, multi-pointed starburst of light is positioned in the center, where the hands are closest together, creating a focal point of intense brightness. The overall composition is set against a plain white background.

**Together We Soar.**

# Toward 2030

Carrying on the entrepreneurial spirit that has run through JCR since its founding in 1975, each individual shares a corporate culture that has grown through R&D and Manufacturing and based on a corporate philosophy that aims to contribute to the rare diseases arena, JCR has established a stable management foundation, created various types of proprietary technologies, including the blood-brain barrier (BBB) penetration technology, J-Brain Cargo®, and built a

basis for thriving globally.

With the conviction that “Team JCR” is the source of its value, JCR has formulated the Mid- to Long-Term Management Vision “Toward 2030” to advance toward full-scale global business by 2030 and is implementing strategies aimed at becoming a “research-oriented specialty pharma with global exposure.”

JCR is proactively collaborating with other companies with a matching corporate culture and accelerating its

moves to being “a global specialty pharma in the rare disease arena,” and by making bold and appropriate decisions in a timely manner, will pursue sustainable and stable growth in the increasingly uncertain pharmaceutical industry.



Our Goal

## Research-oriented specialty pharma with global exposure

### Concrete Corporate Vision

- ◎ Be a global specialty pharma in the rare disease arena
- ◎ Continue to ambitiously create “one step beyond” technologies based on our original technology platforms, including J-Brain Cargo®
- ◎ Continue to ambitiously foster new values with R&D and Manufacturing
- ◎ Continue to overcome challenges with an unwavering resolve to contribute to the treatment of rare diseases

### Basic Strategies

- ◎ Focus on R&D and Manufacturing driven by a dedicated small group of specialists par excellence, embracing the founding spirit of “Team JCR” as our core value
- ◎ Develop human resources with a “Team JCR” spirit so that each individual can realize their full potential in their respective stations
- ◎ Consolidate three pillars of revenues: (1) domestic products such as growth hormone products; (2) the global market for LSDs; and (3) licensing fees from our platform technologies



# Midterm Business Plan for FY2020-FY2022 “REVOLUTION”

JCR will celebrate the 50th anniversary of its foundation in 2025. At the same time, it wants to achieve full-scale globalization from the late 2020s onward. To achieve the Mid- to Long-Term Management Vision “Toward 2030” will require each and every employee to change in all aspect of business experience and not to be bound by past experiences. That is why “REVOLUTION” was made the key word of the midterm business plan for FY2020-FY2022.

JCR believes the greatest responsibility to be performed by a pharmaceutical company is the stable supply of high-quality pharmaceuticals. Based on this recognition and taking into account JCR’s increasing importance in the rare diseases arena going forward, “qualitative and quantitative reorganization of the quality assurance system” has been made our top priority business challenge. Furthermore, we have set five items as important business challenges in anticipation of the

late 2020s becoming a period of rapid business expansion.

From a results aspect, product sales and contract income have both grown steadily and we have already achieved the final targets given in Guidance, even excluding the consideration for manufacturing the bulk solution for AstraZeneca’s COVID-19 vaccine, AZD1222 in FY2021. In FY2022, we will marshal all capabilities of “Team JCR” to further accelerate “REVOLUTION.”

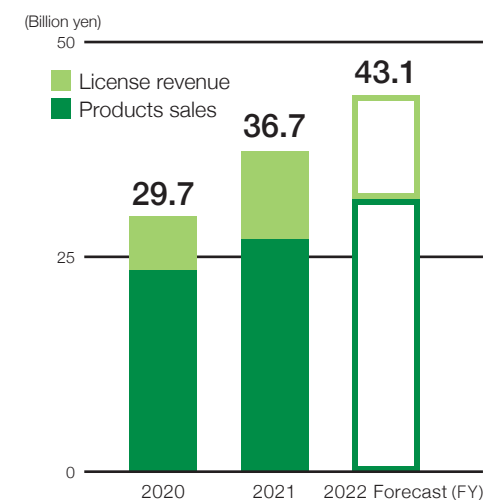
## ■ Key Theme



## ■ Guidance

Financial metric	FY2022 target
Net sales	<b>¥32 to ¥36 billion</b> Based on steady year-on-year sales growth
Operating income	<b>¥7 to ¥10 billion</b>
R&D expenditures	R&D expenditures of around <b>20%</b> of net sales A greater allocation of funds is permitted when required
Dividend payout ratio of <b>30%</b> , under a basic policy of providing stable dividends with a focus on balancing returns shareholders expect and our financial soundness	

## ■ Net Sales Trends (Excluding AZD1222 Bulk Solution)



## [Outline and Progress on Top Priority Business Challenges in the Midterm Business Plan for FY2020-FY2022 “REVOLUTION”]

### Top priority business challenge **[Qualitative and quantitative reorganization of the quality assurance system]**

JCR believes that the most important responsibility of a pharmaceutical company lies in providing a stable supply of high-quality pharmaceuticals. Mindful of this responsibility as well as the growing presence of JCR in the rare disease arena, “qualitative and quantitative reorganization of the quality assurance system” has been identified as our top priority business challenge. In FY 2021, JCR conducted an organizational change, separating the quality testing division from

the Production Division and merging it with the testing method development division and began construction of a quality and testing building for completion in FY2022. These efforts aim to build a quality management structure capable of conducting all tests from consideration of testing methods at the initial stage of research through to shipment following commercial production, and in practical terms seek to achieve waste-free, efficient operations.

### ■ **Actions for sustainable growth of the sales of our products**

JCR is developing a series of drugs for the treatment of lysosomal storage diseases (LSDs), and expects to start global trials for multiples of these within the next few years, and global launches expected in 2025 or later. Sales of existing products constitute the source of funding for all of our research and development activities. For GROWJECT®, a recombinant human growth hormone product, we aim to further improve treatment satisfaction by responding to the needs of patients and medical staff by developing a dedicated injector and connected smartphone app and by developing easily used and long-acting formulations more accessible for patients. We realize how extremely important it is to build a firm earnings foundation, so have accelerated the market penetration of IZCARGO®, a recombinant treatment of MPS II launched in May 2021, and made global alliances for development products. We have adapted appropriately to changes in the business environment, while providing information effectively and efficiently, and will work to preserve and drive growth in net sales of existing products.

### ■ **Expansion of basic and applied research activities**

In research and development, we will strengthen measures to address basic research in order to create new platform technologies in anticipation of the period after we have developed treatments for LSDs. Through the knowledge obtained from multiple development items, we will move forward on collaboration with other companies to create new growth opportunities for J-Brain Cargo® applications for various modalities,

taking into consideration its deployment for a variety of other diseases.

### ■ **Evaluation and implementation of further capital investment for manufacturing and research**

To achieve globalization in earnest, we will actively consider and make capital investments in production and research. The new API plant under construction within the Kobe Science Park will not only produce bulk solution for the COVID-19 vaccine, but has also been designed to manufacture JCR's own products, and we are also planning to build a new plant on an adjacent business-use plot.

### ■ **Product strategy planning including evidence generation**

We recognize that JCR has an important responsibility to provide useful information to clinical sites worldwide that are engaged in the treatment of LSDs, and are promoting proactive and strategic information-gathering activities about IZCARGO®.

### ■ **Transformation of operations and organizations along with human resource development**

We are making steady progress in restructuring our organization to make it more functional and efficient, training next-generation leaders capable of global success, and enhancing IT infrastructure to improve productivity and realize work style reforms.

# Challenge of Multiple Modalities

## Pursuing the further evolution of J-Brain Cargo® for the creation of innovative new drugs in multiple disease areas.



JCR is conducting research and development on lysosomal storage disorders (LSDs) utilizing J-Brain Cargo®, the company's proprietary blood-brain barrier penetration technology. As a result of these efforts, IZCARGO®, a recombinant treatment for MPS II, was approved in Japan, and it is currently in global Phase III clinical trial. Along with IZCARGO®, we have strived to create over 15 types of J-Brain Cargo® technology applied drug candidates for LSDs. J-Brain Cargo® was originally created for the development of therapies for rare diseases, LSDs in particular, but it is not the case that the technology can only be used for this disease area. It could be applicable to all central nervous system diseases.

Until several decades ago, low molecular weight compounds created from chemical synthesis had been central to drug discovery, but more recently recombinant protein drugs, including antibody drugs and other biopharmaceuticals, have come to play a major role in drug discovery. In addition, mRNA drugs, whose profile has been raised by the novel coronavirus vaccine, are also likely to be increasingly utilized going forward. Multiple modalities are now within the realm of possibility, and therapeutics are being developed to treat diseases that have been untreatable so far. Whichever the modality, however, technology is needed to deliver the active ingredient to the targeted part of the body affected by the disease. If the

targeted area is the brain or the spinal cord, for example, there has to be a drug delivery system such as J-Brain Cargo® that can cross the blood-brain barrier to deliver the active ingredient to the central nervous system. Based on our expertise and know-how cultivated in research and development on therapeutics for LSDs, JCR has created an evolved version of J-Brain Cargo® applicable to multiple modalities. Utilizing different modalities with this new J-Brain Cargo®, we will work to create innovative new drugs in central nervous disease areas.

**Hiroyuki Sonoda, Ph.D.**

Vice President,  
Research and Corporate Strategy  
Executive Director, Research Division



An abstract graphic featuring a glowing, multi-layered hexagonal frame in shades of purple, blue, and pink. Inside the frame, there are several scientific and biological icons: a yellow and orange protein ribbon structure at the top, a blue DNA double helix on the right, a red and pink brush border (microvilli) at the bottom right, a colorful, textured cluster of cells or molecules at the bottom center, and a small green plant sprout on the left. The background is dark with flowing, translucent ribbons of green, blue, and red.

# **Multi-Modality Innovator**

Feature 1: Challenge of Multiple Modalities

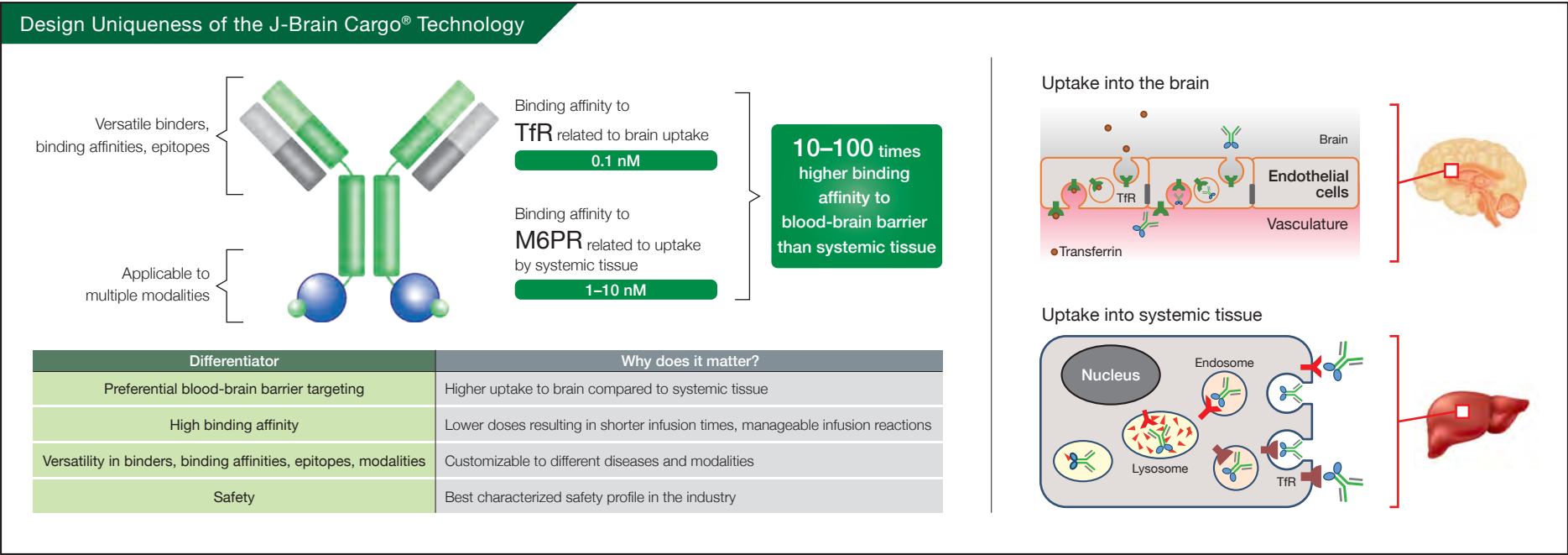
J-Brain Cargo® makes possible the design of well-balanced drugs that are optimized to crossing the blood-brain barrier but can also deliver active ingredients to systemic tissue.

J-Brain Cargo® utilizes an intrinsic physiological mechanism in the body that allows macromolecules to cross the blood-brain barrier. Transferrin, a protein that handles iron metabolism, binds to the transferrin receptor (TfR) and is taken up by vascular endothelial cells to thereby deliver iron to the brain. J-Brain Cargo® utilizes this mechanism, that is, a fusion protein of an antibody to TfR and a drug crosses the blood-brain barrier. While other companies have also been developing technologies that use a similar mechanism, JCR succeeded in resolving numerous issues for its practical

application, and in May 2021, IZCARGO®, a pharmaceutical that applies this blood-brain barrier crossing technology, was made available on the market.

J-Brain Cargo® is a modular platform technology that can be flexibly tailored to different therapeutic purposes. Along with the ability to bind with TfR, IZCARGO® uses the cellular transport of mannose-6-phosphate in the fused medicine (enzyme) and mannose-6-phosphate receptors on somatic cells (M6PR) to make it possible for the drug to be delivered not only to the brain but to systemic tissue as well. Because

M6PR is much more abundantly expressed than TfR, it is important to have a good balance in binding affinities with respect to both. To address this issue, the binding affinity for TfR was designed to be 10-100 times higher than the binding affinity for M6PR, which provides the benefit of increased safety, because the dosage can be lowered, for example, while being optimized to cross the blood-brain barrier.



## J-Brain Cargo® can be applied to therapeutics for a variety of central nervous system and systemic diseases and not only LSDs.

JCR has strived to create over 15 J-Brain Cargo® technology applied drug candidates in the LSDs area following IZCARGO®, a recombinant treatment for MPS II.

Most of the targeted diseases present central nervous system symptoms for which there are no therapeutics or no standard treatment has been established. We are accelerating R&D to try to meet, as quickly as possible, the expectations of patients, families, and medical professionals around the world waiting for groundbreaking new drugs.

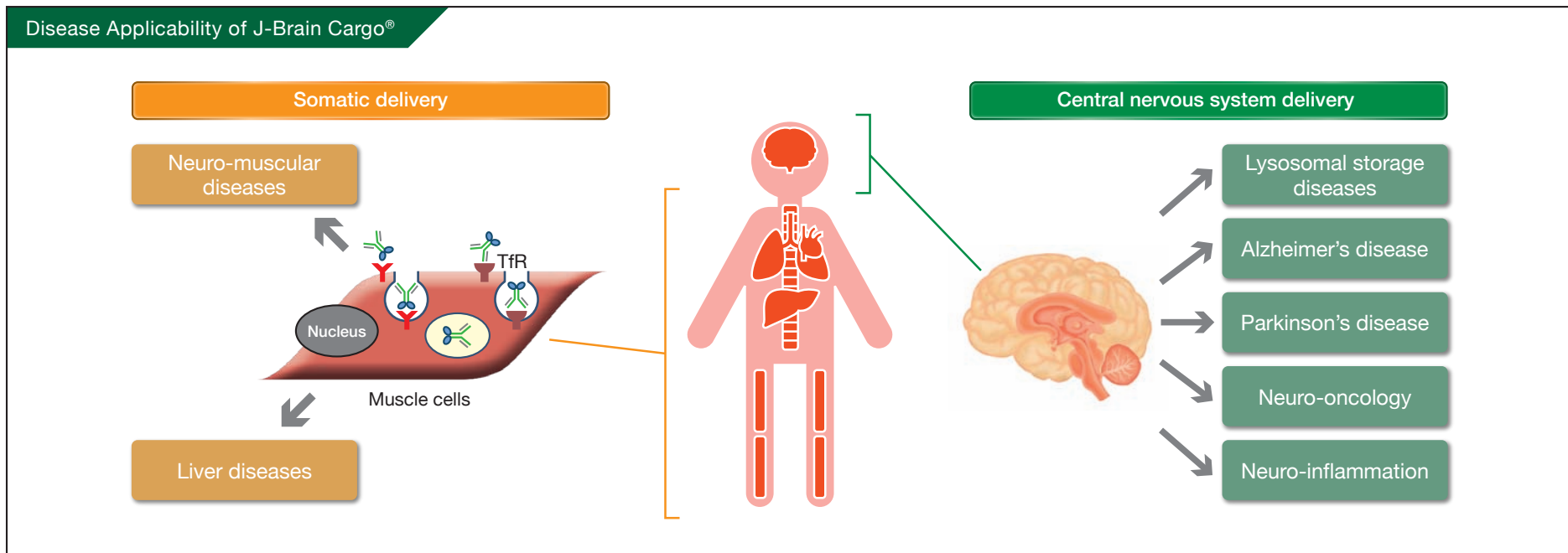
As a platform technology for drug discovery, the

possibilities for J-Brain Cargo® go beyond LSDs. By fusing various drugs with antibodies and creating new proteins, we expect that this technology could create new, game-changing drugs that change the landscape of therapies for a wide range of central nervous system diseases, including Alzheimer's, Parkinson's, brain tumors, and neuroinflammatory diseases.

At the same time, by preferentially targeting transferrin receptors (TfR) expressed in muscle cells and elsewhere, active ingredients can be delivered to peripheral tissues,

creating great possibilities for therapies for neuro-muscular disorders such as amyotrophic lateral sclerosis (ALS).

JCR will seek to contribute to unmet medical needs through the pursuit of the clinical applicability of J-Brain Cargo®.





## Feature 1: Challenge of Multiple Modalities

**Improving and modifying J-Brain Cargo® technology to develop multiple variations.**

**Optimizing the overall drug structure depending on the characteristics of the substance to be delivered.**

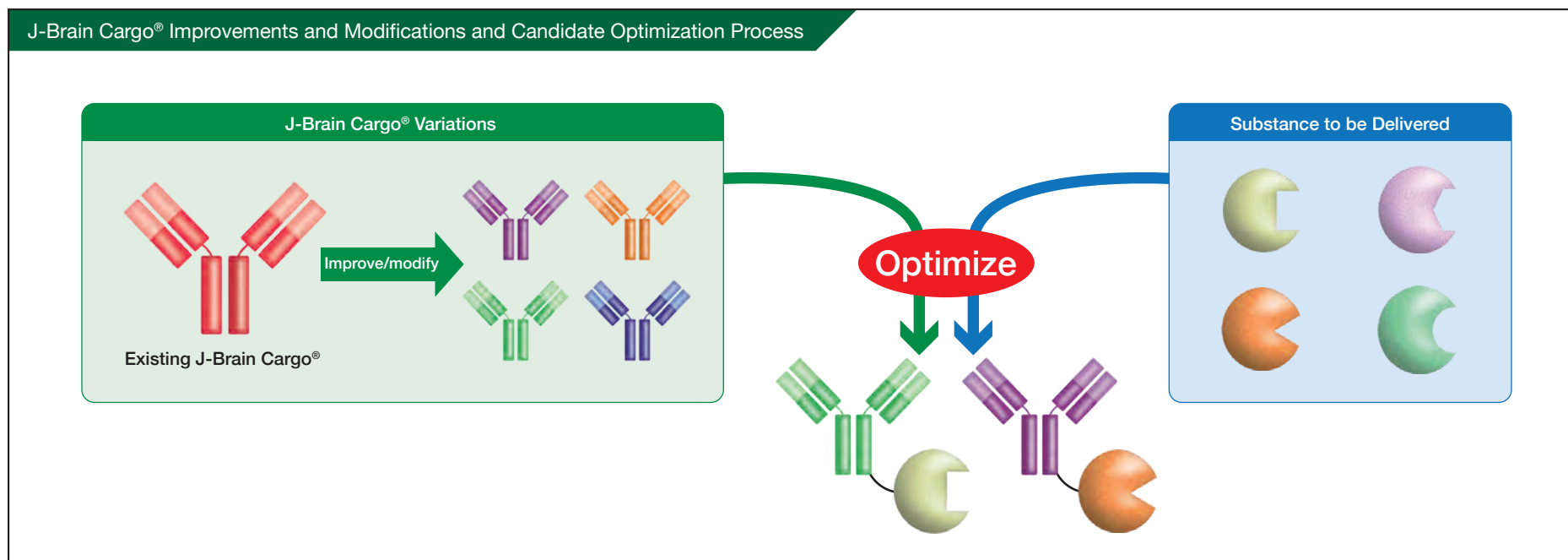
Since its founding in 1975, JCR has always worked to develop technologies and create products “one step beyond” its competitors, and the field of recombinant protein drugs has been its major strength.

Through research processes that draw on our accumulated strengths, including platform technologies that enable appropriate molecular design, technology, experience and know-how in fusion protein production, mouse models for rare diseases, and biomarker discovery and analytical methods, we are making various improvements and

modifications to the existing J-Brain Cargo® in order to develop multiple variations. The variations have chemical characteristics based on their respective molecular designs, which include of course blood-brain barrier crossing, and using different variations of J-Brain Cargo® depending on the properties of the substance to be delivered to optimize the overall structure of the drug makes it possible to efficiently deliver drugs to their target including the brain or systemic tissue.

JCR has effectively utilized these various evolutions of

J-Brain Cargo® to reach the stage that enables us to create drugs for a wide range of central nervous system diseases, neuro-muscular diseases and muscle diseases, as mentioned above, and we are currently accelerating initiatives for such a future.



## Developing a new drug delivery system using VHH antibodies with brain transfer performance.

Improving and modifying J-Brain Cargo® into VHH antibodies and combining them with other modalities has made development possible for a multitude of central nervous system diseases.

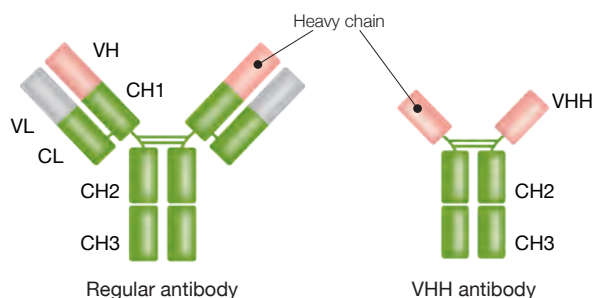
VHH antibodies are unique antibodies found in alpacas and other Camelidae. Compared to the regular IgG antibodies used in J-Brain Cargo®, they have various advantages, including the ability to recognize hidden epitopes\* with their small molecular size, high stability, and the ability to be mass produced inexpensively. While VHH itself is already in clinical

application, JCR is also engaged in the research and has reached the phase of being able to use them as pharmaceutical products.

The VHH antibodies JCR is developing have a molecular design that makes them more suited to antibody medicines than J-Brain Cargo®. In addition to antibody medicines, there are a number of other modalities more compatible as well, so we are actively using these to develop candidates for a larger number of central nervous system diseases.

\*The specific part of the antigen the antibody joins

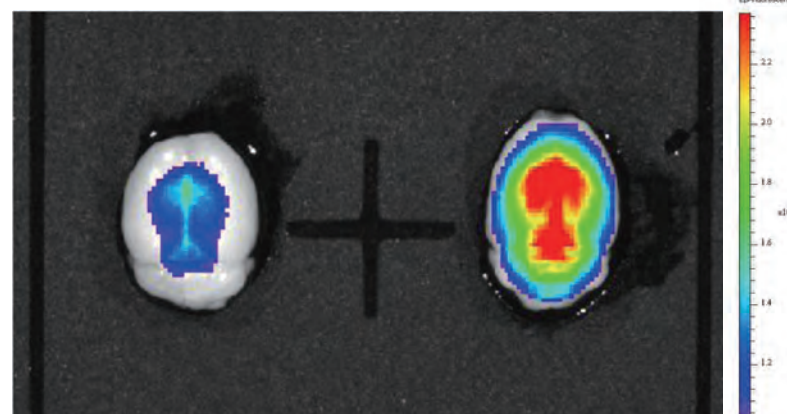
### Development of New Fundamental Technology Using VHH Antibodies



#### Characteristics of VHH Antibodies

- Affinity at the same level as normal antibody
- Hidden epitope can be detected
- High stability (high temperatures, organic solvent, pH)
- Can be bulk produced at low cost by Escherichia coli or yeast
- Can be easily modified to bispecific or tri-specific forms

### Verification of brain transfer performance of VHH antibodies (mouse experiment)



Mice were injected with a test substance in which a fluorescent dye was chemically modified for the VHH antibodies and the accumulation of the antibodies in the brain was evaluated with fluorescence imaging. The image on the right is the mouse injected with the VHH antibodies that JCR has been developing, clearly showing its exceptional brain transfer performance.

## Feature 1: Challenge of Multiple Modalities

### Pursuing the applicability of J-Brain Cargo® to multiple modalities to develop new innovative technologies for the future.

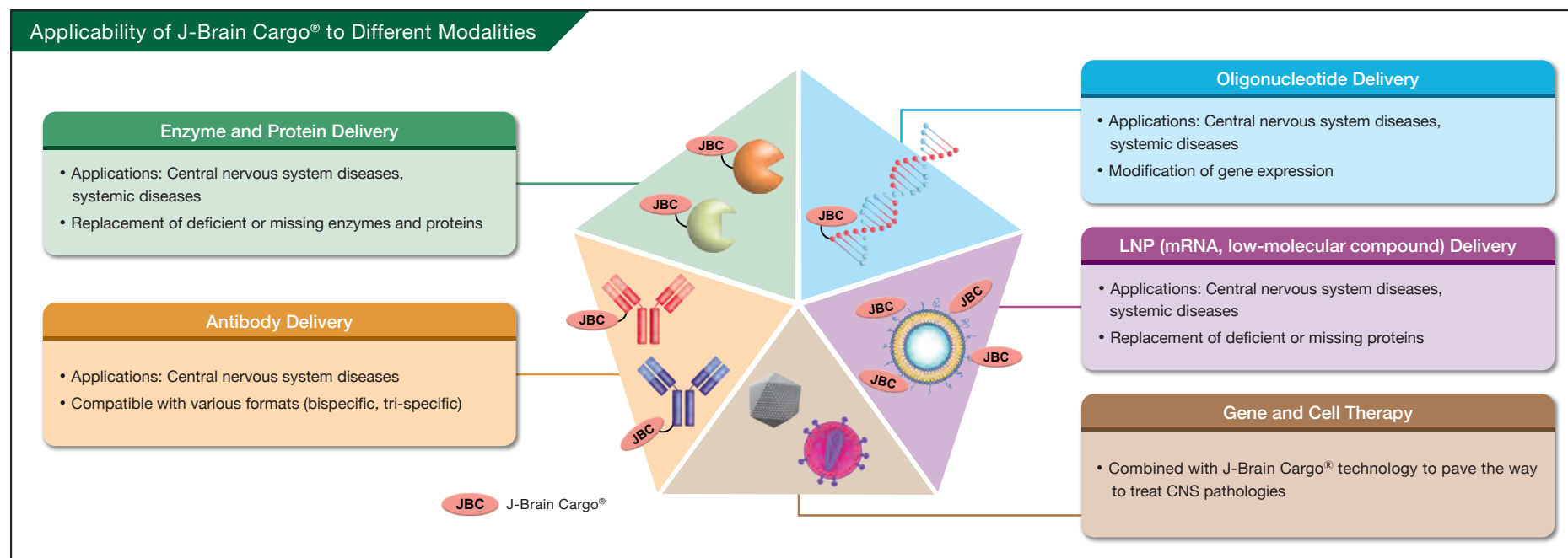
J-Brain Cargo® was developed as a drug delivery system that crosses the blood-brain barrier to deliver enzymes to the central nervous system, but it has the potential to be applied to various different modalities.

As shown in the chart below, JCR is targeting application in five modalities: enzyme and protein delivery, oligonucleotide delivery, LNP, gene and cell therapy, and antibody delivery. By improving, modifying, and optimizing J-Brain Cargo®, we will maximize its potential as a drug delivery system.

In addition, regarding oligonucleotide delivery, LNP, gene therapy, and other modalities, JCR will collaborate with partners capable of working together on complementing technologies and pursue potential applications. As a part of these efforts, in March 2022, we entered into a research and development collaboration and exclusive license agreement with Takeda to develop gene therapies that apply J-Brain Cargo® to LSDs.

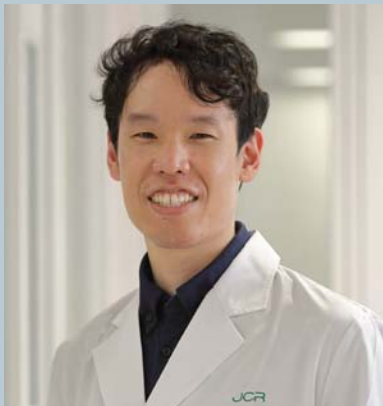
With proprietary innovative technologies as its foundation, starting with J-Brain Cargo®, going forward JCR will

continue the challenge of creating technologies that are constantly “one step beyond” other companies.





## Message /



JCR has significant strengths in the field of drug discovery in recombinant proteins. I am particularly confident in the J-Mab System® and antibody modification technologies that were established to create J-Brain Cargo®. In our variations of J-Brain Cargo®, we are moving forward with development of IgG type, Fab type, and VHH antibodies, aiming to maximize the effectiveness of pharmaceuticals by selecting the type that suits the characteristics of the target pharmaceutical. However, I believe that JCR's truly important strength is its corporate culture and research environment, which allow for freedom and autonomy in R&D activities. In particular, I feel that the Innovative Technology Research Institute, where I work, has an environment that allows us to begin work right away on what we think is necessary, in addition to the policies and directives of our supervisor. Looking ahead, we will use J-Brain Cargo® as a steppingstone to collaborate with external organizations and academia to tackle diseases that are difficult for JCR to address alone. With this kind of foundation technology, JCR is certainly a company that can contribute to society in the future.

**Takashi Onouchi**

Exploratory Research Unit, Biopharmaceutical Innovation Research Institute, Research Division



JCR has a track record as a field-leader in biosimilars and regenerative medicine in Japan. Furthermore, in recombinant protein therapeutics, it has developed J-Brain Cargo®, the world's first technology capable of delivering drugs into the brain. To make further use of these technologies, the Company has recently been focusing on the area of protein engineering as well. Currently, JCR is focusing on enzyme replacement therapy for LSDs; however, the target lysosome enzymes are diverse in nature, and there are enzymes that are difficult to express or have poor stability. By applying JCR's various proprietary protein engineering approaches to such enzymes, we have recently succeeded in creating enzymes that have overcome a range of issues in several drug candidates. To achieve this kind of success requires cooperation frameworks across departments, and it is important to conduct repeated trial and error by rapidly conducting the necessary evaluation and making appropriate revisions. With this kind of "Team JCR" research system, JCR is a company that will be able to continue taking on cutting-edge challenges at the global level, never being satisfied with the status quo.

**Yasunori Sugano**

Exploratory Research Unit, Biopharmaceutical Innovation Research Institute, Research Division

# Global Business Strategy

**Global development and partnerships are instrumental for the successful commercialization of JCR's highly innovative biopharmaceuticals portfolio in rare diseases.**



JCR's portfolio contains more than 15 assets based on the J-Brain Cargo® technology that can turn into game-changing medicines for people with rare or ultra-rare diseases. The approval of IZCARGO® for the treatment of MPS II in Japan in 2021 and the global partnership with Takeda marked two important milestone events for JCR. They herald the importance of JCR's two-pillar strategy to accelerate our highly innovative portfolio in rare diseases: global development and international partnerships.

Advancing our portfolio solely with internal resources and within a geographically confined region would require compromises on the development speed. Alliances with partners and international presence in geographies in which JCR conducts clinical trials are therefore an integral part of JCR's business strategy beyond 2025. Royalties and milestone payments from these partnerships are expected to generate a significant future revenue stream. The global partnership with Takeda both on IZCARGO® and in the J-Brain Cargo® technology applied gene therapy field is an excellent example of how JCR can benefit from an alliance that complements JCR's strengths and helps JCR to build its international presence.

In executing the strategy, JCR reorganized the Development Division and allocated dedicated resources to both its domestic and international development programs. In parallel, international clinical development capabilities were established at JCR USA to ensure successful global clinical development while working cross-functionally with the team in Japan.

The formation of JCR Europe, located close to the European Medicines Agency (EMA) Headquarters in the Netherlands, is a logical

step in executing the strategy to build clinical operations, development, and regulatory affairs expertise in Europe. With a population of around 750 million, Europe is not only one of the most important pharmaceutical markets, but also a vital geographic area for the recruitment of patients for clinical trials in rare diseases. Scalability of the operations in the U.S. and Europe is instrumental in responding nimbly to further acceleration of our development efforts.

To manage our partnerships, JCR re-defined its alliance management and business development to include representation from Research, Manufacturing, Business Development, Corporate Strategy and Legal.

JCR has established a continuous presence at international partnering events to enhance awareness about the game-changing potential of JCR's portfolio and the broad applicability of the J-Brain Cargo® platform in diseases like neurodegeneration, neuro-inflammation, and neuro-oncology, which JCR expects to become an important business pillar.

Internationalization of JCR requires its employees to learn the uniqueness of an international environment. To help them along this steep learning process, JCR launched the JCR Academy program. It is an internal, program to prepare our talent and future leaders for the challenges and opportunities of international exposure.

**Mathias Schmidt, PD, Ph.D.**

Vice President  
Clinical Development, Global Business Strategy  
and Business Development  
ArmaGen, Inc. CEO  
JCR USA, Inc. President and CEO

# Further expanding the product portfolio through partnerships with other companies to create new opportunities for sustainable growth.

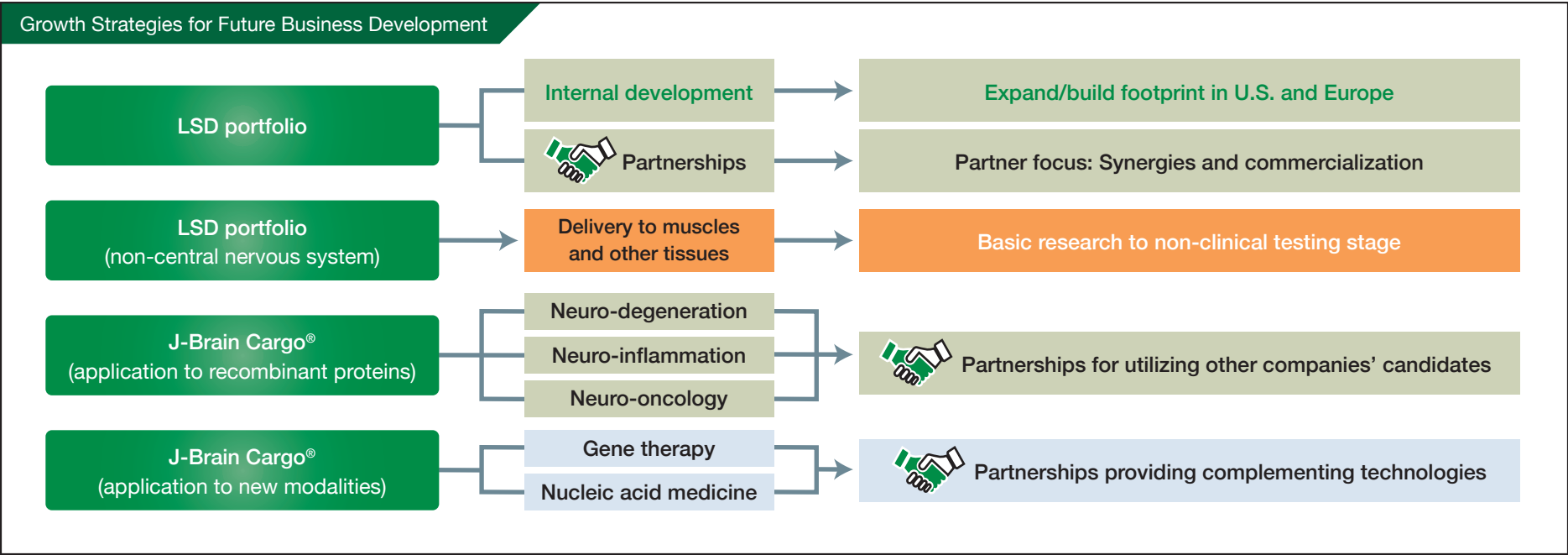
JCR is working to further expand its product portfolio, positioning partnerships with other companies at the core of our growth strategy as we seek to be a “research-oriented specialty pharma with global exposure.”

Regarding developments for lysosomal storage disorders (LSDs) in our existing portfolio, we will actively promote partnerships with companies that possess resources and capabilities that have been constraints for JCR. For programs that will continue to be developed proprietarily, we will expand our footprint in Europe and the U.S., where we

plan to conduct clinical trials. We also plan to continue in-house development of drugs in areas other than central nervous system disorders, including therapeutics with enhanced muscle uptake and therapeutics that address orthopedic diseases, an area with a high level of unmet medical needs in many cases of LSD.

When J-Brain Cargo® is applied to disease areas outside JCR’s core business and to new modalities such as gene therapy and nucleic acid medicine, we will focus on collaborating with partners that have cutting-edge

technologies in these fields as we boldly embrace the opportunities of global growth.





## Feature 2: Global Business Strategy

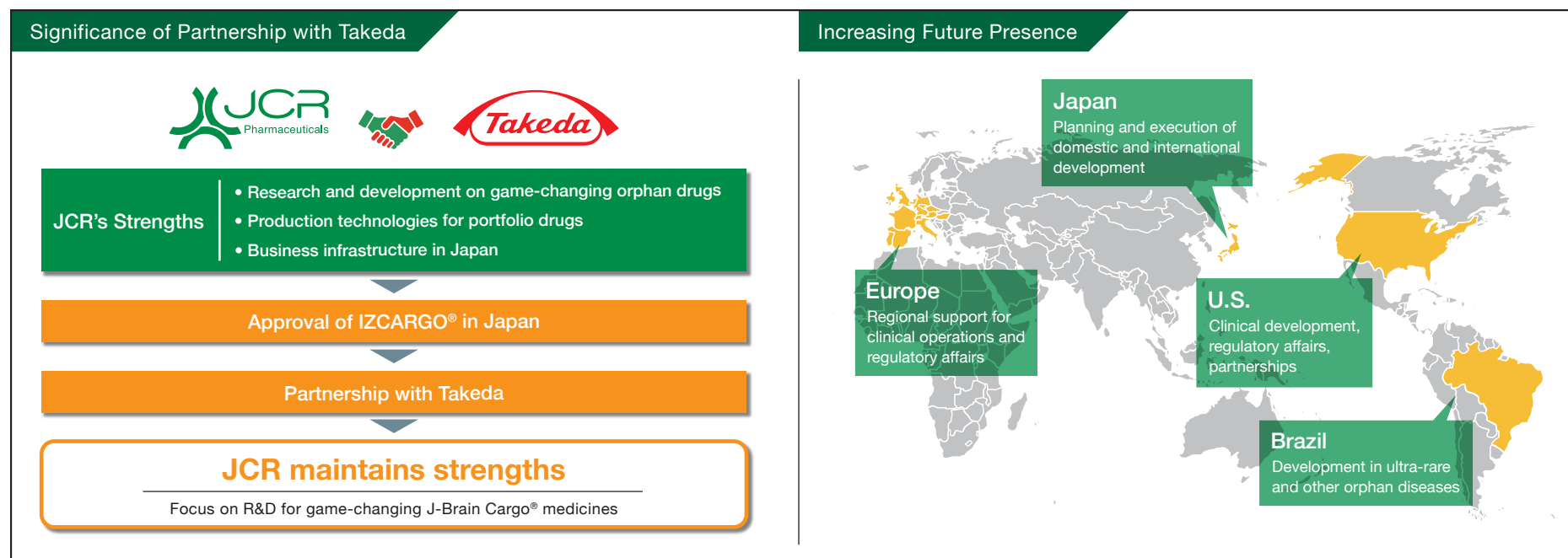
### Promoting global commercialization while maintaining JCR's strengths to further expand our presence in the future.

JCR entered into an agreement with Takeda in September 2021 for exclusive joint development and licensing of JR-141, a therapeutic enzyme for MPS II, in specified regions around the globe. The partnership with Takeda covers most parts of the world and a license option for the U.S. It excludes Japan and some countries in the Asia-Pacific region. With this agreement, JCR is now able to move forward with global commercialization of JR-141 without building an extensive infrastructure. It allows JCR to maintain its focus on the development of game-changing

therapeutics for rare diseases, production of its biopharmaceutical products and commercialization in Japan.

With regard to increasing our future global presence, Japan will continue to be positioned as an important site for clinical development, operations and planning, and Brazil will be an important geography for clinical trials in ultra-rare diseases in particular. In Europe, we will build a regional support center to assist global clinical development and work to further strengthen our network with key influencers. In the U.S., we will further enhance our knowledge and

capabilities in clinical development, clinical operations and regulatory affairs.



## Message



Jens R. Wendland, M.D.

Executive Director, Global Program Lead, JR-141 (pabinafusp alfa),  
Takeda Pharmaceutical Company Limited

We are delighted to be collaborating with JCR on JR-141 (pabinafusp alfa). Since this partnership began in September of 2021, we have made great progress in leveraging each other's strengths to bring this potentially transformative medicine to MPS II patients as soon as possible. We are delighted to see that the remarkable potential of JR-141 was reflected in the PRIME designation granted by the European Medicines Agency, and in the *WORLDSymposium 2022* New Treatment Award. Our collaboration is marked by high levels of trust, respect, and a sense of urgency to serve patients in need.



Hiroko Yuasa

Senior Officer, Alliances, Sales & Marketing Division,  
Sumitomo Pharma Co., Ltd.

Sumitomo Pharma has been selected to handle the marketing and communication activities for Agalsidase Beta BS I.V. Infusion 5 mg [JCR], a recombinant treatment for Fabry disease. Rare disease areas with a high level of unmet medical needs is one of the marketing priorities of our company, and with support from JCR we will leverage our strengths, which include relationships with physicians, to strive to provide the product to as many patients as possible. Based on this good partnership between the two companies, we hope to further expand the alliance going forward.



Hiroshi Kagoshige

Business Development Dept.

In order to deliver JCR's products to patients around the world, manufacturing and marketing approval has to be granted in each country. Through licensing our technologies and know-how to partners involved in development and distribution, we are able to greatly accelerate the commercialization process globally. In fiscal 2021, we entered into a licensing agreement with Takeda for JR-141, a therapeutic enzyme for MPS II, and are working together with Takeda to launch the product globally. We have also signed a licensing and collaboration agreement with Takeda in the field of gene therapy and have initiated conducting joint research and development activities. In Japan, we have entered into a marketing and distribution agreement with Sumitomo Pharma, which actively works to market orphan drugs and raise disease awareness, for Agalsidase Beta BS I.V. Infusion 5 mg [JCR], a recombinant treatment for Fabry disease, and have initiated a business alliance to maximize the product's value. In the Business Development Dept., we are establishing a system for strengthening communication among divisions, and, as a united "Team JCR" we will continue working toward the realization of being a "research-oriented specialty pharma with global exposure."

### Message



JCR has developed a strong momentum in its globalization, and achieved recognition as “Research-oriented specialty pharma with global exposure.” Brazil was the first country for JCR outside Japan where it would start clinical trials, thereby granting earlier access to innovation and experience with new technologies for clinicians and treatment centers, as well as bringing hope and a better quality of life to patients and their families.

With a population of 214 million people and 13 million carriers of rare diseases, Brazil has enormous diversity and potential to conduct

clinical trials with further JCR programs in rare diseases.

Two years ago, JCR DO BRASIL (JCRB) started with a strong engagement and reputational agenda towards stakeholders, including clinicians, key opinion leaders, patient advocacy groups, payers, governmental agencies and medical societies. In alignment with our colleagues in Japan and the U.S., we have been working with the confidence of delivering innovative solutions, such as J-Brain Cargo®, to rare disease patients, our most important stakeholders. Investigators express high belief in the benefits of our product, which contributes towards generating global evidence that JCR delivers the best product for the right patient.

JCRB members are proud to be part of “Team JCR” with the purpose to create a better tomorrow for the patients we serve.

**Vanessa Tubel** CEO, JCR DO BRASIL



Building a European subsidiary is a cornerstone of JCR’s internationalization strategy.

I am Anne Bechet, and I am truly excited to join JCR Europe. Europe is differentiated from the U.S. and Japan with payers having a strong focus on assessing benefits and efficacy, clinical and technical safety, and cost-effectiveness of newly approved therapies. Including these requirements early in clinical development is critical in ensuring successful drug commercialization and broad patient access.

The initial focus of JCR Europe will be to build clinical development, clinical operations capacities and strategic regulatory affairs in support of JCR’s ongoing and future clinical trials globally. We will work seamlessly with the teams in Japan, the U.S., and Brazil. Being near the clinical sites in Europe allows us to further strengthen our relationships with clinical investigators and patient advocacy groups. The Netherlands is an ideal location to expand our network to the regulatory agencies, industry partners and key influencers in the rare disease field.

JCR is a company with one of the most transformative platform technologies to address an unmet need in the lysosomal storage disease space: the brain pathology that prevents affected children and adults from developing their full potential. Together, we can help them fulfill some of their hopes and dreams. Working with a team that is united in this mission gives me a deep sense of purpose and commitment. Together, we will soar!

**Anne Bechet** General Manager, JCR Europe





In the Midterm Business Plan for FY2020-FY2022, “REVOLUTION,” JCR set forth the challenge of global business expansion. Accordingly, the Company realized the launch of IZCARGO®, a recombinant treatment for MPS II, in Japan, and signed an overseas joint development and commercialization agreement with Takeda. The global product pipeline expansion that utilizes our cutting-edge technology, J-Brain Cargo®, is also well underway. Under such circumstances, every employee has been experiencing firsthand the steps toward becoming “a global specialty pharma in the rare disease arena” as a firm vision for our future, boldly challenging business changes such as cross-functional and cross-regional projects and collaboration with relevant partners in Japan and overseas. These changes are not limited to being within the Company. Through building overseas subsidiaries and conducting recruitment to expand our presence in the U.S. and Europe as for clinical development and operation, we have met many potential people who, along with our vision and innovation, have a strong desire to help patients with rare diseases, and fortunately have welcomed them into the Company. What chemistry can be brought by spreading “Team JCR” spirit around the world? – I would like to keep this exciting momentum that lets us tackle the challenge of “REVOLUTION” enthusiastically.

**Masaaki Usui**

Global Business Strategy Dept.

## **Our Goal: Research-Oriented Specialty Pharma with Global Exposure**





# Sustainability

JCR will contribute to the development of a sustainable society through business activities based on its corporate philosophy of “Contributing towards people’s healthcare through pharmaceutical products.”



## Basic Approach to Sustainability

Since its inception in 1975, JCR has sought to create groundbreaking therapeutics that respond to unmet medical needs, particularly in the rare disease field, under its corporate philosophy of “Contributing towards people’s healthcare through pharmaceutical products.” To this end, we have been harnessing forward-looking biotechnologies, as well as technologies for cell therapy and regenerative medicine.

The global environment and conditions and issues facing society have been changing year by year, but JCR believes that it is crucial to create sustained corporate value through its business activities as a pharmaceutical manufacturer and contribute to the development of a sustainable society, and is proactively implementing activities in the core areas of Rare Diseases (RD), Environment (E), Society (S), and Corporate Governance (G).

## Structure for Promoting Sustainability

JCR newly established the Sustainability Advisory Committee, Sustainability Committee and Environmental Committee in July 2022 to enable in-depth discussions and formulating strategies in close alignment with management in response to the ever-changing social and business environment and challenges surrounding JCR. Under the new promotion structure, JCR will continue to work as one team, driven by a sense of purpose in the rare disease field, to pursue sustainability in the manner unique to JCR.

### Sustainability Advisory Committee

Members will be Internal Directors, Independent Outside Directors, and full-time Audit & Supervisory Board Members. This Committee will provide feedback on matters presented to the Board of Directors by the Sustainability Committee.

### Sustainability Committee

Chaired by the director in charge of sustainability, members will be employees appointed from each business division. This Committee will identify material issues, discuss and propose ESG-related initiatives, monitor progress, and report findings to the Board of Directors.

### Environmental Committee

Members will be Internal Directors and employees appointed from each business division. They will consider the environmental impact of business activities as a long-term risk factor affecting business and society, and practice environmentally friendly business activities.

## Message



JCR, as a specialty pharma in the rare disease arena, always thinks first of our patients and their families around the world. With customer satisfaction in mind, JCR provides sustainable value to society in the spirit of “no one will be left behind” by proactively developing world-class pharmaceuticals, aiming for the sustainable development of society and JCR, which in short is sustainability.

Our reason for existence is “contributing towards people’s healthcare through pharmaceutical products” and we believe that our actions moving forward to pursue sustainability in the manner unique to JCR based on this corporate philosophy can change the future for patients and their families.

In July 2022, we newly established the Sustainability Advisory Committee, Sustainability Committee and Environmental Committee. We are committed to achieving sustainability by marshaling all capabilities of “Team JCR” based on our belief of “think by oneself, act by oneself.” Through such activities, JCR will grow together with society, and we will strive to be a company trusted by all stakeholders as a “research-oriented specialty pharma with global exposure.”

**Toru Ashida** Head of Sustainability

# Sustainability

## Addressing the SDGs

JCR believes that partnership and cooperation with the international community are the most important priorities for realizing sustainability.

In the course of advancing these initiatives, JCR has linked its activities to the 17 goals laid out in the SDGs, in keeping with the spirit of “no one will be left behind.” It shares with and returns to a wide range of stakeholders the achievements of these efforts.

## SUSTAINABLE DEVELOPMENT GOALS



## Core Initiatives for FY2022 and Related SDGs

<b>RD</b> Rare Disease	<ul style="list-style-type: none"> <li>Take on the challenges of unmet medical needs and accelerating R&amp;D</li> <li>Work to raise recognition of rare diseases inside and outside of JCR</li> </ul>	
<b>E</b> Environment	<ul style="list-style-type: none"> <li>Disclose information in accordance with the Task Force on Climate-Related Financial Disclosures (TCFD) recommendations</li> <li>Work to conserve the environment in the new plant under construction</li> </ul>	
<b>S</b> Society	<ul style="list-style-type: none"> <li>Create workplace environments comfortable for balancing work and childcare, and not distinguishing between men and women</li> <li>Enhance training programs to develop human resources who can become next-generation leaders</li> </ul>	
<b>G</b> Corporate Governance	<ul style="list-style-type: none"> <li>Build a governance structure to meet the standards required for listing on the Tokyo Stock Exchange Prime Market</li> <li>Enhance effectiveness of supervision over management in the Board of Directors</li> </ul>	
<b>Contribution through our business</b>	<p><b>“Realizing medical care for those living with rare diseases”</b> at the earliest opportunity by transforming every aspect of our business through “Team JCR”</p>	



# Contributions in the Rare Diseases Arena



## RARE DISEASE Project

The RARE DISEASE Project is a cross-sectional internal awareness-raising project, with “What JCR can do for rare diseases” as its motto. We collect information and share it internally to deepen employees’ understanding of rare diseases. We also support and cooperate with patient groups and support organizations that help people with rare diseases. We recruit members through a show of hands, emphasizing the importance of employees showing initiative, and stipulate a two-year appointment without fixed membership.



What JCR can do for rare diseases

As awareness-raising activities within the Company, we conduct such activities as encouraging employees to wear official badges for Rare Disease Day (RDD), fundraising activities, conducting global consciousness-raising activities for MPS Awareness Day, distributing reports on participation by employees in events organized by patient groups and organizations that support patients with rare diseases, and holding in-house lectures.

In FY2020 and again in FY2021, the COVID-19 pandemic compelled us to conduct activities centered on participation in events held online and distribution of reports on those events. In August, we held the RDD Internship online. For this event, we welcomed the participation of students from Osaka Meisei Gakuen

high school.

As a company aiming to become “a global specialty pharma in the rare disease arena,” JCR believes that it is extremely important to provide opportunities for each and every employee to hear opinions directly from patients. In FY2021, we held “MPS I Patient Journeys,” an in-house speech event on MPS I in October, and employees could ask the patients for details from the patients’ points of view, including their actual symptoms, diagnosis histories, and how they spend a week.

And, as a new initiative, we produced an original eco-bag printed with illustrations and the project slogan, “What JCR can do for rare diseases,” and donated the proceeds.

JCR will continue to carry out not only research and development focused on orphan drugs, but also activities that lead to broad-based support for patients on a global basis.

## MPS Awareness Day

In FY2021, the RARE DISEASE Project was kicked off with its first global awareness-raising activity for MPS Awareness Day on May 15, sponsored by the MPS Society, a support group for patients with MPS in the United States.

JCR decided to make this a company project after a subsidiary employee made a proposal that JCR think about what it could do for MPS Awareness Day.

In FY2022, photos in the theme color purple and the message of MPS awareness were solicited Company-wide, the images were distributed in the form of downloadable posters at each business location, and donations in proportion to the number of photos collected were made to the MPS Society. In addition, people wore hand-made purple ribbon badges and a newsletter related to raising awareness of MPS was distributed through the internal bulletin board.



MPS Awareness Day Poster (for in-house awareness-raising)

## Contributions in the Rare Diseases Arena

### Rare Disease Day

From FY2015, JCR has been a supporter of RDD. There are patients suffering from rare and intractable diseases around the world, but the total number of these patients is small, and the disease mechanisms are complicated. Therefore, almost no progress has been made in research and development of therapeutics and methods of diagnoses for some diseases. RDD activities began in Sweden in 2008 with the aim of improving the quality of life of patients with rare and intractable diseases through better diagnoses and



treatments. It is hoped that these activities will create a bridge between patients and society, and help to increase awareness of rare and intractable diseases.



### In-House RDD Awareness-Raising Activities

To commemorate RDD, JCR encourages employees to wear official RDD badges and raises funds in-house in February every year.

Moreover, Japanese professional golfer Masahiro Kawamura and Japanese professional tennis player Masamichi Imamura have continued awareness-raising activities worldwide by placing the logo on clothing, caps, bags, etc., and by distributing postcards and pin badges during domestic and international tours. JCR signed a sponsor agreement with Mr. Kawamura in October 2019 and with Mr. Imamura in April 2021.

## Message



The RARE DISEASE project is a cross-sectional internal awareness-raising project that collects information in such ways as through rare disease-related events, communicates information internally and conducts activities in collaboration with patients' groups and rare disease support organizations. I participated in this project because of a belief in the importance of knowing whatever you can about other people.

In the course of our activities, I heard about what kind of rare diseases exist, the difficulties faced by patients, and the thoughts of doctors and those who support them. This helped me to gain a concrete image of who our work is connected to, which in turn changed my awareness of our work. From now on, too, while contributing to the understanding of rare diseases in "Team JCR" through awareness-raising activities internally and externally, we, as a united "Team JCR," will continue to work to realize "what JCR can do for rare diseases" in various ways, in addition to carrying out R&D related to orphan drugs.

**Wataru Miyawaki**

Structural Elucidation Group, Analysis Development Unit, Analytical R&D Center, Research Division

## E Environment

Related SDGs



### Initiatives for Environmental Conservation

JCR has been taking a wide range of steps to mitigate its environmental impact, including reducing CO<sub>2</sub> emissions and effectively using water resources. For example, we have worked to transition to LED lighting at all company facilities and shift all our company cars, including those used at plants and the Research Institute, to hybrid cars and electric vehicles. In addition, we have promoted measures such as reducing water use at manufacturing sites, along with adopting single-use bioreactors to ensure the efficient use of manufacturing facilities.

In July 2022, as part of efforts to create a new structure for promoting sustainability, JCR established the Environmental Committee which is composed of Internal Directors and employees selected from within the Company. JCR views the environmental impacts through its business activities as risk factors that could potentially impact its long-term business or society, and will work to implement environmentally conscious business



Electric vehicle

activities.

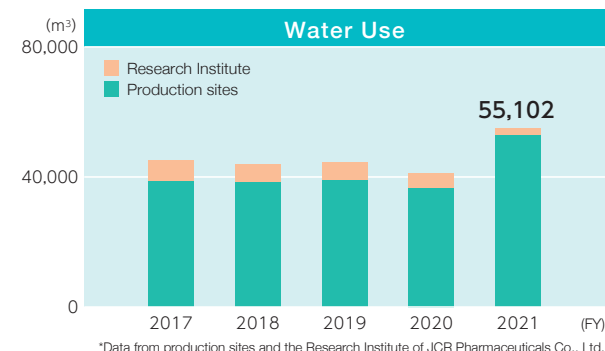
JCR plans to make active use of renewable energy sources, such as solar power generation, at new manufacturing sites that it began constructing from FY2021. Additionally, environmentally friendly investments will be made as part of our efforts to further upgrade and expand production sites, which we are considering in anticipation of full globalization from the mid-2020s.

### Energy Use

JCR has seen an uptrend in total energy use (electricity, gas, etc.) as its business results have grown. In the Research Division, total energy use has increased with the opening of the Clinical Trial Material Manufacturing Center (CTMC) and Cell Processing Center (CPC) in 2016. In the Production Division, total energy use has remained mostly flat, mainly owing to the installation of highly energy-efficient equipment and changes in how we use energy. Information about total energy use will be disclosed in accordance with the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD) from FY2022 onward.

### Water Resources

We have seen a decrease in the use of water resources, despite growth in our business results. The main reasons have been reductions in the amount of water used in research and production processes and efforts such as promoting the recovery and reuse of exhaust steam. Notably, there has been a consistent decline in the use of water resources in production activities. All water used in research and production activities has been treated appropriately.



### Information Disclosure in Accordance with the TCFD

JCR will deliberate on matters such as establishing medium- to long-term GHG reduction targets in light of its business plans and initiatives such as the GHG reduction targets set by various companies, with the aim of keeping the rise in temperatures that has occurred since the industrial revolution below 1.5°C.

JCR will continue to handle the analysis of risks and information disclosure related to climate change in accordance with TCFD recommendations, and is working to calculate the GHG emissions of its entire supply chain. In addition to the above, it will consider enhancing disclosures regarding scenario analysis and strategic resilience in the future.

### [Governance]

JCR is working to strengthen governance initiatives related to climate change. Policies regarding activities and specific contents are deliberated by the Sustainability Committee, and the Board of Directors make decisions on them, taking into consideration the opinions of the Sustainability Advisory Committee.

# Environmental Awareness

## [Strategy]

Regarding physical and transition risks and opportunities related to climate change, JCR plans to identify those that affect operations to a high degree as important risks and opportunities after assessing the significance of their short-, medium-, and long-term impact on business, strategy, and finances.

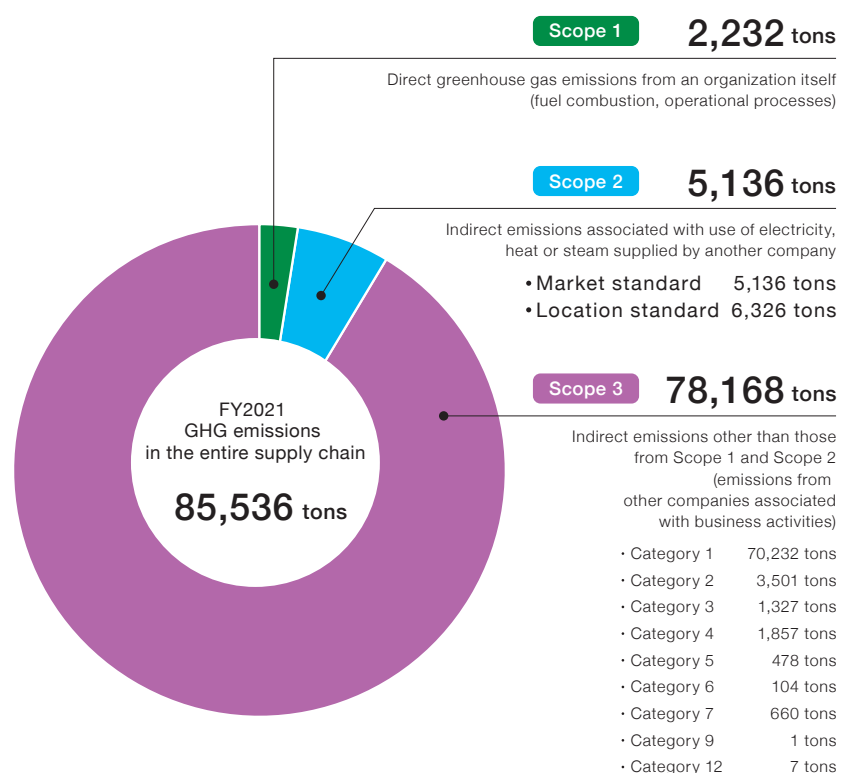
## [Risk Management]

JCR is considering risk identification, assessment, management, and enterprise risk management integration processes, and will disclose information on this moving forward.

## [Metrics and Targets]

JCR will consider climate change performance indices going forward. In addition, our Scope 1, 2, and 3 (some categories) GHG emissions calculated according to the GHG Protocol, an international calculation standard, are as follows.

## FY2021 GHG Emissions by Scope



Scope of calculation	Scope 1, 2, and 3 applied to JCR Pharmaceuticals Co., Ltd.
<b>Scope 1</b>	In addition to the combustion of fossil fuels such as gasoline, freon—which originates from industrial air conditioners—and CO <sub>2</sub> emissions derived from CO <sub>2</sub> canisters are also included in the calculations
<b>Scope 2</b>	Calculated using both market standards and location standards. Coefficients are in compliance with the Act on Promotion of Global Warming Countermeasures.
<b>Scope 3</b>	—
Category 1 (Purchased products and services)	Calculated based on purchase and sales data. Coefficients are referenced from the Ministry of the Environment's Input Output Table Database v3.2
Category 2 (Capital goods)	Calculated based on the increased amount of noncurrent assets. Coefficients are referenced from the Ministry of the Environment's Input Output Table Database v3.2
Category 3 (Fuel and energy-related activities not included in Scope 1 and 2)	Calculated based on energy consumption in Scope 1 and 2. Coefficients are referenced from the Ministry of the Environment's Database v3.2 and IDEA
Category 4 (Shipping, Transport (Upstream))	Calculated using the mileage method for shipping from suppliers to the Company's locations, and calculated using the ton-kilometer method for shipping from the Company's distribution center to a distributor. Coefficients under the mileage method are referenced from the home page of the Japan Trucking Association, while coefficients under the ton-kilometer method are referenced from the Ministry of the Environment's Input Output Table Database v3.2
Category 5 (Waste produced by business)	Amounts of generated waste are calculated according to type. General business-type waste is estimated based on number of employees and statistical data from the Ministry of the Environment. Coefficients are referenced from the Ministry of the Environment's Input Output Table Database v3.2
Category 6 (Business trips)	Calculated based on number of employees. Coefficients are referenced from the Ministry of the Environment's Input Output Table Database v3.2
Category 7 (Employee commutes)	Calculated based on commuting distance. Coefficients are referenced from IDEA
Category 8 (Lease assets (Upstream))	Assets leased by the Company itself are included in the calculations of Scope 1 and 2
Category 9 (Shipping, Transport (Downstream))	Calculated using the ton-kilometer method for shipping from the Company's distribution center to clinics, etc. Coefficients under the ton-kilometer method are referenced from the Ministry of the Environment's Input Output Table Database v3.2
Category 10 (Manufacturing of sold products)	(Currently not calculated because it is difficult to assess and estimate the amount of activity by downstream customers)
Category 11 (Use of sold products)	(Excluded from scope because the final products are pharmaceuticals, and no energy is used)
Category 12 (Disposal of sold products)	Calculated based on product shipment amounts. It is assumed that the products are completely consumed, and that only the glass vials are disposed of.
Category 13 (Leased assets (Downstream))	(Excluded from scope because there are no leased assets that are owned by the Company and leased to other companies)
Category 14 (Franchises)	(Excluded from scope because the Company does not have franchises)
Category 15 (Investment)	(Excluded from scope because investment is not the objective)



# Contributing to Unmet Medical Needs



Society

Related SDGs



## Support for the “International Medical Research Foundation”

JCR supports the activities of the “International Medical Research Foundation,” which helps to foster medical researchers who can succeed internationally through programs such as study abroad grants. Since its establishment in April 2019, the International Medical Research Foundation has carried out a study abroad grant program for young medical researchers as well as a program to provide grants to international symposiums on medical research that are held both in Japan and overseas.

In the past few years, the declining international competitiveness of Japan’s scientific research has become a serious problem. For this reason, efforts to support study abroad opportunities involving research at leading overseas institutions and efforts to support international symposiums that invite internationally recognized foreign researchers at the forefront of their research fields carry tremendous significance. Accordingly, JCR endorses the activities of the International Medical Research Foundation.



## Support for the Swiss Nonprofit Foundation “Global Foundation for Life Sciences”

As part of its efforts to contribute to global health, JCR supports the “Global Foundation for Life Sciences,” a nonprofit foundation established in Switzerland in 1999. This foundation supports the advancement of life sciences,

provides humanitarian assistance to various medically underprivileged countries and also provides support for the development of young researchers.

One example of the humanitarian assistance provided by the foundation is its support for the activities of a group of volunteer Swiss doctors formed to treat women suffering from obstetric fistula in West Africa. Obstetric fistula is a condition where a hole is formed in the birth canal or surrounding tissues due to inadequate medical care in cases where under-aged women become pregnant and give birth, among other situations, causing chronic fecal and urinary incontinence. The number of fistula patients is approximately 2 million worldwide with about 100,000 women newly diagnosed with the condition every year. The nature of the symptoms means that women with obstetric fistula face difficulties in their daily lives, in addition to some reported cases of harm from social discrimination and exclusion. The group of volunteer doctors regularly visits a hospital in Benin, a country in West Africa, and undertakes activities to eradicate obstetric fistula, performs surgeries on patients, and provides technical instruction to local doctors. JCR contributes to people’s health and the advancement of medical care through its support for the foundation.

## Support for the “Award for Promotion of Maternal Child Health”

JCR supports the “Award for Promotion of Maternal Child Health” (sponsored by the Mothers’ and Children’s Health and Welfare Association), as part of its efforts to provide support for pediatric diseases and public health.

The Award for Promotion of Maternal Child Health was created to commemorate the International Year of the Child in 1979. The award seeks to encourage the good work of individuals who have made great contributions to society and the field of community-based maternal and child



health, in areas such as research on motherhood and children’s health, raising widespread awareness of public health principles, providing practical education and instruction, and upgrading and expanding the development of public health facilities. By recognizing these accomplishments, the award program seeks to further promote the development of maternal and child health. Every year, 15 award recipients are selected from among candidates working in the field of maternal and child health. The recipients include public health nurses, midwives, nurses, doctors, dentists, nutritionists, dental hygienists, nursery school teachers, and maternal and child health support workers, who are chosen for the award based on recommendations from the head of prefectures, ordinance-designated cities, core cities and special wards.

# Contributing to Unmet Medical Needs

## Momiji House, a Short-Stay Medical Care Facility

JCR supports Momiji House, which was established as Japan's first hospice for children. The facility was built on the grounds of the National Center for Child Health and Development (Setagaya-ku, Tokyo) in April 2016. Momiji House provides 24-hour-a-day medical care for children who require constant medical care at home. Those with serious illness and disabilities and their families can stay for several days at Momiji House, feeling secure and comfortable as if they were at home. Aiming to realize medical care for patients living with rare and intractable diseases and their family members, JCR has continued to provide continuous support dating back to the time before the opening of Momiji House.



もみじの家

## Donations to Kyoto University (Third-Party Allotment of Treasury Stock)

At the Ordinary General Meeting of Shareholders held on June 22, 2022, a motion to dispose of treasury stock through third-party allotment for the purpose of making a donation to Kyoto University was submitted, and received approval.

This proposal is aimed at providing financial support to enable young researchers involved in life science or basic research as well as cancer immunotherapy research to concentrate on their studies, and involves a donation through third-party allotment of treasury stock to two funds established within Kyoto University, the Tasuku Honjo "Yuh-shi" Fund and the Cancer Immunotherapy Research Fund. By donating to these two funds, we believe that it will lead to JCR's corporate philosophy of "contributing toward people's healthcare through pharmaceutical products" by supporting the development of challenging and creative basic research that could cause a paradigm shift in the field of life science and research aiming at realizing full cancer recovery, which is a long-cherished wish of humankind, and also believe that strengthening the JCR corporate brand and raising employee morale will contribute to the sustainable growth of JCR and enhance corporate value from a medium- to long-term perspective.

## Transmitting Information at Academic Conferences

As a company that seeks to be "a global specialty pharma in the rare disease arena," JCR strives not only to deliver superior pharmaceuticals, but also to actively provide information on cutting-edge technologies, clinical trial evidence, and related matters.

At the 18th Annual *WORLD Symposium™* held in February 2022, JCR made verbal presentations and presented posters on six topics related to JR-141, JR-171, and JR-441, treatments for lysosomal storage disorders which it is developing using its proprietary J-Brain Cargo® technology, while it also opened a booth at the venue and held a virtual chat and exchanged information with relevant parties.

Additionally, IZCARGO®, which was approved in Japan for the treatment of MPS II in May 2021, was bestowed the New Treatment Award at this conference. The award honors new treatments that are viewed as providing value to patients with LSDs, with general acceptance as evidenced by regulatory approval for pharmaceuticals. In receiving the award for IZCARGO®, JCR was specifically saluted for providing clinical data meriting approval by the Ministry of Health, Labour and Welfare.



New Treatment Award trophy

# Human Resource Management



Society

Related SDGs



## Basic Concept

In an aim to realize its Mid- to Long-Term Management Vision “Toward 2030,” JCR is working to create a workplace environment where richly diverse employees can shine and to promote human resources development based on a common understanding that the source of its value lies in “Team JCR.” With a view toward global business expansion, it is strengthening development and employment of next-generation leaders, and accelerating the “REVOLUTION” aimed at rearranging the Company into an active organization.

Related page

[Human Resources](#) **P.72**

## Global Personnel Development

### Transformation of Personnel Hiring and Human Resource Systems in Anticipation of the Future

For personnel hiring, JCR periodically aligns its way of thinking about future human resources with the Human Resource Planning Department and each division in order to establish mutual understanding, and formulates human resources planning. JCR is also accelerating initiatives to strategically hire human resources. These initiatives include optimizing the recruitment management system essential for data analysis and recruitment efficiency, renewing the recruitment website and moving forward on constructing a PDCA cycle for recruitment, and, as a new hiring method, systematically implementing referral hiring in which employees introduce friends and acquaintances.

For human resource systems, it has introduced a challenge sheet based on its evaluation system, and visualizes the goals of the organization so that they can be appropriately reflected in individual goals, while also working further to transform its evaluation system through

detailed breakdowns of general evaluations and the use of objective figures.

### Training System to Support Employee Growth

JCR is pouring energy into employee training, because it believes that improving employee skills will help it to grow. In the span of roughly one month after new graduate recruits join the Company, we effectively conduct group training aimed at business etiquette and improving communication skills and presentations about operations from each business division while effectively making use of the Web. We also regularly conduct tier-specific training where participation is mandatory for each level. Since FY2020, we have been conducting voluntary training that emphasizes employee autonomy, incorporating e-learning, and carrying out training programs matched to individual needs. In recent years, we have also been concentrating on English language training. More than 350 employees continually participate in conversational lessons, which began in FY2017, with a foreign English teacher, helping to improve their practical English abilities.

## Main Initiatives for Human Resource Management

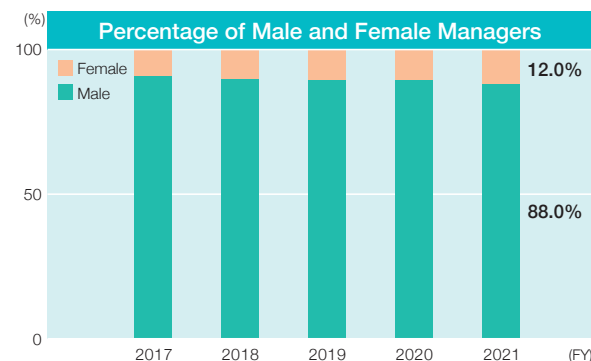
Global personnel development	<ul style="list-style-type: none"> <li>Formulation of human resources planning and implementation of management systems to achieve personnel hiring and a human resource system in anticipation of the future</li> <li>Enhance the training system to support growth including improvements to employees' practical abilities and language abilities, with emphasis placed on their autonomy</li> <li>Develop next-generation leaders with the skills that will enable them to thrive on a global stage</li> </ul>
Diversity and inclusion	<ul style="list-style-type: none"> <li>Create a corporate culture that utilizes the individual abilities of richly diverse employees</li> <li>Promote the creation of a workplace where employees can thrive regardless of gender</li> <li>Enhance initiatives for career support of persons with disabilities</li> </ul>
Diverse work styles	<ul style="list-style-type: none"> <li>Introduce a system that is convenient for workers and enables flexible work</li> <li>Support people raising children through a nursery located within the office or subsidies for childcare, etc.</li> <li>Establish a system to encourage men to take childcare leave and promote enlightenment activities</li> </ul>
Occupational safety and health	<ul style="list-style-type: none"> <li>Promote the creation of a workplace environment that protects the safety and health of employees, and allows them to work with peace of mind</li> <li>Thoroughly implement measures to prevent the spread of COVID-19</li> </ul>



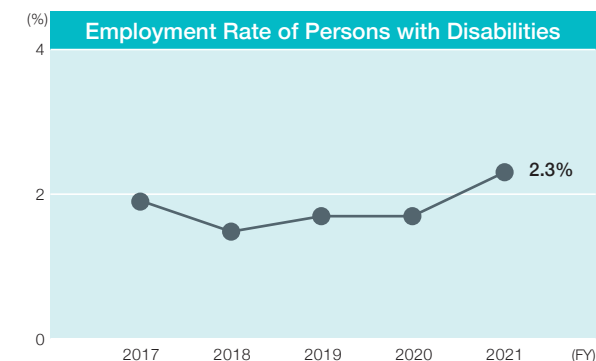
# Human Resource Management

Training Track Record						
FY		2017	2018	2019	2020	2021
Group training	Number of sessions	10	15	15	8	16
	Hours	90	135	126	60	112
	Tier-specific training					
Voluntary training	Amount (Millions of yen)	4.6	6.6	9.0	5.1	11.4
English language training	Amount (Millions of yen)	2.0	5.7	7.2	17.0	27.9

\*Data from JCR Pharmaceuticals Co., Ltd.



\*Data from JCR Pharmaceuticals Co., Ltd.



\*Data from JCR Pharmaceuticals Co., Ltd.

## Developing Next-Generation Global Leaders (JCR Academy)

JCR Academy is a new initiative to develop next-generation leaders who have acquired the skills that will enable them to thrive on a global stage, in anticipation of future global business expansion. The goal is for participants to acquire the soft skills required to thrive as global leaders, including communication skills, project management skills, and leadership skills, through a practical program.

## Diversity and Inclusion

### Creating a Corporate Culture That Utilizes Diversity of Human Resources

Based on a firm belief that “Team JCR” is the source of JCR’s value, we mutually respect different attributes such as gender, age, nationality, and disability, and believe it is important to maximize the individual abilities of richly diverse employees. For this reason, we promote diversity and inclusion.

## Creation of a Workplace Where Employees Can Thrive Regardless of Gender

In October 2018, JCR was recognized in the Third Annual Hyogo Women’s Active Participation Awards by Hyogo Prefecture for its efforts to expand career opportunities for women, raise the ratio of female employees in managerial positions (from 5.8% in FY2012 to 12.0% in FY2021), establish in-house daycare facilities, and encourage the participation of male employees in parenting activities.

In January 2019, we received Eruboshi certification (Grade 2) from the Minister of Health, Labour and Welfare for excellence in promoting the active participation of women in the workplace based on the Act on Promotion of Women’s Participation and Advancement in the Workplace. In FY2021, we were evaluated for creating a workplace environment that balances childcare and work based on a policy of eliminating distinctions between men and women, and received the Hyogo Work-Life Balance Company Award.



We will continue working to create a workplace where employees can thrive regardless of gender.

## Promoting Employment for Persons with Disabilities

In order to support work for persons with disabilities, JCR is undertaking initiatives centered on ability development matched to each individual. Those with physical as well as mental disabilities meet with the Human Resource Planning Department as needed to affirm their physical condition and motivation, and to exchange opinions about work styles. In FY2021, the employment rate of persons with disabilities was 2.3%, which met the legally required rate.

## Diverse Work Styles

### Introducing Worker Friendly Systems

We believe that work and private life are both important. Based on this belief, we have introduced a flexible working system and other systems unique to JCR, such as a flextime system and allowing employees to use their annual paid leave in hourly



# Human Resource Management

increments. Since 2020, we have been working to enhance this initiative by, for example, gradually expanding the target of the flextime system to each plant in the Production Division.

In addition, beginning in 2019, we introduced a savable paid leave system\* on a trial basis as a system unique to JCR. This savable paid leave system can be used by employees whenever they need to provide childcare or nursing care to family members, or whenever they need to see a doctor regularly for the treatment or screening of a personal injury, illness, or chronic disease, among other situations. From 2021, the scope of eligibility for nursing care, which had previously been limited to parents in terms of its scope of use, has been expanded to family members. JCR aims to introduce a variety of systems in order to provide a workplace environment where employees can work comfortably.

\* The unused portion of paid leave may be carried over to the following fiscal year. However, under the provisions of the Labor Standards Act, any unused paid leave expires two years after it is granted. The new system allows employees to save and use up to 40 days of their expired paid leave.

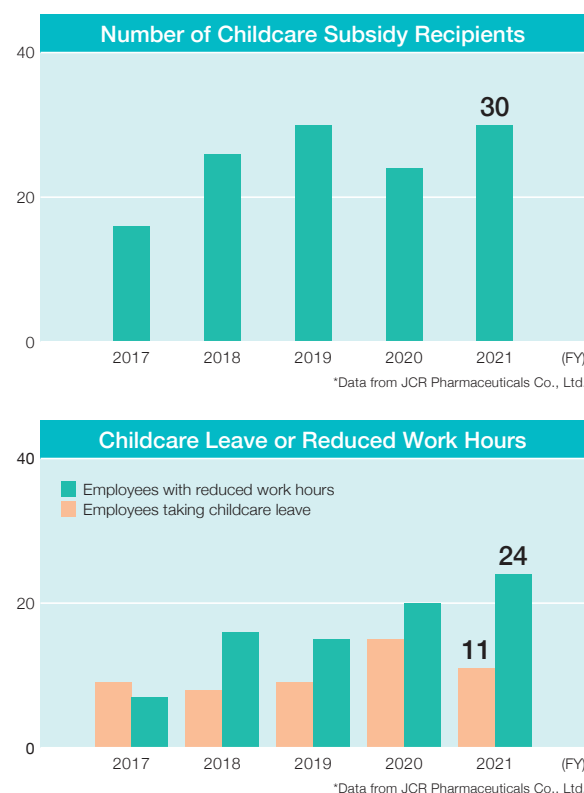
## Supporting Employees Raising Children

We have provided an in-house daycare center at the Research Institute for employees who are raising children. In addition, we provide a monthly childcare subsidy to support employees who are unable to use the in-house childcare center due to their work location. In recognition of these and other efforts, we received the Kurumin certification from the Ministry of Health, Labour and Welfare in October 2022. JCR has now been certified for two consecutive fiscal periods since 2018.



## Measures to Improve the Childcare Leave Acquisition Rate among Men

As a social issue, childcare leave taken by men has not yet fully become entrenched in society. Even at JCR, the childcare leave acquisition rate among men (80%\* in FY2020, \*Includes



leave taken for childcare purposes) is lower than the childcare leave acquisition rate among women (100% in FY2020).

We believe that fostering workplace understanding and instilling awareness among male employees are essential to improving the childcare acquisition rate among men. Based on this belief, the Child-Raising Support Café (37 voluntary participants in FY2020) and Ikuboss training (seven voluntary participants in FY2020) (Ikuboss: a boss supportive of child-raising) were held as in-house seminars. Furthermore, staff from human resources departments explained various

programs that enable male employees to actively acquire childcare leave. As a first step, JCR is working to foster awareness of the acquisition of childcare leave by men within the Company. Through these measures, the childcare acquisition rate among men has been increasing every year.

## Occupational Safety and Health

### Creation of a Workplace Environment That Protects the Safety and Health of Employees, and Allows Them to Work Comfortably

As an initiative to create an ideal workplace environment that protects the safety and health of employees and allows them to work with peace of mind, we are encouraging the use of annual paid leave. We also provide group administration of influenza vaccinations and support employees aged 35 years and over who wish to receive a comprehensive health check. To improve the workplace environment, we hold a monthly Safety and Health Committee meeting on a Company-wide basis. Whenever improvements are necessary, the committee members discuss what steps JCR should take. We also have appointed two corporate physicians, one of whom provides mental healthcare as a designated mental healthcare physician. Furthermore, inside the Research Institute, we have created a space called "JCR Oasis," where employees can get a massage and refresh themselves during work.

### Preventing the Spread of COVID-19

The COVID-19 pandemic has wreaked havoc around the world. As a measure to prevent the spread of COVID-19, JCR has formed the COVID-19 Action Team to carry out a broad spectrum of initiatives to protect employees from infections. The team also encourages employees, as members of a pharmaceutical company, to adhere to behavior that will prevent infections.

# Quality Assurance and Stable Supply



Society

Related SDGs



## Stable Supply of High-Quality Pharmaceuticals

### Quality Assurance Based on Global Standards

All of JCR's production sites have established a system that scientifically guarantees quality, encompassing the purchase of raw materials, manufacturing, shipment of products and product distribution in compliance with PIC/S GMP, an international standard, and continue efforts to raise those standards even further. JCR utilizes single-use equipment and supplies in the manufacturing of its biopharmaceutical products, with a wide range of culture medium and diagnostic agent suppliers in Japan and overseas. Because it also utilizes custom-made items, JCR enters into multiple-year contracts with suppliers worldwide and ensures quality by conducting regular on-site visits according to the level of risk.

### Consistent Quality

Biopharmaceuticals require more highly sophisticated manufacturing and quality control than what is required by small molecule pharmaceuticals. Moreover, detailed manufacturing and quality test plans are required. At its production sites, JCR sets quality targets to continuously manufacture high-quality products, and evaluates the status of achievement of those targets every year. Eyeing future global expansion, we are operating a consistent quality system to ensure that no differences arise between production sites in terms of their positions on

quality standards. At the same time, through the quality testing division which has been integrated with the Development Division conducting testing, we have established a quality management system that enables a streamlined process from consideration of testing methods in the early stages of research to testing during shipment for commercial production. Furthermore, the status of achievement of quality targets is reported to management once a year.

### Ensuring a Stable Supply

Since many JCR products are administered to patients over the long term, an unstable supply can be directly detrimental to the interests of patients. In terms of product characteristics, JCR products require a longer period of time to manufacture than small molecule pharmaceuticals because they involve more time-consuming and complicated manufacturing processes. To ensure a steady supply of products, JCR secures appropriate levels of product inventories, along with manufacturing at its in-house manufacturing sites in Japan to allow for flexible manufacturing schedules. That said, the ratio of products for overseas markets will increase in the future and there is a need to ensure a stable supply during emergencies. Therefore, we are considering manufacturing products and storing key intermediates at manufacturing sites overseas.

## Ensuring Product Safety

### Safety Monitoring System

Given that the safety evaluation carried out when a new product is approved is based on limited clinical trials, JCR continues to collect and evaluate safety and validity information on products after they have been

manufactured and sold in accordance with a risk management plan (RMP). All the safety information collected is evaluated in a timely manner, and the need for implementing any additional safety measures is considered. Concurrently, JCR periodically evaluates the accumulated safety data and verifies whether there are any changes in trends such as side effects. If safety measures are necessary, JCR will convey information swiftly and reliably to all users that require it, such as medical professionals.

In order to implement these measures appropriately, JCR carries out safety management operations in accordance with laws and regulations. Notably, JCR provides regular training on the importance of collecting safety information to medical representatives (MRs), who directly interface with medical professionals, as well as the departments implementing safety management operations. This training is part of JCR's efforts to improve the safety awareness vital to undertaking its corporate business activities.

### System of Cooperation among Three Executives

In accordance with the Pharmaceuticals and Medical Devices Act, JCR has set up a system of cooperation among three executives, namely the Marketing Supervisor-General, Quality Assurance Manager and Safety Management Supervisor. This system is designed to scientifically evaluate the quality and safety of products independently of the Sales Division and Production Division, which are the principal agents of JCR's corporate business activities. The system decides whether or not to implement product release, recall and safety measures, which are critical decisions for JCR. Through this independent governance system, JCR assures the quality and safety of its products.

# Quality Assurance and Stable Supply

## Logistics Measures

Pharmaceutical logistics operations entail fulfilling supply obligations by delivering pharmaceuticals to distributors, wholesalers and medical institutions without delay, while maintaining pharmaceutical quality from the time of shipment from plants. As a pharmaceutical company without its own means of transporting products, JCR believes that it is crucial to build win-win relationships with carriers contracted to provide specialized transportation services for pharmaceuticals. Notably, JCR supplies pharmaceuticals for rare diseases, and it believes that the transportation of these pharmaceuticals presents issues such as the need for even higher-quality packaging methods and the development of transportation methods together with related contractors.

JCR works to grasp the conditions surrounding pharmaceutical logistics and to make daily improvements. In the process, JCR strives to achieve “seamless logistics” by establishing internally developed logistics standards, along with implementing logistics measures in compliance

with Good Distribution Practice (GDP) guidelines.

Until now, JCR has realized packaging and delivery that permits temperature control suited to the characteristics of its products. For example, pharmaceuticals such as GROWJECT® are packaged in Eco Thermostat Shuttle (ETS) boxes designed and developed in-house. TEMCELL® HS Inj. is delivered and stored using an ultra-low cold chain system developed jointly with MEDIPAL HOLDINGS CORPORATION.

In April 2019, JCR endorsed the “White Logistics Movement” at an early stage. The “White Logistics Movement” is a national campaign to secure lasting and stable logistics operations. JCR makes the considerations necessary to ensure that compliance can be maintained with laws and regulations related to labor matters for transportation service contractors and the laws and regulations related to the motor truck transportation business. JCR also strives to reduce the waiting time for truck drivers during the loading or unloading of shipments by providing advance notice of arrival and shipment

information.

In the past few years, drugmakers have been accelerating the outsourcing of their logistics operations to Third-Party Logistics (3PL) providers that own advanced temperature-controlled warehouses for pharmaceuticals. The drugmakers are taking this step to ensure distribution quality based on GDP guidelines. In response, the 3PL providers have been developing proprietary joint cold chain systems together with specialist pharmaceutical transportation service providers to enhance their transportation capabilities. Meanwhile, we have seen pharmaceutical wholesalers and distributors form an alliance with the 3PL providers to jointly reform the logistics chain from manufacturers to patients in a consistent manner.

Looking ahead, JCR also believes that transforming its logistics operations is an urgent priority for strengthening its global GDP response and BCP measures. Logistics operations could be transformed by, for example, outsourcing logistics operations to external contractors including 3PL providers.

## Voluntary Pledge on Actions to Realize Sustainable Logistics

JCR endorses the aims of the “White Logistics Movement” and pledges to tackle this issue in the following manner.

### Action Policy

JCR recognizes that securing the sustainable and stable logistics essential to business activities is a key management priority. Accordingly, JCR will work to improve logistics by fostering mutual understanding and cooperation with business partners, logistics service providers and other related parties, with a view to achieving highly productive logistics and workstyle reforms.

### Considerations for Compliance

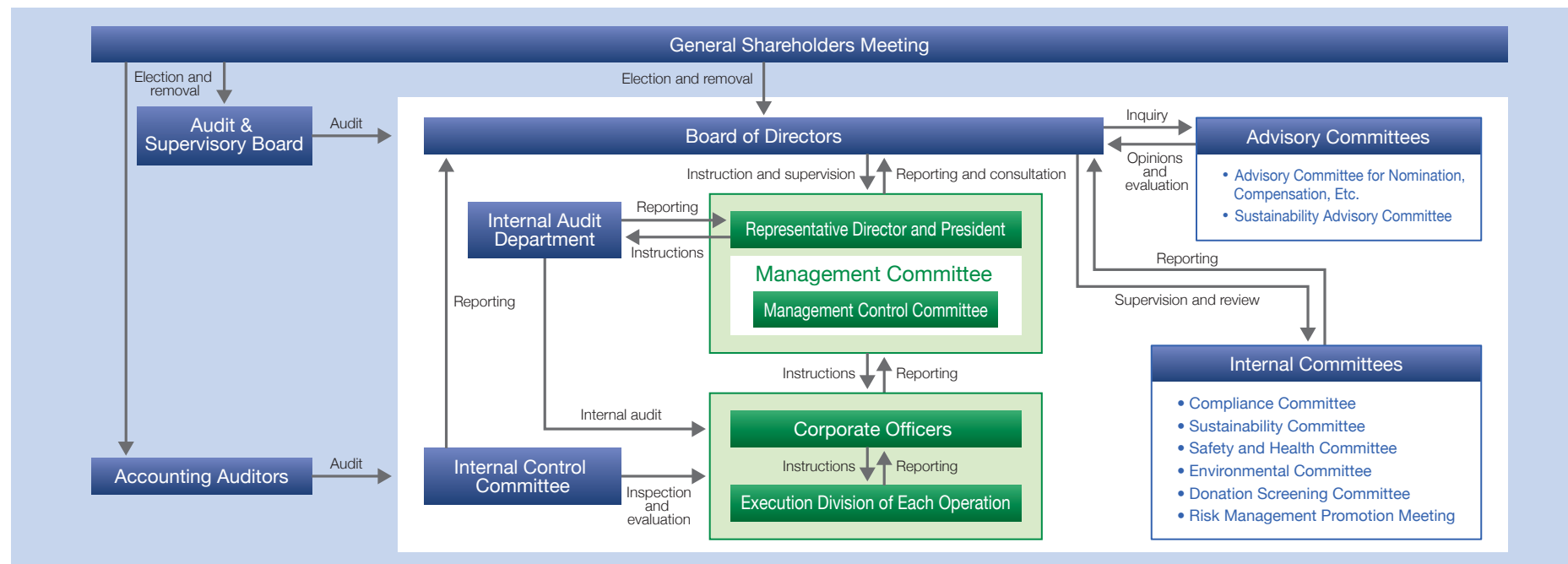
JCR will make the necessary considerations to ensure that the logistics service providers of its business partners are able to comply with laws and regulations related to labor matters and the motor truck transportation business. For example, JCR will respond appropriately to revise the content of contracts and transportation services in cases where there is a risk of a violation of laws and regulations.

### Clarification and Compliance with the Content of Contracts

JCR will strive to clarify the content of contracts related to transportation services and non-transportation services such as loading/unloading and inspection. Concurrently, JCR will strive to ensure compliance with the content of contracts by obtaining the cooperation of business partners, logistics service providers and other related parties.

# Corporate Governance

Corporate Governance System (As of July 12, 2022)



Related SDGs



enhance the legality, transparency and objectivity of its management, to heighten its corporate value further, and at the same time to build a system to ensure the protection of shareholder interests. To this end, we will work to secure implementation and operation of effective internal control systems, to evaluate the effectiveness of such systems on our own, and to fulfill our corporate social responsibilities.

For the purpose of compliance, we recognize that it is important to adhere to laws and regulations, global standards, and various industrial standards, and also to foster a corporate culture with the highest standards of ethics in the course of day-to-day business activities.

## Overview of Corporate Governance System

JCR is a company with an Audit & Supervisory Board. As such, we have established the Board of Directors consisting of 11 Directors, including six Outside Directors, the Audit & Supervisory Board consisting of five Outside Audit & Supervisory Board Members, and Accounting Auditors.

In addition to these organs, we have established the Management Control Committee, Advisory Committee for Nomination, Compensation, Etc., Sustainability Advisory Committee, Management Committee, Internal Audit Department, Internal Control Committee, Compliance Committee, Sustainability Committee,

## Basic Concept

The JCR Group believes that for the purpose of providing superior quality and more useful pharmaceutical products and medical equipment to society, it is important to aim to



Safety and Health Committee, Environmental Committee, Donation Screening Committee, and Risk Management Promotion Meeting. As for the composition of the corporate governance system we believe the corporate governance system covers an appropriate scope in line with our current condition, and that it enables efficient management of business operations. Also, we have judged that the current governance system, which includes six Outside Directors and five Outside Audit & Supervisory Board Members, is effective for ensuring management transparency, objectivity (impartiality) and independent supervision over management.

## Description of Organs of the Company

### Board of Directors

The Board of Directors consists of 11 Directors, and in principle, an ordinary Board of Directors' meeting is held once per month, and an extraordinary Board of Directors' meeting is held as necessary. The Board of Directors decides important matters concerning the management of the Company in addition to matters specified by laws and regulations.

Our Articles of Incorporation state that the Company may have no more than 11 Directors and that the appointment of those Directors must be resolved at a meeting attended by shareholders who hold at least one-third of the voting rights of all the shareholders who have voting rights and that it must be passed by a majority of the votes. Furthermore, the resolutions to appoint Directors shall not be decided by cumulative voting.

### Management Control Committee

The Management Control Committee consists of Representative Directors and Internal Directors. The Management Committee deliberates and decides important management matters related to management policy, management strategy and other priorities, in principle. However, the Management Control Committee operates as a

meeting body when expeditious responses are needed depending on the matter in question.

### Advisory Committee for Nomination, Compensation, Etc.

The Advisory Committee consists of one Internal Director, four Independent Outside Directors and two Independent Outside Audit & Supervisory Board Members (one full-time member and one part-time member). The Committee deliberates on important matters concerning nomination and compensation for Directors and Corporate Officers and Audit & Supervisory Board Members. It also provides opinions on the evaluation of the effectiveness of the Board of Directors, etc.

### Sustainability Advisory Committee

The Sustainability Advisory Committee is scheduled to consist of Internal Directors, independent Outside Directors, and full-time Auditors, who will state their opinions of matters submitted to the Board of Directors by the Sustainability Committee.

### Management Committee

The Management Committee consists of five Internal Directors, one Senior Corporate Officer and three Corporate Officers. The Committee meets twice per month, in principle. The purpose of the Committee is to carry out deliberations and make decisions necessary for management to make judgments after sharing important matters related to management policy, management strategies and other matters related to company management among departments, and to submit results to the Board of Directors.

### Corporate Officer System

We have introduced the corporate officer system for the purpose of ensuring the efficiency of management of the Company and to accelerate the execution of operations. One Senior Corporate Officer and three Corporate Officers execute operations based

on the management policy decided by the Board of Directors.

### Audit & Supervisory Board

JCR is a company with an Audit & Supervisory Board. Five Audit & Supervisory Board Members have assumed office (one full-time Audit & Supervisory Board Member and four part-time Audit & Supervisory Board Members) and all of them are Independent Outside Audit & Supervisory Board Members.

The Audit & Supervisory Board holds a meeting once per month and also an extraordinary Audit & Supervisory Board meeting as needed.

Audit & Supervisory Board Members attend important meetings, including Board of Directors' meetings. The Audit & Supervisory Board also serves as a supervisory body over management, and ascertains the Company's status through consultations with top executives including General Managers in charge.

### Internal Audit Department

The Internal Audit Department is directly under the control of the President. It performs audits to determine whether operations are executed by departments in line with laws and regulations as well as internal rules.

The Internal Audit Department consists of four full-time employees, including one Director of the Internal Audit Department. The results of internal audits are submitted to the Audit & Supervisory Board Members, in addition to the President.

### Internal Control Committee

The Internal Control Committee consists of members of departments such as the Legal Affairs Dept., Accounting Dept., General Affairs Dept., Internal Audit Dept., and Production Management Dept. It exchanges opinions with and provides reports to the Audit & Supervisory Board Members and others, as necessary, and further ensures appropriate financial reporting by the Accounting Auditors with respect to the effectiveness of the reporting of internal controls through self-inspection processes.

## Compliance Committee

JCR has a Compliance Committee in place to implement and promote company management in line with social norms and corporate ethics as well as compliance with laws and regulations. The Committee consists of two sub-committees: a Compliance Control Committee chaired by the Chief Compliance Officer, with committee members including our Directors and Corporate Officers, as well as external experts; and a Compliance Promotion Committee comprising employees nominated by the Compliance Control Committee members and assigned by the Representative Director. To promote compliance at JCR, the Compliance Committee holds meetings on a regular basis, determines JCR's compliance action plans and policies, and provides employee training and education in accordance with the Compliance Code of Conduct and the Compliance Handbook, along with making compliance matters more widely known and raising awareness through a compliance newsletter.

## Sustainability Committee

JCR will establish the Sustainability Committee in order to implement and promote sustainability management, which aims to contribute to the realization of a sustainable society and achieve sustainable growth for JCR based on its management philosophy of "Contributing toward people's healthcare through pharmaceutical products." The committee will be chaired by an officer in charge of sustainability and is scheduled to consist of employees selected from each internal department.

## Safety and Health Committee

JCR has set up the Safety and Health Committee for the purposes of securing the safety and health of employees at our workplaces, and establishing and promoting a comfortable work environment. The Committee consists of employees selected from each division of JCR, along with a licensed social insurance labor consultant, and industrial physicians, all of whom serve as outside committee

members. The Committee holds meetings every month to report on the status of each workplace and exchange opinions, as it works to secure and improve occupational safety and health.

## Environmental Committee

JCR views the environmental impacts through its business activities as risk factors that could potentially impact its long-term business or society, and believes that ensuring environmental protection is the responsibility of management and will establish the Environmental Committee to practice and promote environmentally conscious business activities. This committee is scheduled to consist of Internal Directors and employees selected from each internal department.

## Donation Screening Committee

JCR has established the Donation Screening Committee to screen donations made by JCR and its subsidiaries to ensure they are made appropriately and are socially and internally transparent and fair.

The Donation Screening Committee is composed of the Executive Director of Administration Division, members of the General Affairs Department, Accounting Department, Legal Affairs Department, Internal Control Promotion Department, and a medical expert. It meets once a month, in principle, to evaluate matters such as the practice of donations and the appropriateness of donation amounts in accordance with their type, from an objective standpoint, with reference to factors such as relevant laws and regulations, industry rules, and internal standards. Details of the donation screenings are reported quarterly to the Board of Directors.

## Risk Management Promotion Meeting

JCR has established the Risk Management Promotion Meeting, which is led by the Risk Management Officer (Director) appointed by the Representative Director, and includes division general managers (or department general managers for departments that

do not use the division system), as well as representative directors of subsidiaries, as business risk managers. The Risk Management Promotion Meeting meets regularly to promote JCR's risk management and implements measures such as summarizing the risk management activities of each division, etc., preventing the occurrence of Company-wide risks, and formulating Business Continuity Plans (BCPs).

## Status of the Risk Management System

As a company that handles pharmaceutical products that concern people's health, JCR has established procedures for risk control in each of its divisions along with ascertaining risk in business activities. It also determines basic risk management guidelines and develops its risk management system based on those guidelines. Furthermore, JCR is creating systems to address risk prevention, risk management, and risk contingencies through collaboration with related committees such as the Risk Management Promotion Office, Internal Control Committee and Compliance Committee.

JCR has listed the important risks it should be aware of and selected and decided on the three items below as BCP priorities. The BCP is reviewed each fiscal year and revised if needed.

1. Response measures in the event of a disruption in the supply of GROWJECT®
2. Company-wide response measures in the event of a large-scale disaster
3. Response measures in the event of a major compliance violation

In particular, as a pharmaceutical company, JCR regularly holds meetings of the three executives of manufacturing and marketing (Marketing Supervisor-General, Quality Assurance Manager and Safety Management Supervisor) in accordance with laws and regulations, and has constructed systems that assure the quality, effectiveness and safety of drugs.

Moreover, while expanding its operations globally, JCR will introduce a world-class drug quality system and pursue an even higher level of safety.

# Corporate Governance

## Risk Management System



Please refer to our "Corporate Governance Report" for details.

<https://www.jcrpharm.co.jp/en/site/en/company/governance.html>

## Composition, Number of Meetings Held, and Attendance Rate for Internal Committees and Other Organs of the Company in FY2021 (As of end of FY2021)

Advisory Committee for Nomination, Compensation, Etc.		Composition	6 members (1 Internal Director, 3 Independent Outside Directors, 2 Independent Outside Audit & Supervisory Board Members)
		Number of meetings held	6
		Attendance rate	100.00%
Internal Control Committee		Composition	12 members (1 Executive Director of Administration Div., 1 from Legal Affairs Dept., 2 from Internal Control Dept., 5 from Internal Audit Dept., 1 from Accounting Dept., 1 from General Affairs Dept., and 1 from Production Management Dept.)
		Number of meetings held	5
		Attendance rate	87.27%
Compliance Committee	Compliance Control Committee	Composition	12 members (2 attorneys at law, 5 Internal Directors, 1 Independent Outside Audit & Supervisory Board Member, and 4 Corporate Officers)
		Number of meetings held	2
		Attendance rate	95.83%
	Compliance Promotion Committee	Composition	17 members (1 from Legal Affairs Dept., 3 from Internal Control Dept., 1 from Sales Div., 1 from Development Div., 2 from Research Div., 6 from Production Div., 1 from Pharmacovigilance Dept., 1 from Tokyo Office, and 1 from Accounting Dept.)
		Number of meetings held	3
		Attendance rate	91.18%
Safety and Health Committee		Composition	15 members (1 labor and social security attorney, 2 industrial physicians, 1 from Human Resources Dept., 3 from General Affairs Dept., 1 from Sales Div., 1 from Regulatory Affairs Dept., 1 from Tokyo Office, 1 from Development Div., 2 from the Production Division Safety and Health Committee, and 2 from the Research Institute Safety and Health Committee)
		Number of meetings held	12
		Attendance rate	92.13%
Donation Screening Committee		Composition	9 members (1 Adviser, 1 Executive Director of Administration Division, 1 from Legal Affairs Dept., 1 from Accounting Dept., 1 from General Affairs Dept., 1 from Development Div., and 3 from Internal Control Dept.)
		Number of meetings held	12
		Attendance rate	94.23%
Risk Management Promotion Meeting		Composition	15 members (4 Internal Directors, 1 Independent Outside Audit & Supervisory Board Member, 4 Corporate Officers, 1 from Corporate Strategy Dept., 1 from Global Strategy Dept., 1 from Business Development Dept., 1 from Sales Div., 1 from Internal Audit Dept., and 1 from HR Planning Dept.)
		Number of meetings held	2
		Attendance rate	100.00%

## Outside Directors and Outside Audit & Supervisory Board Members

### Functions and Roles of Outside Directors

JCR has six Outside Directors, comprising five Independent Outside Directors and one Outside Director. It has five Outside Audit & Supervisory Board Members, all of whom are Independent Outside Audit & Supervisory Board Members.

Outside Directors supervise management from an independent standpoint to contribute to JCR's sustainable growth and medium- to long-term improvement of corporate value through decision-making at Board of Directors' meetings. Outside Directors strengthen cooperation with the Audit & Supervisory Board, exchange information, share awareness, and appropriately reflect these aspects in Board of Directors' meetings from an objective point of view. Four Independent Outside Directors are also members of the Advisory Committee for Nomination, Compensation, Etc.

To further increase the independence and neutrality of our audit system, Outside Audit & Supervisory Board Members proactively acquire information necessary for audits by sharing information with an audit firm and the Internal Audit Dept., and monitor the execution of Directors' duties through operational and accounting audits. As they are expected to present objective opinions on audits, Outside Audit & Supervisory Board Members ask unreserved questions and offer comments to the Representative Directors and the Board of Directors. Two of the Independent Outside Audit & Supervisory Board Members (one full-time member and one part-time member) are members of the Advisory Committee for Nomination, Compensation, Etc.

### Interests between JCR and Its Outside Directors or Outside Audit & Supervisory Board Members

Outside Director Toshihide Yoda concurrently holds the post of Managing Director at MEDIPAL HOLDINGS CORPORATION (MEDIPAL HOLDINGS). JCR and MEDIPAL HOLDINGS concluded a contract for a capital and business tie-up, as well as multiple contracts for investment in development. MEDIPAL HOLDINGS also holds 23.49% of JCR's shares.

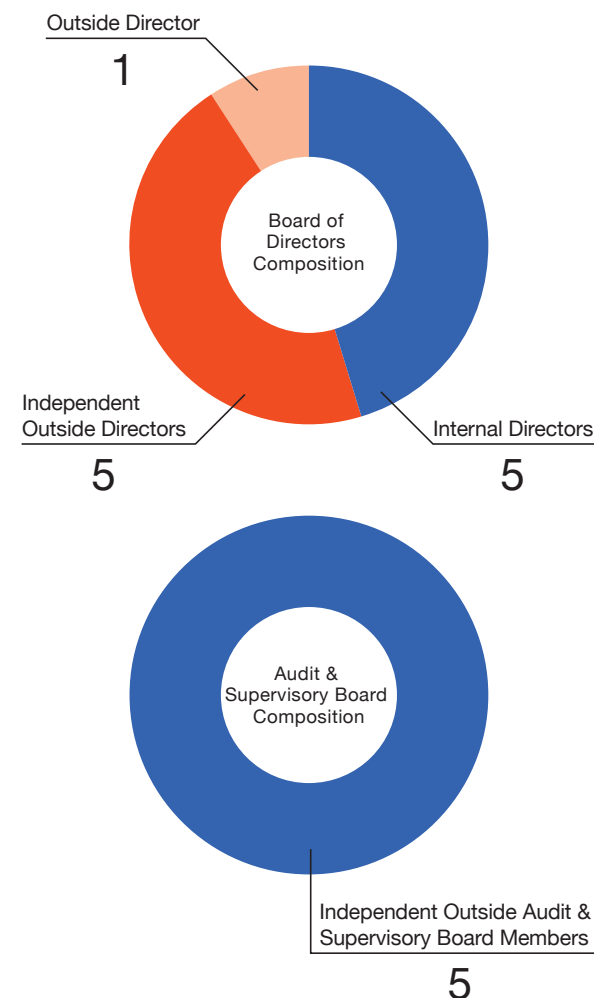
The status of Outside Directors and Outside Audit & Supervisory Board Members' stock investments in JCR is recorded in our annual Securities Report. Otherwise, there are no special interests between JCR and its Outside Directors or Outside Audit & Supervisory Board Members.

JCR designates 10 members as Independent Directors or Audit & Supervisory Board Members, as stipulated by the listing regulations for the Tokyo Stock Exchange. The 10 members are Outside Directors Toshihiro Ishikiriya, Takashi Suetsuna, Yuko Hayashi, Yutaka Atomi, and Philippe Fauchet, as well as Outside Audit & Supervisory Board Members Kazumasa Oizumi, Kazuhiko Yamada, Kenjiro Miyatake, Takeshi Komura, and Shuichi Tani.

### Composition of Board of Directors and Audit & Supervisory Board

JCR's Board of Directors consists of five Internal Directors, five Independent Outside Directors, and one Outside Director. Although traditionally more than one-third of the appointed members were Independent Outside Directors, two Independent Outside Directors were newly appointed at the Ordinary General Meeting of Shareholders held on June 22, 2022, and these two sufficiently meet the conditions required in the Corporate Governance Code which was revised in June 2021. Furthermore, the Audit & Supervisory Board consists of five Independent Outside Auditors.

Composition Percentages of Board of Directors and Audit & Supervisory Board (as of June 22, 2022)





# Corporate Governance

Skill Matrix of Directors and Audit & Supervisory Board Members and Attendance Rate at Board of Directors and Audit & Supervisory Board Meetings in FY2021

			Advisory Committee for Nomination, Compensation, Etc.	Skill													Attendance Rate of the Board Meetings (FY2021)
				Overall Management	Industry Knowledge	Global Experience	R&D	Production	Sales	ICT	Administrative Experience	Legal Affairs	Tax, Finance and Accounting	Sustainability	Risk Management	Other	
Board of Directors	Shin Ashida	Representative Director CEO & COO	●	●	●		●	●					●	●		100%	
	Toru Ashida	Senior Vice President		●	●			●				●				100%	
	Mathias Schmidt	Vice President		●	●	●	●								Business Development and Contract Negotiation	100%	
	Hiroyuki Sonoda	Vice President			●		●							●		100%	
	Yoshio Hiyama	Senior Executive Director			●	●		●			●			●	Quality and Safety	100%	
	Toshihiro Ishikiriyama	Director (Independent/Outside)	●	●	●	●	●	●				●				100%	
	Takashi Suetsuna	Director (Independent/Outside)	●			●					●	●	●		●	93%	
	Toshihide Yoda	Director (Outside)		●	●	●						●				93%	
	Yuko Hayashi	Director (Independent/Outside)	●							●				●		Diversity and Inclusion	100%
	Yutaka Atomi	Director (Independent/Outside)	●		●		●								●		—
Philippe Fauchet	Director (Independent/Outside)		●	●	●										Business Development and Business Alliance	—	
Audit & Supervisory Board	Kazumasa Oizumi	Audit & SBM* (Independent/Outside)	●	●					●							Audit Practice	100%
	Kazuhiko Yamada	Audit & SBM* (Independent/Outside)									●		●				100%
	Kenjiro Miyatake	Audit & SBM* (Independent/Outside)		●	●				●		●						100%
	Takeshi Komura	Audit & SBM* (Independent/Outside)	●	●							●	●		●			92%
	Shuichi Tani	Audit & SBM* (Independent/Outside)		●	●						●						100%

\* Audit & Supervisory Board Member

# Board of Directors

(As of July 1, 2022)



## Directors

(From left) Hiroiyuki Sonoda  
Toru Ashida  
Shin Ashida  
Mathias Schmidt  
Yoshio Hiyama

### Shin Ashida

Representative Director  
Chairman, President, CEO and COO

1975	Appointed Representative Director (current post) at the establishment of JCR Pharmaceuticals
	Appointed President and Director
2005	Appointed Chairman and Director (current post)
	Appointed Chief Executive Officer (CEO) (current post)
2007	Appointed President and Director (current post)
	Appointed Chief Operating Officer (COO) (current post)
2015	Appointed Representative Director and President of JCR INTERNATIONAL SA (current post)

### Toru Ashida

Senior Vice President  
In charge of Sales and Administration  
Executive Director, Sales Division

1992	Entered Nippon Life Insurance Company
2002	Appointed Representative Director and President at the establishment of JBS Co., Ltd.
2014	Entered JCR Pharmaceuticals Appointed Corporate Officer Executive Director, Corporate Business Support Division and Director, Corporate Strategy Department
2016	General Manager, Office of the President
2018	Appointed Director Head of Quality Assurance Division, Corporate Planning Division, Medical Affairs Department and Office of the President
2019	In charge of Corporate Strategy Head of Quality Assurance Division, Administration Division, Medical Affairs Department and Office of the President
2020	Executive Director, Sales Division (current post) Appointed Vice President In charge of Corporate Strategy and Head of Sales Division
2021	Appointed Senior Vice President (current post) In charge of Sales and Administration (current post)

### Mathias Schmidt, PD, Ph.D.

Vice President  
In charge of Clinical Development, Global Business Strategy and Business Development  
ArmaGen, Inc. CEO  
JCR USA, Inc. President and CEO

2001	Laboratory Head and Senior Group Leader, Oncology, Altana Pharma AG, Germany
2003	Lecturer in Disease Biology, Pharmacology, Human Biology, Drug Discovery and Development, University of Konstanz, Germany
2010	Principal and Head of Biologics Department, Nycomed GmbH, Germany (currently, Takeda GmbH)
2012	Vice President of Biological Sciences, Takeda California, Inc.
2016	Chief Executive Officer, ArmaGen, Inc. (current post)
2019	Executive Vice President, Head of Research and Development, Triphase Accelerator Corporation
2020	Appointed Director, JCR Pharmaceuticals In charge of Global Strategy President and Chief Executive Officer, JCR USA, Inc. (current post)
2021	Appointed Vice President (current post) In charge of Clinical Development, Global Business Strategy and Business Development (current post)

### Hiroiyuki Sonoda, Ph.D.

Vice President  
In charge of Research and Corporate Strategy  
Executive Director, Research Division

2003	Entered JCR Pharmaceuticals
2016	Director of Corporate Planning Division (Research)
2017	Leader of Frontier Research Unit and Director of Corporate Planning Division (Research)
2018	Executive Director of Research Planning Division Appointed Corporate Officer
2020	Appointed Director Head of Research and Development Division Executive Director, Research Division Director, Drug Discovery Research, Research Division
2021	Appointed Vice President (current post) In charge of Research and Corporate Strategy (current post) Executive Director, Research Division (current post)

### Yoshio Hiyama, Ph.D.

Senior Executive Director  
In charge of Production and Quality & Safety Management  
Head of Production Division

1986	Entered Daiichi Pharmaceuticals Co., Ltd. (currently Daiichi Sankyo Co., Ltd.)
1999	Manager, Regulatory Affairs Group, PMD-VAC Co., Ltd. (secondment)
2005	Marketing Supervisor-General, General Manager of the same
2011	Group Manager, R&D Group in Vaccine Planning Dept., Daiichi Sankyo Co., Ltd. (returned)
2012	Marketing Supervisor, General and Quality and Safety Management Director, Japan Vaccines Co., Ltd. (secondment)
2019	Entered JCR Pharmaceuticals Assistant Director, Production Division
2020	Marketing Supervisor-General Director of Pharmacovigilance Dept. and PMS Office Manager Director of Corporate Planning Division (In charge of Vaccine Business) and Pharmacovigilance Dept.
2021	Appointed Senior Executive Director (current post) In charge of Production and Quality & Safety Management (current post) Head of Production Division (current post)



## Outside Directors

(From left) Yutaka Atomi  
Toshihide Yoda  
Toshiiro Ishikiriya  
Takashi Suetsuna  
Yuko Hayashi  
Philippe Fauchet

### Toshiiro Ishikiriya Outside Director

1996 General Manager, Corporate Planning, Hoechst Marion Roussel Inc. (currently Sanofi K.K.)  
2002 Entered GlaxoSmithKline K.K.  
Director and General Manager, Corporate Planning of the same  
2005 Director, General Manager, Financial Affairs and Head of Business Development of the same  
2008 Managing Director of the same  
2012 Managing Director and General Manager, Vaccine Business Promotion Division of the same  
Chairman and Representative Director, Japan Vaccine Co., Ltd.  
2014 President and Representative Director of the same  
2015 Appointed Director, JCR Pharmaceuticals (current post)  
2016 President's Assistant, MEDINET Co., Ltd.  
2018 Outside Auditor, GlaxoSmithKline K.K. (current post)  
2019 Outside Auditor, GSK Capital K.K. (current post)  
Outside Auditor, GKK K.K. (current post)  
Outside Auditor, GlaxoSmithKline Consumer Healthcare Japan K.K. (current post)  
Outside Auditor, Viiv Healthcare K.K. (current post)  
Representative Director and President, Rege Nephro Co., Ltd. (current post)

### Takashi Suetsuna Outside Director

1974 Entered the National Police Agency  
1994 Chief, Kochi Prefectural Police Headquarters  
1997 Director, Finance Division, Commissioner-General's Secretariat, National Police Agency  
2001 Chief Inspector General Commissioner-General's Secretariat, National Police Agency  
2002 Chief, Kanagawa Prefectural Police Headquarters  
2004 Deputy Superintendent General, National Police Agency  
2005 Grand Chamberlain to the Crown Prince at the Imperial Household Agency  
2009 Ambassador Extraordinary and Plenipotentiary to Grand Duchy of Luxembourg  
Retired from the above office  
2012 Outside Auditor, Marubeni Corporation  
2013 Outside Director, Totetsu Kogyo Co., Ltd. (current post)  
2015 Outside Auditor, Kandenko Co., Ltd. (current post)  
2016 Outside Auditor, Keikyu Corporation (current post)  
Appointed Audit & Supervisory Board Member, JCR Pharmaceuticals  
2017 Appointed Director, JCR Pharmaceuticals (current post)  
2018 Outside Auditor, Aioi Nissay Dowa Insurance Co., Ltd.

### Toshihide Yoda Outside Director

1985 Entered Nippon Kangyo Kakumaru Securities  
1989 Entered UBS Securities Japan Co., Ltd.  
1996 Entered ING Bearing Securities  
2000 Entered Lehman Brothers Securities  
2008 Entered Barclays Capital Securities Japan Limited  
Managing Director of the same  
2010 Director, MEDIPAL HOLDINGS CORPORATION  
2012 Director and Managing Director of the same  
In charge of IR and General Manager, Business Development Department CMA® of the same (current post)  
2016 Director, SPLINE Corporation  
Director, MEDIE Co., Ltd.  
Director, MEDICEO CORPORATION  
2018 Director, JCR USA, Inc. (current post)  
Senior Managing Director, MEDIPAL HOLDINGS CORPORATION (current post)  
Appointed Director, JCR Pharmaceuticals (current post)  
2020 Manager Business Investment Department, Business Development Division, MEDIPAL HOLDINGS CORPORATION  
2021 Director, PharField Corporation

### Yuko Hayashi, Ph.D. Outside Director

1988 Entered IBM Japan Ltd.  
2003 Visiting Researcher, Research Center for Advanced Science and Technology of The University of Tokyo  
2007 Lecturer, Graduate School of Innovation and Technology Management of Yamaguchi University  
Visiting Researcher, National Graduate Institute for Policy Studies  
2011 Executive Director, 3.11 Earthquake Orphans Cultural and Sports Support Facilitation Corporation of Public Interest Incorporated Association (current post)  
2012 Associate Professor, Graduate School of Innovation and Technology Management of Yamaguchi University  
Professor, Graduate School of Innovation and Technology Management of the same (current post)  
2015 Executive Board Member, Special Olympics Nippon of Public Interest Incorporated Foundation (current post)  
2017 Researcher, Graduate School of Frontier Sciences of The University of Tokyo (current post)  
2018 Appointed Director, JCR Pharmaceuticals (current post)

### Yutaka Atomi, M.D., Ph.D. Outside Director

1970 Attending Surgeon, First Department of Surgery, Faculty of Medicine, The University of Tokyo  
1982 Chief of Medical Staff, First Department of Surgery, Faculty of Medicine of the same  
1988 Visiting Researcher, Department of Surgery, University of California, San Francisco  
1992 Assistant Professor, First Department of Surgery, Faculty of Medicine, The University of Tokyo  
Professor, First Department of Surgery, Faculty of Medicine, Kyorin University  
2004 Dean, Faculty of Medicine of the same  
2010 President of the same  
2013 Outside Audit & Supervisory Board Member, Sumitomo Dainippon Pharma Co., Ltd. (currently Sumitomo Pharma Co., Ltd.)  
2017 Outside Director of the same (current post)  
2018 President Emeritus, Kyorin University (current post)  
President, Pancreas Research Foundation of Japan  
2019 President, International Medical Research Foundation (current post)  
2022 Outside Audit & Supervisory Board Member, Sanki Engineering Co., Ltd. (current post)  
Appointed Director, JCR Pharmaceuticals (current post)

### Philippe Fauchet, OBE Outside Director

1984 Entered Roussel UCLAF S.A., France (currently, Aventis S.A.)  
1996 Entered Sanofi S.A. France  
2001 President and Representative Director, Sanofi-Synthelabo K.K. (currently, Sanofi K.K.)  
2005 President and Representative Director, Sanofi-Aventis K.K. (currently, Sanofi K.K.)  
2010 President and Representative Director, GlaxoSmithKline K.K.  
2013 Appointed Director, JCR Pharmaceuticals Co., Ltd.  
2017 Chairman of GlaxoSmithKline plc. Resigned as Director, JCR Pharmaceuticals Co., Ltd.  
2019 Stepped down as Chairman, GlaxoSmithKline K.K.  
Outside Director, Bonac Corporation (current post)  
2020 Outside Director, Nolle-Immune Biotech Inc. (current post)  
Outside Director, Rezolute, Inc. (RZLT) (current post)  
2022 Appointed Director, JCR Pharmaceuticals (current post)



## Audit & Supervisory Board Members and Corporate Officers

(As of July 1, 2022)

### Audit & Supervisory Board Members

(From left) Takeshi Komura  
Kazuhiko Yamada  
Kazumasa Oizumi  
Kenjiro Miyatake  
Shuichi Tani



#### Kazumasa Oizumi

Full-time Outside Audit & Supervisory Board Member

1992	Utsunomiya Branch Manager, Nippon Life Insurance Company
1997	Nihonbashi Branch Manager of the same
2001	No. 4 General Manager, Tokyo Metropolitan Area Agency of the same
2002	Full-time Auditor, SOHGO SECURITY SERVICES CO., LTD.
2009	Corporate Officer of the same
2013	Appointed Audit & Supervisory Board Member, JCR Pharmaceuticals (current post)
2014	Full-time Outside Audit & Supervisory Board Member, JCR Pharmaceuticals (current post)

#### Kazuhiko Yamada

Outside Audit & Supervisory Board Member

1996	Head of Wadayama Tax Office
1999	Corporate Tax Section Chief, No. 2 Taxation Department, Osaka Regional Taxation Bureau
2001	East Taxation Department Chief
2002	Head of Kazuhiko Yamada Tax Accountant Office (current post)
2006	Appointed Temporary Corporate Auditor, JCR Pharmaceuticals
	Appointed Audit & Supervisory Board Member, JCR Pharmaceuticals (current post)
2016	Outside Director, Audit and Supervisory Committee Member, CREATE CORPORATION (current post)

#### Kenjiro Miyatake

Outside Audit & Supervisory Board Member

1981	Director, Dainippon Pharmaceuticals Co., Ltd. (currently Sumitomo Dainippon Pharma Co., Ltd.)
1999	Representative Director and President of the same
2005	Representative Director and President, Sumitomo Dainippon Pharma Co., Ltd.
2008	Representative Director and Chairman of the same
2011	Outside Director, Japan Wool Textile Co., Ltd. Advisor, Sumitomo Dainippon Pharma Co., Ltd.
2013	Appointed Audit & Supervisory Board Member, JCR Pharmaceuticals (current post)
2015	Chairman of the Board, Kobe Pharmaceutical University

#### Takeshi Komura

Outside Audit & Supervisory Board Member

1963	Entered Ministry of Finance
1993	Deputy Vice Minister of Finance
1995	Director-General of the Budget Bureau
1997	Administrative Vice Minister of Finance
2001	Governor, Development Bank of Japan Inc.
2012	Outside Director, Maezawa Industries, Inc.
2014	President, Capital Market Promotion Foundation, Public Interest Incorporated Foundation (current post)
2017	Appointed Audit & Supervisory Board Member, JCR Pharmaceuticals (current post)
2019	CHAIRMAN OF BOARD OF TRUSTEES, The Iwatani Naoji Foundation (current post)

#### Shuichi Tani, M.D., M.P.H.

Outside Audit & Supervisory Board Member

1964	Entered Ichihara Public Health Center, Chiba Prefecture
1969	Entered Ministry of Health and Welfare
1988	Director, Health Science Division, Minister's Secretariat, Ministry of Health and Welfare
1990	Minister's Secretariat Councilor (Science and Technology), Ministry of Health and Welfare
1992	Director-General of Health Service Bureau
1995	Director-General of Health Policy Bureau
1998	Vice Chairman, All Japan Federation of Social Insurance Associations
2001	President, International University of Health and Welfare
2009	President Emeritus, International University of Health and Welfare (current post)
2017	Appointed Audit & Supervisory Board Member, JCR Pharmaceuticals (current post)

### Corporate Officers

#### Yutaka Honda

Senior Corporate Officer  
Executive Director, Administration Division  
and Director, General Affairs Dept.

#### Takayo Egawa

Corporate Officer  
Director, International Affairs Office

#### Kazunori Tanizawa

Corporate Officer  
Executive Director,  
Development Division

#### Junichi Ando

Corporate Officer  
Executive Director,  
Quality Assurance Division



### Message



After being appointed as an Outside Director, my first impression was that JCR is truly a youthful and energetic company. Chairman Ashida wrote in his message that “we will continue to take on further challenges with the determination to welcome our second foundation,” and it truly seems like the passion that was felt during the foundational period is present in the current form of JCR.

J-Brain Cargo®, which was developed from proprietary technologies, was commercialized as IZCARGO® for the treatment of MPS II, and was approved in Japan last year. This was incredibly significant for JCR, and enabled it to become an internationally recognized company. The high level of research at JCR has been demonstrated, and the importance of fundamental research has once again been confirmed. One could say that it was JCR’s comprehensive strengths that enabled it to simultaneously make it through a difficult path and provide the success of its research to the market as a drug. JCR also possesses abundant R&D pipelines, and expectations for future development are high.

One important thing to mention is risk management. Global development is being undertaken, which in fact requires risk management from a global perspective. A system for managing risk on a companywide level is also in place which JCR must implement step-by-step. This goes without saying, but what is critical when it comes to things like R&D and risk management is people. This of course involves self-enlightenment activities and educational activities through various methods, but human resource development from a broad perspective is also necessary. I believe this will enable “Team JCR” to function fully, and allow JCR to achieve its vision of a global specialty pharma in the rare disease arena.

**Yutaka Atomi, M.D., Ph.D.** Outside Director



Businesses around the world are being confronted by huge challenges arising from a never-before-seen combination of crises: a permanently evolving pandemic crisis, an uncertain and dangerous political climate and, consequently, a prolonged financial and economic crisis. Confronting such a “perfect storm,” “Team JCR” must be fit to navigate these troubled waters without losing its purpose and corporate value to protect and save the lives of patients suffering from rare diseases. Companies making a difference will be the ones able to train, adapt and anticipate the evolution of the environments in which they operate. In the life sciences area, this implies anticipating the development and regulatory needs/evolution of core markets, meeting the stronger demands of society in terms of sustainability commitments and quality of operating standards, and maintaining a sense of urgency in the execution of all activities to maintain leadership in JCR’s core areas of expertise.

As JCR becomes an international player, its reinforced visibility and patients’ expectations will require further efforts with regard to governance, social contribution, development and enhancement of the team, and protection of the environment, alongside delivery of stellar outcomes from the R&D and partnering side.

Based on the abovementioned principles and areas of focus, I will be attentive to the harmonious and professional development of the company and of “Team JCR” as an Independent Outside Director.

**Philippe Fauchet, OBE** Outside Director



# Business Activities

Since its inception in 1975, JCR has been constantly working on the development and creation of technologies and products “one step beyond” other companies, and achieved sustainable growth. This section offers a detailed explanation of the business activities in which “Team JCR” is banding together to accelerate its “REVOLUTION” in an aim to become a global specialty pharma in the rare disease arena.



A person wearing a white protective suit, hood, and mask is working in a laboratory. They are wearing yellow gloves and are focused on a piece of medical equipment. The background is a blurred laboratory setting with various pieces of equipment and shelves.

## **Changing the world of rare diseases — “Team JCR”**

## History of Growth

**1975**

JCR Pharmaceuticals Co., Ltd. founded

**1978**

Started sales of Urokinase drug solution (intermediate)

**1985**

Started import and sales of Gorm®  
Launched Urokinase product

**2010**

Launched Epoetin Alfa BS Inj. [JCR] for treatment of renal anemia, the first domestically produced biosimilar

**2013**

Listed on the First Section of the Tokyo Stock Exchange (TSE)

**2014**

Changed Japanese corporate name to **JCRファーマ 株式会社**

**2018**

Established JCR USA, Inc.

Launched Agalsidase Beta BS I.V. Infusion [JCR], a recombinant treatment for Fabry disease

**2019**

Launched Darbepoetin Alfa BS Inj. [JCR], a long-acting erythropoiesis-stimulating agent

**2021**

Launched IZCARGO®, a recombinant treatment for mucopolysaccharidosis II

Concluded an agreement with Takeda Pharmaceutical Company Limited for collaboration and commercialization of next-generation treatment for Hunter Syndrome

30 billion yen

**1993**

Launched GROWJECT® Inj. 4IU, a recombinant human growth hormone (hGH) product

**2003**

Concluded license agreement for mesenchymal stem cells (MSCs) with Osiris Therapeutics, Inc. (U.S.)\*

**2016**

Launched TEMCELL® HS Inj., the first allogeneic regenerative medical product in Japan

**2017**

Launched new liquid formulation of GROWJECT®, a recombinant hGH product  
Concluded a business capital alliance agreement with MEDIPAL HOLDINGS CORPORATION

**2020**

Acquired ArmaGen, Inc. (U.S.)

Commenced business activities at JCR DO BRASIL FARMACÊUTICOS IMPORTAÇÃO E EXPORTAÇÃO LTDA. (JCR DO BRASIL)

### Trends in net sales since 1975

(Consolidated figures are shown for FY2004 and subsequent years)

1975 1980 1985 1990 1995 2000 2005 2010 2015 (FY)

\* The licensor was changed to Mesoblast Group (Australia) in 2013, following the transfer of MSC-related rights from Osiris Therapeutics, Inc. to Mesoblast Group.

#### Established purification technology



Production at the time of foundation

#### Established technologies ranging from cell development to culture technologies



Production today

#### Entered the regenerative medical product field

JCR's history started from the production of "Urokinase," a urine-derived protein-degrading enzyme. JCR aims to evolve as a specialty pharma company that ambitiously develops drugs for rare diseases, which have been our target since our inception. We aim to develop these drugs with our proprietary biotechnologies, technologies for cell therapy and regenerative medicine, and gene therapy technologies.



# Key Topics for FY2021

For details, please refer to news releases found at the URL address listed under each topic.

## May 2021

---

### First Patient Dosed In Phase II Clinical Trial of JR-142, a Recombinant Long-Acting Growth Hormone

<https://ssl4.eir-parts.net/doc/4552/tdnet/1974225/00.pdf>

## May 2021

---

### NHI Reimbursement Price Listing and Sales Launch of IZCARGO® (JR-141) for Treatment Of MPS II in Japan

As a world first, sales of the first pharmaceutical using J-Brain Cargo® were launched in Japan.

<https://ssl4.eir-parts.net/doc/4552/tdnet/1974327/00.pdf>

## September 2021

---

### Concluded an Agreement with Takeda Pharmaceutical Company Limited for Collaboration and Commercialization of Next-Generation Treatment for Hunter Syndrome

<https://ssl4.eir-parts.net/doc/4552/tdnet/2028565/00.pdf>

## October 2021

---

### U.S. Food and Drug Administration (FDA) Grants Fast Track Designation for JR-171 for the Treatment of MPS I

<https://ssl4.eir-parts.net/doc/4552/tdnet/2029920/00.pdf>

## October 2021

---

### European Medicines Agency (EMA) Grants PRIME Designation for JR-141

<https://ssl4.eir-parts.net/doc/4552/tdnet/2033446/00.pdf>

## January 2022

---

### European Commission (EC) Grants Orphan Drug Designation to JR-441 for the Treatment of MPS IIIA

<https://ssl4.eir-parts.net/doc/4552/tdnet/2071282/00.pdf>

## February 2022

---

### JCR Receives the New Treatment Award at the WORLDSymposium™ 2022 for IZCARGO®

At an international annual research conference dedicated to lysosomal storage disorders (LSDs), JCR was evaluated for the marketing approval of IZCARGO® using J-Brain Cargo® in Japan and for its future potential.

<https://ssl4.eir-parts.net/doc/4552/tdnet/2076945/00.pdf>

## February 2022

---

### First Patient Dosed in Phase III Global Clinical Trial of JR-141

<https://ssl4.eir-parts.net/doc/4552/tdnet/2087202/00.pdf>

## March 2022

---

### Concluded Agreement Related to Market Alliance for Agalsidase Beta BS I.V. [JCR] for Treatment of Fabry Disease in Japan with Sumitomo Dainippon Pharma Co., Ltd. (currently Sumitomo Pharma Co., Ltd.)

<https://ssl4.eir-parts.net/doc/4552/tdnet/2091921/00.pdf>

## March 2022

---

### Initiated Development of New Drug Candidate (JR-479) for GM2 Gangliosidosis Using J-Brain Cargo®

<https://ssl4.eir-parts.net/doc/4552/tdnet/2097674/00.pdf>

## March 2022

---

### Acquisition of Non-Current Assets (Land)

Acquired land in Kobe Science Park to upgrade and expand JCR's drug substance manufacturing and finished product manufacturing facilities in order to simultaneously advance research and development of therapeutics for 17 types of LSDs currently being researched and developed.

<https://ssl4.eir-parts.net/doc/4552/tdnet/2098874/00.pdf>

## March 2022

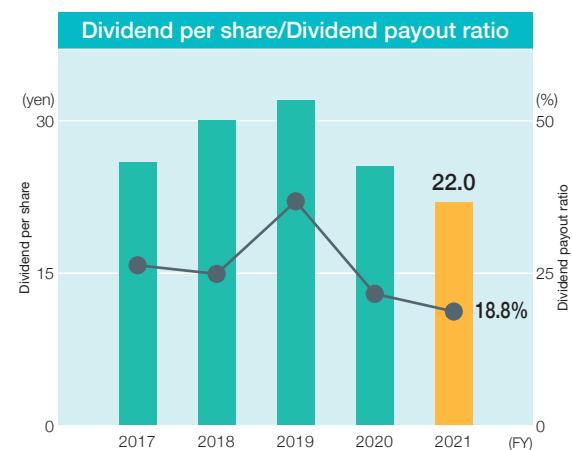
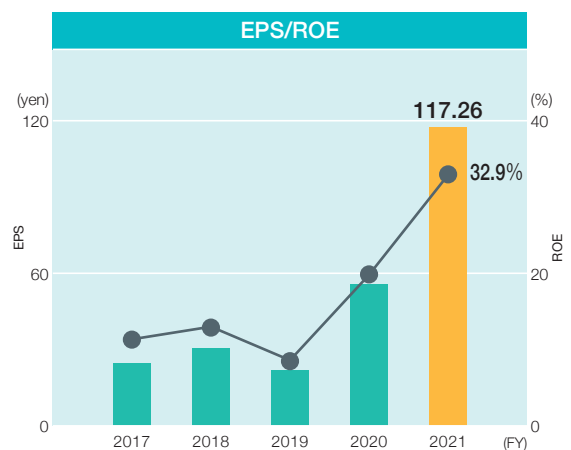
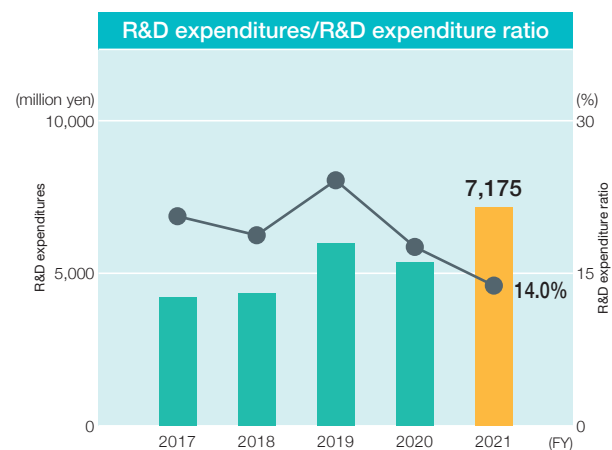
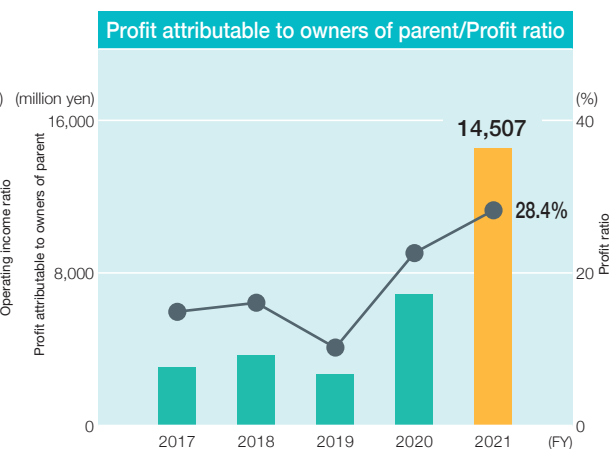
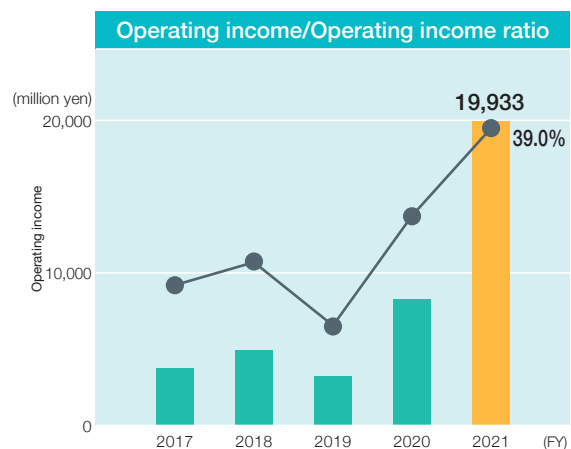
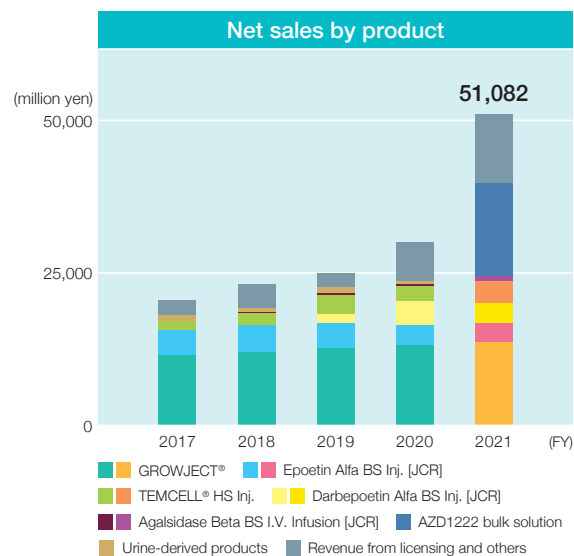
---

### Concluded a License and Collaboration Agreement with Takeda Pharmaceutical Company Limited to Develop Gene Therapies Using J-Brain Cargo® for LSDs

<https://ssl4.eir-parts.net/doc/4552/tdnet/2100005/00.pdf>

# Consolidated Financial and Non-Financial Highlights

JCR Pharmaceuticals Co., Ltd. and Subsidiaries



\* On October 1, 2020, JCR conducted a 4-for-1 stock split of its common shares. For information on EPS and dividend per share, please refer to the note on page 78.

Related pages

Sustainability

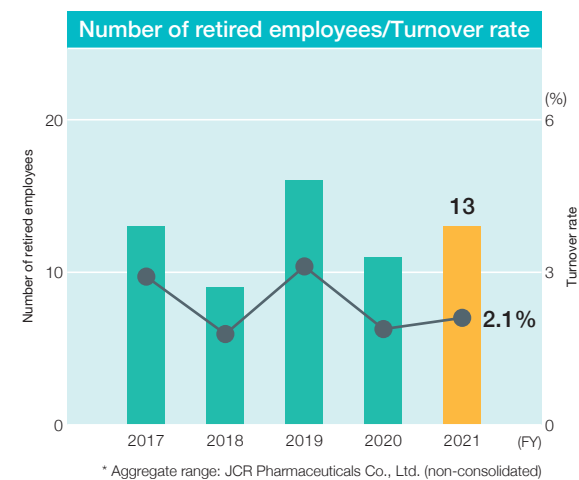
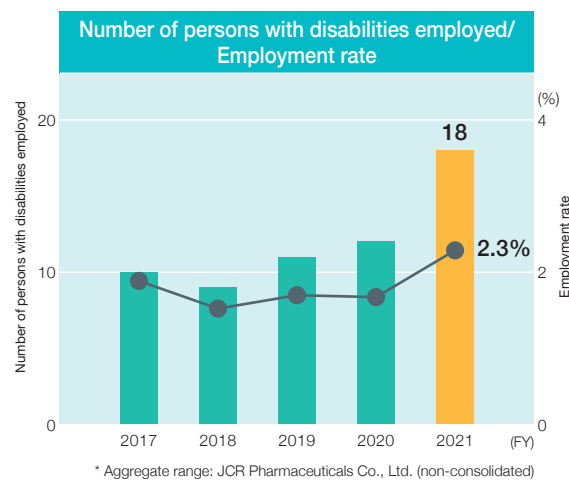
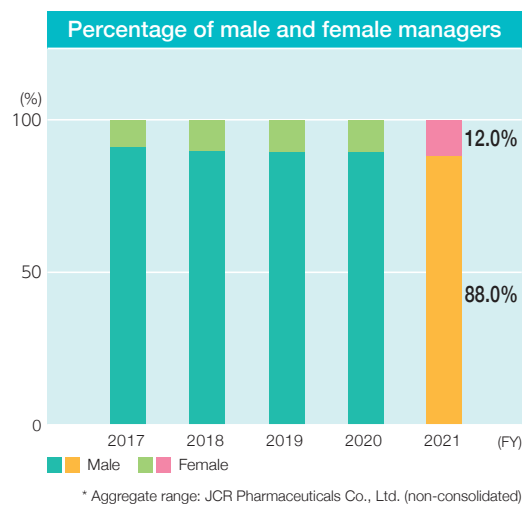
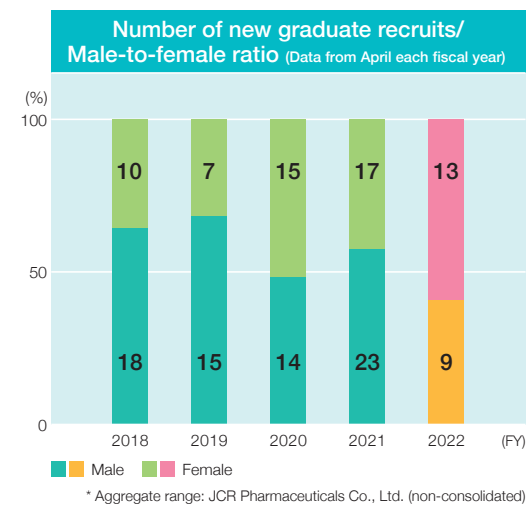
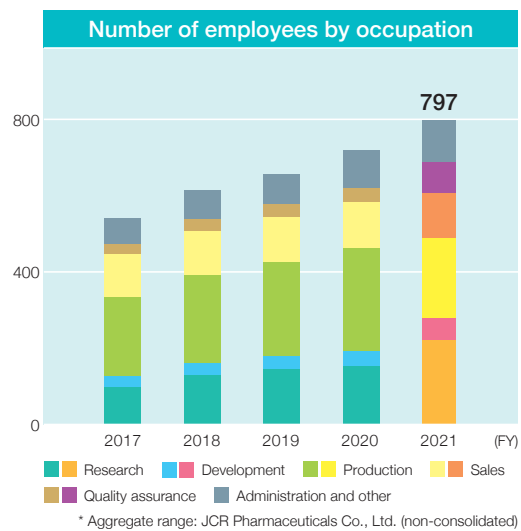
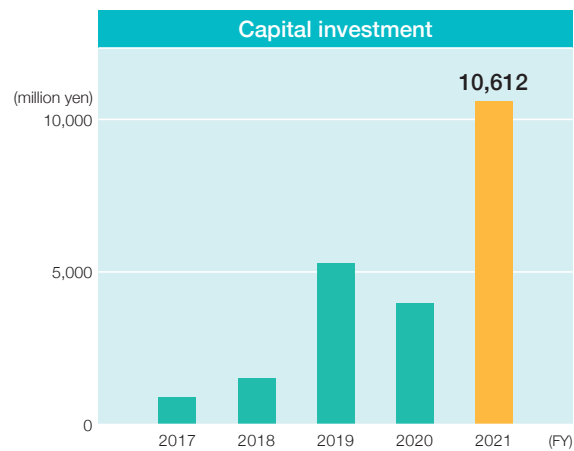
P.30

Financial Highlights

P.76

11-Year Financial Data

P.78





**JCR is ambitiously creating groundbreaking new medicines based on a widely shared aspiration in the Company to help patients with rare diseases around the world.**

### **Research and Development that Leverages JCR's Strengths**

Since its founding in 1975, JCR has focused on rare disease fields with high barriers to entry for other companies, and it has been pursuing research and development to address unmet medical needs in those fields.

We have been boldly tackling challenges by harnessing JCR's strengths, such as our advanced technologies and extensive experience and expertise in the field of biopharmaceuticals, and our entrepreneurial spirit, which we have fostered since our founding. As a result, JCR achieved the first-ever commercialization of the technology, J-Brain Cargo®, which delivers active ingredients directly to the brain. In 2021, JCR received marketing approval of JR-141 (product name: IZCARGO®) in Japan. JR-141 is a therapeutic enzyme that applies J-Brain Cargo® for the treatment of MPS II, which is a rare disease.

Following on from JR-141's success, JCR has been working to enhance its pipeline of therapeutics for lysosomal storage disorders (LSDs) that apply J-Brain Cargo®. In selecting development targets, JCR's basic policy is to advance the research and development of targets that have large numbers of patients in countries or regions where there are strong medical needs. We are accelerating commercialization globally to deliver groundbreaking new medicines to patients eagerly awaiting such treatments around the world as soon as possible.






JCR's strengths in research and development lie in its corporate culture, which gives each individual the freedom to pursue research based on a flexible and rapid decision-making process made possible by closeness between management and the frontlines, as well as its passion for manufacturing, which has been fostered since its founding. These strengths have been demonstrated through accomplishments such as the creation of TEMCELL® HS Inj., which is Japan's first allogeneic regenerative medical product, and contract manufacturing of the bulk solution of AstraZeneca's COVID-19 vaccine to JCR.

# Research and Development



## Development Pipeline and Progress (As of August 2022)

■ LSDs 
 ■ Other biopharmaceuticals 
 ■ Regenerative medical products

Code	Nonproprietary Name	Indication	Region	Preclinical	Clinical trials	Filed	Approved	Remarks
<b>JR-141</b>	BBB-penetrating iduronate-2-sulfatase (rDNA origin)	Mucopolysaccharidosis II (Hunter syndrome)	 Global	Phase III				Enzyme replacement therapy (ERT) J-Brain Cargo® <sup>*1</sup>
<b>JR-171</b>	BBB-penetrating α-L-iduronidase (rDNA origin)	Mucopolysaccharidosis I (Hurler syndrome, etc.)	 Global	Phase I/II				ERT J-Brain Cargo® J-MIG System® <sup>*2</sup>
<b>JR-162</b>	J-Brain Cargo®-applied acid α-glucosidase (rDNA origin)	Pompe disease	—	Preclinical				ERT J-Brain Cargo®
<b>JR-441</b>	BBB-penetrating heparan N-sulfatase (rDNA origin)	Mucopolysaccharidosis III-A (Sanfilippo syndrome type A)	—	Preclinical				ERT J-Brain Cargo®
<b>JR-443</b>	BBB-penetrating β-glucuronidase (rDNA origin)	Mucopolysaccharidosis VII (Sly syndrome)	—	Preclinical				ERT J-Brain Cargo®
<b>JR-446</b>	BBB-penetrating α-N-acetylglucosaminidase (rDNA origin)	Mucopolysaccharidosis III-B (Sanfilippo syndrome type B)	—	Preclinical				ERT J-Brain Cargo®
<b>JR-479</b>	BBB-penetrating β-Hexosaminidase A (rDNA origin)	GM2 gangliosidosis (Tay-Sachs disease, Sandhoff disease)	—	Preclinical				ERT J-Brain Cargo®
<b>JR-401X</b>	Somatropin (rDNA origin)	SHOX deficiency	 Japan	Filed				Expanded indication of GROWJECT®
<b>JR-142</b>	Long-acting growth hormone (rDNA origin)	Pediatric growth hormone deficiency	 Japan	Phase II				J-MIG System®
<b>JR-031HIE</b>	Human mesenchymal stem cells	Hypoxic ischemic encephalopathy in neonates	 Japan	Phase I/II				Expanded indication of TEMCELL® HS Inj.

\*1 Blood-brain barrier penetration technology \*2 CHO cell high-level expression technology

## Research and Development

### Future Research and Development Strategy

JCR will continue pursuing globalization in earnest by maintaining an organization led by a small group of specialists par excellence and focusing on R&D and manufacturing.

For development programs that will continue to be developed proprietarily, we will actively promote collaboration with partners who have enough resources

and capacity, which are constraints for JCR, as we enhance our footprint in Europe and the U.S. This process will accelerate commercialization globally.

In September 2021, JCR and Takeda entered into an exclusive collaboration and licensing agreement for JR-141, a therapeutic enzyme for MPS II, in specified regions around the globe. Combining JCR's unique technological capabilities and Takeda's extensive knowledge and solid sales network worldwide will drive

the global commercialization of JR-141 while maintaining JCR's strengths. In March 2022, JCR entered into a research and development collaboration and exclusive license agreement with Takeda to develop gene therapies that will apply J-Brain Cargo®, with LSDs as the priority area. Looking ahead, we will continue to explore the potential for application to a wide range of modalities through collaboration with other companies.



### Number of Patients and Size of Market for Seven LSDs

Indication	Status	Number of patients <sup>*1</sup>		Est. market size (2019) <sup>*2</sup>	
		Japan	Worldwide	Japan	Worldwide
MPS II: Hunter syndrome	Phase III	Approx. 250	Approx. 7,800	Approx. 7.6 billion yen	Approx. 87.0 billion yen
MPS I: Hurler syndrome etc.	Phase I/II	Approx. 60	Approx. 3,600	—	Approx. 70.0 billion yen
MPS III-A: Sanfilippo syndrome type A	Phase I (from FY2023)	Approx. 30 (AB total)	Approx. 4,000	—	>70.0 billion yen
MPS III-B: Sanfilippo syndrome type B	Phase I (from FY2023)		Approx. 1,800	—	
MPS VII: Sly syndrome	TBD	Several	Approx. 200	—	Approx. 9.8 billion yen
GM2 gangliosidosis	Phase I (from FY2025)	Approx. 30	—	—	—
Pompe disease	TBD	Approx. 80	Approx. 10,000	Approx. 3.0 billion yen	Approx. 110.0 billion yen

Source: JCR analysis <sup>\*1</sup> Number of patients: Calculated by JCR based on information published in the Ministry of Health, Labour and Welfare's research and others <sup>\*2</sup> Market size: Internal analysis

# Research and Development

In July 2022, JCR's Board of Directors resolved to subscribe to a third-party allotment of shares for Mycenax Biotech Inc. in Taiwan, thereby strengthening its ties with this company. Mycenax is a company that conducts a full-line contract development and manufacturing (CDMO) business\*, with a strong reputation in the process development and contract manufacturing of biopharmaceuticals. This measure will help JCR to solve its resource issues, enabling it to rapidly proceed with global clinical trials for several development candidates that are scheduled to take

place within the next few years.

Furthermore, we will emphasize our partnership with patient groups, which originally inspired the development of J-Brain Cargo®. We will identify needs through patient groups and keep in mind what JCR can accomplish for patients from the earliest stages of research, as we move forward with development. By doing so, we will continue our efforts to address unmet medical needs of patients through the discovery of innovative medicines.

By strengthening strategic partnerships, JCR will

address multiple pipelines while retaining an organizational structure that allows for flexible and rapid decision-making. Concurrently, JCR will work with its strategic partners to advance global commercialization and accelerate efforts to rapidly deliver innovative medicines to patients around the world.

\* A business that provides a comprehensive range of services from formulation development to investigational drug manufacturing and commercial production

## Message /



Since joining JCR in 2010, I've worked in the development and research departments as a project manager. Throughout the process, I've been reminded that the corporate culture of "Team JCR," which promotes collaboration among individuals and departments, is a critical strength for us. However, I believe that modernizing this "Team JCR" model will be essential to the future global development of our expanding pipelines. The increase in the number of employees and the compartmentalization of the organization have become obstacles to the team's agility in the past few years. Even in such a setting, each employee should consider what would actually serve the interests of patients beyond the constraints of their particular station and capitalize on the unique strengths of their individual backgrounds. I believe this will multiply the team's effectiveness and maximize its worth. In a tumultuous environment, we are determined to rapidly deliver new medicines, which are the culmination of JCR's R&D capabilities, to patients around the world. To that end, I'm certain that the "Team JCR" culture will be a driving force that we should continue to preserve into the future.

**Jun Tsushima**

Project Coordination Unit, Research Division



## **Our mission is to provide a stable supply of high-quality pharmaceuticals.**

JCR's quality policy is "At all stages of our products, we shall put patients and their families first and secure a stable supply of safe and high-quality products." Guided by this policy, we strive to ensure a stable supply of high-quality products.

JCR currently has four production sites in Nishi-ku, Kobe. Our production sites carry out the full-fledged manufacturing of pharmaceuticals from drug substances to finished products and regenerative medical products. We perform manufacturing under the appropriate manufacturing and quality controls in compliance with applicable laws and regulatory requirements, along with Good Manufacturing Practice (GMP) and Good Gene, Cellular, and Tissue-based Products Manufacturing Practice (GCTP).

For drug substance manufacturing, we utilize cutting-edge technologies including disposable culture vessels and single-use bioreactors. These technologies eliminate significant amounts of tank cleaning and sterilizing between product changeover and enable the efficient production of many different small volume drug substances for pharmaceuticals such as orphan drugs. Our unique production platform incorporates serum-free cultivation technology focused on the non-use of animal origin components.

In finished product manufacturing, the Kobe Plant manufactures finished products for all JCR pharmaceuticals delivered in Japan, such as our core product GROWJECT®, along with Epoetin Alfa BS Inj. [JCR], Agalsidase Beta BS I.V. Infusion [JCR], and IZCARGO®. For IZCARGO®, the Kobe Plant has assumed responsibility for all manufacturing employing the active pharmaceutical ingredients (APIs) supplied by JCR's API plant, ranging from manufacturing of experimental drugs to investigational drugs and final products on the market. Being involved from the initial stage of pharmaceutical development has made it possible for us to carry out production under the best possible conditions.

JCR's finished product plants possess facilities that enable them to carry out flexible manufacturing according to the scale of production. These plants can efficiently manufacture biosimilars such as Epoetin Alfa BS Inj. [JCR] and Darbepoetin Alfa BS Inj. [JCR], and many different pharmaceuticals in small volumes, such as orphan drugs.

# **Production System**



For TEMCELL® HS Inj., an allogeneic regenerative medical product, we have established a production system at the Seishin Plant that is capable of supplying this product to medical facilities throughout Japan.

We remain committed to maintaining and improving our production systems with advanced technologies and information to ensure stable and timely supply of high-quality and useful pharmaceuticals.

## Production Sites



### Seishin Plant

Regenerative medical products, medical devices

#### Main manufactured items

- TEMCELL® HS Inj.
- TWIN-JECTOR® EZ II, a medical device



### Murotani Plant

Active pharmaceutical ingredients (APIs)

#### Main manufactured items

- APIs for Epoetin Alfa BS Inj. [JCR]



### Kobe Plant

Finished products

#### Main manufactured items

- Finished products for all JCR pharmaceuticals (products in vials, lyophilized products, liquid products, and pre-filled syringe products)



### Kobe API Plant

APIs

#### Main manufactured items

- APIs for Agalsidase Beta BS I.V. Infusion [JCR], Darbepoetin Alfa BS Inj. [JCR] and IZCARGO®
- APIs for investigational products such as JR-141

◎ A new production site is currently under construction in Kobe Science Park (Nishi-ku, Kobe)

## Message



I joined JCR in 1986. Our plant was located in Higashinada-ku, Kobe, at the time and this was the year we began to relocate the plant to the Seishin Industrial Park in Nishi-ku. Since then, 36 years have passed. During this time, our products have evolved from a urine-derived protein-degrading enzyme to biopharmaceuticals. The Company has grown in size with each increase in product and development compound. I consider myself fortunate to have witnessed this growth firsthand.

In the Midterm Business Plan for FY2020-FY2022 “REVOLUTION,” JCR has identified six important business challenges. I believe that we have made significant progress particularly in “Transformation of operations and organizations along with human resource development.” I am encouraged to see ideas flowing freely in a comfortable and productive workplace environment, and to watch young employees growing rapidly and thriving in a variety of situations.

Looking ahead, I would like management, young staff, and experienced employees to continue working together as “Team JCR,” with the aim of making JCR a “research-oriented specialty pharma with global exposure.”

**Kiyoji Onishi**

Production Management Dept., Production Division



## JCR will reflect its new quality policy into its products and deliver them to patients.

The Quality Assurance Division comprises the Regulatory Affairs Dept., Pharmacovigilance Dept., and Quality Assurance Dept. The Quality Assurance Division is involved in the entire process from the pharmaceutical development stage to the approval and post-marketing stages. It conducts activities to supply products and information that are trusted by society as a whole, including patients and their families. In FY2022, JCR adopted a new quality policy. Guided by this policy, the Quality Assurance Division strives to provide even higher-quality, more reliable, and safer products.

In the development stage, the Regulatory Affairs Dept. prepares materials for applications together with each department based primarily on quality-related materials prepared by the Research Division and Development Division, and data obtained from pre-clinical and clinical trials. The department also works to address post-submission reviews and perform other duties. GCP\* audits are a duty essential to ensuring the reliability of clinical trial data for applications. After approval, the Regulatory Affairs Dept. conducts maintenance and management of regulatory approvals and manufacturing and marketing business, along with providing the necessary support to provide a stable supply of products.

The Pharmacovigilance Dept. gathers and manages safety information about investigational products and marketed items. The department evaluates the information it gathers while constantly considering the balance between benefits and risks. In order to ensure proper use, the department conducts communication activities to convey the evaluation results to the medical frontlines in a timely manner. In addition, as the department initiates safety monitoring activities as part of global clinical trials of development compounds, it conducts risk management based on an understanding of laws and regulations in each country and a constant awareness of the importance of collaboration worldwide.

The Quality Assurance Dept. assures the quality, effectiveness and safety of pharmaceuticals and regenerative medical products by confirming the entire process related to products, from the raw materials used to manufacturing, packaging, examination and testing, storage, and distribution management. It has an organizational structure that integrates quality assurance sections for production and marketing.

\* Ministerial orders concerning implementation standards for clinical trials of pharmaceuticals

# Quality Assurance

Under a unified quality assurance system, the department assures the high quality of JCR's proprietary products while maintaining close collaboration.

Strict compliance with laws and regulations is essential to ensuring the reliability of products and information. Each department has adopted Quality First as its shared principle and is working to implement "qualitative and quantitative reorganization of the quality assurance system," which is the top priority business challenge of the Midterm Business Plan for FY2020-FY2022 "REVOLUTION." Concurrently, each department is establishing a structure for compliance with laws and regulations and conducting activities to maintain and promote this compliance. By practicing strict compliance, JCR will assure the high quality of its products and provide safety and peace of mind to patients.

## Quality Policy

The corporate philosophy of JCR Pharmaceuticals Co., Ltd. is  
**"Contributing towards people's healthcare through pharmaceutical products."**

Under this philosophy, we will contribute to patients' well-being all over the world by adopting the following quality policy:

**At all stages of our products, we shall put patients and their families first and secure a stable supply of safe and high-quality products**

## Message



"JCR finally has more than 100 employees!" Those were my supervisor's words when I joined JCR as a new graduate. Around 25 years have passed since then. As JCR's products have evolved to encompass biological products, biosimilars, and regenerative medical products, the extent of laws and regulations that JCR must address has grown. I am very aware of the significance and stringency of safety monitoring as I monitor information on side effects and other issues on a daily basis. It brings me great joy to know that these steadfast efforts are being put to good use on the medical frontlines as information on proper use.

We recently implemented a new system and have been preparing to meet each country's regulatory requirements in accordance with globalization. When we first started, we were stumbling in the dark. However, members of our department have contributed their knowledge and ideas to this effort, making our work worthwhile every day. As I have worked at JCR, I've felt like something new is always on the horizon. "Team JCR" members are able to make the difficulties and surprises that come during this process enjoyable. I'm confident that our shared corporate culture has aided JCR's "REVOLUTION."

**Mariko Okada**

Pharmacovigilance Dept., Quality Assurance Division





## JCR will promote initiatives to achieve market penetration of IZCARGO® and drive sustained growth through digitalization, including existing products.

In May 2021, IZCARGO® was placed on the National Health Insurance (NHI) reimbursement price list, and it has been on the market for one year. IZCARGO® has been steadily penetrating the market, acting as a growth driver for JCR to accomplish its future milestones.

This product is JCR's first-ever pharmaceutical to apply J-Brain Cargo®, JCR's proprietary technology. It is a groundbreaking new medicine that allows therapeutic enzymes to penetrate the blood-brain barrier (BBB), thereby improving central nervous system symptoms and fulfilling unmet medical needs. The product has steadily gained acceptance by the medical frontlines. JCR will continue working to gather and provide information that will ensure the appropriate use of this product. It will also strive to promote further market penetration and awareness-raising activities. Through these measures, JCR will foster relationships of trust by supporting the needs of patients and their families, as well as medical professionals.

JCR's core product GROWJECT® continued to post growth in sales volume and market share, despite being impacted by a price reduction due to NHI price revisions and Japan's decline in the number of children. In August 2022, GROWJECTOR® L, the only electronically controlled injector available on the growth hormone product market in Japan, was upgraded to support Bluetooth. Through enhanced interfaces for the future and design changes made from the perspective of patients, GROWJECTOR® L now has the features needed to support the injections of patients almost every day while reducing their burden.

Melon Nikki™ is a dedicated smartphone app that links GROWJECTOR® L and smartphones. In August 2022, JCR released the iOS version of the app, following on from the Android version. JCR anticipates that this app expansion will help patients to support one another's treatment by, for example, enabling many more patients to participate in events that encourage them to continue their treatment and to interact with one another.



JCR will strive to improve added value in step with the times through such means as developing apps and providing information that help patients to continue their treatment. Through these efforts, JCR will seek to increase its market share further and achieve sustained, stable growth, with a view to establishing a solid management platform.

### Introduction of a New Customer Relationship Management (CRM) System

JCR has upgraded to a new CRM system as part of its “REVOLUTION” to raise efficiency through digital technologies. The new system not only visualizes the activities of medical representatives (MR), but it can also be used for human resources development through knowledge sharing. Moreover, the accumulation and analysis of various types of data enable JCR to provide highly accurate, optimal information to medical professionals.

Rare diseases are defined as one of JCR’s core areas. The number of medical professionals engaged in the

treatment and care of patients with rare diseases is limited because only a few patients have such diseases. In fact, there are many instances where adequate information on diseases cannot be obtained. JCR believes that the efficient supply and exchange of information among specialist doctors and from specialist to non-specialist doctors are crucial to ensuring that the interests of patients with rare diseases are not harmed. JCR will continue to use digital tools to conduct web seminars and related activities. It will advance plans to implement marketing strategies that will increase productivity through a hybrid approach that anticipates the post-pandemic era by combining digital and in-person marketing activities.

## Message



In meetings with doctors and other settings, I often hear that patients with rare diseases are concerned about a variety of issues as they receive daily care, owing to the scarcity of information about the symptoms, treatment methods, and other aspects of rare diseases in comparison to other disorders. Patients frequently express concerns such as “Will I ever recover from this illness?” and “How will I live my life in society from now on?”

As a JCR MR who works with orphan drugs, I would like to understand the feelings of patients and their families, conduct activities to gather and provide highly specialized information to medical professionals, and contribute to reducing the variety of treatment concerns that patients and their families may have. I feel great joy when I meet medical professionals and realize that these MR activities have contributed to the happiness of as many patients as possible, and such experiences lead to improved motivation.

“Team JCR” will continue to make a concerted effort to support the needs and desires of as many patients as possible.

**Haruna Uda**

Tokyo Metropolitan Area Sales Dept., Sales Division

## JCR will accelerate its global business in earnest through optimal and robust patent strategies.

The Intellectual Property Dept. conducts activities such as maintaining and managing patent applications and conducting patent office procedures, so that patent rights are established over the most extensive and effective scope of rights, with the aim of protecting the inventions and products created by JCR as intellectual property. Eyeing global business expansion in the future, JCR has filed patent applications in many countries and regions. Patent reviews are undertaken independently in each country and patent systems can vary with the country. For this reason, the department considers the need to establish optimal patent rights for each country as it performs its duties.

In the development of new drugs, there are many cases where individual patent rights have a direct bearing on the protection of products. It is absolutely essential to build a defensive wall with patents that can withstand lawsuits brought by third parties. Planning for the creation of such a defensive wall requires sophisticated strategies. JCR not only has numerous new drug development projects that are expected to lead to product launches, but it is also creates new technologies and discovers new substances on a daily basis at the Research Institute. The importance of acquiring robust patent rights to safeguard new technologies and products has only increased over time.

Keeping this in mind, the Intellectual Property Dept. is working to establish wide-ranging intellectual property rights that will, for example, protect multiple substances with a single patent. To protect each project, the department files strategic patent applications based on careful consideration of the content and timing of patent applications to ensure that several patents function in a variety of ways on multiple levels and the protection period for those patents is as long as possible. Furthermore, the department examines the patent application filing status of peer companies in the same industry so that filing patent applications does not breach the scope of rights of the existing technologies of other companies, or so that it establishes intellectual property rights ahead of other companies. This strategy has produced results. In the past few years, JCR has entered into alliances with other companies based on

In FY2021, JCR and Takeda entered into an exclusive collaboration and license agreement for JR-141, a therapeutic enzyme for MPS II, in specified regions around the world. In addition, JCR and Takeda entered into a research and development collaboration and exclusive license agreement to develop gene therapies using J-Brain Cargo® technology for lysosomal storage disorders (LSDs). With optimal and robust patent strategies, the Intellectual Property Dept. will support the promotion of JCR's global business expansion in earnest.

There are now a number of new projects that are extensions of those existing technologies. Another duty of the Intellectual Property Dept. is to effectively establish intellectual property rights for these projects. However, there is more. Throughout the period covered by the Midterm Business Plan for FY2020-2022 "REVOLUTION," the Research Institute has been creating a steady stream of entirely new technologies and inventions that anticipate what lies beyond the plan. In response to this innovation, our patent strategies have become increasingly sophisticated and complex.

Akira Kobayashi

JCR Report 2022 71

Looking toward global business expansion, JCR is developing workplaces where every employee can work and remain highly motivated.

In response to rapid global business expansion, the JCR Group's number of employees reached 816 as of the end of FY2021, marking an increase of around 300 employees in comparison to FY2015, the first year of the previous midterm business plan. Meanwhile, to maintain and develop the "Team JCR" corporate culture, JCR must prioritize human capital even more than before, while working to secure highly diverse human resources. JCR believes that it must create an organization where every employee who empathizes with JCR's corporate culture can achieve growth while having a high level of job satisfaction.

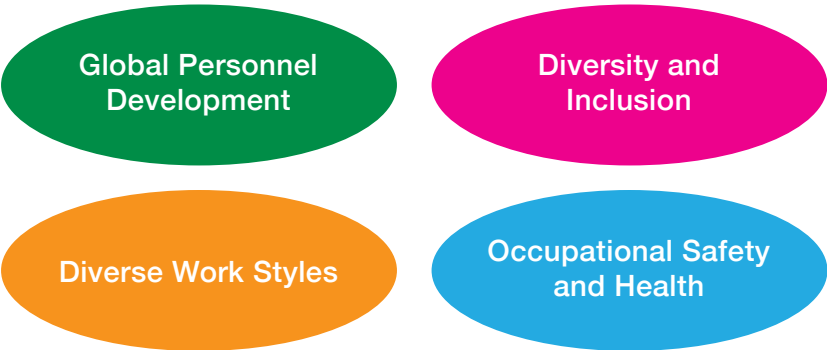
Based on the basic stance described above, JCR is implementing a wide range of initiatives to address the core issues in its human resources "REVOLUTION." These issues are

global personnel development, diversity and inclusion, diverse work styles, and occupational safety and health. Notably, we believe that the development of next-generation global leaders who will vigorously drive JCR's future is an urgent priority. As a new initiative, we will help every "Team JCR" member to achieve further growth, through measures such as the launch of JCR Academy, which is a program for acquiring new skills as global leaders, and concentrating efforts on English language training. JCR is also implementing key measures in other areas. One of its goals is to secure diverse human resources who are a good fit with JCR's values even while the Company grows rapidly. To this end, we have started implementing referral recruitment (recruitment via employee referrals) to bring onboard personnel

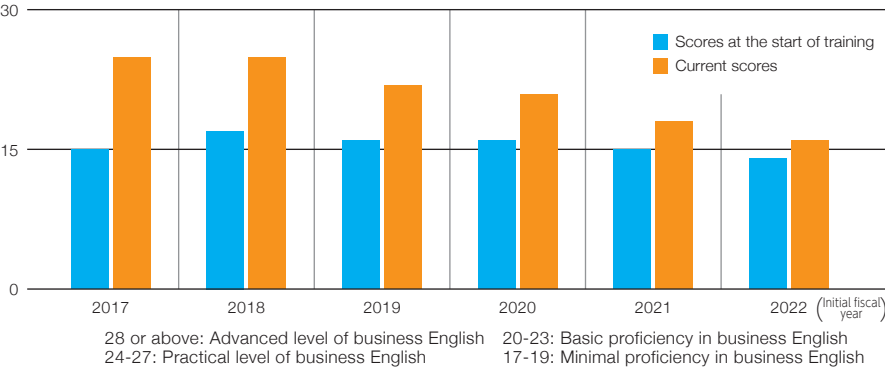
who can empathize with JCR's corporate culture, in addition to using existing methods of new graduate and mid-career recruitment. As part of efforts to foster diverse work styles, we are expanding the flextime system in the Production Division, which was considered difficult to introduce. As a workplace development measure, we are improving employee access to corporate programs by creating an in-house frequently asked questions (FAQs) list. In these and other ways, we are pushing ahead with activities to improve core issues on a daily basis.

Going forward, we will continue to listen closely to the voices of employees, even in a period of accelerated globalization and rapid business expansion. Our goal is to create a robust organization for "Team JCR."

Core Issues in the Human Resources "REVOLUTION"



Growth in Test Scores of English Language Training Participants (Comparison of Scores at the Start of Training and Current Scores)





### Through an information system “REVOLUTION,” JCR supports overall business activities that seek to make the Company a “research-oriented specialty pharma with global exposure.”

JCR is pushing ahead with an information system “REVOLUTION” while ensuring security. In doing so, we strive to always keep a Company-wide perspective, not just to simply pursue short-term efficiency, with our sights set on the business expansion that will follow our full globalization.

In 2015, we overhauled our core mission-critical system by introducing a virtualized platform that allowed us to achieve overall optimization by centralizing and integrating multiple servers. This measure was taken to improve our previously inefficient data infrastructure environment, which had been operated with servers installed at each site. In 2016, we transitioned our virtualized platform to a

data center, as part of efforts to improve operational stability and security management.

In 2019, JCR revamped its internal network, switching from desktop to notebook computers, in response to increases in the numbers of sites and employees. Additionally, addressing remote work has also become an urgent priority in light of further advances in global business expansion and the need to prevent the spread of COVID-19. Therefore, JCR worked to develop a remote work-friendly environment by taking steps such as introducing Web conferencing systems and various cloud services. Furthermore, as part of its measures to address globalization, JCR has introduced Microsoft 365, which

can be used with ease to access Web conferencing and Office products, while also offering a high security level.

Previously, JCR operated a variety of systems that it could not interconnect with one another, resulting in multiple divisions duplicating the entry and management of the same data. To improve this situation, JCR introduced SAP, a shared system across all divisions, to unify the management of business processes within the Company. With the introduction of SAP, JCR will be able to grasp information about resources in real time and rapidly assess situations. We believe that this will lead to an increase in management agility.





### Recombinant human growth hormone product

## GROWJECT®

GROWJECT® was approved for manufacture and marketing in 1993. It is a pharmaceutical indicated for the treatment of disorders such as pediatric short stature caused by the deficiency of growth hormone. In January 2017, we launched a new liquid formulation that does not require the dissolving step that was needed with the existing lyophilized formulation, along with the third generation of dedicated electronically controlled injectors, GROWJECTOR® L. In this manner, we provide a wide range of treatment options for growth disorders.

#### [Indications]

- Growth hormone deficiency
- Turner syndrome
- Adult growth hormone deficiency
- Small for gestational age



### Recombinant treatment for mucopolysaccharidosis II

## IZCARGO®

In May 2021, JCR launched IZCARGO® as a treatment for mucopolysaccharidosis II (Hunter syndrome). IZCARGO® is the world's first-ever approved enzyme replacement treatment (ERT) to apply JCR's proprietary J-Brain Cargo® blood-brain barrier (BBB) penetration technology. It is the world's first treatment of its kind that penetrates the BBB via intravenous administration, acting directly on parenchymal brain cells, in addition to demonstrating effectiveness against systemic symptoms. By acting directly on the parenchymal brain cells, IZCARGO® is expected to alleviate or suppress the progression of central nervous system symptoms.

#### [Indication]

- Mucopolysaccharidosis II



### Human somatic stem cell-processed products

### Human (allogeneic) bone marrow-derived mesenchymal stem cells

## TEMCELL® HS Inj.

In February 2016, JCR launched TEMCELL® HS Inj., the world's first product of its kind. It is a treatment of acute graft-versus-host disease (GVHD), which is a severe complication arising from hematopoietic stem cell transplantation. TEMCELL® HS Inj. is Japan's first allogeneic regenerative medical product manufactured by isolating and expanding mesenchymal stem cells derived from the bone marrow aspirate of a healthy adult donor, along with utilizing the function of the mesenchymal stem cells.

#### [Indication]

- Acute GVHD following hematopoietic stem cell transplantation



## Therapeutic Products for Renal Anemia

### Recombinant erythropoietin product

## Epoetin Alfa BS Inj. [JCR]\*

Epoetin Alfa BS Inj. [JCR] was developed utilizing our serum-free technology and proprietary biotechnologies. The product was launched in May 2010 as the first domestically produced biosimilar. There are growing needs for highly cost-effective biosimilars for dialysis treatment, where the cost is controlled by the flat sum reimbursement system.

### [Indications]

- Renal anemia in dialysis patients
- Anemia of prematurity



### Long-acting erythropoiesis-stimulating agent

## Darbepoetin Alfa BS Inj. [JCR]\*

In November 2019, JCR launched Darbepoetin Alfa BS Inj. [JCR], a biosimilar developed based on experience gained through Epoetin Alfa BS Inj. [JCR]. By supplying this product as a new treatment option for renal anemia, JCR believes that it can have an even greater impact on healthcare.

### [Indication]

- Renal anemia

\* These products were developed jointly with Kissei Pharmaceutical Co., Ltd. JCR manufactures it while Kissei Pharmaceutical provides medical information to medical institutions and conducts marketing activities.



### Recombinant treatment for Fabry disease

## Agalsidase Beta BS I.V. Infusion [JCR]\*

Agalsidase Beta BS I.V. Infusion [JCR] is JCR's first enzyme replacement therapy (ERT) for lysosomal storage disorders (LSDs) and the first domestically produced ERT product for LSDs. JCR launched this product in November 2018. JCR has realized high-quality manufacturing through its serum-free culture technology and will strive to increase market penetration of this product as a new treatment option for Fabry disease.

### [Indication]

- Fabry disease

\* On March 1, 2022, JCR and Sumitomo Dainippon Pharma Co., Ltd. (currently Sumitomo Pharma Co., Ltd.) concluded an agreement regarding a marketing alliance in Japan. Based on this agreement, from April 1, 2022, Sumitomo Pharma Co., Ltd. has engaged in the information dissemination activities for this product.

# Financial Highlights

## Operating Results

### Net Sales

Sales volume of our recombinant human growth hormone product GROWJECT® increased, but sales were affected by National Health Insurance (NHI) price revisions in April 2021. Although sales of therapeutic products for renal anemia decreased significantly because of similar NHI price revisions, there was a substantial contribution to sales from IZCARGO®, a recombinant treatment for MPS II, which was placed on the NHI reimbursement price list in May 2021. As a result, total net sales of our mainstay products increased year on year.

Moreover, JCR was contracted by AstraZeneca to carry out the domestic production of the bulk solution for its COVID-19 vaccine AZD1222. Furthermore, revenue from licensing increased year on year. As a result, JCR Group's net sales for FY2021 amounted to 51,082 million yen (69.8% increase from the previous fiscal year), marking the tenth straight year of sales growth and record-high sales.

#### Trend of Sales by Product

(Unit: Million yen)

	FY2020	FY2021
GROWJECT®	13,256	12,945
IZCARGO®	—	3,003
TEMCELL® HS Inj.	2,441	3,497
Epoetin Alfa BS Inj. JCR	3,278	2,876
Darbepoetin Alfa BS Inj. [JCR]	3,809	2,998
Agalsidase Beta BS I.V. Infusion [JCR]	470	711
AZD1222 bulk solution	404	14,375
Revenue from licensing	6,406	10,571
Others	19	102
Total	30,085	51,082

## Gross Profit

Due to the increase in net sales, gross profit increased 82.4% from the previous fiscal year to 40,620 million yen. As a result of the increase in revenue from licensing, the cost of sales ratio improved 5.5 percentage points from FY2020 to 20.5%.

## Operating Income

JCR conducted proactive R&D activities and development activities in line with progress on clinical trials, resulting in an increase in R&D expenditures of 33.9% from FY2020, and selling, general and administrative expenses, including R&D expenditures, were 20,686 million yen, up 47.7% from the previous fiscal year. As a result, operating income increased 141.1% year on year to 19,933 million yen.

## Ordinary Income

JCR recorded non-operating income, primarily foreign exchange gains. As a result, ordinary income increased 141.6% year on year to 20,512 million yen.

## Profit Attributable to Owners of Parent

Extraordinary losses were 1,108 million yen, an increase of 1,103 million yen year on year, mainly due to factors such as the recording of loss on cancellation of contracts. As a result of the foregoing, income before income taxes was 19,404 million yen, up 124.2% year on year. Profit attributable to owners of parent rose 110.5% year on year to 14,507 million yen.

## Financial Position

### Assets

Total assets as of March 31, 2022 stood at 97,134 million yen, an increase of 23,349 million yen from March 31, 2021.

Current assets rose 13,642 million yen from a year earlier to 62,188 million yen. This increase was mainly due to an increase in cash and deposits and notes and accounts receivable – trade, and contract assets. Non-current assets increased 9,707 million yen from a year ago to 34,946 million yen. This increase was mainly due to an increase in property, plant and equipment.

### Liabilities

Total liabilities as of March 31, 2022 stood at 46,045 million yen, an increase of 10,817 million yen from March 31, 2021.

Current liabilities rose 13,025 million yen from a year earlier to 42,054 million yen. This increase was mainly due to increases in income taxes payable and special suspense account for tax purpose reduction entry. Non-current liabilities decreased 2,208 million yen from March 31, 2021 to 3,990 million yen. This decrease was mainly due to a decrease in long-term loans payable.

### Net Assets

Net assets rose 12,531 million yen from March 31, 2021 to 51,089 million yen. This increase was mainly due to the recording of profit attributable to owners of parent, while there was a payment of dividends.

As a result, the equity ratio as of March 31, 2022 was 51.8%, up 0.5 percentage point from March 31, 2021.



## Cash Flow

Net cash provided by operating activities in FY2021 amounted to 9,289 million yen, a decrease of 1,052 million yen from the previous fiscal year. The main components were income before income taxes of 19,404 million yen, while there was an increase in notes and accounts receivable - trade of 7,402 million yen and income taxes paid of 2,517 million yen.

Net cash used in investing activities amounted to 3,250 million yen (a decrease of 40 million yen from net cash used in the previous fiscal year). Cash was used mainly for the purchase of property, plant, and equipment of 11,333 million yen, while there were subsidies received of 8,167 million yen.

Net cash used in financing activities amounted to 2,179 million yen (an increase of 10,483 million yen in cash used in comparison to cash provided in the previous fiscal year). The main use of cash was cash dividends paid of 2,169 million yen.

## Forecast for FY2022

In terms of sales, we anticipate an increase in sales of IZCARGO®, a recombinant treatment for MPS II on top of a steady increase in sales volume, and we will continue our proactive efforts in the licensing business. As a result of the completion of the contract with AstraZeneca to carry out domestic production of the bulk solution for its COVID-19 vaccine, the JCR Group's overall sales are forecast to decrease by 11.9% from the current year to 45,000 million yen. However, sales of our core products, including GROWJECT®, are expected to continue increasing, following on from FY2021.

On the earnings front, over the next several years, we project active investment in R&D activities, which we regard as a critical element in further advancing our business. In addition to an increase in R&D expenditures, gross profit is forecast to decrease in line with the decline

in sales from the completion of the contract with AstraZeneca to carry out domestic production of the bulk solution for its COVID-19 vaccine. Based on this outlook, we anticipate operating income of 14,500 million yen, down 27.3% from the current fiscal year. Ordinary income is forecast to decrease 29.3% year on year to 14,500 million yen. Profit attributable to owners of parent is forecast at 10,300 million yen, a decrease of 29.0% from the current fiscal year.

## Dividends Policy

### Basic Policy on Profit Distribution and Dividends

JCR regards returning profits to shareholders as an important management policy.

Our basic policy on matters pertaining to setting dividends of surplus is to pay out continuous and stable dividends. In doing so, management takes into account factors such as business performance and cash flow while securing sufficient internal reserves for the development of new drugs and the strengthening of our enterprise, both of which will be sources of future profits.

In accordance with Article 459, Paragraph 1 of the Companies Act, JCR has decided that it may provide dividends of surplus and interim dividends based on a Board of Directors' resolution. As our basic policy, we offer dividends twice a year as the interim dividend and the term-end dividend.

Given that we achieved record-high operating results in FY2021, we have resolved to pay a special dividend of 2 yen per share for the term-end dividend for FY2021. Under the above basic policy, we will pay out a term-end dividend for FY2021 of 12 yen per share (including the special dividend of 2 yen per share). JCR conducted a 4-for-1 stock split of its common shares on October 1, 2020. Assuming that the stock split was conducted at the beginning of FY2020, the full-year dividend would be 12

yen per share for FY2020 and 22 yen per share for FY2021, comprising an interim dividend of 10 yen and a term-end dividend of 12 yen. The full-year dividend for FY2021 thus represents an increase of 10 yen from the previous fiscal year.

Internal reserves will be effectively used to fund efforts to strengthen our enterprise, sustainably increase revenue, and return profits to shareholders.

We expect to pay out a full-year dividend for FY2022 (the term ending March 2023) of 20 yen per share, comprising an interim dividend and term-end dividend of 10 yen each.

# 11-Year Financial Data

Consolidated fiscal years ended March 31

	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020	(Millions of yen) FY2021
<b>Fiscal year</b>											
Net sales	12,845	14,099	15,705	16,855	17,438	18,085	20,594	23,160	24,781	30,085	<b>51,082</b>
Operating income	1,089	1,150	1,545	2,014	2,152	2,362	3,784	4,967	3,244	8,269	<b>19,933</b>
Profit attributable to owners of parent	633	730	1,296	1,682	1,789	1,863	3,070	3,715	2,678	6,892	<b>14,507</b>
Comprehensive income	664	1,161	1,544	1,936	1,557	1,831	3,016	4,008	2,504	6,841	<b>14,514</b>
R&D expenditures	1,841	1,991	2,202	3,334	3,348	4,071	4,211	4,354	5,997	5,360	<b>7,175</b>
Capital investment	487	1,494	2,260	1,522	1,237	1,409	908	1,517	5,296	3,965	<b>10,612</b>
Depreciation and amortization	1,101	979	1,111	1,352	1,407	1,447	1,382	1,343	1,434	1,892	<b>1,945</b>
Cash flows from operating activities	(421)	1,661	4,565	499	2,201	2,651	3,133	3,905	4,927	10,341	<b>9,289</b>
Cash flows from investing activities	1,539	(178)	(2,668)	(1,419)	(980)	(841)	(1,587)	240	(4,161)	(3,290)	<b>(3,250)</b>
Cash flows from financing activities	(1,065)	(238)	(369)	(1,261)	(1,314)	146	(2,175)	(917)	2,048	8,304	<b>(2,179)</b>
<b>End of fiscal year</b>											
Total assets	28,967	31,286	33,464	34,086	35,346	36,385	38,398	42,516	47,775	73,784	<b>97,134</b>
Net assets	22,633	23,496	24,580	26,264	27,062	27,585	27,528	30,874	32,579	38,557	<b>51,089</b>
Shareholders' equity	22,535	23,368	24,417	26,101	26,819	27,305	26,999	30,249	31,806	37,864	<b>50,316</b>

	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020	(Yen) FY2021
<b>Information per share</b>											
Earnings per share (EPS)	4.94	5.76	10.20	13.21	14.03	14.74	24.68	30.17	21.72	55.81	<b>117.26</b>
Net assets	177.70	183.97	192.03	204.66	210.84	216.17	219.46	245.54	257.92	306.31	<b>406.57</b>
Dividends	12.00	12.00	17.00	18.50	22.00	22.00	26.00	30.00	32.00	25.50	<b>22.00</b>
<b>Financial indicators</b>											
Equity ratio (%)	77.8	74.7	73.0	76.6	75.9	75.0	70.3	71.1	66.6	51.3	<b>51.8</b>
Return on equity (ROE) (%)	2.8	3.2	5.4	6.6	6.8	6.9	11.3	13.0	8.6	19.8	<b>32.9</b>
Dividend payout ratio (%)	60.8	52.1	41.7	35.0	39.2	37.3	26.3	24.9	36.8	21.5	<b>18.8</b>
Numbers of employees	424	437	472	501	526	566	568	632	667	732	<b>816</b>

Note: On October 1, 2020, the Company conducted a 4-for-1 stock split of its common shares. Calculations of earnings per share (EPS) and net assets under information per share are based on the assumption that the stock split was conducted at the beginning of FY2011. Dividends for FY2019 and prior fiscal years under information per share represent the amount of dividends before the stock split.

In addition, the amount of dividends for FY2020 under information per share represents the sum of the interim dividend per share of 18.00 yen before the stock split and the term-end dividend per share of 7.50 yen after the stock split. Dividends for FY2021 under information per share represent the amount of dividends after the stock split.

# Consolidated Financial Statements

(Millions of yen)

## Consolidated Balance Sheets

	As of March 31, 2021	As of March 31, 2022
<b>Assets</b>		
Current assets		
Cash and deposits	26,260	<b>30,733</b>
Notes and accounts receivable – trade, and contract assets	8,183	<b>15,585</b>
Securities	—	<b>244</b>
Merchandise and finished goods	1,367	<b>2,121</b>
Work in process	3,538	<b>5,024</b>
Raw materials and supplies	8,649	<b>7,491</b>
Other	546	<b>986</b>
Total current assets	48,545	<b>62,188</b>
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	6,295	<b>6,086</b>
Machinery, equipment and vehicles, net	1,282	<b>1,308</b>
Land	7,663	<b>10,379</b>
Construction in progress	841	<b>8,019</b>
Other, net	1,088	<b>989</b>
Total property, plant and equipment	17,172	<b>26,782</b>

Intangible assets		
Patent right	2,988	<b>2,711</b>
Other	244	<b>249</b>
Total intangible assets	3,232	<b>2,960</b>
Investments and other assets		
Investment securities	2,572	<b>2,230</b>
Retirement benefit asset	225	<b>213</b>
Deferred tax assets	1,739	<b>2,433</b>
Other	300	<b>330</b>
Allowance for doubtful accounts	(4)	<b>(4)</b>
Total investments and other assets	4,833	<b>5,202</b>
Total non-current assets	25,238	<b>34,946</b>
Total assets	73,784	<b>97,134</b>



(Millions of yen)

	As of March 31, 2021	As of March 31, 2022
<b>Liabilities</b>		
Current liabilities		
Notes and accounts payable-trade	2,932	<b>1,324</b>
Short-term loans payable	12,850	<b>15,150</b>
Accounts payable-other	2,295	<b>5,189</b>
Income taxes payable	2,646	<b>5,915</b>
Special suspense account for tax purpose reduction entry	3,828	<b>11,996</b>
Provision for bonuses	850	<b>902</b>
Provision for bonuses for directors	63	<b>102</b>
Other	3,560	<b>1,473</b>
Total current liabilities	29,028	<b>42,054</b>
Non-current liabilities		
Bonds payable	500	<b>500</b>
Long-term borrowings	4,750	<b>2,450</b>
Allowance for employee stock ownership benefits	62	<b>78</b>
Retirement benefit liability	798	<b>870</b>
Other	88	<b>92</b>
Total non-current liabilities	6,199	<b>3,990</b>
Total liabilities	35,227	<b>46,045</b>

<b>Net assets</b>		
Shareholders' equity		
Share capital	9,061	<b>9,061</b>
Capital surplus	10,941	<b>10,994</b>
Retained earnings	20,904	<b>33,241</b>
Treasury shares	(3,685)	<b>(3,600)</b>
Total shareholders' equity	37,222	<b>49,697</b>
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	691	<b>619</b>
Deferred gains or losses on hedges	0	<b>0</b>
Foreign currency translation adjustment	(18)	<b>30</b>
Remeasurements of defined benefit plans	(31)	<b>(32)</b>
Total accumulated other comprehensive income	641	<b>618</b>
Share acquisition rights	517	<b>567</b>
Non-controlling interests	174	<b>205</b>
Total net assets	38,557	<b>51,089</b>
Total liabilities and net assets	73,784	<b>97,134</b>

# Consolidated Financial Statements

(Millions of yen)

## Consolidated Statements of Income

	FY2020 (From April 1, 2020 to March 31, 2021)	FY2021 (From April 1, 2021 to March 31, 2022)
Net sales	30,085	51,082
Cost of sales	7,812	10,461
Gross profit	22,272	40,620
Selling, general and administrative expenses	14,003	20,686
Operating income	8,269	19,933
Non-operating income		
Interest income	7	7
Dividend income	25	28
Foreign exchange gains	206	551
Other	65	68
Total non-operating income	305	656
Non-operating expenses		
Interest expenses	42	45
Commission expenses	11	12
Other	31	18
Total non-operating expenses	85	77
Ordinary income	8,488	20,512
Extraordinary income		
Gain on liquidation of subsidiaries and associates	22	—
Reversal of provision for loss on guarantees	108	—
Reversal of allowance for doubtful accounts	19	—
Reversal of losses related to voluntary recall	19	—
Gains on sale of investment securities	—	0
Total extraordinary income	170	0

Extraordinary losses		
Loss on disposal of non-current assets	5	2
Loss on cancellation of contracts	—	1,000
Other	—	105
Total extraordinary losses	5	1,108
Profit before income taxes	8,653	19,404
Income taxes – current	2,836	5,549
Income taxes – deferred	(1,072)	(663)
Total income taxes	1,764	4,886
Profit	6,888	14,517
Profit (loss) attributable to non-controlling interests	(4)	10
Profit attributable to owners of parent	6,892	14,507

## Consolidated Statements of Comprehensive Income

Profit	6,888	14,517
Other comprehensive income		
Valuation difference on available-for-sale securities	107	(71)
Deferred gains or losses on hedges	0	0
Foreign currency translation adjustment	(162)	68
Remeasurements of defined benefit plans, net of tax	7	(0)
Total other comprehensive income	(47)	(3)
Comprehensive income	6,841	14,514
(Comprehensive income attributable to)		
Comprehensive income attributable to owners of parent	6,855	14,483
Comprehensive income attributable to non-controlling interests	(14)	31

## Consolidated Statements of Changes in Net Assets

(Millions of yen)

From April 1, 2020 to March 31, 2021	Net assets												
	Shareholders' equity					Accumulated other comprehensive income							
	Share capital	Capital surplus	Retained earnings	Treasury shares	Total shareholders' equity	Valuation difference on available-for-sale securities	Deferred gains or losses on hedges	Foreign currency translation adjustment	Remeasurements of defined benefit plans	Total accumulated other comprehensive income	Stock acquisition rights	Non-controlling interests	Total net assets
Beginning balance	9,061	10,891	15,039	(3,865)	31,127	583	—	134	(39)	679	584	189	32,579
Changes during period													
Dividends of surplus			(1,083)		(1,083)								(1,083)
Profit attributable to owners of parent			6,892		6,892								6,892
Purchase of treasury shares				(0)	(0)								(0)
Disposal of treasury shares		49		181	230								230
Purchase of shares of consolidated subsidiaries		1	55		56								56
Net changes in items other than shareholders' equity						107	0	(152)	7	(37)	(66)	(14)	(118)
Total changes during period	—	50	5,865	180	6,095	107	0	(152)	7	(37)	(66)	(14)	5,977
Ending balance	9,061	10,941	20,904	(3,685)	37,222	691	0	(18)	(31)	641	517	174	38,557

(Millions of yen)

From April 1, 2021 to March 31, 2022	Net assets												
	Shareholders' equity					Accumulated other comprehensive income							
	Share capital	Capital surplus	Retained earnings	Treasury shares	Total shareholders' equity	Valuation difference on available-for-sale securities	Deferred gains or losses on hedges	Foreign currency translation adjustment	Remeasurements of defined benefit plans	Total accumulated other comprehensive income	Stock acquisition rights	Non-controlling interests	Total net assets
Beginning balance	9,061	10,941	20,904	(3,685)	37,222	691	0	(18)	(31)	641	517	174	38,557
Changes during period													
Dividends of surplus			(2,170)		(2,170)								(2,170)
Profit attributable to owners of parent			14,507		14,507								14,507
Disposal of treasury shares		53		85	138								138
Net changes in items other than shareholders' equity						(71)	0	48	(0)	(23)	49	30	56
Total changes during period	—	53	12,336	85	12,475	(71)	0	48	(0)	(23)	49	30	12,531
Ending balance	9,061	10,994	33,241	(3,600)	49,697	619	0	30	(32)	618	567	205	51,089

# Consolidated Financial Statements

(Millions of yen)

## Consolidated Statements of Cash Flows

FY2020  
(From April 1, 2020  
to March 31, 2021)

FY2021  
(From April 1, 2021  
to March 31, 2022)

### Cash flows from operating activities

Profit before income taxes	8,653	<b>19,404</b>
Depreciation	1,892	<b>1,945</b>
Increase (decrease) in provision for loss on guarantees	(108)	<b>—</b>
Increase (decrease) in retirement benefit liability	74	<b>74</b>
Increase (decrease) in provision for bonuses	137	<b>51</b>
Share-based payment expenses	149	<b>177</b>
Interest and dividend income	(33)	<b>(35)</b>
Interest expenses	42	<b>45</b>
Foreign exchange losses (gains)	(140)	<b>(544)</b>
Decrease (increase) in trade receivables	(205)	<b>(7,402)</b>
Decrease (increase) in accounts receivable – other	1	<b>(99)</b>
Decrease (increase) in inventories	(4,699)	<b>(1,082)</b>
Increase (decrease) in trade payables	2,253	<b>(1,608)</b>
Increase (decrease) in accounts payable – other	202	<b>3,033</b>
Increase (decrease) in accrued consumption taxes	175	<b>(120)</b>
Increase (decrease) in advances received	2,493	<b>(1,877)</b>
Other, net	265	<b>(143)</b>
Subtotal	11,156	<b>11,817</b>
Interest and dividends received	39	<b>35</b>
Interest paid	(46)	<b>(45)</b>
Income taxes refund (paid)	(807)	<b>(2,517)</b>
Net cash provided by (used in) operating activities	10,341	<b>9,289</b>

### Cash flows from investing activities

Payments into time deposits	(300)	<b>(300)</b>
Proceeds from withdrawal of time deposits	345	<b>300</b>
Proceeds from sale and redemption of securities	239	<b>—</b>
Purchase of property, plant and equipment	(4,780)	<b>(11,333)</b>
Subsidies received	3,892	<b>8,167</b>
Purchase of patent rights	(2,747)	<b>—</b>
Purchase of investment securities	(91)	<b>—</b>
Other, net	152	<b>(84)</b>
Net cash provided by (used in) investing activities	(3,290)	<b>(3,250)</b>

### Cash flows from financing activities

Increase (decrease) in short-term borrowing	8,320	<b>—</b>
Proceeds from long-term borrowing	1,250	<b>750</b>
Repayments of long-term borrowing	(650)	<b>(750)</b>
Proceeds from issuance of bonds	500	<b>—</b>
Repayments of lease liabilities	(47)	<b>(20)</b>
Net decrease (increase) in treasury shares	13	<b>10</b>
Dividends paid	(1,083)	<b>(2,169)</b>
Other, net	1	<b>—</b>
Net cash provided by (used in) financing activities	8,304	<b>(2,179)</b>
Effect of exchange rate change on cash and cash equivalents	(22)	<b>612</b>
Net increase (decrease) in cash and cash equivalents	15,332	<b>4,472</b>
Cash and cash equivalents at beginning of period	10,928	<b>26,260</b>
Cash and cash equivalents at end of period	26,260	<b>30,733</b>



# Corporate Information

As of March 31, 2022

## Company Profile

### Corporate Name

JCR Pharmaceuticals Co., Ltd.

### Headquarters

3-19 Kasuga-cho Ashiya, Hyogo, 659-0021 Japan

### Representative

Shin Ashida, Chairman, President, CEO and COO

### Founded

September 1975

### Paid-In Capital

9,061 million yen

### Employees

816 (Consolidated) 797 (Non-Consolidated)

## Subsidiaries

Chromatech Co., Ltd. (Japan)

JCR Engineering Co., Ltd. (Japan)

JCR INTERNATIONAL SA (Switzerland)

JCR USA, Inc. (U.S.)

JCR DO BRASIL FARMACÊUTICOS  
IMPORTAÇÃO E EXPORTAÇÃO LTDA. (Brazil)

ArmaGen, Inc. (U.S.)

## Stock Information

### Listed on

Tokyo Stock Exchange First Section  
(Tokyo Stock Exchange Prime Market from April 4, 2022 onward)

### Securities Code

4552

### Total Number of Outstanding Shares

129,686,308

### Transfer Agent for Common Stock

Sumitomo Mitsui Trust Bank, Limited  
1-4-1, Marunouchi, Chiyoda-ku, Tokyo

### Accounting Auditor

Deloitte Touche Tohmatsu LLC

### Number of Shareholders

19,200

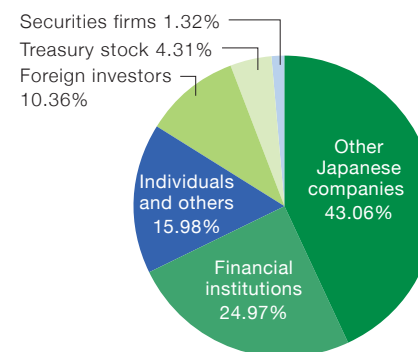
### Principal Shareholders

Name of shareholder	(Unit: 1,000) Number of shares held
MEDIPAL HOLDINGS CORPORATION	29,131
The Master Trust Bank of Japan, Ltd. (Trust account)	12,259
Kissei Pharmaceutical Co., Ltd.	11,318
Future Brain Co., Ltd.	8,711
Custody Bank of Japan, Ltd. (Trust account)	6,526
The Nomura Trust and Banking Co., Ltd. (Trust account: A)	6,514
Sumitomo Dainippon Pharma Co., Ltd.	3,400
Mochida Pharmaceutical Co., Ltd.	2,200
SSBTC CLIENT OMNIBUS ACCOUNT	1,153
Employee Shareholding Association of JCR Pharmaceuticals Co., Ltd.	1,104

\* The Company holds 5,585,744 shares of treasury stock, which are not included in the above table.

\* Sumitomo Dainippon Pharma Co., Ltd. changed its trade name to Sumitomo Pharma Co., Ltd. on April 1, 2022.

### Composition of Shareholders



**FTSE Blossom  
Japan Sector  
Relative Index**

## JCR Selected as a Constituent of the FTSE Blossom Japan Sector Relative Index (March 31, 2022)

The FTSE Blossom Japan Sector Relative Index is created by global index provider FTSE Russell. It reflects the performance of Japanese companies that demonstrate strong environmental, social and governance (ESG) practices relative to their respective sectors and is designed to be sector neutral. To promote the transition to a low-carbon economy, companies with particularly high greenhouse gas emissions are included only if their improvement efforts are positively evaluated using the Transition Pathway Initiative (TPI) Management Quality Score.



## JCR Pharmaceuticals Co.,Ltd.

Headquarters: 3-19 Kasuga-cho Ashiya, Hyogo, 659-0021 Japan Tel: +81-(0)797-32-1995

[www.jcrpharm.co.jp/en/site/en/](http://www.jcrpharm.co.jp/en/site/en/)