JCR Pharmaceuticals

JCR Report 2023

JCR Pharmaceuticals Co.,Ltd.

Year Ended March 31, 2023

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 continues to marshall all capabilities of "Team JCR" to meet the challenges of its growth strategy and business activities. What follows is a comprehensive explanation of those efforts.

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 has launched its Midterm Business Plan for FY2023-2027, "*Reach Beyond, Together*," under which we are continuing to meet the challenge of doing what only JCR can do for patients and their families. In editing this "JCR Report 2023," we have prepared an integrated report that outlines progress on JCR's growth strategy and overall image of business activities for realizing its Mid- to 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.

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- **Period covered**
  FY2022 (From April 1, 2022 to March 31, 2023)
  * This report also contains some information from FY2023.
- **Organizations covered**
  JCR Group (JCR Pharmaceuticals Co., Ltd., consolidated subsidiaries and equity method affiliates)
  * 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 2023" 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.

Embracing innovation as our compass and our strengths as our wind, we set sail for uncharted futures.

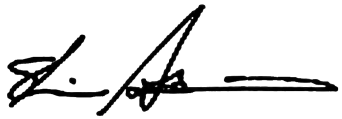
FY2022 fluctuated in various ways as we closed our Midterm Business Plan for FY2020-2022, “REVOLUTION.” Our partnership with AstraZeneca K.K. (AstraZeneca) for the production of COVID-19 vaccine stock solution ended which, combined with a decline in revenue from licensing, showed an overall decrease of revenue and profit. However, we also prospered to engage in multiple contract negotiations incorporating global partnerships for the treatment of lysosomal storage disorders (LSDs) and further expansion of modality licensing. Our J-Brain Cargo® technology further accelerated our challenging initiatives for rare disease treatment and secured multiple partnerships beyond LSD, notably the development of neurodegenerative disease therapeutics and biologics for epilepsy.

In May 2023, we formulated “*Reach Beyond, Together,*” its Midterm Business Plan for FY2023-2027, to deliver pharmaceuticals that only JCR can produce by further strengthening our own R&D and manufacturing capabilities, which have been cultivated since our founding with the cooperation our global partners.

We believe that our “Team JCR” purpose lies solely in contributing to patients and their families around the world by exploring the potential of J-Brain Cargo® and further creating innovative platform technologies to follow it. Looking ahead, our endeavor to be a truly research oriented global company will continue to be embedded in our corporate challenges.

November 2023

Shin Ashida
Representative Director, Chairman,
President, CEO and COO



FY2022 Business Overview

Revenue and profit declined following the end of COVID-19 vaccine stock solution manufacturing and others.

Our FY2022 net sales amounted to 34,343 million yen (32.8% decrease year on year). Some aspects include the scheduled end of the domestic production of AZD1222 stock solution for AstraZeneca COVID-19 vaccine, and certain delays in contract negotiations regarding licensing revenue. Operating profit was 4,975 million yen (75.0% decrease year on year) and profit attributable to owners of parent was 3,772 million yen (74.0% decrease year on year).

Sales of the mainstay recombinant human growth hormone product GROWJECT® and treatments for renal anemia were affected by an NHI price revision, but with a contribution of IZCARGO® I.V. infusion, recombinant treatment for mucopolysaccharidosis II (MPS II), and other factors, total net sales of our key products maintained consistency from FY2021.

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Financial Highlights P.84

R&D and Manufacturing Progress

Advancing global development and manufacturing

We are currently leveraging our proprietary blood-brain barrier (BBB) penetration technology J-Brain Cargo® to work on more than 17 types of new drug developments in the arena of LSDs, a rare disease. We are advancing the global Phase III clinical trial for JR-141, an enzyme treatment for MPS II launched in Japan in May 2021, through our global partnership with Takeda Pharmaceutical Company Limited (Takeda). In December 2022, it was granted a Rare Pediatric Disease designation by the U.S. Food and Drug Administration (FDA).

Regarding JR-171, a therapeutic enzyme for MPS I, we have been advancing preparations for the early launch of Phase III global clinical trial, and started conducting Phase I/II global clinical trial for JR-441, a therapeutic enzyme for MPS IIIA, in October 2023. We are also propelling to implement global clinical trials of therapeutic enzymes for JR-446 for MPS IIIB, JR-162 for Pompe disease, for JR-443 for MPS VII, and JR-479 for the treatment of GM2 gangliosidosis.

In October 2022, we began working with MEDIPAL HOLDING CORPORATION (MEDIPAL HOLDINGS) on the development of therapeutics for ultra-rare diseases. Following this, we entered into agreements in October 2022 for JR-471, a treatment for fucosidosis, and in September 2023 for JR-446, a treatment for MPS IIIB. Leveraging our resources and advantages with MEDIPAL HOLDINGS, our efforts stand to promptly deliver new treatments to ultra-rare disease patients.

Going beyond the application of J-Brain Cargo® for LSDs. we proactively concluded an agreement in March 2023 with Alexion, AstraZeneca Rare Disease (Alexion) for the development of therapeutics for neurodegenerative diseases and in May 2023, with Angelini Pharm for the development of biologics for epilepsy.

R&D for Cell therapy, regenerative medicine and human growth hormone products are also key areas we will continue to build on.

Our new API plant, Kobe Science Park Center, completed in November 2022. It complies to the Ministry of Health, Labor and Welfare's 2020 Emergency Vaccine Production System Improvement Project and installs four units of 2,000 liters of single-use equipment culture vessel each. This will fully contribute to ensuring a contract production system for vaccines and more in the event of an emergency, as well as strengthening our proprietary product manufacturing capacity.

Related pages

Feature 1: The Challenge of R&D P.24

Feature 2: The Pursuit of Manufacturing P.32

Midterm Business Plan for FY2023-2027

Advancing our strategies to be distinctive

During the term of "REVOLUTION," its Midterm Business Plan for FY2020-2022, we succeeded in application of J-Brain Cargo® and achieved the milestone of creating the world's first drug providing direct penetration to parenchymal brain cells.

As we keep our aim towards becoming an international biopharmaceutical company, our top priority is to ensure a stable supply of high-quality drugs. We expanded our "Qualitative and quantitative reorganization of the quality assurance system," to advance our business activities based on "REVOLUTION." Looking ahead into a new phase, in May 2023, we established a Midterm Business Plan for FY2023-2027 "*Reach Beyond, Together,*" to reinforce our advantages and leverage various opportunities to enhance our compelling values. In May 2023, we formulated "*Reach Beyond, Together,*" our Midterm Business Plan for FY2023-2027, to further reinforce the strengths we uncovered in this process and to continue creating new value during the period of our second foundation.

In the new Midterm Business Plan, we will marshal the combined strengths of "Team JCR" and primarily focus on the following five initiatives.

(1) Creation of innovative core technologies

Based on the basic concept behind J-Brain Cargo®, our proprietary platform technology, we plan to create groundbreaking treatment beyond LSDs.

(2) Demonstrating global standard production capacity

(3) Expansion of global quality assurance system in terms of quality and quantity

We will strengthen manufacturing (MONOZUKURI) and build a resilient global supply chain that can provide a stable supply of any product in any situation.

(4) Early launch of products for rare diseases

We will initiate five new clinical trials from our development pipeline of 17 plus LSD therapeutics using J-Brain Cargo®.

(5) Human resource development to support growth

We plan to further invest in human resource to maximize our corporate values and generate an HR management framework to acquire the ideal talent profiles.

JCR is now one of the few companies in Japan that can address the entire biopharmaceutical process, from research to manufacturing. We believe our essence is to keep pursuing “What Only JCR Can Do” in a quest to touch the lives of countless patients and the hearts of their families, by harmonizing our unique R&D and manufacturing capabilities we have cultivated since our founding.

Moving forward, our new Midterm Business Plan intentionally avoids offering quantitative guidance, and instead firmly commits to investing in the potential of growth through advancements in R&D. With our compelling innovations expected to develop through our challenges, we strongly believe we will be able to exceed a net sales of nearly 100 billion yen from 2030 onwards.

Related page

Midterm Business Plan for FY2023-2027, *“Reach Beyond, Together”* P.14

Sustainability

Our commitment and purpose are firmly established in achieving social good.

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

We recognize “Rare Diseases” as the arena that we can make our greatest contribution. In addition to developing treatments for ultra-rare diseases having very few patients, and building new business models, we have also worked to improve drug access. Moving forward, we will actively promote our values “what only JCR can do” to the society and pledge to ensure no one will be left behind.

Related pages

Sustainability P.38

Corporate Governance P.55

Return to Shareholders

Bring out continuous and stable dividends to shareholders.

Returning profits to shareholders is an important management policy for JCR.

Profits declined year on year in FY2022, but steady progress was seen in sales of mainstay products and in R&D. As a result, we decided to pay an annual dividend of 20 yen per share (an interim dividend of 10 yen and a year-end dividend of 10 yen), about on par with the FY2021 dividend (22 yen per share, including a special dividend of 2 yen).

Our projection for FY2023 dividend is currently at 20 yen per share (an interim dividend of 10 yen and a year-end dividend of 10 yen).

We will work closely with patients, their families and healthcare professionals to deliver medicines that can only be made by JCR.

In taking on the challenge of a new stage, we will maximize our focus on providing value to patients. To this end, I believe it is my responsibility to consider from a variety of perspectives what we will or will not change, and then implement those changes.

Beginning in FY2023, JCR will introduce a system of dedicated medical representatives (MRs) for each product. Promoting human resource development that ensures each MR becomes a specialist in their product will enable us to engage in highly specialized activities and establish a presence befitting a leading company in each area.

In addition, rather than focusing solely on the optimization of the Sales Division organization, we will make rigorous efforts to provide valuable sales information in line with changing times through tight cooperation with Medical Affairs and other relevant divisions. By also working closely with patients, their families and healthcare professionals, we will deliver reassurance along with medicines that can only be made by JCR.

To address the expectations of our shareholders and other stakeholders, we will work as a small, elite team, refining everything we do, aiming to further expand market share and reach JCR's future milestones through sustained, stable growth. We will establish a robust operating base while maintaining and developing the organizational soundness required of us.

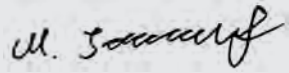
Toru Ashida
Senior Vice President
Sales
Executive Director, Sales Division

By further accelerating growth, JCR will offer its shareholders attractive, long-term investment opportunities.

In the last business plan "Revolution into the future" JCR established several pillars of success: IZCARGO®, the first biotherapeutic designed to cross the blood-brain-barrier was approved in Japan. The J-Brain Cargo® helped JCR build the strongest lysosomal storage disorder (LSD) portfolio in the industry. Expansion of biomanufacturing capacities allows us to advance multiple clinical programs simultaneously. JCR transformed from a domestic to an international biopharmaceutical company and formed multiple partnerships around our portfolio and products.

We will use these pillars of strength to literally "*Reach Beyond, Together*": Advancing our portfolio, we will redefine treatment of LSDs, address unmet needs to bones, eyes, muscle and other organs. Using the J-Brain Cargo® technology, we will expand to other areas of high unmet needs including neuro-degeneration, epilepsy, neuroinflammation or neuro-oncology. Partnerships will be the preferred way to enter these areas with unprecedented growth potential. We expect licensing and royalty income to become a major source of future revenue. These growth prospects, together with a strong domestic product portfolio, position JCR as an attractive long-term investment opportunity for domestic and international investors alike.

Mathias Schmidt, PD, Ph.D.
Vice President
Clinical development (overall supervision)
Business development and IR fields, excluding Japan
ArmaGen, Inc. President and CEO
JCR USA, Inc. President and CEO



JCR will accelerate its own development pipeline and its collaboration with other companies with the goal of maximizing the value of J-Brain Cargo®.

In FY2022, we initiated a number of new collaborations and partnerships for products under development and new drug discovery using J-Brain Cargo®, JCR' s blood-brain barrier penetration technology. First, MEDIPAL HOLDINGS was granted global development rights for ultra-rare disease therapeutics, and the development of JR-471, a treatment for fucosidosis, is underway as the first step in this process. Few companies are involved in developing treatments for ultra-rare diseases, for which the market is small, and thus this partnership with MEDIPAL HOLDINGS represents significant progress for patients.

JCR has also entered into a joint research collaboration agreement with Alexion for the treatment of neurodegenerative disease, and drug discovery is now underway in this area of disease which JCR was not able to address on its own. In addition, we have achieved an important milestone—a non-clinical proof of concept (PoC)—in our gene therapy program with Takeda for LSDs using J-Brain Cargo®. In parallel with the development of our proprietary pipeline, going forward we will accelerate these kinds of collaborations with other companies to maximize the value of the J-Brain Cargo® technology.

JCR will continue utilizing the proprietary biotechnologies it has developed to date, supported by our R&D and manufacturing capabilities, in discovering new high value-added therapies, as we work to further advance our efforts to become a global specialty pharmaceutical company in the rare disease arena.

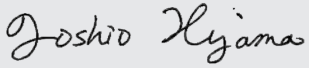
Hiroyuki Sonoda, Ph.D.
Vice President
Research
Executive Director, Research Division

We will expand our quality assurance and safety management platforms with a view to global production and sales.

Products manufactured and sold by JCR can be divided into existing drugs (growth hormone products, biosimilars and regenerative medicine products), drugs for rare diseases and vaccine APIs. In existing products, JCR looks to maximize the advantages of having drug substance manufacturing and finished product manufacturing sites in Japan to achieve stable supply through finely tuned production. In FY2023 in particular, we will prioritize a stable supply of growth hormone products to ensure the market will not be depleted. Drugs for rare diseases are expected to be approved in major countries outside of Japan in the next few years, and JCR is in the process of building an overseas supply chain with an eye to supplying other countries in the future. We would like to create a mechanism to ensure the delivery of our products to patients around the world, while still maintaining quality. While JCR currently has no plans for commercial production of vaccines, we will contribute to the nation's public health by maintaining a system capable of manufacturing APIs in response to government requests, while building a new plant for formulation and for integrated production in the event of an emergency.

Expansion of our quality assurance and safety management platforms is essential in global production and sales. Working closely with our overseas partner companies, we are strengthening our quality and safety platforms to meet overseas standards, which are becoming increasingly rigorous by the year. Employees are given opportunities for self-improvement, English language training and job rotations to improve their abilities, and we are also committed to fostering a workplace environment that allows individuals to maximize their capabilities.

Yoshio Hiyama, Ph.D.
Senior Executive Director
Production and Quality
Assurance Executive Director, Production Division



Determinedly investing in opportunities for growth through advancements in R&D, we aim to create new innovation and maximize value.

Be a 100 billion yen company by the mid-2030s

A more stable profit and loss structure
- Growth of domestic product sales

Determined investing (R&D, production facilities)
- R&D investment focused on rare diseases

Global growth
- Three profit pillars centered on lysosomal storage disorder (LSD) therapies

Reach Beyond, Together
- Contribute to rare disease patients and their families
- Investment in R&D, production facilities and human resources
- Enhancement of shareholder returns

Related page
Growth Strategy P.11

Financial strategy under "*Reach Beyond, Together,*" the Midterm Business Plan for FY2023-2027

JCR has been in business for 48 years and recorded net sales of 34.3 billion yen and operating profit of 5.0 billion yen in FY2022. However, from a global perspective, JCR is still a bio-venture company with unique technology. Therefore, we believe that what is expected of us is to achieve growth by resolutely investing in R&D for drugs for rare diseases without being preoccupied with profit levels. So, we did not set a numerical target in "*Reach Beyond, Together,*" the medium-term business plan for FY2023-2027 announced in May 2023. Fortunately, in FY2023, sales of a recombinant human growth hormone product, GRWOJECT® grew greater than expected, and we are now in a position to further stabilize our profit and loss structure. Taking advantage of this tailwind, we will "reach beyond" with patients with rare diseases and their families, JCR employees, and our shareholders, aiming to grow globally with three pillars—domestic sales of our own products; income from LSD therapies licensed overseas; and income from licensing JCR' s proprietary J-Brain Cargo® technology—and through aggressive investment in R&D, production facilities, and human resources.

Yoh Ito
Senior Corporate Officer, Corporate Strategy, Executive Director, Corporate Strategy Division

[Business Process]

R&D
We leverage our biotechnologies as well as technologies for cell therapy, regenerative medicine, and gene therapy technology to accelerate development of innovative drugs and drug discovery platforms.

Production
We have built manufacturing and quality structures using production technologies that we have cultivated and developed to world standard.

Marketing
We provide and collect information focused on target domains at seven business sites across Japan and support the needs of medical professionals in each region.

Quality Assurance / Medical Affairs
We assure the quality of our products from R&D to manufacturing and post-marketing stages, along with generating high-quality evidence in support of medical needs.

Intellectual Property
JCR seeks to maximize the value of inventions and products it creates by obtaining rights to them as intellectual property and by filing strategic patent applications in anticipation of global business.

Departments supporting all business activities | **Business Development / Global Business Strategy / Human Resources / Information Systems / Legal Affairs, etc.**

Related page
Business Activities P.69

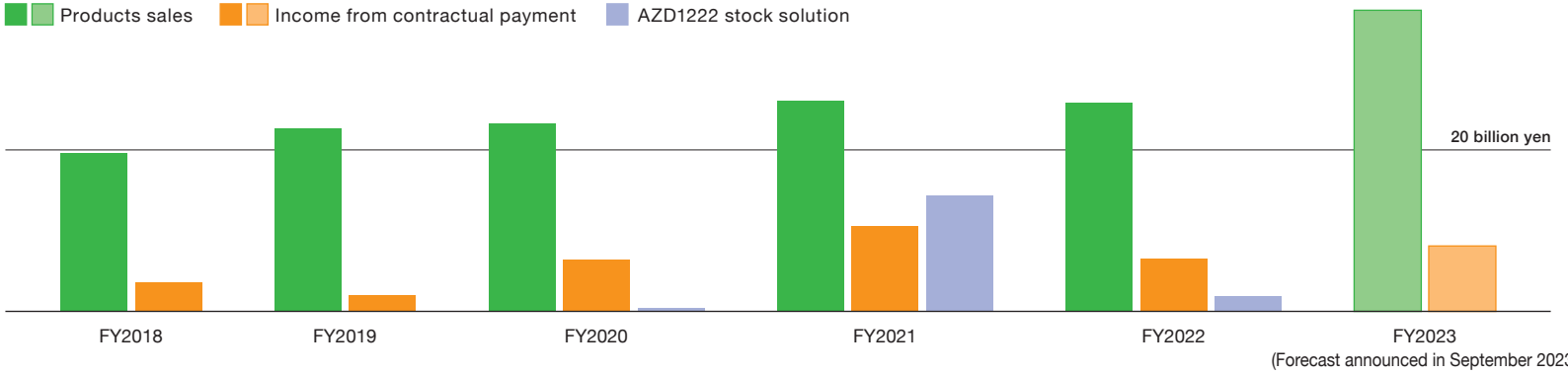
Value Creation Indicators

Net Sales Trends

Net Sales

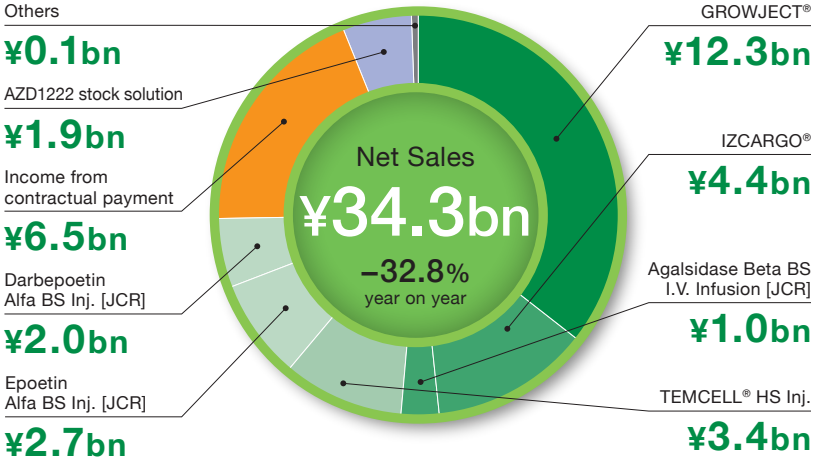
FY2018	FY2019	FY2020	FY2021	FY2022	FY2023 (Forecast announced in September 2023)
¥23.2bn	¥24.8bn	¥30.1bn	¥51.1bn	¥34.3bn	¥45.4bn

Breakdown of Net Sales



FY2022 Actual

Breakdown of Net Sales



R&D Expenditures

¥8.8bn

25.6% of net sales (+11.6% year on year)

Capital Investment

¥8.0bn

Operating Profit

¥5.0bn

14.5% of net sales (–24.5% year on year)

ROE

7.4%

No. of Partnerships

J-Brain Cargo® collaborations: 4

*As of May 2023

LSD asset collaborations: 3

*As of October 2023

Growth Strategy

JCR is accelerating business development globally based on the Mid- to Long-term Management Vision “Toward 2030” and Midterm Business Plan for FY2023-2027, “*Reach Beyond, Together.*” Based on the conviction that “Team JCR,” which shares our corporate culture, is the source of our value, we will bring together the unique R&D capabilities and manufacturing capabilities cultivated since JCR’s founding, with the goal of becoming a research-oriented specialty pharma with global exposure.

Summary of Midterm Business Plan for FY2020-2022 “REVOLUTION”

Based on the conviction that “Team JCR” is the source of its value, JCR has formulated a Mid- to Long-term Management Vision, “Toward 2030,” looking toward the year 2030 in advancing a full-scale global business, and is executing a strategy aimed at becoming a research-oriented specialty pharma with global exposure. To serve as a touchstone toward achieving that goal, our Midterm Business Plan for FY2020-2022, “REVOLUTION,” set out six key imperatives, and we have continued to boldly take on challenges over the past three years. As a result, we have achieved some remarkable results, including the May 2021 launch in Japan of IZCARGO®, a recombinant treatment for MPS II, the first product to which JCR’s proprietary blood-brain barrier (BBB) penetration technology, J-Brain Cargo® was applied.

In numerical terms, JCR for the most part met its guidance (target for FY2022). Operating profit, which was not achieved, reached a record high of 19.9 billion yen in FY2021, mainly due to the contract for manufacturing the stock solution for AstraZeneca’s COVID-19 vaccine, and that will be utilized to fund future growth.

	FY2020	FY2021	**FY2022**	**Guidance** (Target for FY2022)
Net sales (billion yen)	30.1	51.1	**34.3**	**32.0 to 36.0**
Operating profit (billion yen)	8.3	19.9	**5.0**	**7.0 to 10.0**
R&D expenditures (billion yen) (to sales)	5.4 (17.8%)	7.2 (17.8%)	**8.8 (25.6%)**	**Approx. 20% of net sales**
Capital investment (billion yen)	4.0	10.6	**8.0**	—
Employees (Consolidated)	732	817	**879**	—
Dividend payout ratio	21.5%	18.8%	**65.9%**	**Approx. 30%**

Key Imperatives	Accomplishments
Qualitative and quantitative reorganization of the quality assurance system	Remodeled QA system from research to manufacturing—Analytical R&D center Improved data integrity—Introduction of LIMS
Actions for sustainable growth of the sales of our products	GROWJECT®—Developed Melon Nikki™ app for improving treatment adherence Developed fully-automated electric injector and novel device development
Expansion of basic and research activities	Generated 17 drug candidates for lysosomal storage disorders (LSDs) Applied J-Brain Cargo® to various modalities—partnered with multiple companies AlliedCel, a joint venture to realize the social implementation of regenerative medicine and cell therapy
Evaluation and implementation of further capital investment for manufacturing and research	Expanded DS/DP capacity, enabling multiple developments in parallel – Expanded research center, Kobe Science Park Center – Established collaboration with Mycenax Biotech Inc. (Mycenax) through equity participation
Product strategy planning including evidence generation	Communicated the value of J-Brain Cargo® technology via conferences and publications Sales forces specialized in pediatric field Transferred marketing rights for Agalsidase Beta BS to Sumitomo Pharma
Transformation of operations and organizations along with human resource development	Optimized organizational efficiency, started global development, and created international footprints Established JCR Academy to nurture next-generation leaders with global perspective Implemented state-of-the-art IT infrastructure to improve productivity Reformed workplace policies

Achievements of Midterm Business Plan for FY2020-FY2022 “REVOLUTION”

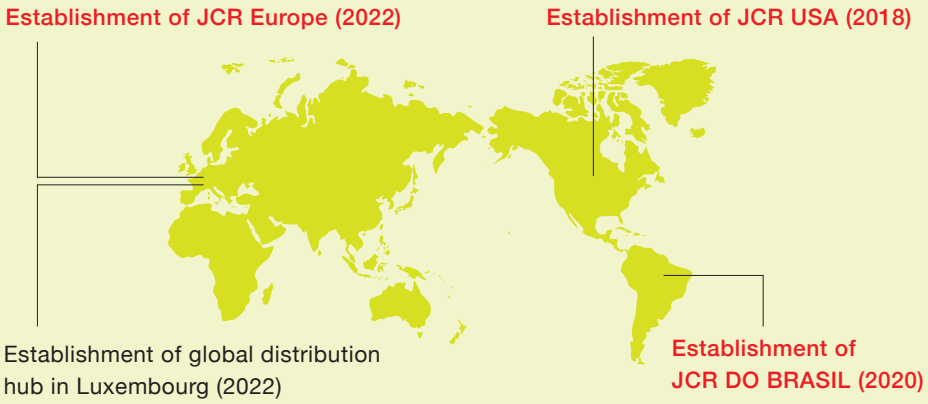
Realization of J-Brain Cargo® technology

- Entering development stage of JR-443, JR-446, JR-479, JR-471
- Launch of IZCARGO®, the world’s first-ever BBB penetrating type ERT, in Japan
- Agreement with Takeda for joint development and business development of JR-141
- Agreement with Takeda for joint R&D and licensing of gene therapy, milestone achievement for non-clinical trials
- Agreement with MEDIPAL HOLDINGS on Ultra Four project (four ultra-rare LSDs)
- Out-licensing of J-Brain Cargo® to Alexion, Angelini Pharma, and Sumitomo Pharma

Strategic CAPEX and demonstration of prominent biomanufacturing capability

- Securing of manufacturing capacity through investment in Mycenax
- Completion of Kobe Science Park Center
- Contracting and completion of the AstraZeneca COVID-19 vaccine drug substance production

Foundation for global expansion



Significance for the Future

- Applicability of J-Brain Cargo® to various disease areas
- Foundation of licensing revenue from partnering strategy
- Supply chain construction towards global standard manufacturing
- Realization of full-scale globalization based on overseas subsidiaries

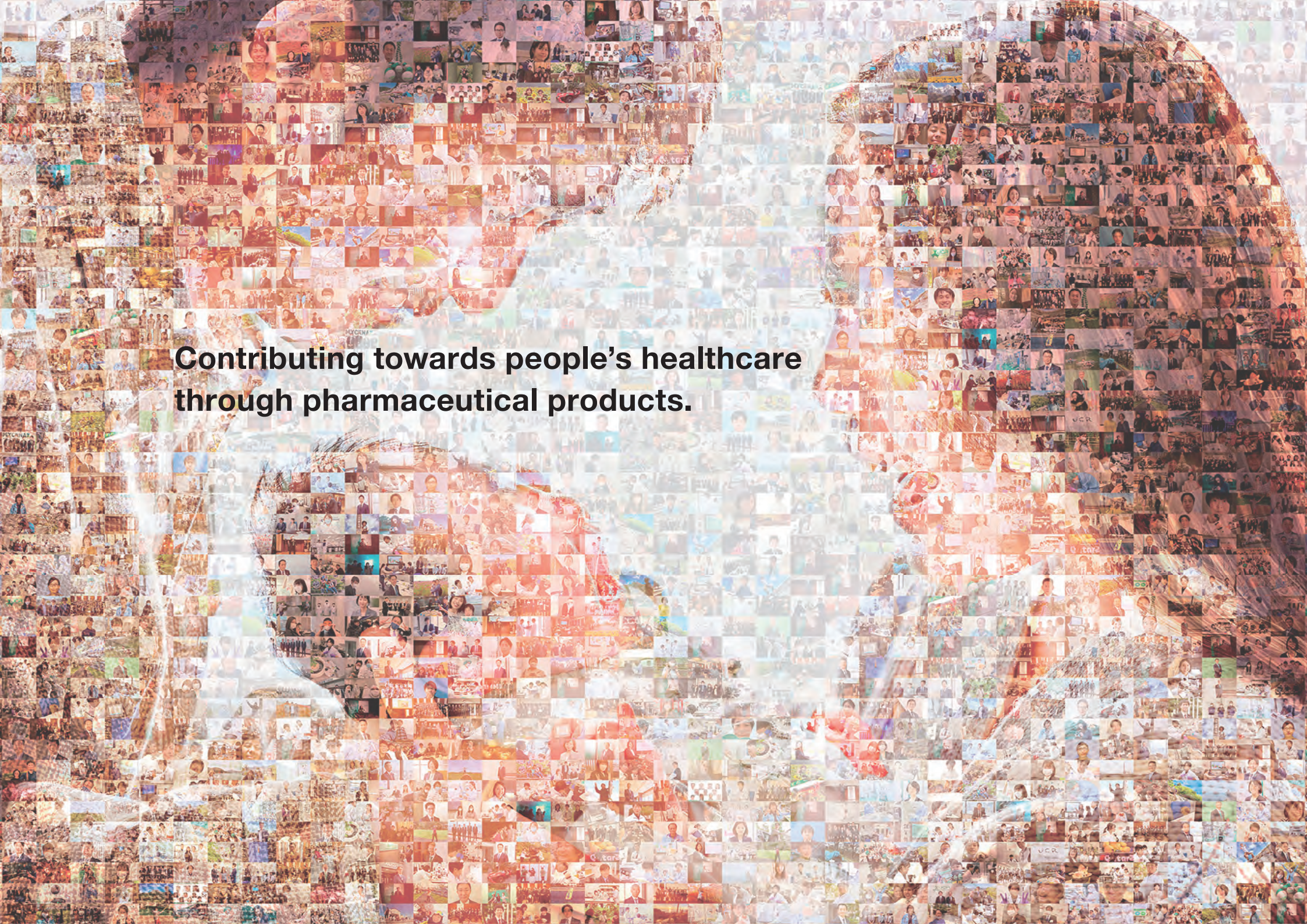
Midterm Business Plan for FY2023-2027

Reach Beyond, Together

Since its founding in 1975, JCR has introduced pharmaceuticals featuring new mechanisms available for the first time anywhere in the world, such as TEMCELL® HS Inj. and IZCARGO®, on the strength of its unique R&D and manufacturing capabilities in areas other companies do not handle. Our proprietary J-Brain Cargo® drug discovery platform technology, which we have established and are focused on developing further, will enable us to provide patients around the world with drugs that can be expected to have significant benefits for diseases that were previously untreatable.

JCR is now one of the few pharmaceutical companies in Japan that can operate the entire biopharmaceutical process, from research through to manufacturing. To maximize this potential, and to provide even more patients and their families with “medicines that only JCR can provide,” we have formulated our Midterm Business Plan for FY2023-2027, “*Reach Beyond, Together.*”

In this section, we will introduce our strategy for creating new value during our second foundation, while also providing basic information to help readers better understand JCR’s business activities through more detailed sidebars as appropriate.


Contributing towards people's healthcare
through pharmaceutical products.

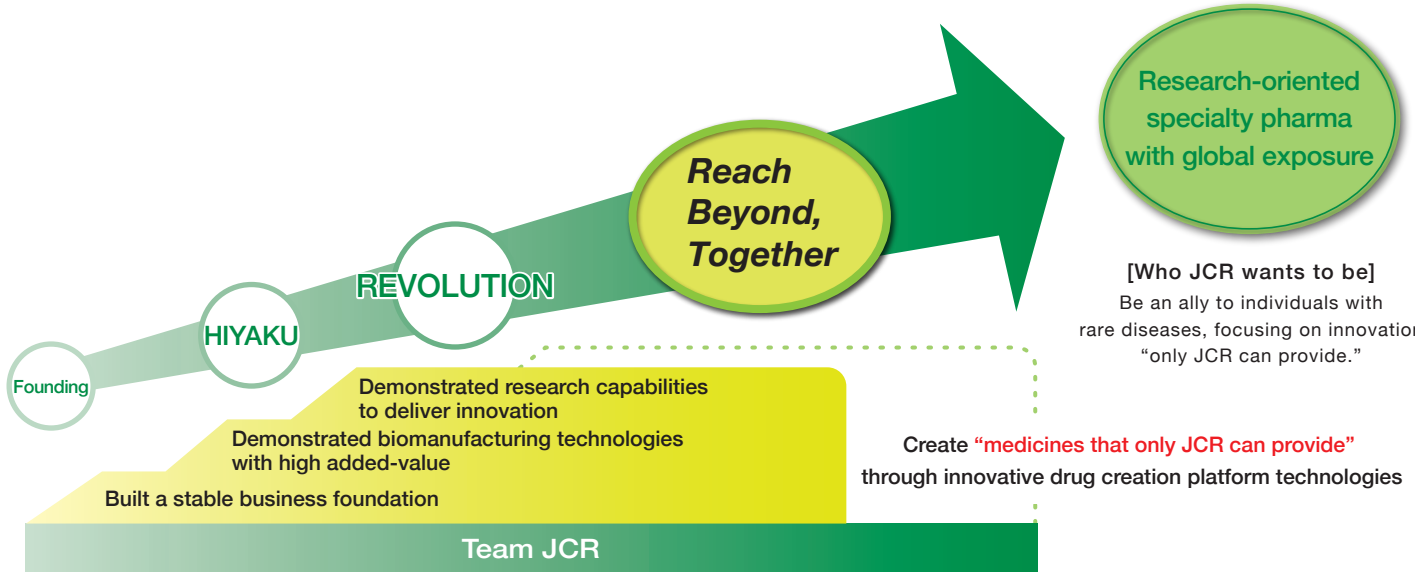
Our goal is to become a research-oriented specialty pharma with global exposure, handing down to the next generation the spirit of challenge that has guided us since our founding.

Since its inception, JCR has continued to grow as a specialty pharma by targeting the field of drugs for rare diseases►1, developing them with proprietary biotechnologies, technologies for cell therapy and regenerative medicine, and gene therapy technologies.

During JCR’s Midterm Business Plan for FY2015-2019, “HIYAKU (Leap into the Future),” in February 2016 we launched TEMCELL® HS Inj., the first allogeneic regenerative medical product►2 in Japan. During the Midterm Business Plan for FY2020-2022 “REVOLUTION” that followed, we succeeded in the human clinical application of J-Brain Cargo®, the world’s first technology for delivering active ingredients directly to the brain, as well as launching IZCARGO®, a revolutionary new drug that is expected to improve central nervous symptoms of lysosomal storage disorders►3 (LSDs), for which there had been no effective treatment.

Under the Midterm Business Plan for FY2023-2027, “*Reach Beyond, Together,*” we aim to become a research-oriented specialty pharm with global exposure by handing down and further developing these successes, taking on the challenge of using our innovative drug creation platform technologies to create “medicines that can only be made by JCR.”

Corporate Philosophy Contributing towards people’s healthcare through pharmaceutical products.



►1 Drugs for Rare Diseases

These are drugs used for diseases with an extremely small number of patients, defined in Japan as those intended for fewer than 50,000 patients. While about 7,000 rare diseases have been identified around the world, it is estimated that approved treatment methods exist for no more than 5% of them.

►2 Allogeneic Regenerative Medical Products

Regenerative medical products that use cells other than the patient’s own. Their advantages include the ability to respond to need for emergency treatment by manufacturing and stocking products in advance.

►3 Lysosomal Storage Disorders

Rare deceases in which a specific enzyme is either congenitally missing or functionally deficient, resulting in the accumulation of metabolic waste which fails to dissolve and causing a variety of symptoms. It is the collective name for a group of about 50 types of disease.

Reference
P.70 History of Growth
P.82 Core Products

JCR will contribute to patients and their families around the world by further reinforcing its strengths and working to maximize value.

Under the Midterm Business Plan for FY2023-2027, "*Reach Beyond, Together,*" we will work toward achieving our vision for who JCR wants to be, bringing together our foundational proprietary R&D and manufacturing capabilities►1 in the pursuit of what only JCR can provide to patients and their families, even in the case of diseases with an extremely small number of patients. To do this, we will marshall all capabilities of "Team JCR" at focusing on the following five initiatives.

From a global perspective, JCR is still positioned as a biotech company with proprietary technology, and we believe that, to achieve global growth during our second foundation, we should invest in R&D to the extent our resources allow. In addition, since profits may fluctuate significantly over the next five years due to timing differences, etc. in revenue from licensing, rather than establish quantitative guidance, we will determinedly invest in opportunities for growth.

Given the above, we recognize the importance of providing timely information to investors and our shareholders, and will strive to disclose information promptly and with a high degree of transparency.

Five Initiatives

1. Creation of innovative core technologies
2. Demonstrating global standard production capacity
3. Expansion of global quality assurance system in terms of quality and quantity
4. Early launch of products for rare diseases
5. Human resource development to support growth

**Rather than establish quantitative guidance,
we will determinedly invest in opportunities for growth through advancements in R&D,
create new innovation, and work to maximize value**

►1 Bringing Together R&D and Manufacturing Capabilities

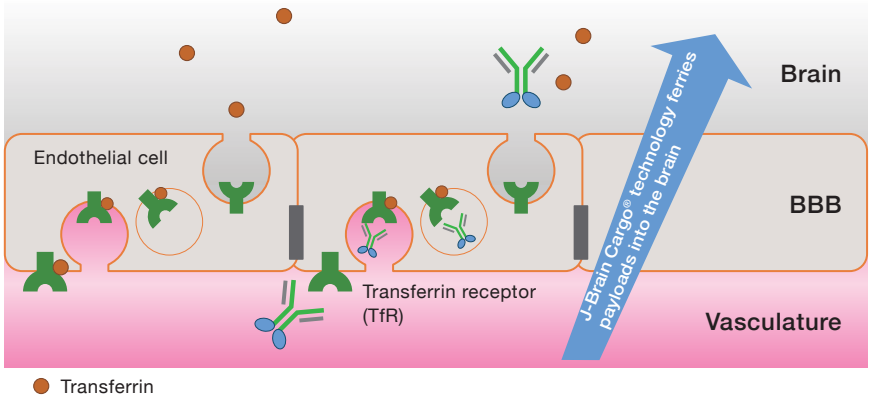
JCR is one of the few companies in Japan that can operate the entire biopharmaceutical process, from research through to manufacturing. More than 70% of our employees are highly skilled personnel involved in R&D and in production and quality assurance, which are strengths we have preserved from the time of our founding. Research and production sites are concentrated in the Kobe area to allow for close collaboration across divisions.

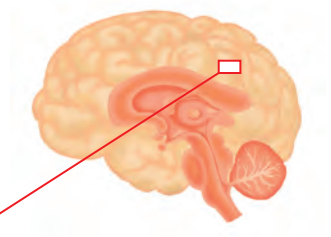
Reference
P.8 Profit and Investment Model
P.24 Feature 1: The Challenge of R&D
P.32 Feature 2: The Pursuit of Manufacturing

We will accelerate the development of innovative platform technologies by exploring the potential of J-Brain Cargo®.

JCR is engaged in research aimed at expanding potential applications for J-Brain Cargo®►1, its proprietary blood-brain barrier penetration technology, to further increase its value. Research to date has made it possible to utilize J-Brain Cargo® in a manner appropriate for the substance being delivered. Optimizing the molecular structure of the substance to which J-Brain Cargo® is applied has allowed us to successfully fabricate molecules that are more highly productive and can be delivered to the brain efficiently.

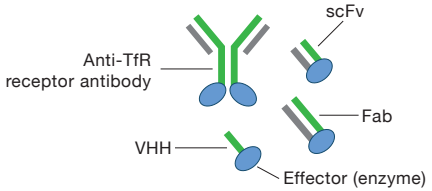
Under the Midterm Business Plan for FY2023-2027, “*Reach Beyond, Together,*” we will not only apply J-Brain Cargo® to LSD drugs such as IZCARGO®►2, which we have already accomplished, but will also take on the challenge of applying J-Brain Cargo® to nucleic acid drugs, for which potential applications have been suggested in a variety of disease areas. We will also accelerate research to realize the next generation of J-Brain Cargo®, aimed at being able to deliver drugs to tissues such as the eye, skeletal muscle, cartilage and others, where conventional technologies face hurdles to drug delivery.





IZCARGO®, world’s first drug proven to penetrate the BBB to deliver ERT to CNS. Launched in Japan in 2021.

J-Brain Cargo®-applied therapeutics



Selecting J-Brain Cargo® molecules best suited for unique effector properties

Protein engineering expertise accumulated since JCR’s founding

- Plentiful J-Brain Cargo® variations
- Creation of biopharmaceuticals that are difficult to produce

►1 J-Brain Cargo®

A proprietary technology for delivering drugs into the brain by penetrating the blood-brain barrier, a structure that exists in the brain. For years, many researchers and companies have worked to develop similar technology, but JCR is the first in the world to succeed in its human clinical application.

►2 IZCARGO®

This drug is the world's first successful human clinical application of a technology for delivering active ingredients to the brain. It was launched in Japan in May 2021 as a treatment for MPS II.

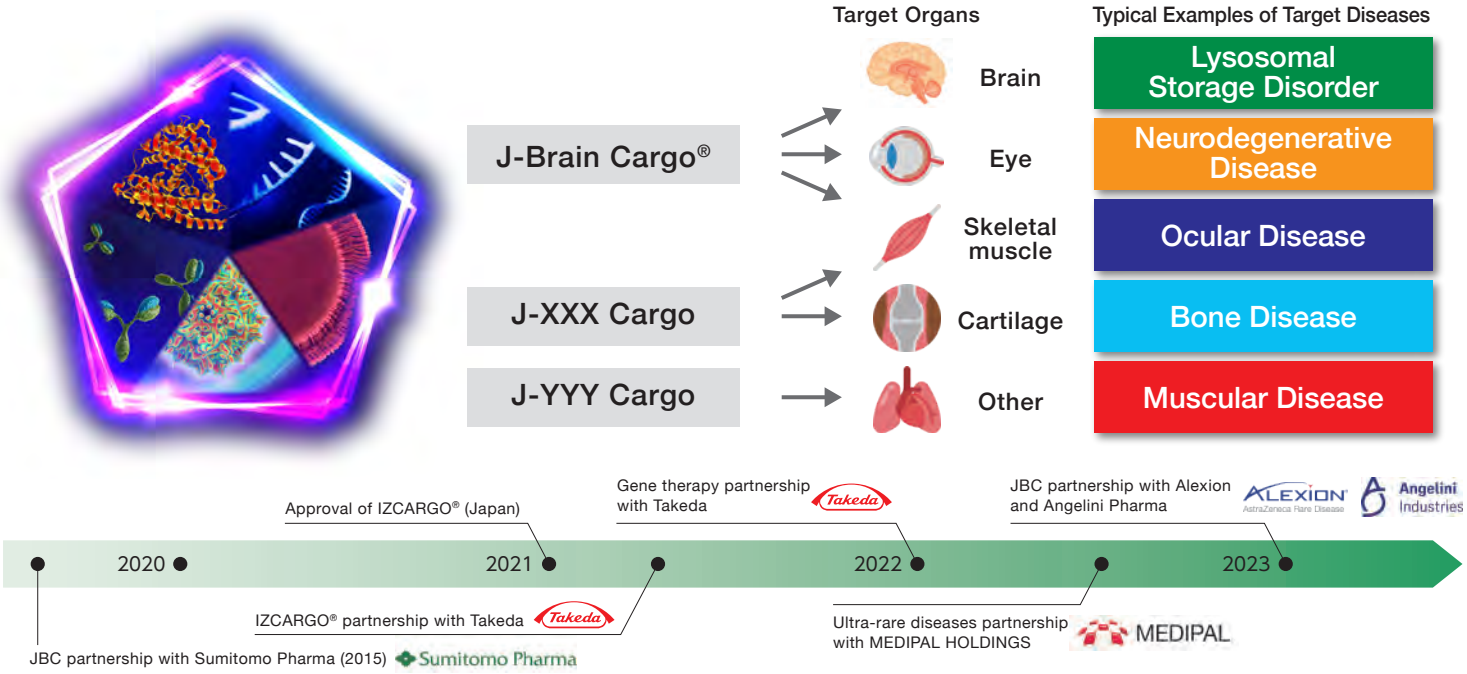
Reference
P.74 Research and Development
P.76 Global Development Operations
P.80 Marketing

Continuing to explore the potential for application of J-Brain Cargo® to a wide range of modalities through active promotion of collaboration with other companies.

Utilizing J-Brain Cargo®, JCR is working with a development pipeline of more than 17 new drugs in the LSD field. However, the potential of the J-Brain Cargo® new drug platform technology is not limited to this field. It can apply to a wide range of modalities►1, and can target a variety of organs and diseases. We are actively moving forward to collaborate with partners who have cutting-edge technology in each of these fields.

In the field of LSDs, we are working with Takeda on the global commercialization of JR-141 for the treatment of MPS II. In October 2022, we also entered into a global development agreement with MEDIPAL HOLDINGS for drugs to treat ultra-rare diseases.►2

In March 2023, we entered into an agreement with Alexion►3 for the development of drugs for the treatment of neurodegenerative diseases, and in May 2023, signed an agreement with Angelini Pharma►4 to develop biological products for epilepsy. Going forward, JCR will continue to explore further partnerships and accelerate these efforts with a view to the future.



►1 Modalities

Treatment methods including small molecule pharmaceuticals, enzymes, antibody delivery, oligonucleotide delivery, cell therapy, gene therapy and others.

►2 Ultra-rare Diseases

Rare diseases with an extremely small number of patients, defined by the National Institutes of Biomedical Innovation, Health and Nutrition as those diseases with fewer than 1,000 patients.

►3 Alexion

Founded in the U.S. in 1992, Alexion is a global developer of biologics involved in R&D, manufacturing and sales of drugs for rare diseases.

►4 Angelini Pharma

An Italian global pharmaceutical company with nearly 100 years of history, focused on R&D and commercialization of drugs in the field of the central nervous system.

Reference
P.24 Feature 1: The Challenge of R&D

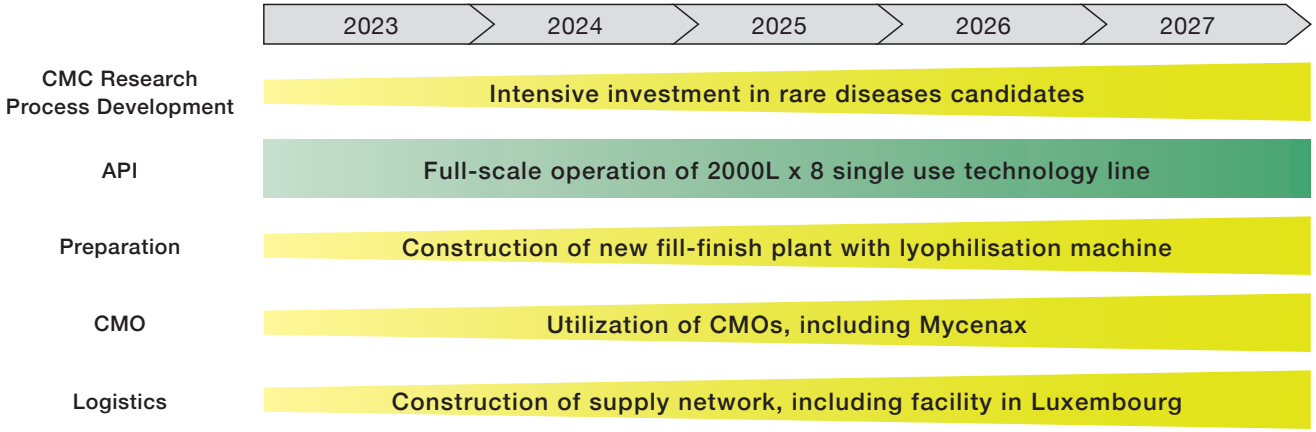
We will further reinforce our strengths in manufacturing to build a global supply chain capable of providing a stable supply in any situation.

Since its founding, JCR has taken manufacturing as its strength, and for more than 15 years has developed manufacturing experience drawing on single-use technology►1 to build a manufacturing and quality assurance system that enables the stable supply of high-quality biopharmaceuticals. We currently have five production sites, including the new API plant, Kobe Science Park Center►2, which was completed in November 2022.

To expedite global clinical trials of multiple development products, in July 2022 we moved to strengthen our relationship with Mycenax►3, a Taiwanese company with an established reputation as a contract manufacturing and development firm for biopharmaceuticals.

Under the Midterm Business Plan for FY2023-2027, “*Reach Beyond, Together*,” we plan for over $300 million in capital expenditures and investments in contract development and manufacturing organizations (CDMOs) as we work to further expand supply capacity. We are also working to build a global supply chain capable of providing a stable supply even in emergencies such as natural disasters and pandemics.

- **Over $300m CAPEX and investment in CDMOs, leading to supply expansion.**
- **Constructing a resilient global supply chain for emergencies.**



►1 Single-use Technology

Technology that allows for the efficient production of small lots of many different drugs with single-use culture vessels using disposable plastic bags.

►2 Kobe Science Park Center

A new API plant that meets the requirements of the FY2020 State of Emergency Vaccine Production System Improvement Project by the Ministry of Health, Labour and Welfare (MHLW). Equipped with four 2,000 L single-use culture vessels, this plant will secure contract production systems for vaccines and other products in an emergency, and will greatly contribute to strengthening manufacturing capacity for JCR’s own products.

►3 Mycenax

A contract manufacturing and development company specializing in biopharmaceuticals, founded in 2001, with a track record in a variety of global development projects, including in recombinant proteins, enzymes, antibodies, antibody drug conjugates, and gene and cell therapies.

Reference
P32 Feature 2:The Pursuit of Manufacturing
P78 Production System / Quality Assurance

JCR aims to launch clinical trials of five LSD therapeutics during the term of its Midterm Business Plan for FY2023-2027.

Utilizing its proprietary J-Brain Cargo® blood-brain barrier penetration technology, JCR is working on the development of more than 17 new drugs in the field of LSDs, including global clinical trials►1 of JR-141 and JR-171. Many of these are currently in the basic research and preclinical phase.

During the term of its Midterm Business Plan for FY2023-2027, "*Reach Beyond, Together*," JCR aims to enter clinical trials for five products, including JR-441, JR-446, JR-479, JR-471, and JR-194, accelerating efforts in candidates for Krabbe disease. Global Phase I/II clinical trials for JR-441 were launched in October 2023.

Among these candidates, JR-471 and JR194 are indicated for fucosidosis and Batten disease, respectively, both of which are ultra-rare diseases with an extremely small number of patients around the world. In dealing with these kinds of diseases, in fields large corporations may find it difficult to enter, JCR considers it its mission to deliver "medicines that can only be made by JCR," and aims to commercialize them globally through collaboration with its partners.

Basic Research	Preclinical	Clinical (Phase I/II)	Clinical (Phase III)	Review Period	Approved
JR-194 (Batten disease type I)	**JR-446** MPS IIIB (Sanfilippo B syndrome)	**JR-171** MPS I (Hurler syndrome, etc.)	**JR-141** MPS II (Hunter syndrome)		**JR-141** MPS II (Hunter syndrome)
Krabbe disease	**JR-162** Pompe disease	**JR-441*** MPS IIIA (Sanfilippo A syndrome)			
GM1 gangliosidosis	**JR-443** MPS VII (Sly syndrome)				
CLN2 (Batten disease type II)	**JR-479** GM2 gangliosidosis (Tay-Sachs, Sandhoff disease)				
Gaucher disease	**JR-471** Fucosidosis				
α-Mannosidosis					
Niemann-Pick					
Metachromatic leukodystrophy					
Galactosialidosis					

Aiming to begin clinical trials for five items

(Candidates) JR-441*, JR-446, JR-479, JR-471, JR-194, Krabbe disease

As of November 2023

*At the preclinical development stage as of the announcement of the Midterm Business Plan for FY2023-2027

►1 Global Clinical Trials

Clinical trials in which medical institutions in multiple countries or regions participate, and which proceed simultaneously based on common clinical trial protocols, with the aim of developing and gaining approval for new drugs on a global scale. This has the advantage of making it easier to gather test subjects than if each country were to conduct their trials individually, leading to faster development of drugs for rare diseases.

Reference
P.76 Global Development Operations

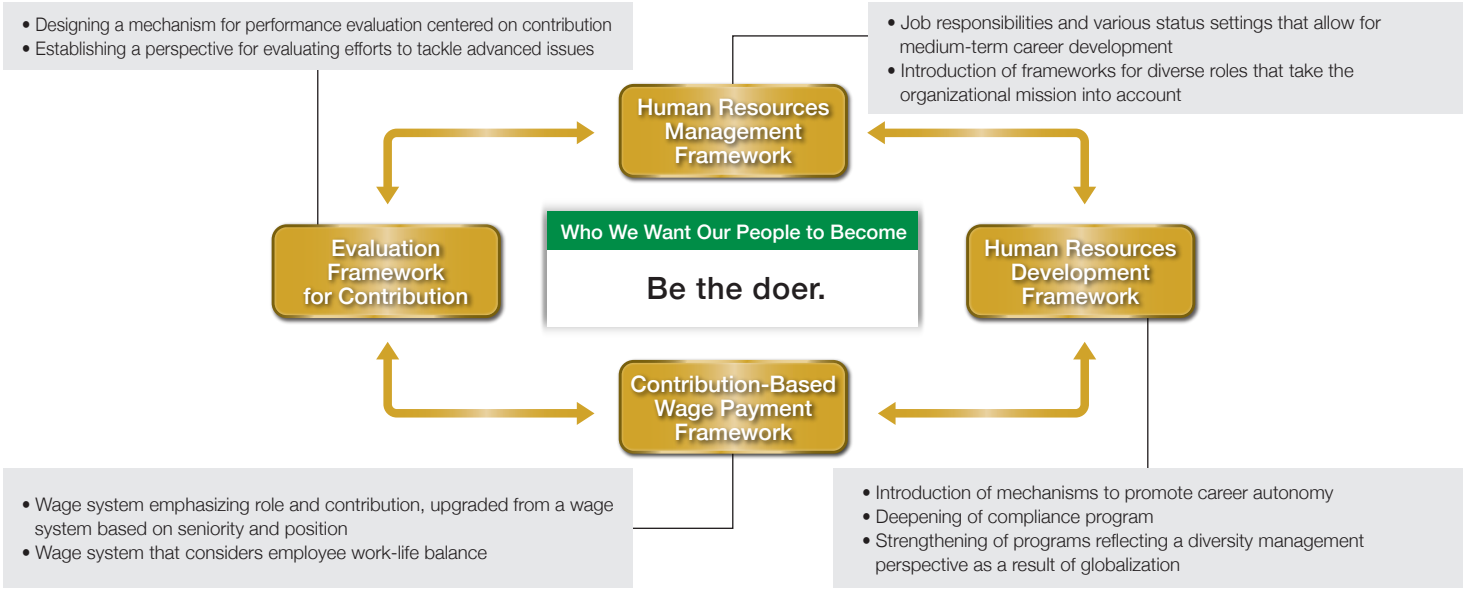
JCR will advance investments in human capital, reinforce the collective strength of “Team JCR,” and establish a human resources strategy that will contribute to enhancing corporate value.

Based on its conviction that “Team JCR” is the source of its own value, JCR has set out three main pillars under its Midterm Business Plan for FY2023-2027, “*Reach Beyond, Together*,” for establishing a human resources strategy that will contribute to enhancing corporate value. These are: construction of a dynamic human resource portfolio that will help to accomplish the strategy; development and organizational permeation of diversity and inclusion; and activation of individuals and organizations, and promotion of improvements to engagement.

We see the development and securing of human resources who can contribute to the enhancement of corporate value as central to our investment in human capital. Going forward, we will strive to enhance programs that contribute to the development of our human resources portfolio and the advancement of human capital management, including the JCR Academy,►1 a program to develop the next generation of global leaders, as well as training programs to improve language skills.

We will also formulate an image of who we want our people to become and a description of our optimal corporate culture. As a mechanism for realizing these goals, we will build a human resources management framework consisting of four sub-frameworks, including human resource management, evaluation of contribution, contribution-based wage framework, and human resource development.

Build a human resource management framework to realize the image of who we want our people to become



►1 JCR Academy

The JCR Academy is an initiative launched in FY2022 to develop next-generation leaders who have acquired the skills to perform on a global level. The objective is to offer a practical program where participants can gain the soft skills needed in their roles as global leaders, including communication, project management, leadership, and other abilities.

Reference
P.49 Human Resource Management

Through business activities based on our corporate philosophy, we will contribute to achieving a sustainable society that leaves no one behind.

JCR aims to realize sustainability through its business activities founded on Rare Diseases, the Environment, Society, and Corporate Governance.

Rare diseases, in particular, relate closely to JCR's business activities, and we see this as one area in which JCR can truly contribute. We are working to enhance initiatives such as the development of drugs for ultra-rare diseases, and construction of new business models, as well as efforts to improve access to drugs (Named Patient Supply►1).

With regards to the Environment, JCR considers the environmental impact of its business activity as a risk factor that could have a long-term impact on business and society. We will thus work to implement environmentally friendly business practices, such as reducing CO_2 emissions and making effective use of water resources, while also expanding information disclosure in line with the recommendations of the Task Force on Climate-Related Financial Disclosure (TCFD) as a response to climate change.

Ideal state of mind | **Achieve sustainability through business activities based on RD-E-S-G**

Rare Diseases

- Develop drugs for ultra-rare diseases and construction of new business models
- Make efforts to improve access to medicines (Named Patient Supply) to deliver innovative medicines to people around the world

Environment

- Investigate and implement measures to reduce environmental impact through business activities
- Promote environmentally friendly procurement on the premise of ensuring the quality and stable supply of pharmaceuticals

Society

- Address the challenge of unmet medical needs by creating platform technologies
- Develop human resources so that each member of "Team JCR" can shine in their own station

Corporate Governance

- Pursue governance in line with the Company's growth
- Ensure thorough compliance and strengthen risk management

►1 Named Patient Supply

A system under which manufacturing and sales companies individually provide drugs to physicians seeking to use pre-approval drugs after first registering their patients. In March 2023, JCR began a program to supply IZCARGO® in response to the need for access to drugs in countries where they have not yet been approved.

Reference
P.38 Sustainability

Feature 1

The Challenge of R&D

We are bringing deep knowledge and expertise, as well as a strong passion for new drug creation, to our efforts in the creation of innovative core technologies.

Hiroyuki Sonoda, Ph.D.
Vice President
Research
Executive Director, Research Division

In its Midterm Business Plan for FY2023-2027, "*Reach Beyond, Together,*" JCR has presented five initiatives on which it will focus going forward. The first of these is the creation of innovative core technologies. The creation of new drugs requires support from the development of core technologies. While the development of technology leading to drug discovery is not easy, our researchers continue to bring deep knowledge, expertise, and a strong passion for new drug creation to this challenge on a daily basis. Going forward, we will work constantly to develop new technologies based on the belief, "no drug discovery without technology."

JCR has two approaches to drug discovery. The first is the development of new platform technologies to address unmet medical needs. As we advance development of technology in the field of rare diseases, which is JCR's focus, we also aim to create core technologies that can be applied to other than rare diseases. In modalities, we are not limiting our work to recombinant proteins, but are also advancing technology development in the fields of gene therapy, oligonucleotide delivery, and regenerative medicine.

Our second approach is horizontal development using already developed and proven technologies such as J-Brain Cargo® and others. Crucial to this is a deep understanding and knowledge of disease: which diseases have what kind of pathologic mechanisms, and what medical needs exist as a result? How can they be solved using JCR's technologies and capabilities? A deeper understanding of disease makes it possible to discover potential new drugs. Many of our development products utilizing J-Brain Cargo® are treatments for lysosomal storage disorders (LSDs), because they are diseases which JCR has addressed through R&D over the course of many years, and in which it has a high degree of expertise and extensive knowledge. We will continue to deepen our knowledge of the central nervous system and neuromuscular diseases to create new treatments for rare diseases utilizing J-Brain Cargo®.

JCR's reason for being is to fulfill unmet medical needs in rare and intractable diseases. We will continue to create new drugs through our specialty in biotechnologies, advancing R&D in new drug candidates to the clinical stage with the highly robust manufacturing capabilities we have built through long years of experience and trial and error.

Be an ally to individuals with rare diseases, focusing on innovation “only JCR can provide.”

J-Brain Cargo® is the world's first technology to overcome a 100 year challenge in drug discovery and be implemented in a pharmaceutical product.

Since its founding in 1975, JCR has steadily grown through R&D based on protein engineering, genetic engineering and cell engineering, and through unique R&D in fields that other companies do not address. Each of our employees has continued to take on bold challenges out of a desire to contribute to patients with rare diseases around the world, and as a result, JCR was the first company in the world to successfully commercialize a technology to deliver drugs to the brain across the blood-brain barrier, a technology called J-Brain Cargo®.

In the 100 years since the concept of a blood-brain barrier was first proposed, numerous academic institutions and pharmaceutical companies have attempted to research pathways and methods, as shown in the chart below, for delivering drugs to the brain. Inspired by the "Trojan Horse Technology" method, which utilizes the innate mechanism of receptor-mediated transcytosis originally proposed by William M. Partridge, M.D. and his colleagues in the U.S., JCR successfully demonstrated for the first time in the world drug efficacy on the central nervous system through a fusion of lysosomal enzymes and other substances based on an anti-human transferrin receptor antibody. In 2021, we received approval in Japan to manufacture and market IZCARGO®, a therapeutic enzyme preparation applying J-Brain Cargo® for the treatment of MPS II, an LSD, enabling us to deliver this therapy to patients and their families.

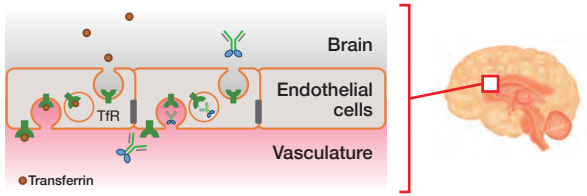
J-Brain Cargo® targets not only diseases and tissues involving LSDs and the brain, but can be flexibly customized to deliver required substances to other target tissues. This technology is a drug discovery DDS platform that, combined with new modalities such as enzymes and proteins, oligonucleotide delivery, nanoparticles, gene and cell therapy, and antibody drugs, can then be applied to a wide range of central nervous system diseases, including Alzheimer's disease, Parkinson's disease, neuro-oncology, and neuro-inflammation. Further, it has the potential to be applied to the treatment of systemic diseases, including neuromuscular and muscular disease, to create innovative new drugs.

The Challenge of Delivering Drugs to the Brain

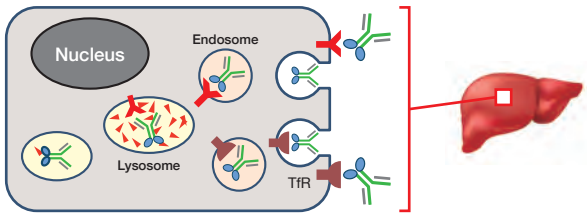
Transcellular pathways	• Passive diffusion through cell membranes in the BBB • Receptor-mediated transport through the BBB • Liposome-mediated drug delivery • Nanoparticle delivery • Exome-mediated delivery • Viral vector delivery
Paracellular pathways	• Osmotic delivery (hypertonic solution to disrupt the tight junctions) • Disruption of protein-protein interactions to increase the porocity of the tight junctions by claudin and occluding peptides

Drug Delivery with J-Brain Cargo®

Uptake into the brain



Uptake into systemic tissue



Focusing on the field of LSDs, we will build a pillar of revenue for new growth, while accelerating R&D in “medicines that only JCR can provide.”

In JCR’s development strategy, we will initially focus on the field of LSDs to build a new pillar of revenue for growth from a market worth more than 1 trillion yen per year. We will then leverage the knowledge, expertise, and experience we have gained through R&D in LSD treatments in an effort to expand our target to diseases with an even greater market size. In doing so, we will expand our product portfolio by actively promoting collaboration with partners who have resources and capabilities that represent a constraint for JCR.

In the area of LSDs, on which JCR is focused, we are now conducting global Phase III clinical trials for the worldwide launch of IZCARGO®. In addition to IZCARGO®, work is now progressing on more than 17 other development products in the LSD field using J-Brain Cargo®. Of these, global clinical trials have begun on JR-171 and JR-441, while steady results have been generated in non-clinical trials of JR-443, JR-446, JR-479, and JR-471, giving JCR a strong portfolio in this field. LSDs are rare diseases, with some affecting as few as 100 patients worldwide. There are also diseases for which there is still no cure, and even when a cure exists, there remain many unmet medical needs in central nervous system symptoms due to the inability to deliver drugs to the brain. By developing medicines that only JCR can provide, our goal is to make as many treatments as possible, as quickly as possible, for patients and their families around the world.

Market Potential for LSD Treatments

Indication	Est. Annual Sales*1	JCR Innovation
MPS IIIA	$500m+	JR-441
MPS IIIB	$200m+	JR-446
GM2 gangliosidosis	$400m+	JR-479
GM1 gangliosidosis	$200m+	Animal model study
Fucosidosis	$100m+	JR-471
Krabbe disease	$300m+	Process development
CLN1	$150m+	JR-194
Niemann-Pick	$100m+	Animal model study
Galactosialidosis	$100m+	Basic research
Total	$2bn+	

Indication	Annual Sales*2	JCR Innovation
Gaucher disease	$1,519m	Animal model study
Fabry disease	$1,793m	Agalsidase Beta BS
Pompe disease	$1,232m	JR-162
MPS I	$285m	JR-171
MPS II	$721m	JR-141
MPS IVA	$664m	—
MPS VI	$444m	—
MPS VII	$21m	JR-443
LAL-D	$160m	—
CLN2	$154m	Animal model study
Metachromatic leukodystrophy	$19m	Animal model study
α-Mannosidosis	—	Animal model study
Total	$7bn	

Source: JCR analysis *1 Internal estimates based on epidemiology *2 From data published by companies carrying existing therapeutics

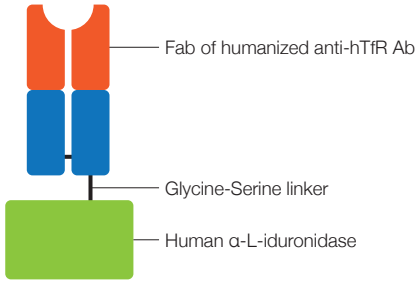
Close Up Building evidence for JR-171, a therapeutic enzyme for MPS I.

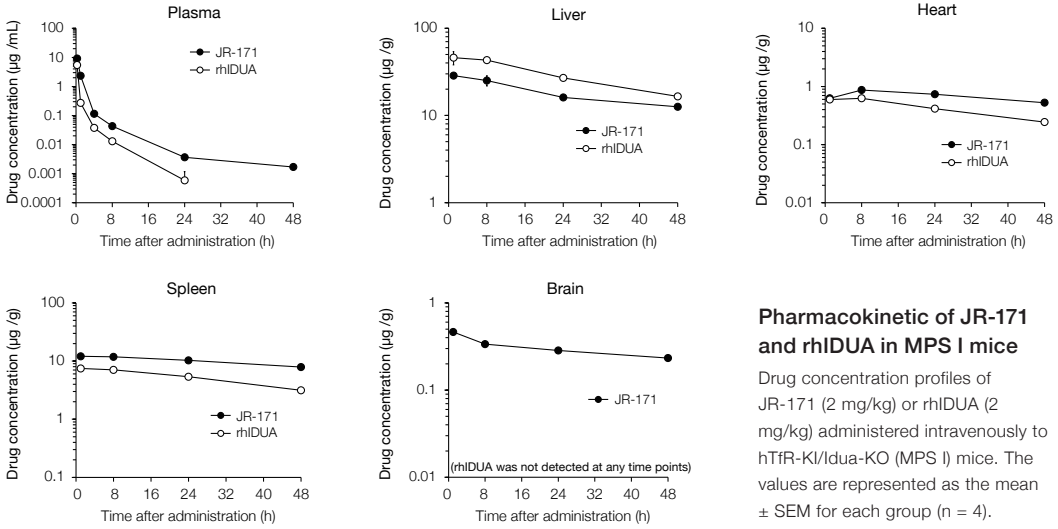
JCR is advancing development of JR-171, targeting MPS I. JR-171 is a protein preparation that fuses humanized anti-human transferrin receptor antibody Fab, the J-Brain Cargo® component, with α-L-iduronidase (IDUA).

JCR evaluated the brain delivery efficacy and safety of JR-171 using monkeys and MPS I mice. Intravenously administered JR-171 was distributed in major organs, including the brain, and reduced dermatan sulfate (DS) and heparan sulfate (HS) concentrations in the central nervous system and peripheral tissues. Further, improvements were seen in brain pathology and spatial learning ability in MPS I mice. These non-clinical results suggest that JR-171 might potentially prevent and even improve disease conditions and progression in patients with MPS I.

This non-clinical data demonstrates the same trends as for JR-141, approved in Japan for MPS II, and may suggest similar effectiveness and safety in different variations of J-Brain Cargo®.

Molecular Structure of JR-171 Therapeutic Enzyme for MPS I



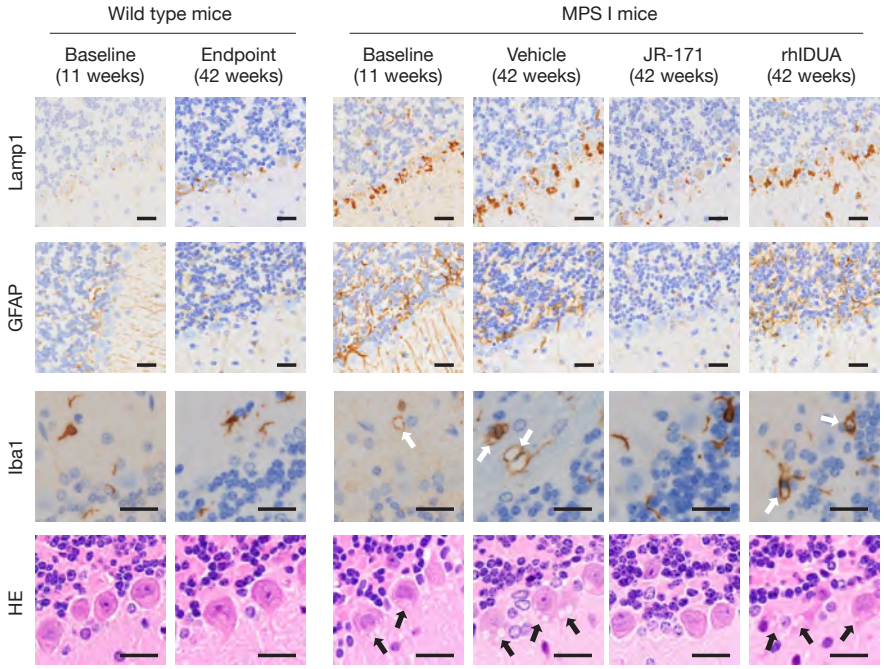


Pharmacokinetic of JR-171 and rhIDUA in MPS I mice

Drug concentration profiles of JR-171 (2 mg/kg) or rhIDUA (2 mg/kg) administered intravenously to hTfR-KI/Idua-KO (MPS I) mice. The values are represented as the mean ± SEM for each group (n = 4).

*Excerpted and translated from Sachiho Kida et al., Mol Ther Methods Clin Dev., 2023 May 12:29:439-449.

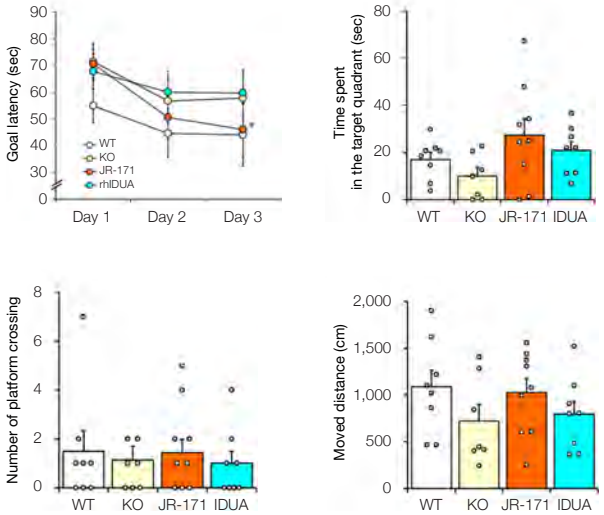
Close Up Building evidence for JR-171, a therapeutic enzyme for MPS I.



Effects of JR-171 on brain pathology in MPS I mice

JR-171 (1 mg/kg) or rhIDUA (0.58 mg/kg) was administered intravenously to 11-week-old MPS I mice once every week for 31 weeks. Representative photomicrographs of cerebellum sections are shown. Brown signals indicate positive staining for Lamp1, GFAP, or Iba1. White arrows indicate vacuolated Iba1-positive microglial cells, and black arrows indicate vacuolation or swelling of Purkinje neurons (H&E). Each square indicates an individual animal.

Morris water maze performance in MPS I mice treated with JR-171



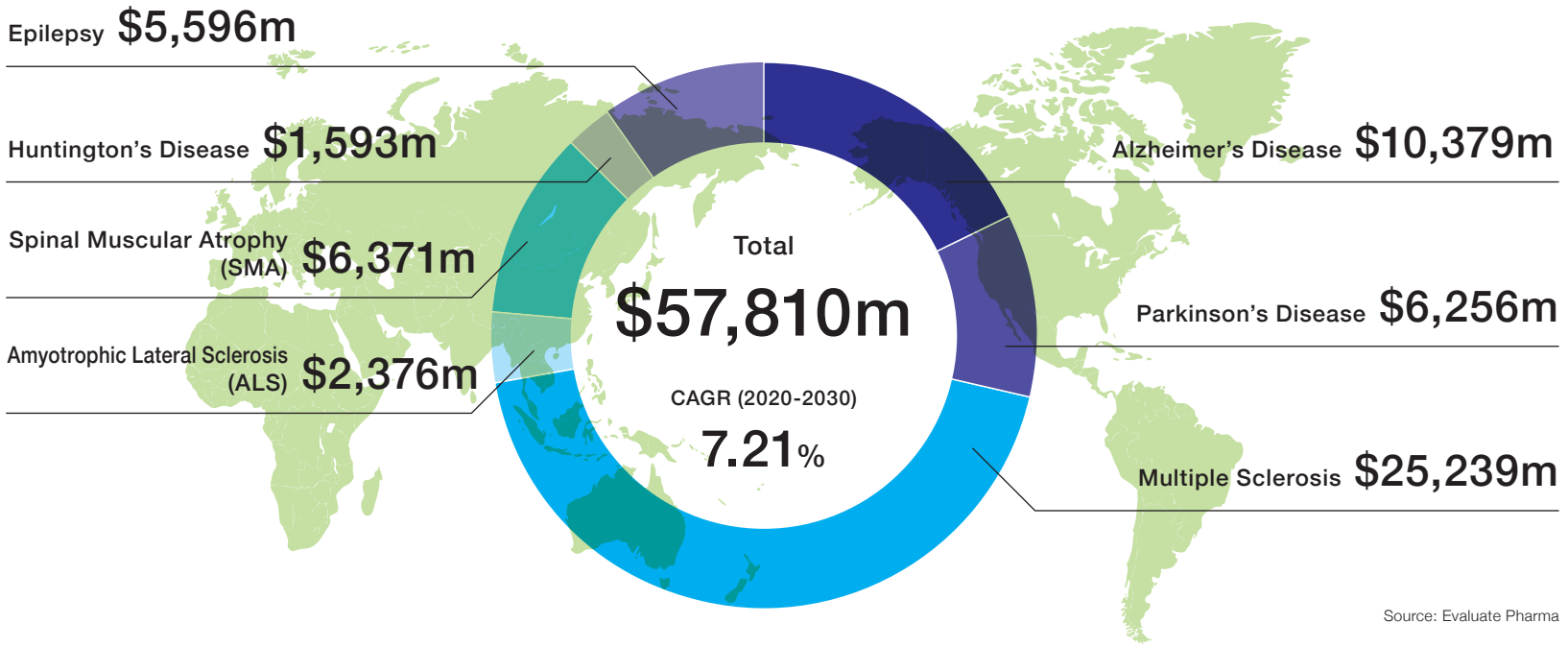
*Excerpted and translated from Sachiho Kida et al., Mol Ther Methods Clin Dev., 2023 May 12:29:439-449.

Through strategic partnerships, we will expand the potential of J-Brain Cargo® and invest the revenues gained through those partnerships in the R&D challenge.

JCR is working to expand its innovative portfolio through strategic partnerships. In March 2023, we signed our first global partnership with Alexion for the application of J-Brain Cargo® technology in the treatment of neurodegenerative diseases. In May 2023, we also entered into a global partnership with Angelini Pharma to develop and commercialize novel blood-brain barrier penetrating biologic therapeutics for the treatment of epilepsy. These partnerships represent an important first step in demonstrating that J-Brain Cargo® can be applied to neurodegenerative and a wide range of other diseases.

As we expand these international partnerships going forward, we expect to generate significant revenues from upfront payments, milestones and tiered royalties from these disease groups, which we believe will be an important source of future revenue for the Company. To continuously maximize JCR's corporate value, the revenues and resources generated by these alliances will be actively invested in the development and enhancement of drug discovery platform technologies, so that we can continue to contribute to patients and their families around the world and other stakeholders.

Neurodegenerative Diseases Estimated Market Size (2028)



Source: Evaluate Pharma

MESSAGE

Alexion Research is excited to be working with JCR to address a key challenge in drug discovery and development: how to deliver therapeutics effectively to the tissues of interest. Despite many advances in new modalities and novel targets, this remains a significant obstacle. JCR is a leader in the field with an approved therapy shown to transit the blood brain barrier, and very encouraging preclinical data with new modalities such as VHH targeting domains and oligonucleotide cargo. We believe this offers a unique capability to create effective therapeutics for rare disease patients and we look forward to building our collaboration and following the science. We will leverage the innovative J-Brain Cargo® platform discovered and developed at JCR, and Alexion's rare disease expertise. Together we will explore our ability to deliver novel modalities to brain and muscle, creating transformative therapies for patients.

Sharon Barr
Executive Vice President BioPharmaceuticals R&D, Alexion Pharmaceuticals, Inc.

MESSAGE

Our level of excitement about the collaboration with JCR continues to grow, especially now that we' re expecting the first results. It is a true win-win alliance where both parties bring to the table unique expertise.

Epilepsy therapy is currently dominated by small molecules which are not able to address some of the well-validated targets driving disease pathology. The success of this collaboration is aiming to change that and could open a new therapeutic direction. Thanks to the technology from JCR, we now have the opportunity to develop innovative brain-penetrant biologics for people living with epilepsy.

Rafal Kaminski
Chief Scientific Officer, Angelini Pharma S.p.a.

Feature 2

The Pursuit of Manufacturing

We will redouble our commitment to manufacturing and continue to meet new challenges in order to provide a stable supply of high-quality biopharmaceuticals to patients worldwide.

Yoshio Hiyama, Ph.D.
Senior Executive Director
Production and Quality Assurance Executive Director,
Production Division

One of JCR's strengths is manufacturing. All of the products supplied by JCR are biopharmaceuticals. Recombinant proteins, regenerative medical products, and other biopharmaceuticals have more complicated manufacturing methods and quality testing than small molecule pharmaceuticals, and therefore require a longer period of time to manufacture. To ensure a stable supply of biopharmaceuticals, advanced technologies are needed in areas including management of raw materials and maintenance of manufacturing equipment. Furthermore, the lot sizes that are manufactured at one time can range widely from several thousand to tens of thousands of units per product and there are many different items that are produced. For this reason, production schedules must be managed carefully at multiple production sites. JCR emphasizes the following seven principles in its manufacturing activities:

(1) Remain strongly committed to manufacturing in Japan: Currently, numerous pharmaceuticals sold in Japan are imported from abroad. JCR produces pharmaceuticals at its own manufacturing sites in Japan as much as possible, to reduce production lead times and proactively conduct process and quality improvements.

(2) No compromise on quality: Biopharmaceuticals have complicated manufacturing processes, so irregularities often occur. Quality evaluations are carried out scientifically by an independent department separate from the Production Division, and JCR will not hesitate to dispose of unsuitable lots.

(3) Constantly strive to improve manufacturing and quality testing methods: We will continuously improve processes and testing methods by cooperating with the adjacent Research Institute, in order to improve quality and productivity, even for older products.

(4) Our employees will adapt flexibly to circumstances and make every effort to supply products: Every one of our employees will exercise skill and execute superbly to ensure a stable supply of products, in order to fulfill JCR's mission of "Contributing toward people's healthcare and public health." In this manner, JCR's employees are able to sharpen their professional skills by assuming multiple duties.

(5) Prioritize logical and highly transparent discussion: We encourage staff to dismantle instructions based on organizational hierarchies and sectionalism and to hold essential and logical discussions unbounded in any direction.

(6) The worse the information, the sooner it must be reported: We have a rule in place that states that if problems that have occurred are reported immediately, the person in charge will not be evaluated negatively. This rule is intended to encourage employees to focus on minimizing harm and preventing a recurrence.

(7) Always remember to smile and be thankful: This is a priceless principle and the most important prerequisite for teamwork. It lies at the heart of corporate business activities.

The second foundation marks the beginning of a new challenge toward growth.

By centralizing research and production sites, and promoting close collaboration, we have established a structure for efficiently implementing integrated manufacturing.

JCR currently has five production sites in Nishi-ku, Kobe. 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). With research facilities located in the same area, we have established a structure to efficiently implement integrated manufacturing by promoting close interdepartmental collaboration across departments from the research stage to commercial production. In this environment, we have fostered a corporate culture that is deeply devoted to manufacturing, leveraging our extensive track record in biopharmaceuticals that we have built up since our founding.

JCR manufactures and sells regenerative medical products whose main ingredients are biopharmaceuticals using recombinant DNA technology and allogeneic mesenchymal stem cells from human bone marrow. There has been an increase in the number of cases in which biopharmaceuticals manufacturing has been outsourced to contract manufacturing organizations (CMOs) in recent years. Because JCR has basically carried out in-house manufacturing, it was able to harness its accumulated knowledge and expertise to successfully establish serum-free cultivation technology, which was previously very difficult. Apart from this, JCR has continuously tackled challenges based on an entrepreneurial spirit that calls on it to always be “one step beyond” other companies, with initiatives such as the launch of TEMCELL® HS Inj., the first allogeneic regenerative medical product in Japan, and the outsourcing to JCR of the manufacturing of the stock solution for the AstraZeneca K.K. (AstraZeneca) COVID-19 vaccine, which uses a recombinant chimpanzee adenovirus vector.

Kobe Science Park Center

In November 2022, JCR completed construction of Kobe Science Park Center (KSPC), a new API plant built to satisfy the public solicitation requirements per the FY2020 State of Emergency Vaccine Production System Improvement Project by the Ministry of Health, Labour and Welfare (MHLW). The KSPC is equipped with four 2,000 L single-use culture vessels. JCR believes that the KSPC will allow it to secure a system to undertake contract manufacturing of vaccines and other remedies in the event of a public health emergency, along with contributing immensely to strengthening the production capacity of JCR products.

JCR has proven the advanced manufacturing technologies it has accumulated since its founding through manufacturing of the stock solution for the AstraZeneca's COVID-19 vaccine.

Setting the rare disease arena as the target of drug discovery, JCR has concentrated its management resources and proactively made investments in research and development, manufacturing, facilities and people. The accumulation of technology and expertise through investment in manufacturing has also paved the way for contract manufacturing of the stock solution for the AstraZeneca's COVID-19 vaccine. When JCR was approached with an informal request to undertake such contract manufacturing in spring 2020, it did not have expertise in the manufacturing of stock solutions for vaccines. We were also concerned about the impact on manufacturing of therapies for rare diseases that were being developed. Furthermore, we needed to overcome a wide range of issues to start this project. These issues ranged from modifying facilities to securing raw materials, recruiting personnel, transferring technologies and addressing regulatory affairs. Considering these issues, it would have ordinarily taken over a year to deal with them. However, JCR completed its responses to all of the issues in four months by harnessing its rapid management decision-making speed, the strong skills and entrepreneurial spirit of its employees, its knowledge of vector-based pharmaceuticals under development and its track record over many years in biopharmaceutical technologies and manufacturing. The manufacturing of a stock solution for a vaccine was an entirely new endeavor for JCR. Despite launching this activity in a short space of time, JCR was able to start manufacturing as initially planned, and it completed manufacturing without any large setbacks, thereby fulfilling its mission as a pioneering biopharmaceuticals company. AstraZeneca had outsourced the manufacturing of the stock solution for its COVID-19 vaccine to partners in 15 countries worldwide. JCR was among the partners with the highest level of performance in terms of yield and quality. Through the manufacturing of this stock solution for the vaccine, JCR was able to demonstrate its advanced manufacturing technologies, which it has amassed since its founding, once again both in Japan and to the rest of the world.

JCR receives the European Award for Best Practices 2022 from the European Society for Quality Research (ESQR)

In its Midterm Business Plan for FY2020-2022, "REVOLUTION," JCR positioned the "qualitative and quantitative reorganization of the quality assurance system" as its top management priority. JCR has established a new department in charge of integrated quality control and constructed a new quality testing facility within its Kobe Science Park Center, which was completed in November 2022. JCR is continuously improving its production and quality assurance system to achieve an even more stable supply, and it believes that this award by the ESQR is a recognition of these ongoing efforts.

To ensure the stable delivery of pharmaceuticals for rare diseases to patients around the world, we aim to build a supply network based on global standards.

In July 2022, JCR strengthened its ties with Mycenax Biotech Inc., a Taiwan-based contract development and manufacturing organization (CDMO) company that provides a full line of CDMO business* services, by subscribing to a third-party allotment of its shares. This measure will enable JCR to address resource issues in manufacturing for several development programs planned within the next few years, as well as carry out global clinical trials more rapidly. Furthermore, in December 2022, JCR founded JCR Luxembourg S.A. as a European hub for packaging and global distribution of its investigational and commercial products for rare diseases in the State of the Grand Duchy of Luxembourg. JCR is developing therapeutic drugs targeting rare diseases. In the future, we plan to develop therapeutic drugs for super-rare diseases for which there may be only around 100 patients worldwide. For this reason, JCR anticipates an even greater need to conduct production of many different small volume products in the near future. JCR currently outsources a large portion of its investigational drug packaging to a manufacturing contractor. It is difficult to find a new contractor, and expenses are likely to rise. JCR believes that putting JCR Luxembourg S.A. in charge of these functions will allow it to conduct manufacturing with a greater degree of flexibility and establish a supply network based on global standards.

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

Single-use Culture Vessels Optimized for Production of Many Different Small Volume Products

Single-use culture vessels that employ disposable polymer bags eliminate the need for tank cleaning between product changeover and enable the efficient production of many different small volume products such as orphan drugs. For over 15 years, JCR has amassed manufacturing experience harnessing single-use technologies, and it has established a manufacturing and quality control system that can provide a stable supply of high-quality biopharmaceuticals.

In response to an unforeseen supply shortage in the growth hormone market, we set up an expanded production system for GROWJECT® within three months, with production capacity boosted to more than double our annual plan.

In May 2023, shipments of a therapeutic drug with the top share of Japan's growth hormone market were restricted and suspended. As a result, JCR was asked upon to supply its mainstay product GROWJECT® as an alternative product for patients.

This meant that JCR had to meet the challenge of manufacturing more than double the amount of drug formulation than its annual plan and supply it to the market in a stable manner. As with the drug formulation, this also meant that we had to more than double the planned production of the dedicated electronically controlled injector GROWJECTOR® L from the planned amount. The GROWJECTOR® L device was developed jointly by JCR and PHC Corporation, so the device is manufactured by a company in Japan like JCR. PHC Corporation also responded to the situation by ramping up production while keeping patients' needs foremost in mind.

From order reception to shipment from the plant, the production lead time for biopharmaceuticals is approximately two years. JCR has a production lead time of less than one year, which is significantly lower than the industry average. The increase in production in response to the additional demand required even more speed than this. Faced with these challenging circumstances, we were able to mount an initial response with plenty of leeway because our manufacturing sites were concentrated in Japan, and we had secured adequate inventories of intermediate products and drug substances. As a result, we successfully set up the expanded production system in three months. Another key factor behind our success was that we identified the raw materials that posed supply concerns based on their supply conditions; presented manufacturers with the amount we needed and the required schedule for the next year; and exchanged information with them closely. And above all, we believe that this is the outcome of instilling in all our employees an awareness that JCR will always flexibly supply critical pharmaceuticals to meet medical needs. Based on this shared awareness, we decided to prioritize the manufacturing of GROWJECT® to ensure that patients did not lose out on crucial treatment opportunities. Team JCR made a concerted effort to address the situation by conducting internal personnel transfers and hiring additional staff, along with setting up the expanded production system by implementing a two-shift manufacturing work schedule. JCR will continue to keep patients first and foremost in mind, as it strives to adapt flexibly to demand and ensure a stable supply of pharmaceuticals.

Recombinant human growth hormone product GROWJECT®


Dedicated electronically controlled injector GROWJECTOR® L and GROWJECTOR® Duo

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."

Sustainability Management

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 implementing activities in the core areas of Rare Diseases, Environment, Society, and Corporate Governance. Rare Diseases, in particular, are closely related to JCR’s business activities and are a domain to which JCR can especially contribute. In addition to developing treatments for ultra-rare diseases and building new business models, JCR has also worked to improve access to medicines. We will proactively engage in things that only JCR can provide even for ultra-rare diseases where there are only few patients as we aim to achieve a society where no one will be left behind.

MESSAGE

In the Midterm Business Plan for FY2023-2027 “*Reach Beyond, Together,*” which was announced in May 2023, JCR set out its “ideal state of mind:” to achieve sustainability through business activities based on Rare Diseases, Environment, Society and Corporate Governance. JCR believes that its mission is to harness its R&D and manufacturing capabilities to deliver new treatment opportunities to patients who are living with rare or ultra-rare diseases and their families around the world.

“Team JCR” shares this mission, and its business activities and beliefs are aligned with the spirit of the Sustainable Development Goals (SDGs) of “no one will be left behind.” We are committed to establishing a production system that ensures a stable supply of high-quality pharmaceuticals with consideration for the environment and to defining KPIs that must be addressed for JCR to continue sustainable growth. By each employee taking these challenges as their own, we will pursue the realization of a sustainable global society. Because we seek to continuously address the voices of patients and their families around the world, we will realize sustainability in the manner unique to JCR, with a view to remaining a company that is chosen by all people involved with JCR and its diverse spectrum of stakeholders.

Toru Ashida
Head of Sustainability

Sustainability Management

Structure for Promoting Sustainability

In July 2022, JCR established 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 surrounding JCR. 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

The members of this Committee are Internal Directors, Independent Outside Directors, and Corporate Officers. The Committee provides 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.

Core Sustainability Initiatives

RD Rare Diseases	• Development of drugs for ultra-rare diseases and construction of new business models • Efforts to improve access to medicines (Named Patient Supply) to deliver innovative medicines to people around the world
E Environment	• Investigation and implementation of measures to reduce environmental impact through business activities • Promote environmentally friendly procurement on the premise of ensuring the quality and stable supply of pharmaceuticals
S Society	• Address the challenge of unmet medical needs by creating platform technologies • Develop human resources so that each member of “Team JCR” can shine in their own station
G Corporate Governance	• Pursue governance in line with the Company’s growth • Ensure thorough compliance and strengthen risk management

Addressing the SDGs

JCR believes that partnership and cooperation with the international community are the most important priorities for realizing sustainability. JCR proactively conducts sustainability initiatives, in keeping with the spirit of the SDGs of “no one will be left behind.” It shares with and returns to a wide range of stakeholders the achievements of these efforts.

Process for Identifying Materiality (Material Issues)

JCR believes that it is crucial to continue pursuing the sustained creation of corporate value through its business activities, thereby contributing to a sustainable society. To that end, JCR identifies the materiality issues it should address through the process outlined to the right.

1 List materiality issues

Derive materiality issues by referring to international guidelines, principles and frameworks, as well as conditions and challenges faced by the pharmaceutical industry, and from the perspectives of what JCR is uniquely capable of doing and what it should be doing.

2 Assess materiality

Assess the importance of the materiality issues derived in 1. from the perspective of their impact on society and the environment as well as their impact on JCR’s business.

3 Assign priority to materiality issues

Based on the assessment in 2., organize materiality issues into categories and assign priority to highly important materiality issues for JCR from a long-term perspective, in light of JCR’s corporate philosophy, purpose, business activities, and Midterm Business Plan.

4 Determine materiality

The issues identified in 3. are discussed and approved by the Board of Directors and are established as JCR’s material issues. The identified materiality is explained and shared internally so that each employee can take ownership of each issue, and further enhancements are made. In addition, specific materiality issues are shared with a wide range of stakeholders through disclosure via JCR’s website and other channels.

Contributions in the Rare Diseases Arena

Rare Diseases

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 stipulate a two-year appointment without fixed membership to allow as many people as possible to participate.

As awareness-raising in-house activities, we promote our employees to wear official badges for Rare Disease Day (RDD), conduct fundraising activities, global consciousness-raising activities for MPS Awareness Day, hold open public lectures and in-house lectures, and distribute participants’ reports about the events organized by patient groups.

What JCR can do for rare diseases

Although the COVID-19 pandemic continued through FY2022, patient groups gradually resumed in-person meetings. Several RARE DISEASE Project members participated in a social event and joint symposium of the Japan MPS Patient and Family Group held in Tokyo in August 2022. We also welcomed students from Kobe Kaisei Girls’ Senior High School, Osaka Meisei Gakuen Senior High School, and National Institute of Technology, Tsuruoka College in November 2022 for an online RDD high school study tour (JCR internship).

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 learn what patients are going through. As a new initiative in FY2022, *Given: Ima koko ni aru Shiawase* (Given: The happiness of being here now), a documentary movie featuring patients with rare diseases such as MPS and their families, was made available to employees through on-demand streaming from August to September 2022. Many of our employees viewed the documentary and gave many comments and feedback about it.

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 and their families 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, and they were distributed through the internal bulletin board in a format that could be downloaded as posters at each business location. We also donated funds to the National MPS Society in proportion to the number of photos collected. In addition, employees wore hand-made purple ribbon badges and newsletters related to raising awareness of MPS were distributed through the internal e-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.

RAREDISEASEDAY.ORG

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, Japanese professional tennis player Masamichi Imamura, and Japanese professional tennis player Shinji Hazawa have been appointed as RDD Japan ambassadors by RDD Japan secretariat office and they have continued awareness-raising activities worldwide by placing the RDD official logo mark on their 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, Mr. Imamura in April 2021 and Mr. Hazawa in April 2022.

MESSAGE

I joined the RARE DISEASE Project because I wanted to hear directly from patients and their families, to reconsider the question “what can I do for them?” and to put what I learned into action. This is the second year of my appointment to the project. I’ve had several opportunities to speak with patients and hear their views firsthand through sessions and other events. By engaging with the patients, I was able to feel their daily suffering in the absence of effective treatment options, as well as their strong determination to fight their disease and stay alive, and their yearning for the creation of new medicines.

As a clinical development professional, I want to truly understand “what patients are suffering from and what they are thinking” and apply this knowledge to the development of clinical trial design. Furthermore, using scientific data from clinical trials and other studies, I would like to raise awareness of the fact that many people are suffering from diseases all over the world, as well as convey the voices of patients and their families, through the process of applying for new drug approval.

Marin Noda
Domestic Project Coordination Group, Domestic Development Unit, Development Division

Environment

Initiatives for Environmental Conservation

JCR has been taking a wide range of steps to mitigate its environmental impact, including reducing CO_2 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 to hybrid cars, electric vehicles, and hydrogen-powered cars. In addition, we have promoted measures such as reducing water use at production sites, along with adopting single-use bioreactors to ensure efficient use of manufacturing facilities.

In July 2022, JCR established a new Environmental Committee to further strengthen its environmental initiatives, including efforts toward carbon neutrality. The Committee is responsible for setting basic policies involving the environment and for identifying material issues, and will establish and manage progress with targets based on those issues

The Kobe Science Park Center, JCR's new production site completed in November 2022, makes proactive use of solar power generation and other types of renewable energy. In addition, we are working to contribute to reducing global environmental impact by recycling industrial waste (waste plastics) generated by our production sites through material recycling, thermal recycling, and conversion into recycled solid fuel.

1. Recycling industrial waste (waste plastics)

Since FY2022, we have been working to select global environmentally friendly waste collection, transport, and intermediate treatment operators, and to strengthen our understanding and sorting of different types of industrial waste. This is intended to optimize disposal methods and monitor the volume of waste plastics disposed, as issues in recycling and reuse of industrial waste (waste plastics) and improving recycling rates.

As part of future efforts, in FY2023 we will actively promote material recycling of waste plastics discharged by our production sites. We are working to help mitigate the global environmental burden by reducing CO_2 emissions, conserving depletable resources, and extending the life of landfills through thermal recycling of waste plastics for which material recycling is difficult, and by converting them into recycled solid fuels—alternatives to fossil fuels—including RPF*1 (solid fuel made from waste plastics and paper waste) and fluff*2 (shredded soft plastic).

*1 Refuse Paper & Plastic Fuel (RPF): A high-grade solid fuel made primarily from waste plastics, with a calorific value comparable to coal. It not only offers excellent handling and storage properties, but also advantages in terms of economy and CO_2 reduction.

RPF

*2 Fluff fuel: Fluff fuel is produced by sorting and shredding waste plastics. Compared to RPF fuel, derived from general waste plastic, fluff fuel is characterized by a low environmental impact since it requires no process for adding heat.

Fluff fuel

2. Consideration for biodiversity and proper management of chemicals and hazardous substances in wastewater management

In order to minimize our impact on biodiversity, we appropriately manage methods for handling and disposing of chemical substances used in R&D and manufacturing based on risk assessments. In addition, sewage containing chemical substances and hazardous materials generated at each production site is properly treated via the wastewater treatment system described below. We then monitor the effluent to ensure it is discharged into the public sewer system at levels at or below the standards required by law.

■ Wastewater treatment tank using yeast (new production site)

Because drug substance manufacturing often generates highly concentrated BOD, we have installed a system that uses yeast to decompose the BOD and includes compliance with wastewater regulations. Chemical dosing via a continuous neutralization device capable of neutralizing manufacturing wastewater is also used to adjust pH values to within values permitted by wastewater regulations; the wastewater is then discharged into the public sewer system.

Wastewater treatment tank

■ Virus inactivation equipment (new production site)

We have installed a system to inactivate microorganisms, viruses, etc. contained in wastewater from the process of manufacturing biopharmaceuticals and other products. This process ensures that sewage is disinfected and discharged into the public sewer system with consideration for the environment.

Virus inactivation treatment system

3. Consideration for the surrounding residential environment at the new production site

At the Kobe Science Park Center, manufacturing facilities and equipment that generate noise and wastewater odors, etc., are located on the factory side of the property, while the office building is located on the residential side in consideration of the need to preserve the residential environment for the people who live near the factory.

Kobe Science Park Center

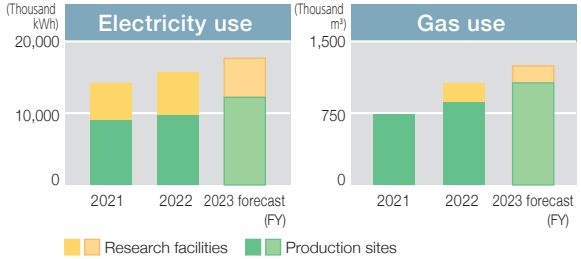
4. Other initiatives

- We use rental uniforms made of recycled materials, and used uniforms are collected and recycled as raw material, contributing to a reduction in the use of petroleum-derived raw materials.
- We are reducing the use of copy paper by going paperless (digitizing documents and records related to GMP). We also use paper products with a FSC certification mark (switch completed in some departments, with plans for Company-wide rollout going forward).
- We use 100% recycled toilet paper (with flushable cores and wrappers). (Switch completed in some departments, with plans for Company-wide rollout going forward.)
- We are switching electric cars used as company vehicles to long-range models.

Electric vehicle

Energy Use

Total energy use has increased since heat source equipment went into full-scale operation at our research facilities around May 2022, and the new production site began operation in the latter half of FY2022.



*Data from production sites and research facilities of JCR Pharmaceuticals Co., Ltd.

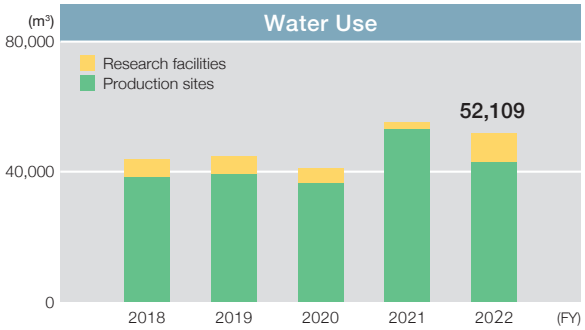
At the Kobe Science Park Center, we have installed 588 solar panels on the roof of the office building, and use renewable energy in staff spaces, the cafeteria, and elsewhere. In accordance with recommendations from the Task Force on Climate-Related Financial Disclosures (TCFD), we have been disclosing information on total energy use since FY2021.

Solar power generation panels that have been installed over the entire roof of the Kobe Science Park Center office building

Water Resources

In FY2021, we saw a partial reduction in the use of water resources thanks in part to reductions in the amount of water used in research and production processes and efforts such as promoting the recovery and reuse of exhaust steam. However, water use increased temporarily due to growth in manufacturing business results (manufacturing of stock solution for COVID-19 vaccine). In FY2022, water use increased significantly due to full-scale operation of heat source equipment at the research facilities and other factors. Among production sites, operation of a new plant brought an increase in water use, but it decreased overall with the end of contract manufacturing stock solution for COVID-19 vaccine.

All water used in research and production activities is treated appropriately on site before being discharged.



*Data from production sites and research facilities of JCR Pharmaceuticals Co., Ltd.

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. Scope 3 emissions represented about 90% of GHG emissions overall in FY2022. For Category 1, which represents half of that amount, we plan to work with suppliers to prioritize reviewing and implementing measures to reduce those emissions.

[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.

[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.

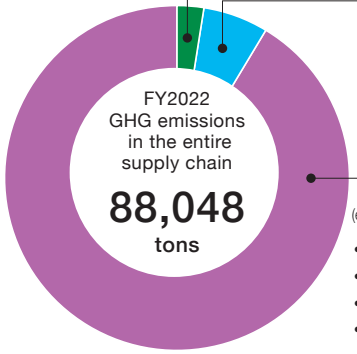
[Risk Management]

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.

FY2022 GHG Emissions by Scope



Scope 1 3,315 tons

Direct greenhouse gas emissions from an organization itself (fuel combustion, operational processes)

Scope 2 5,266 tons

Indirect emissions associated with use of electricity, heat or steam supplied by another company

- Market standard 5,266 tons
- Location standard 7,670 tons

Scope 3 79,466 tons

Indirect emissions other than those from Scope 1 and Scope 2 (emissions from other companies associated with business activities)

• Category 1	38,635 tons	• Category 5	186 tons
• Category 2	39,094 tons	• Category 6	115 tons
• Category 3	1,155 tons	• Category 7	153 tons
• Category 4	127 tons	• Category 8-15	0 tons

Scope of calculation	Scope 1, 2, and 3 applied to JCR Pharmaceuticals Co., Ltd.
Scope 1	In addition to the combustion of fossil fuels such as gasoline, freon—which originates from industrial air conditioners—and CO_2 emissions derived from CO_2 canisters are also included in the calculations
Scope 2	Calculated using both market standards and location standards. Coefficients are in compliance with the Act on Promotion of Global Warming Countermeasures.
Scope 3	–
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

S Society

Basic Concept

With the aim of contributing to the unmet medical needs of patients and their families around the world, JCR supports medical research and the development of young researchers; provides humanitarian assistance in medically underserved countries; offers aid for the development of maternal and child health care; and supports children undergoing medical care and their families. Further, in an effort to address the world's medical needs as quickly as possible, we are working to disseminate the latest developments and expand access to pharmaceuticals.

Through such activities, we aim for a society in which no one will be left behind and the sustainable growth of JCR.

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.

公益財団法人
国際医学研究振興財団
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 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


©fistula group

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.

Contributing to Unmet Medical Needs

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

JCR aims to provide financial support to enable young researchers involved in life science or basic research as well as cancer immunotherapy research to concentrate on their studies, donating 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 support 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.

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 schoolteachers, 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.

Momiji House, a Short-Stay Medical Care Facility

JCR supports Momiji House, which was established as Japan's first short-term facility for children with complex medical care needs. 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

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.

In February 2023, at the 19th Annual WORLD*Symposium*™, an international research conference on the basic research and clinical application of LSDs, 10 topics related to JR-141, JR-171, and JR-441, JR-471, and other candidate treatments for LSDs which it is developing using its proprietary J-Brain Cargo® technology were presented orally or as posters, while it also opened a booth at the venue where information was exchanged with relevant parties.

Clinical trial results for JR-141 were also presented at the 6th Asian Congress on Inherited Metabolic Diseases 2023 held in March 2023.

Efforts to Expand Access to Pharmaceuticals

IZCARGO® was approved and launched in Japan in 2021, and Phase III global clinical trials for JR-141 are currently underway outside of Japan. While JCR is working to strengthen product development and registration in order to deliver this treatment to patients around the world, it has also entered into an agreement with Clinigen Limited ("Clinigen") of the UK, and in March 2023 began addressing access to the drug in countries where it has not yet been approved through its Named Patient Supply program for IZCARGO®.

Clinical trials are conducted in selected regions, and registration requirements limit the number of patients who can participate. We have thus decided to implement a program through Clinigen to provide access to this treatment to patients who meet the medical needs, regulations, and standards of each country. Our goal through this program is to expand appropriate access to pharmaceuticals.

S Society

Basic Concept

As noted in its newly formulated Midterm Business Plan, "*Reach Beyond, Together,*" JCR aims to continue investments in human capital and to establish a human resources strategy that will help to improve corporate value. It will work to construct a dynamic human resource portfolio that will help to accomplish the strategy, develop and organize permeation of diversity and inclusion, and activate individuals and organizations promote improvements to engagement. JCR will also advance efforts toward individual and organizational growth by creating a workplace environment in which our richly diverse employees can shine, and strengthening hiring and development of next-generation leaders in anticipation of full-scale global business expansion.

Construction of a Dynamic Human Resource Portfolio That Will Help to Accomplish the Strategy

Promoting Human Capital Management, Including Development of a Human Resources Portfolio

JCR sees developing and securing personnel who might contribute to enhancing its corporate value as central to its efforts to invest in human capital that will aid in advancing its business plans. Going forward, JCR will strive to expand and enhance programs that will contribute to promoting human capital management, including development of a human resources portfolio.

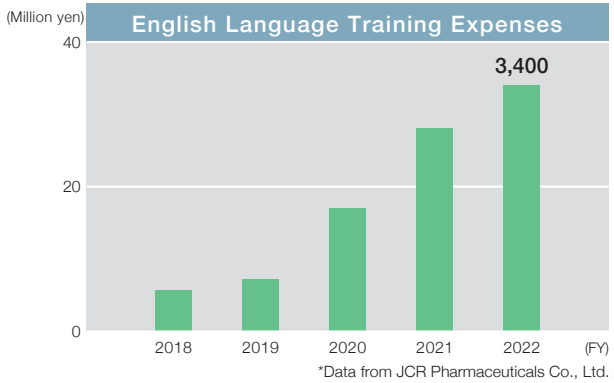
To remain a group that is attractive to a diverse workforce and to retain talent, we value the ability to share our core values with others regardless of nationality, gender, or age. To secure those human resources, we are working to strengthen not only recruitment of new graduates, but also mid-career hires with diverse skills and attributes who can make immediate contributions. In FY2022, we spent approximately 41 million yen on this effort. We will continue this proactive investment in hiring in FY2023 and beyond with a focus on securing human resources with an even greater degree of specialization and diverse human resources. Our goal is to enhance our human resources portfolio with people better able to contribute to advancing our global strategy.

Offering Online English Conversation and In-Person Practical Training Programs to All Those Wishing to Improve Their Language Skills

JCR focuses on employee training from the viewpoint that employee growth leads to the development of the Company itself. In addition to holding regular training for new hires and for employees at each level of the organization, we also offer English-language training and beginning in FY2020, we have incorporated voluntary training in which employees can express their own interest in participating and e-learning to support employee efforts at self-improvement and growth. We also take into consideration the needs of our employees and the ease with which they can participate in these training programs, whether in the form of group training with outside instructors or participation in open lectures held outside the Company. English-language training is also offered with a variety of content and formats, including group lessons, web-based training and others.

Key Efforts Aimed at Personal and Organizational Growth

Construction of a dynamic human resource portfolio that will help to accomplish the strategy	• Promote human capital management, including building a human resources portfolio • Offer online English conversation and in-person practical training programs to all those wishing to improve their language skills • Develop next-generation global leaders (JCR Academy)
Development and organizational permeation of diversity and inclusion	• Create a corporate culture that utilizes the individual abilities of richly diverse employees • Promote the creation of a workplace where employees can thrive regardless of gender • Enhance initiatives for career support of persons with disabilities • Introduce a system that enables flexible work • Support those raising children through in-house daycare centers and subsidies for childcare, etc. • Measures to improve the childcare leave acquisition rate among males
Activation of individuals and organizations promotion of improvements to engagement	• Build a human resource management framework as a system for realizing the image of who we want our people to be • Promote the creation of a workplace environment that protects the safety and health of employees and allows them to work with peace of mind



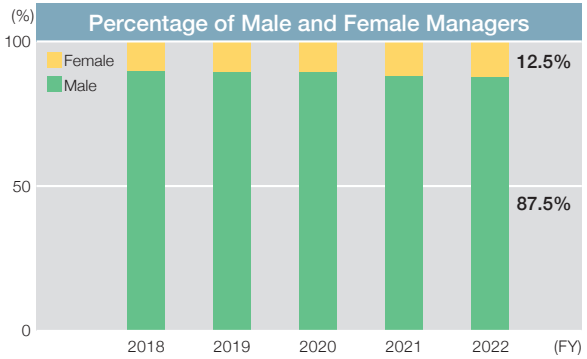
*Data from JCR Pharmaceuticals Co., Ltd.

Human Resource Management

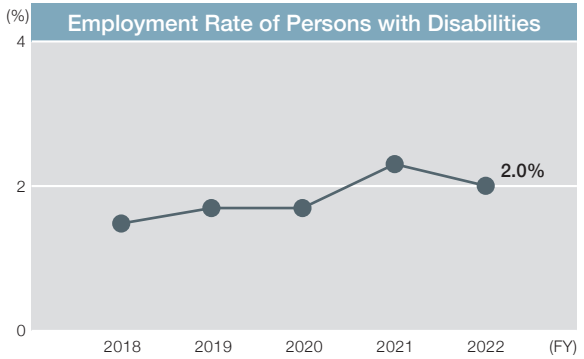
Training Track Record

FY		2018	2019	2020	2021	2022
Group training Tier-specific training Voluntary training	Number of sessions	15	15	8	16	— *1
	Hours	135	126	60	112	— *1
	Amount (Millions of yen)	6.6	9.0	5.1	11.4	**16.0** *2
English language training	Amount (Millions of yen)	5.7	7.2	17.0	27.9	**34.0**

*1 FY2022 employee training was reassigned to compliance training
*2 JCR Academy, voluntary e-learning training, etc.
*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 was launched in FY2022 as a training initiative to develop next-generation global leaders and nurture the skills that will enable them to thrive on a global stage. 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.

Development and Organizational Permeation of Diversity and Inclusion

Creating a Corporate Culture That Utilizes the Individual Talents of a Richly Diverse Employees

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 12.5% in FY2022), 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.

Going forward, we will continue to conduct hiring and promotions free of gender bias, so that we can remain a company that enables women to continue working without interrupting their careers for significant life events or other reasons.

Promoting Employment of Persons with Disabilities

JCR aims to promote and normalize diversity, and to create an environment in which those with disabilities can work comfortably. It assigns counselors and uses in-person interviews to check individual wellness and motivation and to exchange information on work styles. The legally required rate of employment of persons with disabilities was met in FY2021, at 2.3%, but with an increase in the total number of employees, in FY2022 that rate was 2.0%.

Going forward, we aim to become a company in which diverse human resources can play an active role, both by continuously creating employment from the perspective of work sharing, and by establishing a system to ensure ongoing follow-up.

Human Resource Management

Introducing Systems to Enable Flexible Work

In the belief that both work and private life are important to our employees, we have introduced flexible work systems, some unique to JCR. These include introduction of flextime and telecommuting systems, allowing employees to take annual paid leave in hourly increments, and others. Since 2020, we have been working to enhance this initiative, including gradually expanding eligibility for the flextime system to each plant in the Production Division.

Beginning in 2019, we also began trial introduction of a paid leave accumulation system*, unique to JCR. This system can be used by employees whenever they need to provide childcare or nursing care to family members, or when they need to see a doctor regularly for the treatment or screening of 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, has been expanded to family members. JCR aims to introduce a variety of systems to provide a workplace environment in which 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.

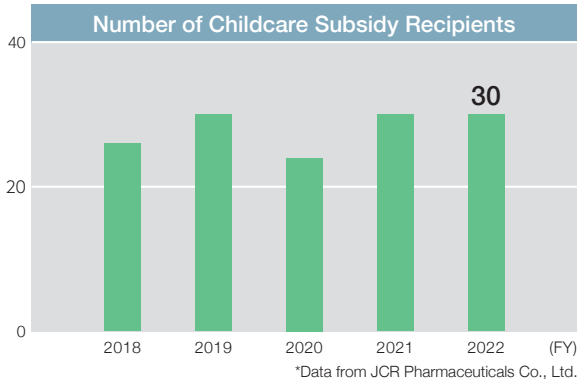
Support for Employees Raising Children, through In-house Childcare Centers and Childcare Subsidies, etc.

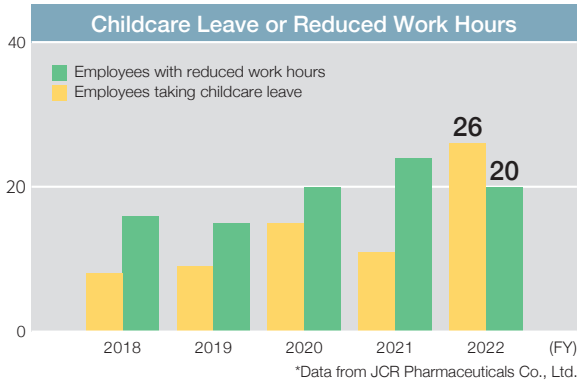
We have provided an in-house childcare center at the Research Institute for employees who are raising children. In addition, we provide monthly childcare subsidies to support employees who are unable to use the in-house childcare center due to their work location. In recognition of these and other efforts,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

In addition, as a system for shortened working hours for childcare, JCR provides for shortening working hours by up to two hours per day until the child reaches the end of the second grade of elementary school.

Measures to Improve the Childcare Leave Acquisition Rate among Males

As a social issue, childcare leave taken by males has not yet fully become entrenched in society. Even at JCR, the childcare leave acquisition rate among males (17% in FY2020) was lower than the childcare leave acquisition rate among females (100% in FY2020). We believe that fostering workplace understanding and instilling awareness among male employees are essential to improving the childcare leave acquisition rate among males. Based on this belief, the Child-Raising Support Café (37 voluntary participants in FY2020) and Ikuboss training (14 participants in FY2021 and 28 in FY2022) (Ikuboss: a boss supportive of child-raising) were held as in-house seminars. At the seminar, an outside lecturer spoke about the benefits of childcare for males, and male employees and managers who have taken childcare leave in the past shared their experiences to promote understanding and cooperation for male employees to take childcare leave. Furthermore, staff from human resources departments explained various programs that enable male employees to actively acquire childcare leave, and published interviews in the in-house newsletter with those who have taken childcare leave. With these and other steps, JCR is working to foster awareness of the acquisition of childcare leave by males within the Company. Through these measures, the childcare leave acquisition rate among males has increased every year, reaching 67% in FY2022. Going forward, we will continue working to improve the childcare leave acquisition rate.





Human Resource Management

Activation of Individuals and Organizations Promotion of Improvements to Engagement

Building a Human Resource Management Frame as a Framework to Realize the Image of Who We Want Our People to Become

To ensure proper communication between the Human Resource Planning Department and each department, regular discussions are held to align the Company's approach to future human resource needs before formulating a personnel plan. This effort to build a human resource management framework for people who can excel globally is centered on a newly formulated the image of who we want our people to become, and our desired corporate climate.

To study the current status of the above initiatives, in FY2023 we conducted an engagement survey of all employees to measure employee satisfaction levels. We also conducted a human resource trend analysis (competency measurement). We were able to obtain responses from about 90% of employees, and the results of our analysis of the survey were used in formulating our image of who we want our people to become and our desired corporate climate. Going forward, we will use the information in considering new human resource systems, and will also begin considering a system for measuring engagement on an ongoing basis.

In addition, with the aim of accumulating and visualizing human resources information as human capital, we introduced SAP SuccessFactors, a talent management system, in parallel with the deployment and building of the Company's core SAP S/4 HANA system. The system, a standardized solution for human resource management, not only allows for the centralized management of human resource data, but will enable us to analyze and utilize data to achieve talent management in line with our image of who we want our people to become. Examples of these initiatives include management of employee goals and evaluations, and use of a Career Vision Sheet. The Career Vision Sheet is a system unique to JCR, and is used to obtain information from employees once a year regarding the jobs they desire going forward and their career goals several years into the future. This allows us to understand each employee's vision for their own career, and consider appropriate assignments, transfers, and employee career development in light of future business operations. It also functions as a tool for communication between the Company and its employees.

Related page
Midterm Business Plan for FY2023-2027, *"Reach Beyond, Together"* P.22

Promotion 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.

Close Up Initiatives for Hiring Those with Disabilities

Hiring and Creating Places for Those with Disabilities to Excel

With the aim of promoting and normalizing diversity, in addition to its existing recruitment activities JCR has undertaken a wide-ranging review of work for individuals with disabilities. Since 2021, we have worked to create a system that would allow for stable operations even during the COVID-19 pandemic, while also introducing diverse work styles, including a hybrid of teleworking and office-based work for employment of those with disabilities. Through this system, we also worked to expand employment of those with mental disabilities. To create a more comfortable working environment, we have also assigned counselors who conduct one-on-one interviews to check on employee wellness and motivation, and to discuss how they work. The legally required rate of employment of persons with disabilities was met in FY2021, at 2.3%, but with an increase in the total number of employees, in FY2022 that rate was 2.0%.

Going forward, we will look from the perspective of work sharing to create a base for employment of those with disabilities, continue to expand eligible occupations, and strive to ensure each person can make full use of their abilities in their areas of strength. In addition, we will put in place a system for continually following up with those with disabilities, with the goal of being a company in which diverse human resources can excel.

Support System for Employees with Disabilities

The Act for Eliminating Discrimination against Persons with Disabilities, enacted in 2016, requires businesses to make “reasonable accommodations” to remove as many barriers as possible in the lives of people with disabilities. At JCR, we are working to improve and maintain the working environment to enable employees with disabilities to lead stable professional lives in accordance with the characteristics of their particular disabilities. This includes, in the hybrid work teams mentioned above, direct individual support, including cooperation with specialized welfare agencies, as well as assigning counselors to conduct regular one-on-one employee interviews.

MESSAGE

I work as a member of a nine-person team, using software called AutoCAD to digitalize hand-drawn blueprints created in the past. Since I had no experience with AutoCAD until I joined JCR, when I first started the job, I often made mistakes in operating the software and in drafting procedures. To overcome those problems, I worked to identify the details behind my mistakes, verbalizing what steps I could take to avoid repeating them and implementing those steps.

At JCR, each drawing is handled by a team, so a system is in place to cover for any absences among the team, which makes it easy to take leave when necessary. Reasonable accommodations are made for the characteristics of each team member’s disability, and among other things, the environment is such that we can immediately check on any questions we may have about the work, allowing us to continue to work without feeling too much of a burden. We are also able to maintain a good work-life balance, including time to pursue our hobbies.

Tomomi Tashiro
HR Planning Dept., Administration Division

Quality Assurance and Stable Supply

S Society

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, complex manufacturing and quality control than what is required by small molecule pharmaceuticals. Moreover, detailed manufacturing and quality test plans are required. Each production site sets quality targets under common, Company-wide quality policy to continuously manufacture high-quality products, evaluates the status of achievement of those targets each year, and reports the results to management. 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 Department which has been integrated with the Analytical Methods Development Department, we have established a quality control system that enables a streamlined process from consideration of testing methods in the early stages of research to release testing for commercial production.

Ensuring a Stable Supply of Products

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 raw material and product inventories, along with manufacturing of drug substances and finished products at its in-house production sites in Japan to allow for flexible manufacturing schedules. 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 production sites overseas.

Ensuring Product Safety

Pharmacovigilance 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 Responsible Persons

In accordance with the Pharmaceuticals and Medical Devices Act, JCR has set up a system of cooperation among three responsible persons, namely the Marketing Supervisor-General, Quality Assurance Manager and Safety Management Supervisor. This system is designed to scientifically and objectively evaluate the quality and safety of products independently of the Sales Division and Production Division, which are the principal bodies of JCR's corporate business activities. The system decides whether or not to release products and if there is a need for product recalls or additional safety measures, all important factors for JCR. By also reporting to and working in cooperation with the Representative Director and President and other responsible officers, management and this system work together to ensure the quality and safety of JCR's products.

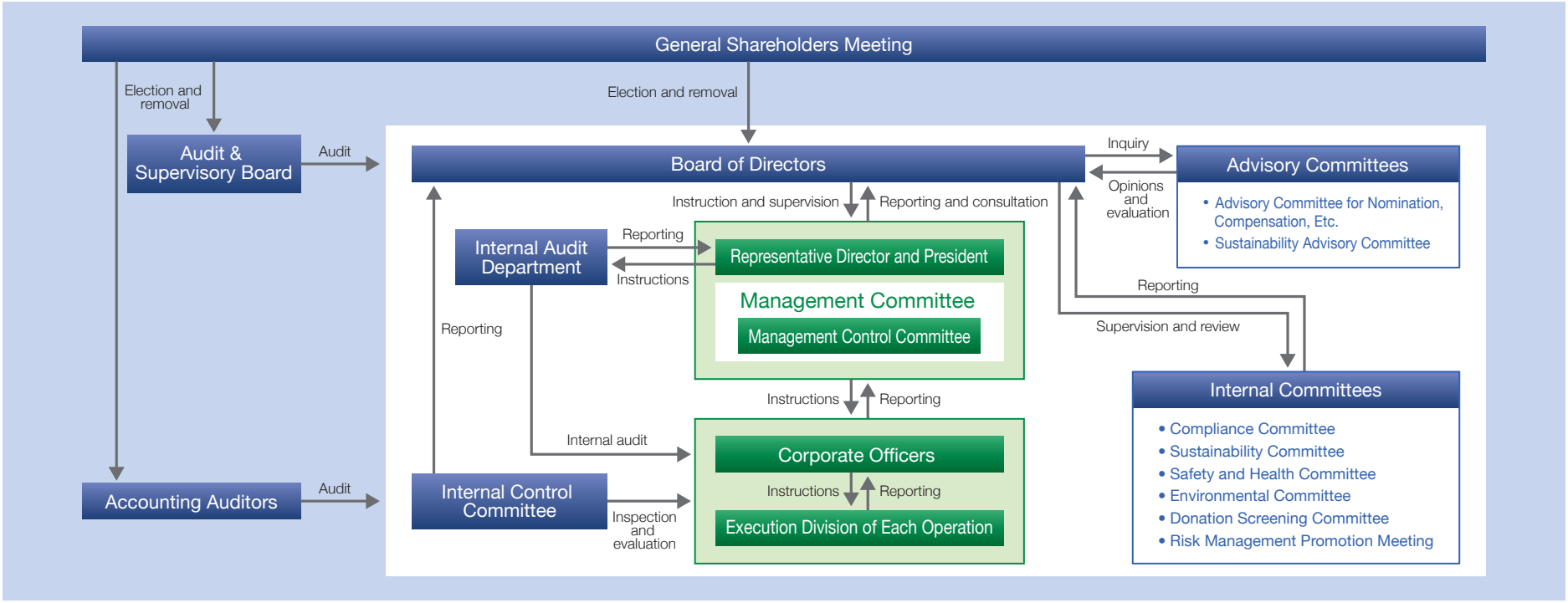
G Corporate Governance

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 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.

Corporate Governance System (As of July 6, 2023)



Corporate Governance

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 12 Directors, including seven 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, 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 it 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 seven 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 12 Senior Executive 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. In FY2022, the Board of Directors discussed and made decisions on the establishment of an overseas subsidiary, important capital expenditures, and collaboration and license agreements with other companies.

Our Articles of Incorporation state that the Company may have no more than 12 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 Senior Executive Directors, 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 Senior Executive 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. In FY2022, it reported to the Board of Directors in response to inquiries regarding appointments of Senior Executive Directors and Corporate Officers and major organizational changes.

Sustainability Advisory Committee

The Sustainability Advisory Committee comprises a total of five members: one Internal Senior Executive Directors, one Corporate Officer, and three independent Outside Directors. The Committee reports to the Board of Directors in response to inquiries on the content of discussions by the Sustainability Committee and Environmental Committee. In FY2022, it reported on JCR's current conditions, such as external ESG assessments, and challenges, as well as the Sustainability Committee and Environmental Committee's annual activity report and planned initiatives for FY2023 and beyond.

Management Committee

The Management Committee consists of five Internal Senior Executive Directors, two Senior Corporate Officers, and three Corporate Officers, as well as Outside Audit & Supervisory Board Members and outside experts acting as observers. 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. Two Senior Corporate Officers 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, which is directly under the control of the Representative Director, performs audits on whether or not administrative and operational structures of JCR's management activities as a whole and business operations are reasonably executed by departments in line with laws and regulations, confirming and evaluating objectively from an independent position. The purpose of the internal audit is to help the Company achieve management targets effectively and improve its operations.

The Internal Audit Department consists of two employees, including one department Director. Internal audit results are reported to the Representative Director and Audit & Supervisory Board Members.

Internal Control Committee

JCR established the Internal Control Committee to respond to the Internal Control Reporting System under the Financial Instruments and Exchange Act. The Internal Control Committee is chaired by the Director of the Internal Control Department, with members appointed from relevant departments in the Company, and Outside Audit & Supervisory Board Members and Accounting Auditors serving as observers. In principle, meetings are held every two months. It promotes and supervises the designing and operation of appropriate internal control relating to various business processes to ensure the reliability of financial reporting.

Sustainability Committee

JCR has established the Sustainability Committee in order to implement and promote sustainability management initiatives, with a view to contributing to the realization of a sustainable society and achieving sustainable growth for JCR based on its management philosophy of "Contributing toward people's healthcare through pharmaceutical products." The Sustainability Committee is chaired by the director in charge of sustainability with employees selected from each division of the Company as members.

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 is chaired by the general safety and health manager and consists of an industrial physician, safety administrator, health administrator, and employees at management level, all of whom are nominated by the Company, as well as employees nominated by an employee representative and a labor and social security attorney acting as an observer. 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 of 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 has established the Environmental Committee in order to practice and promote environmentally conscious business activities. This committee consists 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 regularly evaluates 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.

Compliance

Compliance System

JCR has established Compliance Rule to ensure that the group of companies comprising JCR and its subsidiaries conduct operations appropriately. Concurrently, the Compliance Control Committee and the Compliance Promotion Committee have been formed in order to establish the necessary measures concerning compliance and oversee their implementation.

The Compliance Control Committee, whose members are nominated by the Board of Directors, fulfills roles such as formulating basic policies and plans for promoting compliance activities, and presenting these matters to the Board of Directors, as necessary. Furthermore, the Compliance Promotion Committee, whose members are nominated by the Compliance Control Committee, is engaged in duties related to promoting compliance.

Separately from these committee organizations, the Compliance Rule requires that the heads of each division be appointed as the person responsible for the execution of compliance and assume responsibility for the implementation of compliance in the divisions they manage. Meanwhile, the Compliance Rule requires that education and training be provided regularly in each division to improve compliance-related awareness and enable employees to obtain and retain relevant knowledge. The Rule also requires each employee to make a sincere effort to participate in such education and training.

Compliance Initiatives

JCR defines compliance as: “All of the Company’s executives and employees acting in accordance with laws and regulations (including rules, guidelines, voluntary industry standards, JCR’s corporate philosophy and internal rules, etc.) with an ethical spirit for the Company to fulfill its social mission, meet the demands of society, realize sound, sincere management, and achieve sustainable development.”

The most important principle in promoting compliance is to not turn a blind eye when you encounter situations where you have doubts about compliance-related issues. We will neither hide our problems, nor try to turn them into a personal responsibility, but shall work together to resolve them. We should constantly review what we are doing, what we have done, and what we are trying to do in the future from the perspective of “creating sincere Team JCR.” With our Compliance Manual and Compliance Handbook serving as our compass, we shall realize our vision for the Company by resolving problems whenever they arise.

JCR implemented the following compliance activities in FY2022: it issued a compliance newsletter and compliance e-mail magazine every month; provided general compliance training, including messages from management, every month; conducted a questionnaire on harassment; improved internal awareness through Compliance Awareness Month held twice a year; and provided compliance training for new employees and managers.

Composition, Number of Meetings Held, and Attendance Rate for Internal Committees and Other Organs of the Company in FY2022 (As of end of FY2022)

Advisory Committee for Nomination, Compensation, Etc.		Composition	7 members (1 Internal Director, 4 Independent Outside Directors, 2 Independent Outside Audit & Supervisory Board Members)
		Number of meetings held	10
		Attendance rate	94.12%
Internal Control Committee		Composition	11 members (1 from Administration Div., 4 from Internal Control Dept., 3 from Internal Audit Dept., 1 from Accounting Dept., 1 from General Affairs Dept., and 1 from Production Management Dept.)
		Number of meetings held	7
		Attendance rate	90.79%
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	100%
	Compliance Promotion Committee	Composition	18 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., 2 from Quality Assurance Div., 1 from Tokyo Office, and 1 from Accounting Dept.)
		Number of meetings held	2
		Attendance rate	94.59%
Safety and Health Committee		Composition	14 members (1 labor and social security attorney, 2 industrial physicians, 1 from HR Planning Dept., 2 from General Affairs Dept., 1 from Sales Div., 1 from Quality Assurance Div., 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	91.62%
Donation Screening Committee		Composition	9 members (1 Adviser, 1 Executive Director of Administration Div., 1 from Legal Affairs Dept., 1 from Accounting Dept., 1 from Development Div., and 4 from Internal Control Dept.)
		Number of meetings held	10
		Attendance rate	96.63%
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%

Whistleblowing System (JCR Hotline)

JCR has established whistleblowing and consultation desks within and outside the Company. Regarding the permissible content of reports and consultations, JCR has adopted a system that accepts not only reports and consultations on violations of laws and regulations or internal rules, but also consultations on harassment and mental health, as well as opinions, requests, and suggestions for improvements. In addition, JCR has distributed to all employees business card-sized cards carrying the 27-item JCR Compliance Policy and contact information for the consultation desk, along with distributing and displaying posters in each department. JCR strives to make the whistleblowing system more generally known and easy to utilize through these measures.

Risk Management

Risk Management Promotion Meeting

JCR has established the Risk Management Promotion Meeting, which is led by the Risk Management Officer appointed by the President, and includes division Executive Directors (or department Directors for departments that do not use the division system), as well as presidents 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 the Basic Risk Management Rule and develops its risk management system and ascertains risk in its business activities based on that rule. 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.

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.

Please refer to our "Corporate Governance Report" for details.
https://www.jcrpharm.co.jp/en/site/en/company/governance.html

Risk Management System

Outside Directors and Outside Audit & Supervisory Board Members

Functions and Roles of Outside Directors

JCR has seven Outside Directors, comprising five Independent Outside Directors and two Outside Directors. 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 23.28% of JCR's shares.

Outside Director Marc Dunoyer concurrently holds the post of Chief Executive Officer of Alexion, AstraZeneca Rare Disease. JCR and Alexion have signed a Research Collaboration, Option and License Agreement concerning a treatment for a neurodegenerative disease that applies JCR's J-Brain Cargo® technology.

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 Ishikiriyama, 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 two Outside Directors. Accordingly, JCR has appointed Independent Outside Directors who account for more than one-third of the Board of Directors, sufficiently meeting 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.

MESSAGE

I am honored to become again a director of JCR, and I believe that the pursuit of science to discover medicines that change patients' lives is an important mission for JCR. The shared values of the Company put the patients we serve at the center of our priorities, and the whole company contributes to these innovations, beyond our researchers and scientists. JCR is involved in a wide range of products and technologies, and its recent contribution to the production of a COVID-19 vaccine is truly remarkable. It is an exciting time to contribute to the success of JCR as a Board member.

Marc Dunoyer
Outside Director

Skill Matrix of Directors and Audit & Supervisory Board Members and Attendance Rate at Board of Directors and Audit & Supervisory Board Meetings in FY2022

			Advisory Committee for Nomination, Compensation, Etc.	Skill													Attendance Rate of the Board Meetings (FY2022)
				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, Chairman, CEO and 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)	●			●					●	●	●		●		100%
	Toshihide Yoda	Director (Outside)		●	●	●							●				100%
	Yuko Hayashi	Director (Independent/Outside)	●	●		●				●				●		Diversity and Inclusion	100%
	Yutaka Atomi	Director (Independent/Outside)	●		●		●								●		90.91%
	Philippe Fauchet	Director (Independent/Outside)		●	●	●	●	●	●	●	●	●	●	●	●	Business Development, Medical Affairs, Public Relations and Government Affairs	100%
	Marc Dunoyer	Director (Outside)		●	●	●	●	●	●		●	●	●		●	Corporate Planning	—
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)	●	●							●	●	●	●	●		92.31%
	Shuichi Tani	Audit & SBM* (Independent/Outside)		●	●						●						100%

* Audit & Supervisory Board Member

Board of Directors, Audit & Supervisory Board Members, and Corporate Officers (As of August 1, 2023)

Directors

Director Profiles

❶ Shin Ashida

Representative Director
Chairman, President,
Chief Executive Officer (CEO) and Chief Operating Officer (COO)
[Significant Concurrent Position]
Representative Director and President of JCR INTERNATIONAL SA

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

❷ Toru Ashida

Senior Vice President
In charge of Sales
Executive Director, Sales Division
[Significant Concurrent Position]
Representative Director and President of Future Brain Co., Ltd.

1992	Entered Nippon Life Insurance Company
2002	Appointed Representative Director and President at the establishment of JBS Co., Ltd.
2007	Representative Director and President of Future Brain Co., Ltd.
2014	Entered JCR Pharmaceuticals Appointed Corporate Officer Executive Director, Corporate Business Support Division and Director, Corporate Strategy Department
2016	Head of Office of the President
2018	Appointed Director Head of Quality Assurance Division, Corporate Planning Division, and Medical Affairs Department
2019	In charge of Corporate Strategy Head of Quality Assurance Division, Administration Division, and Medical Affairs Department
2020	Executive Director, Sales Division (current post) Appointed Vice President In charge of Sales Division
2021	Appointed Senior Vice President (current post) In charge of Sales and Administration
2023	In charge of Sales (current post)

❸ Mathias Schmidt, PD, Ph.D.

Vice President
In charge of Clinical development (overall supervision)
Business development and IR fields, excluding Japan
ArmaGen, Inc. President and CEO
JCR USA, Inc. President and CEO
[Significant Concurrent Positions]
President and CEO of ArmaGen, Inc., USA /
President and CEO of JCR USA, Inc. /
Director of JCR Luxembourg S.A. /
Director of JCR Europe B.V.

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 Constance, Germany
2007	Associate Principal of Strategic Planning and Business Support Department of Nycomed GmbH, Germany (currently Takeda GmbH)
2010	Principal & Head of Biologics Department of the same
2012	Vice President of Biological Sciences, Takeda California, Inc.
2016	President and CEO, ArmaGen, Inc. (current post)
2019	Executive Vice President, Head of Research and Development, Triphase Accelerator Corporation, USA
2020	Appointed Director, JCR Pharmaceuticals In charge of Global Strategy President and CEO, JCR USA, Inc. (current post)
2021	Appointed Vice President (current post) In charge of Clinical Development, Global Business Strategy and Business Development
2022	Director of JCR Luxembourg S.A. (current post) Director of JCR Europe B.V. (current post)
2023	In charge of Clinical Development (current post)

❹ Hiroyuki Sonoda, Ph.D.

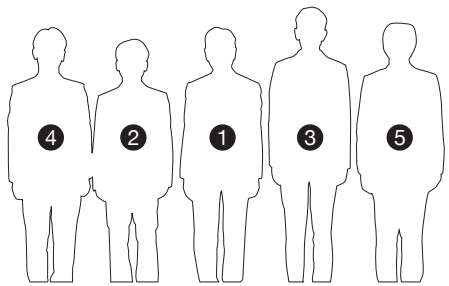
Vice President
In charge of Research
Executive Director, Research Division
[Significant Concurrent Position]
Representative Director and President of AlliedCel Corporation

2003	Entered JCR Pharmaceuticals
2016	Director of Corporate Planning Division (in charge of Research)
2017	Leader of Frontier Research Unit and Director of Corporate Planning Division (in charge of Research)
2018	Executive Director of Research Planning Division Appointed Corporate Officer
2020	Appointed Director In charge of Research and Development Division Executive Director, Research Division Director, Drug Discovery Research Institue
2021	Appointed Vice President (current post) In charge of Research and Corporate Strategy Executive Director, Research Division (current post)
2022	Representative Director and President of AlliedCel Corporation (current post)
2023	In charge of Research (current post)

❺ Yoshio Hiyama, Ph.D

Senior Executive Director
In charge of Production and Quality Assurance
Exectutive Director, 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 Assurance (current post) Executive Director, Production Division (current post)



Board of Directors, Audit & Supervisory Board Members, and Corporate Officers (As of August 1, 2023)

Outside Directors

Outside Director Profiles

❶ Toshihiro Ishikiriyama

Outside Director
[Significant Concurrent Positions]
Audit & Supervisory Board Member of GlaxoSmithKline K.K. /
Outside Audit & Supervisory Board Member of
GlaxoSmithKline Consumer Healthcare Japan K.K. /
Outside Audit & Supervisory Board Member of ViiV Healthcare K.K. /
Member of the Board of RegeNephro Co., Ltd.

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 Outside Director, JCR Pharmaceuticals (current post)
2018	Outside Auditor, GlaxoSmithKline K.K. (current post)
2019	Outside Auditor & Supervisory Board Member, GSK Capital K.K.
	Outside Auditor & Supervisory Board Member, GKK K.K.
	Outside Auditor & Supervisory Board Member, GlaxoSmithKline Consumer Healthcare Japan K.K. (current post)
	Outside Auditor & Supervisory Board Member, ViiV Healthcare K.K. (current post)
	Representative Director and President, Rege Nephro Co., Ltd.
2023	Member of the Board of the same (current post)

❷ Takashi Suetsuna

Outside Director
[Significant Concurrent Positions]
Outside Director of Totetsu Kogyo Co., Ltd. /
Outside Audit & Supervisory Board Member of Keikyu Corporation /
Outside Audit & Supervisory Board Member of Kandenko Co., Ltd.

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
2012	Retired from the above office
2013	Outside Auditor & Supervisory Board Member, Marubeni Corporation
2015	Outside Director, Totetsu Kogyo Co., Ltd. (current post)
2016	Outside Auditor & Supervisory Board Member, Keikyu Corporation (current post)
	Outside Auditor & Supervisory Board Member, Kandenko Co., Ltd. (current post)
	Appointed Outside Audit & Supervisory Board Member, JCR Pharmaceuticals
2017	Appointed Outside Director, JCR Pharmaceuticals (current post)
2018	Outside Auditor & Supervisory Board Member, Aioi Nissay Dowa Insurance Co., Ltd.

❸ Toshihide Yoda

Outside Director
[Significant Concurrent Positions]
Senior Vice President of Medipal Holdings Corporation /
Director of JCR USA, Inc.

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
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 Outside Director, JCR Pharmaceuticals (current post)
2022	General Manager of Business Development Department, MEDIPAL HOLDINGS CORPORATION (current post)

❹ Yuko Hayashi, Ph.D.

Outside Director
[Significant Concurrent Positions]
Professor of Graduate School of Innovation and Technology Management of Yamaguchi University /
Executive Director of 3.11 Earthquake Orphans Cultural and Sports Support Facilitation Corporation of Public Interest Incorporated Association

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
	Executive Director, 3.11 Earthquake Orphans Cultural and
2011	Sports Support Facilitation Corporation of Public Interest Incorporated Association (current post)
2012	Associate Professor, Graduate School of Innovation and Technology Management of Yamaguchi University
2015	Professor, Graduate School of Innovation and Technology Management of the same (current post)
2017	Executive Board Member, Special Olympics Nippon of Public Interest Incorporated Foundation
2018	Researcher, Graduate School of Frontier Sciences of The University of Tokyo (current post)
	Appointed Outside Director, JCR Pharmaceuticals (current post)

❺ Yutaka Atomi, M.D., Ph.D.

Outside Director
[Significant Concurrent Positions]
President Emeritus of Kyorin University /
Outside Audit & Supervisory Board Member of
Sanki Engineering Co., Ltd. /
President of International Medical Research Foundation /
Executive Director of Japan Medical Education Foundation

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
2018	President Emeritus, Kyorin University (current post)
	President, Pancreas Research Foundation of Japan
2019	President, International Medical Research Foundation (current post)
	Outside Audit & Supervisory Board Member, Sanki Engineering Co., Ltd. (current post)
2022	Appointed Outside Director, JCR Pharmaceuticals (current post)

❻ Philippe Fauchet, OBE

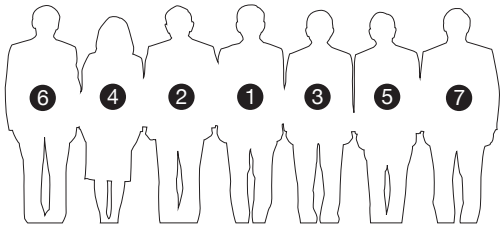
Outside Director
[Significant Concurrent Positions]
External Director of Noile-Immune Biotech Inc. /
External Director of Rezolute, Inc.(RZLT) /
Outside Director of LUCA Science Inc.

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 Outside 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.
2019	Outside Director, Bonac Corporation
2020	Outside Director, Noile-Immune Biotech Inc. (current post)
	Outside Director, Rezolute, Inc. (RZLT) (current post)
2022	Outside Director of LUCA Science Inc. (current post)
	Appointed Outside Director, JCR Pharmaceuticals (current post)

❼ Marc Dunoyer

Outside Director
[Significant Concurrent Positions]
Chief Strategy Officer of AstraZeneca Group /
CEO of Alexion, AstraZeneca's Rare Disease Group /
Chairman of AstraZeneca KK /
Member of the Board of Directors of Orchard Therapeutics PLC

1999	Representative Director Vice President of GlaxoWellcome KK
2000	Representative Director President of the same
2001	Representative Director President of GlaxoSmithKline KK
2003	Corporate Executive Team Member of GlaxoSmithKline PLC
2008	Regional President of Asia Pacific & Japan of the same
2010	Representative Director Chairman of GlaxoSmithKline KK
	Foundational Global Head of Rare Diseases Unit of GlaxoSmithKline PLC
	Appointed Outside Director, JCR Pharmaceuticals
2013	Resigned as Outside Director, JCR Pharmaceuticals
	Executive Vice President of Global Portfolio & Product Strategy of AstraZeneca PLC
	Member of the Board of Directors and Executive Director and Chief Financial Officer of the same
	Chairman of AstraZeneca KK (current post)
2018	Member of the Board of Directors of Orchard Therapeutics PLC (current post)
2021	Chief Executive Officer of Alexion, AstraZeneca's Rare Disease Group (current post)
	Chief Strategy Officer of AstraZeneca Group (current post)
2023	Appointed Outside Director, JCR Pharmaceuticals (current post)



Board of Directors, Audit & Supervisory Board Members, and Corporate Officers (As of August 1, 2023)

Audit & Supervisory Board Members

Audit & Supervisory Board Member Profiles

❶ Kazumasa Oizumi

Full-time Outside Audit & Supervisory Board Member (Active)

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 & Supervisory Board Member, SOHGO SECURITY SERVICES CO., LTD.
2009 Corporate Officer of the same
2013 Appointed Outside Audit & Supervisory Board Member, JCR Pharmaceuticals (current post)
2014 Full-time Outside Audit & Supervisory Board Member, JCR Pharmaceuticals (current post)

❷ Kazuhiko Yamada

Outside Audit & Supervisory Board Member
[Significant Concurrent Positions]
Head of Kazuhiko Yamada Tax Accountant Offices /
Outside Director of Create Corporation (Member of Audit and Supervisory Committee)

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 Outside Audit & Supervisory Board Member, JCR Pharmaceuticals (current post)
2009 Audit & Supervisory Board Member of Create Corporation
2016 Director of the same (Member of Audit and Supervisory Committee) (current post)

❸ Kenjiro Miyatake

Outside Audit & Supervisory Board Member
[Significant Concurrent Positions]
Advisor of TAMURA PHARMACEUTICAL CO., LTD. /
Advisor of Kwansei Gakuin University /
Member of the Board of Councilors of Foundation for Kobe International Medical Alliance /
Member of the Board of Councilor of Mirai Research Institute University of
TOHO HOLDINGS CO., LTD.

1981 Director, Dainippon Pharmaceuticals Co., Ltd. (currently Sumitomo Pharma Co., Ltd.)
1994 Advisor of TAMURA PHARMACEUTICAL CO., LTD. (current post)
1999 Representative Director and President of Dainippon Pharmaceuticals Co., Ltd. (currently Sumitomo Pharma Co., Ltd.)
2005 Representative Director and President, Sumitomo Dainippon Pharma Co., Ltd. (currently Sumitomo 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. (currently Sumitomo Pharma Co., Ltd.)
2013 Appointed Outside Audit & Supervisory Board Member, JCR Pharmaceuticals (current post)
2015 Chairman of the Board, Kobe Pharmaceutical University

❹ Takeshi Komura

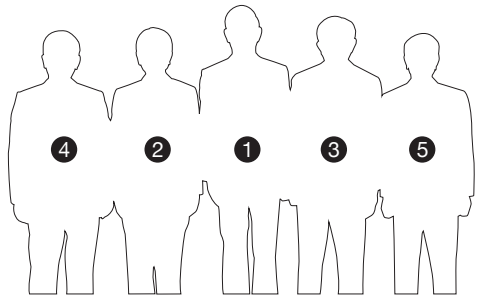
Outside Audit & Supervisory Board Member
[Significant Concurrent Positions]
President, Capital Market Promotion Foundation,
Public Interest Incorporated Foundation /
CHAIRMAN OF BOARD OF TRUSTEES, The Iwatani Naoji Foundation

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 Outside Audit & Supervisory Board Member, JCR Pharmaceuticals (current post)
2019 CHAIRMAN OF BOARD OF TRUSTEES, The Iwatani Naoji Foundation (current post)

❺ Shuichi Tani, M.D., M.P.H.

Outside Audit & Supervisory Board Member
[Significant Concurrent Position]
President Emeritus, International University of Health and Welfare

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 Outside Audit & Supervisory Board Member, JCR Pharmaceuticals (current post)



Board of Directors, Audit & Supervisory Board Members, and Corporate Officers (As of August 1, 2023)

Corporate Officers

Kazunori Tanizawa
Corporate Officer
Executive Director, Development Division

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

Yoh Ito
Senior Corporate Officer
Corporate strategy
Executive Director, Corporate Strategy Division

Takayo Egawa
Corporate Officer
International Affairs
Director, International Affairs Office

Junichi Ando
Corporate Officer
Executive Director, Quality Assurance Division

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 has achieved sustainable growth. This section offers a detailed explanation of the business activities that deliver value only JCR can provide in order to contribute to patients with rare diseases and their families.

History of Growth

1975
JCR Pharmaceuticals Co., Ltd. founded

1978
Started sales of Urokinase drug solution (intermediate)

1985
Started import and sales of Grorm®
Launched Urokinase product

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.)*

2009
Concluded a comprehensive agreement concerning biopharmaceuticals with the GlaxoSmithKline Group

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

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

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

2020
Acquired ArmaGen, Inc. (U.S.)

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

2021
Launched IZCARGO®, a recombinant treatment for mucopolysaccharidosis II

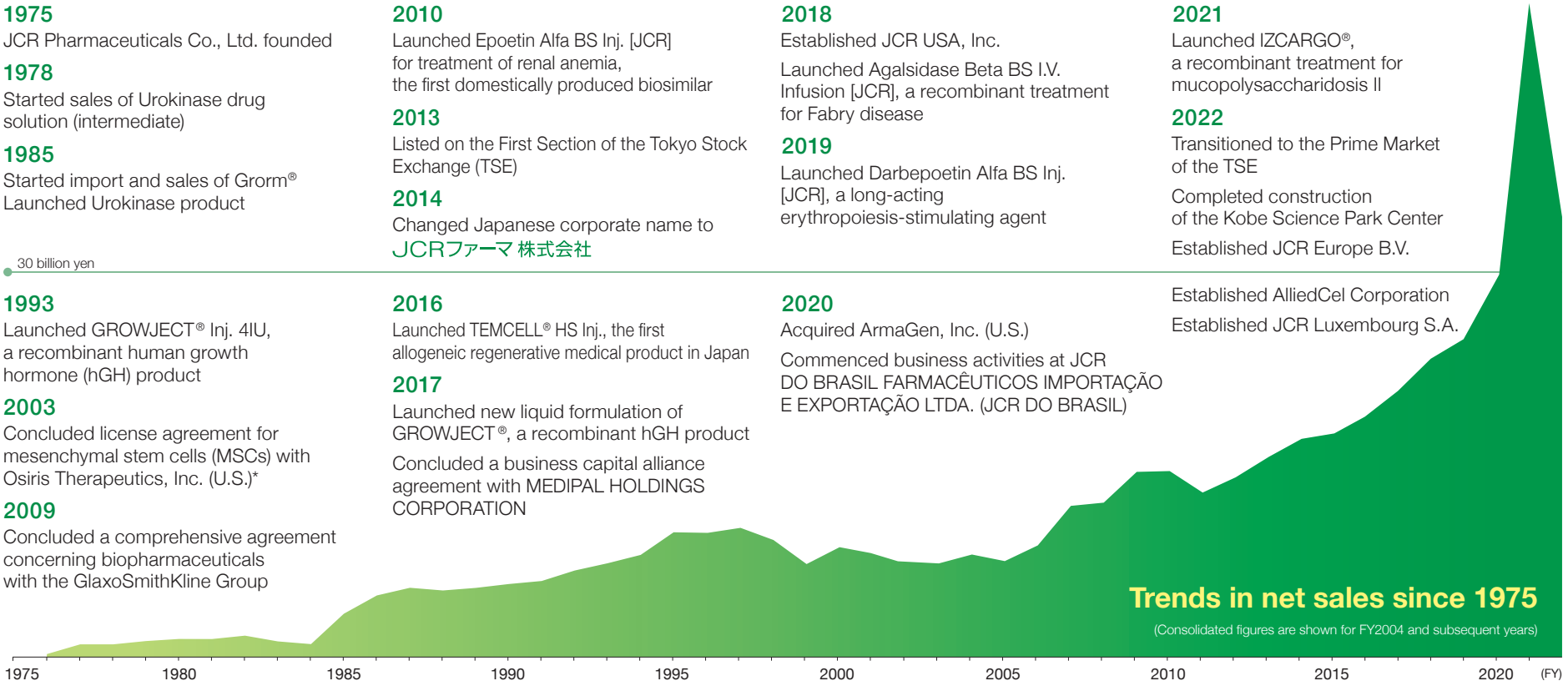
2022
Transitioned to the Prime Market of the TSE

Completed construction of the Kobe Science Park Center

Established JCR Europe B.V.

Established AlliedCel Corporation

Established JCR Luxembourg S.A.



* 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

Established technologies ranging from cell development to culture technologies

Entered the regenerative medical product field


Production at the time of foundation

Production today

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

Key Topics for FY2022

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

July 2022

Filed a Partial Change Application for a Supplemental Indication of GROWJECT® for the Treatment of Short Stature Due to Short Stature Homeobox-containing Gene (SHOX) Deficiency

In June 2023, JCR received partial change approval for the supplemental indication of GROWJECT®.

▶ https://ssl4.eir-parts.net/doc/4552/tdnet/2161425/00.pdf

August 2022

Upgrated Medication Management App Melon Nikki™ for Pediatric Patients Undergoing Growth Hormone Therapy

▶ https://ssl4.eir-parts.net/doc/4552/announcement1/81631/00.pdf

September 2022

Established JCR Europe B.V. as an Overseas Subsidiary to Become a Base for Development in Europe

▶ https://ssl4.eir-parts.net/doc/4552/tdnet/2185245/00.pdf

October 2022

JCR and Sysmex Corporation Established Joint Venture AlliedCel Corporation

AlliedCel aims to conduct research and development and early commercialization of regenerative medical products using diverse cells such as stem cells.

▶ https://ssl4.eir-parts.net/doc/4552/tdnet/2186410/00.pdf

Selection as a METI "Project for Establishing Biopharmaceutical Manufacturing Sites to Strengthen Vaccine Production"

JCR will use the grant from this project to construct a new plant for drug product filling and finishing.

▶ https://ssl4.eir-parts.net/doc/4552/tdnet/2186623/00.pdf

▶ https://ssl4.eir-parts.net/doc/4552/tdnet/2192404/00.pdf

Obtained "Kurumin" Certification for the Second Consecutive Term as a Company Supporting Childcare

▶ https://ssl4.eir-parts.net/doc/4552/announcement1/83392/00.pdf

Initiated Development of New Drug Candidate that Uses J-Brain Cargo® for the Treatment of Fucosidosis (Development Code: JR-471)

▶ https://ssl4.eir-parts.net/doc/4552/tdnet/2195075/00.pdf

Concluded a Memorandum and Agreement with MEDIPAL HOLDINGS CORPORATION Concerning Global Commercialization of Drug Candidates for Ultra-rare Diseases

The two companies concluded a licensing agreement for a drug candidate that uses J-Brain Cargo® for the treatment of fucosidosis.

▶ https://ssl4.eir-parts.net/doc/4552/tdnet/2195077/00.pdf

November 2022

Completed Construction of the New API Plant Kobe Science Park Center

The Kobe Science Park Center will produce vaccines and other remedies in case of such a pandemic emergency and will carry out research, development, and manufacturing of JCR's proprietary biopharmaceutical drugs for rare diseases.

▶ https://ssl4.eir-parts.net/doc/4552/tdnet/2200173/00.pdf

Received the FY2022 Hyogo Childcare Support Award

December 2022

Established JCR Luxembourg S.A. in Luxembourg as a European Packaging and Logistics Hub for Global Distribution

▶ https://ssl4.eir-parts.net/doc/4552/tdnet/2212726/00.pdf

January 2023

U.S. Food and Drug Administration (FDA) Grants Rare Pediatric Disease Designation for JR-141 for the Treatment of Mucopolysaccharidosis Type II (Hunter Syndrome)

▶ https://ssl4.eir-parts.net/doc/4552/tdnet/2223488/00.pdf

Received the European Award for Best Practices 2022 by the European Society for Quality Research (ESQR)

▶ https://ssl4.eir-parts.net/doc/4552/tdnet/2223490/00.pdf

March 2023

Achieved Preclinical Proof-of-Concept Milestone in a Collaboration with Takeda Pharmaceutical Company Limited to Develop Gene Therapies Using J-Brain Cargo® Technology

▶ https://ssl4.eir-parts.net/doc/4552/tdnet/2255762/00.pdf

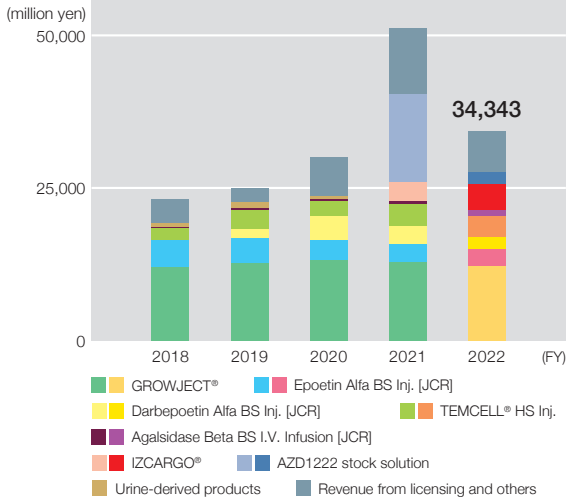
Concluded a Research Collaboration, Option and License Agreement with Alexion, AstraZeneca Rare Disease to Develop a Therapy Using J-Brain Cargo® for the Treatment of a Neurogenerative Disease

▶ https://ssl4.eir-parts.net/doc/4552/tdnet/2257038/00.pdf

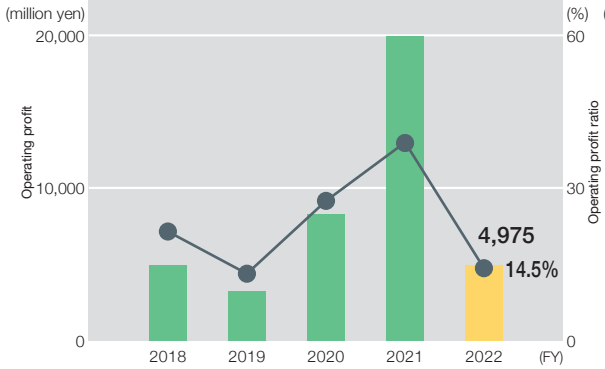
Consolidated Financial and Non-Financial Highlights

JCR Pharmaceuticals Co., Ltd. and Subsidiaries

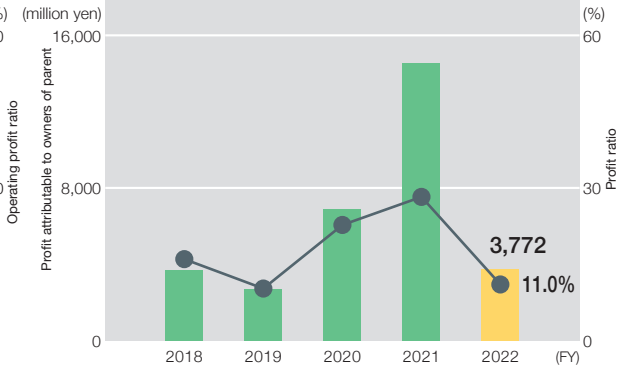
Net sales by product



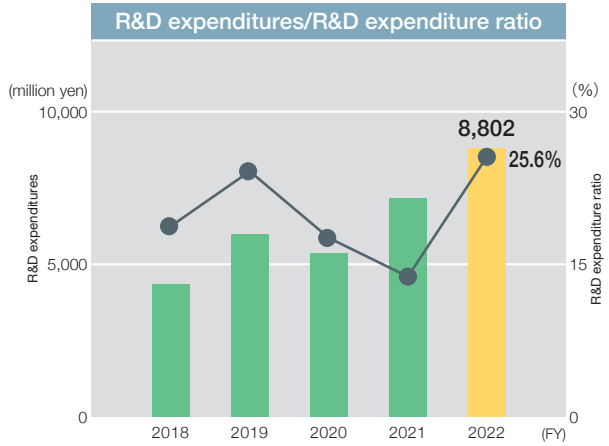
Operating profit/Operating profit ratio



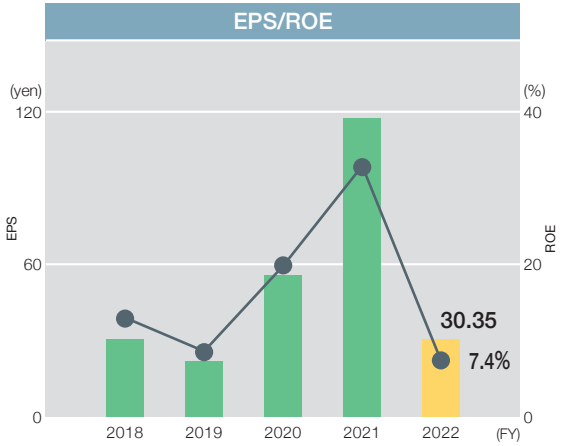
Profit attributable to owners of parent/Profit ratio



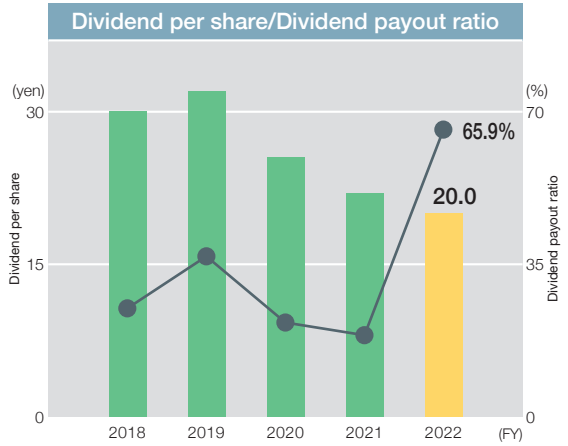
R&D expenditures/R&D expenditure ratio



EPS/ROE



Dividend per share/Dividend payout ratio

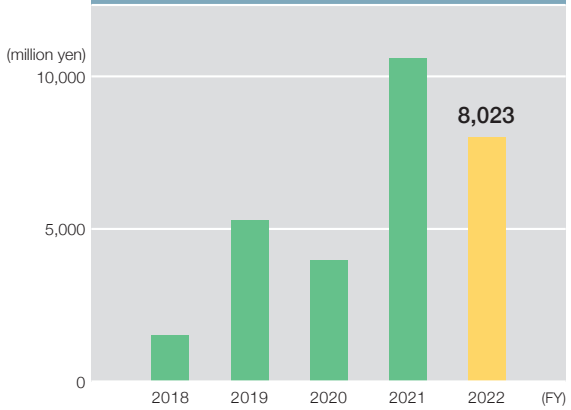


* On October 1, 2020, JCR conducted a 4-for-1 stock split of its common shares. For information on EPS and dividend per share, please refer to the note on page 87.

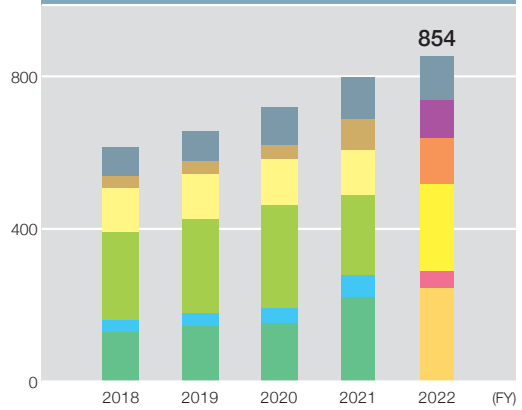
Related pages

Sustainability P.38 Financial Highlights P.84 11-Year Financial Data P.86

Capital investment

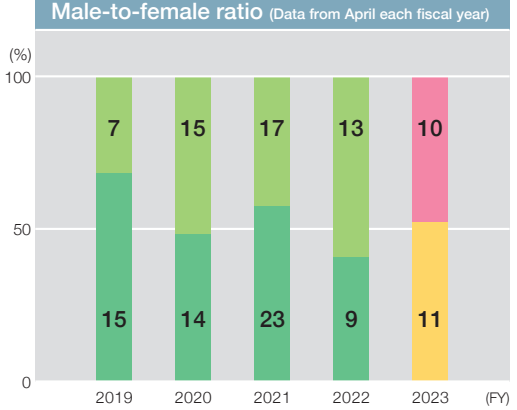


Number of employees by occupation



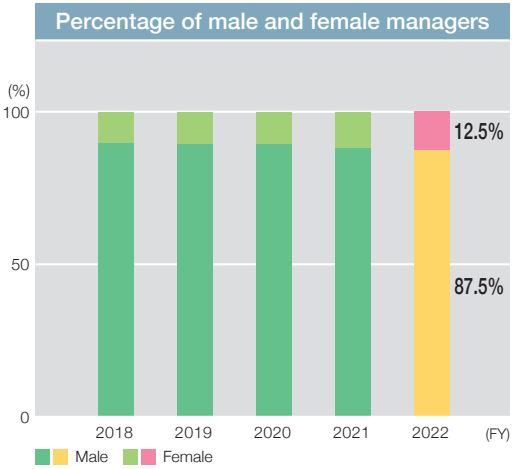
* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)

Number of new graduate recruits/ Male-to-female ratio (Data from April each fiscal year)



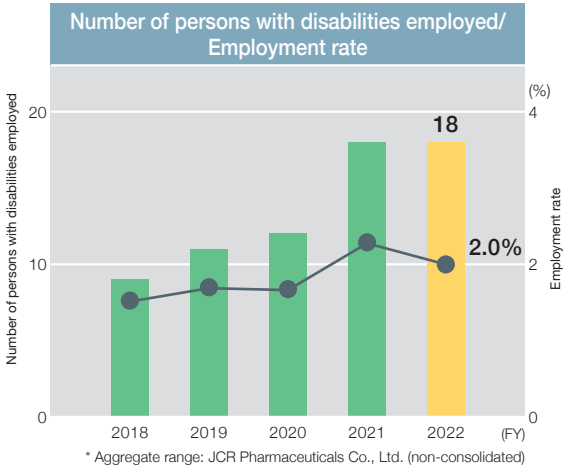
* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)

Percentage of male and female managers



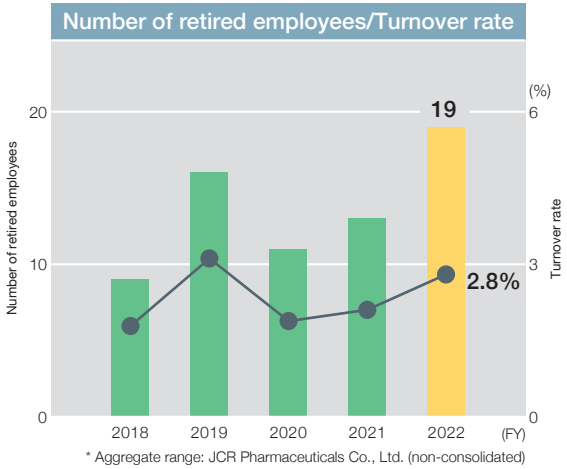
* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)

Number of persons with disabilities employed/ Employment rate



* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)

Number of retired employees/Turnover rate



* Aggregate range: JCR Pharmaceuticals Co., Ltd. (non-consolidated)

We will continue to ambitiously deliver medicines that only JCR can make to as many rare disease patients as possible, as soon as possible.

Reach Beyond, Together

"Who JCR Wants to Be in Five Years" in Research and Development

JCR is a specialty pharma that has been focused on the fields of pediatrics and rare diseases since its founding in 1975. JCR has been conducting research and development to address unmet medical needs in those fields, based on its strengths in protein engineering, cellular engineering, and genetic engineering. We have been boldly tackling challenges by harnessing our advanced technologies and extensive experience and expertise developed so far 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 and started delivering it to patients. JR-141 is a therapeutic enzyme that applies J-Brain Cargo® for the treatment of MPS II, which is a rare disease and a type of lysosomal storage disorder (LSD). JCR is working to enhance its pipeline of therapeutics for LSDs that apply J-Brain Cargo®. Our current pipeline of over 17 development targets includes JR-471, which is a therapeutic enzyme indicated for fucosidosis, a condition with only 100 and several dozen reported cases worldwide. Even with such ultra-rare diseases, we will continue to deliver value that only JCR can provide, thereby continuing to contribute to patients and their families. We firmly believe that our mission for the next five years and beyond is to continue to contribute in this way.

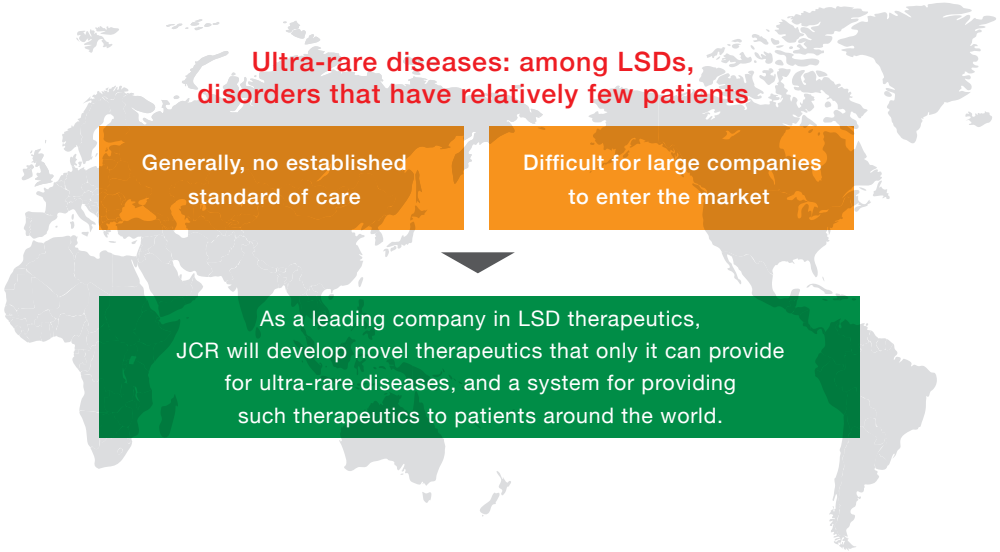
Research and Development

Issues and Initiatives for Becoming "Who JCR Wants to Be"

In the Midterm Business Plan for FY2023-2027, "*Reach Beyond, Together,*" we did not establish quantitative guidance. Instead, we declared that we would determinedly invest in the opportunities for growth through advancements in research and development. This reflected our belief that given the entry of multiple companies into the field of rare diseases, it would be extremely important to commercialize and deliver medicines to patients before other companies do so. To make this happen, it would be essential to make proactive investments based on foresight without missing any opportunities. We will simultaneously advance measures with urgency, even as we prioritize them. These measures include the development of more than 17 therapeutic drugs for LSDs, research to expand J-Brain Cargo® to other diseases, applying J-Brain Cargo® to other drug discovery modalities, and creating the next drug discovery platform. In addition, we will address investigational drug manufacturing for the global clinical trials of our multiple therapeutic drugs. We will also proactively move forward with building a global supply chain in anticipation of commercial production thereafter.

JCR will continue to focus on the field of LSDs, primarily advancing in-house development. In addition, in areas other than LSDs, we are starting to see the possibility emerge for applying J-Brain Cargo® to therapeutic drugs for CNS degenerative diseases such as Parkinson's disease, Alzheimer's disease and epilepsy. For these disorders, JCR will accelerate global commercialization by proactively stepping up collaboration with partners who possess resources and capabilities that are constraints for JCR. In March 2023, JCR signed a Research Collaboration, Option and License Agreement with Alexion concerning a therapy using J-Brain Cargo® technology for a neurodegenerative disease. In May 2023, JCR entered into a global collaboration with Angelini Pharma for the development and commercialization of novel biologic therapies in epilepsy. In these ways, JCR has been steadily expanding the possibilities of J-Brain Cargo®.

Measures to Address Ultra-Rare Diseases



Partnerships with Other Companies in Diseases Other than LSDs

JCR Pharmaceuticals × ALEXION AstraZeneca Rare Disease

March 2023: Concluded a Research Collaboration, Option and License Agreement with Alexion concerning a therapy using J-Brain Cargo® technology for a neurodegenerative disease

JCR Pharmaceuticals × Angelini Industries

May 2023: Entered into an exclusive global development and commercialization agreement with Angelini Pharma for novel biologic therapeutics in epilepsy

Global Development Operations

JCR will accelerate global development of therapeutic drugs for lysosomal storage disorders by fostering cooperation among its four sites in Japan, the U.S., Europe, and South America.

Reach Beyond, Together

"Who JCR Wants to Be in Five Years" in the Global Development Operations

The Global Development Team's mission is to bring our innovation that JCR can only provide to patients across the globe by developing our lysosomal storage disorder (LSD) assets towards regulatory approval in Japan and the rest of the world. The Team is now advancing Phase III global clinical trial of JR-141, a treatment for MPS II that commenced sales in Japan in May 2021. It is also preparing for the early start of Phase III global clinical trial of JR-171, a treatment for MPS I. Phase I/II global clinical trial for JR-441, a treatment for MPS IIIA, started in October 2023. The Team will accelerate efforts to enable the earliest possible initiation of global trials of treatments for JR-446 for MPS IIIB, JR-162 for Pompe disease, JR-443 for MPS VII, and JR-479 for GM2 gangliosidosis.

Issues and Initiatives for Becoming "Who JCR Wants to Be"

JCR is working to establish an infrastructure and work processes to develop multiple programs in parallel with the highest urgency and professionalism. We aim to encompass local requirements and market needs in order to achieve global approval of JCR's portfolio assets.

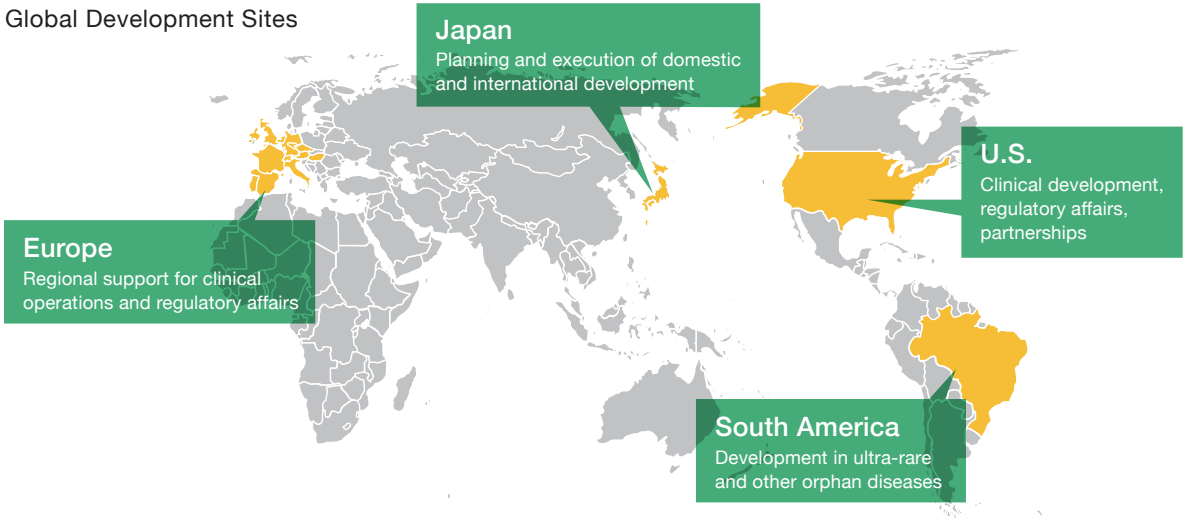
1. Strengthening Overseas Development Capabilities Based on a Global Business Strategy

For the international development of clinical programs, we need to have geo-regional expert knowledge and ensure that the functions of various sites are not duplicated. JCR has established global development sites in Japan, the U.S., Europe, and South America, which it positions as key regions, and is carrying out activities at these sites as one team. JCR has been working under this structure to clearly identify the roles of each site, increase the expert knowledge it needs and enhance its operations in each region.

2. Working as One Seamless Team with Different Skill Sets across Various Geographies

Collaboration on development programs among the four sites provides the operational advantage of not requiring identical competencies to be developed in all regions. By sharing the knowledge required to implement development programs across the entire Team JCR, we can conduct rapid decision-making, and promote efficient global development, along with providing learning opportunities to employees that enable them to understand the regulatory requirements and quality standards in each region.

Global Development Sites



Global Development Operations

Development Pipeline and Progress (As of November 2023)

LSDs　Other biopharmaceuticals　Regenerative medical products

Code	Nonproprietary Name	Indication	Region	Preclinical	Clinical trials	Filed	Approved	Remarks
JR-141	BBB-penetrating iduronate-2-sulfatase (rDNA origin)	Mucopolysaccharidosis II (Hunter syndrome)	Global		Phase III			Enzyme replacement therapy (ERT) J-Brain Cargo®*1
JR-171	BBB-penetrating α-L-iduronidase (rDNA origin)	Mucopolysaccharidosis I (Hurler syndrome, etc.)	Global		Phase I/II			ERT J-Brain Cargo® J-MIG System®*2
JR-441	BBB-penetrating heparan N-sulfatase (rDNA origin)	Mucopolysaccharidosis III-A (Sanfilippo syndrome type A)	Germany (Global)		Phase I/II			ERT J-Brain Cargo®
JR-162	J-Brain Cargo®-applied acid α-glucosidase (rDNA origin)	Pompe disease	—	Preclinical				ERT J-Brain Cargo®
JR-443	BBB-penetrating β-glucuronidase (rDNA origin)	Mucopolysaccharidosis VII (Sly syndrome)	—	Preclinical				ERT J-Brain Cargo®
JR-446	BBB-penetrating α-N-acetylglucosaminidase (rDNA origin)	Mucopolysaccharidosis III-B (Sanfilippo syndrome type B)	—	Preclinical				ERT J-Brain Cargo®
JR-479	BBB-penetrating β-Hexosaminidase A (rDNA origin)	GM2 gangliosidosis (Tay-Sachs disease, Sandhoff disease)	—	Preclinical				ERT J-Brain Cargo®
JR-471	BBB-penetrating α-L-fucosidase (rDNA origin)	Fucosidosis	—	Preclinical				ERT J-Brain Cargo®
JR-142	Long-acting growth hormone (rDNA origin)	Pediatric growth hormone deficiency	Japan		Phase II			J-MIG System®
JR-031HIE	Human mesenchymal stem cells	Hypoxic ischemic encephalopathy in neonates	Japan		Phase I/II *3			Expanded indication of TEMCELL® HS Inj.

*1 Blood-brain barrier penetration technology *2 CHO cell high-level expression technology *3 Plan for future development under consideration

We will promote initiatives for stable supply alongside initiatives for frontiers, as we uphold our responsibility to patients worldwide.

Reach Beyond, Together

"Who JCR Wants to Be in Five Years" in Production System and Quality Assurance

Providing a continuous supply of pharmaceuticals to patients is our responsibility as a pharmaceutical company. Every day, JCR strives to perform complex processes and implement rigorous quality control. Furthermore, factors including the global COVID-19 pandemic and Russia's invasion of Ukraine have impacted the global supply chains for a number of materials, with an attendant rise in procurement risk expected going forward. Our initiatives for stable supply to control the supply chain from procurement to production to delivery, address issues that will remain in perpetuity, rather than being resolved in five to ten years. In this situation, JCR's innovative products featuring J-Brain Cargo® are being developed globally, and we are now engaging in initiatives for frontiers, such as making effective use of new technologies and production capacity, undertaking GMP inspection by regulatory authorities outside of Japan, etc. in order to deliver new drugs as quickly as possible to patients living with rare diseases, and their families across the globe. In terms of production volume and production technology, there are some conflicts between initiatives for stable supply and initiatives for frontiers, but by incorporating new knowledge, experience, and methods, we expect to overcome hindrances and see further synergy effects generated.

Issues and Initiatives for Becoming "Who JCR Wants to Be"

Complex Processes and Rigorous Quality Control

Pharmaceutical products manufactured by JCR require complex manufacturing processes and rigorous quality control. We address this by composing manufacturing teams mainly from younger employees, adopting a structure that gives them a sense of ownership and encourages teams to discuss when challenges arise. Moreover, we create a workplace culture that facilitates timely consultation with other manufacturing plants, the Quality Assurance Dept. and the Research Institute, and we diligently update and share information to solve problems.

Securing Raw Materials

Some of the raw materials that we use have no substitute, so if the materials cannot be obtained, production stops directly. We therefore strive to monitor the delivery data information for key raw materials by keeping in close contact with suppliers, and we always keep enough inventory for about one year. We have also concentrated our previously distributed purchasing functions into a single function and are focusing on enhancing our purchasing capability. We are also taking steps to replace manufacturing slots with other products in the event that we are unable to procure raw materials.

Use of New Technologies and Capacity

JCR manufactures a high mix of products in small lot sizes, which requires frequent change over of products that tend to cause the occurrence of inefficient use of manufacturing slots. To address this, we apply a priority order to products, including investigational products, and incorporate them flexibly into manufacturing slots to effectively use the production capacity. We are also constructing a new formulation plant incorporating new technologies.

Production in Extremely Small Lot Sizes

In a step towards global development of new products for ultra-rare diseases, we have been working on starting up a packaging and storage facility in Luxembourg. Currently, most of the packaging of our investigational products is outsourced to contracted manufacturers, but by having an in-house function in Europe, we expect to be able to flexibly package and supply a high mix of products in small lot sizes.

Production System / Quality Assurance

Research and Production Sites

Research Institute

Bioresearch Center

Seishin Plant

Regenerative medical products, medical devices

Murotani Plant

Active pharmaceutical ingredients (APIs)

Kobe Plant

Finished products

Kobe API Plant

APIs

New formulation product plant (scheduled for completion in 2027) **/ Kobe Science Park Center** (completed in 2022)

Creating an environment that enables each MR to function as a specialist in the area of rare diseases in their daily marketing activities.

Reach Beyond, Together

"Who JCR Wants to Be in Five Years" in Marketing

The Sales Division has the following goals for who JCR wants to be in five years.

(1) Achieving sales targets each fiscal year and continuously generating operating profit
(2) Medical representatives (MRs) are being developed as specialists in the area of rare diseases to perform their role as representatives of JCR on the medical front lines with an individual career vision

Meanwhile, the following factors are recognized as risks that could keep JCR from becoming who it wants to be.

(1) The superiority of JCR's existing products in the form of research technology and manufacturing capability is not being properly promoted, and this is not leading to increased value
(2) The Company has not achieved an organization that can grow on the basis of human resource development and support human resources

Issues and Initiatives for Becoming "Who JCR Wants to Be"

Priority Issues to Be Addressed

(1) Create a Sales Division that does not cause differences in understanding of the Company's direction between ranks
(2) Ensure that the sales activities are in line with JCR's basic principles are understood such as "helping patients with rare diseases" and "contributing to the capital base of the company's management"

Basic Action Policy

(1) Promote understanding of the Sales Division's roles and responsibilities through continuous regular messaging from top management of the Company and the division, and two-way communication
(2) Create new marketing evidence through continued implementation of the marketing support system in use since the previous Midterm Business Plan
(3) Feed back insights obtained through information provision activities targeting medical professionals to the development and research departments to assist JCR's drug discovery and fostering
(4) Conduct an open, multi-perspective exchange of opinions based on human resource development regarding the ideal human resources needed by the organization

Marketing

Specific Initiatives

Open Exchange of Opinions and Communication

- Conduct communicative discussions regarding human resource development at monthly Sales Division managers meetings

Use of MR Support System

- Visualization of marketing activities, connecting with other MR's approaches and ideas every month to select an MVP, and sharing details of activities

Contribution to Patients Living with Lysosomal Storage Disorders

- April 2023: Started operational organization for a dedicated MR system for IZCARGO®
- April 2023: Launch of comprehensive information gathering and provision activities through co-promotion with Sumitomo Pharma Co., Ltd.
- Strengthen awareness raising activities for local governments and healthcare professionals serving as central facilities for conducting newborn mass screening in the future

Contribution to Patients Living with Short Stature Disorder

- Grasp medical needs and propose treatment centered on health checkups through the additional indication for short stature (short stature due to SHOX deficiency)
- Launch GROWJECTOR® Duo, a new dedicated motorized digital injector jointly developed with PHC Corporation based on feedback of insights obtained through information provision activities targeting medical professionals

GROWJECTOR® Duo, a dedicated motorized digital injector for GROWJECT®

MESSAGE

JCR and PHC started discussing development of GROWJECTOR® Duo from a desire to provide an injector that would accommodate patients as they grow.

We aimed to realize a self-care regime for patients that would be independent of the extensive support by retaining the convenience of the current GROWJECTOR® L while enabling speedy injections through a simple operation as a daily routine. The result is the GROWJECTOR® Duo, with its stylish exterior and new motorized injector featuring a smart system. Each element has been carefully designed, and the screen display emphasizes ease of use. Since the development took place during the COVID-19 pandemic, the project faced hurdles such as high prices of materials, difficulty in obtaining them, and barriers to direct discussion. By overcoming the challenge of coordination between both companies, mutual understanding, and problem solving, I am sure that we have made even stronger ties.

The motorized injector has made history together with JCR, and we will continue to evolve the project. PHC is committed to prioritizing patients' needs and will continue working with JCR to bring fresh innovation to the medical front line.

Junichi Hyogo
Deputy Director of In Vitro Diagnostics Division, PHC Corporation

Core Products

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, and added a fifth indication in June 2023. In August 2023, we launched a fourth generation, dedicated motorized digital injector GROWJECTOR® Duo. In this manner, we continue to provide a wide range of treatment options for growth disorders.

[Indications]

- Growth hormone deficiency
- Turner syndrome
- Adult growth hormone deficiency
- Small for gestational age
- Short stature due to SHOX deficiency (indication added in June 2023)

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

*From April 24, 2023, the Company has been conducting medical information provision activities to medical institutions for this product in cooperation with Sumitomo Pharma Co., Ltd.

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]*1

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]*1

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

*1 These products were developed jointly with Kissei Pharmaceutical Co., Ltd.
JCR manufactures them 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]*2

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

*2 From April 1, 2022, Sumitomo Pharma Co., Ltd. has been conducting medical information provision activities and sales of this product to medical institutions.

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 2022. 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 were about level year on year.

Moreover, outside of its mainstay products, income from contractual payment declined, and JCR completed a contract with AstraZeneca to carry out the domestic production of AZD1222 stock solution for the COVID-19 vaccine as planned. As a result, JCR Group's net sales for FY2022 amounted to 34,343 million yen (32.8% decrease from the previous fiscal year).

Trend of Sales by Product (Unit: Million yen)

	FY2021	FY2022
GROWJECT®	12,945	**12,261**
IZCARGO®	3,003	**4,428**
TEMCELL® HS Inj.	3,497	**3,404**
Epoetin Alfa BS Inj. [JCR]	2,876	**2,710**
Darbepoetin Alfa BS Inj. [JCR]	2,998	**1,986**
Agalsidase Beta BS I.V. Infusion [JCR]	711	**964**
AZD1222 stock solution	14,375	**1,931**
Income from contractual payment	10,571	**6,546**
Others	102	**109**
Total	51,082	**34,343**

Gross Profit

Due to the decrease in net sales, gross profit decreased 37.3% from the previous fiscal year to 25,456 million yen. Due to impacts such as the decrease in income from contractual payment, the cost of sales ratio improved 5.4 percentage points from FY2021 to 25.9%.

Operating Profit

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 22.7% from FY2021, and selling, general and administrative expenses, including R&D expenditures, were 20,480 million yen, down 1.0% from the previous fiscal year. As a result, operating profit decreased 75.0% year on year to 4,975 million yen.

Ordinary Profit

JCR recorded non-operating income, primarily foreign exchange gains. As a result, ordinary profit was 5,418 million yen, a decrease of 73.6% year on year.

Profit Attributable to Owners of Parent

Profit before income taxes was 5,412 million yen, down 72.1% year on year, and profit attributable to owners of parent was 3,772 million yen, down 74.0% year on year.

Financial Position

Assets

Total assets as of March 31, 2023 amounted to 94,937 million yen, a decrease of 2,196 million yen from March 31, 2022.

Current assets decreased by 14,385 million yen from March 31, 2022 to 47,802 million yen. This decrease was mainly due to decreases in cash and deposits, accounts receivable – trade, and contract assets. Non-current assets increased by 12,188 million yen from March 31, 2022 to 47,135 million yen. This increase was mainly due to an increase in property, plant and equipment.

Liabilities

Total liabilities as of March 31, 2023 amounted to 42,523 million yen, a decrease of 3,521 million yen from March 31, 2022.

Current liabilities decreased by 6,292 million yen from March 31, 2022 to 35,762 million yen. This decrease was mainly due to a decrease in income taxes payable. Non-current liabilities increased by 2,770 million yen from March 31, 2022 to 6,761 million yen. This increase was mainly due to an increase in long-term borrowings.

Net Assets

Net assets rose 1,324 million yen from March 31, 2022 to 52,413 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, 2023 was 54.2%, up 2.4 percentage points from March 31, 2022.

Cash Flow

Net cash used in operating activities in FY2022 amounted to 5,500 million yen, an increase of 14,789 million yen in net cash used in the previous fiscal year. The main factor was the recording of profit before income taxes of 5,412 million yen, which was partly offset by an increase of inventories of 3,877 million yen and income taxes paid of 8,279 million yen.

Net cash used in investing activities amounted to 15,002 million yen (an increase of 11,752 million yen in net cash used in the previous fiscal year). The main uses of cash were 7,654 million yen for the purchase of property, plant and equipment and 6,717 million yen for the purchase of shares of subsidiaries and associates.

Net cash provided by financing activities amounted to 1,948 million yen (an increase of 4,127 million yen in net cash provided in the previous fiscal year). This was mainly attributable to dividends paid of 2,739 million yen, which was partly offset by increase in long-term borrowings of 4,750 million yen.

Forecast for FY2023 (Revised forecast of September 28, 2023)

In terms of net sales, we anticipate significant growth in sales of the recombinant human growth hormone product GROWJECT®, and growth in sales of our mainstay products including IZCARGO® and TEMCELL® HS Inj. The JCR Group's overall net sales are forecast to increase by 32.2% from the current fiscal year to 45,400 million yen.

On the profit 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. Despite the increase in R&D expenditures, considering the anticipated growth in net sales, we anticipate operating profit of 10,500 million yen, up 111.0% from the current fiscal year, ordinary profit of 10,000 million yen, up 84.6%, and profit attributable to owners of parent of 7,300 million yen, up 93.5%.

Dividends Policy

Basic Policy on Profit Distribution and Dividends

JCR regards the distribution of its 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.

Despite a year-on-year decrease in earnings in FY2022, sales of our mainstay products and progress on R&D have both been steady, and under the above basic policy, we paid out a term-end dividend of surplus for FY2022 of 10 yen per share. The full-year dividend for FY2021 was 22 yen per share, and the full-year dividend for FY2022 was 20 yen, comprising an interim dividend and term-end dividend of 10 yen each.

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 FY2023 (the term ending March 2024) 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

(Millions of yen)

	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021	**FY2022**
Fiscal year											
Net sales	14,099	15,705	16,855	17,438	18,085	20,594	23,160	24,781	30,085	51,082	**34,343**
Operating profit	1,150	1,545	2,014	2,152	2,362	3,784	4,967	3,244	8,269	19,933	**4,975**
Profit attributable to owners of parent	730	1,296	1,682	1,789	1,863	3,070	3,715	2,678	6,892	14,507	**3,772**
Comprehensive income	1,161	1,544	1,936	1,557	1,831	3,016	4,008	2,504	6,841	14,514	**3,881**
R&D expenditures	1,991	2,202	3,334	3,348	4,071	4,211	4,354	5,997	5,360	7,175	**8,802**
Capital investment	1,494	2,260	1,522	1,237	1,409	908	1,517	5,296	3,965	10,612	**8,023**
Depreciation and amortization	979	1,111	1,352	1,407	1,447	1,382	1,343	1,434	1,892	1,945	**1,997**
Cash flows from operating activities	1,661	4,565	499	2,201	2,651	3,133	3,905	4,927	10,341	9,289	**(5,500)**
Cash flows from investing activities	(178)	(2,668)	(1,419)	(980)	(841)	(1,587)	240	(4,161)	(3,290)	(3,250)	**(15,002)**
Cash flows from financing activities	(238)	(369)	(1,261)	(1,314)	146	(2,175)	(917)	2,048	8,304	(2,179)	**1,948**
End of fiscal year											
Total assets	31,286	33,464	34,086	35,346	36,385	38,398	42,516	47,775	73,784	97,134	**94,937**
Net assets	23,496	24,580	26,264	27,062	27,585	27,528	30,874	32,579	38,557	51,089	**52,413**
Shareholders' equity	23,368	24,417	26,101	26,819	27,305	26,999	30,249	31,806	37,864	50,316	**51,421**

(Yen)

	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021	**FY2022**
Information per share											
Earnings per share (EPS)	5.76	10.20	13.21	14.03	14.74	24.68	30.17	21.72	55.81	117.26	**30.35**
Net assets	183.97	192.03	204.66	210.84	216.17	219.46	245.54	257.92	306.31	406.57	**412.11**
Dividends	12.00	17.00	18.50	22.00	22.00	26.00	30.00	32.00	25.50	22.00	**20.00**
Financial indicators											
Equity ratio (%)	74.7	73.0	76.6	75.9	75.0	70.3	71.1	66.6	51.3	51.8	**54.2**
Return on equity (ROE) (%)	3.2	5.4	6.6	6.8	6.9	11.3	13.0	8.6	19.8	32.9	**7.4**
Dividend payout ratio (%)	52.1	41.7	35.0	39.2	37.3	26.3	24.9	36.8	21.5	18.8	**65.9**
Numbers of employees	437	472	501	526	566	568	632	667	732	816	**879**

Note: On October 1, 2020, JCR 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 FY2012. 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 onwards under information per share represent the amount of dividends after the stock split.

(Millions of yen)

Consolidated Balance Sheets	As of March 31, 2022	**As of March 31, 2023**
Assets		
Current assets		
Cash and deposits	30,733	**13,278**
Accounts receivable-trade, and contract assets	15,585	**11,137**
Securities	244	**—**
Merchandise and finished goods	2,121	**1,098**
Work in process	5,024	**5,717**
Raw materials and supplies	7,491	**11,699**
Other	986	**4,870**
Total current assets	62,188	**47,802**
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	6,086	**7,128**
Machinery, equipment and vehicles, net	1,308	**1,003**
Land	10,379	**10,379**
Construction in progress	8,019	**13,008**
Other, net	989	**1,161**
Total property, plant and equipment	26,782	**32,681**
Intangible assets		
Patent right	2,711	**2,434**
Other	249	**1,217**
Total intangible assets	2,960	**3,652**
Investments and other assets		
Investment securities	2,230	**8,867**
Retirement benefit asset	213	**214**
Deferred tax assets	2,433	**1,357**
Other	330	**366**
Allowance for doubtful accounts	(4)	**(4)**
Total investments and other assets	5,202	**10,800**
Total non-current assets	34,946	**47,135**
Total assets	97,134	**94,937**

(Millions of yen)

	As of March 31, 2022	**As of March 31, 2023**
Liabilities		
Current liabilities		
Accounts payable-trade	1,324	**1,563**
Short-term borrowings	15,150	**16,800**
Current portion of bonds payable	—	**500**
Accounts payable-other	5,189	**2,803**
Income taxes payable	5,915	**33**
Special suspense account for tax purpose reduction entry	11,996	**11,996**
Provision for bonuses	902	**974**
Provision for bonuses for directors (and other officers)	102	**114**
Other	1,473	**975**
Total current liabilities	42,054	**35,762**
Non-current liabilities		
Bonds payable	500	**—**
Long-term borrowings	2,450	**5,500**
Provision for employee stock ownership plan	78	**95**
Retirement benefit liability	870	**924**
Other	92	**241**
Total non-current liabilities	3,990	**6,761**
Total liabilities	46,045	**42,523**

Net assets		
Shareholders' equity		
Share capital	9,061	**9,061**
Capital surplus	10,994	**10,384**
Retained earnings	33,241	**34,273**
Treasury shares	(3,600)	**(2,978)**
Total shareholders' equity	49,697	**50,740**
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	619	**555**
Deferred gains or losses on hedges	0	**—**
Foreign currency translation adjustment	30	**146**
Remeasurements of defined benefit plans	(32)	**(20)**
Total accumulated other comprehensive income	618	**681**
Share acquisition rights	567	**740**
Non-controlling interests	205	**251**
Total net assets	51,089	**52,413**
Total liabilities and net assets	97,134	**94,937**

(Millions of yen)

Consolidated Statements of Income

	FY2021 (From April 1, 2021 to March 31, 2022)	**FY2022 (From April 1, 2022 to March 31, 2023)**
Net sales	51,082	**34,343**
Cost of sales	10,461	**8,886**
Gross profit	40,620	**25,456**
Selling, general and administrative expenses	20,686	**20,480**
Operating profit	19,933	**4,975**
Non-operating income		
Interest income	7	**33**
Dividend income	28	**28**
Foreign exchange gains	551	**387**
Other	68	**91**
Total non-operating income	656	**541**
Non-operating expenses		
Interest expenses	45	**44**
Commission expenses	12	**15**
Loss on abandonment of inventories	—	**20**
Other	18	**18**
Total non-operating expenses	77	**99**
Ordinary profit	20,512	**5,418**
Extraordinary income		
Gain on sale of investment securities	0	**10**
Total extraordinary income	0	**10**
Extraordinary losses		
Loss on disposal of non-current assets	2	**16**
Loss on cancellation of contracts	1,000	**—**
Other	105	**—**
Total extraordinary losses	1,108	**16**
Profit before income taxes	19,404	**5,412**
Income taxes – current	5,549	**525**
Income taxes – deferred	(663)	**1,099**
Total income taxes	4,886	**1,625**
Profit	14,517	**3,787**
Profit attributable to non-controlling interests	10	**14**
Profit attributable to owners of parent	14,507	**3,772**

Consolidated Statements of Comprehensive Income

Profit	14,517	**3,787**
Other comprehensive income		
Valuation difference on available-for-sale securities	(71)	**(63)**
Deferred gains or losses on hedges	0	**(0)**
Foreign currency translation adjustment	68	**147**
Remeasurements of defined benefit plans, net of tax	(0)	**11**
Total other comprehensive income	(3)	**94**
Comprehensive income	14,514	**3,881**
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	14,483	**3,834**
Comprehensive income attributable to non-controlling interests	31	**46**

Consolidated Statements of Changes in Net Assets

(Millions of yen)

FY2021 (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
Balance at beginning of period	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
Balance at end of period	9,061	10,994	33,241	(3,600)	49,697	619	0	30	(32)	618	567	205	51,089

(Millions of yen)

FY2022 (From April 1, 2022 to March 31, 2023)	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
Balance at beginning of period	**9,061**	**10,994**	**33,241**	**(3,600)**	**49,697**	**619**	**0**	**30**	**(32)**	**618**	**567**	**205**	**51,089**
Changes during period													
Dividends of surplus			**(2,740)**		**(2,740)**								**(2,740)**
Profit attributable to owners of parent			**3,772**		**3,772**								**3,772**
Purchase of treasury shares				**(0)**	**(0)**								**(0)**
Disposal of treasury shares		**(610)**		**621**	**10**								**10**
Net changes in items other than shareholders' equity					**—**	**(63)**	**(0)**	**115**	**11**	**62**	**173**	**45**	**282**
Total changes during period	**—**	**(610)**	**1,031**	**621**	**1,042**	**(63)**	**(0)**	**115**	**11**	**62**	**173**	**45**	**1,324**
Balance at end of period	**9,061**	**10,384**	**34,273**	**(2,978)**	**50,740**	**555**	**—**	**146**	**(20)**	**681**	**740**	**251**	**52,413**

(Millions of yen)

Consolidated Statements of Cash Flows	FY2021 (From April 1, 2021 to March 31, 2022)	FY2022 (From April 1, 2022 to March 31, 2023)
Cash flows from operating activities		
Profit before income taxes	19,404	**5,412**
Depreciation	1,945	**1,997**
Increase (decrease) in retirement benefit liability	74	**56**
Increase (decrease) in provision for bonuses	51	**71**
Share-based payment expenses	177	**173**
Interest and dividend income	(35)	**(62)**
Interest expenses	45	**44**
Foreign exchange losses (gains)	(544)	**(959)**
Decrease (increase) in trade receivables	(7,402)	**4,448**
Decrease (increase) in accounts receivable – other	(99)	**(1,179)**
Decrease (increase) in inventories	(1,082)	**(3,877)**
Increase (decrease) in trade payables	(1,608)	**238**
Increase (decrease) in accounts payable – other	3,033	**(2,401)**
Increase (decrease) in accrued consumption taxes	(120)	**(312)**
Increase (decrease) in income taxes payable	236	**(417)**
Increase (decrease) in contract liabilities	—	**417**
Other, net	(2,257)	**(887)**
Subtotal	11,817	**2,762**
Interest and dividends received	35	**62**
Interest paid	(45)	**(46)**
Income taxes refund (paid)	(2,517)	**(8,279)**
Net cash provided by (used in) operating activities	9,289	**(5,500)**
Cash flows from investing activities		
Payments into time deposits	(300)	**—**
Proceeds from withdrawal of time deposits	300	**—**
Proceeds from sale and redemption of securities	—	**259**
Purchase of property, plant and equipment	(11,333)	**(7,654)**
Proceeds from subsidy income	8,167	**—**
Purchase of intangible assets	(74)	**(906)**
Purchase of shares of subsidiaries and associates	—	**(6,717)**
Other, net	(9)	**15**
Net cash provided by (used in) investing activities	(3,250)	**(15,002)**
Cash flows from financing activities		
Net increase (decrease) in short-term borrowings	—	**3,000**
Proceeds from long-term borrowings	750	**4,750**
Repayments of long-term borrowings	(750)	**(3,050)**
Repayments of lease liabilities	(20)	**(22)**
Net decrease (increase) in treasury shares	10	**10**
Dividends paid	(2,169)	**(2,739)**
Net cash provided by (used in) financing activities	(2,179)	**1,948**
Effect of exchange rate change on cash and cash equivalents	612	**1,099**
Net increase (decrease) in cash and cash equivalents	4,472	**(17,454)**
Cash and cash equivalents at beginning of period	26,260	**30,733**
Cash and cash equivalents at end of period	30,733	**13,278**

Corporate Information

As of March 31, 2023

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
879 (Consolidated) 854 (Non-Consolidated)

Consolidated Subsidiaries

Chromatech Co., Ltd.

JCR Engineering Co., Ltd.

JCR USA, Inc. (U.S.)

ArmaGen, Inc. (U.S.)

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

JCR Europe B.V. (The Netherlands)

JCR Luxembourg S.A. (Luxembourg)

JCR INTERNATIONAL SA (Switzerland)

Equity Method Affiliates

AlliedCel Corporation (Joint venture)

Mycenax Biotech Inc. (Taiwan)

Stock Information

Listed on
Tokyo Stock Exchange Prime Market

Securities Code
4552

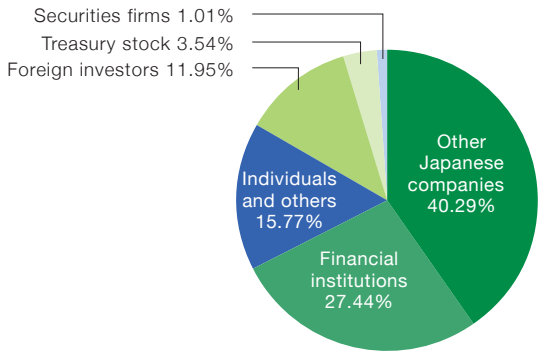
Total Number of Outstanding Shares
129,686,308

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
17,524

Composition of Shareholders



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)	15,414
Future Brain Co., Ltd.	8,711
Custody Bank of Japan, Ltd. (Trust account)	7,677
The Nomura Trust and Banking Co., Ltd. (Trust account: A)	6,508
Kissei Pharmaceutical Co., Ltd.	6,418
Sumitomo Pharma Co., Ltd.	3,400
Mochida Pharmaceutical Co., Ltd.	2,200
GOVERNMENT OF NORWAY	1,593
Employee Shareholding Association of JCR Pharmaceuticals Co., Ltd.	1,139

* The Company holds 4,585,873 shares of treasury stock, which are not included in the above table.

JCR Pharmaceuticals Co.,Ltd.
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